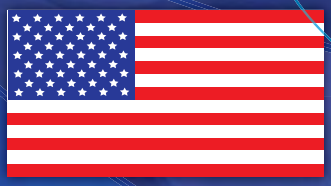
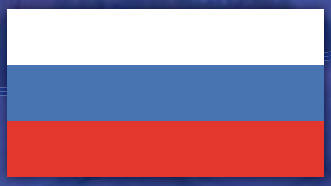
Joint Coordinating Committee for Radiation Effects Research



2009



7TH International U.S. - Russian Meeting

September 16 - 17, 2009
Washington D.C.

Participant Booklet

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WELCOME

GLENN S. PODONSKY
CHIEF HEALTH SAFETY AND SECURITY OFFICER
OFFICE OF HEALTH, SAFETY AND SECURITY
U.S. DEPARTMENT OF ENERGY

As the United States Co-Chair of the Joint Coordinating Committee for Radiation Effects Research (JCCRER), I am pleased to host the upcoming 7th International Meeting of the U.S.-Russian JCCRER planned for September 16 - 17, 2009, in Washington, DC.

The JCCRER was established through a bilateral U.S.-Russian agreement originally signed on January 14, 1994, to coordinate scientific research on the health effects of exposure to ionizing radiation in the Russian Federation from the production of nuclear weapons. The goal of the program is to assess worker and public health risks from radiation exposure, these data being essential to validate current radiation protection standards and practices. JCCRER research funded by the U.S. Department of Energy is called the Russian Health Studies Program.

Through the JCCRER's efforts, the program has a rich history of accomplishments making significant contributions to science and improving our understanding of the adverse health effects of radiation. We have reached a major milestone of 15 years of collaborative U.S. and Russian efforts that resulted in over 200 peer-reviewed publications in U.S., Russian, and international scientific journals. Please join us in celebrating our collective success.

The planned meeting is designed to promote and advance the goals of the JCCRER by facilitating technical exchange of scientific information and results, highlighting program successes and accomplishments, defining common goals and milestones for the coming year, and planning for the future.

In addition to the scientific sessions, we have also planned an optional cultural day-tour of Washington, DC, on Tuesday, September 15, 2009.

Please visit: http://www.hss.energy.gov/healthsafety/jccrer/jccrer_2009/index.htm to find more information about the meeting agenda, accommodations, cultural day-tour, and other items of interest.

We look forward to an enjoyable and productive meeting, and we welcome each one of you to the JCCRER meeting.

Spaseeba balshoye,

Glenn S. Podonsky

Chief Health, Safety and Security Officer
U.S. Department of Energy

PURPOSE OF THE JCCRER

WHAT IS THE JCCRER?

JCCRER is the Joint Coordinating Committee for Radiation Effects Research. This is a bilateral Government committee representing agencies from the United States and the Russian Federation tasked with coordinating scientific research on the health effects of exposure to ionizing radiation in the Russian Federation from the production of nuclear weapons.

WHY IS THE JCCRER IMPORTANT?

Jointly conducting radiation research with the Russian Federation provides a unique opportunity to learn more about possible risks to groups of people from long-term exposure to radiation. This could include people receiving exposure from uranium mining, operation of nuclear facilities, transport and disposal of radioactive materials, testing and dismantling nuclear weapons, radiation accidents, and grossly contaminated sites or facilities.

In 1948, the Soviet Union established a nuclear weapons production complex called the Mayak Production Association (Mayak) in the Southern Urals about 100 km (60 miles) northeast of the city of Chelyabinsk. Enormous amounts of radioactive materials were released into the environment after a series of accidents and poor management practices at the Mayak complex between 1948 and 1967. As a result, thousands of square kilometers have been contaminated and hundreds of thousands of people have received significant radiation exposures. Furthermore, because of limited and inadequate (by today's standards) radiation protection measures and procedures, thousands of Mayak workers were seriously overexposed to radiation.

Most of our knowledge of health effects and risks associated with radiation exposures is based on studies of atomic bomb survivors in Japan. The atomic bomb survivors, however, were exposed to a very short burst of external radiation, unlike the pattern of exposure normally encountered or expected in the nuclear industry and in other uses of radiation. The people in the Southern Urals, on the other hand, experienced chronic exposures over a much longer period. The exposures were also from both external radiation and internally deposited radioactive compounds. Definitive studies on the Southern Urals populations, coupled with comparisons with U.S. nuclear worker data,
.

may prove to be a key factor in future reassessments of radiation protection standards and regulations in the United States and worldwide. Thus, the preservation, restoration, and analysis of radiation exposure medical and environmental data in the Southern Urals are extremely important to the United States and to the world. The Southern Urals' database may provide an opportunity to answer the question of whether chronic low-level exposures pose a risk different from previously assumed.

Given these opportunities to advance our knowledge about the effects of ionizing radiation on humans and on the environment, on January 14, 1994, the Governments of the United States and the Russian Federation signed an Agreement on Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment. In diplomatic terms, a bilateral agreement is one of the highest levels of government-to-government agreements. The Agreement was renewed in 2000 and 2007, and is in the process of being renewed through January 14, 2014.

JCCRER projects funded by the Department of Energy are called the Russian Health Studies Program. It is administered by the Department of Energy's Office of International Health Studies in the United States and by the Federal Medical Biological Agency (FMBA) for radiation health effects research and by the Ministry for International Civil Defense Affairs, Emergencies, and the Elimination of Consequences of Natural Disasters (EMERCOM) for radiation accidents in Russia.

Abstract

The Importance of the Scientific Review Group (SRG) to the JCCRER Studies

David Rush, MD
Professor of Nutrition, Community Health, and Pediatrics (emeritus), Tufts University SRG member, 1994-

We will discuss the origins of peer review, who the US reviewers have been, and the importance of objective, technically proficient oversight by a group with no direct involvement in the research, nor from an institution receiving any contract funding. This review was created to optimize the scientific quality and relevance of the JCCRER research, and its credibility to scientists, other governments, and the public.

Joint Coordinating Committee for Radiation Effects Research

(JCCRER)

7TH International U.S. - Russian Meeting

2009

September 16 - 17, 2009
Washington D.C.

My personal history with JCCRER Projects

- **Late 1980's: asked by a US NGO to review all health research relating to radiation exposure among DOE workers**
- **Published ~ January, 1991. Chelyabinsk no longer closed city**
- **May 1991- Chelyabinsk symposium on health & environmental impact of Mayak Production Association; I describe US experience**
- **~1992 Gore Chernomyrdin agreement ► ~1993 JCCRER**
- **Attend Both St Petersburg conferences (US 1993& Russia 1994)**
- **Appointed SRG epidemiologist with Geoff Howe & Jon Samet**

History of Peer Review- 1

- **It is the duty of a visiting physician to make duplicate notes of the condition of the patient on each visit. When the patient has been cured or has died, the notes of the physician are to be examined by a local council of physicians, who adjudicate as to whether the physician has performed to adequate standards. On the basis of their rulings, the practicing physician can be sued for damages by a maltreated patient.**

- ***Ethics of the Physician* by Ishap bin Ali Al Rahwi (854–931) of Al Raha, Syria,**
- Modified from Spier, R. The history of the peer-review process, Trends in Biotechnology, 20, 357-358, 2002

History of Peer Review- 2

- **1645, London: group formed concerning the 'New Philosophy' of Francis Bacon.**
- **1662 Royal Charter of Incorporation: became the Royal Society of London for Improving Natural Knowledge.**
- **1665 Royal Society began a journal, *Philosophical Transactions,* whose editor was solely responsible for decisions**
- **1752 Society assumed editorial responsibility. Adopted a review procedure: articles submitted for publication were subjected to inspection by a group of knowledgeable members, whose recommendation to the editor was influential.**

- ***This is usually regarded as the beginning of the modern peer-review process*.**

Why Peer Review?

To maximize scientific

1) **Currency & relevancy**
2) **Technical Standards**
3) **Appropriateness of approach**
4) **Objectivity**
5) **Credibility**

(4&5 <u>especially</u> important if sponsors or executors of research potentially liable to or suspected of bias)

JOINT COORDINATING COMMITTEE FOR RADIATION EFFECTS RESEARCH
2009
7TH INTERNATIONAL U.S. - RUSSIAN MEETING
WASHINGTON D.C.

Current and Past ( ) members of US Scientific Review Group

Dosimetry

- **Nolan E. Hertel; chair of SRG;** Prof. Georgia Tech; Vice President, Council on Ionizing Radiation Measurements and Standards
- **Harold Beck,** former Director, Environmental Science Division, US DOE
- **(John E. Till)** President, Risk Assessment Corporation
- **(Marvin Goldman)** Prof. emeritus, UC Davis; former Pres, Health Physics Society
- **(Michael Ryan; ex-chair of SRG);** Editor, Health Physics; Reactor Safeguards Advisory Committee , Nuclear Regulatory Commission
- **(John Poston)** Professor & former Chair, Nuclear Engineering, Texas A&M University

Epidemiology

- **Scott Davis,** Professor & Chair, Epidemiology, U. Washington; Member, BEIR VII
- **David Rush,** Prof emeritus, Tufts Univ; former President, Soc. for Epidemiologic Research
- **(Jonathan Samet; ex-chair of SRG)** Director, Institute Global Health, USC; chair, BEIR VI
- **(Geoffrey Howe)** (deceased) former chair Epidemiology, Columbia Univ; member, NCRP

Radiation Biology

- **TBD**
- **(H. Rodney Withers)** Prof emeritus, radiation oncology UCLA; Enrico Fermi Award
- **(Peter G. Shields)** Professor, Medicine & Oncology, Georgetown University
- **(William F. Morgan)** Director, Radiation Biology & Biophysics, PNNL, US EPA

Who May Not Serve on US SRG

- Scientists who are not US citizens or permanent residents
- US Government employees
- Anyone employed by a contractor receiving JCCRER funds

Peer Review by JCCRER US Scientific Review Group

Evaluate all new Research Proposals

2x/y: Review Progress Reports

2x/y: Evaluate PI Responses to last review

Advice and Support to DOE Program Managers

SRG comments go to PIs, DOE managers, Russian JCCRER , Russian Institute Directors, U.S. JCCRER Executive Committee, NCI, EC

SRG Evaluation of Research Proposals

- **Done before onset of every research project**
- **Judged on:**
  - **Importance to JCCRER goals**
  - **Unique relevance of Mayak/ Techa River cohorts**
  - **Appropriate objectives**
  - **Manageable and realistic scope**
  - **Quality of Work Plan**
  - **Available human and other resources**

Biannual Comment on Progress Reports from PIs

- Pace of progress
- Validity of assumptions
- Reasonableness of observations
- Concerns and issues
- Application to other research
- Suggestions for modification of &/or additions to work
- Publication potential
- Costs within budget

Evaluate PI Responses to last review

- **Reasonableness**
- **Responsiveness to SRG concerns**
- **Follow up comments**

Program Management Advice and Support

- Data integration
- Interfaces among PIs
- Research Priorities
- Concerns and issues

Federal Medical Biological Agency of Russia

Scientific Review Group Role in JCCRER Research

Nataliya Shandala

Federal Medical Biophysical Centre, Moscow

7th International U.S.-Russian JCCRER Meeting, Washington D.C., 16-17 September 2009

