MEDIA RELEASE

For immediate release
Contact: Cindy Folkers, (240) 354-4314
Paul Gunter, (301) 523-0201
Linda Gunter (media director), (301) 455-5655

BEYOND NUCLEAR

Agency to leave children unprotected and public in the dark on cancer risks around nuclear power facilities
Vital cancer study canceled as nuclear industry moves in to offer end-run cover-up

TAKOMA PARK, MD, September 8, 2015 — Beyond Nuclear, a leading U.S. NGO of record on the health, safety and environmental dangers of nuclear power facilities, today decried the outrageous decision by the U.S. Nuclear Regulatory Commission (NRC) to cancel a study that would have examined cancer incidence and mortalities and the connection to U.S. nuclear facilities.

"Study after study in Europe has shown a clear rise in childhood leukemia around operating nuclear power facilities, yet the NRC has decided to hide this vital information from the American public," said Cindy Folkers, radiation and health specialist at Beyond Nuclear. The study, initiated in 2009 and carried out under the auspices of the National Academy of Sciences (NAS), had completed Phase 1 and was looking at seven pilot nuclear sites around the country, a project that was estimated to cost $8 million.

"An $8 million price tag for the next phase of this study is a drop in the bucket for an agency with a $1 billion annual operating budget," added Folkers. The NRC identified the "significant amount of time and resources needed and the agency's current budget constraints" as its excuse for terminating the study.

Folkers noted that, in reality, nuclear industry manipulation, rather than budget constraints, could be behind the NRC's sudden decision to abandon the NAS study.

In documents obtained by Beyond Nuclear it was revealed that NRC staff had been approached by the president of U.S. National Council on Radiation Protection and Measurements (NCRP), John Boice, offering a cheaper, faster and less sensitive study design to replace the NAS study, although the NRC has not yet agreed to accept the NCRP bid.

"NCRP is not only funded in part by the nuclear industry but its decision-makers also have strong pro-nuclear ties," said Folkers, who has been leading a six-year effort by Beyond Nuclear and other groups to ensure the NAS cancer study went forward with scientific integrity.

"John Boice has repeatedly taken industry funding for health studies and has testified against plaintiffs in radiation exposure cases," Folkers continued. "The public will have absolutely no confidence in any conclusions reached by such a study and would recognize it as an attempt by the NRC to, yet again, bury public concerns about radiation exposure," Folkers added.

What's also behind the cancelation, Folkers alleges, is the incontrovertible evidence of negative health impacts caused by the routine operation of nuclear power reactors and especially on children, that such a study would have made public.

Last year, Dr. Ian Fairlie, a noted British radiation biologist, conducted a meta-analysis of cancer studies around nuclear plants in the UK, Germany, France and Switzerland and found "a highly statistically significant 37% increase in childhood leukemias within 5 km (3 miles) of almost all nuclear power plants" in those countries.

Reacting to the NRC's decision, Fairlie said it was "highly regrettable and inexplicable given the large amount of good evidence from countries outside the U.S. which strongly pointed to increased leukemias near nuclear power plants."

The influence of the nuclear industry over the NRC is no surprise, given the agency receives 90% of its funding from the nuclear industry itself. But a recent pattern of dismissing public engagement and canceling minimal safety measures at U.S. nuclear plants is a worrying trend.

"Funding a cancer study around nuclear power plants is a legitimate cost of doing radioactive business that the NRC could have collected through its licensing fees," said Paul Gunter, Director of Reactor Oversight at Beyond Nuclear and an NRC watchdog. "Instead, the NRC has decided to pass along another cost savings to the nuclear industry at the expense of public health and safety."

-30-

Beyond Nuclear aims to educate and activate the public about the connections between nuclear power and nuclear weapons and the need to abandon both to safeguard our future. Beyond Nuclear advocates for an energy future that is sustainable, benign and democratic. The Beyond Nuclear team works with diverse partners and allies to provide the public, government officials, and the media with the critical information necessary to move humanity toward a world beyond nuclear.
Beyond Nuclear: 6930 Carroll Avenue, Suite 400, Takoma Park, MD 20912. Info@beyondnuclear.org. www.beyondnuclear.org.

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ANALYSIS OF CANCER RISKS IN POPULATIONS NEAR NUCLEAR FACILITIES: PHASE 1

John Burris, Committee Chair

Briefing to the U.S. Nuclear Regulatory Commission

March 26, 2012

THE NATIONAL ACADEMIES

Advisers to the Nation on Science, Engineering, and Medicine

TOPICS TO BE ADDRESSED

- Study Request
- Statement of Task
- Committee Membership
- Key Messages
- Findings and Recommendations
- Report Organization

STUDY REQUEST

U.S. Nuclear Regulatory Commission (USNRC) approached the Academies to update the 1990 National Cancer Institute study which:

- Compared rates of cancer deaths in counties with a nuclear facility to those without
- Had no data on radiation exposures
- Included only facilities that were operational as of 1982

The Academies agreed to carry out a two-phase study:

- Phase 1: Scoping study to identify scientifically sound approaches for carrying out the cancer risk assessment
- Phase 2: Cancer risk assessment informed by Phase 1 results

STATEMENT OF TASK

Methodological approaches for assessing

(1) off-site radiation dose and

(2) cancer epidemiology

including consideration of:

- Availability, completeness, and quality of information
  - on gaseous and liquid radioactive releases
  - cancer occurrence and cancer death data
- Different epidemiologic study designs
- Approaches for characterizing and communicating uncertainties

PHASE 1 COMMITTEE MEMBERSHIP

John E. Burris, Chair, Burroughs Wellcome Fund

John C. Bailar, III, University of Chicago (retired)

Harold L. Beck, Environmental Measurements Laboratory (retired)

Andre Bouville, National Cancer Institute (retired)

Phaedra S. Corso, University of Georgia

Patricia J. Culligan, Columbia University

Paul M. DeLuca, Jr., University of Wisconsin

Raymond A. Guilmette, Lovelace Respiratory Research Institute

George M. Hornberger, Vanderbilt Institute for Energy and Environment

Margaret Karagas, Dartmouth University

Roger E. Kasperson, Clark University (retired)

James E. Klaunig, Indiana University

Timothy Mousseau, University of South Carolina

Sharon B. Murphy, University of Texas Health Science Center (retired)

Roy E. Shore, Radiation Effects Research Foundation

Daniel O. Stram, University of Southern California

Margot Tirmarche, Institute of Radiation Protection and Nuclear Safety

Lance Waller, Emory University

Gayle E. Woloschak, Northwestern University

Jeffrey J. Wong, California Environmental Protection Agency

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KEY MESSAGES

- Several challenges for carrying out the epidemiology studies.
- Several approaches possible.
- Effluent releases suitable for dosimetry.
- Two study designs recommended.
- Pilot study needed.
- Stakeholder engagement important.

FINDING 1

There are several challenges for carrying out epidemiology studies of cancer risks in populations near U.S. Nuclear Regulatory Commission-licensed nuclear facilities in the United States, including the following:

- Uneven availability and quality of data on cancer mortality and incidence at geographic levels smaller than a county.
- Uneven availability and quality of data on nuclear facility effluent releases.
- Inability to reliably capture information on population mobility, risk factors, and potential confounding factors.
- Low expected statistical power.

The committee paid close attention to these challenges as it assessed the scientific merit of various epidemiology study designs.

FINDING 2

An assessment of cancer risks in populations near nuclear facilities could be carried out using several study designs. Each design has strengths and limitations for estimating cancer risks.

- Risk projection models.
- An ecologic study based on estimates of exposure levels at the census-tract level.
- Variations of cohort studies tracking estimates of individual exposure levels and recording case incidence.
- Variations of case-control studies comparing estimates of individual exposure levels between cancer cases and controls.

FINDING 3

Effluent release, direct exposure, and meteorology data, if available, can be used to obtain rough estimates of annual variations in dose as a function of distance and direction from nuclear facilities.

- Facility-specific evaluations will be required to determine quality and availability of data.
- Environmental monitoring data have limited usefulness for estimating absorbed doses from effluent releases.
- Computer models have been developed to estimate absorbed doses from airborne and waterborne radioactive effluent releases.

RECOMMENDATION 1

Should the U.S. Nuclear Regulatory Commission decide to proceed with an epidemiology study of cancer risks in populations near nuclear facilities, the committee recommends that this investigation be carried out by conducting the following two studies, subject to the feasibility assessment described in Recommendation 2:

1. An ecologic study of multiple cancer types of populations living near nuclear facilities;
2. A record-linkage based case-control study of cancers in children born near nuclear facilities.

Absorbed doses to individual organs will be estimated for those living/born within approximately 50 km of nuclear facilities.

RECOMMENDATION 2

A pilot study should be carried out to assess the feasibility of the committee-recommended dose assessment and epidemiology studies and to estimate the required time and resources.

Suggested sites for pilot

Dresden, Illinois
Millstone, Connecticut
Oyster Creek, New Jersey
Haddam Neck , Connecticut
Big Rock Point, Michigan
San Onofre, California
Nuclear Fuel Services, Tennessee

RECOMMENDATION 3

The epidemiology studies should include processes for involving and communicating with stakeholders. A plan for stakeholder engagement should be developed prior to the initiation of data gathering and analysis for these studies.

RECOMMENDED STUDIES ARE COMPLEMENTARY, MUTUALLY INDEPENDENT, AND COULD BE CARRIED OUT INDIVIDUALLY OR TOGETHER

Questions such studies could answer:

Ecologic: Are observed cancer incidence/mortality rates higher in census tracts with higher estimated exposures (as estimated from reported releases from the nuclear facility)?

Record-based case-control: Among children born within 50 km of a nuclear facility, are pediatric cancers associated with higher exposure at maternal residence at time of birth?

THE COMMITTEE EMPHASIZES THAT:

In any of the studies considered, population sizes, estimated doses, and resulting risk estimates may be too low to demonstrate statistically significant increased risks near nuclear facilities. Extremely large sample sizes are required.

DECISIONS ON IMPLEMENTATION OF THE RECOMMENDED STUDIES INVOLVE POLICY AND OTHER CONSIDERATIONS

- Which age groups and cancer types are most important to address in the epidemiology study or studies?
- How much time is available to carry out the study or studies?
- How much funding is available to carry out the study or studies?
- Which public concerns are most in need help with addressing?

Some of these considerations are outside the charge for this Phase 1 study

REPORT ORGANIZATION

Summary: 3 Findings, 3 Recommendations

Chapter 1: Introduction

Chapter 2: Effluent Releases

Chapter 3: Radiation Dose Assessment

Chapter 4: Epidemiology Studies

Chapter 5: Risk communication and public engagement

Appendices (radiation as a carcinogen and literature review, committee bios, presentations and visits, origin of radioactivity in nuclear facilities, RETS and REMP programs, letter templates to cancer registries, other)

ACKNOWLEDGMENTS

USNRC

- Brian Sheron
- Terry Brock
- Vered Shaffer
- Marilyn Diaz
- John Tomon
- Scott Burnell
- Dave McIntyre
- Richard Conatser
- John Cassidy
- Don Stearns

Presenters at the committee's information-gathering meetings

Members of the public and non- governmental organizations

For written advice on study design

- *The Electric Power Research Institute*
- Raid Amin, University of West Florida
- Steve Wing, University of North Carolina

Pacific Northwest National Laboratory

- Rosanne Aaberg
- David Baker

For supporting facility visits

- Willie Harris and Robert Osgood, Dresden
- Kathy Yhip and Mike Russell, San Onofre
- Marie Moore and Mark Elliott, NFS

Nuclear Energy Institute

- Ralph Andersen
- Andrew Mauer

For guidance on sources of health & population data

- Robert Anderson, CDC
- Christie Eheman, CDC
- Kevin Ward, Georgia Center for Cancer Statistics,
- Scott Boggess, U.S. Census Bureau

Directors and staff of state departments of public health, cancer registries, and vital statistics offices

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BACKUP SLIDES

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STUDY SCHEDULE

- Study approved by NAS: July 2010
- Study start date: October 2010
- Committee approved: December 2010
- Five committee meetings: February - October 2011
- Independent report review: February 2012
- Prepublication copy of report to be released: March 29, 2012
- Public comments on Phase 1 report: April-May 2012

INFORMATION GATHERING

- Expert opinions of committee members
- Briefings from subject-matter experts
- Nuclear site visits
- Public comments
- Literature and report reviews
- Letter-requests to offices that collect health and other information
- Phone and other communication
- Original analyses

NUMBER OF CASES IN THE AT RISK ZONE (<= 5 KM FROM A FACILITY) IN EUROPEAN STUDIES OF LEUKEMIA

[illegible]	[illegible]	[illegible]	[illegible]
Germany	Kaatsch et al., 2008	23	37
France	Sermage-Faure et al., 2012	17	24
Britain	COMARE, 2011	35	20
Switzerland	Spycher et al., 2011	24	8

Kaatsch, P., C. Spix, et al. (2008). "Leukaemia in young children living in the vicinity of German nuclear power plants." Int J Cancer **122**(4): 721-726.

Sermage-Faure C., Laurier D., Goujon-Bellec S., Chartier M., Guyot-Goubin A., Rudant J., Hémon D., Clavel J., Childhood leukemia around French nuclear power plants – the Geocap study, 2002-2007, International Journal of Cancer, accepted preprint

COMARE (2011). Fourtheenth report: Further consideration of the incidence of childhood leukemia around nuclear power plants in Great Britain.

Spycher, B. D., M. Feller, et al. (2011). "Childhood cancer and nuclear power plants in Switzerland: a census-based cohort study." Int J Epidemiol.

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STATISTICAL POWER

Risk increase	[illegible]			[illegible]		
	Cases	Years Leukemia	Years Breast ca	Cases	Years Leukemia	Years Breast ca
20%	14,000	31	2	8,200	18	1
40%	3,800	8	<1	2,200	5	<1
200%	765	1.7	<1	<1	<1	<1

Demographic parameters and simplifying assumptions

1. In 2010, about 15% of the US population lived within 50 km (30 miles) and 0.3% lived within 8km (5 miles) of a nuclear facility
2. Distribution of demographics and risk factors do not differ by distance
3. Two categories of exposure: 0-5 miles, 5-30 miles from the facility

RECOMMENDED ECOLOGIC STUDY WOULD UPDATE AND IMPROVE THE 1990 NCI STUDY

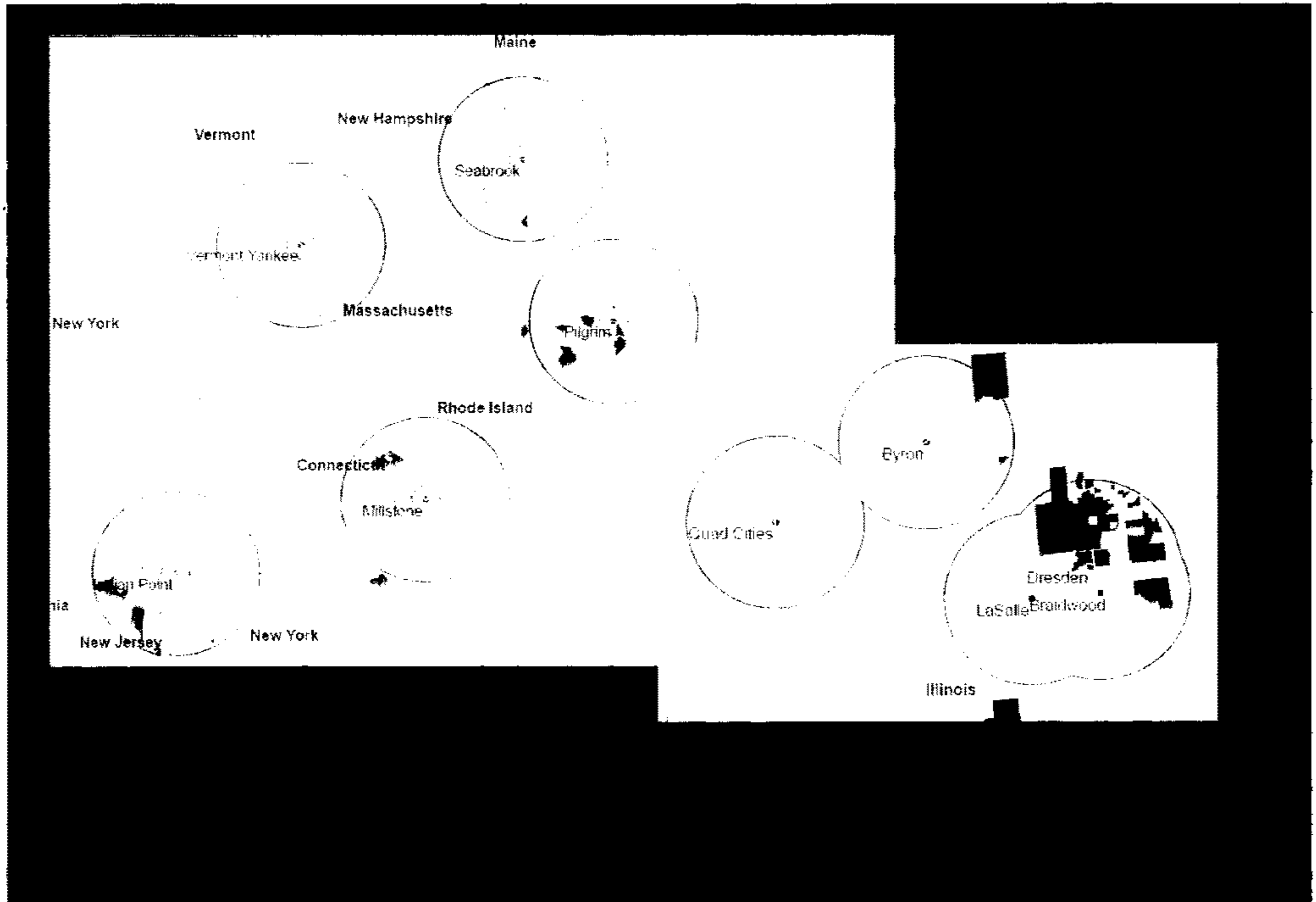
1. Reduce the size of the geographic unit.
2. Use the current nuclear facility inventory.
3. Include years of mortality and incidence data that are relevant to the years of exposure.
4. Incorporate estimated exposure levels for each geographic unit.
5. Use stronger analytic methods
    - Direct adjustment for possible confounding variables
    - Population mobility
    - Temporal changes in the socio-demographic characteristics

ECOLOGIC VERSUS RECORD-BASED CASE-CONTROL APPROACH

Examines groups.	Examines individuals.
Examines all cancers, all ages. More cases, more statistical power.	Restricted to childhood cancers. Fewer cases, less statistical power.
Examines both incidence and mortality.	Examines incidence only.
No control needed.	Control selection is required.
Examines associations based on residence at diagnosis or death.	Examines associations based on birth place which can be considered more relevant.
Can control for confounding only by using aggregate data.	Relevant information is available in the birth certificates.
Can only estimate average in- and out-migration rates.	In-migration of cancer cases (but not controls) can be estimated; less mobile population.
Particularly subject to "false positive" findings.	"False positive" findings are an issue.
IRB approvals may be needed and are likely to be undemanding.	IRB or equivalent body approvals will be needed.
Hypothesis generating.	Hypothesis testing.

UNCERTAINTIES

- Dose reconstruction
- Completeness of cancer case ascertainment
- Population mobility
- Variability in risk factors and potential confounding
- Inability to distinguish risks from different sources of radiation
- Statistical uncertainty



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FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: NEXT STEPS FOR THE ANALYSIS OF CANCER RISKS IN POPULATIONS NEAR NUCLEAR FACILITIES STUDY

PURPOSE:

The purpose of this paper is to inform the Commission of staff plans for the next steps of the Nuclear Regulatory Commission (NRC)-sponsored Analysis of Cancer Risks in Populations near Nuclear Facilities study.

SUMMARY:

In April 2010, the NRC staff requested the National Academy of Sciences (NAS) to perform a study on cancer mortality and incidence risks in populations living near NRC-licensed facilities to update the 1990 National Cancer Institute (NCI) report on "Cancer Risks in Populations near Nuclear Facilities." The study was divided into two phases. In Phase 1, NAS explored the feasibility of conducting an updated study by developing modern methods to perform the analysis. The staff has reviewed the results of the Phase 1 study and the NAS recommendations for the next phase. The staff's next step will be to proceed with the NAS-recommended approach to determine the feasibility of the Phase 1 methods through pilot studies at seven sites recommended by the NAS committee: Dresden in Illinois, Millstone in Connecticut, Oyster Creek in New Jersey, Haddam Neck (decommissioned) in Connecticut, Big Rock Point (decommissioned) in Michigan, San Onofre in California, and Nuclear Fuel Services in Tennessee. Upon completion of the pilot studies, NAS will comment whether further study is beneficial, and the NRC staff will determine whether to perform the studies at all NRC-licensed facilities (i.e., balance of operating nuclear power plants and fuel-cycle facilities).

CONTACT: Terry Brock, RES/DSA
301-251-7487

Chidichimo, Gabriele

From:	Weber, Michael
Sent:	Tuesday, September 20, 2016 5:55 PM
To:	Albert, Michelle
Cc:	Ammon, Bernice; Clark, Michael; Clark, Lisa; Hackett, Edwin; Tadesse, Rebecca; Spencer, Mary; Campbell, Tison; Pessin, Andrew; Mikula, Olivia; Colgary, James; Lewis, Robert
Subject:	RESPONSE - Quick Turnaround - FW: LRM [EHF-114-323] ENERGY Oversight Testimony on DOE's Decision to end its Low Dose Radiation Research Program #1140231926#

Thanks, Michelle. Just seeing this now. We can live with the revised testimony. I would note that they did not address the two larger policy comments, but we have accomplished our objective of advising OMB of the concerns.

From: Albert, Michelle
Sent: Tuesday, September 20, 2016 2:51 PM
To: Lewis, Robert <Robert.Lewis@nrc.gov>; Weber, Michael <Michael.Weber@nrc.gov>; Hackett, Edwin <Edwin.Hackett@nrc.gov>; Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>; Spencer, Mary <Mary.Spencer@nrc.gov>; Campbell, Tison <Tison.Campbell@nrc.gov>; Pessin, Andrew <Andrew.Pessin@nrc.gov>; Mikula, Olivia <Olivia.Mikula@nrc.gov>; Colgary, James <James.Colgary@nrc.gov>
Cc: Ammon, Bernice <Bernice.Ammon@nrc.gov>; Clark, Michael <Michael.Clark@nrc.gov>; Clark, Lisa <Lisa.Clark@nrc.gov>
Subject: RE: Quick Turnaround - FW: LRM [EHF-114-323] ENERGY Oversight Testimony on DOE's Decision to end its Low Dose Radiation Research Program #1140231926#

OMB circulated a revised version of the draft testimony. Please see the attached for the response to the NRC staff's comments.

I plan to inform OMB at **3 p.m. today** that the NRC staff has no further comments, unless I hear otherwise from you before then.

Thank you,

Michelle D. Albert
Senior Attorney | Office of the General Counsel
Legal Counsel, Legislation, and Special Projects Division
U.S. Nuclear Regulatory Commission
(301) 287-9259 | Michelle.Albert@nrc.gov

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From: Albert, Michelle
Sent: Tuesday, September 20, 2016 8:23 AM
To: EDO_ACS Distribution <EDO_ACSDistribution@nrc.gov>; EDO_ETAs <EDO_ETAs@nrc.gov>; Spencer, Mary <Mary.Spencer@nrc.gov>; Campbell, Tison <Tison.Campbell@nrc.gov>; RidsNmssOd Resource <RidsNmssOd.Resource@nrc.gov>; Roman-Cuevas, Cinthya <Cinthya.Roman@nrc.gov>; Weber, Michael <Michael.Weber@nrc.gov>; Hackett, Edwin <Edwin.Hackett@nrc.gov>; Wylie, Maureen <Maureen.Wylie@nrc.gov>; Muessle, Mary <Mary.Muessle@nrc.gov>; Rossi, Anthony <Anthony.Rossi@nrc.gov>; Colgary, James <James.Colgary@nrc.gov>
Cc: RidsOgcMailCenter Resource <RidsOgcMailCenter.Resource@nrc.gov>; RidsEdoMailCenter Resource

<RidsEdoMailCenter.Resource@nrc.gov>; Ammon, Bernice <Bernice.Ammon@nrc.gov>; Clark, Michael <Michael.Clark@nrc.gov>; Clark, Lisa <Lisa.Clark@nrc.gov>
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Importance: High

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Please provide any comments on the attached to me and Lisa Clark by **11:30 a.m. today** (Tuesday, September 20, 2016).

(b)(5)

Thank you,

Michelle D. Albert
Senior Attorney | Office of the General Counsel
Legal Counsel, Legislation, and Special Projects Division
U.S. Nuclear Regulatory Commission
(301) 287-9259 | Michelle.Albert@nrc.gov

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From: LLO Resource
Sent: Monday, September 19, 2016 5:49 PM
To: Ammon, Bernice <Bernice.Ammon@nrc.gov>; Clark, Michael <Michael.Clark@nrc.gov>; Albert, Michelle <Michelle.Albert@nrc.gov>; Clark, Lisa <Lisa.Clark@nrc.gov>; Michel, Eric <Eric.MichelOGC@nrc.gov>
Subject: FW: LRM [EHF-114-323] ENERGY Oversight Testimony on DOE's Decision to end its Low Dose Radiation Research Program #1140231926#

From: Fitter, E. Holly H. EOP/OMB
Sent: Monday, September 19, 2016 5:48:40 PM (UTC-05:00) Eastern Time (US & Canada)
To: DL-CEQ-LRM; 'EPA'; 'HHS'; 'JUSTICE'; 'NASA'; DL-OSTP-LRM; LLO Resource
Cc: Zaidi, Ali A. EOP/OMB; DL-WHO-WHGC-LRM; Pasquantino, John C. EOP/OMB; McDonald, Christine A. EOP/OMB; Bar-Shalom, Tali EOP/OMB; Robinson, Donovan O. EOP/OMB; Arnett, Benton T. EOP/OMB; Laity, Jim A. EOP/OMB; Dorjets, Vlad EOP/OMB; Burnim, John D. EOP/OMB; Vaeth, Matt J. EOP/OMB; Fucile, Tamara L. EOP/OMB; Dee, Carolyn M. EOP/OMB; Menter, Jessica N. EOP/WHO; Bauserman, Trent D. EOP/WHO; Hickey, Mike J. EOP/OMB; Burgess, Scott H. EOP/OMB; Aguilar, Brenda L. EOP/OMB; DL-WHO-DPCEC-LRM; Fahiye (Fahiye.Yusuf@Hq.Doe.Gov) Yusuf (Fahiye.Yusuf@Hq.Doe.Gov); 'Owen, Lil'
Subject: [External_Sender] LRM [EHF-114-323] ENERGY Oversight Testimony on DOE's Decision to end its Low Dose Radiation Research Program #1140231926#

DEADLINE: 12:00 Noon Tuesday, September 20, 2016

Please review the attached DOE statement for a 9/21 House Science hearing on DOE's decision to end its Low Dose Radiation Research Program in FY 2016, and provide any comments by the deadline above. Thanks.

LRM ID: EHF-114-323
EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET

LEGISLATIVE REFERRAL MEMORANDUM
Monday, September 19, 2016

(b)(5)

Thank you.

Weber, Michael

From: Weber, Michael
Sent: Tuesday, September 20, 2016 8:24 AM
To: Albert, Michelle
Cc: Gartman, Michael; Sampson, Michele
Subject: RESPONSE - Quick Turnaround - FW: LRM [EHF-114-323] ENERGY Oversight Testimo on DOE's Decision to end its Low Dose Radiation Research Program #1140231926#

Got it. Will advise this morning by 1130.

Thanks

From: Albert, Michelle
Sent: Tuesday, September 20, 2016 8:23 AM
To: EDO_ACS Distribution <EDO_ACSDistribution@nrc.gov>; EDO_ETAs <EDO_ETAs@nrc.gov>; Spencer, Mary <Mary.Spencer@nrc.gov>; Campbell, Tison <Tison.Campbell@nrc.gov>; RidsNmssOd Resource <RidsNmssOd.Resource@nrc.gov>; Roman-Cuevas, Cinthya <Cinthya.Roman@nrc.gov>; Weber, Michael <Michael.Weber@nrc.gov>; Hackett, Edwin <Edwin.Hackett@nrc.gov>; Wylie, Maureen <Maureen.Wylie@nrc.gov>; Muessle, Mary <Mary.Muessle@nrc.gov>; Rossi, Anthony <Anthony.Rossi@nrc.gov>; Colgary, James <James.Colgary@nrc.gov>
Cc: RidsOgcMailCenter Resource <RidsOgcMailCenter.Resource@nrc.gov>; RidsEdoMailCenter Resource <RidsEdoMailCenter.Resource@nrc.gov>; Ammon, Bernice <Bernice.Ammon@nrc.gov>; Clark, Michael <Michael.Clark@nrc.gov>; Clark, Lisa <Lisa.Clark@nrc.gov>
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Importance: High

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Please provide any comments on the attached to me and Lisa Clark by **11:30 a.m. today** (Tuesday, September 20, 2016).

(b)(5)

Thank you,

Michelle D. Albert
Senior Attorney | Office of the General Counsel
Legal Counsel, Legislation, and Special Projects Division
U.S. Nuclear Regulatory Commission
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LRM ID: EHF-114-323
EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET

LEGISLATIVE REFERRAL MEMORANDUM
Monday, September 19, 2016

(b)(5)

Weber, Michael

From:	Weber, Michael
Sent:	Tuesday, September 20, 2016 10:26 AM
To:	Tadesse, Rebecca
Cc:	Case, Michael; Webber, Kimberly; Hackett, Edwin; Difrancesco, Nicholas; Armstrong, Kenneth; Gartman, Michael
Subject:	RESPONSE - Quick Turnaround - FW: LRM [EHF-114-323] ENERGY Oversight Testimoı on DOE's Decision to end its Low Dose Radiation Research Program #1140231926#

Thanks, Rebecca. Appreciate the prompt and quality turn-around on this review.

From: Tadesse, Rebecca
Sent: Tuesday, September 20, 2016 10:18 AM
To: Weber, Michael <Michael.Weber@nrc.gov>; Albert, Michelle <Michelle.Albert@nrc.gov>
Cc: Clark, Lisa <Lisa.Clark@nrc.gov>; Case, Michael <Michael.Case@nrc.gov>; Webber, Kimberly <Kimberly.Webber@nrc.gov>; Hackett, Edwin <Edwin.Hackett@nrc.gov>; Gartman, Michael <Michael.Gartman@nrc.gov>; Sampson, Michele <Michele.Sampson@nrc.gov>; Brock, Terry <Terry.Brock@nrc.gov>
Subject: RE: RESPONSE - Quick Turnaround - FW: LRM [EHF-114-323] ENERGY Oversight Testimony on DOE's Decision end its Low Dose Radiation Research Program #1140231926#

Hi Michelle,

Attached is a background information on the Million Worker Study.

Thanks
Rebecca Tadesse, Chief
Radiation Protection Branch
Division of Systems Analysis
Office of Nuclear Regulatory Research
301-415-1824

From: Weber, Michael
Sent: Tuesday, September 20, 2016 9:25 AM
To: Albert, Michelle <Michelle.Albert@nrc.gov>
Cc: Clark, Lisa <Lisa.Clark@nrc.gov>; Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>; Case, Michael <Michael.Case@nrc.gov>; Webber, Kimberly <Kimberly.Webber@nrc.gov>; Hackett, Edwin <Edwin.Hackett@nrc.g Gartman, Michael <Michael.Gartman@nrc.gov>; Sampson, Michele <Michele.Sampson@nrc.gov>
Subject: RESPONSE - Quick Turnaround - FW: LRM [EHF-114-323] ENERGY Oversight Testimony on DOE's Decision its Low Dose Radiation Research Program #1140231926#

Good morning, Michelle. As promised, please find attached a few comments on the draft testimony. Oι biggest concern is the premature and disruptive termination of the Million Worker Study. Although the testimony indicates the merits of the study, it does not specifically state why the study is being terminate point out the loss of this research to the Federal government and Nation. We can provide you with mor background from NRC's perspective on the Million Worker Study as you deem necessary.

In addition, although DOE is testifying why it is bringing the low dose radiation research program to a c does not clearly indicate that DOE (and the AEC before) has shouldered the primary obligation for con the radiation effects research for the US Government back to the 1940s. Termination of this program eliminates this support for the Federal government. Because fundamental issues remain (as alluded t

draft testimony), re-establishment of this program in one or more agencies would require additional resource and a substantial investment of intellectual and human resources and may not be as effective or efficient if it distributed across multiple agencies. By terminating the program without previously coordinating and establishing a successor program, DOE is putting this body of knowledge and the country at risk.

From: Albert, Michelle
Sent: Tuesday, September 20, 2016 8:23 AM
To: EDO_ACS Distribution <EDO_ACSDistribution@nrc.gov>; EDO_ETAs <EDO_ETAs@nrc.gov>; Spencer, Mary <Mary.Spencer@nrc.gov>; Campbell, Tison <Tison.Campbell@nrc.gov>; RidsNmssOd Resource <RidsNmssOd.Resource@nrc.gov>; Roman-Cuevas, Cinthya <Cinthya.Roman@nrc.gov>; Weber, Michael <Michael.Weber@nrc.gov>; Hackett, Edwin <Edwin.Hackett@nrc.gov>; Wylie, Maureen <Maureen.Wylie@nrc.gov>; Muessle, Mary <Mary.Muessle@nrc.gov>; Rossi, Anthony <Anthony.Rossi@nrc.gov>; Colgary, James <James.Colgary@nrc.gov>
Cc: RidsOgcMailCenter Resource <RidsOgcMailCenter.Resource@nrc.gov>; RidsEdoMailCenter Resource <RidsEdoMailCenter.Resource@nrc.gov>; Ammon, Bernice <Bernice.Ammon@nrc.gov>; Clark, Michael <Michael.Clark@nrc.gov>; Clark, Lisa <Lisa.Clark@nrc.gov>
Subject: Quick Turnaround - FW: LRM [EHF-114-323] ENERGY Oversight Testimony on DOE's Decision to end its Low Dose Radiation Research Program #1140231926#
Importance: High

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Please provide any comments on the attached to me and Lisa Clark by **<u>11:30 a.m. today</u>** (Tuesday, September 20, 2016).

(b)(5)

Thank you,

Michelle D. Albert
Senior Attorney | Office of the General Counsel
Legal Counsel, Legislation, and Special Projects Division
U.S. Nuclear Regulatory Commission
(301) 287-9259 | Michelle.Albert@nrc.gov

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From: LLO Resource
Sent: Monday, September 19, 2016 5:49 PM
To: Ammon, Bernice <Bernice.Ammon@nrc.gov>; Clark, Michael <Michael.Clark@nrc.gov>; Albert, Michelle <Michelle.Albert@nrc.gov>; Clark, Lisa <Lisa.Clark@nrc.gov>; Michel, Eric <Eric.MichelOGC@nrc.gov>
Subject: FW: LRM [EHF-114-323] ENERGY Oversight Testimony on DOE's Decision to end its Low Dose Radiation Research Program #1140231926#

From: Fitter, E. Holly H. EOP/OMB
Sent: Monday, September 19, 2016 5:48:40 PM (UTC-05:00) Eastern Time (US & Canada)
To: DL-CEQ-LRM; 'EPA'; 'HHS'; 'JUSTICE'; 'NASA'; DL-OSTP-LRM; LLO Resource
Cc: Zaidi, Ali A. EOP/OMB; DL-WHO-WHGC-LRM; Pasquantino, John C. EOP/OMB; McDonald, Christine A. EOP/OMB; Ba Shalom, Tali EOP/OMB; Robinson, Donovan O. EOP/OMB; Arnett, Benton T. EOP/OMB; Laity, Jim A. EOP/OMB; Dorjets, Vlad EOP/OMB; Burnim, John D. EOP/OMB; Vaeth, Matt J. EOP/OMB; Fucile, Tamara L. EOP/OMB; Dee, Carolyn M. EOP/OMB; Menter, Jessica N. EOP/WHO; Bauserman, Trent D. EOP/WHO; Hickey, Mike J. EOP/OMB; Burgess, Scott H. EOP/OMB; Aguilar, Brenda L. EOP/OMB; DL-WHO-DPCEC-LRM; Fahiye (Fahiye.Yusuf@Hq.Doe.Gov) Yusuf (Fahiye.Yusuf@Hq.Doe.Gov); 'Owen, Lil'
Subject: [External_Sender] LRM [EHF-114-323] ENERGY Oversight Testimony on DOE's Decision to end its Low Dose Radiation Research Program #1140231926#

DEADLINE: 12:00 Noon Tuesday, September 20, 2016

Please review the attached DOE statement for a 9/21 House Science hearing on DOE's decision to end its Low Dose Radiation Research Program in FY 2016, and provide any comments by the deadline above. Thanks.

LRM ID: EHF-114-323
EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET

LEGISLATIVE REFERRAL MEMORANDUM
Monday, September 19, 2016

(b)(5)

Thank you.

Testimony of Associate Director Sharlene Weatherwax
Office of Biological and Environmental Research
Office of Science
U.S. Department of Energy
Before the Committee on Science, Space, and Technology
U.S. House of Representatives
September 21, 2016

(b)(5)

[7] http://www.battelle.org/docs/default-document-library/economic_impact_of_the_human_genome_project.pdf

Pre-decisional. DRAFT.

(b)(5)

Lignocellulosic Biomass for Advanced Biofuels
and Bioproducts workshop report:
http://science.energy.gov/~/media/ber/pdf/workshop%20reports/Lignocellulosic_Biomass_for_Advanced_Biofuels_and_Bioproducts.pdf

[3] 2014 Bioenergy Research Centers report available online:
http://genomicscience.energy.gov/centers/BRCs2014HR.pdf

(b)(5)

[4] Millisievert. The sievert is the SI unit for dose of ionizing radiation on the human body. The average person receives about 3.1 mSv per year from natural radiation. http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/bio-effects-radiation.html

(b)(5)

[5] https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf

(b)(5)

[6] http://energy.gov/seab/downloads/letter-low-level-radiation-research
[7] http://science.energy.gov/~/media/ber/berac/pdf/Reports/LD_Program_Charge_Letter.pdf

Pre-decisional. DRAFT.

(b)(5)

Weber, Michael

From:	Weber, Michael
Sent:	Tuesday, September 20, 2016 8:26 AM
To:	Case, Michael; Webber, Kimberly
Cc:	Rebecca Tadesse (Rebecca.Tadesse@nrc.gov); Brock, Terry; Armstrong, Kenneth; Hackett, Edwin; Difrancesco, Nicholas
Subject:	ACTION - Quick Turnaround - FW: LRM [EHF-114-323] ENERGY Oversight Testimo DOE's Decision to end its Low Dose Radiation Research Program #1140231926#
Attachments:	Weatherwax Invite.pdf; HSST Low Dose Testimony-Weatherwax.docx
Importance:	High

Please advise promptly (next couple of hours) on whether we have any comments on the attached draft testimony by DOE. I'll review in parallel. We need to get back with any comments to Michele and Lisa by 1130 today.

Thanks

From: Albert, Michelle
Sent: Tuesday, September 20, 2016 8:23 AM
To: EDO_ACS Distribution <EDO_ACSDistribution@nrc.gov>; EDO_ETAs <EDO_ETAs@nrc.gov>; Spencer, Mary <Mary.Spencer@nrc.gov>; Campbell, Tison <Tison.Campbell@nrc.gov>; RidsNmssOd Resource <RidsNmssOd.Resource@nrc.gov>; Roman-Cuevas, Cinthya <Cinthya.Roman@nrc.gov>; Weber, Michael <Michael.Weber@nrc.gov>; Hackett, Edwin <Edwin.Hackett@nrc.gov>; Wylie, Maureen <Maureen.Wylie@nrc.gov Muessle, Mary <Mary.Muessle@nrc.gov>; Rossi, Anthony <Anthony.Rossi@nrc.gov>; Colgary, James <James.Colgary@nrc.gov>
Cc: RidsOgcMailCenter Resource <RidsOgcMailCenter.Resource@nrc.gov>; RidsEdoMailCenter Resource <RidsEdoMailCenter.Resource@nrc.gov>; Ammon, Bernice <Bernice.Ammon@nrc.gov>; Clark, Michael <Michael.Clark@nrc.gov>; Clark, Lisa <Lisa.Clark@nrc.gov>
Subject: Quick Turnaround - FW: LRM [EHF-114-323] ENERGY Oversight Testimony on DOE's Decision to end its Lı Dose Radiation Research Program #1140231926#
Importance: High

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Please provide any comments on the attached to me and Lisa Clark by **11:30 a.m. today** (Tuesday, September 20, 2016)

(b)(5)

Thank you.

Michelle D. Albert
Senior Attorney | Office of the General Counsel
Legal Counsel, Legislation, and Special Projects Division
U.S. Nuclear Regulatory Commission

(301) 287-9259 | Michelle.Albert@nrc.gov

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Subject: FW: LRM [EHF-114-323] ENERGY Oversight Testimony on DOE's Decision to end its Low Dose Radiation Research Program #1140231926#

From: Fitter, E. Holly H. EOP/OMB
Sent: Monday, September 19, 2016 5:48:40 PM (UTC-05:00) Eastern Time (US & Canada)
To: DL-CEQ-LRM; 'EPA'; 'HHS'; 'JUSTICE'; 'NASA'; DL-OSTP-LRM; LLO Resource
Cc: Zaidi, Ali A. EOP/OMB; DL-WHO-WHGC-LRM; Pasquantino, John C. EOP/OMB; McDonald, Christine A. EOP/OMB; Shalom, Tali EOP/OMB; Robinson, Donovan O. EOP/OMB; Arnett, Benton T. EOP/OMB; Laity, Jim A. EOP/OMB; Dorje Vlad EOP/OMB; Burnim, John D. EOP/OMB; Vaeth, Matt J. EOP/OMB; Fucile, Tamara L. EOP/OMB; Dee, Carolyn M. EOP/OMB; Menter, Jessica N. EOP/WHO; Bauserman, Trent D. EOP/WHO; Hickey, Mike J. EOP/OMB; Burgess, Scott EOP/OMB; Aguilar, Brenda L. EOP/OMB; DL-WHO-DPCEC-LRM; Fahiye (Fahiye.Yusuf@Hq.Doe.Gov) Yusuf (Fahiye.Yusuf@Hq.Doe.Gov); 'Owen, Lil'
Subject: [External_Sender] LRM [EHF-114-323] ENERGY Oversight Testimony on DOE's Decision to end its Low Dos Radiation Research Program #1140231926#

DEADLINE: 12:00 Noon Tuesday, September 20, 2016

Please review the attached DOE statement for a 9/21 House Science hearing on DOE's decision to end its Low Do: Radiation Research Program in FY 2016, and provide any comments by the deadline above. Thanks.

LRM ID: EHF-114-323
EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET

LEGISLATIVE REFERRAL MEMORANDUM
Monday, September 19, 2016

(b)(5)

(b)(5)

Thank you.

Weber, Michael

From: Weber, Michael
Sent: Thursday, May 12, 2016 6:06 PM
To: Brock, Terry
Cc: Case, Michael; Webber, Kimberly; Hackett, Edwin; Armstrong, Kenneth; DiFrancesco, Nicholas; Harrison, John; Tadesse, Rebecca; Oxenberg, Tanya; Araguas, Christian; Milligan, Patricia
Subject: RESPONSE - Info on Ketones Protective of Ionizing Radiation

Thanks, Terry. Very helpful. For greater awareness in the Federal community, it would be worthwhile for him to make a brief presentation at the ISCORS (Interagency Steering Committee on Radiation Standards), as well as his outreach to NCRP. NMSS/MSTR (Dan Collins/Pam Henderson) coordinate NRC's participation in ISCORS. Not sure when the next meeting is, but interaction now will be helpful to get this topic on the agency for awareness. He might also want to volunteer to make a presentation at the local chapter meeting of the Health Physics Society, which he could access through Tanya Oxenberg.

From: Brock, Terry
Sent: Thursday, May 12, 2016 11:57 AM
To: Weber, Michael <Michael.Weber@nrc.gov>; Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>
Cc: Case, Michael <Michael.Case@nrc.gov>; Webber, Kimberly <Kimberly.Webber@nrc.gov>; Hackett, Edwin <Edwin.Hackett@nrc.gov>; Armstrong, Kenneth <Kenneth.Armstrong@nrc.gov>; DiFrancesco, Nicholas <Nicholas.DiFrancesco@nrc.gov>; Harrison, John <John.Harrison@nrc.gov>
Subject: UPDATE RE: Response - Info on Ketones Protective of Ionizing Radiation

Hi Mike,

I spoke with Dr. Veech, the NIH biochemist and the interviewee of the podcast you forwarded on the subject-line topic. As I started digging, he's actually one of the more well-known biochemists in the field—he co-authored and worked with the noble-prize winning biochemist Dr. Krebs of the "Krebs Cycle" fame. My best analogy is that he's probably the John Boice of his field in stature—admittedly, I don't run in his circles but that's my sense at this time. His lab is located in NIH's satellite campus just up the road near the Twinbrook metro station and the HHS complex on Parklawn Drive. With him being so close, I went up there yesterday for about an hour meeting with him and his staff to see where they are in developing ketone esters for wide-scale use as described in their patent sent earlier (https://www.ott.nih.gov/technology/e-258-2012).

Dr. Veech informed me that they are currently at the laboratory-scale for production of the ketone-ester compound and are exploring options on increasing to an industrial-scale production. He envisions the compound could be administered orally to the public or workers prior to radiation exposure and/or up to seven days after an improvised nuclear device, reactor, and/or radioactive materials event. What's interesting about this compound is that it uses your own metabolism to create a reductive state in the cell to mitigate the damage from the free radicals produced by an acute irradiation. They are also testing it to alleviate the symptoms from Parkinson's disease (interestingly, one of the researchers at the meeting has Parkinson's and has been taking the ketone-ester and he told me it reduces his shaking). They seem to have the theory worked out, but one of the fundamental questions I asked is how effective is the compound in raising the LD50/30 (reducing mortality) for acute radiation doses--have they published any in vivo efficacy testing, and the answer was no. In vivo testing in this case would involve administering the compound to an animal model (e.g., mice/rat), irradiating them, and observing what impact the compound has on survivability. Veech told me they are waiting on some animal study results from the Armed Forces Radiobiology Research Institute (AFFRI), but have had some trouble with AFFRI sharing the results. I know NIH has some Cs-137-CI irradiators from when we were doing increased security measures, so I suggested he look in his own institution to do the in-vivo study.

Bottom-line:
As far as the NRC is concerned, if efficacy can be demonstrated in vivo, I see utility in NIH developing this for potential use by the general public and/or workers in a large scale radiation accident or even a single event like an industrial radiographer receiving an accidental acute dose. However, they seem to be far away from having a product available for wide-scale use after an accident. Dr Veech did not want any money from NRC, but some moral support for the effort as he attempts to get the compound produced on a large-scale and navigates the approval process. He's not plugged into the radiation protection community, so we could help by facilitating some interactions with NCRP (I can do this passively in my routine interactions with Boice). I suggest we continue to monitor this work and I'll let you know of any new developments.

Terry

Terry Brock, Ph.D.
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington D.C. 20555
Mail Stop TWFN-10
phone: 301-415-1793

From: Weber, Michael
Sent: Wednesday, April 27, 2016 11:40 AM
To: Brock, Terry <Terry.Brock@nrc.gov>; Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>
Cc: Case, Michael <Michael.Case@nrc.gov>; Webber, Kimberly <Kimberly.Webber@nrc.gov>; Hackett, Edwin <Edwin.Hackett@nrc.gov>; Armstrong, Kenneth <Kenneth.Armstrong@nrc.gov>; DiFrancesco, Nicholas <Nicholas.DiFrancesco@nrc.gov>; Harrison, John <John.Harrison@nrc.gov>
Subject: Response - Info on Ketones Protective of Ionizing Radiation

Thanks, Terry. Please keep us informed as you proceed.

From: Brock, Terry
Sent: Wednesday, April 27, 2016 10:59 AM
To: Weber, Michael; Tadesse, Rebecca
Cc: Case, Michael; Webber, Kimberly; Hackett, Edwin; Armstrong, Kenneth
Subject: RESPONSE: RE: FYI/QUERY - Info on Ketones Protective of Ionizing Radiation

Mike,

I did a little digging ... interesting stuff.

There seems to be something to this idea. The interviewee from the podcast, Richard Veech, holds a patent on this idea of using ketones as a prophylaxis and treatment to reduce cell apoptosis via DNA and RNA damage from radiation exposure. Veech and NIH have an open solicitation for research collaboration on this very topic. I've reached out to the NIH POC to get more information on the status of the work, scope, etc. I'll send an update when I hear more. In the meanwhile, here's the NIH web link for the proposal. https://www.ott.nih.gov/technology/e-258-2012

Best,
Terry

Terry Brock, Ph.D.
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington D.C. 20555
Mail Stop TWFN-10

phone: 301-415-1793

From: Weber, Michael
Sent: Friday, April 22, 2016 3:09 PM
To: Brock, Terry <Terry.Brock@nrc.gov>; Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>
Cc: Case, Michael <Michael.Case@nrc.gov>; Webber, Kimberly <Kimberly.Webber@nrc.gov>; Hackett, Edwin <Edwin.Hackett@nrc.gov>; Armstrong, Kenneth <Kenneth.Armstrong@nrc.gov>
Subject: FYI/QUERY - Info on Ketones Protective of Ionizing Radiation

Good afternoon, Radiation Protection Branch. Anything new here? I discussed this briefly with John, who was excited to share this with me earlier this week when I saw him in the cafeteria. I told him that research like this has existing for years indicating some level of prophylactic effect of certain chemicals in preventing or mitigating damage from ionizing radiation. Something worth pursuing?

From: Harrison, John
Sent: Friday, April 22, 2016 2:12 PM
To: Weber, Michael <Michael.Weber@nrc.gov>
Subject: Info on Ketones Protective of Ionizing Radiation

Hi Mike,

Here's a link to the podcast that I mentioned to you on Wednesday in which Dr. Richard Veech states that ketones protect the body from ionizing radiation:
https://www.bulletproofexec.com/exclusive-interview-with-ketone-expert-dr-richard-veech-299/

The transcript of this podcast is attached.

Also, here's a link to a patent (application?) for a method of protecting animal tissue and cells from damage caused by radiation exposure. Dr. Veech is listed as a co-inventor:
http://www.google.com/patents/US20150250755

Anyway, I couldn't help thinking of you when I stumbled across this info and wondered if the NRC, through its research program or otherwise, could somehow use this information to benefit those who are either intentionally or accidently exposed to ionizing radiation.

It was good to see you. Take care!

John

John Harrison
Sr. Business Process Improvement Specialist
OCFO/DOC/ARB
T-9D39, (301) 415-0151

Weber, Michael

From: Weber, Michael
Sent: Wednesday, April 13, 2016 6:22 AM
To: Armstrong, Kenneth
Cc: Case, Michael; Webber, Kimberly; Bush-Goddard, Stephanie; Brock, Terry; Hackett, Edwin
Subject: Response - Update Cancer Study One Pager

Thanks, Ken

From: Armstrong, Kenneth
Sent: Tuesday, April 12, 2016 10:34 AM
To: Rihm, Roger <Roger.Rihm@nrc.gov>
Cc: Weber, Michael <Michael.Weber@nrc.gov>; Hackett, Edwin <Edwin.Hackett@nrc.gov>; Araguas, Christian <Christian.Araguas@nrc.gov>; Case, Michael <Michael.Case@nrc.gov>; Webber, Kimberly <Kimberly.Webber@nrc.gov>; Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>; Brock, Terry <Terry.Brock@nrc.gov>
Subject: Response - Update Cancer Study One Pager

Roger,

Please see the attached updated file and let me know if you have any questions.

Thanks!

From: Rihm, Roger
Sent: Friday, April 08, 2016 2:54 PM
To: Landau, Mindy <Mindy.Landau@nrc.gov>
Subject: ACTION: Update One Pager
Importance: High

Mindy, just got out of a post-hearing meeting with the Chairman and he asked that we provide an update of the cancer study one pager for the house hearing coming up on 4/20. I've attached what I believe is the last version RES prepared (for hearings last fall). Not sure what update(s) might be necessary. The only thing that comes to my mind is that perhaps, since this is a budget hearing, we should include in the "facts" the actual cost estimate for the study so the chairman is informed on what kind of financial commitment it would be (?) Just a thought... I assume he expects to get questioned along the lines of why aren't we doing this, it's important, etc...

Can I get this by TUESDAY AM?

Weber, Michael

From: Weber, Michael
Sent: Monday, April 11, 2016 12:27 PM
To: Case, Michael; Hackett, Edwin
Cc: Armstrong, Kenneth; Webber, Kimberly; Bush-Goddard, Stephanie; Araguas, Christian; Rihm, Roger
Subject: Response - Update Cancer Study One Pager

Thanks, Mike. My only suggestion is to broaden the types of facilities beyond nuclear power plants in the last bullet. Could we just say "civilian nuclear facilities and users of radioactive material?" With this change, I support.

From: Case, Michael
Sent: Monday, April 11, 2016 07:41 AM
To: Weber, Michael; Hackett, Edwin
Cc: Armstrong, Kenneth; Webber, Kimberly
Subject: FYI: Update Cancer Study One Pager

FYI. We got a request to update the Cancer Study one-pager for the House hearing on 4/20

From: Tadesse, Rebecca
Sent: Friday, April 08, 2016 3:18 PM
To: Brock, Terry <Terry.Brock@nrc.gov>
Cc: Landau, Mindy <Mindy.Landau@nrc.gov>; Armstrong, Kenneth <Kenneth.Armstrong@nrc.gov>; Webber, Kimberly <Kimberly.Webber@nrc.gov>; Case, Michael <Michael.Case@nrc.gov>
Subject: FW: ACTION: Update Cancer Study One Pager
Importance: High

Terry,

I don't think there is any new information to add but could you please see if an update is needed if so please let Kim or Mike see it before you send it to Roger.

Thanks
Rebecca

From: Landau, Mindy
Sent: Friday, April 08, 2016 3:04 PM
To: Armstrong, Kenneth <Kenneth.Armstrong@nrc.gov>; Case, Michael <Michael.Case@nrc.gov>; Webber, Kimberly <Kimberly.Webber@nrc.gov>; Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>
Cc: Weber, Michael <Michael.Weber@nrc.gov>; Hackett, Edwin <Edwin.Hackett@nrc.gov>
Subject: ACTION: Update Cancer Study One Pager
Importance: High

See below request to update the attached one-pager on Cancer Study – note short turnaround back to Roger by Tuesday a.m....

Thanks.
Mindy

From: Rihm, Roger
Sent: Friday, April 08, 2016 2:54 PM
To: Landau, Mindy <Mindy.Landau@nrc.gov>
Subject: ACTION: Update One Pager
Importance: High

Mindy, just got out of a post-hearing meeting with the Chairman and he asked that we provide an update of the cancer study one pager for the house hearing coming up on 4/20. I've attached what I believe is the last version RES prepared (for hearings last fall). Not sure what update(s) might be necessary. The only thing that comes to my mind is that perhaps, since this is a budget hearing, we should include in the "facts" the actual cost estimate for the study so the chairman is informed on what kind of financial commitment it would be (?) Just a thought... I assume he expects to get questioned along the lines of why aren't we doing this, it's important, etc...

Can I get this by TUESDAY AM?

Analysis of Cancer Risks in Populations Living Near Nuclear Facilities Project Closeout

Key Messages

- **The NRC staff reviewed the National Academy of Sciences (NAS) Pilot Planning Project Report and Pilot Execution Proposal. The pilot project's duration, cost, and lack of useful results for communicating cancer risks preclude the agency from devoting further resources to this effort in the NRC's current budget environment.**

- **The methods developed by NAS in Phase 1, and discussed further in the pilot planning project are publicly available for other agencies or organizations to use.**

- **The staff will continue to monitor international and national studies in this area to determine if any future work in this area is warranted.**

Facts

- The NAS Phase I report called out several challenges to completing the study, not least of which was the work "may not have adequate statistical power to detect the presumed small increases in cancer risks arising from... monitored and reported releases."

- The Phase 2 report also explicitly warned that "any data collected during the pilot study will have *limited use for estimating cancer risks* in populations near each of the nuclear facilities or for the seven nuclear facilities combined because of the imprecision inherent in estimates from small samples."

- These issues, when considered alongside the significant time and resources estimated for the pilot study, argue against continuing the project in the current budget environment.

- The NRC continues to find U.S. nuclear power plants comply with strict requirements that limit radiation releases from routine operations. The NRC and state agencies regularly analyze environmental samples from near the plants. These analyses show the releases, when they occur, are too small to cause observable increases in cancer risk near the facilities.

Weber, Michael

From: Weber, Michael
Sent: Friday, April 08, 2016 3:24 PM
To: Brock, Terry
Cc: Tadesse, Rebecca; Araguas, Christian
Subject: ACTION: Update Cancer Study One Pager
Attachments: Cancer Study One Pager.docx

Importance: High

From: Landau, Mindy
Sent: Friday, April 08, 2016 09:04 PM
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Cc: Weber, Michael; Hackett, Edwin
Subject: ACTION: Update Cancer Study One Pager

See below request to update the attached one-pager on Cancer Study – note short turnaround back to Roger by Tuesday a.m....

Thanks.
Mindy

From: Rihm, Roger
Sent: Friday, April 08, 2016 2:54 PM
To: Landau, Mindy <Mindy.Landau@nrc.gov>
Subject: ACTION: Update One Pager
Importance: High

Mindy, just got out of a post-hearing meeting with the Chairman and he asked that we provide an update of the cancer study one pager for the house hearing coming up on 4/20. I've attached what I believe is the last version RES prepared (for hearings last fall). Not sure what update(s) might be necessary. The only thing that comes to my mind is that perhaps, since this is a budget hearing, we should include in the "facts" the actual cost estimate for the study so the chairman is informed on what kind of financial commitment it would be (?) Just a thought... I assume he expects to get questioned along the lines of why aren't we doing this, it's important, etc...

Can I get this by TUESDAY AM?

Weber, Michael

From: Weber, Michael
Sent: Wednesday, March 30, 2016 5:30 PM
To: 'John Boice'
Subject: RESPONSE - Meeting today

Thanks, John. I also had a meeting with the Commissioner. We might have just missed each other up there. He enjoyed his meeting with you. I emphasized our close cooperation with NCRP and also raised the Million Worker Study and DOE cancelling the funding for their part of the project.

From: John Boice [mailto(b)(6)
Sent: Wednesday, March 30, 2016 4:14 PM
To: Weber, Michael <Michael.Weber@nrc.gov>
Subject: [External_Sender] Meeting today

Hi Mike

Had a pleasant meeting with Commissioner Baran and also met Raeann Shane.

Purpose was just to make him aware of NCRP and our NRC collaborations.

Non Responsive

He was aware of the DOE problems with Low Dose Radiation and we discussed our NCRP needs to complete the Million Person Study ($20M over next 5 y and we finish in 5 years; $1M per year and its 20 years)!

Non Responsive

Non Responsive

Best wishes

John

--
John D. Boice, Jr., Sc.D.
President, National Council on Radiation Protection and Measurements
boice@ncrponline.org 301.657.2652 ext 19
Professor of Medicine, Vanderbilt University School of Medicine

john.boice@vanderbilt.edu Also: (b)(6) [redacted]

[redacted]@NCRP_ORG

One Pager for the Million Worker Study

9/20/16

In 2012, the Office of Nuclear Regulatory Research (RES) entered into an interagency agreement with the U.S. Department of Energy (DOE) - Office of Science (SC) to study the health effects of more than 1 million radiation workers and atomic veterans, which is often referred to as the "Million Worker Study." The U.S. Nuclear Regulatory Commission (NRC), the U.S. Environmental Protection Agency (EPA), and the National Aeronautics and Space Administration (NASA) provided support to DOE in this multiagency effort with the goal to provide new information for future radiation protection standards setting bodies and any resultant occupational radiation dose standards.

Recently, staff learned that DOE - Office of Science cancelled the multiagency Million Worker Study. NRC believes that there is still a very strong scientific and policy interest in the nuclear and health physics communities to complete this study to get actual risk estimates experienced by workers as a complement to the current paradigm of extrapolating risks from high dose and dose rate populations (e.g., Hiroshima and Nagasaki atomic bomb survivors). In addition, this study was supported by the Advisory Committee on Reactor Safeguards in the last RES program review. The results would be very influential in our understanding of radiation risk, particularly at lower dose rates, at the typical occupational exposure patterns the U.S. work force experiences. These results can be used to support future radiation protection standard setting bodies in broad areas such as reactor and facility siting, occupational dose, emergency response, off-site consequence analysis, and decommissioning and waste disposal. Scientific and medical committees continue to grapple with how best to estimate risks associated with the gradual exposures received from environmental, medical, and occupational radiation.

As a result of NRC's participation in the Million Worker Study, two NRC radiation worker cohorts in the nuclear power and industrial radiographer occupations were established. In addition to the NRC cohorts, the study was to research DOE uranium workers, atomic veterans, DOE plutonium workers, and medical workers. The Million Worker Study would provide a definitive study on the health risks to workers exposed to radiation at the dose rates experienced in an occupational setting. The results would be very influential in our understanding of radiation risk at the typical occupational exposure patterns the U.S. work force experiences.

DOE's original estimate was $25M over 5 years to complete the study. So far, DOE contributed $1M in fiscal year (FY) 2012 to this study; no further monies were provided. The NRC contributed $1.5M in FY12, $517K in FY14 and $100K in FY16. NASA has contributed nearly $1M to date, while EPA's contribution was smaller, on the order of $200K.

Examining the Reasons for Ending the Cancer Risk Study

Scott Burnell
Public Affairs Officer

One way NRC regulations protect communities around U.S. nuclear power plants is by requiring the plants to regularly sample air, water, and vegetation around their sites. Results of this sampling are sent to the NRC (and in some cases state agencies) to show only very tiny amounts of radioactive material are released during normal operations.

Even with this scrutiny -- and a 1990 study showing no difference in cancer mortality rates between those living near U.S. reactors and those living elsewhere -- questions persist about cancer risk from nearby reactors. The NRC had worked with the National Academy of Sciences (NAS) since 2010 on a study into the potential cancer risk of living near a U.S. nuclear power plant. But we ended this work earlier this month after a hard look at our budget situation and the low likelihood of getting usable results in a reasonable time frame.

Why are we comfortable that this decision is in line with our mission to protect public health and safety?

First and foremost, the staff considered existing conditions around U.S. reactors, as shown by the ongoing environmental sampling and analysis we mentioned earlier. That evidence supports the conclusion that the average U.S. citizen's annual radiation dose from natural sources, such as radon and cosmic rays, is about a hundred times greater than the largest potential dose from a normally operating reactor.

This information shows how complicated it would be to single out an operating reactor's potential contribution to cancer risk. Researchers looking for small effects need a very large study population to be confident in their results. The NAS discussed this issue in its report on Phase 1 of the cancer risk study. The NAS said that the effort "may not have adequate statistical power to detect the presumed small increases in cancer risks arising from... monitored and reported releases."

The NRC staff examined the NAS Phase 2 report plans to validate the methods recommended in Phase 1. The Academy was very clear that the pilot study at seven U.S. sites was unlikely to answer the basic risk question. The NAS proposal said: "any data collected during the pilot study will have limited use for estimating cancer risks in populations near each of the nuclear facilities or for the seven nuclear facilities combined because of the imprecision inherent in estimates from small samples."

The pilot study would also examine potential differences between individual states' cancer registries. Large differences in registry quality or accessibility would hurt the study's chances of generating useful results.

The NAS concluded they would need more than three years and $8 million to complete the pilot study. If the pilot succeeded, expanding the research to all U.S. operating reactors would require additional years and tens of millions of dollars. The NRC decided that in our current budget environment the time and money would not be well spent for the possible lack of useful results.

~~OFFICIAL USE ONLY – SENSITIVE INTERNAL INFORMATION~~

NOTE TO COMMISSIONERS' ASSISTANTS

OCM/SGB

x Jason Zorn
x Steve Baggett
___ Tracey Stokes
___ Clare Kasputys
___ Nanette Gilles
___ Johari Moore
x Kathleen Blake
x Sandra Cianci

OCM/WCO

x Eric Benner
___ Molly B. Marsh
___ Amy Cubbage
___ Tamara Bloomer
x Linda Herr
x Sunny Bozin

OCM/KLS

___ Maxwell Smith
___ Patrick Castleman
___ Alan Frazier
x Janet Lepre
x Nicole Riddick

OCM/JMB

x Amy Powell
___ Jody Martin
___ Robert Krsek
___ Raeann Shane
x Stacy Schumann

FROM: Melanie A. Galloway
Assistant for Operations, OEDO

(b)(5) Deliberative Privilege

ML15251A298

(b)(5) Deliberative Privilege

(b)(5) Deliberative Privilege

Million Person Study

- Welcome to the NRC, Michael Weber, Deputy Executive Director for Materials, Waste, Research, State, Tribal and Compliance Programs
- Pleased to host and support this meeting
- Congratulate John Boice on his nomination as President NCRP – an important national asset that supports the U.S. Government on radiation protection by providing unbiased, scientifically sound recommendations; vital to supporting our mission of protecting public health and safety and the environment
- Recognize the group – you are leaders in the field of radiation epidemiology; you play a key role in building the scientific basis for our system of radiation protection
- NRC adheres to the three principles of radiation protection
    - Justification of exposure
    - Individual dose limits
    - ALARA or optimization
- Dose limits are based on a combination of scientific information and value judgments – we need the best scientific information on radiation risk to inform our decision making; your work here this week directly fulfills this need – not just for the NRC and other agencies of the U.S. government, but all the nations of the world committed to protecting public health
- Exciting aspect of your work is that the radiation risks you are evaluating occur in populations of workers in a somewhat controlled environment – doses and dose rates much closer to existing limits; avoids the uncertainty associated with extrapolating risks from higher doses and dose rates
- Because of the importance of your work, pleased to announce that NRC will be joining DOE in a collaborative effort to support your work – working out the details of an interagency agreement with our DOE colleagues
- Welcome again to the NRC and wish you a productive and successful workshop; look forward to seeing the results of your deliberations

From: John Boice
To: Brock, Terry
Subject: [External_Sender] Re: Re: Re: input needed on MWS
Date: Wednesday, November 18, 2015 2:31:23 PM
Attachments: ~WRD000.jpg

I'm with ya! I remain optimistic, but if the nation chooses another direction there's not much else we could have done.

John

Duplicate Record

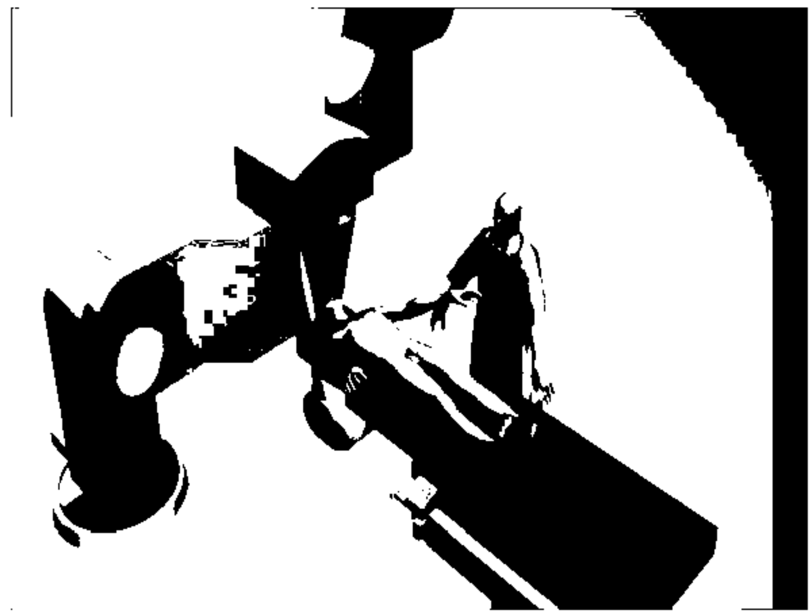
Guidance on Radiation Dose Limits for the Lens of the Eye

Status of NCRP SC 1-23, Commentary 26

NCRP
National Council on Radiation Protection & Measurements

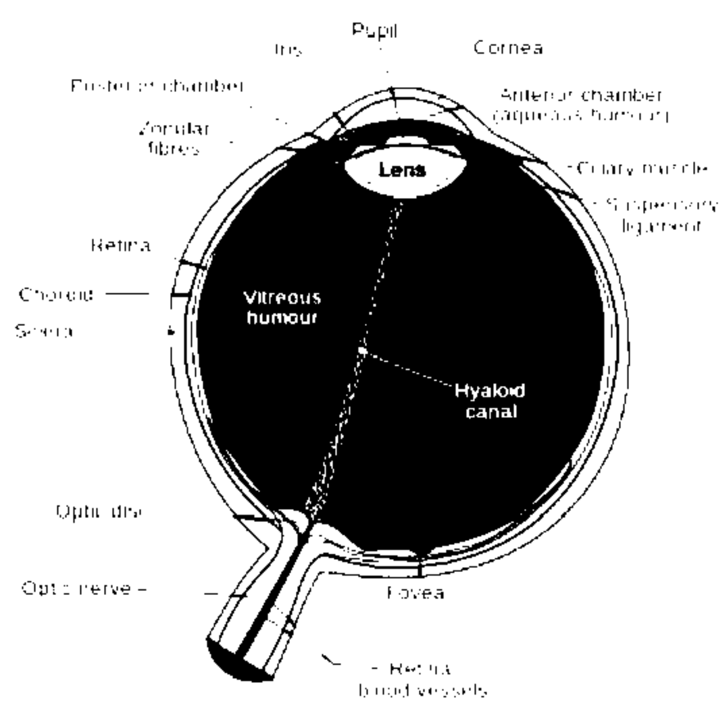
LAWRENCE T. DAUER

Memorial Sloan Kettering Cancer Center



Guidance on Radiation Dose Limits for the Lens of the Eye

Status of NCRP SC 1-23, Commentary 26



NCRP SC 1-23

Members

- Eleanor Blakely (Co-Chair)
- Lawrence Dauer (Co-chair)
- Elizabeth Ainsbury
- Joseph Dynlacht
- David Hoel
- Barbara Klein
- Don Mayer
- Christina Prescott
- Raymond Thornton
- Eliseo Vano
- Gayle Woloschak

Consultants

- Cynthia Flannery
- Lee Goldstein
- Nobuyuki Hamada
- Phung Tran

NCRP Staff Consultant

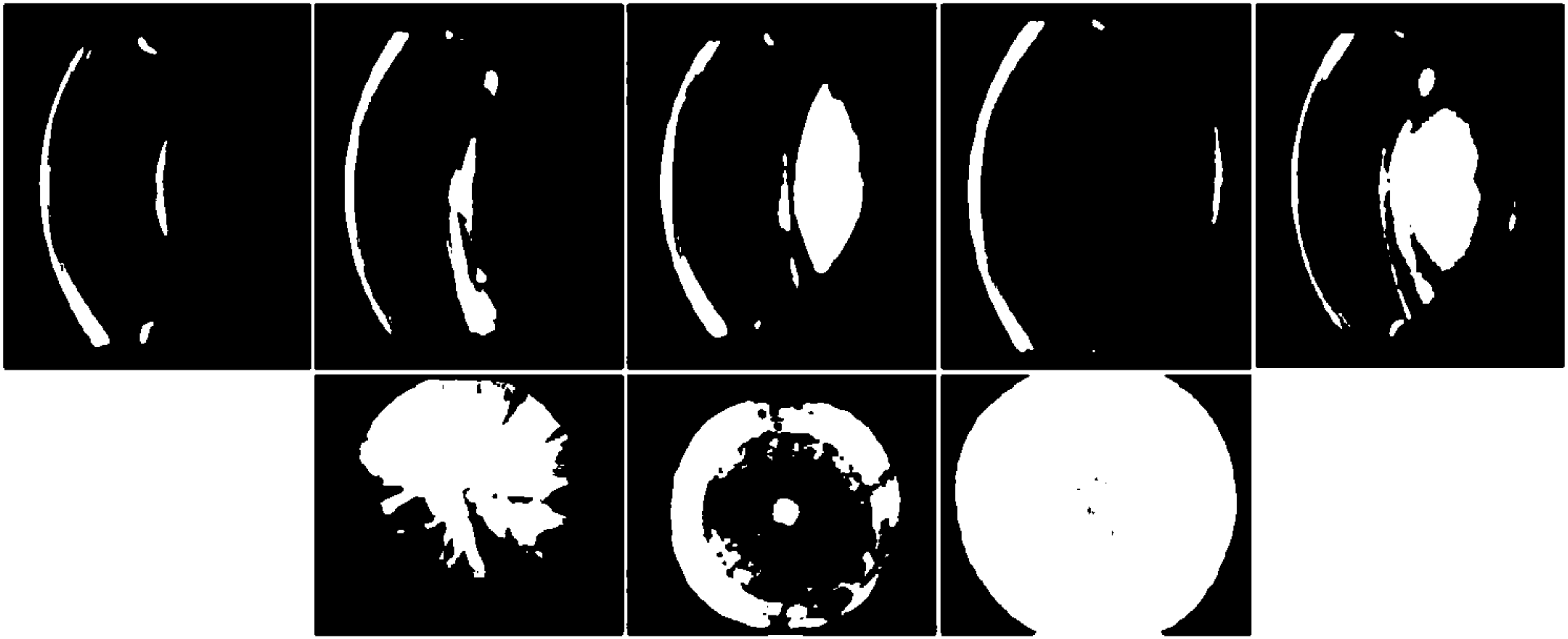
- Michael Grissom

Status

- In Final Publication

U.S.NRC

Cataract Types



Normal Cortical Nuclear PSC Mixed

NCRP Commentary 26

Guidance on Radiation Dose Limits for the Lens of the Eye

NCRP SC 1-23, Commentary 26

CORE QUESTIONS

SC 1-23 Core Questions

- Should radiation-induced cataracts be characterized as stochastic or deterministic effects?
- What effects do LET, dose rate, acute and/or protracted dose delivery have on cataract induction and progression?
- How should detriment be measured and/or evaluated for cataracts?
- Based on current evidence, should NCRP change the recommended limit for the lens of the eye?

Guidance on Radiation Dose Limits for the Lens of the Eye

CURRENT NCRP GUIDANCE

National Council on Radiation Protection & Measurements

Objectives of Radiation Protection

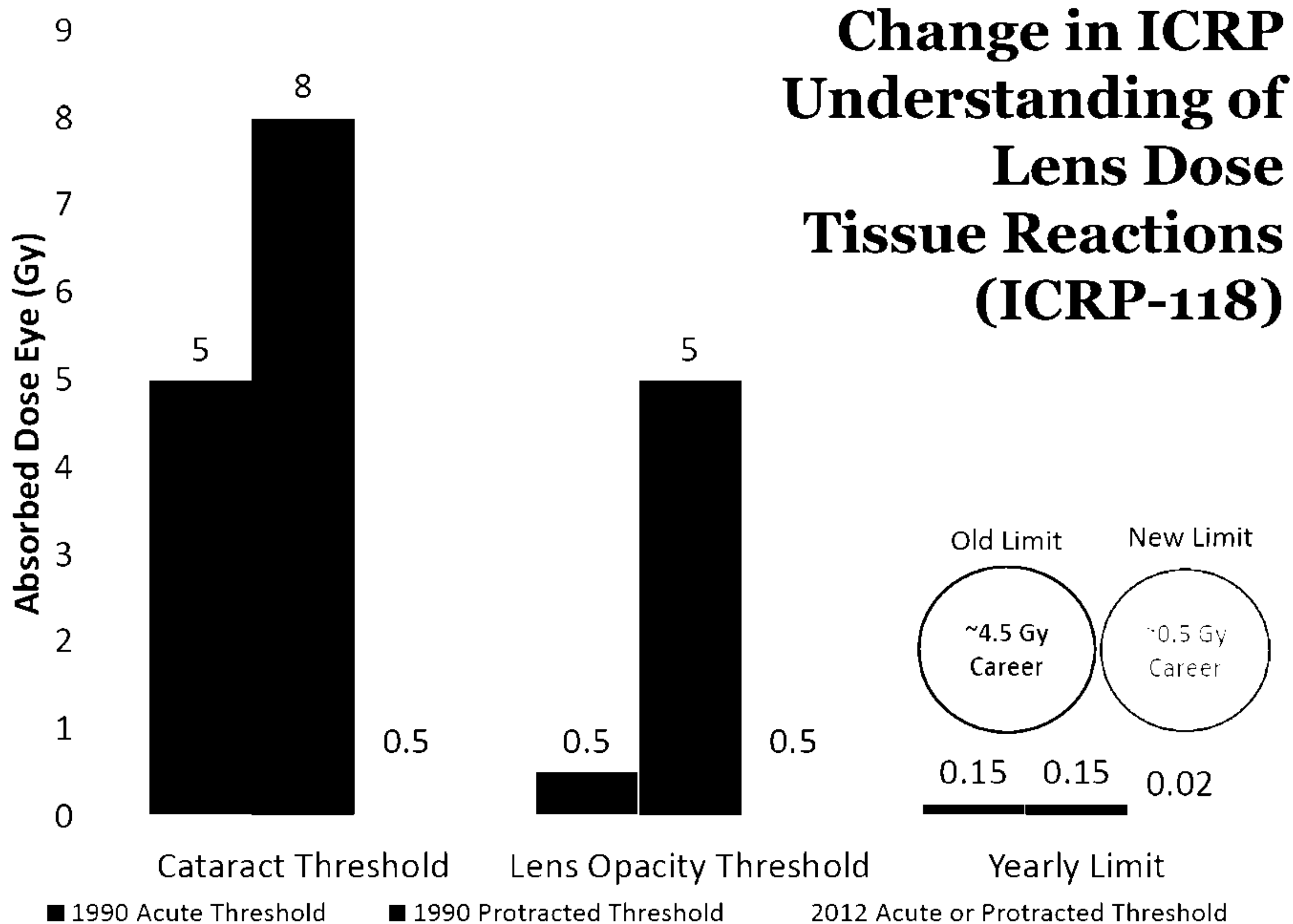
- To prevent the occurrence of clinically significant radiation induced **deterministic effects** by adhering to dose limits that are below the apparent threshold levels and…
- To limit the risk of **stochastic effects, cancer and genetic effects** to a reasonable level in relation to societal needs, values, benefits gained and economic factors.

NCRP-116 (1993)

Principles of Radiation Protection

- **Justification** – on the basis that the expected benefits to society exceed the overall societal cost.
- **Optimization** – to ensure that the total societal detriment from justifiable activities is maintained ALARA, economic and social factors being taken into account.
- **Limitation** – application of individual limits to ensure that procedures of justification and ALARA do not result in individuals or groups exceeding levels of acceptable risk.

NCRP-91 (1987) & NCRP-116 (1993)


Change in ICRP Understanding of Lens Dose Tissue Reactions (ICRP-118)
Absorbed Dose Eye (Gy)
0
1
2
3
4
5
6
7
8
9
5
8
0.5
0.5
5
0.5
Old Limit
New Limit
~4.5 Gy Career
~0.5 Gy Career
0.15
0.15
0.02
Cataract Threshold
Lens Opacity Threshold
Yearly Limit
1990 Acute Threshold
1990 Protracted Threshold
2012 Acute or Protracted Threshold

Current Occupational Dose Limits (mSv)

Limit	NCRP-116	ICRP-103/118
Effective Dose		
- Annual	50 /y	20 /y
- Cumulative	10 x Age	Avg of 5 y, no y > 50
Equivalent Dose		
- Lens	150 /y	20/y
		Avg of 5 y, no y > 50
- Skin, Hands, Feet	500 /y	500 /y

Relevant Earlier NCRP Documents

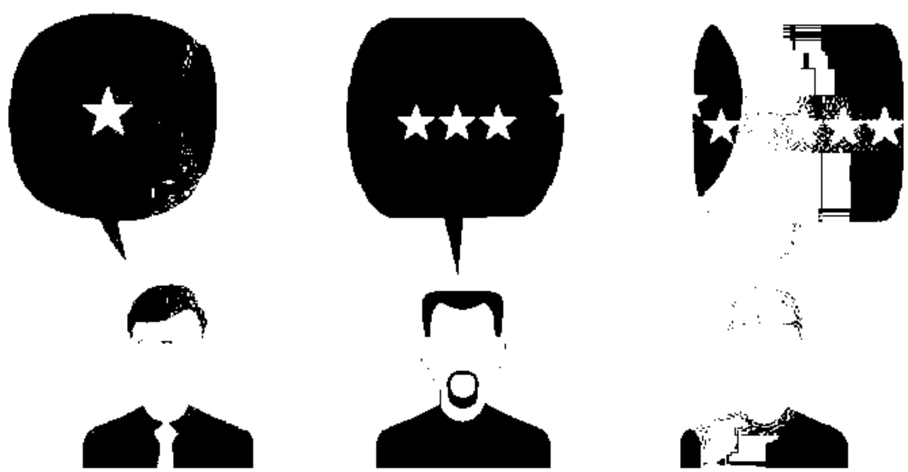
- NCRP-91: Lens opacification ID as nonstochastic.
- NCRP-115: Cataract as late somatic effect.
- NCRP-116: Lens of eye limit for deterministic effects.
- NCRP-132: Limit scatter dose to lens to ~1-3 Gy.
- NCRP-153: Likely unidirectional nature of cataracts.
- NCRP-167: New research questioning threshold?
- NCRP-168: Emphasizes ALARA principle for eye.

NCRP
National Council on Radiation Protection & Measurements

Guidance on Radiation Dose Limits for the Lens of the Eye

Status of NCRP SC 1-23 Commentary

OTHER RECENT REVIEWS



Other Recent Lens of Eye Reviews

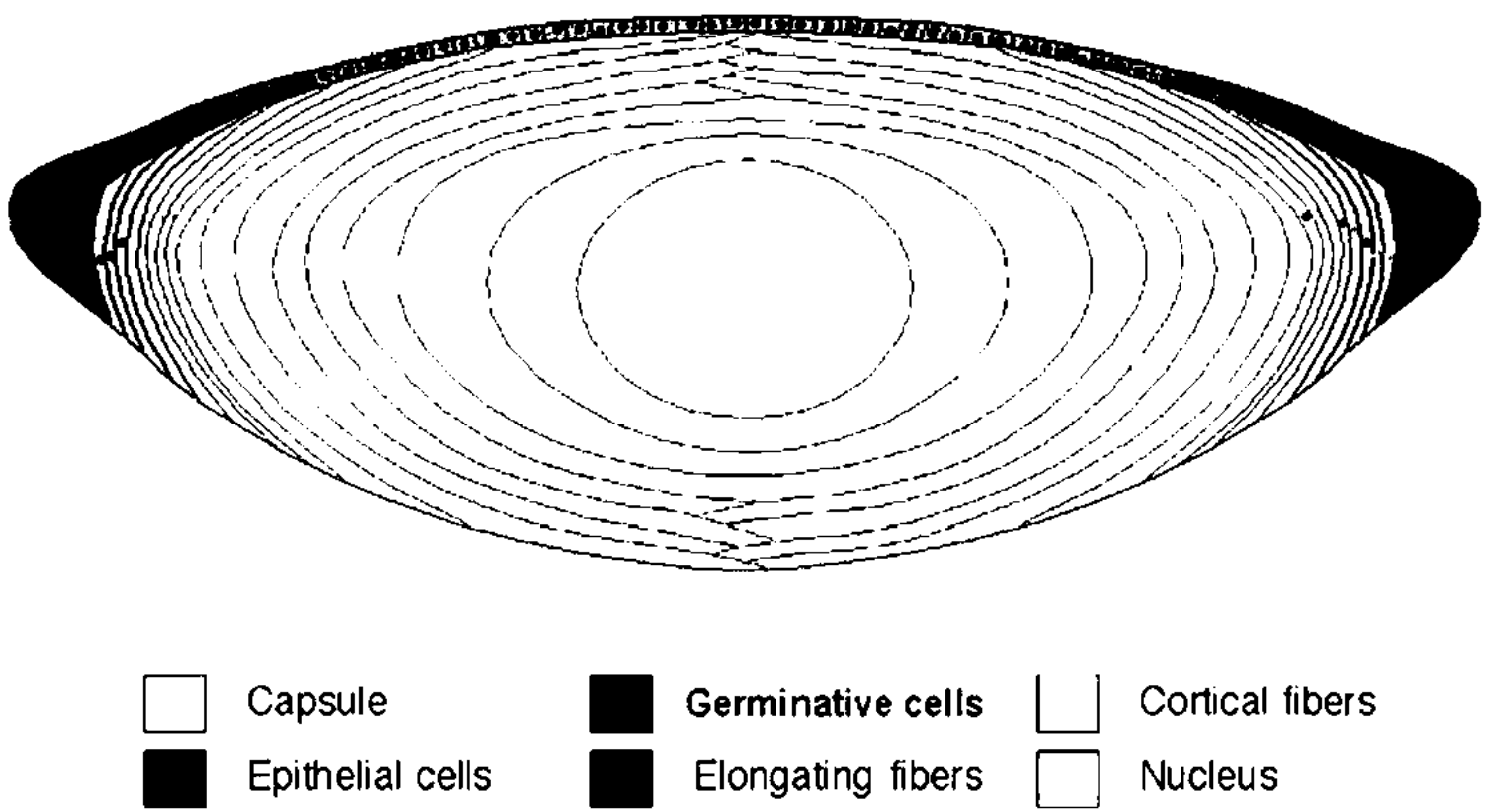
- ICRP-118: Nominal threshold of 0.5 Gy acute or protracted.
- UNSCEAR (2008, 2011, 2013): pre-clinical lens opacity lesions possible < 1 Gy, additional follow-up of cohorts is needed. Weak evidence for 2x sensitivity in children.
- IAEA BSS/EC Directive: incorporated ICRP-118.
- UKHPA/PHE: endorsed conclusion of ICRP-118.
- CNSC: proposed new recommendations in alignment.
- IRPA: causality should be verified. Concerned with treating fatal and non-fatal effects similarly.
- HPS: need to delineate the scientific basis for cataract development from chronic exposures before changing the annual eye dose limit.
- EPRI: recent review of radiobiology and radioepidemiological literature.

Guidance on Radiation Dose Limits for the Lens of the Eye

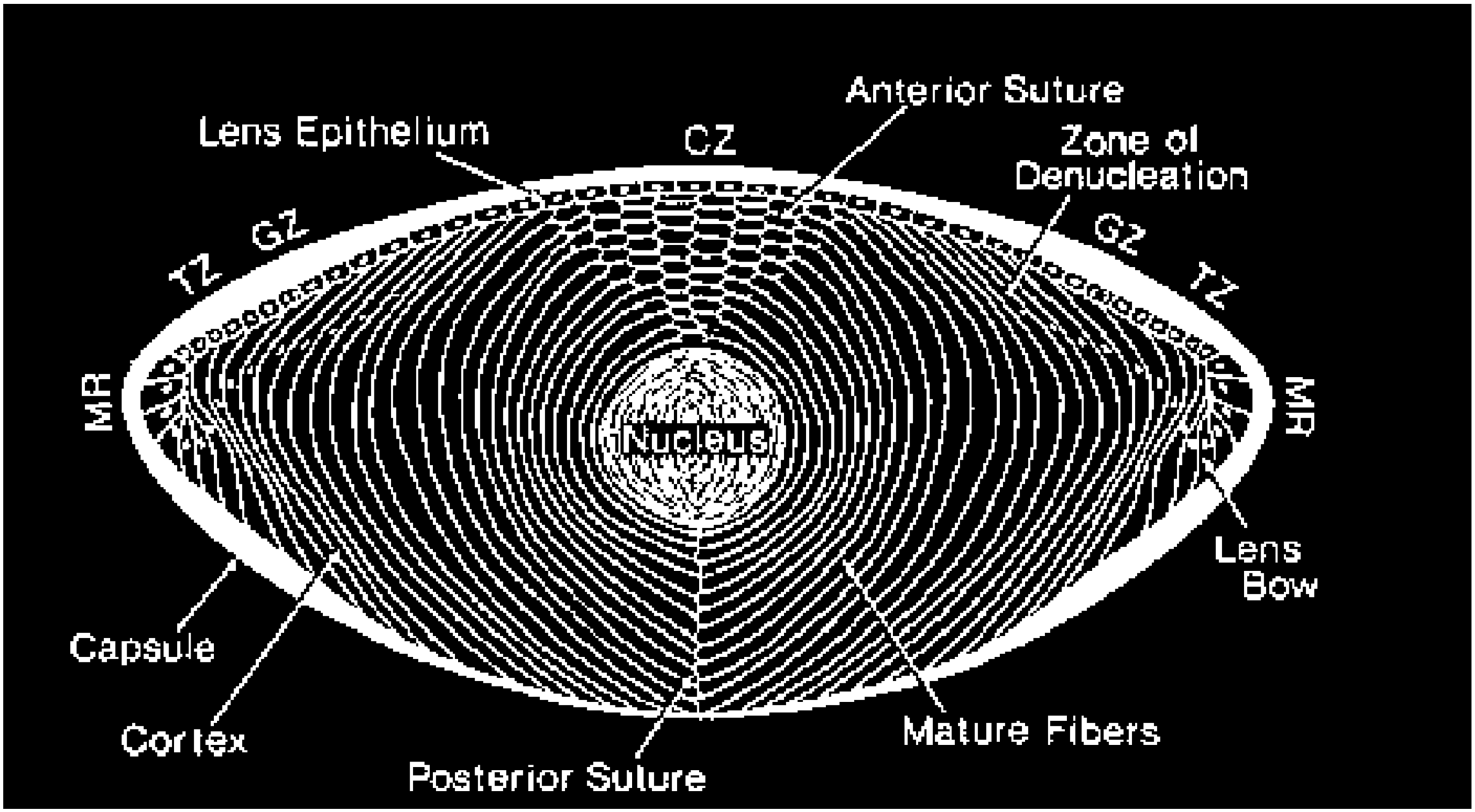
Status of NCRP SC 1-23, Commentary 26

EYE BIOLOGY & LENS EFFECTS

Cross-section of Human Lens



Cross-section of Human Lens



Normal Differentiation of Lens epithelial cells

Lens fiber cells

Migration
towards lens bow

Elongation
& enucleation

Lens epithelium

Molecular Hallmarks

Differentiation genes
Apoptosis sensitivity
Cyclin-dependent kinase inhibitors CDKIs

Cyclin-dependent kinases
E2F1/Rb

Blakely,
2014

Underlying Mechanism of Radiation-induced Cataractogenesis

Lens fiber cells

Migration towards lens bow →

Elongation & enucleation →

Lens epithelium

Etiology still not fully known – multifactorial.

Differentiation genes
Apoptosis sensitivity
Cyclin-dependent kinase inhibitor CDKI (p21)

Cyclin dependent kinases E2F1/Rb

Blakely, 2014

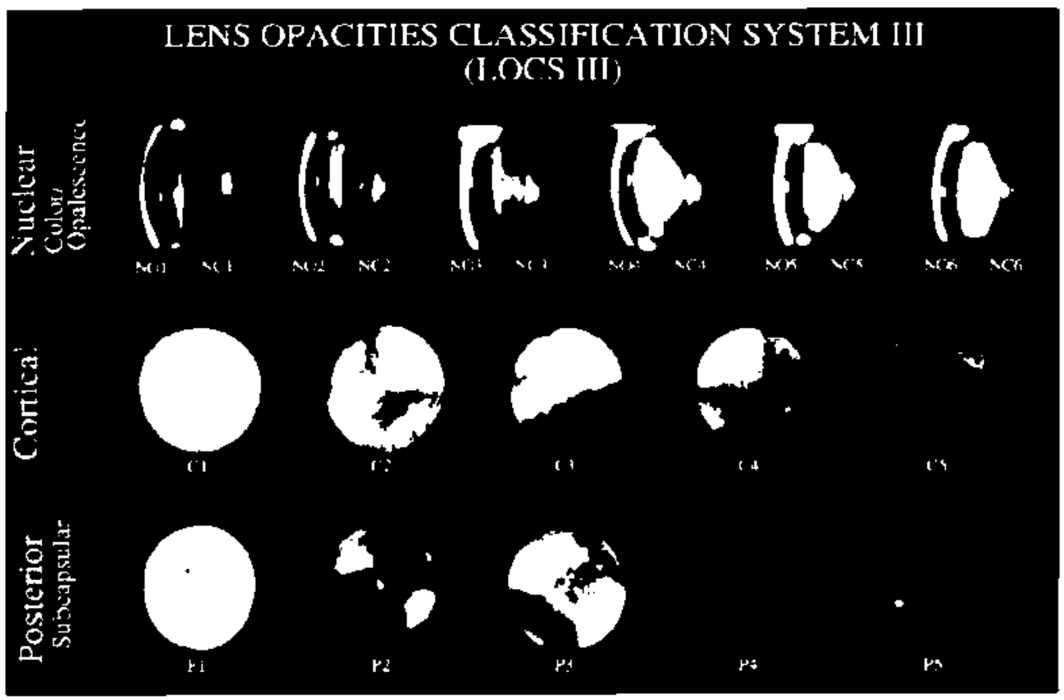
Review and Summary of Eye Biology & Lens Effects

- Lens Anatomy & Proliferative Organization
- Cataracts
  - Cataracts / Opacifications
  - Types / Severity
  - Causes / Mechanisms
  - Examination and Quantification of Lens Changes (scoring)
- Radiation Effects
  - Normal Tissue Complication Probability for Lens
- Radiation Cataractogenesis
  - Dose / Dose Rate
  - Fractionation / RBE
  - Age / Gender / Steroid
  - Latency
- Mechanisms
  - Cell Biology
  - Protein Accumulation
  - Molecular Biology
  - Oxidative Stress
  - DNA Damage
  - Genetic Susceptibility

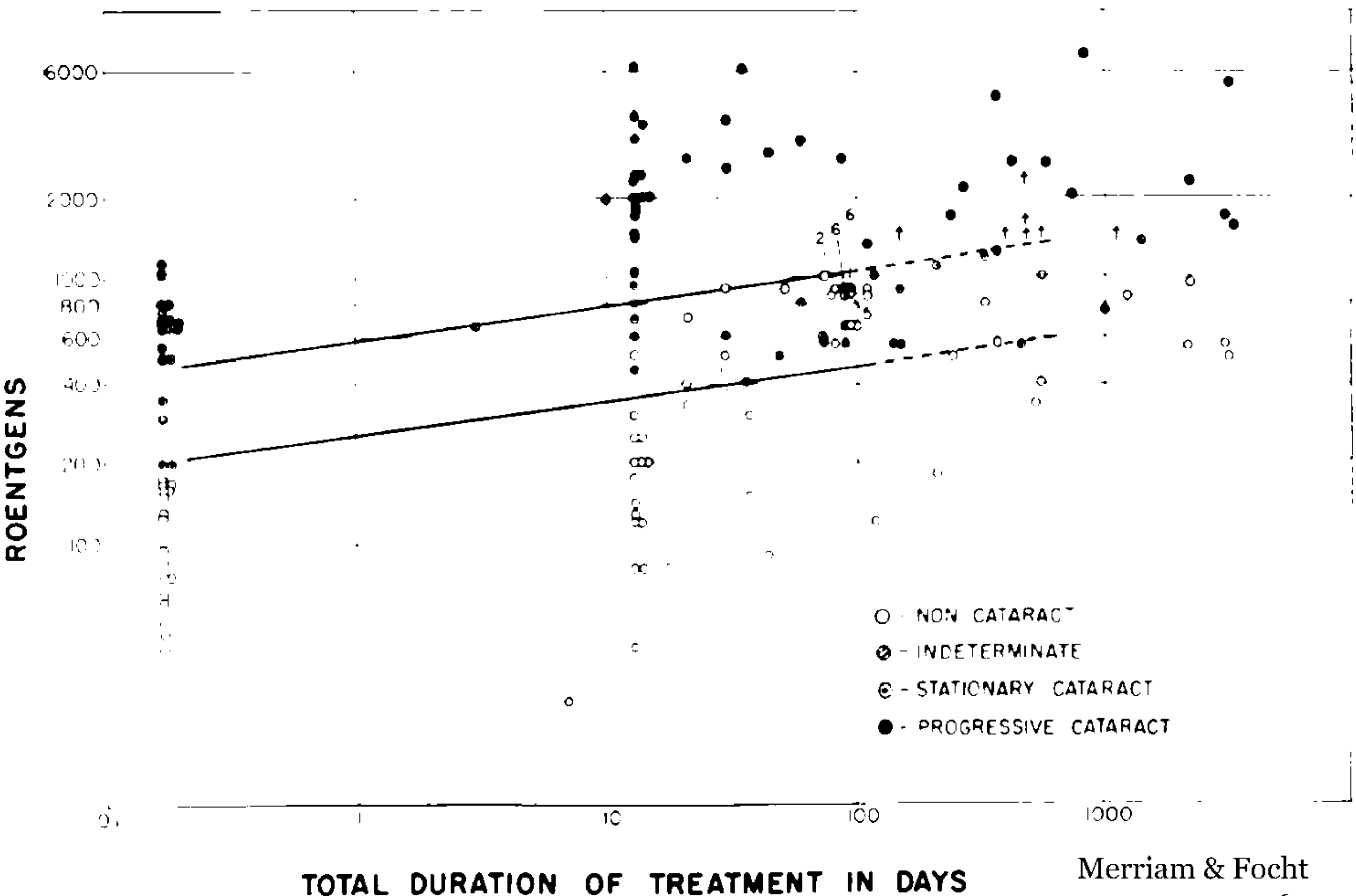
Guidance on Radiation Dose Limits for the Lens of the Eye

Status of NCRP SC 1-23, Commentary 26

EPIDEMIOLOGY



Dose for Cataract / Non-Cataract Cases vs. Overall Treatment Time



Merriam & Focht
1962

Other Recent Reviews of Radiation Cataractogenesis Epidemiological Studies

- Shore & Worgul, 1999.
- Ainsbury et al, 2009.
- Cooper et al, 2009.
- Blakely et al, 2010.
- Shore et al, 2010.
- Blakely, 2011.
- Martin, 2011.
- Bouffler et al, 2012
- ICRP, 2012.
- Hammer et al, 2013
- Little, 2013.
- EPRI, 2014.
- Hamada, 2014.
- Hamada & Fujimichi, 2014.
- Shore, 2016.

- General Conclusions:

  Strong likelihood of an association between exposure to ionizing radiation and initiation or development of various opacifications and/or cataracts.

  Recognize large uncertainty.

  A lower threshold or no threshold *may* be an appropriate model for radiation cataractogenesis risk.

Populations Evaluated (>60 publications)

- Atomic Bomb Survivors.
- Chernobyl Liquidators and Cleanup workers.
- Medical Patients.
- Health Care Personnel.
- Flight Personnel and Astronauts
- Other Occupational
- External Exposure
- Internal Exposure
- Single Person Results
- Population Studies and Residentially Exposed

- Large Variation in Studies:
  - Only a few investigate low dose effects.
  - Differ in:
    - Radiation source / type.
    - Exposure condition.
    - Study design / size.
    - Method (if any) of dose estimation.
    - Range of lens doses.
    - Lens detriment endpoint.
    - Method (and possible scoring) of endpoints.
    - Adjustments or assessment of potential other risk factors and/or confounders.

Quality of Epidemiological Studies (EPRI, 2014)

- Quality score according to methodology strengths and weakness
  - Typical approach when evaluating available epidemiologic evidence for outcomes due to exposures (as does the EPA, e.g., Wartenberg et al, 2010).
  - 0 for expected good design.
  - +1 for strengths.
  - -1 for evident shortcomings.
- 9 Tier I – most informative.
- 15 Tier II – important.
- 34 Tier III – unreliable.

Quality Evaluated On:

1. Study Design
2. Dosimetry
3. Age Adjustment
4. Confounding Causes
5. Numerical Risk Assess
6. Exposure-Response
7. Account for Latency
8. Reporting Bias
9. Selection Bias
10. Pathology Method
11. Blinded Path or Scoring
12. Cataract Scoring Method

Odds Ratio Meta-analysis

- Tier 1 and 2 Studies that provided Odds Ratio covered ~4 population groups:
  - Atomic Bomb Survivor Cohorts
    - Some difficulties – lack of standard photographic method, unclear focus of photographs difficult to judge, retro-illumination camera not used for examination of cortical and PSC cataracts.
    - In process of revising the studies (RERF 2014).
  - Chernobyl Liquidators and Clean-up Workers
  - Clinically Exposed Infants
  - Radiation Technologists
    - < 60 mGy questionnaire study with relatively high RR but not statistically significant.

Odds Ratio Meta-analysis

- Recognizing several limitations and questions, the meta-analysis results of these 4 study populations:

PSC	OR=1.45 at 1 Gy (95%, 1.15-1.85).
Cortical	OR=1.37 at 1 Gy (95%, 1.20-1.56).
Mixed	OR=1.75 at 1 Gy (95%, 1.26-2.46).
Nuclear	OR=1.07 at 1 Gy (95%, 0.5-2.0).

- Likelihood of an association between exposure to ionizing radiation at ~1 Gy and initiation or development of PSC, mixed, and/or cortical cataracts.

Threshold Evaluations ?

- Only two(2) Tier 1 or Tier 2 study populations evaluated threshold for cataractogenesis: A-Bomb (being re-evaluated), and Chernobyl.
- Considerable uncertainty in these estimates, which depend heavily upon the dose response function used and uncertainties in dose estimates.
- Too few data, not possible to perform meta-analysis.
- Currently not enough available information to make any new specific conclusions with regard to chronic or acute exposure thresholds for cataracts.

Guidance on Radiation Dose Limits for the Lens of the Eye

Status of NCRP SC 1-23, Commentary 26

POPULATIONS / PROTECTION

Members of the Public – per ICRP

- Equivalent Dose for Lens of Eye Limit of 15 mSv/y.
- Effective Dose Limit of 1 mSv/y.
- ICRP-118 – no new limit for public exposure to lens of the eye, as the Commission judged that the existing limit was adequately protective, and therefore a reduction could impose unnecessary restrictions.
- Highly improbable a member of the public would receive >0.5 Gy in a planned exposure situation, considering application of the effective dose limit of 1 mSv/y, low likelihood of the lens being preferentially exposed for significant periods, and optimization of protection below the equivalent dose limit for lens of the eye.

Occupational: Populations / Protection

- Medical
  - Interventional Radiology and Cardiology
  - Radiopharmacy, Radiochemistry, Nuclear Medicine
  - Other workers
  - Patients
- Nuclear Facilities
  - Issues with EDEX?
  - High Beta Fields?
- Industrial Radiography
- Astronauts / Pilots

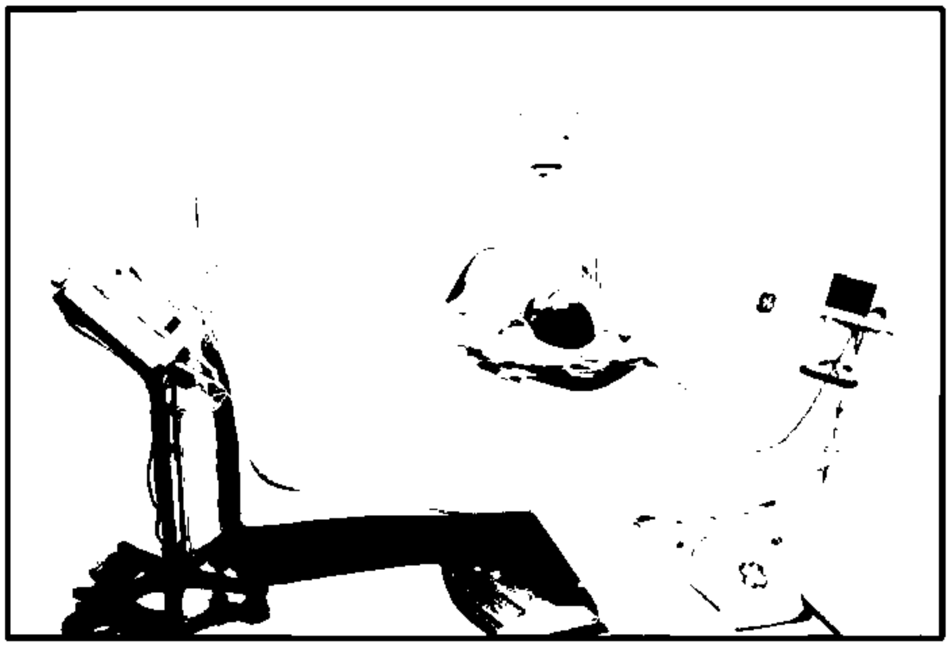
- Engineering, Safe Work Practices, Administrative Controls
- PPE
  - Screens, Goggles, Leaded Glasses
  - Face Shields
  - Respirator Face Shields
  - Bubble Suit Masks
- Monitoring Lens Dose

Lens of Eye Radiation Protection
Medical Considerations

- PATIENT IMPLICATIONS
- OCCUPATIONAL IMPLICATIONS
- NEEDS AND OPPORTUNITIES

Lens of Eye Radiation Protection
Medical Considerations

PATIENT IMPLICATIONS/OPPORTUNITIES



Rising Use of Radiation in Medicine

- Annual E per capita for Med Procedures:

  United States 0.5 mSv (1980) to 3.0 mSv (2006)

  Worldwide 0.3 mSv (1980) to 0.6 mSv (2007)

- United States (2006)

  337 M Diagnostic/Interventional Radiology

  18 M Nuclear Medicine

- Worldwide (2006)

  3.6 B Total

  3.1 B Diagnostic/Interventional Radiology

  0.5 B Dental

  37 M Nuclear Medicine

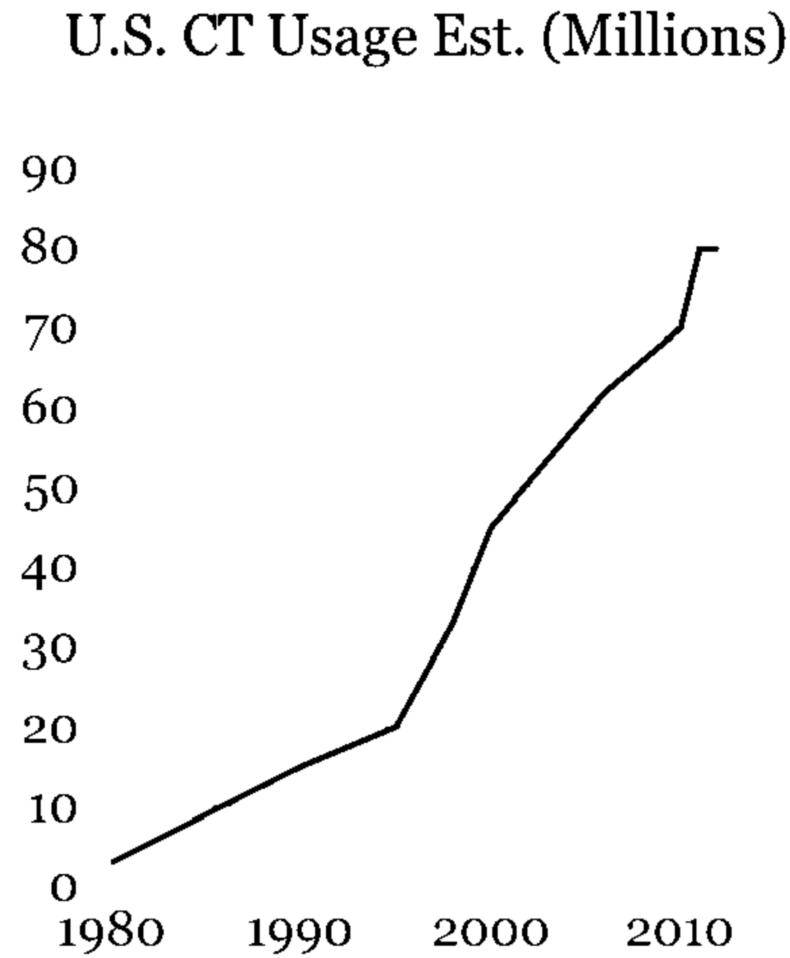
Mettler et al, Radiology, 2009,253

Computed Tomography Usage

- Was growing ~10%/y
- Up to ~**80** M/y in U.S.
- ~10% in children
- Perhaps slowing some…
- ED CT usage continues to increase. (Larson 2011).

  Growing ~16%/y

  Double every 4.7 y



Radiation Therapy – Cataract Epidemiology

- Early studies specifically associated with RT (1950s)
- ~ 2-8 Gy threshold
  - 0-84 y age
  - 1-40 y followup
  - 0.2-69Gy Lens doses
  - Small case series
  - Cogan and Dreisler ('53)
  - Merrriam and Focht ('57)
  - Qvist and Zachau ('59)

- Recent studies – lower thresholds for posterior lens changes
- 0.2-0.8 Gy (Tinea capitis) Albert ('68)
- 0.1-0.4 Gy (Skin hemangioma) Wilde and Sjostrand ('97), Hall ('99).
- Uncertainties, but still lower than before.
- See NCRP SC 1-23.

Comparing Some Potential RT Complications

Detriment/Effect	Tissue	Gy (Acute to Fractionated)
Loss of Eyelashes	Eyelid	10 to >20
Acute Conjunctivitis	Conjunctiva	27 to >30
Chronic Conjunctivitis	Conjunctiva	50
Ocular Dryness	Lacrimal	>30 to > 50 (1+ y latency)
Ulceration	Cornea	20 to >60
Irisitis	Iris	20 to >70
Retinopathy	Retina	30 to >70
Cataract	**Lens**	**~0.5 - 2 (10+ y latency)**

RT Optimization Possible?

- Tradeoff between high tumor dose and clinically acceptable organs at risk dose.
- Threshold doses for tissue reactions can be reached in some patients during RT (including lens).
- Most treatment planning systems do not accurately account for such low doses (especially out of field).
- Doses to RT patients from associated imaging procedures are not generally accounted for.
- While local control is paramount, RT plans and processes should be examined with care.

Dauer L, York E, et al 2016

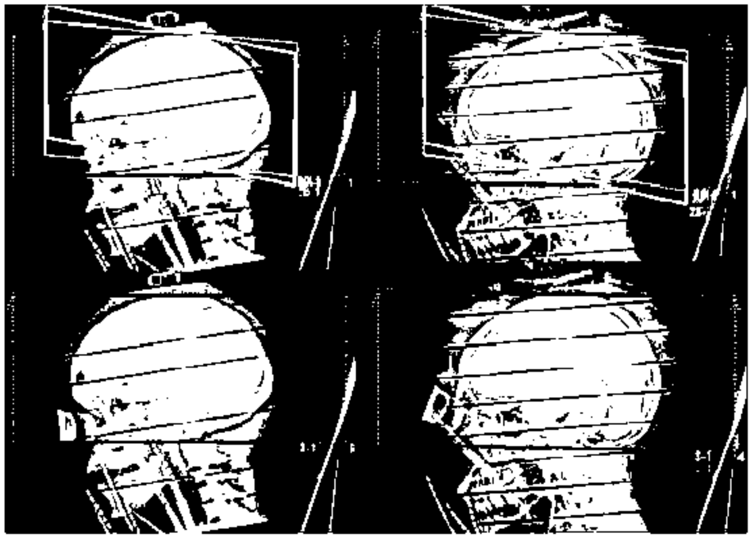
Patient Potential for >0.5 Gy to Lens of Eye

- Radiation Therapy
  - External Beam
  - Brachytherapy
- Neuroradiology Interventional Procedures
- Repeated Brain Perfusion CT
  - 81-348 mGy (Zhang2012)
  - 124 mGy (Perisinakis2013)
- Repeated Head CT
- Repeated Dental Cone Beam CT?

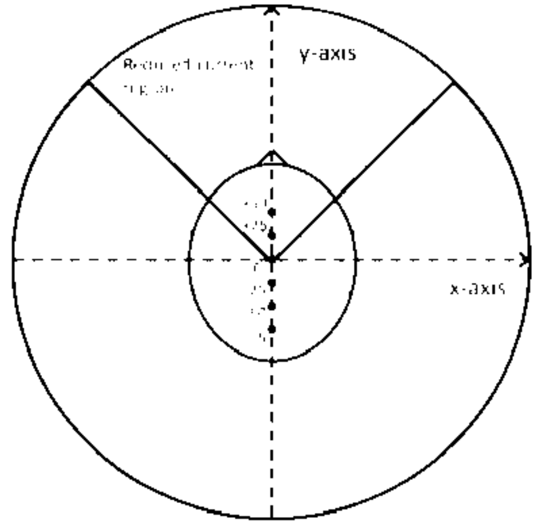
- Optimization strategies should attempt to minimize the possibility of exceeding 0.5 Gy for lens of eye in patients, both for individual high-dose exposures and multiple moderate dose exposures (repeated head CT or interventional procedures)

(Vano, Miller, Dauer 2015)

Lens Dose – CT Optimization Strategies



(Nikupaavo et al 2015, AJR)



(Kudomi et al 2014, ECR)

(Prins et al 2011, Oral Surg)

Lens Dose - CT Optimization Strategies

CT	Dose	Image Noise
Bismuth Shield	<10-40%	>20-30%
Organ Based TCM	<25-50%	>20-30%
Gantry Tilt Angle		
10-12 degrees	<75-85%	<~25%
6-7.5 degrees	<7-20% (shorter range <DLP overall)	~
Dental Cone Beam CT	**Dose**	**Image Noise**
< Field of View	<20-50%	<~25%
Patient Lead Glasses	<60-70%	~ take care positioning

Lens of Eye Radiation Protection
Medical Considerations

OCCUPATIONAL IMPLICATIONS

UNSCEAR (2008 Annex B)

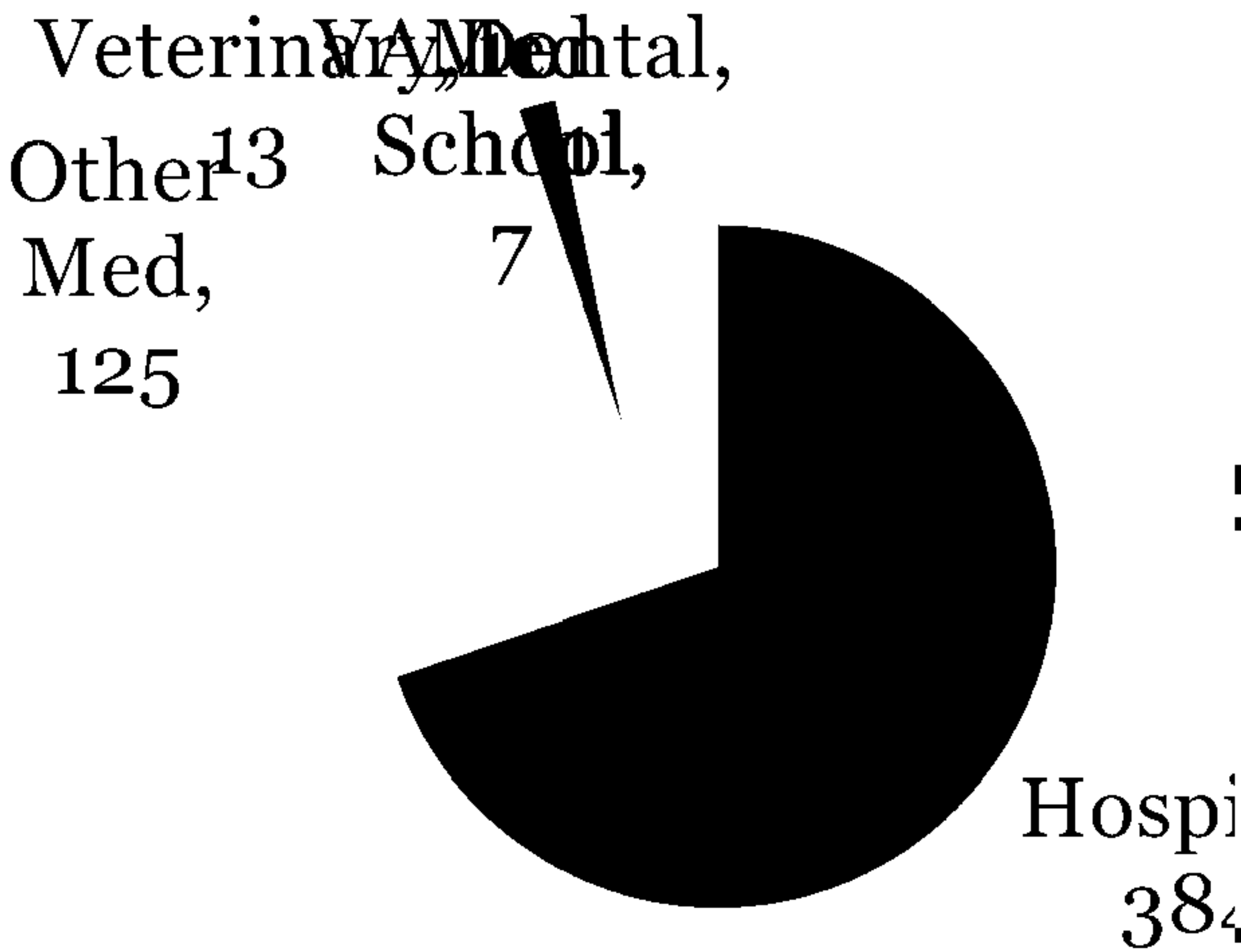
UNSCEAR

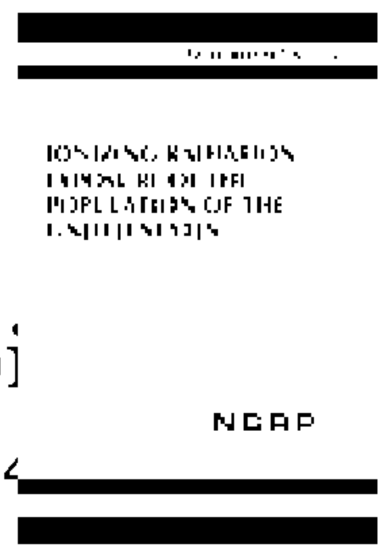
- ~760 person-Sv worldwide in 1994.
- ~3540 person-Sv worldwide in 2002.
- **Physicians, technicians, nurses** and others involved constitute the largest single group of workers occupationally exposed to man-made sources of radiation.
- More than 80% of CT techs and general radiographers do not have measurable exposure.
- **IR/IC FGI MDs are the most exposed in medicine.**

NCRP-160 (2009)

- **Medical staff exposures contributed the most (39%) to the U.S. occupational exposures**.
- ~2.5 Million monitored workers.
- ~0.75 Million received measured doses.
- ~550 Person-Sv.
- Average E = 0.75 mSv.
- Data from ~2006.

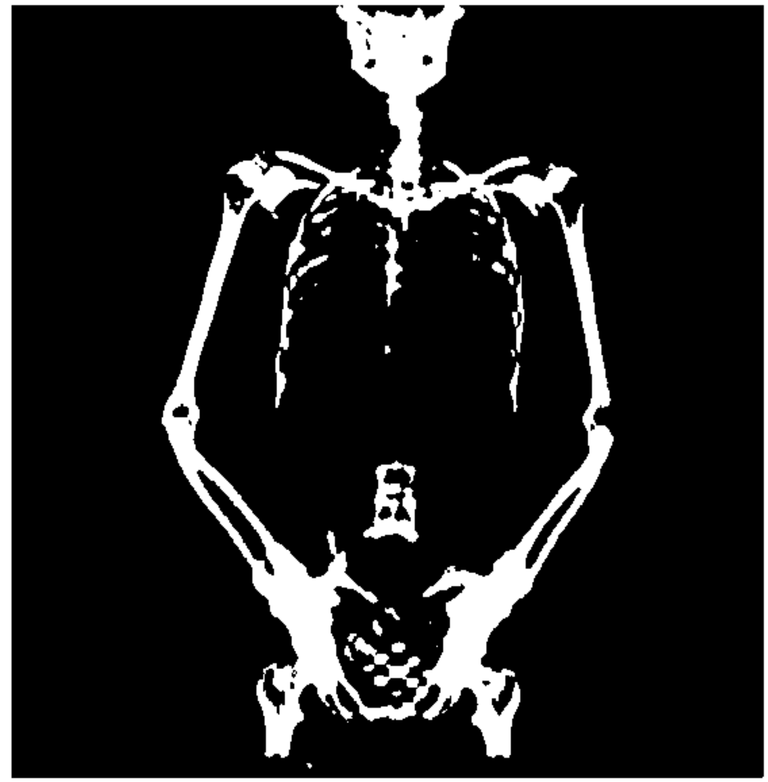
NCRP-160 (2009) – Person-Sv - 2006





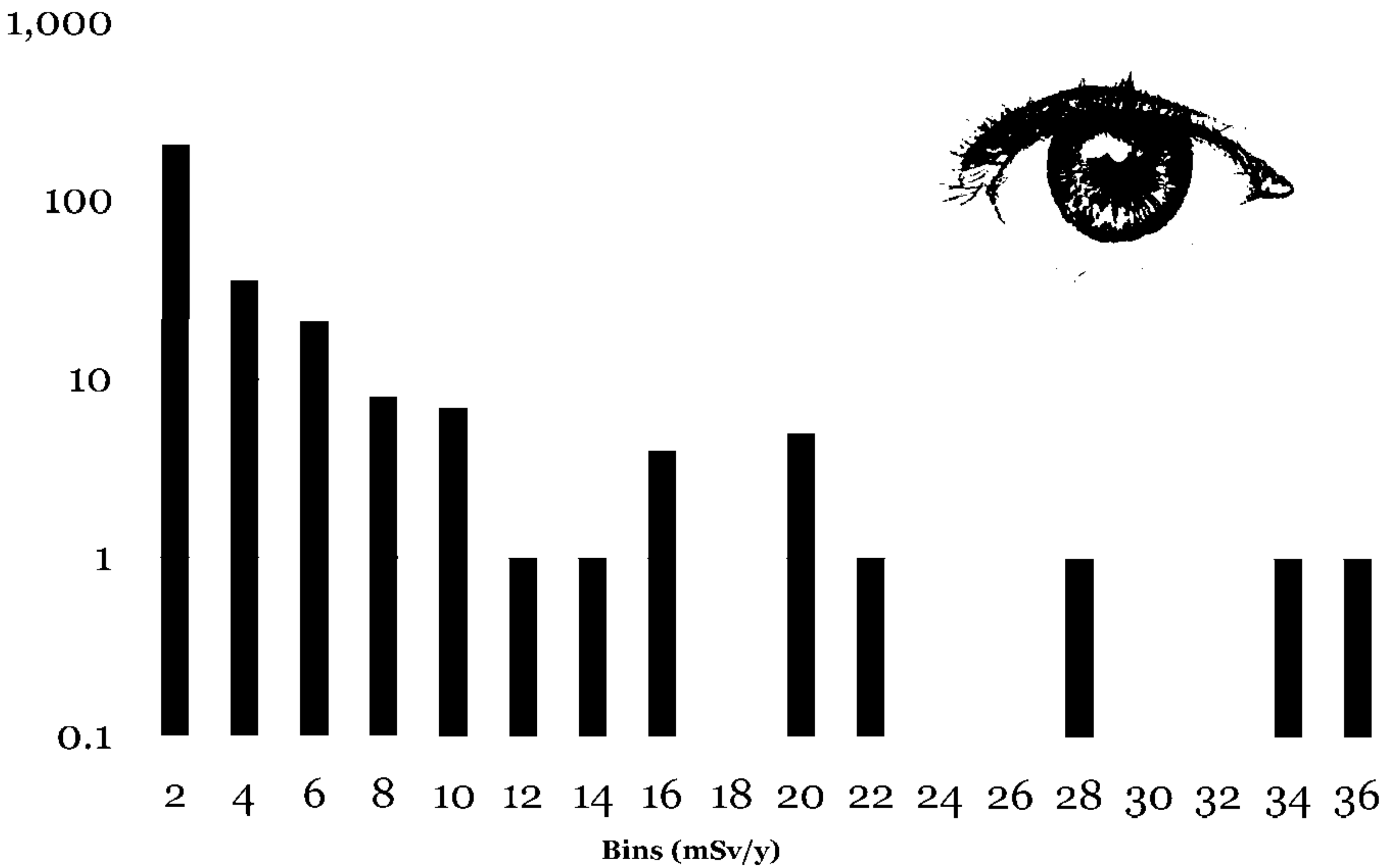
Expanding Use of Radioactive Materials

- Diagnostic Imaging/IR/IC
- PET Imaging
  - Scans and Rad Onc Sims
- Multimodality
  - PET/CT
  - PET/MRI
- Nuclear Medicine
  - Tracers
  - Stress Tests
  - Scan
- Localization
  - Sentinel Node
  - Rad Seed Localization



Measurable Unprotected LDE (mSv/y)

2011 Data MSKCC (Dauer, HPJ, 2013)



Measurable Unprotected LDE (mSv/y)

2011 Data MSKCC and Commercial Radiopharmaceuticals

(Dauer, HPJ, 2013)

Exposed Medical Staff	Avg	Min	25%	50%	75%	95%	99%	Max
IR/FGI MD no Pb glasses	11.1	0.1	0.5	7.0	19.3	32.5	35.7	36.5
Radiopharmacist	4.7	0.1	4.3	5.0	6.4	8.0	8.5	8.6
IR/ FGI Tech-Nurse no Pb	2.5	0.1	0.4	1.1	1.9	12.0	19.1	19.3
NM Tech-Nurse	2.4	0.1	0.3	0.9	2.8	9.8	15.5	19.0
Hospital Average **	2.1	0.1	0.2	0.5	2.0	8.5	19.6	36.5
NM MD	1.9	0.1	0.5	1.4	2.6	6.2	7.2	7.6
Research Radiochem	1.9	0.1	0.1	0.6	3.3	6.3	7.8	8.2
Commercial Radiopharm	1.6	0.1	0.1	0.3	1.3	7.1	23.5	**70.2**
Health Physics – Rad Safety	1.1	0.1	0.5	1.0	1.9	2.2	2.3	2.3
Inpatient Nurse	0.4	0.1	0.2	0.3	0.4	0.9	1.8	2.2

IR/IC FGI Lens Doses Vary by Procedure

Unshielded LDE Nominal Estimates

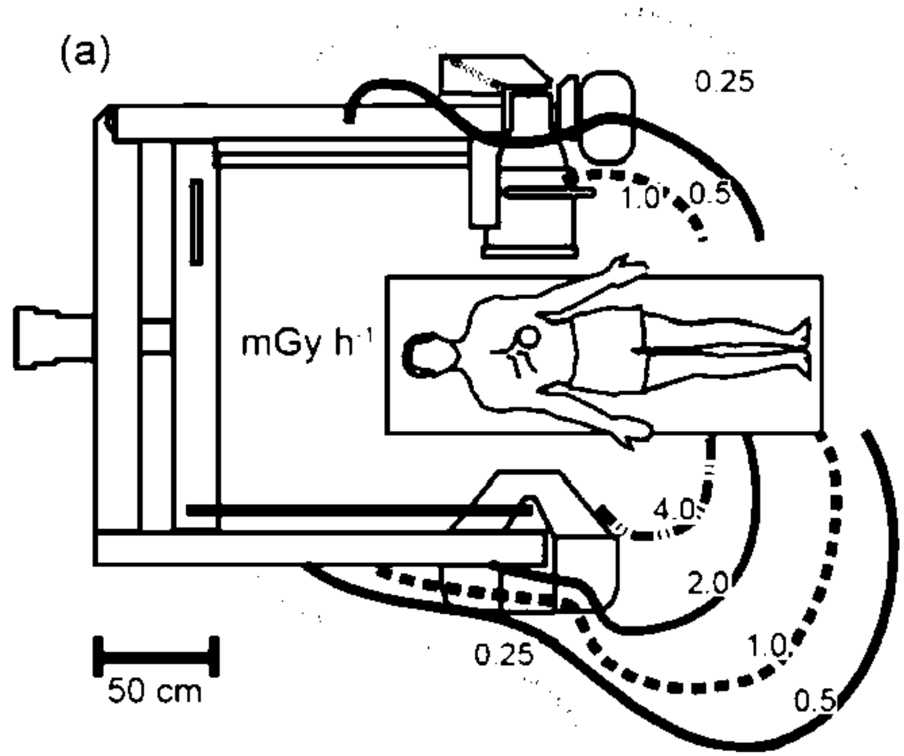
Procedure	**~~mSv/Procedure**
Embolization	0.8
Cardiology	0.5
ERCP	0.5
Biliary Stent/Drain	0.3
Vertebroplasty	0.1
TIPS	0.03
Cerebral Angio	0.02

- Training
- Methodology
- Complexity
- Patient Factors
- Equipment
- Lens Dose correlates with Patient Dose

~4-7 μGy Lens /Gy cm²

FGI IR/IC Protection Controls (NCRP-168)

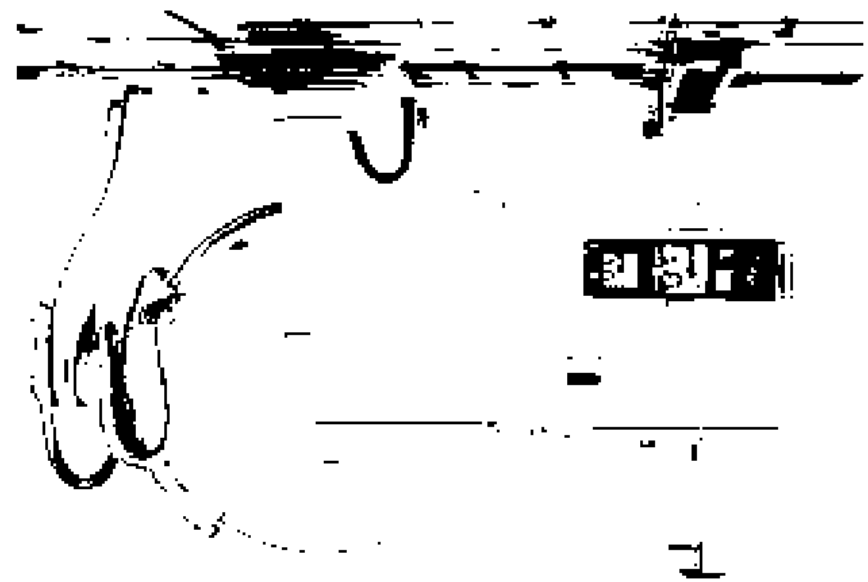
- Engineering
  - Equipment
  - Structural Shielding
  - Equipment Shielding
- Safe Work Practices
  - SOPs
  - 10 Commandments/Pearls
- Administrative
  - Training/Credentialing
  - Expectations
- PPE (aprons/collar/glasses, etc.)



NCRP-168

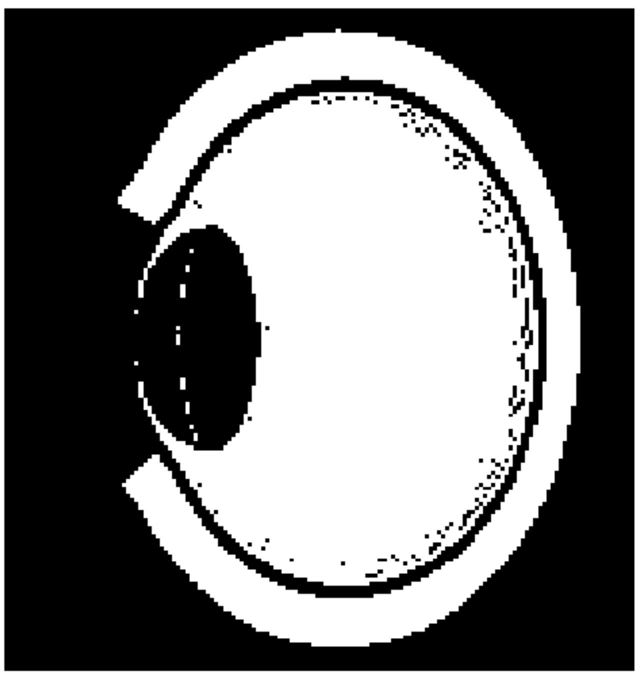
Operator Training / Credentialing

- Equipment design and shielding help…BUT
- Training and Credentialing needs improvement.
- Europe leads in operator training requirements.
- Not all states have enacted legislation regarding radiation education for FGI operators



Lens of Eye Radiation Protection

DOSIMETRY - MONITORING



Important to Perform a Monitoring Assessment

<u>Assessment Categories:</u>

- Exposure Scenario
- Type of Radiation Field
- Energy and Angle
- Geometry
- Homogeneity
- Protective Equipment
- Mixed Radiation Fields

(UCSF, 2016)

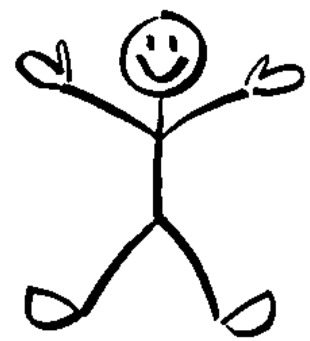
How to Monitor Lens Dose?

Radiation Field	$H_p(0.07)/H_{lens}$	$H_p(3)/H_{lens}$	$H_p(10)/H_{lens}$
Photons < 30 keV	0.9 – 5	0.6 – 1	0.01 – 0.9
Photons > 30 keV	0.8 – 1.1	1 – 1.2	0.9 – 1.2
Electrons	1-500	~1	<<1 – 1.2
Adequate?	Perhaps for photon radiation	OK for Photons. Necessary for Beta	**Not for low E photons or beta.**

R. Behrens and G. Dietze
Phys Med Bio 55 (2010) 4047-4062
Phys Med Bio 56 (2011) 511

Practical Lens Dosimeter Choices
– Starts with actually wearing them!

- DDE dosimeters (Whole Body) $H_p(10)$:
  - On trunk or waist far from eyes.
  - Underestimate at low photon energies (too thick)
  - Under lead apron if in use.



- SDE dosimeters (Extremity) $H_p(0.07)$:
  - Must be worn facing the beam/scatter
  - Worn near eye (note NCRP-168 factor of ~1 at collar)
  - OK for photons, overestimates for high energy beta (too thin)
- LDE dosimeters (Eye) $H_p(3)$ – exist?:
  - Must be worn facing the beam/scatter
  - Only type OK for both photons and high energy beta.

How to Monitor Lens Dose?

IEAE TE-1731, 2013

TABLE 3. DOSES DUE TO PHOTON RADIATION

Impact factor	Comment		
A (Energy and angle)	Is the mean photon energy below about 40 keV?		
	If yes ↓ $H_p(0.07)$ may be used but not $H_p(10)$ (see Fig. 6 in Ref. [65] and Fig. 1 in Ref. [66])	If no ↓ Is the radiation coming mainly from the front or is the person moving in the radiation field?	
		If yes ↓ $H_p(0.07)$ or $H_p(10)$ may be used (see Fig. 1 in Ref. [66])	If no ↓ $H_p(0.07)$ may be used but not $H_p(10)$ (see Fig. 1 in Ref. [66])
B (Geometry)	Are homogeneous radiation fields present?		
	If yes ↓ Monitoring on the trunk may be used.	If no ↓ Monitoring near the eyes is necessary.	
C (Protective equipment)	Is protective equipment such as lead glasses, ceiling, table shields, and lateral suspended shields in use?		
	If used for the eye ↓ Monitoring near the eyes and below the protective equipment or below an equivalent layer of material is necessary. Otherwise, appropriate correction factors to take the shielding into account should be applied.	If used for the trunk (e.g. a lead apron) ↓ Monitoring below the shielding underestimates the dose to the lens of the eye as the eye is not covered by the trunk shielding. ↓ Separate monitoring near the eyes is necessary.	

TABLE 4. DOSES DUE TO BETA RADIATION

Impact factor	Comment	
A (Energy and angle)	Is the maximum beta energy above about 0.7 MeV?	
	If no ↓ No monitoring due to beta radiation is necessary as it does not penetrate to the lens of the eye	If yes ↓ Monitoring is necessary as described in lines B and C.
B (Geometry)	As beta radiation fields are usually rather inhomogeneous, monitoring of the dose to the lens of the eye is necessary with the dosimeter placed near the eyes. However, it may not be needed if a thick enough shield is used, see impact factor C	
C (Protective equipment)	Is protective equipment such as shields and glasses that are thick enough to absorb the beta radiation in use?	
	If used for the eye ↓ Consider 'photon radiation' as the beta radiation is completely absorbed in the shielding; however, bremsstrahlung has to be taken into account — the contributions from both that produced outside and that produced inside the shielding.	If not used ↓ $H_p(3)$ is the only appropriate quantity.