Content

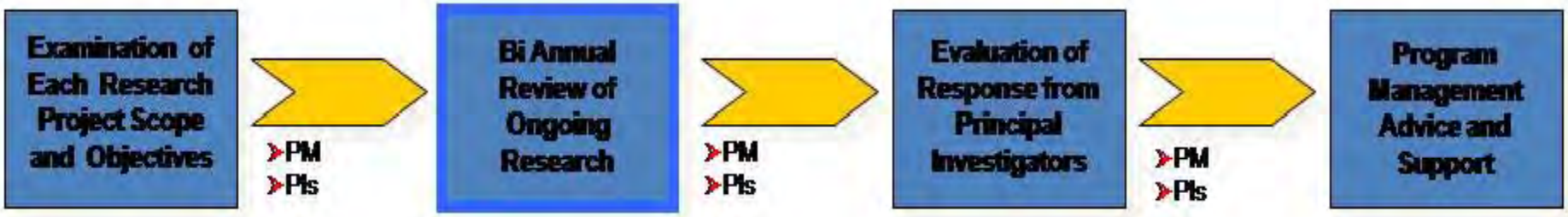
1. Coordination of technical SRG work
2. Scientific review of target provisions of the Agreement
3. Contribution into practical regulation
4. Long-term outlooks

Issue 1

Coordination of technical SRG work

- Arrangement of scientific seminars
- Proposals of new research topics taking into account long-term outlooks
- Popularization of the researches over the wide auditory of other description scientists

Bilateral coordination



- Onset of research project
- Comments and observations:
  - Relevancy
  - Scope
  - Objectives
  - Plan
  - Resources
  - Skill mix
  - Data needs
- Coordination and interface with other ongoing tasks

- Pace of progress
- Validity of assumptions
- Reasonableness of observations
- Concerns and issues
- Application to other research
- Publication potential

- Reasonableness
- Follow up comments

- Data integration
- Interfaces among PIs
- Research Priorities
- Concerns and issues

with other projects accepted

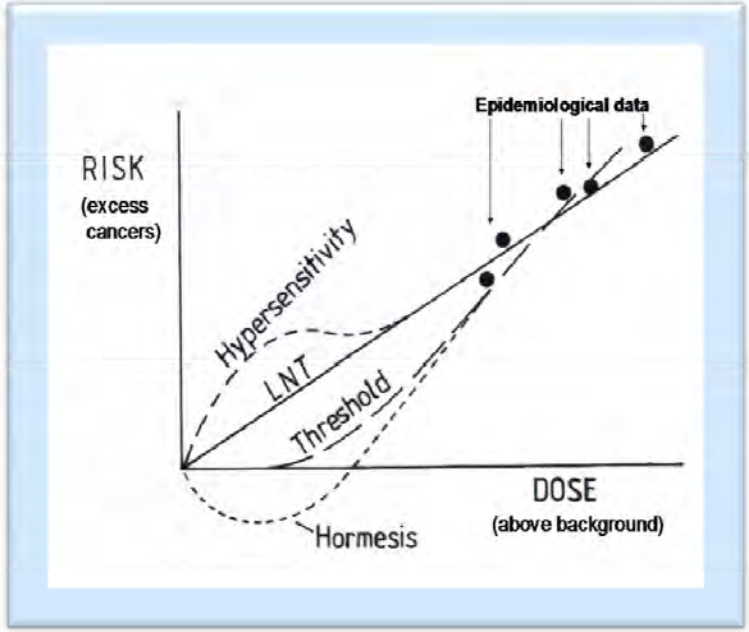
workshop with participation of performers and reviewers to discuss findings and perhaps to hold topical symposiums

Issue 2

Target Provisions in the Field of Radiation Protection and Public Health

Principal task of research is

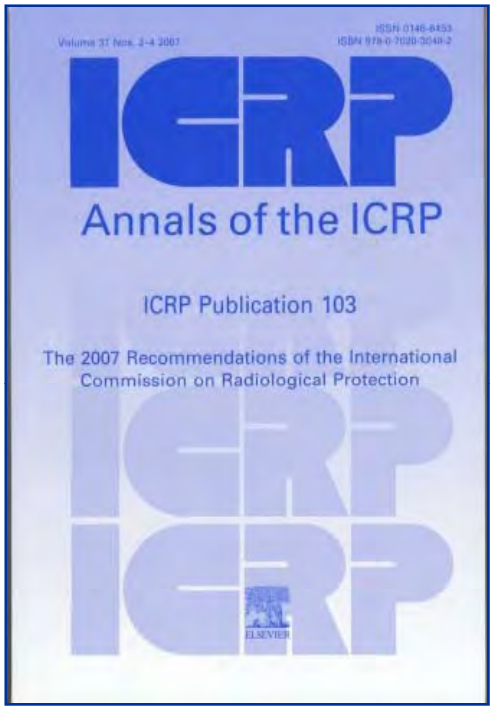
- **to obtain the most correct radiation risk assessments**



Bases for ICRP cancer risk estimates

- Largely based on new cancer incidence data for the **Japanese A- bomb survivors**
  - not available at the time of ICRP Publication 60; mortality data used there
  - more accurate diagnoses in incidence data
- A-bomb data cover population of all ages and both genders, with a wide range of doses & long follow-up

Nominal Risk Coefficients (10^{-2}/Sv)

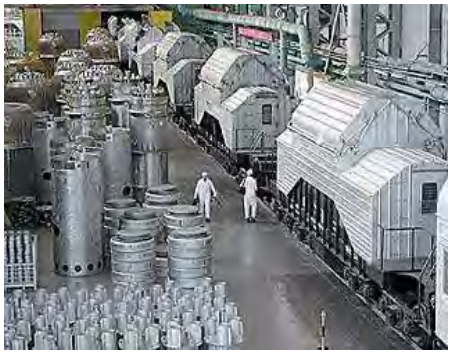


Exposed population	Cancer	Heritable effects	Total 2007	Total ICRP 60
Whole population	5.5/6.0	0.2/1.3	5.7	7.3
Adult workers	4.1/4.8	0.1/0.8	4.2	5.6

The more important issues

- The shape of dose-response for cancer
- Tissue sensitivities for cancer induction
- Individual variability in cancer risk
- Risks from internal radiation exposure
- Dose response relationships for non-cancer diseases

How robust is the system of radiation protection?



To give international status to the Russian cohorts

Issue 3

Interpretation of the research findings from the point of view of their contribution into regulation

- **Regulatory and scientific outlooks**

Main goals for today

Need for development of national system of control and support of radiation protection:

- **Management of nuclear legacy**
- **Regulation of environmental remediation**
- **Development of nuclear power generation complex**

Issue 4

Long-term outlooks

- **Environmental impact ?**
- **New cohorts ?**

Recommendations

- to approve the progress in ongoing projects
- to continue practice of the scientific report reviews
- to plan future meetings
- to develop role of SRG

Abstract

Current and Planned Activities of the National Council on Radiation Protection and Measurements

David A. Schauer, Executive Director

The National Council on Radiation Protection and Measurements (NCRP) was chartered by the U. S. Congress in 1964 to formulate and widely disseminate information, guidance and recommendations on radiation protection and measurements which represent the consensus of leading scientific experts. The Council monitors areas in which the development and publication of NCRP materials can make important contributions to the government and public.

The Council's mission also encompasses the responsibility to facilitate and stimulate cooperation among organizations with interest in the scientific and related aspects of radiation protection and measurements. This presentation will provide an overview of NCRP's organizational and operational structures, recent publications and current scientific committees with potential interest to the Joint Coordinating Committee for Radiation Effects Research. Topics related to radiation exposures, dosimetry, biological interactions, and health effects will be emphasized.

NCRP's strategic program plan for the period 2008 to 2010 is available online at http://www.ncrponline.org/PDFs/NCRP_2008-10_Strat_Plan-3-19.pdf.

Current and Planned Activities of the National Council on Radiation Protection and Measurements

David A. Schauer
Executive Director

Joint Coordinating Committee for Radiation Effects Research

7th International U.S. – Russian Meeting

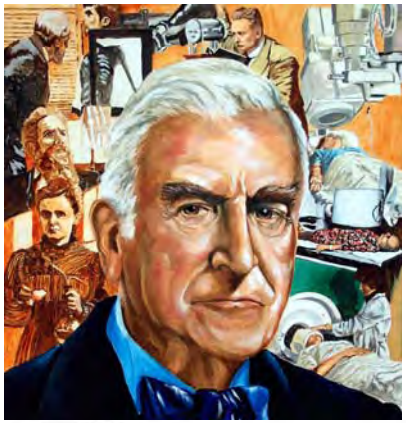
Washington, DC
September 16 - 17, 2009

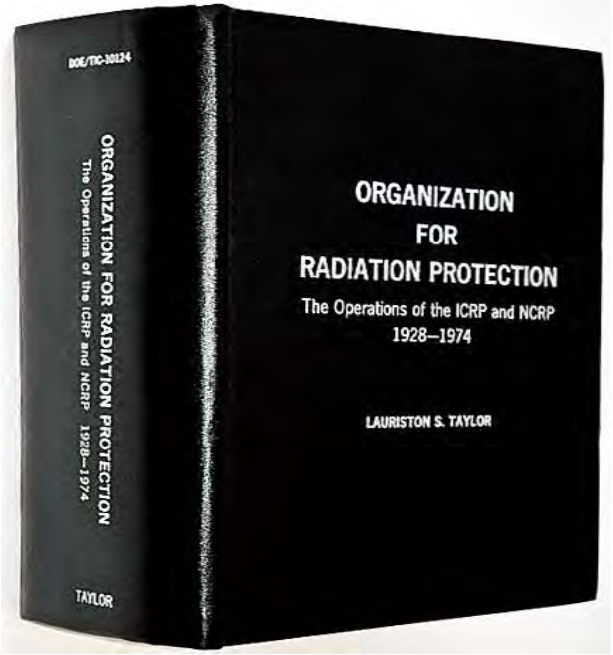
Key Dates in NCRP's History

<u>1929</u>: U.S. Advisory Committee on X-ray and Radium Protection

<u>1946</u>: U.S. National Committee on Radiation Protection

<u>1964</u>: National Council on Radiation Protection and Measurements (NCRP) chartered by U.S. Congress (Public Law 88-376)





Key Elements of NCRP's Charter Under U.S. Public Law 88-376

- **Cornerstones of role in radiation health protection:**
  1) *Collect and analyze* information and recommendations in the public interest about:
     a) protection against radiation; and
     b) radiation measurements, quantities and units.
  2) *Develop* basic concepts of radiation protection;
  3) *Facilitate* effective use of combined resources of organizations concerned with radiation protection; and
  4) *Cooperate* with national and international governmental and private organizations; and
  5) *Disseminate* the Council's work.