Monitoring in Medicine

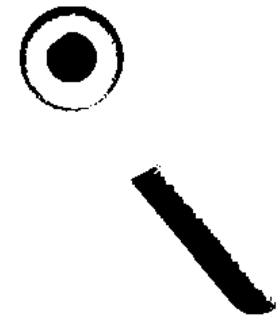
Properly calibrated $H_p(3)$ with dosimeter worn close to eye – if impractical … consider the following:

Hp(0.07) or Hp(10)	**Hp(0.07)**	**Hp(3)**
At trunk	At Eyes behind glasses - *or* At neck and apply CF	If beta >0.7 MeV – *and* Not shielded
Radiochemistry	Interventional Radiology	Beta Brachytherapy
Radiopharmacy	Interventional Cardiology	Beta Radiochemistry
Nuclear Medicine Staff	Interventional Tech	Beta Radiopharmacy
Researchers (> 40 keV)	Interventional Nurse	Beta Researchers
Brachytherapy general	Interventional Anesthesia	
Floor Nurses	Implant Brachytherapy	
General Radiology Tech		
Health Physics		

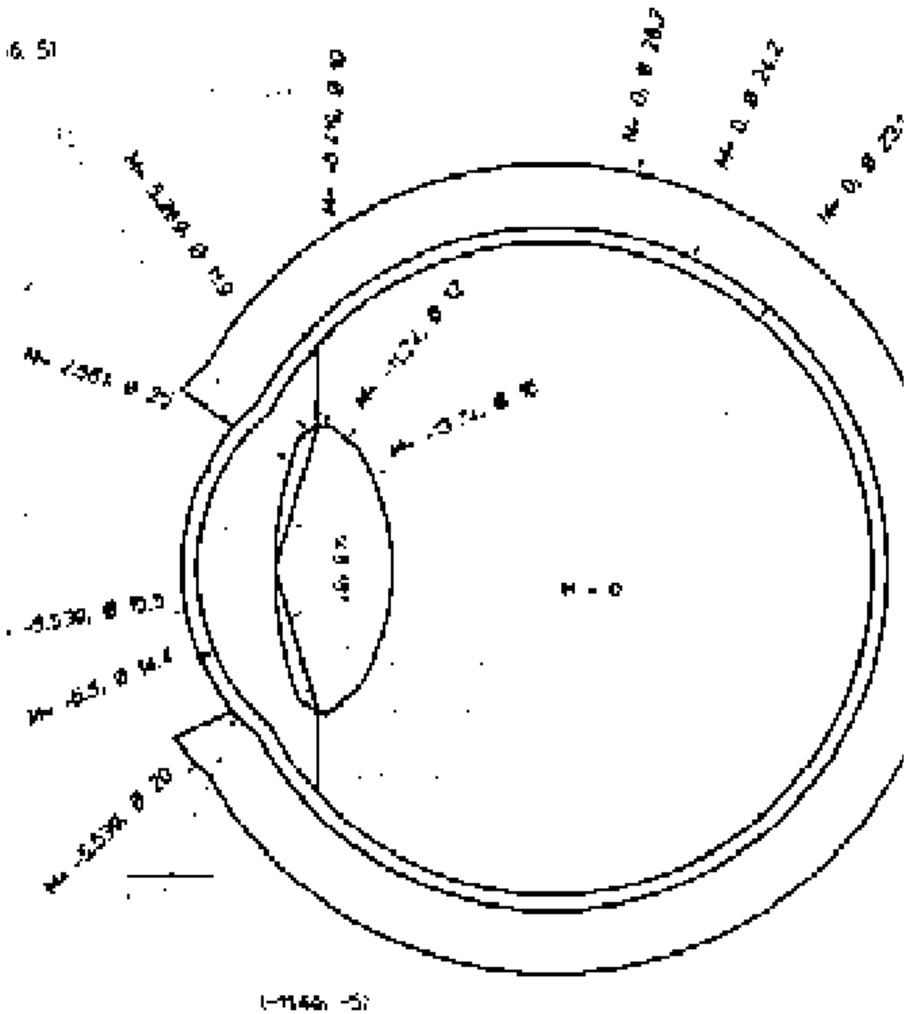
(Quinn B, Miodownik D, Dauer L, et al 2016)

Lens of Eye Monitoring - Some Challenges

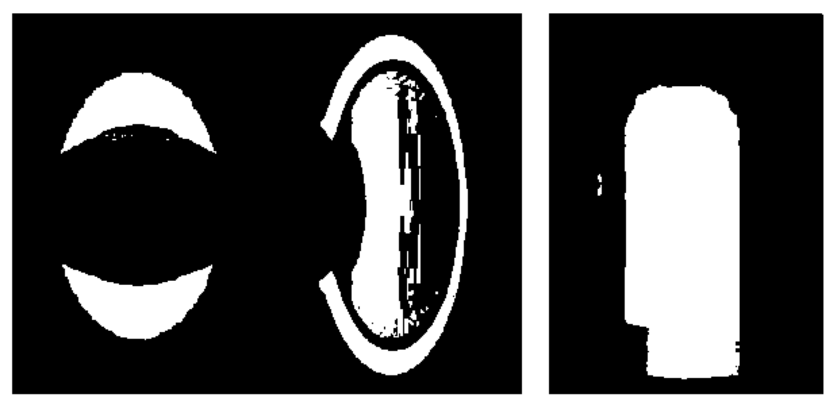
- Absorbed dose to the lens in mGy.
  - Lens modeling
  - How best to monitor with available dosimeters?
- Shielding and PPE modeling
- Interventionalists (radiology/cardiology)
  - Badge location (generally outside the collar, nearer eye needed?, shield correction factor?)
- What if leaded glasses or ceiling shields are used?
  - Divide by 3+ if audited use can be verified/validated– likely a conservative estimate of actual lens dose.



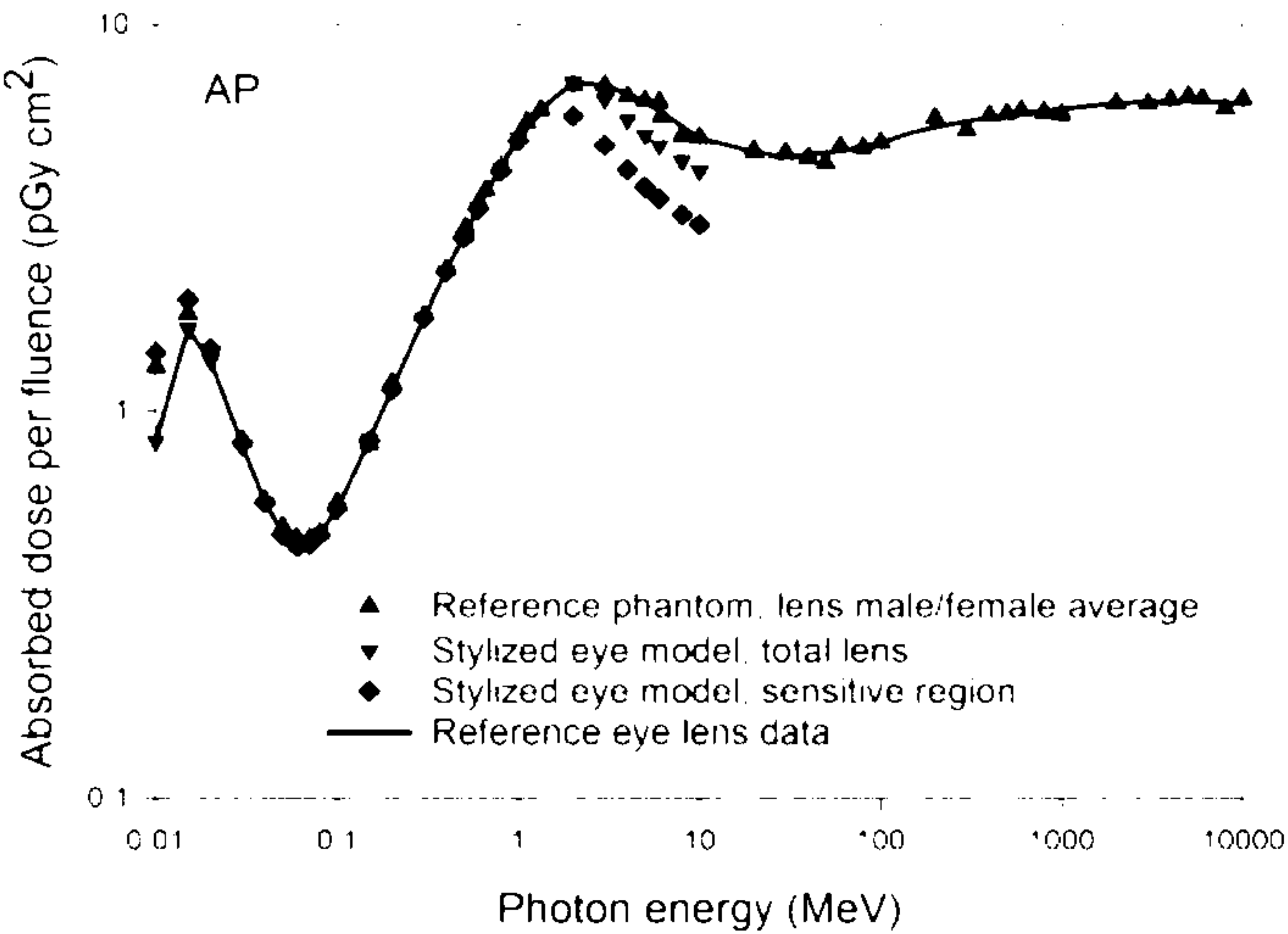
ICRP External Dose Factors for Lens of Eye



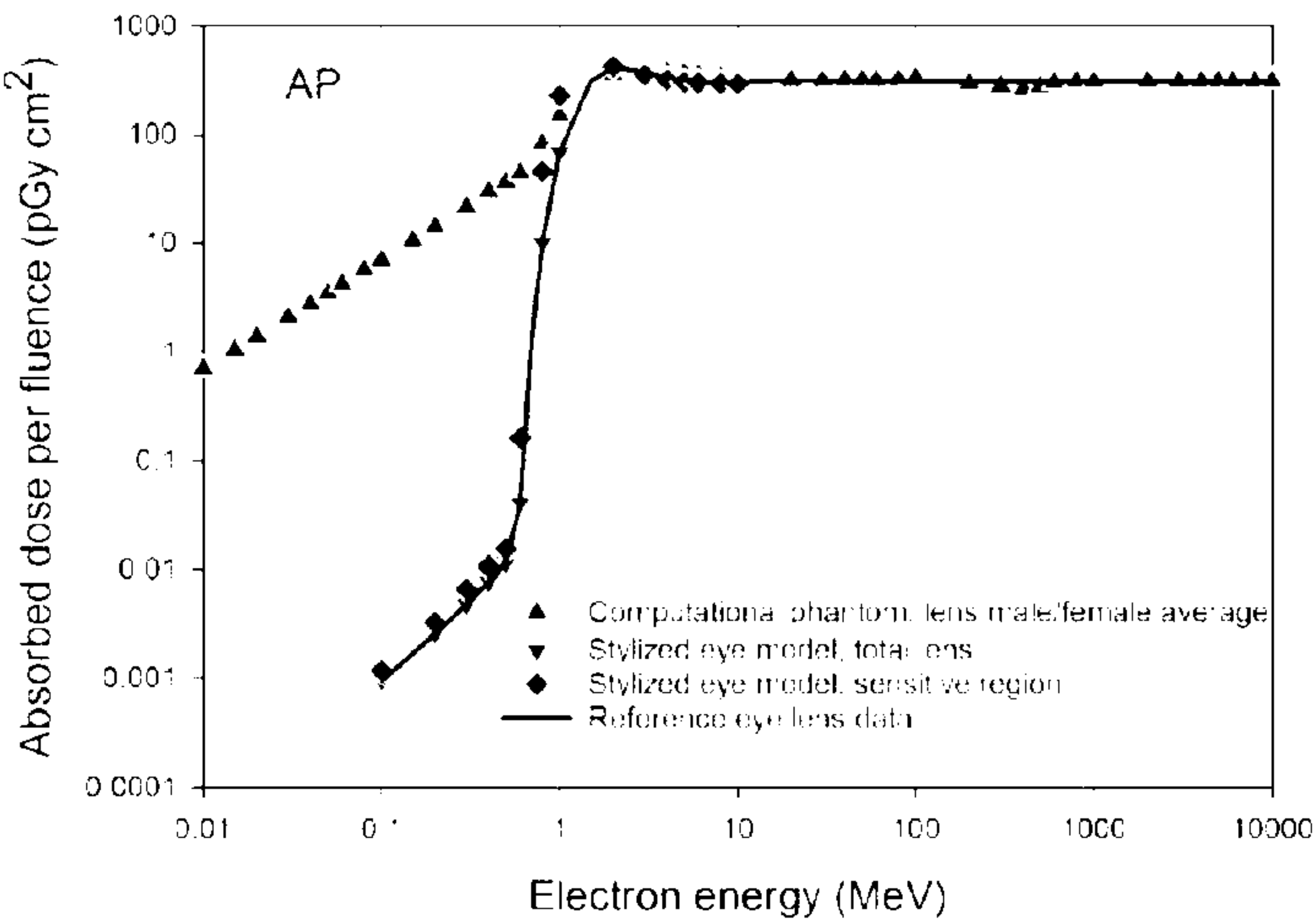
- Stylized eye phantoms.
- New dose conversion coefficients.
- ICRP-116, Appendix F.



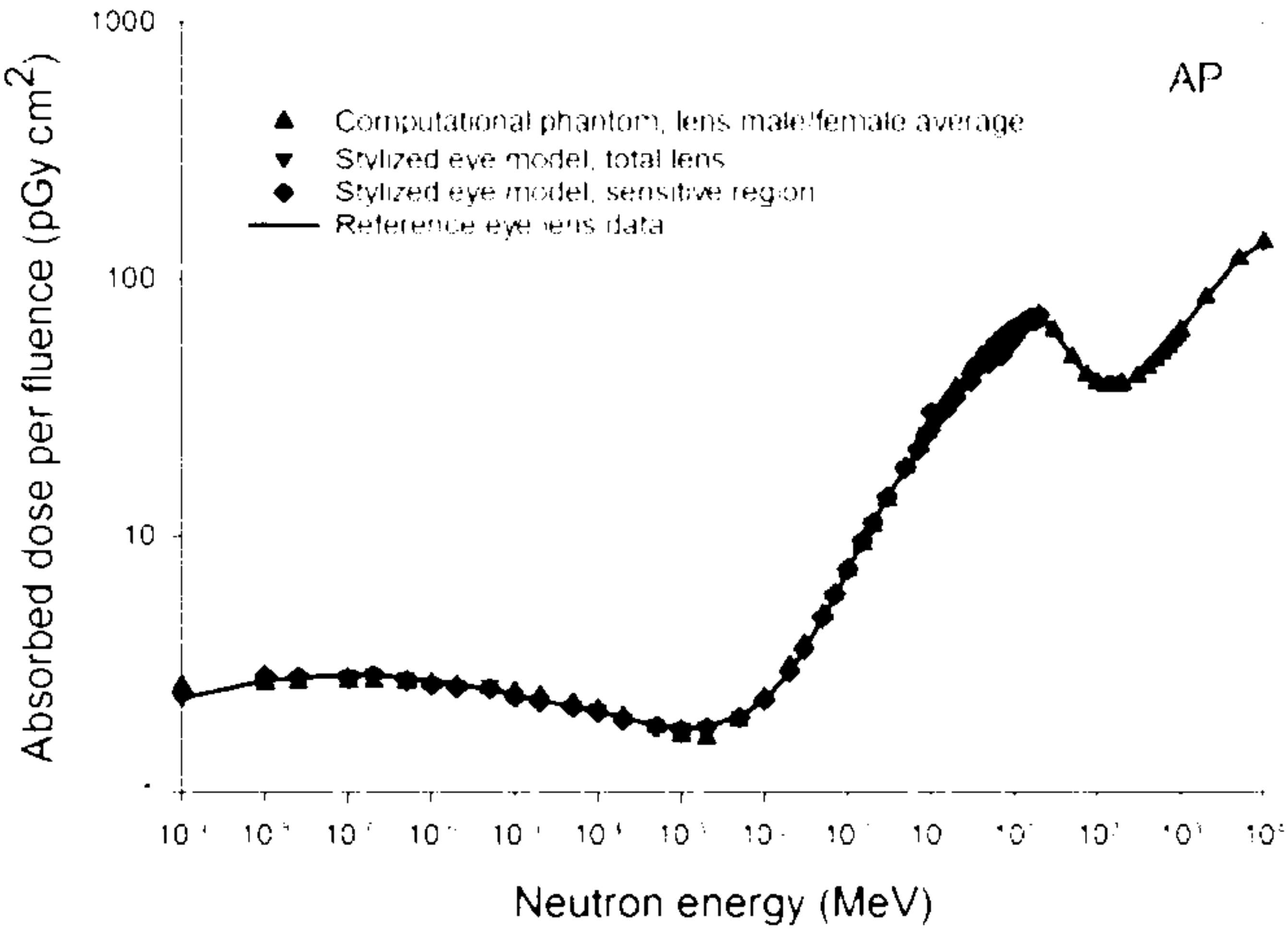
ICRP Publication 116, App. F



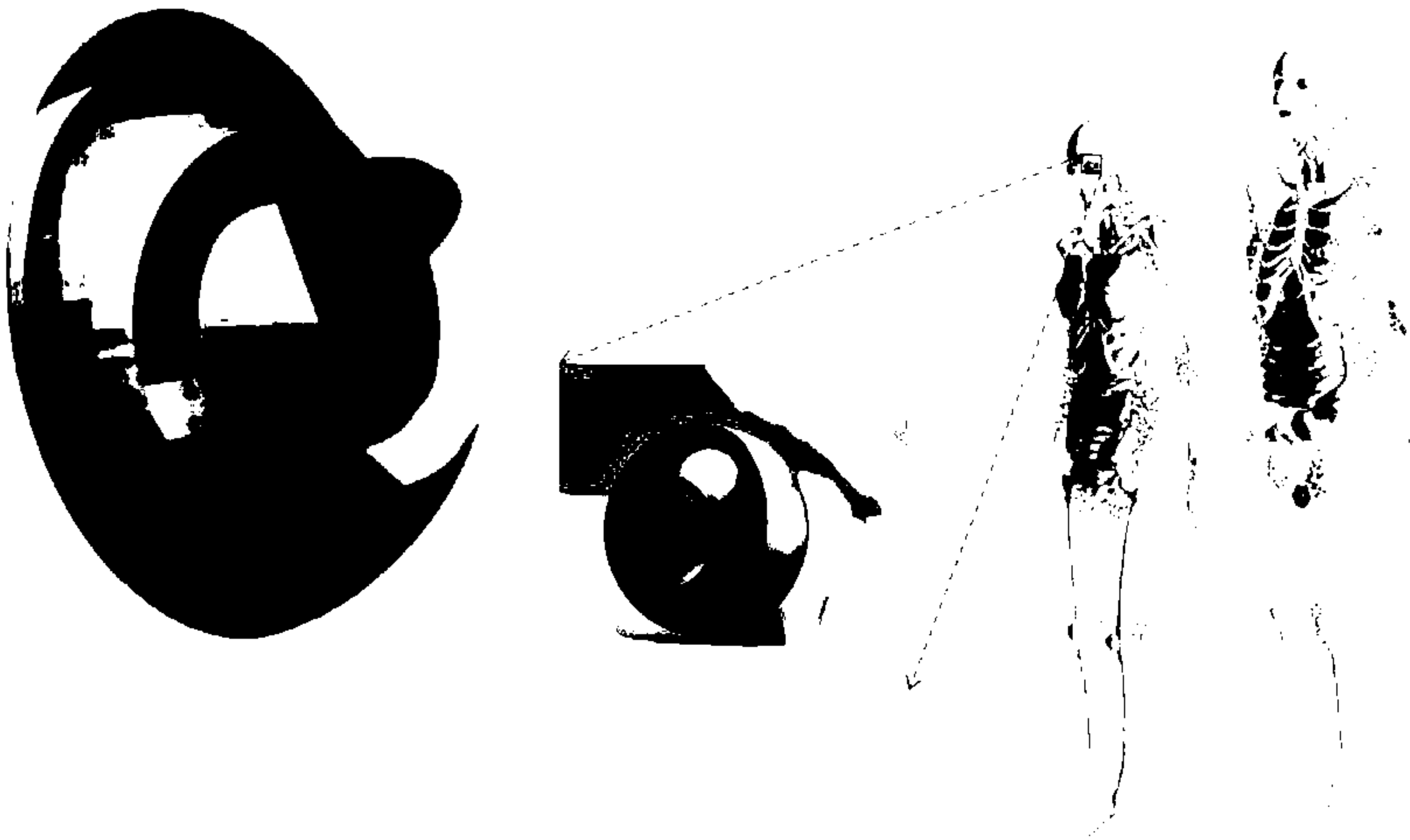
ICRP Publication 116, App. F



ICRP Publication 116, App. F

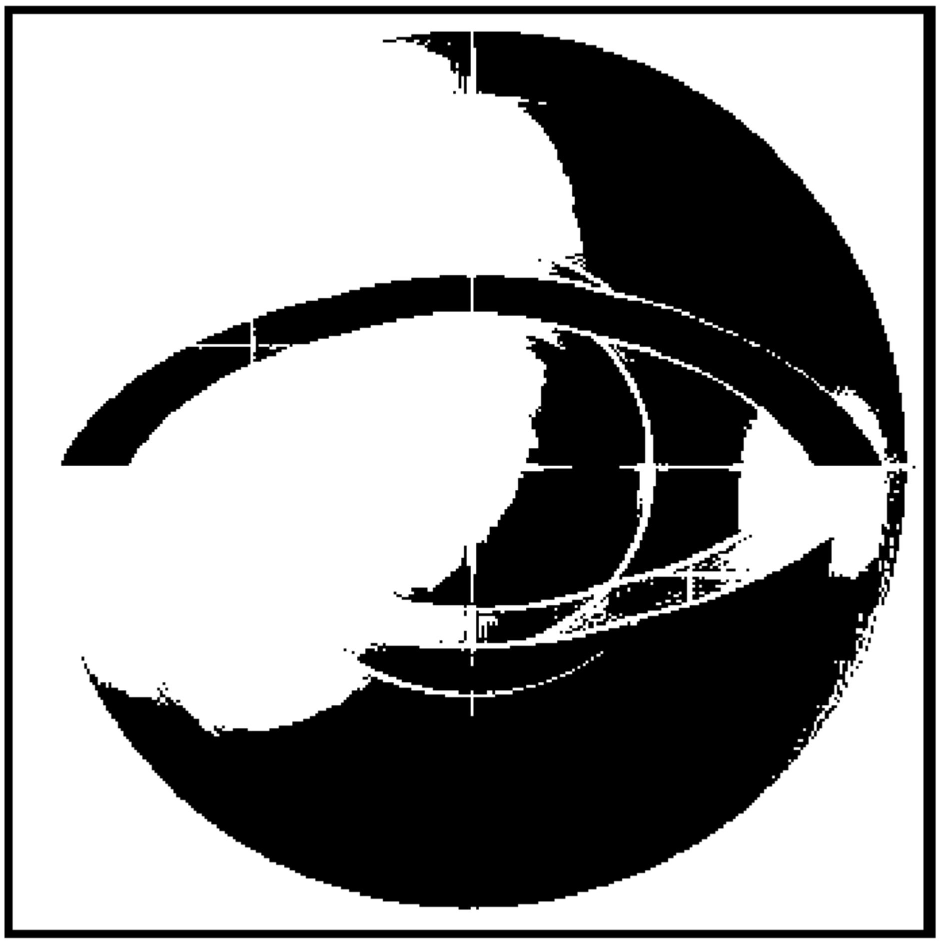


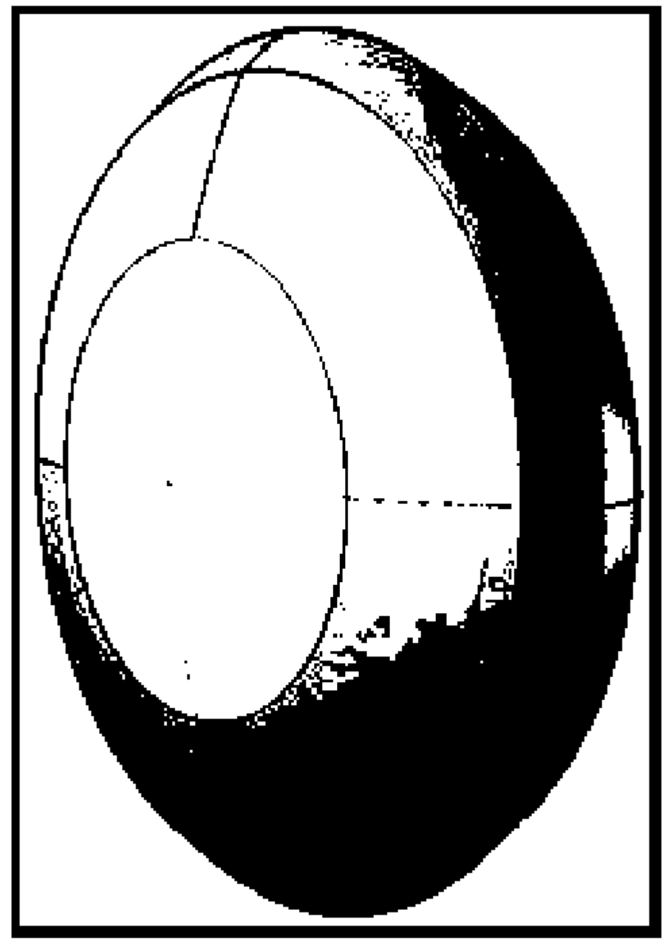
Eye Model in Poly-Mesh ICRP 110



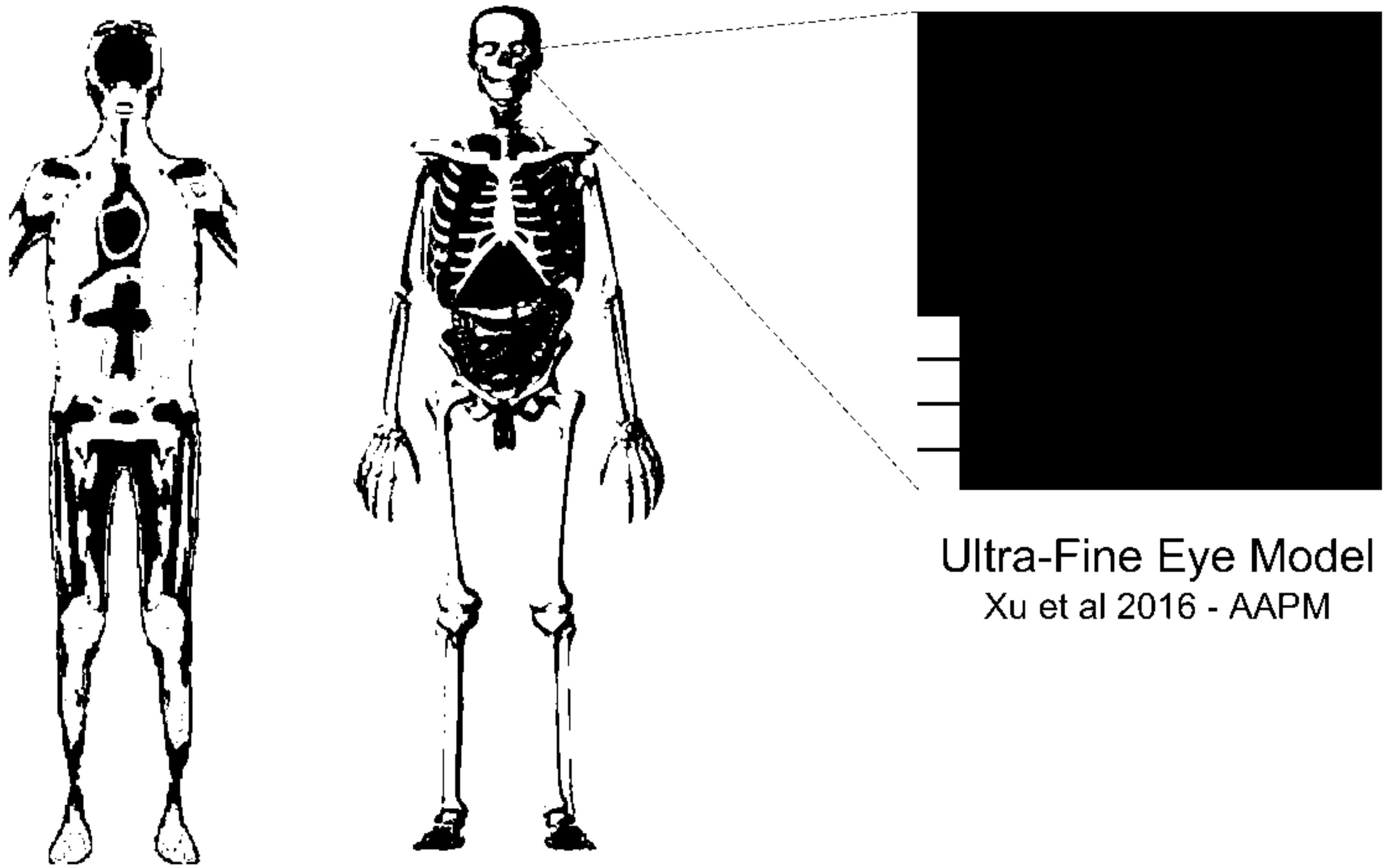
Nguyen et al 2015 PMB 60(22):8695-707.

Voxel Eye Model
(RPI - Caracappa et al PMB 59 - 2014)





RPI Adult Male Voxel Phantom



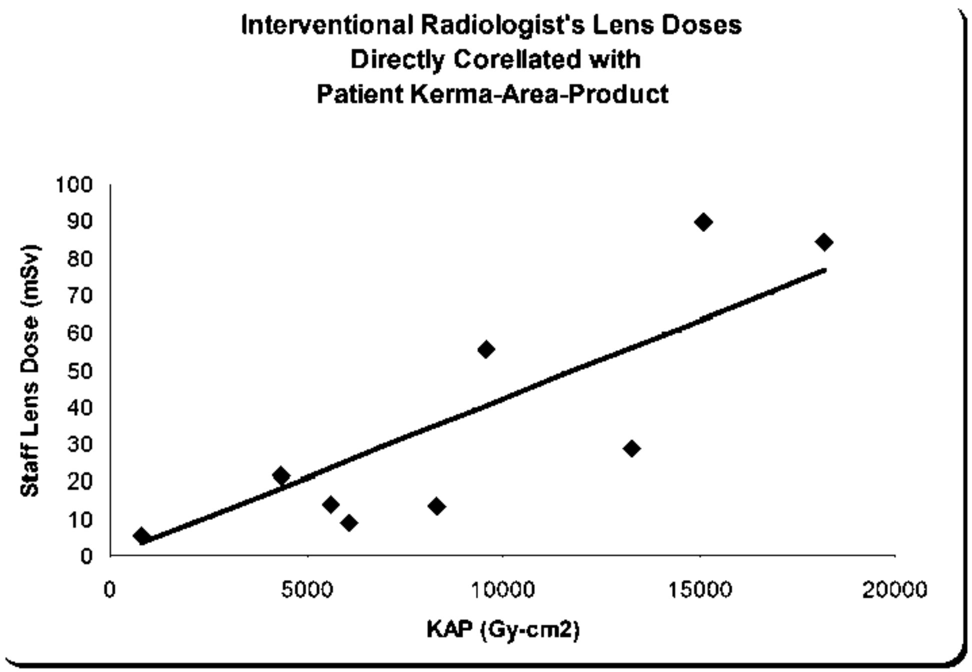
Ultra-Fine Eye Model
Xu et al 2016 - AAPM

Lens of Eye Radiation Protection
Medical Considerations

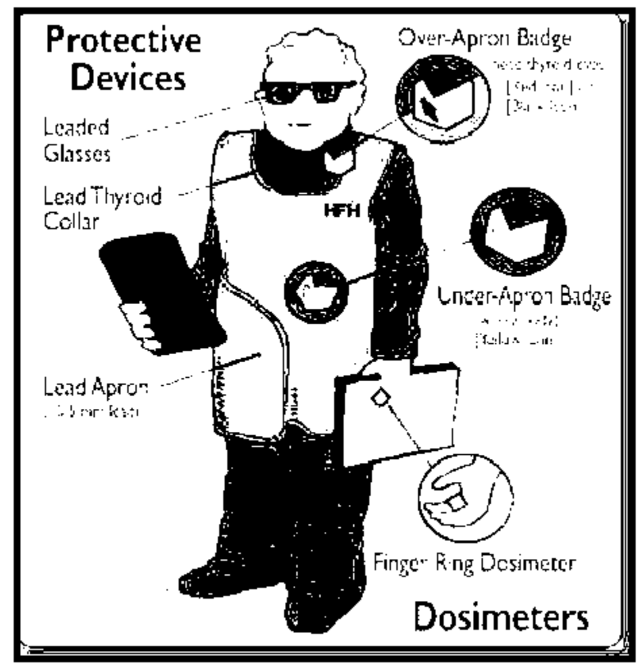
STAFF PROTECTION

ALARA / Optimization for IR Staff

- Training, Behavior Modification & PPE
  - ~45% reduction in LDE over 3 year period.
- Protect the Patient = Protect the staff



Dauer et al, 2010, JVIR



Lieto and Jackson 2000

Optimization in IR Procedures Reduces Lens of Eye Dose as well

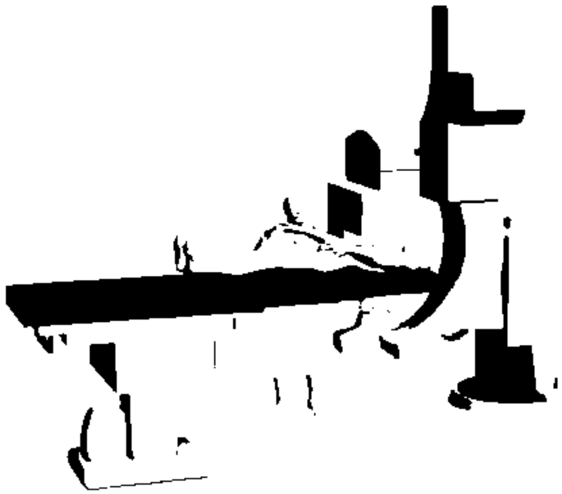
- Dose > in larger patients.
- mA low as possible.
- kVp high as needed.
- Patient at max distance from x-ray tube
- Detector as close to the patient as possible.
- Don't overuse geometric or electronic magnification.
- Remove grid on small patients if image quality not compromized.
- Always collimate down to the area of interest.
- Use PPE (shield patient, use ceiling shields, leaded eyewear).
- Keep beam on time, photospot shots, and movies to minimum.

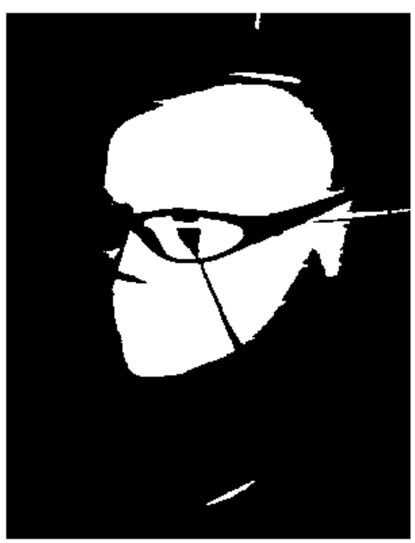
Shielding Strategies for FGI LDE reduction

Strategy	Reduction Factor
Leaded glasses	**3** - 10
Shielded drape	25
Leaded glasses + drape	140
Ceiling shield	130
Rolling shield	1000

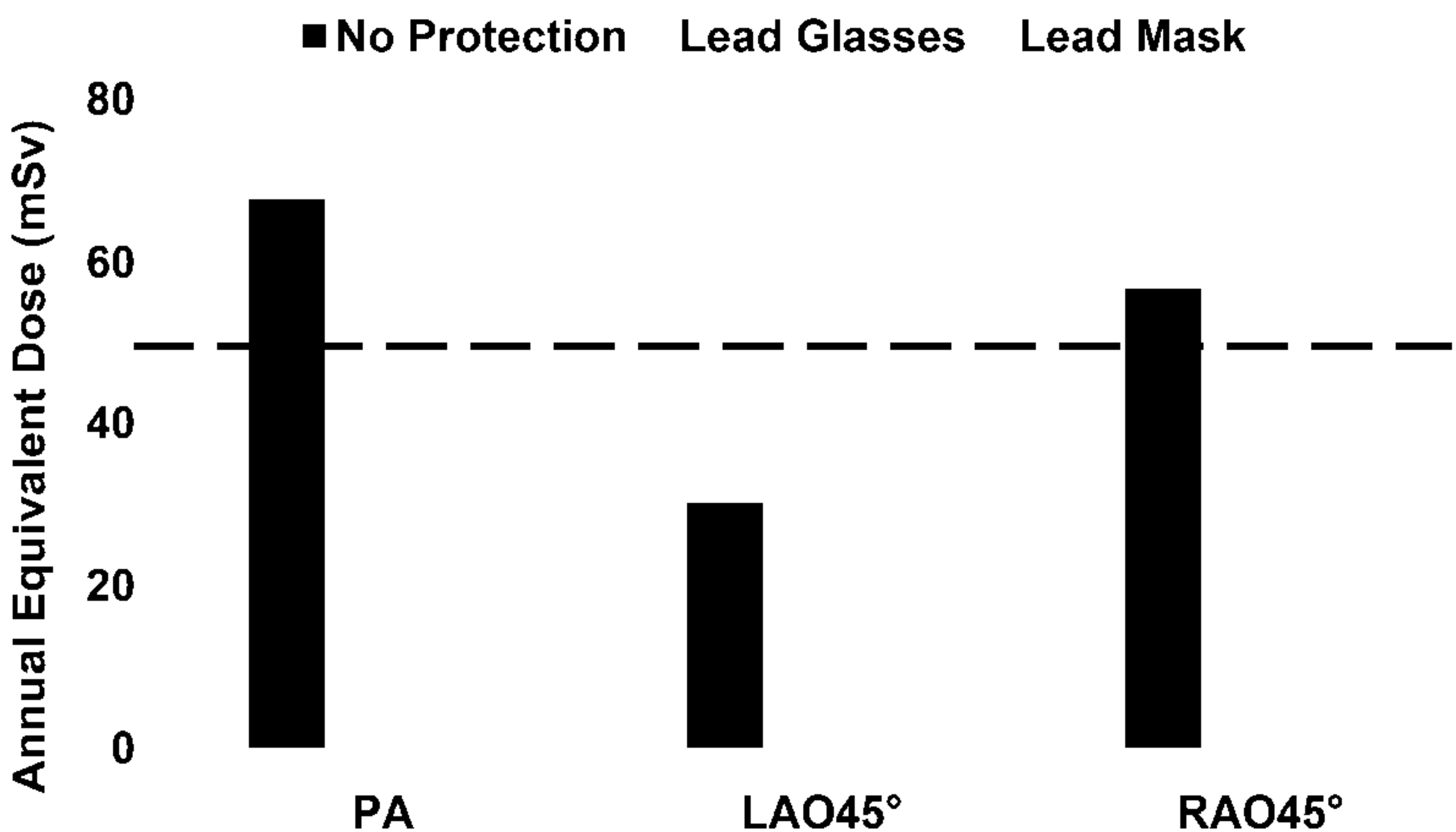
Thornton, Dauer et al 2010 JVIR

Monte Carlo Assessment of Dose to the Lens of the Eye IR (Xu, Dauer et al. 2016 [RPI/MSKCC]– AAPM meeting)

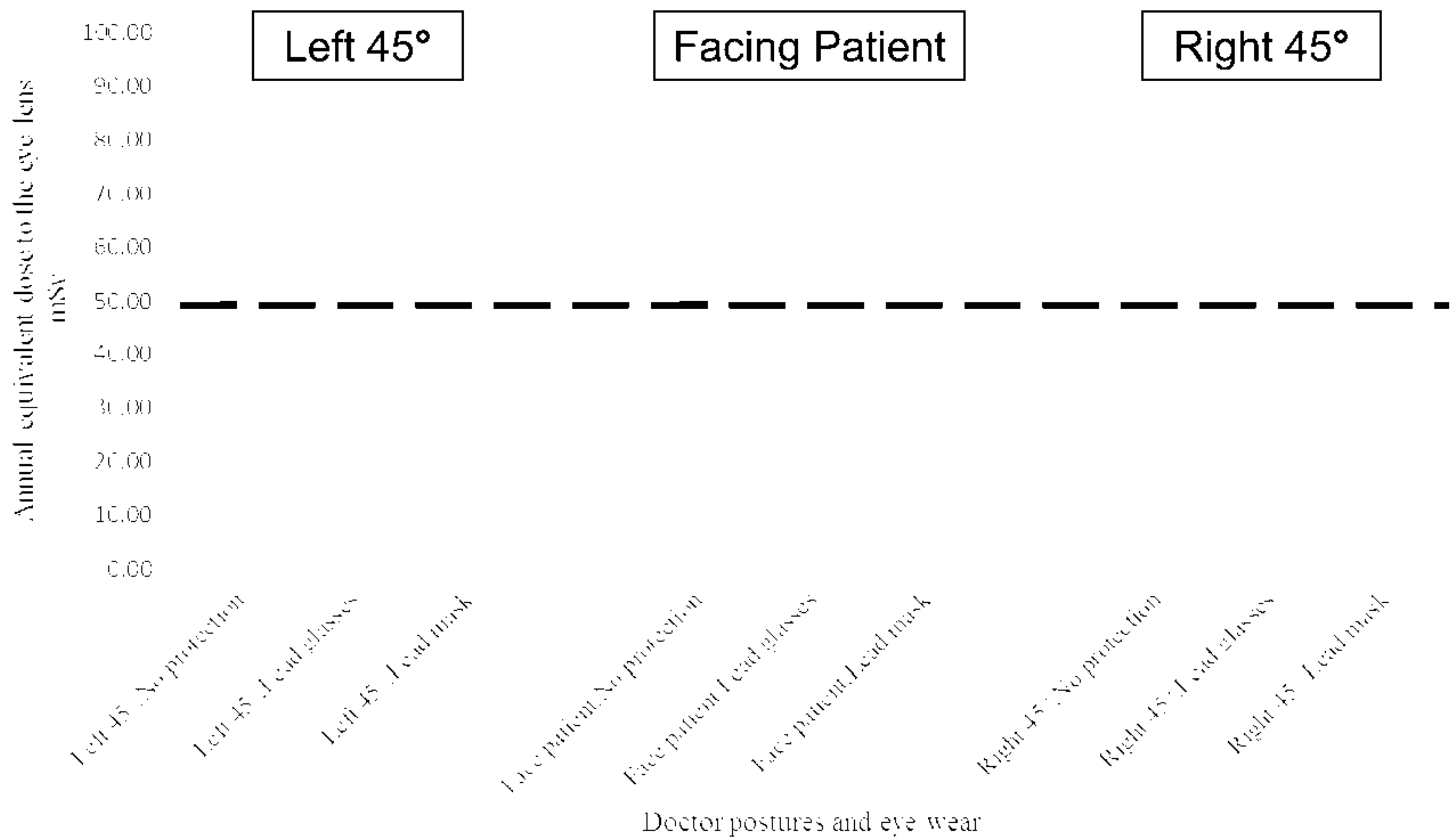




Monte Carlo Assessment of Dose to the Lens of the Eye IR
(Xu, Dauer et al. 2016 [RPI/MSKCC]– AAPM meeting)



Monte Carlo Assessment of Dose to the Lens of the Eye IR (Xu, Dauer et al. 2016 [RPI/MSKCC]– AAPM meeting)



Guidance on Radiation Dose Limits for the Lens of the Eye

Status of NCRP SC 1-23, Commentary 26

CONCLUSIONS

SC 1-23, Commentary 26 Conclusions

- Should radiation-induced cataracts be characterized as stochastic or deterministic effects?
  - Several authors indicate radiation-induced opacities may be stochastic in nature.
  - Mechanism and link between induction of minor opacities and occurrence of clinically-relevant, visual-impairing cataracts within a relevant timescale is still far from clear.
  - Best epidemiological evidence still indicates a threshold model.
  - Continue to use this model for radiation protection purposes.
  - Not possible to make a specific quantitative estimate of the threshold at this time.

SC 1-23, Commentary 26 Conclusions

- What effects do LET, dose rate, acute and/or protracted dose delivery have on cataract induction and progression?

  Although different studies have looked at many of these factors independently, there is still very little evidence upon which to base an answer to this question.

  Mechanistic evidence is perhaps stronger in some instance (e.g., differential effect of increased radiation ionization qualities enhancing the induction and progression of opacities).

  More high-quality epidemiological and mechanistic studies are required. Need for better dosimetry and scoring methods.

SC 1-23, Commentary 26 Conclusions

- How should detriment be evaluated for cataracts?

  Vision-impairing cataracts could be considered the endpoint of greatest concern. They certainly may affect individuals' ability to carry out their occupations or other daily tasks.

  Mechanisms underlying transition of minor lens opacifications to clinically significant vision-impairing cataracts are still not well understood.

  NCRP SC 1-23 encourages NCRP-168 recommendation to regard eye exposures in much the same way as whole-body exposures (*i.e., ensure exposures are consistent with ALARA principles*). This includes careful justification and optimization in exposure situations including radiation doses to the lens of the eye.

SC 1-23, Commentary 26 Conclusions

- Based on current evidence, should NCRP change the recommended limit for the lens of the eye at this time?
  - Current epidemiology and biology studies indicate an association between exposure to ionizing radiation and initiation or development of PSC, cortical and/or mixed visually-impairing cataracts for various exposure situations, perhaps even at lower doses than previously considered for lens dose limits.
  - As in prior NCRP Report No. 132, use absorbed dose when addressing specific tissue reactions (or deterministic effects).
  - Reduce Occupational Annual lens of eye limit to **50 mGy.**
  - Member of Public Annual lens of eye limit as **15 mGy.**

Guidance on Radiation Dose Limits for the Lens of the Eye

Status of NCRP SC 1-23, Commentary 26

OTHER RECOMMENDATIONS

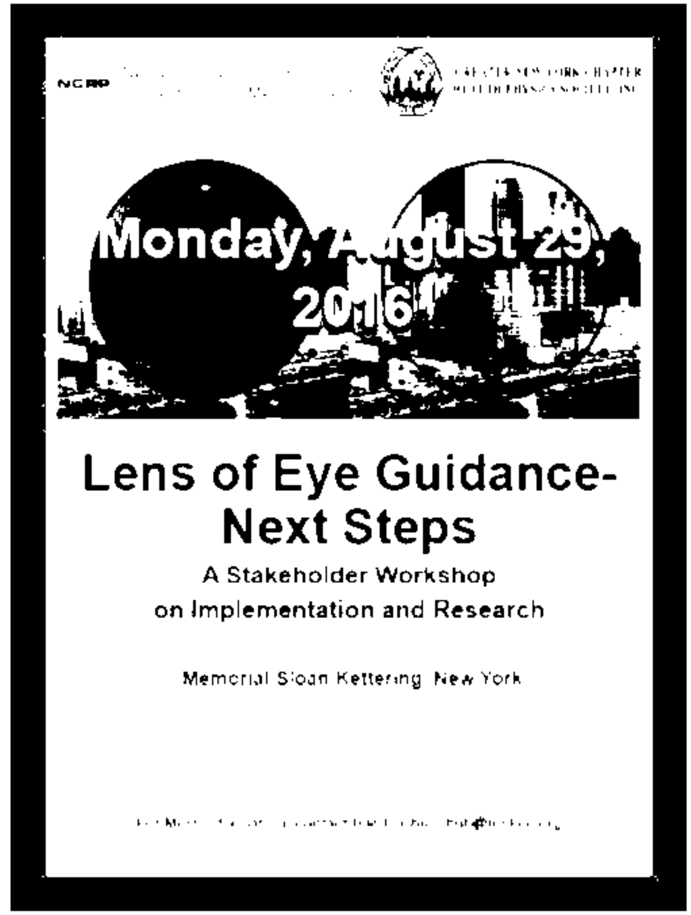
Several Needs and Opportunities

- Need for new, high-quality epidemiology and basic research on mechanisms of action.
  - Patients
  - Occupational Staff
- Increasing knowledge of pathogenesis, prevention and treatment of lens damage.
- Quality treatment planning in EBRT, Brachy.
- Dosimetry – modeling + algorithms for occupational exposure scenarios?
- On-going opportunity for dose-sparing optimization (e.g. CT) and the need for more education and more accurate dose assessment for potentially exposed populations.
- Need additional information on children effects.
- Longitudinal studies.

Stakeholder Engagement & Actions

EPRI

NCRP & GNYCHPS



Guidance on Radiation Dose Limits for the Lens of the Eye

Status of NCRP SC 1-23, Commentary 26

From: Brock, Terry
Sent: 1 Sep 2016 13:44:08 +0000
To: Flannery, Cindy
Cc: Holahan, Vincent;Tadesse, Rebecca
Subject: dose to the lens of the eye - workshop summary
Attachments: Summary Aug 29 2016_Cataract Workshop NYC.pptx

Cindy.

I thought the workshop was well done. Below is a link to the slides and John Boice's sketch summary is attached.

Larry Dauer did some interesting work at his hospital looking at the distribution of lens doses--my read is that current lens doses are low, almost all below the new NCRP recommended limit of 50 mGy/year, but I think we need to know the distribution of doses from some other big hospitals in the country due to the lack of reporting to REIRS. I found the dosimetry piece interesting and the lack of guidance/standards on how to measure/calculate the lens dose--Landauer came up with their own approach using a combo of the DDE and SDE dosimeter measurements that are reported by the licensee to REIRS.

As a reminder, Larry plans to give NRC a sponsor briefing on the NCRP commentary on 9/21 at 10 AM.

Terry

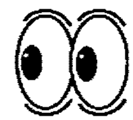
http://ncrponline.org/wp-content/themes/ncrp/PDFs/2016/LensEye_Workshop_presentations.pdf

New NCRP Guidance – Ellie Blakely – lower than before but not as low as ICRP recommends
Lens of Eye Dosimetry – Chris Passmore – How to measure what you've not been told what
Nuclear Power Plant – Dennis Quinn – not a problem EXCEPT .. Fuel pools, higher energies,
Could do a study of NPP workers 150K. Also 150K medical.. Landauer files.
Medical Facilities – Larry Dauer – Medicine. Were the dose is. Increasing. 10% children.
IRPA Guidelines – Steve Balter – Hp10 emphasis, Some IR/FGI approach higher 20 mSm.
Glasses, need them on the side.
Emergency... mix of gammas and betas differ and challenging issues.
Europe, Radiobiology, Mechanisms – Liz Ainsbury - a lot we don't know, what are target cells
Research & Study Needs – Gayle Woloschak – radiation doesn't cause cancer, but cataracts.
Q&A Moderator – Mike Grissom

[] So much is needed. Is it worth the cost for rad protection. Biology epidemiology.

[] Practical Need for guidance on measurements, Hp3 vs Hp10. Orientation, PPE
What is the "dose" to measure for compliance and how to do it.

[] Wear the badge, where to wear, training. Training. Training. Medical and NPP



[] NCRP/160 medical doses update – CDC – UNSCEAR update also.

[] Scanners in airport. Less than 2 minutes in flight – Aircrew doses – CDC

[] Dosimetry complex. Not sure what to measure. Hp3 etc and how to do it. Can be 5% differences. Soares NCRP council. But 5% differences. So what? If the orientation badge position >> does it matter? If 1 mGy or 100 mrem .. Does it matter whether its even 2 mGy. Or re NRC, is the cost (which can be substantial) worth the level of protection.

[] Science. NASA .. HZE and high LET ... but what is the % exposure to high LET.

[] Reducing patient exposure could be meaningful. Dental cone beam CT. Pt Lead Glasses... BMT Recognized. See Inskip paper (CCSS 2016). But workers increase.

[] IR/FGI MD no Pb glasses. Average 11 mSv, 75% percentile 19 mSv

[] Medical, Hp .07 shallow today, Hp3 switch ok photons, but needed for beta. Hp10 not so great.

[] Protect patient = protect the staff .. training important

[] Studies. 150K NPP. Link with Medicare. All eye disease. Cataracts.

[] Time to wear bowtie.

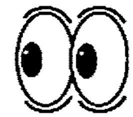
[] Spherical geometry? Better for above and below exposures.

[] Hp3 not universal? Hp10.

[] Wear badge in medicine, or leave in desk and don't be hassled. Industrial radiographers... leave in truck.

[] Dosimeters that recognize if being worn ..

[] Look at stochastic effects-makes a difference in regulations. And more on monitoring. Because enough room to cover.



[] Slides being put on NCRP website "soon". Pdf'd and permissions needed.
[] Major cause of blindness in world
[] We will all get cataract if we live long enough ..
[] Don't understand how initial result of insult on eye results in cataract.
[] PPE matters, but remember the sides.
[] medical, under or over the apron?
[] Education and training most important
[] Rad Protection Week .. Oxford in Sept.
[] Epi evidence suggest a threshold
[] Deterministic or stochastic... critical regulations. IF number of cells die, then easier to regulat. Stochachstic then look differently.
[] How to add to detriment. Based on fatal cancer weights of assume genetics. Quality of life...
[] High LET neutrons. Cataracts in pilots, Lufthansa, flyers. Proton therapy, baths in low level neutrons. Astro doses are low but specialized on effectiveness of HZE particles.
[] NEEDS. Regulations on what to measure and how. LET matters. RESEARCH needs. NASA has no human analogue for HZE bullets. Fe.. Zipping threw space. Dose rate matters. Sex vs Males. Males more sensitive. Than females. Opposite with cancer. Limits time in space.
[] Humans only, rad bio only, doesn't work. We are trying to integrate with best of both epidemiology
[] Wonder world of omics, biology, connectomics, Computer power, genectic sequencing. Huge capability.
[] Speakers. Come for picture.
[] Do we protect plastic lens. Should we, affects quality of life etc. 3pm.
[] Don't be stupid. Radiation causes cataracts. Your occupation gets it.

Public Health
England

Mechanisms: Biological and biochemical considerations for initiation and development of cataracts, especially at low doses

- What are the target cells (technological development needed)?
- What is the initiating event?
- How is latency determined (Hamada *et al.*, 2014)?
- What is the effect of dose, LET, age, gender, genetics (Hamada *et al.*, 2016)...
- Consideration of the lens as a bioindicator of global radiosensitivity (Worgul *et al.*, 1996)
- Potential role of countermeasures (e.g. Lin *et al.*, 2016)

Epidemiology:

- Development/implementation of a single classification scheme for cataracts
- Large scale reanalyses to be carried out to reduce statistical uncertainty
- Development of screening programs for occupational exposures

Public Health
England

There have been few radiobiology studies of the lens that have been done in the past 20 years.

Technology has changed drastically during this time; the initiation of new studies at this time could benefit from this technology revolution.

Radiation-induced cataracts are risks of occupational and therapeutic exposures and affect a significant population of people. While effects might not be life-threatening, morbidity is significant.

Understanding mechanisms will help us understand basic questions in radiobiology that will have a broader consequence.

From: John Boice
Sent: 15 Jul 2016 13:13:12 -0400
To: Brock, Terry;Mike Boyd
Subject: [External_Sender] DOE and MPS March 2016
Attachments: Low Dose Radiation U.S DOE Mar 2016.pdf

FYI ....Interesting support of MPS (attached also) ... hope the transfer to DOE to NCRP works (thanks Terry).

"The Low Dose Program is also supporting, through intra- and interagency efforts, a mortality study of the early U.S. workers of the nuclear age. The "Million U.S. Worker Study" builds on the investments made and foundations laid by researchers and government agencies over the past 30-40 years. These efforts had established early worker cohorts that can now provide answers to questions on the lifetime human health risks associated with low-level radiation exposures."

MIke... thanks for kind words re HPS award .. see you in Spokane!

John

--
John D. Boice, Jr., Sc.D.
President, National Council on Radiation Protection and Measurements
boice@ncrponline.org 301.657.2652 ext 19
Professor of Medicine, Vanderbilt University School of Medicine
john.boice@vanderbilt.edu Also: (b)(6)
@NCRP_ORG

From: John Boice
Sent: 21 Jul 2016 11:55:37 -0700
To: Brock, Terry
Cc: Mike Boyd
Subject: [External_Sender] Fwd: NRC funding to DOE DE-SC0008944 Million Man Study
Attachments: DE-SC0008944_AwardModRequest_NCE_2016-07-21.pdf

Terry

FYI .. submitted the NCE. Should be able to submit the required grant.gov stuff, budget, justification etc by today.

Thanks again for all your efforts (and with DOE especially)!

John

---------- Forwarded message ----------
From: **John Boice** (b)(6)
Date: Thu, Jul 21, 2016 at 9:50 AM
Subject: Re: NRC funding to DOE DE-SC0008944 Million Man Study
To: "Anderson, Todd" <Todd.Anderson@science.doe.gov>
Cc: "boice@ncrponline.org" <boice@ncrponline.org>, "Corcoran, Joanne" <Joanne.Corcoran@science.doe.gov>, Kathy Held <kathy.held@ncrponline.org>, Laura Atwell <Laura.Atwell@ncrponline.org>

Todd

1. PAMS has in their records that I submitted a request to you on July 19 for additional access...
"User Requested Additional Award Access Boice, John D7/19/2016 01:07 PM ET "

2. But doesn't matter for the here and now, since Laura found and sent me Dave Smith's authorization password, and I was able to submit the NCE just now under his authority... He's still our ED for about a week.

Here's the justification ... and attachment from PAMS for the NCE request. Hope adequate.
"07/20/2016
REQ-0000001376 No Cost Extension Submitted"

We would like to request a one-year, no cost extension for our grant entitled "Epidemiologic Study of One Million U.S. Radiation Workers and Veterans" (DOE Grant No. DESC0008944). Although we have made substantial progress, additional time

is needed to complete some of the aims of the investigation. Specifically to finalize the dosimetry assessments andmanuscript submissions of several important cohorts, specifically the nuclear power plant workers and industrial radiographers. Funds will remain in the grant after the current end date of 14 September 2016.

We would like to request a one-year no-cost extension until 14 September 2017. The justification is to complete the aims and manuscripts for the two cohorts below.

1. Dose-Response among Nuclear Power Plant (NPP) Workers: Follow-up through 2011 identified 30,993 deaths from all causes, including 71 from chronic lymphocytic leukemia (CLL) and 319 from leukemia other than CLL. The mean dose to active bone marrow from external radiation was 19.5 mGy (maximum 1.0 Gy) overall, and the percent of workers with cumulative doses >100 mGy was 8.3%. Nearly 40,000 workers had >50 mSv career dose estimates. The extension will allow us to finalize the manuscript on leukemia dose-response, and complete dose response manuscripts on lung cancer, heart disease and other sites of particular interest.

2. Dose-Response among Industrial Radiographers: Follow-up through 2011 identified 21,045 deaths from all causes, including 41 from chronic lymphocytic leukemia (CLL) and 174 from leukemia other thanCLL. The mean dose to active bone marrow from external radiation was 12.2 mGy (maximum 1.0 Gy) overall, and the percent of workers with cumulative doses >100 mGy was 3.0%. Nearly 17,000 workers had >50 mSv career dose estimates. The extension will allow us to finalize the manuscript on leukemia dose-response, and complete dose response manuscripts on lung cancer, heart disease and other sites of particular interest.

Results for the NPP and industrial radiographer studies would be subsequently combined for enhanced statistical power.

Thanks for help!

On Wed, Jul 20, 2016 at 7:58 AM, Anderson, Todd <Todd.Anderson@science.doe.gov> wrote:

Thanks John.

Safe Travels.

Todd

From: John Boice [mailto(b)(6)
Sent: Wednesday, July 20, 2016 10:57 AM

To: Anderson, Todd <Todd.Anderson@science.doe.gov>
Cc: boice@ncrponline.org; Corcoran, Joanne <Joanne.Corcoran@science.doe.gov>
Subject: Re: NRC funding to DOE DE-SC0008944 Million Man Study

Todd

Thanks. I've been checking too. Request to you was sent and the response was that I'll get an email. I'll recheck ...

But no problems. Our Office manager who was on vacation just got back to me and she had the codes for me to enter for login and I'll be able to enter the NCE. I'm now in Denver about to take off for Dulles. I'll have the NCE submitted tonight.

The proposal not that far behind.

Best wishes and thanks for help.

John

On Wed, Jul 20, 2016 at 6:24 AM, Anderson, Todd <Todd.Anderson@science.doe.gov> wrote:

> John,
>
> I have not yet received any NCE request via PAMS. Please double check to be sure it was submitted and not just saved within the PAMS system.
>
> Thanks,
>
> Todd
>
> **From:** John Boice [mailto(b)(6)
> **Sent:** Tuesday, July 19, 2016 1:10 PM

To: Anderson, Todd <Todd.Anderson@science.doe.gov>
Cc: boice@ncrponline.org; Corcoran, Joanne <Joanne.Corcoran@science.doe.gov>
Subject: Re: NRC funding to DOE DE-SC0008944 Million Man Study

Todd

Thanks! Understood.

It turns out on PAMS I didn't have "approval" to submit the NCE ... only to view. I just sent you a request a minute ago through PAMS ...

"Todd, It turns out I didn't have authority to submit the NCE. So if this was granted I'd move quickly. Sorry for delay. John"

John

On Tue, Jul 19, 2016 at 7:45 AM, Anderson, Todd <Todd.Anderson@science.doe.gov> wrote:

> John,
>
> Just FYI. When you prepare your budget you will need to plan for a total amount of $97,087.38 instead of the full $100,000. There is an administrative fee (~3%) that will need to come out of the interagency funds.
>
> Best,
>
> Todd
>
> **From:** John Boice [mailt(b)(6)
> **Sent:** Monday, July 18, 2016 5:50 PM
> **To:** Anderson, Todd <Todd.Anderson@science.doe.gov>
> **Cc:** boice@ncrponline.org; Corcoran, Joanne <Joanne.Corcoran@science.doe.gov>
> **Subject:** Re: NRC funding to DOE DE-SC0008944 Million Man Study

Dear Todd

Thanks for good news. Sorry about the time rush.

I'm in Spokane at Health Physics Society and chairing a session for rest of afternoon and have evening activities I have to attend. I'll try to get this all out ASAP. Now 5:50 pm your time, 2:50pm my time ... Pacific.

I'm on PAMS but couldn't find a way to submit and NCE (should be obvious but I'm missing something). We're in between Executive Directors (new one starts next week),. Thought I might move quickly on this ...

Any chance you might quickly remind me how to submit the NCE? I wrote it as below. (The other specific are pretty straightforward... changing to 2017 etc) . Will start work on proposal between breaks.

Thanks

John

No Cost Extension for DOE Grant No. DESC0008944

Dear Dr. Anderson:

We would like to request a one-year, no cost extension for our grant entitled "Epidemiologic Study of One Million U.S. Radiation Workers and Veterans" (DOE Grant No. DESC0008944). Although we have made substantial progress, additional time is needed to complete some of the aims of the investigation. Specifically to complete the follow-up, dosimetry assessments and manuscripts of several important cohorts including nuclear power plant workers and industrial radiographers among others. Funds will remain in the grant after the current end date of 14 September 2016, i.e., $3,329.48.

.

We would like to request a one-year no-cost extension until 14 September 2017.

Thanks very much for your continued support of this ongoing research effort.

On Mon, Jul 18, 2016 at 11:46 AM, Anderson, Todd
<Todd.Anderson@science.doe.gov> wrote:

Dear Dr. Boice,

I received confirmation from my DOE-Chicago Office colleagues (and Terry Brock) that the NRC supplied funding (back in March) to the Million Man Study (DE-SC0008944) via the interagency collaborative arrangement with DOE. NCRP has not received these funds because I was not aware that any funds were sent until today. Had we known about this earlier we could have assembled the required information in a timelier manner. Now we will be under a rush to assemble the required documents to allow NCRP to access these funds.

We're going to need:

1) a no-cost extension request submitted by NCRP for this project through the PAMS system ASAP. The award currently expires in 60 days.

2) a proposal (with a budget), submitted via Grants.gov, in response to the annual solicitation (DE-FOA-0001414). As a supplement within scope of the original award, there's no need for additional merit review. The proposal might be (mostly) a copy of whatever was submitted to NRC to justify the additional funds.

These things need to happen quickly. We are already 18 days beyond DOE's deadline for this fiscal year to complete award actions. Apologies in advance for the rushed schedule but that's where we are.

Best Regards,

Todd

****

Robert T. Anderson Ph.D.

Director, Biological Systems Science Division

Office of Biological and Environmental Research

SC-23.2 / Germantown Building

U.S. Department of Energy

1000 Independence Ave., S.W.

Washington, DC 20585-1290

tel 301-903-3213

fax 301-903-0567

Todd.Anderson@science.doe.gov

****

BER advances world-class biological and environmental research programs and scientific facilities for DOE missions in energy, environment, and basic research.

--

John D. Boice, Jr., Sc.D.
President, National Council on Radiation Protection and Measurements
boice@ncrponline.org 301.657.2652 ext 19
Professor of Medicine, Vanderbilt University School of Medicine
john.boice@vanderbilt.edu Also: (b)(6)
@NCRP_ORG

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@NCRP_ORG

--

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President, National Council on Radiation Protection and Measurements
boice@ncrponline.org 301.657.2652 ext 19
Professor of Medicine, Vanderbilt University School of Medicine
john.boice@vanderbilt.edu Als (b)(6)

@NCRP_ORG

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President, National Council on Radiation Protection and Measurements
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Professor of Medicine, Vanderbilt University School of Medicine
john.boice@vanderbilt.edu Also (b)(6)

@NCRP_ORG

--
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President, National Council on Radiation Protection and Measurements
boice@ncrponline.org 301.657.2652 ext 19
Professor of Medicine, Vanderbilt University School of Medicine
john.boice@vanderbilt.edu Also (b)(6)

@NCRP_ORG

Tracking #: REQ-0000001376 Award Modification Request - No Cost Extension

Award Information

Institution	National Council on Radiation Protection and Measurements, Bethesda, MD
PI	Boice, John
Award	DE-SC0008944. Epidemiologic Study of One Million U.S. Radiation Workers and Veterans
Budget Period	09/15/2012 - 09/14/2016
Project Period	09/15/2012 - 09/14/2016

Submitter Information

Name	Smith, David
Submitted On	07/21/2016 12:34 PM ET
Email	smith@ncrponline.org
Phone	(301) 657-2652 Ext: 20
PAMS Award Role	SRO/BO/AO
Position Title	Not Provided

Award Modification Request Information (Provided by Submitter)

Proposed End Date	09/14/2017
Amount of Funding Still Unspent	$ 3,329.00

Justification (Provided by Submitter)

We would like to request a one-year, no cost extension for our grant entitled "Epidemiologic Study of One Million U.S. Radiation Workers and Veterans" (DOE Grant No. DESC0008944). Although we have made substantial progress, additional time is needed to complete some of the aims of the investigation. Specifically to finalize the dosimetry assessments and manuscript submissions of several important cohorts, specifically the nuclear power plant workers and industrial radiographers. Funds will remain in the grant after the current end date of 14 September 2016.

We would like to request a one-year no-cost extension until 14 September 2017. The justification is to complete the aims and manuscripts for the two cohorts below.

. Dose-Response among Nuclear Power Plant (NPP) Workers: Follow-up through 2011 identified 30,993 deaths from all causes, including 71 from chronic lymphocytic leukemia (CLL) and 319 from leukemia other than CLL. The mean dose to active bone marrow from external radiation was 19.5 mGy (maximum 1.0 Gy) overall, and the percent of workers with cumulative doses >100 mGy was 8.3%. Nearly 40,000 workers had >50 mSv career dose estimates. The extension will allow us to finalize the manuscript on leukemia dose-response, and complete dose response manuscripts on lung cancer, heart disease and other sites of particular interest.

:. Dose-Response among Industrial Radiographers: Follow-up through 2011 identified 21,045 deaths from all causes, including 41 from chronic lymphocytic leukemia (CLL) and 174 from leukemia other than CLL. The mean dose to active bone marrow from external radiation was 12.2 mGy (maximum 1.0 Gy) overall, and the percent of workers with cumulative doses >100 mGy was 3.0%. Nearly 17,000 workers had >50 mSv career dose estimates. The extension will allow us to finalize the manuscript on leukemia dose-response, and complete dose response manuscripts on lung cancer, heart disease and other sites of particular interest.

Results for the NPP and industrial radiographer studies would be subsequently combined for enhanced statistical power.

From: John Boice
Sent: 5 Aug 2016 12:15:32 -0400
To: Brock, Terry
Cc: Mike Boyd
Subject: [External_Sender] Fwd: Recommendation for DOE Office of Science Supplemental Award

Thanks! Looks like we're golden, and retroactive to 7/22/16.
John

---------- Forwarded message ----------
From: **PAMS** <PAMS.Autoreply@science.doe.gov>
Date: Fri, Aug 5, 2016 at 11:53 AM
Subject: Recommendation for DOE Office of Science Supplemental Award
To: boice@ncrponline.org
Cc: Robert Anderson <Todd.Anderson@science.doe.gov>, Joanne Corcoran <Joanne.Corcoran@science.doe.gov>, Theresa Lagana <Terry.Lagana@science.doe.gov>

The following supplemental proposal has been recommended by the Office of Biological & Environmental Research within the Department of Energy (DOE) Office of Science for negotiation of a financial award:

Award Number: DE-SC0008944
Institution: National Council on Radiation Protection and Measurements, Bethesda, MD
Principal Investigator: Boice, John
Proposal Title: Epidemiological study of one million U.S. radiation workers and veterans
Solicitation: DE-FOA-0001414, FY 2016 Continuation of Solicitation for the Office of Science Financial Assistance Program
Award Type: Grant
Supplement Start Date: 07/22/2016
Amount Recommended for Supplement: $97,087

If an award is to be made, the Office of Science - Chicago of the DOE will be in contact with the appropriate business representatives at your institution to negotiate that award.

The DOE makes no commitment and assumes no obligation with this letter. Only an award document signed by the appropriate official obligates DOE to support a project.

Thank you for your submission to the DOE Office of Science. We look forward to continuing to work with you.

Sincerely,
Robert Anderson

Program Manager, Office of Biological & Environmental Research
Todd.Anderson@science.doe.gov

--

John D. Boice, Jr., Sc.D.
President, National Council on Radiation Protection and Measurements
boice@ncrponline.org 301.657.2652 ext 19
Professor of Medicine, Vanderbilt University School of Medicine
john.boice@vanderbilt.edu Also: (b)(6)

@NCRP_ORG

From: Held, Kathryn D
Sent: 27 Sep 2016 18:36:49 +0000
To: Brock, Terry
Cc: Laura Atwell
Subject: [External_Sender] Re: NRC-HQ-60-14-G-0011: M0002

Terry,
Thank you! We really appreciate your help and support.
Kathy

Sent from my iPhone

On Sep 27, 2016, at 1:29 PM, Brock, Terry <Terry.Brock@nrc.gov> wrote:

FYI

Terry Brock, Ph.D.
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington D.C. 20555
Mail Stop TWFN-10
phone: 301-415-1793

From: Carr, M'Lita
Sent: Tuesday, September 27, 2016 1:11 PM
To: boice@ncrponline.org
Cc: Shaffer, Sarah <Sarah.Shaffer@nrc.gov>; Zuber, Gordana <Gordana.Zuber@nrc.gov>; Brock, Terry <Terry.Brock@nrc.gov>
Subject: NRC-HQ-60-14-G-0011: M0002

Dr. Boice,

Please see the attached modification. Thank you.

Thanks,

M'Lita R. Carr
Contract & Grant Specialist
U.S. Nuclear Regulatory Commission
Acquisition Management Division
Mail Stop: TWFN- T5-E02
Phone: (301) 415-6869
Email: MLita.Carr@nrc.gov
Office Schedule: Monday - Thursday 5:00 am - 3:30 pm

<downloadForm.pdf>

From: Held, Kathryn D
Sent: 23 Sep 2016 12:40:09 +0000
To: Brock, Terry
Cc: Laura Atwell;John Boice
Subject: [External_Sender] Re: Re: 3-month No cost extension for NCRP grant HQ-60-14-G-011

Thank you!

Kathy

From: Brock, Terry <Terry.Brock@nrc.gov>
Sent: Friday, September 23, 2016 8:39 AM
To: Held, Kathryn D
Cc: Laura Atwell; John Boice
Subject: RE: Re: 3-month No cost extension for NCRP grant HQ-60-14-G-011

Thanks Kathy. That should do it. I'll let you know if we need anything else.

Terry

From: Held, Kathryn D [mailto:Kathy.Held@ncrponline.org]
Sent: Thursday, September 22, 2016 5:06 PM
To: Brock, Terry <Terry.Brock@nrc.gov>
Cc: Laura Atwell <Laura.Atwell@ncrponline.org>; John Boice <(b)(6)
Subject: [External_Sender] Re: 3-month No cost extension for NCRP grant HQ-60-14-G-011

Dear Terry,

I apologize for not expressing our NCE request correctly in the modified budget on the request and thus causing confusion. Attached is a modified request on which I have changed the budget request (I hope expressing it correctly now) and included an explanation for why our NCE request is for $21,810, although we had $60,495.49 as of the end of August, 2016. I hope this is a clear explanation. If there are additional questions or other information needed, please let me know.

Thank you so much for your help!

Kathy

From: Held, Kathryn D
Sent: Thursday, September 22, 2016 11:10 AM
To: Brock, Terry
Cc: Laura Atwell; John Boice
Subject: Re: 3-month No cost extension for NCRP grant HQ-60-14-G-011

Hi Terry,
Thanks for update. The $60,495 amount was as of the end of August. Because of the very heavy expected effort by staff consultant, editor and other staff in September as we do pre-publication work and final reviewing on the report, we estimated about $39k in total costs to be charged in September, hence the NCE request of about $22k.
I'm out of my office until 3:30 and don't have detailed numbers with me, but will send you full info when I get back to my office at 3:30.
Thanks.
Kathy

Sent from my iPhone

On Sep 22, 2016, at 10:14 AM, Brock, Terry <Terry.Brock@nrc.gov> wrote:

> Hi Kathy,
>
> The revised budget for the NCE should reflect the total for the grant. See below. We have on record that there is still **$60,495.49 remaining.** Would you please verify the exact amount left on the submittal as soon as possible.
>
> Thanks,
> Terry
>
> Terry Brock, Ph.D.
> Office of Nuclear Regulatory Research
> U.S. Nuclear Regulatory Commission
> Washington D.C. 20555
> Mail Stop TWFN-10
> phone: 301-415-1793
>
> **From:** Davis, Chon
> **Sent:** Thursday, September 22, 2016 9:39 AM
> **To:** Brock, Terry <Terry.Brock@nrc.gov>
> **Cc:** Shaffer, Sarah <Sarah.Shaffer@nrc.gov>; Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>
> **Subject:** RE: 3-month No cost extension for NCRP grant HQ-60-14-G-011
> **Importance:** High
>
> Hi Terry.
> Sarah and I just reviewed the budget you sent us. It looks like they are asking for an additional $21,810. If this is truly a no-cost extension the budget should look like this:

Category	Year 1	Year 2	Total	NCE
Personnel	$44,928.82	$14,136.00	$64,310.14	$5,245
Fringe	$11,901.64	$3,733.11	$17,035.75	$1,401

Benefits				
Travel	$29,116.29	$14,794.24	$43,910.53	0
Other	$25,000.00	$5,900.00	35,000,00	$4,100
Indirect Charges	$114,053.25	$39,626.33	$164,743.59	$11,064
Totals	**$225,000.00**	**$78,190**	**$325,000.00**	**$21,810**

Their ASAP report shows that they have **$60,495.49** remaining as of 9/12/16. We need to know exactly how much money they have left and how they plan to use it during the extension period.

Please have the recipient revise the budget to reflect a true no cost extension and please contact M'Lita Carr with a CC to us to ensure she is willing to process the no cost extension given that the grant expires on 9/29/16 and this request is coming with a less than 30 day turnaround time. I've copied her on this email so that she will be aware that you'll be speaking to her.

Thanks very much!
Chon and Sarah

From: Brock, Terry
Sent: Friday, September 16, 2016 11:36 AM
To: Davis, Chon <Chon.Davis@nrc.gov>
Cc: Shaffer, Sarah <Sarah.Shaffer@nrc.gov>
Subject: RE: 3-month No cost extension for NCRP grant HQ-60-14-G-011

Here you go.

Thanks

From: Davis, Chon
Sent: Tuesday, September 13, 2016 12:46 PM
To: Brock, Terry <Terry.Brock@nrc.gov>
Cc: Shaffer, Sarah <Sarah.Shaffer@nrc.gov>
Subject: RE: 3-month No cost extension for NCRP grant HQ-60-14-G-011

Hi Terry. They should be able to submit it in the same format they used initially, unless there's something I'm unaware of. Sarah is out of the office the rest of this week so if you could please forward the revised budget to me I will initiate the zeroreq.

From: Brock, Terry
Sent: Tuesday, September 13, 2016 10:28 AM
To: Shaffer, Sarah <Sarah.Shaffer@nrc.gov>; Davis, Chon <Chon.Davis@nrc.gov>
Cc: Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>
Subject: RE: 3-month No cost extension for NCRP grant HQ-60-14-G-011

Do you have a preferred format for the budget?

Terry

From: Shaffer, Sarah
Sent: Tuesday, September 13, 2016 9:57 AM
To: Brock, Terry <Terry.Brock@nrc.gov>; Davis, Chon <Chon.Davis@nrc.gov>
Cc: Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>
Subject: RE: 3-month No cost extension for NCRP grant HQ-60-14-G-011

Terry
The grantee needs to send in a revised budget. And we need it ASAP, since we only have a couple of weeks until it expires.

From: Brock, Terry
Sent: Tuesday, September 13, 2016 9:43 AM
To: Shaffer, Sarah <Sarah.Shaffer@nrc.gov>; Davis, Chon <Chon.Davis@nrc.gov>
Cc: Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>
Subject: 3-month No cost extension for NCRP grant HQ-60-14-G-011

Sarah/Chon,

NCRP requested a 3 month no-cost extension for grant NRC-HQ-60-14-G-0011 "Dose to the Lens of the eye". It was to end on 9-29-16, now to end on 12-31-2016.

Here's the justification:

NCRP has finalized the Report and processing will begin shortly for publication as a hard copy and in electronic form. The reason for the request is that the processing costs for publication will continue after the grant ends on 09/29/2016. Funds allocated for the publication processing remain in the grant, and NCRP needs a no cost extension through 12/31/2016 just to cover the publication processing cost. NCRP anticipates, however, that the publication will be out in a shorter time since this is their highest priority for publication.

Terry Brock, Ph.D.
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington D.C. 20555
Mail Stop TWFN-10
phone: 301-415-1793

From: John Boice
Sent: 18 Nov 2015 11:44:37 -0500
To: Brock, Terry
Subject: [External_Sender] Re: Re: input needed on MWS
Attachments: Million Person Study of Low Dose Radiation Health Effects 2015-07-11.pdf

Terry

I may have sent the CDC Foundation Proposal ... but here it is again. It was my attempt to explain why the MPS is so critical to the nation.
A thumbnail sketch of all things associated with the study.

Best wishes

John

On Wed, Nov 18, 2015 at 11:31 AM, John Boice (b)(6) wrote:

> Terry
>
> Thanks! Comforting that discussions are being held at such high levels!
>
> Best
> John
>
> On Wed, Nov 18, 2015 at 11:26 AM, Brock, Terry <Terry.Brock@nrc.gov> wrote:
>
>> Thanks John. This is very helpful. Mike Weber will be calling DOE-NE soon. Our Chairman meets with the DOE-NE Asst. Secretary John Kotek in December and the MWS is on the agenda for them to take over from SC.
>>
>> Best,
>>
>> Terry
>>
>> **From:** John Boice [mailt(b)(6)
>> **Sent:** Wednesday, November 18, 2015 11:04 AM
>> **To:** Brock, Terry <Terry.Brock@nrc.gov>
>> **Subject:** [External_Sender] Re: input needed on MWS
>>
>> Terry
>>
>> Thanks very much for the call about Bill... Bil was well liked/loved and it's a tragic loss. He was only 62 y.

I'm in Emergency Response meeting in Norwich CT and will try to provide as I can

Title is

Epidemiologic study of one million U.S. radiation workers and veterans

The total amount was $21,733,858.00

Technically I am not certain whether "award" is the proper term. It was "approved" .

The attached was the original submission, approved for $21M. Then resubmission in July 2012 for reduced amount,

Effective date of award was Effective Date: 9/15/2012 (see attached) for $2,544,000.00

Period of Performance through 9/14/2014.

We've had 2 NCE's... the one just recently was through 9/14/2016 (attached). $4K was the carryover through 9/14/2016. DOE said this would be a mechanism for which other agencies could provide funds, but not necessarily any funds from them. See attached NCE.

Over the years, NRC, EPA, NASA contributed funds through the mechanism. Adam DeMella asked me to prepare a total funding description for the Million Person Study ... I've attached this also FYI, updated as of today for you.

FYI ... I've attached a June 2015 letter to Sec Moniz from the DOE SEAB regarding low dose studies. "SEAB does not believe DOE should abandon its research effort on low-level radiation effects."

NASA did provide a 3 year grant which keeps the lights on. It was $75K for this year. As we've discussed, the subcontractors are now moving to other projects that support their level of effort needed. And, tragically, Bill Morgan provides an example of what continues to concern me ... if we don't act now, the national opportunity is lost.

If more needed, I'll try to get back when I can...

Best

John

On Wed, Nov 18, 2015 at 9:30 AM, Brock, Terry <Terry.Brock@nrc.gov> wrote:

John,

We're going to call DOE-NE about the MWS, but I need some info before we call

The information I need is facts like –

official title of project-I know it has morphed a bit over the years?

grant with NCRP? When started? Current period of performance?

Thanks,

Terry

--

John D. Boice, Jr., Sc.D.
President, National Council on Radiation Protection and Measurements
boice@ncrponline.org 301.657.2652 ext 19
Professor of Medicine, Vanderbilt University School of Medicine
john.boice@vanderbilt.edu Also: (b)(6)

@NCRP_ORG

--

John D. Boice, Jr., Sc.D.
President, National Council on Radiation Protection and Measurements
boice@ncrponline.org 301.657.2652 ext 19
Professor of Medicine, Vanderbilt University School of Medicine
john.boice@vanderbilt.edu Also: (b)(6)

@NCRP_ORG

--

John D. Boice, Jr., Sc.D.
President, National Council on Radiation Protection and Measurements
boice@ncrponline.org 301.657.2652 ext 19
Professor of Medicine, Vanderbilt University School of Medicine
john.boice@vanderbilt.edu Also: (b)(6)

@NCRP_ORG

Title: Million Person Study of Low Dose Radiation Health Effects

Principal Investigator: John D. Boice, Jr., Sc.D. (Brief bio)

President, National Council on Radiation Protection and Measurements, Bethesda, MD

Professor of Medicine, Vanderbilt University School of Medicine, Nashville, TN

Overview: A study of one million Americans to determine the health effects of exposure to ionizing radiation at low doses and low dose rates. The populations include:

- Manhattan Project workers (360,000) - Department of Energy (DOE)
- Veterans who participated at Atmospheric Weapons Tests (115,000) - Department of Defense (DOD)
- Nuclear Power Plant Workers (150,000) - Nuclear Regulatory Commission (NRC) Licensees
- Industrial Radiographers (150,000) - Nuclear Regulatory Commission (NRC) Licensees
- Medical Workers (225,000) – radiologists, technologists, radiation oncologists, nuclear medicine

Why it matters: A critically important gap in knowledge surrounds the health consequences of exposure to radiation received *gradually over time*. Much is known about the health effects of brief high dose exposures, such as from the atomic bombings in Japan, but the concerns today focus on the frequent low dose exposures received by the public. Ever-increasing population exposures come from medicine (CT scans), nuclear waste and facility cleanups, nuclear power generation, occupation (interventional radiologists), increased air travel and cosmic-ray exposures, technologically enhanced naturally occurring radioactive materials (TENORM) in the environment from hydraulic fracturing, reactor accidents (Fukushima) and the possibility of terrorist events with dirty bombs or improvised nuclear devises.

Policy and health: The importance of the Million Person Study is reflected in the Low Dose Radiation Research Act of 2015 that was passed by the House and is now being considered by the Senate. The purpose of H.R. 35 is "To increase the understanding of the health effects of low doses of ionizing radiation" in order to improve public protection and "to inform improved risk management methods".

The research is timely as the NRC and EPA are currently assessing radiation standards in the United States and will propose changes that continue to protect workers and the public from adverse health effects without unduly restricting beneficial uses. Precise and accurate knowledge of radiation health effects on prolonged exposures typically experienced by Americans today can inform protection actions that are neither excessively restrictive nor overly lenient.

The need for relevant population studies: The direct study of low doses and low dose rates is of immeasurable value in understanding the possible range of health effects from gradual exposures and in providing guidance for radiation protection and worker compensation. Healthy American workers are more representative of the American public than are Japanese atomic bomb survivors exposed in 1945 who lived in a war-torn country and subjected to malnutrition, infections, and deprivation. Current radiation standards and guidance, however, are based largely on the atomic bomb survivor data, which requires rather tenuous assumptions on how to extrapolate brief high dose exposures received by an Asian population in 1945 to low-dose gradual exposures received by Americans today.

Population identification: Since the 1940s, the diverse populations of American workers and veterans exposed to radiation have been assembled by US government agencies for occupational monitoring, epidemiologic research, licensee requirements and compensation purposes. Access to these populations has taken nearly 30 years, including the necessary IRB and Human Subjects Research approvals, and one million persons are now available for study. Also available are the essential ingredients for high quality epidemiologic research: well defined populations with personal identifiers (name, date of birth and social security number); occupational records (dates of employment, job titles); radiation records on doses received over time; and bioassay data (e.g., urine samples) as needed to determine any intakes of radioactive material. Women comprise approximately 35% of the study population.

Vital Status: Tracing populations from the 1940s and 1950s is challenging. We match the study rosters against the Social Security Mortality Files of over 80 million deaths in the US since the 1960s using the CDC probabilistic matching program (LinkPlus). We make similar matches against 19 state mortality tapes such as California, Texas, and Florida. The National Death Index began in 1979 and provides cause of death directly. Alive status is determined by sending our rosters to the Social Security Administration who match our data against Medicare files, Internal Revenue tax returns and other data sets to report back whether a person is known to be alive. These strategies have resulted in location rates above 95%.

Dosimetry: The key to good epidemiology is reflected in the quality of the exposure assessment. As such we have assembled the top dosimetry experts in the United States to provide guidance on the collection, utilization and reconstruction of radiation doses for the diverse populations. Initial guidance has been published in 2015 for the entire Million Person Study and in 2014 for the atomic veterans.

Analysis: A variety of statistical analyses are being used to compare the mortality experience of the million person with the estimates of radiation organ doses (e.g., to bone marrow for leukemia evaluations). Time dependent Cox analyses, Poisson regression approaches, standardized mortality ratio programs are all being used. Approaches to handle possible uncertainties in dosimetry have been developed. The estimates of risk at low doses will be compared directly to the risks extrapolated from high dose studies to learn whether they are the same, lower or higher, and thus inform risk management decisions, compensation schemes, and models of carcinogenesis.

Progress: The feasibility to conduct the Million Person Study was confirmed in methodological, dosimetric and statistical studies that were followed by proof of principal investigations of workers at Rocketdyne (Atomics International), Mound (Dayton, Ohio) and currently Mallinckrodt (St. Louis, Missouri). Preliminary results have been submitted for publication on health effects among atomic bomb survivors and nuclear utility workers.

How Unique is the Study: The Million Person Study is 12 times larger than the study of 86,000 atomic bomb survivors and, because of sheer numbers, has many more low-dose subjects and many more high-dose subjects. Because of the average age of the population, it is estimated that nearly 400,000 deaths will have occurred. Such large numbers and broad dose distributions provide substantial statistical ability to uncover and reveal precise estimates of radiation risk for individual organ sites from exposures received gradually over time. One ultimate goal is to integrate radiation biology with the Million Person Study to even further enhance the understanding and prediction of disease following low dose exposures. Because of the greying of the radiation workforce and the associated diminution of human capital, the opportunity to conduct paradigm changing research (with implications for science, prevention, and policy decisions) is now.

Collaborators: National Council on Radiation Protection and Measurements, Vanderbilt University, University of Southern California, Harvard University, Oak Ridge Associated Universities, Oak Ridge National Laboratory, Risk Assessment Corp., International Epidemiology Institute, Landauer Inc., University of Washington, Mel Chew Assoc.

Sponsors: Over the years, financial and in-kind support has come from a variety of sources including the NRC, EPA, NASA, DOE, DOD, CDC, the Department of Veterans Affairs, Vanderbilt University, the National Cancer Institute, and the military services (US Army, US Navy and US Air Force). It is a nationwide study but support has been irregular and mainly on a year by year basis.

Financial need: The inspiration for the Million Person Study and the assembling of the cohorts have occurred, and it is only the perspiration (the straightforward but arduous and mundane tasks of tracing the populations, obtaining death certificates and causes of death, reconstructing the radiation doses and analyzing the data) that remains. At the current rate of funding it will take 20 years to complete the study in its entirety, which is longer than the expected lifespan of many of the senior investigators. To complete the research in the next five years approximately 5 million dollars annually would be required.

From: John Boice
Sent: 14 Sep 2016 18:43:51 -0400
To: Held, Kathryn D
Cc: Brock, Terry;Laura Atwell
Subject: [External_Sender] Re: Re: NCE for NRC-HQ-60-14-G-0011

Thanks Kathy!
John

On Wed, Sep 14, 2016 at 6:41 PM, Held, Kathryn D <Kathy.Held@ncrponline.org> wrote:

Hi Terry,

As per your instructions, we've prepared a budget for the no-cost extension (requesting carry forward of $21,810 into the NCE period), showing it as an additional column on our original budget request. I have included this at the bottom of Dr. Boice's previous letter, and this revised version is attached.

If you have questions or we can provide any additional information, please let us know.

Thank you for your kind attention to our request.

Kathy

Kathryn D. Held, Ph.D.

Executive Director/Chief Science Officer

National Council on Radiation Protection and Measurements (NCRP)

Kathy.held@ncrponline.org (301) 657-2652 ext. 20 or (cell) (b)(6)

From: Held, Kathryn D
Sent: Tuesday, September 13, 2016 11:18 AM
To: Brock, Terry
Cc: Laura Atwell; John Boice
Subject: Re: Re: NCE for NRC-HQ-60-14-G-0011

Hi Terry,

Thanks so much! I'll get it to you ASAP.

Kathy

From: Brock, Terry <Terry.Brock@nrc.gov>
Sent: Tuesday, September 13, 2016 11:07 AM
To: Held, Kathryn D
Cc: Laura Atwell; John Boice
Subject: RE: Re: NCE for NRC-HQ-60-14-G-0011

Hi Kathy,

Just send the budget info to me. Add another column for the last 3 months and the planned expenditures. Here's the format from your research updates to use Add it to John's earlier write-up and send it to me.

Terry

[cid:image003.png@01D20DAF.059870C0]

Terry Brock, Ph.D.
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington D.C. 20555
Mail Stop TWFN-10
phone: 301-415-1793

From: Held, Kathryn D [mailto:Kathy.Held@ncrponline.org]
Sent: Tuesday, September 13, 2016 10:14 AM
To: Brock, Terry <Terry.Brock@nrc.gov>
Cc: Laura Atwell <Laura.Atwell@ncrponline.org>; John Boice
(b)(6)
Subject: [External_Sender] Re: NCE for NRC-HQ-60-14-G-0011

Hi Terry,

Does this budget need to be on any specific form or in any specific format? Does it get sent directly to you or submitted in some other fashion online?

Thanks so much for you help.

Kathy

Kathryn D. Held, Ph.D.

Executive Director/Chief Science Officer

National Council on Radiation Protection and Measurements (NCRP)

Kathy.held@ncrponline.org (301) 657-2652 ext. 20 or (cell) (b)(6)

From: John Boice (b)(6)
Sent: Tuesday, September 13, 2016 10:08 AM
To: Brock, Terry
Cc: Held, Kathryn D; Laura Atwell
Subject: Re: NCE for NRC-HQ-60-14-G-0011

Thanks Terry, I'll ask Kathy to put this together,
John

On Tue, Sep 13, 2016 at 10:00 AM, Brock, Terry
<Terry.Brock@nrc.gov<mailto:Terry.Brock@nrc.gov>> wrote:
John,

To process the no cost extension I need a revised budget of the remaining funds over the extended time period—we need this soon to process before the end of the month.

Thanks,
Terry

Terry Brock, Ph.D.
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington D.C. 20555
Mail Stop TWFN-10
phone: 301-415-1793<tel:301-415-1793>

From: John Boice [mailto:(b)(6) <mailto(b)(6)]
Sent: Saturday, September 10, 2016 12:56 PM

To: Brock, Terry <Terry.Brock@nrc.gov<mailto:Terry.Brock@nrc.gov>>
Cc: Held, Kathryn D
<kathy.held@ncrponline.org<mailto:kathy.held@ncrponline.org>>; Laura Atwell
<Laura.Atwell@ncrponline.org<mailto:Laura.Atwell@ncrponline.org>>
Subject: [External_Sender] NCE for NRC-HQ-60-14-G-0011

Hi Terry
Hope you enjoyed beautiful downtown Oak Ridge last week. I'll be there on Monday. The cataract Workshop at memorial was very successful (in my view) and it was great you were able to attend. Hopefully the Commentary will be valuable for the NRC, the nation (and perhaps the world).
The Commentary is going to Cindy for publication processing next week and is our highest priority.
We'd like to request a NCE for 3 months (attached) to cover the publication processing costs. There are more than adequate funds remaining in the Grant. The Commentary will be complete but the hard copy publication and electronic version takes some time (and effort) to finalize. We can probably complete in October but are requesting through December to cover any glitches (unexpected at this stage).
Best wishes
John
PS: Though you and family might be interested in a recent photo of Jennifer and Helen Maroulis (the USA first female gold medal winner in wrestling). Helen is local and went to Cashell. She came back to her elementary school a week ago to speak with the kids and mesmerized them for 2 hours, and then gave them her medal to pass from one to another. Jennifer was her elementary school music teacher.

--
John D. Boice, Jr., Sc.D.
President, National Council on Radiation Protection and Measurements
boice@ncrponline.org <mailto:john.boice@ncrponline.org> 301.657.2652 ext 19<tel:301.657.2652%20ext%2019>
Professor of Medicine, Vanderbilt University School of Medicine
john.boice@vanderbilt.edu<mailto (b)(6) Also:
(b)(6) <mailto (b)(6)
[Image removed by sender. https://twitter.com/NCRP_Bethesda]
@NCRP_ORG<https://twitter.com/NCRP_Bethesda>

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John D. Boice, Jr., Sc.D.
President, National Council on Radiation Protection and Measurements
boice@ncrponline.org <mailto:john.boice@ncrponline.org> 301.657.2652 ext 19
Professor of Medicine, Vanderbilt University School of Medicine
john.boice@vanderbilt.edu<mailto: (b)(6) Also:
(b)(6)

[Image removed by sender. https://twitter.com/NCRP_Bethesda]
@NCRP_ORG<https://twitter.com/NCRP_Bethesda>

--
John D. Boice, Jr., Sc.D.
President, National Council on Radiation Protection and Measurements
boice@ncrponline.org 301.657.2652 ext 19
Professor of Medicine, Vanderbilt University School of Medicine
john.boice@vanderbilt.edu Also: (b)(6)
@NCRP_ORG

From: Brock, Terry
Sent: 13 Nov 2015 13:19:37 +0000
To: Case, Michael
Cc: Tadesse, Rebecca;Coffin, Stephanie
Subject: FW: RE: Follow-up on million worker study call

Mike,
From Todd Anderson below . . It doesnâ€™t look like DOE Office of Science has any issue with us working with DOE-NE on the million worker study, nor do they want a phone call between Office Directors.
Terry

From: Anderson, Todd [mailto:Todd.Anderson@science.doe.gov]
Sent: Thursday, November 12, 2015 3:14 PM
To: Brock, Terry
Subject: [External_Sender] RE: Follow-up on million worker study call

Hi Terry,
Schedules are pretty complicated around here over the next couple of weeks. Is a call needed? Is there a particular concern from the NRCâ€™s point of view?
Nobody here is particularly concerned or has an issue about the proposed path forward we talked about last Friday.
Best,
Todd

From: Brock, Terry [mailto:Terry.Brock@nrc.gov]
Sent: Tuesday, November 10, 2015 10:06 AM
To: Anderson, Todd
Subject: Follow-up on million worker study call

Hi Todd,
It was good to talk with you last Friday. I was wondering if we could set-up a call between our respective office directors say next week Wednesday or Thursday?
Thanks,
Terry

Terry Brock, Ph.D.
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington D.C. 20555
Mail Stop TWFN-10
phone: 301-415-1793

From: Brock, Terry
Sent: 20 Sep 2016 14:22:14 +0000
To: Mikula, Olivia
Subject: FW: RESPONSE - Quick Turnaround - FW: LRM [EHF-114-323] ENERGY Oversight Testimony on DOE's Decision to end its Low Dose Radiation Research Program #1140231926#
Attachments: million man worker study.docx

It looks like a couple folks are working on this issue. We did provide funding. DOE's original estimate was $25M over 5 years to complete the study. So far, DOE contributed $1M in fiscal year (FY) 2012 to this study; no further monies were provided. The NRC contributed $1.5M in FY12, $517K in FY14 and $100K in FY16. NASA has contributed nearly $1M to date, while EPA's contribution was smaller, on the order of $200K.

Attached is a one-pager

Terry Brock, Ph.D.
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington D.C. 20555
Mail Stop TWFN-10
phone: 301-415-1793

From: Tadesse, Rebecca
Sent: Tuesday, September 20, 2016 10:18 AM
To: Weber, Michael <Michael.Weber@nrc.gov>; Albert, Michelle <Michelle.Albert@nrc.gov>
Cc: Clark, Lisa <Lisa.Clark@nrc.gov>; Case, Michael <Michael.Case@nrc.gov>; Webber, Kimberly <Kimberly.Webber@nrc.gov>; Hackett, Edwin <Edwin.Hackett@nrc.gov>; Gartman, Michael <Michael.Gartman@nrc.gov>; Sampson, Michele <Michele.Sampson@nrc.gov>; Brock, Terry <Terry.Brock@nrc.gov>
Subject: RE: RESPONSE - Quick Turnaround - FW: LRM [EHF-114-323] ENERGY Oversight Testimony on DOE's Decision to end its Low Dose Radiation Research Program #1140231926#

Hi Michelle,

Attached is a background information on the Million Worker Study.

Thanks
Rebecca Tadesse, Chief
Radiation Protection Branch
Division of Systems Analysis
Office of Nuclear Regulatory Research
301-415-1824

From: Weber, Michael
Sent: Tuesday, September 20, 2016 9:25 AM
To: Albert, Michelle <Michelle.Albert@nrc.gov>
Cc: Clark, Lisa <Lisa.Clark@nrc.gov>; Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>; Case, Michael <Michael.Case@nrc.gov>; Webber, Kimberly <Kimberly.Webber@nrc.gov>; Hackett, Edwin <Edwin.Hackett@nrc.gov>; Gartman, Michael <Michael.Gartman@nrc.gov>; Sampson, Michele

<Michele.Sampson@nrc.gov>
Subject: RESPONSE - Quick Turnaround - FW: LRM [EHF-114-323] ENERGY Oversight Testimony on DOE's Decision to end its Low Dose Radiation Research Program #1140231926#

Good morning, Michelle. As promised, please find attached a few comments on the draft testimony. Our biggest concern is the premature and disruptive termination of the Million Worker Study. Although the testimony indicates the merits of the study, it does not specifically state why the study is being terminated or point out the loss of this research to the Federal government and Nation. We can provide you with more background from NRC's perspective on the Million Worker Study as you deem necessary.

In addition, although DOE is testifying why it is bringing the low dose radiation research program to a close, it does not clearly indicate that DOE (and the AEC before) has shouldered the primary obligation for conducting the radiation effects research for the US Government back to the 1940s. Termination of this program eliminates this support for the Federal government. Because fundamental issues remain (as alluded to in the draft testimony), re-establishment of this program in one or more agencies would require additional resources and a substantial investment of intellectual and human resources and may not be as effective or efficient if it is distributed across multiple agencies. By terminating the program without previously coordinating and establishing a successor program, DOE is putting this body of knowledge and the country at risk.

From: Albert, Michelle
Sent: Tuesday, September 20, 2016 8:23 AM
To: EDO_ACS Distribution <EDO_ACSDistribution@nrc.gov>; EDO_ETAs <EDO_ETAs@nrc.gov>; Spencer, Mary <Mary.Spencer@nrc.gov>; Campbell, Tison <Tison.Campbell@nrc.gov>; RidsNmssOd Resource <RidsNmssOd.Resource@nrc.gov>; Roman-Cuevas, Cinthya <Cinthya.Roman@nrc.gov>; Weber, Michael <Michael.Weber@nrc.gov>; Hackett, Edwin <Edwin.Hackett@nrc.gov>; Wylie, Maureen <Maureen.Wylie@nrc.gov>; Muessle, Mary <Mary.Muessle@nrc.gov>; Rossi, Anthony <Anthony.Rossi@nrc.gov>; Colgary, James <James.Colgary@nrc.gov>
Cc: RidsOgcMailCenter Resource <RidsOgcMailCenter.Resource@nrc.gov>; RidsEdoMailCenter Resource <RidsEdoMailCenter.Resource@nrc.gov>; Ammon, Bernice <Bernice.Ammon@nrc.gov>; Clark, Michael <Michael.Clark@nrc.gov>; Clark, Lisa <Lisa.Clark@nrc.gov>
Subject: Quick Turnaround - FW: LRM [EHF-114-323] ENERGY Oversight Testimony on DOE's Decision to end its Low Dose Radiation Research Program #1140231926#
Importance: High

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Please provide any comments on the attached to me and Lisa Clark by **11:30 a.m. today** (Tuesday, September 20, 2016).

(b)(5)

Thank you,

Michelle D. Albert
Senior Attorney | Office of the General Counsel
Legal Counsel, Legislation, and Special Projects Division
U.S. Nuclear Regulatory Commission
(301) 287-9259 | Michelle.Albert@nrc.gov

*** OFFICIAL USE ONLY -- ATTORNEY-CLIENT PRIVILEGED INFORMATION, ATTORNEY WORK PRODUCT, AND/OR PREDECISIONAL INFORMATION ***

From: LLO Resource
Sent: Monday, September 19, 2016 5:49 PM
To: Ammon, Bernice <Bernice.Ammon@nrc.gov>; Clark, Michael <Michael.Clark@nrc.gov>; Albert, Michelle <Michelle.Albert@nrc.gov>; Clark, Lisa <Lisa.Clark@nrc.gov>; Michel, Eric <Eric.MichelOGC@nrc.gov>
Subject: FW: LRM [EHF-114-323] ENERGY Oversight Testimony on DOE's Decision to end its Low Dose Radiation Research Program #1140231926#

From: Fitter, E. Holly H. EOP/OMB
Sent: Monday, September 19, 2016 5:48:40 PM (UTC-05:00) Eastern Time (US & Canada)
To: DL-CEQ-LRM; 'EPA'; 'HHS'; 'JUSTICE'; 'NASA'; DL-OSTP-LRM; LLO Resource
Cc: Zaidi, Ali A. EOP/OMB; DL-WHO-WHGC-LRM; Pasquantino, John C. EOP/OMB; McDonald, Christine A. EOP/OMB; Bar-Shalom, Tali EOP/OMB; Robinson, Donovan O. EOP/OMB; Arnett, Benton T. EOP/OMB; Laity, Jim A. EOP/OMB; Dorjets, Vlad EOP/OMB; Burnim, John D. EOP/OMB; Vaeth, Matt J. EOP/OMB; Fucile, Tamara L. EOP/OMB; Dee, Carolyn M. EOP/OMB; Menter, Jessica N. EOP/WHO; Bauserman, Trent D. EOP/WHO; Hickey, Mike J. EOP/OMB; Burgess, Scott H. EOP/OMB; Aguilar, Brenda L. EOP/OMB; DL-WHO-DPCEC-LRM; Fahiye (Fahiye.Yusuf@Hq.Doe.Gov) Yusuf (Fahiye.Yusuf@Hq.Doe.Gov); 'Owen, Lil'
Subject: [External_Sender] LRM [EHF-114-323] ENERGY Oversight Testimony on DOE's Decision to end its Low Dose Radiation Research Program #1140231926#

DEADLINE: 12:00 Noon Tuesday, September 20, 2016

Please review the attached DOE statement for a 9/21 House Science hearing on DOE's decision to end its Low Dose Radiation Research Program in FY 2016, and provide any comments by the deadline above. Thanks.

LRM ID: EHF-114-323
EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET

LEGISLATIVE REFERRAL MEMORANDUM
Monday, September 19, 2016

(b)(5)

(b)(5)

Thank you.

From: Metting, Noelle
Sent: 1 Dec 2011 10:16:11 -0500
To: Brock, Terry
Subject: FW: reviewer form and conflict of interest
Attachments: Boice renewal.pdf

FYI

NF Metting, Sc.D.
Voice: 301-903-8309
Fax: 301-903-0567
noelle.metting@science.doe.gov

From: Corcoran, Joanne
Sent: Wednesday, November 30, 2011 4:42 PM
To: Metting, Noelle
Subject: reviewer form and conflict of interest

Proposal #
0000200031

U.S. Department of Energy
Office of Science

GrantsGov #
GRANT10992744

APPLICATION/PROPOSAL COVER SHEET

THE ATTACHED APPLICATION/PROPOSAL IS FOR YOUR REVIEW & APPROPRIATE ACTION

INSTITUTION: International Epidemiology Institute, Rockville, Maryland

TYPE OF REQUEST: Renewal

P.I.: Boice, John

DATE RECEIVED: 10/27/2011 10:23:05 AM

AWARD NO: DE-SC0004307

SOLICITATION NO: DE-FOA-0000600

TITLE: Epidemiologic study of one million U.S. radiation workers and veterans

TOTAL NUMBER OF PAGES SUBMITTED: 303

ERROR LIST:
No Errors

Table Of Contents

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE

State Application Identifier

1. * TYPE OF SUBMISSION

☐ Pre-application ☒ Application ☐ Changed/Corrected Application

4. a. Federal Identifier DOE

b. Agency Routing Identifier

2. DATE SUBMITTED

Applicant Identifier

5. APPLICANT INFORMATION

*** Organizational DUNS:** 937418432

* Legal Name: International Epidemiology Institute

Department:

Division:

* Street1: 1455 Research Boulevard, Suite 550

Street2:

* City: Rockville

County / Parish:

* State: MD: Maryland

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code: 20850-3194

Person to be contacted on matters involving this application

Prefix: Ms.

* First Name: Maida

Middle Name:

* Last Name: Montes

Suffix:

* Phone Number: 301-279-4263

Fax Number:

Email: maida@iei.us

6. * EMPLOYER IDENTIFICATION *(EIN) or (TIN):* 52 1882011

7. * TYPE OF APPLICANT: R: Small Business

Other (Specify):

Small Business Organization Type ☐ Women Owned ☐ Socially and Economically Disadvantaged

8. * TYPE OF APPLICATION:

☐ New ☐ Resubmission

☒ Renewal ☐ Continuation ☐ Revision

If Revision, mark appropriate box(es).

☐ A. Increase Award ☐ B. Decrease Award ☐ C. Increase Duration ☐ D. Decrease Duration

☐ E. Other (specify):

* Is this application being submitted to other agencies? Yes ☐ No ☒ What other Agencies?

9. * NAME OF FEDERAL AGENCY: Office of Science

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: 81.049

TITLE: Office of Science Financial Assistance Program

11. * DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

Epidemiologic study of one million U.S. radiation workers and veterans

12. PROPOSED PROJECT:

* Start Date 01/16/2012

* Ending Date 01/15/2017

*** 13. CONGRESSIONAL DISTRICT OF APPLICANT**

MD 006

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: Dr.

* First Name: John

Middle Name: D.

* Last Name: Boice

Suffix: Jr.

Position/Title: Scientific Director

* Organization Name: International Epidemiology Institute

Department:

Division:

* Street1: 1455 Research Boulevard, Suite 550

Street2:

* City: Rockville

County / Parish:

* State: MD: Maryland

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code: 20850-3194

* Phone Number: 301-279-4271

Fax Number:

* Email: boice@iei.us

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE **Page 2**

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested	21,840,906.00
b. Total Non-Federal Funds	0.00
c. Total Federal & Non-Federal Funds	21,840,906.00
d. Estimated Program Income	0.00

16. * IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES ☐ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

b. NO ☒ PROGRAM IS NOT COVERED BY E.O. 12372; OR

☐ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalities. (U.S. Code, Title 18, Section 1001)

☒ * I agree

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL or other Explanatory Documentation

Add Attachment

19. Authorized Representative

Prefix: Dr. * First Name: William Middle Name: J.

* Last Name: Blot Suffix:

* Position/Title: Chief Executive Officer

* Organization: International Epidemiology Institute

Department: Division:

* Street1: 1455 Research Boulevard, Suite 550

Street2:

* City: Rockville County / Parish:

* State: MD: Maryland Province:

* Country: USA: UNITED STATES * ZIP / Postal Code: 20850-3194

* Phone Number: 301-279-4262 Fax Number:

* Email: blotw@iei.us

*** Signature of Authorized Representative:** William Blot

*** Date Signed:** 10/27/2011

20. Pre-application Add Attachment

RESEARCH & RELATED Other Project Information

1. * Are Human Subjects Involved? [X] Yes [ ] No
   1.a If YES to Human Subjects
   Is the Project Exempt from Federal regulations? [ ] Yes [X] No
   If yes, check appropriate exemption number. [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ] 6
   If no, is the IRB review Pending? [ ] Yes [X] No
   IRB Approval Date: 01/20/2011
   Human Subject Assurance Number: FWA0000754
2. * Are Vertebrate Animals Used? [ ] Yes [X] No
   2.a. If YES to Vertebrate Animals
   Is the IACUC review Pending? [ ] Yes [ ] No
   IACUC Approval Date:
   Animal Welfare Assurance Number
3. * Is proprietary/privileged information included in the application? [ ] Yes [X] No

4.a. * Does this project have an actual or potential impact on the environment? [ ] Yes [X] No

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? [ ] Yes [ ] No

4.d. If yes, please explain:

5. * Is the research performance site designated, or eligible to be designated, as a historic place? [ ] Yes [X] No

5.a. If yes, please explain:

6. * Does this project involve activities outside of the United States or partnerships with international collaborators? [ ] Yes [X] No

6.a. If yes, identify countries:

6.b. Optional Explanation:

7. * Project Summary/Abstract 1238-Project Summary.pdf | Delete Attachment | View Attachment

8. * Project Narrative 1239-NARRATIVE and PROGRESS REPORT.pd | Delete Attachment | View Attachment

9. Bibliography & References Cited 1240-Appendix 3 References.pdf | Delete Attachment | View Attachment

10. Facilities & Other Resources 1241-Appendices 4 & 5 Facilities and | Delete Attachment | View Attachment

11. Equipment | Add Attachment | View Attachment

12. Other Attachments Add Attachments | Delete Attachments | View Attachments [X]

OMB Number: 4040-0010
Expiration Date: 08/31/2011

Project/Performance Site Location(s)

Project/Performance Site Primary Location

☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: International Epidemiology Institute, Ltd.

DUNS Number: 9574184520000

* Street1: 1455 Research Boulevard, Suite 550

Street2:

* City: Rockville County:

* State: MD: Maryland

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code: 20850-3194 * Project/ Performance Site Congressional District: MD-006

Project/Performance Site Location 1

☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: International Epidemiology Institute, Ltd.

DUNS Number: 9574184520000

* Street1: 1455 Research Boulevard, Suite 550

Street2:

* City: Rockville County:

* State: MD: Maryland

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code: 20850-3194 * Project/ Performance Site Congressional District: MD-006

Project/Performance Site Location 2

☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: Oak Ridge Associated Universities

DUNS Number: 0411522240000

* Street1: 120 Badger Road

Street2:

* City: Oak Ridge County:

* State: TN: Tennessee

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code: 37830-9999 * Project/ Performance Site Congressional District: TN-004

Project/Performance Site Location(s)

Project/Performance Site Location 3 ☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: Oak Ridge National Laboratory

DUNS Number: 0991142870000

* Street1: P.O. Box 2008

Street2:

* City: Oak Ridge County:

* State: TN: Tennessee

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code: 37831-3480 * Project/ Performance Site Congressional District: TN-004

Project/Performance Site Location 4 ☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: University of Southern California

DUNS Number: 0729333930000

* Street1: 1540 Alcazar Street, CHP-220

Street2:

* City: Los Angeles County:

* State: CA: California

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code: 90033-9011 * Project/ Performance Site Congressional District: CA-032

Project/Performance Site Location 5 ☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: Vanderbilt University Medical Center

DUNS Number: 0044134560000

* Street1: 3319 West End Avenue

Street2:

* City: Nashville County:

* State: TN: Tennessee

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code: 37203-1059 * Project/ Performance Site Congressional District: TN-005

Project/Performance Site Location(s)

Project/Performance Site Location 6

☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	Risk Assessment Corporation
DUNS Number:	1771157970000
* Street1:	417 Till Road
Street2:	
* City:	Neeses
County:	
* State:	SC: South Carolina
Province:	
* Country:	USA: UNITED STATES
* ZIP / Postal Code:	29107-9545
* Project/ Performance Site Congressional District:	SC-002

Project/Performance Site Location 7

☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	Los Alamos National Laboratory
DUNS Number:	1752528940000
* Street1:	Occupational Medicine Division
Street2:	P.O. Box 1663, 0421
* City:	Los Alamos
County:	
* State:	NM: New Mexico
Province:	
* Country:	USA: UNITED STATES
* ZIP / Postal Code:	87544-0600
* Project/ Performance Site Congressional District:	NM-003

Budget Period: 1 Duration: 12 months	DOE Funded Person-mos. CAL	ACAD	SUMR	Funds Requested (Salary+Fringe)
A. Senior Personnel: PI/PD, Co-PI's, Faculty and Other Senior Associates			**Total Senior Personnel (1-8)**	$566,862.00
1. Boice, John	6	0	0	$187,030.00
2. Blot, William	1	0	0	$31,170.00
3. Tarone, Robert	1	0	0	$19,186.00
4. Mumma, Michael	3	0	0	$53,863.00
5. McLaughlin, Joseph	0	0	0	$7,765.00
6. Cohen, Sarah	3	0	0	$48,171.00
7. TBN, TBN	12	0	0	$100,996.00
8. TBN, TBN	12	0	0	$215,850.00
B. Other Personnel			**Total Other Personnel**	$141,056.00
(1) Secretarial - Clerical	4			$26,936.00
(2) Data support/abstractors	24			$115,120.00
Total Personnel Costs			**Total Salaries and Wages (A+B)**	$945,523.00
C. Permanent Equipment			**Total Permanent Equipment**	$14,500.00
3 personal computers and related software ($14,500.00)				
D. Travel			**Total Travel**	$40,000.00
1. Domestic (including Canada, Mexico and U.S. possessions)				$40,000.00
2. Foreign				$0.00
E. Trainee/Participant Costs (Total Participants: 0)			**Total Cost**	$0.00
1. Tuition Fees Health Insurance				$0.00
2. Stipends				$0.00
3. Trainee Travel				$0.00
4. Subsistence				$0.00
5. Other				$0.00
F. Other Direct Costs			**Total Other Direct Costs**	$3,097,573.00
1. Materials and Supplies				$4,000.00
2. Publication Costs/Documentation/Dissemination				$0.00
3. Consultant Services				$61,750.00
4. Computer (ADP) Services				$6,000.00
5. SubAwards/Consortium/Contractual Costs				$1,264,523.00
6. Equipment or Facility Rental/User Fees				$0.00
7. Alterations and Renovations				$0.00
8. Cohort Follow Up				$1,010,000.00
9. Dosimetry records				$625,000.00
10. ORNL and LANL				$466,100.00
G. Direct Costs			**Total Direct Costs (A through F)**	$4,097,546.00
H. Indirect Costs			**Total Indirect Costs**	$548,403.00
		Indirect Cost Rate	**Indirect Cost Base**	
Labor		58.00%	$945,523.00	$548,403.00
I. Direct and Indirect Costs			**Total Direct and Indirect Costs (G+H)**	$4,645,949.00
J. Fee			**Total Fee**	$0.00
K. Cost of Project			**Total Cost of Project (I+J)**	$4,645,949.00

Budget Period: 2 Duration: 12 months	DOE Funded Person-mos. CAL	ACAD	SUMR	Funds Requested (Salary+Fringe)
A. Senior Personnel: PI/PD, Co-PI's, Faculty and Other Senior Associates	**Total Senior Personnel (1-8)**			[illegible]
1. Boice, John	8	0	0	$258,909.00
2. Blot, William	1	0	0	$32,114.00
3. Tarone, Robert	1	0	0	$19,762.00
4. Mumma, Michael	3	0	0	$56,581.00
5. McLaughlin, Joseph	0	0	0	$8,026.00
6. Cohen, Sarah	3	0	0	$49,815.00
7. TBN, TBN	12	0	0	$106,716.00
8. TBN, TBN	12	0	0	$222,306.00
B. Other Personnel	**Total Other Personnel**			$146,256.00
(1) Secretarial - Clerical	4			$27,882.00
(5) Data collectors abstractors	24			$118,574.00
Total Personnel Costs	**Total Salaries and Wages (A+B)**			$1,028,113.00
C. Permanent Equipment	**Total Permanent Equipment**			$2,987.00
1 personal computer and related software $2,987.00				
D. Travel	**Total Travel**			$41,260.00
1. Domestic (including Canada, Mexico and U.S. possessions)				$41,260.00
2. Foreign				$0.00
E. Trainee/Participant Costs (Total Participants: 0)	**Total Cost**			$0.00
1. Tuition/Fees/Health Insurance				$0.00
2. Stipends				$0.00
3. Trainee Travel				$0.00
4. Subsistence				$0.00
5. Other				$0.00
F. Other Direct Costs	**Total Other Direct Costs**			$2,809,309.00
1. Materials and Supplies				$5,157.00
2. Publication Costs/Documentation/Dissemination				$0.00
3. Consultant Services				$64,203.00
4. Computer (ADP) Services				$6,180.00
5. SubAwards/Consortium/Contractual Costs				$1,099,276.00
6. Equipment or Facility Rental/User Fees				$0.00
7. Alterations and Renovations				$0.00
8. Follow up of the cohort				$660,000.00
9. Dosimetry records				$625,000.00
10. ORNL and LANL				$420,000.00
G. Direct Costs	**Total Direct Costs (A through F)**			$3,892,209.00
H. Indirect Costs	**Total Indirect Costs**			$602,106.00
	Indirect Cost Rate	**Indirect Cost Base**		
Labor	58.00%	$1,028,113.00		$602,106.00
I. Direct and Indirect Costs	**Total Direct and Indirect Costs (G+H)**			$4,494,315.00
J. Fee	**Total Fee**			$0.00
K. Cost of Project	**Total Cost of Project (I+J)**			$4,494,315.00

Budget Period: 3 Duration: 12 months	DOE Funded Person-mos.			Funds Requested
	CAL	ACAD	SUMR	(Salary+Fringe)
A. Senior Personnel: PI/PO, Co-PI's, Faculty and Other Senior Associates	**Total Senior Personnel (1-8)**			$773,554.00
1. Boice, John	8	0	0	$264,516.00
2. Blot, William	1	0	0	$33,077.00
3. Tarone, Robert	1	0	0	$20,356.00
4. Mumma, Michael	3	0	0	$57,749.00
5. McLaughlin, Joseph	0	0	0	$8,270.00
6. Cohen, Sarah	3	0	0	$51,154.00
7. TBN, TBN	12	0	0	$109,516.00
8. TBN, TBN	12	0	0	$226,355.00
B. Other Personnel	**Total Other Personnel**			$150,644.00
(1) Secretarial - Clerical	4			$28,513.00
(3) Data collectors abstractors	24			$122,131.00
Total Personnel Costs	**Total Salaries and Wages (A+B)**			$1,069,258.00
C. Permanent Equipment	**Total Permanent Equipment**			$2,987.00
1 personal computer and related software: $2,987.00				
D. Travel	**Total Travel**			$42,436.00
1. Domestic (including Canada, Mexico, and U.S. possessions)				$42,436.00
2. Foreign				$0.00
E. Trainee/Participant Costs (Total Participants: 0)	**Total Cost**			$0.00
1. Tuition Fees Health Insurance				$0.00
2. Stipends				$0.00
3. Trainee Travel				$0.00
4. Subsistence				$0.00
5. Other				$0.00
F. Other Direct Costs	**Total Other Direct Costs**			$2,634,668.00
1. Materials and Supplies				$5,305.00
2. Publication Costs Documentation Dissemination				$0.00
3. Consultant Services				$66,729.00
4. Computer (ADP) Services				$6,025.00
5. SubAwards Consortium Contractual Costs				$1,516,209.00
6. Equipment or Facility Rental User Fees				$0.00
7. Alterations and Renovations				$0.00
8. Follow up of the cohort				$460,000.00
9. Dosimetry records				$125,000.00
10. ORNL and LANL				$455,400.00
G. Direct Costs	**Total Direct Costs (A through F)**			$3,749,349.00
H. Indirect Costs	**Total Indirect Costs**			$620,170.00
	Indirect Cost Rate	**Indirect Cost Base**		
Labor	58.00%	$1,069,258.00		$620,170.00
I. Direct and Indirect Costs	**Total Direct and Indirect Costs (G+H)**			$4,369,519.00
J. Fee	**Total Fee**			$0.00
K. Cost of Project	**Total Cost of Project (I+J)**			$4,369,519.00

Budget Period: 4 Duration: 12 months	DOE Funded Person-mos.			Funds Requested
	CAL	ACAD	SUMR	(Salary+Fringe)
A. Senior Personnel: PI/PO, Co-PI's, Faculty and Other Senior Associates	**Total Senior Personnel (1-8)**			[illegible]
1. Boice, John	8	0	0	$272,556.00
2. Blot, William	1	0	0	$34,070.00
3. Tarone, Robert	1	0	0	$20,866.00
4. Mumma, Michael	3	0	0	$58,866.00
5. McLaughlin, Joseph	0	0	0	$8,517.00
6. Cohen, Sarah	3	0	0	$52,857.00
7. TBN, TBN	12	0	0	$113,215.00
8. TBN, TBN	12	0	0	[illegible]
B. Other Personnel	**Total Other Personnel**			[illegible]
(1) Secretarial - Clerical	4			$29,368.00
(2) Tracers coders abstractors	24			$125,795.00
Total Personnel Costs	**Total Salaries and Wages (A+B)**			$1,101,325.00
C. Permanent Equipment	**Total Permanent Equipment**			$2,987.00
1 personal computer and related software $2,987.00				
D. Travel	**Total Travel**			$45,020.00
1. Domestic (including Canada, Mexico and U.S. possessions)				$45,020.00
2. Foreign				$0.00
E. Trainee/Participant Costs (Total Participants: 0)	**Total Cost**			$0.00
1. Tuition Fees Health Insurance				$0.00
2. Stipends				$0.00
3. Trainee Travel				$0.00
4. Subsistence				$0.00
5. Other				$0.00
F. Other Direct Costs	**Total Other Direct Costs**			$2,488,541.00
1. Materials and Supplies				$5,454.00
2. Publication Costs Documentation Dissemination				$0.00
3. Consultant Services				$99,711.00
4. Computer (ADP) Services				$6,556.00
5. SubAwards Consortium Contractual Costs				$1,525,210.00
6. Equipment or Facility Rental User Fees				$0.00
7. Alterations and Renovations				$0.00
8. Follow up of the cohort				$360,000.00
9. Dosimetry records				$50,000.00
10. ORNL and LANL				$443,[illegible]
G. Direct Costs	**Total Direct Costs (A through F)**			$3,637,883.00
H. Indirect Costs	**Total Indirect Costs**			$638,774.00
	Indirect Cost Rate	**Indirect Cost Base**		
Labor	58.00%	$1,101,325.00		$638,774.00
I. Direct and Indirect Costs	**Total Direct and Indirect Costs (G+H)**			$4,276,657.00
J. Fee	**Total Fee**			$0.00
K. Cost of Project	**Total Cost of Project (I+J)**			$4,276,657.00

Budget Period: 5 Duration: 12 months	DOE Funded Person-mos.			Funds Requested
	CAL	ACAD	SUMR	(Salary+Fringe)
A. Senior Personnel: PI/PO, Co-PI's, Faculty and Other Senior Associates	**Total Senior Personnel (1-8)**			$820,956.00
1. Boice, John	8	0	0	$280,722.00
2. Blot, William	1	0	0	$35,031.00
3. Tarone, Robert	1	0	0	$21,555.00
4. Mumma, Michael	3	0	0	$60,736.00
5. McLaughlin, Joseph	0	0	0	$8,773.00
6. Cohen, Sarah	3	0	0	$54,216.00
7. TBN, TBN	12	0	0	$116,812.00
8. TBN, TBN	12	0	0	$212,841.00
B. Other Personnel	**Total Other Personnel**			$170,818.00
(1) Secretarial - Clerical	4			$30,249.00
(3) Tracers coders abstractors	24			$129,569.00
Total Personnel Costs	**Total Salaries and Wages (A+B)**			$1,124,377.00
C. Permanent Equipment	**Total Permanent Equipment**			$2,987.00
1 personal computer and related software $2,987.00				
D. Travel	**Total Travel**			$45,020.00
1. Domestic (including Canada, Mexico, and U.S. possessions)				$45,020.00
2. Foreign				$0.00
E. Trainee/Participant Costs (Total Participants: 0)	**Total Cost**			$0.00
1. Tuition/Fees/Health Insurance				$0.00
2. Stipends				$0.00
3. Trainee Travel				$0.00
4. Subsistence				$0.00
5. Other				$0.00
F. Other Direct Costs	**Total Other Direct Costs**			$2,214,143.00
1. Materials and Supplies				$5,927.00
2. Publication Costs/Documentation/Dissemination				$0.00
3. Consultant Services				$102,765.00
4. Computer (ADP) Services				$6,752.00
5. Subawards/Consortium/Contractual Costs				$1,389,500.00
6. Equipment or Facility Rental/User Fees				$0.00
7. Alterations and Renovations				$0.00
8. Follow up of the cohort				$210,000.00
9. Dosimetry records				$50,000.00
10. ORNL and LANL				$449,500.00
G. Direct Costs	**Total Direct Costs (A through F)**			$3,396,527.00
H. Indirect Costs	**Total Indirect Costs**			$657,959.00
	Indirect Cost Rate	**Indirect Cost Base**		
Labor	58.50%	$1,124,377.00		$657,959.00
I. Direct and Indirect Costs	**Total Direct and Indirect Costs (G+H)**			$4,054,486.00
J. Fee	**Total Fee**			$0.00
K. Cost of Project	**Total Cost of Project (I+J)**			$4,054,486.00

Cumulative Total	Subtotal ($)	Totals ($)
Section A, Senior/Key Person		[illegible]
Section B, Other Personnel		$753,877.00
Total Number Other Personnel	35	
Total Salary, Wages and Fringe Benefits (A+B)		$5,280,806.00
Section C, Equipment		$26,448.00
Section D, Travel		$213,676.00
1. Domestic	$213,676.00	
2. Foreign	$0.00	
Section E, Participant/Trainee Support Costs		$0.00
1. Tuition/Fees/Health Insurance	$0.00	
2. Stipends	$0.00	
3. Travel	$0.00	
4. Subsistence	$0.00	
5. Other	$0.00	
Number of Participants/Trainees	3	
Section F, Other Direct Costs		$13,244,764.00
1. Materials and Supplies	$25,548.00	
2. Publication Costs	$0.00	
3. Consultant Services	[illegible]	
4. ADP/Computer Services	$91,854.00	
5. Subawards/Consortium/Contractual Costs	$6,844,393.00	
6. Equipment or Facility Rental/User Fees	$0.00	
7. Alterations and Renovations	$0.00	
8. Other 1	$2,700,300.00	
9. Other 2	$875,000.00	
10. Other 3	$2,212,300.00	
Section G, Direct Costs (A thru F)		[illegible]
Section H, Indirect Costs		[illegible]
Section I, Total Direct and Indirect Costs (G+H)		[illegible]
Section J, Fee		$0.00
Section K, Total Cost of Project (I+J)		$21,840,906.00

Budget Justification (International Epidemiology Institute (IEI))

The proposed study involves the ascertainment, from multiple sources, of information identifying previously studied cohorts of radiation workers, determining the timing and doses of exposure to ionizing radiation, following the cohorts to ascertain vital status through December 31, 2012 of the workers and cause of death of those who died, and computing rates of mortality from cancer and other diseases according to exposure level. The prime grantee will be the International Epidemiology Institute (IEI), with consortium partners of the Oak Ridge Associated Universities (ORAU), Risk Assessment Corporation (RAC), Vanderbilt University (VU) and the University of Southern California (USC). In addition, arrangements will be made for specialized support from Oak Ridge National Laboratory (ORNL) and Los Alamos National Laboratory (LANL).

A summary listing of tasks to be performed by each institution for each of the 6 study Aims is provided in the table below. Detailed budget justifications for each institution follow thereafter.

Epidemiologic Study of One Million U.S. Workers and Military Veterans Exposed to Ionizing Radiation
Study Organization Plan

	Aim 1	Aim 2	Aim 3	Aim 4	Aim 5	Aim 6
Task	Uranium workers	Atomic veterans	Radiologists & other medical	Nuclear power plant workers	Plutonium workers	Combined cohorts
Cohort identification	ORAU, IEI	RAC, IEI	Landauer (IEI)	Landauer (IEI)	ORAU, LANL, IEI	IEI,ORAU
External dosimetry	ORAU	RAC, IEI	Landauer (IEI)	Landauer (IEI)	ORAU, LANL	ORAU
Internal dosimetry	ORAU,ORNL	RAC			ORNL, LANL	ORAU
Cohort follow up	IEI, ORAU	IEI	IEI	IEI	IEI, ORAU	IEI, ORAU
Statistical analysis	ORAU, IEI, VU, USC	IEI, VU, USC	IEI, VU, USC	IEI, VU, USC	ORAU, LANL, IEI, VU, USC	IEI, VU, USC, ORAU
Report writing	ORAU, IEI, ORNL	RAC, IEI	IEI	IEI	ORAU, LANL, IEI, ORNL	All

The proposed team from the International Epidemiology Institute (IEI) has extensive experience in occupational epidemiology research, having conducted numerous health studies of workers and other populations exposed to radiation for the past 30 years. The IEI and overall Principal Investigator, Dr. John Boice, developed and was the first Chief of the Radiation Epidemiology Branch at the National Cancer Institute and has over 400 publications related to epidemiologic research. He serves as a Commissioner on the International Commission of Radiological Protection (ICRP), a Distinguished member of the National Council on Radiological Protection and Measurements (NCRP), and on the Congressionally-mandated Veteran's Advisory Board for Dose Reconstruction (VBDR). He has represented the United States as a delegate since 1994 to the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). This proposed research is further strengthened by the collaboration of internationally known physicists and other scientists deeply experienced in the issues of external and internal dosimetry from ORAU, ORNL, LANL, RAC and VU and senior biostatistical personnel at VU and USC.

Funds for the International Epidemiology Institute are requested for the following:

Personnel

John D. Boice, Jr., Sc.D. (6 calendar months, Year 1; 8 calendar months, Years 2 -5), Scientific Director at IEI, will serve as ***Principal Investigator*** of this project and will be responsible for the overall conduct of the study. He will also serve as the project's senior epidemiologist involved with study design, study conduct, data analysis and manuscript preparation. He will assure coordination between the participating institutions.

William J. Blot, Ph.D. (1 calendar months, Years 1-5), will serve as Co-Investigator of this project and will share responsibility for the overall conduct of the study. He will also serve as a senior epidemiologist involved with study design, study conduct, data analysis and manuscript preparation.

Joseph K. McLaughlin, Ph.D. (0.25 calendar months, Years 1-5), Senior epidemiologist with extensive experience in occupational and other cohort studies will advise on issues of design, methods and interpretation of study findings.

Michael T. Mumma, M.S. (3 calendar months, Years 1-5), Systems Analyst, will serve as computer systems manager and will be responsible for overseeing the assembly and maintenance of the master cohort population files of the uranium workers, military veterans, radiologists and other medical professionals, nuclear power plant workers and plutonium workers, combining results from the various outcome and exposure registries (both vital status and dosimetry), coordinating the flow of data between study institutions/investigators, and preparing the final edited data files for analysis.

Robert E. Tarone, Ph.D. (1 calendar months, Years 1-5), Director of Biostatistics, will serve as statistician overseeing aspects of study design, data analyses, and interpretation of data. He will provide the biostatistical oversight needed for integrating the complex dosimetry systems with the cohort outcome analyses. He will assist with the analyses and manuscript preparation.

Sarah Cohen, Ph.D. (2 calendar months, Years 1-5), Statistician and epidemiologist, will assist in performing computer-related activities in support of the project, as well as preparing the edited datasets for statistical analyses. She will assist with the analyses and manuscript preparation.

Epidemiologist, Ph.D. (TBA) (12 calendar months, Years 1-5). The doctoral level person to be hired will assist in multiple activities, including assembly and review of the worker rosters and associated dose information and follow up for the various cohorts. He/she will assist Drs. Boice, Blot and Tarone in the overall conduct, design and coordination of the efforts. Several senior epidemiologists experienced in the conduct and analysis of populations exposed to ionizing radiation have expressed interested in joining IEI in the event that the submission is successful.

Field manager, M.S. (TBA) (12 calendar months, Years 1-5). The master level person to be hired will be responsible for preparing and assisting in the linkages of the various datasets required for the conduct of the study. This would involve formatting the rosters of cohort members for linkage with dosimetry data by the Department of Energy, military services, Landauer Inc, and Nuclear Regulatory Commission. Data files for vital status determination will be prepared for the National Death Index, PBI, Social Security Administration, the Centers for Medicare and Medicaid Services, various state death indexes and other sources. He/she would coordinate submissions to the Department of Veteran Affairs and collection of data from the Department of Energy, the Nuclear Regulatory Commission and the Department of Defense, and participate in analyses of the collected data.

Associate database manager (TBA) (12 calendar months, Years 1-5). This individual will assist Mr. Mumma in development and maintenance of the multiple complex databases. The new hire will have expertise in SQL relational database administration.

Tracing/abstracting/data reviewers (TBA) (24 calendar months, Years 1-5). These part-time individuals will assist in LexisNexis and other methods of tracing the cohorts to determine vital status, in review and processing of Landauer microfilm records, in review of returns from mortality and cancer incidence searches and perform other manual data processing activities in support of the study.

Consultants

The consultants will provide expert advice and collaboration with regard to specific areas covered by the project. Dr. Clark Heath, former vice president of the American Cancer Society and Director at the Radiation Effects Research Foundation (RERF) in Hiroshima, Japan, conducted the first study of atomic veterans in the United States in the 1970s that uncovered an excess of leukemia among Nevada Test Site participants. He

was a member of the National Academy of Sciences committee, "The Five Series Study" (and co-chaired the dosimetry working group). Dr. Heath will serve as Senior Epidemiologist on the project and will be involved in the study design, protocol development, interfacing with Department of Defense and Department of Veteran Affairs agencies, study conduct, interpretation of study results and manuscript development.

Howard Sesso, Sc.D., a cardiovascular disease epidemiologist at Brigham and Women's Hospital and Harvard Medical School, will provide necessary expertise in the evaluation of the possible association between radiation and the long-term risk of developing coronary heart disease among the radiation workers and atomic veterans, including the design of abstract forms to acquire coronary heart disease risk factor information within the medical records available through the VA system.

Dr. Kenneth Kopecky of the Fred Hutchinson Cancer Research Center will provide advice and assistance regarding dose reconstruction, the uncertainties of reconstructed dose estimates, and the accounting for uncertainties in the estimation of radiation effects; will assist with the planning and conduct of a workshop conference with outside experts to develop methodology to address the unique and challenging problems of dose reconstruction for the atomic veterans; and will assist with the analysis and reporting of results. In the first year of this project Dr. Kopecky will make two trips to the Washington DC area: one for overall project planning and startup and workshop planning, and the second for the workshop. Dr Kopecky has conducted many epidemiologic analyses of radiation-related diseases in which dose estimates were based on complex dosimetry systems. He works with the Radiation Effects Research Foundation (RERF) in Hiroshima to enhance the studies of Japanese atomic bomb survivors. Dr Kopecky will coordinate additional statistical support and guidance on uncertainty analyses with Duncan Thomas and Dan Stram at the University of Southern California, experts in statistical analyses of radiation data. Recent developments in statistical methodology will be adapted and extended to account for the unique uncertainties in the reconstructed radiation doses.

Consulting costs for Drs. Heath, Sesso and Kopecky are estimated to be approximately $36,750 per year for approximately 40 hours of participation for Dr. Heath, 25 hours for Dr. Sesso and 40 hours for Dr. Kopecky (each @ $350/hr).

Dr. Han Kang is Director, Environmental Epidemiology Service, Veterans Health Administration, Department of Veterans Affairs and will provide access to the HARDTACK 1 military cohort follow-up data, facilitate linkages of the Seven Series military cohorts with BIRLS (Beneficiary Identification Record Location Subsystem) for vital status determination and death certificate retrieval as necessary. Total consulting costs, including travel to the annual meeting and linkages with BIRLS data systems and medical records are $25,000 per year.

Advisors for the One Million worker study include Dr Richard Wakeford at Manchester University in the United Kingdom, Dr Roy Shore at the Radiation Effects Research Foundation in Hiroshima, Japan, and one other to be selected. They will provide overall advice throughout the study and will be relied upon to provide guidance during annual meetings as well as review prepared documents on study design, conduct and eventually publication. Total costs for advisors, including international travel to the annual meeting, are $20,000 per year.

The total for all consultants sums to $81,750 per year.

Supplies
Supplies pertaining to telephone, fax, and photocopying expenses as well as computer software, storage, printing, and imaging costs are requested for each year at $4,000 per year. In addition, $6,000 per year is requested for ADP and computer services.

Travel
Travel is requested for the PI and senior personnel to attend the annual Investigators Meeting at $900 per trip per person. Also, travel is requested for the PI and other personnel as needed to visit each of the collaborating institutes, as well as the Department of Defense and Department of Veterans Affairs facilities, to coordinate study data collection activities. Costs for these trips to Oak Ridge (ORAU, ORNL), Chicago (Landauer), Los Angeles (USC), Los Alamos (LANL), South Carolina (RAC), Virginia (DOD) and Washington D.C. (VA) are estimated to be $20,000 each year.

An annual meeting will be held each year lasting approximately two days. It is envisioned that three will be held at Oak Ridge given its central location to study participants, and two in Washington, D.C. given the proximity to DOE and DOD resources. The coordination costs include hotel reservations, audio-visuals, coffee breaks and luncheon, handout preparation, mailings, minutes, and travel coordination. It is envisioned that these annual meetings will cost approximately $20,000 per year.

The total for travel sums to $40,000 per year.

Equipment

5 computers and peripherals are requested in year 1 for the senior epidemiologist, field manager, associate database manager and for 2 tracers. Cost in Year 1 is $14,500. One replacement computer is requested per year thereafter.

Other Expenses

Follow up of the cohort: Cause of Death. Funds are needed for obtaining cause of death from the National Death Index and/or procuring death certificates. It is estimated that approximately 500,000 deaths will have occurred among the radiation workers and veterans, some of whom were exposed to radiation as early as the 1940s. Cause of death is currently known for approximately 125,000 deaths among the uranium and plutonium workers and atomic veterans from the earlier follow up of these cohorts, but complete ascertainment of deaths since the last follow up is needed for these groups as well as for the entire radiologist and nuclear power plant worker cohorts. For non-veterans, the unit costs are $5 per cause of death so that approximately $725,000 will be required in year one, $525,000 in year two, $325,000 in year three, $225,000 in year four, and $75,000 in year 5. Costs for deaths prior to 1979 when the National Death Index began will be higher per certificate because it will require acquisition from state vital statistics departments and nosologist coding (any nosology services will be provided by ORAU).

Follow up of the cohort: Vital Status. In addition to costs listed above for assessing causes of death among the deceased, confirmation of living status will be sought for the estimated 600,000 persons likely to be alive as of 2012. Several sources for ascertainment of vital status will be utilized, including SSA, credit bureau resources and in particular LexisNexis so as to reduce the number of persons "lost to follow-up" to a very low percentage. The VA BIRLS system will also be used for members of the cohorts who are known to be veterans. State mortality files will also be purchased to enhance the success of tracing through the use of probabilistic matching programs. These costs are estimated to average $50,000 per year.

Follow up of the cohort: Cancer Incidence. It will be possible to conduct focused cancer incidence studies for certain worker populations, exemplified by the Mound cohort in Ohio. Fees charged by registries are estimated to average $40,000 per year.

Follow up of the cohort: Other Diseases. Rosters will be linked with the US Renal Data System to identify serious nonmalignant kidney disease. Medical imaging examination such as CT scans and nuclear medicine procedures will be sought by requesting linkages with the Centers for Medicare and Medicaid Services (CMS) Medicare procedure records. Associated fees are estimated to average about $45,000 per year, with a Year 1 CMS additional charge of $150,000 to establish the linkage of the radiation workers' cohorts with CMS files.

The total for follow up sums to $1,010,000 in year 1, $660,000 in year 2, $460,000 in year 3, $360,000 in year 4, and $210,000 in year 5.

Ascertaining records for dosimetry determinations: Computerized linkages. Career occupational doses will be sought through linkages with REIRS, REMS, Landauer and military dosimetry data bases.

Ascertaining records for dosimetry determinations: Microfilm Scanning and Data Entry. Approximately 1 million persons have dosimetry records from 1958 through 1978 on microfilm at Landauer, Inc. These are on 3,000 microfilm reels with approximately 2,500 images per reel. These include the very early radiation workers in the

USA, with some "inception dates" as early as the 1940s and cumulative doses in excess of 100 rem (over 1,100 such workers have been identified to date based only on the later electronic file data). These microfilm records will be used to supplement workers identified in AIM 3 (Radiologists and radiotherapists and other medical) and in AIM 4 (Nuclear Power Plant workers). Agencies that specialized in converting microfilm images will be used to convert the microfilm to digital images. Preliminary scanning indicates the total scanning cost to be $75 per roll, with a total cost of $225,000. IEI and Landauer staff will develop protocols to facilitate targeted and efficient abstraction of dosimetry and personnel identifying information necessary for the epidemiologic study. Customized data abstraction software will be developed. It is envisioned that 2 years will be required to complete this task at a cost estimated to average $325,000 per year in years 1 and 2, $125,000 in year 3, and $50,000 in years 4 and 5.

Special arrangements with US national laboratories

Oak Ridge National Laboratory (ORNL) will provide dosimetric evaluations that address internal deposition of uranium and other radioactive elements via inhalation, ingestion, or contaminated wounds among DOE uranium and plutonium workers. The following ORNL personnel will take part in the research:

Keith Eckerman, Ph.D. (6 calendar months, Years 1-5), Dosimetry Research Team Leader, Environmental Science Division; and Chairman, ICRP Task Group on Dose Calculations. Dr. Eckerman will be responsible for applying the latest ICRP biokinetic and dosimetric models to estimate annual doses for workers for approximately 20 organs or tissues, taking into account the probable time and mode of exposure, form of internally deposited radionuclides, and patterns of excretion of activity. He will also serve as senior scientist on the study team involved in the design, conduct, data analysis, and manuscript preparation.

Richard Leggett, Ph.D. (6 calendar months, Years 1-5), Distinguished Scientist, Environmental Sciences Division; and member of ICRP Task Group on Internal Dosimetry (INDOS), will be responsible for overseeing with ORAU the creation of internal dosimetry necessary for the computation of doses to individual organs for DOE workers. He will oversee the processing and evaluation of the hundreds of thousands of individual bioassay measurements, recorded on a variety of bioassay forms, will require processing, deciding the appropriate screening levels for comprehensive organ dose determination, and preparing final dosimetry data files for analysis.

Health Physicist/s, M.S. (TBA) (18 calendar months, Years 1-5). To be hired Health Physicists will participate in the review of historical dosimetry records, linkage of data from various sources and development of data sets for use in constructing dose estimates for the DOE nuclear workers. This individual will interface with the ORAU team providing data collection and other dosimetry support for the overall project.

ORNL costs are budgeted at $400,000 per year.

Los Alamos National Laboratory (LANL). Dr. Laurie Wiggs at LANL will be responsible for providing advice and assistance regarding the study of plutonium workers at LANL and other DOE facilities. Dr. Wiggs is Team Leader and Epidemiologist in the Department of Occupational Medicine at LANL where she has been employed for nearly 30 years. She has been a lead epidemiologist on a number of studies, including Mound and several others included in our one million worker study. LANL will also provide records as necessary to validate the existing data files and to capture bioassay data necessary for the internal dosimetry evaluations. The cost to provide this support is $66,100 for the first year and $212,300 overall.

Funds requested in the personnel, supplies, travel, and computer software and support categories have been increased by 3% annually to account for rising costs.

R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

Instructions: On this form, you will attach the R&R Subaward Budget files for your grant application. Complete the subawardee budget(s) in accordance with the R&R budget instructions. Please remember that any files you attach must be a Pure Edge document.

Important: Please attach your subawardee budget file(s) with the file name of the subawardee organization. Each file name must be unique.

1) Please attach Attachment 1	ORAU subaward.pdf
2) Please attach Attachment 2	RAC subaward.pdf
3) Please attach Attachment 3	USC subaward.pdf
4) Please attach Attachment 4	VU subaward.pdf

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0411522240000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Oak Ridge Associated Universities

*** Start Date:** 01-16-2012 *** End Date:** 01-15-2013 **Budget Period:** 1

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	Elizabeth		Dupree-Ellis		PD/PI	125,757.00	3.60			32,249.00	15,963.00	48,212.00
2.	Mr.	Phillip		Wallace		Systems Analyst	126,776.00	3.00			27,092.00	13,411.00	40,503.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **88,715.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
1	Secretarial/Clerical	0.48			1,540.00	763.00	2,303.00
2	Senior Scientific Staff	1.80			21,548.00	10,666.00	32,214.00
4	Other Scientific Staff	12.60			75,948.00	37,594.00	113,542.00
3	Health Physicist/Industrial Hygienist	4.20			36,540.00	18,087.00	54,627.00
10	**Total Number Other Personnel**					**Total Other Personnel**	**202,686.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**291,401.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0411522240000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Oak Ridge Associated Universities

*** Start Date:** 01-16-2012 *** End Date:** 01-15-2013 **Budget Period: 1**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	31,636.00
2. Foreign Travel Costs	
Total Travel Cost	**31,636.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant/Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0411522240000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Oak Ridge Associated Universities

*** Start Date:** 01-16-2012 *** End Date:** 01-15-2013 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)
1. Materials and Supplies	4,500.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Death Certificates	4,500.00
9. Shipping	1,000.00
Total Other Direct Costs	**10,000.00**

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	**333,037.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1. G&A	6.25	521,191.74	32,574.48
2. Site Services	28.30	194,917.56	55,161.67
3. Overhead	11.50	194,917.56	22,415.50
4. Office and Operations		194,917.56	110,570.68
		Total Indirect Costs	**220,722.33**

Cognizant Federal Agency United States Department of Energy, Frederick G. Pieper, 865.241.4621

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	**553,759.33**

J. Fee	Funds Requested ($)
	14,791.44

K. * Budget Justification File Name: 1234-ORAU Budget Justification.pdf Mime Type: application/pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 0411522240000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Oak Ridge Associated Universities

*** Start Date:** 01-16-2013 *** End Date:** 01-15-2014 **Budget Period:** 2

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	Elizabeth		Dupree-Ellis		PD/PI	127,224.00	3.60			32,628.00	16,151.00	48,779.00
2.	Mr.	Phillip		Wallace		Systems Analyst	128,255.00	4.20			38,371.00	18,994.00	57,365.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **106,144.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
1	Secretarial/Clerical	0.48			1,558.00	771.00	2,329.00
2	Senior Scientific Staff	1.20			15,076.00	7,462.00	22,538.00
4	Other Scientific Staff	16.20			107,007.00	52,969.00	159,976.00
3	Health Physicist/Industrial Hygienist	4.80			41,883.00	20,732.00	62,615.00
10	**Total Number Other Personnel**					**Total Other Personnel**	**247,458.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**353,602.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 0411522240000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Oak Ridge Associated Universities

*** Start Date:** 01-16-2013 *** End Date:** 01-15-2014 **Budget Period:** 2

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	50,000.00
2. Foreign Travel Costs	
Total Travel Cost	**50,000.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant/Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 0411522240000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Oak Ridge Associated Universities

*** Start Date:** 01-16-2013 *** End Date:** 01-15-2014 **Budget Period:** 2

F. Other Direct Costs	**Funds Requested ($)**
1. Materials and Supplies	5,500.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Death Certificate	5,500.00
9. Shipping	1,500.00
Total Other Direct Costs	**12,500.00**

G. Direct Costs	**Funds Requested ($)**
Total Direct Costs (A thru F)	**416,102.00**

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	*** Funds Requested ($)**
1. G&A	6.25	645,925.28	40,370.33
2. Site Services	28.30	236,522.72	66,935.93
3. Overhead	11.50	236,522.72	27,200.12
4. Office and Operations		236,522.72	135,647.49
		Total Indirect Costs	**270,153.87**

Cognizant Federal Agency United States Department of Energy, Frederick G. Pieper, 865.241.4621

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)**
Total Direct and Indirect Institutional Costs (G + H)	**686,255.87**

J. Fee	**Funds Requested ($)**
	18,331.36

K. * Budget Justification File Name: 1234-ORAU Budget Justification.pdf Mime Type: application/pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 0411522240000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: Oak Ridge Associated Universities

*** Start Date:** 01-16-2014 *** End Date:** 01-15-2015 **Budget Period:** 3

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	Elizabeth		Dupree-Ellis		PD/PI	131,685.00	4.20			39,398.00	19,502.00	58,900.00
2.	Mr.	Phillip		Wallace		Systems Analyst	132,746.00	4.80			45,389.00	22,467.00	67,856.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **126,756.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
1	Secretarial/Clerical	0.48			1,613.00	798.00	2,411.00
2	Senior Scientific Staff	1.80			22,563.00	11,169.00	33,732.00
4	Other Scientific Staff	16.20			125,609.00	62,177.00	187,786.00
3	Health Physicist/Industrial Hygienist	9.00			81,605.00	40,394.00	121,999.00
10	**Total Number Other Personnel**					**Total Other Personnel**	**345,928.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**472,684.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 0411522240000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Oak Ridge Associated Universities

*** Start Date:** 01-16-2014 *** End Date:** 01-15-2015 **Budget Period:** 3

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	40,000.00
2. Foreign Travel Costs	
Total Travel Cost	**40,000.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant/Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 0411522240000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Oak Ridge Associated Universities

*** Start Date:** 01-16-2014 *** End Date:** 01-15-2015 **Budget Period:** 3

F. Other Direct Costs	Funds Requested ($)
1. Materials and Supplies	6,500.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Death Certificates	9,500.00
9. Shipping	1,500.00
Total Other Direct Costs	**17,500.00**

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	**530,184.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1. G&A	6.25	835,265.60	52,204.10
2. Site Services	28.30	316,176.75	89,478.01
3. Overhead	11.50	316,176.75	36,360.33
4. Office and Operations		316,176.75	179,226.72
		Total Indirect Costs	**357,269.16**

Cognizant Federal Agency United States Department of Energy, Frederick G. Pieper, 865.241.4621

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	**887,453.16**

J. Fee	Funds Requested ($)
	23,704.84

K. * Budget Justification File Name: 1234-ORAU Budget Justification.pdf Mime Type: application/pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 0411522240000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Oak Ridge Associated Universities

*** Start Date:** 01-16-2015 *** End Date:** 01-15-2016 **Budget Period:** 4

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	Elizabeth		Dupree-Ellis		PD/PI	136,302.00	4.80			46,605.00	23,069.00	69,674.00
2.	Mr.	Phillip		Wallace		Systems Analyst	137,384.00	4.80			46,975.00	23,253.00	70,228.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **139,902.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
1	Secretarial/Clerical	0.48			1,669.00	826.00	2,495.00
2	Senior Scientific Staff	2.40			31,427.00	15,556.00	46,983.00
4	Other Scientific Staff	15.00			131,347.00	65,017.00	196,364.00
3	Health Physicist/Industrial Hygienist	7.80			73,474.00	36,370.00	109,844.00
10	**Total Number Other Personnel**					**Total Other Personnel**	**355,686.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**495,588.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 0411522240000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Oak Ridge Associated Universities

*** Start Date:** 01-16-2015 *** End Date:** 01-15-2016 **Budget Period: 4**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)

Total funds requested for all equipment listed in the attached file

Total Equipment

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	50,000.00
2. Foreign Travel Costs	
Total Travel Cost	**50,000.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant/Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 0411522240000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Oak Ridge Associated Universities

*** Start Date:** 01-16-2015 *** End Date:** 01-15-2016 **Budget Period:** 4

F. Other Direct Costs	**Funds Requested ($)**
1. Materials and Supplies	4,000.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Death Certificates	3,000.00
9. Shipping	1,000.00
Total Other Direct Costs	**8,000.00**

G. Direct Costs	**Funds Requested ($)**
Total Direct Costs (A thru F)	**553,588.00**

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	*** Funds Requested ($)**
1. G&A	6.25	868,413.12	54,275.82
2. Site Services	28.30	331,497.09	90,447.45
3. Overhead	11.50	331,497.09	38,122.16
4. Office and Operations		331,497.09	186,237.00
		Total Indirect Costs	**369,082.43**

Cognizant Federal Agency United States Department of Energy, Frederick G. Pieper, 865.241.4621

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)**
Total Direct and Indirect Institutional Costs (G + H)	**922,670.43**

J. Fee	**Funds Requested ($)**
	24,645.57

K. * Budget Justification File Name: 1234-ORAU Budget Justification.pdf Mime Type: application/pdf

(Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

*** ORGANIZATIONAL DUNS:** 0411522240000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Oak Ridge Associated Universities

*** Start Date:** 01-16-2016 *** End Date:** 01-15-2017 **Budget Period:** 5

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	Elizabeth		Dupree-Ellis		PD/PI	141,066.00	3.60			36,175.00	17,907.00	54,082.00
2.	Mr.	Phillip		Wallace		Systems Analyst	142,189.00	3.60			36,463.00	18,049.00	54,512.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **108,594.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
1	Secretarial/Clerical	0.96			3,455.00	1,710.00	5,165.00
2	Senior Scientific Staff	2.40			32,528.00	16,101.00	48,629.00
4	Other Scientific Staff	15.00			135,938.00	67,289.00	203,227.00
3	Health Physicist/Industrial Hygienist	7.20			70,590.00	34,942.00	105,532.00
10	**Total Number Other Personnel**					**Total Other Personnel**	**362,553.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**471,147.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

*** ORGANIZATIONAL DUNS:** 0411522240000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Oak Ridge Associated Universities

*** Start Date:** 01-16-2016 *** End Date:** 01-15-2017 **Budget Period:** 5

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	*** Funds Requested ($)**

Total funds requested for all equipment listed in the attached file

Total Equipment

Additional Equipment: File Name: Mime Type:

D. Travel	**Funds Requested ($)**
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)**
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant/Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

*** ORGANIZATIONAL DUNS:** 0411522240000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Oak Ridge Associated Universities

*** Start Date:** 01-16-2016 *** End Date:** 01-15-2017 **Budget Period:** 5

F. Other Direct Costs	**Funds Requested ($)**
1. Materials and Supplies	2,000.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**2,000.00**

G. Direct Costs	**Funds Requested ($)**
Total Direct Costs (A thru F)	**473,147.00**

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	*** Funds Requested ($)**
1. G&A	6.25	771,656.48	48,228.53
2. Site Services	28.30	315,149.08	85,703.22
3. Overhead	11.50	315,149.08	36,242.15
4. Office and Operations		315,149.08	176,581.48
		Total Indirect Costs	**346,755.38**

Cognizant Federal Agency United States Department of Energy, Frederick G. Pieper, 865.241.4621

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)**
Total Direct and Indirect Institutional Costs (G + H)	**819,902.38**

J. Fee	**Funds Requested ($)**
	21,899.62

K. * Budget Justification File Name: 1234-ORAU Budget Justification.pdf Mime Type: application/pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		**570,111.00**
Section B, Other Personnel		**1,514,311.00**
Total Number Other Personnel	50	
Total Salary, Wages and Fringe Benefits (A+B)		**2,084,422.00**
Section C, Equipment		
Section D, Travel		**171,636.00**
1. Domestic	171,636.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		**50,000.00**
1. Materials and Supplies	22,500.00	
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	22,500.00	
9. Other 2	5,000.00	
10. Other 3		
Section G, Direct Costs (A thru F)		**2,306,058.00**
Section H, Indirect Costs		**1,563,983.17**
Section I, Total Direct and Indirect Costs (G + H)		**3,870,041.17**
Section J, Fee		**103,372.83**

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 1771157970000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Risk Assessment Corporation

*** Start Date:** 01-16-2012 *** End Date:** 01-15-2013 **Budget Period:** 1

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	John	E.	Till		PD/PI	217,282.01	0.82			14,857.00	3,111.00	17,968.00
2.	Ms.	Jill	Weber	Aanenson		Consultant	229,602.00	1.30			24,874.00	0.00	24,874.00
3.	Mr.	Harold	L.	Beck		Consultant	287,007.60	1.65			39,533.00	0.00	39,533.00
4.	Ms.	Cynthia		Galvin		Consultant	103,326.00	0.12			1,013.00	0.00	1,013.00
5.	Dr.	Helen	A.	Grogan		Consultant	275,522.40	1.71			39,303.00	0.00	39,303.00
6.	Mr.	H.	Justin	Mohler		Consultant	229,602.00	1.36			25,999.00	0.00	25,999.00
7.	Ms.	S.	Shawn	Mohler		Consultant	183,681.60	1.12			17,198.00	0.00	17,198.00
8.	Mr.	Paul	G.	Voilleque		Consultant	252,572.40	1.65			34,789.00	0.00	34,789.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **200,677.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**				**Total Other Personnel**		
					Total Salary, Wages and Fringe Benefits (A+B)		**200,677.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 1771157970000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Risk Assessment Corporation

*** Start Date:** 01-16-2012 *** End Date:** 01-15-2013 **Budget Period: 1**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	7,833.00
2. Foreign Travel Costs	
Total Travel Cost	**7,833.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant/Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 1771157970000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Risk Assessment Corporation

*** Start Date:** 01-16-2012 *** End Date:** 01-15-2013 **Budget Period:** 1

F. Other Direct Costs	**Funds Requested ($)**
Total Other Direct Costs	

G. Direct Costs	**Funds Requested ($)**
Total Direct Costs (A thru F)	208,510.00

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	*** Funds Requested ($)**
1. F&A	18.50	208,510.00	38,575.00
		Total Indirect Costs	**38,575.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)**
Total Direct and Indirect Institutional Costs (G + H)	**247,085.00**

J. Fee	**Funds Requested ($)**

K. * Budget Justification	File Name: 1235-Budget Justification RAC.pdf (Only attach one file.)	Mime Type: application/pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

* ORGANIZATIONAL DUNS: 1771157970000

* Budget Type: ○ Project ● Subaward/Consortium

Enter name of Organization: Risk Assessment Corporation

* Start Date: 01-16-2013 * End Date: 01-15-2014 Budget Period: 2

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	John	E.	Till		PD/PI	224,360.00	0.82			15,302.00	3,204.00	18,506.00
2.	Ms.	Jill	Weber	Aanenson		Consultant	236,497.00	1.12			22,142.00	0.00	22,142.00
3.	Mr.	Harold	L.	Beck		Consultant	295,616.00	1.42			34,923.00	0.00	34,923.00
4.	Ms.	Cynthia		Galvin		Consultant	106,427.00	0.12			1,043.00	0.00	1,043.00
5.	Dr.	Helen	A.	Grogan		Consultant	283,784.00	1.36			32,135.00	0.00	32,135.00
6.	Mr.	H.	Justin	Mohler		Consultant	236,497.00	0.98			19,244.00	0.00	19,244.00
7.	Ms.	S.	Shawn	Mohler		Consultant	189,190.00	0.98			15,395.00	0.00	15,395.00
8.	Mr.	Paul	G.	Voilleque		Consultant	260,141.00	1.42			30,732.00	0.00	30,732.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **174,120.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	
						Total Salary, Wages and Fringe Benefits (A+B)	**174,120.00**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 1771157970000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Risk Assessment Corporation

*** Start Date:** 01-16-2013 *** End Date:** 01-15-2014 **Budget Period:** 2

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	7,833.00
2. Foreign Travel Costs	
Total Travel Cost	**7,833.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant/Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 1771157970000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Risk Assessment Corporation

*** Start Date:** 01-16-2013 *** End Date:** 01-15-2014 **Budget Period:** 2

F. Other Direct Costs	**Funds Requested ($)**
Total Other Direct Costs	

G. Direct Costs	**Funds Requested ($)**
Total Direct Costs (A thru F)	**181,953.00**

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	*** Funds Requested ($)**
1. F&A	18.50	181,953.00	33,662.00
		Total Indirect Costs	**33,662.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)**
Total Direct and Indirect Institutional Costs (G + H)	**215,615.00**

J. Fee	**Funds Requested ($)**

K. * Budget Justification	File Name: 1235-Budget Justification RAC.pdf (Only attach one file.)	Mime Type: application/pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 1771157970000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Risk Assessment Corporation

*** Start Date:** 01-16-2014 *** End Date:** 01-15-2015 **Budget Period:** 3

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	John	E.	Till		PD/PI	231,102.00	0.52			10,030.00	2,100.00	12,130.00
2.	Ms.	Jill	Weber	Aanenson		Consultant	243,596.00	1.12			22,806.00	0.00	22,806.00
3.	Mr.	Harold	L.	Beck		Consultant	304,490.00	1.42			35,971.00	0.00	35,971.00
4.	Ms.	Cynthia		Galvin		Consultant	109,609.00	0.05			430.00	0.00	430.00
5.	Dr.	Helen	A.	Grogan		Consultant	292,312.00	1.51			36,681.00	0.00	36,681.00
6.	Mr.	H.	Justin	Mohler		Consultant	243,596.00	1.12			22,806.00	0.00	22,806.00
7.	Ms.	S.	Shawn	Mohler		Consultant	194,861.00	1.12			18,245.00	0.00	18,245.00
8.	Mr.	Paul	G.	Voilleque		Consultant	267,954.00	1.42			31,654.00	0.00	31,654.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **180,723.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**				**Total Other Personnel**		
					Total Salary, Wages and Fringe Benefits (A+B)		**180,723.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 1771157970000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Risk Assessment Corporation

*** Start Date:** 01-16-2014 *** End Date:** 01-15-2015 **Budget Period:** 3

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	7,833.00
2. Foreign Travel Costs	
Total Travel Cost	**7,833.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant/Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 1771157970000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Risk Assessment Corporation

*** Start Date:** 01-16-2014 *** End Date:** 01-15-2015 **Budget Period:** 3

F. Other Direct Costs	**Funds Requested ($)**
Total Other Direct Costs	

G. Direct Costs	**Funds Requested ($)**
Total Direct Costs (A thru F)	188,556.00

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	*** Funds Requested ($)**
1. F&A	18.50	188,556.00	34,883.00
		Total Indirect Costs	**34,883.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)**
Total Direct and Indirect Institutional Costs (G + H)	223,439.00

J. Fee	**Funds Requested ($)**

K. * Budget Justification	File Name: 1235-Budget Justification RAC.pdf	Mime Type: application/pdf
	(Only attach one file.)	

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 1771157970000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Risk Assessment Corporation

*** Start Date:** 01-16-2015 *** End Date:** 01-15-2016 **Budget Period:** 4

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	John	E.	Till		PD/PI	238,021.00	0.52			10,331.00	2,163.00	12,494.00
2.	Ms.	Jill	Weber	Aanenson		Consultant	250,900.00	0.56			11,807.00	0.00	11,807.00
3.	Mr.	Harold	L.	Beck		Consultant	313,609.00	1.33			34,744.00	0.00	34,744.00
4.	Ms.	Cynthia		Galvin		Consultant	112,894.00	0.00			0.00	0.00	0.00
5.	Dr.	Helen	A.	Grogan		Consultant	301,063.00	0.86			21,547.00	0.00	21,547.00
6.	Mr.	H.	Justin	Mohler		Consultant	250,900.00	0.56			11,807.00	0.00	11,807.00
7.	Ms.	S.	Shawn	Mohler		Consultant	200,716.00	0.56			9,445.00	0.00	9,445.00
8.	Mr.	Paul	G.	Voilleque		Consultant	275,992.00	1.33			30,575.00	0.00	30,575.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **132,419.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**				**Total Other Personnel**		
					Total Salary, Wages and Fringe Benefits (A+B)		**132,419.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 1771157970000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Risk Assessment Corporation

*** Start Date:** 01-16-2015 *** End Date:** 01-15-2016 **Budget Period:** 4

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	7,833.00
2. Foreign Travel Costs	
Total Travel Cost	**7,833.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant/Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 1771157970000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Risk Assessment Corporation

*** Start Date:** 01-16-2015 *** End Date:** 01-15-2016 **Budget Period:** 4

F. Other Direct Costs	**Funds Requested ($)**
Total Other Direct Costs	

G. Direct Costs	**Funds Requested ($)**
Total Direct Costs (A thru F)	**140,252.00**

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	*** Funds Requested ($)**
1. F&A	18.50	140,252.00	25,947.00
		Total Indirect Costs	**25,947.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)**
Total Direct and Indirect Institutional Costs (G + H)	**166,199.00**

J. Fee	**Funds Requested ($)**

K. * Budget Justification File Name: 1235-Budget Justification RAC.pdf Mime Type: application/pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

*** ORGANIZATIONAL DUNS:** 1771157970000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Risk Assessment Corporation

*** Start Date:** 01-16-2016 *** End Date:** 01-15-2017 **Budget Period:** 5

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	John	E.	Till		PD/PI	245,165.00	0.67			13,681.00	2,865.00	16,546.00
2.	Ms.	Jill	Weber	Aanenson		Consultant	258,427.00	0.12			2,534.00	0.00	2,534.00
3.	Mr.	Harold	L.	Beck		Consultant	323,034.00	1.32			35,628.00	0.00	35,628.00
4.	Ms.	Cynthia		Galvin		Consultant	116,280.00	0.00			0.00	0.00	0.00
5.	Dr.	Helen	A.	Grogan		Consultant	310,100.00	0.59			15,201.00	0.00	15,201.00
6.	Mr.	H.	Justin	Mohler		Consultant	258,427.00	0.12			2,534.00	0.00	2,534.00
7.	Ms.	S.	Shawn	Mohler		Consultant	206,734.00	0.12			2,027.00	0.00	2,027.00
8.	Mr.	Paul	G.	Voilleque		Consultant	284,254.00	1.32			31,353.00	0.00	31,353.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **105,823.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**				**Total Other Personnel**		
					Total Salary, Wages and Fringe Benefits (A+B)		**105,823.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

*** ORGANIZATIONAL DUNS:** 1771157970000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Risk Assessment Corporation

*** Start Date:** 01-16-2016 *** End Date:** 01-15-2017 **Budget Period:** 5

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	7,833.00
2. Foreign Travel Costs	
Total Travel Cost	**7,833.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant/Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

*** ORGANIZATIONAL DUNS:** 1771157970000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Risk Assessment Corporation

*** Start Date:** 01-16-2016 *** End Date:** 01-15-2017 **Budget Period:** 5

F. Other Direct Costs	**Funds Requested ($)**
Total Other Direct Costs	

G. Direct Costs	**Funds Requested ($)**
Total Direct Costs (A thru F)	**113,656.00**

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	*** Funds Requested ($)**
1. F&A	18.50	113,656.00	21,027.00
		Total Indirect Costs	**21,027.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)**
Total Direct and Indirect Institutional Costs (G + H)	**134,683.00**

J. Fee	**Funds Requested ($)**

K. * Budget Justification	File Name: 1235-Budget Justification RAC.pdf	Mime Type: application/pdf
	(Only attach one file.)	

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - Cumulative Budget

		Totals ($)
Section A, Senior/Key Person		**793,762.00**
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		**793,762.00**
Section C, Equipment		
Section D, Travel		**39,165.00**
1. Domestic	39,165.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		**832,927.00**
Section H, Indirect Costs		**154,094.00**
Section I, Total Direct and Indirect Costs (G + H)		**987,021.00**
Section J, Fee		

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0729333930000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: University of Southern California

*** Start Date:** 01-16-2012 *** End Date:** 01-15-2013 **Budget Period:** 1

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	Dan		Stram		PD/PI	197,726.00	2.40			39,545.00	12,496.00	52,041.00
2.		Duncan		Thomas		Co-PI	199,700.00	0.60			9,985.00	3,155.00	13,140.00
3.		TBN		TBN		Programmer	81,500.00	6.00			40,750.00	12,877.00	53,627.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **118,808.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
1	Post Doctoral Associates	6.00			40,750.00	12,877.00	53,627.00
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	**Total Number Other Personnel**					**Total Other Personnel**	**53,627.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**172,435.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0729333930000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: University of Southern California

*** Start Date:** 01-16-2012 *** End Date:** 01-15-2013 **Budget Period: 1**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	4,600.00
2. Foreign Travel Costs	
Total Travel Cost	**4,600.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant/Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0729333930000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: University of Southern California

*** Start Date:** 01-16-2012 *** End Date:** 01-15-2013 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)
1. Materials and Supplies	1,000.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Workstation/Data-Storage Capacity	8,000.00
Total Other Direct Costs	**9,000.00**

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	**186,035.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1. MDTC	63.50	186,035.00	118,133.00
		Total Indirect Costs	**118,133.00**

Cognizant Federal Agency DHHS, Lori Ahlstrand, 415-437-8360
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	304,168.00

J. Fee	Funds Requested ($)

K. * Budget Justification File Name: 1236-Budget Justification USC.pdf Mime Type: application/pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 0729333930000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: University of Southern California

*** Start Date:** 01-16-2013 *** End Date:** 01-15-2014 **Budget Period:** 2

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	Dan		Stram		PD/PI		2.40			39,940.00	12,621.00	52,561.00
2.	Dr.	Duncan		Thomas		Co-Investigator		0.60			9,985.00	3,155.00	13,140.00
3.		TBN		TBN		Programmer		6.00			41,973.00	13,263.00	55,236.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **120,937.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
1	Post Doctoral Associates	6.00			41,973.00	13,263.00	55,236.00
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	**Total Number Other Personnel**					**Total Other Personnel**	**55,236.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**176,173.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 0729333930000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: University of Southern California

*** Start Date:** 01-16-2013 *** End Date:** 01-15-2014 **Budget Period:** 2

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	*** Funds Requested ($)**
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name: Mime Type:

D. Travel	**Funds Requested ($)**
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	4,692.00
2. Foreign Travel Costs	
Total Travel Cost	**4,692.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)**
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant/Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 0729333930000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: University of Southern California

*** Start Date:** 01-16-2013 *** End Date:** 01-15-2014 **Budget Period:** 2

F. Other Direct Costs	**Funds Requested ($)**
1. Materials and Supplies	1,020.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**1,020.00**

G. Direct Costs	**Funds Requested ($)**
Total Direct Costs (A thru F)	**181,885.00**

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	*** Funds Requested ($)**
1. MTDC	64.00	181,885.00	116,406.00
		Total Indirect Costs	**116,406.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)**
Total Direct and Indirect Institutional Costs (G + H)	**298,291.00**

J. Fee	**Funds Requested ($)**

K. * Budget Justification File Name: 1236-Budget Justification USC.pdf Mime Type: application/pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 0729333930000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: University of Southern California

*** Start Date:** 01-16-2014 *** End Date:** 01-15-2015 **Budget Period:** 3

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	Dan		Stram		PD/PI		2.40			39,940.00	12,621.00	52,561.00
2.	Dr.	Duncan		Thomas		Co-Investigator		0.60			9,985.00	3,155.00	13,140.00
3.		TBN		TBN		Programmer		6.00			43,232.00	13,661.00	56,893.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **122,594.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
1	Post Doctoral Associates	6.00			43,232.00	13,661.00	56,893.00
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	**Total Number Other Personnel**					**Total Other Personnel**	**56,893.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**179,487.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 0729333930000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: University of Southern California

*** Start Date:** 01-16-2014 *** End Date:** 01-15-2015 **Budget Period:** 3

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)

Total funds requested for all equipment listed in the attached file

Total Equipment

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	4,786.00
2. Foreign Travel Costs	
Total Travel Cost	**4,786.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant/Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 0729333930000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: University of Southern California

*** Start Date:** 01-16-2014 *** End Date:** 01-15-2015 **Budget Period:** 3

F. Other Direct Costs	**Funds Requested ($)**
1. Materials and Supplies	1,040.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**1,040.00**

G. Direct Costs	**Funds Requested ($)**
Total Direct Costs (A thru F)	**185,313.00**

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	*** Funds Requested ($)**
1. MTDC	64.25	185,313.00	119,064.00
		Total Indirect Costs	**119,064.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)**
Total Direct and Indirect Institutional Costs (G + H)	**304,377.00**

J. Fee	**Funds Requested ($)**

K. * Budget Justification File Name: 1236-Budget Justification USC.pdf Mime Type: application/pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 0729333930000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: University of Southern California

*** Start Date:** 01-16-2015 *** End Date:** 01-15-2016 **Budget Period:** 4

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	Dan		Stram		PD/PI		2.40			39,940.00	12,621.00	52,561.00
2.	Dr.	Duncan		Thomas		Co-Investigator		0.60			9,985.00	3,155.00	13,140.00
3.		TBN		TBN		Programmer		6.00			44,529.00	14,071.00	58,600.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **124,301.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
1	Post Doctoral Associates	6.00			44,529.00	14,071.00	58,600.00
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	**Total Number Other Personnel**					**Total Other Personnel**	**58,600.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**182,901.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 0729333930000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: University of Southern California

*** Start Date:** 01-16-2015 *** End Date:** 01-15-2016 **Budget Period:** 4

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	4,882.00
2. Foreign Travel Costs	
Total Travel Cost	**4,882.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant/Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 0729333930000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: University of Southern California

*** Start Date:** 01-16-2015 *** End Date:** 01-15-2016 **Budget Period:** 4

F. Other Direct Costs	**Funds Requested ($)**
1. Materials and Supplies	1,061.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**1,061.00**

G. Direct Costs	**Funds Requested ($)**
Total Direct Costs (A thru F)	**188,844.00**

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	*** Funds Requested ($)**
1. MTDC	64.75	188,844.00	122,276.00
		Total Indirect Costs	**122,276.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)**
Total Direct and Indirect Institutional Costs (G + H)	**311,120.00**

J. Fee	**Funds Requested ($)**

K. * Budget Justification File Name: 1236-Budget Justification USC.pdf Mime Type: application/pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

*** ORGANIZATIONAL DUNS:** 0729333930000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: University of Southern California

*** Start Date:** 01-16-2015 *** End Date:** 01-15-2016 **Budget Period:** 5

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	Dan		Stram		PD/PI		2.40			39,940.00	12,621.00	52,561.00
2.	Dr.	Duncan		Thomas		Co-Investigator		0.60			9,985.00	3,155.00	13,140.00
3.		TBN		TBN		Programmer		6.00			45,864.00	14,493.00	60,357.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **126,058.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
1	Post Doctoral Associates	6.00			45,864.00	14,493.00	60,357.00
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	**Total Number Other Personnel**					**Total Other Personnel**	**60,357.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**186,415.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

*** ORGANIZATIONAL DUNS:** 0729333930000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: University of Southern California

*** Start Date:** 01-16-2015 *** End Date:** 01-15-2016 **Budget Period:** 5

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)

Total funds requested for all equipment listed in the attached file

Total Equipment

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	4,979.00
2. Foreign Travel Costs	
Total Travel Cost	**4,979.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant/Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

*** ORGANIZATIONAL DUNS:** 0729333930000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: University of Southern California

*** Start Date:** 01-16-2015 *** End Date:** 01-15-2016 **Budget Period:** 5

F. Other Direct Costs	Funds Requested ($)
1. Materials and Supplies	1,082.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**1,082.00**

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	**192,476.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1. MTDC	65.00	192,476.00	125,109.00
		Total Indirect Costs	**125,109.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	**317,585.00**

J. Fee	Funds Requested ($)

K. * Budget Justification File Name: 1236-Budget Justification USC.pdf Mime Type: application/pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - Cumulative Budget

		Totals ($)
Section A, Senior/Key Person		**612,698.00**
Section B, Other Personnel		**284,713.00**
Total Number Other Personnel	5	
Total Salary, Wages and Fringe Benefits (A+B)		**897,411.00**
Section C, Equipment		
Section D, Travel		**23,939.00**
1. Domestic	23,939.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		**13,203.00**
1. Materials and Supplies	5,203.00	
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	8,000.00	
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		**934,553.00**
Section H, Indirect Costs		**600,988.00**
Section I, Total Direct and Indirect Costs (G + H)		**1,535,541.00**
Section J, Fee		

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0044134560000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Vanderbilt University Medical Center

*** Start Date:** 01-16-2012 *** End Date:** 01-15-2013 **Budget Period:** 1

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	Randy		Brill		PD/PI	201,858.00	1.20			20,186.00	4,481.00	24,667.00
2.	Dr.	Yu		Shyr		Sr Biostatistician	274,458.00	0.30			6,861.00	1,523.00	8,384.00
3.	Dr.	William		Wu		Biostatistician	88,050.00	1.80			13,208.00	2,932.00	16,140.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **49,191.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	
						Total Salary, Wages and Fringe Benefits (A+B)	**49,191.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0044134560000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Vanderbilt University Medical Center

*** Start Date:** 01-16-2012 *** End Date:** 01-15-2013 **Budget Period: 1**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)
1. N/A	0.00

Total funds requested for all equipment listed in the attached file

Total Equipment **0.00**

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	2,400.00
2. Foreign Travel Costs	
Total Travel Cost	**2,400.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	0.00
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
0 **Number of Participants/Trainees** — **Total Participant/Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0044134560000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Vanderbilt University Medical Center

*** Start Date:** 01-16-2012 *** End Date:** 01-15-2013 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)
1. Materials and Supplies	500.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	3,000.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Biennial statisital meeting	5,000.00
9. Biostats Core	3,794.00
Total Other Direct Costs	**12,294.00**

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	**63,885.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1. MDTC	56.00	63,885.00	35,776.00
		Total Indirect Costs	**35,776.00**

Cognizant Federal Agency DHHS, Jay Mervis, 202-401-2808

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	**99,661.00**

J. Fee	Funds Requested ($)
	0.00

K. * Budget Justification File Name: 1237-Vanderbilt Budget Justification.pdf Mime Type: application/pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 0044134560000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: Vanderbilt University Medical Center

*** Start Date:** 01-16-2013 *** End Date:** 01-15-2014 **Budget Period:** 2

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	Randy		Brill		PD/PI	205,895.00	1.20			20,590.00	4,571.00	25,161.00
2.	Dr.	Yu		Shyr		Sr Biostatistician	279,947.00	0.30			6,999.00	1,553.00	8,552.00
3.	Dr.	William		Wu		Biostatistician	89,811.00	1.80			13,471.00	2,991.00	16,462.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **50,175.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	
						Total Salary, Wages and Fringe Benefits (A+B)	**50,175.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 0044134560000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Vanderbilt University Medical Center

*** Start Date:** 01-16-2013 *** End Date:** 01-15-2014 **Budget Period:** 2

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)

Total funds requested for all equipment listed in the attached file

Total Equipment

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	2,400.00
2. Foreign Travel Costs	
Total Travel Cost	**2,400.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	0.00
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
0 **Number of Participants/Trainees** **Total Participant/Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 0044134560000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Vanderbilt University Medical Center

*** Start Date:** 01-16-2013 *** End Date:** 01-15-2014 **Budget Period:** 2

F. Other Direct Costs	Funds Requested ($)
1. Materials and Supplies	500.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	3,000.00
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Veterans cohort statistical Meeting	10,000.00
9. Biostats Core	3,870.00
Total Other Direct Costs	**17,370.00**

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	**69,945.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1. MDTC	56.00	69,945.00	39,169.00
		Total Indirect Costs	**39,169.00**

Cognizant Federal Agency DHHS, Jay Mervis, 202-401-2808
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	**109,114.00**

J. Fee	Funds Requested ($)
	0.00

K. * Budget Justification File Name: 1237-Vanderbilt Budget Justification.pdf Mime Type: application/pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 0044134560000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: Vanderbilt University Medical Center

*** Start Date:** 01-16-2014 *** End Date:** 01-15-2015 **Budget Period:** 3

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	Randy		Brill		PD/PI	210,013.00	1.20			21,001.00	4,662.00	25,663.00
2.	Dr.	Yu		Shyr		Sr Biostatistician	285,546.00	0.30			7,139.00	1,585.00	8,724.00
3.	Dr.	William		Wu		Biostatistician	91,608.00	1.80			13,741.00	3,051.00	16,792.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **51,179.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**				**Total Other Personnel**		
					Total Salary, Wages and Fringe Benefits (A+B)		**51,179.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 0044134560000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Vanderbilt University Medical Center

*** Start Date:** 01-16-2014 *** End Date:** 01-15-2015 **Budget Period:** 3

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)
1. N/A	0.00
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	2,400.00
2. Foreign Travel Costs	
Total Travel Cost	**2,400.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	0.00
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
0 **Number of Participants/Trainees** **Total Participant/Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 0044134560000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Vanderbilt University Medical Center

*** Start Date:** 01-16-2014 *** End Date:** 01-15-2015 **Budget Period:** 3

F. Other Direct Costs	Funds Requested ($)
1. Materials and Supplies	500.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	3,000.00
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Biennial statisitcla meeting	5,000.00
9. Biostats Core	3,947.00
Total Other Direct Costs	**12,447.00**

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	**66,026.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1. MDTC	56.00	66,026.00	36,974.00
		Total Indirect Costs	**36,974.00**

Cognizant Federal Agency DHHS, Jay Mervis, 202-401-2808

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	**103,000.00**

J. Fee	Funds Requested ($)
	0.00

K. * Budget Justification File Name: 1237-Vanderbilt Budget Justification.pdf Mime Type: application/pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 0044134560000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Vanderbilt University Medical Center

*** Start Date:** 01-16-2015 *** End Date:** 01-15-2016 **Budget Period: 4**

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	Randy		Brill		PD/PI	214,213.00	1.20			21,421.00	4,756.00	26,177.00
2.	Dr.	Yu		Shyr		Sr Biostatistician	291,258.00	0.30			7,281.00	1,616.00	8,897.00
3.	Dr.	William		Wu		Biostatistician	93,440.00	2.40			18,688.00	4,149.00	22,837.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **57,911.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**				**Total Other Personnel**		
					Total Salary, Wages and Fringe Benefits (A+B)		**57,911.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 0044134560000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Vanderbilt University Medical Center

*** Start Date:** 01-16-2015 *** End Date:** 01-15-2016 **Budget Period: 4**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)
1. N/A	0.00

Total funds requested for all equipment listed in the attached file

Total Equipment	**0.00**

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	2,400.00
2. Foreign Travel Costs	
Total Travel Cost	**2,400.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	0.00
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
0 **Number of Participants/Trainees** — **Total Participant/Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 0044134560000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Vanderbilt University Medical Center

*** Start Date:** 01-16-2015 *** End Date:** 01-15-2016 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)
1. Materials and Supplies	500.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	3,000.00
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Veterans cohort statistical Meeting	10,000.00
9. Biostats Core	5,176.00
Total Other Direct Costs	**18,676.00**

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	**78,987.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1. MDTC	56.00	78,987.00	44,233.00
		Total Indirect Costs	**44,233.00**

Cognizant Federal Agency DHHS, Jay Mervis, 202-401-2808

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	**123,220.00**

J. Fee	Funds Requested ($)
	0.00

K. * Budget Justification File Name: 1237-Vanderbilt Budget Justification.pdf Mime Type: application/pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

*** ORGANIZATIONAL DUNS:** 0044134560000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Vanderbilt University Medical Center

*** Start Date:** 01-16-2016 *** End Date:** 01-15-2017 **Budget Period:** 5

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	Randy		Brill		PD/PI	218,498.00	1.20			21,850.00	4,850.00	26,700.00
2.	Dr.	Yu		Shyr		Sr Biostatistician	297,082.00	0.30			7,427.00	1,649.00	9,076.00
3.	Dr.	William		Wu		Biostatistician	95,309.00	2.40			19,062.00	4,232.00	23,294.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **59,070.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	
						Total Salary, Wages and Fringe Benefits (A+B)	**59,070.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

*** ORGANIZATIONAL DUNS:** 0044134560000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Vanderbilt University Medical Center

*** Start Date:** 01-16-2016 *** End Date:** 01-15-2017 **Budget Period:** 5

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)
1. N/A	0.00

Total funds requested for all equipment listed in the attached file

Total Equipment	**0.00**

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	2,400.00
2. Foreign Travel Costs	
Total Travel Cost	**2,400.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	0.00
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
0 **Number of Participants/Trainees** **Total Participant/Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

*** ORGANIZATIONAL DUNS:** 0044134560000

*** Budget Type:** ○ Project ● Subaward/Consortium

Enter name of Organization: Vanderbilt University Medical Center

*** Start Date:** 01-16-2016   *** End Date:** 01-15-2017   **Budget Period:** 5

F. Other Direct Costs	Funds Requested ($)
1. Materials and Supplies	500.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	3,000.00
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Biennial statistical meeting	5,000.00
9. Biostats Core	5,280.00
Total Other Direct Costs	**13,780.00**

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	**75,250.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1. MDTC	56.00	75,250.00	42,140.00
		Total Indirect Costs	**42,140.00**

Cognizant Federal Agency DHHS, Jay Mervis, 202-401-2808

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	**117,390.00**

J. Fee	Funds Requested ($)
	0.00

K. * Budget Justification File Name: 1237-Vanderbilt Budget Justification.pdf Mime Type: application/pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		**267,526.00**
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		**267,526.00**
Section C, Equipment		**0.00**
Section D, Travel		**12,000.00**
1. Domestic	12,000.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		**0.00**
1. Tuition/Fees/Health Insurance	0.00	
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees	0	
Section F, Other Direct Costs		**74,567.00**
1. Materials and Supplies	2,500.00	
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services	12,000.00	
5. Subawards/Consortium/Contractual Costs	3,000.00	
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	35,000.00	
9. Other 2	22,067.00	
10. Other 3		
Section G, Direct Costs (A thru F)		**354,093.00**
Section H, Indirect Costs		**198,292.00**
Section I, Total Direct and Indirect Costs (G + H)		**552,385.00**
Section J, Fee		**0.00**

Budget Justification (Oak Ridge Associated Universities (ORAU))

ORAU will provide expertise in the conduct of the follow-up of DOE worker cohorts enrolled in the study and will assist with the vital status determination, cause of death determination, identification and capture of occupational records, and dosimetry determinations for exposures among the uranium and plutonium workers.

Personnel

Elizabeth (Betsy) Dupree Ellis, Ph.D. (3.6 calendar months, Years 1-2 and 5; 4.2 calendar months, Years 3; 4.8 calendar months, Year 4) Associate Director of the Center for Epidemiologic Research (CER) will serve as Co-Principal Investigator of this project and with John Boice will assist in the overall conduct of the study. She will also serve as senior epidemiologist involved in the study design, study conduct, data analysis, and manuscript preparation.

Phillip Wallace, M.B.A. (3 months, Year 1; 4.2 calendar months, Year 2; 4.8 calendar months Years 3-4; 3.6 calendar months, Year 5) Systems Analyst, will be responsible for overseeing creation of cohort population files for DOE workers, combining results from the various outcome and exposure files, coordinating the flow of data between ORAU and IEI, and preparing final data files for analysis.

Donna L. Cragle, Ph.D. (1.2 calendar months, Year 1-3; 1.8 calendar months, Years 4-5) Vice President, ORAU and Director of CER will serve as senior epidemiologist involved in the study design, study conduct, data analysis, and manuscript preparation.

Janice Watkins, M.S. (0.6 calendar months Years 1-2; 1.2 calendar months, Year 3; 1.8 calendar months, Years 4-5) Biostatistician will serve as statistician providing input to study design, data analysis and interpretation. She will assist with data analysis and manuscript preparation.

Richard Toohey, Ph.D. (0.6 calendar months, Years 1 and 3-5) Health Physicist will provide advice and assistance regarding the quality control aspect of the dose reconstruction. He will lead a group of outside experts to develop methodology to address the unique and challenging problems of dose reconstruction associated with this study. He will assist with the analysis and reporting of results.

Nancy Daugherty, M.S. (1.2 calendar months, Years 4-5) Health Physicist will provide advice and assistance regarding the quality control aspect of the dose reconstruction. She will assist with the analysis and reporting of results.

William Tankersley, M.S. (0.6 calendar months, Years 1-2, 4-5; 1.2 calendar months, Year 3) Industrial Hygienist will provide advice and assistance to the dose reconstruction effort. He will also provide assistance in the evaluation of non-radiation exposures that the DOE workers may have received.

Derek Hagemeyer, B.S. (0.6 calendar months Years 1 and 5; 1.2 calendar months Years 2 and 4; 1.8 calendar months, Year 3) Health Physicist will assist with the collection and interpretation of dosimetry data from DOE REMS and NRC REIRS for the populations studied in Aims 1-4.

Jolene Jones, (0.5 calendar months Years 1 through 4; 1.0 calendar months Year 5) Administrative Assistant will provide day-to-day administrative support to team members for all tasks. These include answering telephones, assisting with scheduling site visits, making travel preparing manuscripts for publication by using prescribed formatting procedures, and editing reports before submittal.

Certified Records Manager, (TBH) (9 calendar months Year 1; 9.6 calendar months, Year 2; 6 calendar months Year 3; 3 calendar months Years 4-5) will assist in the identification and capture of data needed to

support the DOE worker studies. This will involve interacting with staff at NARA Records Center and records managers at Doe facilities to identify and collect data of interest.

Epidemiologist, Ph.D. (TBA) (3 calendar months Year 1; 6 calendar months Year 2; 9 calendar months Years 3-5) Epidemiologist will work under the direction of senior epidemiologists to assist with the study design, study conduct, data analysis, and manuscript preparation.

Health Physicist, M.S. (TBA) (3 calendar months Years 1-2; 6 calendar months Years 3-5) Health Physicist will participate in the review of historical dosimetry records, linkage of data from various sources and development of data sets for use in constructing dose estimates for the DOE nuclear workers. This individual will also provide support to the QA efforts under the guidance of Dr. Toohey.

Supplies
Supplies pertaining to telephone, fax, and photocopying and expenses for computer software, storage, printing and imaging as well as death certificate purchases for workers whose death information is not available from the National Death Index are requested at the following levels: $10,000 Year 1; $12,500 Year 2; $17,500 Year 3; $8,000 Year 4; $2,000 Year 5.

Travel
Travel is requested for the Co-Pi and Epidemiologists to travel to the annual investigators meetings plus additional travel to review and collect relevant information identified at the 15 NARA Records Centers as well as various DOE facilities and Records Centers are requested at the following levels: $31,636 Year 1; $50,000 Year 2; $40,000 Year 3; $50,000 Year 4.

Budget Justification (Risk Assessment Corporation (RAC))

RAC will provide the dosimetry determinations on individual military participants. Risk Assessment Corporation (RAC) is a team of independent scientists, led by Dr. John E. Till, who collaborate in multidisciplinary scientific research. In particular, RAC has worked extensively in the field of historical dose reconstruction for more than 20 years. Because of the unique talents required in historical dose reconstruction and RAC's desire to employ the best talent available in its work, collaborators with RAC are all consultants to the group. This format permits RAC to get the optimum amount of labor hours from very highly qualified scientists at very competitive costs. RAC has employed this format for work successfully in many key historical dose reconstruction projects for over 30 years. With the exception of Mr. Beck, the consultants listed below have worked with the RAC team on previous projects, some for many years. Consultants to RAC in this proposal are listed below along with their approximate annual level of effort (in person months) and a brief description of their duties. Consultants are listed alphabetically.

John E. Till, Ph.D., (0.82 calendar months, Years 1-2; 0.52 calendar months, Years 3-4; 0.67 calendar months, Year 5)

Jill Weber Aanenson, M.S. (1.30 calendar months, Year 1; 1.12 calendar months, Years 2-3; 0.56 calendar months, Year 4; 0.12 calendar months, Year 5)
Ms. Aanenson will be responsible for reviewing historical records and assist Mr. Beck and Mr. Voillequé in making the dose assignments. She will also be the primary individual responsible for maintaining the dosimetry database. Ms. Aanenson will be responsible for leading the quality assurance of dose assignments within the RAC team, collaborating with the external quality assurance group who will be primarily responsible for quality assurance of the project as a whole.

Harold L. Beck, B.S. (1.65 calendar months, Year 1; 1.42 calendar months, Years 2-3; 1.33 calendar months, Year 4; 1.32 calendar months, Year 5)
Mr. Beck will be responsible for reviewing historical records and making the dose final assignments. Mr. Beck (along with Mr. Voillequé) will use dose measurement information available in the historical records and information on scenarios of exposure created by other members of the team to assign doses to the veterans. Mr. Beck's experience in understanding the complex dosimetry related to atomic veterans has been extensive. He will also assist the team in developing methods for evaluating uncertainties for the dose assignments.

Cynthia Galvin (0.12 calendar months, Years 1-2; 0.05 calendar months, Year 3)
Ms. Galvin will be responsible for providing technical editing and document management within the RAC Team. She will also assist Ms. Aanenson with quality assurance. All documents developed by RAC are produced with high quality and must meet our editorial and internal review.

Helen A. Grogan, Ph.D. (1.71 calendar months, Year 1; 1.36 calendar months, Year 2; 1.51 calendar months, Year 3; 0.86 calendar months, Year 4; 0.59 calendar months, Year 5)
Dr. Grogan will be responsible for coordinating the different activities and milestones within the RAC dosimetry team. A very important element of historical dose reconstruction is coordination within the team. Dr. Grogan will provide this coordination. She will make sure team members are in close communication to avoid overlap of responsibilities and also to be sure all necessary information is being gathered and reported in the correct format for the epidemiologists.

H. Justin Mohler, M.S. (1.36 calendar months, Year 1; 0.98 calendar months, Year 2; 1.12 calendar months, Year 3; 0.56 calendar months, Year 4; 0.12 calendar months, Year 5)
Mr. Mohler is the RAC team database expert. With input from the other team members, Mr. Mohler will design and implement a user-friendly database that will maintain dosimetry information for atomic veterans. The database will be accessible to all members of the team.

S. Shawn Mohler, M.S. (1.12 calendar months, Year 1; 0.98 calendar months, Year 2; 1.12 calendar months, Year 3; 0.56 calendar months, Year 4; 0.12 calendar months, Year 5)

Ms. Shawn Mohler will be responsible for developing scenarios of exposure for veterans based on information found in the historical records (primarily service records). She will also work with Mr. Beck and Mr. Voillequé in making dose assignments.

Paul G. Voillequé, M.S., C.H.P. (1.65 calendar months, Year 1; 1.42 calendar months, Years 2-3; 1.33 calendar months, Year 4; 1.32 calendar months, Year 5)
Mr. Voillequé will be responsible for reviewing historical records and making the dose final assignments. Mr. Voillequé (along with Mr. Beck) will provide guidance to other members of the dosimetry team in the review of historical records and identifying categories of exposure to facilitate dose assignments to the veterans. Mr. Voillequé's extensive experience in historical dose reconstruction and health physics will be particularly important early in the study as a consistent and reliable methodology for the dosimetry is planned. Once the dosimetry plan is implemented, Mr. Voillequé and Mr. Beck will be the two lead dosimetry experts for the team.

Travel

The use of consultants to bring together the right combination of talent in historical dose reconstruction requires more travel than might be necessary if all individuals were working together in the same location. Nevertheless, with today's technology such as electronic mail, powerful desktop computers, conference calls and webinars (web versions of conference calls), the amount of travel can be kept to a minimum. Nevertheless, some travel is essential among the team to be certain the project is being undertaken with highest quality and scientific integrity. The planned travel will be used primarily for planning the methodology to be used, training of the team, and meetings to discuss progress on the work. It is expected that all meetings will be held in Washington, D.C. Where possible, travel to be combined with other business related travel to keep costs to a minimum.

Supplies
There are no supplies or other direct costs requested in this proposal. All of these costs are borne by Risk Assessment Corporation or by individual consultants.

Budget Justification (University of Southern California (USC))

USC will assist in the statistical analyses, including the handling of uncertainty in the dose estimates, of the separate and combined cohort data.

Dan Stram, Ph.D. (2.4 calendar months), Professor, Department of Preventive Medicine will serve as the senior biostatistician of this project and will oversee all aspects of the pooled analyses of the combined data, as well designing the approach to handle the varied statistical uncertainties associated with the variety of cohorts to be studied. He will direct and collaborate on the analyses of the various cohort studies and will participate in manuscript preparation.

Duncan Thomas, Ph.D. (0.6 calendar months), Co-Director, Division of Biostatistics, Department of Preventive Medicine, University of Southern California will assist the study investigators on statistical approaches to be used in analyzing the complex dosimetric information collected. Guidance on uncertainty analyses will be of prime importance. Dr Thomas will participate in the various focused workshops and subcommittee meetings.

Programmer, M.S. (TBA) (6 calendar months), will assist Dr Stram and Thomas in all aspects of the biostatistical programming needs of the project as it pertains to the combining and pooling of the various data sets in the last year of the proposal.

Post Doctoral Biostatistician, Ph.D. (TBA) (6 calendar months), will assist Dr Stram and Thomas in all aspects of the biostatistical needs of the varied projects involving uranium and plutonium workers, medical professionals, atomic veterans and nuclear power plant workers.

Supplies
Supplies pertaining to telephone, fax, and photocopying and expenses for computer software, storage, printing and imaging are estimated to be $1000per year with a 2% cost of living for years 2-5. We also have included in the budget for this project funds to purchase a workstation and data-storage capacity that will enable us to run most analyses locally while reserving the USC-HPCC facility for extremely high computational intensive analyses such as those that may be required for addressing missing data and measurement error issues. The cost for this equipment is $8000 in year 1.

Travel
Travel is requested for Drs Stram and Thomas to attend the annual Investigators Meeting at $2,300 per trip per Investigator, total $4,600.

Budget Justification (Vanderbilt University (VU))

Vanderbilt University (VU) faculty will assist in oversight and services of aspects of the study related to radiology, radiation dosimetry, risk assessment and statistics, as follows.

Personnel

A. Bertrand Brill, M.D., Ph.D. (1.2 calendar months, Years 1-5), Research Professor, Radiology, and Physics, will serve as the Co- Principal Investigator of this project from Vanderbilt University and will assist in the overall conduct of the study. He will serve as radiation specialist helping to oversee the radiation dosimetry and risk assessment and participate in data interpretation and in manuscript preparation.

Yu Shyr, Ph.D. (0.3 calendar months, Years 1-5), Professor of Biostatistics and Preventive Medicine and head of Vanderbilt's Cancer Biostatistics Center will serve as a senior biostatistician of this project and will oversee aspects of the sampling procedures for the case-cohort design for the cohort of nuclear weapons test participants in particular and collaborate on analysis of the study results and manuscript preparation. Dr. Shyr will work closely with other study statisticians in handling the complex statistical issues, including uncertainty analyses, associated with studying one million radiation workers and veterans in the United States.

William Wu, Ph.D. (1.8 calendar months, Years 1-3, 2.4 calendar months in Years 4-5), Biostatistician, will work with Dr. Shyr on the biostatistical needs of this project and will assist Drs. Brill and Shyr in aspects of the data analysis pertaining to the proposed case-cohort studies for the different radiation-exposed groups being studied and, in particular, for the cohort of nuclear weapons test participants.

Meetings

Statistical meetings will be held each year in coordination with, but as supplements to, the overall study annual meetings For the meetings expected to be held in Nashville in years 1, 3 and 5, coordination costs including hotel reservations, audio-visuals, coffee breaks and luncheon, handout preparation, mailings, minutes, and travel coordination are budgeted at approximately $5,000 in years 1, 3 and 5. Two meetings of the atomic veterans cohort group also will be held in addition to the overall study annual meetings. This larger meeting will be held in Nashville and is budgeted as $10,000 in years 2 and 4.

Computer Software and Support

Support is needed for the computer database management of the cohort of atomic veterans and the preparation of edited data files for analyses. This support is estimated to be $3,000 each of the five years.

Project telephone/fax/photocopying

Funds are requested for study-related expenses related to telephone, fax, and photocopying. These expenses are budgeted at $500/year.

Travel

Travel is requested for two collaborators to attend non-Nashville investigators meetings at $1,200 per person trip per year.

Biostatistics Core Charges

The Biostatistics Collaboration Center at Vanderbilt (BCC) is a university sponsored core resource whose goal is to provide for, enhance, and/or facilitate statistical collaborations involving the design, conduct, analysis or publication of biomedical research at the university. The BCC is comprised of biostatisticians and computer systems analysts from the Department of Biostatistics who are available to work with faculty on a variety of projects. They offer a wide range of highly trained experts with unique expertise for almost any collaboration. The BCC has considerable expertise in the design, conduct, and analysis of large scale clinical trials and research design for basic biomedical research. Varying levels of expertise are also available for consultation,

from bachelors and masters level trained biostatisticians and computer systems analysts to full professors.

The BCC is a revenue neutral university resource. Rates are based on the complete cost of performing collaborative services including, but not limited to, salaries, administrative costs, supplies, computing (software, hardware, and shared resources such as the Advanced Computing Center for Research and Education (ACCRE)), information technology support, and relevant professional development costs. ACCRE offers computing resources flexible enough to enable high performance computing applications in a wide variety of research and education areas, and also provides access to high performance storage resources. Rates have been calculated based on 1500 hour work year, explicitly excluding common professional activities not related to this specific project (e.g., seminars, meeting attendance etc.). Vanderbilt University annually reviews the BCC to ensure that it is in compliance with all applicable federal and state regulations, including OMB Circulars A-21, A-110 and A-133. Rates are adjusted annually to ensure that the BCC is operating on a strict non-profit cost recovery basis.

Typically, faculty biostatisticians who are listed as key personnel have supporting staff statisticians that are funded through the BCC. As a result, faculty recoverables, staff recoverables, and staff salary+fringe costs are bundled into one core cost. Years 1-5: $3,794; $3,870; $3,947; $5,176; $5,280

Applicant/Institution The International Epidemiology Institute
Principal Investigator John D. Boice, Jr., Sc.D.
Project Title Epidemiologic Study of One Million U.S. Radiation Workers and Veterans

Objectives. The single most important question in radiation epidemiology is determining the level of risk associated with exposures that occur gradually over time. The nuclear reactor accident at Fukushima, Japan has emphasized the scientific and societal interest in understanding the health risks of low-level radiation exposures. Existing studies, however, have not provided robust estimates of risk following low dose rate exposures. The study of one million early U.S. radiation workers and veterans will provide information on risk following chronic exposures by focusing on five occupational groups with differing radiation exposure patterns, including intakes of radionuclides: (1) uranium workers at multiple Department of Energy (DOE) locations; (2) nuclear weapons test participants (atomic veterans); (3) nuclear power plant (NPP) workers; (4) industrial radiographers, radiologists and other medical practitioners; and (5) plutonium workers at multiple DOE locations. The study is cost efficient because it builds on the investments made and foundations laid by investigators and government agencies over the past 30-40 years, which have established early worker cohorts that can now provide answers to questions on the lifetime human health risks associated with low-level radiation exposures.

Description. We will conduct a retrospective mortality study of the early workers of the nuclear age, follow the workers for up to 60 years and evaluate lifetime health effects. The uranium cohorts, many from the Manhattan Project era, comprise 202,000 workers. Over 120,000 atomic veterans participated in above ground nuclear weapons tests in Nevada and the Pacific in the 1940s and 1950s. The Landauer, Inc. dosimetry files contain over 400,000 long-term medical workers and industrial radiographers. The Landauer and Nuclear Regulatory Commission files contain over 212,000 NPP workers employed prior to 1984. Early plutonium cohorts comprise over 156,000 workers.

Methods. Our feasibility study assembled over one million radiation workers and military veterans who will be traced, cause of death determined, mortality from cancer and other diseases evaluated, and radiation doses estimated (including intakes of radionuclides). The methodology will follow the state-of-the-art approach we used to study Rocketdyne workers.

Impact. Much knowledge has been gained from the study of atomic bomb survivors, but exposure was acute and to a Japanese population living in a war-torn country in 1945. As exemplified by the Fukushima accident, scientific and medical committees continue to grapple with how best to estimate risks (and set protection standards for workers and the public) when exposures are received gradually over time. Existing studies are not statistically strong enough to provide answers, yet governmental agencies must deal with the complex issues of compensating workers, veterans and citizens potentially harmed by past exposures. Protection committees deliberate over how best to estimate and apply a "dose and dose rate effectiveness factor" to scale the risks from the a-bomb survivor data for relevant and current occupational and environmental circumstances. Evaluation of risk following intakes of radioactive substances assumes greater importance as society debates the role of nuclear energy and deals with nuclear waste and threats of terrorist attacks with nuclear devices. The remarkable increase in medical exposures to CT scans and nuclear imaging raises concerns of future health consequences. Our study also will be a service to American workers and veterans and their families.

Collaborating institutions. Oak Ridge Associated Universities, Oak Ridge National Laboratory, Los Alamos National Laboratory, Landauer, Inc., Risk Assessment Corporation, Harvard Medical School, University of Southern California, Vanderbilt University.

Epidemiologic Study of
One Million U.S. Radiation Workers and Veterans

Applicant/Institution The International Epidemiology Institute
Street Address/City/State/Zip: 1455 Research Boulevard, Suite 550, Rockville MD 20850
Principal Investigator (PI): John D. Boice, Jr., Sc.D.
PI Address: International Epidemiology Institute
1455 Research Boulevard, Suite 550
Rockville MD 20850
PI Telephone Number: (301) 424-1054 x4271
PI Email: boice@iei.us or john.boice@vanderbilt.edu
Funding Opportunity Announcement Number: DE-FOA-0000600
DOE/Office of Science Program Office: Biological and Environmental Research (BER)
DOE/Office of Science Program Manager Contact: Noelle F. Metting Phone: 301-903-8309 Division: SC-23.2
DOE/Project ID for Pilot: 0016044
DOE/Award Register # for Pilot: ER64954

Performance Project Sites:

1. International Epidemiology Institute, Rockville, Maryland
2. Oak Ridge Associated Universities, Oak Ridge, Tennessee
3. Oak Ridge National Laboratory, Oak Ridge, Tennessee
4. University of Southern California, Los Angeles, California
5. Vanderbilt University, Nashville, Tennessee
6. Risk Assessment Corporation, Neeses, South Carolina
7. Los Alamos National Laboratory, Los Alamos, New Mexico

A summary listing of tasks to be performed by each institution for each of the 6 study Aims is provided in the table below. The Research Plan is then presented. A successful Pilot study has been conducted and results included in the PROGRESS REPORT section.

Epidemiologic Study of One Million U.S. Radiation Workers and Veterans						
Study Organization Plan						
	Aim 1	Aim 2	Aim 3	Aim 4	Aim 5	Aim 6
Task	Uranium workers	Atomic veterans	Radiologists & other medical	Nuclear power plant workers	Plutonium workers	Combined cohorts
Cohort identification	ORAU, IEI	RAC, IEI	Landauer (IEI)	Landauer (IEI)	ORAU, LANL, IEI	ORAU
External dosimetry	ORAU	RAC, IEI	Landauer (IEI)	Landauer (IEI)	ORAU, LANL	ORAU
Internal dosimetry	ORAU,ORNL	RAC			ORNL, LANL	ORAU
Cohort follow up	IEI, ORAU	IEI	IEI	IEI	IEI, ORAU	ORAU
Statistical analysis	ORAU, IEI, VU, USC	IEI, VU, USC	IEI, VU, USC	IEI, VU, USC	ORAU, LANL, IEI, VU, USC	IEI, VU, USC, ORAU
Report writing	ORAU, IEI, ORNL	RAC, IEI	IEI	IEI	ORAU, LANL, IEI, ORNL	All

Overall Project Objectives

The single most important question in radiation epidemiology is determining the level of risk associated with exposures that occur gradually over time. The nuclear reactor accident at Fukushima, Japan has emphasized the scientific and societal interest in understanding the health risks of low-level radiation exposures (Barcellos-Hoff 2011; Vano 2011; Normile 2011a, 2011b; Kaiser 2011; Stone 2011; Christodouleas 2011; Dauer 2011; Walsh 2011; Loomis 2011; Wakeford 2011b; Boice 2011c). Studies of occupationally and environmentally-exposed groups, however, have not been of sufficient size or quality to provide robust estimates of risk (NRC 2006; Wakeford 2005; ICRP 2007; UNSCEAR 2008; Boice 2010a, 2010b). Nonetheless, some studies have been interpreted as suggesting that chronic low dose rate exposures may be as harmful as the acute high dose rate exposures experienced by Japanese atomic bomb survivors (Jacob 2009; Cardis 2007b; Daniels 2011) that form the basis of radiation protection standards for workers and the public. The United States could provide substantial information on low dose rate risks but unfortunately has fallen seriously behind in studying the U.S. occupationally-exposed populations (Wakeford 2009). To fill the gaps in knowledge about health effects associated with low-dose ionizing radiation, a study of one million U.S. radiation workers and veterans is proposed (Boice 2011a). The study is cost efficient in that it builds on the investments made and foundations laid by investigators and government agencies over the past 30-40 years which have established radiation worker cohorts that, upon completion of the proposed research, can now provide precise answers to questions on the lifetime human health risks associated with low-level radiation exposures.

The United States was one of the first countries to develop both nuclear weapons and nuclear power reactors to generate electricity and fuel military ships and submarines. The early workers of the nuclear age can be followed for up to 60 years and late effects evaluated. We propose to ascertain the mortality experience through 2012 of five occupational groups with differing radiation exposure patterns: (1) uranium workers at multiple Department of Energy (DOE) locations and Rocketdyne; (2) nuclear weapons test participants (atomic veterans); (3) radiologists, other medical practitioners and industrial radiographers; (4) nuclear power plant (NPP) workers; and (5) plutonium workers at multiple DOE locations. The sizes of these occupational groups are large: the early uranium cohorts, many from the Manhattan Project era, comprise 200,000 workers; well over 120,000 atomic veterans participated in above ground nuclear weapons tests in Nevada and the Pacific in the 1940s and 1950s; dosimetry files with cumulative radiation exposure information exist for over 400,000 early medical and other radiation workers; over 212,000 workers employed prior to 1984 at NPPs with dose information have been identified; and over 156,000 plutonium workers can be studied.

The Pilot study has assembled the targeted cohorts and a unique opportunity now exists to evaluate one million U.S. radiation workers and veterans, follow them to the present, reconstruct their radiation doses (including inhaled or ingested radionuclides), and provide new knowledge on the level of risk from low-level radiation experienced gradually and up to 60 years ago. The methods are patterned after the comprehensive approach used to study the workers at Rocketdyne/Atomics International (Boice 2006a, 2006b, 2011b; Leggett 2005).

The significance of the proposed study is considerable because it applies directly to existing concerns about and standards for chronic radiation exposure relevant to the protection of workers and the public. Much knowledge has been gained from the study of atomic bomb survivors, but the single exposure was acute to a Japanese population living in a war-torn country in 1945. It is challenging to generalize these results to current populations with substantially different circumstances, i.e., healthier, better health care, ethnic and risk factor differences, and lifestyle differences. Scientific and medical committees continue to grapple with how best to estimate risks associated with the gradual exposures received from environmental, medical and occupational

radiation (ICRP 2005; NRC 2006; Tubiana 2006; UNSCEAR 2008; Gilbert 2009; HLEG 2009; Goodhead 2009; Shore 2009). Some studies, though limited, have suggested that chronic exposures may be more hazardous than currently accepted (Jacob 2009; Cardis 2007a, 2007b; Daniels 2011). Governmental agencies tackle the complex issues of compensating prior workers, veterans and citizens potentially harmed by past exposures (NRC 2003, 2005; Wakeford 2006; Kocher 2008). Protection committees agonize over how best to estimate and apply a "dose and dose rate effectiveness factor" (DDREF) to scale the risks from the bomb survivor data for relevant and current circumstances (NRC 2006; ICRP 2007; UNSCEAR 2008; Tenforde 2008; Wakeford 2010; Brooks 2011). The remarkable increase in population medical exposures to CT scans and other imaging technologies (Mettler 2008; NCRP 2009) has raised concerns about possible future health consequences (Brenner and Hall 2007; ASA 2011). The million U.S. radiation worker and veteran study addresses all these issues while providing direct estimates of risk following the types of radiation exposures of current concern to workers and the public.

Evaluation of risk among persons with intakes of radioactive substances also assumes greater importance as society debates expansion of nuclear energy and deals with nuclear waste and other uses of radioactive materials (Corradini 2011). Knowledge of the effects of internal exposures to radioactive substances takes on increased importance in light of the possibility of terrorist attacks with nuclear devices (Radioactive Dispersal Devices, Improvised Nuclear Devices) (NCRP 2001; ICRP 2005; González 2005; IOM 2009). Finally, the study will be a service to American workers and veterans and their families by providing a sound understanding of the risks they may have incurred while working in service to their country.

The urgent need for such a comprehensive study was emphasized in a DOE-supported Workshop on Low-Dose Radiation Epidemiology (Hall 2009). *"There is a pressing need, and a golden opportunity, to obtain more information on the long-term effects of relatively low radiation doses, delivered over protracted periods by pooling and updating the data for the various groups of occupationally exposed U.S. nuclear workers. This represents a large and relatively untapped database. In the long run this could become an international effort by integrating these data with studies from around the world. With the large increase in the use of diagnostic radiation, large studies with good dosimetry of both patients and medical personnel can also contribute much-needed data."* In light of the Fukushima Daiichi nuclear reactor accident, the FY 2012 Senate Appropriations Bill for the Department of Energy: Science (http://www.aip.org/fyi/2011/109.html) confirmed the need for further research to evaluate "health risks from exposures to low levels of ionizing radiation to properly protect radiation workers and the general public". We are poised, ready and enthusiastic about fulfilling these recommendations and restoring the United States as a leader in occupational studies of radiation.

The recently conducted Pilot study (see Progress Report) demonstrated that the proposed study is feasible. A cohort of one million U.S. workers and veterans was identified that is ten times larger than the atomic bomb survivor study (Douple 2011; Preston 2004), has more high-dose subjects (>10 rem) and many more deaths. The large size and broad dose distribution indicate the substantial statistical power available to evaluate low-dose rate radiation effects. In addition, following peer review of a separate grant application, NIH awarded funds for the atomic veterans component of the million person cohort, thus enabling us to reduce the funds requested to carry out the full-scale study. Our specific goals are described below as six independent and complementary aims or research thrusts that could be funded in total, separately, or in various combinations.

Aim 1. Department of Energy and Rocketdyne Uranium Workers (200,000). The Rocketdyne and 13 individual DOE worker cohorts involved with the Manhattan Project and subsequent development of nuclear weapons and reactor materials are ready for immediate study. Many of these cohorts have not been evaluated for over 30 years and the proposed extended follow-up, coupled with comprehensive dose reconstruction, will enable estimation of nearly lifetime risks of

cancer and other diseases associated with protracted low-level radiation exposure and propel the United States once again to the forefront of occupational study research (Hall 2009; Wakeford 2009). The study would provide critical information on effects following chronic exposure and on the DDREF used in radiation protection (ICRP 2007; UNSCEAR 2008; Canu 2008).

Aim 2. Department of Defense Atomic Veterans (120,000). The United States conducted 230 aboveground nuclear detonations from 1945 through 1962. Over 120,000 veterans were previously studied by the Department of Veterans Affairs (Dalager 2000; Watanabe 1995b) and the Medical Follow-Up Agency of the Institute of Medicine (IOM 1996, 2000). The study population consists of veterans who participated at any of eight nuclear weapons test series, including Trinity the first nuclear bomb detonation in1945. Statistical increases in leukemia were reported as were excesses of several other cancers, including bone, thyroid, salivary gland, liver and breast. However, no dose assessments for epidemiologic study were made and the last follow-up was 15 years ago. An extended follow-up coupled with dose reconstruction of individual veterans who developed leukemia and other cancers not previously studied would provide important quantitative information on the level of risk possible from prolonged exposures to radiation experienced up to 60 years ago. NIH has award a grant to evaluate a portion of the cancer cases (but not all those in excess) which allowed us to reduce the funds request for the current proposal.

Aim 3. Other Radiation Workers, including Radiologists, Radiotherapists, Other Medical Professionals and Industrial Radiographers (400,000). Landauer, Inc. has provided radiation dosimetry services since 1953 for United States medical and other facilities. A computerized database of 15 million workers is maintained with identifiers and cumulative doses. Included in the database are radiologists, radiotherapists, cardiologists, others in the medical profession and industrial radiographers who experienced frequent radiation exposures during the course of their employment. The Nuclear Regulatory Commission (NRC) REIRS database also includes industrial radiographers. These dosimetry records can be used for epidemiologic study by selecting and following the approximately 400,000 workers with relatively complete and long-term dosimetry coverage over time. This provides a complementary component to the overall program by including a large number of medically-exposed workers. The study is designed not to overlap with other investigations of medical radiological technicians (Boice 1992; Mohan 2003), but to focus on potentially higher-exposed workers such as interventional radiologists with measured exposures. The Pilot study evaluated a sample of 77,000 of these "other" radiation workers who had received > 5 rem and determined the feasibility of studying the larger cohort.

Aim 4. Nuclear Power Plant (NPP) (212,000 Workers). The U.S. developed nuclear reactors to produce electricity as early as 1957. There are over 650,000 past and current utility workers. Early workers were allowed 3 rem/quarter and 12 rem/year. Landauer records (Muirhead 1996) supplemented with NRC REIRS records have identified over 212,000 NPP workers employed prior to 1984. Additional early workers can be identified from microfilm dosimetry records. These early NPP workers will provide needed information above and beyond that produced by a smaller study of 54,000 NPP workers (Howe 2004) which was limited due to the young age of the cohort, the small number of deaths and low cumulative radiation doses. A reported association with heart disease (Howe 2004) needs to be evaluated in a more powerful study as we propose (Little 2008; Darby 2010).

Aim 5. Department of Energy Plutonium Workers (150,000). Over 150,000 workers with potential for plutonium exposure have been assembled from cohorts at Los Alamos National Laboratory, Rocky Flats, Hanford, Mound and several other facilities (Gilbert 1993a; Wiggs 1991, 1994; Daugherty 2001). These workers were last followed between 1979 - 1990 and extending their follow-up to the present would provide needed quantitative information on the long-term risks possibly associated with inhalation or ingestion of plutonium and other radionuclides. The Mound cohort, for example, offered an opportunity to study not only plutonium but also polonium, a

compound which received interest in light of the poisoning of the Russian national in the U.K. (Harrison 2007) and because it is a component of tobacco smoke (Rego 2011).

Aim 6. Combined cohort analyses. The pooled analysis of the combined data from all these studies will maximize statistical power to detect and characterize radiation effects, and to minimize the variability of the estimates of these effects. The study is over ten times as large as the Japanese study of atomic bomb survivors and already has identified more relatively high-dose persons who received > 10 rem cumulative dose. Generalized proportional hazards regression modeling of mortality data from the combined cohorts will allowing for the time-dependent nature of the exposures and of effect modification variables such as age at exposure, time since exposure, and exposure dose rate. Analyses will utilize the best estimates of both external and internal (where grouped estimates will be used) radiation exposures and will provide uncertainty analysis that reflect likely errors in dose estimation particularly for internal dose (NCRP 2008, 2009, 2010).

The integration of these U.S. worker and military populations would unquestionably provide the most definitive evaluation possible of risks associated with low-dose radiation exposures experienced over a prolonged period of time, and thus have implications with regard to protection standards for workers and the general population, the assessment of risk associated with the enhanced medical technologies such as CT scans, the assessment of health risks associated with radiation accidents such as Chernobyl and Fukushima, the expansion of nuclear power, the handling of nuclear waste and the compensation of workers with prior exposures to ionizing radiation.

Co-Investigators

International Epidemiology Institute: John Boice (radiation epidemiology), William Blot (epidemiology), Joseph McLaughlin (epidemiology) Bob Tarone (biostatistics), Clark Heath (epidemiology), Sarah Cohen (biostatistics)
Oak Ridge Associated Universities: Betsy Ellis Dupree, Donna Cragle, Phil Wallace, Janice Watkins, Dick Toohey, Bill Tankersley, Derek Hagemeyer
Oak Ridge National Laboratory: Rich Leggett and Keith Eckerman (radiation dosimetry)
Los Alamos National Lab: Laurie Wiggs (radiation epidemiology)
Harvard University: Howard Sesso (cardiology)
Risk Assessment Corporation: John Till, Harold Beck, Paul Voillequé, Helen Grogan (dosimetry)
Landauer, Inc.: Craig Yoder (dosimetry systems)
University of Southern California: Dan Stram (biostatistics), Duncan Thomas (biostatistics)
Vanderbilt University: Randy Brill (radiation effects), Yu Shyr and William Wu (biostatistics)
Advisors: Richard Wakeford (University of Manchester, U.K.), Roy Shore (RERF, Japan), Andre Bouville (National Cancer Institute, USA)

Proposal Overview

In this proposal we describe research studies of five occupational groups: uranium workers; veterans exposed to atomic bomb atmospheric tests; radiologists and other radiation workers; nuclear power plant (NPP) workers; and plutonium workers. Study of each group involves the extended and long-term follow up for cancer or other causes of mortality of previously identified radiation-exposed cohorts, the reconstruction of individualized estimates of cumulative radiation doses and the evaluation of dose-response relationships. Study of each group addresses a different aspect of radiation-related cancer because of the varying types (e.g., internal uptakes and external exposures), durations, and/or levels of radiation dose across the cohorts. In combination, the proposed research among one million radiation workers and veterans will provide the greatest precision yet available for the evaluation of long-term health effects of low-dose ionizing radiation.

The novel features of the studies of the five groups are described below in five Aims corresponding to the five groups to be studied. Most detail is provided for Aim 1, since the others share many of the same methodologies as in the study of uranium workers. The final and sixth Aim then describes the planned combined analysis, and summarizes the usefulness of the research for advancing knowledge of risks of cancer and other diseases among workers chronically exposed to low radiation levels.

Institutional Review Board approvals for the proposed studies have been received and various other approvals have been received from the Department of Energy, the Department of Defense, the Department of Veterans Affairs and the Nuclear Regulatory Commission (Appendix 6).

We reiterate that a successful Pilot study was conducted (see Progress Report at the end of this NARRATIVE) which confirmed not only that the proposed study is feasible but that it is even more statistically powerful than originally suspected with more relatively high dose workers (> 10 rem) already identified than in the study of Japanese atomic bomb survivors.

Aim 1 - Uranium Workers

We propose the long-term follow up for cancer mortality and other health outcomes of occupational cohorts comprising nearly 200,000 uranium workers. Most worked at Department of Energy (DOE) facilities and were included in prior DOE research which generally was completed over two decades ago.

Despite some reassuring data to date, concerns about the limitations of existing studies and the potential for adverse health effects associated with uranium exposure persist. Weaknesses of previous research studies include low statistical power, inaccurate assessment of internal exposure to uranium and limited follow-up (Canu 2008, 2010a). To remedy these shortcomings, a systematic long-term assessment of cancer and other disease mortality among large numbers of uranium-exposed workers, with adequate exposure measurement, is needed.

During the early years of uranium processing, enrichment, manufacturing and milling, aboveground workers had the potential to inhale or ingest uranium dust with minimal exposure to radon gas (UNSCEAR 2008). Well over 120,000 of these workers have been studied and, overall, no consistent elevations in cancer risk were observed (Harley 1999; U.K. Royal Society 2001; IOM 2001, 2008; NRC 2008; McGeoghegan and Binks 2000a, 2000b). Because of its long half-life, solubility properties and lack of significant associations in epidemiologic studies to date, uranium has not been classified as a human carcinogen (IARC 2001). Recent studies of uranium millers have found increases in some cancers and nonmalignant disease but no

consistent associations with duration of employment (Boice 2008; Pinkerton 2004). Studies of workers with estimates of organ doses from uranium intakes reported only suggestive evidence of dose-response relationships (Dupree 1995; Boice 2006a, 2011b). Analyses of Oak Ridge workers followed through 1990, however, suggest an association between cumulative dose and lung cancer (Richardson and Wing 2006) and of leukemia in a combined series (Schubauer-Berigan 2007). A case-control study of multiple myeloma reported an association with internal uranium exposures based on urine samples (Yin 2009). In contrast, studies of underground uranium miners have revealed consistent and substantial increases in lung cancer attributed to radon gas and its decay products (NRC 1999).

Recent reviews of studies of uranium-exposed workers recommend that additional research be undertaken to clarify the existence, nature and level of cancer and other health risks associated with uranium intakes (Canu 2008). Uranium from reprocessing of irradiated fuel is more radioactive than natural uranium because of contaminants such as uranium-232, which has a half-life of 72 years (Canu 2010b). Furthermore, the possible chemical toxicity of natural or low-enriched uranium, a heavy metal, has been considered more important for human health than the risk of cancer from its radioactive properties (Leggett 1989). Ingesting large amounts of uranium might cause kidney damage because the kidney is involved in removing uranium from the body. Permanent renal disease has rarely been observed in humans, although changes in kidney function have been reported to be associated with uranium compounds (Kathren and Moore 1986; Kathren and Burklin 2008; McDiarmid 2007; Kurttio 2006a;IOM 2000; Royal Society 2001; NRC 2008). In Finland, environmental exposures to high intakes of uranium, radium, radon and other radionuclides in drinking water were not associated with increased rates of cancers of the bladder, kidney or stomach, or of leukemia (Auvinen 2002, 2005; Kurttio 2006b).

The Rocketdyne (Atomics International) study exemplifies the approach to be taken in the study of uranium workers. Potential exposures were from a variety of sources including ten research nuclear reactors, seven criticality test facilities, and other activities such as fabricating nuclear fuel, disassembling and decontaminating reactor facilities, decladding spent nuclear fuel and storing nuclear material. Enriched uranium and plutonium fuels were fabricated for research, space and power reactors. Results of analyses of mortality data on 5,801 workers employed at Rocketdyne (Atomics International) during 1948-1999 were reported in 2006 (Boice 2006a) and most recently in 2011 (Boice 2011b). A comprehensive dose reconstruction program incorporated lifetime occupational doses received at all places of employment into the analyses as well as internal doses from radionuclide intakes (Leggett 2005; Boice 2011b). For all leukemia excluding CLL the RR at 100 mSv was increased (1.06; 95% CI 0.50-2.23) and for all cancers excluding leukemia it was 0.98 (95% CI 0.82-1.17). An extended follow-up will add five years of observations during the ages later in life when cancer rates are increasing.

The proposed extended follow-up of much larger groups of workers, coupled with comprehensive dose reconstruction, will propel the United States once again to the forefront of occupational radiation research (Hall 2009; Wakeford 2009). The risk of cancer and chronic diseases, including coronary heart disease (Little 2008; Muirhead 2009; Darby 2010; Shimizu 2010), possibly associated with prolonged low-dose exposures accumulating to levels for which effects conceivably could be detected would provide critical information on radiation effects and on the Dose and Dose-Rate Effectiveness Factor used in radiation protection (ICRP 2007; UNSCEAR 2008; Canu 2008, 2010a). This research will address directly recent claims that chronic low dose rate exposures may be similar or more hazardous than the acute high dose rate exposures that form the basis of current radiation protection standards (Jacob 2009; Cardis 2005, 2007a, 2007b; Krestinina 2007; Daniels 2011).

METHODS

We propose to follow methods similar to those in the recently completed a study of uranium exposed workers at Rocketdyne (Atomics International) (Boice 2006a, 2006b, 2011b; Leggett 2005). We will apply this methodology to additional uranium worker populations to provide quantitative information on the long-term risk of cancer and other diseases following chronic low-dose radiation exposures, with emphasis on the uranium intakes. The study will seek lifetime occupational exposure information and will provide quantitative assessments of the risks of inhaled or ingested uranium. Strengths include the large study size, the inclusion of more female and non-white workers than previously studied, use of the established Rocketdyne model for dose reconstruction, and the very long (up to 60 years) follow up.

Table 1-1. Studies of uranium workers

Worker cohort	No.	Relevant publication/s	Last follow-up	No. dead	Comment	Total in database
Oak Ridge Segment	106,020	Frome 1997	Not given	27,982	All Oak Ridge	
K-25	35,712	Dupree 1994	1989	12,848	White males	49,794
X-10	6,348	Gilbert 1993; Cardis 1995	1984	1,246		28,528
Y-12 (TEC)	18,869	Polednak 1981	1977	5,394	White males	41,107
Y-12 (UCCND)	8,116	Loomis 1996	1990	1,861	Electromagnetic enrichment	26,059
Portsmouth Gaseous Diffusion	9,215	Rinsky 2001	1991	1,275	Enriched uranium	9,308
Paducah	6,820	Reinhart APHA 2007	2003	1,672	Gaseous diffusion	5,731
Manhattan Engineering District (Uranium)						
Niagara Frontier						
Harshaw, Electromet, Bethlehem	N/A	None			Never studied	1,144
Linde	995	Dupree 1987	1979	429	Employed 1943-49	1,551
Middlesex	N/A	None			Never studied	387
FMPC (Fernald)	4,014	Cragle 1996; Ritz1999; CEDR	1989	1,064	White males	7,337
MCW (Mallinckrodt)	2,514	Dupree 2000	1993	1,013	White males	3,272
SRS (uranium processing)	18,883	Richardson 2007; Cragle 1988	2002	5,096	Internal exposure to U, H3	21,509
Pantex (Weapons assembly)	4,668	Silver 2005; Acquavella 1985	1995	1,031	Min U, possible control	12,670
Rocketdyne (Atomics International)	5,801	Boice 2006a, 2006b	1999	1,468	Comprehensive dosimetry	5,801
Sum of unique workers				62,379		**202,990***

* Because workers may be in more than one cohort, the individual sites sum to more than the total which is for unique workers.

Cohort identification. The population to be studied will be comprised of uranium workers from the cohorts shown in Table 1-1. Included are workers participating in prior DOE Health and Mortality Studies, along with the recently studied cohort of Rocketdyne (Atomics International) workers. Workers to be included in the new combined cohort will be those with sufficient information to conduct the mortality follow-up and comprehensive dose evaluations. In total 202,990 workers have already been identified and will form the study base population for extended observation. Because workers were often employed at more than one facility, linkages with all worker and dosimetry (e.g., REMS) databases will determine duration of employment and career dose accurately. Characteristics of the combined cohorts of uranium workers are shown in Table 1-2.

Health outcome determination. Updated mortality and vital status as of December 31, 2012 for the radiation workers will be determined from various linkages of the study rosters with national databases including the National Death Index (NDI) (1979+), the Social Security Administration (SSA) Death Master File and other SSA files (1960+), the California Death Statistical Master File (1960+) and Comserv, a computer services firm specializing in locating persons. SSA files and LexisNexis searches will confirm vital status for those alive. For linkage with the SSA Master Death File of over 83 million deaths, and for state mortality tapes we have acquired (e.g., California, Florida, Texas, Ohio, New Jersey), probabilistic matching analyses will be conducted to account for the possibility that there might be errors or incomplete information in names, dates of birth or social security numbers. LinkPlus from CDC will be used (Campbell 2008). These programs also have unique "de-duplication" features, i.e., datasets can be

evaluated to identify possible duplicate subjects who have been entered more than once with slightly different identifying information. Cause of death will be determined mainly from NDI matches since causes deaths prior to 1979 when the NDI began have already been obtained in large part in previous studies.

Table 1-2. Characteristics of the combined uranium worker cohorts

Characteristic	N	%	Characteristic	N	%
Gender			1970-1979	15,538	7.7
Male	139,900	68.9	1980-1989	15,402	7.6
Female	51,836	25.5	1990+	7,997	3.9
Unknown (currently)	11,254	5.5	Unknown (currently)	53,250	26.2
Race			**DOE employment duration**		
White	172,045	84.8	<3 months	31,032	15.3
Non-white	15,359	7.6	3-6 months	14,686	7.2
Unknown (currently)	15,586	7.7	6 months - 1 year	15,907	7.8
Pay type			1 - 4.9 years	46,656	23.0
Hourly/non-exempt/weekly	78,579	38.7	5 - 9.9 years	12,235	6.0
Salaried/exempt/monthly	78,858	38.7	10 - 19.9 years	11,730	5.8
Unknown (currently)	45,826	22.6	20 - 29.9 years	8,326	4.1
Year of birth			30+ years	8,021	4.0
<1900	9,603	4.7	Unknown (currently	43,597	26.8
1900-1909	18,399	9.1	**SSN known**		
1910-1919	36,761	18.1	Yes	200,667	98.9
1920-1929	56,755	28.0	No (currently)	2,323	1.1
1930-1939	23,824	11.7	**Vital status**		
1940-1949	21,831	10.8	Known alive	75,617	37.3
1950-1959	22,450	11.1	Dead	107,187	52.8
1960-1969	8,536	4.2	Unknown (currently)	20,186	9.9
1970+	1,825	0.9			
Year of hire			**Among N=74,947 known dead:**		
<1940	99	0.05	**Year of death**		
1940-1949	85,811	42.3	1940-1949	1,183	1.6
1950-1959	34,937	17.2	1950-1959	4,498	6.0
1960-1969	16,922	8.3	1960-1969	9,673	12.9
1970-1979	19,463	9.6	1970-1970	15,289	20.4
1980-1989	13,479	6.6	1980-1989	18,855	25.2
1990+	4,711	2.3	1990-1999	6,602	9.0
Unknown (currently)	27,568	13.6	2000-2009	2,709	3.6
Year of Termination			Unknown (currently)	16,138	21.5
1940-1949	72,936	35.9	**Cause of death**		
1950-1959	19,031	9.4	Known	54,986	73.4
1960-1969	18,836	9.3	Unknown (currently)	19,961	26.6

Given that uranium exposure would include depositions in certain organs, there is an *a priori* interest in mortality from lung cancer, nonmalignant respiratory disease, kidney cancer, non-malignant renal disease, liver cancer and bone cancer. Also, because of the current scientific interest in the possibility that heart disease may be related to radiation doses lower than previously thought likely, evaluation of coronary heart disease and ischemic heart disease mortality will be made (Preston 2003; Howe 2004; Little 2008; Muirhead 2009; Shimizu 2010).

Linkage with the Centers for Medicine and Medicaid Services (CMS) claims data will be investigated as a possible way to supplement identification of chronic health conditions. The Medicare files contain information on hospitalizations and other medical encounters for nearly all persons age 65 and older in the United States. Since most Rocketdyne and DOE former employees are over the age of 65, the Medicare files could provide a unique resource for ascertainment of multiple health outcomes. The Medicare files include complete inpatient and outpatient stay records beginning in 1999.

Similar to a previous study of uranium millers (Pinkerton 2004), we received approval to link with the US Renal Data System to identify nonmalignant kidney disease from 1977. Preliminary returns revealed that at least 1% of our population had been reported to this system.

Exposure classification and dose determination. We will seek to capture career doses from external radiation and to compute organ doses from internal uranium and other radionuclide exposures. Essentially there will be four aspects to the approach for dose determination among the uranium workers. First, there will be an attempt to capture all uranium intakes and other internal and external radiation received at all DOE and other facilities as done in the Rocketdyne study. Record linkage will be attempted within the DOE worker facilities (the REMS database; approval to link against the DOE REMS database has already been received), the NRC databases (approval to link with the NRC REIRS database has already been received), the Landauer Inc. commercial dosimetry company database, the U.S. military dosimetry databases (U.S. Army, U.S. Air Force, U.S. Navy and the Defense Threat Reduction Agency (DTRA) of the Department of Defense), and other individual sites as possible and as described in detail in the Rocketdyne dosimetry paper (Boice 2006a). For many DOE sites, there will be internal dosimetry data as well as external dosimetry data. For example, more than 250,000 bioassays were available and processed for the Mound feasibility study. Linkages with the Landauer, Inc. database, the largest such occupational database in the United States, have been conducted and revealed internal doses for 4,213 workers. These additional doses were recorded from 1947 through 2009 and ranged up to 135.5 rem (5% >5 rem). For the Rocketdyne workers, linkages with other dosimetry databases revealed that 32% had received radiation exposures elsewhere and showed the importance of capturing lifetime career doses (Boice 2006b).

Second, there will be a comprehensive evaluation of internal radionuclide exposures following the approach described in the Rocketdyne (Atomics International) dosimetry papers (Boice 2006b; Leggett 2005). Essentially all individuals monitored for uranium and other radionuclides will be identified on the basis of urinalysis results, whole body counts, lung counts and other sources of monitoring data. Workers with positive measurements will be identified. A screening level will then be determined to select which levels of radionuclide intake might be associated with meaningful deposition and organ dose. In the Rocketdyne study, this was taken as 10 mSv committed dose to the organ that would receive the highest dose. The ICRP models will then be used to compute annual organ doses that can be incorporated into the epidemiologic analyses. In the Rocketdyne study, radiation doses from internal intakes of 14 different radionuclides were calculated for 16 organs or tissues using biokinetic models of the ICRP. The radionuclides with documented intakes included isotopes of uranium, plutonium, americium, calcium, cesium, cerium, zirconium, thorium, polonium, promethium, iodine, zinc, strontium and hydrogen (tritium). The Mound feasibility study computed organ doses for workers exposed to tritium and polonium.

Thirdly, it is possible that we will be able to incorporate the comprehensive approach developed by ORAU for dose reconstruction in association with the EEOICPA and by DTRA with the veterans' compensation programs (www.orau.org/busops/oews/raddata-doserecon.htm; NRC 2003). The radiation environment for practically all DOE facilities has effectively been characterized and individual doses computed for the purposes of compensation. Procedures will be modified to be acceptable for epidemiologic purposes, i.e., to provide best estimates of dose rather than claimant-favorable estimates. For the Mound feasibility study, the dose reconstructions and bioassays available for polonium and plutonium intakes were provided, i.e., additional bioassay results were obtained through the PORECON (Polonium Reconstruction) and PURECON (Plutonium Reconstruction) databases that had been created at the Mound Laboratory from logbooks and other original hard-copy records.

Fourthly, the uncertainties of the dosimetry approaches will be evaluated following the methods recently published with regard to external radiation (Gilbert 2006; Schafer and Gilbert, 2006; NCRP 2008). For internal dose uncertainties the methods of Stram and Kopecky (2003) and NCRP (2009, 2010) will be followed. The uncertainties associated with radionuclide deposition

and organ dose determination are complex and involve many variables such as the timing and frequency of bioassays, the sensitivity of the bioassay test, the accuracy of the biokinetic models, and other assumptions that are used. For some of the more complicated exposure scenarios with likely high doses, the uncertainty will be bounded by Monte Carlo simulations (NRC 2003; Raine 2007). A Monte Carlo simulation can also be used to propagate estimated uncertainties in the various contributions to the dose (Kopecky 2004). A subcommittee on dosimetry to review and evaluate these approaches will include Dan Stram, Keith Eckerman, Ken Kopecky, Rich Leggett, Dick Toohey, John Till, Duncan Thomas and Andre Bouville.

Study size and statistical power. A rough estimate of study size and statistical power to uncover a radiation effect is presented. Approximately 200,000 DOE workers are available for study and approximately 62,000 deaths had been identified prior to the Pilot study (Table 1-1). Because of the age characteristics of these early workers, some first employed as early as 1943, it can be roughly estimated that approximately 60%, or 120,000 deaths, will have occurred by December 31, 2012, of which about 30,000 will be from cancer. These numbers are consistent with our Pilot study which found 104,186 deaths among 194,284 uranium workers, excluding those who worked at Mound.

Table 1-3. Detectable relative risks and associated power for leukemia and other cancers, contrasting the exposed workers (> 10 mSv) with the lowest exposed workers (< 1 mSv). Baseline rates in parentheses.

RR	Leukemia (1.3%)	Lung (6.4%)	Bone (0.07%)	Kidney (1.3%)	Liver (0.53%)	NHL (1.9%)
1.2	0.89	0.99	0.18	0.93	0.65	0.98
1.3	0.99	0.99	0.29	0.99	0.91	0.99
1.4	0.99	0.99	0.41	0.99	0.99	0.99
1.5	0.99	0.99	0.54	0.99	0.99	0.99
2.0	0.99	0.99	0.94	0.99	0.99	0.99

The power values are given in Table 1-3 for a one-sided 5% nominal significance level. Baseline rates are from the American Cancer Society and SEER cumulative cancer probability tables for males (ACS 2008) up to age 85 years. The estimate of the number of workers exposed and non-exposed is taken from Frome (1997). The referent group for the purposes of these power computations is taken as the 118,000 workers estimated to have received <1 mSv (0.10 rem). The "highest" exposed group for these computations is taken as the 26,000 workers estimated to have received >10 mSv (1 rem). The incorporation of internal doses as well as career doses received elsewhere would increase the numbers in the higher exposure levels, and thus the power computations are conservative. Power is greater than 80% to detect relative risks of the order of 1.2 for leukemia, lung cancer, kidney cancer and NHL, 1.3 for liver cancer; and 2.0 for bone cancer.

Study power is sufficient to detect even modest increases in risk for leukemia and cancers of the lung and kidney and NHL. Power is recognized to be less for rare cancers such as bone. As mentioned, attempts to identify cancer incidences among those over age 65 years will be pursued using Medicare file linkages available from 1999 and with selected state cancer registries. Power to detect increases for these outcomes, however, depends on the organ dose which is influenced by radionuclide intakes, e.g., uranium for lung, bone and liver, which are yet to be determined.

Analyses. Both external and internal analyses will be conducted to estimate the relative risks (RR) of death from cancer and other diseases. Standardized mortality ratio (SMR) analyses will compare the numbers of deaths observed among cohort members with the numbers expected based on general population rates for persons of the same age, race and sex over the same time periods (Marsh 1998). Internal analyses will apply proportional hazards regression models comparing non-exposed workers to radiation workers over categories of estimated radiation dose to specific organs. Multiplicative risk models (Cox 1972) or the linear excess relative risk model -- which is standard in radiation epidemiology (Preston 1993) -- are among those that will

be used to estimate excess risk due to radiation. The external SMR analyses will be based on the underlying cause of death as coded from the death certificate which is standard practice in epidemiological studies as underlying causes of death are thought to be recorded in a more systematic fashion across time and physicians than 'associated' causes. However, for the internal proportional hazards analyses, the contributing causes of death will be included for additional statistical power since the likelihood of systematic bias is small. The latter approach was used in the Mound study. For workers of unknown race, a weighted approximation based on the proportions of race for the workers with known race will be used to compute expected numbers. In some analyses exposures will be lagged 10 years for solid cancers and 2 years for leukemia, i.e., exposures occurring in these intervals prior to end of follow-up will be excluded. Observed and expected numbers of deaths will be distributed over categories of external radiation dose and trend analyses conducted following the methods of Breslow and colleagues (Breslow 1983).

Internal comparisons, which are expected to minimize any biases that might exist when external comparisons with a general population are made, will be carried out. Year of birth, year of hire, sex, pay type (hourly/salary), and duration of employment will be sought for inclusion in all models. Pay type is considered a surrogate measure of socio-economic status, and an indirect control of smoking (Boice 2006a). For the internal analyses, radiation workers will enter the risk set at their first date of radiation monitoring plus six months. Workers not monitored for radiation will enter the risk set at their first date of hire plus six months. Radiation exposure category will be treated as a time-dependent covariate, allowing workers to be assigned to increasingly higher dose categories over time as their individual radiation doses accrued. Parameter estimates and standard errors for the exposure categories in the Cox models will be used to obtain risk (or hazard) ratios and confidence intervals for death due to the cause under investigation compared to those in the referent group. Trend tests will treat the radiation dose as a single, time-dependent continuous measure, and one-sided p-values will be presented unless otherwise stated. Relative risks at 100 mSv will be computed for all cancers excluding leukemia, all leukemia excluding CLL and lung cancer.

Dose errors. Doses for monitored workers have inherent uncertainty, especially for internal dose. Our approach to uncertainty in dose estimation is based upon methods described by Prentice (1982) and by Stram and Kopecky (2003) who distinguish between the effects of shared and unshared dose errors and between multiplicative and additive errors. For a test of a null hypothesis (of no dose effect) a single best estimate of dose for each worker is used in the proportional hazards analyses detailed above. More elaborate dose error methods may be required when constructing point estimates and confidence limits for effect estimates especially when shared errors in dose reconstruction exist (Stram and Kopecky 2003). The comprehensive approaches outline in recent NCRP (2008, 2009, 2010) reports will also be considered to address the uncertainties in external and internal exposure estimation.

Socioeconomic status (SES). Interpretation of study results will be based primarily on internal comparisons of mortality by level of radiation dose. A possible source of bias is that the socioeconomic characteristics of workers performing jobs involving occupational radiation exposure may have been different from those of workers performing other jobs. Accordingly, SES will be characterized and adjustments made by pay type (salaried managerial/professional, salaried technical/administrative, hourly union), and possibly pay-code (monthly, weekly, hourly).

Smoking information. Although detailed smoking information is not available for all workers, several occupational studies have in fact determined smoking histories based on information in occupational health questionnaires and medical records (Mahoney 1987; Petersen 1990;

Dupree 1995; Brown 2004). In one investigation (Mahoney 1987), questionnaires from 1978 were available that asked

- Do you now regularly smoke a pipe, cigars or cigarettes?
- Are you now regularly smoking cigarettes < 1 pack/day, between 1 & 2 packs/day, over 2 packs /day
- How long did you smoke cigarettes <1 year; between 1 & 5 yrs, 5 &10 yrs, 10 &15 yrs, 15 & 20 yrs; over 20 yrs
- About how much did you smoke? <1 pack/day; between 1 & 2 packs/day; over 2 packs /day

The conclusion from our Pilot investigation was that, when available, occupational medical records appear to be a reasonable source of smoking data; within a facility, however, no standard set of smoking questions was used over time; the percent of a study population with smoking data identified varied but increased over time. While smoking was clearly identified as a risk factor for lung cancer, there was little evidence that smoking was associated with the level of cumulative radiation, although numbers were small. A sample of 300 Rocketdyne workers interviewed via a mail questionnaire, however, did indicate that blue collar workers were more likely to be or have been cigarette smokers indicating that importance of controlling for pay type in the analyses (Boice 2006b). Although not systematically collected, medical record information on smoking histories appear available for many of the DOE worker populations, particularly for those working after about 1978, and the archival records can be sought for those who developed lung cancer and a representative sample. Because of the large number of deaths, it is anticipated that a substantial number of lung cancer among non-smokers will be identified.

Medical records will not be available for all workers, however, and indirect methods will be used to evaluate and adjust for possible confounding by smoking. Pay type is often seen as a predictor of cancer risk with somewhat higher risks of cancers of the lung and other smoking-related sites found for hourly compared with salaried workers. Such a difference is often seen in occupational studies and has been attributed to higher prevalences of tobacco use among blue collar (hourly) compared with white collar (salaried) workers (Howe 1988; CDC 2004). During the last 2 decades, the prevalence of cigarette smoking has declined faster in the general population and among salaried workers than among hourly workers. Hourly workers continue to smoke in large numbers (Lee 2004; Howard 2004) and at a rate up to twice that of salaried workers (CDC 2004; Sorensen 2004). Any increases in lung cancer among blue collar (hourly) workers in comparison with the general population could reflect in part this non-comparability in tobacco use. We will control for pay type in the intracohort analyses to account for possible differences in socioeconomic and demographic characteristics of hourly and salaried workers and thus indirectly adjusted for smoking. We will also evaluate "smoking-related" cancers as an entity and compare risks with cancers that are not strongly linked to cigarette smoking. Possible increases of heart disease might also be associated with smoking (as suggested in the U.K. radiation worker registry study, Muirhead 2009) and these sites will be similarly evaluated. We note again that there have been a few DOE studies that obtained some information on smoking (e.g., Dupree 1995) and we will evaluate and incorporate such information as available.

Other potential confounders. Factors related to the healthy worker effect, particularly selection of workers on the basis of their health, may be strongest during the first years of employment, leading to unusually low death rates during this period (Gilbert 1989). Thus, the pattern of cancer risk in relation to time since first employment will be carefully evaluated. Duration of employment is also correlated with cumulative dose so, again, patterns of cancer risk by duration will be carefully evaluated. We recognize that other occupational exposures, e.g.,

chemical and asbestos, may have occurred but that any available exposure information will be much less detailed than for radiation. Nonetheless, to the extent possible, other occupational exposures will assessed, such as by considering job titles and departments in some detail. As above, adjustment for SES will be taken as an indirect approach to handling unknown lifestyle and other factors.

SUMMARY

The proposed study of over 200,000 uranium workers will extend the mortality follow-up of the previously studied cohorts, making no restrictions as to sex or race, and utilize internal and external dosimetry assessments following the Rocketdyne (Atomics International) model. Linkages for dosimetry will be made with other national dosimetry data bases such as the REMS dosimetry files maintained by DOE, the REIRS database maintained by NRC and others as described in the Rocketdyne (Atomics International) worker study to capture career occupational radiation exposure. These dosimetry linkages also will provide data on the extent to which workers left specific DOE facilities and were employed at other nuclear facilities. A focus on radionuclide internal doses is a main feature of the study and a comprehensive dose reconstruction approach using expertise from ORNL, ORAU, DTRA and other groups and agencies is planned. The wealth of dosimetry information (both external and internal) available within the NIOSH dose reconstruction programs will be accessed to the extent possible.

Aim 2 - Atomic Veterans

A follow-up study will be conducted of 120,000 military personnel who participated in nuclear weapons testing between 1945 and 1958. There are few if any populations that can provide such unique information on lifetime radiation risks among persons exposed over 60 years ago. The proliferating use of CT x-ray and radionuclide imaging (e.g., PET scans) has highlighted the need for reliable estimates of lifetime radiation risk following chronic low-dose exposures for which cumulative population doses could be substantial (ASA 2011; NCRP 2009; Hall and Brenner 2008; Brenner and Hall 2007). Further, evaluation of risks among persons with intakes of radioactive substances assumes greater importance as society debates expansion of nuclear energy and the disposal of nuclear waste, and copes with the possibility of terrorist attacks with "dirty bombs" and other nuclear devices (IOM 2009). There has been recent concern over the possible health effects from depleted uranium (IOM 2008) and from radioactive fallout to exposed populations (Merali 2009).

During the Pilot study, and NIH grant to study the atomic veterans was submitted and an award was made last year. While the NIH award has allowed us to reduce the levels of funds requested for the Full study proposed here, the funding level for the NIH grant was reduced by 25% and thus there is a need to request a smaller amount (reduced by 75% of our original request to DOE) to conduct the full research described below. There is no duplication of effort, just a complete dosimetry reconstruction of all selected cancer sites with reported excess (and not just for leukemia as currently restructured) and enhancing the follow-up capabilities to locate all 120,000 veterans.

We propose to follow the 120,000 soldiers, sailors, airmen and marines present at one or more of the 230 aboveground detonations for an additional 20 years since last studied. All cancers and other causes of death, including heart disease, will be evaluated. A comprehensive dose reconstruction methodology will be used to estimate doses for specific cancers previously found to be increased, e.g., leukemia (and cancers of the liver, bone, salivary gland, male breast and thyroid), and for a representative sample of the cohort for comparison. External radiation exposures have been estimated for all atomic veterans but are highly uncertain and require validation; dose reconstruction is required to include internal intakes of radionuclides.

The military codenames for the eight test series selected for study are shown in Table 2-1. The sites were selected because they had the highest recorded exposures (IOM 2000; Johnson 1996; Watanabe 1995b) or because of historical importance (the Trinity detonation in 1945 was the first testing of an atomic bomb). The earliest test participants were exposed in 1945 and their follow-up will be equivalent to that of the Japanese atomic bomb survivors exposed in 1945. The majority (nearly 70,000 to date) of test participants have now died. Significant elevations have been reported for leukemia and cancers of the liver, bone, salivary gland, male breast and thyroid, but evaluations by radiation dose were not possible. The Five Series study (IOM 2000), for example, included nearly 70,000 soldiers, sailors, and airmen who participated in one or more of five U.S. nuclear weapons test series in the 1950s and also included 65,000 comparable non-participants, or referents. Follow-up was through 1996. Participants and referents had similar low risks of death from cancer (SMR 0.74 for both groups), reflecting the "healthy soldier effect" (Seltzer 1974, 1977; Kang 1996). Leukemia, however, was increased among participants compared to the reference cohort (RR 1.15, n=185), and the excess among participants at the "ground-based" Nevada Test Site (NTS) was statistically significant (RR 1.49; 95% CI 1.04, 2.13). Previous studies have not provided details on the risk of heart disease among nuclear weapons test participants, although reported elevations, albeit small, were based on large numbers of deaths, e.g., RR 1.09 (n=504) in the U.K. study (Muirhead 2004) and in the Five Series study, RR 1.02 (n=6,970).

A unique aspect of the proposed study is that individual dose assignments will be "best estimates" and not based on veteran-favorable assumptions or approaches used in compensation program. New developments in statistical methodology also will be applied to account for the uncertainties in the reconstructed radiation doses (NCRP 2008, 2009, 2010; NRC 2003; Raine 2007). The Eight Series study thus provides a unique and timely opportunity to take advantage of existing radiation dose data on well-defined and previously studied veteran cohorts and to extend these data for epidemiologic lifetime risk assessment.

METHODS

Population identification. Seven cohorts of 120,000 military personnel (Table 2-1) have been carefully constructed and studied by the Medical Follow-Up Agency (MFUA) (Robinette 1985; Johnson 1996; IOM 2000) and the U.S. Department of Veterans Affairs (VA) (Watanabe 1995b). These individuals will form the study population whose recent mortality experience will be assessed.

Table 2-1. Number of participants at each of the seven nuclear weapon test series by military service. Military service was missing for 2 participants. These tests involved 99 bomb detonations.

Test series	Year	Test site	Air Force	Army	Marine Corps	Navy	Total
CROSSROADS	1946	Pacific	0	3,395	551	39,188	43,134
GREENHOUSE	1951	Pacific	2,442	1,548	70	3,854	7,914
UPSHOT-KNOTHOLE	1953	Nevada	2,175	13,401	2,256	886	18,718
CASTLE	1954	Pacific	2,763	1,644	306	11,918	16,631
REDWING	1956	Pacific	2,976	1,708	250	6,993	11,927
PLUMBBOB	1957	Nevada	2,216	7,052	2,120	601	11,989
HARDTACK I	1958	Nevada	3,476	1,535	187	9,487	14,685
TRINITY	1945	N Mexico		~700			
Total			16,048	~31,000	5,740	72,927	~120,000

Population tracing. Approaches for ascertaining deaths described in Aim 1 will be used, but with the enhancement of the unique Department of Veterans Affairs BIRLS system (Beneficiary Identification Record Location Subsystem). This system has been used extensively for epidemiologic research on veterans (Kang 1996, 2000, 2002, 2006; Bullman 2000, 2005; Smith

2004; Thomas 1991; Watanabe 1991, 1995a). The data files contain identifying information on individuals who have submitted claims for veterans' benefits (Fisher 1995; Page 1996; Boyko 2000; Maynard 2004). BIRLS data files can be searched on name and military service number and were used in the previous studies to verify and update information for atomic veterans. Only military service number is required which is available for all 120,000 test participants. In the NIH grant application, we were able to confirm that 92% of a random sample of 100 veterans without Social Security Numbers could be located; the use of probabilistic matching programs would have increased this percentage further. For veterans who have died, death certificates can be retrieved from the VA claims record folder if a death benefit is awarded or from the Federal Archives or from the state of death. Numerous other national electronic databases are available on veterans including the Patient Treatment File (hospital abstracts) and the Outpatient Care File (Maynard 2004; Cowper 2002). Cancer incidence studies have also been conducted on veteran populations (Young 2010). As of our last mortality evaluation, nearly 70,000 (or about 60%) of the study veterans were known to have died. It is estimated that over 80,000 deaths will have occurred by the end of 2012.

Exposure assessment (dose reconstruction). The goal is to provide unbiased best estimates of annual external and internal absorbed doses to selected tissues and organs of individual veterans. The dosimetry approach is based on a validated and tested methodology and takes advantage of the considerable new information not available when the previous studies were conducted. A comprehensive ongoing program of dose reconstruction coordinated by the DTRA has collected and developed new information on military personnel and exposure scenarios used to determine reliable estimates of radiation dose for U.S. atomic veterans (IOM 2000; NRC 1989, 1995, 2003; DTRA 2007a, 2007b, 2007c). Over 300 million dollars have been spent over the past three decades in developing the complex exposure scenarios used in individual dose reconstructions.

Two members of the study team served on the NAS Committee (one as Chair) which reviewed the dosimetry data available on nuclear test personnel in 1995 and made recommendations on how they could be "recalculated" for "epidemiologic purposes" (Heath and Till 2000, p. 103). We are following these recommendations to provide dose estimates suitable for epidemiologic analyses. Members of the study team also served on the subsequent NAS Committee (one as chair) reviewing the DTRA dose reconstruction program (NRC 2003). Three members currently serve on the Congressionally-mandated Veterans' Advisory Board for Dose Reconstruction and have provided guidance and direction on over 600 dose reconstructions on nuclear weapons test participants using the revised methodologies currently used by the Department of Defense. One member has provided independent quality review of each completed dose reconstruction as a subcontractor to DTRA and is a member of two current NCRP committees: one dealing with uncertainties in internal dose estimates and the other with fundamental principles of dose reconstruction. Recently, one of our members chaired the NCRP committee on uncertainties in measurements and dosimetry, including applications for atomic veterans (NCRP 2008). Other members have been involved in other NCRP committees on uncertainties in measurements and dose reconstruction (NCRP 2009, 2010). Dr Andre Bouville is the NCI Project Scientist assisting with the dosimetry aspects and oversight of the NIH cooperative agreement. The approach outlined below has gone through strenuous testing and is considered the state-of-the-art methodology for deriving "best estimates" of dose with associated uncertainty for use in epidemiologic studies of atomic veterans.

Methods to estimate individual radiation doses for epidemiologic analyses. DTRA has developed a comprehensive series of reports that describe the radiation exposure environment for practically every ship and land unit at every test in every series; these reports provide the basic scientific data needed for individual dose reconstruction. Over 4,000 detailed dose

reconstructions have been performed by DTRA over the course of the Nuclear Test Personnel Review (NTPR) program. Over 600 complex dose reconstructions since 2004 have applied the same methodology and used the same databases and data sources that we will use. The comprehensive methodology has been audited, validated and codified in a detailed set of standard operating procedures. Some of the newer methodologies have also undergone detailed peer review by committees of the NCRP (2008, 2009).

Military unit exposure scenarios include direct gamma and neutron radiation from the detonation, gamma exposure from activated soils or deposited fallout, inhalation of descending fallout or resuspended fallout and activated soils, and ingestion of contaminated water or foodstuffs. Individual dose reconstruction for a particular veteran begins with the standard scenario common to all members of his unit, and then takes into account any unique exposure situations the veteran may have encountered, such as maintenance of cloud-penetrating aircraft, reboarding target ships, or operating small boats in contaminated lagoons. Over 10% of the veterans (>12,500) had participated in more than one weapon test series (IOM 2000; Johnson 1996) indicating the potential for relatively high doses among some veterans since a single test series might involve 10 or more aboveground detonations.

There were over 375,000 individual estimates of radiation dose based on film badges. Most of the estimates pertained to gamma-ray exposures but nearly 4% of the badges also provided neutron exposures. Nearly half of the exposures were based on film badge readings and the other half were based on some method of dose reconstruction, including cohort badges. Estimates of external radiation exposure are available for all 120,000 atomic veterans and range from minimal to nearly 100 rem (1 Sv). Interestingly, the mean exposure of the 95,000 atomic veterans with nonzero estimates is 16.7 mSv and thus comparable with the 19.4 mSv reported in the 15-country worker study (Cardis 2007). To date little attention had been given to exposure pathways involving intakes of radionuclides with estimates made for only 2% of the veterans.

The Nuclear Test Review and Information System (NuTRIS) database contains all available physical dosimetry information for every nuclear weapons test participant. If the review identifies the potential for internal exposure, we will use information about contamination levels and activities at locations identified in the exposure scenario to estimate inhalation and ingestion doses to tissue(s) of interest. The updated FIIDOS code (A Computer Code for the Computation of Fallout Inhalation and Ingestion Dose to Organs, Raine 2007) will be used to facilitate the internal dose calculations.

On the basis of previous epidemiologic studies and knowledge of exposures possible during atmospheric weapons testing, red bone marrow, bone surface, thyroid, salivary gland, breast and liver will be the tissues of *a priori* dosimetric and epidemiologic interest. Other known radiosensitive sites include cancers of the lung and colon. All dose reconstruction will be conducted blindly without knowledge of cancer status. Doses for all the organs of interest will be calculated. About 33,000 veterans are expected to have been minimally exposed (<1 mSv or 0.10 rem). External radiation doses, whether to penetrating photons or to neutrons, will be estimated on a year by year basis, and any radionuclide intakes will be processed so that yearly doses for specific organs or tissues can be estimated using current International Commission on Radiological Protection (ICRP) biokinetic models (ICRP 2007; Raine 2007; Boice 2006b).

Quality assurance. A quality assurance (QA) plan will ensure that consistent, accurate, traceable, and reproducible methodologies are implemented to calculate the doses (Toohey 2002, 2008).

Case-cohort study. Because it would be prohibitively expensive to perform individual dose reconstructions on all 120,000 test participants, or even the 92,000 with non-minimal exposures, the case-cohort design will be used. Cases are all test participants who developed leukemia or

cancers of the liver, bone, thyroid, salivary gland and breast. The subcohort for comparison will be a 1% random sample (n=1,200) within defined strata from the cohort of 120,000 test participants. However, all cancers and causes of death will be evaluated and if notable increases are observed in the extended follow-up or if additional resources become available from other governmental agencies, the number of dose reconstructions will be increased accordingly, i.e., extended to other cancers or conditions. Case-cohort analytical techniques will assess risk within the cohort over categories of reconstructed radiation dose to specific organs (Kelsey 1996). Stratification factors will be test series, sex, rank, service and age at the time of the tests. Trend tests will be performed with year of birth, year of participation, sex and rank (officer/enlisted) included in all models. Rank and/or pay grade will be considered surrogate measures of socio-economic status. Trend tests will treat radiation dose as a single, time-dependent measure, and one-sided p-values presented. Relative risks at 100 mSv will be computed. Models will be developed to access directly the contribution of inhaled and ingested radioactive fallout to risk, controlling for external exposures. Intra-cohort dose-response analyses would be expected to minimize any biases that might exist when external comparisons are made with a general population are made.

Statistical considerations. The available external radiation dose estimates can provide an approximate and useful guide for power computations. The estimate of average dose, though uncertain, is about 17 mSv (1.7 rem) for the 95,000 participants with estimated exposures; 3,600 likely received greater than 50 mSv (5 rem) and nearly 1,000 over 100 mSv (10 rem). The highest recorded dose was 970 mSv (97 rem). These estimates are "low-sided" in the sense that internal radiation exposures are not included and film badge records were often incomplete. Based on available film badge readings, approximately 33,000 veterans presumably received <1 mSv (0.10 rem) and represent a minimally exposed referent group for these power computations. When interpreting the power computations below, it might be noted that the current estimates of relative risk for leukemia are of the order of 1.3 to 1.5 for doses between 50 and 100 mSv (5 to 10 rem) (UNSCEAR 1994, 2000, 2008; NRC 2006; Preston 1994). Estimates of risk for other cancers are lower, but intakes of certain radionuclides could increase the dose appreciably for certain organs such as the thyroid, liver and bone (IARC 2001) and excess risks have already been reported for these sites. Preliminary linkages with the REIRS database indicates that at least 0.7% of the nuclear weapons test participants were subsequently employed at a nuclear power plant of whom over 8% received > 5 rem. Preliminary linkages with the Landauer datafiles also indacted that at least 0.6% of the atomic veterans had worked elsewhere in a radiation protection of whom about 2% received > 5 rem.

Power. In the Table 2-2, we present various sizes of the relative risks (RR) and the associated power to detect a difference in leukemia and five other cancers is presented. The power values are given for a one-sided 5% nominal significance level and baseline rates are based on the referent groups and minimally-exposed participants in previous studies (IOM 2000; Johnson 1996) and from the American Cancer Society and SEER cumulative cancer probability tables for males (ACS 2008). Power is greater than 80% to detect relative risks of the order of 1.2 for leukemia, 1.3 for liver cancer, 2.0 for bone cancer, and 2.2 for the other cancers.

Table 2-2. Detectable relative risks and associated power for leukemia and other cancers, contrasting the 40,000 "highest" exposed participants (>10 mSv) with the 33,000 lowest exposed participants (<1 mSv). Baseline rates in parentheses.

RR	Leukemia (0.95%)	Liver (0.7%)	Bone (0.05%)	Thyroid (0.046%)	Salivary (0.04%)	Male Breast (0.031%)
1.2	0.80	0.69	0.14	0.14	0.13	0.12
1.3	0.97	0.93	0.21	0.20	0.19	0.16
1.4	0.99	0.99	0.29	0.28	0.26	0.22
1.5	0.99	0.99	0.38	0.36	0.33	0.28
2.0	0.99	0.99	0.80	0.77	0.72	0.62
2.2	0.99	0.99	0.90	0.87	0.83	0.74

In Table 2-3 the Cochran-Armitage trend test (Nam 1987) is applied to estimate the study power for the case-cohort study. The power to detect a linear trend in excess relative risk (ERR) over 5 dose categories is evaluated. The dose categories, based on current dose reconstructions for Seven Series participants, are <1 mSv, 1-5 mSv, 5-10 mSv, 10-50 mSv and >50 mSv with the corresponding subcohort population distributions of 13%, 30%, 23%, 31% and 2.5%, respectively. The subcohort consists of a 1% random sample from the entire cohort (n=1,250). The estimated numbers of cancer cases, based on previous studies and preliminary mortality linkages, are estimated to be of the order of 1000 for leukemia, 500 for liver cancer, and 25-50 each for cancers of the bone, thyroid, salivary gland and male breast. Similar to the dichotomous power computations in Table 2-3, the trend evaluations indicate substantial power to detect relatively low level increases in the ERR (0.20) for leukemia and liver cancer. For the other rarer cancers, the proposed study reaches at least 80% power to detect a trend in the ERR of 0.20 with one-sided type I error = 5%.

Study power is sufficient to detect even modest increases in risk for leukemia and liver cancer, but is recognized to be less for the other rare cancers. Power to detect increases for these outcomes, however, depends on the organ dose which is influenced by radionuclide uptakes, e.g., radioactive iodine by thyroid and plutonium and uranium by bone and liver, which are yet to be determined.

Characterization of medical radiation exposures and other potential confounders. To address the possibility that increased exposures to medical radiation (Mettler 2008; NCRP 2009; ASA 2011) may have contributed significantly to the total radiation exposure received by some atomic veterans, medical records for all selected cancer cases and members of the subcohort comparison group will be sought within the Veterans Affairs' health care system. The electronic files will be searched initially, including the Patient Treatment File (hospital abstracts), the Outpatient Care File, and BIRLS (Maynard 2004). Then medical record folders will be retrieved and medical radiation, both diagnostic and therapeutic, abstracted. At a minimum, the information will be used to learn whether there are any marked differences in medical radiation received over categories of estimated dose from test participation. It is recognized, however, that most of the atomic veterans have died prior to the rapid increase in radiological imaging procedures to evaluation of leukemia deaths is unlikely to be confounded by such exposures. Nonetheless, all cases of leukemia and the random sample of the cohort will be carefully evaluated using VA records (and Medicare records as described in AIM 1). Any information on hepatitis infection, cigarette smoking and alcohol abuse will be similarly sought in these records and carefully evaluated.

Table 2-3. Detectable dose response trend in the excess relative risk (ERR) over 5 dose categories and associated power for leukemia, bone, liver, thyroid, salivary, and male breast cancer in case-cohort study. Baseline rates in parentheses.

Trend (ERR)	Leukemia (0.95%)	Liver (0.70%)	Bone (0.05%)	Thyroid (0.046%)	Salivary (0.04%)	Male breast (0.031%)
.05	0.92	0.88	0.44	0.43	0.42	0.39
.10	0.99	0.99	0.63	0.62	0.59	0.55
.15	0.99	0.99	0.80	0.78	0.75	0.69
.20	0.99	0.99	0.91	0.90	0.87	0.81
.25	0.99	0.99	0.97	0.96	0.94	0.90

Uncertainty in dose estimates. Recent developments in statistical methodology will be adapted and extended to account for the uncertainties in the reconstructed radiation doses for atomic veterans (NRC 1995, 2003; Ron 1999; Kopecky 2004; Schafer 2006; Stayner 2007; NCRP 2008, 2009, 2010). Uncertainties can be viewed as the range of values of estimated dose within which the true value of dose is estimated to lie (NCRP 1996, 2008, 2009; Ron 1999; Thomas 2005). Uncertainty is a best estimate of possible inaccuracies due to both random and systematic errors. *Random errors* are those that vary in a non-reproducible way around a

limiting mean. These errors can be treated statistically by use of the laws of probability. *Systematic errors*, on the other hand, are errors that are reproducible and tend to bias a result in one direction. For instance, it has been estimated that a few film badge readings were biased and the amount of possible bias can be estimated (NRC 1989). Probabilistic uncertainty analysis methods currently under development for the DTRA Nuclear Test Personnel Review dose reconstruction program will also be considered.

SUMMARY

The atomic veteran cohorts can be followed for more than 60 years which is equivalent to the observation time for Japanese atomic bomb survivors (Douple 2011). The studies of populations exposed to Chernobyl radiation have the potential to provide knowledge on chronic exposure, but the event in 1986 is too recent to address long-term or lifetime risks (Wakeford 2011a; UNSCEAR 2011). There remains scientific debate over the appropriate factor to "adjust" the Japanese survivor risk estimates (from acute and high doses) for the purposes of radiation protection (involving chronic and low doses). The BEIR VII Committee (NRC 2006) favored 1.5 as the Dose and Dose Rate Reduction Factor, whereas UNSCEAR (2008, 2000) and ICRP (2007, 1991) continued with 2.0 and the French Academy of Sciences questioned both the evidence on carcinogenic risks below about 100 mSv (10 rem) and the level of risk predicted based on linearity (Tubiana 2006). The chronic low-dose exposures received by weapons participants would allow this issue to be addressed directly. Another limitation of the Japanese atomic bomb survivor data is the somewhat uncertain process of "transporting" radiation risks from an Asian population exposed in 1945 to those of Western countries with widely varying background rates of cancer. Risks associated with veteran populations are directly applicable to U.S. populations.

Compared with external radiation, there are surprisingly few data on human risks for the ingestion or inhalation of radioactive substances such as those present in fallout, nuclear wastes and even nuclear medicine procedures (COMARE 2004; Harrison 2003, 2005; Little 2007; UNSCEAR 2008). Nuclear weapons tests at the Nevada Test Site and the Pacific Proving Ground provided the opportunity for inhaled or ingested radioactivity (Beck 2006) which can be evaluated in the current design. This unique opportunity has struck a responsive chord as indicated by the collaborations forged with the Departments of Defense and Veterans Affairs, the National Association of Atomic Veterans and our scientific team of experts in radiation epidemiology, biostatistics, coronary heart disease and dosimetry. Few opportunities remain to study large and well-defined populations who accumulated radiation doses gradually over time.

Aim 3 - Radiologists, Radiotherapists, Other Radiation Workers

Landauer, Inc. has provided radiation dosimetry services since 1953 for United States medical facilities. A computerized database is maintained of over fifteen million workers with identifiers and cumulative dose measurements. Included in the database are radiologists, radiotherapists, cardiologists and others such as industrial radiographers who experienced frequent radiation exposures during the course of their employment. An opportunity exists to utilize these dosimetry records for epidemiologic study by following the approximately 400,000 workers with relatively complete dosimetry coverage over time. Given the increasing use of medical radiation and the increased potential for personnel exposures (NCRP 2009, Hall and Brenner 2008), the study of medical radiological practitioners has the potential to provide quantitative information needed to address current concerns about the long-term effects of chronic radiation exposures experienced over a period of many years by workers and the general population.

The first cancer attributed to ionizing radiation occurred on the hand of a radiologist in 1902, and leukemia was first associated with chronic exposure in studies of radiologists (March 1944).

Excess leukemia and solid cancers have also been observed among pioneering radiologists (March 1944; Lewis 1963; Matanoski 1975; Smith and Doll 1981; Berrington 2001; Wang 1990, 2002; Linet 2010). Studies of medical x-ray technologists have been less clear in revealing excess cancers (Jablon and Miller 1978; Yoshinaga 1999; Doody 1998; Mohan 2003; Yoshinaga 2004). The absence of reliable dosimetry in practically all of these studies has precluded quantitative estimation of risk, although recent attempts for dose reconstructions are vastly improved over past studies (Simon 2006, 2010; Bhatti 2007).

The most comprehensive study to date, conducted by NCI, is of 143,000 technologists who were certified by the American Registry of Radiologic Technologists for at least two years during 1926-1982 (Boice 1992; Mohan 2003; Yoshinaga 2004; Simon 2006, 2010). In this study, cumulative doses for most technologists were estimated to average about 1.7 rem (17 mSv) overall based largely on records linkage with Landauer, Inc., which covered about 19% of the population (Boice 1992). These estimates are consistent with subsequent ones (Chodick 2008) based on comprehensive modeling and biodosimetry approaches (Simon 2006, 2010, 2011; Bhatti 2007). In the proposed study we will identify all medical professionals within the Landauer database, with special focus on interventional radiologists, cardiologists, radiotherapists and other potentially high-dose groups so that there will be little overlap with the NCI cohort. Our study population is selected based on long-term coverage within Landauer, Inc.

The Pilot study (see Progress Report) successfully evaluated a sample of 70,000 of the 400,000 other radiation workers based on the electronic data file who received > 5 rem cumulative exposures. The dose distribution is noteworthy in that 1,180 workers received > 100 rem (1 Sv) and 26,536 > 10 rem (100 mSv), indicating the substantial statistical power to uncover any radiation effects associated with protracted exposures.

METHODS

The Landauer database. The Landauer, Inc. database contains records on15 million individual workers. The record for each individual contains personal identifiers (social security number, name, date of birth, sex), employment data (employer account number, account inception and termination dates with Landauer, Inc.) and dose data (annual whole body deep dose, cumulative whole body deep dose, and previous deep dose prior to inception with Landauer (if provided)). Since 1978, annual doses for workers monitored by Landauer have been stored in the computerized database, together with the cumulative dose prior to that time. Records for periods from the1950s through 1977 have been stored on microfilm. Actual film badges from these early years have been stored in underground salt mine in Kansas. Doses incurred at facilities not covered by Landauer are included if reported by an account holder and are available as early as the 1940s.