Organizational & Operational Structures

Board of Directors

(13 members including NCRP's President)

•**Approve** topics to be addressed and committee membership

Council

(100 members elected for 6 year terms)

•**Review** reports, commentaries and statements

Program Area Committees

(~12 members serving annual renewable terms)

•**Identify** topics to be addressed and possible funding sources
•**Suggest** committee members
•**Perform** peer reviews of draft reports prior to Council review

Scientific Committees

(various sizes and compositions)

•**Draft** reports, commentaries and statements

Program Area Committees

- **PAC1** - Basic criteria, epidemiology, radiobiology and risk (WF Morgan)
- **PAC2** - Operational radiation safety (DS Myers)
- **PAC3** - Nuclear and radiological safety and security (JW Poston)
- **PAC4** - Radiation protection in medicine (JL Bushberg)
- **PAC5** – Environmental radiation and radioactive waste issues (SY Chen)
- **PAC6** - Radiation measurements and dosimetry (RA Guilmette)

Current NCRP Scientific Committees Working on Radiation Effects and Risk Assessment

- **<u>Report of Scientific Committee 1-13</u>** (to be published in 2009): *Impact of Individual Susceptibility and Previous Radiation Exposure on Radiation Risk for Astronauts*
- **<u>Report of Scientific Committee 1-16</u>** (to be published in 2011): *Uncertainties in the Estimation of Radiation Risks and Probability of Disease Causation*
- **<u>Report of Scientific Committee 1-20</u>** (to be published in 2012): *Variation in Biological Effectiveness of Photons as a Function of Energy*

Proceedings of 2008 Annual Meeting in *Health Physics*, Vol. 97(5), 2009

Analysis of Biological and Human Health Impacts of Low-Dose Radiation Exposures

Forty-Fourth
Annual Meeting Program

Low Dose and Low Dose-Rate Radiation Effects and Models

April 14–15, 2008

Bethesda North Marriott Hotel
& Conference Center
5701 Marinelli Road
North Bethesda, MD 20852

NCRP
National Council on Radiation Protection & Measurements

Major Planned NCRP Activity

- Major report is planned on *Low Dose and Low Dose Rate Biological Effects and Implications for Human Health*
  - will incorporate results of extensive research on low-dose biological interactions sponsored by U.S. Department of Energy and other organizations worldwide
  - will provide an extension of recently published analyses of low-dose radiation effects in ICRP Publication 99 (2004), the French Academy of Sciences report (2005), and the U.S. National Academy of Sciences BEIR VII report (2006)

NCRP's Strategic Initiative on Biological and Human Health Effects of Low-Dose Radiation

- *Primary Goal:* Prepare definitive publication during 2011 to 2016 on biological effects and potential human health implications of exposure to low dose and low dose rate radiation
- Report will contain:
  - up-to-date reviews of *laboratory and human epidemiology studies*
  - effects of *radiation quality* and *dose rate*
  - integration of results into *reliable, predictive models of human health effects* at low doses
  - *health protection* and *regulatory implications* of findings, and *effective communication* of projected risks of low dose radiation exposure

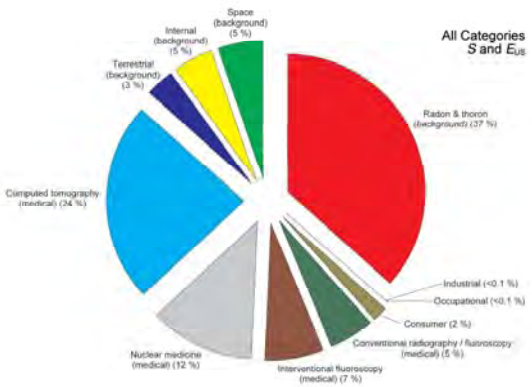
NCRP

NCRP REPORT No. 160

IONIZING RADIATION EXPOSURE OF THE POPULATION OF THE UNITED STATES

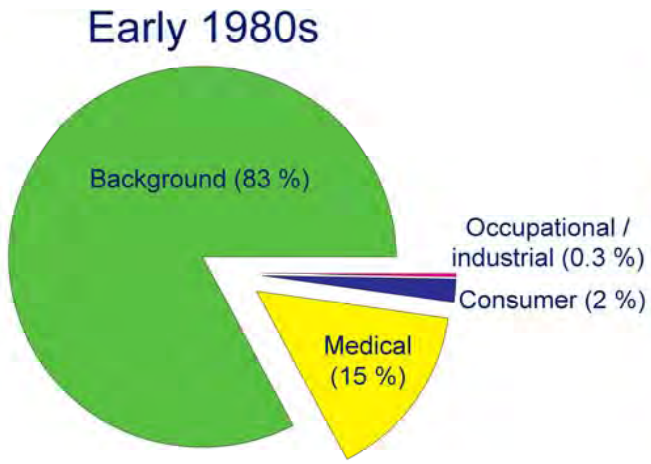
PREPUBLICATION COPY

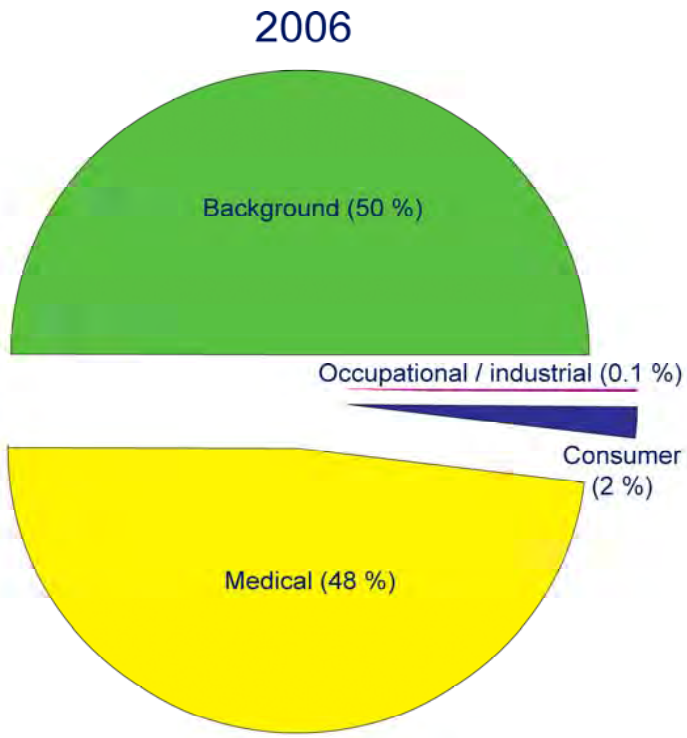
(This Report is undergoing final editing. Revisions due to style, format, or inadvertent errors may occur.)



NCRP 1929 2009

NCRP Report No. 160, *Ionizing Radiation Exposure of the Population of the United States*





	Early 1980s	2006
Collective effective dose (person-Sv)	835,000	1,870,000
Effective dose per individual in the U.S. population (mSv)	3.6	6.2

Radiation Exposure to US Population - Medical Exposures

	Number of Procedures (millions)	%	Collective Effective Dose (person Sv)	%	$\underline{E}_{US}$ (mSv)
Computed Tomography	**67**	**17**	**438,000**	**49**	**1.5**
Nuclear Medicine	**18**	**5**	**231,000**	**26**	**0.8**
Interventional	**17**	**4**	**128,000**	**14**	**0.4**
Conventional Radiography & Fluoroscopy	**292**	**74**	**99,000**	**11**	**0.3**
TOTALS	426	100	898,000	100	~3

(600 % increase)

Collaborative Efforts Related to Radiation Protection in Medicine

- "American College of Radiology White Paper on Radiation Dose in Medicine", *JACR* 4:272.284; (2007)
- Image Gently and Step Lightly Campaigns
- WHO Global Initiative on Radiation Safety in Health Care Settings
  - Role of ***justification*** in medical imaging
- American Board of Radiology Foundation: Summit 2009, "Medical Imaging: Addressing Overutilization in the Era of Healthcare Reform"
  - Justification, optimization and implementation
  - August 6-7, 2009
- Computed Tomography in Emergency Medicine: Ensuring Appropriate Use
  - Co-sponsored by AAPM, ACEP, ACR, ASER, SAEM, CDC and Landauer, Inc.
  - September 23-24, 2009

Recent Publications and Current Scientific Committees Working on Issues Related to Radiation Dosimetry and Measurements

- **Report No. 156**: *Development of a Biokinetic Model for Radionuclide-Contaminated Wounds and Procedures for Their Assessment, Dosimetry and Treatment* (2006)
- **Report No. 158**: *Uncertainties in the Measurement and Dosimetry of External Radiation* (2007)
- **Report of Scientific Committee 6-3** (to be published in 2010): *Uncertainties in Internal Radiation Dosimetry*
- **Report of Scientific Committee 6-4** (to be published in 2010): *Principles and Practices of Radiation Dose Reconstruction*

NCRP Publications – "Disseminate"

- NCRP reports and current activities are described online at http://NCRPonline.org
- Publications can be purchased online at http://NCRPpublications.org
- Institutional license agreements are now available through:
  - **Knovel** (http://www.Knovel.com)
  - **NetLibrary** (http://www.NetLibrary.com)
  - **ebrary** (http://www.ebrary.com)

2010 Annual Meeting

- *Communication of Radiation Benefits and Risks in Decision Making* (Chairman, Dr. Locke, Johns Hopkins)
  - Will build on topics discussed at previous NCRP annual meetings, *e.g.*,
    - Exposures from medical imaging and nuclear power
  - March 8-9, 2010 at the Bethesda Hyatt

Abstract

JCCRER Project 1.1 - Further Study of Uncertainty, Confounding, and Validation of the Doses in the Techa River Dosimetry System

Marina O. Degteva,
Urals Research Center for Radiation Medicine
Lynn R. Anspaugh,
University of Utah
Bruce A. Napier,
Pacific Northwest National Laboratory

JCCRER Project 1.1 on "Further Study of Uncertainty, Confounding, and Validation of the Doses in the Techa River Dosimetry System" deals specifically with dosimetry for the approximately 30,000 members of the Extended Techa River Cohort (ETRC), exposed to radioactive releases from the Mayak Production Association. This cohort has many desirable features for continuing study in an effort to determine if a dose-rate-effectiveness reduction factor might exist for persons exposed to high doses at low-to-moderate dose rates.

During the first phase of Project 1.1, an updated methodology for the calculation of individualized doses was implemented within the Techa River Dosimetry System (TRDS-2000). Many improvements had been accomplished in the derivation and implementation of TRDS-2000; these improvements included calculation of internal doses from short-lived radionuclides for the first time; re-evaluation of external doses on the basis of more complete examination of the existing data and on more realistic assumptions; and evaluation of the uncertainty in both internal and external doses for the first time. The results of the uncertainty analysis have been particularly useful in that a picture emerged of what meaningful steps might be accomplished in order to achieve major reductions in uncertainty in the doses calculated for individual members of the ETRC. The second phase of the project dealt mainly with reducing uncertainty in the final dose estimates; validation of the revised estimates of external dose; and evaluation of other sources of dose that could confound the analysis of the epidemiologic data. The current phase of Project 1.1 has created a new improved version of the TRDS code, which integrates all achievements of the second phase, plus recent efforts to better define the nature and amounts of the radionuclides released from Mayak into the Techa River. The new TRDS-2009 is being used to calculate more precisely individual-organ doses for members of ETRC and other

investigated cohorts.

The deterministic version of TRDS, TRDS-2009D, is now operational. The TRDS is designed as a flexible system that uses, depending on the input data for an individual, various elements of system databases to provide the dosimetric variables requested by the user. Doses are estimated in several steps. The first step includes calculations with use of a common protocol for all cohort members based on village-average intake functions and external dose rates accounted for individual data on age, gender and history of residence. This step results in dose estimates similar to those obtained with TRDS-2000, which have been used previously to derive risks of health effects in the Techa River Cohort. The second step includes refinement of individual doses for those persons who have body-burden measurements or exposure parameters specific to the household where he/she lived on the Techa River. The third step includes summation of individual doses from environmental exposure and from radiological examinations.