The Landauer database has been used in occupational studies to provide and/or enhance the dosimetry information of workforces, including those in the Rocketdyne, the x-ray technologist, atomic veterans, Mound and other studies.

Population identification. Based on the years of coverage within the Landauer database, approximately 400,000 workers will be selected who have nearly complete coverage of at least 5 years. The cohort will be identified using the electronic datafiles for persons employed in 1978 or thereafter, but which are known to include earlier inception dates to the 1940s. These data will be supplemented through the computerization of the 2500 roles microfilm records to capture the relatively higher exposures experienced by persons who terminated employment prior to 1978.

Population tracing. Similar to the approaches described in Aim 1, mortality and vital status searches will be comprehensive and include state-of-the art approaches to locate and obtain

cause of death for all study subjects. Follow up will begin at the date when 5 years of dosimetry information is available, and continue until censoring at December 31, 2012.

Dose reconstruction. The Landauer dosimetry measurements have followed stringent procedures to provide accurate dose information for workers, often to comply with legal requirements. The measurements have been made by a variety of techniques over the years, from film badges to thermoluminescent dosimetry technology (TLD) to optical methods (i.e., OSL or optically stimulated luminescence). For the medical professionals in our proposed study the measurements are considered consistent and reproducible. Because selection of the population for study focuses on those with long-term coverage within Landauer, there are unlikely to be serious gaps in monitoring. However, to correct for any incomplete coverage we will, as described in Aim 1, link the Landauer data roster with national databases available from military, government and commercial sources but then apply modeling approaches to handle any residual gaps. The modeling approaches will be similar to those used in the NCI radiological technologist study, which we have been involved with over the years (Boice 1992; Mohan 2003) and for which Dr. Yoder remains so (Simon 2006, 2010). In brief, our approach to dose reconstruction will rely on the estimated 4 million film badge and TLD measurements for workers in our study, the additional information available from archived Landauer records which will require abstraction, linkages with other dosimetry databases, and the modeling that is needed to account for different average energies of medical x-rays and gamma rays, use of protective aprons, placement of dosimeters when worn, and minimal detectable doses over calendar years (Gilbert 1996; Simon 2006, 2010, 2011).

In the NCI technologist study (Boice 1992; Simon 2006, 2010; Bhatti 2007), Landauer badge measurements were estimated cumulative does to average about 1.7 rem (17 mSv). Our study will involve higher exposures because we will include interventional radiologists, radiotherapists and industrial radiographers for whom exposures are known to be higher than for technologists. Our Pilot study has already identified 77,000 other radiation workers within the Landauer files with > 5 rem (50 mSv). The NCI study also had about 19% coverage of their population with film badge reading from Landauer and thus modeling and extrapolation was paramount in making dose reconstructions. We, by definition, should have near complete coverage with dosimeter measurements; but we recognize that personal exposures to medical x-rays as captured in the NCI study will not be similarly recorded and adjustments in the analyses will have to be considered using, in part, the methods described in Simon (2006).

Statistical analyses. The distribution of doses for the medical professionals has not been determined except for the Pilot sample which was selected based on workers with > 5 rem cumulative exposure. Although, we accordingly do not present statistical power computations, we are confident that the power to detect underlying effects is substantial given the large study size and our finding in the Pilot study of high exposures with nearly 2% having cumulative doses over 100 rem (1 Sv). In fact, the 26,536 identified with having > 10 rem is already larger than the 18,444 Japanese atomic bomb survivors with > 10 rem (Preston 2004). Prior studies of the early technologists indicate associations that are likely radiation-related for leukemia, breast and thyroid cancer, and study of pioneering radiologists reported elevations for lung cancer, skin cancer, multiple myeloma and several other malignancies, although not consistently. Our investigation will quantify such risks in a working population with comprehensive measurements and dose reconstructions.

Uncertainty analyses will be conducted as described in previous Aims and also in the recent x-ray technologist paper by Simon (2006). The overall goal of an uncertainty analysis is to quantify the state of knowledge on doses for individuals, which in turn allows estimation of reasonable bounds on the population cancer risk. Limitations to the data include incomplete Landauer monitoring coverage for individuals across time periods and employers, lack of

information on whether badges were worn consistently and appropriately, and incomplete information on wearing of aprons and placement of badges relative to aprons.

A variety of techniques to account for and to propagate uncertainty will be used, including analytic error propagation, simulation, temporal correlation and correction for bias. Each of these techniques is explained in some detail in Simon (2006). Dose estimation is not always separate from the analysis of uncertainty, since the dose calculations include both aspects. Integration of dosimetry and uncertainty analysis is often an important aspect of epidemiologic studies of radiation exposed populations (Ron 1999). Each technologist's annual badge and organ dose will be characterized by a lognormal uncertainty distribution from which alternative realizations of an individual's true annual dose will be generated. Similar to all the uncertainty approaches taken for the studies described in this proposal, a subcommittee has been developed to address the issues of uncertainties which includes Dan Stram, Duncan Thomas, Ken Kopecky and the dosimetrists familiar with the specifics of each workforce to be analyzed.

SUMMARY

Preliminary linkages indicate that over 400,000 individual workers within the Landauer, Inc. dosimetry database have monitoring records that span at least 10 years. Identifying information such as Social Security number, name and date of birth exist, and cumulative and annual radiation doses are recorded in a systematic fashion. Prior annual records exist on microfilm and will be abstracted from the 1950s to 1977. Electronic records exist after 1977. Date of inception, i.e., the date of first radiation dose, is available as early as the mid-1940s. The population will be traced as described in Aim 1. Dosimetry uncertainty will be evaluated, taking into account measurement, positioning, shielding, and the unique errors associated with medical workers. The proliferating use of CT scans and medical procedures in the U.S. and other developed countries (NCRP 2009), indicates the clear need to reliably estimate the risk experienced from low dose radiation exposures, not received acutely as in the atomic bomb investigations, but chronically over time, as during medical profession circumstances (ASA 2011; Hall and Brenner 2008; Brenner and Hall 2007). Previous studies of the pioneering medical radiation workers have indicated clear elevations of leukemia and certain other cancers. However, the absence of reliable dosimetry has hindered interpretation as to the level of risk and comparisons with acute exposures. The Pilot study found a broad dose distribution with substantial numbers of workers receiving > 100 rem indicating the statistical power to evaluate late effects. The Landauer dosimetry study of medical professionals with long term exposures will provide important knowledge on lifetime risks associated with these exposures of current scientific and societal concern.

Aim 4 - Nuclear Power Plant (NPP) Workers

The United States developed nuclear reactors to produce electricity in 1957. Early workers were allowed 3 rem per quarter and 12 rem per year, although the percentage that received such levels was small. Maximum exposure limits were subsequently reduced to 5 rem per year and actual exposures to workers are much lower today and of the order of 0.2 rem per year (Blevins 2011; Andersen 2008). Studies of the early NPP workers have the potential to provide useful information on radiation risks because of the relatively high exposures (Goldsmith 1989; Muirhead 1996; Jablon and Boice 1993; Hall 2009). An early study of 9,000 workers at the Calvert Cliffs NPP, for example, was able to include contract workers and that 12% of all workers had career doses >5 rem (50 mSv) [max 47 rem (470 mSv)] (Jablon and Boice 1993). A recent study of 53,698 U.S. nuclear power plant workers was limited because the study design included mainly recent hires, which resulted in a young workforce, a low mean cumulative dose [2.6 rem (26 mSv)] and narrow dose range, and few deaths (1,190) (Howe

2004). Nonetheless, the study reported a significant association with coronary heart disease which merits further attention. There are over 650,000 past and current utility workers and 350,000 currently are included in a recently developed registry, the Personnel Access Data System (PADS). Herein we propose to assess cancer and other disease mortality in a cohort of NPP workers with documented radiation exposure histories.

METHODS

Population identification. Landauer, Inc. provides dosimetry services for a large number of radiation workers in the United States. Although most of these workers are employed in the medical professions (Aim 3), about 15,000-20,000 NPP workers were monitored by Landauer during the late 1970s, which comprised about 10-15% of all NPP workers at that time. This percentage increased to about 25% (or about 40,000 workers) by the mid-1980s (Muirhead 1996). The Pilot study identified additional early nuclear power plant workers though evaluation of "accounts" and other sources. Over 212, 000 workers were identified, incorporating supplemental information obtained from linkages with the NRC REIRS database. These 212,000 workers will form the basis of the nuclear power plant cohort to be studied. Additional NPP workers who terminated employment prior to 1978 will be included by review of Landauer records that are not computerized, i.e., that are on the 2500 rolls of microfilm from the 1960s to 1977. NRC REIRS termination notices will be sought to supplement as well as fill in any gaps in years of coverage and to supplement the early worker numbers. Workers had to be employed prior to 1984. Although average worker exposures decreases over time, after the 1979 reactor accident at Three Mile Island, the NRC required that additional modifications be made on existing nuclear reactors which slightly increased worker exposures for a few year; thus the selection of 1984 as the cutoff date.

Population tracing. Similar to the methods outlined in Aim 1, vital status and cause of death will be sought using a wide-range of national databases, including the social security administration, the National Death Index, the Social Security death index (available in-house for probabilistic matching), various credit bureau and other record systems. Tracing will begin from the date the first radiation reading was recorded until December 31, 2012. The availability of social security number, name, and date of birth will facilitate accurate determination of deaths and vital status through 2010 for nuclear utility and other worker cohorts. The Pilot study found that 54,641 of the workers had died; a number that is greater than the total workers studied in the 15-utility investigation of more recent NPP workers of whom only 1,190 were found to have died (Howe 2004).

Dose reconstruction. Methods for doses reconstructed for the NPP workers will be similar to what was described in Aim 3 (other radiation workers). The Landauer dosimetry measurements have followed stringent procedures to provide accurate dose information for workers, often to comply with legal requirements. To address any incomplete coverage we will, as described in Aim 1 (uranium workers), link the Landauer data roster with national databases available from military, government and commercial sources and then apply modeling approaches to handle any residual gaps. Our approach to dose reconstruction for the Landauer-based NPP workers will rely on the estimated > 1,000,000 film badge and TLD measurements for workers in our study, the additional information available from archived Landauer records which will require abstraction, linkages with other dosimetry databases, including the Nuclear Regulatory Commission REIRS system, and the modeling required to account for errors associated with film badge readings as described below (NCRP 2008; Thierry-Chef 2007; Schafer and Gilbert 2006; Gilbert 1996, 1998, 2009; Stram and Kopecky 2003; NRC 1989).

Several U.S. NPP cohorts were included in the 15-country study (Cardis 2005) for which dose reconstructions were carefully considered (Gilbert 2006; Thierry-Chef 2007). Errors in recorded

doses were quantified after review of historical dosimetric practices and technologies at participating facilities. The main sources of dose errors from "high-energy" photons (100-3,000 keV) were related to how the dosimeters responded to workplace exposure conditions and the methods for calibration. Doses from "lower-energy" photons (<100 keV) and from "higher-energy" photons (>3 MeV) were estimated to be small. Errors were quantified to derive estimates of bias and uncertainties in recorded doses based on measurement studies, dosimetry expert assessment and on the estimated energy and geometry response of dosimeters. A lognormal error structure model was developed to describe errors in doses. Doses from other radiation types, i.e., neutrons and radionuclide intake, could not be adequately reconstructed in the framework of the 15-country study, but these internal and neutron exposures will be addressed directly in our study (see Methods described in Aim 1).

Statistical analyses. The distribution of doses for the NPP workers has not been finalized so we do not present statistical power computations. However, given the allowable doses for these earlier workers (up to 12 rem per year), the preliminary linkages for Landauer-based workers identifying cumulative doses over 100 rem (1 Sv), and the feasibility study of 9,000 workers at Calvert Cliffs (12% >5 rem, max 47 rem), there should be sufficient statistical power to detect excess cancers should they occur given the relatively long follow-up for workers first employed 1957-1984. Similar to previous Aims, analyses will be made using external comparisons with the general population of the U.S., i.e. SMR analyses (Marsh 1998) followed by internal dose-response analyses over categories of radiation doses using Cox proportional hazards models or Poisson regression models (Preston 1993).

Uncertainty analyses will be conducted as described in previous Aims (NCRP 2008) and also in the recent x-ray technologist paper by Simon (2006) and the 15-country study paper by Thiery-Chef (2007). A subcommittee has been formed to address the issues of uncertainties in all study cohorts which includes Dan Stram, Duncan Thomas, Ken Kopecky, and the dosimetrists familiar with the specifics of each workforce to be analyzed.

SUMMARY

Early NPP workers will be studied, with the records of Landauer, Inc. and the NRC REIRS files used to identify over 212,000 early workers employed before 1984. The focus on these early workers will enable assessment of risk across a wide dose range, since relatively high doses were allowed, i.e., 3 rem per quarter and 12 rem per year depending on age and prior cumulative dose.

As emphasized in all previous Aims, study of these early radiation workers, as recently recommended by the DOE workshop on low-dose epidemiologic studies (Hall 2009), will provide important opportunities to clarify the risks of radiation exposures that are experienced gradually over time. The resultant information will directly address public, scientific and radiation protection issues, especially in light of recent claims that chronic low dose rate exposures may be as harmful as acute high dose rate exposures that form the basis of today's radiation protection standards (Jacob 2009; Cardis 2005, 2007a, 2007b; Krestinina 2005, 2007; Daniels 2011).

Aim 5 - Plutonium Workers

Studies of plutonium workers have not found consistent evidence of radiation risks except at rather high dose levels experienced by early weapons production workers in the former Soviet Union (UNSCEAR 1994, 2008; Voelz 1997; Omar 1999; IARC 2001; Gilbert 2004). The

inconsistencies in worker studies in the USA (Voelz 1997) and UK (Omar 1999) were attributed to the much lower exposure to plutonium than experienced by Russian Mayak workers during the 1940s and 1950s who showed increased cancers of heavily irradiated sites, i.e., the lung, liver and bone (IARC 2001). Studies of 15,727 workers at the Los Alamos National Laboratory, however, suggest an increased risk of lung cancer, osteosarcoma and several other malignancies (Wiggs 1994; Wilkinson 1987), which highlight the need for further study. Studies of the Russian Mayak workers have also evaluated cerebrovascular disease and cardiovascular disease (Azizova 2010a, 2010b).

The mortality experience of nearly 31,500 males and 12,600 female workers employed between 1944 and 1978 at the Hanford nuclear installation in Richland, Washington, has been reported by several investigators. Analyses up to 1986, which includes 5,413 workers at Rocky Flats, revealed a strong "healthy worker" effect, a significant deficit of cancer mortality, including leukemia and no evidence for increasing risk with increasing film badge exposure for any cancer (Gilbert 1993a, 1993b; see also Daugherty 2001). A more recent follow-up of 26,389 Hanford workers through 1994 identified 8,153 deaths and a negative dose response for leukemia, but a positive dose response for lung cancer (Wing 2005). Associations between duration of employment at Hanford in jobs with routine potential for plutonium exposure and mortality were also reported suggesting occupational exposure effects (Wing 2004). An association between age at first internal lung dose and lung cancer was also reported in a case-control study of Rocky Flats workers (Brown 2004). Follow up of these cohorts, however, ended in 1990 or earlier, and updates of the plutonium workers mortality experience are needed.

METHODS

Population identification. Table 5-1 shows that the plutonium worker cohorts available for study include approximately 155,000 workers at Los Alamos, Rocky Flats, Hanford and Mound (Wiggs 1991a, 1991b, 1994; Gilbert 1993a), and at Sandia.

Table 5-1. Cohorts of plutonium workers

Worker cohort	No.	Relevant publication/s	Last follow-up	No. dead	Total in database*
Los Alamos	15,727	Wiggs 1991;Wilkinson 1987;Gilbert 1993a	1990	3,196	23,288
Rocky Flats	5,413	Gilbert 1993; Brown 2004	1979	409	53,033
Hanford	32,643	Gilbert 1993a, 1993b; Wing 2004, 2005	1986	9,452	56,688
Mound	4,402	Wiggs 1991a, 1991b	1984	987	7,293
Sandia	N/A	None			24,685
Sum of unique workers	58,185			52,430**	154,928

* Because workers may be in more than one cohort, the individual sites sum to more than the total which is for unique workers.
** Number found to have died during the Pilot investigation are included in total.

Population tracing. Similar to the methods outlined in Aim 1, vital status and cause of death will be sought using a wide-range of national databases, including the social security administration, the National Death Index, the Social Security death index, various credit bureau and other record systems. The availability of social security number, name, and date of birth will facilitate accurate determination of deaths and vital status through 2010 for the plutonium worker cohorts.

Dose reconstruction. Methods for doses reconstructed for the plutonium workers will be similar to what was described in Aim 1.

Statistical analyses. The statistical approaches to be followed will mirror those applied to the study of uranium workers.

Mound pilot study. To demonstrate that the previously identified plutonium cohorts could be effectively studied, a feasibility project of over 7,261 workers at the Mound nuclear weapons facility (1944-1972) located near Dayton, Ohio was conducted. The cohort data included non-white and female workers (who had not been previously studied), radiation dose information evaluated (including internal uptakes), and population tracing conducted (Table 5-2). The pilot project was successful in that vital status of 98.2% of the population was obtained, the inclusion of females (24.9%) and non-whites (6.2%) was found to be feasible and the bioassay data necessary for internal dose assessments was incorporated into the analyses. Over 250,000 assay for polonium were evaluated with lung doses > 100 rem (RBE=1) for nearly 2% of the over 4400 workers with polonium exposures. Additional bioassay results were obtained and incorporated through the PORECON (Polonium Reconstruction) and PURECON (Plutonium Reconstruction) databases that were created at the Mound Laboratory from logbooks and other original hard-copy records. Over 800 workers had bioassays available for plutonium and over 1000 had bioassays available for tritium.

Table 5-2. Demographic and occupational characteristics of 7,261 Mound, Ohio workers

Characteristic	N	%	Characteristic	N	%
Gender			**Year of Hire**		
Male	5,455	75.1	1940-1949	2,578	35.5
Female	1,806	24.9	1950-1959	1,146	15.8
			1960-1969	2,289	31.5
Race			1970-1979	823	11.3
White	5,834	80.4	Missing	425	5.9
Non-White	453	6.2			
Missing	974	13.4	**Years of follow-up**		
			<30	1,782	24.5
Year of Birth			30-49	4,218	58.1
<1920	2,015	27.8	≥50	1,261	17.4
1920-1929	2,051	28.3			
1930-1939	1,316	18.1	**Vital Status as of 12/31/08**		
1940-1949	1,377	19.0	Confirmed Alive	3,550	48.9
1950-1959	467	6.4	Dead	3,580	49.3
≥1960	35	0.5	Lost to follow-up	131	1.8

SUMMARY

The study of workers with the potential for plutonium exposure would add a final dimension to the overall proposal. Over 150,000 such workers in the United States have not been recently followed, and more importantly, comprehensive dose reconstructions of internal intakes have not been completed. All workers are available for study and follow-up and dose reconstructions would be completed similar to that described for uranium workers. These plutonium worker studies are cost-effective because the cohorts have, in large part, already been identified, follow-up conducted to the mid 1980s and dose information has been collected.

Aim 6 - Combined Million Radiation Worker Analyses

The pooling of data from the U.S. worker and military populations described in Aims 1-5 would provide the most definitive evaluation yet available of the possible lifetime risks associated with low-dose radiation exposures experienced over a prolonged period of time. The resultant findings will thus have implications with regard to protection standards for workers and the general population, the assessment of risk associated with today's enhanced medical technologies such as CT scans, the expansion of nuclear power, the handling of nuclear waste and the compensation of workers with prior exposures to radiation (Hall 2009; Dreyer 1981).

METHODS

The study team has substantial experience in pooling radiation exposure data sets and providing estimates of effects and interactions that were not apparent when the individual studies were published alone. Assessment of uncertainty associated with shared errors of exposure have also been addressed. These include studies of radiation-induced breast cancer (Boice 1979; Preston 2002), cervical cancer patients (Boice 1985), radiation-induced thyroid cancer (Ron 1995), underground miner cohorts (Lubin 1994a, 1995; Thomas 1985), indoor radon-lung cancer case control studies (Lubin 1994b, 1997, 2004), and occupational cohorts (Cardis 1995; Stayner 2007). Uncertainty analysis and measurement error effects in radiation epidemiology has been a long-standing interest of members of the study team (Stram 1999, 2003; Pierce 1990; NCRP 2008, 2009).

Pooled analysis of the combined data from all the studies described Aims 1-5 will maximize statistical power to detect and characterize radiation effects, and to minimize the variability of the estimates of these effects. Generalized proportional hazards regression modeling of mortality data from the combined cohorts will allow for modeling of the risk allowing for the time-dependent nature of exposures and of effect modification variables such as age at exposure, time since exposure, and exposure dose rate. Analyses will utilize the best estimates of both external and internal (where grouped estimates will be used) radiation exposures and will provide uncertainty analysis that reflect likely errors in dose estimation particularly for internal dose.

SUMMARY

The proposed studies, to be carried out nearly simultaneously, provide a golden opportunity to embark on a well-defined research program in human populations followed for nearly entire lifetimes. The Pilot study confirmed the feasibility and importance of the proposed study in that a cohort of one million US radiation workers and veterans has been identified and preliminary tracing and dosimetry activities conducted. The one million US radiation worker and veteran study is ten times larger than that of the Japanese atomic bomb survivors, has a similar broad dose distribution with meaningful numbers > 100 rem and more high dose workers receiving > 10 rem than Japanese bomb survivors with > 10 rem. The enthusiasm for the one million workers and atomic veterans study is reflected by the broad range of consortium experts who are willing to commit a significant portion of their next five years to completing this work.

PROGRESS REPORT

May 2010 through September 2011

Title	Epidemiologic Study of One Million US Radiation Workers and Veterans
Project ID	0016044
Program Manager	Noelle F. Metting Phone: 301-903-8309 Division: SC-23.2
PI	John D. Boice, Jr., Sc.D.
Award Register #	ER64954
Applicant/Institution	The International Epidemiology Institute
Period of Award:	May 01, 2010 to January 15, 2012

Summary of Progress. Substantial progress has been made and all Aims of the Pilot study have been addressed and successfully completed. ***The Pilot study has demonstrated that the full-scale Epidemiologic Study of One Million U.S. Radiation Workers and Veterans is feasible.*** Indeed, during the Pilot study we successfully identified a cohort of one million early workers and veterans, a study population ten times larger than the atomic bomb survivor study and with more high-dose subjects (>10 rem) and many more deaths. The cohort consists of 202,000 DOE uranium workers, 156,000 DOE plutonium workers, 212,000 nuclear power plant workers, over 400,000 other radiation workers, and 120,000 atomic veterans. The large size of this unique population will provide substantial statistical power to evaluate low-dose rate radiation effects. Also during the Pilot study we extended follow up of 6,000 radiation exposed workers at Rocketdyne (Atomics International), publishing the findings in Radiation Research, and of 7,000 Mound polonium and plutonium workers. In addition, following peer review of a separate grant application, NIH awarded funds for the atomic veterans component of the million person cohort, thus enabling us to reduce the funds requested to carry out the study of the full cohort. These and other accomplishments are documented in the study website developed during this pilot period (http://www.onemillionworkerstudy.org). The Pilot effort thus has set the stage for the initiation of the full-scale study of one million U.S. radiation workers and military veterans.

Full-scale Study Synopsis. The single most important unanswered question in radiation epidemiology is the level of risk associated when exposures are experienced over prolonged periods of time. The One Million U.S. Radiation Worker and Veteran study is designed to provide information on risk following low dose rate exposures. The study focuses on five occupational groups with differing radiation exposure patterns, including intakes of radionuclides: (1) uranium workers at multiple Department of Energy locations; (2) nuclear weapons test participants (atomic veterans); (3) nuclear power plant workers; (4) industrial radiographers, radiologists and other medical practitioners; and (5) plutonium workers at multiple Department of Energy locations. The study will be cost efficient because it builds on the investments made and foundations laid by investigators and government agencies over the past 30-40 years, which have established early worker cohorts that can now provide answers to questions on the lifetime human health risks associated with low-level radiation exposures.

Accomplishments to Date. Although a proposal for the full study was submitted in September 2009, resources at that time were available only to conduct a feasibility study. The award for this Pilot study was effective May 01, 2010. DOE also provided resources directly to Oak Ridge Associated Universities, Oak Ridge National Laboratory and Los Alamos National Laboratory. The Pilot study involved four Aims which are described below.

PILOT STUDY AIM 1. Determine the feasibility of studying the Department of Energy Uranium Workers, 1943-2008.

During the pilot study the following activities were completed:

- Over 202,000 unique DOE workers from 16 facilities identified, and dose information obtained. The 16 facilities included: the Oak Ridge Segment (K-25, X-10, Y-12 (TEC), Y-12 (UCCND), Portsmouth Gaseous Diffusion, Paducah), the Manhattan Engineering District (Harshaw, Electromet, Bethlehem, Linde, Middlesex), FMPC (Fernald), MCW (Mallinckrodt), Savannah River Site, Pantex, Rocketdyne (Atomic International).
- Over 104,000 uranium workers were found to have died, as of 2009.
- Social Security Administration application was approved and linkage identified 75,000 workers who are alive.
- Application was made and approval received from National Death Index to obtain "cause of death."
- Additional dosimetry was received from linkages with Landauer (1953-2008) and REMS dose files.
- Approval and linkage with US Renal Data System identified 1% of workers being treated for kidney disease after 1977.
- State mortality tapes (e.g., California, Ohio, Florida, Texas, New Jersey) and the Social Security Mortality files were purchased which enhanced the tracing of workers using the CDC probabilistic program (LinkPlus)
- An approach to determine smoking histories based on available questionnaire data was outlined.

AIM 1 CONCLUSION: It is feasible to study DOE Uranium workers and relate radiation doses received over years of employment to the lifetime risk of death from cancer and renal disease.

AIM 1 RELEVANCE FOR THE FULL-SCALE STUDY TO BE FUNDED BY THE RENEWAL: Remaining tasks for the renewal include vital status determination and dose reconstruction. The causes of death need to be determined for those known to have died and death certificates requested for those who died prior to 1979 when the National Death Index began. Additional dosimetry linkages will be made with the NRC Radiation Exposure Information and Reporting System (REIRS), the DOE Radiation Exposure Monitoring Systems (REMS), Landauer files and military data bases. Dose reconstructions, including intakes of radionuclides (incorporating determinations made over the years within the NIOSH dose reconstruction project) will be conducted. Potential confounding information from tobacco use will be attempted from site medical record data. Evaluation of serious kidney disease will be made through linkage with the US Renal Data System. Analytical approaches, including uncertainty analyses will be developed.

PILOT STUDY AIM 2. Conduct a Second Follow-Up of the Rocketdyne (Atomics International) Radiation Worker Study, 1948-2008.

During the pilot study the following activities were completed:

- A second follow-up was conducted and manuscript published: Boice JD, Cohen S, Mumma M, Ellis E, Eckerman K, Leggett R, Boecker B, Brill AB, Henderson BE. Updated mortality analysis of radiation workers at Rocketdyne (Atomics International), 1948-2008. Radiat Res 2011.

- The study is unique in capturing radiation doses from practically all places of employment and incorporating internal doses from ingested radionuclides, notably uranium aluminide.
- No significant associations between radiation and cancer were found, but numbers were relatively small. Thus, the need for an expanded study of one million workers as proposed.
- Historical Notes: Rocketdyne (Atomics International) developed a sodium reactor that provided the first commercial use of electricity in the US, lighting the city of Moorpark in 1957. Rocketdyne also developed the Saturn rocket used during Apollo for the moon landings.

AIM 2 CONCLUSION: The Aim to conduct a second follow-up of the Rocketdyne Radiation Worker population was successfully completed and report was published.

AIM 2 RELEVANCE FOR THE RENEWAL FULL-SCALE STUDY. The Rocketdyne (Atomics International) Radiation worker study remains the model for the expansion and the vision to study one million US radiation workers and military veterans, i.e., capture all occupational exposures available from all facilities worked at and incorporate the intake of radionuclides into the estimate of organ doses for individuals.

PILOT STUDY AIM 3. Conduct a Second Follow-Up of the Mound Radiation Worker Study, 1944-2008.

During the pilot study the following activities were completed:

- A second follow-up was conducted and a manuscript is nearing completion.
- Among 7,291 workers, 49.7% have died and 49.0% are known alive based on linkages with the Social Security Administration files, the National Death Index and state mortality files.
- The study is unique in that workers were potentially exposed to three radionuclides in addition to external radiation: polonium, plutonium and tritium.
- Over 250,000 bioassay records have been obtained and individual organ dose estimates made for polonium and tritium and are ongoing for plutonium. Additional bioassay results were obtained through the PORECON (Polonium Reconstruction) and PURECON (Plutonium Reconstruction) databases that were created at the Mound Laboratory from logbooks and other original hard-copy records.
- The study is noteworthy in that the occurrence of serious renal disease, possibly related to exposure to heavy radioactive metals, was determined through linkage with the US Renal Data System which began in 1977.
- The study is also noteworthy in that cancer incidence (as opposed to cancer mortality) was obtained by linkage with the Ohio Cancer Incidence Registry. The importance of such linkage was seen in that the number of cancers identify (525) was nearly as great as the number of cancer deaths (579) despite the fewer years of observation covered by the cancer registry which began in 1996.
- LexisNexis was used to confirm that workers were alive when the matching with Social Security Administration files was incomplete. LexisNexis was also used to confirm that 64% of the population known to be alive after 1996 was living in Ohio for cancer registry linkage.
- Historical Notes: Polonium from Mound was used with beryllium to generate neutrons and trigger/initiate the bombs detonated at the Trinity Site and at Nagasaki ("Fat Man").

Polonium also was the 2006 poison that resulted in the death of a Russian citizen in London. It is also a component of tobacco which has been suggested as a contributor to lung cancer.

AIM 3 CONCLUSION: The Aim to conduct a second follow-up of the Mound Radiation Worker population was successfully completed and a manuscript is in preparation.

AIM 3 RELEVANCE FOR THE RENEWAL FULL-SCALE STUDY. The Mound Radiation Worker study resulted in two innovations. For workers exposed to radioactive heavy metals such as uranium and plutonium, linkage with US Renal System was conducted to learn whether such exposure might result in nonmalignant, but serious, kidney disease. Data from the comprehensive NIOSH dose reconstruction project was used to enhance internal dosimetry determinations. Additional bioassay results were obtained through the PORECON (Polonium Reconstruction) and PURECON (Plutonium Reconstruction) databases that were created at the Mound Laboratory from logbooks and other original hard-copy records.

PILOT STUDY AIM 4. Investigate the Feasibility to Study DOE Plutonium Workers, Nuclear Power Plant Workers, Other Radiation Workers, and Atomic Veterans. Each of these study components is discussed separately below.

- **Plutonium workers**: Data files and dosimetry files for over 156,000 plutonium workers at 6 DOE facilities were obtained after permission was received from the Director, Office of Health and Safety, DOE. Death certificates for 29,300 workers were obtained, scanned and catalogued. Linkages with state mortality tapes and the Social Security Mortality Files have identified 52,000 deaths to date.

CONCLUSION: It is feasible to study plutonium workers and extend the previous follow-up by over 20 years. Remaining tasks for the renewal include vital status determination and dose reconstruction. The causes of death need to be determined for those known to have died and death certificates requested for those who died prior to 1979 when the National Death Index began. Additional dosimetry linkages will be made with the NRC Radiation Exposure Information and Reporting System (REIRS), the DOE Radiation Exposure Monitoring Systems (REMS), Landauer files and military data bases. Dose reconstructions, including intakes of radionuclides (incorporating determinations made over the years within the NIOSH dose reconstruction project) will be conducted. Potential confounding information from tobacco use might be evaluated from site medical record data. Evaluation of serious kidney disease will be made through linkage with the US Renal Data System. Analytical approaches, including uncertainty analyses will be developed.

- **Nuclear Power Plant (NPP) Workers:** 212,000 nuclear power plant workers were identified from the Landauer dosimetry records and supplemented with the Nuclear Regulatory Commission (NRC) REIRS data files for utility workers employed from 1957 to 1984. Microfilm records from 1960s are being scanned to identify additional early workers. Linkages with state mortality files and the Social Security Administration mortality files have identified nearly 55,000 deaths (a number larger than any previously studied population of nuclear power plant workers). Career occupational doses are being sought.

CONCLUSION: It is feasibly to study nuclear power plant workers and many of the early workers have been identified. Remaining tasks for the renewal include enhancing the population

through the identification additional early workers through NRC and Landauer records, learning the causes of death (and not just the fact of death), determining vital status, conducting comprehensive dose reconstructions and uncertainty analyses to estimate organ-specific dose, and determination of other occupational doses through linkages with REIRS, REMS and military dosimetry files. Nuclear power plant workers have a lower potential for intakes of radionuclides than uranium and plutonium workers which minimizes the complexity of the dose reconstruction procedures, while enhancing the generalization of results to other worker and medically-exposed populations.

- **Other Radiation Workers**, including Medical and Industrial Radiography workers. Over 2700 roles of microfilm of early radiation workers from the 1950s to 1976 are available from Landauer and 550 roles are being scanned. In addition, 15 million records are available in electronic format since 1976. The number of early workers in this database exceeds 400,000. In the electronic files alone, over 70,000 non-NPP workers have been identified to date with cumulative dose > 5 rem, with over 1,100 workers recorded as having > 100 rem (1 Sv). The number of workers in this small series who received > 10 rem (26,500) protracted cumulative dose is greater than the number of atomic bomb survivors with comparable but acute dose (18,444). 3100 deaths have been identified in this pilot sample. Industrial Radiographers are to be identified from Landauer files supplemented with REIRS files. Additional historical account information was obtained from Landauer to help identify specific occupational groups for study.

CONCLUSION: It is feasible to study early medical workers, e.g., radiologists, and medical radiographers who have the potential for large cumulative exposures. In fact, the dose distribution is as broad as that of the study of atomic bomb survivors indicating the substantial statistical power of the One Million U.S. Radiation Worker and Veteran study to detect radiation effects following protracted exposures received over a period of many years. Remaining tasks for the renewal include enhancing the population by identifying additional early workers through the Landauer microfilm records and NRC databases, learning the causes of death (and not just the fact of death), determining vital status, conducting comprehensive dose reconstructions and uncertainty analyses to estimate organ-specific dose, evaluation of cancer incidence through selective state cancer registry linkages and determination of other occupational doses through linkages with REIRS, REMS and military dosimetry files. Similar to the NPP workers, early medical workers and industrial radiographers have a lower potential for intakes of radionuclides than uranium and plutonium workers which minimizes the complexity of the dose reconstruction procedures, while enhancing the generalization of results to other worker and medically-exposed populations.

- **Atomic Veterans**: Not only was it determined to be feasible to conduct a study of 120,000 military nuclear weapons test participants, but a 5 year NIH grant (1 U01 CA137026) was awarded during the Pilot study period in cooperation with Department of Defense (DTRA) and Department of Veteran Affairs (VA). The population includes participants at the first nuclear weapon detonation at the Trinity site in 1945 and at 7 other series in Nevada and the Bikini Islands. Present at the Trinity site were such historical figures as Robert Oppenheimer, General Leslie Groves, Enrico Fermi, Hans Bethe, Owen Chamberlain, Ken Bainbridge, Philip Morrison, Richard Feynman, Louis Hempelmann, Hymer Friedell and Theodore Hall. Nearly 70,000 veterans are known to have died, including those identified through the VA linkages with BIRLS (The Beneficiary Identification Records Location Subsystem). Complex dosimetry determinations have begun for veterans who developed leukemia and a subcohort sample. Initial linkages with the US Renal Data System for veterans with known Social Security number (a little over half at the moment) identified 1,304 with nonmalignant kidney disease. Preliminary linkages with REIRS and Landauer dosimetry files indicated that nearly 1-2% had received

additional occupational exposures. Unfortunately, the NIH had reduced the initial funding by 17% and then progressively reduced funding by 5 to 8 % for each of the remaining 4 years. Thus there is a need for supplemental funding to enhance the dosimetry capability and, equally important, to evaluate through the veteran electronic medical records systems and archival data the possible influence of medical imaging examinations (such as CT scans) on cancer risk.

CONCLUSION: It is feasible to study atomic veterans first exposed as early as 1945. This will be a comparatively low-dose population. An NIH grant was awarded to cover most of the costs of this component of the million person study, but the effective 25% cut in requested funding indicates the need for cost sharing in this renewal application. Remaining tasks include learning the causes of death (and not just the fact of death), determining vital status, obtaining additional social security numbers (which has been successfully addressed using LexisNexis and other approaches), conducting comprehensive dose reconstructions and uncertainty analyses to estimate organ-specific dose, determination of serious kidney disease through linkage with the US Renal Data System and determination of other occupational doses through linkages with REIRS, REMS, Landauer and military dosimetry files. Further, the unique VA medical record system would allow the evaluation of subsequent medical imaging examination (such as CT scans and nuclear medicine procedures) and there influence on cancer risk. Activities enabled by funds provided by the full-scale million person study for the veterans component would supplement (and not duplicate or overlap) activities funded by the NIH grant.

Other Accomplishments and Study Possibilities.

- **Websites were developed.** http://www.onemillionworkerstudy.org/ and http://www.atomicvetstudy.org/

- **Workshops** at Oak Ridge were held Oct 2010 and Feb 2011 and another is planned December 2011.

- **Presentations** were made before the Congressional Committee on Science, Space and Technology, the DOE Low-Dose Program, the DOE Energy Facility Contractors Group (EFCOG) - Occupational Medicine Subgroup Meeting, the DOE Integrated Safety Management Workshop of Champions, the Nuclear Regulatory Commission, the Veterans Advisory Board on Dose Reconstruction (VBDR), the International Congress of Epidemiology and the International Expert Symposium in Fukushima.

- **Other previously studied populations to be considered.** Nuclear Navy submariners (76,000) and Navy Shipyard Workers (70,000) would be valuable to include, recognizing that special permissions from the U.S. Navy/others would be required. A meeting has been organized in October 2011 by DTRA with Naval Reactors personnel to discuss possibilities. The INEL (Idaho) cohort is of possible interest. Neutron exposures (e.g., Rocky Flats) and other high-LET radiation exposures will be carefully evaluated. Lung cancer among non-smokers exposed to high-LET radiations of possible NASA and other interest and can be evaluated. Priority for inclusion of new studies is given to radiation cohorts that have previously been identified and followed beyond 1979.

- **Summary of other noteworthy accomplishments.** Nonmalignant kidney disease can be evaluated using the US Renal Data System. Acquisition of state mortality files (e.g., California, Florida, Texas, New Jersey, and Ohio) enhances tracing capabilities by allowing probabilistic matching on incomplete variables. Medical record questionnaires exist for certain occupational study groups that include information on important risk factors such as cigarette smoking.

Career occupational doses can be estimated though facility records and linkages with national data bases such as REIRS, REMS, Landauer and various military dosimetry systems. Incorporation of bioassay data to estimate intakes of radionuclides is possible, and data obtained from the comprehensive NIOSH dose reconstruction projects have been accessed in this regard.

- **Current Relevance and Importance**. As mentioned in the FY 2012 Senate Appropriations Bill for the Department of Energy: Science (http://www.aip.org/fyi/2011/109.html):

> The funds provided "shall be used for radiobiology to help determine health risks from exposures to low levels of ionizing radiation to properly protect radiation workers and the general public. The Fukushima Daiichi disaster in Japan is an opportunity to learn about the impacts of the disaster on human health and apply lessons learned to make more informed decisions on protection if a similar accident occurs in the future, including dose trip points for evacuation and shelter-in-place orders."

APPENDIX 3
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APPENDIX 4 and APPENDIX 5

FACILITIES AND EQUIPMENT

Epidemiologic Study of One Million U.S. Radiation Workers and Veterans

The facilities and equipment available to the study consortium are provided in this combined appendix with detailed listings for the International Epidemiology Institute, Vanderbilt University, Oak Ridge Associated Universities, Risk Assessment Corporation and the University of Southern California.

VANDERBILT UNIVERSITY

Cancer Biostatistics Center

With more than 15 full-time faculty members as well as 15 staff biostatisticians, computer systems analysts, and administrative staff, Vanderbilt's Cancer Biostatistics Center (CBC) provides statistical support to almost 120 different investigators each year, in departments throughout the Vanderbilt School of Medicine. Support provided includes assistance with statistical aspects of experimental design, sample size estimation, and study power analysis; data acquisition and database development; statistical analysis and interpretation of findings; collaboration on presentation of results; and development of new statistical procedures as required by specific projects. In a typical year, CBC members design about 20 investigator-initiated clinical trials, review 70 clinical protocols to ensure sound statistical inputs, and co-author 50 manuscripts, including about five statistical methodology papers. In addition to providing statistical expertise for almost 30 active R01 research projects, the CBC provides ongoing biostatistics core support to a number of large research programs, including 5 Specialized Center Grants (P50), 4 Program Project Grants (P01), 3 Research Project Cooperative Agreement Grants (U01), 2 Specialized Center Cooperative Agreement Grants (U54), 1 Resource-Related Research Project Cooperative Agreement Grant (U24), and 1 Center Core Grant (P30). The quality of the biostatistical support provided by the CBC has been recognized by *The Cancer Letter* (2002:28(16);6-7) as well as a *GI SPORE Summary Statement* (2007; p. 9) and *Breast Cancer SPORE Summary Statement* (2008; p. 7), all of which describe the CBC as a "model" biostatistics core.

In addition to our work within the Vanderbilt community, the CBC also is involved in several national and international collaborative projects. For example, we house the Sentinel Node Oncology Foundation (SNOF) database. SNOF recruits medical institutions, nationally and internationally, to participate in the Sentinel Lymph Node Working Group (SLNWG); the CBC collects and manages cancer clinical data from SLNWG members. Data reside in the SNOF database, which the CBC custom-designed for this application. The long-term goal of the SNOF database is to collect sufficient data to build statistical models for prediction of disease course in cancer patients undergoing selective sentinel lymph node dissection, with the goal of facilitating the development of personalized medicine. Another international collaboration involves data-sharing with Melbourne University, through the use of the BioGrid Australia data repository.

EQUIPMENT

The study of cancer mortality among military participants at U.S. atmospheric nuclear weapons tests will involve equipment for data processing and analyses. The associated computers and software are described below.

The **Biostatistics Shared Resource** at the Vanderbilt-Ingram Cancer Center is a shared resource that contains an Ethernet network with Windows XP, 2000, NT 4.0 and UNIX workstations. Network printers available include a Hewlett Packard LaserJet 4050 printer and a Xerox/Tektronix Phaser750N color printer. Four Intel Pentium 4 3.0 GHz, four Intel Pentium 4 1.7 GHz, two Pentium III 550 and one Sun Ultra 10 workstation are on this network. Each computer also has Hewlett Packard LaserJet 4 Plus and 4L printers attached for local use. These eleven computers contain 300 gigabytes or more of storage capacity which are backed up nightly by a Hewlett Packard Surestore DLT 40 tape backup system. All campus wide servers are attachable from these computers via the network. In addition, the equipment for the resource includes: a database file-server, a Hewlett Packard Scanjet 4500 document scanner and corresponding software for document and data input, two Xerox copiers, and a fax machine. The computer connections between the Head and Neck Cancer SPORE investigators

and Biostatistics Core are attained via the Vanderbilt Medical campus Novell network using the Internet Packet eXchange (IPX) protocol.

The Advanced Computing Center for Research and Education (ACCRE) provides high-performance computing support to computational studies across the Vanderbilt campus. The ACCRE is built and operated by Vanderbilt faculty and offers computing resources flexible enough to enable high performance computing applications in a wide variety of research and education areas. All ACCRE hardware resources are housed in the University's secure data center and administered by a team of ACCRE system administrators. In addition to the high performance computing system, ACCRE has several terabytes of disk space and a robotic tape storage system. The ACCRE high performance computing system consists of 924 x86 processors (756 2.0 GHz Xeon and Opteron processors plus 168 1.8 GHz Opteron processors) running under 32-bit Linux and 668 PowerPC processors (2.2 GHz IBM JS20 Blades) running the SuSe Linux 64-bit operating system. Each processor has at least 1 GB of memory, a 40 GB disk drive, and dual Gigabit copper Ethernet ports. Over one-third of the systems also have Myrinet networking. Each node is monitored via Nagios. The disk servers and gateways are equipped with external gigabit Ethernet connections.

Extensive computer facilities are also available at the **International Epidemiology Institute** for this project. In the Rockville, Maryland office suite, hardware includes 15 personal workstations, 3 servers, 2 network attached storage units, 10 laser printers (1 color), 2 multi-function printers/scanners, and several fax machines. Office network consists of wired (cat-6) peer-to-peer network with a T1 (1.5 Mbps) internet connection via a firewall (with VPN capabilities). Software for word and video processing, statistical and geographical analysis and database and document management is available, including Microsoft Office (Word, Excel, Access, PowerPoint, etc.), SAS, Epicure, Alchemy (electronic document database system), ArcGIS Software, and a wide selection of other software. Record linkage software includes LinkPlus and The Link King for probabilistic matching rosters against large databases such as the Social Security Master Death File (83 million records) and various State death files, such as from California (9 million records). In addition, an on-site web server can be utilized for project related internet services, such as web pages and file transfer services (ftp).

FACILITIES

Laboratory and Clinical:

The study is entirely record linkage, matching the roster of nuclear weapons test participants with national mortality and vital statistics files to obtain fact and cause of death. Dose reconstructions involve only an appraisal of previously collected records. There are no contacts with any study subjects or their families, and no Laboratory or Clinical resources will be used.

Animal: N/A

Computer:

APCC is on Vanderbilt's MSP (Managed Support Program) plan. All of the software is downloaded from a central server to the PC via a NAL (Novell Application Launcher) window. NCS (Network Computing Services keeps all of the applications updated by upgrading the programs at the server level, instead of upgrading each PC individually. NCS maintains all of the "core build" applications (MS Windows, MS Office, Lotus Notes, Netscape, Epic, Medipac, Virus Checker, etc.) to the latest versions, any fixes or patches they may need, and their software licensing. Specialized Applications: If there is a need for any specialized applications, they will be loaded onto the server and delivered via a NAL window along with the "core build" applications. When the specialized programs need to be upgraded, NCS will get the software

and upgrade it. The computer centers support university and Cancer Center research with a comprehensive and unified set of computing services, including hardware and software. The center staff is available for consultation/assistance with programming and/or analysis. Numerous software packages including major statistical packages such as SAS, GLIM, and SSCP are supported by the computer centers and will be available for the analysis of data collected from this study.

Office:

The Vanderbilt-Ingram Cancer Center and the Vanderbilt Center for Health Services Research will provide adequate office space for investigators and their associated staff. The lab collaborators also have adequate office space for this study.

Other:

The Biostatistics Shared Resource at the Vanderbilt-Ingram Cancer Center, directed by Dr. Yu Shyr, contains an Ethernet network with Windows XP, 2000, NT 4.0 and UNIX workstations. Network printers available include a Hewlett Packard LaserJet 4050 printer and a Xerox/Tektronix Phaser750N color printer. Four Intel Pentium 4 3.0 GHz, four Intel Pentium 4 1.7 GHz, two Pentium III 550 and one Sun Ultra 10 workstation are on this network. Each computer also has Hewlett Packard LaserJet 4 Plus and 4L printers attached for local use. These eleven computers contain 300 gigabytes or more of storage capacity which are backed up nightly by a Hewlett Packard Surestore DLT 40 tape backup system. All campus wide servers are attachable from these computers via the network. In addition, the equipment for the resource includes: a database file-server, a Hewlett Packard Scanjet 4500 document scanner and corresponding software for document and data input, two Xerox copiers, and a fax machine. The computer connections between the Head and Neck Cancer SPORE investigators and Biostatistics Core are attained via the Vanderbilt Medical campus Novell network using the Internet Packet eXchange (IPX) protocol.

Software available in the Cancer Center Biostatistics Shared Resource includes statistical packages such as S-PLUS, SAS, SPSS, STATA, Resampling Stats, EGRET, EPICURE, nQuery, EaSt, and PASS. Conversion of statistical data is accomplished by using DBMS/Copy or Open Database Connectivity Drivers and the accompanying software packages. Other software includes Mathematica for mathematical equations, DeltaGraph for producing high quality statistical graphs, Python which is an interpreted, interactive, object-oriented programming language and Ox which is an object-oriented matrix language with a comprehensive mathematical and statistical function library. There is also a full line of integrated Microsoft products such as Microsoft Visual C++, Microsoft Access, Excel, Word, and PowerPoint. These products support data sharing and object sharing to increase productivity.

The Bioinformatics and Data Analysis Core Facility of CHGR, directed by Dr. Marylyn Ritchie is currently staffed by 15 individuals with training and expertise in PCs, UNIX workstations, web-based activities, programming, and database design. The CGC occupies approxmiately 2,000 sf of space on the 5th floor of Light Hall. The CGC maintains an extensive computing enviornment that includes 19 Unix and Linux servers with processor speeds varying from 1-3 GHz. These are in constant use for statistical analysis by the P.I.s, students, and analysts. Three Dell dual processor servers and four Dell quad processor servers are used for database applications. A mass storage RAID disk array provides the necessary redundant back-up systems. The remaining workstations are used for specific projects. Over 100 Pentium PCs are available for word processing, graphics, etc. We also have 12 MacIntosh computers. All computers have direct Internet access. These are networked to 18HP LaserJet, two HP color laser printers, three HP color injet printers, and one Officejet (all-in-one) printer. Nine non-networked inkjet printers, three non-networked officjets, and five non-networked laser printers

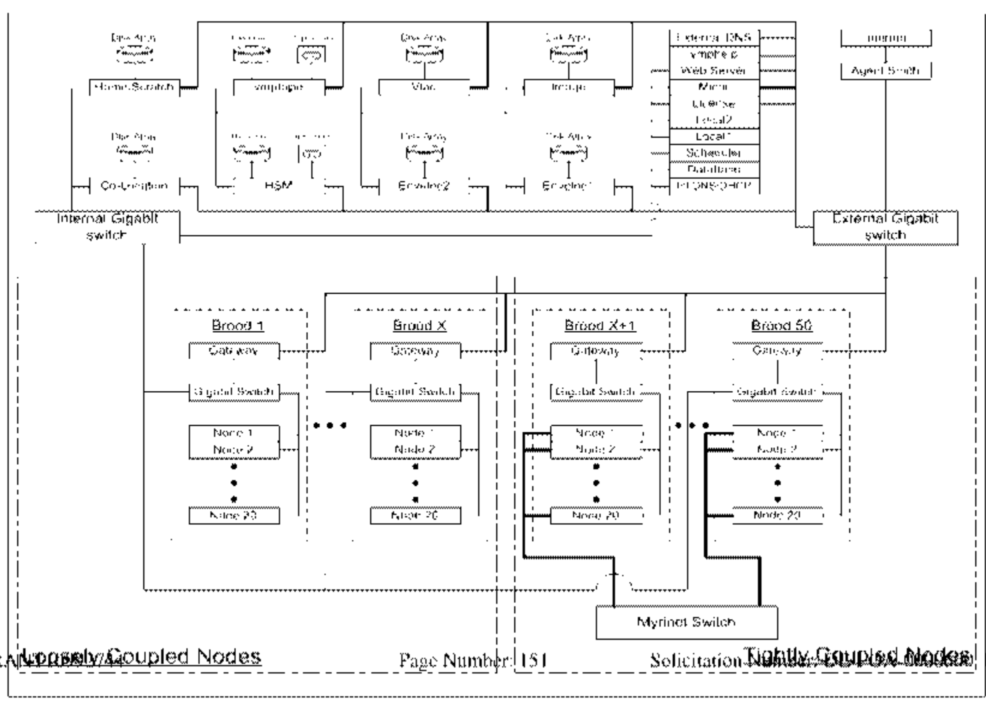
are also available for use. The workstations have a full suite of genetic epidemiological programs as described below. The CGC has a 12 node Linux cluster used primarily for program development and testing. Most PCs are housed in individual offices. The servers are housed in a shared, secure server room within the Vanderbilt University Hospital, a three minute walk from the CHGR.

The Advanced Computing Center for Research and Education (ACCRE) provides high-performance computing support to computational studies across campus. The ACCRE is built and operated by Vanderbilt faculty and offers computing resources flexible enough to enable high performance computing applications in a wide variety of research and education areas. All ACCRE hardware resources are housed in the University's secure data center and administered by a team of ACCRE system administrators. In addition to the high performance computing system (described in detail below), ACCRE has several terabytes of disk space and a robotic tape storage system. The "/home" directories of all users are backed-up daily. Vanderbilt University is an Internet2 member and a participant in the Abilene network.

The ACCRE high performance computing system (schematic shown below) consists of 924 x86 processors (756 2.0 GHz Xeon and Opteron processors plus 168 1.8 GHz Opteron processors) running under 32-bit Linux and 668 PowerPC processors (2.2 GHz IBM JS20 Blades) running the SuSe Linux 64-bit operating system. Each processor has at least 1 GB of memory, a 40 GB disk drive, and dual Gigabit copper Ethernet ports. Over one-third of the systems also have Myrinet networking. Each node is monitored via Nagios. The disk servers and gateways are equipped with external gigabit Ethernet connections. All machines see the same disk which holds the user "/home" directories. Resource management, scheduling of jobs, and tracking usage is handled by the Moab/Torque schedulers. These utilities include an "advance reservation" system that allows a block of nodes to be reserved for pre-specified periods of time (e.g., a class or lab session) for educational purposes.

BMs General Parallel File System (GPFS) is used for user "/home" directories and scratch space and can sustain 10 Gb/s to the cluster. The internal network design is a classic tree with a Foundry BigIron RX-16 at the root providing 1.54 Tb/s of available bandwidth (3.84 Tb/s total switch capacity) to the cluster. All of the disk servers and management nodes are connected to the top level. A collection of compute nodes, typically 20, are connected to a small local gigabit switch with a 1 Gb uplink to the RX-16.

The ACCRE's suite of computing resources also has one high-memory 16-processor (1.5 GHz Itanium2) SGI Altix with 6MB cache per processor and a total of 32GB memory.



Resources and Facilities, International Epidemiology Institute

Computer:

Extensive computer facilities are available at IEI for support of this project. In the Rockville, Maryland office, hardware includes 15 personal workstations, 3 server, 2 network attached storage units, 10 laser printers (1 color), 3 multi-function printers/scanners, and 3 fax machines. Office network consists of wired (cat-6) peer-to-peer network with bundled T1 (3.0 Mbps) internet connection and firewall with VPN capability. Software for word and video processing, statistical and geographical analysis and database and document management is available, including Microsoft Office (Word, Excel, Access, PowerPoint, etc.), SAS, Epicure, Alchemy (electronic document database system), ArcGIS Software, and a wide selection of other software. In addition, an on-site web server can be utilized for project related internet services, such as web pages and file transfer services (ftp).

Office:

The IEI Rockville office occupies one floor including offices and conference rooms, encompassing over 8,000 square feet. Five offices, totaling 1,800 square feet, in the Jacksonville, Florida office are also available for this project.

OAK RIDGE ASSOCIATED UNIVERSITIES (ORAU)

ORAU is a diverse organization headquartered in Oak Ridge, Tennessee, with staff at several other locations across the country. ORAU's mission is to advance scientific research and education through academic partnerships, our partnership with the U.S. Department of Energy (DOE), and our investment in the community. ORAU promotes collaborative partnerships with universities, federal laboratories, and industry for the benefit of our 99 member institutions. ORAU's Office of Partnership Development focuses our efforts and resources on the active management of opportunities that leverage the value a university consortium brings to our nation's research and development enterprise. As a partner and contractor with DOE, ORAU operates the Oak Ridge Institute for Science and Education (ORISE) to provide operational capabilities and conduct research, education, and training in the areas of science and technology, national security, environmental safety and health, and environmental management.

ORAU's Mission as a university consortium: To create and promote collaborative partnerships with national laboratories.

ORAU's Mission as a non-profit corporation: To operate as a contractor, providing expertise in three core areas:

- Worker health and environmental stewardship.
- Weapons of mass destruction, national preparedness, and emergency response.
- Science education, peer review management, and research support.

ORAU has headquarters in Oak Ridge, Tennessee, with additional Occupational Exposure and Worker Health (OEWH) program offices in Arvada, Colorado and Cincinnati, Ohio. Office space and full computing capabilities are available in support of this project. ORAU has been recognized as one of top ten employers in Tennessee for 2007 and 2008. DOE has named ORAU/ORISE as a Star Site in the Voluntary Protection Program. ORAU holds ISO 14001 registration.

Embracing the ORAU motto of *Partnerships for Innovation*, our focus within the ORAU OEWH program is to provide comprehensive capabilities and expertise to drive the science of worker health and wellness throughout the cycle of medical surveillance, health information management, epidemiologic analysis, and policy evolution for the enhancement of worker protection and safety. To accomplish our client's objectives, we partner with leaders in healthcare and information sciences to provide truly innovative solutions to worker health concerns.

The OEWH program is headed by Donna L. Cragle, Ph.D. The OEWH staff includes our program occupational medicine doctor, epidemiologists, statisticians, industrial hygienists, nosologists, laboratory personnel, health physicists, information specialists, and quality assurance specialists.

In our current work for the U.S. Department of Energy (DOE) and individual DOE sites, CDC and NIOSH, NRC, DuPont, Johns Hopkins, Boston University and others; we have partnered with National Jewish Medical and Research Center, Occupational HealthLink (OHL), Dade Moeller and Associates, MJW, Comprehensive Health Services (CHS), IEI, UT-Battelle and Oak Ridge National Laboratory to provide solutions with a consistently high level of satisfaction.

We conduct medical surveillance for current and former DOE workers, and have a cooperative agreement to perform medical screening of former DOE workers in all 50 states, called the National Supplemental Screening Program (NSSP). For that program, we teamed with Comprehensive Health Services, Inc. (CHS) for the physician network. Please note: we have proven experience in teaming with other health practices and networks. Our services and system is not restricted to a single healthcare provider group. For example, we also hold a contract with Argonne National Laboratory's in-house Occupational Medicine Department, where we are presently implementing a comprehensive, web-based clinic management system for a workplace that offers more than 20 different types of hazard-based examinations, voluntary examinations, and certification examinations.

The work is conducted by the program staff at ORAU and utilizes facilities which are housed in a 13,000 square foot purpose-built component of an office-conference complex owned and operated by ORAU on its main campus in oak ridge, Tennessee. This facility, known as the Center for Epidemiologic Research (CER), houses a Limited security area that is a specially constructed records storage area and is included in the ORAU Security Plan for surveillance. Access to the facility is monitored and restricted to persons with a "need to know" and a Q clearance. All staff sign a confidentiality agreement and receive training in maintaining confidentiality of personally sensitive data. CER has a client/server environment utilizing LANs and WANs within ORAU. Locking perimeter doors and network passwords from computer system network logon provide security for hardware and data. Relevant to this proposal, ORAU maintains major data centers for DOE and holds an "Authority to Operate (ATO) a Federal Data System." The ATO granted by DOE indicates compliance with FISMA, FIPS 140.2, and NIST 800-53A.

Risk Assessment Corporation

RAC is a consortium of independent scientists who live throughout the US but who work together on environmental dosimetry and risk analysis research. This approach to work is efficient and has proven extremely effective for over 30 years. Many team members have work within the RAC organization for 20 years or more. As a result of this organizational structure team members provide their own offices and equipment. Technology today allows individuals to own very powerful computers and to support them with hardware accessories that permit virtually any types of computations to be undertaken.

RAC Team members have powerful personal computer systems with high-speed internet access. Communication between team members is generally via e-mail but frequently conference calls are used to hold discussions about technical issues. RAC Team members use a common suite of software, including Microsoft Office programs, to ensure file compatibility. Individual members, with specialties ranging from modeling to geographic information systems to radiation and chemical dose calculation, maintain additional software supporting their specialties. Both personal computer and Macintosh hardware are used within the team, allowing easy communication with the majority of systems used by outside organizations.

Hardware. RAC maintains a server that is used within the team for file transfers and as a temporary location for keeping files accessed by the team routinely. Researchers use a variety of desktop and portable personal computers. Systems are upgraded or replaced regularly, allowing use of the most effective software during RAC research. All RAC team members have local printer capabilities including small and large format color units. Geographic information system capabilities include large format color printer/plotters and high-resolution monitors. Team members also have scanners with optical character recognition capabilities. Computer data backup capabilities include standard tape drives, removable hard drives, digital-format tape systems, and CD/DVD writers. These backup systems and the RAC server also allow transfer of large files to other systems.

Software. *RAC* scientists use current versions of Microsoft Office products to generate technical reports and also use a variety of other software packages that support optical character recognition, statistical and graphical analysis, file management, communications, web design and management, portable document creation, and geographic information systems.

Resources and Facilities, University of Southern California

The primary needs of this application are office space and computing capability.

Adequate office space for all investigators and students is provided by the Department of Preventive Medicine at the University of Sourthern California.

Through the Division of Biostatistics, the Norris Cancer Center, and the University of Southern California we have access to an expanding array of high-throughput computing solutions including the High Performance Computing Center at USC. The HPCC comprises a diverse mix of computing and data resources. The principal computing resources are a Linux cluster supercomputer and Sun x4600 large memory systems. In addition, HPCC has a central facility that provides more than 200 terabytes of combined disk storage and potential access to nearly a petabyte of tape storage, as well as a Condor cluster that uses spare cycles on Unix workstations in USC's public user rooms.

We and others at USC conducting studies requiring large scale computing are working directly with the administrators of the HPCC in order to establish large-scale disk storage and dedicated nodes for our projects. We have included in the budget for this project funds to purchase a workstation and data-storage capacity that will enable us to run most analyses locally while reserving the USC-HPCC facility for extremely high computational intensive analyses such as those that may be required for addressing missing data and measurement error issues.

Attachment for Additional IEI Personnel

Yr Name	Role	Salary	Cal mo	Req salary	Fringe	Total
1. TBA	Assoc Database manager	$95,000	12	$95,000	$41,705	$136,705
2. TBA	Assoc Database manager	$97,850	12	$97,850	$42,956	$140,806
3. TBA	Assoc Database manager	$100,785	12	$100,785	$44,245	$145,030
4. TBA	Assoc Database manager	$103,808	12	$103,808	$45,572	$149,380
5. TBA	Assoc Database manager	$106,922	12	$106,922	$46,939	$153,861

Attachment for Additional IEI Personnel

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1. TBA	Assoc Database manager	$95,000	12	$95,000	$41,705	$136,705
2. TBA	Assoc Database manager	$97,850	12	$97,850	$42,956	$140,806
3. TBA	Assoc Database manager	$100,785	12	$100,785	$44,245	$145,030
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5. TBA	Assoc Database manager	$106,922	12	$106,922	$46,939	$153,861

APPENDIX 1 AND APPENDIX 2

BIOGRAPHICAL SKETCHES AND OTHER SUPPORT

Epidemiologic Study of One Million U.S. Radiation Workers and Veterans

This combined appendix contains both the Biosketches and the Other Support for the investigators associated with the "Epidemiologic Study of One Million U.S. Workers and Military Veterans Exposed to Ionizing Radiation."

The ordering is by performance site.

International Epidemiology Institute
John D. Boice, Jr. (PI)
William J. Blot
Joseph K. McLaughlin
Robert Tarone
Clark Heath
Sarah Cohen
Michael Mumma

Oak Ridge Associated Universities
Betsy Ellis Dupree
Donna Cragle
Phil Wallace
Janice Watkins
Dick Toohey
Bill Tankersley
Derek Hagermeier
Nancy Daugherty

Oak Ridge National Laboratory
Richard Leggett
Keith Eckerman

Los Alamos National Laboratory
Laurie Wiggs

Harvard University
Howard Sesso

National Cancer Institute
Andre Bouville

Risk Assessment Corporation
John Till
Harold Beck
Paul Voillequé
Helen Grogan

University of Southern California
Dan Stram
Duncan Thomas

Vanderbilt University
Randy Brill
Yu Shyr
William Wu

Department of Veterans Affairs
Han Kang

Fred Hutchinson Cancer Research Center
Ken Kopecky

Advisors/Consultants
Roy Shore
Richard Wakeford
Howard Sesso
Han Kang
Ken Kopecky

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
John D. Boice, Jr.	Professor of Medicine
eRA COMMONS USER NAME Boicej	

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY
The University of Texas at El Paso, TX	BS	1967	Physics/Mathematics
Rensselaer Polytechnic Institute, Troy, NY	MS	1968	Nuclear Engineering and Science
Harvard University, School of Public Health,	SM	1974	Medical Physics
Boston, MA	ScD	1977	Epidemiology

A. Personal Statement

For over 30 years, I have conducted large-scale, national and international epidemiologic studies into the causes of cancer and other disease. During 27 years of service in the U.S. Public Health Service, I developed and became the first chief of the Radiation Epidemiology Branch at the National Cancer Institute, establishing programs of research in all major areas of radiation epidemiology, with major projects dealing with populations exposed to medical, occupational, military, and environmental radiation. These and current research efforts include comprehensive tracing activities, biospecimen collection, pathological tissue review, genetic-environmental interaction analyses, community outreach, and educational material development (including video presentations and distribution). Many of the resulting publications have been used to formulate public health measures to reduce population exposure to radiation and other agents to prevent associated diseases. In cooperation with the Department of Defense and the Department of Veterans Affairs, I currently direct the Study of Nuclear Weapons Test Participants of atomic veterans who participated in atmospheric nuclear weapons tests between 1946 and 1958. In collaboration with the Department of Energy, I direct ongoing pilot efforts to study a Million US Radiation Workers to examine the lifetime risk of cancer following relatively low-dose exposures received gradually over time.

B. Positions and Honors

Positions and Employment

1976-77 Epidemiologist, Bureau of Radiological Health, FDA, Rockville, MD
1979-83 Section Head, Radiation Studies Section, National Cancer Institute (NCI), Bethesda, MD
1984-96 Branch Chief, Radiation Epidemiology Branch, NCI, Bethesda, MD
1996- Scientific Director, International Epidemiology Institute, Rockville, MD
2000- Professor, Department of Medicine, Vanderbilt University Medical Center, Nashville, TN

Other Experience and Professional Memberships

1979- Member, National Council on Radiation Protection and Measurements
1979- Visiting Lecturer on Epidemiology, Harvard University School of Public Health
1986- Member, American Association for Cancer Research
1987- Associate Editor, Journal of the National Cancer Institute
1993- Advisor, U.S. Delegation to United Nations Scientific Committee on the Effects of Atomic Radiation
1994- Steering Committee, Childhood Cancer Survivor Study, St Jude Children's Research Hospital
1997- Main Commission, International Commission on Radiation Protection
1998-01 Member, IARC Monograph Working Group on Ionizing Radiation
1999-05 Consultant, NAS Committee on the Health Risks from Exposure to Low Levels of Ionizing Radiation
2005- Member, Veterans' Advisory Board on Dose Reconstruction (VBDR)
2007- Vice Chair, NCRP Committee on Second Cancers and Cardiac Effects after Radiotherapy
2010- Senior Editor, Radiation Research

Honors

1991 Distinguished Service Medal, Public Health Service
1994 Gorgas Medal, Association of Military Surgeons of the United States

1995	E. O. Lawrence Award, Department of Energy
1999	Distinguished Alumnus Award, The University of Texas at El Paso
2002	R. S. Landauer Memorial Lecture, Health Physics Society
2007	Distinguished Scientific Achievement Award, Health Physics Society
2008	Alumni Award of Merit, Harvard School of Public Health
2009	Lauriston Taylor Lecturer, National Council on Radiation Protection and Measurement
2010	Elis Berven Lecture, Swedish Society of Oncology

C. Selected Peer-reviewed Publications (from over 430 peer-reviewed articles)

Most relevant to the current application

1. Goldsmith R, **Boice JD Jr**, Hrubec Z, Hurwitz PE, Goff TE, Wilson J. Mortality and career radiation doses for workers at a commercial nuclear power plant: feasibility study. Health Phys 556:139-50, 1989.
2. **Boice JD Jr**, Mandel JS, Doody MM, Yoder RC, McGowan R. A health survey of radiologic technologists. Cancer 69:586-598, 1992.
3. Jablon S, **Boice JD Jr**. Mortality among workers at a nuclear power plant in the United States. Cancer Causes Control 4:427-30, 1993.
4. Muirhead CR, **Boice JD Jr**, Raddatz CT, Yoder RC. Comparison of dose histories for U.S. nuclear power plant workers, based on records held by a major dosimetry service company and on the NRC REIRS database. Health Phys 70:645-50, 1996.
5. Tucker J, Tawn E, Holdsworth D, Morris S, Langlois R, Ramsey M, Kato P, **Boice JD**, Tarone R, Jensen R. Biological dosimetry of radiation workers at the Sellafield nuclear facility. Radiat Res 148:216-26, 1997.
6. Littlefield LG, McFee AF, Salomaa S, ... Auvinen A, **Boice JD Jr**. Do recorded doses overestimate true doses received by Chernobyl cleanup workers? Results of cytogenetic analyses of Estonian workers by fluorescence in situ hybridization. Radiat Res 150:237-49, 1998.
7. Leggett RW, Eckerman KF, **Boice JD Jr**. A respiratory model for uranium aluminide based on occupational data. J Radiol Prot 25:405-16, 2005.
8. **Boice JD Jr**, Leggett R, Dupree BE, Wallace P, Mumma M, Cohen SS, Brill AB, Chadda B, Boecker B, Yoder RC, Eckerman K. A comprehensive dose reconstruction methodology for former Rocketdyne/Atomics International radiation workers. Health Phys 90:409-30, 2006.
9. **Boice JD Jr**, Cohen SS, Mumma MT, Chadda B, Blot WJ. A cohort study of uranium millers and miners of Grants, New Mexico, 1979-2005. J Radiol Prot 28:303-325, 2008.
10. **Boice JD Jr.**, Cohen SS, Mumma MT, Ellis ED, Eckerman KF, Leggett RW, Boecker BB, Brill AB, Henderson BE. Updated mortality analysis of radiation workers at Rocketdyne (Atomics International), 1948-2008. Radiat Res 176:244-258, 2011.

Additional recent publications of importance to the field

1. **Boice JD Jr**. Ionizing radiation. In: *Cancer Epidemiology and Prevention*, 3rd Edition (Schottenfeld D, Fraumeni JF Jr, eds). New York: Oxford University Press, pp 259-293, 2006.
2. **Boice JD Jr**, Bigbee WL, Mumma MT, Heath CW Jr, Blot WJ. Cancer incidence in municipalities near two former nuclear materials processing facilities in Pennsylvania -- an update. Health Phys 96:118-127, 2009.
3. Bernstein JL, Haile RW, Stovall M, **Boice JD Jr**, Shore RE, Langholz B, Thomas DC, Bernstein L, Lynch CF, Olsen JH, Malone KE, Mellemjkær L, Borresen-Dale AL, Rosenstein BS, Teraoka SN, Diep AT, Smith SA, Capanu M, Reiner AS, Liang X, gatti RA, Concannon P; WECARE Study Collaborative. Radiation exposure, the ATM gene, and contralateral breast cancer in the Woman's Environmental Cancer and Radiation Epidemiology study. J Natl Cancer Inst 102:475-483, 2010. [PMC2902825]
4. **Boice JD Jr**. Uncertainties in studies of low statistical power. J Radiol Prot 30:115-120, 2010.
5. Boice JD Jr, Mumma MT, Blot WJ. Cancer incidence and mortality in populations living near uranium milling and mining operations in Grants, New Mexico, 1950-2004. Radiat Res 174:624-636, 2010.
6. **Boice JD Jr**, Marano DE, Munro HM, Chadda BK, Signorello LB, Tarone RE, Blot WJ, McLaughlin JK. Cancer mortality among U.S. workers employed in semiconductor wafer fabrication. J Occup Environ Med 52:1082-1097, 2010.
7. **Boice JD Jr**. Lauriston S. Taylor lecture: Radiation epidemiology: the golden age and future challenges. Health Phys 100:59-76, 2011.

8. Vano E, Ohno K, Cousins C, Niwa O, **Boice J**. Radiation risks and radiation protection training for healthcare professionals. ICRP and the Fukushima experience. J Radiol Prot 31:285-287, 2011.
9. Lipworth L, Sonderman JS, Mumma MT, Tarone RE, Marano DE, **Boice JD Jr.**, McLaughlin JK. Cancer mortality among aircraft manufacturing workers: an extended follow-up. J Occup Environ Med 53:992-1007, 2011.

D. Research Support

Ongoing Research Support

1 U01 CA137026-01/Vanderbilt University Boice (PI) 08/01/10 - 07/31/15
NIH/NCI - Cancer Mortality among Military Participants at U.S. Nuclear Weapons Tests. To evaluate the risk of radiation-induced cancers and quantify the risk in terms of low-dose radiation received gradually from external exposures and from inhaled or ingested radionuclides in fallout among military participants at aboveground nuclear weapons tests in Nevada and the Pacific testing areas.
Role: Principal Investigator

5R01 CA104666/Vanderbilt University Boice (PI) 09/12/05 - 05/31/12
NIH/NCI - Genetic Consequences of Therapies for Cancer. A large-scale epidemiologic study of the offspring of cancer survivors examining the contribution of curative therapies, radiation and chemotherapy, to adverse health outcomes or other inherited effects.
Role: Principal Investigator

2U24 CA055727-14/St. Jude Children's Research Hospital Robison (PI) 12/01/06 - 11/31/11
NIH/NCI - Childhood Cancer Survivors Study. To provide a resource to investigate questions regarding consequences of therapy, genetic associations, disease processes and causation, interventions, and quality of life among childhood cancer survivors.
Role: Steering Committee

1R01 CA92447/Vanderbilt University Blot (PI) 04/01/07 - 03/31/12
NIH/NCI - Southern Community Cohort Study. A long-term prospective cohort study with emphasis on minority and rural participation in 105,000 individuals in seven southeastern states to provide baseline information on dietary, lifestyle, medical, occupational, genetic, and environmental factors that contribute to cancer development and biologic samples.
Role: Co-investigator

R01 CA97397/Memorial Sloan-Kettering Cancer Center Bernstein (PI) 09/24/07 - 08/31/12
NIH/NCI - Interaction of Radiation, BRCA1/2, and Breast Cancer. To examine the interaction between BRCA1 and BRCA2 and radiation in the development of 2nd breast cancer.
Role: Consultant

5R01 CA129639-02/Memorial Sloan-Kettering Cancer Center Bernstein (PI) 03/01/2010- 02/28/14
NIH/NCI - Genome-wide Association Study of Radiation Exposure and Bilateral Breast Cancer. To delineate the joint roles of genetic predisposition and radiation exposure in the etiology of second primary breast cancer, a genome-wide association (GWA) approach is applied to women with bilateral breast cancer for whom detailed radiation dose estimates exist.
Role: Consultant

Completed Research Support

R01 CA114236/ Memorial Sloan-Kettering Cancer Center Bernstein (PI) 06/01/05 – 05/31/09
NIH/NCI - Breast Cancer, Radiation and ATM-CHEK2 Pathway. To examine the interaction between the six genes involved in the ATM-CHEK2 pathway (CHEK2, TP53BP1, MDC1, MRE11, RAD50, and NBS1) and radiation exposure in the development of second primary contralateral breast cancer.
Role: Consultant

VUMC CA#31609/Vanderbilt University McLaughlin (PI) 08/01/05 - 08/31/10
SIA/Non-Federal Support - An Epidemiologic Study of the Semiconductor Workforce. A cohort mortality study to evaluate rates of cancer and other diseases among computer semiconductor chip manufacturers.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Blot, William James	Professor of Medicine, Vanderbilt University CEO, International Epidemiology Institute
eRA COMMONS USER NAME (credential, e.g., agency login) blotwj	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Florida	BS	12/64	Mathematics
University of Florida	MS	6/66	Statistics
Florida State University	PhD	6/70	Statistics

A. Personal Statement (Specific for the study mentioned below)

The proposed study of 1,000,000 radiation-exposed workers and veterans offers great promise to provide the most precise quantification available of the long-term effects of low-dose exposure to ionizing radiation. This will be the largest cohort study undertaken to assess radiation effects, with the large size needed to clarify uncertainties regarding protracted exposures to relatively low radiation levels. The study significance is exceptionally high, with the results not only useful for our veterans and workers previously exposed to radiation, but also for addressing questions continually arising regarding potential future radiation effects associated with nuclear energy, medical imaging surveillance, and other sources of low-dose radiation exposure to the general population. I will serve as co-investigator, providing overall experience in epidemiologic studies into the etiology of lung, breast, leukemia and other radiation-related cancers and assisting in study design, analysis and interpretation of the cohort data. I have over 35 years experience in the design, conduct, management and interpretation of epidemiologic studies, primarily regarding the causes and means of prevention of cancer, especially in large-scale cohort studies attempting to quantify the effects of environmental exposures such as ionizing radiation, and am looking forward to the possibility of serving as co-investigator in this effort.

B. Positions and Honors

1970-1972	Statistician, Department of Statistics and Epidemiology, Atomic Bomb Casualty Commission, Hiroshima, Japan
1972-1974	Assistant Professor, Departments of International Health and Biostatistics, School of Hygiene and Public Health, The Johns Hopkins University, Baltimore, Maryland
1974-1979	Health Statistician, Epidemiology Branch, National Cancer Institute, Bethesda, Maryland
1979	Elected Fellow American Statistical Association
1979	Visiting Scientist, Department of the Regius Professor of Medicine, Oxford University, Oxford, England
1981	Elected Fellow American College Epidemiology
1981	Elected to American Epidemiological Society
1979-1984	Chief, Analytical Studies Section, Environmental Epidemiology Branch, National Cancer Institute, Bethesda, Maryland
1984-1994	Chief, Biostatistics Branch, National Cancer Institute, Bethesda, Maryland
1986	Surgeon's General Commendation
1992	Public Health Service Superior Service Award
1994	Dept. of Health & Human Services Distinguished Service Award
1994-Present	Chief Executive Officer, International Epidemiology Institute, Rockville, Maryland

2000-Present	Professor, Department of Medicine, Vanderbilt University Medical School, Vanderbilt-Ingram Cancer Center, Nashville, Tennessee
2001-Present	Principal Investigator, Southern Community Cohort Study, Vanderbilt-Ingram Cancer Center, Nashville, Tennessee
2007-present	Associate Director for Cancer Prevention, Control and Population-based Research, Vanderbilt-Ingram Cancer Center, Nashville, Tennessee

C. Selected Peer-reviewed Publications (from over 500 publications)

1. **Blot WJ**, Cohen SS, Aldrich M, McLaughlin JK, Hargreaves MK, Signorello LB. Lung cancer risk among smokers of menthol cigarettes. J Natl Cancer Inst 103:810-816, 2011.
2. Boice JD, Mumma MT, **Blot WJ**. Cancer incidence and mortality in populations living near uranium milling and mining operations in Grants, New Mexico, 1950-2004. Radiat Res 174:624-636, 2010.
3. Boice JD Jr, Bigbee WL, Mumma MT, Tarone RE, **Blot WJ**. County mortality and cancer incidence in relation to living near two former nuclear materials processing facilities i Pennsylvania--an update. Health Phys 96(2):128-137, 2009.
4. Boice JD Jr, Cohen SS, Mumma MT, Chadda B, **Blot WJ**. A cohort study of uranium millers and miners of Grants, New Mexico, 1979-2005. J Radiol Prot 28(3):303-325, 2008.
5. Murff HJ, Peterson NB, Fowke JH, Hargreaves M, Signorello LB, Dittus RS, Zheng W, **Blot WJ**. Colonoscopy screening in African Americans and whites with affected first-degree relatives. Arch Intern Med 168:625-631, 2008.
6. Willett WC, **Blot WJ**, Colditz GA, Folsom AR, Henderson BE, Stampfer MJ. Merging and emerging cohorts: not worth the wait. Nature 445(7125): 257-258, 2007.
7. Boice JD Jr, Marano DE, Cohen SS, Mumma MT, **Blot WJ**, Brill AB, Fryzek JP, Henderson BE, McLaughlin JK. Mortality among Rocketdyne workers who tested rocket engines, 1948-1999. J Occup Environ Med 48(10):1070-1092, 2006.
8. Boice JD Jr, Mumma MT, **Blot WJ**. Cancer mortality among populations residing in counties near the Hanford site, 1950-2000. Health Phys 90:431-445, 2006.
9. Lubin JH, Wang ZY, Boice JD Jr, Xu ZY, **Blot WJ**, De Wang L, Kleinerman RA. Risk of lung cancer and residential radon in China: pooled results of two studies. Int J Cancer 109:132-137, 2004.
10. **Blot WJ**, Ibrahim MA, Ivey TD, Acheson DE, Brookmeyer R, Weyman A, Defauw J, Smith JK, Harrison D. Twenty-five-year experience with the Bjork-Shiley convexoconcave heart valve: a continuing clinical concern. Circulation 111:2850-2857, 2005.
11. **Blot WJ**, Fryzek JP, Henderson BE, Sadler CJ, McLaughlin JK. A cohort mortality study among gas generator utility workers. J Occup Environ Med 42:194-199, 2000.
12. **Blot WJ**, Xu ZY, Boice JD Jr, Zhao DZ, Stone BJ, Sun J, Jing LB, Fraumeni JF Jr. Indoor radon and lung cancer in China. J Natl Cancer Inst 82:1025-1030, 1990.
13. **Blot WJ**. Long-term effects of radiation of the human fetus. In: Queenan JT (Ed). Management of High Risk Pregnancy. New York, Medical Economics Co, 1980, pp. 27-34.
14. Belsky JL, **Blot WJ**. Adult stature in relation to childhood exposure to the atomic bombs of Hiroshima and Nagasaki. Am J Public Health 65:489-494, 1975.
15. Miller RW, **Blot WJ**. Small head size after in-utero exposure to atomic radiation. Lancet ii:784-787, 1972.

D. Research Support

Ongoing Research Support

2R01 CA092447 (Blot) 09/26/11 – 08/31/16
NIH/NCI
Southern Community Cohort Study

The major goal of this project is to investigate the causes of racial disparities in the occurrence of cancer in the southern United States.
Role: PI

3R01 CA092447-08S1 (Blot) 09/01/09 – 03/31/12
NIH/NCI
Southern Community Cohort Study Supplement

To enhance the value of the Southern Community Cohort Study by adding collection of medical records and tumor tissue from participants who develop lung, prostate, breast and colorectal cancer, interviewing these patients about barriers faced in obtaining cancer diagnosis, treatment and care, linking with national Medicare and Medicaid databases, and obtaining contextual neighborhood data
Role: PI

5P50 CA090949 (Carbone)
09/26/07 - 03/31/12
NIH/NCI
SPORE in Lung Cancer

To evaluate potential modifying effects of genetic factors in the association of NSAID use and lung cancer risk.
Role: Co-investigator

5P30 CA068485 (Pietenpol) 09/28/04 - 08/31/15
NIH/NCI
Cancer Center Support Grant

To provide basic support for the administration, research development, and operations of the Vanderbilt-Ingram Cancer Center
Role: To foster the integration of cancer epidemiology, prevention and control activities throughout the Vanderbilt-Ingram Cancer Center activities

1U01 CA136792 (Henderson/Blot) 03/25/09 – 02/28/12
Univ of Southern California/NIH
Genome-wide Association Study of Prostate Cancer among African Americans

To assess genetic polymorphisms associated with risk of prostate cancer
Role: Co-investigator

BIOGRAPHICAL SKETCH

NAME Joseph Kevin McLaughlin	POSITION TITLE Professor of Medicine
eRA COMMONS USER NAME	

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY
West Chester University	B.A.	1971	Sociology-Anthropology
University of Minnesota	M.S.	1974	Environmental Health
University of Minnesota	M.P.H.	1979	Epidemiology
University of Minnesota	Ph.D.	1981	Epidemiology

A. Positions and honors

1977-1981	Research Fellow, Division of Epidemiology, University of Minnesota
1982-1983	Assistant Professor, Department of Epidemiology, Johns Hopkins School of Hygiene and Public Health, Baltimore, Maryland
1983-1988	Senior Staff Fellow, Analytical Studies Section, Biostatistics Branch, Epidemiology and Biostatistics Program, Division of Cancer Etiology, National Cancer Institute, Bethesda, Maryland
1986	Fellow, American College of Epidemiology
1988-1992	Epidemiologist (Tenured), Analytical Studies Section, Biostatistics Branch, Epidemiology and Biostatistics Program, Division of Cancer Etiology, National Cancer Institute, Bethesda, Maryland
1991	Elected to American Epidemiological Society
1992	Public Health Service Special Recognition Award for Research
1992-1994	Deputy Chief, Biostatistics Branch, Epidemiology and Biostatistics Program, Division of Cancer Etiology, National Cancer Institute, Bethesda, Maryland
1994-Present	President, International Epidemiology Institute, Rockville, Maryland
1995-Present	Professor (Adjunct), Department of Epidemiology, Johns Hopkins School of Hygiene and Public Health, Baltimore, Maryland
1998-Present	Chairman, International Epidemiology Foundation, Rockville, Maryland
2000-Present	Professor, Department of Medicine, Vanderbilt University Medical Center, Vanderbilt-Ingram Cancer Center, Nashville, Tennessee

B. Selected peer-reviewed publications

1. **McLaughlin JK**, Blot WJ, Mandel JS, Schuman LM, Mehl ES, Fraumeni JF Jr. Etiology of cancer of the renal pelvis. J Natl Cancer Inst 71:287-291, 1983.
2. **McLaughlin JK,** Mandel JS, Blot WJ, Schuman LM, Mehl ES, Fraumeni JF Jr. Population-based case-control study of renal cell carcinoma. J Natl Cancer Inst 72:275-284, 1984.
3. **McLaughlin JK,** Blot WJ, Mehl ES, Mandel JS. Problems in the use of dead controls in case-control studies. I. General results. Am J Epidemiol 121:131-139, 1985.
4. **McLaughlin JK**, Blot WJ, Mehl ES, Fraumeni JF Jr. Relation of analgesic use to renal cancer: Population-based findings. Natl Cancer Inst Mongr 69:213-215, 1985.
5. **McLaughlin JK,** Malker HSR, Stone BJ, Weiner JA, Malker BK, Ericsson JLE, Blot WJ, Fraumeni JF Jr. Occupational risks for renal cancer in Sweden. Br J Ind Med 44:119-123, 1987.
6. **McLaughlin JK,** Malker HSR, Blot WJ, Malker BK, Stone BJ, Weiner JA, Ericsson JLE, Fraumeni JF Jr. Occupational risks for intracranial gliomas in Sweden. J Natl Cancer Inst 78:253-257, 1987.
7. **McLaughlin JK,** Brookmeyer R: The epidemiologic method. In: McCunney RJ (Ed). The Handbook of Occupational Medicine. Boston, Little, Brown and Company, 1988, pp. 282-296.

8. **McLaughlin JK**, Gridley G, Block G, Winn DM, Preston-Martin S, Schoenberg JB, Greenberg RS, Stemhagen A, Ershow AG, Blot WJ, Fraumeni JF Jr. Dietary factors in oral and pharyngeal cancer. J Natl Cancer Inst 80:1237-1243, 1988.
9. **McLaughlin JK,** Hrubec, Z, Linet MS, Heineman E, Blot WJ, Fraumeni JF Jr. Cigarette smoking and leukemia among U.S. veterans: A 26-year follow-up. J Natl Cancer Inst 81:1262-1263, 1989.
10. **McLaughlin JK,** Hrubec Z, Blot WJ, Fraumeni JF Jr. Cigarette smoking and stomach cancer among U.S. veterans. Cancer Res 50:3804, 1990.
11. Gridley G, **McLaughlin JK**, Block G, Blot WJ, Winn DM, Greenberg RS, Schoenberg JB, Preston-Martin S, Austin DF, Fraumeni JF Jr. Diet and oral and pharyngeal cancer among blacks. Nutr Cancer 14:219-225, 1990.
12. **McLaughlin JK**, Chen JQ, Dosemeci M, Chen RA, Rexing SH, Wu Z, Hearl FJ, McCawley MA, Blot WJ. A nested case-control study of lung cancer among silica-exposed workers in China. Br J Ind Med 49:167-171, 1992.
13. Wacholder S, **McLaughlin JK,** Silverman DT, Mandel JS. Selection of controls in case-control studies. I. Principles. Am J Epidemiol 135:1019-1028, 1992.
14. Gao YT, **McLaughlin JK**, Blot WJ, Ji BT, Dai Q, Fraumeni JF Jr. Reduced risk of esophageal cancer associated with green tea consumption. J Natl Cancer Inst 86:855-858, 1994.
15. Nyren O, **McLaughlin JK**, Gridley G, Ekbom A, Johnell O, Fraumeni JF Jr, Adami HO. Cancer risk after hip replacement with metal implants: A population-based cohort study in Sweden. J Natl Cancer Inst 87:28-33, 1995.
16. **McLaughlin JK**, Hrubec Z, Blot WJ, Fraumeni JF Jr. Smoking and cancer mortality among U.S. veterans: A 26-year follow-up. Int J Cancer 60:190-193, 1995.
17. **McLaughlin JK**, McCredie M, Mellemgaard A, Lindblad P, Mandel JS, Schlehofer B, Pommer W, Adami HO. International renal cell cancer study. I. Tobacco use. Int J Cancer 60:194-198, 1995.
18. **McLaughlin JK**, Nyren O, Blot WJ, Yin L, Josefsson S, Fraumeni JF, Jr, Adami HO. Cancer risk among women with cosmetic breast implants: a population-based cohort study in Sweden. J Natl Cancer Inst 90:57-59, 1998.
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21. Blot WJ, **McLaughlin JK**. The changing epidemiology of esophageal cancer. Semin Oncol 26:2-8, 1999.
22. Dalton SO, Johansen C, Mellemkjaer L, Sørensen HT, **McLaughlin JK**, Olsen J, Olsen JH. Antidepressant medications and risk of cancer. Epidemiology 11:171-176, 2000.
23. **McLaughlin JK**, Lipworth L. Epidemiologic aspects of renal cell cancer. Semin Oncol 27:115-123, 2000.
24. Sørensen HT, Olsen JH, Mellemkjaer L, Thulstrup AM, Steffensen FH, **McLaughlin JK**, Baron JA. Cancer risk and mortality in users of calcium channel blockers: Cohort study. Cancer 89: 165-170, 2000.
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26. Johansen C, Boice JD, **McLaughlin JK**, Olsen JH. Cellular telephones and cancer—a nationwide cohort study in Denmark. J Natl Cancer Inst 93:203-207, 2001.
27. Johansen C, Boice JD Jr, **McLaughlin JK**, Christensen HC, Olsen JH. Mobile phones and malignant melanoma of the eye. Br J Cancer 86:348-349, 2002.
28. Friis S, Nielsen GL, Mellemkjær L, **McLaughlin JK**, Thulstrup AM, Blot WJ, Lipworth L, Vilstrup H, Olsen JH. Cancer risk in persons receiving prescriptions for paracetamol: A Danish cohort study. Int J Cancer 97:96-101, 2002.
29. Blot WJ, Lipworth L, **McLaughlin JK**. Esophageal cancer: epidemiology and risk factors. In: Kelsen DP, Daly JM, Kern SE, Leven B, Tepper JE (Eds): Gastroinstestinal Oncology: Principles and Practice. Philadelphia: Lippincott Williams & Wilkins, 2002, pp. 203-209.
30. Fryzek JP, Ye W, Signorello LB, Lipworth L, Blot WJ, **McLaughlin JK**, Nyren O. Incidence of cancer among patients with knee implants in Sweden, 1980-1994. Cancer 94:3057-3062, 2002.
31. Ji B-T, Dai Q, Gao Y-T, Hsing AW, **McLaughlin JK**, Fraumeni JF, Chow W-H. Cigarette and alcohol consumption and the risk of colorectal cancer in Shanghai, China. Eur J Cancer Prev 11:237-244, 2002.

32. Boice JD Jr, **McLaughlin JK**. Epidemiologic studies of cellular telephones and cancer risk—a review. SSI rapport: 2002:16. Stockholm: Swedish Radiation Protection Authority, pp 1-38, 2002.
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34. Pukkala E, Boice JD Jr, Hovi S-L, Hemminki E, Asko-Seljavaara S, Keskimäki I, **McLaughlin JK,** Pakkanen M, Teppo L. Incidence of breast and other cancers among Finnish women with cosmetic breast implants, 1970-1999. J Long Term Eff Med Implants 12:271-279, 2002.
35. Lipworth L, Johansen C, Arnsbo P, Møller M, **McLaughlin JK**, Olsen JH. Cancer risk among pacemaker recipients in Denmark, 1982-1996. J Long Term Eff Med Implants 12:263-270, 2002.
36. Hölmich LR, Mellemkjaer L, Gunnarsdóttir KA, Tange UB, Krag C, Møller S, **McLaughlin JK**, Olsen JH. Stage of breast cancer at diagnosis among women with cosmetic breast implants. Br J Cancer 88:832-838, 2003.
37. Chiu BCH, Ji BT, Dai Q, Gridley G, **McLaughlin JK**, Gao YT, Fraumeni JF Jr., Chow WH. Dietary factors and risk of colon cancer in Shanghai, China. Cancer Epidemiol Biomarkers Prev 12:201-208, 2003.
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39. Fryzek JP, Chadda B, Marano D, White K, Schweitzer S, **McLaughlin JK**, Blot WJ. A cohort mortality study among titanium dioxide manufacturing workers in the United States. J Occup Environ Med 45:400-409, 2003.
40. Sørensen HT, Friis S, Nørgård B, Mellemkjaer L, Blot WJ, **McLaughlin JK**, Ekbom A, Baron JA. Risk of cancer in a large cohort of nonaspirin NSAID users: a population-based study. Br J Cancer 88:1687-1692, 2003.
41. Bosetti C, La Vecchia C, Talamini R, Negri E, Levi F, Fryzek J, **McLaughlin JK**, Garavello W, Franceschi S. Energy, macronutrients and laryngeal cancer risk. Ann Oncol 14:907-912, 2003.
42. Bosetti C, La Vecchia C, Lipworth L, **McLaughlin JK**. Occupational exposure to vinyl chloride and cancer risk: a review of the epidemiologic literature. Eur J Cancer Prev 12:427-430, 2003.
43. Raaschou-Nielsen O, Hansen J, **McLaughlin JK**, Kolstad H, Christensen JM, Tarone RE, Olsen JH. Cancer risk among workers at Danish companies using Trichloroethylene: a cohort study. Am J Epidemiol 158:1182-1192, 2003.
44. Fored CM, Nise G, Ejerblad E, Fryzek JP, Lindblad P, **McLaughlin JK**, Nyren O, Elinder CG. Absence of association between organic solvent exposure and risk of chronic renal failure: a nationwide population-based case-control study. J Am Soc Nephrol 15:180-186, 2004.
45. **McLaughlin JK,** Lipworth L. Brain cancer and cosmetic breast implants: a review of the epidemiologic evidence. Ann Plast Surg 52;115-117, 2004.
46. Ye W, Held M, Lagergren J, Engstrand L, Blot WJ, **McLaughlin JK**, Nyrén O. *Helicobacter pylori* infection, gastric atrophy: risk of adenocarcinoma and squamous-cell carcinoma of the esophagus and adenocarcinoma of the gastric cardia. J Natl Cancer Inst 96:388-396, 2004.
47. Blot WJ, **McLaughlin JK**. Are women more susceptible to lung cancer? J Natl Cancer Inst 96:812-813, 2004.
48. Tarone RE, Lipworth L, Young VL, **McLaughlin JK**. Breast reduction surgery and breast cancer risk: does reduction mammoplasty have a role in primary prevention strategies for women at high risk of breast cancer? Plast Reconstr Surg 113:2104-2110, 2004.
49. Blot WJ, **McLaughlin JK**. Response. Re: Are women more susceptible to lung cancer. J Natl Cancer Inst 96:1560-1561, 2004.
50. Friis S, Poulsen AH, Johnsen SP, **McLaughlin JK**, Fryzek JP, Dalton SO, Sorensen HT, OlsenJH. Cancer risk among statin users: a population-based cohort study. Int J Cancer 114:643-647, 2005.
51. Fryzek JP, Ye W, Nyren O, Tarone RE, Lipworth L, **McLaughlin JK**. A nationwide epidemiologic study of breast cancer incidence following breast reduction surgery in a large cohort of Swedish women. Breast Cancer Res Trt Dec 3:1-4, 2005 (Epub ahead of print).
52. Johnsen Sp, larsson H, Tarone RE, **McLaughlin JK**, Norgard B, Friis S, Sorensen HT. Risk of hospitalization for myocardial infarction among users of Rofecoxib, Celecoxib and other NSAIDs: a population-based case-control study. Arch Intern med 165:978-984, 2005.

53. Olsen JH, Friis S, Frederiksen K, **McLaughlin JK**, Mellemkjaer L, Moller H. Atypical cancer pattern in patients with Parkinson disease. Br J Cancer 92:201-205, 2005.
54. Sorensen HT, Skriver MV, Friis S, **McLaughlin JK**, Blot WJ, Baron JA. Use of antibiotics and risk of breast cancer: a population-based case-control study. Br J Cancer 92:135-140, 2006.
55. **McLaughlin JK**, Lipworth L, Fryzek JP, Ye W, Tarone RE, Nyren O. Long-term cancer risk among Swedish women with silicone breast implants: an update of a nationwide study. J Natl Cancer Inst 98:557-560, 2006.
56. Norgaard M, Jacobsen J, Ratanajamit C, Jepsen P, **McLaughlin JK**, pedersen L, Sorensen HT. Valporic acid and risk of acute pancreatitis: a population-based case-control study. Am J Ther 13:113-117, 2006.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Tarone, Robert Ernest	Biostatistics Director
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	MM/YY	FIELD OF STUDY
University of California, Davis	B.S.	06/68	Mathematics
University of California, Davis	M.S.	06/69	Mathematics
University of California, Davis	Ph.D.	06/74	Mathematics

A. Personal Statement

I have extensive experience in providing statistical direction and analysis in a variety of areas of medical research that are relevant to the goals of the Southern Community Cohort Study. As a Mathematical Statistician at the National Cancer Institute I was heavily involved in providing statistical assistance to a wide variety of laboratory and clinical researchers, including investigators in the fields of immunology, DNA repair, and cancer-prone inherited diseases. In addition, I was involved in the design, conduct and statistical analysis of several large scale observational studies, including the ALTS trial of HPV testing to detect cervical cancer, the nationwide NCI case-control study of electromagnetic fields and childhood leukemia risk, the prospective Agricultural Health Study, and the NCI case-control study of cell phones and brain tumor risk, and a cohort study of mortality in Navy radar technicians. I have also had extensive experience, while at the International Epidemiology Institute and Vanderbilt University Department of Medicine, in the conduct of prospective cohort studies to evaluate potential health risks in numerous areas of environmental and occupational epidemiology. In summary, my record of statistical collaboration in productive epidemiologic research demonstrates that I am well qualified for my role in the proposed investigation.

B. Positions and Honors

Positions and Employment

1971 - 74 Associate in Biostatistics, Department of Epidemiology and Preventive Medicine, UCD, Davis, CA
1974 - 76 Staff Fellow, Division of Cancer Cause and Prevention, National Institutes of Health, Bethesda, MD
1976 - 93 Mathematical Statistician, Division of Cancer Etiology, National Institutes of Health, Bethesda, MD
1993 - 02 Chief, Statistical Research and Applications Section, Division of Cancer Epidemiology and Genetics, National Institutes of Health, Bethesda, MD
2002 - Biostatistics Director, International Epidemiology Institute, Rockville, MD
2003 - Professor, Department of Medicine, Vanderbilt University, Nashville, TN

Other Experience and Professional Memberships

1969 - 71 Medical Corpsman, United States Army
1974 - American Statistical Association
1983 - International Statistical Institute (elected member)

Honors and Awards

1979 Public Health Service Special Achievement Award
1983 Fellow, American Statistical Association
1992 National Institutes of Health Director's Award
1999 Division of Cancer Epidemiology and Genetics Exemplary Service Award
2001 National Institutes of Health Merit Award

C. Selected Peer-reviewed Publications.

1. Tarone RE. Tests for trend in life table analysis. Biometrika 1975;62:679-82.
2. Tarone RE, Ware J. On distribution-free tests for equality of survival distributions. Biometrika 1977;64:156-60.
3. Linet MS, Hatch EE, Kleinerman RA, Wacholder S, Robison LL, Kaune WT, Severson RK, Haines CM, Hartsock CT, Niwa S, Tarone RE. Residential magnetic field exposure and childhood acute lymphoblastic leukemia. N Engl J Med 1997;337:1-7.
4. Tarone RE, Alavanja MCR, Zahm SH, Lubin JH, Sandler DP, McMaster SB, Rothman N, Blair A. The agricultural health study: factors affecting completion and return of self-administered questionnaires in a large prospective cohort study of pesticide applicators. Am J Ind Med 1997;31:233-42.
5. Gilbert ES, Tarone R, Bouville A, Ron E. The relationship of thyroid cancer rates and ^{131}I doses from atmospheric nuclear bomb tests. J Natl Cancer Inst 1998;90:1654-60.
6. Inskip PD, Tarone RE, Hatch EE, Wilcosky TC, Shapiro WR, Selker RG, Fine HA, Black PM, Loeffler JS, Linet MS. Cellular-telephone use and brain tumors. N Engl J Med 2001;344:79-86.
7. Groves FD, Page WF, Gridley G, Lisimaque L, Stewart PA, Tarone RE, Gail MH, Boice JD Jr, Beebe GW. Cancer in Korean war navy technicians: mortality survey after 40 years. Am J Epidemiol 2002;155:810-8.
8. Sherman ME, Wang SS, Tarone RE, Rich L, Schiffman M. Histopathologic extent of cervical intraepithelial neoplasia 3 lesions in the atypical squamous cells of undetermined significance low-grade squamous intraepithelial lesion triage study: implications for subject safety and lead-time bias. Cancer Epidemiol Biomarkers Prev 2003;12:372-79.
9. Chu KC, Tarone RE, Freeman HP. Trends in prostate cancer mortality among black men and white men in the United States. Cancer 2003;97:1507-16.
10. Raaschou-Nielsen O, Hansen J, McLaughlin JK, Kolstad H, Christensen JM, Tarone RE, Olsen JH. Cancer risk among workers at Danish companies using trichloroethylene: a cohort study. Am J Epidemiol 2003;158:1182-92.
11. Tawn EJ, Whitehouse CA, Tarone RE. FISH chromosome aberration analysis on retired radiation workers from the Sellafield nuclear facility. Radiation Res 2004;162:249-56.
12. Bosetti C, McLaughlin JK, Tarone RE, Pira E, La Vecchia C. Formaldehyde and cancer risk: a quantitative review of cohort studies through 2006. Ann Oncol 2008;19:29-43.
13. Tarone RE, Lipworth L, McLaughlin JK. The epidemiology of environmental perchlorate exposure and thyroid function: a comprehensive review. J Occup Environ Med 2010;52:653-60.
14. Boice JD Jr, Marano ED, Munro HM, Chadda BK, Signorello LB, Tarone RE, Blot WJ, McLaughlin JK. Cancer mortalityamong US workers employed in semiconductor wafer fabrication. J Occup Environ Med 2010;52:1082-97.
15. Lipworth L, Sonderman JS, Mumma MT, Tarone RE, Marano DE, Boice JD Jr, McLaughlin JK. Cancer mortality among aircraft manufacturing workers: an extended follow-up. J Occup Environ Med 2011;53:992-1007.

D. Research Support

2R01 CA092447-08 (Blot) **04/01/07 – 03/31/12** **0.6 calendar months**
NIH/NCI
Southern Community Cohort Study

The major goal of this project is to investigate the causes of racial disparities in the occurrence of cancer in the southern United States.
Role: Consultant

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Clark Wright Heath, Jr.	Epidemiologist
eRA COMMONS USER NAME	

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY
Oberlin College, Oberlin, OH	AB	1954	Epidemiology
Johns Hopkins University School of Medicine, Baltimore, MD	MD	1958	Medicine

A. Positions and Honors.

Professional Experience

1965-72	Chief, Leukemia Section, Epidemiology Program, Center for Disease Control (CDC)
1968-72	Deputy Chief, Viral Diseases Branch, Epidemiology Program, CDC
1972-75	Chief, Cancer and Birth Defects Branch, Epidemiology Program, CDC
1975-80	Director, Chronic Diseases Division, Bureau of Epidemiology, CDC
1981-84	Visiting Professor, University of Minnesota, School of Public Health (summer sessions)
1980-82	Director, Chronic Diseases Division, Center for Environmental Health, CDC
1982-83	Program Development Officer, Office of the Director, CDC
1983-85	Professor of Community Health, Master of Public Health Program, Department of Community Health, Emory University School of Medicine, and Community Health Consultant, Office of the Director, CDC
1985-88	Director, Bureau of Preventive Health Services, South Carolina Department of Health and Environmental Control
1990-98	Clinical Professor of Community Health, Emory University School of Public Health
1988-98	Vice President for Epidemiology and Surveillance Research, American Cancer Society
1999	Associate Chief of Research, Radiation Effects Research Foundation (Hiroshima, Japan), National Academy of Sciences (NAS)

Honors and Awards

1978	Public Health Service (PHS) Meritorious Service Medal, DHEW
1979	Certificate of Appreciation, DHEW
1979	PHS Certificate of Appreciation
1979	CDC Medal of Excellence

Professional Organizations

American Association for Cancer Research
American Association for the Advancement of Science (Fellow 1998)
American College of Epidemiology (Fellow 1981)
American Epidemiological Society
American Medical Association
American Public Health Association
American Society of Preventive Oncology
International Epidemiological Association
International Society for Environmental Epidemiology
Society for Epidemiologic Research

Specialty Board Certification
2/2/1987 American Board of Preventive Medicine, #50300 (Public Health and General Preventive Medicine)

Medical Practice Licensure
7/27/1966 Georgia, #11365
4/19/1986 South Carolina, #12720

Other Professional Experience

1978-79	Chairperson, Work Group on Science, Interagency Taskforce on the Health Effects of Ionizing Radiation, U.S. Government
1979-82	Member, Interagency Radiation Research Committee (IRRC), U.S. Government
1980	Chairperson, IRRC study group to evaluate research proposals to study delayed health effects of fall-out radiation in Utah, Nevada, and Arizona
1981	Chairperson, Subcommittee on the Use of Long-term Registries for Health Follow-up of Populations Exposed to Toxic Hazards, Committee to Coordinate Environmental and Related Programs, PHS
1983-86	Member, Committee on Toxicology, NAS
1984-86	Member, Governing Council, Epidemiology Section, American Public Health Association
1984-88	Member, Dioxin Registry Peer Review Panel, National Institute for Occupational Safety and Health
1988-90	Member, Scientific Advisory Committee, Center for Environmental Epidemiology, University of Pittsburgh, Graduate School of Public Health
1989-97	Member, Scientific Council, Radiation Effects Research Foundation (U.S./Japan joint oversight of atomic bomb survivor studies), NAS
1989-91	Chairperson, Committee on Occupational Health Effects of Ionizing Radiation among Nuclear Utility Workers, NAS
1989-90	Member, Secretarial Panel for the Evaluation of Epidemiologic Research Activities, U.S. Department of Energy
1990-94	Member, Non-ionizing Electric & Magnetic Fields Subcommittee, U.S. Environmental Protection Agency
1993-98	Chairperson, Committee to Study the Mortality of Military Personnel Present at Atmospheric Tests of Nuclear Weapons, NAS, Medical Followup Agency
1997-99	Member, Board of Directors, American College of Epidemiology
1997-03	Chair, Awards Committee, American College of Epidemiology
1998-	Chair, Expert Advisory Committee to advise the New York Department of Health on Love Canal Health Studies
1999-	Advisor, International Epidemiology Institute, Rockville, MD
2000-	Member, Board of Scientific and Policy Advisors, American Council on Science and Health

B. Selected Peer-Reviewed Publications. (selected from over 180 articles)

1. **Heath CW Jr**, Hasterlik RJ. Leukemia among children in a suburban community. Am J Med 34:796-812, 1963. Reprinted in CA Cancer J Clin 40:29-50, 1990.
2. **Heath CW Jr**, Manning MD, Zelkowitz L. Case clusters in the occurrence of leukemia and congenital malformations. Lancet 2:136-7, 1964.
3. **Heath CW Jr**, Moloney WC. Familial leukemia. Five cases of acute leukemia in three generations. N Engl J Med 272:882-7, 1965.
4. **Heath CW Jr**, Moloney WC. The Philadelphia chromosome in an unusual case of myeloproliferative disease. Blood 26:461-8, 1965.
5. McPhedran P, **Heath CW Jr**. Multiple cases of leukemia associated with one house. JAMA 209:2021-5, 1969.
6. McPhedran P, **Heath CW Jr**. Acute leukemia occurring during chronic lymphocytic leukemia. Blood 35:-11, 1970.
7. McPhedran P, **Heath CW Jr**, Garcia JS. Racial variations in leukemia incidence among the elderly. J Natl Cancer Inst 45:25-8, 1970.

8. **Heath CW Jr**, Brodsky AL, Potolsky AI. Infectious mononucleosis in a general population. Am J Epidemiol 95:46-52, 1972.
9. **Heath CW Jr**. Cancer as a sequel to therapy. N Engl J Med 287:1146-7, 1972.
10. Larsen RJ, Holmes CL, **Heath CW Jr**. A statistical test for measuring unimodal clustering. A description of the test and of its application to cases of acute leukemia in metropolitan Atlanta, Georgia. Biometrics 29:301-9, 1973.
11. Brown TM Jr, **Heath CW Jr**. Time-space clustering among cases of Burkitt's tumor. Cancer Res 34:1216-8, 1974.
12. Falk H, Creech JL Jr, **Heath CW Jr**, Johnson MN, Key MM. Hepatic disease among workers at a vinyl chloride polymerization plant. JAMA 230:59-63, 1974.
13. Randolph VI, **Heath CW Jr**. Influenza during pregnancy in relation to subsequent childhood leukemia and lymphoma. Am J Epidemiol 100:399-409, 1974.
14. **Heath CW Jr**. Epidemiology of leukemia. In: Schottenfeld D (ed), Cancer Epidemiology and Prevention: Current Concepts. Springfield, IL: CC Thomas, pp 318-50, 1975.
15. **Heath CW Jr**, Caldwell GG, Feorino PC. Viruses and other microbes. In: Fraumeni JF Jr (ed). Persons at High Risk of Cancer. An Approach to Cancer Etiology and Control. New York: Academic press, pp 241-64, 1975.
16. Brown TM Jr, **Heath CW Jr**, Lang RM, Lee SK, Whalley BW. Nasopharyngeal cancer in Bermuda. Cancer 37:1464-8, 1976.
17. **Heath CW Jr**, Dumont CR, Gamble J, Waxweiler RJ. Chromosomal damage in men occupationally exposed to vinyl chloride monomer and other chemicals Environ Res 14:68-72, 1977.
18. Zack MM Jr, **Heath CW Jr**, Andrews MD, Grivas SA Jr, Christine BW. High school contact among persons with leukemia and lymphoma. N Jatl Cancer Inst 59:1343-9, 1977.
19. **Heath CW Jr**. Environmental pollutants and the epidemiology of cancer. Environ Health Perspect 27:7-10, 1978.
20. Blot WJ, Harrington JM, Toledo A, Hoover R, **Heath CW Jr**, Fraumeni JF Jr. Lung cancer after employment in shipyards during World War II. N Engl J Med 299:620-4, 1978.
21. Caldwell GG, Kelley DB, **Heath CW Jr**. Leukemia among participants in military maneuvers at a nuclear bomb test. A preliminary report. JAMA 244:15757-8, 1980.
22. **Heath CW Jr**. The leukemias. In: Schottenfeld D, Fraumeni J Jr (eds). Cancer Epidemiology and Prevention. Philadelphia, PA: WB Saunders, pp 728-38, 1982.
23. Caldwell GG, Lelley D, Zack M, Falk H, **Heath CW Jr**. Mortality and cancer frequency among military nuclear test (Smoky) participants, 1957 through 1979. JAMA 250:620-4, 1983.
24. Kilbourne EM, Rigau-Perez JG, **Heath CW Jr**, Zack MM, Falk H, Martin-Marcos M, de Carlos A. Clinical epidemiology of toxic-oil syndrome. Manifestations of a new illness. N Engl J Med 309:1408-14, 1983.
25. **Heath CW Jr**, Nadel MR, Zack MM Jr, Chen ATL, Bender MA, Preston RJ. Cytogenetic findings in persons living hear the Love Canal. JAMA 251:1437-40, 1984.
26. Caldwell GG, Kelley DB, **Heath CW Jr**, Zack M. Polycythemia vera among participants of a nuclear weapons test. JAMA 252:662-4, 1984.
27. **Heath CW Jr**. Cigarette smoking and hematopoietic cancer. J Natl Cancer Inst 82:1800-1, 1990.
28. **Heath CW Jr**. Ionizing radiation as a cause of cancer. CA Cancer J Clin 40:A13-4, 1990.
29. **Heath CW Jr**. Fluoride and cancer. CA Cancer J Clin 49:A13-4, 1990.
30. Thun MJ, Namboodiri MM, **Heath CW Jr**. Aspirin use and reduced risk of fatal colon cancer. N Engl J Med 25:1593-6, 1991.
31. Peto R, Lopez AD, Boreham J, Thun M, **Heath CW Jr**. Mortality from tobacco in developed countries: indirect estimation from national vital statistics. Lancet 339:1268-78, 1992.
32. Thun MJ, Calle EE, Namboodiri MM, Flanders WD, Coates RJ, Byers T, Boffetta P, Garfinkel L, **Heath CW Jr**. Risk factors for fatal colon cancer in a large prospective study. J Natl Cancer Inst 84:1491-500, 1992.
33. Boring CC, Squires TS, **Heath CW Jr**. Cancer statistics for African Americans. CA Cancer J Clin 42:7-17, 1992.
34. Thun MJ, Namboodiri MM, Calle EE, Flanders WD, **Heath CW JR**. Aspirin use and risk of fatal cancer. Cancer Res 53:1322-7, 1993.

35. Calle EE, Miracle-McMahill HL, Thun MJ, **Heath CW Jr**. Cigarette smoking and risk of fatal breast cancer. Am J Epidemiol 139:1001-7, 1994.
36. Thun MJ, Day-Lally CA, Calle EE, Flanders WD, **Heath CW Jr**. Excess mortality among cigarette smokers: changes in a 20 year interval. Am J Public Health 85:1223-30, 1995.
37. **Heath CW Jr**. Electromagnetic field exposure and cancer: a review of epidemiologic evidence. CA Cancer J Clin 46:29-44, 1996.
38. Peto R, Lopez AD, Boreham J, Thun M, **Heath C**, Doll R. Mortality from smoking worldwide. Brit Med Bull 52:12-21, 1996.
39. Wingo PA, Bolden S, Tong T, Parker SL, Martin LM, **Heath CW Jr**. Cancer statistics for African Americans, 1996. CA Cancer J Clin 46:113-25, 1996.
40. **Heath CW Jr**. Investigating causation in cancer clusters. Rad Environ Biophys 35:133-6, 1996.
41. Oakley GP Jr, **Heath CW Jr**. Cancer, environmental health, and birth defects: examples of new directions in public health practice. Am J Epidemiol 144:S58-64, 1996.
42. **Heath CW Jr**. Pesticides and cancer risk. Cancer 80:1998-8, 1997.
43. Thun MJ, Lally CA, Flannery JT, Calle EE, Flanders WD, **Heath CW Jr**. Cigarette smoking and changes in the histopathology of lung cancer. J Natl Cancer Inst 89:1580-6, 1997.
44. Rodriguez C, Tatham LM, Thun MJ, Calle EE, **Heath CW Jr**. Smoking and fatal prostate cancer in a large cohort of adult men. Am J Epidemiol 145:466-75, 1997.
45. Thun MJ, Peto R, Lopez AD, Monaco JH, Henley SJ, **Heath CW Jr**. Alcohol consumption and mortality in middle-aged and elderly US adults. N Engl J Med 337:1705-14, 1997.
46. Collaborative Group on Hormonal Factors in Breast Cancer (Calle EE, **Heath CW Jr**, with others). Breast cancer and hormone replacement therapy: collaborative reanalysis of data from 51 epidemiological studies of 52,705 women with breast cancer and 108,411 women without breast cancer. Lancet 350:1047-59, 1997.
47. Rodriguez C, Calle EE, Miracle-McMahill HL, Tatham LM, Wingo PA, Thun MJ, **Heath CW Jr**. Family history and risk of fatal prostate cancer. Epidemiol 8:653-7, 1997.
48. Parker SL, Davis KJ, Wingo PA, Ries LAG, **Heath CW Jr**. Cancer statistics by race and ethnicity. CA Cancer J Clin 48:31-48, 1998.
49. Bergmann MM, Calle EE, Mervix CA, Miracle-McMahill HL, Thun MJ, **Heath CW**. Validity of self-reported cancers in a prospective cohort study in comparison to data from state cancer registries. Am J Epidemiol 147:556-62, 1998.
50. Kahn HS, Tatham LM, Patel AV, Thun MJ, **Heath CW Jr**. Increased cancer mortality following a history of nonmelanoma skin cancers. JAMA 280:910-2, 1998.
51. Williamson DF, Pamuk E, Thun M, Flanders D, Byers T, **Heath C**. Prospective study of intentional weight loss and mortality in overweight white men aged 40-64 years. Am J Epidemiol 149:491-503, 1999.
52. Calle EE, Thun MJ, Petrelli JM, Rodriguez C, **Heath CW Jr**. Body-mass index and mortality in a prospective cohort of U.S. adults. N Engl J Med 341:1097-105, 1999.
53. Enstrom JE, **Heath CW Jr**. Smoking cessation and mortality trends among 118,000 Californians, 1960-97. Epidemiology 10;500-12, 1999.
54. Watkins ML, Erickson JD, Thun MJ, Mulinare J, **Heath CW Jr**. Multivitamin use and mortality in a large prospective study. Am J Epidemiol 152:149-62, 2000.
55. Wartenberg D, Calle EE, Thun MJ, **Heath CW Jr**, Lally C, Woodruff T. Passive smoking exposure and female breast cancer mortality. J Natl Cancer Inst 92:1666-73, 2000.
56. **Heath CW Jr**, Fontham ETH. Cancer etiology. In: Lenhard RE Jr, Osteen RT, Gansler T (eds). Clinical Oncology. Atlanta, GA: American Cancer Society, pp 37-54, 2001.
57. **Heath CW Jr**, Bond PD, Hoel DG, Meinhold CB. Residential radon exposure and lung cancer risk: commentary on Cohen's county-based study. Health Phys 87:647-55, 2004.
58. Boice JD Jr, Mumma MT, Blot WJ, **Heath CW Jr**. Childhood cancer mortality in relation to the St. Lucie nuclear power station. J Radiol Prot 25:229-240, 2005.
59. **Heath CW Jr**. Community clusters of childhood leukemia and lymphoma; evidence of infection? Am J Epidemiol 162:817-22, 2005.
60. Boice JD Jr, Bigbee WL, Mumma MT, **Heath CW Jr**, Blot WJ. Cancer incidence in municipalities near two former nuclear materials processing facilities in Pennsylvania -- an update. Health Phys 96:118-27, 2009.

Program Director/Principal Investigator (Last, First, Middle):

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Sarah Schweitzer Cohen	Biostatistical Epidemiologist
eRA COMMONS USER NAME (credential, e.g., agency login) sschweit	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of North Carolina, Chapel Hill, NC	BSPH	05/00	Biostatistics
University of Michigan, Ann Arbor, MI	MS	05/02	Biostatistics Public Health Genetics
University of North Carolina, Chapel Hill, NC	PhD	05/10	Epidemiology

A. Personal Statement

I have been a collaborator on numerous occupational epidemiology studies, with many focused on radiation exposure, for the past eight years. Most notably I was a key collaborator for both an original analysis as well as an updated analysis nine years later of the workers at Rocketdyne (Atomics International) where a unique approach was taken to obtain lifetime occupational radiation doses. I have created and managed multiple large and complex databases related to these studies. My strong analytic background with training and extensive employment experience as a biostatistician has allowed me to serve as the primary analyst for multiple radiation and occupational epidemiology studies. Collectively, my extensive experience with prior studies, strong analytic skills, and keen interest and knowledge in a wide variety of environmental exposures positions me to play an important role in moving forward the aims of this project.

B. Positions and Honors

Positions and Employment

1996 – 1999	Professional Internship Progam, Oak Ridge National Laboratory, Oak Ridge, TN
1999 – 2000	Statistics Intern, Glaxo Wellcome, Inc., Research Triangle Park, NC
2000 – 2002	Research Assistant, University of Michigan, Ann Arbor, MI
2005 – 2008	NRSA Cancer Epidemiology Trainee, University of North Carolina, Chapel Hill, NC
2008 – 2010	Cancer Control Education Program Predoctoral Fellow, Lineberger Comprehensive Cancer Center, University of North Carolina, Chapel Hill, NC
2002 – Present	Biostatistician (2002-2010), Biostatistical Epidemiologist (2010-present), International Epidemiology Institute, Rockville, MD

Professional Memberships and Honors

2009 -	Member, The Obesity Society
2010	Delta Omega, Honorary Public Health Society
2010	Nominee, Greenberg Award for Excellence in Doctoral Research, University of North Carolina, Chapel Hill, NC

C. Selected Peer-reviewed Publications (Selected from 34 peer-reviewed publications)

Most relevant to the current application

1. Boice JD, **Cohen SS,** Mumma MT, Ellis ED, Eckerman KF, Leggett RW, Boecker BB, Brill AB, Henderson BE. Updated Mortality Analysis of Radiation Workers at Rocketdyne (Atomics International), 1948-2008. *Radiat Res* 7 mar 2011 [Epub ahead of print]
2. Boice JD Jr, Leggett RW, Ellis ED, Wallace PW, Mumma M, **Cohen SS**, Brill AB, Chadda B, Boecker BB, Yoder RC, Eckerman KF. A comprehensive dose reconstruction methodology for former Rocketdyne/Atomics International radiation workers. *Health Phys* 90(5): 409-430, 2006.
3. Boice JD Jr, **Cohen SS**, Mumma M, Ellis ED, Eckerman KF, Leggett RW, Boecker BB, Brill AB, Henderson B. Mortality among radiation workers at Rocketdyne (Atomics International), 1948-1999. *Radiat Res* 166: 98-115, 2006
4. Boice JD Jr, Marano D, **Cohen SS,** Mumma MT, Blot WJ, Brill AB, McLaughlin JK, Henderson B. Mortality among Rocketdyne workers who tested rocket engines, 1948-1999. *J Occup Environ Med* 48(10): 1070-1092, 2006.

Additional recent publications of importance to the field (in chronological order)

5. Boice JD, **Cohen SS,** Mumma MT, Chadda B, Blot WJ. A cohort study of uranium millers and miners of Grants, NM, 1979-2005. *J Radiol. Prot.* 28:303-325, 2008.
6. Boice JD, **Cohen SS**, Mumma MT, Chadda B, Blot WHJ. Mortality among residents of Uravan, Colorado who lived near a uranium mill, 1936-1984. *J Radiol Prot.* 27: 299-319, 2007.
7. Fryzek JP, Hansen J, **Cohen S**, Bonde JP, Llambias MT, Kolstad H, Skytthe A, Lipworth L, Blot WJ, Olsen JH. A cohort study of Parkinson's disease and other neurodegenerative disorders in Danish welders. *J Occup Environ Med* 47: 466-472, 2005.
8. Fryzek JP, Chadda B, **Cohen S**, Marano D, White K, Steinwandel M, McLaughlin JK. Retrospective cohort mortality study of workers engaged in motion picture film processing. *J Occup Environ Med* 47: 278-286, 2005.
9. Boice JD Jr, Mumma M, **Schweitzer S,** Blot WJ. Cancer mortality in a Texas county with prior mining and milling activities, 1950-2001. *J Radiol Prot* 23:247-262, 2003.
10. Fryzek JP, Chadda B, Marano D, White K, **Schweitzer S**, McLaughlin JK, Blot WJ. A cohort mortality study among titanium dioxide manufacturing workers in the United States. *J Occup Environ Med* 45:400-409, 2003.

D. Research Support

On-going Research Support - None

Completed Research Support

Cancer Epidemiology Training Grant (NCI, T32 CA09330-26) 9/1/2005 – 8/31/2010
Cancer Control Education Program Predoctoral Fellowship (NCI, 5-R25-CA057726) 9/1/2008 – 8/31/2010

Select Environmental and Genetic Determinants of Adiponectin and Obesity in Black and White Women

The goal of this project was to examine serum adiponectin levels and body mass index in relation to environmental and behavioral factors as well as several single nucleotide polymorphisms (SNPs) in three adiponectin-related genes (*ADIPOQ*, *ADIPOR1*, and *ADIPOR2*) among 2,000 black and white women enrolled in the Southern Community Cohort Study.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Michael T. Mumma	Director of Information Technology

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY
Frostburg State University, Frostburg, Maryland	BS	1994	Biology
University of Florida, Gainesville, Florida	MS	1996	Limnology

A. Positions and Honors

Professional Experience:

1991-1994 Genetics Research Assistant, Frostburg State University, Frostburg, Maryland.
1994-1996 Graduate Research Assistant, University of Florida, Gainesville, Florida
1996-1998 Research Biologist, North Carolina State University, Raleigh, North Carolina
1998-2000 Programmer Analyst, Westat, Rockville, Maryland
2000-2006 Systems Analyst, International Epidemiology Institute, Rockville, Maryland
2006-present Director of Information Technology; International Epidemiology Institute, Rockville, Maryland

Technical Training:

Data management and analysis using SAS datastep, macro, and SQL
Develop database interfaces using Power Builder
Develop data entry systems using Delphi and Visual Basic
Develop relational databases using Microsoft Access

B. Selected Peer-Reviewed Publications

Greene **Mumma MT**. The Importance of Weed Science to World Health and Environment. Florida Weed Science Society Newsletter 17 (2), 1995.

Mumma MT, Cichra CE. Benthic Macroinvertibrate Monitoring in the Tri-County Agricultural Area of the Lower St. Johns River, Florida. Final Report to St. Johns River Water Management District. Project # 93W240-B, 1996.

Mumma MT, Cichra CE, Sowards JT. Effects of Recreation on the Submerged Aquatic Plant Community of Rainbow River, Florida. J Aquat Plant Manage 34:53-56, 1996.

Mumma MT. The Redmond to Cary Express – A Comparison of Methods to Automate the Conversion of Data Between SAS and Microsoft Excel. Proceedings of the Twelfth Annual Northeast SAS Users Group, Washington, DC, 1999.

Fryzek JP, **Mumma MT**, McLaughlin JK, Henderson BE, Blot WJ. Cancer mortality in relation to environmental chromium exposure. J Occup Environ Med 43:635-640, 2001.

Boice JD Jr, Bigbee WL, **Mumma MT**, Blot WJ. Cancer mortality in counties near two former nuclear materials processing facilities in Pennsylvania, 1950-1995. Health Phys 85:691-700, 2003.

Boice JD Jr, Bigbee WL, **Mumma MT**, Blot WJ. Cancer incidence in municipalities near two former nuclear materials processing facilities in Pennsylvania. Health Phys 85:678-690, 2003.

Boice JD Jr, **Mumma M**, Schweitzer S, Blot WJ. Cancer mortality in a Texas county with prior uranium mining and milling activities, 1950-2001. J Radiol Prot 23:247-262, 2003.

Blot WJ, Fischer T, Nielsen GL, Friis S, McLaughlin JK, **Mumma MT**, Lipworth L, DuBois R. Outcome of upper gastro-intestinal bleeding and use of ibuprofen vs. paracetamol. Pharm World Sci 26:319-323. 2004.

Boice JD Jr, **Mumma MT**, Blot WJ, Heath CW Jr. Childhood cancer mortality in relation to the St Lucie Nuclear Power Station. J Radiol Prot 25:229-240,2005.

Boice JD Jr, Cohen SS, **Mumma MT**, Ellis ED, Eckerman KF, Leggett RW, Boecker BB, Brill AB, Henderson BE. Mortality among radiation workers at Rocketdyne (Atomics International), 1948-1999. Radiat Res 166:98-115, 2006.

Boice JD Jr, Leggett RW, Ellis ED, Wallace PW, **Mumma M**, Cohen SS, Brill AB, Chadda B, Boecker BB, Yoder RC, Eckerman KF. A comprehensive dose reconstruction methodology for former radiation workers. Health Phys 90:409-430, 2006.

Boice JD Jr, Marano DE, Cohen SS, **Mumma MT**, Blot WJ, Brill AB, Fryzek JP, Henderson BE, McLaughlin JK. Mortality among Rocketdyne workers who tested rocket engines, 1948-1999. J Occup Environ Med 48:1070-1092, 2006.

Boice JD Jr, Cohen SS, **Mumma MT**, Chadda B, Blot WJ. Mortality among residents of Uravan, Colorado who lived near a uranium mill, 1936-84. J Radiol Prot 27:299-319, 2007.

Boice JD Jr, **Mumma MT**, Blot WJ. Cancer and noncancer mortality in populations living near uranium and vanadium mining and milling operations in Montrose County, Colorado, 1950-2000. Rad Res 167:711-726, 2007.

Boice JD Jr, Cohen SS, **Mumma MT**, Chadda B, Blot WJ. A cohort study of uranium millers and miners of Grants, New Mexico, 1979-2005. J Radiol Prot 28:303-325, 2008.

Boice JD Jr, Bigbee WL, **Mumma MT**, Heath CW Jr, Blot WJ. Cancer incidence in municipalities near two former nuclear materials processing facilities in Pennsylvania -- an update. Health Phys. 2009 Feb;96(2):128-37, 2009.

Boice JD Jr, Bigbee WL, **Mumma MT**, Tarone RE, Blot WJ. County mortality and cancer incidence in relation to living near two former nuclear materials processing facilities in Pennsylvania -- an update. Health Phys. 2009 Feb;96(2):118-27, 2009.

Boice JD Jr, **Mumma MT**, Blot WJ. Cancer incidence and mortality in populations living near uranium milling and mining operations in Grants, New Mexico, 1950-2004. Radiat Res174(5):624-636, 2010.

McLaughlin JK, **Mumma MT**, Jennifer S. Sonderman, Farnsworth EP, Lipworth L. Cancer mortality among workers at a satellite manufacturing facility. J Occup Environ Med 53(4):427-433, 2011.

Boice JD Jr, Cohen SS, **Mumma MT**, Ellis ED, Eckerman KF, Leggett RW, Boecker BB, Brill AB, Henderson BE. Updated mortality analysis of radiation workers at Rocketdyne (Atomics International), 1948-2008. Radiat Res 176(2):224-258, 2011.

Lipworth L, Sonderman JS, **Mumma MT**, Tarone RE, Marano DE, Boice JD Jr, McLaughlin JK. Cancer mortality among aircraft manufacturing workers: an extended follow-up. J Occup Environ Med 53(9):992-1007, 2011.

Resumes

ELIZABETH A. DUPREE ELLIS, PH.D.

EDUCATION

- B.A., Zoology, Duke University, 1973
- Sc.M., Epidemiology, Johns Hopkins University, 1978
- Ph.D., Epidemiology, University of North Carolina, Chapel Hill, 1989

POSITIONS

Oak Ridge Associated Universities, Associate Director, Center for Epidemiologic Research, 2007-present.

Oak Ridge Associated Universities, Associate Director, Center for Epidemiologic Research, 1998-2007.
Serves as Associate Director for the Center for Epidemiologic Research which conducts and supports quality epidemiologic research with primary emphasis on occupational health studies. The program has offices in Oak Ridge, TN and Arvada, CO.

- **Associate Director, Center for Epidemiologic Research, ORAU. 1991-1998.**
- **Leader, Epidemiology Support Section, Center for Epidemiologic Research, 1987-1991.**
- **Epidemiologist, Center for Epidemiologic Research, ORAU, 1983-1987.**
- **Associate Epidemiologist, Center for Epidemiologic Research, ORAU, 1978-1981.**
- **The Johns Hopkins University, Baltimore, MD, Department of Epidemiology, Research Assistant, 1977-1978.**
- **Energy Research and Development Administration, Office of Environmental Research, Human Health Studies Program, Intern, 1977.**

PUBLICATIONS

- Dupree, EA. 1980. Mortality among workers at a uranium refining and processing plant. American Journal of Epidemiology 112:446 (abstract).

- Hudson DR, EL Frome, EA Dupree, MS Hansard, WL Beck, and CC Lushbaugh. 1981. Exploratory analysis of mortality in a cohort of nuclear material workers. American Journal of Epidemiology 114:446 (poster session).

- Lushbaugh CC, WL Beck, EA Dupree, EL Frome, SA Fry, MS Hansard, DR Hudson, and AP Polednak. 1981. Health and mortality of DOE workers. Trans. Am. Nuclear Soc. 38:81.

- Fry SA, CC Lushbaugh, CM Shy, DL Cragle, H Checkoway, S Blum, AV Carpenter, EA Dupree, EL Frome, PG Groer, and J Wilson. 1985. The U.S. Department of Energy Health and Mortality Study: The Oak Ridge studies. In: Epidemiological studies of some populations exposed to ionizing radiation, (Weeks JL, compiler), pp. 18-40, Pinawa, Manitoba: Atomic Energy of Canada Limited, (AECL publication no. 8360).

- Dupree EA, DL Cragle, RW McLain, DJ Crawford-Brown, and MJ Teta. 1987. Mortality among workers at a uranium processing facility: Linde Air Products Ceramics Plant, 1943-49. Scandinavian Journal of Work, Environment and Health13:100-107.

- Fry SA, AV Carpenter, DL Cragle, EA Dupree, PG Groer, CC Lushbaugh, H Checkoway, DJ Crawford-Brown, CM Shy, JE Watson, and EL Frome. 1988. Studies of mortality among populations of U.S. nuclear industry workers. In: Proceedings of the International Conference, Health Effects of Low Dose Ionizing Radiation--Recent Advances and Their Implications. London, England: British Nuclear Energy Society, pp. 77-80.

- Dupree EA. 1989. Doctoral dissertation, University of North Carolina, School of Public Health, Department of Epidemiology, Chapel Hill, NC. An epidemiologic investigation of mortality among workers occupationally exposed to uranium compounds at a uranium processing plant.

- Dupree EA, J Watkins, J Ingle, P Wallace, C West, and W Tankersley. 1993. Risk of lung cancer among uranium processing workers. American Journal of Epidemiology138:640 (abstract).

- Dupree EA, J Watkins, JN Ingle, PW Wallace, CM West, and WG Tankersley. 1995. Uranium dust exposure and lung cancer risk in four uranium processing operations. Epidemiology 6:370-375.

- Fry SA, DL Cragle, DJ Crawford-Brown, EA Dupree, EL Frome, ES Gilbert, GR Petersen, CM Shy, WG Tankersley, GL Voelz, PW Wallace, JP Watkins, JE Watson, and LD Wiggs. 1995. Health and Mortality among Contractor Employees at U.S. Department of Energy Facilities. In: Radiation and Public Perception: Benefits and Risks (Young JP, Yalow RS, editors). Developed from the symposium Radiation and Society, held at the April 1992 national meeting of the American Chemical Society, San Francisco, pp. 239-258.

- Fry SA, EA Dupree, AH Sipe, DL Seiler, and PW Wallace. A study of mortality and morbidity among persons occupationally exposed to > 5 rem (> 50 mSv) in a year. Phase I: Mortality, through 1984. Applied Occupational and Environmental Hygiene suppl. March 1996.

- Ellis ED, Watkins J, Ingle J, Phillips J. 2000. External radiation exposure and mortality among a cohort of uranium processing workers. American Journal of Epidemiology 152:91-95.

- Boice JD, RW Leggett, ED Ellis, PW Wallace, M Mumma, SS Cohen, AB Brill, BB Boecker, JG Barnes, RC Yoder, and KF Eckerman. 2006. A comprehensive dose reconstruction methodology for former Rocketdyne/Atomics International radiation workers. Health Physics 90(5):409-430.

- Boice JD, SS Cohen, MT Mummaw, ED Ellis, KF Eckerman, RW Legett, BB Boecker, AB Brill, and B Henderson. 2006. Mortality among radiation workers at Rocketdyne (Atomics International), 1948-1999. Radiation Research 166:98-115.

- Guseva IC, Ellis ED Tirmarche M. 2007. Cancer risk in nuclear workers occupationally exposed to uranium emphasis on internal exposure. Health Physics 94(1):1-17.

- Ellis ED, Watkins J, Tankersley W, Phillips J, Girardi D. 2010. Mortality among titanium dioxide workers at three DuPont plants. Journal of Occupational and Environmental Medicine. Journal of Occupational and Environmental Medicine 52(3):303-309.

- Boice JD, SS Cohen, MT Mummaw, ED Ellis, KF Eckerman, RW Legett, BB Boecker, AB Brill, and B Henderson. 2011. Updated mortality analysis of radiation workers at Rocketdyne (Atomics International), 1948-2008. Radiation Research 176:244-258.

- Tirmarche M, Harrison JD, Pacquet F, Blettner M, Laurier D, Shilnikova N, Blanchondon E, Lecomte JF, Sokolnikov M, Ellis E, and Marsh JW Assessment and control of lung cancer risk from radon.
- Annals of the ICRP (accepted for publication)

Synergistic Activities

- 2006 - Present. Member, International Commission on Radiation Protection, Committee 2, Task Group 64 to review knowledge and make recommendations on further study of the health effects of occupational radiation exposure to alpha emitters.

- 1994 Present. Program Director for the DOE Illness and Injury Surveillance Program. The program assesses the overall health of contractor workers employed at 13 DOE sites.

- 2000 Present. Chair of the Oak Ridge Site-wide Institutional Review Board (IRB) and member of the DOE Central IRB.

DONNA LYNNE CRAGLE, PH.D.

EDUCATION

- B.A., Biological Sciences, Indiana University, 1974
- M.S., Human Genetics, Virginia Commonwealth University, 1978
- Ph.D., Environmental Epidemiology, University of North Carolina, Chapel Hill, 1984

POSITIONS

Oak Ridge Associated Universities, Vice President and Director, Occupational Exposure and Worker Health, 2007-present

Oak Ridge Associated Universities, Basic and Applied Research, Center for Epidemiologic Research, Director, Basic and Applied Research, 1998-2007

- Serves as Program Director and chief administrative officer for a multi-faceted science division. The Center for Epidemiologic Research conducts and supports quality epidemiologic research with primary emphasis on occupational health studies. The program has offices in Oak Ridge, TN; Cincinnati, OH; Arvada, CO; and Livermore, CA.

Director, Center for Epidemiologic Research, ORAU, 1991-present

Deputy Director, Center for Epidemiologic Research and Epidemiologic, Research Section Leader, ORAU, 1986-1991

Epidemiology Research Section Leader, ORAU, 1983-1985

Epidemiologist, ORAU, 1981-1982

University of North Carolina, Department of Epidemiology, 1979-1980
North Carolina Memorial Hospital, Blood Bank, 1977-1981
Medical College of Virginia, Department of Human Genetics , 1976-1977
Department of Clinical Pathology, Chemistry Division, 1975-1976
Indiana University, Department of Microbiology, 1974-1974

PUBLICATIONS

- Cragle DL, DR Hollis, CM Shy, and TH Newport. 1984. A retrospective cohort mortality study among workers occupationally exposed to metallic nickel power at the Oak Ridge Gaseous Diffusion Plant. In Symposium on Nickel in the Human Environment, International Agency for Research on Cancer, Lyon, France. IARC Publications No. 53, pp 57-64.

- Cragle DL, DR Hollis, JR Qualters, WG Tankersley, and SA Fry. 1984. A mortality study of men exposed to elemental mercury. Journal of Occupational Medicine 26:817-821.

- Checkoway H, NE Pearce, DJ Crawford-Brown, and DL Cragle. 1988. Radiation doses and cause-specific mortality among workers at a nuclear materials fabrication plant. American Journal of Epidemiology 127:255-266.

- Cragle DL, RW McLain, JR Qualters, JLS Hickey, GS Wilkinson, WG Tankersley, and CC Lushbaugh. 1988. Mortality among workers at a nuclear fuels production facility. American Journal of Industrial Medicine 14:379-401.

- Gilbert ES, SA Fry, LD Wiggs, GL Voelz, DL Cragle, and GR Petersen. 1989. Analyses of combined data on workers at the Hanford Site, Oak Ridge National Laboratory, and Rocky Flats Nuclear Weapons Plants. Radiation Research 120:19-35.

- Frome EL, DL Cragle, and RW McLain. 1990. Poisson regression analysis of the mortality among a cohort of World War II nuclear industry workers. Radiation Research 123:138-152.

- Gilbert ES, SA Fry, LD Wiggs, GL Voelz, DL Cragle, and GR Petersen. 1990. Methods for analyzing combined data from studies of workers exposed to low doses of radiation. American Journal of Epidemiology 131:917-927.

- Wing S, CM Shy, JL Wood, S Wolf, DL Cragle, and EL Frome. 1991. Mortality among workers at Oak Ridge National Laboratory: Evidence of radiation effects in follow-up through 1984. Journal of the American Medical Association 265:1397-1402.

- Cragle DL, SM Wells, and WG Tankersley. 1992. A morbidity study of workers potentially exposed to epoxy resins, hardeners, and solvents. Journal of Applied Occupational and Environmental Hygiene 7:826-834.

- Wing S, CM Shy, JL Wood, S Wolf, DL Cragle, W Tankersley, and EL Frome. 1993. Job factors, radiation and cancer mortality at Oak Ridge National Laboratory: Follow-up through 1984. American Journal of Industrial Medicine 23:265-279.

- Watkins, JP, DL Cragle, EL Frome, JL Reagan, CM West, D Crawford-Brown, and WG Tankersley. 1997. Collection, validation, and treatment of data for a mortality study of nuclear industry workers. Applied Occupational and Environmental Hygiene 12:195-205.

- Frome, EL, DL Cragle, JP Watkins, S Wing, C Shy, WG Tankersley, and CM West. 1997. A mortality study of employees of the nuclear industry in Oak Ridge, Tennessee. Radiation Research 148:64-80.

- Cragle, DL, JP Watkins, and K Robertson-DeMers. 1999. Mortality among workers at the Savannah River Nuclear Fuels Production Facility. Proceedings of the American Statistical Association.

- Letz, R, F Gerr, D Cragle, RC Green, J Watkins, and AT Fidler. 2000. Residual neurologic deficits 30 years after occupational exposure to elemental mercury. NeuroToxicology 21(4):459-474.

- Frome EL, Newman LS, Cragle DL, Colyer SP, and Wambach PF. 2003. Identification of an abnormal beryllium lymphocyte proliferation test. Toxicology 183:39-56

- Watkins JP, Frome EL, Cragle DL. 2005. "Age-based methods to explore time-related variables in occupational epidemiology studies." 2005 Proceedings in the American Statistical Association, Section on Statistics in Epidemiology [CD-ROM], Alexandria, VA: American Statistical Association: 2652 - 2657.

- Van Dyke, MV, JW Martyny, MA Mroz, LS Silveira, M Strand, DL Cragle, WG Tankersley, SM Wells, LS Newman, and LA Maier. 2011. Exposure and Genetics Increase Risk of Beryllium

Sensitization and Chronic Beryllium Disease in the Nuclear Weapons Industry, Submitted to Occupational and Environmental Medicine. Occup Environ Med. 2011 Apr 2 [Epub ahead of print]

CHAPTERS, REVIEW ARTICLES AND OTHER PUBLICATIONS:

- Fry SA, AV Carpenter, DL Cragle, EA Dupree, PG Groer, CC Lushbaugh, H Checkoway, DJ Crawford-Brown, CM Shy, JE Watson, and EL Frome. 1988. Studies of mortality among populations of US nuclear industry workers. In Health effects of low dose ionizing radiation. BNES, London, Paper 14, pp.77-80.

- Doll R, A Andersen, WC Cooper, I Cosmatos, DL Cragle, D Easton, P Enterline, M Goldberg, L Metcalfe, T Norseth, J Peto, J-P Rigaut, R Roberts, SK Sielkop, H Shannon, F Speizer, FW Sunderman, Jr., P Thornhill, JS Warner, J Weglo, and M Wright. 1990. Report of the International Committee on Nickel Carcinogenesis in Man. Scandinavian Journal of Work, Environment & Health 16:1-82 (special issue).

- Watkins, JP, JL Reagan, DL Cragle, EL Frome, CM West, DJ Crawford-Brown, and WG Tankersley. 1993. Data collection, validation, and description for the Oak Ridge nuclear facilities mortality study. Oak Ridge Institute for Science and Education technical report 93/J-42.

- Watkins, JP, DL Cragle, EL Frome, CM West, DJ Crawford-Brown, and WG Tankersley. 1994. Adjusting external doses from the ORNL and Y-12 Facilities for the Oak Ridge Nuclear Facilities Mortality Study. Supplemental Report to ORISE 93/J-42. Oak Ridge Institute for Science and Education technical report 94/G-34.

- Fry, SA, DL Cragle, DJ Crawford-Brown, EA Dupree, EL Frome, ES Gilbert, GR Petersen, CM Shy, WG Tankersley, GL Voelz, PW Wallace, JP Watkins, JE Watson Jr, and LD Wiggs. 1995. Health and mortality among contractor employees at U.S. Department of Energy facilities. IN: Radiation and Public Perception: Benefits and risks, edited by Jack P. Young and Rosalyn S. Yalow. American Chemical Society. pp.239-258.

SYNERGISTIC ACTIVITIES

- 2006 - 2009. Board Member of the Beryllium Health and Safety Committee and Chair of the Epidemiology subsection of this committee. Member of NNSA Blue Ribbon Advisory Committee on Beryllium.
- 2002 present. Program Director for NIOSH Dose Reconstruction Project for claimants under the Energy Employees Occupational Illness Compensation Program Act.
- 1998 present. Program Director for the nationwide Former Beryllium Worker Medical Surveillance Program.
- 1992 – Program Director for the Y12 Beryllium Surveillance Research Project.
- 1995 – 2004. Member of a Project Research Team (PRT) for the U.S. Department of Energy's Office of International Health Studies. The PRT is working with researchers in Chelyabinsk, Russia on studies of the health effects of working at and living in the vicinity of the Mayak plutonium processing facility in that region.
- May 6-7, 1987: Faculty member for a course entitled "Basic Concepts of Radiation for Attorneys," taught to the Department of Justice Radiation Defense Attorneys, Washington, D.C.

- June 11-18, 1987: Faculty member for the Taiwan Power Company sponsored seminar "Conference on Risk Assessment, Preventive Analysis and Emergency Preparedness," Taipei, Taiwan.
- June 29-July 1, 1987, and January 6-8, 1993: Faculty member for a course entitled "Basic Concepts of Radiation for Attorneys," taught at the Radiation Emergency Assistance Center/Training Site of Oak Ridge Associated Universities. Oak Ridge, Tennessee.
- 1985 – 1990. Member of an international scientific steering committee (Chairman, Sir Richard Doll, UK) to determine whether exposure to specific forms of nickel significantly increases the risk of developing cancer. Sponsored by the U.S. Environmental Protection Agency and various European Agencies.
- 1984-1985: Member of a panel to produce the document, "A Panel's Review and Findings of Ongoing Health Effects and Epidemiological Studies of Operations at the Savannah River Plant, Aiken, SC."
- 1983-1986: Consultant to the Coal Employment Project, Oak Ridge, TN, in a study of reproductive outcomes in female coal miners.
- 1981-1992: Member of the Oak Ridge Associated Universities/University of North Carolina Research Planning Group to plan and approve ongoing and new projects and set the strategic research agenda for the Health and Mortality Study of DOE Workers.
- 1982, 1983, 1984: Recipient of Department of Health and Human Services/Public Health Service Minority High School Student Research Apprentice Program Grant to expose minority high school students to health research through supervision of summer research projects.
- Former faculty member for "Basic Concepts of Radiation for Attorneys," taught to the Department of Justice Radiation Defense Attorneys, and adjunct faculty in Genetics/Biology at local community college.

PHILLIP W. WALLACE

EDUCATION

- B.S., Industrial Management, University of Tennessee, 1974
- M.B.A., Management, University of Tennessee, 1975

POSITIONS

Oak Ridge Associated Universities, 1984-present, Center for Epidemiologic Research, Manager, Information Technologies

- Manager of Information Technology for project network supporting and performing dose reconstructions as part of EEOICPA compensation efforts. Network supports over 400 users on the project, utilizes 22 servers, and links Cincinnati, Buffalo, and Richland WA to accomplish this effort.
- Manage the technical effort of CER Former Worker Beryllium Surveillance program, ensuring the programmatic needs are met by the application, including scheduling, contacting workers, tracking history, etc.
- Oversaw the design and implementation of the DOE Beryllium Registry (10 CFR 850) and current oversee the routine operation, work with DOE HQ staff on requirements, work with DOE sites to provide guidance on data submissions, and provide analyses of the data to DOE HQ.
- Oversee the daily operation of the DOE Epidemiologic Surveillance program, interact with DOE HQ staff to review program status and plan future directions, oversee the functions of receiving data and returning errors to the submitting site, creating special reports as required, and working with sites to assess health situations as specified by the site Occupational Medicine Director.
- Currently transitioning the operation of the Human Subject Research Database from EML in New York City to CER.
- Hands-on experience supporting epidemiologic studies through software development and data manipulation.
- Direct and oversee work of scientific programmer analysts.
- Maintain validity and integrity of data on over 400,000 DOE workers.
- Create tables containing over 4,000,000 dosimetry records, ensuring quality for use in health studies.

Lockheed Missiles and Spacecraft Corporation, 1983-1984, Manager, Space Telescope Management Information System Project
Directed computer science efforts on project for building NASA space telescope.

Systems Development Corporation, 1980-1983, Manager, Computer Systems
Directed programming efforts on project management for DOE's Gas Centrifuge Enrichment project.

Union Carbide Corporation, Nuclear Division, 1978-1980, Programmer/Analyst
Responsible for software that tracked nuclear material shipments across DOE and NRC facilities.

Burroughs Corporation, 1975-1978, Programmer/Analysts and Software/Technical Representative

SELECTED PUBLICATIONS

- Wallace PW. Project management using information systems. Presented at the American Society for Engineering Management 4th Annual Meeting, October 1983.

- Dupree EA, J Watkins, JN Ingle, P Wallace, and C West. Risk of lung cancer among uranium processing workers. American Journal of Epidemiology 1993; 138:640 (abstract).

- Groer PG, CA Pereira, and PW Wallace. 1989. Weight of evidence analysis of lung cancer in Colorado Plateau uranium miners. In: Proceedings of the 14th L. H. Gray Conference on Low Dose Radiation: Biological Bases of Risk Assessment.

- Payne D, J Reagan, and P Wallace. Data Modeling of Scientific Data. In: Proceedings of the 1991 International Oracle Users Group Conference.

- Fry SA, EA Dupree, AH Sipe, DL Seiler, and PW Wallace. 1992. A study of mortality and morbidity among persons occupationally exposed to >5 rem (>50 mSv) in a Year. Phase I: Mortality, through 1984. Applied Occupational and Environmental Hygiene suppl.; March 1996.

- Dupree EA, JP Watkins, JN Ingle, PW Wallace, CM West, and WG Tankersley. 1995. Uranium Dust Exposure and Lung Cancer Risk in Four Uranium Processing Operations. Epidemiology; 6:370-375.

SYNERGISTIC ACTIVITIES

- Extensive direct experience in working with epidemiologists, biostatisticians, and health physicists in the area of health studies and dosimetry data assessments, writing software routines, developing algorithms, and documentation.
- Managing the Computer Science section of the ORAU Center for Epidemiologic Research for 18 years.
- Managing the IT effort of the NIOSH Dose Reconstruction project for ORAU since project startup.
- Ensuring data quality and integrity in all facets of IT tasks for CER.
- Applying experience with related activities and DOE to achieve optimally designed application systems that fit program needs.

JANICE P. WATKINS

EDUCATION

- B.A., Mathematics, Pennsylvania State University, State College, PA
- M.A., Mathematics, University of Illinois, Urbana, IL
- M.S., Statistics, University of Tennessee, Knoxville, TN
- 24th and 27th Annual International Graduate Summer Sessions in Epidemiology, University of Michigan, Ann Arbor, MI

POSITIONS

Oak Ridge Associated Universities
Occupational Exposure and Worker Health (OEWH), Center for Epidemiologic Research (CER)

Biostatistician, ORAU	**1989 - Present**
Statistical Programmer/Analyst, ORAU	**1988**
Graduate Teaching Associate, Department of Statistics University of Tennessee, Knoxville, TN	**1987 - 1988**
Instructor, Department of Mathematics, University of Southwestern Louisiana, Lafayette, LA	**1985 -1987**
Insurance Underwriter, ULLICO, San Francisco, CA	**1984 - 1985**
Mathematics Teacher, Secondary Schools	**Prior to 1984**

SELECTED PUBLICATIONS

- Watkins, J.P., Reagan, J.L., Cragle, D.L., Frome, E.L., West, C.M., Crawford-Brown, D.J., and Tankersley, W.G. Data Collection, Validation, and Description for the Oak Ridge Nuclear Facilities Mortality Study. ORISE Technical Report 1993;93/J-42. http://orise.orau.gov/oews/addl-reports.htm

- Watkins, J.P., Cragle, D.L., Frome, E.L., West, C.M., Crawford-Brown, D.J., and
- Tankersley, W.G. Adjusting External Doses from the ORNL and Y-12 Facilities for the Oak Ridge Nuclear Facilities Mortality Study. ORISE Technical Report 1994;94/G-34.
- http://orise.orau.gov/oews/addl-reports.htm

- Dupree, E.A., Watkins, J.P., Ingle, J.N., Wallace, P.W., West, C.L., and Tankersley, W.G. Uranium Dust Exposure and Lung Cancer Risk in Four Uranium Processing Operations, Epidemiology, Vol 6, No 4:370-375, July 1995.

- West, C.M., Watkins, J.P., Tankersley, W.G., and Payne, D. Lung Dose Estimates from Air Sampling and Bioassay Data - A Comparison, Health Physics, Vol 69, No 4:481-486, 1995.

- Watkins, J.P., An Evaluation of the Accelerated Access Authorization Program from 1991-1993. Prepared for the U.S. DOE Office of Safeguards and Security, Center for Human Reliability Studies, Jan. 1996.

- Watkins, J.P., Cragle, D.L., Frome, E.L., Reagan, J.L., West, C.M., Crawford-Brown, D.J., and Tankersley, W.G. Collection, Validation, and Treatment of Data for a Mortality Study of Nuclear Industry Workers. Applied Occupational and Environmental Hygiene, 12(3);195-205, 1997.

- Frome, E.L., Cragle, D.L., Watkins, J.P., Wing, S., Shy, C., Tankersley, W.G., and West, C.M. A Mortality Study of Employees of a Nuclear Industry in Oak Ridge, Tennessee. ORNL Technical Report 1997;ORNL 6785. http://www.epm.ornl.gov/frome/ORMS

- Frome, E.L., Cragle, D.L., Watkins, J.P., Wing, S., Shy, C., Tankersley, W.G., and West, C.M. A Mortality Study of Employees of a Nuclear Industry in Oak Ridge, Tennessee. Radiation Research, pp. 64-80, July 1997.

- Eisele, G.R., Watkins, J.P., and Matthews, K.O. Workplace Violence at Government Sites. American Journal of Industrial Medicine 33:485-492 (1998).

- Watkins, J.P., User's Guide for the Random Drug Screening System. Prepared for the U.S. DOE Office of Safeguards and Security, Center for Human Reliability Studies, ORISE 98-0985, 1998.

- Cragle, D.L., Watkins, J.P. and Robertson-DeMers, K. Mortality among Workers at the Savannah River Nuclear Fuels Production Facility. American Statistical Association 1998 Proceedings of the Section of Statistics in Epidemiology, pp. 83-87 http://orise.orau.gov/oews/addl-reports.htm

- Dupree Ellis, E., Watkins, J.P., Ingle, J.N., and Phillips, J.A. External Radiation Exposure and Mortality in a Cohort of Uranium Processing Workers, AJE, vol. 152(1), July 1, 2000.

- Watkins, J.P., Eisele, G.R., and Matthews, K.O. Occupational Medical Program Alcohol Screening: Utility of the CAGE and BMAST, Journal of Substance Abuse Treatment 19 (2000) 51-57.

- Watkins, J.P., Borges, H.T., Stafford, R., Biggar, R., and Goedert, J. Collection and Verification for Matched Records from United States Cancer and HIV/AIDS Registries. American Statistical Association 1999 Proceedings of the Section of Statistics in Epidemiology, pp. 114-118 http://orise.orau.gov/oews/addl-reports.htm

- Letz R, Gerr F, Cragle D, Green R, Watkins J, Fidler A. Residual Neurologic Deficits 30 Years after Occupational Exposure to Elemental Mercury. Neurotoxicology 21(4): 459-474, 2000.

- Watkins, J.P., and Eisele, G., Study of Administrative Review Outcomes, U.S. Department of Energy, Office of Safeguards and Security, (ORISE 01-0932) July 2001.

- Borges, H.Tim., Watkins, J.P., Stafford, R., Biggar, R, J. Linkage of Selected AIDS and Cancer Registries in the United States, J. of Registry Management, vol.28(2), Summer 2001, pp.89-92.

- Watkins, J.P., DeBrandt, D., Whalen, J., and Eisele, G., Comparison of FBI and OPM Security Reinvestigations, U.S. Department of Energy, Office of Security, (ORISE 01-1541) December 2001.

- Watkins, J.P., and Eisele, G., Personnel Security Assurance Program: Profile from 1992 through 2001, U.S. Department of Energy, Office of Security, (ORISE 02-0225) Feb 2002.

- Watkins, J.P., Frome, E.L., Cragle, D.L., Evaluating Time-Related Variables in Occupational Epidemiology Studies, Final Project Report to NIOSH Health-Related Energy Research Branch, April 7, 2004.

- Ellis, E.A., Watkins, J.P., and Phillips, J., Mortality through 2000 among Workers Employed between 1944 and 1992 at the Pittsburgh Energy Technology Center, Project Report to DOE, September 2004.

- Watkins, J.P., Kerr, G.D., Frome, E.L., Tankersley, W.G., and West, C.M., Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Facility in Oak Ridge, Tennessee, Part 1 Gamma Radiation, ORAU 2004-0888, August 2004. http://orise.orau.gov/oews/addl-reports.htm

- Frome, E. L. and J. Watkins, (2004), Statistical Analysis of Data with Non-detectable Values, ORNL/TM-2004/146. http://orise.orau.gov/oews/addl-reports.htm

- Center for Human Reliability Studies, Final Report: Detection of Deception Using Volatile Organic Compound (VOC) Emissions, ORISE 2005-0330, June 2005.

- Kerr, G.D., Tankersley, W.G., and Watkins, J.P., Technical Information Bulletin: External Radiation Monitoring at the Y-12 Facility during the 1948-1949 Period, ORAUT-OTIB-0047, September 2005.

- Watkins, J.P., Frome, E.L., and Cragle, D.L. (2005), "Age-Based Methods to Explore Time-Related Variables in Occupational Epidemiology Studies," 2005 Proceedings of the American Statistical Association, Section on Statistics in Epidemiology [CD-ROM], Alexandria, VA: American Statistical Association: pp 2652-2657.

- Watkins, J.P., Ellis, E.D., Furman, F.J., Falk, R.B., Aldrich, J.M., and Cragle, D.L., Health Surveillance of Rocky Flats Radiation Workers, ORAU Technical Report #2006-0408, April, 2006.

- Kerr GD, Frome EL, Tankersley WG, and Watkins JP, Technical Information Bulletin: Historical Evaluation of the Film Badge Program at the Y-12 Facility in Oak Ridge, Tennessee: Part 2 –Neutron Radiation, ORAUT-OTIB-0045 Rev 01, November 2009.

- LaBone, T.R. and Watkins, J.P., Technical Information Bulletin: Use of Claimant Datasets for Coworker Modeling, ORAUT-OTIB-0075, Rev 00-D, May, 2009.

- McCartney KA, Watkins JP, Kerr GD, and Tankersley WG, Technical Information Bulletin: Coworker External Data for the Y-12 National Security Complex, ORAUT-OTIB-0064, Rev 01, December 2009.

- Ellis ED, Watkins J, Tankersley W, Phillips J, Girardi D. Mortality among Titanium Dioxide

Workers at three DuPont Plants. Journal of Occupational and Environmental Medicine 52(3):303-309, March 2010.

- Kerr GD, Frome EL, Watkins JP, and Tankersley WG, Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Plant in Oak Ridge, Tennessee: Part 3 Beta Radiation, ORAU Technical Report # 10-OEWH-1220, Sept. 2010.

SYNERGISTIC ACTIVITIES

- Extensive experience working with data from a wide variety of areas, including occupational epidemiology, radiation dosimetry, dose reconstruction, workplace violence, drugs/alcohol, safety training, cancer/AIDS, beryllium, mercury, childhood vaccinations, mining safety, trade association, and health effects.

- Hands-on experience includes collecting, verifying, and analyzing data, interpreting statistical results, writing reports, making presentations, designing and writing computer applications, developing statistical methods, and managing projects.

RICHARD E. TOOHEY, PHD

EDUCATION

- Ph. D. in Nuclear Physics. Dissertation title: Valence Component in the Threshold Photoneutron Spectrum of Zr-91. University of Cincinnati, Cincinnati, Ohio, 1973.
- M.S. in Physics, University of Cincinnati, Cincinnati, Ohio, 1970.
- A.B. in Physics (Magna Cum Laude), Xavier University, Cincinnati, Ohio, 1968.
- Certified Health Physicist

RELEVANT ACCOMPLISHMENTS

- Responded to radiological incidents as REAC/TS Team Leader, 1997-2002.
- Taught radiological emergency response procedures to EMT-Paramedics under the National Domestic Preparedness Training Program, 1998-2001.
- Reviewed and critiqued the emergency response to the Tokai-Mura criticality accident for the National Institute of Radiological Sciences, Chiba, Japan 1999.
- Reviewed and critiqued the emergency response to the Seibersdorf plutonium vial explosion for the IAEA, Vienna, Austria 2009.
- Investigated and provided a review report of the Boulder laboratory plutonium incident for the National Institute for Standards and Technology, June 2009.
- Reviewed and critiqued the internal dosimetry response to the Savannah River plutonium-contaminated wound case for REAC/TS, 2010.
- Developed a technical basis document for hand-held screening of exposed persons in Japan for CDC-RSB, 2011.

RECENT EXPERIENCE

Associate Director, IEAV, 2010-Present

Manages ORAU's Professional Training programs, providing training in the radiological sciences to U.S. NRC and agreement state personnel, as well as to private sector clients; personally conducts courses in internal dosimetry, environmental radioactivity, and radiological emergency response. Manages the Health Physics Services group, providing technical support to DOE, DOD, NRC, CDC-RSB, and other clients in technical areas including radiological monitoring, external and internal dose assessment, environmental pathway analysis, clearance of materials and equipment, and radiological emergency response.

Director, Dose Reconstruction Programs, 2002-2010

Supervised radiation dose reconstructions for World War II era through present-day workers in the U.S. DOE weapons complex. Project scope included researching exposure histories, site operations, and accidental exposures; to date over 28,000 individual dose reconstructions for workers in the DOE weapons complex have been completed. Served as senior technical quality reviewer of dose reconstructions for atomic veterans performed by the Defense Threat Reduction Agency, 2006-2011. Technical reviews included researching fallout patterns from atmospheric nuclear weapons tests, exposure pathways, decontamination of military personnel and equipment, exposures to U.S prisoners of war in Japan in August 1945, and exposure to U.S. occupation troops in Japan, September 1945—August 1946.

Oak Ridge Associated Universities, 1994 to Present

- Instructor, REAC/TS "Public Health in Radiation Accidents" courses sponsored by CDC.
- Technical advisor, ORAU support to CDC-RSB to develop the Radiological Terrorism toolkit, the Guide

to Population Monitoring in Radiation Emergencies, and the Handbook for Clinical Response to Nuclear and Radiological Incidents Including Terrorism.

- Member, NCRP 2006-present; Director, 2010-present; Contributing author to: Report 156: Development of a Biokinetic Model for Radionuclide-Contaminated Wounds and Procedures for Their Assessment, Dosimetry and Treatment (2006); Report 163: Radiation Dose Reconstruction: Principles and Practices (2009); and Report 164: Uncertainties in Internal Radiation Dose Assessment (2010).

Training Courses in Radiation Sciences, Health Physics, and Radiation Protection for NRC Personnel. Contract DE-AC05-06OR23100, November 7, 2005 Current Task: July 2009 to June 2014. Develop and provide training in the radiation sciences, health physics, and radiation protection to NRC and Agreement State personnel, principally health physics and radiation safety inspectors. This training encompasses an understanding of health physics principles, current methodologies, recommended radiation safety practices and other relevant information.

Radiation Internal Dose Information Center. Contract DE-AC05-06OR23100, 1995-2005. Manage a central information center providing internal dosimetry models and dose estimates to the U.S. Department of Energy, U.S. Nuclear Regulatory Commission, and U.S. Food and Drug Administration (radiopharmaceuticals). Provide internal dose estimates for radiological accident victims to REAC/TS. Provide courses in occupational and medical internal dosimetry. Respond to public inquiries and requests for information in internal dose estimates, methodology and risks.

SELECTED PEER-REVIEWED PUBLICATIONS

- **Toohey RE**. An experimental method of estimating the depth of ^{241}Am deposited in the chest. Health Phys 29:417-8, 1975.
- Larsen RP, **Toohey RE**, Ilcewicz FH. Macrodistribution of plutonium in selected bones from an abnormal skeleton. In: The Health Effects of Plutonium and Radium. Proceedings of a symposium, Sun Valley, ID, 6-9 October 1975, Jee SS (ed). Salt Lake City, UT: The J. W. Press, pp 315-20, 1976.
- **Toohey RE**, Essling MA. Gross distribution of ^{241}Am in a man seven years after inhalation. In: Biological and Environmental Effects of Low-Level Radiation. Proceedings of a symposium, Chicago, Ill, 3-7 November 1975. Vienna, Austria: International Atomic Energy Agency, pp 153-60, 1976.
- **Toohey RE**, Essling MA, Huff DR. Retention and gross distribution of ^{75}Se following intravenous injection of ^{75}Se-selenomethionine. Health Phys 37:395-7, 1979.
- **Toohey RE**, Essling MA. Measurements of ^{241}Am in vivo at long times after inhalation. Health Phys 38:139-45, 1980.
- Serio CS, Henning CB, **Toohey RE**, Lloyd EL. Mitogenic responses of normal human lymphocytes of radium workers. Int J Radiat Biol 38:583-8, 1980.
- **Toohey RE**, Cacic CG, Larsen RP, Oldham RD. The concentration of plutonium in hair following intravenous injection. Health Phys 40:881-6, 1981.
- **Toohey RE**, Rundo J, Essling MA, Sha JY, Oldham RD, Sedlet J, Robinson JJ. Radioactivity measurements of former military personnel exposed to weapon debris. Science 213:676-8, 1981.
- Rundo J, **Toohey RE**. Radon in homes and other technologically enhanced radioactivity. In: Environmental Radioactivity. Proceedings of the Nineteenth Annual Meeting of the National Council

of Radiation Protection and Measurements, April 6-7, 1983. Washington, DC: National Academy of Sciences, pp 17-25, 1983.

- **Toohey RE**, Keane AT, Rundo J. Measurement techniques for radium and the actinides in man at the Center for Human Radiobiology. Health Phys 44:(Suppl 1):323-42, 1983.
- Serio CS, Henning CB, **Toohey RE**, Lloyd EL. Measurement of lymphoblastogenic activity from thorium workers. Int J Radiat Biol 44:251-6, 1983.
- **Toohey RE**, Bhattacharyya MH, Oldham RD, Larsen RP, Moretti ES. Retention of plutonium in the beagle after gastrointestinal absorption. Radiat Res 97:373-9, 1984.
- **Toohey RE**, Essling MA, Rundo J, Hangde W. Measurements of radon daughter deposition on indoor surfaces. Radiat Prot Dosimetry 7:143-6, 1984.
- Serio CS, Henning CB, **Toohey RE**, Lloyd EL. The effects of sera from Ra dial painters on the mitogenic responses of normal lymphocytes. Health Phys 47:309-13, 1984.
- Nazaroff WW, Feustel H, Nero AV, Revzan KL, Grimsrud DT, Essling MA, **Toohey RE**. Radon transport into a detached one-story house with a basement. Atmos Environ 19:31-46, 1985.
- **Toohey RE**. Assessing internal radionuclides. In: Proceedings of the Physicians Seminar on Human Radiation Exposure, White Haven, PA, 18-20 October 1985, Miller DW (ed). Pennsylvania Power and Light, 1985.
- **Toohey RE**, Rundo J, Sha JY, Essling MA, Pedersen JC, Slane JM. Activity ratios of thorium daughters in vivo. Strahlentherapie 80(Suppl):147-50, 1986.
- **Toohey RE**. Intercalibration experiments with inhaled mock plutonium. In: Proceedings of the Department of Energy Workshop on Radiobioassay and Internal Dosimetry, Albuquerque, NM, 20-22 Jan 1986. Battelle Pacific Northwest Laboratory Report PNL-SA-114043, pp 279-92, 1987.
- **Toohey RE**, Essling MA, Wang H, Rundo J. Some measurements of the equilibrium factor for radon daughters in houses. Health phys 53:89-91, 1987.
- **Toohey RE**, Brown W, Stebbings JH. Random geographic sampling with UTM coordinates. Env International 14:207, 1988.
- Borak TB, **Toohey RE**. A survey of winter, summer and annual average radon concentrations in family dwellings. Health Phys 57:465, 1989.
- Bierman TJ, **Toohey RE**. Correlation of dose with radon concentration, WL, and radon daughter deposition. Health Phys 57:429, 1989.
- **Toohey Re**. Whole-body counting. In: Proceedings of the 1985 Health Physics Society Summer School, Evanston, IL, 3-7 June 1985, Cember H (ed). McLean, VA: Health Physics Society, 1990.
- **Toohey RE**, Anderson AL, Berger CD, Cohen N, Palmer HE. Current status of whole-body counting to detect and qualify previous exposures to radioactive materials. Health Phys 60:S5, 1991.
- **Toohey RE**. The U.S. transuranium and uranium registries. In: Proceedings of the Depleted Uranium Health and Safety Information Exchange Meeting, Oak Ridge, TN, 30 Nov-1 Dec 1993. Oak Ridge, TN: Martin Marietta Energy Systems, pp 237-57, 1994.
- **Toohey RE**. Biokinetics of bone-seeking radionuclides. In: Internal Radiation Dosimetry. Proceedings of the Health Physics Society Summer School, Davis CA, 1994, Raabe OG (ed). Madison, WI: Medical Physics Publishing, pp 197-216, 1994.

- **Toohey RE**. Contamination control and internal dosimetry. In: Radiation Protection at Nuclear Reactors. Proceedings of the Health Physics Society Summer School, Beverly, MA, 1995, Maletskos CJ (ed). Madison, WI: Medical Physics Publishing, pp 155-84, 1995.
- **Toohey RE**, Kathren RL. Overview and dosimetry of the Hanford americium accident case. Health Phys 69:310-7, 1995.
- McInroy JF, Kathren RL, **Toohey RE**, Swint MJ, Breitenstein BD. Postmortem tissue contents of ^{241}Am in a person with a massive acute exposure. Health Phys 69:318-23, 1995.
- Schlenker RA **Toohey RE**, Thompson EG, Oltman BG. Bone surface concentrations and dose rates 11 years after massive accidental exposure to ^{241}Am. Health Phys 69:324-9, 1995.
- Filipy RE, **Toohey RE**, Kathren RL, Dietert SE. Deterministic effects of ^{241}Am exposure in the Hanford Americium accident case. Health Phys 69:338-45, 1995.
- Stabin MG, Stubbs JB, **Toohey RE**. Radiation Dose Estimates for Radiopharmaceuticals. Oak Ridge, TN: Oak Ridge Institute for Science and Education, NUREG/CR-6345, 1996.
- **Toohey RE**, Stabin MG. Comparative analysis of dosimetry parameters for nuclear medicine. In: Proceedings of the Sixth International Radiopharmaceutical Dosimetry Sumposium, Gatlinburg, TN, May 7-10, 1996. ORISE Report 99-1064, pp 532-51, 1999.
- **Toohey RE**, Stabin MG, Watson EE. Internal radiation dosimetry: principles and applications. Radiographics 20:533-46, 2000.
- **TooheyRE**, Goans RE. Inadvertent fetal exposure in nuclear medicine. In: Proceedings of the Tenth International Congress of the International Radiation Protection Association, Hiroshima, Japan, May 14-19, 2000.
- **Toohey RE**. The role of the health physicist in dose assessment. In: The Medical Basis for Radiation-Accident preparedness. Proceedings of the Fourth International REAC/TS Conference, Orlando, FL, March 5-8, 2001, Ricks RC, Berger ME, O'Hara FM Jr (eds). New York, NY: Parthenon Publishing, pp 33-44, 2002.
- **Toohey RE**. Excretion of depleted uranium by Gulf War veterans. Radiat Prot Dosimetry 105:171-4, 2003.
- **Toohey RE**. Internal dose assessment in radiation acidents. Radiat Prot Dosimetry 105:329-31, 2003.
- Guilmette RA, Durbin PW, **Toohey RE**, Bertelli L. The NCRP wound model: development and application. Radiat Prot Dosimetry Aug 31, 2007 [Epub ahead of print].
- **Toohey RE**. Scientific issues in radiation dose reconstruction. Health Phys 95: 26-35, 2008.
- Moeller DW, **Toohey RE**. The NIOSH radiation dose reconstruction program: origin, goals, scope and results. Health Phys 95: 1-5, 2008 (editorial).

WILLIAM G. TANKERSLEY

EDUCATION

- B.S., Biology, Tennessee Technological University, 1967
- M.S., Microbiology, University of Tennessee, 1970
- Professional development courses in industrial hygiene, industrial toxicology, epidemiology, industrial ventilation, noise, personal sampling, risk communication, professional ethics, data analysis, and anti-terrorism; Occupational Safety and Health Educational Resource Center, University of North Carolina, AIHA; 1981-present.

POSITIONS

Oak Ridge Associated Universities **1990–present**
Section Leader, Hazards Assessment, Center for Epidemiologic Research

- Managed activities of health physics and industrial hygiene group charged with assessment of radiation and chemical exposures to large populations for epidemiologic analyses.
- Developed innovative methods and models for estimation of exposure potential from qualitative records for use in worker protection programs and health studies.
- Designed practical analytical methods for dealing with incomplete and flawed data sets for use in epidemiologic studies.
- Developed reliable and cost-effective monitoring methods using modern technologies for surveillance of worker exposures to multiple materials.
- Presented and published contract-required and scientific reports.
- Contributed to several EPA Guidance Documents.
- Authored chapters in several NIOSH Criteria Documents.

Oak Ridge Associated Universities **1981–1989**
Research Industrial Hygienist, Hazards Assessment, Center for Epidemiologic Research

- Evaluated historical data and other exposure-related records for use in epidemiologic analyses.
- Investigated monitoring programs and procedures.
- Conducted records quality control tasks.
- Presented reports of assessment activities to supervisor and at professional meetings.

Oak Ridge Associated Universities **1970–1981**
Research Associate, Microbiology

- Conducted research relevant to support and treatment of patients undergoing bone marrow transplantation.
- Conducted research on radioprotective drugs for military use.
- Conducted research on relationship of gut microflora to colon cancer.

The University of Tennessee **1967–1970**
National Defense Education Act Graduate Fellow, Department of Microbiology

- Identified and conducted research on non-replicating strain of Salmonella typhimurium for use as a live, noninfectious vaccine.

The University of Tennessee **1968–1970**
Laboratory Instructor in Microbiology and Bacterial Physiology

- Assisted teaching professor in undergraduate laboratory activities.

PUBLICATIONS

- Tankersley WG, GC Kingdon, and S Colyer. Effects of total-body irradiation on phagocytosis by human PMN leukocytes. Presented at the Annual Meeting of American Society for Microbiology, Philadelphia, Pennsylvania 1972.

- Tankersley WG and JM Woodward. Induction and isolation of the mini-cell producing strain of Salmonella typhimurium. Proc. Soc. Exp. Biol. Med. 145, 802-805, 1974.

- Tyndall R, W Tankersley, S Chaskes, and S Colyer. A study of lowered resistance to infections in irradiated patients. In: Current Cancer Research on Clinical Radiotherapy of Cancer and Related Preclinical Studies, NCI/ICRDB/SL-76/47, #232, July 15, 1977.

- Tankersley WG, CB Richter, and JS Batson. Therapy of filariasis in tamarins. Lab. Anim. Sc. 29, 107-108, 1979.

- Tankersley WG: Fecal β-glucuronidase in cancer-susceptible and non-susceptible callitrichidae
- Presented at IX Congress International Primatological Society, Atlanta, Georgia, 1982.

- Strom DJ, WL Beck, PS Stansbury, WG Tankersley, and J. Watson Jr. Standard procedures for pooling health physics data for epidemiologic studies. In: Proceedings of the Health Physics Society Sixteenth Midyear Topical Symposium, Epidemiology Applied to Health Physics, Albuquerque, New Mexico, pp. 221-230, January 9-13, 1983.

- Tankersley WG and H Checkoway. Procedure for assignment of chemical exposure indices for use in epidemiology studies. Presented American Industrial Hygiene Association Conference, Philadelphia, Pennsylvania, May 1983.

- Clapp NK, MA Henke, EC Holloway, and WG Tankersley. Carcinoma of the colon in the cotton-top tamarin: A radiographic study. JAVMA Vol. 183, No. 11, December 1983, pp. 1328-1330.

- Strom DJ, DJ Crawford-Brown, and WG Tankersley. Preparation of 30 years' personnel monitoring data from a uranium fabrication plant for use in epidemiologic studies. Health Phys. 47:123, 1984.

- Cragle DL, DR Hollis, JR Qualters, WG Tankersley, and SA Fry. A mortality study of men exposed to elemental mercury. J. Occup. Med., Vol. 26, No. 11, November 1984, pp. 817-821.

- Sowder CL, D Crawford-Brown, WG Tankersley, and K Gissel. Estimation of internal lung dose from air monitoring data. Presented Health Physics Society Annual Meeting, Chicago, Illinois, May 1985.

- Checkoway H, RM Mathew, CM Shy, JE Watson Jr., WG Tankersley, SH Wolf, JC Smith, and SA Fry. Radiation, work experience, and cause specific mortality among workers at an energy research laboratory. Brit. J. Indus. Med. 42:525-533, 1985.

- Cragle DL and WG Tankersley. Occupational Exposure Assessment: Past, present, and future.
- Presented before the Division of Environmental Chemistry-American Chemical Society, Chicago, Illinois, September 1985.

- Carpenter AV, WD Flanders, EL Frome, WG Tankersley, DL Crawford-Brown, CL Sowder, ML Wray, SA Fry, and CC Lushbaugh. An epidemiologic investigation of central nervous system cancers among workers at diverse nuclear facilities. Am. J. Epidemiol. 124:530-31, 1986.

- Hickey JLS, DJ Crawford-Brown, and WG Tankersley. Occupational exposures of workers to chemicals and radiation during uranium processing at the Linde Ceramics Plant. ORAU Technical Report No. 88/A-16, 1988.

- Carpenter AV, WD Flanders, EL Frome, WG Tankersley, and SA Fry. Chemical exposures and central nervous system cancers: A case-control study among workers at two nuclear facilities. Am. J. Indus. Med. 13(3):351-362, 1988.

- Cragle DL, RW McLain, JR Qualters, JL Hickey, GS Wilkinson, WG Tankersley, and CC Lushbaugh. Mortality among workers at a nuclear fuels production facility. Am. J. Indus. Med. 14(4):379-401, 1988.

- Tankersley WG, DL Cragle, MF Ziegler, and JE Watson. Comparison of assigned exposure indices and radiation monitoring data. Presented American Industrial Hygiene Conference, San Francisco, California, May, 1988.

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- Tankersley WG, CM West, EL Frome, and JL Pignatelli. Dosimetry problem with exposures at or below minimum detectable level in epidemiologic studies. Presented at Eighth Annual Symposium - Epidemiology in Occupational Health, Paris, France, September 10-12, 1991.

- Tankersley WG, CM West, JN Ingle, J Watson, and D Crawford-Brown. Guidelines for inferring occupational exposures in absence of monitoring data. Presented at the AIHA National Meeting, Salt Lake City, Utah, May 18-24, 1991.

- Tankersley WG, NV Hicks, DL Cragle, K Robertson-Demers, JN Ingle, GL Bean, and JM Googin. Exposure assessment for epidemiologic study of nuclear workers potentially exposed to beryllium. Presented at the AIHA National Meeting, Boston, Massachusetts, May 31-June 5, 1992.

- Cragle DL, SM Wells, and WG Tankersley. An occupational morbidity study of a population potentially exposed to epoxy resins, hardeners, and solvents. Appl. Occup. Environ. Hyg. 7(12):826-834, 1992.

- Wing S, CM Shy, JL Wood, S Wolf, DL Cragle, W Tankersley, and EL Frome. Job factors, radiation and cancer mortality at Oak Ridge National Laboratory: Follow-up through 1984. Am. J. Indus. Med. 23:265-279, 1993.

- Wing S, CM West, JL Wood, and W Tankersley. Recording of external radiation exposures at Oak Ridge National Laboratory: implications for epidemiological studies. J. Expos. Analy. Envir. Epid. 4:89-93, 1994.

- Watkins JP, DL Cragle, EL Frome, CM West, DJ Crawford-Brown, and WG Tankersley. Adjusting external doses from the ORNL and Y-12 facilities for the Oak Ridge nuclear facilities mortality study Oak Ridge, TN: ORISE Technical Report 94/G-34, 1994.

- Watson Jr. JE, JL Wood, WG Tankersley, and CM West. Estimation of radiation doses for workers without monitoring data for retrospective epidemiologic studies. Health Phys 1994:67(4):402-405

- Fry SA, DL Cragle, DJ Crawford-Brown, EA Dupree, EL Frome, ES Gilbert, GR Petersen, CM Shy, WG Tankersley, GL Voelz, PW Wallace, JP Watkins, JE Watson Jr., and LD Wiggs. Health and mortality among contractor employees at US Department of Energy facilities. In: Young JP and Yalow RS, eds., Radiation and public perception benefits and risks, advances in chemistry series. Washington, DC: American Chemical Society, 1995;239-258.

- West CM, J Watkins, WG Tankersley, and DD Payne. Lung dose estimates from air sampling and bioassay data - a comparison. Health Phys 1995;69(4):481-486.

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- Watkins JP, DL Cragle, EL Frome, JL Reagan, CM West, D Crawford-Brown, and WG Tankersley. Collection, Validation, and Treatment of Data for a Mortality Study of Nuclear Industry Workers. Appl. Occup. Environ. Hyg. 12(3), 195-205, 1997.

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- West CM, BF Rutherford, and WG Tankersley. Current Programs for Estimating Radiological Dose and Chemical Exposure, Volumes I and II, Final project report prepared for Centers for Disease Control and Prevention, 1997.

- Tankersley WG, CM West, and FE Gray. Hazardous Waste, Deactivation, Dismantlement, and Cleanup Workers Exposure Assessment Feasibility Study at the Department of Energy Savannah River Site, Project Report prepared for the National Institute for Occupational Safety and Health, Health-Related Energy Research Branch, 1998.

- Tankersley WG, CM West, and FE Gray. Hazardous Waste, Deactivation, Dismantlement, and Cleanup Workers Exposure Assessment Feasibility Study at the Department of Energy Oak Ridge Reservation, Project Report prepared for the National Institute for Occupational Safety and Health, Health-Related Energy Research Branch, 1999.

- Watkins, JP, GD Kerr, EL Frome, WG Tankersley, and CM West. Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Facility in Oak Ridge, Tennessee: Part 1 Gamma Radiation, ORAU Technical Report # 2004-0888

- Kerr, GD, EL Frome, WG Tankersley, and JP Watkins. Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Facility in Oak Ridge, Tennessee: Part 2 - Neutron Radiation, ORAU Technical Report # 2004-1406

- Kerr, GD, EL Frome, WG Tankersley, and JP Watkins, "Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Facility in Oak Ridge, Tennessee: Part 3 Beta Radiation" 2010.

- Henn, SA, DF Utterback, KM Waters, AM Markey, and WG Tankersley, Task- and Time-Dependent Weighting Factors in a Retrospective Exposure Assessment of Chemical laboratory Workers, J Occup. and Environ. Hyg. 4(2):71-79, 2007.

- Ellis, ED, JP Watkins, WG Tankersley, JA Phillips, and DJ Girardi. 2010. Mortality among titanium dioxide workers at three DuPont plants, Journal of Occupational and Environmental. Medicine. 52(3):303-309.

- Van Dyke, MV, JW Martyny, MA Mroz, LS Silveira, M Strand, DL Cragle, WG Tankersley, SM Wells, LS Newman, and LA Maier. 2011. Exposure and Genetics Increase Risk of Beryllium Sensitization and Chronic Beryllium Disease in the Nuclear Weapons Industry, Submitted to Occupational and Environmental Medicine. Occup Environ Med. 2011 Apr 2.

SYNERGISTIC ACTIVITIES

- Extensive experience in retrospective assessment of radiation and chemical exposures for DOE contractor populations, including evaluation of monitoring programs, interpretation of data, development of assessment methodologies, and publishing reports.
- Trained and experienced in relatively broad range of health related research and applied activities. Readily accepts and responds to difficult/complex problems with realistic and creative approaches and methods.
- Able to maintain and progress under less than optimum conditions or circumstances.

- Willing to consider other's perspectives and alternative approaches.

PROFESSIONAL ASSOCIATIONS

- American Academy of Industrial Hygiene Diplomate
- American Industrial Hygiene Association Member
- AIHA Tennessee Valley Section Member
- Panel Member of a number of DOE and NIOSH panels including DOE Comprehensive Epidemiologic Data Resources (CEDR) Dosimetry Working Group and NIOSH Workshop on Energy-related Epidemiologic Research Agenda (past)

AWARDS/ACCOMPLISHMENTS

- Certification in Comprehensive Practice of Industrial Hygiene, American Board of Industrial Hygiene, 1992.

DEREK HAGEMEYER

EDUCATION

- B.S., Nuclear Engineering, University of Virginia, City, VA

POSITIONS

2004- Present, Health Physicist and Team Leader, ORAU, Oak Ridge, TN

- Mr. Hagemeyer serves as the project manager and lead analyst for the U.S. Nuclear Regulatory Commission (NRC) Radiation Exposure Information and Reporting System (REIRS) contract, which involves the management and analysis of radiation exposure records received by the NRC. He is also project manager of the DOE central repository for radiation exposure records, which involves the collection and analysis of occupational exposure records for all DOE facilities and the development of the DOE annual radiation exposure report.

1987-2004, Nuclear Engineer, SAIC, Oak Ridge, TN

- Mr. Hagemeyer served as SAIC's principal investigator and lead analyst for the U.S. Nuclear Regulatory Commission (NRC) Radiation Exposure Information and Reporting System (REIRS) and the DOE central repository for radiation exposure records. In addition, Mr. Hagemeyer was the principal investigator for a contract with a nuclear pharmaceutical supply company. He was involved in upgrading and integrating the external and internal dosimetry systems for the company's production facility and developing thyroid monitoring and radioactive material inventory tracking systems.
- Since 1987, Mr. Hagemeyer has managed the collection and analysis of REIRS project radiation exposure information collected under 10 CFR Part 20 from NRC licensees. This project involves the collection and processing of over 100,000 reports annually and includes trend analysis and production of NRC publications concerning these data. Mr. Hagemeyer has managed a staff of over 15 people and been involved in all aspects of the contract. He has initiated numerous improvements and upgrades to REIRS. He expanded analysis to include licensee submittals containing dose information by work type and job function, and career dose analysis from information obtained from termination submittals. He developed a PC data-entry system and software to assist in the analysis of exposure information received from power reactors. Mr. Hagemeyer also managed the conversion of over 2M records from NRC licensee's termination submittals from an ASCII-based Cobol system to an Oracle relational DBMS running under Windows NT. This conversion involved the restructuring of the database, development of procedures for data management, and extensive data verification. As a result of these improvements, the NRC has on-line access to the data and improved query capabilities over the internet.
- With the revision of 10 CFR Part 20, Mr. Hagemeyer served as the technical lead and manager of a project to develop the NRC's Radiation Exposure Monitoring and Information Transmittal (REMIT) system, which is designed to assist licensees in gathering, monitoring, and reporting radiation exposure information to the NRC. The system calculates dose equivalence from internal intake data. It also monitors exposure in excess of regulatory limits based on the new requirements for both routine and planned special exposures. The system produces Form 4 and Form 5 reports in hard copy or electronic format to meet the specifications for submittal to the NRC. Mr. Hagemeyer managed the upgrade of this software package to the Windows operating system during 1998.
- Mr. Hagemeyer developed an internet web site for the NRC that allows users to access NRC occupational radiation exposure information on-line. For 2000, he designed and implemented an

interactive request form to allow individuals and organizations to request dose histories from the web site. He was also involved in a project to develop an interactive web site for the NRC's decommissioning rulemaking process, which allows users to submit comments on the proposed rulemaking and share up-to-date information on-line.

- Mr. Hagemeyer served as project manager for an assessment of DOE's Radiation Exposure Module (REM) System that serves as the central repository of radiation exposure information for all DOE facilities. The system is used to collect and analyze radiation exposure information reported under DOE Order 231.1-1 for all DOE employees, contractors, and visitors. The task involved analyzing the current system specifications and defining requirements to upgrade the system to meet the evolving needs of DOE's Office of Environment and Health (now HSS).
- As a follow-on effort to this task, he developed a new system to upgrade the DOE central radiation exposure repository. The new system allowed researchers to access occupational radiation exposure data and integrate the data with other DOE worker health information systems. The database design involved three week-long workshops involving radiation protection and dosimetry experts from throughout the DOE Complex. The resulting database system incorporates a database management system and a commercial off-the-shelf client-server query tool to facilitate the performance of ad hoc queries. In addition, Mr. Hagemeyer led the effort to redesign the DOE annual report on occupational exposure information.
- For NRC's Generic Communications Branch, Mr. Hagemeyer managed the task to upgrade the Generic Communications Index (GCI). This included categorizing generic letters issued since 1977, upgrading the GCI database and associated software, and converting approximately 1,500 archived documents into ASCII text files for use with the NRC's Data General e-mail system. This system provides on-line access to all past NRC generic communications.

PROFESSIONAL ASSOCIATIONS

- American Youth Soccer Organization (AYSO) An all-volunteer organization. Coach from 1998 to 2004. Referee from 1999 to present. Also coached for the competitive Soccer Club of Oak Ridge (SCOR). USSF Referee certification obtained in 2007.
- Annual National Multiple Sclerosis Society's 150 bike tour to raise funds to fight MS. Participant and rider 2001, 2002, 2003, 2007.

AWARDS/ACCOMPLISHMENTS

SAIC Leadership 2000 – Protégé, 1994

The SAIC 21st Century Leadership Program is designed to provide opportunities for qualified and motivated individuals to develop leadership skills and realize their potential to contribute to SAIC at the highest possible level. It is a year-long formal mentoring program in which senior level technical and administrative leaders mentor protégés. To be considered for the program, employees must demonstrate outstanding performance, leadership potential and be nominated by their Group Manager.

SAIC Executive Science and Technology Committee – Member, 1999 to 2004

The SAIC Executive Science and Technology Council (ESTC) was established to promote high-quality, imaginative technical work and reward distinguished technical accomplishment; to encourage professional career growth outside of the traditional management track; and to develop an organized resource of technical expertise to serve in an advisory and mentoring capacity both to the Company and to other professional staff.

PUBLICATIONS

- Annual presentations at the National Dosimetry Conference - 1996 to the present. Representing the U.S. Nuclear Regulatory Commission and the Department of Energy on issues concerning the collection and analysis of occupation exposure information and related regulatory matters.
- "DOE Occupational Radiation Exposure 2005," January 2007.
- "DOE Occupational Radiation Exposure 2004," December 2005.
- "DOE Occupational Radiation Exposure 2003," DOE/EH-0688, November 2004.
- "DOE Occupational Radiation Exposure 2002," DOE/EH-0675, November 2003.
- "DOE Occupational Radiation Exposure 2001," DOE/EH-0660, December 2002.
- "DOE Occupational Radiation Exposure 2000," DOE/EH-0267, December 2001.
- "DOE Occupational Radiation Exposure 1999," DOE/EH-0629, January 2001.
- "DOE Occupational Radiation Exposure 1998," DOE/EH-0608, December 1999.
- "DOE Occupational Radiation Exposure 1997," DOE/EH-0575, October 1998.
- "DOE Occupational Radiation Exposure 1996," DOE/EH-0564, January 1998.
- "DOE Occupational Radiation Exposure Report, 1995," DOE/EH-0533, October 1997.
- "DOE Occupational Radiation Exposure Report, 1992 - 1994," DOE/EH-0533, January 1997.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 2005," S. Burrows, D. Hagemeyer, NUREG-0713, Vol. 27, November 2006.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 2004," S. Burrows, D. Hagemeyer, NUREG-0713, Vol. 26, December 2005.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 2003," S. Burrows, D. Hagemeyer, NUREG-0713, Vol. 25, October 2004.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 2002," S. Burrows, D. Hagemeyer, NUREG-0713, Vol. 24, October 2003.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 2001," S. Burrows, D. Hagemeyer, NUREG-0713, Vol. 23, September 2002.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 2000," S. Burrows, D. Hagemeyer, NUREG-0713, Vol. 22, September 2001.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1999," H. Karagiannis, D. Hagemeyer, NUREG-0713, Vol. 21, October 2000.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1998," M. L. Thomas, D. Hagemeyer, NUREG-0713, Vol. 20, November 1999.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1997," M. L. Thomas, D. Hagemeyer, NUREG-0713, Vol. 19, November 1998.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1996," M. L. Thomas, D. Hagemeyer, NUREG-0713, Vol. 18, February 1998.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1995," M. L. Thomas, D. Hagemeyer, NUREG-0713, Vol. 17, January 1997.

- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1994," M. L. Thomas, D. Hagemeyer, NUREG-0713, Vol. 16, January 1996.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1993," M. L. Thomas, D. Hagemeyer, NUREG-0713, Vol. 15, December 1994.
- "Experience with REIRS for the Revised 10 CFR 20", presentation at the Annual Dosimetry Conference in Orlando, Florida, 1994.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1992," C.T. Raddatz, D. Hagemeyer, NUREG-0713, Vol. 14, December 1993.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1991," C.T. Raddatz, D. Hagemeyer, NUREG-0713, Vol. 13, July 1993.
- "Radiation Exposure Monitoring and Information Transmittal (REMIT) System," R. Cale, T. Clark, P. Dixson, D. Hagemeyer, NUREG/CR-6050, SAIC-93/1310-01, June 1993.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1990," C.T. Raddatz, D. Hagemeyer, NUREG-0713, Vol. 12, January 1993.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1989," C.T. Raddatz, D. Hagemeyer, NUREG-0713, Vol. 11, April 1992.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1988," C.T. Raddatz, D. Hagemeyer, NUREG-0713, Vol. 10, July 1991.
- "Generic Communications Index, Listings of Communications, 1971-1989," D. Hagemeyer, H. Towle, NUREG/CR-4690, Vol. 1, May 1991.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1987," B.G. Brooks, D. Hagemeyer, NUREG-0713, Vol. 9, November 1990.
- "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1986," B.G. Brooks, D. Hagemeyer, NUREG-0713, Vol. 8, August 1989.

NANCY M. DAUGHERTY, M.S., CHP

EDUCATION

- M.B.A., Business Administration, University of Phoenix, 1985
- M.S., Radiation Health (Health Physics), 1975
- B.A., English, University of Maryland, 1968

RELATED EXPERIENCE

Oak Ridge Associated Universities, Quality Assurance Manager 2002-present

- Manage project external QA review program, staff, and budget for the Department of Defense, Defense Threat Reduction Agency, Nuclear Test Personnel Review Program.
- Provide external, third-party QA reviews of NTPR radiation dose assessments and RDA technical and guidance documents, and develop Lessons Learned and other QA reports for process improvement and communications support for the Veterans' Advisory Board on Dose Reconstruction.
- Develop annual summary reports for the Nuclear Regulatory Commission on nuclear power plant effluent releases and radiation dose to the public.
- Provided technical support to the International Atomic Energy Agency for development of guidance documentation on intermediate phase radiological emergency response (on temporary leave from ORAU).
- Developed and implemented a radiation dose reconstruction project Quality Management System, as documented in a QA Program Plan, for the National Institute for Occupational Safety and Health
- Developed QA procedures, associated forms, and records system.
- Conducted comprehensive, documented internal assessment program, including assessment plans, result reports, corrective action plans, and verification and validation of completion of corrective actions.
- Coordinated and supported project response to NIOSH external assessments and provided documented verification and validation of completion of corrective actions.
- Established and implemented a project administrative document QA review process to assure consistency among project procedures and inclusion of appropriate QA requirements and activities
- Established and implemented project training for quality self-assessment.

Life Scientist (Health Physicist) 1999-2002

- Developed program protocol and supporting documentation for the Former Radiation Worker Medical Surveillance Program for Rocky Flats to include: identifying participant candidates; providing medical examinations, lung and wound counts and urine bioassays; conducting historical site records reviews; performing participant interviews and internal dose re-evaluations; providing for medical and radiation dosimetry data management and evaluation; and ensuring conformance with the Privacy Act and the Freedom of Information Act and with requirements for human subjects research.
- Provided health physics support for implementation of the program protocol described above.
- Served as the Quality Assurance coordinator for the DOE Rocky Flats site Neutron Dose Reconstruction Project, developing supporting QA documentation and forms and providing QA oversight of technician staff for the project.

Colorado Department of Public Health and Environment 1996-1999

- Managed licensing, inspection, and enforcement of radioactive materials licenses for assigned licensees, to include both occupational and environmental radiation protection activities and records.

Private Practice, Consulting Health Physicist **1995-1996**

- Developed health and safety documentation incorporating radiological and non-radiological hazards protection.
- Developed application for NRC license termination of uranium clean-up site.

Woodward Clyde Federal Programs, Sr. Project Scientist/Corporate Health Physicist 1994-1995

- Provided health physics oversight for both company and client personnel, including procedures development, radiation and hazardous materials training, risk assessment, and document review and development.

Rocky Flats Environmental Technology Site **1982-1994**
(Rockwell International, 1982-1989; EG&G Rocky Flats, 1990-1994), Environmental Health Physicist

- Served as the lead environmental health physicist for the site's radiation protection program, for offsite dose assessment and emergency response, for public and governmental agency interface and education regarding environmental issues, and for coordination of occupational and environmental radiation protection activities at the site.

ALARA, Inc., Health Physicist **1981-1982**

- Provided occupational and environmental radiation safety monitoring, auditing, and training to clients.

Pennsylvania State University, Associate Health Physicist **1975-1981**

- Provided occupational and environmental radiation and contamination monitoring, dose assessment, training, research project review and oversight, radioactive materials inventory control, radioactive waste management and shipment, and program documentation for a large research university with approximately 200 laboratories using radioactive materials, as well as clinical and analytical x ray machines.

PROFESSIONAL AFFILIATIONS

- Plenary Member, Health Physics Society (HPS), 1976-present
- Member, American Academy of Health Physics (AAHP)
- Certified Health Physicist (CHP), 1981-present
- Member, Health Physics Society Environmental Section
- Associate Member, Conference of Radiation Control Program Directors, 1996-1999
- Member, Central Rocky Mountain Chapter of the HPS, 1981-present

RICH LEGGETT
Environmental Sciences Division
Oak Ridge National Laboratory

Richard W. Leggett is a research scientist in the Environmental Sciences Division at Oak Ridge National Laboratory (ORNL). He received his Ph.D. in mathematics from the University of Kentucky in 1972 and taught mathematics at the Ruhr University in Bochum, Germany, and the University of Tennessee before joining the Health Physics Division at ORNL in 1976. His main research interest is in physiological systems modeling, with primary applications to the biokinetics and dosimetry of radionuclides and radiation risk analysis. He is a member of Committee 2 of the International Commission on Radiological Protection (ICRP) and the ICRP Task Group on Internal Dosimetry (INDOS). His physiological systems models of the human circulation, skeleton, and gastrointestinal transfer and his systemic biokinetic models for numerous elements are used by the ICRP as dosimetry and bioassay models. He is the author of ICRP Publication 70, Basic Anatomical and Physiological Data for Use in Radiological Protection: The Skeleton and co-author of a number of other ICRP reports including the series of documents on doses to members of the public from intake of radionuclides (1989-1996), the updated Reference Man document (2002), and the Human Alimentary Tract Model (2006). He has authored over 100 open literature publications and in 1995 was named ORNL Author of the Year for the paper, "An age-specific kinetic model of Pb metabolism in humans."

EDUCATION

Union University, Jackson, TN, BS, 1967
University of Kentucky, Lexington, KY, MS (Mathematics), 1969
University of Kentucky, Lexington, KY, PhD (Mathematics), 1972

PROFESSIONAL EXPERIENCE

1972-1974: Scientific Coworker, Ruhr University, Bochum, Germany

1974-1976: Assistant Professor, Department of Mathematics, University of Tennessee

1976-2007: Research Scientist, Oak Ridge National Laboratory: Health Physics Division, Health and Safety Research Division, Life Sciences Division, Environmental Sciences Division

2007-present: Distinguished Scientist, Oak Ridge National Laboratory: Environmental Sciences Division

AWARDS

Martin Marietta Energy Systems Author of the Year, 1995
ORNL Life Sciences Division Career Achievements Award, 2004
ORNL Significant Achievement Awards: 1986, 1989, 1994, 2002

COMMITTEES

International Commission on Radiological Protection (ICRP):
Committee 2 – Doses from Radiation Exposure, 2009-present
Task Group on Dose Calculations (corresponding member), 1985-present
Task Group on Age-Dependent Dosimetry (AGDOS), 1987-1993
Task Group on Internal Dosimetry (INDOS), 1993-present
Task Group on Reference Man, 1990-2002
Task Group on the Human Alimentary Tract, 1998-2007

National Council on Radiation Protection and Measurements (NCRP):
Council Member, 1998-2004; Consociate Member, 2004-present
Committee on Dosimetry and Metabolism of Radionuclides, 1992-1998
Committee on Reliability of Biokinetic and Dosimetric Models, 1992-1998
Committee on Management of Persons Contaminated with Radionuclides, 2004-2010
Committee on Uncertainties in Internal Radiation Dosimetry (Advisor), 2005-2011

SELECTED PUBLICATIONS

R. W. Leggett. A biokinetic model for manganese. Sci. Total Environ. 409:4179-4186; 2011.

R. W. Leggett. The biokinetics of ruthenium in the human body. Radiat. Prot. Dosim. (in press).

R. W. Leggett. A physiological systems model for iodine for use in radiation protection. Radiation Research 174: 496-516 (2010).

R. W. Leggett. Dosimetry and case studies for selected radionuclides. Chapter 20 in: Management of persons contaminated with radionuclides, NCRP report 161, National Council on Radiation Protection and Measurements, Bethesda, MD. pp. 482-781, 2009.

R. W. Leggett. The biokinetics of inorganic cobalt in the human body. Science of the Total Environment 389:259-269; 2008.

J. D. Harrison, R. W. Leggett, A. Phipps, B. Scott. Polonium-210 as a poison. J. Radiol. Prot. 27:17-40; 2007.

R. W. Leggett, J. D. Harrison, A. Phipps. Reliability of the ICRP's dose coefficients for members of the public: IV. Basis of the human alimentary tract model and uncertainties in model predictions. Radiation Protection Dosimetry 123: 156-170; 2007.

R. W. Leggett. Biokinetics of uranium in the human body. Chapter 10 in: "Depleted Uranium", edited by A. Miller. CRC Press, Boca Raton, FL. 2007, pp. 163-181.

R. W. Leggett, K. F. Eckerman, V. F. Khokhryakov, K. G. Suslova, M. C. Krahenbuhl, S. C. Miller. Mayak worker study: An improved biokinetic model for reconstructing doses from internally deposited plutonium. Radiat. Res. 164:111-122; 2005.

R. W. Leggett, K. F. Eckerman, J. D. Boice. A respiratory model for uranium aluminide based on occupational data. J. Radiol. Prot. 25:1-12; 2005.

R. W. Leggett. A biokinetic model for carbon dioxide and bicarbonate. Radiation Protection Dosimetry 108:203-213; 2004.

R. W. Leggett. Reliability of the ICRP's dose coefficients for members of the public. III. Plutonium as a case study of uncertainties in the systemic biokinetics of radionuclides. Radiation Protection Dosimetry 106:103-120; 2003.

R. W. Leggett, L. R. Williams, D. R. Melo, J. L. Lipsztein. A physiologically based biokinetic model for cesium in the human body. Science of the Total Environment 317:235-255; 2003.

R. W. Leggett and T. C. Pellmar. The biokinetics of uranium migrating from embedded DU fragments. Journal of Environmental Radioactivity 64:205-225; 2003.

R. W. Leggett. Consistent biokinetic models for the actinide elements. Rad. Prot. Env. 24:616-622; 2001.

R. W. Leggett. Reliability of the ICRP's dose coefficients for members of the public. 1. Sources of uncertainty in the biokinetic models. Radiation Protection Dosimetry 95:199-213; 2001.

R. W. Leggett and K. F. Eckerman. A systemic biokinetic model for polonium. Science of the Total Environment 275:109-125; 2001.

R. W. Leggett, J. C. Barton, K. F. Eckerman. Mathematical models of metal metabolism in hemochromatosis. In: J. C. Barton and C. Q. Edwards, eds. Hemochromatosis. New York: Cambridge University Press; 2000.

R. W. Leggett, A. Bouville, K. F. Eckerman. Reliability of the ICRP's systemic biokinetic models. Radiat. Prot. Dosim. 79:335-342; 1998.

R. W. Leggett. Basis and implications of the ICRP's new biokinetic model for thorium. Health Physics 73:587-600; 1997.

R. W. Leggett. A model of the distribution and retention of tungsten in the human body. Science of the Total Environment 206:147-165; 1997.

R. W. Leggett. ICRP Publication 70: Basic anatomical and physiological data for use in radiological protection: The skeleton. Oxford: Pergamon Press; 1995.

R. W. Leggett and L. R. Williams. A proposed blood circulation model for Reference Man. Health Physics 69:187-201; 1995.

R. W. Leggett and J. D. Harrison. Fractional absorption of ingested uranium in humans. Health Physics 68:484-498; 1995.

R. W. Leggett. Basis for the ICRP's age-specific biokinetic model for uranium. Health Physics 67:589-610; 1994.

R. W. Leggett and K. F. Eckerman. Evolution of the ICRP's biokinetic models. Radiation Protection Dosimetry 53:147-155; 1994.

R. W. Leggett, An age-specific kinetic model of lead metabolism in humans, Environmental Health Perspectives 101:598-616; 1993.

R. W. Leggett, K. F. Eckerman, L. R. Williams, An elementary method for implementing complex biokinetic models, Health Physics 64:260-278; 1993.

R. W. Leggett, A generic age-specific biokinetic model for calcium-like elements, Radiation Protection Dosimetry 41:183-198; 1992.

R. W. Leggett, Fractional absorption of ingested barium to blood in adult humans, Health Physics 62:556-561; 1992.

R. W. Leggett, A retention-excretion model for americium in humans, Health Physics 62:288-310; 1992.

R. W. Leggett and L. R. Williams, Suggested reference values for regional blood volumes in humans, Health Physics 60, 1991, 139-154.

R. W. Leggett, The behavior and chemical toxicity of uranium in the kidney: a reassessment, Health Physics 57, 1989, 365-383.

R. W. Leggett and L. R. Williams, A biokinetic model for rubidium in humans, Health Physics 55, 1988, 685-702.

R. W. Leggett and K. F. Eckerman, A method for estimating the systemic burden of Pu from urinalyses, Health Physics 52, 1987, 337-346.

R. W. Leggett, M. Cristy, and K. F. Eckerman, A comprehensive approach to age-dependent dosimetric modeling. In: Developments in Nuclear Medicine, Age-related factors in radionuclide metabolism and dosimetry. Proceedings of a workshop held in Angers, France, Nov. 26-28, 1986; 261-270.

R. W. Leggett, Predicting the retention of cesium in individuals, Health Phys. 50, 747-759, 1986.

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R. W. Leggett, A model of the retention, translocation, and excretion of systemic plutonium, Health Phys. 49, 1115-1137, 1985.

R. W. Leggett, D. E. Dunning, Jr., and K. F. Eckerman, Modelling the behaviour of chains of radionuclides inside the body, Radiat. Prot. Dosim. 9, 77-91, 1984.

R. W. Leggett and D. J. Crawford-Brown, The role of age in human susceptibility to radiation, Sci. Prog., Oxford 68, 227-258, 1983.

R. W. Leggett, K. F. Eckerman, and L. R. Williams, Strontium-90 in bone: A case study in age-dependent dosimetric modeling, Health Phys. 43, 307-322, 1982.

R. W. Leggett and D. J. Crawford, A method for projecting age-specific mortality rates for certain

causes of death, Risk Analysis 1, 205-215, 1981.

R. W. Leggett and L. R. Williams, A reliability index for models, Ecological Modelling 13, 303-312, 1981.

R. W. Leggett and L. R. Williams, A fixed point theorem with application to an infectious disease model, J. Math. Anal. Appl. 76, 91-97, 1980.

R. W. Leggett, H. W. Dickson, and F. F. Haywood, A statistical methodology for radiological surveying, Proceedings of the IAEA Symposium on Advances in Radiation Protection Monitoring (Stockholm, June 1978), IAEA-SM-229/103, Vienna, 541-554, 1979.

R. W. Leggett, A new approach to the H-equation of Chandrasekhar, Society for Industrial and Applied Mathematics, J. Math. Anal. 7, 542-550, 1977.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Keith F. Eckerman	Senior Scientist

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY
U Wisconsin-Platteville	BS	1962	Mathematics/Chemistry
Marquette University; Milwaukee, WI	MS	1967	Physics
Northwestern U; Evanston, IL	Ph.D.	1972	Radiological Physics

EXPERIENCE

1962-1966: Instructor of mathematics, physics, and chemistry at Warren High School in Warren, IL. Attended NSF Program at Marquette University during summers of 1964-1966.

1966-1967: Academic year at Oak Ridge Institute of Nuclear Studies, sponsored by the Atomic Energy Commission. Research was carried out using accelerators at U. of Georgia and Oak Ridge National Laboratory for MS degree at Marquette U.

1967-1970: Graduate student in Radiological Health in Civil Engineering Dept., Northwestern U. Part-time employment as physicist at Evanston Hospital.

1960-1972: Guest Fellow and AUA-ANL Fellow, Radiological Physics Division of Argonne National Laboratory.

1972-1974: Environmental Scientist with Environmental Statement Project at Argonne National Laboratory, Argonne, IL. In Sept. 1973 on loan from ANL to AEC-Regulatory in Washington DC.

1974-1978: Senior Radiological Physicists, U.S. Nuclear Regulatory Commission. Responsible for the developing mathematical models to estimate environmental impact of nuclear fuel cycle facilities.

1979- Dosimetry Research Team, Environmental Science Division, Oak Ridge National Laboratory. Responsible for directing research in radiation protection and radiological health risks.

HONORS AND AWARDS

Patent: Temperature measurement device #3,869,918 issued 3/11/75.
NRC Special Achievement Award (1977)
DOE Award – Operation Ivory Purpose (1980)
1995 Distinguished Scientific Achievement Award- Health Physics Society
2001 Loevinger-Berman Award – Soc. of Nuclear Medicine

ADVISORY COMMITTEE MEMBERSHIPS

International Commission on Radiological Protection:
- Member, Committee 2 on Secondary Limits, 1982- present
- Chairman, Task Group on Dose Calculations, 1982-present
- Member of various other task groups and working parties
- National Council on Radiation Protection and Measurements
- Member of Council, 1990- present

PUBLICATIONS (Selected)

K.F. Eckerman and J.C. Ryman. *External Exposure to Radionuclides in Air, Water, and Soil,* Federal Guidance Report No. 12 EPA-402-R-93-081 (1993).
K.F. Eckerman, R.W. Leggett, C.B. Nelson, J.S. Puskin, and A.C.B. Richardson. *Health Risks from Low-Level Environmental Exposure to Radionuclides*, Federal Guidance Report No. 13. EPA-402-R97-014 (1998).

D.A. Weber, K.F. Eckerman, L.T. Dillman, and J.C. Ryman, *MIRD: Radionuclide Data and Decay Schemes*, Society of Nuclear Medicine, New York, NY, 1989.

R.W. Leggett, K.F. Eckerman, and L.R. Williams, "An Elementary Method for Implementing Complex Biokinetic Models," *Health Phys.* 64(3):260-271, 1993.

A. Bouville, K. Eckerman, W. Griffith, O. Hoffman, R. Leggett, and J. Stubbs. "Evaluating the Reliability of Biokinetic and Dosimetric Models and Parameters used to Assess Individual Doses for Risk Assessment Purposes," *Rad. Prot. Dosi. 53*(1-4): 211-215, 1994

R.W. Leggett and K.F. Eckerman, "Evolution of the ICRP's Biokinetic Models," *Rad. Prot. Dosi. 53*(1-4): 147-155, 1994.

A.V. Ulanosvsky and K.F. Eckerman. "Absorbed Fractions for Electron and Photon Emissions in the Developing Thyroid: Fetus to Five Year Old," *Rad. Prot. Dosi.* 79(1):419-424, 1997.

R.W. Leggett, A. Bouville, and K.F. Eckerman. "Reliability of ICRP's Systemic Biokinetic Models," *Rad. Prot. Dosi.* 79(1):335-342, 1997.

A.V. Ulanosvsky and K.F. Eckerman. "Modification of the ORNL Phantom Series in Simulation of the Responses of Thyroid Detectors," *Rad. Prot. Dosi.* 79(1): 429-431, 1997.

N.B. Munro and K.F. Eckerman. "Impacts of Physiological Changes during Pregnancy on Maternal Biokinetic Modelling," *Rad. Prot. Dosi.* 79(1):327-333, 1997.

K.F. Eckerman, "Dosimetry of Ingested Radon and its Associated Risks," in *Risk Assessment of Radon in Drinking Water*, National Research Council, Washington, DC, 1999.

K.F. Eckerman and M.G. Stabin, "Electron Absorbed Fractions and Dose Conversion Factors for Marrow and Bone by Skeletal Region," *Health Phys.* 78(2):199-214, 2000.

P. K. Hopke, T. B. Borak, J. Doull, J. E. Cleaver, K. F. Eckerman, and L.C.S. Gundersen, *et al.* "Health Risks Due to Radon in Drinking Water," *Environ Sci Technol 34(6)*:921-6, 2000.

W. K. Breeden, 3rd, D. M. Hamby, J. E. Carey, Jr, K. F. Eckerman, D. W. McPherson, and F. F. Knapp, Jr. "In Vivo Biodistribution of ^{125}IPIP and Internal Dosimetry of ^{123}IPIP Radioiodinated Agents Selective to the Muscarinic Acetylcholinergic Receptor Complex," *Med Phys* 27(4):778-86, 2000.

R.W. Leggett, N.B. Munro, K.F. Eckerman. "Proposed revision of the ICRP model for inhaled mercury vapor." *Health Phys 81*(4):450-455, 2001.

R.W. Leggett, K.F. Eckerman. "A systemic biokinetic model for polonium." *Sci Tot Env 275*(1-3): 109-125, 2001.

M.G. Stabin, K.F. Eckerman, W.E. Bolch, L.G. Bouchet. "Consensus bone and marrow model for internal dose assessment." *Nuc Med 42*(5) 2001.

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B.R. Bailey, K.F. Eckerman, and L.W. Townsend. "An Analysis of a Puncture Wound Case with Medical Intervention," *Rad. Prot. Dosi. 105*(1): 509-512, 2003.

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Han, Eun Young; Bolch, Wesley E.; Eckerman, Keith F. "Revisions to the ORNL Series of Adult and Pediatric Computational Phantoms for use with the MIRD Schema." *Health Phys.* 90(4):337-356, 2006.

Boice, John D. Jr ; Leggett, Richard W. ; Ellis, Elizabeth Dupree; Wallace, Phillip W. ; Mumma, Michael ; Cohen, Sarah S.; Brill, A Bertrand; Chadda, Bandana; Boecker, Bruce B.; Yoder, R Craig; Eckerman, Keith F. "A Comprehensive Dose Reconstruction Methodology for Former Rocketdyne Atomics International Radiation Workers." *Health Phys.* 90(5):409-430, 2006.

J. D. Boice, R. W. Leggett, K. F. Eckerman, et al. "A Comprehensive Dose Reconstruction Methodology for Former Rocketdyne Radiation Workers." *Health Phys.* 90:409-430; 2006.

E.K. Vasilenko, V.F. Khokhryakov, S.C. Miller, J.J. Fix, K. Eckerman, D.O. Choe, M. Gorelov, V.V. Khokhryakov, V. Knyasev, M.P. Krahenbuhl, R.I. Scherpelz, M. Smetanin, K. Suslova, and V. Vostrotin. "Mayak Worker Dosimetry Study: An Overview." *Health Phys.* 93(3), 2007.

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K.F. Eckerman and A. Endo. *MIRD: Radionuclide Data and Decay Schemes.* Society of Nuclear Medicine, Reston VA (2008).

K.F. Eckerman and A. Endo. "ICRP Publication 107: Nuclear Decay Data for Dosimetric Calculations." Annals of the ICRP 38(3), 2008.

W.E. Bolch, K.F. Eckerman, G. Sgouros, S.R. Thomas. MIRD Pamphlet No. 21 – A Generalized Schema for Radiopharmaceutical Dosimetry: Standardization of Nomenclature, *J Nucl Med 50*:477-484, 2009.

LAURIE DIANE WIGGS, MPH, Ph.D.
Senior Epidemiologist

EDUCATION

Ph.D. (major-epidemiology, minor-biostatistics), Department of Biostatistics and Epidemiology, College of Public Health, University of Oklahoma, 1987

M.P.H. (epidemiology), Department of Biostatistics and Epidemiology, College of Public Health, University of Oklahoma, 1980

EXPERIENCE

04/11t-Present Senior Epidemiologist, Occupational Medicine, Los Alamos National Laboratory (LANL)

7/06-04/11t Technical Staff Member/Team Leader, Epidemiologist, Occupational Medicine, Los Alamos National Laboratory (LANL)

6/05-7/06 Technical Staff Member, Decision Applications Division, (LANL), University of California

1/91-6/05 Laboratory Epidemiologist, Occupational Medicine, Health Safety and Environment Division, (LANL/UC)

1/91-10/99 Team Leader, Epidemiology Section, Occupational Medicine, Health Safety and Environment Division, (LANL/UC)

1998-Present Associate, Department of Epidemiology, School of Hygiene and Public Health, Johns Hopkins Universit

1988-2006 Adjunct Professor, Department of Biostatistics and Epidemiology, OU College of Public Health

4/80-12/90 Epidemiologist, Staff Member, Health Safety and Environment Division, (LANL/UC)

5/79-4/80 Research Fellow, Division of Epidemiology, University of Minnesota School of Public Health, Plutonium Workers Study at the Los Alamos Scientific Laboratory,

SELECTED HONORS/CREDENTIALS

LANL Distinguished Performance Award (1995)
Award of Excellence, Department of Energy (1983)
Phi Beta Kappa (1978)
Q-Clearance, US DOE

SELECTED PUBLICATIONS

National Infrastructure Simulation &Analysis Center and the Critical Infrastructure Protection Decision Support System, "Health Care, Infrastructure Interdependency, and Economic Impacts of Pandemic Influenza: Phase 1 Report," November 30, 2006.

A.B. Stefaniak, V. M. Weaver, M. Cadorette, L. G. Puckett, B. S. Schwartz, **L. D., Wiggs**, M.D. Jankowski, and P. N. Breysse, "Summary of Historical Beryllium Uses and Airborne Concentration Levels at Los Alamos National Laboratory," Applied Occupational and Environmental Hygiene 18: 708-715 (2003).

P.N. Breysse, V. Weaver, M. Cadorette, **L. Wiggs**, B. Curbow, A. Stefaniak, J. Melius, L. Newman, H. Smith, and B. Schwartz, "Development of a Medical Examination Program for Former Workers at a Department of Energy National Laboratory," American Journal of Industrial Medicine 42(5): 443-454 (2002).

E. Cardis, E.S. Gilbert, L. Carpenter, G. Howe, I. Kato, B.K. Armstrong, V. Beral, G. Cowper, A. Douglas, J. Fix, S.A. Fry, J. Kaldor, C. Lave, L. Salmon, P.G. Smith, G.L. Voelz, and **L.D. Wiggs**, "Effects of Low Doses and Low Dose Rates of External Ionizing Radiation: Cancer Mortality among Nuclear Industry Workers in Three Countries", Radiation Research 142: 117-132 (1995).
S.A. Fry, D.L. Cragle, D.J. Crawford-Brown, E.A. Dupree, E.I. Frome, E.S. Gilbert, G.R. Petersen, C.M. Shy, W.G. Tankersley, G.L. Voelz, P.W. Wallace, J.P. Watkins, J.E. Watson, and **L.D. Wiggs**, "Health and Mortality among Contractor Employees at U.

S. Department of Energy Facilities," in Radiation and Public Perception: Benefits and Risks. J.P. Young and R.S. Yalow, eds., Advances in Chemistry Series 243. American Chemical Society (1995).

L.D. Wiggs, E.R. Johnson, C.A. Cox-DeVore, and G.L. Voelz, "Mortality through 1990 among White Male Workers at the Los Alamos National Laboratory: Considering Exposures to Plutonium and External Ionizing Radiation", Health Physics 67(6): 577-588 (1994).

IARC Study Group on Cancer Risk among Nuclear Industry Workers (member), "Direct Estimates of Cancer Mortality Due to Low Doses of Ionising Radiation: An International Study", Lancet 344: 1039-43 (1994).

E.S. Gilbert, D.L. Cragle, and **L.D. Wiggs**, "Updated Analyses of Combined Mortality Data on Workers at the Hanford Site, Oak Ridge National Laboratory and Rocky Flats Weapons Plant", Radiation Research 136: 408-421 (1993).

L.D. Wiggs, C.A. Weber, G.S. Wilkinson, and M. Reyes. "Mortality Among Workers Exposed to External Ionizing Radiation at a Nuclear Facility in Ohio," Journal of Occupational Medicine 33(5):632-637 (1991).

M. Reyes, G.S. Wilkinson, G.L. Tietjen, **L.D. Wiggs**, and W.A. Galke, "Mortality Among Workers at the Mound Facility: A Preliminary Report," Los Alamos report, LA-11997-MS, UC-407 (1991).

L.D. Wiggs, C.A. Cox-DeVore, and G.L. Voelz, "Mortality among a Cohort of Workers Monitored for ^{210}Po Exposure: 1944-1972," Health Physics 61(1): 71-76 (1991).

L.D. Wiggs and G.L. Voelz, "Epidemiology Studies of Plutonium Workers," Invited Speaker, Health Physics Society Meeting, Anaheim, CA, June 27, 1990.

E.S. Gilbert, S.A. Fry, **L.D. Wiggs**, G.L. Voelz, D.L. Cragle, and G.R. Petersen, "Methods for Analyzing Combined Data From Studies of Workers Exposed to Low Doses of Radiation," American Journal of Epidemiology 131: 917-927 (1990).

E.S. Gilbert, S.A. Fry, **L.D. Wiggs**, G.L. Voelz, D.L. Cragle, and G.R. Petersen, "Analyses of Combined Mortality Data on Workers at the Hanford Site, Oak Ridge National Laboratory, and Rocky Flats Nuclear Weapons Plant." Radiation Research 120: 19-35 (1989).

L.D. Wiggs, "Results of Epidemiologic Studies of Nuclear Workers from the Rocky Flats, Pantex and Mound Facilities", presented at the Meeting on Cancer Risk Among Nuclear Industry Workers, International Agency for Research on Cancer, Lyon, France, June 7-10, 1988.

L.D. Wiggs, "Mortality Among Women Employed by the Los Alamos National Laboratory: An Epidemiologic Investigation," Doctoral Dissertation, University of Oklahoma, 1987.

G.S. Wilkinson, G.L. Tietjen, **L.D. Wiggs**, et al., "Mortality Among Plutonium and Other Radiation Workers at a Plutonium Weapons Facility," American Journal of Epidemiology 125: 231-250 (1987).

G.S. Wilkinson, W.A. Galke, G.L. Tietjen, and **L.D. Wiggs**, "Residual Confounding in Follow-up Studies with Time-Dependent Doses (abstract)," American Journal of Epidemiology 124: 526 (1986).

J.F. Acquavella, **L.D. Wiggs**, R.J. Waxweiler, D.G. Macdonell, and G.S. Wilkinson, "Mortality Among Workers at the Pantex Weapons Facility," Health Physics 48: 735-746 (1985).

J.F. Acquavella, **L.D. Wiggs**, R.J. Waxweiler, D.G. Macdonell, and G.S. Wilkinson, "Supplementary Documentation for an Environmental Impact Statement Regarding the Pantex Plant: Occupational Work Force Mortality Study," Los Alamos National Laboratory report LA-9445-PNTX-Q (1983).

J.F. Acquavella, G.S. Wilkinson, **L.D. Wiggs**, G.L. Tietjen, and C.R. Key, "An Evaluation of Cancer Incidence Among Employees at the Los Alamos National Laboratory," in Epidemiology Applied to Health Physics, Proceedings of the 16th Mid-Year Topical Meeting of the Health Physics Society, CONF-830101 (Springfield, VA, NTIS, 1983).

G.L. Voelz, G.S. Wilkinson, J.F. Acquavella, G.L. Tietjen, R.M. Brackbill, M. Reyes, and **L.D. Wiggs**, "An Update of Epidemiologic Studies of Plutonium Workers," Health Physics 44 (Suppl. 1): 493-501 (1983).

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Howard D. Sesso	POSITION TITLE Associate Epidemiologist, Brigham & Women's Hosp Associate Professor of Medicine, Harvard Medical School
eRA COMMONS USER NAME (credential, e.g., agency login) hsesso	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Stanford University	B.A.	1993	Human Biology
George Washington University	M.P.H.	1995	Epidemiology
Harvard School of Public Health	Sc.D.	1999	Epidemiology

A. Personal Statement

I am an experienced epidemiologist with research interests in nutrition, biomarkers, genetic factors, and the risk of cancer and cardiovascular disease, as well as the design and conduct of epidemiologic studies. I oversee the administrative and scientific aspects of the ongoing Physicians' Health Study, a large randomized clinical trial and cancer epidemiology cohort. My research will greatly complement and enhance efforts for the One Million Worker Study to further establish and harmonize these unique, well-characterized, and clinically relevant cohorts of US workers and veterans who were exposed to radiation and have sufficient long-term follow-up to yield critically needed findings on major disease endpoints that will have major public health implications. As there are significant methodological and epidemiologic components to this proposal in lines with my interests and expertise, I will assist in the establishment of the harmonized cohort infrastructure, acquisition of data, and take an active role in the interpretation of study results and writing of manuscripts.

B. Positions and Honors

Positions and Employment

1992-1993	Research Assistant, Stanford Center for Research in Disease Prevention, Stanford University School of Medicine, Stanford, CA
1993-1995	Assistant Data Coordinator, Lipid Research Clinic, George Washington University School of Medicine and Health Sciences, Washington, DC
1995-1999	Research Fellow, Brigham and Women's Hospital, Boston, MA
1995-1999	Research Fellow, Harvard Medical School, Boston, MA
1999-	Associate Epidemiologist, Brigham and Women's Hospital, Boston, MA
1999-2002	Instructor in Medicine, Harvard Medical School, Boston, MA
2002-2011	Assistant Professor of Medicine, Brigham and Women's Hospital, Boston, MA
2011-	Associate Professor of Medicine, Brigham and Women's Hospital, Boston, MA

Other Experience and Professional Memberships

1997-	Member, American Heart Association Council on Epidemiology and Prevention
1999-	Member, Society for Epidemiologic Research
2001-	Member, American Heart Association Council on Nutrition, Metabolism, & Physical Activity

Honors

2001	American Heart Association: Scientist Development Grant *"Biochemical Markers of Incident Hypertension in Men and Women"*
2002	American Cancer Society: Research Scholar Grant *"Flavonoids and Cancer"*

2006 Fellow, American Heart Association Council on Epidemiology and Prevention

C. Selected Peer-reviewed Publications (Selected from more than 120 peer-reviewed publications)

Most relevant to the current application (in chronological order)

1. **Sesso HD**, Paffenbarger RS Jr, Lee I-M. Alcohol consumption and the risk of prostate cancer: the Harvard Alumni Health Study. Int J Epidemiol 2001;30:749-755.
2. Lee I-M, **Sesso HD**, Paffenbarger RS Jr. A prospective study of physical activity and body size in relation to prostate cancer risk (United States). Cancer Causes Control 2001;12:187-193.
3. Koushik A, Tranah GJ, Ma J, Stampfer MJ, **Sesso HD**, Fuchs CS, Giovannucci EL, Hunter DJ. p53 Arg72Pro polymorphism and risk of colorectal adenoma and cancer. Int J Cancer 2006;119:1863-1868.
4. Chavarro JE, Stampfer MJ, Hall MN, **Sesso HD**, Ma J. A 22-year prospective study of fish intake in relation to prostate cancer incidence and mortality. Am J Clin Nutr 2008;88:1297-1303.
5. **Sesso HD**, Buring JE, Christen WG, Kurth T, Belanger C, MacFadyen J, Bubes V, Manson JE, Glynn RJ, Gaziano JM. Vitamins E and C in the prevention of cardiovascular disease in men: The Physicians' Health Study II randomized trial. JAMA 2008;300:2121-2133. PMCID: PMC2586922
6. Gaziano JM, Glynn RJ, Christen WG, Kurth T, Belanger C, MacFadyen J, Bubes V, Manson JE, **Sesso HD**, Buring JE. Vitamins E and C in the prevention of prostate and total cancer in men: The Physicians' Health Study II randomized controlled trial. JAMA 2009;301:52-62. PMCID: PMC2774210

Additional recent publications of importance to the field (in chronological order)

1. **Sesso HD**, Paffenbarger RS Jr, Lee I-M. Physical activity and breast cancer risk in the College Alumni Health Study. Cancer Causes Control 1998;9:433-9.
2. **Sesso HD**, Gaziano JM, VanDenburgh M, Hennekens CH, Glynn RJ, Buring JE. Comparison of baseline characteristics and mortality experience of participants and nonparticipants in a randomized clinical trial: the Physicians' Health Study. Control Clin Trials 2002;23:686-702.
3. Zhu K, Lee IM, **Sesso HD**, Buring JE, Levine RS, Gaziano JM. History of diabetes mellitus and risk of prostate cancer in male physicians. Am J Epidemiol 2004;159:978-982.
4. **Sesso HD**, Buring JE, Zhang SM, Norkus EP, Gaziano JM. Dietary and plasma lycopene and the risk of breast cancer. Cancer Epidemiol Biomarkers Prev 2005;14:1074-1081.
5. Koh KA, **Sesso HD**, Paffenbarger RS Jr, Lee IM. Dairy products, calcium and prostate cancer risk. Br J Cancer 2006;95:1582-1585.
6. Wang L, Lee IM, Zhang SM, Blumberg JB, Buring JE, **Sesso HD**. Dietary intake of selected flavonols, flavones, and flavonoid-rich foods and risk of cancer in middle-aged and older women. Am J Clin Nutr 2009;89:905-912. PMCID: PMC2667658
7. Fiorentino M, Judson G, Penney K, Flavin R, Stark J, Fiore C, Fall K, Martin N, Ma J, Sinnott J, Giovannucci E, Stampfer M, **Sesso HD**, Kantoff PW, Finn S, Loda M, Mucci L. Immunohistochemical expression of BRCA1 and lethal prostate cancer. Cancer Res 2010;70:3136-3139. PMID: 20388772
8. Meyer MS, Penney KL, Stark JR, Schumacher F, **Sesso H**, Loda M, Fiorentino M, Finn S, Flavin R, Kurth T, Price A, Giovannucci E, Fall K, Stampfer MJ, Ma J, Mucci LA. Genetic variation in RNASEL associated with prostate cancer risk and progression. Carcinogenesis 2010;31:1597-1603. PMCID: PMC2930803
9. Penney KL, Sinnott JA, Fall K, Pawitan Y, Hoshida Y, Kraft P, Stark JR, Fiorentino M, Perner S, Finn S, Calza S, Flavin R, Freedman ML, Setlur S, **Sesso HD,** Andersson S-O, Martin N, Kantoff PW, Johansson J-E, Adami H-O, Rubin MA, Loda M, Golub TR, Andrén O, Stampfer MJ, Mucci LA. An mRNA expression signature of Gleason grade predicts lethal prostate cancer. J Clin Oncol 2011; *Epub ahead of print*. PMID: 21421545

D. Research Support

Ongoing Research Support

2 R01 CA097193 Gaziano (PI) 10/01/07 – 09/30/12
Physicians' Health Study II: Prevention Trial of Vitamins

This application seeks funding to extend randomized treatment and follow-up for the multivitamin (Centrum Silver) component of the Physicians' Health Study II (PHS II), an ongoing randomized, double-blind, placebo-controlled trial of vitamin E, vitamin C, and a multivitamin, in the prevention of cancer, cardiovascular disease, eye disease, and declining cognitive function among 14,641 U. S. male physicians aged > 50 years. Role: Project Director

N/A Sesso (PI) 12/19/08 – 12/18/11
Cambridge Theranostics Ltd
Trial of Ateronon for Carotid Atherosclerosis and Biomarkers in Patients with Stable Coronary Heart Disease

The primary objectives of this randomized, double-blind, placebo-controlled trial is to test whether 7 mg of Ateronon™, a lycopene supplement, taken daily for 12 months among men and women aged ≥50 years with a history of coronary heart disease may lead to favorable changes in carotid artery intima-media thickness, as well as improvements in the levels of biomarkers of oxidative stress (oxidized LDL and malondialdehyde) and endothelial dysfunction (E-selectin and von Willebrand factor).

5 R01 CA124908-03 Fuchs (PI) 05/23/08 – 08/31/12
Prospective Cohort Collaborative in Pancreatic Cancer Epidemiology and Pathogenesis

This project will extend findings by pooling several large prospective cohort studies with extensive banked dietary data and biospecimens, including the Physicians' Health Study. Three inter-related pathogenic pathways will be examined in relation to pancreatic cancer incidence as well as specific molecular alterations in pancreatic cancer specimens: 1) energy balance, insulin and insulin-like growth factor signaling, 2) inflammation, and 3) vitamin D-related pathways. Role: PI (Subcontract)

5 R01 CA127532-02 Perera (PI) 01/08/08 – 12/31/12
Molecular Epidemiology and Lung Cancer: A Nested Case-Control Study

The objective of this study is to determine the relationships between adducts, p53 mutation, and risk of developing lung cancer, and to assess patterns of protein expression as biomarkers of early lung cancer detection by calculating their sensitivity and specificity. These parameters will be assessed under different circumstances of histology, stage of disease, smoking status, length of follow-up and treatment in the Physicians' Health Study. Role: PI (Subcontract)

1R01CA136578-01 Mucci (PI) 03/03/09 – 01/31/14
Sex Hormones and the TMPRSS2: ERG Fusion in Prostate Cancer Progression

The recent identification of a common novel translocation in prostate cancer, the TMPRSS2:ERG fusion, may help explain the heterogeneity of this disease. This study seeks to explore the role of the

TMPRSS2:ERG translocation in PCa progression within the Physicians' Health Study and Health Professionals Follow-up Study among men with PCa, and to understand whether genetic factors, hormones or lifestyle factors interact with the fusion to impact cancer mortality. Role: PI (Subcontract)

R21 DK081141 Sesso (PI) 07/20/09 – 04/19/12
Physical Activity and Diet in the Prevention of Obesity in Men and Women

In responding to PA-06-256 (Exploratory/Developmental Clinical Research Grants in Obesity), we seek to develop incident obesity as an endpoint within two large existing prospective cohort studies, the Harvard Alumni Health Study and the Women's Health Study. We will then examine initially non-obese men and women free of cardiovascular disease to see whether physical inactivity or particular dietary factors are associated with an increased risk of becoming obese or greater increases in body weight during long-term follow-up.

R03 CA130068 Lee (PI) 07/01/09 – 06/30/11
Physical Activity and Survival in Cancer Patients

This proposal seeks to provide information on whether physical activity is associated with lower all-cause and cancer mortality rates among 1,683 men (mean age, 67 years) with a history of physician-diagnosed cancer in the Harvard Alumni Health Study. Role: Co-I

N/A Sesso (PI) 10/13/09 – 10/12/12
Cambridge Theranostics Ltd
Atheroabzymes and the Risk of Cardiovascular Disease in PHS

This trial will evaluate the role of Atheroabzymes as a predictor of cardiovascular disease in a nested case-control study in the Physicians' Health Study cohort.

R01 HL102122 Sesso (PI) 02/04/11 – 11/30/15
Effect of Vitamin D and Omega-3 Fatty Acids on Blood Pressure and Hypertension

This proposal will test in a large-scale, long-term randomized trial whether taking vitamin D or fish oil supplements results in 2-year improvements in ambulatory blood pressure in 1,000 participants from the VITAL trial, and whether these supplements prevent the development of hypertension in the overall VITAL trial.

HHSN261201000O693P Sesso (PI) 09/27/10 – 09/26/11
NIH / NCI
Rare Cancer Pooling Project

The objective of this project is to obtain stored, pre-diagnostic blood samples from the liver cancer cases and male breast cancer cases and controls in the Physicians' Health Study and Women's Health Study to examine serologic factors related to each cancer as part of the National Cancer Institute Cohort Consortium Rare Cancer Pooling Project.

20 September 2011

BRIEF RESUME

Name: André Bouville

Date and Place of Birth: 12 June 1939; Toulouse, France

Citizenship: United States

Marital Status: Married, 1966; two children

Addresses:

(office) National Cancer Institute, NIH, DHHS
Division of Cancer Epidemiology and Genetics
Radiation Epidemiology Branch
6120 Executive Boulevard, Room EPS-7094
Bethesda, MD 20892
Phone: (301) 594-7655
Fax: (301) 402-5484
E-mail: bouvilla@mail.nih.gov
(home) 16401 Henry Drive
Gaithersburg, MD 20877
Phone: (301) 330-8781
E-mail: ABouville@aol.com

Education:

1960	B.S. (eq.) (Physics); Université Paul-Sabatier, Toulouse, France
1963	M.A. (eq.) (Nuclear Physics); Université Paul-Sabatier, France
1970	Ph.D. (eq.) (Physics); Université Paul-Sabatier, Toulouse, France

Military Service: French Air Force, 1966-1967

Brief Chronology of Employment:

1962-1965	Assistant Professor, Université Paul-Sabatier, Toulouse, France
1965-1966	Visiting Scientist, National Atmospheric and Oceanic Administration (NOAA), Air Resources Laboratory, Silver Spring, MD 20910
1966-1970	Assistant Professor, Université Paul-Sabatier, Toulouse, France
1970-1972	Scientific Secretary, United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), New York, NY
1972-1974	Physicist, Division of Sanitary Protection, French Atomic Energy Commission, Fontenay-aux-Roses,France
1974-1979	Group Chief, Division of Sanitary Protection, French Atomic Energy Commission, Fontenay-aux-Roses,France
1979-1982	Division Deputy Director, Division of Protection Studies, Institute of Protection and Nuclear Safety, Fontenay-aux-Roses,France
1982-1984	Assistant to the Director of Protection, Institute of Protection and Nuclear Safety, Fontenay-aux-Roses,France
1984-1992	Expert, National Institutes of Health (NIH), National Cancer Institute (NCI), Division of Cancer Etiology, Radiation Effects Branch

1992-1999	Senior Radiation Physicist, NIH, NCI, Division of Cancer Etiology, Radiation Effects Branch
1999-2010	Senior Radiation Physicist, NIH, NCI, Division of Cancer Epidemiology and Genetics, Radiation Epidemiology Branch
2011-present	Part-time consultant, NIH, NCI, Division of Cancer Epidemiology and Genetics, Radiation Epidemiology Branch

Professional Affiliations:

French Society of Radiation Protection
Health Physics Society

Honors and Committee Service:

1996-present	Member, Editorial Advisory Council of the Radiation Protection and Environment journal
2008-present	Member, Senior Advisory Board, Chernobyl Tissue Bank
1989-2009	Member, Committee 2 of the International Commission on Radiological Protection (ICRP)
1993-2010	Council Member, National Council on Radiation Protection and Measurements (NCRP)
1996-2004	Member, Scientific Advisory Committee of the International Consortium for Research on the Health Effects of Radiation (ICRHER)
1998-2001	Member, International Commission on Radiation Units (ICRU) Committee on retrospective dose assessment
1993-2001	Member, Committee on an Assessment of CDC (Centers for Disease Control and Prevention) Radiation Studies of the National Research Council
1973-2000	Consultant, United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)
1989-1991	Group Leader, International Chernobyl Project, International Atomic Energy Agency (IAEA)
1984	Chevalier, Ordre des Palmes Académiques, France
2003	Lifetime Associate, National Academies
2003	Presidential Rank Meritorial Award
2011	Distinguished Emeritus Council Member, National Council on Radiation Protection and Measurements (NCRP)

Research Interest: Radiation Dosimetry

Recent Publications:

1. Lee C, Kim KP, Long D, Fisher R, Tien C, Simon SL, Bouville A, Bolch WE. Organ doses for reference adult male and female undergoing computed tomography estimated by Monte Carlo simulations. Med Phys 38:1196-1206, 2011.

2. Kukush A, Shklyar S, Masiuk S, Likhtarov I, Kovgan L, Carroll RJ, Bouville A. Methods for Estimation of Radiation Risk in Epidemiological Studies Accounting for Classical and Berkson Errors in Doses. Int J Biostat 7(1):Article 15, 2011.

3. Brenner AV, Tronko MD, Hatch M, Bogdanova TI, Oliynik VA, Lubin JH, Zablotska LB, Tereschenko VP, McConnell RJ, Zamotaeva GA, O'Kane P, Bouville AC, Chaykovskaya LV, Greenebaum E, Paster IP, Shpak VM, Ron E. I-131 dose response for incident thyroid cancers in Ukraine related to the Chornobyl accident. Environ Health Perspect 119:933-939, 2011.

4. Hatch M, Furukawa K, Brenner A, Olinjyk V, Ron E, Zablotska L, Terekhova G, McConnell R, Markov V, Shpak V, Ostroumova E, Bouville A, Tronko M. Prevalence of hyperthyroidism after exposure during childhood or adolescence to radioiodines from the chornobyl nuclear accident: dose-response results from the Ukrainian-American Cohort Study. Radiat Res 174:763-772, 2010.

5. Zablotska LB, Ron E, Rozhko AV, Hatch M, Polyanskaya ON, Brenner AV, Lubin J, Romanov GN, McConnell RJ, O'Kane P, Evseenko VV, Drozdovitch VV, Luckyanov N, Minenko VF, Bouville A, Masyakin VB. Thyroid cancer risk in Belarus among children and adolescents exposed to radioiodine after the Chornobyl accident. Br J Cancer 104:181-187, 2011.

6. Drozdovitch V, Schonfeld S, Akimzhanov K, Aldyngurov D, Land CE, Luckyanov N, Mabuchi K, Potischman N, Schwerin MJ, Semenova Y, Tokaeva A, Zhumadilov Z, Bouville A, Simon SL. Behavior and food consumption pattern of the population exposed in 1949-1962 to fallout from Semipalatinsk nuclear test site in Kazakhstan. Radiat Environ Biophys 50:91-103, 2011.

7. Skryabin AM, Drozdovitch V, Belsky Y, Leshcheva SV, Mirkhaidarov AK, Voillequé P, Luckyanov N, Bouville A. Thyroid mass in children and adolescents living in the most exposed areas to Chernobyl fallout in Belarus. Radiat Prot Dosimetry 142:292-299, 2010.

8. Ibrahim SA, Simon SL, Bouville A, Melo D, Beck HL. Alimentary tract absorption (f1 values) for radionuclides in local and regional fallout from nuclear tests. Health Phys 99:233-251, 2010.

9. Beck HL, Bouville A, Moroz BE, Simon SL. Fallout deposition in the Marshall Islands from Bikini and Enewetak nuclear weapons tests. Health Phys 99:124-142, 2010.

10. Drozdovitch V, Khrouch V, Maceika E, Zvonova I, Vlasov O, Bratilova A, Gavrilin Y, Goulko G, Hoshi M, Kesminiene A, Shinkarev S, Tenet V, Cardis E, Bouville A. Reconstruction of radiation doses in a case-control study of thyroid cancer following the Chernobyl accident. Health Phys 99:1-16, 2010.

11. Sholom S, Desrosiers M, Chumak V, Luckyanov N, Simon SL, Bouville A. UV effects in tooth enamel and their possible application in EPR dosimetry with front teeth. Health Phys 98:360-368, 2010.

12. Simon SL, Bouville A, Kleinerman R. Current use and future needs of biodosimetry in studies of long-term health risk following radiation exposure. Health Phys 98:109-117, 2010.

13. Chumak VV, Romanenko AY, Voillequé PG, Bakhanova EV, Gudzenko N, Hatch M, Zablotska LB, Golovanov IA, Luckyanov NK, Sholom SV, Kryuchkov VP, Bouville A. The Ukrainian-American study of leukemia and related disorders among Chornobyl cleanup workers from Ukraine: II. Estimation of bone marrow doses. Radiat Res 170:698-710, 2008.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
John E. Till	President
eRA COMMONS USER NAME	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
U.S. Naval Academy, Annapolis, MD	BS	1967	Engineering
Colorado State University, Fort Collins, CO	MS	1972	Health Physics
Georgia Institute of Technology, Atlanta, GA	PhD	1976	Nuclear Engineering

A. Positions and Honors.

Professional Experience

1971-1972	Research Assistant, Colorado State University, Fort Collins, CO
1973-1974	Research Assistant, Georgia Institute of Technology, Atlanta, GA
1973-1974	Consultant, Allied-General Nuclear Services, Barnwell, SC
1974-1977	Research Associate, Oak Ridge National Laboratory, Oak Ridge, TN
1977-present	President/Owner, Embeford Farm, Neeses, SC
1977-present	President/Owner, Risk Assessment Corporation, Neeses, SC

Military

1967-1971	Officer, U.S. Navy, Nuclear Submarine Force (active duty)
1971-1999	Officer, U.S. Navy Reserve (reserve duty)
1999	Retired, Rear Admiral USNR

Military Awards: National Defense Service Medal, 1964; Navy Achievement Medal, 1971; Naval Reserve Service Medal, 1979; Navy Commendation Medal, 1984, 1987; Meritorious Service Medal, 1990; 1994; Legion of Merit, 1994; National Defense Medal, 1999

Honors and Awards

1983	Recipient, Elda E. Anderson Award, Health Physics Society
1984-2003	Elected Member, National Council on Radiation Protection and Measurements
1985-1995	Adjunct Professor of Physics, Emory University, Atlanta, GA
1986-1987	U.S. Environmental Protection Agency: Chairman, Radiation Advisory Committee, Science Advisory Board; Member, Executive Committee Science Advisory Board
1987-1989	Chairman, South Carolina Governor's Nuclear Advisory Council
1988-1989	Member, National Academy of Sciences Committee to Provide Interim Oversight of the Department of Energy Nuclear Weapons Complex
1988-1994	Chairman, Technical Steering Panel, Hanford Dose Reconstruction Project
1992-1993	Chairman, Advisory Panel "Managing Nuclear Materials from Warheads: Weapons Dismantlement and Its Aftermath," U.S. Congress Office of Technology Assessment
1994-2000	Member, National Academy of Sciences "Advisory Committee to Study the Mortality of Military Personnel Present at Atmospheric Tests of Nuclear Weapons"
1995	Recipient, E. O. Lawrence Award, U.S. Department of Energy
1997-2006	Elected Member, International Commission on Radiological Protection
2001-2003	Chairman, National Academy of Sciences Committee "A Review of the Dose Reconstruction Program of the Defense Threat Reduction Agency"
2003-present	Distinguished Emeritus Member, National Council on Radiation Protection and Measurements

Principal Investigator/Program Director (Last, First, Middle): Boice, John D., Jr.

Other Experience and Professional Memberships

1982-1994	Chairman, Task Group Six on Developing Screening Models for Evaluating Releases of Radionuclides to the Environment, National Council on Radiation Protection and Measurements
1985-2002	Member, National Council on Radiation Protection and Measurements Scientific Committee on Environmental Radioactivity
1989-1994	Board of Directors, National Council on Radiation Protection and Measurements
1993-1995	Member, "Mortality of Military Personnel Present at Atmospheric Tests of Nuclear Weapons," National Academy of Sciences
1993-1995	Chairman, Dosimetry Working Group "Mortality of Military Personnel Present at Atmospheric Tests of Nuclear Weapons," National Academy of Sciences
1994-2000	Chairman, Scientific Committee on Dose Reconstruction, National Council on Radiation Protection and Measurements
1995	Program Chairman, "Environmental Dose Reconstruction and Risk Implications," National Council on Radiation Protection and Measurements Annual Meeting
1995-1997	Scientific Review Group, U.S. Department of Energy, Joint Coordinating Committee for Radiation Effects Research
2001-2003	Chairman, National Academy of Sciences Committee to Review the Dose Reconstruction Program of the Defense Threat Reduction Agency
2003	Chairman, Program Committee for Annual Meeting of the National Council on Radiation Protection and Measurements, "Radiation Protection at the Beginning of the 21st Century - A Look Forward"

Professional Society Memberships

Health Physics Society
Society for Risk Analysis
Society of Exposure Science and Environmental Epidemiology
American Nuclear Society

B. Selected Peer-Reviewed Publications. (selected from over 180 articles)

1. **Till JE**. A comparison of environmentally released recycle ^{232}U fuel and LMFBR plutonium fuel. In: Radioecology and Energy Resources (Cushing CE Jr, ed). New York: Dowden, Hutchinson & Ross, Inc., 1976.
2. **Till JE**, Parzyck DC. An evaluation of operational exposures which could result from potential environmental releases of ^{232}U and daughters. Proceedings Ninth Midyear Topical Symposium on Operational Health Physics, Denver, CO, February, 1976.
3. Etnier EL, **Till JE**. Significance of incorporating age-dependent data into population dose estimates. Health Physics 37:774-7, 1979.
4. Kocher DC, **Till JE**. Iodine-129 dose to the world population from the nuclear power industry. Trans Am Nuc Soc, November 12-16, 1979.
5. Meyer HR, **Till JE**, Bomar ES, Bond WD, Morse LE, Tennery VJ, Yalcintas MG. Radiological impact of thorium mining and milling. Nuclear Safety 20(3), 1979.
6. Meyer HR, Little CA, Witherspoon JP, **Till JE**. A comparison of potential radiological impacts of ^{233}U and ^{239} Pu fuel cycles. Trans Am Nuc Soc, November 12-16, 1979.
7. **Till JE**, Meyer HR, Tennery VJ, Bomar ES, Yalcintas MG, Morse LE, Bond WD. Reprocessing nuclear fuels of the future: a radiological assessment of advanced (Th, U)C fuels. Nuclear Technology 48 (1), 1980.
8. **Till JE**, Etnier EL, Meyer HR. A review of methodologies for calculating dose from environmental releases of tritium. Nuclear Safety 22(2), 1981.

9. **Till JE**. Special case radionuclides. In: Radiological Assessment. U.S. Nuclear Regulatory Commission. NUREG/CR-3332, 1983.
10. Schiager KJ, Bair WJ, Carter MW, Hull AP, **Till JE**. De minimis environmental radiation levels: concepts and consequences. Health Physics 50:569-79, 1986.
11. Meinhold CB, Emma L, Jacobs DG, Templeton WL, **Till JE**. Guidelines for the release of waste water from nuclear facilities with special reference to the public health significance of the proposed release of treated waste waters at Three Mile Island. NCRP Commentary No. 4. Bethesda, MD: National Council on Radiation Protection, 1987.
12. **Till JE**, Moore RE. A pathway analysis approach for determining acceptable levels of contamination of radionuclides in soil. Health Physics 55:541-8, 1988.
13. Stevens W, **Till JE**, Thomas DC, Lyon JL, Kerber RA. A historical dose reconstruction and epidemiologic study of leukemia in Utah residents exposed to fallout. Proceedings Health Physics Society Topical Symposium on Environmental Radiation and Public Policy, Las Vegas, NV, October 23-25. McLean, VA: Health Physics Society, 1990.
14. **Till JE**. Reconstructing historical exposures to the public from environmental sources. Radiation Protection Today - The NCRP at 60 Years. Proceedings of the 25th Annual Meeting of the NCRP, April 1. Bethesda, MD: National Council on Radiation Protection and Measurements, 1990.
15. Lloyd RD, Simon SL, **Till JE**, Hawthorne HA, Gren DC, Rallison ML, Stevens W. Development of a method to estimate dose from fallout radioiodine in a thyroid cohort study. Health Physics 59:669-91, 1990.
16. Lloyd RD, Gren DC, Simon SL, Wrenn ME, Hawthorne HA, Stevens W, **Till JE**, Lotz TM. Individual external exposures from Nevada test site fallout for leukemia cases and controls. Health Physics 59:723-37, 1990.
17. Stevens W, Thomas DC, Lyon JL, **Till JE**, Kerber RA, Simon SL, Lloyd RD, Elghany NA, Preston-Martin S. Leukemia in Utah and radioactive fallout from the Nevada test site: a case-control study. JAMA 264:585-91, 1990.
18. **Till JE**. The Hanford Environmental Dose Reconstruction Project. Proceedings Health Physics Society Topical Symposium on Environmental Radiation and Public Policy, Las Vegas, NV, October 23-25. McLean, VA: Health Physics Society, 1990.
19. Kerber RA, **Till JE**, Simon SL, Lyon JL, Thomas DC, Preston-Martin S, Rallison, ML, Lloyd RD, Stevens W. A cohort study of thyroid disease in relation to fallout from nuclear weapons testing. JAMA 270:2076-82, 1993.
20. Simon SL, **Till JE**, Lloyd RD, Kerber R, Thomas DC, Preston-Martin S, Stevens W. The Utah Leukemia Case-Control Study: dosimetry, methodology and results. Health Physics 68:460-71, 1995.
21. **Till JE**, Simon SL, Kerber R, Lloyd RD, Stevens W, Thomas DC, Lyon JL, Preston-Martin S. The Utah Thyroid Cohort Study: analysis of the dosimetry results. Health Physics 68:472-83, 1995.
22. **Till JE**, Hoffman FO, Schiager KJ, Taschner J. Letter report of the dose assessment working group, committee to study the mortality of military personnel present at atmospheric tests of nuclear weapons. Washington, DC: National Academy of Sciences, 1995.
23. Meyer KP, Voillequé PG, Schmidt DW, Rope SK, Killough GG, Shleien B, Moore RE, Case MJ, **Till JE**. Overview of the Fernald dosimetry reconstruction project and source term estimates for 1951-1988. Health Physics 71:425-37, 1996.
24. **Till JE** (ed). Proceedings Thirty First Annual Meeting of the National Council on Radiation Protection and Measurements (NCRP), Washington DC, April 12-13, 1995. Bethesda, MD: National Council on Radiation Protection, 1997.
25. **Till JE**. A 1993 report on reconstruction of environmental exposures and uncertainties in support of epidemiological studies related to low-dose radiation. Stem Cells 15:(Suppl 2):87-94, 1997.
26. **Till JE**. Environmental dose reconstruction. Proceedings Thirty First Annual Meeting of the National Council on Radiation Protection and Measurements (NCRP), Washington, DC, April 12-13, 1995. Bethesda, MD: National Council on Radiation Protection, 1997.
27. **Till JE**. Keynote address. Proceedings of the First Annual University of Washington Conference on the Ecological, Community and Occupational Health Issues at Hanford, December 3, 1997. Seattle, WA: University of Washington Press, 1998.

28. McGavran PD, Rood AS, **Till JE**. Chronic beryllium disease and cancer risk estimates with uncertainty for beryllium released to the air from the Rocky Flats Plant. Environ Health Perspect 107:731-44, 1999.
29. Rood AS, Killough GG, **Till JE**. Evaluation of atmospheric transport models for use in phase II of the historical public exposures studies at the Rocky Flats Plant. Risk Analysis 19:559-576, 1999.
30. **Till JE**, Killough GG, Meyer KR, Sinclair WS, Voillequé PG, Rope SK, Case MJ. The Fernald Dosimetry Reconstruction Project. Technology 7:270-95, 2000.
31. **Till JE**, Meyer KR. Public involvement in science and decision-making. Health Physics 80:370-9, 2001.
32. Rood AS, McGavran PD, Aanenson JW, **Till JE**. Stochastic estimates of exposure and cancer risk from carbon tetrachloride released to the air from the Rocky Flats Plant. Risk Analysis 21:675-95, 2001.
33. Rood AS, Grogan HA, **Till JE**. A model for a comprehensive assessment of exposure and lifetime cancer incidence risk from plutonium released from the Rocky Flats Plant, 1953-1989. Health Physics 82:182-212, 2002.
34. **Till JE**, Rood AS, Voillequé PG, McGavran PD, Meyer KR, Grogan HG, Sinclair WK, Aanenson JW, Meyer HR, Rope SK, Case MJ. Risk to the public from historical releases of radionuclides and chemicals at the Rocky Flats Nuclear Weapons Plant. J Expo Anal Environ Epidemiol 12:355-72, 2002.
35. **Till JE**, Beck, HL, Brad WJ, Gesell TF, Hoel DG, Kearsley EE, Kocher DC, Moreno JK, Weinberg CR, Douple EB, Al-Nabulsi I. A Review of the Dose Reconstruction Program of the Defense Threat Reduction Agency. Washington, DC: National Academy Press, 2003.
36. Mohler HJ, Meyer KR, Grogan HA, Aanenson JW, **Till JE**. Application of NCRP air screening factors for evaluating both routine and episodic radionuclide releases to the atmosphere. Health Physics 86:135-44, 2004.
37. **Till JE**, Killough GG, Meyer KR, Aanenson JW, Rood AS. Technical basis and public process for deriving cleanup levels at Rocky Flats. Proceedings Workshop on Solutions to Security Concerns about Radioactive Legacy of the Cold War that Remain in Urban Environments, International Institute for Applied System Analysis at Vanderbilt University, Nashville, TN, November 14-16, 2004.
38. **Till JE**. ICRP's new report on the individual: assessing dose of the representative individual for the purpose of radiation protection of the public. Proceedings of the 37th Annual National Conference on Radiation Control Program Directors, Inc., Kansas City, MO, April 25-28, 2005.
39. **Till JE**, McBaugh D. Practical and scientifically based approaches for cleanup and site restoration. Health Physics 89:583-8, 2005.
40. **Till JE**, Grogan HA. Applied modeling and computation in nuclear science; the foundation for risk assessment and decision making. In: Applied Modeling and Computations in Nuclear Science. Oxford University Press, 2006.
41. Grogan HA, Aanenson JW, McGavran PD, Meyer KR, Mohler SS, Mohler HJ, Rocco JR, Wilson, LH, **Till JE**. Applied modeling of the Cerro Grande Fire at Los Alamos: an independent analysis of exposure, health risk, and communication with the public. In: Applied Modeling and Computations in Nuclear Science. Oxford University Press, 2006.
42. **Till JE**, Grogan, HA., eds. Radiological Risk Assessment and Environmental Analysis. Oxford University Press, New York. 2008.
43. **Till JE**. The Radiological Assessment Process. Chapter 1 in Radiological Risk Assessment and Environmental Analysis. Oxford University Press, New York. 2008.
44. Rood AS, Voillequé PG, Rope SK, Grogan HG, **Till JE**. Reconstruction of atmospheric concentrations and deposition of uranium and decay products released from the former uranium mill at Uravan, Colorado. J Environ Radioact 99:1258-78, 2008.
45. **Till JE**, HA Grogan, HJ Mohler, JR Rocco, SS Mohler. RACER: An Integrated Approach to Data Management, Risk Assessment, and Decision Making. Health Physics (in press).
46. Mohler HJ. HA Grogan, JR Rocco, RF Keifer, and JE Till. RACER: Dynamic Use of Environmental Measurement Data for Decision Making and Communication. Operational Radiation Safety (in press).

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Harold L. Beck	Consultant Radiation Dosimetry and Dose Reconstruction
eRA COMMONS USER NAME	

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of Miami, Miami, FL	BS	1960	Physics/Mathematics
Cornell University, Ithaca, NY		1960-62	Physics

A. Positions and Honors.

Professional Experience

1962-62 Technical Intern, U.S. Atomic Energy Commission, Washington, D.C.
1963-88 Physicist, U.S. Atomic Energy Commission/Energy Research and Development Administration/U.S. Department of Energy, Environmental Measurements Laboratory, New York, NY
1988-96 Director, Instrumentation Division, Environmental Measurements Laboratory, New York, NY
1991-96 Acting Deputy Director, U.S. Department of Energy, Environmental Measurements Laboratory, New York, NY
1996-99 Director, Environmental Sciences Division, Environmental Measurements Laboratory, New York, NY
1999- Private consultant

Honors and Awards

1988 U.S. Department of Energy Meritorious Service Award
1992 Elected Fellow of Health Physics Society
2004 Elected Distinguished Emeritus Member, National Council on Radiation Protection and Measurements

Other Experience (Selected) and Professional Membership

1979-1984 Scientific Advisor to the DOE Offsite Radiation Exposure Review Project (ORERP)(Reconstruction of Doses to Downwinders)
1990-1998 U.S. Delegate to the International Electrotechnical Commission's (IEC) Scientific Committee 45B on Radiation Protection Instrumentation
1992-2004 Council Member, National Council on Radiation Protection and Measurements
1996-2003 Scientific Vice president of the National Council on Radiation Protection and Measurements (NCRP) for Radiation Measurement and Chair of NCRP Scientific Committee 93 on Radiation Measurement
1999 Consultant to UNSCEAR for 2000 report
1999-2002 Member of the NAS/NRC Committee to Review the Dosimetry for the Radiation Effects Research Foundation Study of the Effects of the Hiroshima/Nagasaki Explosions
2000 Consultant to NAS/NRC Review Committee of "Hanford Thyroid Disease Study Draft Final Report"
2000-2002 Consultant to NCI for DHHS feasibility study of the health consequences to the American population from nuclear weapons tests conducted by the United States and other nations
2000-2003 Member of the NAS/NRC Committee to Review the Dose Reconstruction Program of the Defense Threat Reduction Agency (DTRA)
2001 Chair of NCRP 2001 Annual Meeting Program Committee on "Fallout from Atmospheric Nuclear Tests-Impact on Science and Society"

2002-2003	Member of Joint USA-Japan Senior Advisory Committee to review the new 2002 Dose System for evaluating doses to survivors of the Hiroshima-Nagasaki nuclear blasts
2002-present	Consultant to National Cancer Institute for development of Joint US-FSU methodology for reconstruction of doses from fallout from weapons testing, other fallout-related studies
2004-2005	Member, Board on Radiation Effects Research (BRER), National Academy of Sciences/National Research Council (NAS/NRC)
2004-2007	Chair, National Council on Radiation Protection and Measurements SC-6-1 on Uncertainty in External Radiation Measurements and Dosimetry
2005-2006	Member, Nuclear and Radiation Studies Board, National Academy of Sciences/National Research Council (NAS/NRC)
2005-present	Member, U.S. Scientific Review Group, Department of Energy Russian Health Studies Program
2005-present	Veteran's Advisory Board on Dose Reconstruction, Defense Threat Reduction Agency, Department of Defense, Board Member (reappointed yearly)
2006-present	Member, NCRP Professional Area Committee-6- Radiation Measurements and Dosimetry
2011-present	Member, National Academy of Sciences/National Research Council (NAS/NRC) Committee on Analysis of Cancer Risks in Populations near Nuclear Facilities-Phase 1

Member of the American Association for the Advancement of Science and the American Nuclear Society
Fellow of the Health Physics Society

B. Selected Peer-Reviewed Publications.

1. Lowder WM, **Beck HL**, Condon WJ. Field spectrometry of environmental gamma radiation. TID-7696. ORO Rep 147:101-10, 1963.
2. **Beck HL**, Condon WJ, Lowder WM. Environmental radiation measurements in the southeastern central and western United States, 1962-1963. HASL-145. HASL Rep 31:1-32, 1964.
3. Lowder WM, **Beck HL**, Condon WJ. Spectrometric determination of dose rates from natural and fall-out gamma-radiation in the United States, 1962-1963. Nature 202:745-9, 1964.
4. **Beck HL**, Condon WJ, Lowder WM. Spectrometric techniques for measuring environmental gamma radiation. HASL-150. HASL Rep 58:1-71, 1964.
5. **Beck HL**, Lowder WM, Bennett BG, Condon WJ. Further studies of external environmental radiation. HASL-170. HASL Rep Feb:1-49, 1966.
6. **Beck HL**. Environmental gamma radiation from deposited fission products 1960-1964. Health Phys 12:313-22, 1966.
7. **Beck HL**, Bennett BG, McCraw TF. External radiation levels on Bikini Atoll - May, 1967. HASL-190. HASL Rep Dec:1-79, 1967.
8. Bennett B, **Beck HL**. External radiation on Bikini Atoll. Nature 223:925-8, 1969.
9. Gudiksen P, Jones DE, **Beck HL**, Mclaughlin JE; Stuart TP; Lynch OD. External dose estimates for future inhabitants of Enewetok Atoll. Nature 257:284-7, 1975.
10. **Beck HL**. Spectral composition of the gamma-ray exposure rate due to noble gases released during a reactor accident. Health Phys 43:335-43, 1982.
11. **Beck HL**, Krey PW. Radiation exposure in Utah from Nevada nuclear tests. Science 220:18-24, 1983.
12. **Beck HL**, de Planque G. Dose rate conversion factors. Health Phys 49:1015-6, 1985.
13. **Beck HL**, Helfer IK, Bouville A, Dreicer M. Estimates of fallout in the Continental U.S. from Nevada weapons testing based on gummed-film monitoring data. Health Phys 59:565-76, 1990.
14. Bouville A, Dreicer M, **Beck HL**, Hoecker WH, Wachholz BW. Models of radioiodine transport to populations within the continental U.S. Health Phys 59:659-68, 1990.
15. Bouville A, **Beck HL**. The HASL gummed-film network and its use in the reconstruction of doses resulting from nuclear weapons tests. Technology 7:355-79, 2000.
16. **Beck HL**, Bennett BG. Historical overview of atmospheric nuclear weapons testing and estimates of fallout In the Continental U.S. Health Phys 82:591-608, 2002.
17. **Beck HL**. Preface to special issue of Health Physics, Proceedings of 37th Annual Meeting of the NCRP: "Fallout from Atmospheric Nuclear Tests-Impact on Science and Society." Health Phys 82, 2002.

18. Bouville A, Miller C, **Beck HL**, Anspaugh L, Simon S. Estimates of doses from global fallout. Health Phys 82:690-705, 2002.
19. Simon SL, Bouville A, **Beck HL**. The geographic distribution of radionuclide deposition across the continental US from atmospheric nuclear testing, J Environ Radioactivity 74:91-105, 2004.
20. Hoffman FO, Anspaugh LR, Apostoaei AI, **Beck HL**, Bouville A, Napier B, Simon SL. Credibility of uncertainty analyses for 131I pathway assessments. Health Phys 86:536-9, 2004.
21. **Beck HL**, Anspaugh LR, Bouville A, Simon SL. Review of methods of dose estimation for epidemiological studies of the radiological Impact of Nevada test site and global fallout. Radiat Res 166:209-18, 2006.
22. Simon SL, **Beck HL**, Gordeev K, Bouville A, Anspaugh LR, Land CE, Luckyanov N, Shinkarev S. External Dose estimates for Dolon Village: Application of the U.S./Russian Joint Methodology. J Radiat Res:47, Suppl., A143-7, 2006.
23. Land CE, Zhumadilov Z, Gusev BI, Hartshome MH, Wiest PW, Woodward PW, Cooks IA, Luckyanov NK, Fillmore CM, Carr Z, Abisheva G, **Beck HL**, Bouville A, Langer J, Weinstock R, Gordeev KI, Shinkarev S, Simon SL. Ultrasound-detected thyroid nodule prevalence and radiation dose from fallout. Radiat Res 169:373-83, 2008.
24. **Beck HL** (Chairman), Brady LA, Cummings FM, Kase KR, Seltzer SM, Simon SL, Soares CG, Yoder RG. Uncertainties in the Measurement and Dosimetry of External Radiation. NCRP Report No. 158. Bethesda, MD: NCRP, 546 pp, 2008.
25. **Beck, Harold L.**,Bouville A., Simon SL Fallout deposition in the Marshall Islands from Bikini and Enewetak Nuclear Weapons Tests. Health Phys 99:124-142, 2010.
26. Simon SL, Bouville A, Land C and **Beck HL**, Radiation doses and cancer risks in the Marshall Islands associated with exposure to radioactive fallout from Bikini and Enewetak nuclear weapons tests:Summary. Health Phys 99:105-123, 2010.

C. Research Support.

None

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Paul G. Voillequé	President MJP Risk Assessment, Inc.
eRA COMMONS USER NAME	

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of Colorado, Boulder, CO	BA	1961	Physics
University of Colorado, Boulder, CO	Mas. Basic Science	1965	Phys., Chem.,Biol.
University of Michigan, Ann Arbor, MI	MS	1966	Envir. Hlth (Radiol.)

A. Positions and Honors.

Professional Experience

1967-75	Health Physicist and Chief of Environmental Studies Section, Atomic Energy Commission (later, Energy Research and Development Administration)
1975-90	Principal Investigator, Science Applications International Corporation (and Science Applications, Inc.), Nuclear Environmental Services Division
1990-	President and Founder, MJP Risk Assessment, Inc., Denver, CO
2005-present	Member, Veteran's Advisory Board on Dose Reconstruction, Defense Threat Reduction Agency, Department of Defense, Board Member (reappointed yearly)

Honors and Awards

1957-61	Boettcher Foundation Scholarship
1965-67	AEC Health Physics Fellowship
1994	Fellow, Health Physics Society

B. Selected Peer-Reviewed Publications. (selected from over 70 articles)

1. **Voillequé PG**. Calculation of organ and tissue burdens and doses resulting from an acute exposure to a radioactive aerosol using the ICRP Task Group report on the human respiratory tract. IDO-12067. IDO Rep June:1-44, 1968.
2. **Voillequé PG**. AERIN, a code for acute aerosol inhalation exposure calculations. Health Phys 19:427-32, 1970.
3. **Voillequé PG**, Adams DR, Echo JB. Transfer of krypton-85 from air to grass. Health Phys 19:835, 1970.
4. Adams DR, **Voillequé PG**. Effects of stomatal opening on the transfer of $^{131}I_2$ from air to grass. Health Phys 21:771-5, 1971.
5. Pelletier CA, **Voillequé PG**. The behavior of cesium-137 and other fallout radionuclides on a Michigan dairy farm. Health Phys 21:777-92, 1971.
6. **Voillequé PG**. Calculatio nof expected urinary and fecal excretion patterns using the ICRP Task Group report on the human respiratory tract. In: Willis CA, Handloser JS (eds). Health Physics Operational Monitoring. New York: Gordon and Breach Science Publishers, pp 773-808, 1972.
7. Moss BR, **Voillequé PG**, Moody EL, Adams DR, Pelletier CA, Hoss D. Effects of feeding sudangrass on iodine metabolism of lactating dairy cows. J Dairy Sci 55:1487-91, 1972.
8. **Voillequé PG**, Pelletier CA. Comparison of external irradiation and consumption of cows' milk as critical pathways for ^{137}Cs, ^{54}Mn, and ^{144}Ce-Pr released to the atmosphere. Health Phys 27:189-99, 1974.
9. **Voillequé PG**, Fix JJ. Transfer of airborne krypton-85 to vegetation. In: Stanley RE, Moghissi AA (eds). Noble gases. Las Vegas, NV: U.S. Environmental Protection Agency, 1984.
10. **Voillequé PG**, Keller JH. Air-to-vegetation transport of ^{131}I as hypoiodous acid (HOI). Health Phys 40:91-4, 1981.
11. **Voillequé PG**, Pavlick RA. Societal cost of radiation exposure. Health Phys 43:405-9, 1982.