Initial results obtained with TRDS-2009D show a moderate increase in individual doses - about 5% for stomach and 34% for bone marrow. This is largely due to improvements in the source term that allow consideration of more short-lived radionuclides, additional pathways of exposure such as ^{137}Cs in cow's milk, and consideration of confounders such as medical x-rays.

The project will also provide estimates of uncertainty for all doses calculated in a form that can be used by biostatisticians to estimate better the uncertainty in calculated radiation risks. This latter activity has been coordinated with the epidemiologists and biostatisticians involved in companion projects. The fourth step, now under development, will include uncertainty analysis with use of Monte Carlo simulations of the basic dose equation in a separate computer code – TRDS-2009MC. The results of current and future individual dose calculations will be used to refine the analyses of radiogenic health effects in the Techa River cohorts.

Project 1.1, under the name "Enhancements in the Techa River Dosimetry System," will continue with the following six major aims:

1. Further improvements of the TRDS to refine the dose estimates in light of the recent discoveries related to the Mayak releases in 1950–1951, through use of a dynamic model of radionuclide transport in the Techa River;
2. Further improvements to the TRDS to incorporate recently discovered information related to household locations of cohort members in villages on the upper-Techa;
3. Validation of the external dose estimates related to radionuclides released in the initial years of Mayak operation;
4. Consideration of another source of dose, the release of noble gases and radioiodines into the atmosphere from Mayak production facilities, which could confound the analysis of epidemiologic data for the members of the ETRC;
5. Addition of calculation capability for villages in the region of the East Urals Radioactive Trace (EURT) that were evacuated after the 1957 accident; and
6. Completion of the stochastic TRDS-2009MC (Monte Carlo) version of the dose-calculation package.

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RADIATION EFFECTS RESEARCH

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7TH INTERNATIONAL U.S. - RUSSIAN MEETING

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Project 1.1:
Techa River Population Dosimetry

M.O. Degteva, Urals Research Center for Radiation Medicine
L.R. Anspaugh, University of Utah
B.A. Napier, Pacific Northwest National Laboratory

Central Issues in Radioprotection are Being Investigated

- Are doses delivered at low dose rates as effective in producing health effects as the same doses delivered at high dose rates?
- Can doses derived from study of one ethnic group be used to predict consequences in other ethnic groups?
  - Absolute risk?
  - Relative risk?
  - To the studies of the Japanese survivors, we add studies of Russian and Bashkir/Tartar populations

The Purpose of Project 1.1 is to Estimate Radiation Dose to:

- Extended Techa River Cohort (ETRC) – ~30,000 persons born before the start of contamination.
- Techa River Offspring Cohort (TROC) – ~21,000 persons born after the start of contamination
  - The Europeans are taking the lead in the evaluation of the TROC, but with dependence upon the results of Project 1.1 for dosimetry
- The doses estimated in Project 1.1 are used in epidemiology projects, including JCCRER 1.2b and a related NCI project

Methodology of Retrospective Dose Assessment Used in the TRDS

- The dose reconstruction process used in the TRDS is based extensively on a large number of measurements of radionuclide burden in humans and on the measurements of external exposure performed directly in the places where people lived.
- The traditional way of analyzing all steps of the pathway of exposure is only used as a backup when other approaches have been exhausted.
- This approach is rather unique in the worldwide practice of environmental dose reconstruction

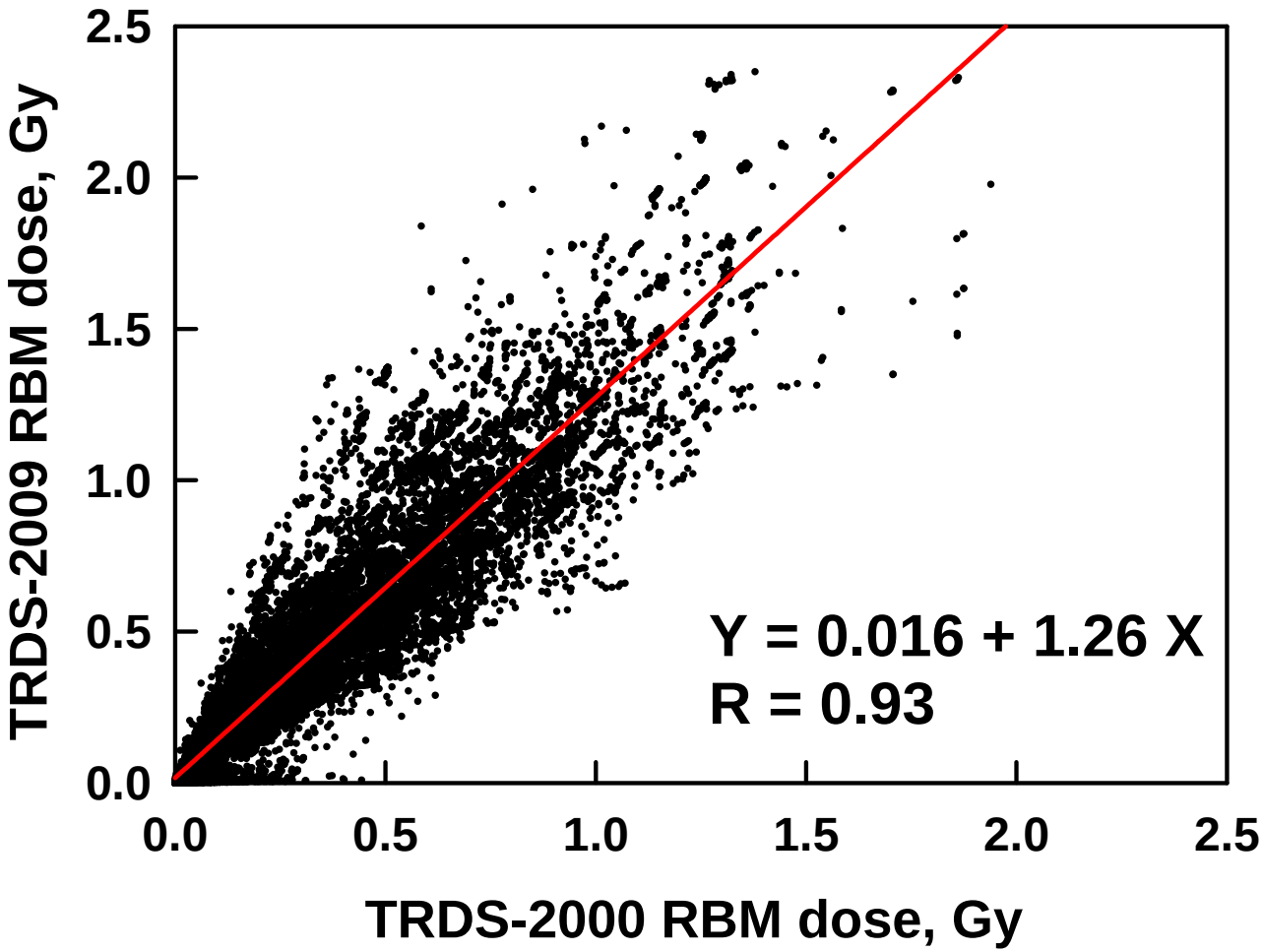
Project 1.1 has had Several Phases

- One-year feasibility study ended in 1996
- Phase I ended in 2000
  - Major changes in external dose
  - Changes in internal dose with inclusion of short-lived radionuclides
  - Culmination in the TRDS-2000
- Phase II began in 2000; ending 9/2009
  - There have been several additions and extensions
  - Medical exposures
  - Other environmental exposures
- Phase III beginning 10/2009

Major Goals of Phase II

- Further study of uncertainty with the goal of reducing uncertainty in the end results
- Validation of dose estimates
- Study of other sources of dose that could confound analysis of the epidemiologic data
- Culmination is dosimetry system TRDS-2009D
  - Deterministic model for exploratory research
  - TRDS-2009D is running; initial doses are now available

TRDS-2009D initial results compared with TRDS-2000



Refinement of Individual Internal Dose

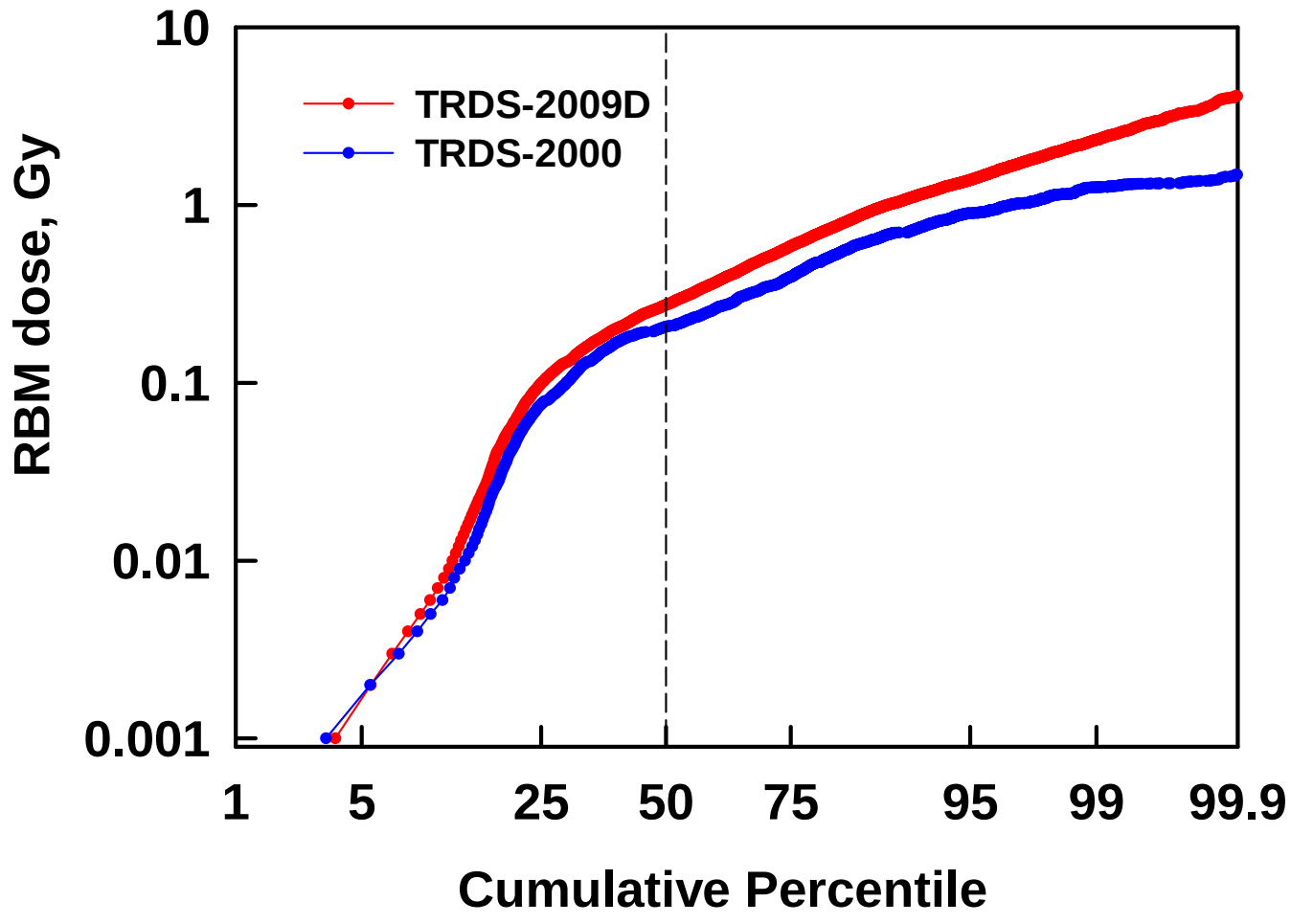
TRDS-2009D includes refinement of individual internal dose based upon a person's or a co-inhabitant's measurement of ^{90}Sr-body burden for 7,903 members of the ETRC (27% of the entire cohort)