12. **Voillequé PG**. Computer code for quantitative ALARA evaluations. In: Kathren RL, Hibgy DP, McKinney MA (Eds). Computer Applications in Health Physics. Richland, WA: Columbia Chapter, Health Physics Society, 1984.
13. **Voillequé PG**. Fission product behavior. In: Toth LM, Malinauskas AP, Eidam GR, Burton HM (eds). The Three Mile Island Accident, Diagnosis and Prognosis. Washington, DC: American Chemical Society, 1986.
14. Mis FJ, Warren SB, Harrison MC, **Voillequé PG**. Particle size distributions for airborne radionuclides in Ginna steam generator work environments. Health Phys 56:233-8, 1989.
15. **Voillequé PG**. Measurements of radioiodine species in samples of pressurized water reactor coolant. Nucl Tech 90:23-33, 1990.
16. Meyer KR, **Voillequé PG**, Schmidt DW, Rope SK, Killough GG, Shleien B, Moore RE, Case MJ, Till JE. Overview of the Fernald disometry reconstruction project and source term estimates for 1951-1988. Health Phys 71:425-37, 1996.
17. Killough GG, Rope SK, Shleien B, **Voillequé PG**. Nonlinear estimation of weathering rate parameters for uranium in surface soil near a nuclear facility. J Environ Radioactivity 45:95-118, 1999.
18. Grogan HA, Sinclair WK, **Voillequé PG**. Risks of fatal cancer from inhalation of plutonium-239,240 by humans: a combined four-method approach with uncertainty evaluation. Health Phys 80:447-471, 2001.
19. Till JE, Rood AS, **Voillequé PG**, McGavran PD, Meyer KR, Grogan HA, Sinclair WK, Aanenson JW, Meyer HR, Mohler HJ, Rope SK, Case MJ. Risks to the public from historical releases of radionuclides and chemicals at the Rocky Flats Environmental Technology Site. J Exposure Analysis and Environmental Epidemiology 12:355-72, 2002.
20. Stepanenko VF, Gavrilin YI, Snykov BP, Shevchuk VE, Göksu HY, **Voillequé PG**, Orlov MY. Elevated exposure rates under inclined birch trees indicate the occurrence of rainfall during radioactive fallout from Chernobyl. Health Phys 82:240-3, 2002.
21. Balonov M, Kaidanovsky G, Zvonova I, Kovtun A, Bouville A, Luchyanov N, **Voillequé PG**. Contributions of short-lived radioiodines to thyroid doses received by evacuees from the Chernobyl area estimated using early in vivo activity measurements. Radiat Prot Dos 105:593-9, 2003.
22. Stepanenko VF, **Voillequé PG**, Gavrilin YI, Khrouch VT, Shinkarev SM, Orlov MY, Kondrashov AE, Petin DV, Iaskova EK, Tsyb AF. Estimating individual thyroid doses for a case-control study of childhood thyroid cancer in Bryansk Oblasst, Russia. Radiat Prot Dos 108:143-160, 2004.
23. Gavrilin Y, Khrouch V, Shinkarev S, Drozdovitch V, Minenko V, Shemiakina E, Ulanovsky A, Bouville A, Anspaugh L, **Voillequé PG**, Luckyanov N. Individual thyroid dose estimation for a case-control study of Chernobyl-related thyroid cancer among children of Belarus - part 1: ^{131}I, short-lived radioiodines (^{132}I, ^{133}I, ^{135}I), and radiotelluriums (^{131m}Te and ^{132}Te). Health Phys 86:565-85, 2004.
24. Stezhko VA, Buglova EE, Danilova LI, Drozd VM, Krysenko NA, Lesnikova NR, Minenko VF, Ostapenko VA, Petrenko SV, Polyanskaya ON, Rzheutski VA, Tronko MD, Bobylyova OO, Bogdanova TI, Ephstein OV, Kairo IA, Kostin OV, Likhtarev IA, Markov VV, Oliynik VA, Shpak VM, Tereshchenko VP, Zamotayeva GA, Beebe GW, Bouville AC, Brill AB, Burch JD, Fink DJ, Greenebaum E, Howe GR, Luckyanov NK, Masnyk IJ, McConnell RJ, Robbins J, Thomas TL, **Voillequé PG**, Zablotska LB, Chornobyl Thyroid Diseases Study Group of Belarus; Chornobyl Thyroid Diseases Study Group of Ukraine, Chornobyl Thyroid Diseases Study Group of the USA. A cohort study of thyroid cancer and other thyroid diseases after the Chernobyl accident: objectives, design, and methods. Rad Res 161:481-92, 2004.
25. Davis S, Stepanenko V, Rivkind N, Kopecky K, **Voillequé PG**, Shakhtarin V, Parshkov E, Kulikov S, Lushnikov E, Abrosimov A, Troshin V, Romanova G, Doroschenko V, Proshin A, Tsyb A. Risk of thyroid cancer in the Bryansk Oblast of the Russian Federation after the Chernobyl power station accident. Radiat Res 162:241-8, 2004.
26. Likhtarov I, Kovgan L, Vavilov S, Chepurny M, Bouville A, Luckyanov N, Jacob P, **Voillequé PG**, Voigt G. Post-Chernobyl thyroid cancers in Ukraine. Report 1: estimation of thyroid doses. Radiat Res 163:125-36, 2005.
27. International Consortium for Research on the Health Effects of Radiation Writing Committee and Study Team, Davis S, Day RW, Kopecky KJ, Mahoney MC, McCarthy PL, Michalek AM, Moysich KB, Onstad LE, Stepanenko VF, **Voillequé PG**, Chegerova T, Falkner K, Kulikov S, Maslova E, Ostapenko V, Rivkind N, Shevchuk V, Tsyb AF. Childhood leukaemia in Belarus, Russia, and Ukraine following the Chernobyl

power station accident: results from an international collaborative population-based case-control study. Int J Epidemiol 35:386-96, 2006.
28. Tronko MD, Howe GR, Bogdanova TI, Bouville AC, Epstein OV, Brill AB, Likhtarev IA, Fink DJ, Markov VV, Greenebaum E, Olijynk VA, Masnyk IJ, Shpak VM, McConnell RJ, Tereshchenko VP, Robbins J, Zvinchuk OV, Zablotska LB, Hatch M, Luckyanov NM, Ron E, Thomas TL, **Voillequé PG**, Beebe GW. A cohort study of thyroid cancer and other thyroid diseases after the Chernobyl accident: thyroid cancer in Ukraine detected during first screening. JNCI 98:987-903, 2006.
26. Minenko VF, Ulanovsky AV, Drozdovitch VV, Shemiankina EV, Gavrilin YI, Khrouch VT, Shinkarev SM, **Voillequé PG**, Bouville A, Anspaugh LR, Luckyanov N. Individual thyroid dose estimation for a case-control study of Chernobyl-related thyroid cancer among children of Belarus - part II. Contributions from long-lived radionuclides and external radiation. Health Phys 90:312-27, 2006.
27. Likhtarev I, Bouville A, Kovgan L, Luckyanov N, **Voillequé PG**, Chepurny M. Questionnaire- and measurement-based individual thyroid doses in Ukraine resulting from the Chernobyl nuclear reactor accident. Radiat Res 166:271-86, 2006.
28. Kopecky KJ, Stepnenko V, Rivkind N, **Voillequé PG**, Onstad L, Shakhtarin V, Parshkov E, Kulikov S, Lushnikov E, Abrosimov A, Troshin V, Romanova G, Doroschenko V, Proshin A, Tsyb A, Davis S. Childhood thyroid cancer, radiation dose from Chernobyl, and dose uncertainties in Bryansk Oblast, Russia: a population-based case-control study. Radiat Res 166:367-74, 2006.
29. Shinkarev SM, **Voillequé PG**, Gavrilin YI, Khrouch VT, Bouville A, Hoshi M, Meckbach R, Minenko VJ, Ulanovsky AV, Luckyanov N. Credibility of Chernobyl thyroid doses exceeding 10 Gy based on in-vivo measurements on 131I in Belarus. Health Phys 94:180-7, 2008.
30. Rood AS, **Voillequé PG**, Rope SK, Grogan HA, Till JE. Reconstruction of atmospheric concentrations and deposition of uranium and decay products released from the former uranium mill at Uravan, Colorado. J Environ Radioact 99:1258-78, 2008.
31. Chumak VV, Romanenko AY, **Voillequé PG**, Bakhanova EV, Gudzenko N, Hatch M, Zablotska LB, Golovanov IA, Luckyanov NK, Sholom SV, Kryuchkov VP, Bouville A. The Ukrainian-American study of leukemia and related disorders among Chernobyl cleanup workers from Ukraine: II. Estimation of bone marrow doses. Radiat Res 170:698-710, 2008.
32. Kryuchkov V, Chumak V, Maceika E, Anspaugh LR, Cardis E, Bakhanova E, Golovanov I, Drozdovitch V, Luckyanov N, Kesminiene A, **Voillequé P**, Bouville A. RADRUE method for reconstruction of external photon doses to Chernobyl liquidators in epidemiological studies. Health Phys 97: 275–298; 2009.
33. Skryabin, A, Drozdovitch V, Belsky Yu, Leshcheva S, Mirkhaidarov A, **Voillequé P**, Luckyanov N, Bouville A. Throid mass in children and adolescents living in the most exposed areas to Chernobyl fallout in Belarus. Radiat Protect Dosimetry 142: 292–299; 2010.
34. Likhtarov I, Chepurny M, Ivanova O, Boyko Z, Ratia G, Masiuk S, Gerasymenko V, Drozdovitch V, Berkovsky V, Hatch M, Brenner A, Luckyanov N, **Voillequé P**, Bouville A. Estimation of the thyroid doses for Ukrainian children exposed in utero after the Chornobyl accident. Health Phys100: 583–593; 2011.

C. Research Support.

None

BIOGRAPHICAL SKETCH

NAME Helen A. Grogan	POSITION TITLE President Cascade Scientific Inc.
eRA COMMONS USER NAME	

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY
Imperial College of Science and Technology, University of London, United Kingdom	BSc	1980	Botany, Life Sciences
Imperial College of Science and Technology, University of London, United Kingdom	PhD	1984	Radioecology

A. Positions and Honors.

Professional Experience

1984-1989 Guest Scientist, Paul Scherrer Institute, Würenlingen, Switzerland
1989-1992 Scientific Consultant, Intera Information Technologies, Henley-on-Thames, United Kingdom
1992-1995 Independent Consultant, Vero Beach, FL
1995-present President, Cascade Scientific Inc., Bend, OR
2002-present Technical Coordinator, Risk Assessment Corporation, Neeses, SC

Honors and Awards

1994-2000 Member, Scientific Committee on Dose Reconstruction, National Council on Radiation Protection and Measurements
1999-2000 Consultant, Environmental Models Subcommittee, Executive Committee, U.S. Environmental Protection Agency
2001-2007 Member, Radiation Advisory Committee, Science Advisory Board, U.S. Environmental Protection Agency
2004 Member, Merit Panel, "Review of the Preliminary Performance Assessment for Waste Management Area C at the Hanford Site, Washington." Convened by CH2M-Hill Hanford Group Inc. with concurrence of the Department of Energy and the State of Washington Department of Ecology
2005-2006 Member, National Academy of Sciences Committee to Review the "Worker and Public Health Activities Program Administered by the Department of Energy and the Department of Health and Human Services"
2011-present Advisor, Scientific Committee on Approach to Optimizing Decision Making for Late-Phase Recovery from Nuclear or Radiological Terrorism Incidents, National Council on Radiation Protection and Measurements

Professional Society Memberships

2004-present American Association for the Advancement of Science (AAAS)

B. Selected Peer-Reviewed Publications.

1. Nair S, **Grogan HA**, Minski MJ, Bell JNB. Models for the prediction of doses from the ingestion of terrestrial floods. In: Ecological Aspects of Radionuclide Releases. Eds. Coughtrey PJ, Bell JNB, Roberts TM. Oxford: Blackwell Scientific, pp. 141-59, 1983.
2. **Grogan HA**, van Dorp F. The reliability of environmental transfer models applied to waste disposal. In: Realiability of Radioactive Transfer Models. Ed. Deems G. Elsevier Applied Science EUR 11367, pp 276-84, 1988.

3. **Grogan HA**, Mitchell NG, Minski MJ, Bell JNB. Pathways of radionuclides from soils to wheat. In: Pollutant Transport and Fate in Ecosystems. Eds. Coughtrey PJ, Martin MH, Unsworth MH. Oxford: Blackwell Scientific, pp. 353-70, 1988.
4. Bell JNB, Minski MJ, **Grogan HA**. Plant uptake of radionuclides. Soil Use and Management 4:76-84, 1988.
5. van Dorp F, **Grogan HA**, McCombie C. Disposal of radioactive waste. International Journal of Radiation Applications and Instrumentation Part C. Radiat Phys Chem 34:337-47, 1989.
6. McKinley IG, **Grogan HA**. Radionuclide sorption databases for Swiss repository safety assessments. Radiochimica Acta 52/53:415-20, 1991.
7. McKinley IG, **Grogan HA**. Consideration of microbiology in modeling the near-field of a L/ILW repository. Experientia 47:573-7, 1991.
8. West JM, **Grogan HA**, McKinley IG. The role of microbiology in the geological containment of radioactive wastes. In: Diversity of Environmental Biogeochemistry, Developments in Geochemistry 6. Ed. Berthelin J. Elsevier Science Publishers BV, pp. 205-15, 1991.
9. Little RH, **Grogan HA**, Smith GM, Torres C. Land disposal practices in Europe and North America. J Inst Water and Environmental Management 7:354-63, 1993.
10. **Grogan HA**, Sinclair WK, Voillequé PG. Risks of fatal cancer from inhalation of plutonium-239,240 by humans: a combined four method approach with uncertainty evaluation. Health Phys 80:447-61, 2001.
11. Rood AS, **Grogan HA**, Till JE. A model for a comprehensive assessment of exposure and lifetime cancer incidence risk from plutonium released from the Rocky Flats Plant, 1953-1989. Health Phys 82:182-212, 2002.
12. Till JE, Rood AS, Voillequé PG, McGavran PD, Meyer KR, **Grogan HG**, Sinclair WK, Aanenson JW, Meyer HR, Rope SK, Case MJ. Risk to the public from historical releases of radionuclides and chemicals at the Rocky Flats Nuclear Weapons Plant. J Expo Anal Environ Epidemiol 12:355-72, 2002.
13. Mohler HJ, Meyer KR, **Grogan HG**, Aanenson JW, Till JE. Application of NCRP air screening factors for evaluating both routine and episodic radionuclide releases to the atmosphere. Health Phys 86:135-44, 2004.
14. Till JE, **Grogan HG**. Applied modelling and computation in nuclear science; the foundation for risk assessment and decision making. In: Applied Modelling and Computations in Nuclear Science. Oxford University Press, 2006.
15. **Grogan HG**, Aanenson JW, McGavran PD, Meyer KR, Holher SS, Mohler HJ, Rocco JR, Wilson LH, Till JE. Applied modeling of the Cerro Grande Fire at Los Alamos: an independent analysis of exposure, health risk, and communication with the public. In: Applied Modelling and Computations in Nuclear Science. New York: Oxford University Press, 2006.
16. Till JE, **Grogan HG** (Eds). Radiological Risk Assessment and Environmental Analysis. New York: Oxford University Press, 2008.
17. Rood AS, Voillequé PG, Rope SK, **Grogan HG**, Till JE. Reconstruction of atmospheric concentrations and deposition of uranium and decay products released from the former uranium mill at Uravan, Colorado. J Environ Radioact 99:1258-78, 2008.
18. Till JE, **HA Grogan**, HJ Mohler, JR Rocco, SS Mohler. RACER: An Integrated Approach to Data Management, Risk Assessment, and Decision Making. Health Physics (in press).
19. Mohler HJ. **HA Grogan**, JR Rocco, RF Keifer, and JE Till. RACER: Dynamic Use of Environmental Measurement Data for Decision Making and Communication. Operational Radiation Safety (in press).

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Stram, Daniel O.	POSITION TITLE Professor
eRA COMMONS USER NAME (credential, e.g., agency login) dstram52	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Tufts University, Medford, MA	B.A.	05/75	Mathematics
Temple University, Philadelphia, PA	Ph.D.	05/83	Statistics
Harvard School of Public Health, Boston, MA	Post Doc	07/86	Biostatistics

B. Positions and Honors

1982-1984	Statistician, Center for Energy and Environmental Studies, Princeton University, Princeton, NJ.
1986-1989	Research Associate, Radiation Effects Research Foundation, Hiroshima, Japan
1989-1996	Assistant Professor, Department of Preventive Medicine, University of Southern California Keck School of Medicine, Los Angeles, CA
1996-2004	Associate Professor, Department of Preventive Medicine, University of Southern California Keck School of Medicine, Los Angeles, CA
2002	Visiting Scientist, Center for Genome Research, Whitehead Institute, Massachusetts Institute of Technology, Cambridge, MA
2004-current	Professor, Department of Preventive Medicine, University of Southern California Keck School of Medicine, Los Angeles, CA
2006- current	Member, U.S. Environmental Protection Agency, Radiation Advisory Committee
2009- current	Member, International Commission on Radiological Protection
2009	Elected Fellow of the American Statistical Association

C. Selected Peer-reviewed Publications (from over 200 total)

1. Stram, D. O., and Mizuno, S. (1989) Analysis of the DS86 atomic bomb radiation dosimetry methods using data on severe epilation, Radiat Res 117, 93-113.
2. Pierce, D. A., Stram, D. O., and Vaeth, M. (1990) Allowing for random errors in radiation dose estimates for the atomic bomb survivor data, Radiat Res 123, 275-284.
3. Sposto, R., Stram, D. O., and Awa, A. A. (1991) An estimate of the magnitude of random errors in the DS86 dosimetry from data on chromosome aberrations and severe epilation, Radiat Res 128, 157-169.
4. Stram, D. O., Sposto, R., Preston, D., Abrahamson, S., Honda, T., and Awa, A. A. (1993) Stable chromosome aberrations among A-bomb survivors: an update, Radiat Res 136, 29-36.
5. Thomas DC, Stram DO, Dweyer J. Exposure Measurement Error: Influence on exposure-disease relationships and methods of correction. Annals of Public Health, 14:69-93, 1993.
6. Stram DO, Lee JW. Variance components testing in the longitudinal mixed-effects model. Biometrics, 50:1171-1177, 1994.
7. Stram DO, Longnecker MP, Shames L, Kolonel LN, Wilkens LR, Pike MC, Henderson BE. Cost efficient design of a diet validation study. American Journal of Epidemiology, 142:353-362, 1995.
8. Stram DO. Meta-analysis of published data using a linear mixed-effects model. Biometrics 52:108-115, 1996.
9. Stram DO, Langholz B, Huberman M, Thomas DC. Correcting for exposure measurement error in a reanalysis of lung cancer mortality for the Colorado Plateau uranium miners cohort. Health Physics 77:265-275, 1999.

10. Stram, D., and Kopecky, K. (2003) Power and uncertainty analysis of epidemiological studies of radiation-related disease risk where dose estimates are based upon a complex dosimetry system; Some observations, Radiation Research 160, 408-417.
11. Stram DO, Huberman J, Wu AH. Is residual confounding a reasonable explanation for the apparent protective effects of beta-carotene found in epidemiologic studies of lung cancer in smokers? Am J Epidemiol 155: 622-628, 2002.
12. Stayner, L., Vrijheid, M., Cardis, E., Stram, D. O., Deltour, I., Gilbert, S. J., and Howe, G. (2007) A Monte Carlo maximum likelihood method for estimating uncertainty arising from shared errors in exposures in epidemiological studies of nuclear workers, Radiat Res 168, 757-763.
13. Stram DO, Liu Y, Henderson KD, Sullivan-Halley J, Luo J, Saxena T, Reynolds P, Chang E T, Neuhausen S L, Horn-Ross PL, Bernstein L, and Ursin G Age-specific effects of hormone therapy use on overall mortality and ischemic heart disease mortality among women in the California Teachers Study. Menopause 18:153-261, 2011
14. Rakovski CS, Stram DO. A kinship-based modification of the Armitage trend test to address hidden population structure and small differential genotyping errors. PLoS One 4:e5825, 2009. PMC2688076;
15. Chen GK, Millikan RC, John EM, Ambrosone CB, Bernstein L, Stram DO (2010) Enhancing the Power of Genetic Association Studies Through The Use of Publicly Available Genotype Data. PLoS Genetics e1001096, 2010. PMC2932740

D. Research Support

Ongoing Research Support

15UB-8402 Stram (PI) 09/01/09-08/31/11
California Breast Cancer Research Program
New Methods for Genomic Studies in African American Women
The goal of this project is to develop statistical methods relevant to the design and analysis of genomic studies, particularly whole genome-wide scans such as that now taking place in the African American Breast Cancer study at USC.
Role: PI

BC075007A Haiman (PI) 06/01/08-05/30/12
DOD
Genome-wide Breast Cancer Scan in African Americans
The major goal of this study is to conduct a genome-wide scan of breast cancer in African Americans.
Role: Co-Investigator

1U01CA136792-01 Henderson (PI) 12/01/08-11/30/11
NIH/NCI
A Genome-wide Association Study of Prostate Cancer in African Americans
The major goal of this project is to conduct a genome-wide scan of prostate cancer in African Americans.
Role: Co-Investigator

1 R01 CA 126895-01A2 Le Marchand (PI) 09/01/08-07/31/13
NIH/NCI
Whole-Genome Scan for Modifier Genes in Colorectal Cancer
The major goal of this project is to conduct a whole-genome association study of colorectal cancer in the Multiethnic cohort study in order to identify susceptibility genes for this cancer.
Role: Co-Investigator

1 U01 HG 004726-01 Haiman (PI) 09/20/08-06/30/10
NIH/NHGRI
A Multiethnic Genome-wide Scan of Prostate Cancer

The major goal of this project is to conduct a multiethnic genome-wide scan of prostate cancer in the Multiethnic Cohort Study.
Role: Co-Investigator

5 U01 CA 098758-06 Henderson (PI) 06/05/03-07/31/11
NIH/NCI
Characterizing Genetic Susceptibility to Breast and Prostate Cancer; the BPC3
The major goal of this collaborative Cohort Consortium is to clarify the inter-relationship between genetic and hormonal risks factors for cancer among five ethnic groups.
Role: Co-Investigator

1 R01DK080720-01A1 Pereira (PI) 03/01/09-02/28/14
NIH
Genetic and Environmental Determinants of Type 2 Diabetes in Chinese Singaporeans
The goal of this project is discovery of genetic causes of Type 2 Diabetes that may be particularly important in Asian populations and/or which interact with dietary exposures, lack of physical exercise etc, in raising the risk of this disease.
Role: PI of USC subcontract for statistical analysis

1 U01 HG 004802-01 Le Marchand (PI) 07/17/08-05/31/12
NIH/NHGRI
Epidemiology of Putative Causal Variants in the Multiethnic Cohort
The goal of this project is to characterize in the five MEC ethnic/racial populations, the associations of putative causal variants discovered for various chronic diseases in large ongoing genomic studies.
Role: Co-Investigator

1 R01 CA129639-01A2 Haile (PI) 04/01/09-02/28/10
NIH/NCI (Memorial Sloan-Kettering P.I.:J. Bernstein)
Genome-wide Association Study of Radiation Exposure and Bilateral Breast Cancer
A genome-wide association study of bilateral and unilateral breast cancer that also incorporates information on radiation exposure into the analyses.
Role: Co-Investigator

1 R01 CA 129435-01A1 Haiman (PI) 09/30/07-07/31/10
NIH
Fine Mapping and Characterization of the 8q24 Prostate Cancer Risk Locus
The major goals of this project are to aid in localizing functional variants as well as reveal the full spectrum of common alleles that contribute to risk of breast and colorectal cancer in the general population.
Role: Co-Investigator

U01 DA020830 Benowitz PNAT (PI), Subcontract to Conti 09/15/05-06/30/10
NIH/NIDA
Pharmacogenetics of Nicotine Addiction and Treatment
The major goal of this project is to create a Pharmacogenetics Research Network (PGRN) group to address pharmacogenetic questions related to nicotine addiction and treatment. We will conduct a series of multidisciplinary integrated studies to investigate the genetic basis for both pharmacokinetic and pharmacodynamic aspects of nicotine as a drug of abuse, as well as individual variation in response to NRT and bupropion as treatments for tobacco dependence.
Role: Co-Investigator

5 P01 CA 017054-30 Henderson/Stram (PI) 02/01/00-07/31/10
NIH/NCI
Unresolved Public Health Issues Related to HT and Cancer

The major goal of this program project is to focus on cancer issues related to exposure to hormone therapy in women. This consists of three epidemiological projects (A-C) and one statistical genetics project (D, Stram PI).
Role: PI

4 R37 CA 054281-16 Kolonel (PI) 01/01/83-02/28/13
NIH/NCI
Multiethnic Cohort Study of Diet and Cancer
The major goal of this project is to perform and report on a prospective study of dietary and other lifestyle risk factors for cancer in a large multiethnic cohort in Hawaii and Los Angeles.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Thomas, Duncan C.	Professor and Director
eRA COMMONS USER NAME (credential, e.g., agency login) dthomas13	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Haverford College, Haverford, Pennsylvania	B.A.	1967	Mathematics
Stanford University, Palo Alto, California	M.S.	1969	Astronomy/Mathematics
McGill University, Montreal, Quebec Canada	Ph.D.	1976	Epidemiology/Biostatistic

A. Personal Statement

Dr. Thomas is the Director of the Study Design and Statistical Methodology Research Core for this Center. His Thomas's primary research interest is in the development of study design and statistical analysis methods for research in both environmental and genetic epidemiology. In the process, he has been a senior coinvestigator on numerous projects in both areas, ranging from radiation carcinogenesis to air pollution to the genetics of cancer, including both pathway-based and agnostic genome-wide association scans. He is particularly well known for contributions to methods development for gene-environment interactions. On this project, I will provide advice on study design and statistical analysis for modeling the exposure-response relationships and their relevant modifying factors.

B. Positions and Honors

Positions and Employment

1976-1982	Assistant Professor, Epidemiology, and Health, McGill University, Montreal, Quebec Canada
1982-1984	Associate Professor, Epidemiology and Health, McGill University Montreal, Quebec Canada
1984-1988	Associate Professor, Department of Preventive Medicine, Keck School of Medicine, University of Southern California, Los Angeles, California
1988-present	Professor, Director of Biostatistics, Verna K Richter Chair in Cancer Research, Department of Preventive Medicine, Keck School of Medicine, University of Southern California, Los Angeles, California
1998-1999	Past President International Genetic Epidemiology Society

Other Expertise and Memberships

1976-1978	Fellowship, Conseil de la recherché en sauté du Quebec,
1982-	Fellow, American College of Epidemiology

Honors

2000	Leadership Award, International Genetic Epidemiology Society
2006	Blaffer Visiting Professorship Award, MD Anderson Cancer Research Center
2006	Lilienfeld Award, Congress of Epidemiology

C. Selected Peer-reviewed Publications (Selected from 206 peer-reviewed publications)

Most relevant to the current application

1. Thomas DC. Multistage sampling for latent variable models. *Lifetime Data Anal* 2007; 13: 565-81.
2. Thomas DC. *Statistical Methods in Environmental Epidemiology*. Oxford University Press 2009, (432pp)
3. Thomas DC, Conti DV, Baurley J, Nijhout F, Reed M, Ulrich CM. Use of pathway information in molecular epidemiology. *Human Genomics*, 2010, 4:21-42, PMC Journal- In Process

4. Thomas DC. Methods for investigating gene-environment interactions in candidate pathway and genome-wide association studies. *Annual Reviews of Public Health*, 2010, 31:21-36, PMCID:20070199.
5. Thomas DC. Gene-environment-wide interaction studies: emerging approaches. *Nature Reviews of Genetics* 2010; 11:259-272, PMCID: 20212493
6. Gauderman WJ, Thomas DC, Murcray C, Conti DV, Li D, Lewinger JP. Efficient genome-wide association testing of gene-environment interaction in case-parent trios. *American Journal of Epidemiology American Journal of Epidemiology* 2010, 112:116-122, PMCID: 20543031
7. Thomas DC. *Statistical Methods in Genetic Epidemiology.* Oxford University Press, 2004 (445 pp.)
8. Baurley J, Conti DV, Gauderman WJ, Thomas DC. Discovery of complex pathways from observational data. *Statistics in Medicine* 2010; 29:1198-2011, *PMCID in process*

Additional recent publications of importance to the field (in chronological order)

9. Berhane K, Gauderman WJ, Stram, DO, Thomas DC. Statistical issues in studies of the long term effects of air pollution: The Southern California Children Health Study. *Statist Sci* 2004; 19: 414-449.
10. Thomas D. Why do estimates of the acute and chronic effects of air pollution on mortality differ? *J Toxicol Environ Health* 2005; *A* 68: 1167-74.
11. Thomas DC. Viewpoint: using gene-environment interactions to dissect the effects of complex mixtures. *J Expo Sci Environ Epidemiol* 2007; 17 Suppl 2: S71-4.
12. Molitor J, Jerrett M, Chang CC, Molitor NT, Gauderman J, Berhane K, McConnell R, Lurmann F, Wu J, Winer A, Thomas D. Assessing uncertainty in spatial exposure models for air pollution health effects assessment. *Environmental Health Perspectives* 2007;115:1147-53.
13. Molitor J, Molitor N-T, Jerrett M, McConnell R, Gauderman WJ, Berhane K, Thomas D. Bayesian modeling of air pollution health effects with missing exposure data. *Am J Epidemiol* 2006; 164: 69-76.
14. Langholz B, Thomas DC, Stovall M, et al. Statistical methods for analysis of radiation effects with tumor and dose location-specific information with application to the WECARE study of asynchronous contralateral breast cancer. *Biometrics*, 2009; 65:599-608. PMCID: PMC2728135
15. Thomas DC, Witte JS, Greenland S. Dissecting complex mixtures: Who's afraid of informative priors? *Epidemiology* 2007; 18:186-90.

D. Research Support

Ongoing Research Support

R01 ES019876-01A1 (D Thomas) 07/01/10-06/30/15
NIH --Methods for Pathway Modeling with Application to Folate
This project is aimed at developing statistical methods for modeling complex metabolic pathways in cancer epidemiology using a combination of physiologically based pharmacokinetic and Bayesian hierarchical models, using external information derived from pathway and genomic ontologies. Methods will be applied to several on-going studies of folate metabolism in colorectal cancer and will be extended to genome-wide scale.

5 P01 ES 011627-06 (Gilliland) 09/13/02 – 05/31/12
NIH/NIEHS - Genetics, Air Pollution, and Respiratory Effects in Children and Young Adults
Building on the existing Children's Health Study, an on-going cohort of 12,000 children, the three projects under this program project will evaluate the relationship between respiratory health (asthma, lung function growth, exhaled NO) and combustion particulate and gaseous pollutants; examine genetic variation in key pathways that modulate response to air pollution and disease occurrence.

1 R01 CA126895-01A2 (Le Marchand) 07/01/08-06/30/13
NIH/NCI - Whole-Genome Scan for Modifier Genes in Colorectal Cancer
The major goal of this project is to conduct a whole-genome association study of colorectal cancer in the Multiethnic cohort study in order to identify susceptibility genes for this cancer.

1R01ES016535-01 (McConnell) 09/10/08-06/30/12
NIH/NIEHS - Childhood asthma, susceptibility, and biological activity of ambient particles

Specific aims of Project: This project introduces a new approach to population studies of complex mixtures of air pollution that will assess exposure based on the in vitro effects of PM on key biological pathways and examine the relationship to the development of chronic disease.

U01 HD061968-01 (Berhane) 07/01/09-06/30/14
NIH/NICHD - Flexible Multi-level Models for Longitudinal Analysis of Childhood Obesity
The major goals of this study are to develop new quantile-regression based multi-level statistical techniques for use in modeling childhood obesity; with focus on the effects of the built environment, genetics and G x E interactions.

CA129639 Subcontract to Memorial Sloan-Kettering Cancer Center (Haile) 04/1/09-02/28/12
NIH/NCI (Memorial Sloan-KetteringP.I.:J. Bernstein)
Genome-wide Association Study of Radiation Exposure and Bilateral Breast Cancer.

U19 CA148107 (Gruber-Subcontract to Casey) 04/1/10-03/31/14
NIH/NCI -- Transdisciplinary Studies of Genetic Variation for Colorectal
The objectives of the Transdisciplinary Studies of Genetic Variation in Colorectal Cancer (TSGVC) consortium are to thoroughly investigate and identify susceptibility loci for colorectal cancer, to characterize the biologic basis of inherited susceptibility, and to recognize how genetic variation may be quantified and modified by genetic and environmental risk factors.

Completed Research Support
RO1 HL087680 (Gauderman) 09/30/06-09/29/10
NHLBI--A Genome-wide Association Study of Childhood Respiratory Outcomes
Role: Principal Investigator
Specific Aims of Project: The major goal of this project is to conduct a genome-wide association study to identify new genetic variants that increase the risk of childhood asthma or affect lung function development

U01 ES015090-03 (Thomas) 09/01/06 – 07/31/09
NIH - Design and Analysis of Genome-wide Association Studies
The major goal of this project is focus on the following methodological issues: (1) tagSNP selection and haplotype-based methods incorporating both case-control association and case-case sharing comparisons; (2) multiple testing procedures for multistage sampling designs, including hierarchical models for prioritizing SNPs for further consideration using external genomic data; (3) family- vs. population-based studies and allowance for population stratification and admixture; and (4) gene-gene and gene-environment

1 R01 CA 112450 (Concannon – Subcontract to Thomas) 07/01/05 – 06/30/08
NIH -- ATM Mutations in Breast Cancer – A Function Approach
This is a case-control study to explore the relationship between ATM mutations, radiation exposure and breast cancer. We plan to test a missense-mutation model that hypothesizes a subset of ATM mutation carriers are at increased risk for breast cancer.

U01 HL 084705-01 (Thomas) 09/01/06 – 08/31/09
NIH -- Design and Analysis of Genome-wide Association Studies
The major goal of this project is focus on the following methodological issues: (1) tagSNP selection and haplotype-based methods incorporating both case-control association and case-case sharing comparisons; (2) multiple testing procedures for multistage sampling designs, including hierarchical models for prioritizing SNPs for further consideration using external genomic data; (3) family- vs. population-based studies and allowance for population stratification and admixture; and (4) gene-gene and gene-environment interactions.

R831845 EPA STAR (McConnell) 07/01/04 - 06/31/09
Environmental Protection Agency STAR
Spatial Exposure Models for Assessing the Relationship

Between Air Pollution and Childhood Asthma at the Intra-Urban Scale Specific aims: To utilize the resources of the Children's Health Study (ARBA033186) to develop the conceptual framework and empirical methods that will guide many future epidemiological studies on the relation between air pollution and health.

2 P30 ES 07048-11 (Gilliland) 04/01/06 – 03/31/11
NIH/NIEHS - Environmental Exposures, Host Factors and Human Disease
The major goals of this multidisciplinary center for research is aimed at identifying and characterizing: (1) the direct human health effects of environmental exposures; and (2) factors which modify susceptibility to environmental exposures, including genetic factors and interactions with other environmental exposures, such as diet.

1 T32 GM 67546-01 (Azen) 04/01/06 - 03/31/11
NIH/NIEHS - Training Grant in Genomics Analysis and Interpretation
To provide multidisciplinary training for three predoctoral scientists and two postdoctoral scientists in specialized training at the interface between environmental health and genomics.

U01 CA 122839 (Casey) 09/27/06-7/31/11
NIH/NCI - Genome-wide association study of Colorectal Cancer
The major goal of this project is to perform a GWAS of CRC to identify novel genetic markers of CRC risk.

3R01MH084678-03S1 (Marjoram) Supplement 07/01/10 – 06/30/11
NIMH -- Statistical Methods for Relating Sequence Data to Phenotype
We aim to develop a raft of statistical machinery to help develop our understanding of how sequence level data can be related to phenotype. The focus is on 'short-read' resequencing data, models for copy number variation, and methods to mitigate the effects of population structure.

1R01 ES016813-01 (Conti) 07/01/09-06/30/11
NIH/NIEHS - Hierarchical Modeling of Interactions in Genome-Wide and Pathway-Based StudiesSpecific Aims: Overall, we aim to develop statistical techniques that formally incorporate our biologic knowledge and make it feasible to detect which genes are involved in disease and, importantly, in which environmental context they act. By identifying both genetic and environmental factors, we will make progress in understanding the underlying mechanism that leads to disease and potentially identify ways in which to both prevent and treat complex diseases.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
A. Bertrand Brill, M.D., Ph.D.	Research Professor Radiology, Physics .Adjunct Professor and Biomedical Engineering
eRA COMMONS USER NAME BRILLAB	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Grinnell College	A.B.	1949	Chemistry/Zoology
University of Utah, Salt Lake City, UT	M.D.	1956	Medicine
University of California, Berkeley, CA	Ph.D.	1961	Biophysics

A. Positions and Honors.

Positions and Academic Honors:

1956-57 Intern, Internal Medicine, Univ. of Utah, Salt Lake Gen. Hospital, Salt Lake City, UT
1957-59 Research Associate Medicine and Statistics Atomic Bomb Casualty Comm., Hiroshima, Japan
1959-61 Fellow Medical Physics. Donner Laboratory, University of California, Berkeley, CA
1961-64 Assistant Professor, Dept of Radiology & Radiological Sci. Johns Hopkins Univ., Baltimore, MD.
1964-72 Associate Professor, Medicine, Radiology, Physics and Biomedical Engineering, Vanderbilt Univ.
1972-79 Professor, Radiology Vanderbilt University, School of Medicine Nashville, TN.
1979-87 Professor, Radiology State University of New York at Stony Brook, and Sr. Scientist, Nuclear Medicine Program Coordinator, Brookhaven National Lab, Upton, NY.
1987-97 Professor, Nuclear Medicine, and Research Director, Nuclear Medicine Department, Univ. of Massachusetts Medical Center, Worcester, MA.
1997-01 Professor, Radiology, Univ. of Massachusetts Medical Center, Worcester, MA.
1992-05 Research Affiliate. MIT, Health Sciences and Technology Program, Cambridge, MA.
1997- Research Professor, Radiology, and Physics, and Adjunct Prof Biomedical Eng, Vanderbilt Univ.

Honors and Awards:

Fellow: American College of Nuclear Physicians (1988); American Institute for Medical and Biomedical Engineering (1997); IEEE Nuclear and Plasma Society (1988). **Awards:** Shea Distinguished Member Award: IEEE/NPSS (1998);
National Academy of Science: "National Associate", 2004-.
Committees: National Academy of Sciences Committees: Committee on Atomic Casualties (1964-68), BEIR III Comm. (1978-80). CDC HTDS Thyroid Radiation Effects Oversight Comm. (1999-2003), NAS Comm. To Assess the Scientific Information for the Radiation Exposure Screening and Education Program (2002-5), NCI Chernobyl Study Group (1992-2006). Advisory Committee to University of Arizona (H. Barrett, P.I.) NIH-sponsored Research Resource: Center for Gamma-ray Imaging (1999-20010). National Council on Radiation Protection: Risk to Thyroid From Ionizing Radiations (2001-2008), Uncertainty in Radiation Risk Estimation (2009-), Society of Nuclear Medicine,(Medical Internal Radiation Dose Comm. (1999-).

B. Selected peer-reviewed publications (in chronological order).

(Publications selected from ~450 publications)

1. Siegel JA, Thomas SR, Stubbs JB, Stabin MG, Hays MT, Koral KF, Robertson JR, Howell RW, Wessels BW, Fisher DR, Weber DA, and Brill AB. MIRD Pamphlet No. 16: Techniques for Quantitative Radio-Pharmaceutical Biodistribution Data Acquisition and Analysis for Use in Human Radiation Dose Estimates. J. Nucl Med. 1999; 40 (2): 37S-61S.

2. Stabin MG, Brill AB. Monoclonal Antibodies in the Treatment of Hematologic Malignancies: Radiation Dosimetry Aspects. Current Pharmaceutical Biotechnology 2001; 2: 351-356
3. Gombia M, Brill AB, Bollini D, DelGuerra A. A Simulation and Modeling Study Comparing the Performance of a Germanium Orthogonal Strip Detector and an Anger Camera. IEEE, Tr Nuc. Sci. 2002. 49: (5) 2196-2302.
4. Stabin MG, Eckerman, KF, Sgouros, G, Brill AB et al. Monte Carlo methods and mathematical models for the dosimetry of skeleton and bone marrow. In Therapeutic Applications of Monte Carlo Calculations in Nuclear Medicine. Ed. Zaidi, and G. Sgouros. IOP. 2002.
5. Di Martino F, Traino AC, Brill AB, Stabin MG, Lazzer M.A theoretical model for prescription of the patient-specific therapeutic activity for radioiodine therapy of Graves' disease. Phys Med Biol 2002 May 7; 47(9):1493-99
6. Siegel JA, Stabin MG, Brill AB The importance of patient-specific radiation dose calculations for the administration of radionuclides in therapy. Cell Mol Biol (Noisy-le-grand) 2002 Jul; 48(5):451-459
7. Schull WJ, Boecker BB, Brill AB, Carter MW, Clark SB, Crouch EAC, Friedman SM, Higley KA, Lederer SE, Levenson M, Paretzke HG, Scott BR, Shore RE, Stram DO., Exposure of the American Population to Radioactive Fallout from Nuclear Weapons Tests. A Review of the CDC-NCI Draft Report on a Feasibility Study. National Academy of Sciences-National Research Council. 2003. Washington DC: National Academic Press. 68 pp.
8. Bouchet LG, Bolch WE, Stabin MG, Eckerman KF, Poston JW, Sr., Brill AB. Monte Carlo methods and mathematical models for the dosimetry of skeleton and bone marrow. Chapter 13. In, Therapeutic Applications of Monte Carlo Calculations in Nuclear Medicine. Ed. H. Zaidi and G. Sgouros. Institute of Physics, 2003.
9. Stabin M, Brill AB. Monte Carlo codes for use in therapeutic nuclear medicine. In, Therapeutic Applications of Monte Carlo Calculations in Nuclear Medicine. Ed. H. Zaidi, and G. Sqouros. IOP. 2003. ISBN 07503 8168.
10. Brill, AB, and Beck, RN. Evolution of Clinical Emission Tomography. In Emission Tomography: The Engineering and Physics of PET and SPECT, Miles N. Wernick and John N. Aarsvold, eds., San Diego: Academic Press, 2004.
11. Stezhko VA, Buglova LI, Brill AB and Zablotska JB. A cohort study of thyroid cancer and other thyroid diseases after the Chornobyl accident: Objectives, Design, and Methods. Rad. Res. 2004; 161 (4): 481-492.
12. Walenta AH, Brill AB, Castoldi A. Conka-Nurdan T, Guazzoni C, Hartman K, Longoni A, Nurdan K, Struder L. Vertex Detection in a Stack of Si-drift Detectors for High Resolution Gamma-Ray Imaging. NPSS, Tr. Nucl Sci. 2005; 52 (5):1434-1439.
13. Lyshchik A, Higashi T, Asato R, Tanaka S, Ito J, Mai JJ, Pellot-Barakat C. Insana MF, Brill AB, Saga T, Hiraoka M, Togashi K. Thyroid gland tumor diagnosis at US elastography. Radiology. 2005; 237:202-11.
14. Stabin M, Brill AB. Quantitative Imaging-Based Dosimetry and Treatment Planning In Radionuclide Therapy. In Quantitative Analysis of Nuclear Medicine Images. Ed. H. Zaidi. 2006. ISBN 0387238549.
15. Boice JD, Leggett RW, Brill AB, et al. A comprehensive Dose Reconstruction Methodology for Former Rocketdyne/Atomics International Workers. Health Phys 2006; 90 (5): 409-430.
16. Brill AB, Stabin M, Bouville A, and Ron E. Normal Organ Radiation Dosimetry and Associated Uncertainties in Nuclear Medicine, with Emphasis on Iodine-131 Radiat Res 2006; 166: 128–140.
17. Boice JD Jr., Cohen SS, Mumma MT, Ellis ED, Eckerman KF, Leggett RW, Boecker BB, Brill AB, and Henderson BE. Mortality among Radiation Workers at Rocketdyne (Atomics International), 1948-1999. Radiat Res 2006; 166:98-116.
18. Boice JD Jr, Marano DE, Cohen SS, Mumma MT, Blot WJ, Brill AB, Fryzek JP, Henderson BE, Mclaughlin JK. Mortality among Rocketdyne workers who tested rocket engines, 1948-1999. J Occup Envion Med 48:1070-1092, 2006.
19. Tronko MD, Brenner AV, Olijnyk VA, Robbins J, Epstein OV, McConnell R J, Bogdanova TI,Fink D J, Likhtarev IA, Lubin JH, Markov VV, Bouville AC, Terekhova GM, Zablotska LB,Shpak VM, Brill AB, Tereshchenko VP, Masnyk IJ, Ron E, Hatch M, and Howe GR. Autoimmune Thyroiditis and Exposure to Iodine 131 in the Ukrainian Cohort Study of Thyroid Cancer and Other Thyroid Diseases after the Chornobyl Accident: Results from the First Screening Cycle (1998–2000). J. Clin Endocrinol Metab 91:4344-4351, 2006.

20. Tronko MD, Howe GR, Bogdanova TI, Bouville AC, Epstein OV, Brill AB, Likhtarev A, Fink DF, Markov VV, Greenebaum E, Olijnyk VA, Masnyk IJ, Shpak VM, McConnell J, Tereshschenko P, Robbins J, Zvinchuk OV, Zablotska LB, Hatch M, Luckyanov NK, Ron E, Thomas TL, Voileque PG, Beebe GW. 2006. A cohort study of thyroid cancer and other thyroid diseases after the Chornobyl accident: Thyroid cancer in Ukraine detected during first screening. Journal of the National Cancer Institute 98:897–903.
21. McConnell RJ, Brennert AV, Oliynyk VA, Robbins J, Terekhova GM, Fink DJ, Epshtein OV, Hatch M, Shpak VM, Brill AB, Shelkovoy YA, Zablotska LB, Masnyk IJ, Howe GR, and Tronko MD. Factors Associated with Elevated Serum Concentrations of anti-TPO Antibodies in Subjects with and without Diffuse Goitre. Results from the Ukrainian-American Cohort Study of Thyroid Cancer and other Thyroid Diseases Following the Chornobyl Accident. Clin. Endoc. 67: 879-890, 2007.
22. Zablotska L B, Bogdanova TI., Ron E, Epstein OV, Robbins J, Likhtarev IA, Hatch M, Markov VV, Bouville AC, Olijnyk VA, McConnell RJ, Shpak VM, Brenner A, Terekhova GN, Greenebaum E, Tereshchenko VP, Fink DJ, Brill AB, Zamotayeva GA, Masnyk I, Howe GR, and Tronko MD. A Cohort Study of Thyroid Cancer and Other Thyroid Diseases after the Chornobyl Accident: Dose-Response Analysis of Thyroid Follicular Adenomas Detected during First Screening in Ukraine (1998–2000). Am J. Epid. 2008;167(3):305-312.
23. Liu S, King MA, Brill AB, Stabin MG, and Farncombe TH. Accelerated SPECT Monte Carlo Simulation Using Multiple Projection Sampling and Convolution-Based Forced Detection IEEE Trans Nucl Sci. 2008; 55(1): 560-567.
24. Vicini P, Brill AB, Stabin MG, and Rescigno A. Kinetic Modeling in Support of Radionuclide Dose Assessment. Sem. Nucl Med. 2008; 38 (5): 335-346.
25. Stabin MG and Brill. State of the Art in Nuclear Medicine Dose Assessment. Semin Nucl Med 2008;38(5):308-20.
26. Stabin MG and Brill. Radiation Dosimetry and Exposure in Nuclear Medicine. Semin Nucl Med 2008; 38(5):306-7.
27. Stabin M and Brill AB. Physics Applications in Nuclear Medicine: 2007; J Nucl Med 2008;49(2):20N-5N.
28. Wessels BW, Konijnenberg MW, Dale RG, Breitz HB, Cremonesi M, Meredith RF, Green AJ, Bouchet LG, Brill AB, Bolch WE, Sgouros G, Thomas SR. MIRD Pamphlet No. 20: The Effect of Model Assumptions on Kidney Dosimetry and Response--Implications for Radionuclide Therapy. Nucl Med. 2008; 49(11):1884-1899.
29. Sgouros G, Roeske JC, McDevitt MR, Palm S, Allen BJ, Fisher DR, Brill AB, Song H, Howell RW, Akabani G. MIRD Pamphlet No. 22 (abridged) - Radiobiology and Dosimetry of Alpha-Particle Emitters for Targeted Radionuclide Therapy. . 2010 Feb;51(2):311-28. Epub 2010 Jan 15.
30. Wessels BW, Dale RG, Cremonesi M, Meredith RF, Green AJ, Brill AB, Bolch WE, Sgouros G, Thomas SR. Cancer Biother Radiopharm. 2010 Oct;25(5):597-9. Epub 2010 Sep 28.
31. Boice JD, Cohen SS, Mumma MT, Ellis ED, Eckerman KF, Leggett RL, Boecker BB, Brill AB, and Henderson BH. Updated Mortality Analysis of Radiation Workers at Rocketdyne (Atomics International), 1948–2008 Radiation Research. Aug; 2011: 176, (2): 244-258.

C. Research Support

Ongoing Research Support

5R01 CA104666-03 Boice (PI) 09/12/05-05/31/10
NIH/NCI
Genetic Consequences of Therapies for Cancer
The major goal is to determine whether genetic hazards of radiation agree with prior data from the A-bomb survivors.
Role: Co-Investigator

Completed Research Support

International Epidemiology Institute (IEI) Brill (PI) 08/30/01-06/30/05
A Cohort Mortality Study of the Rocketdyne Workforce
The overall goal is to evaluate the risks for specific cancers and other diseases in relation to quantitative estimates of both radiation and chemical exposures.
Role: PI

1R41 CA117599-01 Brill (PI) 04/12/06-03/31/07
NIH/NCI (STTR: Sub with AlphaMed Inc.)
High Energy Imaging in Support of Radionuclide Therapy
The overall goal of this project is to design and build cameras that can efficiently detect and image isotopes that have gamma rays with energies that are typically beyond those effectively accessible with conventional cameras.
Role: PI at Vanderbilt University Medical Center

5R01 CA104907-03 Stabin (PI) 09/01/04-08/31/08
NIH/NCI
New Methods for Improved Image-Based Dosimetry
The goal of this project is to determine the accuracy of activity estimation from the quantitative methods and reconstruction algorithms, through comparison of measured activity values in simple and complex anthropomorphic phantoms to known values.
Role: Co-Investigator

5R01 CA116743-02 Stabin (PI) 09/01/05-05/31/08
Rensselaer Polytechnic Institute
Virtual Patients for Computing Radiation Doses
The goal of this project is to set the foundation for a paradigm shift in the US and the rest of the world in the ways that organ doses are calculated for high-energy photon/electron/proton radiotherapy, X-ray/CT imaging and radiation risk epidemiological studies.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Shyr, Yu	Director
eRA COMMONS USER NAME (credential, e.g., agency login)	
YUSHYR	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Tamkang University, Taiwan	B.B.	1985	Statistics
Michigan State University, East Lansing, MI	M.S.	1989	Statistics
University of Michigan, Ann Arbor, Michigan	Ph.D.	1994	Biostatistics

A. Personal Statement

I have nearly 20 years of experience as a statistical consultant, providing experimental design and statistical analysis support for basic science research, clinical trials, and high-dimensional data studies. I have published more than 260 peer-reviewed papers, including many statistical methodology papers, for example, describing techniques for multivariate data analysis and a wavelet-based approach to proteomic data preprocessing, as well as collaborative research papers in the fields of cancer biology, epidemiology, and clinical trials; diabetes and nephrology; orthopedics; immunology; and others. In addition, I have taught numerous seminars and courses on statistical topics such as power and sample size calculation, clinical trial design and analysis, and statistical approaches to high-dimensional data analysis.

B. Positions and Honors

Positions and Employment

1988 - 1989	Graduate Student Teaching Asst., Dept. of Statistics, Michigan State Univ., East Lansing, MI
1989 - 1994	Graduate Student Research Asst, Dept. of Biostatistics, Univ. of Michigan, Ann Arbor, MI
1990	Research Associate, Institute of Gerontology, Univ. of Michigan, Ann Arbor, MI
1991 - 1992	Research Associate, Dept. of Periodontics/Prevention/Geriatrics, Univ. of Michigan
1993 - 1994	Adjunct Lecturer, Dept. of Biostatistics, Univ. of Michigan, Ann Arbor, MI
1994 - 1998	Chief Biostatistician, Ingram Cancer Center, Vanderbilt Univ. School of Med., Nashville, TN
1994 - 1999	Asst. Professor of Biostatistics, Dept. of Preventive Medicine, Nashville, TN
1998 - Present	Director, Biostatistics Shared Resource, Vanderbilt-Ingram Cancer Center, Nashville, TN
1999 - 2002	Associate Professor of Biostatistics, Vanderbilt Univ., Nashville, TN
2000	Tamkang Chair Professor of Statistics, Dept. of Statistics, Tamkang University (Taiwan)
2001 - Present	Director, Biostatistics Core, Lung SPORE, Vanderbilt Univ., Nashville, TN
2002 - Present	Professor of Biostatistics, Dept. of Preventive Medicine, Vanderbilt Univ., Nashville, TN
2002 - Present	Director, Biostatistics Core, GI SPORE, Vanderbilt Univ. School of Medicine, Nashville, TN
2003 - Present	Ingram Professor of Cancer Research, Vanderbilt Univ. School of Medicine, Nashville, TN
2003 - Present	Director, Biostatistics Core, Breast SPORE, Vanderbilt Univ. Medical Center, Nashville, TN
2003 - Present	Professor of Biostatistics, Dept. of Biostatistics, Vanderbilt Univ., Nashville, TN
2006 - Present	Chief, Division of Cancer Biostatistics, Dept. of Biostatistics, Vanderbilt Univ., Nashville, TN
2007 - 2011	Director, Cancer Biostatistics Center, Vanderbilt-Ingram Cancer Center (VICC), Nashville, TN
2009 - Present	Associate Director for Quantitative Sciences Integration, VICC, Nashville, TN
2011 - Present	Professor, Dept. of Cancer Biology, Vanderbilt Univ. School of Medicine, Nashville, TN
2011 - Present	Professor, Dept. of Biomedical Informatics, Vanderbilt Univ. School of Medicine, Nashville, TN
2011 - Present	Director, Vanderbilt Center for Quantitative Sciences, Vanderbilt Univ., Nashville, TN

C. Selected peer-reviewed publications (*15 selected from 266*)

1 Yanagisawa K, **Shyr Y**, Xu BJ, Massion PP, Larsen PH, Whit BC, Roberts JR, Gonzalez A, Nadaf S, Moore JH, Caprioli RM, Carbone DP. Tumor proteomic patterns predict classification and tumor behavior in human non-small cell lung cancer. *Lancet* 2003;362(9382):433-439.

2 Chen S, Hong D, **Shyr Y**. Wavelet-based procedures for proteomic mass spectrometry data processing. *Computational Statistics and Data Analysis* 2007;52(1):211-20.
3 Jiang A, Pan W, Milbauer LC, **Shyr Y**, Hebbel RP. A practical question based on cross-platform microarray data normalization: are BOEC more like large vessel or microvascular endothelial cells or neither of them? *J Bioinform Comput Biol* 2007;5(4):875-93.
4 Ye F, **Shyr Y**. Balanced two-stage design for phase II clinical trials. *Clin Trials* 2007;4(5):514-524.
5 Lin KC, Chen YJ, **Shyr Y**. A nonparametric smoothing method for assessing GEE models with longitudinal binary data. *Stat Med* 2008;27(22):4428-4439.
6 Ni TT, Lemon WJ, **Shyr Y**, Zhong TP. Use of normalization methods for analysis of microarrays containing a high degree of gene effects. *BMC Bioinformatics* 2008;9:505. PMCID: PMC2612699.
7 Chen S, Li M, Hong D, Billheimer D, Li H, Xu BJ, **Shyr Y**. A novel comprehensive wave-form MS data processing method. *Bioinformatics* 2009;25(6):808-814. PMCID: PMC2732299.
8 Bierie B, Chung CH, Parker JS, Stover DG, Cheng N, Chytil A, Aakre M, **Shyr Y**, Moses HL. Abrogation of TGF-b signaling enhances chemokine production and correlates with prognosis in human breast cancer. *J Clin Invest* 2009;119(6):1571-1582. PMCID: PMC2689133.
9 Lovejoy CA, Xu X, Bansbach CE, Glick GG, Zhao R, Ye F, Sirbu BM, Titus LC, **Shyr Y**, Cortez D. Functional genomic screens identify CINP as a genome maintenance protein. *Proc Natl Acad Sci USA* 2009;106(46):19304-19309. PMCID: PMC2780779.
10 Wu J, Qiu Q, Xie L, Fullerton JB, Yu J, **Shyr Y**, George AL, Yi Y. Web-based interrogation of gene expression signatures using EXALT. *BMC Bioinformatics* 2009;10(1):420. PMCID: PMC2799423.
11 Smith JJ, Deane NG, Wu F, Merchant NB, Zhang B, Jiang A, Lu P, Johnson JC, Schmidt C, Edwards CM, Eschrich S, Kis C, Levy S, Washington MK, Heslin MJ, Coffey RJ, Yeatman TJ, **Shyr Y**, Beauchamp RD. An experimentally derived metastasis gene expression profile predicts recurrence and death in colon cancer patients. *Gastroenterology* 2010;138(3):958-968. NIHMSID: NIHMS166548.
12 Ogden SR, Noto JM, Allen SS, Romero-Gallo J, Washington MK, Fingleton B, Israel DA, Lewis ND, Wilson KT, Chatuervedi R, Zhao Z, **Shyr Y**, Peek RM. Matrix metalloproteinase-7 and premalignant host responses in Helicobacter pylori-infected mice. *Cancer Res* 2010;70(1):30-35. PMCID: PMC2804939.
13 Kobayashi H, Huang J, Ye F, **Shyr Y**, Blackwell TS, Lin PC. Interleukin-32b propagates vascular inflammation and exacerbates sepsis in a mouse model. *PLoS ONE* 2010;5(3):e9458. PMCID: PMC2832764.
14 Rosenbluth JM, Mays DJ, Jiang A, **Shyr Y**, Pietenpol JA. Differential regulation of the p73 cistrome by mammalian target of rapamycin reveals transcriptional programs of mesenchymal differentiation and tumorigenesis. *Proc Natl Acad Sci USA* 2011;108(5):2076-81. PMCID: PMC3033306.
15 Lehmann BD, Bauer JA, Chen X, Sanders ME, Chakravarthy AB, **Shyr Y**, Pietenpol JA. Identification of human triple-negative breast cancer subtypes and preclinical models for selection of targeted therapies. *Journal of Clinical Investigation* 2011. PMCID: PMC21633166.

D. Research Support

Selected ongoing and recently completed support

5P50 CA095103-10 (Coffey) 07/25/07-04/30/12
NIH/NCI Role: Core leader
SPORE in GI cancer
The major goal of this project is to investigate the molecular features of gastrointestinal tumors.

5P50 CA090949-10 (Carbone) 09/26/07-03/31/12
NIH/NCI Role: Core leader
SPORE in lung cancer
The major goal of this project is to investigate the molecular features of tumors or tumor-host interactions that determine their clinical behavior and represent potential molecular targets for interventions.

5U54 CA126505-05 (Matrisian) 09/25/06-08/31/12
NIH/NCI Role: Co-Investigator
Paracrine TGF-beta signaling in tumor initiation and progression
The major goal of this project is to establish the Vanderbilt University Tumor Microenvironment Network (VUTMEN) to contribute to the generation of a comprehensive understanding of the role of the tumor stroma.

5P30 CA068485-15 (Pietenpol) 09/10/10-08/31/15
NIH/NCI Role: Core leader
Cancer center support grant
The major goal of this project is to coordinate cancer-related activities of Vanderbilt University.

5P50 CA098131-09 (Arteaga) 09/11/08-05/31/13
NIH/NCI Role: Core leader
SPORE in breast cancer
The major goal of this project is to address basic, clinical, and population research questions in breast cancer.

5R01 CA102162-08 (Moses) 12/01/08-11/30/13
NCI Role: Co-Investigator
TGF-beta in mammary development and tumorigenesis
The major goal of this study is to characterize Cre expression pattern, recombination, and phenotype in various TGF-beta recombinant mouse backgrounds.

5P01 CA116087-03 (Peek) 01/01/09-12/31/13
NCI Role: Core leader
H. pylori-induced inflammation and gastric cancer
The major goal of this project is to delineate the molecular signaling events initiated by *H. pylori*-epithelial cell contact that regulate phenotypes related to gastric carcinogenesis.

2R01 DK058587-10 (Peek) 09/01/07-06/30/16
NIDDKD Role: Co-Investigator
H. pylori and gastrointestinal biology
The major goal of this project is to investigate effects of *H. pylori* on prostaglandin biology using conditionally immortalized gastric cells.

5P50 CA128323-04 (Gore) 09/22/08-08/31/13
NCI Role: Core leader
Vanderbilt *in vivo* cellular and molecular imaging center
The major goal of this project is to establish a new *in vivo* cellular and molecular imaging center at Vanderbilt University, which will be dedicated to highly innovative molecular imaging studies of cancer biology.

5RC2 CA14839-02 (Pao: Colorado) 09/01/09-08/31/11
NIH Role: Core leader
Lung Cancer Mutation Consortium trial
The major goal of this project is to establish a Lung Cancer Mutation Consortium (LCMC) consisting of 13 institutions with a major interest in lung cancer and genomic testing of lung cancer as documented by having major NCI grants in lung cancer.

2R01CA085492-11A1 (Moses) 03/01/11-02/29/16
NCI Role: Co-Investigator
TGFb suppression and promotion of mammary carcinomas
The major goal of this project is to delineate mechanisms of both suppression and promotion of tumors by TGFb.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
William Wu	Associate in Biostatistics
eRA COMMONS USER NAME (credential, e.g., agency login) Wuwill	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Nanchang Health College, China	B.S.	10/81	Public Health
Quingdao Medical College, China	M.S.	07/89	Nutrition
Chinese Academy of Preventive Medicine, China	Ph.D.	08/96	Preventive Medicine
University of Southern California, Los Angeles, CA	M.S.	08/03	Biostatistics/Epidemiology

A. Personal Statement

I am an associate in biostatistics and a full-time biostatistician in the Vanderbilt Center for Quantitative Sciences. I have over eight years of experience in biostatistical consulting. I received my master's degree in applied biostatistics and epidemiology from the University of Southern California and my Ph.D. in preventive medicine from the Chinese Academy of Preventive Medicine. My research interests include statistical methodology development for high-dimensional data analysis and two-stage design of phase II clinical trials.

B. Positions and Honors

Positions and Employment

1990 - 1993	Instructor, Qingdao Medical College, China
1993 - 1996	Research Assistant, Chinese Academy of Preventive Medicine, Beijing, China
1996 - 1998	Postdoctoral Research Associate, University of Louisville, Louisville, KY
1998 - 2000	Postdoctoral Research Associate, University of Cincinnati, Cincinnati, OH
2000 - 2001	Associate Research Scientist, American Health Foundation, Valhalla, NY
2001 - 2003	Research Associate, Department of Preventive Medicine, University of Southern California, Los Angeles, CA
2003 - 2007	Assistant in Biostatistics, Department of Biostatistics, Vanderbilt University, Nashville, TN
2007 - Present	Associate in Biostatistics, Department of Biostatistics, Vanderbilt University , Nashville, TN

C. Selected peer-reviewed publications (15 selected from 33)

1. Xie S, **Wu HY**, Wang Q, Cogswell JP, Husain I, Conn C, Stambrook P, Jhanwar-Uniyal M, Dai W. Plk3 functionally links DNA damage to cell cycle arrest and apoptosis at least in part via the p53 pathway. J Biol Chem 2001;276:43305-12.
2. Xie S, **Wu HY**, Wang Q, Kunicki J, Thomas RO, Hollingsworth RE, Cogswell J, Dai W. Genotoxic stress-induced activation of Plk3 is partly mediated by Chk2. Cell Cycle 2002;1:424-9.
3. **Wu HY**, Dwyer KM, Fan Z, Shircore A, Fan J, Dwyer JH. Dietary fiber and progression of atherosclerosis: the Los Angeles Atherosclerosis Study. Am J Clin Nutr 2003;78:1085-91.
4. Dwyer JH, Allayee H, Dwyer KM, Fan J, **Wu HY**, Mar R, Lusis AJ, Mehrabian M. Arachidonate 5-lipoxygenase promoter genotype, dietary arachidonic acid, and atherosclerosis. N Eng J Med 2004;350:29-37.
5. Boyd A, **Wu HY**, Shyr Y. Monster cells in malignant melanoma. Am J Dermatopathol 2005;27:208-10.
6. Fowler K, Poehling K, Billheimer D, Hamilton R, **Wu HY**, Mulder J, Frangoul H. Hospice referral practices for children with cancer: a survey of 632 pediatric oncologists. J Clin Oncol 2006;24;1099-104.
7. Cuneo KF, **Wu HY**, Hallahan DE. Src family kinase inhibitor SU6656 enhances antiangiogenic effect of irradiation. Int J Radiat Oncol Biol Phys 2006;64(4):1197-203.

8. Kim DW, Blanke CD, **Wu H**, Shyr Y, Berlin J, Beauchamp RD, Chakravarthy B. Phase II study of preoperative paclitaxel/cisplatin with radiotherapy in locally advanced esophageal cancer. Int J Radiat Oncol Biol Phys 2007;67(2): 397-404.
9. Shin A, Shrubsole MJ, Ness RM, **Wu H**, Sinha R, Smalley WE, Shyr Y, Zheng W. Meat and meat-mutagen intake, doneness preference and the risk of colorectal polyps: the Tennessee Colorectal Polyp Study. Int J Cancer 2007;121(1):136-42.
10. Murff HJ, Shrubsole MJ, Smalley WE, **Wu H**, Shyr Y, Ness RM, Zheng W. The interaction of age and hormone replacement therapy on colon adenoma risk. Cancer Detect Prev 2007;31(2):161-5. PMCID: PMC1949417.
11. Tang YW, Li H, **Wu H**, Shyr Y, Edwards KM. Host single-nucleotide polymorphisms and altered responses to inactivated influenza vaccine. J Infect Dis 2007;196(7):1021-5.
12. **Wu H**, Muscato NE, Gonzalez A, Shyr Y. An EGFR and AKT signaling pathway was identified with mediation model in osteosarcomas clinical study. Biomarker Insights 2007;2:469-76. PMCID: PMC2717822.
13. Shrubsole MJ, **Wu H**, Ness RM, Shyr Y, Smalley WE, Zheng W. Alcohol drinking, cigarette smoking, and risk of colorectal adenomatous and hyperplastic polyps. Am J Epidemiol 2008;167(9):1050-8.
14. **Wu H**, Dai Q, Shrubsole MJ, Ness RM, Schlundt D, Smalley WE, Chen H, Li M, Shyr Y, Zheng W. Fruit and vegetable intakes are associated with lower risk of colorectal adenomas. J Nutr 2009;139(2):340-344. PMCID: PMC2646202.
15. Ware LB, Koyama T, Billheimer DD, **Wu W**, Bernard GR, Thompson BT, Brower RG, Standiford TJ, Martin TR, Matthay MA. Prognostic and pathogenetic value of combining clinical and biochemical indices in patients with acute lung injury. Chest 2010;137(2):288-296. PMCID: PMC2816641.

D. Research Support

Selected ongoing and recently completed research support

5K07 CA122827-04 (Peterson) 08/01/07-07/31/11
NCI
Matrix metalloproteinase gene polymorphisms and breast cancer risk and survival
The major goal of this project is to examine how polymorphisms in MMP genes affect breast cancer risk, breast cancer type or disease stage at diagnosis, and all-cause survival and breast cancer-specific survival in breast cancer patients.
Role: Biostatistician

5P01 CA040035-22 (Elefteriou) 09/01/06-08/31/11
NCI
Effects of tumors on the skeleton
The major goal of this project is to identify novel molecular mechanisms responsible for important manifestations of cancer on the skeleton.
Role: Biostatistician

5P50 CA128323-03 (Gore) 09/22/08-08/31/13
NCI
Vanderbilt *in vivo* Cellular and Molecular Imaging Center
The major goal of this project is to establish a new *in vivo* cellular and molecular imaging center at Vanderbilt University, which will be dedicated to highly innovative molecular imaging studies of cancer biology.
Role: Biostatistician

5R01 CA129961-04 (Yankeelov) 04/01/08-01/31/12
NCI
Evaluation of MRI biomarkers of breast cancer response
The major goal of this project is to combine several new imaging methods to obtain quantitative information on how breast tumors respond to treatment.
Role: Co-investigator

5R01 CA104666-05 (Boice) 09/12/05-05/31/11
NCI
Genetic consequences of therapies for cancer
The major goal of this project is to analyze an international collection of data related to possible genetic alterations in offspring of long-term survivors of childhood and adolescent cancer.
Role: Biostatistician

2P30 CA068485-15 (Pietenpol) 09/10/10-08/31/15
NIH/NCI
Cancer Center Support Grant
The major goal of this project is to coordinate cancer-related activities of Vanderbilt University.
Role: Co-investigator

1U01 CA137026-01A2 (Boice) 07/07/10-06/30/15
NCI
Cancer mortality among military participants at US nuclear weapons tests

The major goals of this project are to study the effects of radiation on veterans who participated in atmospheric nuclear weapons tests in Nevada between 1946 and 1958 and to provide new knowledge on the lifetime risk of cancer following relatively low-dose exposures to radiation received gradually over time.
Role: Biostatistician

1U01 CA151925-01 (Moses) 10/01/10-06/30/15
NIH
Role of fibroblasts, myeloid cells, and matrix in PDAC
The major goal of the Vanderbilt portion of this cooperative project is to characterize $Kras^{G12D}$ mice with and without attenuation of TGFb signaling, specifically with regard to chemokine/cytokine expression, myeloid-immune cell (MIC) infiltration, and ability of MIC populations to enhance tumor progression.
Role: Co-investigator

5R01 CA113519-05 (Datta) 03/01/06-01/31/11
NCI
Targeting TGF- ß signaling in lung cancer
The major goal of this project is to understand the molecular mechanism by which lung cancers become resistant to TGF-ß tumor suppressor function and provide new insights into the mechanism by which HDIs target the TGF-ß pathway in lung cancer.
Role: Biostatistician

2011 Clinical Science Development Award (Kim) 07/01/11-06/30/14
DDCF
MicroRNAs in Myelodysplastic Syndrome
The major goal of this project is to define the role of miRNAs in the pathogenesis of MDS and in the response of patients to DNA methyltransferase inhibitors.
Role: Biostatistician

Lung SPORE CDA (Aldrich) 05/01/11-04/30/13
Lung SPORE CDA
Identifying pleiotropic genetic determinants of metformin response and lung cancer
The major goal of this project is to identify pleiotropic genetic variants contributing to the pharmacogenetics of metformin and lung cancer.
Role: Biostatistician

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Han K. Kang	Director Veterans Health Administration Environmental Epidemiology Service
eRA COMMONS USER NAME	

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY
Seoul National University, Seoul, Korea	BS	1967	Pharmacy
Seoul National University, School of Public Health	MPH	1971	Environmental Health
University of California, Los Angeles, CA	DrPH	1976	Environmental Health
University of California, Los Angeles, CA	Post-doc	1978	Environmental Epidemiology

A. Positions and Honors.

Professional Experience

1969-71 Senior Research Pharmacist, Dong-A Pharmaceutical Company, Seoul, Korea
1979-83 Senior Health Scientist, Occupational Safety and Health Administration, Washington, DC
1983- Director, Environmental Epidemiology Service, Veterans Health Administration, Department of Veterans Affairs, Washington, DC
2001- Director, War-Related Illness and Injury Study Center, VA Medical Center, Washington, DC

Other Experience and Professional Membership

1967-68 Deputy Commander, Medical Company, 93rd Regiment, 27th Infantry Division, ROK Army, Sachangri, Korea
1968-69 Director, Hospital Pharmacy, 105 Army Evacuation Hospital, ROK Army, Euzonbu, Korea
1985- Fellow, American College of Epidemiology
2000- Adjunct Associate Professor, The George Washington University, Department of Epidemiology and Biostatistics
2004- Adjunct Associate Professor of Preventive Medicine and Biometrics, Uniformed Services University of the Health Sciences

Honors

2004 Service to America Career Achievement Medal Finalist
2008 Presidential Rank Award

B. Selected Peer-Reviewed Publications. (selected from over 100 articles)

1. Valentine JL, **Kang HK**, Spivey GH. Selenium levels in human blood, urine, and hair in response to exposure via drinking water. Environ Res 17:347-55, 1978.
2. Valentine JL, **Kang HK**, Spivey GH. Arsenic levels in human blood, urine and hair in response to exposure via drinking water. Environ Res 20:24-32, 1979.
3. **Kang HK**, Infante PF, Carra JS. Occupational lead exposure and cancer. Science 207:935-6, 1980.
4. Blackwell M, **Kang HK**. Formaldehyde: evidence of carcinogenicity. Am Ind Hyg Assoc J 42:A34-35, 1981.
5. **Kang HK**, Breslin PP. Effects of military draft on mortality. N Engl J Med 315:454, 1986.
6. **Kang HK**, Weatherbee L, Breslin PP, Lee Y, Shepard BM. Soft tissue sarcomas and military service in Vietnam: a case comparison group analysis of hospital patients. J Occup Med 26:1215-8, 1986.
7. **Kang HK**, Enzinger F, Breslin P, Feil M, Lee Y, Shepard B. Soft tissue sarcoma and military service in Vietnam: a case-control study. J Natl Cancer Inst 79:693-9, 1987.
8. Breslin P, **Kang HK**, Lee Y, Burt V, Shepard BM. Proportionate mortality study of Army and Marine Corps veterans of the Vietnam War. J Occup Med 30:412-9, 1988.
9. Thomas TL, **Kang HK**. Mortality and morbidity among Army Chemical Corps Vietnam veterans: a preliminary report. Am J Ind Med 18:665-73, 1990.

10. Dalager, **Kang HK**, Burt VL. Non-Hodgkin's lymphoma among Vietnam veterans. J Occup Med 33:774-9, 1991.
11. **Kang HK**. Resources for epidemiologic research in Vietnam era veteran populations within the Department of Veterans Affairs. In: Epidemiology in Military and Veterans Populations. Washington, DC: National Academy Press, pp 97-103, 1991.
12. Thomas TL, **Kang HK**, Dalager NA. Mortality among women Vietnam veterans, 1973-1987. Am J Epidemiol 134:973-80, 1991.
13. Watanabe KK, **Kang HK**, Thomas TL. Mortality among Vietnam veterans: with methodological considerations. J Occup Med 33:780-5, 1991.
14. Bullman TA, **Kang HK**. The effects of mustard gas, ionizing radiation, herbicides, trauma, and oil smoke on US military personnel: the results of veterans studies. Annu Rev Public Health 15:69-90, 1994.
15. Bullman TA, **Kang HK**. Posttraumatic stress disorder and the risk of traumatic deaths among Vietnam veterans. J Nerv Ment Dis 182:604-10, 1994.
16. Dalager NA, **Kang HK**, Thomas Tl. Cancer mortality patterns among women who served in the military: the Vietnam experience. J Occup Med 37:604-10, 1995.
17. Blanck RR, Hiatt J, Hyams KC, **Kang HK** et al. Unexplained illnesses among Dessert Storm veterans: a search for causes, treatment, and cooperation. Arch Intern Med 155:262-8, 1995.
18. Dalager NA, **Kang HK**, Burt VL, Weatherbee L. Hodgkin's disease and Vietnam service. Ann Epidemiol 5:400-6, 1995.
19. Watanabe KK, **Kang HK**. Military service in Vietnam and the risk of death from trauma and selected cancer. Ann Epidemiol 5:407-412, 1995.
20. Watanabe KK, **Kang HK**, Dalager NA. Cancer mortality risk among military participants of a 1958 atmospheric nuclear weapons test. Am J Public Health 85:523-7, 1995.
21. Gray GC, Coate BD, Anderson CM, **Kang HK**, Berg SW, Wignall FS, Knoke JD, Barrett-Connor E. The postwar hospitalization experience of U.S. veterans of the Persian Gulf War. N Engl J Med 335:1505-13, 1996.
22. **Kang HK**. Feasibility of an edidemiologic study of submariners who received radium irradiation treatment. Otolaryngol Head Neck Surg 115:433-7, 1996.
23. **Kang HK**, Bullman TA. Mortality among U.S. veterans of the Persian Gulf War. N Engl J Med 335:1498-504, 1996.
24. Page WF, Mahan CM, **Kang HK**. Vital status ascertainment through the files of the Department of Veterans Affairs and the Social Security Administration. Ann Epidemiol 6:102-9, 1996.
25. Dalager ND, **Kang HK**. Mortality among Army Chemical Corps Vietnam veterans. Am J Ind Med 31:719-26, 1997.
26. Mahan CM, Bullman TA, **Kang HK**, Selvin S. A case-control study of lung cancer among Vietnam veterans. J Occup Environ Med 39:740-7, 1997.
27. **Kang HK**, Bullman TA. Counterpoint: negligible "healthy-warrior effect" on Gulf War veterans' mortality. Am J Epidemiol 148:324-5, 1998.
28. Gray GC, Hawksworth AW, Smith TC, **Kang HK**, Knoke JD, Gackstetter GD. Gulf War veterans' health registries. Who is most likely to seek evaluation? Am J Epidemiol 148:343-9, 1998.
29. Murphy FM, **Kang HK**, Dalager NA, Lee KY, Allen RE, Mather SH, Kizer KW. The health status of Gulf War veterans: lessons learned from the Department of Veterans Affairs Health Registry. Mil Med 164:327-31, 1999.
30. Bullman TA, **Kang HK**. A 50 year mortality follow-up of veterans exposed to low level chemical warfare agent, mustard gas. Ann Epidemiol 10;333-8, 2000.
31. Dalager NA, **Kang HK**, Mahan CM. Cancer mortality among the highest exposed U.S. atmospheric nuclear test participants. J Occup Environ Med 42:798-805, 2000.
32. Gray GC, Smith TC, **Kang HK**, Knoke JD. Are Gulf War veterans suffering war-related illnesses? Federal and civilian hospitalizations examined, June 1991 to December 1994. Am J Epidemiol 151:63-71, 2000.
33. **Kang HK**, Bullman TA, Mahan CM. A mortality follow-up study of WWII submariners who received nasopharyngeal radium irradiation treatment. Am J Ind Med 38:441-6, 2000.
34. **Kang HK**, Mahan CM, Lee KY, Magee CA, Murphy FM. Illnesses among United States veterans of the Gulf War: a population-based survey of 30,000 veterans. J Occup Environ Med 42:491-501, 2000.

35. **Kang HK**, Mahan CM, Lee KY, Magee CA, Mather SH, Matanoski G. Pregnancy outcomes among U.S. women Vietnam veterans. Am J Ind Med 38:447-54, 2000.
36. **Kang HK**, Bullman TA. Mortality among U.S. veterans of the Gulf War: seven year follow up. Am J Epidemiol 154:399-405, 2001.
37. **Kang HK**, Dalager NA, Needham LL, Patterson DG, Matanoski GM, Kanchanaraksa S, Lees PSJ. U.S. Army Chemical Corps Vietnam veterans health study: preliminary results. Chemosphere 43:943-9, 2001.
38. **Kang HK**, Mahan CM, Lee KY, Magee CA, Mather SH, Matanoski G. Pregnancy outcomes among U.S. Gulf War veterans: a population-based survey of 30,000 veterans. Ann Epidemiol 11:504-11, 2001.
39. **Kang HK**, Bullman TA, Macfarlane GJ, Gray GC. Mortality among US and UK veterans of the Persian Gulf War: a review. Occup Environ Med 59:794-9, 2002.
40. **Kang HK**, Mahan CM, Lee KY, Murphy FM, Simmens SJ, Young HA, Levine PH. Evidence for a deployment related Gulf War syndrome by factor analysis. Arch Environ Health 57:61-8, 2002.
41. Smith TC, Smith B, Ryan MA, Gray GC, Hooper TI, Heller JM, Dalager NA, **Kang HK**, Gackstetter GD. Ten years and 100,000 participants later: occupational and other factors influencing participation in US Gulf War health registries. J Occup Environ Med 44:758-68, 2002.
42. Hallman WK, Kipen HM, Diefenbach M, Boyd, K, **Kang H**, Leventhal H, Wartenberg D. Symptom patterns among Gulf War registry veterans. Am J Public Health 93:624-9, 2003.
43. **Kang HK**, Natelson BH, Mahan CM, Lee KY, Murphy FM. Post-traumatic stress disorder and chronic fatigue syndrome-like illness among Gulf War veterans: a population based survey of 30,000 veterans. Am J Epidemiol 157:141-8, 2003.
44. Young HA, Simmens SJ, **Kang HK**, Mahan CM, Levine PH. Factor analysis of fatiguing syndrome in Gulf War era veterans. J Occup Environ Med 45:1268-73, 2003.
45. Levine PH, Young HA, Simmens SJ, Koefie V, Rentz ED, Mahan CM, **Kang HK**. Is testicular cancer related to Gulf War deployment? Evidence from a pilot population-based study of Gulf War era veterans and cancer registries. Mil Med 170:149-53, 2004.
46. Mahan CM, **Kang HK**, Dalager NA, Heller JM. Anthrax vaccination and self-reported symptoms, functional status, and medical conditions in the National Health Survey of Gulf War Era Veterans and Their Families. Ann Epidemiol 14:81-8, 2004.
47. Schneiderman AI, Lincoln AE, Curbow BA, **Kang HK**. Racial variations in health communication needs of combat veterans. Am J Public Health 94:2074-6, 2004.
48. Smith TC, Jimenez DK, Smith B, Gray GC, Hooper TI, Gackstetter GD, Heller JM, Dalager NA, **Kang HK**, Hyams KC, Ryan MAK. The postwar hospitalization experience of Gulf War veterans participating in US health registries. J Occup Environ Med 46:386-97, 2004.
49. Bullman TA, Mahan CM, **Kang HK**, Page WF. Mortality in US Army Gulf War veterans exposed to 1991 Khamisiyah chemical munitions destruction. Am J Public Health 95:1382-8, 2005.
50. Eisen SA, **Kang HK**, Murphy FM, Blanchard MS, Reda DJ, Henderson WG, Toomey R, Jackson LW, Alpern R, Parks BJ, Klimas N, Hall C, Pak HS, Hunter J, Karlinsky J, Battistone MJ, Lyons MJ; Gulf War Study Participating Investigators. Gulf War veterans' health: medical evaluation of a U.S. cohort. Ann Intern Med 142:881-90, 2005.
51. Hooper TI, DeBakey SF, Lincoln A, **Kang HK**, Cowan DN, Gackstetter GD. Leveraging existing databases to study vehicle crashes in a combat occupational cohort: epidemiologic methods. Am J Ind Med 48:118-27, 2005.
52. **Kang HK**, Hyams KC. Mental health care needs among recent war veterans. N Engl J Med 352:1289, 2005.
53. **Kang HK**, Dalager NA, Mahan CM, Ishii E. The role of sexual assault on the risk of PTSD among Gulf War veterans. Ann Epidemiol 15:191-5, 2005.
54. Mahan CM, Page WF, Bullman TA, **Kang HK**. Health effects in Army Gulf War veterans possibly exposed to chemical munitions destruction at Khamisiyah, Iraq: Part I. Morbidity associated with potential exposure. Mil Med 170:935-44, 2005.
55. Page WF, Mahan CM, **Kang HK**, Bullman TA. Health effects in Army Gulf War veterans possibly exposed to chemical munitions destruction at Khamisiyah, Iraq: Part II. Morbidity associated with notification of porential exposure. Mil Med 170:945-51, 2005.

56. Blanchard MS, Eisen SA, Alpern R, Karlinsky J, Toomey R, Reda DJ, Murphy FM, Jackson LW, **Kang HK**. Chronic multisymptom illness complex in Gulf War I veterans 10 years later. Am J Epidemiol 163:66-75, 2006.
57. Gackstetter GD, Hooper TI, DeBakey SF, Johnson A, Nagaraj BE, Heller JM, **Kang HK**. Fatal motor vehicle crashes among veterans of the 1991 Gulf War and exposure to munitions demolitions at Khamisiyah: a nested case control study. Am J Ind Med 49:261-70, 2006.
58. Gray GC, **Kang HK**. Healthcare utilization and mortality among veterans of the Gulf War. Philos Trans R Soc Lond B Biol Sci 361:553-69, 2006.
59. **Kang HK**, Bullman TA, Taylor JW. Risk of selected cardiovascular diseases and posttraumatic stress disorder among former World War II prisoners of war. Ann Epidemiol 16:381-6, 2006.
60. **Kang HK**, Dalager NA, Needham LL, Patterson DG, Lees PSJ, Yates K, Matanoski GM. Health status of Army Chemical Corps Vietnam veterans who sprayed defoliant in Vietnam. Am J Ind Med 49:875-84, 2006.
61. Lincoln AE, Helmer DA, Schneiderman AI, Li M, Copeland HL, Prisco MK, Wallin MT, **Kang HK**, Natelson BH. The war-related illness and injury study centers: a resource for deployment-related health concerns. Mil Med 171:577-85, 2006.
62. Miller R, Costigan D, Young H, **Kang H**, Dalager N, Mathes R, Crawford H, Page W, Thaul S. Patterns of health care seeking of Persian Gulf War Registry members prior to deployment. Mil Med 171:370-5, 2006.
63. Toomey R, **Kang HK**, Karlinsky J, Baker D, Vasterling J, Alpern R, Reda D, Henderson W, Murphy F, Eisen S. Mental health of US Gulf War veterans 10 years after the war. Br J Psychiatry 190:385-93, 2007.
64. Schneiderman AI, Braver ER, **Kang HK**. Understanding sequelae of injury mechanisms and mild traumatic brain injury incurred during the conflicts in Iraq and Afghanistan: persistent postconcussive symptoms and posttraumatic stress disorder. Am J Epidemiol;167:1446-1452, 2008.
65. Cypel Y, **Kang H**. Mortality patterns among women Vietnam-era veterans: results of a retrospective study. Ann Epidemiol;18:244-252, 2008.
66. **Kang HK**, Bullman TA. The risk of suicide among U.S. veterans after returning from Iraq or Afghanistan war zones. JAMA 300:652-653, 2008.
67. **Kang HK**, Li B, Mahan CM, Eisen SA, Engel CC. Health of U.S. veterans of 1991 Gulf War: a follow-up survey in 10 years. J Occup Environ Med 51:401-410, 2009.

C. Current Research Support.

Veterans Administration (PI)
Longitudinal Epidemiologic Health Surveillance on the Mortality and Morbidity of OIF and OEF Veterans including Woman Veterans.

Veterans Administration Merit Review (PI)
Post war Mortality from Neurological Diseases in Gulf Veterans

Veterans Administration Merit Review (PI)
Evaluation of Dr. Stellman's Herbicide Exposure Reconstruction Model

Veteran's Administration Merit Review (PI)
Estimates of Cancer Prevalence in Gulf Veterans Using State Registries

Non-VA/Department of Defense (PI)
Longitudinal Health Study of Gulf War Veterans

Non-VA/Henry Jackson Foundation (Co-Investigator)
A Nested Case Control Study of Fatal Motor Vehicle Crashes among Gulf War Era Veterans

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Kopecky, Kenneth J	Full Member
eRA COMMONS USER NAME kkopecky	

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

INSTITUTION AND LOCATION	DEGREE (*if applicable*)	YEAR(s)	FIELD OF STUDY
University of California, Los Angeles, CA	BA	1971	Mathematics
Oregon State University, Corvallis, OR	MS	1975	Statistics
Oregon State University, Corvallis, OR	PhD	1977	Statistics

A. Personal Statement

I have long experience in radiation epidemiology and dose reconstruction, having been a research associate at the Radiation Effects Research Foundation in Hiroshima, Japan; a co-investigator of the Hanford Thyroid Disease Study, case-control studies of leukemia and thyroid cancer in populations exposed to Chernobyl fallout, an ongoing case-control study of breast cancer in residents of Bryansk Oblast, Russia, and an ongoing project to develop functional methods for dose-response analyses with uncertain exposure measurements; and a member of the Technical Steering Panel of the Hanford Environmental Dose Reconstruction Project, of the National Research Council's Committee on Dosimetry for the Radiation Effects Research Foundation, of the WHO/Chernobyl Forum's Expert Group on Health, and of the ongoing Scientific Committee 6-4 (Fundamental Principles of Dose Reconstruction) of the National Council on Radiation Protection and Measurement.

B. Positions and Honors - Positions and Employment

1977-1978	Senior Fellow, Dept of Biostatistics, Univ of Washington, Seattle, Washington.
1977-1978	Postdoctoral Trainee, Program in Epidemiology & Biostatistics, Fred Hutchinson Cancer Research Center, Seattle, Washington.
1978-1980	Associate, Program in Epidemiology & Biostatistics, Fred Hutchinson Cancer Research Center, Seattle, Washington.
1978-1980	Affiliate Assistant Professor, Dept of Biostatistics, Univ of Washington, Seattle, Washington.
1980-1985	Research Assistant Professor, Dept of Biostatistics, Univ of Washington, Seattle, Washington.
1980-1985	Assistant Member, Fred Hutchinson Cancer Research Center, Seattle, Washington.
1982-1985	Research Associate, Radiation Effects Research Foundation, Hiroshima, Japan.
1985-1991	Associate Member, Fred Hutchinson Cancer Research Center, Seattle, Washington.
1985-1993	Research Associate Professor, Dept of Biostatistics, Univ of Washington, Seattle, Washington.
1993-1994	Affiliate Associate Professor, Dept of Biostatistics, Univ of Washington, Seattle, Washington.
1991-present	Member, Fred Hutchinson Cancer Research Center, Seattle, Washington.
1994-present	Affiliate Professor, Dept of Biostatistics, Univ of Washington, Seattle, Washington.

C. Selected peer-reviewed publications (in chronological order).

1. Shakhtarin VV, Tsyb AF, Stepanenko VF, Orlov MY, Kopecky KJ, Davis S. Iodine deficiency, radiation dose, and the risk of thyroid cancer among children and adolescents in the Bryansk region of Russia following the Chernobyl power station accident. Int J Epidemiol 32(4):584-591, 2003.
2. Stram DO, Kopecky KJ. Power and uncertainty analysis of epidemiologic studies of radiation-related disease risk in which dose estimates are based on a complex dosimetry system: some observations. Radiat Res 160(4):408-417, 2003.
3. Kopecky KJ, Davis S, Hamilton TE, Saporito MS, Onstad LE. Estimation of thyroid radiation doses for the Hanford Thyroid Disease Study: results and implications for statistical power of the epidemiological analyses. Health Phys 87(1):15-32, 2004.
4. Davis S, Stepanenko V, Rivkind N, Kopecky KJ, Voillequé P, Shakhtarin V, Parshkov E, Kulikov S, Lushnikov E, Abrosimov A, Troshin V, Romanova G, Doroschenko V, Proshin A, Tsyb A. Risk of thyroid cancer in the Bryansk Oblast of the Russian Federation after the Chernobyl Power Station accident. Radiat Res 162:241-248, 2004.
5. McCarthy PL, Jr, Paltiel O, Maslova E, Kulikov S, Hahn T, Kopecky KJ, Drozdova V, Shmatina N, Tichonova L, Van Hoff J, Gavrilova I, Weinstein H. Histopathologic verification of acute leukemia (AL) in a

cohort of 463 post-Chernobyl patients from Belarus, Russia and Ukraine. Leuk Res 28(12):1273-1280, 2004.
6. Davis S, Kopecky KJ, Hamilton TE, Onstad L, Hanford Thyroid Disease Study Team. Thyroid neoplasia, autoimmune thyroiditis, and hypothyroidism in persons exposed to iodine 131 from the Hanford Nuclear Site. JAMA 292(21):2600-2613, 2004.
7. Kopecky KJ, Onstad L, Hamilton TE, Davis S. Thyroid ultrasound abnormalities in persons exposed during childhood to 131I from the Hanford Nuclear Site. Thyroid 15(6):604-613, 2005.
8. Hamilton TE, Davis S, Onstad L, Kopecky KJ. Hyperparathyroidism in persons exposed to iodine-131 from the Hanford nuclear site. J Clin Endocrinol Metab 90(12):6545-6548, 2005.
9. Davis S, Day RW, Kopecky KJ, et al. Childhood leukaemia in Belarus, Russia, and Ukraine following the Chernobyl power station accident: results from an international collaborative population-based case-control study. Int J Epidemiol 35(2):386-396, 2006.
10. Cardis E, Howe G, Ron E, Bebeshko V, Bogdanova T, Bouville A, Carr Z, Chumak V, Davis S, Demidchik Y, Drozdovitch V, Gentner N, Gudzenko N, Hatch M, Ivanov V, Jacob P, Kapitonova E, Kenigsberg Y, Kesminiene A, Kopecky KJ, et al. Cancer consequences of the Chernobyl accident: 20 years on. J Radiol Prot 26:127-140, 2006.
11. Kopecky KJ, Stepanenko V, Rivkind N, Voillequé P, Onstad L, Shakhtarin V, Parshkov E, Kulikov S, Lushnikov E, Abrosimov A, Troshin V, Romanova G, Doroschenko V, Proshin A, Tsyb, A, Davis S. Childhood thyroid cancer, radiation dose from Chernobyl, and dose uncertainties in Bryansk Oblast, Russia: a population-based case-control study. Radiat Res 166:367-374, 2006.
12. Kimmel RR, Zhao LP, Nguyen D, Lee S, Aronszajn M, Cheng C, Troshin VP, Abrosimov A, Delrow J, Tuttle RM, Tsyb AF, Kopecky KJ, Davis S, Neiman PE. Microarray comparative genomic hybridization reveals genome-wide patterns of DNA gains and losses in post-Chernobyl thyroid cancer. Radiat Res 166(3):519-531, 2006.
13. Appelbaum FR, Kopecky KJ, Tallman MS, Slovak ML, Gundacker HM, Kim HT, Dewald GW, Kantarjian HM, Pierce SR, Estey EH. The clinical spectrum of adult acute myeloid leukaemia associated with core binding factor translocations. Br J Haematol 135:165-173, 2006. PMID: 16939487
14. Stram DO, Thomas DC, Kopecky KJ. Re: Hypothesis testing, statistical power, and confidence limits in the presence of epistemic uncertainly. Health Physics 93(4):326-327, 2007. PMID: 17846531
15. Stirewalt DL, Meshinchi S, Kopecky KJ, Fan W, Pogosova-Agadjanyan EL, Engel JH, Cronk MR, Dorcy KS, McQuary AR, Hockenbery D, Wood N, Heimfeld S, Radich JP. Identification of genes with abnormal expression changes in acute myeloid leukemia. Genes Chromosomes Cancer 47:8-20, 2008. PMID: 17910043
16. Pullarkat V, Slovak ML, Kopecky KJ, Forman SJ, Appelbaum FR. Impact of cytogenetics on the outcome of adult acute lymphoblastic leukemia: results of Southwest Oncology Group 9400 study. Blood 111(5):2563-2572, 2008. PMID: 18156492, PMCID: 2254550
17. Davis S, Onstad L, Kopecky KJ, Wiggins C, Hamilton TE. Locating members of a cohort identified retrospectively from limited data in 50-year-old records: Successful approaches employed by the Hanford Thyroid Disease study. Ann Epidemiol 18(3):187-195, 2008. PMID: 18201901
18. Tuttle RM, Lukes Y, Onstad L, Lushnikov E, Abrosimov A, Troshin V, Tsyb A, Davis S, Kopecky KJ, Francis G. ret/PTC activation is not associated with individual radiation dose estimates in a pilot study of neoplastic thyroid nodules arising in Russian children and adults exposed to Chernobyl fallout. Thyroid 18(8):839-846, 2008. PMID: 18690796 PMCID: PMC2857448
19. Schwartz JL, Kopecky KJ, Mathes RW, Leisenring WM, Friedman DL, Deeg HJ. Basal cell skin cancer after total-body irradiation and hematopoietic cell transplantation. Radiat Res 171(2):155-163, 2009. PMCID: PMC2662700
20. Becker PS, Kopecky KJ, Wilks AN, Chien S, Harlan JM, Willman CL, Petersdorf SH, Stirewalt DL, Papayannopoulou T, Appelbaum FR. Very late antigen-4 function of myeloblasts correlates with improved overall survival for patients with acute myeloid leukemia. Blood 113(4):866-874, 2009. PMID: 18927435, PMCID: 2630271
21. Ho PA, Alonzo TA, Kopecky KJ, Miller KL, Kuhn J, Zeng R, Gerbing RB, Raimondi SC, Hirsch BA, Oehler V, Hurwitz CA, Franklin JL, Gamis AS, Petersdorf SH, Anderson JE, Reaman GH, Baker LH, Willman CL, Bernstein ID, Radich JP, Appelbaum FR, Stirewalt DL, Meshinchi S. Molecular alterations of the IDH1 gene in AML: a Children's Oncology Group and Southwest Oncology Group study. Leukemia 24(5):909-913, 2010. PMID: 20376086
22. McDougall JA, Sakata R, Sugiyama H, Grant E, Davis S, Nishi N, Soda M, Shimizu Y, Tatsukawa Y, Kasagi F, Suyama A, Ross P, Kopecky KJ, Li CI. Timing of menarche and first birth in relation to risk of breast cancer in A-bomb survivors. Cancer Epidemiol Biomarkers Prev 19(7):1746-1754, 2010. PMID: 20570914

23. De Roos AJ, Deeg HJ, Onstad L, Kopecky KJ, Aiello Bowles EJ, Yong M, Fryzek J, Davis S. Incidence of myelodysplastic syndromes within a nonprofit healthcare system in western Washington state, 2005-2006. Am J Hematol 85(10):765-770, 2010. PMID: 20815079
24. Li CI, Nishi N, McDougall JA, Semmens EO, Sugiyama H, Soda M, Sakata R, Hayashi M, Kasagi F, Suyama A, Mabuchi K, Davis S, Kodama K, Kopecky KJ. Relationship between radiation exposure and risk of second primary cancers among atomic bomb survivors. Cancer Res 70(18):7187-7198, 2010. PMCID: PMC2941904

D. Research Support - Ongoing & Completed Research Support

1. **5 U10 CA38926 (Crowley)** 01/01/2010 – 12/31/2015
National Institutes of Health/National Cancer Institute
Southwest Oncology Group Statistical Center/FHCRC
The Southwest Oncology Group is a national consortium of institutions and investigators organized to improve survival of cancer patients through clinical research. The Statistical Center staff assist with study protocols, manage and edit study data, generate semiannual reports of findings, and conduct workshops on data management activities. They also research statistical aspects of Group studies and analyze and publish study results. Several programs previously funded via the Group Operations Office/Cancer Therapy and Research Center are included here: Cooperative Group Outreach Program (CGOP), Pathology Central Office, Urologic Cancer Outreach Program (UCOP), CTEP Minorities Program, High Priority Clinical Trials and Leukemia Biology. Role: Biostatistician

2. **RO1 CA114563-02 (Meshinchi)** 08/01/2005 – 07/31/11
National Cancer Institute *08/01/11-03/31/12
Biology and Prognostic Implications of FLT3 Mutations in Acute Myelogenous Leukemia (AML) *interim funding
This study will evaluate the prognostic significance of mutations of the FLT3 gene, mutations of RTK/Ras signal transduction pathway, as well as the FLT3 transcriptome levels in multi-institutional pediatric and adult AML trials. Role: Co-investigator

3. **R01 CA118914-01A2 (Davis)** 09/26/2007 – 07/31/2012
National Cancer Institute/National Institutes of Health
Breast Cancer Risk and Molecular Change After Chernobyl
This study will investigate whether individual radiation dose to the breast from the Chernobyl accident is associated with breast cancer risk, and to evaluate the relationship of breast cancer phenotype and genotype to radiation dose by comparing rates of inactivating genetic or epigenetic changes in 14 selected DNS repair genes to radiation dose. Role: Co-investigator

4. **VUMC AWOA (John D Boice, Jr, PI)** 04/01/10 – 03/31/15
Vanderbilt University Medical Center
Mortality among Military Participants at US Nuclear Weapons Tests
A new mortality follow-up and comprehensive dose reconstruction to assess the risk of cancer among 120,000 United States military personnel who participated in any of seven aboveground atmospheric weapons tests at the Nevada Test Site (NTS) and the Pacific Proving Grounds between 1946 and 1958, is proposed in conjunction with an NIH R01 grant application to be submitted by Vanderbilt University Medical Center. Role: Co-investigator

5. **R01 TE 5047 (Oehler)** 07/01/2009 – 06/30/2014
NIH/NCI
Integrating Diagnostics with Therapeutic Strategies in Chronic Myeloid Leukemia
1). Identify and validate diagnostic genomic predictors of early CML progression and therapy resistance. 2). Optimize and test sensitive strategies to detect resistance in patients on TKI therapy.
3). Examine the role of select candidates in disease progression and therapy resistance.
Role: Co-investigator

6. **R21 TE 5010 (Stirewalt)** 12/01/2009 – 11/30/2011
NIH/NCI
An Examination of IRF8 as a Biomarker of Aging, Malignant Transformation, and Prognosis
Research that decreased IRF8 expression in aging HPC/HSCs causes myeloid skewing in older adults and the expansion of pre-malignant clones that have the potential to transform into overt myeloid malignancies with additional genetic hit. Dr. Kopecky will collaborate in the design, conduct, analysis and reporting of studies in support of these aims. Role: Co-investigator

7. **R01 ES0173030 (Wang)** 07/01/2010 – 05/30/2013
NIH/ES
Functional Methods for Radiation Exposure and Biomarker Data
The overall goals of this research are to investigate innovative methods for estimating dose-response relationships when exposure is measured with error and biomarker data correlated with exposure are available. Role: Co-investigator

8. **DSA S9031-S9333-S0112-S0301-A (Kopecky)** 04/01/2011 – 03/31/2012
SWOG-CTI (Nodality S9031-S9333-S0112-S0301-A)
Proteomic Signature Associated with Clinical Response to Cytarabine Based Induction Therapy in Patients with AML 56 Years and Older
The goal of this project is to collaborate with investigators at Nodality, Inc. to develop an in vivo multiparameter flow cytometry-based cell signaling signature predictor of response to cytarabine-based chemotherapy for older patients with acute myeloid leukemia. Role: PI

9. **DSA S0106-A (Kopecky)** 08/16/11 – 07/15/12
SWOG-CTI (Nodality S0106-A)
Proteomic Signatures Associated with Complete Response (CR) and Complete Continuous Response at One Year (CCR1) Following Cytarabine-Based Induction Chemotherapy in Younger Adult Patients (18-60 Years of Age) with a Newly Diagnosed Non-M3 AML
The goal of this project is to collaborate with investigators at Nodality, Inc. to develop an in vivo multiparameter flow cytometry-based cell signaling signature predictor of outcomes following cytarabine-based chemotherapy for younger patients with acute myeloid leukemia. Role: PI

10. **SWOG CTI S0325 (Kopecky)** 09/01/2009 – 12/31/2011
SWOG-CTI (Bristol Myers Squibb)
S0325 "A Phase IIb Study of Molecular Responses to Imatinib at Standard or Increased Doses, or Dasatinib for Previously Untreated Patients with Chronic Myelogenous Leukemia (CML) in Chronic Phase"
Develop, in collaboration with BMS and CRAB personnel, the plans for each of three transfers of data for the selected patients on study S0325: (1) a test data set of registration, eligibility and adverse event data, for the Company to use in developing programs for its analysis of the data; (2) a complete set of data regarding registration, eligibility and adverse event data: and (3) a complete data set including registration, eligibility and adverse event data, along with treatment outcomes (response, survival, relapse-free survival).
Role: PI

C1. **R01 CA092553-03 (Davis)** 07/01/2003 – 06/30/2009
National Institutes of Health/National Cancer Institute
Molecular Change and Thyroid Cancer Risk After Chernobyl
This project is designed to investigate the occurrence and molecular characteristics of thyroid cancer in residents of the Bryansk Oblast of the Russian Federation who were exposed to radiation from the Chernobyl power station accident in 1986. Role: Co-investigator

C2. **1 U01 CA114762-01 (Willman)** 09/15/2005 – 08/31/2010

National Cancer Institute

SPECS: Leukemia Signatures for Risk Classification and Targeting

Dr. Kopecky will lead the Fred Hutchinson Cancer Research Center's participation in this multi-Institutional research program, which will include the investigation of gene expression profiles of adult ALL and AML patients registered to clinical trials of the Southwest Oncology Group.

Role: Principal Investigator

C3. **HHSN268200900008C (De Roos)** 01/15/2009 – 01/14/2011

National Heart, Lung and Blood Institute (NHLBI)

Markers of B-Cell Stimulation as Potential Predictors of Non-Hodgkin Lymphoma

The project goal is to design and execute a case-control study of non-Hodgkin lymphoma (NHL) nested within the Women's Health Initiative Observational Study cohort to test whether biologic markers measured in serum/plasma/DNA that are indicative of a B-cell stimulatory host environment are predictive of B-cell NHL incidence. Markers to be measured among 500 cases and 500 pair-matched controls include cytokines (e.g., IL6, IL10, TNFα), cytokine-like molecules (sCD23), soluble cytokine receptors (sCD27, sCD30) and other molecules involved in B-cell response (sCD44, CXCL13), as well as EBV DNA load and antibodies to key EBV antigens (VCA, EBNA1, and EA-D).

Role: Co-investigator

Principal Investigator/Program Director (Last, First, Middle):

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME **Roy E Shore**	POSITION TITLE Vice Chairman and Chief of Research
eRA COMMONS USER NAME SHORER01	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Houghton College	BA	1962	Psychology
Syracuse University	PhD	1967	Psychology
Columbia University	DPH	1982	Epidemiology

A. Positions and Honors.

Positions and Employment

1967-1969 USPHS Post-doctoral Research Fellowship

1969-1987 Ranks of Associate Research Scientist to Associate Professor, Dept. of Environmental Medicine, New York University School of Medicine, New York, NY

1987-2006 Professor, Dept. of Environmental Medicine, New York University School of Medicine, New York, NY.

1996-2006 Director, Division of Epidemiology, Dept. of Environmental Medicine, New York University School of Medicine, New York, NY.

2002-2006 Director, Cancer Epidemiology and Prevention Program, New York University Cancer Institute, New York, NY.

2006- Vice Chairman and Chief of Research, Radiation Effects Research Foundation, Hiroshima, Japan.

Honors and Awards

2002- Lifetime National Associate, National Academy of Sciences

1982- Fellow, American College of Epidemiology,

1986-94 MERIT grant award from NIH

National and International Committees

2011- UNSCEAR, Working group on risks from childhood radiation exposure (United Nations Scientific Committee on the Effects of Atomic Radiation)

2005-2008 NAS-NRC, Committee on Health Risks of Depleted Uranium (National Academy of Sciences-National Research Council)

2003 WHO, Chairman, Expert Group on Chernobyl Thyroid Studies (World Health Organization)

2002-2004 UNSCEAR, Cancer Epidemiology Consultant (United Nations Scientific Committee on the Effects of Atomic Radiation)

1998-2002 EPA, Science Advisory Board (Environmental Protection Agency)

1993-2008 ICRP, Standing Committee on Radiation Biology, Epidemiology and Risk Assessment (International Commission on Radiological Protection)

Principal Investigator/Program Director (Last, First, Middle):

1991-2003 NAS-NRC, Committee on CDC Radiation Studies (National Academy of Sciences-National Research Council)

2000-2001 NAS-NRC, Committee to Review the NIH/CDC Radioepidemiology Tables (National Academy of Sciences – National Research Council)

1998-2003 ICRP, Task Group on the Effects of *In Utero* Radiation (International Commission on Radiological Protection)

1998-2002 NCI, Binational Oversight Committee for Studies of Post-Chernobyl Thyroid Disease in Belarus and Ukraine (National Cancer Institute)

1995-2001 NCRP, Scientific Committee 1-6 on Radiation Low-dose Linearity (National Council on Radiation Protection and Measurements)

1994-2001 NCRP, Standing Committee 1: Radiobiology, Epidemiology, Risk and Basic Radiation Protection (National Council on Radiation Protection and Measurements)

Editorial Boards

Journal of the National Cancer Institute, Editorial Advisory Board (1988-1998)
Cancer Epidemiology, Biomarkers and Prevention, Editorial Advisory Board (1991-2001)
Regulatory Toxicology and Pharmacology, Editorial Board (1992-2000)
Radiation Research, Associate Editor (2002-2007)

Reviewer for Journals

Nature; New England Journal of Medicine; Nature Cancer Reviews; Journal of the American Medical Association; Lancet; American Journal of Epidemiology; Journal of the National Cancer Institute; Cancer; Cancer Epidemiology, Biomarkers and Prevention; Radiation Research; International Journal of Cancer; British Journal of Cancer; British Journal of Industrial Medicine; Regulatory Toxicology and Pharmacology; Epidemiologic Reviews; Health Physics; American Journal of Public Health; Cancer Causes and Control

Membership in Elected Groups

Fellow, American College of Epidemiology (1982-Present).
National Council on Radiation Protection and Measurements (1983-2008).
International Commission on Radiological Protection, Standing Committee I: Radiation Health Effects (1993-2008)

Membership in Professional Societies

Society for Epidemiologic Research
American College of Epidemiology
American Society of Preventive Oncology
American Association for Cancer Research
Radiation Research Society

B. Selected Publications (out of over 240).

1. **Shore RE**, Moseson MM, Xue X, Tse, Y, Harley N, Pasternack BS. Skin cancer following x-ray treatment for scalp ringworm. *Radiat Res,*, 2002; 157:410-18.

2. Preston DL, Mattsson A, Holmberg E, **Shore RE**, Hildreth NG, Boice JD. Radiation effects on breast cancer risk: a pooled analysis of eight cohorts. *Radiat Res,* 2002; 158:220-235.

3. Xue X, **Shore RE**. A method for estimating occupational radiation doses subject to minimum detection levels. *Health Phys,* 2003; 84:61-71.

Principal Investigator/Program Director (Last, First, Middle):

4. NAS-NRC, (Schull WJ, Boecker BB, Brill AB, Carter MW, Clark SB, Crouch EAC, Friedman SM, Higley KA, Lederer SE, Levenson M, Paretzke HG, Scott BR, **Shore RE**, Stram DO). *Exposure of the American Population to Radioactive Fallout from Nuclear Weapons Tests. A review of the CDC-NCI draft report on a feasibility study.* Washington, DC: National Academies Press; 69 pp., 2003.

5. **Shore RE**. Human evidence on the effects of in utero radiation exposure on neurological and mental processes. In: *Biological Effects after Prenatal Irradiation. Annals ICRP* (International Commission on Radiological Protection), 2003, 33:103-124.

6. **Shore RE**. Human carcinogenic risk from in utero irradiation. In: *Biological Effects after Prenatal Irradiation. Annals ICRP* (International Commission on Radiological Protection), 2003, 33:153-185.

7. **Shore RE**, Moseson MM, Harley N, Pasternack BS. Tumors and other diseases following childhood x-ray treatment for ringworm of the scalp (tinea capitis). *Health Phys*, 2003, 85:404-408.

8. Streffer C, **Shore R**, Konermann G, Meadows A, Uma Devi P, Preston J, Withers J, Holm LE, Stather J, Mabuchi K. Biological effects after prenatal irradiation (embryo and fetus). A report of the International Commission on Radiological Protection. *Ann ICRP.* 33:5-206, 2003.

9. Xue X, **Shore RE**, Ye X, Kim M. Estimating the dose response relationship for occupational radiation exposure measured with minimum detection level. *Health Phys*, 2004; 87:397-404.

10. Burns FJ, Samet JM, Rossman TG, Zhang R, Wu F, Uddin AN, **Shore RE**. Radiation carcinogenesis: mechanisms of induction. In: Environmental and Occupational Medicine, 4th edition (Eds: Rom WN, Markowitz S), Baltimore, MD:Lippincott, Williams & Wilkins, pp. 1258-1272, 2006.

11. Cardis E, Howe G, Ron E, Balonov M, Bebeshko V, Buglova E, Bogdanova T, Bouville A, Carr Z, Chumak V, Davis S, Demidchik Y, Drozdovitch V, Gentner N, Gudzenko N, Hatch M, Ivanov V, Jacob P, Kapitonova E, Kenigsberg J, Kesminiene A, Kopecky K, Kryuchkov V, Likhtarev I, Loos A, Pinchera A, Reiners C, Repacholi M, Shibata Y, **Shore R**, Thomas G, Tirmarche M, Wachholz B, Yamashita S, Zvonova I. Cancer consequences of the Chernobyl accident: 20 years after. *J Radiat Protect*, 2006; 26:127-40.

12. Xue X, Kim MY, **Shore RE**. Estimation of health risks associated with occupational radiation exposure: Addressing measurement error and minimum detectable exposure level. *Health Physics*, 2006; 91:582-91.

13. Worgul BV, Kundiyev YI, Sergiyenko NM, Chumak VV, Vitte PM, Medvedovsky CP, Bakhanova EV, Junk AK, Kyrychenko OY, Musijachenko NV, Shylo SA, Vitte OP, Xu S, Xue X, **Shore RE.** Cataracts among Chernobyl clean-up workers: implications regarding permissible eye exposures. *Radiat Res*, 2007; 167:233-43.

14. Chumak VV, Worgul BV, Kundiyev YI, Sergiyenko NM, Vitte PM, Medvedovsky CP, Bakhanova EV, Junk AK, Kyrychenko OY, Musijachenko NV, Sholom SV, Shylo SA, Vitte OP, Xu S, Xue X, **Shore RE**. Dosimetry for a study of low-dose radiation cataracts among Chernobyl clean-up workers. *Radiat Res*, 2007; 167:606-14.

15. Neriishi K, Nakashima E, Minamoto A, Fujiwara S, Akahoshi M, Mishima HK, Kitaoka T, **Shore R.** Postoperative cataract cases among atomic bomb survivors: radiation dose response and threshold. *Radiat Res*, 2007, 168:404-408.

16. Preston D, Cullings H, Suyama A, Funamoto S, Nishi N, Soda M, Mabuchi K, Kodama K, Kasagi F, **Shore RE**. Solid cancer incidence in atomic bomb survivors exposed in utero or as young children. *J Natl Cancer Inst.* 2008; 100:428-36.

17. NAS-NRC Committee (including **Shore RE**). Review of the Toxicologic and Radiologic Risks to Military Personnel from Exposures to Depleted Uranium During and After Combat. Washington, DC: National Academies Press, 2008, 154 pp.

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Richard Wakeford received a BSc in physics and a PhD in sub-nuclear physics from the University of Liverpool. He worked for British Nuclear Fuels Ltd (BNFL) for almost 30 years before taking early retirement in 2006; for much of this time he was concerned with the risks posed by low level exposure to radiation, and he has written and lectured extensively on the subject. In 1994 he received the Founder's Prize of the Society for Radiological Protection for "contributions of distinction to radiological protection". Richard is currently Visiting Professor in Epidemiology at the Dalton Nuclear Institute of The University of Manchester and Editor-in-Chief of the Journal of Radiological Protection, a position he has held since 1997. He is also a member of the Editorial Board of the British Journal of Cancer. Richard was a member of the UK Government's Committee Examining Radiation Risks of Internal Emitters (CERRIE), and is presently a member of the UK Government's Committee on Medical Aspects of Radiation in the Environment (COMARE), of the European Commission's Expert Advisory Group established under Article 31 of the Euratom Treaty, and the Subgroup on Human Radiosensitivity of the Advisory Group on Ionising Radiation (AGIR) of the UK Health Protection Agency (HPA). He is a member of Committee 1 of the International Commission on Radiological Protection and has been a consultant to the United Nations Committee on the Effects of Atomic Radiation (UNSCEAR). Richard was a member of the UK Government's Scientific Advice Group for Emergencies (SAGE) for the Japan Nuclear Incident.

APPENDIX 6

OTHER ATTACHMENTS

Epidemiologic Study of One Million U.S. Radiation Workers and Veterans

This appendix includes the approvals that have already been obtained in the conduct of the "Epidemiologic Study of One Million U.S. Workers and Military Veterans Exposed to Ionizing Radiation" and Letters of Support from advisors and selected collaborators.

IRB and Other Approvals

- Institutional Review Board approvals
  - IRB approval for the One Million U.S. Worker and Veterans Study
  - IRB approval for the Atomic Veterans study
  - IRB approval for Rocketdyne worker study
  - IRB approval for Mound worker study

- Approval from the Department of Defense for access to the Atomic Veterans roster
- Approval from the Department of Energy for access to Uranium worker rosters
- Approval from the Department of Energy for access to Mound worker rosters
- Approval from the Department of Energy for access to REMS dosimetry databases
- Approval from the Department of Energy for access to Plutonium worker databases
- Approval from the Nuclear Regulatory Commission to access the REIRS database
- Approval from the National Institute of Diabetes and Digestive and Kidney Diseases to access the US Renal Data System
- Approval from the Department of Veterans Affairs to access VA data

Letters of Support

- Richard Wakeford, Manchester University, U.D.
- Roy Shore, Radiation Effects Research Foundation
- Laurie Wiggs, Los Alamos National Laboratory
- Craig Yoder, Landauer, Inc.
- R. J. Ritter, National Association of Atomic Veterans
- Howard Sesso, Harvard Medical School
- Clark Heath, Retired, American Cancer Institute, CDC, RERF

Vanderbilt University
Institutional Review Board
504 Oxford House Nashville, Tennessee 37232-4315
(615) 322-2918 Fax: (615) 343-2648
www.mc.vanderbilt.edu/irb

January 20, 2011

John D. Boice, Sc.D.
International Epidemiology Institute

Rockville, MD 20850

RE: IRB# 110024 "Epidemiologic Study of One Million U.S. Radiation Workers" (Department of Energy)

Dear John D. Boice, Sc.D.:

A sub-committee of the Institutional Review Board reviewed the research application identified above. The sub-committee determined the study poses minimal risk to participants, and the application is approved under 45 CFR 46.110 (F)(5). Approval is extended for the Application for Human Research and the Request for Waiver or Alteration of Consent dated January 13, 2011, and the Protocol dated January 3, 2011.

The informed consent process is waived in accordance with 45 CFR 46.116 (d).

As the Principal Investigator, you are responsible for the accurate documentation, investigation and follow-up of all possible study-related adverse events and unanticipated problems involving risks to participants or others. The IRB Adverse Event reporting policy III.G is located on the IRB website at http://www.mc.vanderbilt.edu/irb/.

If this trial requires registration as a clinical trial, accrual cannot begin until this study has been registered at clinicaltrials.gov and a National Clinical Trial Number (NCT) provided. Please provide the NCT# to the IRB as soon as it is obtained. If an approval is required from an additional source other than the Vanderbilt IRB, this must be obtained prior to study initiation. These approvals may include, but are not limited to CRC, SRC, IND, IDE.

Please note that approval is for a 12-month period. Any changes to the research study must be presented to the IRB for approval prior to implementation.

DATE OF IRB APPROVAL: January 20, 2011 DATE OF IRB EXPIRATION: January 19, 2012

Sincerely,

Lani A. Kajihara-Liehr

Lani A. Kajihara-Liehr, M.S.N., Vice-Chair
Institutional Review Board
Health Sciences Committee #2
LAK/pad
Electronic Signature: Lani Akiko Kajihara-Liehr/VUMC/Vanderbilt : (8A568BCF5954690C429F091091E627AF)
Signed On: 01/20/2011 08:16:24 PM CST

Vanderbilt University
Institutional Review Board
504 Oxford House Nashville, Tennessee 37232-4315
(615) 322-2918 Fax: (615) 343-2648
www.mc.vanderbilt.edu/irb

November 1, 2010

John D. Boice, Jr., Sc.D.
International Epidemiology Institute
1455 Research Blvd., Suite 550
Rockville, MD 20850

RE: IRB# 071228 "Cancer Mortality among Military Personnel at U.S. Nuclear Weapons Tests"

Dear John D. Boice, Jr., Sc.D.:

A sub-committee of the Institutional Review Board reviewed the Application for Continuing Review for the research study identified above. The sub-committee determined the study poses minimal risk to participants. This study meets 45 CFR 46.110 (F) category (5) for Expedited Review. Approval is extended for the Application for Continuing Review dated 10/21/2010, the Application for Human Research dated 11/01/2010, the Protocol dated 12/20/2007. The informed consent process is waived in accordance with 45 CFR 46.116 (d).

Please note, the IRB application dated 11/1/2010, has been revised to remove the sections that previously captured key study personnel (KSP) and contact information. DISCOVR-E now serves as your official record of this information.

As the Principal Investigator, you are responsible for the accurate documentation, investigation and follow-up of all possible study-related adverse events and unanticipated problems involving risks to participants or others. The IRB Adverse Event reporting policy III.G is located on the IRB website at http://www.mc.vanderbilt.edu/irb/.

Please note the requirement for annual VU IRB Human Subjects Training is not current or will soon expire for some key study personnel (KSP) associated with this study. It is the Principal Investigator's responsibility to ensure that all KSP have met the annual training requirement (see IRB Procedure VI.B.1). Please log in to DISCOVR-E at https://irb.mis.vanderbilt.edu/pls/htmldb/f?p=106:20, select the "Studies" tab and review the "IRB Training Status for Study Personnel" view to identify those needing to renew training. Those individuals may then access the CITI Basic and Refresher Courses at http://www.mc.vanderbilt.edu/irb/training/citi_instructions.php.

Please note that approval is for a 12-month period. Any changes to the research study must be presented to the IRB for approval prior to implementation.

DATE OF IRB APPROVAL: 11/01/2010 **DATE OF IRB EXPIRATION: 10/31/2011**

Sincerely,

James B. Atkinson, M.D., Ph.D., Vice-Chair
Institutional Review Board
Health Sciences Committee #1

JBA/ao
Electronic Signature: James Atkinson/VUMC/Vanderbilt : (53F618306DD90C220C0ACBE60D90BF7E)
Signed On: 11/01/2010 04:46:03 PM CDT

Vanderbilt University
Institutional Review Board
504 Oxford House Nashville, Tennessee 37232-4315
(615) 322-2918 Fax: (615) 343-2648
www.mc.vanderbilt.edu/irb

June 3, 2011

John D. Boice, Jr., Sc.D.
International Epidemiology Institute
1455 Research Blvd. Suite 550
Rockville, MD 20850

RE: IRB# 010018 "A Cohort Mortality Study of the Rocketdyne Workforce" (International Epidemiology Institute)

Dear John D. Boice, Jr., Sc.D.:

A sub-committee of the Institutional Review Board reviewed the Application for Continuing Review for the research study identified above. The sub-committee determined the study poses minimal risk to participants. This study meets 45 CFR 46.110 (F) category (5) and (7) for Expedited Review. Approval is extended for the Application for Continuing Review dated 6/1/2011, the Proposal Description Section dated December 20, 2000, and the General Information Section dated 6/2/2011.

Please note, the General Information Section of the IRB application has been revised to remove the sections that previously captured key study personnel (KSP) and contact information. DISCOVR-E now serves as the official record of this information.

It is the understanding of the IRB enrollment for the study is closed, therefore approval is not extended to the Consent Form(s). If enrollment should reopen, submission of an amendment and IRB approval would be required prior to any additional accrual. Federal regulations require the original copy of the participant's consent be maintained in the principal investigator's files and that a copy be given to the participant at the time of consent. An additional record (i.e., case report form, medical record, database, etc.) of the consent process should also be maintained in a separate location for documentation purposes.

As the Principal Investigator, you are responsible for the accurate documentation, investigation and follow-up of all possible study-related adverse events and unanticipated problems involving risks to participants or others. The IRB Adverse Event reporting policy III.G is located on the IRB website at http://www.mc.vanderbilt.edu/irb/.

Please note that approval is for a 12-month period. Any changes to the research study must be presented to the IRB for approval prior to implementation.

DATE OF IRB APPROVAL: 6/3/2011 DATE OF IRB EXPIRATION: 6/2/2012

Sincerely,

Lani A. Kajihara-Liehr

Lani A. Kajihara-Liehr, M.S.N., Vice-Chair
Institutional Review Board
Health Sciences Committee #2

LAK/dj
Electronic Signature: Lani Akiko Kajihara-Liehr/VUMC/Vanderbilt : (8A568BCF5954690C429F091091E627AF)
Signed On: 06/05/2011 11:52:52 PM CDT

Partnerships for Innovation
ORAU
OAK RIDGE ASSOCIATED UNIVERSITIES

Oak Ridge Site-wide Institutional Review Board (ORSIRB)
Telephone (865) 576-1725 Facsimile (865) 576-9557
Becky.Hawkins@orise.orau.gov

MEMORANDUM

DATE:	May 17, 2011
TO:	Elizabeth Ellis, Ph.D.
FROM:	Oak Ridge Site-Wide IRB (FWA #00005031)
STUDY TITLE:	[77519-7] Mortality Study of Mound Radiation Workers
IRB REFERENCE #:	ORAU(07)-140
SUBMISSION TYPE:	Continuing Review/Progress Report
ACTION:	APPROVED
APPROVAL DATE:	May 12, 2011
EXPIRATION DATE:	May 11, 2012
REVIEW TYPE:	Expedited Review

Thank you for your submission of Continuing Review/Progress Report materials for this research study. The Oak Ridge Site-Wide IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This study has received Expedited Review based on the applicable federal regulation as outlined in 45 CFR 46.110(b)(2). Waiver of documentation of informed consent continues to be approved.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

Please report all unanticipated events, NON-COMPLIANCE issues, or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

If you have any questions, please contact Becky Hawkins at 865-576-1725 or becky.hawkins@orise.orau.gov. Please include your study title and reference number in all correspondence with this office.

Defense Threat Reduction Agency
8725 John J. Kingman Road MSC 6201
Ft Belvoir, VA 22060-6201

JUN 1 2007

Dr. John D. Boice, Jr.
International Epidemiology Institute
1455 Research Boulevard, Suite 550
Rockville, MD 20850

Dear Dr. Boice:

Your request for access to the Nuclear Test Personnel Review (NTPR) Program's database of Five Series Study participants is approved. As with the previous collaboration (with the Institute of Medicine), the sharing of this information must conform to appropriate provisions of the Privacy Act, and the information must be safeguarded and secured from unauthorized access.

If my agency can provide additional support for your follow-up study, please contact Dr. Paul Blake at (703) 767-3384 or paul.blake@dtra.mil.

Sincerely,

James A. Tegnelia
Director

Defense Threat Reduction Agency
8725 John J. Kingman Road MSC 6201
Ft Belvoir, VA 22060-6201

JUN 1 2007

Dr. Rick Erdtmann
Director, Military and Veterans Health
Institute of Medicine
500 Fifth Street, NW
Washington, DC 20001

Dear Dr. Erdtmann:

The Defense Threat Reduction Agency (DTRA) sponsored "The Five Series Study: Mortality of Military Participants in U.S. Nuclear Weapons Tests," an Institute of Medicine study published in 2000 by the National Academy Press. My agency is interested in supporting a follow-up study on the mortality of this population. The principal investigator for the proposed study is Dr. John D. Boice, Jr., a Special Government Employee who currently serves as a member of the Congressionally mandated Veterans' Advisory Board on Dose Reconstruction.

To facilitate this study, I request that you provide DTRA with the database that was developed for the Five Series Study, including data on causes of death. My staff can accept your data in most formats, although Microsoft Access is preferred.

Per the Privacy Act of 1974, DTRA has documented that it maintains a system of records pertaining to U.S. atmospheric nuclear test participants (*Federal Register*, August 9, 2005), in part to support independent scientific studies or medical follow-up programs. This data is safeguarded and controlled in accordance with Department of Defense information assurance security policy.

If you have any questions or concerns, please contact Dr. Paul Blake of my staff at (703) 767-3384 or paul.blake@dtra.mil.

Sincerely,

James A. Tegnelia
Director

cc:
John D. Boice, Jr., International Epidemiology Institute
James A. Zimble, Chair, Veterans' Advisory Board on Dose Reconstruction

Department of Energy

Washington, DC 20585

February 5, 2009

John D. Boice, Jr., ScD
Professor
Vanderbilt University School of Medicine
D-3100D Medical Center North
Nashville, Tennessee 37232-2358

Dear Dr. Boice:

Thank you for your letter of June 20, 2008, requesting access to epidemiologic data on the Department of Energy contractor workforce. We are pleased to inform you that the Department has determined that an update of the cohort mortality study of uranium-processing workers is warranted.

Your voluntary contribution of data on uranium-exposed workers from the Rocketdyne study to the Comprehensive Epidemiologic Data Resource is much appreciated and reflects on our mutual interest in making these valuable data available to other investigators interested in potential health effects associated with radiation exposure.

We must ask you to forward a protocol for this work to Dr. Gerald Petersen, Acting Director of the Office of Illness and Injury Prevention Programs, for review prior to the release of any data. A member of our staff will work with you to address any technical aspects of your studies as needed, coordinate access to available data at the Oak Ridge Institute for Science and Education, and obtain Institutional Review Board approval as warranted. Please be advised that while the Office of Health and Safety is making access to these data available as a collaborator, no funding for this work is available or implied.

We must defer an answer to your request on tritium-exposed workers at this time.

We wish you success as you initiate this work.

Sincerely,

Patricia R. Worthington, PhD
Director
Office of Health and Safety
Office of Health, Safety and Security

Department of Energy
Washington, DC 20585

March 23, 2007

John Boice, ScD
Professor, Department of Medicine
Vanderbilt University School of Medicine
D-3100 Medical Center North
Nashville, Tennessee 37232-2358

Dear Dr. Boice:

I have received your request regarding access to the Mound worker data. Based on your proposal, it is your intent to update the cohort through 2005 as a pilot project for a larger study to update the radiation worker cohort data owned by the Department of Energy (DOE).

Disclosure of these records is available to you as a collaborating researcher under DOE-88, "Epidemiologic and Other Health Studies, Surveys and Surveillances," and DOE-35, "Personnel Radiation Exposure Records," under the Privacy Act of 1974. As such, you may disclose these records to Federal, State, or local health authorities or subcontractors for the purpose of determining vital status or cause of death. All recipients of such records are required to comply with the Privacy Act, to follow prescribed measures to protect personal privacy, and to disclose or use personally identifiable information only for the above described research purpose.

Access to these records does not imply any agreement of funding. As a collaborating partner, we require that a copy of the final analyses data file be made available to DOE's Comprehensive Epidemiologic Data Repository. A report of your findings to DOE, and a briefing, if requested, is required at the conclusion of the pilot. In the event that you consider the publication of your work in the scientific literature, a copy of that work is requested at the time of submission.

We look forward to a successful workshop, and hope this data provides you the information that you need to support your grant application.

Sincerely,

Bonnie S. Richter, PhD
Director
Office of Illness and Injury
Prevention Programs
Office of Health and Safety

cc: Betsy Ellis Dupree, ORISE

Department of Energy
Washington, DC 20585
August 19, 2009

MEMORANDUM FOR GLENN S. PODONSKY
CHIEF HEALTH, SAFETY AND SECURITY OFFICER
OFFICE OF HEALTH, SAFETY AND SECURITY

FROM: WILLIAM H. ROEGE
DIRECTOR William H. Roege
OFFICE OF CORPORATE SAFETY ANALYSIS
OFFICE OF HEALTH, SAFETY AND SECURITY

SUBJECT: ACTION: Signature on the Collaborative Agreement with Vanderbilt University, and the International Epidemiology Institute

ISSUE: The purpose of this Arrangement is to establish a framework for the Department of Energy (DOE) to provide available data from the DOE Radiation Exposure Monitoring System (REMS) on the total career radiation dose for each U.S. radiation worker included in the Uranium Worker Study.

DISCUSSION: International Epidemiology Institute and Vanderbilt University have recently received DOE approval to conduct a follow-up study on U.S. DOE uranium workers (see attached). The REMS dosimetry information will be essential to capture lifetime career doses for the Uranium workers.

POLICY IMPACT: None

SENSITIVITIES: The uses and disclosure of dosimetry data contains personal identifiers covered by DOE's System of Records, Number 35. The collaborative agreement is necessary to ensure that the disclosure is consistent with Privacy Act considerations.

RECOMMENDATION: Sign the attached two originals of the agreement

ATTACHMENTS:

ARRANGEMENT FOR COLLABORATION AMONG

THE DEPARTMENT OF ENERGY OF THE UNITED STATES OF AMERICA

AND VANDERBILT UNIVERSITY

AND THE INTERNATIONAL EPIDEMIOLOGY INSTITUTE

The Department of Energy of the United States of America (DOE), Vanderbilt University by and through its Medical Center (VU), and the International Epidemiology Institute (IEI), hereafter the "Parties":

Noting that IEI in cooperation with VU is conducting a study involving over 200,000 workers employed at various DOE past and present nuclear facilities, to evaluate the cancer risk associated with occupational exposures to ionizing radiation and uranium in particular;

Noting that the Uranium Worker Study has a documented protocol that requires each worker's radiation dose to be as complete as possible over the worker's entire career;

Noting that the Uranium Worker Study includes workers who were also included in other DOE worker cohorts such as the Hanford and Los Alamos National Laboratory cohorts;

Noting that the VU Institutional Review Board has approved the study;

Noting that IEI is responsible for conducting and preparing the vital status and dosimetry analysis files,

Have agreed as follows:

I. Purpose

A. The purpose of this Arrangement is to provide a framework for DOE to contribute data from the DOE Radiation Exposure Monitoring System (REMS), to provide as complete information as possible on the total career radiation dose for each U.S. radiation worker included in the Uranium Worker Study.

B. The Parties expect that a successful Uranium Worker Study will provide additional information about the health risk at low doses and low dose rates of occupational exposure to uranium (a radioactive element of current scientific interest).

II. Implementing Provisions

Pursuant to the Privacy Act, 5 U.S.C. 552a(b)(3), and under Routine Use Number 5 of DOE-35, Personnel Radiation Exposure Records, permits disclosure of these records to "contractors, grantees, participants in cooperative agreements, and collaborating researchers, or the employees of these parties, in performance of health studies or related health or environmental duties pursuant to their contracts, grants, and cooperating or collaborating research

agreements." Routine use number five also states that "[a]ll recipients of such records are required to comply with the Privacy Act, to follow prescribed measures to protect personal privacy, and to disclose or use personally identifiable information only for the above described research purposes."

A. DOE shall provide IEI and VU with dosimetry information, as recorded in REMS, for each worker identified as being included in the Uranium Worker Study.

B. IEI and VU shall use this information only for the above described research purposes.

C. IEI and VU shall maintain the confidentiality of the subject information and make no disclosure of it to third parties without the prior written consent of the DOE. If, during the examination of DOE-provided data, errors or omissions are found and corrected, these corrected data shall be provided back to DOE REMS.

D. IEI and VU's obligation to maintain the confidentiality of the DOE-provided information shall remain in effect throughout the term of this Arrangement and after its termination, unless and until the said information and all copies thereof are returned to DOE.

III. Contacts

The principal contact for DOE is Ms. Nirmala Rao, Office of Corporate Safety Analysis (HS-30). The principal contact for VU is Dr. John D. Boice, Jr., Professor of Medicine. The principal contact for IEI is Dr. Joseph K. McLaughlin, President.

IV. Management

The Parties shall consult each other whenever they deem it necessary, and shall assess the results of the work carried out and in progress.

V. General Provisions

A. This Arrangement shall become effective upon signature by all Parties, and shall remain in effect for one year. The Parties may extend this Arrangement for additional periods.

B. The terms of this Arrangement may be altered in writing by the Parties, at the mutual consent of the Parties. If any Party wishes to cease its activities under this Arrangement, it shall give ninety (90) days advance written notice to the other Parties.

C. Cooperation under this Arrangement shall be in accordance with the applicable laws and regulations under which each Party operates.

D. Unless otherwise agreed in writing, each Party shall assume responsibility for, and provide funding to cover, the costs individually incurred in participating in the collaboration contemplated by this Arrangement. The collaborative activities are subject to the availability of funds and personnel.

E. The Department of Energy enters into this Agreement under the authority of section 646 of the Department of Energy Organization Act (Pub. L. 95-91, as amended; 42 U.S.C. § 7256).

F. This Agreement in no way restricts any of the parties from participating in any activity with other public or private agencies, organizations, or individuals.

G. This Agreement is neither a fiscal nor a funds obligation document. Nothing in this Agreement authorizes or is intended to obligate the parties to expend, exchange, or reimburse funds, services, or supplies, or transfer or receive anything of value.

H. This Agreement is strictly for internal management purposes for each of the parties. It is not legally enforceable and shall not be construed to create any legal obligation on the part of either party. This Agreement shall not be construed to provide a private right or cause of action for or by any person or entity.

FOR THE DEPARTMENT OF ENERGY
OF THE UNITED STATES OF AMERICA:

______________________________ **Date:** 8/31/09

Glenn S. Podonsky
Chief Health, Safety and Security Officer
Office of Health, Safety and Security
Washington, D.C.

FOR VANDERBILT UNIVERSITY by and through its Medical Center:

Jennifer Pietenpol **Date:** 08.02.09

Dr. Jennifer A. Pietenpol
Director
Vanderbilt-Ingram Cancer Center
Nashville, TN

Authorized By:

______________________________ **Date:** 8/4/09

Libby D. Salberg
Director, Office of Grants and Contracts Management

FOR THE INTERNATIONAL EPIDEMIOLOGY INSTITUTE:

______________________________ **Date:** 8/4/09

Dr. Joseph K. McLaughlin
President
Rockville, MD

Attachment
IRB Approval

Department of Energy
Washington, DC 20585

October 27, 2010

John D. Boice, Jr., Sc.D.
Professor
Department of Medicine
Vanderbilt University School of Medicine
691 Preston Building
Nashville, Tennessee 37232-6858

Dear Dr. Boice:

Thank you for your letter of September 30, 2010, requesting access to epidemiologic data on the Department of Energy (DOE) contractor workforce. Your request for data on plutonium-processing workers has been approved.

We would like to congratulate you on receiving your grant from the DOE Office of Science (SC) to conduct a feasibility cohort mortality study of DOE workers. This is good news since some of these worker cohorts have not been updated for nearly 30 years. Dr. Noelle Metting, SC Senior Radiation Biologist, is working with Dr. Bonnie Richter, Office of Health and Safety Senior Epidemiologist, within the Office of Health, Safety and Security, to co-manage this project.

Dr. Richter will work with you to address any technical aspects of your studies as needed and coordinate access to available data at the Oak Ridge Institute for Science and Education.

Please be advised that while the Office of Health and Safety is making access to these data available as a collaborator, no funding for this work is available or implied.

Your contribution to the Comprehensive Epidemiologic Data Resource is much appreciated. Your effort reflects on our mutual interest in making these valuable data available to other investigators interested in potential health effects associated with radiation exposure.

We wish you success as you initiate this work.