Consideration of Confounding Exposures

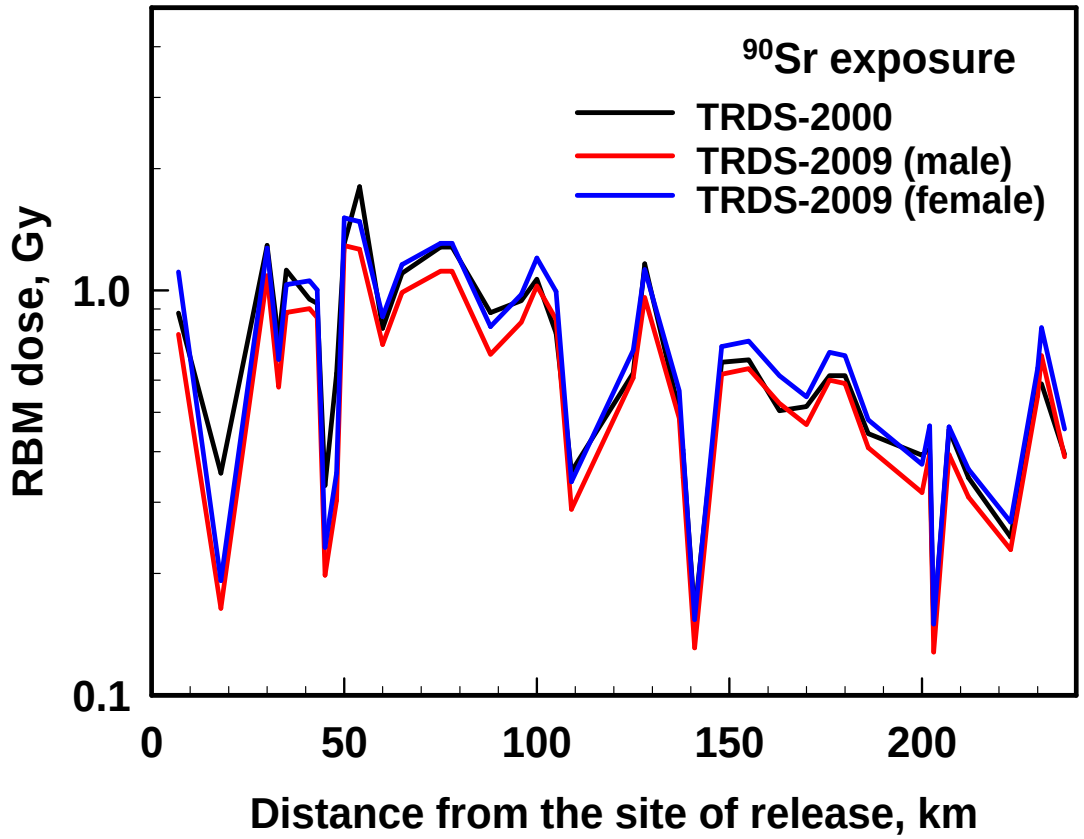
TRDS-2009D includes the calculation of doses of confounding exposure due to residence on EURT area contaminated in 1957 and medical exposures at URCRM clinics

- 4,695 members of the ETRC (16% of the entire cohort) were exposed in the EURT area
  - additions to individual doses for these persons were low: 5.5 mGy on average and 44 mGy at the most
- 6,414 members of the ETRC (22% of the entire cohort) were additionally exposed to X-rays for diagnostic purposes
  - additions to individual doses in different organs of these persons were 30-35 mGy on average and 650-750 mGy at the most

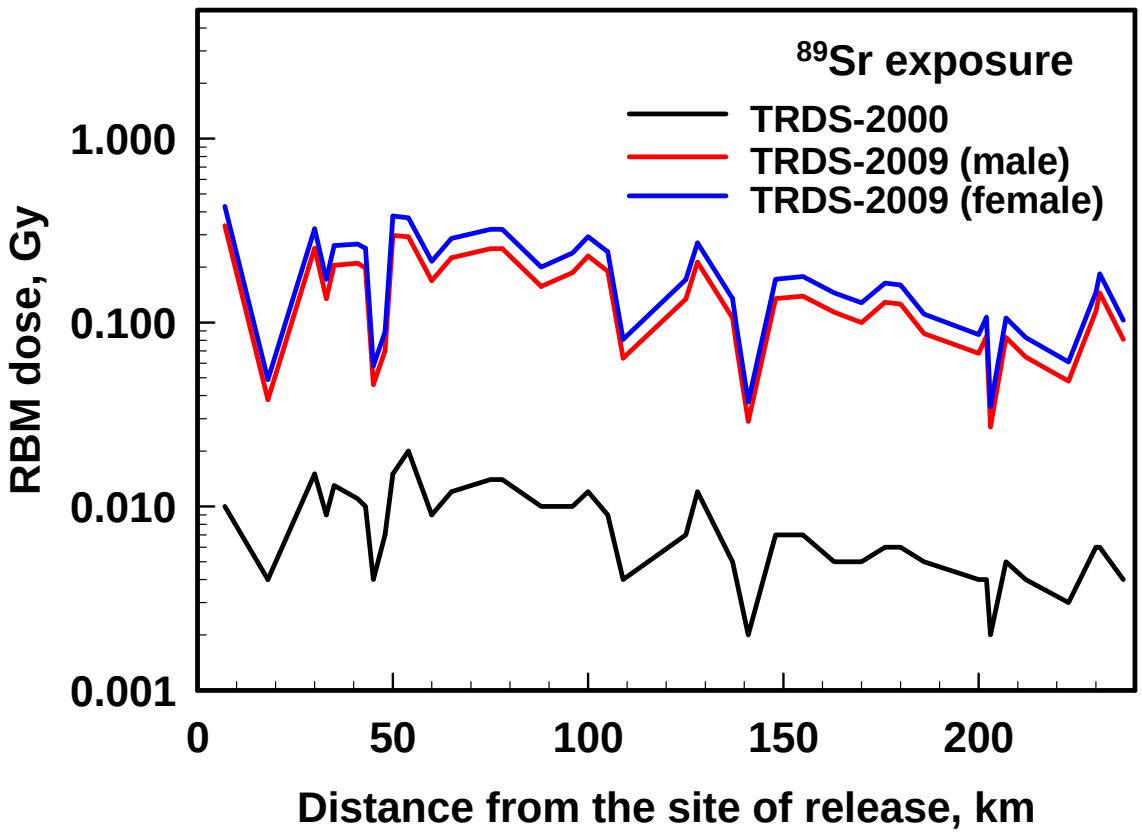
TRDS-2009D initial results compared with TRDS-2000



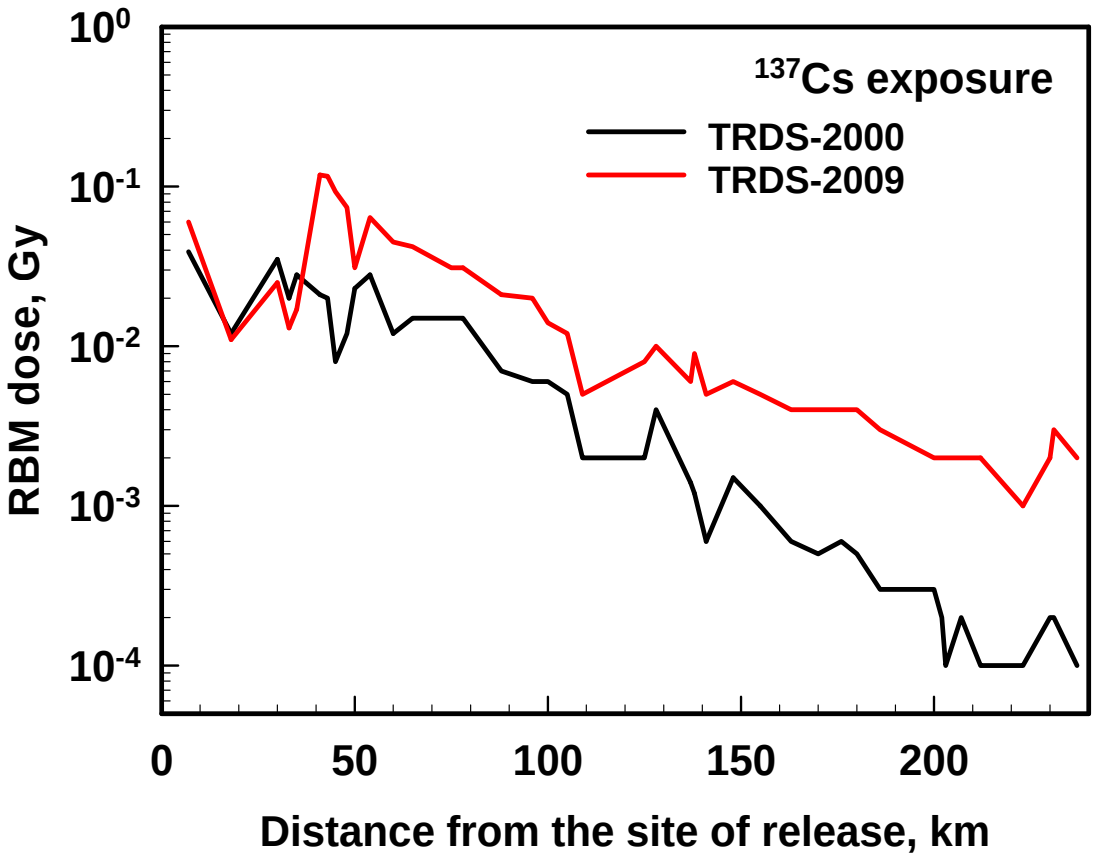
Internal Dose from ^{90}Sr – about the same with New Gender Differences