Sincerely,

Patricia R. Worthington, PhD
Director
Office of Health and Safety
Office of Health, Safety and Security

Gmail

John Boice <john.boice@gmail.com>

Request for REIRS data for our Million Person Study

Lewis, Doris <Doris.Lewis@nrc.gov> **Fri, Dec 10, 2010 at 12:27 PM**
To: "Metting, Noelle" <noelle.metting@science.doe.gov>
Cc: "Richter, Bonnie" <Bonnie.Richter@hq.doe.gov>, "Katz, Arthur" <Arthur.Katz@science.doe.gov>, "John D Boice PhD (boice@iei.ws)" <boice@iei.ws>, "Hagemeyer, Derek" <Derek.Hagemeyer@orise.orau.gov>

Hi Noelle,

Thank you for sending me this email for collaborating with DOE, DoD, and John Boice on this study.

As you are aware, Mr. Derek Hagemeyer is the US NRC REIRS and DOE REMS Principal Investigator. I have included him on this email response so that he is also informed of this collaboration. I will have Mr. Hagemeyer work directly with Dr. Boice, or other identified IEI staff, for the specific REIRS data sets that are needed for this study.

I look forward to working with you on this project.

Sincerely,

Doris Lewis

Health Physicist

REIRS Project Manager

Office of Nuclear Regulatory Research

US Nuclear Regulatory Commission

301-251-7559

From: Metting, Noelle [mailto:noelle.metting@science.doe.gov]
Sent: Friday, December 10, 2010 10:00 AM
To: Lewis, Doris
Cc: Richter, Bonnie; Katz, Arthur; John D Boice PhD (boice@iei.ws)
Subject: Request for REIRS data for our Million Person Study

Doris Lewis

REIRS Project Manager

Office of Nuclear Regulatory Research

U.S. Nuclear Regulatory Commission

Mail Stop: CSB-3A07M

Washington, DC 20555

(301) 251-7559

doris.lewis@nrc.gov

Subject: Request for REIRS data for our Million Person Study

December 10, 2010

Dear Dr Lewis:

Dr. John Boice (International Epidemiology Institute and Vanderbilt University) asked that I contact you for permission to access the REIRS data for the research study entitled "Epidemiologic Study of One Million American Workers and Military Veterans Exposed to Radiation." This research is supported by the Office of Science (BER) U.S. Department of Energy (Grant no. DE-SC0004307).

The overall study is conducted in collaboration with the National Cancer Institute and the Department of Defense. The goal is to clarify the health risks following low dose radiation exposure experienced in the course of occupational employment or military service. It is the broadest epidemiologic study on human radiation effects ever envisioned and currently includes over 350,000 workers who were employed at 24 different DOE facilities, over 125,000 military veterans who participated at one of eight aboveground atmospheric weapon tests, over 50,000 early workers at nuclear power plants, and over 500,000 early medical radiation workers.

Key to the success of this study is comprehensive and complete dose determination of our workers and military veterans. We are following the approach used in the study of Rocketdyne (Atomics International) workers to obtain occupational exposure information from all sources, including government employment, military employment and civilian employment. The quality of this former study was enhanced by being able to access the REIRS data (Boice *et al.* A comprehensive dose reconstruction methodology for former Rocketdyne/Atomics International radiation workers. Health Phys 90:409, 2006).

We are thus requesting identified exposure information for workers employed at Department of Energy facilities, nuclear power plants, medical hospitals and facilities as well as military participants at nuclear weapons tests. Many of these persons in our study may have been employed at NRC facilities.

I am the DOE point of contact for the study and am looking forward to continued interagency collaboration and cooperation as we continue this important research effort.

Sincerely,

Noelle Metting

NF Metting, Sc.D.

Program Manager

Sr. Radiation Biologist

Biological Systems Science Division, SC-23.2

Office of Biological and Environmental Research

Office of Science

U.S. Department of Energy

Voice: 301-903-8309

Fax: 301-903-0567

noelle.metting@science.doe.gov

Attachment: Project Description, Information Requested and Relevant Privacy Act System Notice

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institute of Health

National Institute of Diabetes and
Digestive and Kidney Diseases
Bethesda, Maryland 20892

March 21, 2011

Beth Forrest
USRDS Coordinating Center
914 South 8th Street, Suite D-206
Minneapolis, Minnesota 55404
(612) 347-7776

Dear Beth,

Attached please find a data request from Dr. John Boice, from the International Epidemiology Institute, to use personally identifiable information from 5 occupational cohorts with exposure to nuclear radiation to assess the long term affects of radiation on renal failure. The study is entitled, Epidemiologic Study of One Million US Radiation Workers: Linkage with the US Renal Data System." This has been reviewed by NIDDK and USRDS staff. It meets our requirements for patient confidentiality. I am including the signed data use agreement and IRB exemption. This is data use agreement number 2011-13. Dr. Boice can now contact you directly to arrange for the data matching. This work is being funded by the Department of Energy and the National Cancer Institute.

The data are approved only for this project. The retention date is December 31, 2015, at which time the data will be destroyed or returned to the USRDS. Any use of the data beyond that specified in the project named above requires approval from our office. Dr. Boice will submit any manuscripts to this office for privacy review before publication.

Sincerely,

Paul W Eggers

Kidney and Urology Epidemiology
National Institute of Diabetes and
Digestive and Kidney Diseases
Room 615, 6707 Democracy Blvd
Bethesda, Maryland 20892

Cc: Larry Agodoa
John Boice

Research & Development Committee
Washington DC VA Medical Center
Washington, DC

APPROVAL - Initial Review

Date: May 6, 2011
From: Joao L. Ascensao, MD, PhD, FACP, Chairperson
Marc R. Blackman, MD, ACOS/R&D
Investigator: Han K. Kang, Dr.P.H.
Protocol: Cancer Mortality among Military Participants at U.S. Nuclear Weapons Tests (The Eight Series Study)
ID: 01425 Prom#: N/A Protocol#: N/A

The following items were reviewed and approved at the 05/06/2011 meeting:

- Financial Disclosure Form - Han K. Kang, Dr. P.H. (04/06/2011)
- Financial Disclosure Form - John Boice (04/06/2011)
- Financial Disclosure Form - Michael Mumma (04/06/2011)
- Financial Disclosure Form - Tim Bullman (04/06/2011)
- HIPAA Worksheet (04/06/2011)
- Initial Review Submission Form (04/06/2011)
- Memo - Request for waiver of HIPAA Authorization (04/06/2011; latter dated March 22, 2011)
- Memo - Confidentiality and Privacy of Data (04/06/2011; Letter dated March 22, 2011)
- Application for Waiver of HIPAA Authorization (04/06/2011)
- ISO/PO Checklist for reviewing (04/06/2011)
- Protocol (04/06/2011)
- Privacy reviewed by Kurt Keesler email (04/06/2011; Email dated April 05, 2011)
- PI Certification of Researcher's Eligibility (04/06/2011; John Boice)
- PI Certification of Researcher's Eligibility (04/06/2011; Mike Mumma)
- PI Certification of Researcher's Eligibility (04/06/2011; Tim Bullman)
- Personnel Roster - Investigator Roster (04/06/2011)

updated roster submitted on 4/7/11

- Project Data Sheet - with Abstract (04/06/2011)
- Protocol Face Sheet (04/06/2011)
- Scientific Review - Response to the Scientific Reviews (04/25/2011)
- Scientific Review - #2 (04/14/2011)
- Scientific Review - #1 (04/12/2011)

Approval by each of the following is required prior to study initiation:
Human Studies Subcommittee (IRB) [Approval Granted 04/25/2011]
Research & Development Committee

6 May 2011

Joao L. Ascensao, MD, PhD, FACP, Chairperson Date

M.R. Blackman 5-9-11

Marc R. Blackman, MD, ACOS/R&D Date

Page 2 of 2

The University of Manchester
Dalton Nuclear
Institute

MANCHESTER
1824

21 September 2011

Dr John D Boice, Jnr
International Epidemiology Institute
1455 Research Blvd, Suite 550,
Rockville, MD 20850
USA

Dear John

Letter in Support of The One Million U.S. Radiation Worker Study

I am writing to lend my strong support to The One Million U.S. Radiation Worker Study. The principal concern of everyday radiological protection is to manage the risks arising from protracted exposure to low levels of ionising radiation. At present, these risks are derived from groups briefly exposed to moderate and high doses of radiation, such as the Japanese survivors of the atomic bombings of Hiroshima and Nagasaki in 1945, by making assumptions on how to apply evidence from high dose/dose-rate exposures to low dose or low dose-rate circumstances. It would be highly desirable to confirm that these assumptions are correct through direct investigations.

Potentially, one of the most valuable sources of information on the effects of protracted exposure to radiation is workers occupationally exposed to radiation, especially nuclear industry workers. Early nuclear industry workers were exposed to relatively high levels of radiation when compared to standards pertaining today, so that many workers accumulated moderate to high lifetime doses, but over a period of many years; most of these workers would have worn individual dosemeters from which their radiation doses were recorded in occupational dose records. Workers who received such doses during the period from the 1940s to the 1970s are now reaching the ends of their natural lifespans, so that valuable mortality and morbidity data would be available from the appropriate epidemiological study of these workers.

This is not a hypothetical possibility, since a nationwide study of radiation workers in the UK has found radiation-related cancer risks that are compatible with the assumptions underlying radiological protection; but larger studies are required to properly check these results. The early U.S. radiation workers offer a profound opportunity to conduct a study with substantial statistical power to examine in depth the risks resulting from protracted exposure to low-level radiation – large numbers of early U.S. workers (e.g. the DOE workforces) with relatively high doses would permit an investigation with real scientific merit.

This is the context of my strong support for The One Million U.S. Radiation Worker Study – this study would allow a major advance in understanding of low-level radiation exposure from the direct epidemiological investigation of those workers so exposed. I should emphasise that I have no financial incentive to support this study – I have offered unpaid technical advice to the study from the standpoint of a scientist who has been involved in worker studies in the UK. My interest is in the substantial additional scientific understanding that this study will bring to the evidence base on the risks from low-level radiation exposure, and hence in the potentially large benefit to knowledge underlying radiological protection

Yours sincerely

Richard Wakeford

Dr Richard WAKEFORD PhD

Visiting Professor in Epidemiology

放影研
RERF
http://www.rerf.jp
財団法人 放射線影響研究所
RADIATION EFFECTS RESEARCH FOUNDATION
日米共同研究機関
A Cooperative Japan-United States Research Organization

〒732-0815 広島市南区比治山公園5番2号
5-2 Hijiyama Park, Minami-ku, Hiroshima 732-0815, Japan
Telephone: 082-261-3131 Facsimile: 082-263-7279

〒850-0013 長崎市中川一丁目8番6号
1-8-6 Nakagawa, Nagasaki 850-0013, Japan
Telephone: 095-823-1121 Facsimile: 095-825-7202

7 September 2011

Dr. John Boice
International Epidemiology Institute
1455 Research Blvd, Suite 550, Rockville, MD 20850

Dear Dr. Boice:

The studies you are proposing, to link the mortality experience to radiation dose for numerous cohorts with occupational or environmental radiation exposure, are of great interest to me, and I will be glad to serve as an advisor. The studies you propose have the joint potential to address important questions about radiation risk from low dose-rate exposures and will add significantly to our knowledge-base about radiation risks. The collective studies will provide a more informative assessment of low-dose risks than is available anywhere else. I anticipate being available for meetings, reviews of protocols or draft papers, and whatever other ways you would find useful.

As you know, my interest and expertise is in radiation epidemiology, and I have worked in that field for over 40 years. I currently serve as the Vice Chairman and Chief of Research at the Radiation Effects Research Foundation in Hiroshima and Nagasaki, Japan, where we are tasked with studies of the health of atomic bomb survivors. In the past, I served as an advisor to studies at several of the sites which you now propose to continue to study, including the radiation worker studies at Hanford, Los Alamos and Oak Ridge, and the naval shipyard worker study at Johns Hopkins, so I have a degree of familiarity with a number of the cohorts. I applaud your efforts to develop these studies and will seek to provide whatever advice and assistance is needed.

With best wishes,

Roy E. Shore

Roy E. Shore

Los Alamos
NATIONAL LABORATORY
EST 1943

Occupational Medicine
Los Alamos National Laboratory
P.O. Box 1663, MS D-421
Los Alamos, New Mexico 87545
505-667-8234

Date: September 6, 2011

John D. Boice, Jr., Sc.D
International Epidemiology Institute
1455 Research Blvd. Suite 550
Rockville, Maryland 20850

Subject: One Million Worker Radiation Study

Dear ~~Dr.~~ John Boice

I look forward to continued collaboration on the "Pilot Study Of One Million U.S. Workers And Veterans Exposed to Radiation." I believe this project is very important and I am pleased to be part of this exciting study.

Thank you for including me in this important work.

Sincerely,

Laurie D. Wiggs, Ph.D., MPH
Senior Epidemiologist
Occupational Medicine
Los Alamos National Laboratory

LANDAUER

August 7, 2009

Dr. John D. Boice, Jr.
International Epidemiology Institute
1455 Research Blvd, Suite 550
Rockville, MD 20850-6115

Dear John,

I wish to confirm Landauer's ability to cooperate in studies examining various populations exposed to radiation. Having the largest database on US occupational exposures, Landauer understands the value of being able to retrieve historical data. As you know we have electronically preserved annual and lifetime dosimetry results since 1978 with earlier records preserved on microfiche and microfilm.

Our recent collaborations on studies of Rocketdyne/Atomics International workers and similar collaborations with the Radiation Epidemiological Branch at the National Cancer Institute confirmed the importance of accounting for a workers entire career dose, and not just the radiation exposure received at an index facility. Thus I am pleased to be able to continue with similar collaborative efforts focused on total occupational exposures received by various worker categroizations.

Sincerely,

R Craig Yoder

Dr. R. Craig Yoder
Senior Vice President, Marketing and Technology
Landauer, Inc.
2 Science Road
Glenwood, IL 60425

National Association of Atomic Veterans, Inc.

11214 Sageland Houston, Tx. 77089

281-481-1357

June 6, 2009

John D. Boice, Jr.
International Epidemiology Institute
1455 Research Blvd., Suite 550
Rockville, Md. 20850

Professor of Medicine
Vanderbilt University Medical Center
Vanderbilt-Ingram Cancer Center

Dear Dr. Boice:

As the official spokesmen for America's 193,000 (surviving) Atomic-Veterans, we are in total support of Vanderbilt University's proposed Atomic-Veteran Mortality Experience study. We have not been made aware of any fully explored and documented study that would include an in-depth evaluation of the risks of cancers that may have been precipitated by internal radiation sources, including inhaled or ingested airborne ionizing radiation particles.

Given that a large percentage of the 350,000+ (deceased) Atomic-Veterans may have been victims of a host of health issues resulting from their exposure to the hazardous effects of (internal) radiation particles, we are of the firm belief that such studies should be performed in the best interest of those surviving Atomic-Veterans, including Veterans of the Gulf War and Middle East conflicts, who may have been exposed to Depleted Uranium radiation particles, and future generations of Americans who may be faced with similar radiation exposure events, in light of the current state of International affairs.

Very truly yours;

R. J. Ritter – C.E.M.
Managing Director & National Commander

Dr. F. L. Grahlfs - Director
D. D. Robertson – Director

Col. G. E. Taylor - Director
B. E. Clark - Director

BRIGHAM AND WOMEN'S HOSPITAL

HARVARD MEDICAL SCHOOL

900 Commonwealth Avenue East
Boston, Massachusetts 02215-1204

Tel: 617-732-1965, Fax: 617-731-3843

Division of Preventive Medicine
Department of Medicine

September 15, 2011

John D. Boice, Jr., ScD
International Epidemiology Institute
1455 Research Blvd
Suite 550
Rockville, MD 20850

RE: Epidemiologic Study of One Million U.S. Workers and Military Veterans Exposed to Ionizing Radiation

Dear Dr. Boice:

I would like to provide my strong and enthusiastic support as a Collaborating Consultant for this important proposal to design and initiate an unprecedented prospective cohort study of more than one million radiation workers and military veterans, in whom radiation doses can be quantified over decades of follow-up, along with the long-term risk of various outcomes. Your plan to consider cardiovascular endpoints as part of this proposal is particularly exciting, as this proposed study design is optimally suited to evaluate whether there may be a potential association between long-term exposure to ionizing radiation and the risk of developing cardiovascular disease. I will gladly provide any and all assistance with your work, drawing from my experience in cardiovascular epidemiology as well as the design and conduct of large prospective studies.

I look forward to our collaboration on this proposal.

Sincerely,

Howard D. Sesso, ScD, MPH, FAHA

Associate Professor of Medicine
Department of Medicine
Division of Preventive Medicine
Brigham & Women's Hospital
900 Commonwealth Avenue East – 3rd Floor
Boston, MA 02215
(617) 732-8837

John D. Boice, Jr., Sc.D.

Professor of Medicine

Vanderbilt University Medical Center

International Epidemiology Institute

1455 Research Boulevard, Suite 550

Rockville MD 20850 June 3, 2009

Dear John:

It is a pleasure to express my support for your research application "Cancer Mortality among Military Personnel at U.S. Nuclear Weapons Tests". Its potential for providing important public health information regarding low dose radiation effects is great, particularly at the present time. The cohort is large, and its follow-up in terms of lifetime duration is nearly complete. In addition, improved methods are now at hand both for reconstructing levels of past radiation doses more accurately and for tracing mortality events more completely. I do hope that full funding for this important research undertaking will be granted.

Sincerely yours,

Clark

Clark W. Heath, Jr., M.D.

674 Plantation Point Drive

Woodbine GA 31569

From: Weber, Michael
Sent: 8 Feb 2016 18:43:42 -0500
To: Case, Michael;Coffin, Stephanie;Henderson, Pamela;Collins, Daniel;Mohseni, Aby;Kokajko, Lawrence
Cc: Tadesse, Rebecca;West, Steven;Burnell, Scott;Adams, Darrell;Weil, Jenny;Araguas, Christian;Sampson, Michele;Brock, Terry
Subject: FYI - NCRP UPDATES FOR US
Attachments: 2016 February boice draft 2016-01-23 (003).pdf, Low Level Radiation SEAB Ltr to Moniz (003).pdf

Good evening. John Boice shared the attached with me recently for our information, including the draft of his column for the February edition of the HPS Newsletter and a letter from DOE's SEAB to Secretary Moniz cautioning against the demise of DOE's low dose radiation research program. Sharing for awareness.

Thanks,

Mike

Michael Weber
Director of Nuclear Regulatory Research
US Nuclear Regulatory Commission

301-415-1902
Mail Stop T-10B16

ARM

The Boice Report #45

John D. Boice, Jr., NCRP President
ICRP Main Commissioner
UNSCEAR U.S. Alternate Representative
Vanderbilt Professor of Medicine

From Oak Ridge to Indian Point
Studying Workers at Nuclear Power Plants

Paraphrasing Thomas Edison, epidemiology is 5% inspiration and 95% perspiration. The inspiration for the Million Person Study of Low Dose Health Effects (MPS) came over 30 years ago with recommendations to create a registry of radiation workers among U.S. Nuclear Regulatory Commission (NRC) licensees (see June 2015 Boice Report #37). The 30 years of perspiration is outlined below.

Thirty years in the making. Today, the Radiation Exposure Information and Reporting System (REIRS) database closely approximates a U.S. occupational radiation exposure registry (ORISE 2011). REIRS dates back to 1969 when U.S. Atomic Energy Commission (AEC) licensees were required to report radiation exposure data for individual workers at the end of employment and exposure summaries for sites on an annual basis. At that time, AEC licensees were only required to submit radiation-monitoring records upon an employee's termination of employment. However, in 1986, Gil Beebe and I, both at the National Cancer Institute (NCI), composed a letter sent by NCI Director Vincent DeVita, MD, to NRC Chairman Lando Zech requesting that reporting requirements be changed to support epidemiologic health studies. In 1991 a positive response was received from NRC Chairman Kenneth Carr to NCI Director Samuel Broder. In 1994, as part of the implementation of the 1991 revisions of 10 CFR 20 "Standards for Protection Against Radiation," the NRC began requiring annual radiation exposure records for every monitored worker (NRC Regulatory Guide 8.7). In 1994 I wrote Bill Morris, director of the Division of Regulatory Applications, Office of Nuclear Regulatory Research, urging the voluntary reporting of additional occupational radiation exposure data so that a high-quality radiation worker registry might be created for epidemiologic studies. In 1994 NRC requested that licensed utilities report voluntarily the career doses of current and past employees (NRC Generic Letter 94-04); the utilities responded favorably to this request, and a registry of radiation workers suitable for epidemiologic study was born.

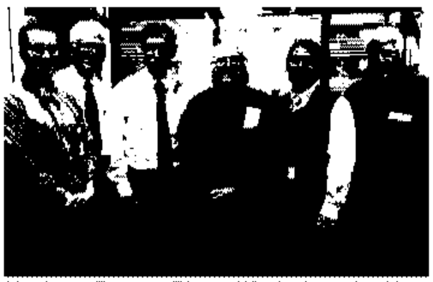
How are REIRS data used for health studies? Annual radiation doses for over 1.1 million unique workers are in REIRS, including external whole-body exposure and, since 1994, internal exposure. Identifying information includes name, social security number, date of birth, sex, licensee code, and dates monitoring began and ended. We selected all 425,713 nuclear power plant workers first monitored before 1985, sampled 10% of the 307,553 workers with cumulative doses less than 10 mSv, and removed 3,688 workers with duplicate, incomplete, or invalid dose records for a study population of 145,227 workers. Workers hired after 1984 were excluded because they received much lower doses than earlier workers and because their younger age would not provide mortality information for many years. 1980 was originally chosen as the cutoff date for inclusion, but after the Three Mile Island accident in 1979, the NRC required reactor modifications that increased workers' exposures for several years. The 10% sample of low-dose subjects was based on cost consideration, i.e., it would be expensive to trace over 300,000 low-dose workers when their contribution to a health study could be adequately addressed by studying 30,000.

How valid are the radiation dose data? The key to high-quality epidemiology is equally high-quality dosimetry. NCRP Scientific Committee 6-9 is providing guidance, direction, and advice for the MPS. The committee has met six times in Oak Ridge, most recently in November 2015 (see photo). Most nuclear utility worker exposure is to high-energy gamma radiation from fission products (e.g., ^{137}Cs) or activation products (^{60}Co and ^{57}Co) and there is minimal neutron exposure or ingestion of radioactive material. Measurement uncertainty includes sensitivity, energy response, angular dependence, calibration, processing, and fading. Model uncertainty includes radiation fields, geometry, badge placement, missing doses, and conversion from badge reading to absorbed dose to organ of interest. A comprehensive report should be out this year that addresses these specific

SC 6-9 Meeting at Oak Ridge, November 2015. Front row, left to right: Dick Toohey (Mel Chew, Inc.), Larry Dauer (Memorial Sloan Kettering Cancer Center [MSKCC]), John Boice (NCRP/Vanderbilt), Andre Bouville (NCI, retired), Kathy Pryor (Pacific Northwest National Laboratory), and John Till (Risk Assessment Corporation); back row, left to right: Keith Eckerman (Oak Ridge National Laboratory [ORNL]), Cary Zeitlin (Southwest Research Institute), Rich Leggett (ORNL), Harold Beck (DOE, retired), Mike Mumma (International Epidemiology Institute [IEI]), Derek Hagemeyer (Oak Ridge Associated Universities [ORAU]), and Craig Yoder (Landauer).

dosimetric concerns and challenges (and ways to overcome them).

How complete is REIRS? Before the NRC reporting changes in 1994 and the voluntary reporting of worker data back to 1957, I wrote that the REIRS data based on termination notices alone were limited. Since the reporting changes, the REIRS data are judged suitable for health effects studies. Further, data completeness back to 1969 was validated based on a comparison with workers identified from utility company records at the Calvert Cliffs Nuclear Power Plant and on comparisons of workers at two utilities included in a prior study (Howe 2004). Comparisons with data available from Landauer, Inc., also were remarkably consistent. The Landauer, Inc., records accounted for less than 0.8% of the cohort.



Nuclear Power Plant Workshop in New York City, December 2015. Left to right: Larry Dauer (MSKCC), John Kelly (retired director, Nuclear Safety Assurance, Entergy Nuclear), Dennis Quinn (DAQ, Inc.), John Boice (NCRP/Vanderbilt), Matthew Williamson (MSKCC), Joseph Perrotta (retired–quality assurance manager, Indian Point Energy Center). Not Pictured: Craig Yoder (Landauer), Don Mayer (director, Indian Point Unit 1), Mike Mumma (IEI), Derek Hagemeyer (ORAU).

Focus group evaluation. Well, not really a focus group (a catchy politically correct phrase), but a daylong meeting with current and former workers at the Indian Point Nuclear Power Plant and other national dosimetry specialists held in December 2015 (see photo). The exchange of information enhanced our understanding of dosimetry and radiation protection practices at nuclear reactors during the early years of the nuclear industry. Insights (for me):

- 80% of exposures occurred during outages for maintenance, modifications, and refueling. Refueling might occur every 18–24 months but maintenance is more frequent.
- Multiple badges were worn by approximately 1% of workers for some repairs, with the highest value reported.
- The conversion from film badge reading, $H_p(10)$, to organ dose is facilitated because most exposure is from high-energy gamma rays, facilitating an adjustment with a scaling factor (conversion coefficient).
- There are few missing doses to impute because of reporting practices and requirements.
- Neutron exposures and intakes of radioactive elements were rare—whole-body counting was done each year, as were annual physicals for radiation workers.
- During one challenging outage, hundreds of welders received up to 20 mSv per quarter over a period of 1 to 2 days—while unusual, some workers with high cumulative doses may have received exposures at a relatively high dose rate.
- A famous incident of a worker who received 100 mSv in 1 minute contributed to a change in NRC regulations for access to high radiation areas.

Future. The first manuscript on radiation-related leukemia is under review. Follow-up through 2011 identified 30,993 deaths from all causes, including 320 from leukemia other than chronic lymphocytic leukemia (CLL). For workers with cumulative doses greater than 10 mSv, the mean active bone marrow dose was 61 mSv (maximum 1.0 Sv; 8.4% of workers had doses greater than 100 mSv). Subsequent manuscripts will evaluate over 1,200 cases of leukemia other than CLL, combining data from industrial radiographers, atomic veterans, and U.S. Department of Energy worker cohorts. Results will significantly augment scientific knowledge on the lifetime risk of cancer and leukemia following relatively low-dose exposures received gradually over time.

Massachusetts Institute of Technology
77 Massachusetts Avenue
Building 6-215
Cambridge, Massachusetts 02139

John Deutch Institute Professor
Department of Chemistry
Tel: 617 253 1479
Fax: 617 258 6700
Email: jmd@mit.edu

Secretary Ernest J. Moniz
U.S. Department of Energy
1000 Independence Avenue S.W.
Washington D.C. 20585

June 23, 2015

Dear Mr. Secretary,

SEAB has requested that I respond to your letter of June 16, 2015 requesting

> "...SEAB's perspective on how DOE should pursue research on the question of a 'linear' or 'threshold' low-level radiation exposure model. Should DOE continue its efforts on this subject or leave it to other agencies such as EPA and NIH? Or is there a research effort that over time may lead to knowledge that will resolve the question of health effects of low-level radiation exposure to citizens and workers in the nuclear industry. Has the scientific community identified specific knowledge gaps that would be appropriate research priorities for DOE to pursue?"

This question of "linear" versus "threshold level" radiation exposure to low levels of radiation is important because its consequences for regulations governing radiation exposure to workers, and citizens in the vicinity of commercial nuclear power plants and associated fuel cycle activities, especially with regard to the increased likelihood of cancer fatality.

For human populations a plausible case can be made for a threshold below which there is no harm to exposure because the human population has forever been exposed and therefore adapted, to natural background levels of radiation. Organisms in the natural environment evolve biological mechanisms to repair radiation damage to cells at the molecular level, thus avoiding or reducing adverse radiation response. This suggests research on radiation damage at the cellular level to identify natural thresholds for radiation damage. However, if a precise understanding of the cellular level dose-response were reached, the challenges of scaling up this understanding to enable establishing a quantitative threshold for human dose-response would remain.

The most direct way to investigate low-level radiation damage is epidemiological studies on human populations exposed to different levels of radiation in one context or another (Denver versus Miami). Such studies do not rely on 'controlled' conditions to establish dose and response but rather attempt to infer the dose-response relationship from statistical information. This is a formidable task because as the dose level approaches zero the "noise" of random fluctuations that reflect different exposure circumstances becomes proportionally larger than the signal that one is seeking to detect.

Despite many years of diligent study on both these approaches there is insufficient evidence to justify replacing the linear low level radiation exposure behavior assumption with any other – in particular a threshold low level exposure behavior. It is highly unlikely – I would say impossible – that a group of experts would, after review and deliberation on the vast literature on this subject, come to a consensus or that consensus would resolve this question to the satisfaction of regulatory authorities or the public.

You have asked a further research program could fill "specific knowledge gaps" that would resolve this question of low-level radiation exposure on humans. Understandably, as a result of inconclusive results of the vast body of past DOE sponsored research, some Office of Science program officers are skeptical and advocate applying these resources to other purposes.

SEAB does not believe DOE should abandon its research effort on low-level radiation effects. There are several reasons. First, the subject is of importance to many DOE constituencies such as commercial nuclear power, stockpile stewardship, waste management, and the nuclear navy. Second, the DOE laboratories are undoubtedly the leading repositories of knowledge on this difficult, but important, subject. The DOE should maintain this expertise; if disbanded, it will be difficult to reassemble. Third, if the DOE were to withdraw from low-level radiation exposure research only the EPA and NIH would sponsor any remaining federal research activity; neither agency has the deep expertise in nuclear science or biological effects of radiation exposure that exists in DOE national laboratories.

Thus, SEAB recommends DOE continue to sponsor a small, sustained, high quality research program mainly in DOE laboratories but also at centers of excellence on this subject that exist in universities, medical schools, and hospitals.

SEAB does not believe it is the right group to put together such a research program. Low-level radiation exposure is a specialized subject and, experience shows, there is not an obvious research program that will yield decisive results. The Director of DOE's Office of Science should be charged with commissioning a small group of experts (including a couple of smart outsiders to the subject) to propose a modest, multi-year, research program in low-level radiation exposure. If requested, SEAB would review this research plan and make suggestions to the Director of the Office of Science. However, you should not assume that the results of such a research program would be conclusive.

If you have any questions or comments, please do not hesitate to get in touch.

Sincerely yours,

John Deutch

John Deutch

CC: Undersecretary F. Lynn Orr
Members of SEAB
Karen Gibson

From: Metting, Noelle
Sent: 28 Apr 2011 13:43:47 -0400
To: Brock, Terry
Subject: Information US Million Worker Study
Attachments: AIMS_Pilot Million Worker Study_01-11-10.pdf, Narrative One Million American Workers 9-11-09.pdf

Hi Terry,

I have attached the Narrative of the big proposal that was originally reviewed. The favorable reviews would have guaranteed full funding, but our budget would not. We were able to fund a one year pilot project, and so I have also attached the revised Aims for the pilot study.

We remain enthusiastic about supporting this work by interagency cooperation and funding.

Best regards,
Noelle

NF Metting, Sc.D.
Program Manager
Sr. Radiation Biologist
Office of Science/BER
U.S. Department of Energy

Voice: 301-903-8309
Fax: 301-903-0567
noelle.metting@science.doe.gov

Pilot Study of One Million American Workers and Veterans Exposed to Radiation

Background. In September 2009 a comprehensive proposal was submitted entitled, "Epidemiologic Study of One Million American Workers and Military Veterans Exposed to Ionizing Radiation." The proposed research of five distinct occupational groups would provide the greatest precision yet available for the evaluation of long-term health effects of low-dose ionizing radiation. Such research was recommended during the Department of Energy Workshop on Low-Dose Epidemiologic Studies (Hall et al. 2009). The specific goals of the one-year pilot study are as follows.

Aim 1. Department of Energy 200,000 Uranium Workers Feasibility. Thirteen individual DOE worker cohorts involved with the Manhattan Project and subsequent development of nuclear weapons and reactor materials are ready for immediate study. Within the one-year pilot, we will combine the worker cohorts of 200,000 uranium workers; initiate tracing activities required for mortality evaluations including permissions to access the National Death Index and the Social Security Administration (SSA) mortality data; link the cohort with SSA and California mortality files; link the files with Landauer dosimetry records; obtain permissions to link cohort with military dosimetry records; and obtain cause of death for workers at one facility to demonstrate feasibility. Dosimetry information on all 200,000 workers will be obtained from records available at the Oak Ridge Associated Universities.

Aim 2. Second Follow-Up of the Rocketdyne Radiation Worker Study. The first follow-up was conducted of nearly 50,000 radiation and non-radiation workers, 1948-1999 (Boice et al. 2006). A comprehensive dose reconstruction program incorporated lifetime occupational doses at all places of employment as well as internal doses from radionuclide intake. An additional follow-up of ten years through 2009 would be conducted and a manuscript prepared for publication.

Aim 3. Second Follow-Up of the Mound Radiation Worker Study. A new follow-up of over 7,000 workers at the Mound nuclear weapons facility (1944-1972) located near Dayton, Ohio will be conducted (Wiggs et al. 1991a, 1991b). Follow-up through 2009 will add an additional 25 years of observations, and dose-response assessments will include internal intakes of polonium in collaboration with the Oak Ridge National Laboratory. A manuscript for publication will be completed.

Aim 4. Feasibility Initiatives to Study DOE Plutonium Workers, Nuclear Power Plant Workers, Radiologists and Other Medical Radiation Workers, and Atomic Veterans. A cohort of over 100,000 plutonium workers, including Hanford, will be assembled after permissions obtained; a nuclear power plant worker cohort from the electronic records (1978+) at Landauer will be assembled and the feasibility of copying microfilm records dating back to 1960 determined; a cohort of radiologists and early medical radiation workers from the Landauer electronic files will be assembled; contacts will be made with U.S. nuclear utility companies for studying early U.S. workers; follow-up efforts will be initiated with the Department of Veterans Affairs to trace 125,000 atomic veterans. A scoping document will be prepared with ORNL describing a comprehensive approach to internal radionuclide dosimetry at all DOE facilities; radionuclides at selected laboratories will be evaluated for illustrative purposes.

References

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Wiggs LD, Cox-DeVore CA, Voelz GL. Mortality among a cohort of workers monitored for 210Po exposure: 1944-1972. Health Phys 61:71-76, 1991a.

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Epidemiologic Study of
One Million American Workers and Military Veterans
Exposed to Ionizing Radiation

Applicant/Institution The International Epidemiology Institute
Street Address/City/State/Zip: 1455 Research Boulevard, Suite 550, Rockville MD 20850
Principal Investigator: John D. Boice, Jr., Sc.D.
Address: International Epidemiology Institute
1455 Research Boulevard, Suite 550
Rockville MD 20850
Telephone Number: (301) 424-1054 x4271
Email: boice@iei.us or john.boice@vanderbilt.edu

Performance Project Sites:

1. International Epidemiology Institute, Rockville, Maryland
2. Oak Ridge Associated Universities, Oak Ridge, Tennessee
3. Oak Ridge National Laboratory, Oak Ridge, Tennessee
4. University of Southern California, Los Angeles, California
5. Vanderbilt University, Nashville, Tennessee
6. Risk Assessment Corporation, Neeses, South Carolina
7. Los Alamos National Laboratory, Los Alamos, New Mexico

Budget total for this institution for each year, including subcontract to the collaborating research entities:

	AIM 1 Uranium	**AIM 2 Atomic Veterans**	**AIM 3 Medical**	**AIM 4 Nuclear Power**	**AIM 5 Plutonium**	**AIM 6 Combined cohorts**	**Total**
Year 1	$1,699,325	$959,768	$732,664	$292,859	$411,162	$0	$4,095,778
Year 2	$1,461,342	$988,578	$839,247	$412,175	$665,719	$0	$4,367,061
Year 3	$1,475,660	$976,272	$883,765	$440,372	$729,292	$74,000	$4,579,360
Year 4	$1,467,965	$841,074	$834,765	$448,084	$584,066	$225,878	$4,401,833
Year 5	$1,476,095	$699,100	$745,517	$468,795	$808,084	$460,741	$4,658,333
Total	$7,580,387	$4,564,793	$4,035,958	$2,062,285	$3,198,322	$760,619	$22,102,365

DOE/Office of Science Program Office: BER
DOE/Office of Science Program Office Scientific/Technical Contact: Dr. Noelle F. Metting

Overall Project Objectives

There is tremendous scientific and societal interest in understanding the health effects of low-level radiation exposures. However, recent studies of occupationally exposed groups have not been of sufficient size or quality to provide robust estimates of risk (NRC 2006; Wakeford 2005; ICRP 2007; UNSCEAR 2008). These studies, however, have been interpreted by some as suggesting that chronic low dose rate exposures may be as harmful as the acute high dose rate exposures experienced by Japanese atomic bomb survivors (Jacob 2009; Cardis 2007b) that form the basis of radiation protection standards. Unfortunately, the United States has fallen behind in studies of occupationally exposed populations (Wakeford 2009). To help fill the gaps in knowledge about health effects associated with low-dose ionizing radiation, a study of one million American workers is proposed. The study is cost efficient in that it builds on the investments made and foundations laid by investigators and government agencies over the past 30-40 years which have established radiation worker cohorts that, upon completion of the proposed research, can provide the most precise estimates yet available of the lifetime risk of cancer and other diseases among individuals chronically exposed to low levels of ionizing radiation.

The United States was the first country to develop both nuclear weapons and nuclear power reactors to generate electricity and fuel military ships and submarines. The early workers of the nuclear age can be followed for up to 60 years and late effects evaluated. We propose to ascertain the mortality experience through 2010 of five occupational groups with differing radiation exposures: (1) radiation-exposed uranium workers at multiple Department of Energy (DOE) locations and Rocketdyne; (2) nuclear weapons test participants (atomic veterans); (3) radiologists and other medical practitioners; (4) nuclear power plant (NPP) workers; and (5) plutonium workers. The sizes of these occupational groups are large: the early uranium cohorts, many from the Manhattan Project era, comprise 200,000 workers; 125,000 atomic veterans participated in above ground nuclear weapons tests in Nevada and the Pacific in the 1940s and 1950s; dosimetry files with cumulative radiation exposure information exist for over 550,000 medical workers; over 40,000 workers employed prior to the mid 1980s at NPPs with dose information have been identified; and over 100,000 plutonium workers can be studied.

A unique opportunity exists to assemble these cohorts of one million Americans workers and veterans, follow them to the present, reconstruct their radiation doses (including inhaled or ingested radionuclides), and provide new knowledge on the level of risk from low-level radiation experienced gradually and up to 60 years ago. The methods are patterned after the comprehensive approach used to study the workers at Rocketdyne/Atomics International (Boice 2006a,2006b; Leggett 2005).

The significance of the proposed study is considerable because it applies directly to existing concerns about and standards for chronic radiation exposure. Much knowledge has been gained from the study of atomic bomb survivors, but the single exposure was acute to a Japanese population living in a war-torn country in 1945. Scientific and medical committees continue to grapple with how best to estimate risks associated with the gradual exposures received from environmental, medical and occupational radiation (NRC 2006; Tubiana 2006; UNSCEAR 2008). Recent studies, though limited, have suggested that chronic exposures may be more hazardous than currently accepted (Jacob 2009; Cardis 2007a, 2007b). Governmental agencies tackle the complex issues of compensating prior workers, veterans and citizens potentially harmed by past exposures (NRC 2003, 2005; Wakeford 2006). Protection committees agonize over how best to estimate and apply a "dose and dose rate effectiveness factor" (DDREF) to scale the risks from the bomb survivor data for relevant and current circumstances (ICRP 2007; Tenforde 2008). The remarkable increase in population medical exposures to CT scans and other imaging technologies (NCRP 2009) has raised concerns about possible future health consequences (Brenner and Hall

2007). The proposed million worker study addresses all these issues while providing direct estimates of risk following the types of radiation exposures of current concern.

Evaluation of risk among persons with intakes of radioactive substances also assumes greater importance as society debates expansion of nuclear energy and deals with nuclear waste and other uses of radioactive materials (Corradini 2009). Knowledge of the effects of internal exposures to radioactive substances takes on increased importance in light of the possibility of terrorist attacks with nuclear devices (Radioactive Dispersal Devices, Improvised Nuclear Devices) (ICRP 2005). Finally, the study will be a service to American workers and veterans and their families by providing a sound understanding of the risks they may have incurred while working in service to their country.

The urgent need for such a comprehensive study was recently emphasized in a DOE-supported Workshop on Low-Dose Radiation Epidemiology (Hall et al., Radiation Research, July 2009). *"There is a pressing need, and a golden opportunity, to obtain more information on the long-term effects of relatively low radiation doses, delivered over protracted periods by pooling and updating the data for the various groups of occupationally exposed U.S. nuclear workers. This represents a large and relatively untapped database. In the long run this could become an international effort by integrating these data with studies from around the world. With the large increase in the use of diagnostic radiation, large studies with good dosimetry of both patients and medical personnel can also contribute much-needed data."* We are poised, ready and enthusiastic about fulfilling this recommendation and restoring the United States as a leader in occupational studies of radiation.

Our specific goals are described below as six independent and complementary aims or research thrusts that could be funded in total, separately, or in various combinations.

Aim 1. Department of Energy and Rocketdyne 200,000 Uranium Workers. The Rocketdyne and 13 individual DOE worker cohorts involved with the Manhattan Project and subsequent development of nuclear weapons and reactor materials are ready for immediate study. Many of these cohorts have not been evaluated for over 30 years and the proposed extended follow-up, coupled with comprehensive dose reconstruction, will enable estimation of nearly lifetime risks of cancer and other diseases associated with protracted low-level radiation exposure and propel the United States once again to the forefront of occupational study research (Hall 2009; Wakeford 2009). The study would provide critical information on effects following chronic exposure and on the DDREF used in radiation protection (ICRP 2007; UNSCEAR 2008; Canu 2008).

Aim 2. Department of Defense Atomic Veterans 125,000 Military Personnel. The United States conducted 230 aboveground nuclear detonations from 1945 through 1962. Over 125,000 veterans were previously studied by the Department of Veterans Affairs (Dalager 2000; Watanabe 1995b) and the Medical Follow-Up Agency of the Institute of Medicine (IOM 1996, 2000). These veterans participated at any of seven of the nuclear weapons test series. Statistical increases in leukemia were reported as were excesses of several other cancers, including bone, thyroid, salivary gland, liver and breast. However, no dose assessments for epidemiologic study were made and the last follow-up was 15 years ago. An extended follow-up coupled with dose reconstruction of individual veterans who developed leukemia and other cancers not previously studied would provide important quantitative information on the level of risk possible from prolonged exposures to radiation experienced up to 60 years ago.

Aim 3. Radiologists, Radiotherapists and Other Medical Professionals 550,000 Workers. Landauer, Inc. has provided radiation dosimetry services since 1953 for United States medical and other facilities. A computerized database of 15 million workers is maintained with identifiers and cumulative doses. Included in the database are radiologists, radiotherapists, cardiologists and others in the medical profession who experienced frequent radiation exposures during the course of their employment. These dosimetry records can be used for epidemiologic study by selecting and following the approximately 550,000 workers with relatively complete and long-term dosimetry

coverage over time. This provides a complementary component to the overall program by including a large number of medically-exposed workers. The study is designed not to overlap with other investigations of medical radiological technicians (Boice 1992; Mohan 2003), but to focus on potentially higher-exposed workers such as interventional radiologists with measured exposures.

Aim 4. Nuclear Power Plant (NPP) 40,000 Workers. The U.S. was the first country to develop nuclear reactors to produce electricity. There are over 650,000 past and current utility workers. Early workers were allowed 3 rem/quarter and 12 rem/year. Landauer records have identified over 40,000 early NPP workers employed prior to the mid-1980s (Muirhead 1996). Following these early workers will provide needed information above and beyond that produced by a recent study of 54,000 NPP recent workers (Howe 2004) which was limited due to the young age of the cohort, the small number of deaths and low cumulative radiation doses. A reported association with heart disease (Howe 2004) needs to be evaluated in a more powerful study as we propose (Little 2008).

Aim 5. Plutonium 100,000 workers

Over 100,000 workers with potential for plutonium exposure have been assembled from cohorts at Los Alamos National Laboratory, Rocky Flats, Hanford, Mound and several other facilities (Gilbert 1993a; Wiggs 1991, 1994). These workers were last followed between 1979 - 1990 and extending their follow-up to the present would provide needed quantitative information on the long-term risks possibly associated with inhalation or ingestion of plutonium and other radionuclides. The Mound cohort, for example, also offers an opportunity to study polonium, a compound which has received recent interest in light of the poisoning of the Russian national in the U.K. (Harrison 2007).

Aim 6. Combined cohort analyses. The pooled analysis of the combined data from all these studies will maximize statistical power to detect and characterize radiation effects, and to minimize the variability of the estimates of these effects. Generalized proportional hazards regression modeling of mortality data from the combined cohorts will allowing for the time-dependent nature of the exposures and of effect modification variables such as age at exposure, time since exposure, and exposure dose rate. Analyses will utilize the best estimates of both external and internal (where grouped estimates will be used) radiation exposures and will provide uncertainty analysis that reflect likely errors in dose estimation particularly for internal dose.

The integration of these U.S. worker and military populations would unquestionably provide the most definitive evaluation possible of risks associated with low-dose radiation exposures experienced over a prolonged period of time, and thus have implications with regard to protection standards for workers and the general population, the assessment of risk associated with the enhanced medical technologies such as CT scans, the expansion of nuclear power, the handling of nuclear waste and the compensation of workers with prior exposures to ionizing radiation.

Co-Investigators

International Epidemiology Institute: John Boice (radiation epidemiology), William Blot (epidemiology), Bob Tarone (biostatistics), Clark Heath (epidemiology), Sarah Cohen
Oak Ridge Associated Universities: Betsy Ellis Dupree, Donna Cragle, Phil Wallace, Janice Watkins, Dick Toohey, Bill Tankersley, Derek Hagemeyer
Oak Ridge National Laboratory: Rich Leggett and Keith Eckerman (radiation dosimetry)
Los Alamos National Lab: Laurie Wiggs (radiation epidemiology)
Harvard University: Howard Sesso (cardiology)
Risk Assessment Corporation: John Till, Harold Beck, Paul Voillequé, Helen Grogan (dosimetry)
Landauer, Inc.: Craig Yoder (dosimetry systems)
University of Southern California: Dan Stram (biostatistics), Duncan Thomas (biostatistics)
Vanderbilt University: Randy Brill (radiation effects), Yu Shyr and William Wu (biostatistics)
Advisors: Richard Wakeford (University of Manchester, U.K.), Roy Shore (RERF, Japan)

Proposal Overview

In this proposal we describe research studies of five occupational groups (uranium workers; veterans exposed to atomic bomb atmospheric tests; radiologists and other medically exposed workers; nuclear power plant (NPP) workers; and plutonium workers) with potential for radiation exposure. Study of each group involves the extended and long-term follow up for cancer or other causes of mortality of previously identified radiation-exposed cohorts, the reconstruction of individualized estimates of cumulative radiation doses and the estimation of dose-response relationships. Study of each group addresses a different aspect of radiation-related cancer because of the varying types (e.g., internal uptakes and external exposures), durations, and/or levels of radiation dose across the cohorts. In combination, the proposed research among one million radiation workers will provide the greatest precision yet available for the evaluation of long-term health effects of low-dose ionizing radiation.

The novel features of the studies of the five groups are described below in five Aims corresponding to the five groups to be studied. Most detail is provided for Aim 1, since the others share many of the same methodologies as in the study of uranium workers. The final and sixth Aim then describes the planned combined analysis, and summarizes the usefulness of the research for advancing knowledge of risks of cancer and other diseases among workers chronically exposed to low radiation levels.

Institutional Review Board approvals for the proposed studies have been received (Appendix 6).

Aim 1 - Uranium Workers

We propose the long-term follow up for cancer mortality and other health outcomes of occupational cohorts comprising nearly 200,000 uranium workers. Most worked at Department of Energy (DOE) facilities and were included in prior DOE research which generally was completed over two decades ago.

Despite some reassuring data to date, concerns about the limitations of existing studies and the potential for adverse health effects associated with uranium exposure persist. Weaknesses of previous research studies include low statistical power, inaccurate assessment of internal exposure to uranium and limited follow-up (Canu 2008). To remedy these shortcomings, a systematic long-term assessment of cancer and other disease mortality among large numbers of uranium-exposed workers, with adequate exposure measurement, is needed.

During the early years of uranium processing, enrichment, manufacturing and milling, aboveground workers had the potential to inhale or ingest uranium dust with minimal exposure to radon gas (UNSCEAR 2008). Well over 120,000 of these workers have been studied and, overall, no consistent elevations in cancer risk were observed (Harley 1999; U.K. Royal Society 2001; IOM 2001, 2008; NRC 2008; McGeoghegan and Binks 2000a, 2000b). Because of its long half-life, solubility properties and lack of significant associations in epidemiologic studies to date, uranium has not been classified as a human carcinogen (IARC 2001). Recent studies of uranium millers have found increases in some cancers and nonmalignant disease but no consistent associations with duration of employment (Boice 2008; Pinkerton 2004). Studies of workers with estimates of organ doses from uranium intakes reported only suggestive evidence of dose-response relationships (Dupree 1995; Boice 2006a). Analyses of Oak Ridge workers followed through 1990, however, suggest an association between cumulative dose and lung cancer (Richardson and Wing 2006) and of leukemia in a combined series (Schubauer-Berigan 2007). A recent case-control study of multiple myeloma reported an association with internal uranium exposures based on urine samples (Yin 2009). In contrast, studies of underground

uranium miners have revealed consistent and substantial increases in lung cancer attributed to radon gas and its decay products (NRC 1999).

Recent reviews of studies of uranium-exposed workers recommend that additional research be undertaken to clarify the existence, nature and level of cancer and other health risks associated with uranium intakes (Canu 2008). Furthermore, the possible chemical toxicity of natural or low-enriched uranium, a heavy metal, has been considered more important for human health than the risk of cancer from its radioactive properties (Leggett 1989). Ingesting large amounts of uranium might cause kidney damage because the kidney is involved in removing uranium from the body. Permanent renal disease has rarely been observed in humans, although changes in kidney function have been reported to be associated with uranium compounds (Kathren and Moore 1986; Kathren and Burklin 2008; McDiarmid 2007; Kurttio 2006a;IOM 2000; Royal Society 2001; NRC 2008). In Finland, environmental exposures to high intakes of uranium, radium, radon and other radionuclides in drinking water were not associated with increased rates of cancers of the bladder, kidney or stomach, or of leukemia (Auvinen 2002, 2005; Kurttio 2006b).

The Rocketdyne (Atomics International) study exemplifies the approach to be taken in the study of uranium workers. Potential exposures were from a variety of sources including ten research nuclear reactors, seven criticality test facilities, and other activities such as fabricating nuclear fuel, disassembling and decontaminating reactor facilities, decladding spent nuclear fuel and storing nuclear material. Enriched uranium and plutonium fuels were fabricated for research, space and power reactors. Results of analyses of mortality data on 5,801 workers employed at Rocketdyne (Atomics International) during 1948-1999 were reported in 2006 (Boice 2006a). A comprehensive dose reconstruction program incorporated lifetime occupational doses received at all places of employment into the analyses as well as internal doses from radionuclide intakes (Leggett 2005; Boice 2006b). For all leukemia excluding CLL the RR at 100 mSv was increased (1.34; 95% CI 0.73-2.45) and for all cancers excluding leukemia it was 1.00 (95% CI 0.81-1.24). An extended follow-up will add ten years of observations during the ages later in life when cancer rates are increasing.

The proposed extended follow-up of much larger groups of workers, coupled with comprehensive dose reconstruction, will propel the United States once again to the forefront of occupational radiation research (Hall 2009; Wakeford 2009). The risk of cancer and chronic diseases, including coronary heart disease (Little 2008), possibly associated with prolonged low-dose exposures accumulating to levels for which effects conceivably could be detected would provide critical information on radiation effects and on the Dose and Dose-Rate Effectiveness Factor used in radiation protection (ICRP 2007; UNSCEAR 2008; Canu 2008). This research will address directly recent claims that chronic low dose rate exposures may be more hazardous than the acute high dose rate exposures that form the basis of current radiation protection standards (Jacob 2009; Cardis 2005, 2007a, 2007b; Krestinina 2007).

METHODS

We propose to follow methods similar to those in the recently completed a study of uranium exposed workers at Rocketdyne (Atomics International) (Boice 2006a, 2006b). We will apply this methodology to additional uranium worker populations to provide quantitative information on the long-term risk of cancer and other diseases following chronic low-dose radiation exposures, with emphasis on the uranium intakes. The study will seek lifetime occupational exposure information and will provide quantitative assessments of the risks of inhaled or ingested uranium. Strengths include the large study size, the inclusion of more female and non-white workers than previously studied, use of the established Rocketdyne model for dose reconstruction, and the very long (up to 60 years) follow up.

Cohort identification. The population to be studied will be comprised of uranium workers from the cohorts shown in Table 1-1. Included are workers participating in prior DOE Health and Mortality Studies, along with the recently studied cohort of Rocketdyne (Atomics International) workers. Workers to be included in the new combined cohort will be those with sufficient information to conduct the mortality follow-up and comprehensive dose evaluations. In total 202,990 workers have already been identified and will form the study base population for extended observation. Because workers were often employed at more than one facility, linkages with all worker and dosimetry (e.g., REMS) databases will determine duration of employment and career dose accurately. Characteristics of the combined cohorts of uranium workers are shown in Table 1-2.

Table 1-1. Studies of uranium workers

Worker cohort	No.	Relevant publication/s	Last follow-up	No. dead	Comment	Total in database
Oak Ridge Segment	106,020	Frome 1997	Not given	27,982	All Oak Ridge	
K-25	35,712	Dupree 1994	1989	12,848	White males	49,794
X-10	6,348	Gilbert 1993; Cardis 1995	1984	1,246		28,528
Y-12 (TEC)	18,869	Polednak 1981	1977	5,394	White males	41,107
Y-12 (UCCND)	8,116	Loomis 1996	1990	1,861	Electromagnetic enrichment	26,059
Portsmouth Gaseous Diffusion	9,215	Rinsky 2001	1991	1,275	Enriched uranium	9,308
Paducah	6,820	Reinhart APHA 2007	2003	1,672	Gaseous diffusion	5,731
Manhattan Engineering District (Uranium)						
Niagara Frontier						
Harshaw, Electromet, Bethlehem	N/A	None			Never studied	1,144
Linde	995	Dupree 1987	1979	429	Employed 1943-49	1,551
Middlesex	N/A	None			Never studied	387
FMPC (Fernald)	4,014	Cragle 1996; Ritz1999; CEDR	1989	1,064	White males	7,337
MCW (Mallinckrodt)	2,514	Dupree 2000	1993	1,013	White males	3,272
SRS (uranium processing)	18,883	Richardson 2007; Cragle 1988	2002	5,096	Internal exposure to U, H3	21,509
Pantex (Weapons assembly)	4,668	Silver 2005; Acquavella 1985	1995	1,031	Min U, possible control	12,670
Rocketdyne (Atomics International)	5,801	Boice 2006a, 2006b	1999	1,468	Comprehensive dosimetry	5,801
Sum of unique workers				62,379		**202,990***

* Because workers may be in more than one cohort, the individual sites sum to more than the total which is for unique workers.

Health outcome determination. Updated mortality and vital status as of December 31, 2010 for the radiation workers will be determined from various linkages of the study rosters with national databases including the National Death Index (NDI) (1979+), the Social Security Administration (SSA) Death Master File and other SSA files (1960+), the California Death Statistical Master File (1960+), MicroBilt, credit bureaus and Comserv, a computer services firm specializing in locating persons. SSA files and LexisNexis searches will confirm vital status for those alive. For linkage with the SSA Master Death File of 83 million deaths, we will apply large-scale probabilistic matching programs to account for the possibility that there might be errors in names, dates of birth or social security numbers. LinkPlus from CDC and LinkKing from Washington State will be used (Campbell 2008). These programs also have unique "de-duplication" features, i.e., datasets can be evaluated to identify possible duplicate subjects who have been entered more than once with slightly different identifying information. Cause of death will be determined mainly from NDI matches since causes deaths prior to 1979 when the NDI began have already been obtained in previous studies.

Table 1-2. Characteristics of the combined uranium worker cohorts

Characteristic	N	%
Gender		
Male	139,900	68.9
Female	51,836	25.5
Unknown (currently)	11,254	5.5
Race		
White	172,045	84.8
Non-white	15,359	7.6
Unknown (currently)	15,586	7.7
Pay type		
Hourly/non-exempt/weekly	78,579	38.7
Salaried/exempt/monthly	78,858	38.7
Unknown (currently)	45,826	22.6
Year of birth		
<1900	9,603	4.7
1900-1909	18,399	9.1
1910-1919	36,761	18.1
1920-1929	56,755	28.0
1930-1939	23,824	11.7
1940-1949	21,831	10.8
1950-1959	22,450	11.1
1960-1969	8,536	4.2
1970+	1,825	0.9
Year of hire		
<1940	99	0.05
1940-1949	85,811	42.3
1950-1959	34,937	17.2
1960-1969	16,922	8.3
1970-1979	19,463	9.6
1980-1989	13,479	6.6
1990+	4,711	2.3
Unknown (currently)	27,568	13.6
Year of Termination		
1940-1949	72,936	35.9
1950-1959	19,031	9.4
1960-1969	18,836	9.3
1970-1979	15,538	7.7
1980-1989	15,402	7.6
1990+	7,997	3.9
Unknown (currently)	53,250	26.2
DOE employment duration		
<3 months	31,032	15.3
3-6 months	14,686	7.2
6 months - 1 year	15,907	7.8
1 - 4.9 years	46,656	23.0
5 - 9.9 years	12,235	6.0
10 - 19.9 years	11,730	5.8
20 - 29.9 years	8,326	4.1
30+ years	8,021	4.0
Unknown (currently	43,597	26.8
SSN known		
Yes	200,667	98.9
No (currently)	2,323	1.1
Vital status		
Known alive	8,035	4.0
Dead	74,947	36.9
Unknown (currently)	120,008	59.1
Among N=74,947 known dead:		
Year of death		
1940-1949	1,183	1.6
1950-1959	4,498	6.0
1960-1969	9,673	12.9
1970-1970	15,289	20.4
1980-1989	18,855	25.2
1990-1999	6,602	9.0
2000-2009	2,709	3.6
Unknown (currently)	16,138	21.5
Cause of death		
Known	54,986	73.4
Unknown (currently)	19,961	26.6

Given that uranium exposure would include depositions in certain organs, there is an *a priori* interest in mortality from lung cancer, nonmalignant respiratory disease, kidney cancer, non-malignant renal disease, liver cancer and bone cancer. Also, because of the current scientific interest in the possibility that heart disease may be related to radiation doses lower than previously thought likely, evaluation of coronary heart disease and ischemic heart disease mortality will be made (Preston 2003; Howe 2004; Little 2008).

Linkage with the Centers for Medicine and Medicaid Services (CMS) claims data will be investigated as a possible way to obtain recent data on cancer incidence and other non-fatal chronic health conditions. The Medicare files contain information on hospitalizations and other medical encounters for nearly all persons age 65 and older in the United States. Since most Rocketdyne and DOE former employees are over the age of 65, the Medicare files provide a unique resource for ascertainment of multiple health outcomes. Linkage of the worker rosters with Medicare files would enable ascertainment, in a systematic and highly cost-efficient manner, of recent medical encounters of workers. In addition to information on the incidence and prevalence of cancer, renal disease, cardiovascular disease and other chronic illnesses can be determined. The Medicare files include complete inpatient and outpatient stay records beginning in 1999, so that up to a 12-year (1999-2010) evaluation of cancer occurrence might be possible (McBean 1994a, 1994b; McClish 1997; Potosky 1993; Warren 2002).

Exposure classification and dose determination. We will seek to capture career doses from external radiation and to compute organ doses from internal uranium and other radionuclide exposures. Essentially there will be four aspects to the approach for dose determination among

the uranium workers. First, there will be an attempt to capture all uranium intakes and other internal and external radiation received at all DOE and other facilities as done in the Rocketdyne study. Record linkage will be attempted within the DOE worker facilities (the REMS database; approval to link against the DOE REMS database has already been received), the NRC databases (REIRS database), the Landauer Inc. commercial dosimetry company database, the U.S. military dosimetry databases (U.S. Army, U.S. Air Force, U.S. Navy and the Defense Threat Reduction Agency (DTRA) of the Department of Defense), and other individual sites as possible and as described in detail in the Rocketdyne dosimetry paper (Boice 2006a). For many DOE sites, there will be internal dosimetry data as well as external dosimetry data. Linkages with the Landauer, Inc. database, the largest such occupational database in the United States, have been conducted and revealed internal doses for 4,213 workers. These additional doses were recorded from 1947 through 2009 and ranged up to 135.5 rem (5% >5 rem). For the Rocketdyne workers, linkages with other dosimetry databases revealed that 32% had received radiation exposures elsewhere and showed the importance of capturing lifetime career doses (Boice 2006b).

Second, there will be a comprehensive evaluation of internal radionuclide exposures following the approach described in the Rocketdyne (Atomics International) dosimetry papers (Boice 2006b; Leggett 2005). Essentially all individuals monitored for uranium and other radionuclides will be identified on the basis of urinalysis results, whole body counts, lung counts and other sources of monitoring data. Workers with positive measurements will be identified. A screening level will then be determined to select which levels of radionuclide intake might be associated with meaningful deposition and organ dose. In the Rocketdyne study, this was taken as 10 mSv committed dose to the organ that would receive the highest dose. The ICRP models will then be used to compute annual organ doses that can be incorporated into the epidemiologic analyses. In the Rocketdyne study, radiation doses from internal intakes of 14 different radionuclides were calculated for 16 organs or tissues using biokinetic models of the ICRP. The radionuclides with documented intakes included isotopes of uranium, plutonium, americium, calcium, cesium, cerium, zirconium, thorium, polonium, promethium, iodine, zinc, strontium and hydrogen (tritium).

Thirdly, it is possible that we will be able to incorporate the comprehensive approach developed by ORAU for dose reconstruction in association with the EEOICPA and by DTRA with the veterans' compensation programs (www.orau.org/busops/oews/raddata-doserecon.htm; NRC 2003). The radiation environment for practically all DOE facilities has effectively been characterized and individual doses computed for the purposes of compensation. Procedures will be modified to be acceptable for epidemiologic purposes, i.e., to provide best estimates of dose rather than claimant-favorable estimates.

Fourthly, the uncertainties of the dosimetry approaches will be evaluated following the methods recently published with regard to external radiation (Gilbert 2006; Schafer and Gilbert, 2006; NCRP 2008). For internal dose uncertainties the methods of Stram and Kopecky (2003) will be followed. The uncertainties associated with radionuclide deposition and organ dose determination are complex and involve many variables such as the timing and frequency of bioassays, the sensitivity of the bioassay test, the accuracy of the biokinetic models, and other assumptions that are used. For some of the more complicated exposure scenarios with likely high doses, the uncertainty will be bounded by Monte Carlo simulations (NRC 2003; Raine 2007). A Monte Carlo simulation can also be used to propagate estimated uncertainties in the various contributions to the dose (Kopecky 2004). A subcommittee on dosimetry to review and evaluate these approaches will include Dan Stram, Keith Eckerman, Ken Kopecky, Rich Leggett, Dick Toohey, John Till, Yu Shyr and Duncan Thomas.

Study size and statistical power. A rough estimate of study size and statistical power to uncover a radiation effect is presented. Approximately 200,000 DOE workers are available for study and approximately 62,000 deaths have been identified (Table 1-1). Because of the age characteristics of these early workers, some first employed as early as 1943, it can be roughly estimated that approximately 60%, or 120,000 deaths, will have occurred by December 31, 2010, of which about 30,000 will be from cancer.

Table 1-3. Detectable relative risks and associated power for leukemia and other cancers, contrasting the exposed workers (> 10 mSv) with the lowest exposed workers (< 1 mSv). Baseline rates in parentheses.

RR	Leukemia (1.3%)	Lung (6.4%)	Bone (0.07%)	Kidney (1.3%)	Liver (0.53%)	NHL (1.9%)
1.2	0.89	0.99	0.18	0.93	0.65	0.98
1.3	0.99	0.99	0.29	0.99	0.91	0.99
1.4	0.99	0.99	0.41	0.99	0.99	0.99
1.5	0.99	0.99	0.54	0.99	0.99	0.99
2.0	0.99	0.99	0.94	0.99	0.99	0.99

The power values are given in Table 1-3 for a one-sided 5% nominal significance level. Baseline rates are from the American Cancer Society and SEER cumulative cancer probability tables for males (ACS 2008) up to age 85 years. The estimate of the number of workers exposed and non-exposed is taken from Frome (1997). The referent group for the purposes of these power computations is taken as the 118,000 workers estimated to have received <1 mSv (0.10 rem). The "highest" exposed group for these computations is taken as the 26,000 workers estimated to have received >10 mSv (1 rem). The incorporation of internal doses as well as career doses received elsewhere would increase the numbers in the higher exposure levels, and thus the power computations are conservative. Power is greater than 80% to detect relative risks of the order of 1.2 for leukemia, lung cancer, kidney cancer and NHL, 1.3 for liver cancer; and 2.0 for bone cancer.

Study power is sufficient to detect even modest increases in risk for leukemia and cancers of the lung and kidney and NHL. Power is recognized to be less for rare cancers such as bone. As mentioned, attempts to identify cancer incidences among those over age 65 years will be pursued using Medicare file linkages available from 1999. Power to detect increases for these outcomes, however, depends on the organ dose which is influenced by radionuclide intakes, e.g., uranium for lung, bone and liver, which are yet to be determined.

Analyses. Both external and internal analyses will be conducted to estimate the relative risks (RR) of death from cancer and other diseases. Standardized mortality ratio (SMR) analyses will compare the numbers of deaths observed among cohort members with the numbers expected based on general population rates for persons of the same age, race and sex over the same time periods (Marsh 1998). Internal analyses will apply proportional hazards regression models comparing non-exposed workers to radiation workers over categories of estimated radiation dose to specific organs. Multiplicative risk models (Cox 1972) or the linear excess relative risk model -- which is standard in radiation epidemiology (Preston 1993) -- are among those that will be used to estimate excess risk due to radiation. All of the analyses will be based on the underlying cause of death as coded from the death certificate. This is standard practice in epidemiological studies as underlying causes of death are thought to be recorded in a more systematic fashion across time and physicians than 'associated' causes. For workers of unknown race, a weighted approximation based on the proportions of race for the workers with known race will be used to compute expected numbers. In some analyses exposures will be lagged 10 years for solid cancers and 2 years for leukemia, i.e., exposures occurring in these intervals prior to end of follow-up will be excluded. Observed and expected numbers of deaths will be distributed over categories of external radiation dose and trend analyses conducted following the methods of Breslow and colleagues (Breslow 1983).

internal comparisons, which are expected to minimize any biases that might exist when external comparisons with a general population are made, will be carried out. Year of birth, year of hire, sex, pay type (hourly/salary), and duration of employment will be sought for inclusion in all models. Pay type is considered a surrogate measure of socio-economic status, and an indirect control of smoking (Boice 2006a). For the internal analyses, radiation workers will enter the risk set at their first date of radiation monitoring plus six months. Workers not monitored for radiation will enter the risk set at their first date of hire plus six months. Radiation exposure category will be treated as a time-dependent covariate, allowing workers to be assigned to increasingly higher dose categories over time as their individual radiation doses accrued. Parameter estimates and standard errors for the exposure categories in the Cox models will be used to obtain risk (or hazard) ratios and confidence intervals for death due to the cause under investigation compared to those in the referent group. Trend tests will treat the radiation dose as a single, time-dependent continuous measure, and one-sided p-values will be presented unless otherwise stated. Relative risks at 100 mSv will be computed for all cancers excluding leukemia, all leukemia excluding CLL and lung cancer.

Dose errors. Doses for monitored workers have inherent uncertainty, especially for internal dose. Our approach to uncertainty in dose estimation is based upon methods described by Prentice (1982) and by Stram and Kopecky (2003) who distinguish between the effects of shared and unshared dose errors and between multiplicative and additive errors. For a test of a null hypothesis (of no dose effect) a single best estimate of dose for each worker is used in the proportional hazards analyses detailed above. More elaborate dose error methods may be required when constructing point estimates and confidence limits for effect estimates especially when shared errors in dose reconstruction exist (Stram and Kopecky 2003).

Socioeconomic status (SES). Interpretation of study results will be based primarily on internal comparisons of mortality by level of radiation dose. A possible source of bias is that the socioeconomic characteristics of workers performing jobs involving occupational radiation exposure may have been different from those of workers performing other jobs. Accordingly, SES will be characterized and adjustments made by pay type (salaried managerial/professional, salaried technical/administrative, hourly union), and possibly pay-code (monthly, weekly, hourly).

Smoking information. The lack of detailed smoking information is a study limitation and indirect methods will be used to evaluate and adjust for possible confounding. Pay type is often seen as a predictor of cancer risk with somewhat higher risks of cancers of the lung and other smoking-related sites found for hourly compared with salaried workers. Such a difference is often seen in occupational studies and has been attributed to higher prevalences of tobacco use among blue collar (hourly) compared with white collar (salaried) workers (Howe 1988; CDC 2004). During the last 2 decades, the prevalence of cigarette smoking has declined faster in the general population and among salaried workers than among hourly workers. Hourly workers continue to smoke in large numbers (Lee 2004; Howard 2004) and at a rate up to twice that of salaried workers (CDC 2004; Sorensen 2004). Any increases in lung cancer among blue collar (hourly) workers in comparison with the general population could reflect in part this non-comparability in tobacco use. We will control for pay type in the intracohort analyses to account for possible differences in socioeconomic and demographic characteristics of hourly and salaried workers and thus indirectly adjusted for smoking. We will also evaluate "smoking-related" cancers as an entity and compare risks with cancers that are not strongly linked to cigarette smoking. Possible increases of heart disease might also be associated with smoking and these sites will be similarly evaluated. We note that there have been a few DOE studies that obtained some information on smoking (e.g., Dupree 1995) and we will evaluate and incorporate such information as available.

Other potential confounders. Factors related to the healthy worker effect, particularly selection of workers on the basis of their health, may be strongest during the first years of employment, leading to unusually low death rates during this period (Gilbert 1989). Thus, the pattern of cancer risk in relation to time since first employment will be carefully evaluated. Duration of employment is also correlated with cumulative dose so, again, patterns of cancer risk by duration will be carefully evaluated. We recognize that other occupational exposures, e.g., chemical and asbestos, may have occurred but that any available exposure information will be much less detailed than for radiation. Nonetheless, to the extent possible, other occupational exposures will assessed, such as by considering job titles and departments in some detail. As above, adjustment for SES will be taken as an indirect approach to handling unknown lifestyle and other factors.

SUMMARY

The proposed study of over 200,000 uranium workers will extend the mortality follow-up of the previously studied cohorts, making no restrictions as to sex or race, and utilize internal and external dosimetry assessments following the Rocketdyne (Atomics International) model. Linkages for dosimetry will be made with other national dosimetry data bases such as the REMS dosimetry files maintained by DOE and others as described in the Rocketdyne (Atomics International) worker study to capture career occupational radiation exposure. These dosimetry linkages also will provide data on the extent to which workers left specific DOE facilities and were employed at other nuclear facilities. A focus on radionuclide internal doses is a main feature of the study and a comprehensive dose reconstruction approach using expertise from ORNL, ORAU, DTRA and other groups and agencies is planned.

Aim 2 - Atomic Veterans

The proliferating use of CT x-ray and radionuclide imaging (e.g., PET scans) has highlighted the need for reliable estimates of lifetime radiation risk following chronic low-dose exposures for which cumulative population doses could be substantial (NCRP 2009; Hall and Brenner 2008; Brenner and Hall 2007). Further, evaluation of risks among persons with intakes of radioactive substances assumes greater importance as society debates expansion of nuclear energy and the disposal of nuclear waste, and copes with the possibility of terrorist attacks with "dirty bombs." There also has been recent concern over the possible health effects from depleted uranium (IOM 2008) and from radioactive fallout to exposed populations (Merali 2009). To address these issues, a follow-up study is proposed of 125,000 military personnel who participated in nuclear weapons testing between 1946 and 1958. There are few if any populations that can provide such unique information on lifetime radiation risks among persons exposed over 60 years ago.

We propose to follow the 125,000 soldiers, sailors, airmen and marines present at one or more of the 230 aboveground detonations for an additional 20 years since last studied. All cancers and other causes of death, including heart disease, will be evaluated. A comprehensive dose reconstruction methodology will be used to estimate doses for specific cancers previously found to be increased, e.g., leukemia, and for a representative sample of the cohort for comparison. External radiation exposures have been estimated for all atomic veterans but are highly uncertain and require validation; dose reconstruction is required to include internal intakes of radionuclides.

The military codenames for the seven test series selected for study are shown in Table 2-1. The sites were selected because they had the highest recorded exposures (IOM 2000; Johnson 1996; Watanabe 1995b). The earliest test participants were exposed in 1946 and their follow-up will be equivalent to that of the Japanese atomic bomb survivors exposed in 1945. The majority

of test participants have now died. Significant elevations have been reported for leukemia and cancers of the liver, bone, salivary gland, male breast and thyroid, but evaluations by radiation dose were not possible. The Five Series study (IOM 2000), for example, included nearly 70,000 soldiers, sailors, and airmen who participated in one or more of five U.S. nuclear weapons test series in the 1950s and also included 65,000 comparable non-participants, or referents. Follow-up was through 1996. Participants and referents had similar low risks of death from cancer (SMR 0.74 for both groups), reflecting the "healthy soldier effect" (Seltzer 1974, 1977; Kang 1996). Leukemia, however, was increased among participants compared to the reference cohort (RR 1.15, n=185), and the excess among participants at the "ground-based" Nevada Test Site (NTS) was statistically significant (RR 1.49; 95% CI 1.04, 2.13). Previous studies have not provided details on the risk of heart disease among nuclear weapons test participants, although reported elevations, albeit small, were based on large numbers of deaths, e.g., RR 1.09 (n=504) in the U.K. study (Muirhead 2004) and in the Five Series study, RR 1.02 (n=6,970).

A unique aspect of the proposed study is that individual dose assignments will be "best estimates" and not based on veteran-favorable assumptions or approaches used in compensation program. New developments in statistical methodology also will be applied to account for the uncertainties in the reconstructed radiation doses (NCRP 2008; NRC 2003; Raine 2007). The Seven Series study thus provides a unique and timely opportunity to take advantage of existing radiation dose data on well-defined and previously studied veteran cohorts and to extend these data for epidemiologic lifetime risk assessment.

METHODS

Population identification. Seven cohorts of 125,000 military personnel (Table 2-1) have been carefully constructed and studied by the Medical Follow-Up Agency (MFUA) (Robinette 1985; Johnson 1996; IOM 2000) and the U.S. Department of Veterans Affairs (VA) (Watanabe 1995b). These individuals will form the study population whose recent mortality experience will be assessed.

Table 2-1. Number of participants at each of the seven nuclear weapon test series by military service. Military service was missing for 2 participants. These tests involved 99 bomb detonations.

Test series	Year	Test site	Air Force	Army	Marine Corps	Navy	Total
CROSSROADS	1946	Pacific	0	3,395	551	39,188	43,134
GREENHOUSE	1951	Pacific	2,442	1,548	70	3,854	7,914
UPSHOT-KNOTHOLE	1953	Nevada	2,175	13,401	2,256	886	18,718
CASTLE	1954	Pacific	2,763	1,644	306	11,918	16,631
REDWING	1956	Pacific	2,976	1,708	250	6,993	11,927
PLUMBBOB	1957	Nevada	2,216	7,052	2,120	601	11,989
HARDTACK I	1958	Nevada	3,476	1,535	187	9,487	14,685
Total			16,048	30,283	5,740	72,927	124,998

Population tracing. Approaches for ascertaining deaths described in Aim 1 will be used, but with the enhancement of the unique Department of Veterans Affairs BIRLS system (Beneficiary Identification Record Location Subsystem). This system has been used extensively for epidemiologic research on veterans (Kang 1996, 2000, 2002, 2006; Bullman 2000, 2005; Smith 2004; Thomas 1991; Watanabe 1991, 1995a). The data files contain identifying information on individuals who have submitted claims for veterans' benefits (Fisher 1995; Page 1996; Boyko 2000; Maynard 2004). BIRLS data files can be searched on name and military service number and were used in the previous studies to verify and update information for atomic veterans. Only military service number is required which is available for all 125,000 test participants. For veterans who have died, death certificates can be retrieved from the VA claims record folder if a death benefit is awarded. Numerous other national electronic databases are available on

veterans including the Patient Treatment File (hospital abstracts) and the Outpatient Care File (Maynard 2004; Cowper 2002). As of last follow-up, 43,577 (or 34.9%) of the study veterans were known to have died. It is estimated that over 75,000 deaths will have occurred by the end of 2010, i.e., an additional 31,000 deaths since last follow-up.

Exposure assessment (dose reconstruction). The goal is to provide unbiased best estimates of annual external and internal absorbed doses to selected tissues and organs of individual veterans. The dosimetry approach is based on a validated and tested methodology and takes advantage of the considerable new information not available when the previous studies were conducted. A comprehensive ongoing program of dose reconstruction coordinated by the DTRA has collected and developed new information on military personnel and exposure scenarios used to determine reliable estimates of radiation dose for U.S. atomic veterans (IOM 2000; NRC 1989, 1995, 2003; DTRA 2007a, 2007b, 2007c). Over 300 million dollars have been spent over the past three decades in developing the complex exposure scenarios used in individual dose reconstructions.

Two members of the study team served on the NAS Committee (one as Chair) which reviewed the dosimetry data available on nuclear test personnel in 1995 and made recommendations on how they could be "recalculated" for "epidemiologic purposes" (Heath and Till 2000, p. 103). We are following these recommendations to provide dose estimates suitable for epidemiologic analyses. Members of the study team also served on the subsequent NAS Committee (one as chair) reviewing the DTRA dose reconstruction program (NRC 2003). Three members currently serve on the Congressionally-mandated Veterans' Advisory Board for Dose Reconstruction and have provided guidance and direction on over 600 dose reconstructions on nuclear weapons test participants using the revised methodologies currently used by the Department of Defense. One member has provided independent quality review of each completed dose reconstruction as a subcontractor to DTRA and is a member of two current NCRP committees: one dealing with uncertainties in internal dose estimates and the other with fundamental principles of dose reconstruction. Recently, one of our members chaired the NCRP committee on uncertainties in measurements and dosimetry, including applications for atomic veterans (NCRP 2008). The approach outlined below has gone through strenuous testing and is considered the state-of-the-art methodology for deriving "best estimates" of dose with associated uncertainty for use in epidemiologic studies of atomic veterans.

Methods to estimate individual radiation doses for epidemiologic analyses. DTRA has developed a comprehensive series of reports that describe the radiation exposure environment for practically every ship and land unit at every test in every series; these reports provide the basic scientific data needed for individual dose reconstruction. Over 4,000 detailed dose reconstructions have been performed by DTRA over the course of the Nuclear Test Personnel Review (NTPR) program. Over 600 complex dose reconstructions since 2004 have applied the same methodology and used the same databases and data sources that we will use. The comprehensive methodology has been audited, validated and codified in a detailed set of standard operating procedures. Some of the newer methodologies have also undergone detailed peer review by committees of the NCRP (2008).

Military unit exposure scenarios include direct gamma and neutron radiation from the detonation, gamma exposure from activated soils or deposited fallout, inhalation of descending fallout or resuspended fallout and activated soils, and ingestion of contaminated water or foodstuffs. Individual dose reconstruction for a particular veteran begins with the standard scenario common to all members of his unit, and then takes into account any unique exposure situations the veteran may have encountered, such as maintenance of cloud-penetrating aircraft, reboarding target ships, or operating small boats in contaminated lagoons. Over 10% of the veterans (>12,500) had participated in more than one weapon test series (IOM 2000;

Johnson 1996) indicating the potential for relatively high doses among some veterans since a single test series might involve 10 or more aboveground detonations.

There were over 375,000 individual estimates of radiation dose based on film badges. Most of the estimates pertained to gamma-ray exposures but nearly 4% of the badges also provided neutron exposures. Nearly half of the exposures were based on film badge readings and the other half were based on some method of dose reconstruction, including cohort badges. Estimates of external radiation exposure are available for all 125,000 atomic veterans and range from minimal to nearly 100 rem (1 Sv). Interestingly, the mean exposure of the 95,000 atomic veterans with nonzero estimates is 16.7 mSv and thus comparable with the 19.4 mSv reported in the 15-country worker study (Cardis 2007). To date little attention had been given to exposure pathways involving intakes of radionuclides with estimates made for only 2% of the veterans.

The Nuclear Test Review and Information System (NuTRIS) database contains all available physical dosimetry information for every nuclear weapons test participant. If the review identifies the potential for internal exposure, we will use information about contamination levels and activities at locations identified in the exposure scenario to estimate inhalation and ingestion doses to tissue(s) of interest. The updated FIIDOS code (A Computer Code for the Computation of Fallout Inhalation and Ingestion Dose to Organs, Raine 2007) will be used to facilitate the internal dose calculations.

On the basis of previous epidemiologic studies and knowledge of exposures possible during atmospheric weapons testing, red bone marrow, bone surface, thyroid, salivary gland, breast and liver will be the tissues of *a priori* dosimetric and epidemiologic interest. Other known radiosensitive sites include cancers of the lung and colon. All dose reconstruction will be conducted blindly without knowledge of cancer status. Doses for all the organs of interest will be calculated. About 33,000 veterans are expected to have been minimally exposed (<1 mSv or 0.10 rem). External radiation doses, whether to penetrating photons or to neutrons, will be estimated on a year by year basis, and any radionuclide intakes will be processed so that yearly doses for specific organs or tissues can be estimated using current International Commission on Radiological Protection (ICRP) biokinetic models (ICRP 2007; Raine 2007; Boice 2006b).

Quality assurance. A quality assurance (QA) plan will ensure that consistent, accurate, traceable, and reproducible methodologies are implemented to calculate the doses (Toohey 2002, 2008).

Case-cohort study. Because it would be prohibitively expensive to perform individual dose reconstructions on all 125,000 test participants, or even the 92,000 with non-minimal exposures, the case-cohort design will be used. Cases are all test participants who developed leukemia or cancers of the liver, bone, thyroid, salivary gland and breast. The subcohort for comparison will be a 1% random sample (n=1,250) within defined strata from the cohort of 125,000 test participants. However, all cancers and causes of death will be evaluated and if notable increases are observed in the extended follow-up or if additional resources become available from other governmental agencies, the number of dose reconstructions will be increased accordingly, i.e., extended to other cancers or conditions. Case-cohort analytical techniques will assess risk within the cohort over categories of reconstructed radiation dose to specific organs (Kelsey 1996). Stratification factors will be test series, sex, rank, service and age at the time of the tests. Trend tests will be performed with year of birth, year of participation, sex and rank (officer/enlisted) included in all models. Rank and/or pay grade will be considered surrogate measures of socio-economic status. Trend tests will treat radiation dose as a single, time-dependent measure, and one-sided p-values presented. Relative risks at 100 mSv will be computed. Models will be developed to access directly the contribution of inhaled and ingested radioactive fallout to risk, controlling for external exposures. Intra-cohort dose-response

analyses would be expected to minimize any biases that might exist when external comparisons are made with a general population are made.

Statistical considerations. The available external radiation dose estimates can provide an approximate and useful guide for power computations. The estimate of average dose, though uncertain, is about 17 mSv (1.7 rem) for the 95,000 participants with estimated exposures; 3,600 likely received greater than 50 mSv (5 rem) and nearly 1,000 over 100 mSv (10 rem). The highest recorded dose was 970 mSv (97 rem). These estimates are "low-sided" in the sense that internal radiation exposures are not included and film badge records were often incomplete. Based on available film badge readings, approximately 33,000 veterans presumably received <1 mSv (0.10 rem) and represent a minimally exposed referent group for these power computations. When interpreting the power computations below, it might be noted that the current estimates of relative risk for leukemia are of the order of 1.3 to 1.5 for doses between 50 and 100 mSv (5 to 10 rem) (UNSCEAR 1994, 2000, 2008; NRC 2006; Preston 1994). Estimates of risk for other cancers are lower, but intakes of certain radionuclides could increase the dose appreciably for certain organs such as the thyroid, liver and bone (IARC 2001) and excess risks have already been reported for these sites.

Power. In the Table 2-2, we present various sizes of the relative risks (RR) and the associated power to detect a difference in leukemia and five other cancers is presented. The power values are given for a one-sided 5% nominal significance level and baseline rates are based on the referent groups and minimally-exposed participants in previous studies (IOM 2000; Johnson 1996) and from the American Cancer Society and SEER cumulative cancer probability tables for males (ACS 2008). Power is greater than 80% to detect relative risks of the order of 1.2 for leukemia, 1.3 for liver cancer, 2.0 for bone cancer, and 2.2 for the other cancers.

Table 2-2. Detectable relative risks and associated power for leukemia and other cancers, contrasting the 40,000 "highest" exposed participants (>10 mSv) with the 33,000 lowest exposed participants (<1 mSv). Baseline rates in parentheses.

RR	Leukemia (0.95%)	Liver (0.7%)	Bone (0.05%)	Thyroid (0.046%)	Salivary (0.04%)	Male Breast (0.031%)
1.2	0.80	0.69	0.14	0.14	0.13	0.12
1.3	0.97	0.93	0.21	0.20	0.19	0.16
1.4	0.99	0.99	0.29	0.28	0.26	0.22
1.5	0.99	0.99	0.38	0.36	0.33	0.28
2.0	0.99	0.99	0.80	0.77	0.72	0.62
2.2	0.99	0.99	0.90	0.87	0.83	0.74

In Table 2-3 the Cochran-Armitage trend test (Nam 1987) is applied to estimate the study power for the case-cohort study. The power to detect a linear trend in excess relative risk (ERR) over 5 dose categories is evaluated. The dose categories, based on current dose reconstructions for Seven Series participants, are <1 mSv, 1-5 mSv, 5-10 mSv, 10-50 mSv and >50 mSv with the corresponding subcohort population distributions of 13%, 30%, 23%, 31% and 2.5%, respectively. The subcohort consists of a 1% random sample from the entire cohort (n=1,250). The estimated numbers of cancer cases, based on previous studies and preliminary mortality linkages, are estimated to be of the order of 1000 for leukemia, 500 for liver cancer, and 25-50 each for cancers of the bone, thyroid, salivary gland and male breast. Similar to the

Table 2-3. Detectable dose response trend in the excess relative risk (ERR) over 5 dose categories and associated power for leukemia, bone, liver, thyroid, salivary, and male breast cancer in case-cohort study. Baseline rates in parentheses.

Trend (ERR)	Leukemia (0.95%)	Liver (0.70%)	Bone (0.05%)	Thyroid (0.046%)	Salivary (0.04%)	Male breast (0.031%)
.05	0.92	0.88	0.44	0.43	0.42	0.39
.10	0.99	0.99	0.63	0.62	0.59	0.55
.15	0.99	0.99	0.80	0.78	0.75	0.69
.20	0.99	0.99	0.91	0.90	0.87	0.81
.25	0.99	0.99	0.97	0.96	0.94	0.90

dichotomous power computations in Table 2-3, the trend evaluations indicate substantial power to detect relatively low level increases in the ERR (0.20) for leukemia and liver cancer. For the other rarer cancers, the proposed study reaches at least 80% power to detect a trend in the ERR of 0.20 with one-sided type I error = 5%.

Study power is sufficient to detect even modest increases in risk for leukemia and liver cancer, but is recognized to be less for the other rare cancers. Power to detect increases for these outcomes, however, depends on the organ dose which is influenced by radionuclide uptakes, e.g., radioactive iodine by thyroid and plutonium and uranium by bone and liver, which are yet to be determined.

Characterization of medical radiation exposures and other potential confounders. To address the possibility that increased exposures to medical radiation (Mettler 2008; NCRP 2009) may have contributed significantly to the total radiation exposure received by atomic veterans, medical records for all selected cancer cases and members of the subcohort comparison group will be sought within the Veterans Affairs' health care system. The electronic files will be searched initially, including the Patient Treatment File (hospital abstracts), the Outpatient Care File, and BIRLS (Maynard 2004). Then medical record folders will be retrieved and medical radiation, both diagnostic and therapeutic, abstracted. At a minimum, the information will be used to learn whether there are any marked differences in medical radiation received over categories of estimated dose from test participation. Any information on hepatitis infection, cigarette smoking and alcohol abuse will be similarly sought in these records and carefully evaluated.

Uncertainty in dose estimates. Recent developments in statistical methodology will be adapted and extended to account for the uncertainties in the reconstructed radiation doses for atomic veterans (NRC 1995, 2003; Ron 1999; Kopecky 2004; Schafer 2006; Stayner 2007; NCRP 2008). Uncertainties can be viewed as the range of values of estimated dose within which the true value of dose is estimated to lie (NCRP 1996, 2008; Ron 1999; Thomas 2005). Uncertainty is a best estimate of possible inaccuracies due to both random and systematic errors. *Random errors* are those that vary in a non-reproducible way around a limiting mean. These errors can be treated statistically by use of the laws of probability. *Systematic errors,* on the other hand, are errors that are reproducible and tend to bias a result in one direction. For instance, it has been estimated that a few film badge readings were biased and the amount of possible bias can be estimated (NRC 1989). Probabilistic uncertainty analysis methods currently under development for the DTRA Nuclear Test Personnel Review dose reconstruction program will also be considered.

SUMMARY

The atomic veteran cohorts can be followed for more than 60 years which is equivalent to the observation time for Japanese atomic bomb survivors. The studies of populations exposed to Chernobyl radiation have the potential to provide knowledge on chronic exposure, but the event in 1986 is too recent to address long-term or lifetime risks. There remains scientific debate over the appropriate factor to "adjust" the Japanese survivor risk estimates (from acute and high doses) for the purposes of radiation protection (involving chronic and low doses). The BEIR VII Committee (NRC 2006) favored 1.5 as the Dose and Dose Rate Reduction Factor, whereas UNSCEAR (2008, 2000) and ICRP (2007, 1991) continued with 2.0 and the French Academy of Sciences questioned both the evidence on carcinogenic risks below about 100 mSv (10 rem) and the level of risk predicted based on linearity (Tubiana 2006). The chronic low-dose exposures received by weapons participants would allow this issue to be addressed directly. Another limitation of the Japanese atomic bomb survivor data is the somewhat uncertain process of "transporting" radiation risks from an Asian population exposed in 1945 to those of

Western countries with widely varying background rates of cancer. Risks associated with veteran populations are directly applicable to U.S. populations.

Compared with external radiation, there are surprisingly few data on human risks for the ingestion or inhalation of radioactive substances such as those present in fallout, nuclear wastes and even nuclear medicine procedures (COMARE 2004; Harrison 2003, 2005; Little 2007; UNSCEAR 2008). Nuclear weapons tests at the Nevada Test Site and the Pacific Proving Ground provided the opportunity for inhaled or ingested radioactivity (Beck 2006) which can be evaluated in the current design. This unique opportunity has struck a responsive chord as indicated by the collaborations forged with the Departments of Defense and Veterans Affairs, the National Association of Atomic Veterans and our scientific team of experts in radiation epidemiology, biostatistics, coronary heart disease and dosimetry. Few opportunities remain to study large and well-defined populations who accumulated radiation doses gradually over time.

Aim 3 - Radiologists, Radiotherapists and Other Medical Workers

Landauer, Inc. has provided radiation dosimetry services since 1953 for United States medical facilities. A computerized database is maintained of over fifteen million workers with identifiers and cumulative dose measurements. Included in the database are radiologists, radiotherapists, cardiologists and others in the medical profession who experienced frequent radiation exposures during the course of their employment. An opportunity exists to utilize these dosimetry records for epidemiologic study by following the approximately 550,000 workers with relatively complete dosimetry coverage over time. Given the increasing use of medical radiation and the increased potential for personnel exposures (NCRP 2009, Hall and Brenner 2008), the study of medical radiological practitioners has the potential to provide quantitative information needed to address current concerns about the long-term effects of chronic radiation exposures experienced over a period of many years by workers and the general population.

The first cancer attributed to ionizing radiation occurred on the hand of a radiologist in 1902, and leukemia was first associated with chronic exposure in studies of radiologists (March 1944). Excess leukemia and solid cancers have also been observed among pioneering radiologists (March 1944; Lewis 1963; Matanoski 1975; Smith and Doll 1981; Berrington 2001; Wang 1990, 2002). Studies of medical x-ray technologists have been less clear in revealing excess cancers (Jablon and Miller 1978; Yoshinaga 1999; Doody 1998; Mohan 2003; Yoshinaga 2004). The absence of reliable dosimetry in practically all of these studies has precluded quantitative estimation of risk, although recent attempts for dose reconstructions are vastly improved over past studies (Simon 2006; Bhatti 2007).

The most comprehensive study to date, conducted by NCI, is of 143,000 technologists who were certified by the American Registry of Radiologic Technologists for at least two years during 1926-1982 (Boice 1992; Mohan 2003; Yoshinaga 2004; Simon 2006). In this study, cumulative doses for most technologists were estimated to average about 1.7 rem (17 mSv) overall based largely on records linkage with Landauer, Inc., which covered about 19% of the population (Boice 1992). These estimates are consistent with subsequent ones (Chodick 2008) based on comprehensive modeling and biodosimetry approaches (Simon 2006; Bhatti 2007). In the proposed study we will identify all medical professionals within the Landauer database, with special focus on interventional radiologists, cardiologists, radiotherapists and other potentially high-dose groups so that there will be little overlap with the NCI cohort. Our study population will be selected based on long-term coverage within Landauer, Inc.

METHODS

The Landauer database. The Landauer, Inc. database contains records on15 million individual workers. The record for each individual contains personal identifiers (social security number, name, date of birth, sex), employment data (employer account number, account inception and termination dates with Landauer, Inc.) and dose data (annual whole body deep dose, cumulative whole body deep dose, and previous deep dose prior to inception with Landauer (if provided)). Since 1978, annual doses for workers monitored by Landauer have been stored in the computerized database, together with the cumulative dose prior to that time. Records for periods from the1950s through 1977 have been stored on microfilm. Doses incurred at facilities not covered by Landauer are included if reported by an account holder and are available as early as the 1940s.

The Landauer database has been used in occupational studies to provide and/or enhance the dosimetry information of workforces, including those in the Rocketdyne, the x-ray technologist, atomic veterans, Mound and other studies.

Population identification. .Based on the years of coverage within the Landauer database, approximately 550,000 workers will be selected who have nearly complete coverage of at least 5 years. The cohort will be identified using the electronic datafiles for persons employed in 1978 or thereafter, but which are known to include earlier inception dates to the 1940s. These data will be supplemented through the computerization of the microfilm records to capture the relatively higher exposures experienced by persons who terminated employment prior to 1978.

Population tracing. Similar to the approaches described in Aim 1, mortality and vital status searches will be comprehensive and include state-of-the art approaches to locate and obtain cause of death for all study subjects. Follow up will begin at the date when 5 years of dosimetry information is available, and continue until censoring at December 31, 2010.

Dose reconstruction. The Landauer dosimetry measurements have followed stringent procedures to provide accurate dose information for workers, often to comply with legal requirements. The measurements have been made by a variety of techniques over the years, from film badges to thermoluminescent dosimetry technology (TLD) to optical methods. For the medical professionals in our proposed study the measurements are considered consistent and reproducible. Because selection of the population for study focuses on those with long-term coverage within Landauer, there are unlikely to be serious gaps in monitoring. However, to correct for any incomplete coverage we will, as described in Aim 1, link the Landauer data roster with national databases available from military, government and commercial sources but then apply modeling approaches to handle any residual gaps. The modeling approaches will be similar to those used in the NCI radiological technologist study, which we have been involved with over the years (Boice 1992; Mohan 2003) and for which Dr. Yoder remains so (Simon 2006). In brief, our approach to dose reconstruction will rely on the estimated 4 million film badge and TLD measurements for workers in our study, the additional information available from archived Landauer records which will require abstraction, linkages with other dosimetry databases, and the modeling that is needed to account for different average energies of medical x-rays and gamma rays, use of protective aprons, placement of dosimeters when worn, and minimal detectable doses over calendar years (Gilbert 1996; Simon 2006).

In the NCI technologist study (Boice 1992; Simon 2006; Bhatti 2007), Landauer badge measurements were estimated cumulative does to average about 1.7 rem (17 mSv). Our study will involve higher exposures because we will include interventional radiologists and radiotherapists for whom exposures are known to be higher than for technologists. The NCI study also had about 19% coverage of their population with film badge reading from Landauer and thus modeling and extrapolation was paramount in making dose reconstructions. We, by definition, should have near complete coverage with dosimeter measurements; but we

recognize that personal exposures to medical x-rays as captured in the NCI study will not be similarly recorded and adjustments in the analyses will have to be considered using, in part, the methods described in Simon (2006).

Statistical analyses. The distribution of doses for the medical professionals has not been finalized so we do not present statistical power computations. We are confident that the power to detect underlying effects is substantial, however, given the large study size and our finding in preliminary linkages of high exposures approaching 1 Sv (100 rem). Prior studies of the early technologists indicate associations that are likely radiation-related for leukemia, breast and thyroid cancer, and study of pioneering radiologists reported elevations for lung cancer, skin cancer, multiple myeloma and several other malignancies, although not consistently. Our investigation will quantify such risks in a working population with comprehensive measurements and dose reconstructions.

Uncertainty analyses will be conducted as described in previous Aims and also in the recent x-ray technologist paper by Simon (2006). The overall goal of an uncertainty analysis is to quantify the state of knowledge on doses for individuals, which in turn allows estimation of reasonable bounds on the population cancer risk. Limitations to the data include incomplete Landauer monitoring coverage for individuals across time periods and employers, lack of information on whether badges were worn consistently and appropriately, and incomplete information on wearing of aprons and placement of badges relative to aprons.

A variety of techniques to account for and to propagate uncertainty will be used, including analytic error propagation, simulation, temporal correlation and correction for bias. Each of these techniques is explained in some detail in Simon (2006). Dose estimation is not always separate from the analysis of uncertainty, since the dose calculations include both aspects. Integration of dosimetry and uncertainty analysis is often an important aspect of epidemiologic studies of radiation exposed populations (Ron 1999). Each technologist's annual badge and organ dose will be characterized by a lognormal uncertainty distribution from which alternative realizations of an individual's true annual dose will be generated. Similar to all the uncertainty approaches taken for the studies described in this proposal, a subcommittee has been developed to address the issues of uncertainties which includes Dan Stram, Duncan Thomas, Ken Kopecky, Yu Shyr and the dosimetrists familiar with the specifics of each workforce to be analyzed.

SUMMARY

Preliminary linkages indicate that approximately 500,000 individual workers within the Landauer, Inc. dosimetry database have monitoring records that span at least 10 years. Identifying information such as Social Security number, name and date of birth exist, and cumulative and annual radiation doses are recorded in a systematic fashion. Prior annual records exist on microfilm and will be abstracted from the 1950s to 1977. Electronic records exist after 1977. Date of inception, i.e., the date of first radiation dose, is available as early as the mid-1940s. The population will be traced as described in Aim 1. Dosimetry uncertainty will be evaluated, taking into account measurement, positioning, shielding, and the unique errors associated with medical workers. The proliferating use of CT scans and medical procedures in the U.S. and other developed countries (NCRP 2009), indicates the clear need to reliably estimate the risk experienced from low dose radiation exposures, not received acutely as in the atomic bomb investigations, but chronically over time, as during medical profession circumstances (Hall and Brenner 2008; Brenner and Hall 2007). Previous studies of the pioneering medical radiation workers have indicated clear elevations of leukemia and certain other cancers. However, the absence of reliable dosimetry has hindered interpretation as to the level of risk and comparisons with acute exposures. The Landauer dosimetry study of medical professionals with long term

exposures will provide important knowledge on lifetime risks associated with these exposures of current scientific and societal concern.

Aim 4 - Nuclear Power Plant (NPP) Workers

The United States was the first country to develop nuclear reactors to produce electricity. Early workers were allowed 3 rem per quarter and 12 rem per year. Maximum exposure limits were subsequently reduced to 5 rem per year and actual exposures to workers are much lower today and of the order of 0.2 rem per year (Andersen 2008). Studies of the early NPP workers have the potential to provide useful information on radiation risks because of the relatively high exposures (Goldsmith 1989; Muirhead 1996; Jablon and Boice 1993; Hall 2009). A feasibility study of 9,000 workers at the Calvert Cliffs NPP, for example, was able to include contract workers and that 12% of all workers had career doses >5 rem (50 mSv) [max 47 rem (470 mSv)] (Jablon and Boice 1993). A recent study of 53,698 U.S. nuclear power plant workers was limited because the study design included mainly recent hires, which resulted in a young workforce, a low mean cumulative dose [2.6 rem (26 mSv)] and narrow dose range, and few deaths (1,190) (Howe 2004). Nonetheless, the study reported a significant association with coronary heart disease which merits further attention. There are over 650,000 past and current utility workers and 350,000 currently are included in a recently developed registry, the Personnel Access Data System (PADS). Herein we propose to assess cancer and other disease mortality in a cohort of NPP workers with documented radiation exposure histories.

METHODS

Population identification. Landauer, Inc. provides dosimetry services for a large number of radiation workers in the United States. Although most of these workers are employed in the medical professions (Aim 3), about 15,000-20,000 NPP workers were monitored by Landauer during the late 1970s, which comprised about 10-15% of all NPP workers at that time. This percentage increased to about 25% (or about 40,000 workers) by the mid-1980s (Muirhead 1996). These 40,000+ workers within the Landauer database will form the basis of the nuclear power plant cohort to be studied. Additional NPP workers who terminated employment prior to 1978 also may be included by review of Landauer records that are not computerized, i.e., that are on microfilm from the 1960s to 1977. NRC REIRS termination notices will be sought to fill in any gaps in years of coverage.

Population tracing. Similar to the methods outlined in Aim 1, vital status and cause of death will be sought using a wide-range of national databases, including the social security administration, the National Death Index, the Social Security death index (available in-house for probabilistic matching), various credit bureau and other record systems. Tracing will begin from the date the first radiation reading was recorded until December 31, 2010. The availability of social security number, name, and date of birth will facilitate accurate determination of deaths and vital status through 2010 for nuclear utility and other worker cohorts.

Dose reconstruction. Methods for doses reconstructed for the NPP workers will be similar to what was described in Aim 3 (medical workers). The Landauer dosimetry measurements have followed stringent procedures to provide accurate dose information for workers, often to comply with legal requirements. To address any incomplete coverage we will, as described in Aim 1 (uranium workers), link the Landauer data roster with national databases available from military, government and commercial sources and then apply modeling approaches to handle any residual gaps. Our approach to dose reconstruction for the Landauer-based NPP workers will rely on the estimated 200,000 film badge and TLD measurements for workers in our study, the additional information available from archived Landauer records which will require abstraction, linkages with other dosimetry databases, including the Nuclear Regulatory Commission REIRS

system, and the modeling required to account for errors associated with film badge readings as described below (Thierry-Chef 2007; Schafer and Gilbert 2006; Gilbert 1996, 1998; Stram and Kopecky 2003; NRC 1989).

Several U.S. NPP cohorts were included in the 15-country study (Cardis 2005) for which dose reconstructions were carefully considered (Gilbert 2006; Thierry-Chef 2007). Errors in recorded doses were quantified after review of historical dosimetric practices and technologies at participating facilities. The main sources of dose errors from "high-energy" photons (100-3,000 keV) were related to how the dosimeters responded to workplace exposure conditions and the methods for calibration. Doses from "lower-energy" photons (<100 keV) and from "higher-energy" photons (>3 MeV) were estimated to be small. Errors were quantified to derive estimates of bias and uncertainties in recorded doses based on measurement studies, dosimetry expert assessment and on the estimated energy and geometry response of dosimeters. A lognormal error structure model was developed to describe errors in doses. Doses from other radiation types, i.e., neutrons and radionuclide intake, could not be adequately reconstructed in the framework of the 15-country study, but these internal and neutron exposures will be addressed directly in our study (see Methods described in Aim 1).

Statistical analyses. The distribution of doses for the NPP workers has not been finalized so we do not present statistical power computations. However, given the allowable doses for these earlier workers (up to 12 rem per year), the preliminary linkages for Landauer-based workers identifying cumulative doses over 100 rem (1 Sv), and the feasibility study of 9,000 workers at Calvert Cliffs (12% >5 rem, max 47 rem), there should be sufficient statistical power to detect excess cancers should they occur given the relatively long follow-up for workers first employed 1960-1985. Similar to previous Aims, analyses will be made using external comparisons with the general population of the U.S., i.e. SMR analyses (Marsh 1998) followed by internal dose-response analyses over categories of radiation doses using Cox proportional hazards models or Poisson regression models (Preston 1993).

Uncertainty analyses will be conducted as described in previous Aims and also in the recent x-ray technologist paper by Simon (2006) and the 15-country study paper by Thiery-Chef (2007). A subcommittee has been formed to address the issues of uncertainties in all study cohorts which includes Dan Stram, Duncan Thomas, Ken Kopecky, Yu Shyr and the dosimetrists familiar with the specifics of each workforce to be analyzed.

SUMMARY

Early NPP workers will be studied, with the records of Landauer, Inc. used to identify at least 40,000 early workers employed before 1985. The focus on these early workers will enable assessment of risk across a wide dose range, since relatively high doses were allowed, i.e., 3 rem per quarter and 12 rem per year depending on age and prior cumulative dose.

As emphasized in all previous Aims, study of these early radiation workers, as recently recommended by the DOE workshop on low-dose epidemiologic studies (Hall 2009), will provide important opportunities to clarify the risks of radiation exposures that are experienced gradually over time. The resultant information will directly address public, scientific and radiation protection issues, especially in light of recent claims that chronic low dose rate exposures may be as harmful as acute high dose rate exposures that form the basis of today's radiation protection standards (Jacob 2009; Cardis 2005, 2007a, 2007b; Krestinina 2005, 2007).

Aim 5 - Plutonium Workers

Studies of plutonium workers have not found consistent evidence of radiation risks except at rather high dose levels experienced by early weapons production workers in the former Soviet

Union (UNSCEAR 1994; Voelz 1997; Omar 1999; IARC 2001; Gilbert 2004). The inconsistencies in worker studies in the USA (Voelz 1997) and UK (Omar 1999) were attributed to the much lower exposure to plutonium than experienced by Russian Mayak workers during the 1940s and 1950s who showed increased cancers of heavily irradiated sites, i.e., the lung, liver and bone (IARC 2001). Studies of 15,727 workers at the Los Alamos National Laboratory, however, suggest an increased risk of lung cancer, osteosarcoma and several other malignancies (Wiggs 1994; Wilkinson 1987), which highlight the need for further study

The mortality experience of nearly 31,500 males and 12,600 female workers employed between 1944 and 1978 at the Hanford nuclear installation in Richland, Washington, has been reported by several investigators. Analyses up to 1986, which includes 5,413 workers at Rocky Flats, revealed a strong "healthy worker" effect, a significant deficit of cancer mortality, including leukemia and no evidence for increasing risk with increasing film badge exposure for any cancer (Gilbert 1993a, 1993b). A more recent follow-up of 26,389 Hanford workers through 1994 identified 8,153 deaths and a negative dose response for leukemia, but a positive dose response for lung cancer (Wing 2005). Associations between duration of employment at Hanford in jobs with routine potential for plutonium exposure and mortality were also reported suggesting occupational exposure effects (Wing 2004). An association between age at first internal lung dose and lung cancer was also reported in a case-control study of Rocky Flats workers (Brown 2004). Follow up of these cohorts, however, ended in 1990 or earlier, and updates of the plutonium workers mortality experience are needed.

METHODS

Population identification. Table 5-1 shows that the plutonium worker cohorts previously studied include nearly 100,000 workers at Los Alamos, Rocky Flats, Hanford and Mound (Wiggs 1991a, 1991b, 1994; Gilbert 1993a). It is noted that other workforces with potential exposure to plutonium such as Sandia (n=24,685) have been identified for study.

Table 5-1. Cohorts of plutonium workers

Worker cohort	No.	Relevant publication/s	Last follow-up	No. dead	Total in database*
Los Alamos	15,727	Wiggs 1991;Wilkinson 1987;Gilbert 1993a	1990	3,196	23,288
Rocky Flats	5,413	Gilbert 1993; Brown 2004	1979	409	9,586
Hanford	32,643	Gilbert 1993a, 1993b; Wing 2004, 2005	1986	9,452	56,688
Mound	4,402	Wiggs 1991a, 1991b	1984	987	7,293
Sandia	N/A	None			24,685
Sum of unique workers	58,185			14,044	121,540

Population tracing. Similar to the methods outlined in Aim 1, vital status and cause of death will be sought using a wide-range of national databases, including the social security administration, the National Death Index, the Social Security death index, various credit bureau and other record systems. The availability of social security number, name, and date of birth will facilitate accurate determination of deaths and vital status through 2010 for the plutonium worker cohorts.

Dose reconstruction. Methods for doses reconstructed for the plutonium workers will be similar to what was described in Aim 1.

Statistical analyses. The statistical approaches to be followed will mirror those applied to the study of uranium workers.

Mound pilot study. To demonstrate that the previously identified plutonium cohorts could be effectively studied, a feasibility project of over 7,261 workers at the Mound nuclear weapons facility (1944-1972) located near Dayton, Ohio was conducted. The cohort data included non-

white and female workers (who had not been previously studied), radiation dose information evaluated (including internal uptakes), and population tracing conducted (Table 5-2). The pilot project was successful in that vital status of 98.2% of the population was obtained, the inclusion of females (24.9%) and non-whites (6.2%) was found to be feasible and the bioassay data necessary for internal dose assessments was found to be adequate.

Table 5-2. Demographic and occupational characteristics of 7,261 Mound, Ohio workers

Characteristic	N	%	Characteristic	N	%
Gender			**Year of Hire**		
Male	5,455	75.1	1940-1949	2,578	35.5
Female	1,806	24.9	1950-1959	1,146	15.8
			1960-1969	2,289	31.5
Race			1970-1979	823	11.3
White	5,834	80.4	Missing	425	5.9
Non-White	453	6.2			
Missing	974	13.4	**Years of follow-up**		
			<30	1,782	24.5
Year of Birth			30-49	4,218	58.1
<1920	2,015	27.8	≥50	1,261	17.4
1920-1929	2,051	28.3			
1930-1939	1,316	18.1	**Vital Status as of 12/31/05**		
1940-1949	1,377	19.0	Confirmed Alive	3,922	54.0
1950-1959	467	6.4	Dead	3,208	44.2
≥1960	35	0.5	Lost to follow-up	131	1.8

SUMMARY

The study of workers with the potential for plutonium exposure would add a final dimension to the overall proposal. Over 100,000 such workers in the United States have not been recently followed, and more importantly, comprehensive dose reconstructions of internal intakes have not been completed. It is envisioned that such workers would be available for study in year 2 of the proposed grant and follow-up and dose reconstructions completed similar to that described for uranium workers. These plutonium worker studies are cost-effective because the cohorts have, in large part, already been identified, follow-up conducted to the mid 1980s and dose information has been collected.

Aim 6 - Combined Million Radiation Worker Analyses

The pooling of data from the U.S. worker and military populations described in Aims 1-5 would provide the most definitive evaluation yet available of the possible lifetime risks associated with low-dose radiation exposures experienced over a prolonged period of time. The resultant findings will thus have implications with regard to protection standards for workers and the general population, the assessment of risk associated with today's enhanced medical technologies such as CT scans, the expansion of nuclear power, the handling of nuclear waste and the compensation of workers with prior exposures to radiation (Hall 2009; Dreyer 1981).

METHODS

The study team has substantial experience in pooling radiation exposure data sets and providing estimates of effects and interactions that were not apparent when the individual studies were published alone. Assessment of uncertainty associated with shared errors of exposure have also been addressed. These include studies of radiation-induced breast cancer (Boice 1979; Preston 2002), cervical cancer patients (Boice 1985), radiation-induced thyroid cancer (Ron 1995), underground miner cohorts (Lubin 1994a, 1995; Thomas 1985), indoor radon-lung cancer case control studies (Lubin 1994b, 1997, 2004), and occupational cohorts (Cardis 1995; Stayner 2007). Uncertainty analysis and measurement error effects in radiation

epidemiology has been a long-standing interest of members of the study team (Stram 1999, 2003; Pierce 1990).

Pooled analysis of the combined data from all the studies described Aims 1-5 will maximize statistical power to detect and characterize radiation effects, and to minimize the variability of the estimates of these effects. Generalized proportional hazards regression modeling of mortality data from the combined cohorts will allow for modeling of the risk allowing for the time-dependent nature of exposures and of effect modification variables such as age at exposure, time since exposure, and exposure dose rate. Analyses will utilize the best estimates of both external and internal (where grouped estimates will be used) radiation exposures and will provide uncertainty analysis that reflect likely errors in dose estimation particularly for internal dose.

SUMMARY

The proposed studies, to be carried out nearly simultaneously, provide a golden opportunity to embark on a well-defined research program in human populations followed for nearly entire lifetimes. The enthusiasm for the one million workers and atomic veterans study is reflected by the broad range of consortium experts who are willing to commit a significant portion of their next five years to completing this work.

Grant and Cooperative Agreement

CHOOSE ONE:
- [ ] COOPERATIVE AGREEMENT
- [X] GRANT

CHOOSE ONE: [ ] EDUCATION [ ] FACILITIES [X] RESEARCH [ ] SDCR [ ] TRAINING

1. GRANT/COOPERATIVE AGREEMENT NUMBER	2. SUPPLEMENT NUMBER	3. EFFECTIVE DATE	4. COMPLETION DATE
NRC-HQ-60-14-G-0011	M0002	09/27/2016	

5. ISSUED TO
NAME/ADDRESS OF RECIPIENT (No., Street, City/County, State, Zip)
NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS INC
WOODMOUNT AVE STE 400
BETHESDA MD 20814-3074

6. ISSUED BY US NRC - HQ
Mailing Address: ACQUISITION MANAGEMENT DIVISION
MAIL STOP 3WFN-05-C64MP
WASHINGTON DC 20555-0001

7. TAXPAYER IDENTIFICATION NO. (TIN)

8. COMMERCIAL & GOVERNMENT ENTITY (CAGE) NO.

9. PRINCIPAL INVESTIGATOR/ORGANIZATION'S PROJECT OR PROGRAM MGR. (*Name & Phone*)
Dr. John Dunning Boice
Email: boice@ncrponline.org Phone: 301-657-2652

10. RESEARCH, PROJECT OR PROGRAM TITLE
Radiation Protection Guidance for the United States

11. PURPOSE
See Schedule

12. PERIOD OF PERFORMANCE (*Approximately*)
09/30/2014 through 12/31/2016

13A.	AWARD HISTORY	13B.	FUNDING HISTORY
PREVIOUS	$325,000.00	PREVIOUS	$325,000.00
THIS ACTION	$0.00	THIS ACTION	$0.00
CASH SHARE	$0.00	TOTAL	$325,000.00
NON-CASH SHARE	$0.00		
RECIPIENT SHARE	$0.00		
TOTAL	$325,000.00		

14. ACCOUNTING AND APPROPRIATION DATA

PURCHASE REQUEST NO.	JOB ORDER NO.	AMOUNT	STATUS

15. POINTS OF CONTACT

	NAME	MAIL STOP	TELEPHONE	E-MAIL ADDRESS
TECHNICAL OFFICER	SARAH B. SHAFFER		301-251-7942	SARAH.SHAFFER@NRC.GOV
NEGOTIATOR				
ADMINISTRATOR	M'LITA R. CARR		(301) 415-6869	MLITA.CARR@nrc.gov
PAYMENTS				

16. THIS AWARD IS MADE UNDER THE AUTHORITY OF :
Pursuant to Section 31b and 141b of the Atomic Energy Act of 1954, as amended

17. APPLICABLE STATEMENT(S), IF CHECKED:
- [X] NO CHANGE IS MADE TO EXISTING PROVISIONS
- [ ] FDP TERMS AND CONDITIONS AND THE AGENCY-SPECIFIC REQUIREMENTS APPLY TO THIS GRANT

18. APPLICABLE ENCLOSURE(S), IF CHECKED:
- [ ] PROVISIONS
- [ ] SPECIAL CONDITIONS
- [ ] REQUIRED PUBLICATIONS AND REPORTS

UNITED STATES OF AMERICA		COOPERATIVE AGREEMENT RECIPIENT	
CONTRACTING/GRANT OFFICER	DATE	AUTHORIZED REPRESENTATIVE	DATE
M'LITA R. CARR	09/27/2016		

Grant and Cooperative Agreement

ITEM NO. (A)	ITEM OR SERVICE (Include Specifications and Special Instructions) (B)	QUANTITY (C)	UNIT (D)	ESTIMATED COST UNIT PRICE (E)	ESTIMATED COST AMOUNT (F)
	CFDA Number: 77.009 DUNS Number: 097783914 ZEROREQ-RES-16-0267 The purpose of this modification is: 1) To extend the period of performance and; 2) Approve the use of funds. As a result of this modification: 1) The period of performance is extended for three (3) months from September 29, 2016 to December 31, 2016. 2)Under section, ATTACHMENT A - SCHEDULE, A.2 PERIOD OF GRANT, delete in its entirety and replace with the following: "1. The effective date of this Grant is September 30, 2014. The estimated completion date of this Grant is December 31, 2016. 2. Funds obligated hereunder are available for program expenditures for the estimated period: September 30, 2014 - December 31,2016." 3) Under section, A.4 AMOUNT OF AWARD AND PAYMENT PROCEDURES, item #1, delete in its entirety and replace with the following: "1. The total estimated amount of this Award is $325,000.00 for a two year and three month period." 4) Remaining funds in the amount of $21,810.00 are hereby approved for publication processing Continued ...				

Grant and Cooperative Agreement

ITEM NO. (A)	ITEM OR SERVICE (Include Specifications and Special Instructions) (B)	QUANTITY (C)	UNIT (D)	ESTIMATED COST UNIT PRICE (E)	ESTIMATED COST AMOUNT (F)
	cost. LIST OF CHANGES: Period Of Performance End Date changed from 2016-09-29 00:00:00 to 2016-12-31 00:00:00 Payment: ASAP GRANT FUNDS REIMBURSEMENT SYS US TREASURY Period of Performance: 09/30/2014 to 12/31/2016				

From: Brock, Terry
Sent: 13 Apr 2016 13:16:25 +0000
To: Webber, Kimberly;Case, Michael
Cc: Armstrong, Kenneth;Bush-Goddard, Stephanie
Subject: NCRP briefing book April 2016_1.docx
Attachments: NCRP briefing book April 2016_1.docx

Hey Mike/Kim,

Response to Kim's comments inside attached.
Terry

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

BRIEFING PACKAGE

Drop-in by National Council on Radiation Protection and Measurements

April 25, 2016

MLxxxxxxxx

Drop-in Visit by National Council on Radiation Protection and Measurements

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BIOGRAPHICAL DATA OF NCRP PRESIDENT

(b)(5) Deliberative Privilege

From: Tadesse, Rebecca
Sent: 11 Apr 2016 09:56:24 -0400
To: Armstrong, Kenneth
Cc: Brock, Terry;Tomon, John
Subject: NCRP Drop-in
Attachments: NCRP Drop-in.docx

Ken,

Attached is the revised briefing book. After I reviewed what terry sent me I think it is best to keep it as it is since they are doing everything we want them to do.

Thanks
Rebecca

U.S.NRC

United States Nuclear Regulatory Commission

Protecting People and the Environment

BRIEFING PACKAGE

Drop-in by
National Council on Radiation Protection and Measurements

April 25, 2016

MLxxxxxxxx

From: Brock, Terry
Sent: 16 Jun 2016 14:53:03 +0000
To: Tadesse, Rebecca
Subject: NCRP sponsor briefing on Dose to the Lens of the Eye

Rebecca,

Dr. Larry Dauer, Chair of the NCRP cmt developing the subject line Commentary is available to brief Mike Weber on the results on either September 20, 21, or 22. I suggest Mike W invite the NMSS Office Director-or designee at least to hear the brief. This would be similar to the NAS sponsor briefings we did for the cancer study. Would you let Mike Case know to see if he has any questions before I schedule this with Mike W.

Thanks

Terry Brock, Ph.D.
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington D.C. 20555
Mail Stop TWFN-10
phone: 301-415-1793

From: Metting, Noelle
Sent: 13 Dec 2012 13:27:26 -0500
To: Brock, Terry
Subject: new NCRP study
Attachments: Integration of Epidemiology With Biology.pdf.pdf

Hi Terry,

Nice talking with you this morning. Attached please find some information on NCRP's new study, supported by CDC. Let's stay in touch. Hopefully , in the coming weeks Congress will give us a better budget for research.

Happy Holidays!
Noelle

NF Metting, Sc.D.
Program Manager
Sr. Radiation Biologist
Office of Science/BER
U.S. Department of Energy

Voice: 301-903-8309
Fax: 301-903-0567
noelle.metting@science.doe.gov

NCRP COMMENTARY No. 23

INTEGRATING BASIC SCIENCE WITH EPIDEMIOLOGICAL STUDIES ON LOW-DOSE RADIATION EFFECTS

2012-2014

NCRP

Sally Amundson, *Chairman*
Columbia University Medical Center
New York, New York

Jonine Bernstein, *Vice Chairman*
Memorial Sloan Kettering Cancer Center
New York, New York

Members

John D. Boice, Jr.
National Council on Radiation Protection and Measurements
Bethesda, Maryland

Keith F. Eckerman
Oak Ridge, Tennessee

Raymond A. Guilmette
Lovelace Respiratory Research Institute
Albuquerque, New Mexico

Amy Kronenberg
Lawrence Berkeley National Laboratory
Berkeley, California

Mark Little
National Cancer Institute
Bethesda, Maryland

R. Julian Preston,
U.S. Environmental Protection Agency
Research Triangle Park, North Carolina

Joe A. Nickoloff
Colorado State University
Fort Collins, Colorado

Simon N. Powell
Memorial Sloan Kettering Cancer Center
New York, New York

Daniel O. Stram
University of Southern California
Los Angeles, California

NCRP Secretariat
Terry Pellmar, *Staff Consultant*

NCRP is grateful to CDC for financial support.

Overview: NCRP is currently preparing a report on how basic science on low-dose radiation effects (e.g., the DOE Low Dose Program) might be integrated with human epidemiological investigations of exposed populations (e.g., the Million U.S. Worker and Veteran Study).

Scope of Activities: Because of the interest and importance in gaining a greater understanding of the biological interactions and health effects of low radiation doses, NCRP has significantly increased its activities in studies on low-dose radiation since 2008. The 2008 Annual Meeting was held on the subject of Low Dose and Low Dose-Rate Radiation Effects and Models (proceedings published in Health Physics, Vol. 97 (No. 5) in 2009). In December, 2008 NCRP held a workshop supported by the Centers for Disease Control and Prevention (CDC) that involved 30 participants with expertise in the area of low-dose radiation effects. A decision was made to convene a panel of experts to provide advice on a new NCRP commentary related to critical issues and research needs for gaining a better understanding of low-dose radiation effects. The advisory panel met in August, 2010 which led to the selection of Scientific Committee 1-21. SC 1-21 has begun the preparation of a commentary on critical research needs for evaluation of low-dose radiation biological and health effects which should be completed in late 2013 or early 2014. A focus of the commentary will be on the integration of results of basic science studies with epidemiological studies on health effects of low-dose radiation exposures. The full title of the working document is "Multiplatform National Approach for Providing Guidance on Integrating Basic Science and Epidemiological Studies on Low-Dose Radiation Biological and Health Effects".

Committee Membership. Members were selected because of their scientific expertise and experience in attempting to link human epidemiologic studies (with quantitative measures of radiation organ dose) with biological indicators, not only biomarkers, but also susceptibility states. For example, Jonine Bernstein, Dan Stram and John Boice are active members of the WECARE (Women's Environmental Cancer and Radiation Epidemiology) Study which has collected bloods from 1000s of women who developed breast cancer and 1000s of women who developed bilateral breast cancer, sequenced the genes for mutations and polymorphisms in susceptibility genes (such as BRCA1/2, ATM, etc) and related the genetic profiles with quantitative measures of radiation dose (e.g., *J Natl Cancer Inst* 102:475, 2010).

NRC FORM 562 (3-2007) U.S. NUCLEAR REGULATORY COMMISSION

AWARD OF INTERAGENCY AGREEMENT

1. DATE OF ISSUE	[illegible]
2. AGREEMENT NUMBER	NRC-HQ-60-12-I-000[illegible]
3. MOD NO.	[illegible]
4. AGENCY LOCATOR NO.	31000001
5. B & R NUMBER	2012-60-11-5-[illegible]
7. JOB CODE	[illegible]
8. APPROPRIATION SYMBOL	31X0200
9. BOC	254A
10. DOCUMENT IDENTIFICATION NUMBER	

6. ISSUED BY

U. S. Nuclear Regulatory Commission
Office of Nuclear Regulatory Research
ATTN:
Washington, DC 20555-0001

PROJECT MANAGER
Terry Brock

11. NAME AND ADDRESS OF SERVICING AGENCY

U.S. Department of Energy
Office of Science
1000 Independence Ave., SW
Washington DC 20585

12. JOB CODE TITLE

US Nuclear Worker Health Studies
Contract No. TBD

13. AGREEMENT PERFORMANCE PERIOD

BEGIN 6/1/2012 END 7/31/2017

14. OBLIGATION AVAILABILITY PROVIDED BY

A. THIS ACTION	$ $1,500,000.00
B. TOTAL PLACED PRIOR TO THIS ACTION WITH THE PERFORMING ORGANIZATION UNDER THIS JOB CODE FOR THIS FISCAL YEAR	$
C. TOTAL ORDERS TO DATE FOR THIS JOB CODE FOR THIS FISCAL YEAR	$
D. TOTAL ORDERS TO DATE FOR THIS AGREEMENT	$ 1,500,000.00

15. ATTACHMENTS

THE FOLLOWING ATTACHMENTS ARE MADE A PART OF THIS AGREEMENT

- [X] STATEMENT OF WORK
- [ ] ADDITIONAL TERMS AND CONDITIONS
- [ ] OTHER (Specify)

16. SECURITY

- [ ] WORK ON THIS AGREEMENT INVOLVES CLASSIFIED INFORMATION
- [ ] WORK ON THIS AGREEMENT INVOLVES SENSITIVE UNCLASSIFIED INFORMATION
- [X] WORK ON THIS AGREEMENT IS UNCLASSIFIED AND NOT SENSITIVE

17. FEE BILLABLE UNDER 10 CFR PART 170 [ ] YES [X] NO

18. REMARKS

This action provides full NRC funding to the DOE grant. Requirements doc, priority of NPP cohort, T&C are attached

19. AUTHORITY TO ENTER INTO INTERAGENCY AGREEMENT (Check only one)

- [X] ENERGY REORGANIZATION ACT OF 1974, AS AMENDED
- [ ] THE ECONOMY ACT OF 1932
- [ ] THE CLINGER-COHEN ACT OF 1996
- [ ] OTHER (Specify)

20. ADVANCE PAYMENT [X] IS NOT AUTHORIZED [ ] IS AUTHORIZED (Requires approval by Director, DFS/OCFO)

21. ESTIMATED COST FOR FULL PERFORMANCE OF THIS AGREEMENT

FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	TOTAL
$ $1,500,000.00	$ $0.00	$ $0.00	$ $0.00	$ $0.00	$ $1,500,000.00

22. CERTIFICATION OF FUNDS

This certifies that funds in the amount cited in Block 14.A are available in the current fiscal year allowance for work authorized by this agreement.

FUNDS CERTIFICATION OFFICIAL (Typed Name) [illegible] Lam

SIGNATURE

DATE 6/12/12

23. SIGNATURES

NRC ISSUING AUTHORITY (Typed Name and Title) Kathy Halvey Gibson, Division Director RES/DSA

SIGNATURE

DATE 6/[illegible]/12

SERVICING AGENCY OFFICIAL/DESIGNEE (Typed Name and Title) MARK A. SENA [illegible]

SIGNATURE

DATE [illegible]

NRC FORM 562 (3-2007)

NRC CONTACTS:

TECHNICAL:

FULL NAME	ADDRESS
Terry Brock	U. S. Nuclear Regulatory Commission Office of Nuclear Regulatory Research ATTN: Terry Brock Washington, DC 20555-0001
TELEPHONE NUMBER / FACSIMILE NUMBER: (301) [illegible]	
E-MAIL ADDRESS: Terry.Brock@nrc.gov	

ADMINISTRATIVE:

FULL NAME	ADDRESS
Heather Dempsey	U. S. Nuclear Regulatory Commission Office of Nuclear Regulatory Research ATTN: Heather Dempsey Washington, DC 20555-0001
TELEPHONE NUMBER / FACSIMILE NUMBER: (301) [illegible]	
E-MAIL ADDRESS: Heather.Dempsey@nrc.gov	

OTHER AGENCY'S CONTACTS:

TECHNICAL:

FULL NAME	ADDRESS
[illegible]	U.S. Department of Energy Office of [illegible] 1000 Independence Ave., SW Washington DC 20585
TELEPHONE NUMBER / FACSIMILE NUMBER: [illegible]	
E-MAIL ADDRESS: [illegible]	

ADMINISTRATIVE:

FULL NAME	ADDRESS
Cedric Thomas	U.S. Department of Energy Office of Acquisition and Assistance 9800 South Cass Avenue, Building 201 Argonne, IL 60439
TELEPHONE NUMBER / FACSIMILE NUMBER: (630) 252-[illegible]	
E-MAIL ADDRESS: Cedric.Thomas@[illegible]	

BILLING INFORMATION: To receive reimbursement under this agreement, forward to NRC on a (check one):

___ monthly ___ quarterly XX other Mutually agreed upon basis, an original and three copies of Standard Form 1081 in accordance with the Treasury Fiscal Requirements Manual, Bulletin No. 76-05, or if possible, bill monthly through the OPAC system. Send reimbursement requests to the following address.

Payment Policy and Obligations Team
Mail Stop: T-9 E30
Division of Financial Services
Office of the Chief Financial Officer
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Any NRC funds remaining unexpended at the end of a fiscal year may be carried over into future fiscal years unless otherwise notified by NRC.

REPORTING REQUIREMENTS. Submit reports to the NRC in accordance with the statement of work. Submit financial status reports on a (check one):

___ monthly ___ quarterly XX other Mutually agreed upon basis. These reports shall contain a brief letter status report which summarizes the expenditure of NRC funds. This report shall address the following categories, as applicable: (1) staff effort, (2) travel, (3) equipment and supplies, and (4) subcontract costs. Each report shall include by category: (a) costs for the previous month, (b) cumulative costs and uncosted obligations to date, and (c) projections for the remainder of the NRC obligated funds. The first monthly report shall provide the initial projections, and subsequent reports shall either indicate revised projections or indicate "no change in the cost and uncosted expenditure projection."

Submit these reports to the NRC Technical Contact by the 20th day of the month following the reporting period.

TERMINATING THE AGREEMENT: This agreement may be unilaterally terminated by either party generally upon 30 days' written notice to the other party. NRC will pay its share of any project expenses up to the termination date. Any expenses incurred in terminating this agreement will be paid by the party terminating the agreement. Any unexpended funds shall be returned to the NRC.

Statement of Work NRC-HQ-60-12-I-0006
Between
U.S. NUCLEAR REGULATORY COMMISSION and U.S. DEPARTMENT OF ENERGY
Related to
The Low Dose Radiation Research Program

Introduction

The U.S. Nuclear Regulatory Commission (NRC) and U. S. Department of Energy (DOE) have a history of agreements with regards to Cooperative Nuclear Safety Research. In order to conserve resources and to avoid needless duplication of effort, the parties agree it is in the best interest of both parties to cooperate and share data and technical information and, in some cases, the costs related to such research, whenever such cooperation and cost sharing may be done in a mutually beneficial fashion.

I. Objectives

The objective of this cooperative program is to share data and resources to support the DOE Office of Science (SC) Low Dose Radiation Research Program and other mutually beneficial radiation health effects programs in our respective agencies. The specific work to be performed under this agreement encompasses research that addresses radiation health effects, and will include, but is not limited to DOE's currently funded epidemiological study of more than one million U.S. radiation workers. Joining DOE's effort will provide valuable new information for radiation future protection standards-setting bodies and any resultant occupational radiation dose standards.

In these studies we expect to better understand the overall cancer mortality experience of Nuclear Power Plant (NPP) and other non-NPP workers. We also plan to learn how accurate the linear no-threshold dose response model is in predicting health effects in the NRC cohorts. Additionally, we will evaluate the accuracy of the dose and dose rate effectiveness factor assumption used in radiation protection to extrapolate risks from the Hiroshima and Nagasaki atomic bomb survivors—the atomic bomb survivors were exposed instantaneously in contrast to nuclear workers who are exposed to comparable doses over a career.

II. Scope and Plan

NRC will be supporting DOE's grant and will monitor the following tasks:

a) Prioritizing the study of NPP workers and some non-NPP NRC licensee cohorts (e.g., industrial radiographers).

b) Identifying NPP workers and other non-NPP licensee workers through the NRC's Radiation Exposure Information and Reporting System databases (REIRS) and Landauer Company's dosimetry records. Study the causes of death, determining vital status, conduct dose reconstructions and uncertainty analyses to estimate organ-specific dose. Cancer incidence will be evaluated through selective state cancer registry linkages and determination of other occupational doses through linkages with, the DOE's Radiation Exposure Management System (REMS) and military dosimetry files,

c) Conducting retrospective mortality studies of NPP workers and other non-NPP NRC licensee cohorts

d) Conducting research and technical expert workshops as necessary

e) Providing regularly scheduled progress reports to the NRC Office of Research (RES) project manager

f) Publishing results in the open, peer-reviewed literature

The program elements are as follows:

Programmatic Information Exchange. Both parties will exchange information as appropriate concerning the objectives, project scopes, milestones, planned approaches, and schedules for their ongoing and planned tasks.

Technical Information Exchange. DOE/SC and NRC/RES will facilitate as appropriate the exchange of technical information between researchers and project managers.

Future Collaborative Areas. Additional activities may be identified and added as appropriate. SC and RES will continue to jointly participate, when appropriate, in the identification of additional areas of mutual interest for joint collaborative activities.

Data Policies. Both agencies recognize the need to protect from public disclosure data and information exchanged between them that fall within the definition of trade secrets; privileged, confidential commercial or financial information; or other information that is exempted from public disclosure under the Atomic Energy Act of 1954, as amended; the Freedom of Information Act, as amended; and other applicable law. All DOE data and materials subject to commercial or other use restrictions will be appropriately marked and submitted to RES under separate cover to ensure they are identified and segregated from nonrestricted data, documents, and materials.

If one agency provides the other with nonpublic information, the recipient agency will not release the information without the written consent of the other agency. This provision will apply to information obtained from either agency or its contractors and will apply to

the posting of information on Agencywide Document Access and Management System (ADAMS) and other publicly available Web sites or document rooms. Freedom of Information Act requests, congressional requests, or other request for documents will be referred to the agency that provided the nonpublic information for resolution.

III. Period and Performance

The initial period of performance will be from August 1 2012 through July 31 2017, to be extended in writing if mutually agreeable to SC and RES.

IV. Project Direction and Coordination

All technical interactions will be managed through a single designated point of contact for each party. Meetings to coordinate this effort and to discuss project progress will be arranged through the respective project contacts. The project contacts are:

Technical Contacts:

Terry Brock, PhD, Senior Health Physicist
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission

Noelle Metting, ScD, Senior Radiation Biologist, Office of Science/BER
U.S. Department of Energy

Administrative Contacts:

Heather Dempsey, Program Analyst
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission

Cedric Thomas, Contract Specialist
Office of Acquisition and Assistance
U.S. Department of Energy

V. Costs and Schedules

This statement of work will facilitate expected joint funding of DOE's Million U.S. Worker grant. The NRC Form 662, "Award of Interagency Agreement" shall be the obligating document for this and all such other Agreements. The NRC Form 662 must be countersigned by DOE and provided back to NRC designated points of contact for processing. DOE will process an Intragovernmental Payment and Collection System (IPAC) to receive funds for this and all such other Agreements. The IPAC submissions will occur at minimum of quarterly.

GENERAL PROVISIONS/REQUIREMENTS

a. Termination. NRC may terminate this Agreement upon 30 days written notice of such termination addressed to the Servicing Agency. In the event of such termination the Servicing Agency shall be reimbursed, to the extent permitted, for obligations actually incurred to the effective date of the termination and for commitments extending beyond the effective date of termination to a date not later than the date upon which the Agreement would have expired if not terminated under this paragraph, which the Servicing Agency, in the exercise of due diligence, is unable to cancel. Payments under this Agreement, including payments under this article shall not exceed the amount(s) committed under this Agreement.

b. Patents and Technical Data. Disposition of rights to inventions made in any contract, grant or cooperative agreement under this Agreement with any small business firm or domestic nonprofit organization will be in accordance with 35 U.S.C. 200-212. In all other contracts, grants or cooperative agreements under this Agreement, or in the event work under this agreement is performed by employees of the Agency, the Servicing Agency shall coordinate the disposition of rights to inventions with NRC. In all cases, the agency shall obtain for NRC substantially the same rights in data as those set forth in NRC's acquisition and assistance regulations when requested by NRC or as deemed appropriate by the agency.

c. Issue Resolution. The parties agree to resolve disputes in accordance with instructions provided in the Treasury Financial Manual (TFM), Vol. 1, Intragovernmental Business Rules Bulletin No. 2011-04, available on the TFM Web site at http://www.fms.treas.gov/tfm/vol1/bull.html. Disputes resolution shall involve (1) the program offices, (2) the accounting offices, (3) the Contracting Officers, and (4) the agency's Chief Financial Officer, as appropriate.

d. Payment.