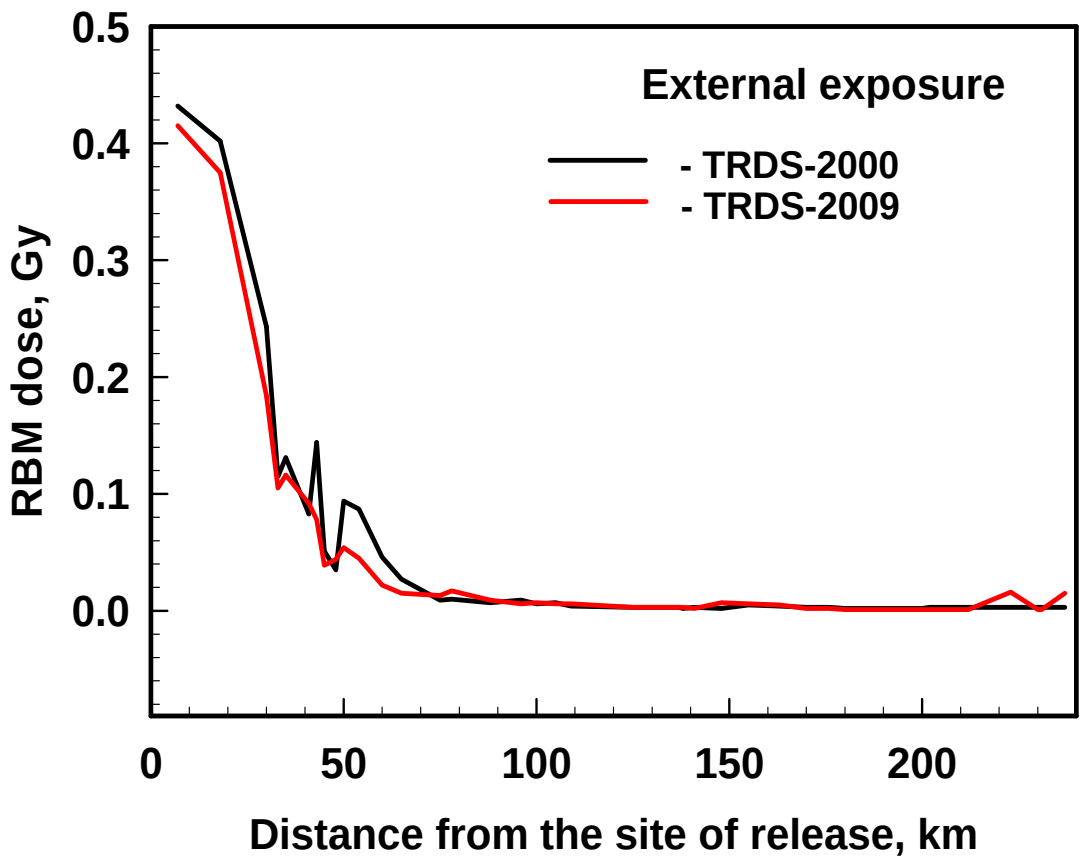
Revised source term – increase in dose from short-lived nuclides



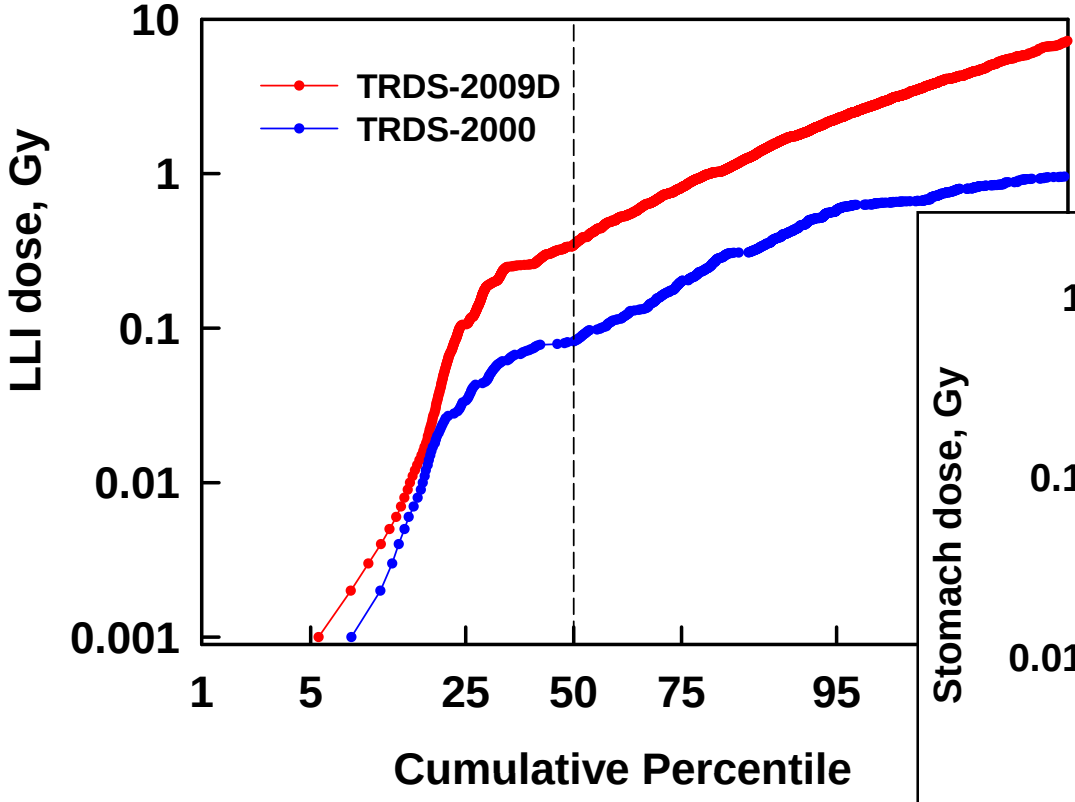
Additional pathways – ^{137}Cs in cow's milk

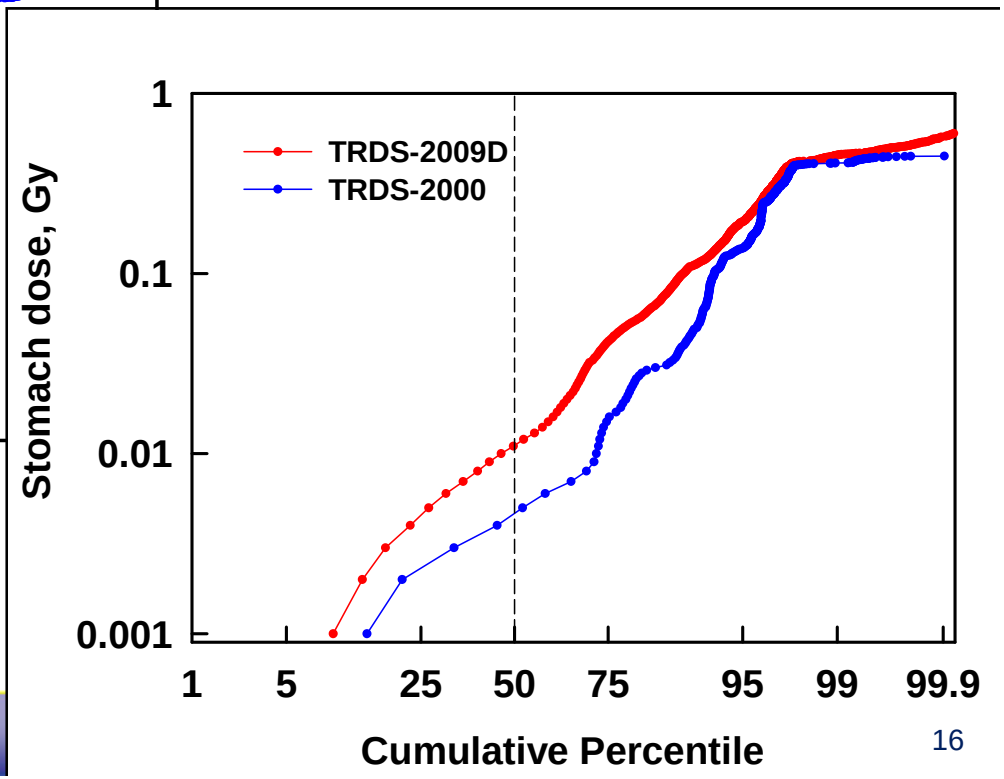


External doses remain about the same as TRDS-2000



TRDS-2009D includes doses for 23 organs/tissues





Future Project 1.1 efforts

- Use of a dynamic Techa River model of radionuclide transport in light of the recent discoveries related to the Mayak releases in 1950–1951
- Incorporation of recently discovered information related to household locations of cohort members in villages on the upper-Techa
- Validation of the external dose estimates related to radionuclides released in the initial years of Mayak operation
- Consideration of the release of noble gases and radioiodines into the atmosphere from Mayak facilities
- Addition of calculation capability for villages in the region of the East Urals Radioactive Trace (EURT) that were evacuated after the 1957 accident
- Completion of the stochastic TRDS-2009MC (Monte Carlo) version of the dose-calculation package

Cooperative activities

- Study of the ETRC is a joint activity with US and Russian dosimetrists and epidemiologists.
- The results from Project 1.1 are being and will be used to support other epidemiologic studies being undertaken by the Commission of European Communities (CEC).
- Studies funded by the CEC have been and continue to be very important in terms of external dose validation.
- There is a joint JCCRER-CEC working group on uncertainty.

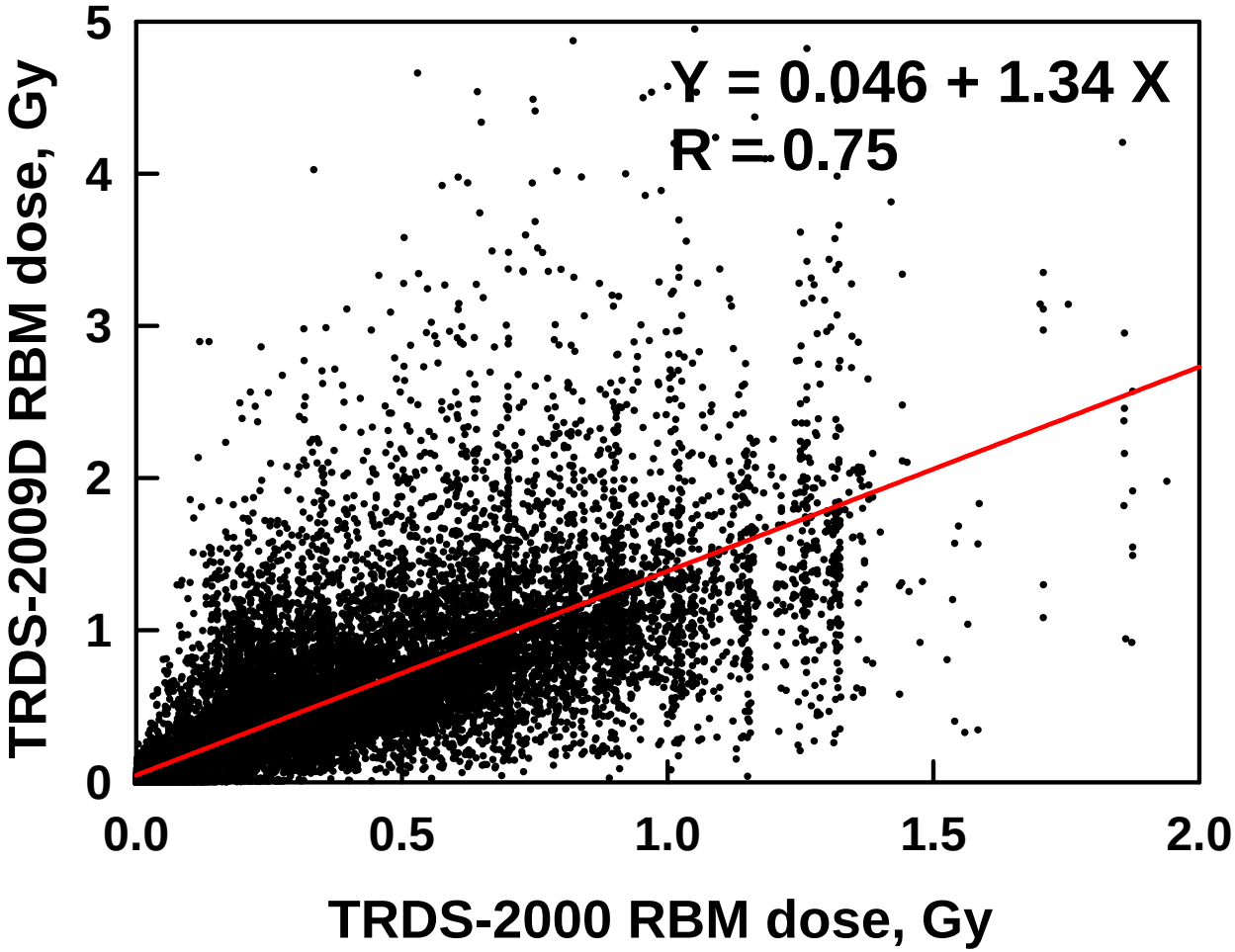
Many publications have resulted from the activities of Project 1.1

- 86 articles in peer-reviewed literature
- 178 publications (abstracts, etc.) in the open literature
- 38 milestone and other technical reports
- 27 progress reports

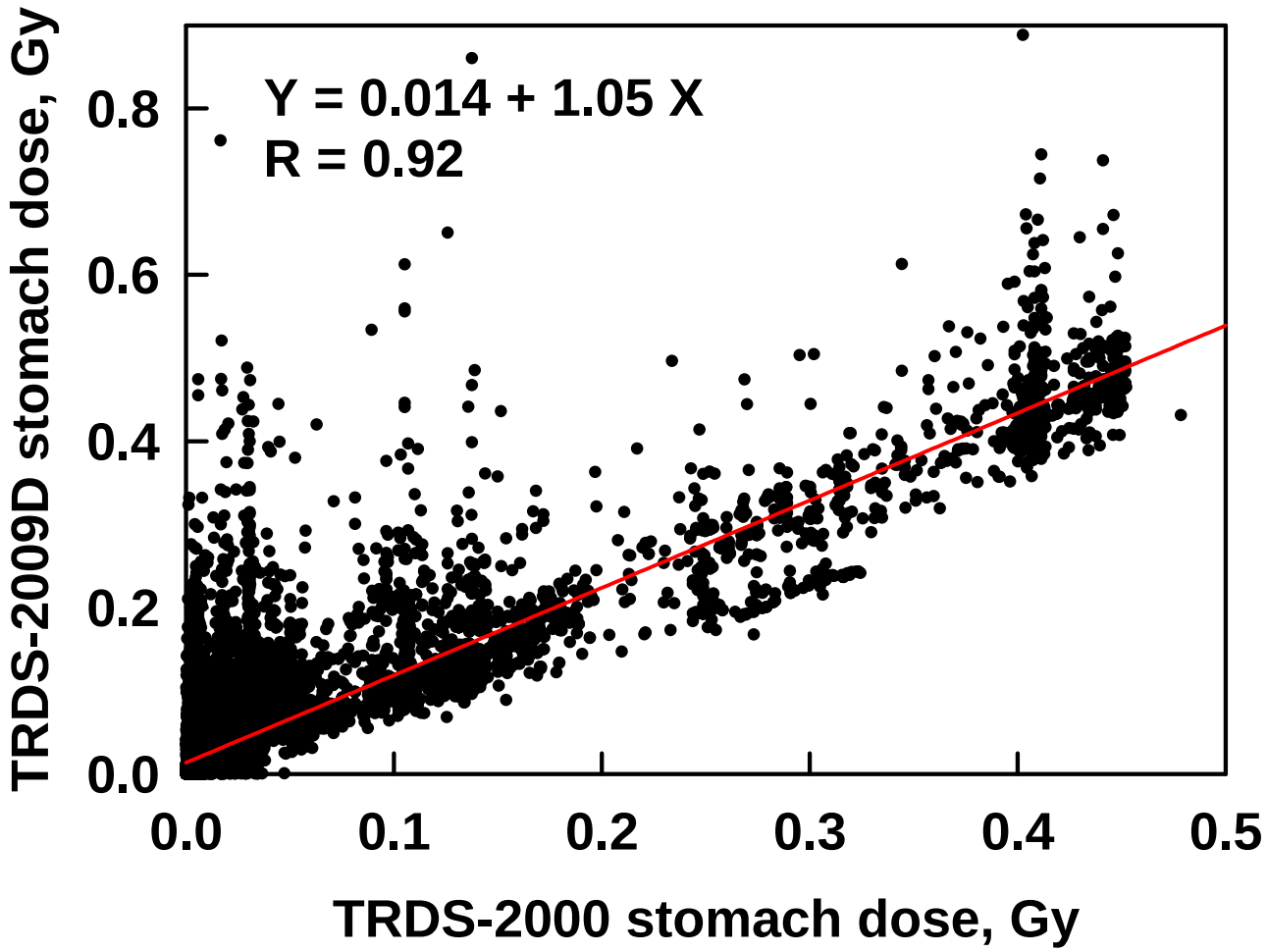
Thank you!

- This study is currently funded by
  - Office of International Health Studies, US Department of Energy;
  - Federal Medical-Biological Agency of the Russian Federation; and
  - Office of Radiation and Indoor Air, US Environmental Protection Agency.
- In prior years funding had been received from the US National Aeronautics and Space Administration.

Comparison of all changes (third step)



Comparison of all changes (third step)



Abstract

JCCRER Project 1.4 - Reconstruction of dose to the residents of Ozersk from the operation of the MAYAK PA: 1948–2002

YG Mokrov, DA Beregich, PM Stukalov, IA Ivanov, II Teplyakov, SI Rovny;
Mayak PA
Lynn R. Anspaugh,
University of Utah
Bruce A. Napier,
Pacific Northwest National Laboratory

Russian and US investigators have worked on JCCRER Project 1.4 from 2004 through 2009. Initial research had indicated that releases of ^{131}I and other radionuclides from Mayak PA stacks in the period from 1948 to the 1950s resulted in significant exposure to the population living in Ozersk, and possibly to persons living in other nearby locations. This additional source of exposure should be considered in epidemiological studies of the following cohorts in the Urals region:

- Ozersk Children's Cohort;
- Extended Techa River Cohort;
- Mayak Worker Cohort; and
- East Urals Radioactive Trace (EURT) Cohort.

Temporal patterns of radionuclide releases from Mayak PA stacks have been developed, and maximum annual doses to the population were identified for periods 1949–1951 and 1954–1955. The releases of ^{131}I from radiochemical plant stacks were the primary contributor to dose, and the critical group consisted of residents born in 1948–1950, who regularly consumed local cows' milk. External doses due to atmospheric releases of noble gases (^{41}Ar, isotopes of Kr and Xe) have also been calculated. The estimated air submersion doses (10-15 mGy) coincided well with experimental thermoluminescent measurements of brick sampled from buildings in the central part of Ozersk.

Preliminary estimates of dose to the thyroid due to ^{131}I releases from the stacks of the reactor and radiochemical productions of Mayak PA have been calculated. The thyroid

dose to different groups of Ozersk residents are in the range of 0.5–1.5 Gy. Thyroid doses to persons living in Metlino (on theTecha River) are estimated to have been 2–3 times higher, because of prevailing wind directions.The results of this investigation were also used in ISTC Project 2841 on reconstruction of liquid radioactive waste discharges into the Techa River. It is planned that all results from this study will be validated to the extent possible and uncertainties in dose estimates will be derived by the end of 2009.

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JCCRER Project 1.4: Reconstruction of dose to the residents of Ozersk from the operation of the MAYAK PA: 1948-2002

Y.G. Mokrov, D.A. Beregich, P.M. Stukalov, I.A. Ivanov,
I.I. Teplyakov, S.I. Rovny, Mayak Production Association
L.R. Anspaugh, University of Utah
B.A. Napier, Pacific Northwest National Laboratory

Purpose of the project

- Calculate time-dependent doses to representative individuals living in Ozersk and nearby settlements due to atmospheric releases of ^{131}I and other radionuclides from the Mayak PA in the period 1948–2002.
- Provide the scientific basis for a future dosimetry system to reconstruct thyroid doses to a cohort of children in Ozersk. Data on individual residence history and food-consumption patterns would be required.

Background:

1. Scoping studies performed by Mayak PA experts in 1991–1999 demonstrated that the total ^{131}I release to the atmosphere could reach ~400 kCi (~15 PBq), and radiation dose to the thyroid (among children born in 1951) was estimated as ~4 Gy.
2. Scoping epidemiologic studies performed by researchers from the Southern Urals Biophysics Institute revealed an excess prevalence of thyroid nodules and an increased incidence of thyroid cancer among Ozersk residents born in the early 1950s.

Interaction with Other Projects

- ^{131}I atmospheric releases from the Mayak PA stacks resulted in additional exposure to be accounted for in epidemiologic studies for the following population groups:
  - Extended Techa River Cohort (ETRC) – JCCRER, Direction 1;
  - Mayak PA workers – JCCRER, Direction 2;
  - East Urals Radioactive Trace Cohort (EURT cohort)
- Insufficient information on doses due to atmospheric releases of ^{131}I (and other radionuclides) may result in incorrect estimation of radiation risks for the members of these cohorts