(1) NRC authorizes the Servicing Agency to expend funds in adherence to the requested work and/or deliverables cited herein. NRC's preferred method for reimbursing the Servicing Agency is via the Intra-governmental Payment and Collection (IPAC) system. NRC has provided the funding with the expectation that IPAC submissions will occur as expenditures are incurred. Each IPAC charge must clearly make reference to NRC's job code No. cited in Block 7 (V6317), NRC's IAA No. cited in Block 2 (NRC-HQ-60-12-I-0006), and the Agency Location Code (ALC) cited in Block 4 (31000001).

(2) The servicing agency voucher and other required documentation shall be submitted to:
Department of Interior/NBC
NRCPayments@nbc.gov Attn: Fiscal Services Branch - D2770 7301 W. Mansfield Ave
Denver, CO 80235-2230

(3) When applicable, any funds advanced which are expected to remain beyond the original period of performance for a project which is incomplete, or for which there is an increased scope of work, will remain available to the Servicing Agency if the Agreement is modified by the NRC to extend the period of performance for the work beyond the original completion date. Request for such time extensions should be made to the NRC by the Servicing Agency at least 30 days prior to the end of the performance period.

(4) When applicable, any funds advanced for a continuing project remain available for the entire performance period of the project; unless there is a date specified as a required completion date after which no further funds shall be expended. Any NRC funds remaining unexpended

at the conclusion of performance of all tasks under this Agreement shall be returned promptly to NRC.

e. Other Provisions. N/A

ADMINISTRATIVE INFORMATION

The following business and financial information is provided as required by the U.S. Department of Treasury Financial Manual, Bulletin No. 2007-03, Volume 1:

	Requesting Agency: **U.S. Nuclear Regulatory Commission**	**Servicing Agency:** **U.S. Department of Energy**
Agency Location Code (ALC)	See IAA Page 1, Block 10	89000001
Business Partner Network No./ DUNS No. (BPN/DUNS)	See IAA Page 1, Block 10	175376516
Business Event Type Code (BETC)	DISB	COLL
Treasury Account Symbol (TAS)	31X0200	89X0222
Billing Method through IPAC	Reimbursement ☒	Advance Payment ☐
Type of Funds	No Year ☒ One Year ☐	Two Year ☐ Other ☐
Business Contact	Heather Dempsey Phone: 301-251-7666 Fax: 301-251-7426 heather.dempsey@nrc.gov	Cedric Thomas Phone: 630-252-4329 Fax: 630-252-5045 cedric.thomas@ch.doe.gov
Program Manager/Technical Contact	Terry Brock Phone: 301-251-7487 Fax: 301-251-7423 terry.brock@nrc.gov	Noelle F. Metting Phone: 301-903-8309 Fax: 301-903-0567 noelle.metting@science.doe.gov
Accounting Contact	Lisa Bamford Phone: 301-251-7927 Fax: 301-251-7426 lisa.bamford@nrc.gov	Brooke Bond Phone: 630-252-3397 Fax: 630-252-9691 brooke.bond@ch.doe.gov
DOE Contracting Officer/ Servicing Agency Contracting Officer or Authorized Signatory	Kathy Gibson Phone: 301-251-7499 Fax: 301-251-7423 kathy.gibson@nrc.gov	Mark A. Sojka Phone: 630-252-2017 Fax: 630-252-5045 mark.sojka@ch.doe.gov

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 30, 2014

Dr. John Dunning Boice
National Council on Radiation, Inc.
Protection and Measurements
7910 Woodmont Ave, Suite 400
Bethesda, Maryland 20814

VIA Electronic Mail
boice@ncrponline.org

SUBJECT: GRANT NO: NRC-HQ-60-14-G-0011

Dear Dr. Boice:

Pursuant to the authority contained in the Federal Grant and Cooperative Grantee Act of 1977 and the Atomic Energy Act of 1954, the Nuclear Regulatory Commission (NRC) hereby awards to National Council on Radiation Protection and Measurements (hereinafter referred to as the "Grantee" or "Recipient"), the sum of $325,000.00 to provide support for " Radiation Protection Guidance for the United States" entitled "Program Description."

This award is effective as of the date of this letter and shall apply to expenditures made by the Grantee furtherance of program objectives during the period beginning with the effective date of September 30, 2014 and ending September 29, 2016.

This award is made to the Recipient on condition that the funds will be administered in accordance with the terms and conditions as set forth in Attachment A (the Schedule); Attachment B (the Program Description); and Attachment C (the Standard Provisions); all of which have been agreed to by your organization.

Please ensure individuals selected as beneficiaries of support under this grant meet the legal requirements consistent with recent Supreme Court Decisions including *Fisher, Gratz, and Grutter.*

Please sign the enclosed grant to acknowledge your receipt of the award, and return as a pdf file to Ms. Gordana Zuber by email at Gordana.Zuber@nrc.gov.

Sincerely yours,

Sheila Bumpass

Sheila Bumpass
Grants Officer
Resources & Grants Team
Acquisition Management Division (AMD)

Attachments:
Attachment A – Schedule
Attachment B – Program Description
Attachment C – Standard Terms and Conditions

Grant and Cooperative Agreement

CHOOSE ONE:
- [ ] COOPERATIVE AGREEMENT
- [X] GRANT

CHOOSE ONE: [ ] EDUCATION [ ] FACILITIES [X] RESEARCH [ ] SDCR [ ] TRAINING

1. GRANT/COOPERATIVE AGREEMENT NUMBER	2. SUPPLEMENT NUMBER	3. EFFECTIVE DATE	4. COMPLETION DATE
NRC-HQ-60-14-G-0011		09/30/2014	

5. ISSUED TO
NAME/ADDRESS OF RECIPIENT (No., Street, City/County, State, Zip)
NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS
WOODMOUNT AVE STE 400
BETHESDA MD 20814-3074

6. ISSUED BY U.S. NRC - HQ
Mailing Address: Acquisition Management Division
Mail Stop: 3WFN-05-C64MP
Washington DC 20555-0001

7. TAXPAYER IDENTIFICATION NO. (TIN)

8. COMMERCIAL & GOVERNMENT ENTITY (CAGE) NO.

9. PRINCIPAL INVESTIGATOR/ORGANIZATION'S PROJECT OR PROGRAM MGR. (*Name & Phone*)
Dr. John Dunning Boice
Email: boice@ncrponline.org Phone: 301-657-2652

10. RESEARCH, PROJECT OR PROGRAM TITLE
Radiation Protection Guidance for the United States

11. PURPOSE
See Schedule

12. PERIOD OF PERFORMANCE (*Approximately*)
09/30/2014 through 09/29/2016

13A.	AWARD HISTORY	13B.	FUNDING HISTORY
PREVIOUS	$0.00	PREVIOUS	$0.00
THIS ACTION	$325,000.00	THIS ACTION	$291,000.00
CASH SHARE	$0.00	TOTAL	$291,000.00
NON-CASH SHARE	$0.00		
RECIPIENT SHARE	$0.00		
TOTAL	$325,000.00		

14. ACCOUNTING AND APPROPRIATION DATA
See Schedule

PURCHASE REQUEST NO.	JOB ORDER NO.	AMOUNT	STATUS
RES-14-0466			

15. POINTS OF CONTACT

	NAME	MAIL STOP	TELEPHONE	E-MAIL ADDRESS
TECHNICAL OFFICER	SARAH B. SHAFFER		301-251-7942	SARAH.SHAFFER@NRC.GOV
NEGOTIATOR				
ADMINISTRATOR	GORDANA ZUBER		301-287-0900	gordana.zuber@nrc.gov
PAYMENTS				

16. THIS AWARD IS MADE UNDER THE AUTHORITY OF :
Pursuant to Section 31b and 141b of the Atomic Energy Act of 1954, as amended

17. APPLICABLE STATEMENT(S), IF CHECKED:
- [ ] NO CHANGE IS MADE TO EXISTING PROVISIONS
- [ ] FDP TERMS AND CONDITIONS AND THE AGENCY-SPECIFIC REQUIREMENTS APPLY TO THIS GRANT

18. APPLICABLE ENCLOSURE(S), IF CHECKED:
- [ ] PROVISIONS
- [ ] SPECIAL CONDITIONS
- [ ] REQUIRED PUBLICATIONS AND REPORTS

UNITED STATES OF AMERICA		COOPERATIVE AGREEMENT RECIPIENT	
CONTRACTING/GRANT OFFICER	DATE	AUTHORIZED REPRESENTATIVE	DATE
SHEILA H. BUMPASS	09/24/2014		

Grant and Cooperative Agreement

ITEM NO. (A)	ITEM OR SERVICE (Include Specifications and Special Instructions) (B)	QUANTITY (C)	UNIT (D)	ESTIMATED COST UNIT PRICE (E)	ESTIMATED COST AMOUNT (F)
	CFDA Number: 77.009 Payment will be made through the Automated Standard Application for Payment (ASAP.gov) unless the recipient has failed to comply with the program objectives, award conditions, Federal reporting requirements or other conditions specified in 2 CFR 215 (OMB Circular A110). Technical Analyst: Terry Brock Phone: 301-251-7487 Email: terry.brock@nrc.gov Payment: ASAP GRANT FUNDS REIMBURSEMENT SYS US TREASURY Period of Performance: 09/30/2014 to 09/29/2016				

ATTACHMENT A - SCHEDULE

A.1 PURPOSE OF GRANT

The purpose of this Grant is to provide support to the "Radiation Protection Guidance for the United States" as described in Attachment B entitled "Program Description."

A.2 PERIOD OF GRANT

1. The effective date of this Grant is September 30, 2014. The estimated completion date of this Grant is September 29, 2016.

2. Funds obligated hereunder are available for program expenditures for the estimated period: September 30, 2014 – September 29, 2016.

A. GENERAL

1. Total Estimated NRC Amount:	$325,000.00
2. Total Obligated Amount:	$291,000.00
3. Cost-Sharing Amount:	$0.00
4. Activity Title:	Radiation Protection Guidance for the United States
5. NRC Project Officer:	Sarah Shaffer
6. NRC Technical Analyst	Terry Brock
7. DUNS No.:	097783914

A.3 BUDGET

Revisions to the budget shall be made in accordance with Revision of Grant Budget in accordance with 2 CFR 215.25.

Category	Year 1	Year 2	Total
Personnel	$44,928.82	$19,381.32	$64,310.14
Fringe Benefits	$11,901.64	$5,134.11	$17,035.75
Travel	$29,116.29	$14,794.24	$43,910.53
Other	$25,000.00	$10,000.00	$35,000.00
Indirect Charges	$114,053.25	$50,690.33	$164,743.59
Totals	**$225,000.00**	**$100,000**	**$325,000.00**

All travel must be in accordance with National Council on Radiation Protection and Measurements Travel Regulations or the US Government Travel Policy absent Grantee's travel regulation.

A.4 AMOUNT OF AWARD AND PAYMENT PROCEDURES

1. The total estimated amount of this Award is $325,000.00 for the two year period.

2. NRC hereby obligates the amount of $291,000.00 for program expenditures during the period set forth above and in support of the Budget above. The Grantee will be given written

notice by the Grants Officer when additional funds will be added. NRC is not obligated to reimburse the Grantee for the expenditure of amounts in excess of the total obligated amount.

3. Payment shall be made to the Grantee in accordance with procedures set forth in the Automated Standard Application for Payments (ASAP) Procedures set forth below.

Attachment B – Program Description

ATTACHMENT 4 Program Description

Background:
Radiation-related cataracts and the associated radiation protection issues are of current interest. There is debate over the new annual 20 mSv dose limit for the lens of the eye recommended by the International Commission on Radiological Protection (ICRP) and accepted by many countries (ICRP Publication 118; 9). The scientific and operational issues for reducing the current occupational dose limit from 150 mSv to 20 mSv are complex. The only general agreement is that radiation-induced cataracts (serious lens opacities leading to visual impairment) can occur at doses lower than previously recognized: the previous threshold dose was thought to be ~5 Gy and now is estimated to be ~0.5 Gy. ICRP did not recommend changing the lens of the eye limit of 15 mSv y^{-1} for members of the public.

Currently in the US, dose limits to the lens of the eye are set at 150 mSv in a given year based on consideration of the induction of cataracts as a deterministic effect of radiation exposure. Rather high occupational exposures to the eyes can occur today among several occupations, e.g., industrial radiographers, interventional radiologists and cardiologists, with the potential to attain radiation doses to the lens above the ICRP recommended 20 mSv per year limit.

The ICRP recommended the change from 150 mSv y-1 to 20 mSv y-1 and the EU accepted the recommendation in part because of new evidence that supported increased cataract occurrence at dose levels lower than previously recognized. Several reports have documented excesses of cataracts among several medical occupations including interventional cardiologists and nurses (1-4) and others (5). Anecdotal comments among interventional radiologists have revealed similar problems, suggesting that cataract induction may occur at lower doses than previously thought. It is generally agreed that a threshold dose of 5 Gy is no longer tenable and such a threshold, if it exists, may be closer to 0.5 Gy. Hence, radiation workers in the US with eye exposure as a consequence of their work may be at greater risk for the development of cataracts than anticipated because of the high historical dose limits.

Data are also available from American astronauts who have been exposed not only to low-LET x-rays but also high-LET HZE radiation in space. While the study numbers are low, preliminary indications are that cataract induction in astronauts can occur at doses lower than predicted by the 2 Sv threshold model (6, 7). A variety of studies of low-LET radiation also suggest that excess cataracts are seen at lens doses under 1 Gy, especially for those who are young at the time of exposure (see reviews (8, 9)).

In addition, for many years it has been reported that radiation-induced cataracts differ from those associated with aging and health consequences (diabetes, etc.) by being induced in

the posterior subcapsular portion of the eye. Several recent studies, however, have found a dose-related excess of cortical opacities as well (10), so both types of cataracts need to be considered in epidemiological studies.

OVERRIDING ISSUES TO ADDRESS

- *Is cataract development stochastic or deterministic?* It is not entirely clear whether the mechanism for radiation induced cataracts is a deterministic process which requires a significant number of cells to become dysfunctional or possibly a stochastic process similar to cancer induction that would imply that no matter how low the dose a small risk might be present, albeit undetectable. Some evidence supports a stochastic process (11); while the most recent investigation from the study of the atomic-bomb survivors appears consistent with a threshold effect at 0.5 Gy based on surgically removed lenses there were no significant findings < 1 Gy and the elevation at dose < 1 Gy appeared only in Nagasaki (12).
- *Does protraction matter?* It is not entirely clear whether the risk following protracted exposures is the same or lower than what has been seen following acute or brief exposures (11). Studies of interventional radiologists and cardiologists indicating that protracted exposure can result in serious lens opacities, albeit at high cumulative doses (2), and the recent ICRP Publication 118 (9) implies that protraction may not be that important in cataract formation. The quantification of dose to the lens is challenging in studies of protracted exposure.
- *How should severity of the effect be addressed?* Cancer and some non-cancer effects, such as coronary heart disease and cataracts, can occur at dose levels lower than previously recognized. Coronary heart disease is substantially more serious than a cataract. Should equal weight be given to nonfatal outcomes as to fatal ones in protection guidance? Should cataracts be placed at the same level of concern as radiation induced cancer? And if so, how could lens dose be incorporated into any computation of effective dose? The ICRP measure of detriment includes a factor for lethality but because cataract is a nonfatal outcome, dose to the lens might not contribute to effective dose under the current system of protection.
- *If a change is protection limits is justified, what limit should be considered?* The current annual dose limit for lens of the eye in the United States is 150 mSv. The ICRP recommendation is 20 mSv y^{-1}. The annual whole-body dose limit for the United States today is 50 mSv and is unlikely to change in the near future. The NCRP recommendation for cumulative whole body exposures is 10 mSv × age which is actually more conservative (i.e., protective) than the 20 mSv y^{-1} limit in terms of limiting cumulative dose (NCRP Report No. 116; 13). One perplexing issue for the United States would be considering a limit to the lens of the eye that is lower than the limit for whole-body exposure— the ramifications with regard to implementation could be challenging and formidable to address.

Attachment C – Standard Terms and Conditions

The Nuclear Regulatory Commission's
Standard Terms and Conditions for U.S. Nongovernmental Grantees

Preface

This award is based on the application submitted to, and as approved by, the Nuclear Regulatory Commission (NRC) under the authorization 42 USC 2051(b) pursuant to section 31b and 141b of the Atomic Energy Act of 1954, as amended, and is subject to the terms and conditions incorporated either directly or by reference in the following:

- Grant program legislation and program regulation cited in this Notice of Grant Award.
- Restrictions on the expenditure of Federal funds in appropriation acts, to the extent those restrictions are pertinent to the award.
- Code of Federal Regulations/Regulatory Requirements - 2 CFR 215 Uniform Administrative Requirements For Grants And Agreements With Institutions Of Higher Education, Hospitals, And Other Non-Profit Organizations (OMB Circulars), as applicable.

To assist with finding additional guidance for selected items of cost as required in 2 CRF 220, 2 CFR 225, and 2 CFR 230 this URL to the Office of Management and Budget Cost Circulars is included for reference: http://www.whitehouse.gov/omb/circulars_index-ffm.

Any inconsistency or conflict in terms and conditions specified in the award will be resolved according to the following order of precedence: public laws, regulations, applicable notices published in the Federal Register, Executive Orders (EOs), Office of Management and Budget (OMB) Circulars, the Nuclear Regulatory Commission's (NRC) Mandatory Standard Provisions, special award conditions, and standard award conditions.

Certifications and Representations: These terms incorporate the certifications and representations required by statute, executive order, or regulation that were submitted with the SF424B application through Grants.gov.

I. Mandatory General Requirements
The order of these requirements does not make one requirement more important than any other requirement.

1. Applicability of 2 CFR Part 215

All provisions of 2 CFR Part 215 and all Standard Provisions attached to this grant/cooperative agreement are applicable to the Grantee and to sub-recipients which meet the definition of "Grantee" in Part 215, unless a section specifically excludes a sub-recipient from coverage. The Grantee and any sub-recipients must, in addition to the assurances made as part of the application, comply and require each of its sub-awardees employed in the completion of the project to comply with Subpart C of 2 CFR 215 and include this term in lower-tier (subaward) covered transactions.

Grantees must comply with monitoring procedures and audit requirements in accordance with OMB Circular A-133.

2. Award Package

§ 215.41 Grantee responsibilities.
The Grantee is obligated to conduct project oversight as may be appropriate, to manage the funds with prudence, and to comply with the provisions outlined in 2 CFR 215.41. Within this framework, the Principal Investigator (PI) named on the award face page, Block 11, is responsible for the scientific or technical direction of the project and for preparation of the project performance reports. This award is funded on a cost reimbursement basis not to exceed the amount awarded as indicated on the face page, Block 16, and is subject to a refund of unexpended funds to NRC.

The standards contained in this section do not relieve the Grantee of the contractual responsibilities arising under its contract(s). The Grantee is the responsible authority, without recourse to the NRC, regarding the settlement and satisfaction of all contractual and administrative issues arising out of procurements entered into in support of an award or other agreement. This includes disputes, claims, protests of award, source evaluation or other matters of a contractual nature. Matters concerning violation of statute are to be referred to such Federal, State or local authority as may have proper jurisdiction.

Subgrants
Appendix A to Part 215—Contract Provisions

Sub-recipients, sub-awardees, and contractors have no relationship with NRC under the terms of this grant/cooperative agreement. All required NRC approvals must be directed through the Grantee to NRC. See 2 CFR 215 and 215.41.

Nondiscrimination
This provision is applicable when work under the grant/cooperative agreement is performed in the U.S. or when employees are recruited in the U.S.

The Grantee agrees to comply with the non-discrimination requirements below:

- Title VI of the Civil Rights Act of 1964 (42 USC §§ 2000d et seq)
- Title IX of the Education Amendments of 1972 (20 USC §§ 1681 et seq)
- Section 504 of the Rehabilitation Act of 1973, as amended (29 USC § 794)
- The Age Discrimination Act of 1975, as amended (42 USC §§ 6101 et seq)
- The Americans with Disabilities Act of 1990 (42 USC §§ 12101 et seq)
- Parts II and III of EO 11246 as amended by EO 11375 and 12086.
- EO 13166, "Improving Access to Services for Persons with Limited English Proficiency."
- Any other applicable non-discrimination law(s).

Generally, Title VI of the Civil Rights Act of 1964, 42 USC § 2000e et seq, provides that it shall be an unlawful employment practice for an employer to discharge any individual or otherwise to discriminate against an individual with respect to compensation, terms, conditions, or privileges of employment because of such individual's race, color, religion, sex, or national origin. However, Title VI, 42 USC § 2000e-1(a), expressly exempts from the prohibition against discrimination on the basis of religion, a religious corporation, association, educational

institution, or society with respect to the employment of individuals of a particular religion to perform work connected with the carrying on by such corporation, association, educational institution, or society of its activities.

Modifications/Prior Approval
NRC's prior written approval may be required before a Grantee makes certain budget modifications or undertakes particular activities. If NRC approval is required for changes in the grant or cooperative agreement, it must be requested and obtained from the NRC Grants Officer in advance of the change or obligation of funds. All requests for NRC prior approval, including requests for extensions to the period of performance, should be made, in writing (which includes submission by e-mail), to the designated Grants Specialist and Program Office 30 days before the proposed change. The request should be signed by the authorized organizational official. Failure to obtain prior approval, when required, from the NRC Grants Officer, may result in the disallowance of costs, or other enforcement action within NRC's authority.

Lobbying Restrictions
The Grantee will comply, as applicable, with provisions of the Hatch Act (5 U.S.C. §§1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.

The Grantee will comply with provisions of 31 USC § 1352. This provision generally prohibits the use of Federal funds for lobbying in the Executive or Legislative Branches of the Federal Government in connection with the award, and requires disclosure of the use of non-Federal funds for lobbying.

The Grantee receiving in excess of $100,000.00 in Federal funding shall submit a completed Standard Form (SF) LLL, "Disclosure of Lobbying Activities," regarding the use of non-Federal funds for lobbying within 30 days following the end of the calendar quarter in which there occurs any event that requires disclosure or that materially affects the accuracy of the information contained in any disclosure form previously filed. The Grantee must submit the SF-LLL, including those received from sub-recipients, contractors, and subcontractors, to the Grants Officer.

§ 215.13 Debarment And Suspension.
The Grantee agrees to notify the Grants Officer immediately upon learning that it or any of its principals:

(1) Are presently excluded or disqualified from covered transactions by any Federal department or agency;

(2) Have been convicted within the preceding three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, receiving stolen property, making false claims, or obstruction of justice; commission of any other offense indicating a lack of business integrity or business honesty that seriously and directly affects your present responsibility;

(3) Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph (1)(b); and

(4) Have had one or more public transactions (Federal, State, or local) terminated for cause or default within the preceding three years.

b. The Grantee agrees that, unless authorized by the Grants Officer, it will not knowingly enter into any subgrant or contracts under this grant/cooperative agreement with a person or entity that is listed as Exclusion on SAM (http://sam.gov).

The Grantee further agrees to include the following provision in any subgrant or contracts entered into under this award:

'Debarment, Suspension, Ineligibility, and Voluntary Exclusion'

The Grantee certifies that neither it nor its principals is presently excluded or disqualified from participation in this transaction by any Federal department or agency. The policies and procedures applicable to debarment, suspension, and ineligibility under NRC-financed transactions are set forth in 2 CFR Part 180.'

Drug-Free Workplace
The Grantee must be in compliance with The Federal Drug Free Workplace Act of 1988. The policies and procedures applicable to violations of these requirements are set forth in 41 USC 702.

Implementation of E.O. 13224 -- Executive Order On Terrorist Financing
The Grantee is reminded that U.S. Executive Orders and U.S. law prohibits transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Grantee to ensure compliance with these Executive Orders and laws. This provision must be included in all contracts/sub-awards issued under this grant/cooperative agreement.

The Grantee must comply with Executive Order 13224, Blocking Property and Prohibiting Transactions with Persons who Commit, Threaten to Commit, or Support Terrorism. Information about this Executive Order can be found at: www.fas.org/irp/offdocs/eo/eo-13224.htm.

Procurement Standards § 215.40-48
Sections 215.41 through 215.48 set forth standards for use by Grantees in establishing procedures for the procurement of supplies and other expendable property, equipment, real property and other services with Federal funds. These standards are furnished to ensure that such materials and services are obtained in an effective manner and in compliance with the provisions of applicable Federal statutes and executive orders. No additional procurement standards or requirements will be imposed by the Federal awarding agencies upon Grantees, unless specifically required by Federal statute or executive order or approved by OMB.

Travel
Travel must be in accordance with the Grantee's Travel Regulations or the US Government Travel Policy and Regulations at: www.gsa.gov/federaltravelregulation and the per diem rates set forth at: www.gsa.gov/perdiem, absent Grantee's travel regulations. Travel costs for the

grant must be consistent with provisions as established in Appendix A to 2 CFR 220 (J.53). All other travel, domestic or international, must not increase the total estimated award amount.

Domestic Travel:
Domestic travel is an appropriate charge to this award and prior authorization for specific trips are not required, if the trip is identified in the Grantee's approved program description and approved budget. Domestic trips not stated in the approved budget require the written prior approval of the Grants Officer, and must not increase the total estimated award amount.

All common carrier travel reimbursable hereunder shall be via the least expensive class rates consistent with achieving the objective of the travel and in accordance with the Grantee's policies and practices. Travel by first-class travel is not authorized unless prior approval is obtained from the Grants Officer.

International Travel:
International travel requires **PRIOR** written approval by the Project Officer and the Grants Officer, even if the international travel is stated in the approved program description and the approved budget.

The Grantee will comply with the provisions of the Fly American Act (49 USC 40118) as implemented through 41 CFR 301-10.131 through 301-10.143.

Property and Equipment Management Standards
Property and equipment standards of this award shall follow provisions as established in 2 CFR 215.30-37.

Intangible and Intellectual Property
Intangible and intellectual property of this award shall generally follow provisions established in 2 CFR 215.36.

Inventions Report - The Bayh-Dole Act (P.L. 96-517) affords Grantees the right to elect and retain title to inventions they develop with funding under an NRC grant award ("subject inventions"). In accepting an award, the Grantee agrees to comply with applicable NRC policies, the Bayh-Dole Act, and its Government-wide implementing regulations found at Title 37, Code of Federal Regulations (CFR) Part 401. A significant part of the regulations require that the Grantee report all subject inventions to the awarding agency (NRC) as well as include an acknowledgement of federal support in any patents.

Patent Notification Procedures - If the NRC or its Grantees, without making a patent search, knows (or has demonstrable reasonable grounds to know) that technology covered by a valid United States patent has been or will be used without a license from the owner, EO 12889 requires NRC to notify the owner. If the Grantee uses or has used patented technology under this award without license or permission from the owner, the Grantee must notify the Grants Officer. This notice does not mean that the Government authorizes and consents to any copyright or patent infringement occurring under the financial assistance.

Data, Databases, and Software - The rights to any work produced or purchased under a NRC federal financial assistance award, such as data, databases or software are

determined by 2 CFR 215.36. The Grantee owns any work produced or purchased under a NRC federal financial assistance award subject to NRC's right to obtain, reproduce, publish or otherwise use the work or authorize others to receive, reproduce, publish or otherwise use the data for Government purposes.

Copyright - The Grantee may copyright any work produced under a NRC federal financial assistance award subject to NRC's royalty-free nonexclusive and irrevocable right to reproduce, publish or otherwise use the work or authorize others to do so for Government purposes. Works jointly authored by NRC and Grantee employees may be copyrighted but only the part authored by the Grantee is protected because, under 17 USC § 105, works produced by Government employees are not copyrightable in the United States. On occasion, NRC may ask the Grantee to transfer to NRC its copyright in a particular work when NRC is undertaking the primary dissemination of the work. Ownership of copyright by the Government through assignment is permitted under 17 USC § 105.

Records Retention and Access Requirements
Grantee shall follow established provisions in 2 CFR 215.53.

Conflict Of Interest Standards
Conflict of Interest Standards for this award will follow OCOI requirements set forth in Section 170A of the Atomic Energy Act of 1954, as amended, and provisions set forth at 2 CFR 215.42 Codes of Conduct.

Dispute Review Procedures
a. Any request for review of a notice of termination or other adverse decision should be addressed to the Grants Officer. It must be postmarked or transmitted electronically no later than 30 days after the postmarked date of such termination or adverse decision from the Grants Officer.

b. The request for review must contain a full statement of the Grantee's position and the pertinent facts and reasons in support of such position.

c. The Grants Officer will promptly acknowledge receipt of the request for review and shall forward it to the Director, Office of Administration, who shall appoint an intra-agency Appeal Board to review a grantee appeal of an agency action, if required, which will consist of the program office director, the Deputy Director of Office of Administration, and the Office of General Counsel.

d. Pending resolution of the request for review, the NRC may withhold or defer payments under the award during the review proceedings.

e. The review committee will request the Grants Officer who issued the notice of termination or adverse action to provide copies of all relevant background materials and documents. The committee may, at its discretion, invite representatives of the Grantee and the NRC program office to discuss pertinent issues and to submit such additional information as it deems appropriate. The chairman of the review committee will insure that all review activities or proceedings are adequately documented.

f. Based on its review, the committee will prepare its recommendation to the Director, Office of Administration, who will advise the parties concerned of his/her decision.

Termination and Enforcement
Termination of this award will follow provisions as established in 2 CFR 215.60-62.

Monitoring and Reporting § 215.50-53
Grantee Financial Management systems must comply with the provisions in 2 CFR 215.21

- Payment – 2 CFR 215.22
- Cost Share – 2 CFR 215.23
- Program Income – 2 CFR 215.24
  - Earned program income, if any, will be added to funds committed to the project by the NRC and Grantee and used to further eligible project or program objectives or deducted from the total project cost allowable cost as directed by the Grants Officer or the terms and conditions of award.
- Budget Revision – 2 CFR 215.25
  - The Grantee is required to report deviations from the approved budget and program descriptions in accordance with 2 CFR 215.25 and request prior written approval from the Program Officer and the Grants Officer.
  - The Grantee is not authorized to rebudget between direct costs and indirect costs without written approval of the Grants Officer.
  - The Grantee is authorized to transfer funds among direct cost categories up to a cumulative 10 percent of the total approved budget. The Grantee is not allowed to transfer funds if the transfer would cause any Federal appropriation to be used for purposes other than those consistent with the original intent of the appropriation.
  - Allowable Costs – 2 CFR 215.27

Federal Financial Reports -
The Grantee shall submit a "Federal Financial Report" (SF-425) on a quarterly basis for the periods ending March 31, June 30, September 30, and December 31, or any portion thereof, unless otherwise specified in a special award condition. Reports are due no later than 30 days following the end of each reporting period. A final SF-425 is due within 90 days after expiration of the award. The report should be submitted electronically to the following:

1. Grants_FFR.Resource@NRC.gov (NOTE: There is an underscore between Grants and FFR);
2. RESGrants.Resource@NRC.gov;
3. Technical Analyst; and
4. Grants Officer.

Period of Availability of Funds 2 CFR § 215.28
If a funding period is specified, a Grantee may charge to the grant only allowable costs resulting from obligations incurred during the funding period and any pre-award costs authorized by the NRC.

Unless otherwise authorized in 2 CFR 215.25(e)(2) or a special award condition, any extension of the award period can only be authorized by the Grants Officer in writing. Verbal or written assurances of funding from other than the Grants Officer shall not constitute authority to obligate funds for programmatic activities beyond the expiration date.

The NRC has no obligation to provide any additional prospective or incremental funding. Any modification of the award to increase funding and to extend the period of performance is at the sole discretion of the NRC.

Automated Standard Application For Payments (ASAP) Procedures
Unless otherwise stated, grantee payments are made using the Department of Treasury's Automated Standard Application for Payment (ASAP) system http://www.fms.treas.gov/asap/index.html, through preauthorized electronic funds transfers. To receive payments, Grantees are required to enroll with the Department of Treasury, Financial Management Service, and Regional Financial Centers, which allows them to use the on-line method of withdrawing funds from their ASAP established accounts. The following information is required to make ASAP withdrawals: (1) ASAP account number – the award number found on the cover sheet of the award; (2) Agency Location Code (ALC) – 31000001; and Region Code. Grantees enrolled in the ASAP system do not need to submit a "Request for Advance or Reimbursement" (SF-270).

II. Audit Requirements

Audits
Organization-wide or program-specific audits are performed in accordance with the Single Audit Act Amendments of 1996, as implemented by OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations." Grantees are subject to the provisions of OMB Circular A-133 if they expend $500,000.00 or more in a year in Federal awards.

The Form SF-SAC and the Single Audit Reporting packages for fiscal periods ending on or after January 1, 2008 are submitted online.

1. Create your online report ID at http://harvester.census.gov/fac/collect/ddeindex.html;
2. Complete the Form SF-SAC;
3. Upload the Single Audit;
4. Certify the Submission;
5. Click "Submit."

Organizations expending less than $500,000.00 a year are not required to have an annual audit for that year but must make their grant-related records available to NRC or other designated officials for review or audit.

III. Programmatic Requirements

Performance Progress (Technical) Reports
The Grantee shall submit performance (technical) reports electronically to the NRC Project Officer and Grants Officer on a quarterly for the periods ending March 31, June 30, September 30, and December 31, or any portion thereof, unless otherwise specified in a special award condition. Reports are due no later than 30 days following the end of each reporting period. The report should be submitted electronically to the following:

1. Grants_PPR.Resource@NRC.gov (NOTE: There is an underscore between Grants and PPR);
2. RESGrants.Resource@NRC.gov;
3. Technical Analyst; and
4. Grants Officer.

Unless otherwise specified in the award provisions, performance progress (technical) reports shall contain brief information as prescribed in the applicable uniform administrative requirements 2 CFR §215.51 which are incorporated in the award.

Unsatisfactory Performance
Failure to perform the work in accordance with the terms of the award and maintain at least a satisfactory performance rating, may result in designation of the Grantee as high risk and the assignment of special award conditions. Further action may be required as specified in the standard term and condition entitled "Termination."

Failure to comply with the award provisions may result in a negative impact on future NRC funding. In addition, the Grants Officer may withhold payments; change the method of payment from advance to reimbursement; impose special award conditions; suspend or terminate the grant.

Other Federal Awards With Similar Programmatic Activities
The Grantee will immediately notify the Project Officer and the Grants Officer in writing if after award, other financial assistance is received to support or fund any portion of the program description stated in the NRC award. NRC will not pay for costs that are funded by other sources.

Prohibition Against Assignment By The Grantee
The Grantee will not transfer, pledge, mortgage, or otherwise assign the award, or any interest to the award, or any claim arising under the award, to any party, banks, trust companies, or other financing or financial institutions without the written approval of the Grants Officer.

Site Visits
The NRC, through authorized representatives, has the right to make site visits to review project accomplishments and management control systems and to provide technical assistance as required. If any site visit is made by the NRC on the premises of the Grantee or contractor under an award, the Grantee shall provide and shall require his/her contractors to provide all reasonable facilities and assistance for the safety and convenience of the Government representative in the performance of their duties.

IV. Miscellaneous Requirements

Criminal and Prohibited Activities
The Program Fraud Civil Remedies Act (31 USC §§ 3801-3812), provides for the imposition of civil penalties against persons who make false, fictitious, or fraudulent claims to the Federal government for money (including money representing grant/cooperative agreements, loans, or other benefits.)

False statements (18 USC § 287), provides that whoever makes or presents any false, fictitious, or fraudulent statements, representations, or claims against the United States shall be subject to imprisonment of not more than five years and shall be subject to a fine in the amount provided by 18 USC § 287.

False Claims Act (31 USC 3729 et seq), provides that suits under this Act can be brought by the government, or a person on behalf of the government, for false claims under federal assistance programs.

Copeland "Anti-Kickback" Act (18 USC § 874), prohibits a person or organization engaged in a federally supported project from enticing an employee working on the project from giving up a part of his compensation under an employment contract.

American-Made Equipment And Products
Grantees are encouraged to purchase American-made equipment and products with funding provided under this award.

Increasing Seat Belt Use in the United States
EO 13043 requires Grantees to encourage employees and contractors to enforce on-the-job seat belt policies and programs when operating company-owned, rented or personally-owned vehicle.

Federal Leadership of Reducing Text Messaging While Driving
EO 13513 requires Grantees to encourage employees, sub-awardees, and contractors to adopt and enforce policies that ban text messaging while driving company-owned, rented vehicles or privately owned vehicles when on official Government business or when performing any work for or on behalf of the Federal Government.

Federal Employee Expenses
Federal agencies are barred from accepting funds from a Grantee to pay transportation, travel, or other expenses for any Federal employee unless specifically approved in the terms of the award. Use of award funds (Federal or non-Federal) or the Grantee's provision of in-kind goods or services, for the purposes of transportation, travel, or any other expenses for any Federal employee may raise appropriation augmentation issues. In addition, NRC policy prohibits the acceptance of gifts, including travel payments for Federal employees, from Grantees or applicants regardless of the source.

Minority Serving Institutions (MSIs) Initiative
Pursuant to EOs 13256, 13230, and 13270, NRC is strongly committed to broadening the participation of MSIs in its financial assistance program. NRC's goals include achieving full participation of MSIs in order to advance the development of human potential, strengthen the Nation's capacity to provide high-quality education, and increase opportunities for MSIs to participate in and benefit from Federal financial assistance programs. NRC encourages all applicants and Grantees to include meaningful participations of MSIs. Institutions eligible to be considered MSIs are listed on the Department of Education website: http://www.ed.gov/about/offices/list/ocr/edlite-minorityinst.html

Research Misconduct
Scientific or research misconduct refers to the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest errors or differences of opinions. The Grantee organization has the primary responsibility to investigate allegations and provide reports to the Federal Government. Funds expended on an activity that is determined to be invalid or unreliable because of scientific misconduct may result in a disallowance of costs for which the institution may be liable for repayment to the awarding agency. The Office of Science and Technology Policy at the White House published in the Federal Register on December 6, 2000, a final policy that addressed

research misconduct. The policy was developed by the National Science and Technology Council (65 FR 76260). The NRC requires that any allegation be submitted to the Grants Officer, who will also notify the OIG of such allegation. Generally, the Grantee organization shall investigate the allegation and submit its findings to the Grants Officer. The NRC may accept the Grantee's findings or proceed with its own investigation. The Grants Officer shall inform the Grantee of the NRC's final determination.

Publications, Videos, and Acknowledgment of Sponsorship

Publication of the results or findings of a research project in appropriate professional journals and production of video or other media is encouraged as an important method of recording and reporting scientific information. It is also a constructive means to expand access to federally funded research. The Grantee is required to submit a copy to the NRC and when releasing information related to a funded project include a statement that the project or effort undertaken was or is sponsored by the NRC. The Grantee is also responsible for assuring that every publication of material (including Internet sites and videos) based on or developed under an award, except scientific articles or papers appearing in scientific, technical or professional journals, contains the following disclaimer:

> "This [report/video] was prepared by [Grantee name] under award [number] from [name of operating unit], Nuclear Regulatory Commission. The statements, findings, conclusions, and recommendations are those of the author(s) and do not necessarily reflect the view of the [name of operating unit] or the US Nuclear Regulatory Commission."

Trafficking In Victims Protection Act Of 2000 (as amended by the Trafficking Victims Protection Reauthorization Act of 2003)

Section 106(g) of the Trafficking In Victims Protection Act Of 2000 (as amended as amended, directs on a government-wide basis that:

> "any grant, contract, or cooperative agreement provided or entered into by a Federal department or agency under which funds are to be provided to a private entity, in whole or in part, shall include a condition that authorizes the department or agency to terminate the grant, contract, or cooperative agreement, without penalty, if the grantee or any subgrantee, or the contractor or any subcontractor (i) engages in severe forms of trafficking in persons or has procured a commercial sex act during the period of time that the grant, contract, or cooperative agreement is in effect, or (ii) uses forced labor in the performance of the grant, contract, or cooperative agreement." (22 U.S.C. § 7104(g)).

EXECUTIVE COMPENSATION REPORTING

2 CFR 170.220 directs agencies to include the following text to each grant award to a non-federal entity if the total funding is $25,000 or more in Federal funding.

Reporting Subawards and Executive Compensation.

a. *Reporting of first-tier subawards.*

1. *Applicability.* Unless you are exempt as provided in paragraph d. of this award term, you must report each action that obligates $25,000.00 or more in Federal funds that does not include Recovery funds (as defined in section 1512(a)(2) of the American Recovery and Reinvestment Act of 2009, Pub. L. 111–5) for a subaward to an entity (see definitions in paragraph e. of this award term).

2. *Where and when to report.*

i. You must report each obligating action described in paragraph a.1. of this award term to *http://www.fsrs.gov.*

ii. For subaward information, report no later than the end of the month following the month in which the obligation was made. (For example, if the obligation was made on November 7, 2010, the obligation must be reported by no later than December 31, 2010.)

3. *What to report.* You must report the information about each obligating action that the submission instructions posted at *http://www.fsrs.gov* specify.

b. *Reporting Total Compensation of Recipient Executives.*

1. *Applicability and what to report.* You must report total compensation for each of your five most highly compensated executives for the preceding completed fiscal year, if—

i. the total Federal funding authorized to date under this award is $25,000.00 or more;

ii. in the preceding fiscal year, you received—

(A) 80 percent or more of your annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

(B) $25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

iii. The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at *http://www.sec.gov/answers/execomp.htm.*)

2. *Where and when to report.* You must report executive total compensation described in paragraph b.1. of this award term:

i. As part of your registration profile at *http://www.sam.gov* .

ii. By the end of the month following the month in which this award is made, and annually thereafter.

c. *Reporting of Total Compensation of Subrecipient Executives.*

1. *Applicability and what to report.* Unless you are exempt as provided in paragraph d. of this award term, for each first-tier subrecipient under this award, you shall report the names and total compensation of each of the subrecipient's five most highly compensated executives for the subrecipient's preceding completed fiscal year, if—

i. in the subrecipient's preceding fiscal year, the subrecipient received—

(A) 80 percent or more of its annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

(B) $25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts), and Federal financial assistance subject to the Transparency Act (and subawards); and

ii. The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at *http://www.sec.gov/answers/execomp.htm*.)

2. *Where and when to report.* You must report subrecipient executive total compensation described in paragraph c.1. of this award term:

i. To the recipient.

ii. By the end of the month following the month during which you make the subaward. For example, if a subaward is obligated on any date during the month of October of a given year (*i.e.*, between October 1 and 31), you must report any required compensation information of the subrecipient by November 30 of that year.

d. *Exemptions*

If, in the previous tax year, you had gross income, from all sources, under $300,000.00, you are exempt from the requirements to report:

i. Subawards,

and

ii. The total compensation of the five most highly compensated executives of any subrecipient.

e. *Definitions.* For purposes of this award term:

1. *Entity* means all of the following, as defined in 2 CFR part 25:

i. A Governmental organization, which is a State, local government, or Indian tribe;

ii. A foreign public entity;

iii. A domestic or foreign nonprofit organization;

iv. A domestic or foreign for-profit organization;

v. A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.

2. *Executive* means officers, managing partners, or any other employees in management positions.

3. *Subaward:*

i. This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.

ii. The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see Sec. __ .210 of the attachment to OMB Circular A–133, "Audits of States, Local Governments, and Non-Profit Organizations").

iii. A subaward may be provided through any legal agreement, including an agreement that you or a subrecipient considers a contract.

4. *Subrecipient* means an entity that:

i. Receives a subaward from you (the recipient) under this award; and

ii. Is accountable to you for the use of the Federal funds provided by the subaward.

5. *Total compensation* means the cash and noncash dollar value earned by the executive during the recipient's or subrecipient's preceding fiscal year and includes the following (for more information see 17 CFR 229.402(c)(2)):

i. *Salary and bonus.*

ii. *Awards of stock, stock options, and stock appreciation rights.* Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Statement of Financial Accounting Standards No. 123 (Revised 2004) (FAS 123R), Shared Based Payments.

iii. *Earnings for services under non-equity incentive plans.* This does not include group life, health, hospitalization or medical reimbursement plans that do not discriminate in favor of executives, and are available generally to all salaried employees.

iv. *Change in pension value.* This is the change in present value of defined benefit and actuarial pension plans.

v. *Above-market earnings on deferred compensation which is not tax-qualified.*

vi. Other compensation, if the aggregate value of all such other compensation (e.g. severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds $10,000.00.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 30, 2014

Dr. John Dunning Boice
National Council on Radiation, Inc.
Protection and Measurements
7910 Woodmont Ave, Suite 400
Bethesda, Maryland 20814

VIA Electronic Mail
boice@ncrponline.org

SUBJECT: GRANT NO: NRC-HQ-60-14-G-0012

Dear Dr. Boice:

Pursuant to the authority contained in the Federal Grant and Cooperative Grantee Act of 1977 and the Atomic Energy Act of 1954, the Nuclear Regulatory Commission (NRC) hereby awards to National Council on Radiation Protection and Measurements (hereinafter referred to as the "Grantee" or "Recipient"), the sum of $675,000.00 to provide support for " Radiation Protection Guidance for the United States" entitled "Program Description."

This award is effective as of the date of this letter and shall apply to expenditures made by the Grantee furtherance of program objectives during the period beginning with the effective date of September 30, 2014 and ending September 29, 2017.

This award is made to the Recipient on condition that the funds will be administered in accordance with the terms and conditions as set forth in Attachment A (the Schedule); Attachment B (the Program Description); and Attachment C (the Standard Provisions); all of which have been agreed to by your organization.

Please ensure individuals selected as beneficiaries of support under this grant meet the legal requirements consistent with recent Supreme Court Decisions including *Fisher, Gratz, and Grutter.*

Please sign the enclosed grant to acknowledge your receipt of the award, and return as a pdf file to Ms. Gordana Zuber by email at Gordana.Zuber@nrc.gov.

Sincerely yours,

Sheila Bumpass

Sheila Bumpass
Grants Officer
Resources & Grants Team
Acquisition Management Division (AMD)

Attachments:
Attachment A – Schedule
Attachment B – Program Description
Attachment C – Standard Terms and Conditions

From: Brock, Terry
Sent: 20 Sep 2016 13:46:01 +0000
To: Tadesse, Rebecca
Subject: One Million U.S. Radiation Workers and Veterans Study_081712.docx
Attachments: One Million U.S. Radiation Workers and Veterans Study_081712.docx

Here's the RES NUREG one-pager. Out of date, but shows our optimism back in 2012

Office of Nuclear Regulatory Research

Radiation Worker Health Studies

Background

The U.S. Nuclear Regulatory Commission (NRC) has entered into an interagency agreement with the DOE Office of Science (SC) Low Dose Radiation Research Program to study the health effects of over one-million radiation workers and atomic veterans. Supporting DOE and this multi-agency effort will provide valuable new information for future radiation protection standards-setting bodies and any resultant occupational radiation dose standards.

The significance of the proposed research is considerable, because it applies directly to existing concerns about standards for chronic radiation exposure. Much knowledge has been gained from the study of atomic bomb survivors, but exposure was acute and among a Japanese population living in a war-torn country. Scientific and medical committees continue to grapple with how best to estimate risks associated with the gradual exposures received from environmental, medical and occupational radiation. Recent studies, though limited, have suggested that chronic exposures may be more hazardous than currently accepted. Governmental agencies must deal with the complex issues of compensating prior workers, veterans and citizens potentially harmed by past exposures. Protection committees deliberate over how best to estimate and apply a "dose and dose rate effectiveness factor" to scale the risks from the a-bomb survivor data for relevant and current circumstances. Evaluation of risk among persons with intakes of radioactive substances assumes greater importance as society debates expansion of nuclear energy and deals with nuclear waste and threats of terrorist attacks with nuclear devices. The remarkable increase in population medical exposures to CT scans and other imaging technologies has raised concerns of future health consequences.

Approach

A unique opportunity exists to assemble over one million radiation workers and military veterans, follow them to the present, calculate rates of mortality from cancer and other diseases, reconstruct radiation doses received (including doses from inhaled or ingested radionuclides), and provide new and essential knowledge on the level of lifetime risk from low-level ionizing radiation experienced chronically and beginning over 60 years ago. The methodology will follow the state-of-the-art approach recently used in studying cancer and other diseases among Rocketdyne radiation workers.

U.S. DEPARTMENT OF ENERGY | Office of Science LOW DOSE RADIATION RESEARCH PROGRAM

Collaborating institutions: U.S. National Council on Radiation Protection and Measurements (lead), Vanderbilt University, Oak Ridge Associated Universities, Oak Ridge National Laboratory, Los Alamos National Laboratory, Landauer, Inc., Risk Assessment Corporation, Harvard Medical School, University of Southern California, and the International Epidemiology Institute.

Collaborating or cooperating agencies: Department of Energy, Department of Defense, Department of Veteran Affairs, National Cancer Institute, National Aeronautics and Space Administration.

Study Status

Research began on the nuclear power worker cohorts in the fall of 2012. We expect to see the results in late 2014. The study webpage can be accessed at http://www.onemillionworkerstudy.org/

For More Information
Contact Terry Brock at 301-251-7487 or Terry.Brock@nrc.gov

05/26/2016 T.Brock/M. Weber

Issue: NCRP to recommend reducing occupational dose limit to the lens of the eye from 15 rem per year to 5 rem per year.

The U.S. National Council on Radiation Protection and Measurements (NCRP) plans to recommend in a forthcoming NRC-sponsored commentary to reduce the dose limit to the lens of the eye to **5 rad** (50 mGy) per year—equivalent to 5 rem (50 mSv) per year for low linear energy transfer radiation. The NRC's current dose limit is **15 rem** (150 mSv) per year—established in 1991 based on the International Commission on Radiological Protection (ICRP) recommendations at the time (i.e., ICRP report 60). The NCRP proposed reduction is based on recent epidemiological evidence suggesting vision impairing cataracts at doses lower than previously considered when setting the current NRC dose limit.

- NCRP expects to publish the final report in September of 2016

- ICRP in 2012 recommended reducing the limit to 2 rem (20 mSv) in a year, averaged over 5 years, with no single year exceeding 5 rem (50 mSv) (ICRP report 118).

- The International Atomic Energy Agency (IAEA) and cooperating agencies soon-after adopted the ICRP recommendation in the Basic Safety Standards. The European Union in 2014 adopted the ICRP recommendation—must be implemented by 2018

- NRC in 2014 accepted an NCRP grant proposal of $325,000 to provide a Commentary review for a period of performance from September 30, 2014 to September 29, 2016.

- NRC was considering revising the limit in the recently canceled update to 10 CFR 20.

- A review of the NRC's Radiation Exposure Information and Records System (REIRS) data for CY 2014 found no individual exceeded the NCRP proposed recommended 5 rem per year limit recommendation (maximum individual annual eye dose reported was 4.832 rem). 56,604 had measurable dose to the lens of the eye, with 13% (7,358) of those workers receiving doses > 25% of the current eye dose limit.

- REIRS does not collect dose information for medical practitioners (e.g., interventional cardiologists) and only collects limited industrial radiographer data. NRC would only be aware of doses exceeding current limits.

- EPRI is considering this issue and is meeting on June 1-2 in Charlotte to discuss.

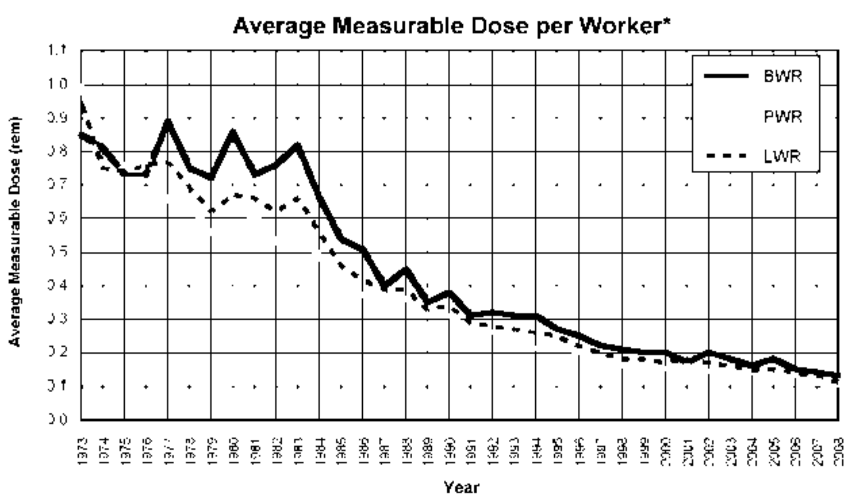
- The staff will develop and recommend to the Commission a path forward once we receive and have reviewed NCRP's commentary.

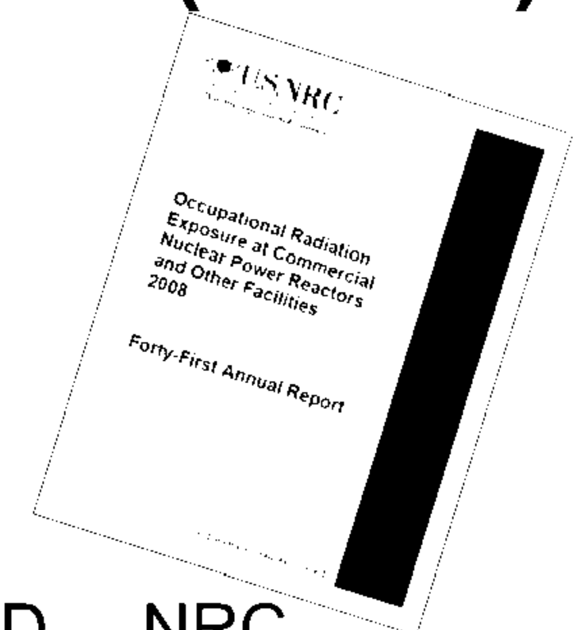
U.S.NRC

UNITED STATES NUCLEAR REGULATORY COMMISSION

Protecting People and the Environment

Radiation Exposure Information and Reporting System (REIRS)





Terry A. Brock, Ph.D. – NRC

February 15, 2012

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UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

REIRS – Designed with health studies in mind

103-005

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

CHAIRMAN

March 5, 1991

Chairman Kenneth M. Carr

Dr. Samuel Broder, Director
National Cancer Institute
Department of Health and Human
Services
9000 Rockville Pike
Building 31, Room 11A48
Bethesda, Maryland 20892

Dear Dr. Broder:

I am writing to inform you of the Nuclear Regulatory Commission's (NRC's) decision to establish new reporting requirements for radiation exposure information and to request the views of the National Cancer Institute (NCI) on the relative merits of conducting additional radioepidemiological studies on radiation workers. As you know, the NCI in 1986 requested that the Commission consider incorporating provisions for a Registry of Radiation Workers into the final revision of 10 CFR Part 20. I am pleased to inform you that the Commission has approved the final revision of 10 CFR Part 20 and that the final rule contains reporting requirements that will allow the collection of information necessary to establish such a registry. A total of seven categories of licensees, including nuclear power reactors, fuel cycle facilities, radiographers, major byproduct materials facilities, high- and low-level waste repositories, and independent spent fuel storage facilities, will be required to provide dose records for each monitored employee for each year. The Commission will retain this information in its currently existing Radiation Exposure Information Reporting System (REIRS) for potential use in epidemiologic studies.

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REIRS Database

- Began in 1969, collecting:
  - Annual distribution of dose per licensee
  - Termination records of individual exposure
- In 1974, the systems were split between NRC REIRS and DOE Radiation Exposure Monitoring System databases
- In 1989, REIRS database was moved to Oracle
- In 1995, the NRC and DOE systems were brought back together and are separate Oracle databases on the same server at ORAU

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Individual Dose Records

- The dose records are identified by individual (PII)
- Termination records that were submitted under 10 CFR 20.408 from 1969 up to 1994. ***Records go back to the 1940s.***
- Responses to the Generic Letter 94-04 that requested records that had not been reported prior to the revision of Part 20.
- Individual monitoring records under 10 CFR 20.2206 for all required NRC licensees from 1994 to the present.

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Individual Information

- Full name
- ID number
- ID type
  - (social security number, passport number, international drivers license, Canadian social index, work permit number, NEI's PAD system id number, other)
  - **98.5**% of the individuals are identified by SSN
- Date of birth
  - **83.9**% of the individuals have date of birth, or at least the year of birth

Exposure data

- Type of licensee (NRC program code)
  - Vast majority are nuclear power plant
- Dates of monitoring (typically annual, but some shorter increments)
- External dose
  - Deep dose total (includes neutron)
  - Shallow dose whole body
  - Shallow dose to max extremity
- Internal dose
  - Requirements have changed over time
  - Old requirements had %MPBB or dose to organ
  - Since 1994 - has CEDE, CDE, intake µCi, radionuclide

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Totals:

- # of individuals in database:

  910,934 *~largest in the world*

  (~ 1.2 million after data clean-up)

- Exposure records:

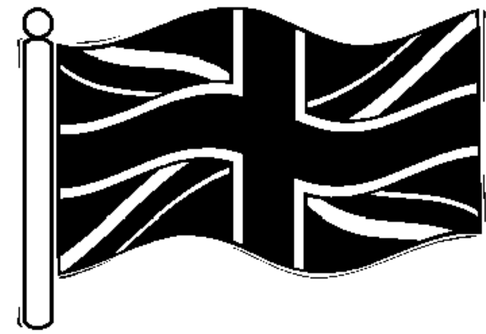
  5,864,765

- Individuals with measurable dose:

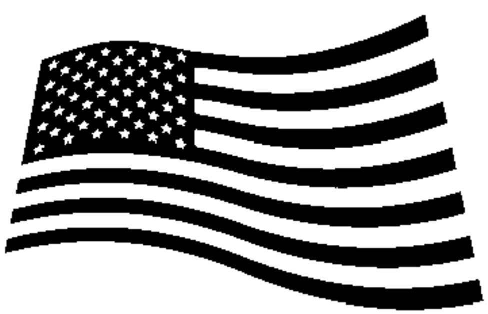
  578,523 (63%)

Database size - UK vs. US-NRC

Lifetime dose (rem)*	*Number of individuals*		*Collective dose (person rem*)*	
<1.0	118,766	68%	24,500	6%
1.0 - 4.9	35,402	20%	84,000	19%
5.0 - 9.9	9,869	6%	69,200	16%
10.0 and above	10,504	6%	257,100	59%
Total	**174,541**		**434,800**	



** Converted from sieverts in the original Muirhead study*



Lifetime dose (rem)	*Number of individuals*		*Collective dose (person rem)*	
0	332,411	36%	0	0%
>0 - 1.0	395,758	43%	86,437	8%
1.0 - 4.9	126,254	14%	295,582	28%
5.0 - 9.9	31,841	3%	223,291	21%
10.0 - 49.9	24,290	3%	429,720	40%
50.0 - 99.9	345	0%	21,396	2%
100 & above	35	0%	5,962	1%
Total	**910,934**		**1,062,387**	

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Protecting People and the Environment

What about Industrial Radiographers?

- **NRC Industrial Radiography Workers by Lifetime Dose and First Radiation Work**

Period	Dose Range (rem)				Total number of workers	Collective dose (person rem)	Mean dose (rem)
	<1.0	1.0-	5.0-	10.0+			
1940-44	1,466	388	128	100	2,082	4,074	1.96
1945-49	414	115	57	66	652	2,312	3.55
1950-54	761	359	151	130	1,401	5,152	3.68
1955-59	933	422	193	236	1,784	7,417	4.16
1960-64	1,866	834	371	492	3,563	15,096	4.24
1965-69	4,452	1,813	666	626	7,557	22,818	3.02
1970-74	7,590	1,966	478	446	10,480	18,637	1.78
1975-79	4,250	1,740	614	517	7,121	18,946	2.66
1980-84	2,328	1,010	371	321	4,030	11,461	2.84
1985-89	2,004	642	208	130	2,984	5,511	1.85
1990-94	2,406	811	271	175	3,663	7,318	2.00
1995-99	2,720	892	212	127	3,951	6,068	1.54
2000-04	2,118	947	237	57	3,359	5,169	1.54
2005+	2,502	1,007	75	8	3,592	3,484	0.97
Total	**35,810**	**12,946**	**4,032**	**3,431**	**56,219**	**133,462**	**2.37**

~7500 workers > 5 rem

Questions

U.S.NRC

UNITED STATES NUCLEAR REGULATORY COMMISSION

Protecting People and the Environment

Radiation Worker Health Studies: Current State of Knowledge and Future Opportunities

Terry A. Brock, Ph.D. – RES

Patricia Milligan, CHP, RPh – NSIR

Radiation Protection Steering Committee

June 21, 2011

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Protecting People and the Environment

Introduction

- Why study occupationally exposed workers?

Health Studies - epidemiology

- The primary basis for our judgments and decisions on the effects of ionizing radiation on man
- Epidemiology is the study of the distribution and determinants of disease in human populations

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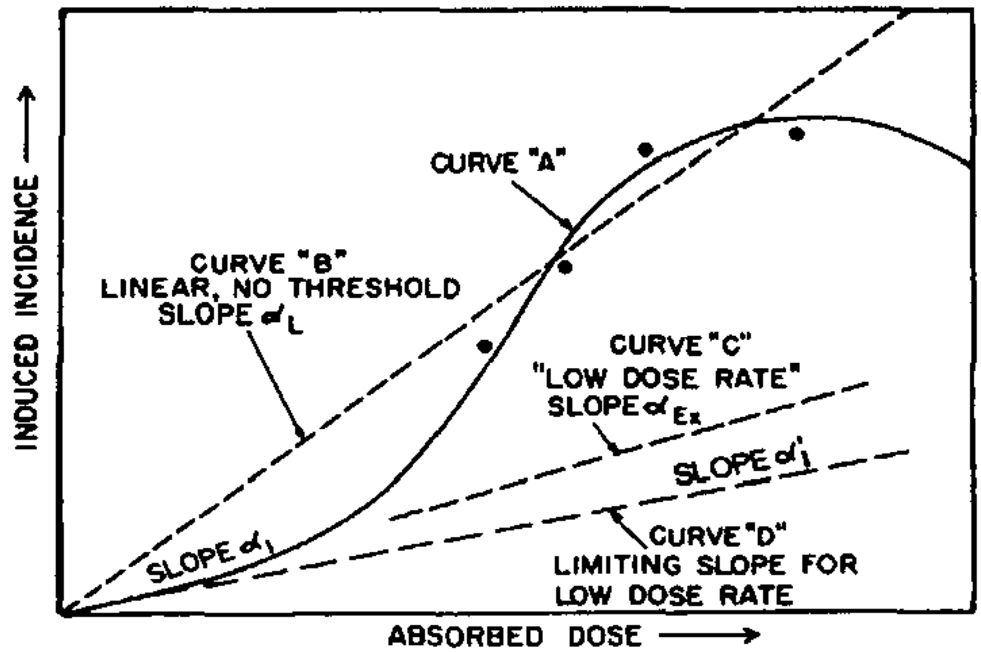
Current Risk Estimates

- Based on high dose, dose-rate exposures
- LNT interpolation to lower dose and dose rates
- Dose and Dose-Rate Effectiveness factor (DDREF)



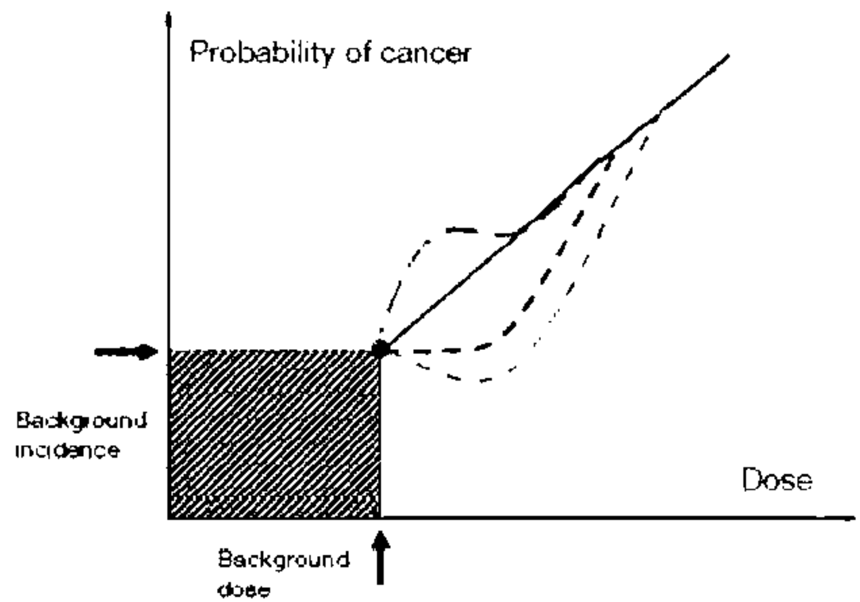
NCRP

LNT – Plausible and Practical Although Risk Below 10 REM Uncertain

From ICRP 103: the adoption of the LNT model combined with a judged value of a dose and dose rate effectiveness factor (DDREF) provides a prudent basis for the practical purposes of radiological protection, i.e., the management of risks from low dose radiation exposure.

Radiation epidemiology has yet to tell us about low dose and low dose rate exposures

Dose-Response Relationships



Boice, 2-22-11

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Protecting People and the Environment

Why now?

- Industry interest
- Scientific interest
- Health outcomes for early nuclear workers
- Graying expertise

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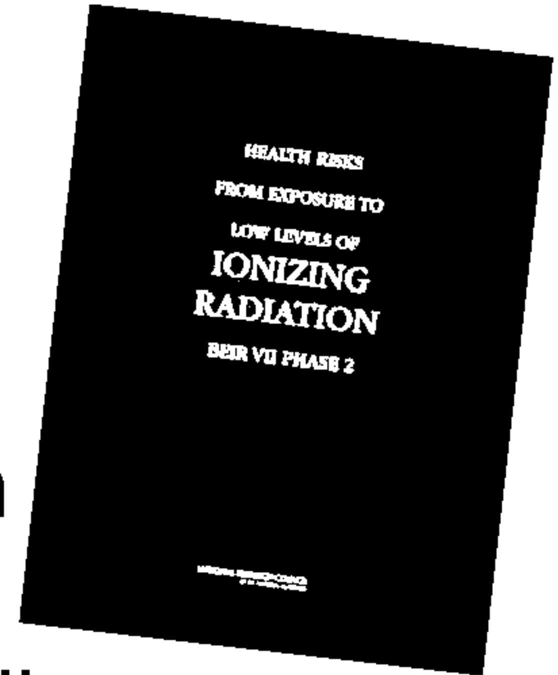
Protecting People and the Environment

BEIR VII Recommendation



"Studies of occupational radiation exposures, particularly among nuclear industry workers, including nuclear power plant workers, are well suited for direct assessment of the carcinogenic effects of long-term, low-level radiation exposure in humans."

UK National Registry for Radiation Workers

- Established in 1976
- 174,541 workers
- 2009 analysis (3rd analysis)
  - Increasing cancer risk with dose
    - Leukemia and solid cancer mortality and incidence
  - Overall mortality less than expected when compared to the general population – "Healthy Worker Effect"

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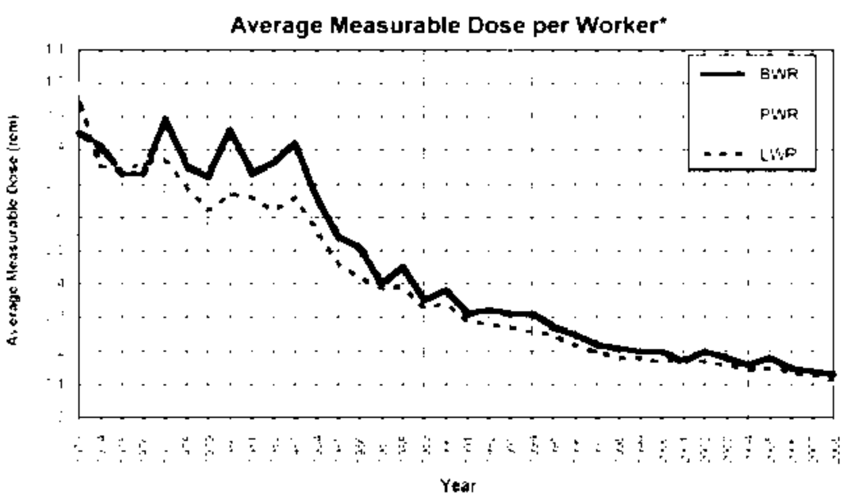
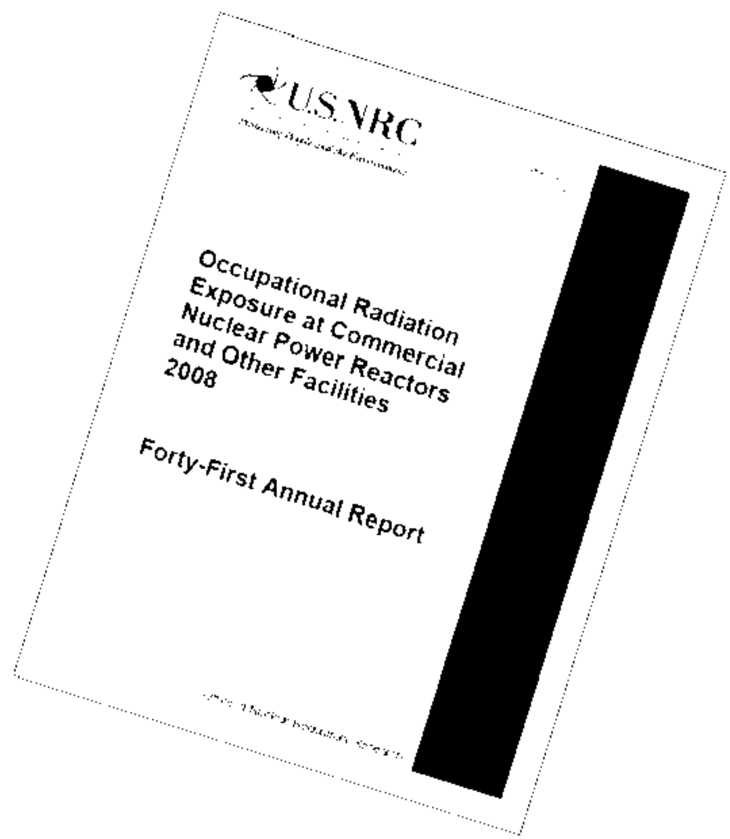
Protecting People and the Environment

NRC's Radiation Exposure Information and Reporting System (REIRS) for Radiation Workers





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Protecting People and the Environment

REIRS – Designed with health studies in mind

103-005

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

CHAIRMAN

March 5, 1991

Chairman Kenneth M. Carr

Dr. Samuel Broder, Director
National Cancer Institute
Department of Health and Human Services
9000 Rockville Pike
Building 31, Room 11A48
Bethesda, Maryland 20892

Dear Dr. Broder:

I am writing to inform you of the Nuclear Regulatory Commission's (NRC's) decision to establish new reporting requirements for radiation exposure information and to request the views of the National Cancer Institute (NCI) on the relative merits of conducting additional radioepidemiological studies of radiation workers. As you know, the NCI in 1986 requested that the Commission consider incorporating provisions for a Registry of Radiation Workers into the final revision of 10 CFR Part 20. I am pleased to inform you that the Commission has approved the final revision of 10 CFR Part 20 and that the final rule contains reporting requirements that will allow the collection of information necessary to establish such a registry. A total of seven categories of licensees, including nuclear power reactors, fuel cycle facilities, radiographers, major byproduct materials facilities, high- and low-level waste repositories, and independent spent fuel storage facilities, will be required to provide dose records for each monitored employee for each year. The Commission will retain this information in its currently existing Radiation Exposure Information Reporting System (REIRS) for potential use in epidemiologic studies.

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- Exposure records:

  5,864,765

- Individuals with measurable dose:

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Protecting People and the Environment

What about FSME?

NRC Industrial Radiography Workers by Lifetime Dose and First Radiation Work

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	<1.0	1.0-	5.0-	10.0+			
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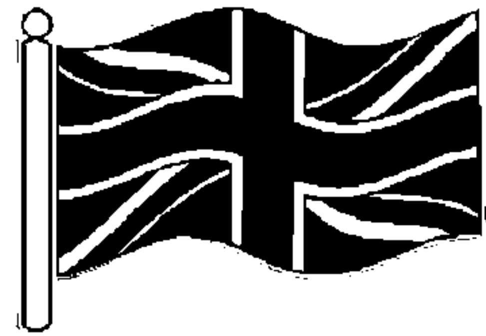
1945-49	414	115	57	66	652	2,312	3.55
1950-54	761	359	151	130	1,401	5,152	3.68
1955-59	933	422	193	236	1,784	7,417	4.16
1960-64	1,866	834	371	492	3,563	15,096	4.24
1965-69	4,452	1,813	666	626	7,557	22,818	3.02
1970-74	7,590	1,966	478	446	10,480	18,637	1.78
1975-79	4,250	1,740	614	517	7,121	18,946	2.66
1980-84	2,328	1,010	371	321	4,030	11,461	2.84
1985-89	2,004	642	208	130	2,984	5,511	1.85
1990-94	2,406	811	271	175	3,663	7,318	2.00
1995-99	2,720	892	212	127	3,951	6,068	1.54
2000-04	2,118	947	237	57	3,359	5,169	1.54
2005+	2,502	1,007	75	8	3,592	3,484	0.97
Total	**35,810**	**12,946**	**~~4,032~~**	**~~3,431~~**	**~~56,219~~**	**133,462**	**2.37**

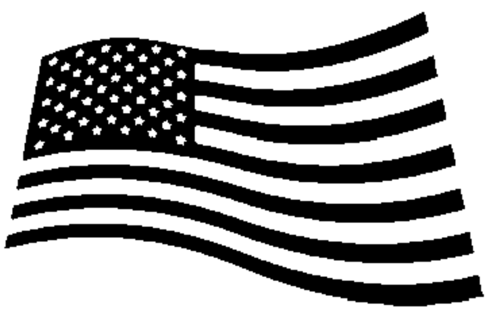
~7500 workers > 5 rem

Database size - UK vs. US-NRC

Lifetime dose (rem)*	*Number of individuals*		*Collective dose (person rem*)*	
<1.0	118,766	68%	24,500	6%
1.0 - 4.9	35,402	20%	84,000	19%
5.0 - 9.9	9,869	6%	69,200	16%
10.0 and above	10,504	6%	257,100	59%
Total	**174,541**		**434,800**	



** Converted from sieverts in the original Muirhead study*



Lifetime dose (rem)	*Number of individuals*		*Collective dose (person rem)*	
0	332,411	36%	0	0%
>0 - 1.0	395,758	43%	86,437	8%
1.0 - 4.9	126,254	14%	295,582	28%
5.0 - 9.9	31,841	3%	223,291	21%
10.0 - 49.9	24,290	3%	429,720	40%
50.0 - 99.9	345	0%	21,396	2%
100 & above	35	0%	5,962	1%
Total	**910,934**		**1,062,387**	

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United States Nuclear Regulatory Commission
Protecting People and the Environment

Future Studies

U.S. DEPARTMENT OF ENERGY | Office of Science

LOW DOSE RADIATION RESEARCH PROGRAM

- Last ~10 years focused on biology
- Now plan to perform occupational worker epidemiology studies in these cohorts
  - Uranium miners   Plutonium workers
  - Atomic Veterans   **Nuclear Power**
  - Medical   Combined cohorts

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Government Collaborators w/ DOE

- Department of Defense
- National Institutes of Health - National Cancer Institute
- Veterans Affairs
- Centers for Disease Control - NIOSH, EPA, NASA (interest)

Research Collaboration – 5 year proposal already accepted

- International Epidemiology Institute, Rockville, Maryland
  - John Boice, Sc.D.
- Oak Ridge Associated Universities, Oak Ridge, Tennessee
  - Donna Cragle, Ph.D., Richard Toohey, CHP, Ph.D., Derek Hagemeyer, REIRS PM
- Oak Ridge National Laboratory, Oak Ridge, Tennessee
  - Keith Eckerman, Ph.D., Richard Leggett, Ph.D.
- University of Southern California, Los Angeles, California
  - Daniel O. Stram, Ph.D.
- Vanderbilt University, Nashville, Tennessee
- Risk Assessment Corporation, Neeses, South Carolina
  - Jon E. Till, Ph.D.
- Los Alamos National Laboratory, Los Alamos, New Mexico

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Next Steps

- User-need request
- Possible Options
  - Interagency Agreement with DOE Low-Dose Research Program to ensure NRC interests are met
  - Sole-source with ORAU
  - Commercial solicitation

U.S.NRC

UNITED STATES NUCLEAR REGULATORY COMMISSION

Protecting People and the Environment

END

From: Brock, Terry
Sent: 11 Apr 2016 12:30:46 +0000
To: Tadesse, Rebecca
Cc: Armstrong, Kenneth
Subject: Re: ACTION: OEDO-16-00193 - Briefing Package Request for Meeting with National Council on Radiation Protection & Measurements on April 25, 2016

The NCRP could help the NRC by completing the analysis and publication of the health studies on the early nuclear power plant and industrial radiographer worker cohorts. Additionally, the NCRP could provide assistance by completing the ongoing review of the adequacy of LNT for use in radiation protection by the first quarter of CY 2017 or earlier.

From: Tadesse, Rebecca
Sent: Monday, April 11, 2016 8:20 AM
To: Brock, Terry
Cc: Armstrong, Kenneth
Subject: RE: ACTION: OEDO-16-00193 - Briefing Package Request for Meeting with National Council on Radiation Protection & Measurements on April 25, 2016
Terry,
I did not realize you are at NCRP meeting just give me a couple of sentences what additional work they can do and I will update the other part of the briefing book before I leave for the airport.
From: Brock, Terry
Sent: Monday, April 11, 2016 8:07 AM
To: Armstrong, Kenneth ; Tadesse, Rebecca
Subject: Re: ACTION: OEDO-16-00193 - Briefing Package Request for Meeting with National Council on Radiation Protection & Measurements on April 25, 2016
Nothing else to add. We already have NCRP working on a number of things for us as I listed in the update.
Terry

From: Armstrong, Kenneth
Sent: Friday, April 8, 2016 10:29 AM
To: Tadesse, Rebecca; Brock, Terry
Subject: RE: ACTION: OEDO-16-00193 - Briefing Package Request for Meeting with National Council on Radiation Protection & Measurements on April 25, 2016
My bad, off my TA game, here was the most recent version (sent up):
View ADAMS P8 Properties ML16089A067
Open ADAMS P8 Document (OEDO-16-00193 - Renee Taylor, OCM/JB, Email re: Briefing Package Request for Meeting with the National Council on Radiation Protection and Measurements (NRCP) on March 30, 2016 (Briefing Book/RES))
In the profile, we can find the word version to update the front page and anything else? Please note the following question:
Then a broad question to the Commissioner as to any areas he felt the NCRP might be helpful to the NRC mission.

Can we send this book up (perhaps with the HPS book) early next week?

From: Armstrong, Kenneth
Sent: Thursday, April 07, 2016 10:06 AM
To: Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>; Brock, Terry <Terry.Brock@nrc.gov>
Subject: FW: ACTION: OEDO-16-00193 - Briefing Package Request for Meeting with National Council on Radiation Protection & Measurements on April 25, 2016
Importance: High

I believe that we just need to change the first page:

View ADAMS P8 Properties ML13360A322

Open ADAMS P8 Document (Briefing Package for Meeting with NCRP (National Council on Radiation Protection and Measurements) on January 3, 2014 (RES).)

From: RidsResPmdaMail Resource
Sent: Thursday, April 07, 2016 9:58 AM
To: Armstrong, Kenneth <Kenneth.Armstrong@nrc.gov>
Subject: FW: ACTION: OEDO-16-00193 - Briefing Package Request for Meeting with National Council on Radiation Protection & Measurements on April 25, 2016
Importance: High

Good Morning!

Ken,

A new action has been assigned to your Division:

Subject: Briefing Package Request for Meeting with the National Council on Radiation Protection and Measurements (NRCP) on April 25, 2016

Due to OEDO Christian Araguas April 14, 2016

Ken, they only need 2 copies.

Subject Matter: Email below

From: Laura Atwell [mailto:Laura.Atwell@ncrponline.org]
Sent: Thursday, April 07, 2016 9:17 AM
To: Bloomer, Tamara <Tamara.Bloomer@nrc.gov>
Subject: [External_Sender] RE: Topics of discussion with Commissioner Ostendorff.

Hi Tammy,

Here are some discussion points:

Brief introduction of NCRP and how we have worked closely over the decades with NRC

Brief mention of ongoing collaboration with NRC on (1) Million Person Study (2) Guidance for Regulations for US and (3) Guidance for lens of the eye and (4) guidance on the use of LNT (Linear NonThreshold) model for radiation protection.

Collaborations with the Nuclear Navy

Then a broad question to the Commissioner as to any areas he felt the NCRP might be helpful to the NRC mission.

Thanks.

Laura

Thank you.

Kevin

From: EDOBriefingPkgRequest Resource
Sent: Wednesday, April 06, 2016 10:09 AM
To: RidsResPmdaMail Resource <RidsResPmdaMail.Resource@nrc.gov>; Johnson, Kevin <Kevin.Johnson@nrc.gov>

Cc: Araguas, Christian <Christian.Araguas@nrc.gov>
Subject: ACTION: OEDO-16-00193 - Briefing Package Request for Meeting with National Council on Radiation Protection & Measurements on April 25, 2016

Good morning,

Please review the additional briefing package requests below from Commissioner Ostendorff's office for ticket OEDO-16-00177. The incoming e-mail was added into the ADAMS package (ML16081A220). Note: the due date to OEDO is April 14, 2016.

Thank you,

Denise

View ADAMS P8 Properties ML16097A180

Open ADAMS P8 Document (OEDO-16-00193 - Linda Herr, OCM/WCO, Email re: Briefing Package Request for Meeting with the National Council on Radiation Protection and Measurements (NRCP) on April 25, 2016.)

From: Brock, Terry
Sent: 3 Feb 2016 15:38:23 +0000
To: Decker, David
Subject: RE: call to Adam Demalla, Re: million worker study (MWS)

Thanks so much David. Would you let Adam know they need $4-5 million per year for five years ($20-25 million total) to finish the Million Worker Study. I think I forgot to tell him on the phone call last Sept. This may help him as he starts FY17 discussions.

Thanks again,
Terry

Terry Brock, Ph.D.
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington D.C. 20555
Mail Stop TWFN-10
phone: 301-415-1793

From: Decker, David
Sent: Wednesday, February 03, 2016 9:44 AM
To: Brock, Terry <Terry.Brock@nrc.gov>
Subject: RE: call to Adam Demall, Re: million worker study (MWS)

Terry,
Adam just returned my call, and his input is that their working approach is that they support the program and want to see it continue. Although it was too late last year to do anything in FY16, for FY17 his going-in approach appears to be increasing funding for DOE (maybe DOE-NE and DOS-EHSS) at a level that will provide a useful continuation of the program (not sure how much that would be).

David

From: Brock, Terry
Sent: Wednesday, January 27, 2016 12:25 PM
To: Decker, David <David.Decker@nrc.gov>
Subject: RE: call to Adam Demall, Re: million worker study (MWS)

Thanks so much

From: Decker, David
Sent: Wednesday, January 27, 2016 11:48 AM
To: Brock, Terry
Subject: RE: call to Adam Demall, Re: million worker study (MWS)

Terry,
I did give the staffer a call but didn't hear back from him last week. I was hoping to see an e-mail from him today, but no such luck. I'll call him again today to see if I can get anything.

David

From: Brock, Terry
Sent: Wednesday, January 27, 2016 10:44 AM
To: Decker, David <David.Decker@nrc.gov>
Subject: call to Adam Demall, Re: million worker study (MWS)

Hi David,

I hope you survived the blizzard. I was just checking to see if you had a chance to follow-up with Adam Demalla of the Senate Appropriations Cmt. about the million worker study. AS you know, we had a conference call with him late last September about the study. We were wondering if he sees any progress in moving forward with the study. Adam should be aware that our Chairman has spoken to Asst, Secretary Koteck of DOE-Nuclear Energy (NE) about them taking over this study from DOE-Office of Science (OS). We coordinated with OS leadership and they supported DOE-NE taking it over.
Thanks for letting me know,

Terry

Terry Brock, Ph.D.
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington D.C. 20555
Mail Stop CSB-3A07
phone: 301-251-7487

From: Metting, Noelle
Sent: 16 Nov 2012 10:57:31 -0500
To: Dempsey, Heather
Cc: Brock, Terry;Shaffer, Sarah
Subject: RE: Discussion on IPAC for Worker Study Grant

Yes, that time is good for me--

From: Dempsey, Heather [mailto:Heather.Dempsey@nrc.gov]
Sent: Friday, November 16, 2012 10:06 AM
To: Metting, Noelle
Cc: Brock, Terry; Shaffer, Sarah
Subject: RE: Discussion on IPAC for Worker Study Grant

Hi Noelle,

How about Wednesday at 9:30? I will send you the appointment with the call in number shortly.

Thanks!

From: Metting, Noelle [mailto:noelle.metting@science.doe.gov]
Sent: Friday, November 16, 2012 9:35 AM
To: Dempsey, Heather
Cc: Brock, Terry; Shaffer, Sarah
Subject: RE: Discussion on IPAC for Worker Study Grant

Hi Heather,

Sorry, I am out of the office all day on Tuesday. I am available both Monday and Wednesday.

Noelle
NF Metting, Sc.D.
Voice: 301-903-8309
Fax: 301-903-0567
noelle.metting@science.doe.gov

From: Dempsey, Heather [mailto:Heather.Dempsey@nrc.gov]
Sent: Thursday, November 15, 2012 6:03 PM
To: Metting, Noelle
Cc: Brock, Terry; Shaffer, Sarah
Subject: Discussion on IPAC for Worker Study Grant

Hi Noelle,

I am the administrative person that helped put the worker study agreement in place with your organization. Terry has been looking into some information on when we can expect the IPAC and I have spoken with Mark Sojka this morning. Mark and I have a common understanding of what needs to happen and I wanted to bring both you and Terry up to speed.

Would you be available for a quick conference call on Tuesday (11/20) at 10am?

Program Analyst
RES/PMDA/POFCT
Phone:251-7666
Mailstop: CSB-6D20M

From: Brock, Terry
Sent: 1 Mar 2016 15:03:02 +0000
To: 'Bond, Brooke'
Cc: Wang, Charles (HQ);Grady, Christine
Subject: RE: FW: 2ND REQUEST FOR IPAC APPROVAL CN: NRC-HQ-60-12-I-0006 (04/2016)

Hello,

I was wondering if this has been resolved? My understanding is the funds from the NRC interagency agreement to support the million worker epidemiology study were depleted and no more work was being performed.

Thanks,
Terry

Terry Brock, Ph.D.
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington D.C. 20555
Mail Stop TWFN-10
phone: 301-415-1793

From: Bond, Brooke [mailto:Brooke.Bond@science.doe.gov]
Sent: Thursday, February 25, 2016 12:07 PM
To: Brock, Terry <Terry.Brock@nrc.gov>
Cc: Wang, Charles (HQ) <charles.wang@hq.doe.gov>; Grady, Christine <Christine.Grady@science.doe.gov>
Subject: [External_Sender] FW: 2ND REQUEST FOR IPAC APPROVAL CN: NRC-HQ-60-12-I-0006 (04/2016)

Mr. Brock,

I wanted to let you know we are looking into the IPAC charge on the subject agreement and will get back to you as soon as possible.

Thank you,

Brooke Bond
Accountant
Office of Chief Financial Officer
U.S. Department of Energy
Office of Science - Integrated Support Center - Chicago Office
9800 South Cass Avenue
Argonne, IL 60439
Phone (630) 252-3397

Our Service Excellence Pledge:

We pledge to respect and value our partners and customers, communicate responsively and professionally, and build our reputation for delivering excellent professional services with each task performed.

From: Brock, Terry
Sent: 9 Dec 2015 13:59:16 +0000
To: Case, Michael;Tadesse, Rebecca
Bcc: Bush-Goddard, Stephanie
Subject: RE: FYI - INFORMATION ON THE MILLION WORKER STUDY

May we consider this good news? Did Mike W give any indication on what they thought?

Terry

From: Case, Michael
Sent: Wednesday, December 09, 2015 7:33 AM
To: Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>; Brock, Terry <Terry.Brock@nrc.gov>
Subject: FW: FYI - INFORMATION ON THE MILLION WORKER STUDY

FYI

From: Weber, Michael
Sent: Tuesday, December 08, 2015 2:56 PM
To: Kelly, John E (NE) <JohnE.Kelly@Nuclear.Energy.Gov>; sal.golub@hq.doe.gov
Cc: West, Steven <Steven.West@nrc.gov>; Case, Michael <Michael.Case@nrc.gov>; Coffin, Stephanie <Stephanie.Coffin@nrc.gov>
Subject: FYI - INFORMATION ON THE MILLION WORKER STUDY

Good afternoon, John and Sal. Steve and I enjoyed our meeting this morning and opportunity for lunch together. As committed, I am providing some specifics regarding the "Million Worker Study" that we discussed:

- The official title of the study has evolved. The latest from John Boice, National Council on Radiation Protection and Measurements (NCRP) is the "Epidemiologic Study of One Million U.S. Radiation Workers and Veterans."

- The DOE's Office of Science (SC) in early 2012 approved a grant to NCRP for 5-years at, $21,733,858 through the now defunct Low Dose Radiation Research Program. SC pulled the funds soon after we joined the effort in June 2012 and reprogrammed the funds to other research areas related to climate change and biofuels.

- The NRC Interagency Agreement Number with DOE-SC is NRC-HQ-60-12-I-0006. The period of performance is 06/1/2012 to 07/31/2017.

- NRC's contribution of $2.5M has resulted in the formation of the nuclear power and industrial radiographer cohorts (N=147,600 and 128,364, respectively) with cause of death ascertainment completed. Funds are needed to perform the leukemia and solid cancer risk assessments for both cohorts.
    - Other cohorts to be studied are medical workers, Manhattan Project workers, and atomic veterans

- The other cooperating agencies with DOE-SC agreements are the U.S. EPA and NASA. We understand that DOD's Defense Threat Reduction Agency (DTRA) would be interested in joining the project, but were waived off by SC because they said no new contributions are being accepted.
    - The EPA contact is Mike Boyd--phone: 202-343-9395 or e-mail: boyd.mike@epa.gov.
    - The NASA contact is Lisa Simonsen—phone: 757-864-4432 or e-mail: lisa.c.simonsen@nasa.gov
    - The DTRA contact is Paul Blake—phone: 703-767-3433 or e-mail paul.k.blake.civ@mail.mil
- Adam Demella, majority Senate appropriations staffer, spoke to NRC staff about their interest in the study and the status.

If you need additional information, please advise. Happy Holidays!

Mike

Michael Weber
Director of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission

301-415-1902
Mail Stop T-10B16

ARM

DELIVERING OUR FUTURE

From:	Brock, Terry
Sent:	14 Sep 2016 14:10:46 +0000
To:	Tadesse, Rebecca;Sherbini, Sami;Case, Michael
Cc:	Webber, Kimberly
Subject:	RE: FYI - Meeting on Low Dose Radiation Research

Yes, I should go.

Terry

From: Tadesse, Rebecca
Sent: Wednesday, September 14, 2016 8:34 AM
To: Sherbini, Sami <Sami.Sherbini@nrc.gov>; Case, Michael <Michael.Case@nrc.gov>; Brock, Terry <Terry.Brock@nrc.gov>
Cc: Webber, Kimberly <Kimberly.Webber@nrc.gov>
Subject: RE: FYI - Meeting on Low Dose Radiation Research

I agree with Sami

Rebecca Tadesse, Chief
Radiation Protection Branch
Division of Systems Analysis
Office of Nuclear Regulatory Research
301-415-1824

From: Sherbini, Sami
Sent: Wednesday, September 14, 2016 8:02 AM
To: Case, Michael <Michael.Case@nrc.gov>; Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>; Brock, Terry <Terry.Brock@nrc.gov>
Cc: Webber, Kimberly <Kimberly.Webber@nrc.gov>
Subject: RE: FYI - Meeting on Low Dose Radiation Research

Mike,

We (first me and then Terry) have been involved in an NCRP effort to use the huge REIRS and other dosimetry data bases maintained at ORAU and elsewhere in an epidemiology study on low dose cancer risk. The project was intended to use the data, which is essentially a chronic low dose rate database (as opposed to the Japanese mostly acute high dose database) to determine if any increases in cancer rates can be detected at these chronic low doses. I understand that there are some interesting preliminary results, but it's unclear if they are ready to be made public. Terry should know, and if so, that would make a very interesting presentation. The presenter would probably be the lead author of the study, namely John Boise, who is the current president of the NCRP. I would suggest that Terry represent NRC at the meeting.

Sami

From: Case, Michael
Sent: Wednesday, September 14, 2016 6:51 AM
To: Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>; Brock, Terry <Terry.Brock@nrc.gov>; Sherbini, Sami <Sami.Sherbini@nrc.gov>
Cc: Webber, Kimberly <Kimberly.Webber@nrc.gov>
Subject: FW: FYI - Meeting on Low Dose Radiation Research

Thoughts?

From: Weber, Michael
Sent: Tuesday, September 13, 2016 6:52 PM
To: Case, Michael <Michael.Case@nrc.gov>; Webber, Kimberly <Kimberly.Webber@nrc.gov>; Dapas, Marc <Marc.Dapas@nrc.gov>; Moore, Scott <Scott.Moore@nrc.gov>
Cc: Collins, Daniel <Daniel.Collins@nrc.gov>; Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>; Gartman, Michael <Michael.Gartman@nrc.gov>; Difrancesco, Nicholas <Nicholas.DiFrancesco@nrc.gov>; Hackett, Edwin <Edwin.Hackett@nrc.gov>
Subject: FYI - Meeting on Low Dose Radiation Research

Should we participate? We could partner with NMSS and others and represent the agency, if you deem this worthwhile.

From: Cool, Donald [mailto:dcool@epri.com]
Sent: Tuesday, September 13, 2016 9:34 AM
To: Holahan, Vincent <Vincent.Holahan@nrc.gov>; Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>; Weber, Michael <Michael.Weber@nrc.gov>
Subject: [External_Sender] Meeting on Low Dose Radiation Research

Mike, Rebecca, Vince:

Greetings from Charlotte.

I am in the process of setting up a meeting on low dose radiation research. My desire is that organizations be able to talk about what their research program is, their objectives, plans, etc., as a way of facilitating discussions across the United States and the world. The meeting announcement is now available, with meeting dates of November 9 and 10, 2016, in Charlotte, North Carolina, USA.

As Jacques Repessard said in the opening of last year's MELODI meeting, there is a need for an international forum for discussion and coordination. That is what I hope the International Dose Effect Alliance (IDEA) can be.

I would greatly appreciate it if you could consider attending and presenting, and provide the information below to others in NRC and the Federal Sector, and encourage both their attendance, and a presentation on the work being done. I am already reaching out to DOE through Pat Worthington and Isaf Al-Nabulsi. I would also wish to have the potential contacts names and emails, if possible, so that I can follow up and answer any questions. I will be reaching out separately to many others, including ICRP folks, and contacts in Japan, Korea, and Europe, as well as in the U.S.

Thanks

Don

Donald A. Cool, Ph.D.
Technical Executive - Radiation Safety
EPRI
1300 West WT Harris Blvd | Charlotte NC 28262-2867
Office: 704-595-2541 | **Email:** dcool@epri.com
Together ... Shaping the Future of Electricity

From: Crosby, UnChu
Sent: Friday, September 09, 2016 11:06 AM
To: Crosby, UnChu <ucrosby@epri.com>
Subject: Invitation to the International Dose Effect Alliance Workshop 2016

International Dose Effect Alliance Workshop 2016

The International Dose Effect Alliance (IDEA) Workshop is an initial formation workshop to explore the opportunities and interest in national and international collaboration on Low Dose Radiation Effects Research. Low Radiation Dose continues to be a significant issue, and there is a need for a framework and platform to facilitate communication and collaboration on low dose radiation research programs within the United States, and with international partners. The vision for IDEA is for an international platform for information exchange, discussion, cooperation, and collaboration in low dose radiation research.

When
Wednesday, November 9, 2016 7:30 AM - Thursday, November 10, 2016 5:00 PM
Eastern Time
Where
EPRI - Charlotte
1200 West WT Harris Blvd, Building 3, Rooms 741 A and D, Charlotte, North Carolina 28262, USA
Dress Code
Business Casual
View Event Summary
Registration Deadline
Wednesday, November 9, 2016
Please respond by clicking one of the buttons below

Having trouble with the link? Simply copy and paste the entire address listed below into your web browser:
http://www.cvent.com/d/-EAfqheZD0ykDPETWI7J-w/snh9/P1/1Q?
If you no longer want to receive emails from EPRI Events please click the link below.
Opt-Out

From: Metting, Noelle
Sent: 10 Sep 2012 14:39:51 -0400
To: Brock, Terry
Subject: RE: hi and status of worker study grant

Hi Terry,

The Million Worker Study is still slated to be awarded on 15 September, and I have no worries about this 1st budget period. My concern is with the out-years, but we will see how the future unfolds.

I am well, and hope you are, too.

Best Noelle
NF Metting, Sc.D.
Voice: 301-903-8309
Fax: 301-903-0567
noelle.metting@science.doe.gov

From: Brock, Terry [mailto:Terry.Brock@nrc.gov]
Sent: Monday, September 10, 2012 2:33 PM
To: Metting, Noelle
Subject: hi and status of worker study grant

Hi Noelle,

I hope you are well. I was just checking in to see how close you all are in awarding NCRP the worker study grant. The last I heard was that it was in the Chicago office.

Cheers,
Terry

Terry Brock, Ph.D.
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington D.C. 20555
Mail Stop CSB-3A07
phone: 301-251-7487

From: Brock, Terry
Sent: 16 Feb 2016 14:52:26 +0000
To: Case, Michael
Cc: Tadesse, Rebecca
Subject: Re: Million Worker Study
Attachments: 45-From-Oak-Ridge-to-Indian-Point-Feb-2016.pdf

I'm heading to the airport, but here is what I know. I spoke to Patricia Worthington in DOE-EHHS where the DOE epidemiologists reside and they are fully supportive still of continuing the study. I heard back from Capitol Hill--Adam Demalla the majority senate appropriations staffer plans to try and get funding for the MWS in FY17 to DOE-NE or EHHS. Bottom-line: we need 4-5 million for 5 years to finish. Attached is a nice and timely update from Boice for your reading pleasure.

Thanks

From: Case, Michael
Sent: Tuesday, February 16, 2016 9:41 AM
To: Brock, Terry; Tadesse, Rebecca
Subject: Million Worker Study

We're meeting with DOE today and MWS in on the agenda. If you're here yet, can you stop on by and give me a refresher/update?

The Boice Report #45

John D. Boice, Jr., NCRP President
ICRP Main Commissioner
UNSCEAR U.S. Alternate Representative
Vanderbilt Professor of Medicine

NCRP

From Oak Ridge to Indian Point
Studying Workers at Nuclear Power Plants

Paraphrasing Thomas Edison, epidemiology is 5% inspiration and 95% perspiration. The inspiration for the Million Person Study of Low Dose Health Effects (MPS) came over 30 years ago with recommendations to create a registry of radiation workers among U.S. Nuclear Regulatory Commission (NRC) licensees (see June 2015 Boice Report #37). The 30 years of perspiration are outlined below.

Thirty years in the making. Today, the Radiation Exposure Information and Reporting System (REIRS) database closely approximates a U.S. occupational radiation exposure registry (ORISE 2011). REIRS dates back to 1969 when U.S. Atomic Energy Commission (AEC) licensees were required to report radiation exposure data for individual workers at the end of employment and exposure summaries for sites on an annual basis. At that time, AEC licensees were only required to submit radiation-monitoring records upon an employee's termination of employment. However, in 1986, Gil Beebe and I, both at the National Cancer Institute (NCI), composed a letter sent by NCI Director Vincent DeVita, MD, to NRC Chairman Lando Zech requesting that reporting requirements be changed to support epidemiologic health studies. In 1991 a positive response was received from NRC Chairman Kenneth Carr to NCI Director Samuel Broder. In 1994, as part of the implementation of the 1991 revisions of 10 CFR 20 "Standards for Protection Against Radiation," the NRC began requiring annual radiation exposure records for every monitored worker (NRC Regulatory Guide 8.7). In 1994 I wrote Bill Morris, director of the Division of Regulatory Applications, Office of Nuclear Regulatory Research, urging the voluntary reporting of additional occupational radiation exposure data so that a high-quality radiation worker registry might be created for epidemiologic studies. In 1994 NRC requested that licensed utilities report voluntarily the career doses of current and past employees (NRC Generic Letter 94-04); the utilities responded favorably to this request, and a registry of radiation workers suitable for epidemiologic study was born.

How are REIRS data used for health studies? Annual radiation doses for over 1.1 million unique workers are in REIRS, including external whole-body exposure and, since 1994, internal exposure. Identifying information includes name, social security number, date of birth, sex, licensee code, and dates monitoring began and ended. We selected all 425,713 nuclear power plant workers first monitored before 1985, sampled 10% of the 307,553 workers with cumulative doses less than 10 mSv, and removed 3,688 workers with duplicate, incomplete, or invalid dose records for a study population of 145,227 workers. Workers hired after 1984 were excluded because they received much lower doses than earlier workers and because their younger age would not provide mortality information for many years. 1980 was originally chosen as the cutoff date for inclusion, but after the Three Mile Island accident in 1979, NRC required reactor modifications that increased workers' exposures for several years. The 10% sample of low-dose subjects was based on cost consideration, i.e., it would be expensive to trace over 300,000 low-dose workers when their contribution to a health study could be adequately addressed by studying 30,000.

How valid are the radiation dose data? The key to high-quality epidemiology is equally high-quality dosimetry. NCRP Scientific Committee 6-9 is providing guidance, direction, and advice for the MPS. The committee has met six times in Oak Ridge, most recently in November 2015 (see photo). Most nuclear utility worker exposure is to high-energy gamma radiation from fission products (e.g., ^{137}Cs) or activation products (^{60}Co and ^{58}Co) and there is minimal neutron exposure or ingestion of radioactive material. Measurement uncertainty includes sensitivity, energy response, angular dependence, calibration, processing, and fading. Model uncertainty includes radiation fields, geometry, badge placement, missing doses, and conversion from badge reading to absorbed dose to organ of interest. A comprehensive report should be out this year that addresses these specific

SC 6-9 Meeting at Oak Ridge, November 2015. Front row, left to right: Dick Toohey (MH Chew, Inc.), Larry Dauer (Memorial Sloan Kettering Cancer Center [MSKCC]), John Boice (NCRP/Vanderbilt), Andre Bouville (NCI, retired), Kathy Pryor (Pacific Northwest National Laboratory), and John Till (Risk Assessment Corporation); back row, left to right: Keith Eckerman (Oak Ridge National Laboratory [ORNL]), Cary Zeitlin (Southwest Research Institute), Rich Leggett (ORNL), Harold Beck (DOE, retired), Mike Mumma (International Epidemiology Institute [IEI]), Derek Hagemeyer (Oak Ridge Associated Universities [ORAU]), and Craig Yoder (Landauer).

dosimetric concerns and challenges (and ways to overcome them).

How complete is REIRS? Before the NRC reporting changes in 1994 and the voluntary reporting of worker data back to 1957, I wrote that the REIRS data based on termination notices alone were limited. Since the reporting changes, the REIRS data are judged suitable for health effects studies. Further, data completeness back to 1969 was validated based on a comparison with workers identified from utility company records at the Calvert Cliffs Nuclear Power Plant and on comparisons of workers at two utilities included in a prior study (Howe 2004). Comparisons with data available from Landauer, Inc., also were remarkably consistent. The Landauer, Inc., records accounted for less than 0.8% of the cohort.

Nuclear Power Plant Workshop in New York City, December 2015. Left to right: Larry Dauer (MSKCC), John Kelly (former radiation protection manager at Indian Point 3), Dennis Quinn (DAQ, Inc.), John Boice (NCRP/Vanderbilt), Matthew Williamson (MSKCC), Joseph Perrotta (retired–quality assurance manager, Indian Point Energy Center). Not Pictured: Craig Yoder (Landauer), Don Mayer (director, Indian Point Unit 1), Mike Mumma (IEI), Derek Hagemeyer (ORAU).

Focus group evaluation. Well, not really a focus group (a catchy politically correct phrase), but a daylong meeting with current and former workers at the Indian Point Nuclear Power Plant and other national dosimetry specialists held in December 2015 (see photo). The exchange of information enhanced our understanding of dosimetry and radiation protection practices at nuclear reactors during the early years of the nuclear industry. Insights (for me):

- 80% of exposures occurred during outages for maintenance, modifications, and refueling. Refueling might occur every 18–24 months but maintenance is more frequent.
- Multiple badges were worn by approximately 1% of workers for some repairs, with the highest value reported.
- The conversion from film badge reading, $H_p(10)$, to organ dose is facilitated because most exposure is from high-energy gamma rays, facilitating an adjustment with a scaling factor (conversion coefficient).
- There are few missing doses to impute because of reporting practices and requirements.
- Neutron exposures and intakes of radioactive elements were rare—whole-body counting was done each year, as were annual physicals for radiation workers.
- During one challenging outage, hundreds of welders received up to 20 mSv over a period of one to two days—while unusual, some workers with high cumulative doses may have received exposures at a relatively high dose rate.
- A famous incident of a worker who received 100 mSv in one minute contributed to a change in NRC regulations for access to high radiation areas.

Future. The first manuscript on radiation-related leukemia is under review. Follow-up through 2011 identified 30,993 deaths from all causes, including 320 from leukemia other than chronic lymphocytic leukemia (CLL). For workers with cumulative doses greater than 10 mSv, the mean active bone marrow dose was 61 mSv (maximum 1.0 Sv; 8.4% of workers had doses greater than 100 mSv). Subsequent manuscripts will evaluate over 1,200 cases of leukemia other than CLL, combining data from industrial radiographers, atomic veterans, and U.S. Department of Energy worker cohorts. Results will significantly augment scientific knowledge on the lifetime risk of cancer and leukemia following relatively low-dose exposures received gradually over time.

From: Tadesse, Rebecca
Sent: 20 Sep 2016 09:48:10 -0400
To: Brock, Terry
Subject: RE: One Million U.S. Radiation Workers and Veterans Study_081712.docx

I think we need to look for the one that we used for DOE. I have asked Ken to look for it as well but can you start putting one together if we don't have one.

Rebecca Tadesse, Chief
Radiation Protection Branch
Division of Systems Analysis
Office of Nuclear Regulatory Research
301-415-1824

From: Brock, Terry
Sent: Tuesday, September 20, 2016 9:46 AM
To: Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>
Subject: One Million U.S. Radiation Workers and Veterans Study_081712.docx

Here's the RES NUREG one-pager. Out of date, but shows our optimism back in 2012

From: Armstrong, Kenneth
Sent: 20 Sep 2016 10:32:22 -0400
To: Brock, Terry;Tadesse, Rebecca
Subject: RE: Request for Input - Meeting Request for Briefing with the Department of Energy on December 14, 2015

Think that I finally found it:

ML15334A109

From: Brock, Terry
Sent: Tuesday, September 20, 2016 9:45 AM
To: Armstrong, Kenneth <Kenneth.Armstrong@nrc.gov>; Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>
Subject: FW: Request for Input - Meeting Request for Briefing with the Department of Energy on December 14, 2015

Rebecca,

This is what we used for the Chairman / Kotek quarterly meeting with discussion about the worker study. Ken do you have the final to share with Weber?

Terry

Terry Brock, Ph.D.
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington D.C. 20555
Mail Stop TWFN-10
phone: 301-415-1793

From: Armstrong, Kenneth
Sent: Tuesday, November 10, 2015 2:49 PM
To: Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>
Cc: Brock, Terry <Terry.Brock@nrc.gov>
Subject: FW: Request for Input - Meeting Request for Briefing with the Department of Energy on December 14, 2015

Rebecca,

Terry and I just put the attached edits together to highlight the Million Workers Study, will you please take a look (page 2 and page 7)?

Thanks!

From: Armstrong, Kenneth
Sent: Tuesday, November 10, 2015 6:56 AM
To: Lee, Richard <Richard.Lee@nrc.gov>; Porter, Ian <Ian.Porter@nrc.gov>; Bajorek, Stephen

<Stephen.Bajorek@nrc.gov>; Hoxie, Chris <Chris.Hoxie@nrc.gov>; Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>; Tomon, John <John.Tomon@nrc.gov>; Santiago, Patricia <Patricia.Santiago@nrc.gov>
Cc: Krotiuk, William <William.Krotiuk@nrc.gov>; Brock, Terry <Terry.Brock@nrc.gov>
Subject: RE: Request for Input - Meeting Request for Briefing with the Department of Energy on December 14, 2015

All,

Just a reminder. I have already received input from RSAB on the spent fuel cask work. As discussed in the BC meeting yesterday, Mike would like to see something added on the Million Workers Study (RPB).

Thanks!

From: Armstrong, Kenneth
Sent: Tuesday, November 03, 2015 7:18 AM
To: Lee, Richard <Richard.Lee@nrc.gov>; Elkins, Scott <Scott.Elkins@nrc.gov>; Bajorek, Stephen <Stephen.Bajorek@nrc.gov>; Hoxie, Chris <Chris.Hoxie@nrc.gov>; Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>; Santiago, Patricia <Patricia.Santiago@nrc.gov>
Cc: Case, Michael <Michael.Case@nrc.gov>; Coffin, Stephanie <Stephanie.Coffin@nrc.gov>
Subject: Request for Input - Meeting Request for Briefing with the Department of Energy on December 14, 2015

Good morning!

The next quarterly meeting between the Chairman and the DOE Deputy Assistant Secretary, Office of Nuclear Energy, John Kotek will be held on December 14, 2015.

Attached is the briefing information from the September 4, 2015 quarterly meeting which includes the following topics:

- General MOU with DOE on Cooperative Nuclear Safety Research
- Fuels Research, including Accident Tolerant Fuels
- Consortium for Advanced Simulation of LWRs (CASL)
- Fukushima-Based Research on Severe Accidents
- Experiments to Analyze Thermal Hydraulic Margins of Spent Fuel Casks

Please provide me any updates as a red line strike out version to this document **by November 10, 2015**.

Thanks!
From: Cruz, Holly
Sent: Monday, November 02, 2015 1:29 PM
To: Johnson, Kevin <Kevin.Johnson@nrc.gov>
Cc: Schroer, Suzanne <Suzanne.Schroer@nrc.gov>; Issa, Alfred <Alfred.Issa@nrc.gov>; Armstrong, Kenneth <Kenneth.Armstrong@nrc.gov>; RidsResPmdaMail Resource

<RidsResPmdaMail.Resource@nrc.gov>
Subject: RE: Request for ticket (OEDO-15-00747-RES) -Revised Due Date

My apologies, Kevin. I should have waited for the official inquiry from NRO. Please note the highlighted changes to the ticket request below. In addition, please note the updated file, with the request to include changes as redline strikeout. Please let me know if you need anything additional.

Thanks again,

Holly

From: Cruz, Holly
Sent: Tuesday, October 27, 2015 2:10 PM
To: Johnson, Kevin <Kevin.Johnson@nrc.gov>
Cc: Schroer, Suzanne <Suzanne.Schroer@nrc.gov>; Issa, Alfred <Alfred.Issa@nrc.gov>; Armstrong, Kenneth <Kenneth.Armstrong@nrc.gov>; RidsResPmdaMail Resource <RidsResPmdaMail.Resource@nrc.gov>
Subject: Request for ticket (OEDO-15-00747-RES)

Kevin,

Could you please create a ticket for the below request? Please let me know if you have any questions or need anything additional.

Request:

- Please revise the attached quarterly input to support the 12/14/15 meeting between Chairman Burns and Mr. Kotek, DOE.

Subject:

- The Chairman and Mr. Kotek agreed that meeting quarterly would be beneficial. Please provide the Chairman with any topics or current issues that would assist him in this meeting. This input should be an update of the package developed in support of the Sept 4th meeting.

Due dates:

- Due date to provide RES input (to Holly Cruz): 11/12/15 (assign to Divisions)
- Due date to NRO (to Jan Mazza): 11/16/15 (assign to Holly Cruz)

Thanks for your help,

Holly

Holly Cruz, Acting Technical Assistant
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Phone: (301) 415-1053
Location: T10A64
email: holly.cruz@nrc.gov

NRC-DOE Quarterly Meeting - Joint Activities and Memoranda of Understanding

Monday, December 14, 2015

ORGANIZATION: Department of Energy

SUBJECT MATTER: The Chairman and Mr. Kotek agreed that meeting quarterly would be beneficial.

ATTENDEE: Mr. John Kotek, Principal Deputy Assistant Secretary, Office of Nuclear Energy, Department of Energy

TOPICS: Memorandum of Understanding (MOU) between the U.S. Nuclear Regulatory Commission (NRC) and the U.S. Department of Energy (DOE) on Cooperative Nuclear Safety Research and other Joint Activities; Cooperation Between NRC and DOE regarding NRO Activities

Key Messages

1.

2.

Non-Responsive Record

3.

4. **Request for DOE to Restore Support for the Million Workers and Atomic Veterans Study** - Recently, staff learned that DOE - Office of Science decided to discontinue support for the multiagency Million Worker Study due to funding needs for other priority research areas. NRC believes that there is still strong scientific and policy interest in the nuclear and health physics communities to complete this study to get actual risk

estimates experienced by workers as a complement to the current paradigm of extrapolating risks from high dose and dose rate populations (e.g., Hiroshima and Nagasaki atomic bomb survivors). In addition, this study was supported by the Advisory Committee on Reactor Safeguards in the last RES program review. The results would be influential in our understanding of radiation risk, particularly at lower dose rates, at the typical occupational exposure patterns the U.S. work force experiences. These results can be used to support future radiation protection standard setting bodies in broad areas such as reactor and facility siting, occupational dose, emergency response, off-site consequence analysis, and decommissioning and waste disposal.

Background

1.

Non-Responsive Record

2.

Non-Responsive Record

NRC-DOE Quarterly Meeting - Joint Activities and Memoranda of Understanding

Monday, December 14, 2015

Non-Responsive Record

Non-Responsive Record

Non-Responsive Record

4. **Request for DOE to Restore Support for the Million Workers and Atomic Veterans Study (CA Note: ML15288A509)**

In 2012, the Office of Nuclear Regulatory Research (RES) entered into an interagency agreement with the U.S. Department of Energy (DOE) - Office of Science (SC) to study the health effects of more than 1 million radiation workers and atomic veterans, which is often referred to as the "Million Worker Study." The U.S. Nuclear Regulatory Commission (NRC), the U.S. Environmental Protection Agency (EPA), and the National Aeronautics and Space Administration (NASA) provided support to DOE in this multiagency effort with the goal to provide new information for future radiation protection standards setting bodies and any resultant occupational radiation dose standards. Recently, staff learned that DOE-SC cancelled the study to focus on other research areas related to biofuels. Staff believes that there is still a very strong scientific and policy interest in the nuclear and health physics communities to complete the Million Worker Study to get actual risk estimates experienced by workers as a complement to the current paradigm of extrapolating risks from high dose and dose rate populations. In addition, this study was supported by the Advisory Committee on Reactor Safeguards in the last RES program review. As a result, staff plans to engage DOE, Office of Nuclear Energy (NE) and DOE-SC about DOE's continued funding of the Million Worker Study through RES's current memorandum of understanding with NE.

The significance of the Million Worker Study is considerable because it applies directly to the existing concerns about standards for chronic radiation exposure. Much knowledge has been gained from the study of atomic bomb survivors, but exposure was acute and among a Japanese population living in a war-torn country. Scientific and medical committees continue to grapple with how best to estimate risks associated with the gradual exposures received from environmental, medical, and occupational radiation. As a result of NRC's participation in the Million Worker Study, two NRC radiation worker cohorts in the nuclear power and industrial radiographer occupations were established. In addition to the NRC cohorts, the study was to research DOE uranium workers, atomic veterans, DOE plutonium workers, and medical workers. The Million Worker Study would provide a definitive study on the health risks to workers exposed to radiation at the dose rates experienced in an occupational setting. The results would be very influential in our understanding of radiation risk at the typical occupational exposure patterns the U.S. work force experiences.

DOE's original estimate was $25M over 5 years to complete the study. So far, DOE contributed $1M in fiscal year (FY) 2012 to this study; no further monies were provided. The NRC contributed $1.5M in FY12 and an additional $517K in FY14. NASA has contributed nearly $1M to date, while EPA's contribution was smaller, on the order of $200K.

Non-Responsive Record

Non-Responsive Record

NRC-DOE Quarterly Meeting - Joint Activities and Memoranda of Understanding

Monday, December 14, 2015

Non-Responsive Record

Non-Responsive Record

- Non-Responsive Record

From: ADAMS p8_icm_service
Sent: Monday, October 26, 2015 6:58 AM
To: ICM_STARS_RES
Subject: FYI STARS OEDO Office Notification (OEDO-15-00747-RES)

A new OEDO Ticket has been assigned to you by Boyer, Rachel (rcj3) on 10/26/2015.

Last User Comment has been added to a Ticket by 10/26/2015 on 10/26/2015. The comment was -

10/26/2015

The Ticket information is below.

Ticket Info

Activity Information

Case Number	OEDO-15-00747-RES
Status	FYI
Activity Type	Task
EDO Due Date	12/07/2015
SECY Due Date	
Requested Due Date	
Assigned Offices	NRO
Routing Copies to	NMSS | RES
EDO Point of Contact	Rosales-Cooper, Cindy (cer2)
Other Parties	

Incoming ADAMS Accession ML15299A008

Date of

	Incoming	
Incoming ADAMS Package	ML15299A00 7	
	Frequency	
Incoming Information		
	Originator	Kathleen Blake, OCM/SGB
	Originator Organization	Commission
	Task	E-mail
	Addressee Name	
	Addressee Affiliation	
	Incoming Received Date	10/23/2015
	Subject	Meeting Request for Briefing with the Department of Energy on December 14, 2015
	Description	
Process Information		
	Special Instructions Type	Briefing Package
	Special Instructions	Please prepare briefing package in accordance with OEDO Procedure 0240 (ML13262A361/ML13262A365). Provide input to Cindy Rosales-Cooper, OEDO by December 7, 2015.
	Near Term Comment	
	Requested Action Type	Briefing Package
	Cross Reference Numbers	
	Signature Level	No Signature Required
	OIG Recommend	
	OEDO Concurrence	
	OCM Concurrence	
	OCA	

Concurrence

From: Tadesse, Rebecca
Sent: 17 Mar 2016 14:03:02 -0400
To: Mitchell, Jeffrey;Brock, Terry;Davis, Chon
Subject: RE: RES-16-0255

Thanks for all your help Jeff.

From: Mitchell, Jeffrey
Sent: Thursday, March 17, 2016 11:04 AM
To: Brock, Terry <Terry.Brock@nrc.gov>; Davis, Chon <Chon.Davis@nrc.gov>
Cc: Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>
Subject: RE: RES-16-0255

RES,

After reviewing the agreement file and the nature of this work, a revised SOW and IGCE is not needed to increase the ceiling/funding levels. This is a unique agreement in which is really a funding mechanism to transfer funds to DOE for the worker study. Please use similar language as presented in the FY14 req (RES-14-0246)

Jeff

From: Brock, Terry
Sent: Wednesday, March 16, 2016 8:53 AM
To: Davis, Chon <Chon.Davis@nrc.gov>; Mitchell, Jeffrey <Jeffrey.Mitchell@nrc.gov>
Cc: Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>
Subject: Re: RES-16-0255

Hi Chon/Jeff,

This Inter-agency Agreement with DOE was established as a financial assistance mechanism for NRC participation in a much larger ongoing DOE-grant project to the National Council on Radiation Protection ad Measurements "Million Worker Study" (original DOE budget was $25 million for the entire project). As such, the current SOW is still valid and an IGCE is not needed because we are providing financial assistance for this overall larger project. The funding mechanism is already established and we have provided funding in the past without any modification to the original SOW or the need for an IGCE since this a financial assistance award.

Please continue processing in STAQs.

Thanks,
Terry

From: Davis, Chon
Sent: Tuesday, March 15, 2016 12:56 PM

To: Tadesse, Rebecca
Cc: Brock, Terry
Subject: FW: RES-16-0255

Confirmation that a modified SOW and IGCE are required.

From: Mitchell, Jeffrey
Sent: Tuesday, March 15, 2016 12:46 PM
To: Davis, Chon <Chon.Davis@nrc.gov>
Subject: RE: RES-16-0255

Chon,
You are correct a track changes or redline strike out SOW and an IGCE on the new work.
Jeff

From: Davis, Chon
Sent: Tuesday, March 15, 2016 12:41 PM
To: Mitchell, Jeffrey <Jeffrey.Mitchell@nrc.gov>
Subject: FW: RES-16-0255

Hi Jeff.
I'm advising COR and BC that a modified SOW and IGCE are required for the ceiling increase they are proposing. I'd just like to confirm with you that my advice is accurate. It seems that sometimes these things are not required and I don't want to hold up the process if you really don't need them. The person who processed the last action on this agreement was Edna Knox-Davin, as far as I can tell.

Please let me know the correct path forward in this case.

As always, thank you for your help.
Chon

From: Davis, Chon
Sent: Tuesday, March 15, 2016 12:36 PM
To: Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>
Cc: Brock, Terry <Terry.Brock@nrc.gov>
Subject: RES-16-0255

Hi Rebecca.
I'm emailing you and copying Terry because I see he's out of the office until March 21st.

I think I have to disapprove his requisition (RES-160-0255).

I looked in NEAT and the information on record with AMD states a ceiling of $2,017,000 with no ceiling remaining. He has a different ceiling in his notes to buyer so, based on NEAT, his information below is incorrect:

Original Ceiling: $2,001,942
New Ceiling: $2,101,942

Paid Balance: $1,997,553.58
Remaining Balance: $104,388.42

Ceiling increases usually come with attachments (i.e., modified SOWs and IGCEs). There are no attachments to his requisition.

Also – the requisition form that goes to the contractor contains the following information in box 9. This information is not up to date. As a matter of fact it references FY14 (two FYs ago). I believe it should be revised as this text is confusing. I believe this text was appropriate for a former requisition.

9. DESCRIPTION OF ITEMS OR SERVICES
Modification to V6317 (NRC-HQ-60-12-I-0006) Interagency Agreement with the U.S. DOE's Office of Science Low Dose Research Program - Worker Health Studies. Modification to provide $517,000 FY14 funding and to increase the financial assistance funding ceiling level by the same amount. This will increase the ceiling from $1.5M to $2,017,000. The period of performance will stay the same from 6/1/2012 to 7/31/2017. The NRC provides support to this multi-agency effort to study cancer risks in radiation exposed workers. NRC's contribution ensures the nuclear power and industrial radiographer cohorts are prioritized for analysis. The additional funding will allow for continued work on these cohorts to develop the dose response analysis to determine if the slope of the LNT cancer risk model currently assumed in radiation protection is supported by empirical data.

Do you happen to know if the contract specialist stated that he does not need a modified SOW and IGCE for the ceiling increase? I will try to contact someone in AMD to see if there is anything we can do to move this forward. However I suspect it may have to wait until Terry's return to be addressed.

Please advise regarding next steps.

Thanks!
Chon

Chon Davis
NRC/RES/PMDA/FPMT
T-10B38
301-415-6610
Mail Stop T-10B16

Be in love with your life. Every minute of it.
Jack Kerouac

From: Metting, Noelle
Sent: 11 Jan 2013 12:01:13 -0500
To: Brock, Terry
Subject: RE: status of worker study spending

Hi Terry,

Sorry I have not gotten back to you, for reasons I can chat about when we next talk. I am gaining an understanding of the problem that your bosses have—it looks like uncosted funds at this point, and they are worried that the money will not be spent within the year. I now believe that an "interagency transfer" does not really "transfer" funds at all…!

I tried to call your office. Please give me a call after lunch, if you are at work today. Otherwise, I hope to talk with you on Monday.

Best—Noelle

NF Metting, Sc.D.
Voice: 301-903-8309
Fax: 301-903-0567
noelle.metting@science.doe.gov

From: Brock, Terry [mailto:Terry.Brock@nrc.gov]
Sent: Friday, January 04, 2013 9:08 AM
To: Metting, Noelle
Subject: status of worker study spending

Hi Noelle,

Happy New Year. I hope the holidays went well for you. I was wondering when you were going to send over the IPAC for the worker study grant to start drawing down the funds. I'm getting some unwanted attention on this.
I'm working at home today at (b)(6) if you want to chat.

Thanks for your help,
Terry

From: Albert, Michelle
To: Tadesse, Rebecca; Weber, Michael
Cc: Ammon, Bernice; Clark, Michael; Clark, Lisa; Case, Michael; Webber, Kimberly; Hackett, Edwin; Gartman, Michael; Sampson, Michele; Brock, Terry
Subject: RE: RESPONSE - Quick Turnaround - FW: LRM [EHF-114-323] ENERGY Oversight Testimony on DOE"s Decision to end its Low Dose Radiation Research Program #1140231926#
Date: Tuesday, September 20, 2016 11:02:39 AM

Rebecca and Mike,

Has the NRC staff engaged DOE to discuss these concerns about the termination of the Million Worker Study and DOE's Low Dose Radiation Research Program? I need a little additional information before I can advise on the best way for the NRC staff to proceed in response to this request from OMB. Our response is due to OMB by noon today, so unfortunately it would be good if we could touch base as soon as possible.

Thank you,

Michelle

Michelle D. Albert
Senior Attorney | Office of the General Counsel
Legal Counsel, Legislation, and Special Projects Division
U.S. Nuclear Regulatory Commission
(301) 287-9259 | Michelle.Albert@nrc.gov

Duplicate Record

From: Brock, Terry
Sent: 17 Nov 2015 17:04:47 +0000
To: Weber, Michael
Cc: West, Steven;Case, Michael;Coffin, Stephanie;Tadesse, Rebecca
Subject: REQUEST: Please Contact DOE-NE about the million worker study

Hi Mike,
I called my DOE-Office of Science (SC) contact, Dr. Todd Anderson, about our plan to ask DOE-NE to take over the million worker study (MWS). I also told him you wanted to talk to the SC Director to give a heads-up that we were contacting NE. Todd ran the request up to the top of SC and they donâ€™t need a callâ€"SC has no problem with us asking NE to take over the project.
So with this information, I recommend you contact John Kelly of NE about the request--I think it would be beneficial to have this call with him before the Chairman meets with John Kotek on December 14, 2015. Shirley told me you plan to have a meeting with John Kelly on December 8th, so maybe the MWS could be an agenda item?
Please let me know if you need anything.
Thanks,
Terry

Terry Brock, Ph.D.
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington D.C. 20555
Mail Stop TWFN-10
phone: 301-415-1793

From: Weber, Michael
Sent: 15 Dec 2015 18:21:35 -0500
To: Brock, Terry
Cc: Case, Michael;Coffin, Stephanie;Chen, Yen-Ju;Baggett, Steven;Moore, Johari;West, Steven
Subject: RESPONSE -- McClatchy News Series on Nuclear Workers

Don't know, Terry. Good question. Steve/Johari, please advise (MWS = Million Worker Study).

----- Original Message -----
From: Brock, Terry
Sent: Tuesday, December 15, 2015 08:56 AM
To: Weber, Michael
Cc: Case, Michael; Coffin, Stephanie
Subject: RE: RESPONSE -- McClatchy News Series on Nuclear Workers

Just curious...Did the MWS make it on the Chairman's meeting agenda with DOE-NE Asst. Sec Kotek? I remember submitting info for it.

Terry

-----Original Message-----
From: Weber, Michael
Sent: Monday, December 14, 2015 3:50 PM
To: Brock, Terry <Terry.Brock@nrc.gov>
Cc: Case, Michael <Michael.Case@nrc.gov>; Coffin, Stephanie <Stephanie.Coffin@nrc.gov>
Subject: RESPONSE -- McClatchy News Series on Nuclear Workers

Thanks, Terry. I'll forward to DOE/NE for awareness and as a follow-up to our meeting last week.

-----Original Message-----
From: Brock, Terry
Sent: Monday, December 14, 2015 3:47 PM
To: Weber, Michael <Michael.Weber@nrc.gov>
Cc: Case, Michael <Michael.Case@nrc.gov>; Coffin, Stephanie <Stephanie.Coffin@nrc.gov>; Burnell, Scott <Scott.Burnell@nrc.gov>; Weil, Jenny <Jenny.Weil@nrc.gov>; Foster, Jack <Jack.Foster@nrc.gov>
Subject: Re: Query - McClatchy News Series on Nuclear Workers

Hi Mike,

Thanks for the heads up. I didn't know they were looking at this. I found the entire article here >> http://media.mcclatchydc.com/static/features/irradiated/#story

As you stated, the analysis is be based on the compensation programs. The mortality data cited in the headline appears to be from normal mortality. This is an older aged cohort so you would expect a large number to have died. The authors risk comparison to actual deaths from recent wars is a bit specious, in that attributing the death of someone in battle is easy, to radiation exposure not so much.

The million worker study would be an excellent study to reign in this type of reporting. For example, the first and usually simplest analysis to do is to look at all-cause mortality in the cohort and compare the death rate to the general public for what-ever disease you are interested in. This will give some indication if the cohort is dying at higher, lower, or same rate. Also establishing the dose-response for these cohorts would be extremely helpful in explaining the risk and possibly establishing new risk estimates. Any new risk

estimates could be used by these compensation boards when they are judging the probability of causation for a certain claimant cancer.

As far as leverage with DOE, I think you might have something here and I think it is a good idea to let them know about the article. NRC may be running in to this someday too. The U.S. really needs to get a comprehensive handle on the actual risks to workers experienced at the dose rates we regulate to. These compensation programs can get quite spendy and it seems to be a reasonable investment to finish the study. The MWS cohorts already include these workers from the article and completing the epidemiology would shed a lot of light on worker risks and addressing these types of future claims.

Let me know if you need anything more, I'm out of the office today but will be back in on Tuesday

Terry

From: Weber, Michael
Sent: Friday, December 11, 2015 8:15 PM
To: Brock, Terry
Cc: Case, Michael; Coffin, Stephanie; Burnell, Scott; Weil, Jenny; Foster, Jack
Subject: Query - McClatchy News Series on Nuclear Workers

Good evening, Terry. Hope all is well with you and that you are enjoying your weekend. I heard on the Newshour program tonight an interview with a correspondent from McClatchy News regarding workers from the nuclear complex who were harmed as they built nuclear weapons. Sounds like the journalists mined the data from the USG compensation programs for radiation and beryllium exposure. Were you aware of this journalistic research? Any connection to the Million Worker Study? Any way to leverage DOE to move forward?

Please advise.

From:	Weber, Michael
Sent:	20 Nov 2015 08:49:46 -0500
To:	Brock, Terry
Cc:	Coffin, Stephanie;Tadesse, Rebecca
Subject:	RESPONSE - SPECIFICS FOR MILLION WORKER STUDY

Thanks, Terry

From: Brock, Terry
Sent: Wednesday, November 18, 2015 12:15 PM
To: West, Steven ; Weber, Michael
Cc: Case, Michael ; Coffin, Stephanie ; Tadesse, Rebecca
Subject: RESPONSE: RE: QUERY - SPECIFICS FOR MILLION WORKER STUDY

Yes, DOE can terminate, but they never notified us, EPA, or NASAâ€"see below. We all heard it second hand from our colleagues at various meetings. No one was pleased, that was the reason we set-up the call with DOE-SC with all the parties involved. Thereâ€™s unanimity among the three agencies for DOE to keep this going. Also, the DODâ€™s Defense Threat Reduction Agency wants to join the mix, but as I mentioned in my earlier e-mail, DOE-SC shot them down.

> TERMINATING THE AGREEMENT: This agreement may be unilaterally terminated by either party generally upon 30 days' written notice to the other party. NRC will pay its share of any project expenses up to the termination date. Any expenses incurred in terminating this agreement will be paid by the party terminating the agreement. Any unexpended funds shall be returned to the NRC

Terry

From: West, Steven
Sent: Wednesday, November 18, 2015 11:53 AM
To: Brock, Terry <Terry.Brock@nrc.gov>; Weber, Michael <Michael.Weber@nrc.gov>
Cc: Case, Michael <Michael.Case@nrc.gov>; Coffin, Stephanie <Stephanie.Coffin@nrc.gov>; Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>
Subject: RE: RESPONSE: RE: QUERY - SPECIFICS FOR MILLION WORKER STUDY

Terry,

Does the interagency agreement allow DOE to unilaterally terminate the study? Did DOE inform us of the termination? (It seems that we just â€œfound outâ€ by happenstance that it had been cancelled.)

If you have any solid insights on the other participating agencyâ€™s views about the termination and the possibility of restarting the study, they may be helpful.

Steve

Steven West, Deputy Director
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
301-415-1914
Steven.West@nrc.gov

From: Brock, Terry
Sent: Wednesday, November 18, 2015 11:31 AM
To: Weber, Michael <Michael.Weber@nrc.gov>
Cc: West, Steven <Steven.West@nrc.gov>; Case, Michael <Michael.Case@nrc.gov>; Coffin, Stephanie <Stephanie.Coffin@nrc.gov>; Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>
Subject: RESPONSE: RE: QUERY - SPECIFICS FOR MILLION WORKER STUDY

Mike,

Here are some facts about the million worker study to support your forthcoming call with John Kelly of DOE-NE.
Let me know if you need anything else.
Terry

- The official title of the study has morphed a bit. The latest from John Boice, NCRP is calling it the â€œEpidemiologic Study of One Million U.S. Radiation Workers and Veteransâ€ .
- The DOEâ€™s Office of Science (SC) in early 2012 approved a grant to NCRP for 5-years at, $21,733,858 million dollar through the now defunct Low Dose Radiation Research Program. SC pulled the funds soon after we joined the effort in June, 2012 and reprogrammed the funds to other research areas related to climate change and biofuels.
- The NRC Interagency Agreement Number with DOE-SC is NRC-HQ-60-12-I-0006. The period of performance is 06/1/2012 to 07/31/2017.
- NRCâ€™s contribution of $2M has resulted in the formation of the nuclear power and industrial radiographer cohorts (N=147,600 and 128,364, respectively) with cause of death ascertainment completed. Funds are needed to perform the leukemia and solid cancer risk assessments for both cohorts.
    - Other cohorts to be studied are medical, Manhattan Project, and atomic veterans
- The other cooperating agencies with DOE-SC agreements are the U.S. EPA and NASA. Iâ€™ve personally spoken to the DODâ€™s Defense Threat Reduction Agency (DTRA) and they want to join DOE, but were waived off by SC because they said no new contributions are being accepted.
    - The EPA contact is Mike Boyd--phone: 202-343-9395 or e-mail: boyd.mike@epa.gov.
    - The NASA contact is Lisa Simonsenâ€"phone: 757-864-4432 or e-mail: lisa.c.simonsen@nasa.gov
    - The DTRA contact is Paul Blakeâ€"phone: 703-767-3433 or e-mail paul.k.blake.civ@mail.mil
- Adam Demella, majority senate appropriations staffer, spoke to NRC staff about their interest in the study and the status. Adam was supportive of NRC asking DOE-NE to take over the study.
- DOE-SC has no issue with DOE-NE taking over the study.

From: Weber, Michael
Sent: Wednesday, November 18, 2015 7:25 AM
To: Brock, Terry <Terry.Brock@nrc.gov>
Cc: Tadesse, Rebecca <Rebecca.Tadesse@nrc.gov>; Coffin, Stephanie <Stephanie.Coffin@nrc.gov>; Cruz, Holly <Holly.Cruz@nrc.gov>; West, Steven <Steven.West@nrc.gov>
Subject: QUERY - SPECIFICS FOR MILLION WORKER STUDY

Good morning, Terry. In preparation for my call with John Kelly, can you provide me with the specifics for the Million Worker Study, so I can share with John? Iâ€™d like to give him sufficient information to avoid making extra work for him. The information I need is facts like â€" official title of project? grant with NCRP? When started? Interagency agreement number? Current period of performance? Other cooperating agencies and points of contact? Etc.
Thanks,

Mike

Michael Weber
Director of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission

301-415-1902
Mail Stop T-10B16

ARM

DELIVERING OUR FUTURE

From: Brock, Terry
Sent: 23 Sep 2016 12:27:39 +0000
To: Weber, Michael;Case, Michael;Tadesse, Rebecca
Subject: Scientist claims 'unrelenting intimidation' from Energy management - FederalNewsRadio.com

All,

Here's some reporting from the DOE testimony on the Low Dose Program. Dr. Noelle Metting was my counterpart/POC for the Million Worker Study.

Terry

http://federalnewsradio.com/agency-oversight/2016/09/scientist-claims-unrelenting-intimidation-energy-management/