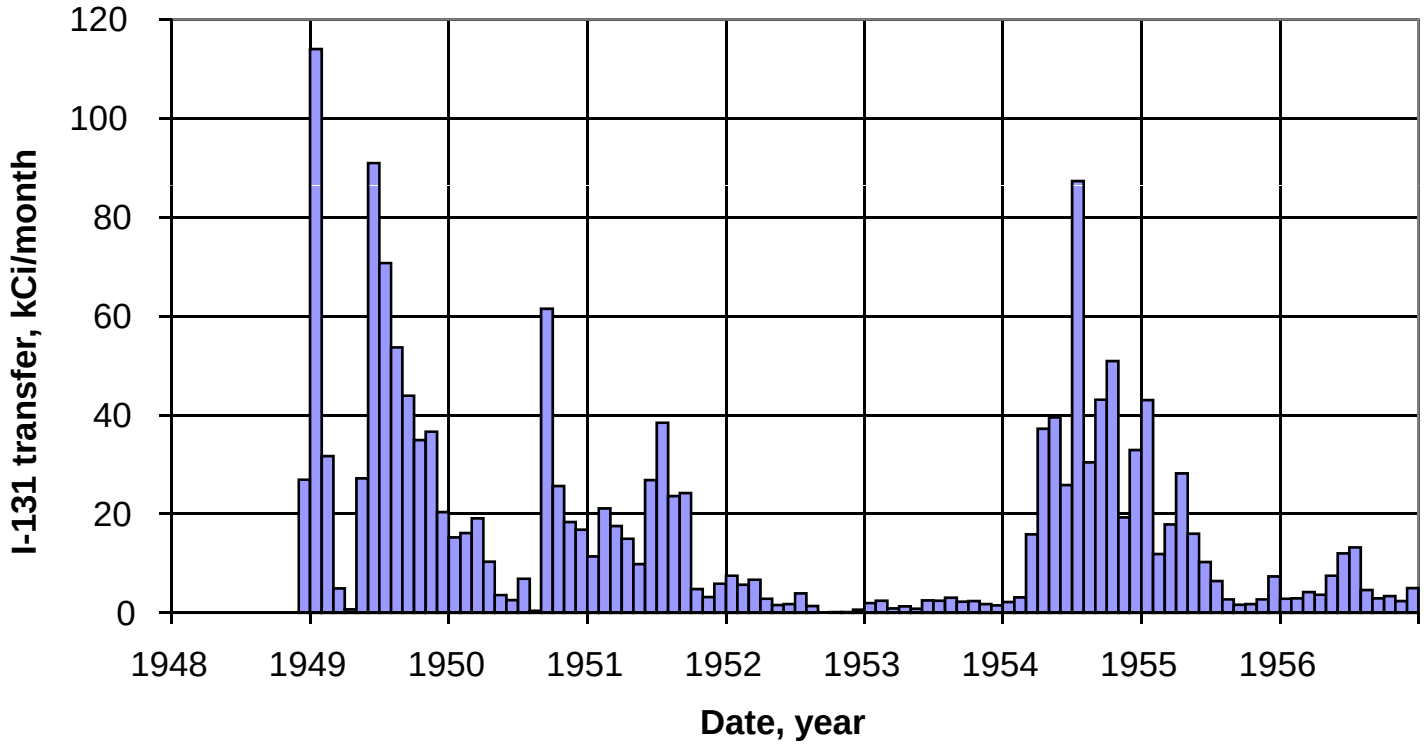
Project description:

1. Project start: September 2004.
2. Project end: September 2009.
3. The project contains 14 main tasks.
4. 12 deliverables (reports) are planned.
5. The following have been issued to date (July 2008):
   - Milestone deliverables – 8;
   - Additional reports – 6;
   - Manuscripts – 7;
   - Prepared for publication – 3.
6. Project Manager – S. I. Rovny (Mayak PA).
7. Principal investigators:
   - Y. G. Mokrov (Mayak PA);
   - L. R. Anspaugh (University of Utah);
   - B. A. Napier (PNNL).

Principal steps of calculations:

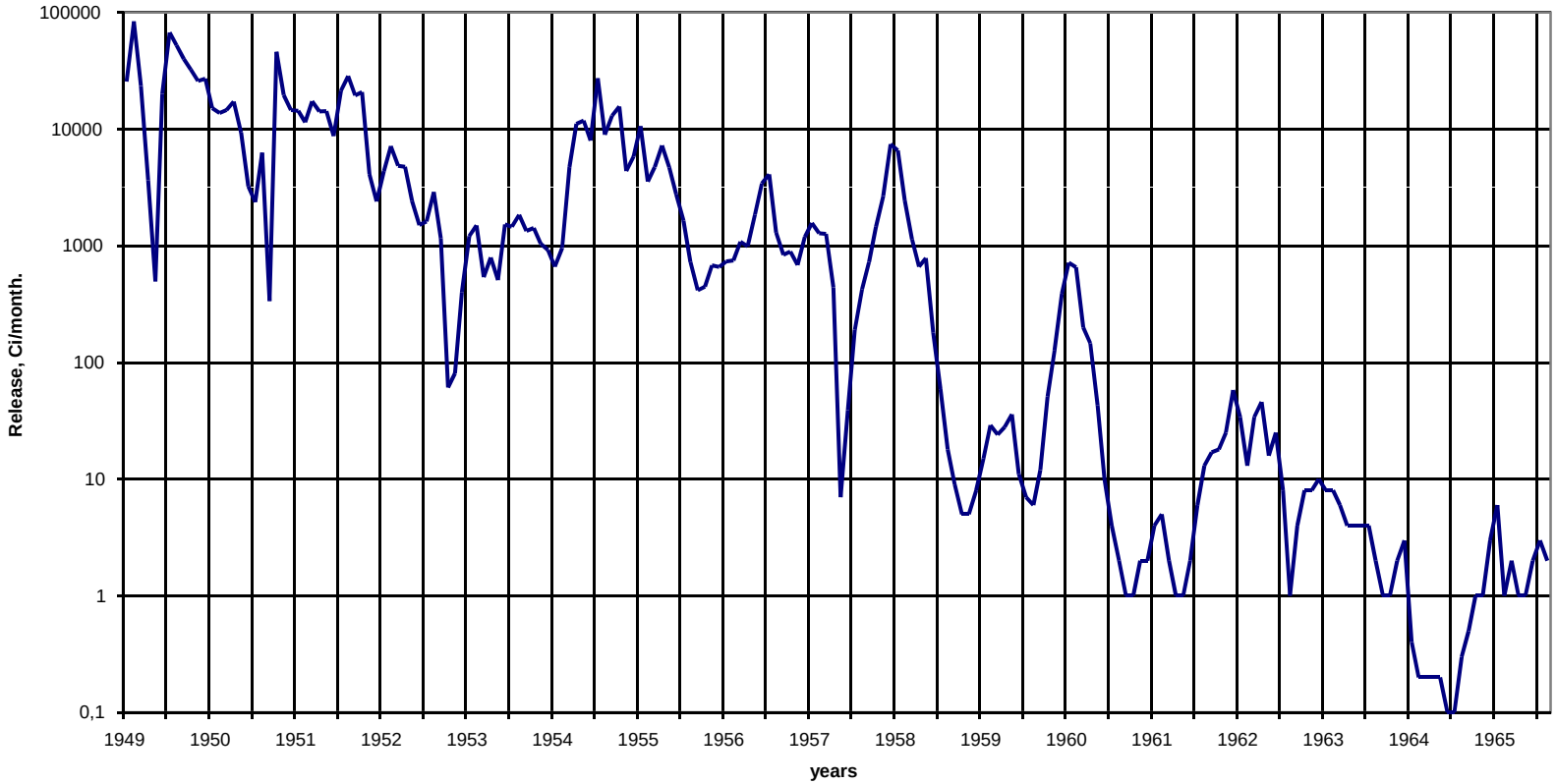
Process	Model (developer)	Calculated results
Uranium irradiation in reactor	Reactor model (MPA)	^{131}I accumulated in uranium by the fuel discharge from reactor
Cooling of irradiated uranium	Cooling pond model (MPA)	Transfer to radiochemical plant
Radiochemical reprocessing of uranium	Model of radiochemical reprocessing and gas purification (MPA)	1. ^{131}I atmospheric release 2. Physicochemical forms of iodine
^{131}I dispersion and transfer in atmosphere	RATCHET: model of atmospheric transfer (PNNL)	Surface air concentrations and fallout of ^{131}I
Migration of ^{131}I through biological chains	Migration model: atmosphere–vegetation-soil-cow/goat-milk. Analogue to DESCARTES (PNNL/MPA)	^{131}I content in foodstuffs
^{131}I intake in human body	Model of dietary intake and food supply (MPA)	Thyroid dose estimation

Intermediate Results: Iodine Transfer Rates



Reconstruction of the total monthly transfer of ^{131}I from Mayak PA cooling ponds to radiochemical reprocessing in 1948–1956. Total ^{131}I delivery for the period 1948–1956 was 1.61 MCi.

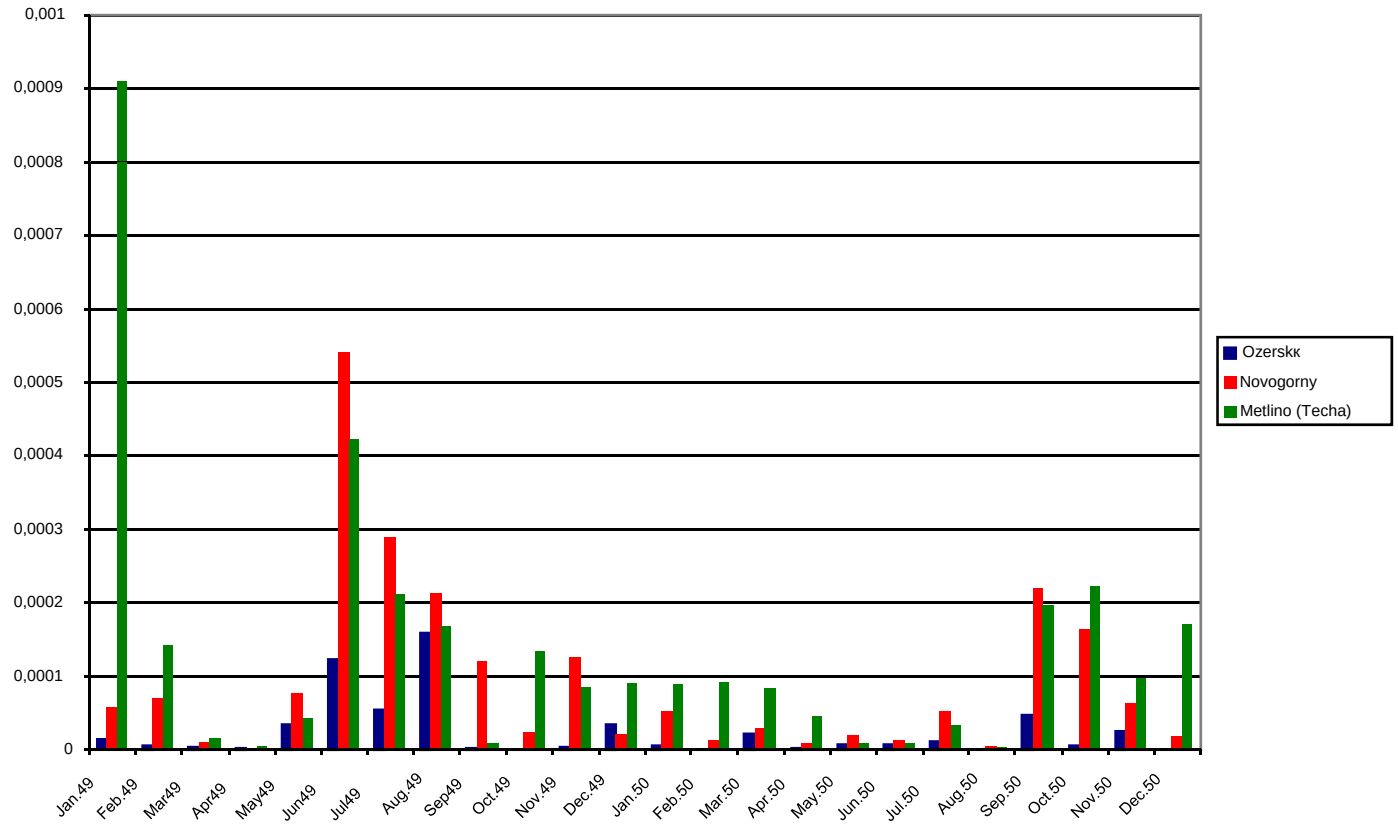
Intermediate Results: Iodine Release Rates



Results of reconstruction (most probable estimates) of monthly ^{131}I releases to the atmosphere from the stacks of Radiochemical Plant B. Total release was ~1MCi (37 PBq).

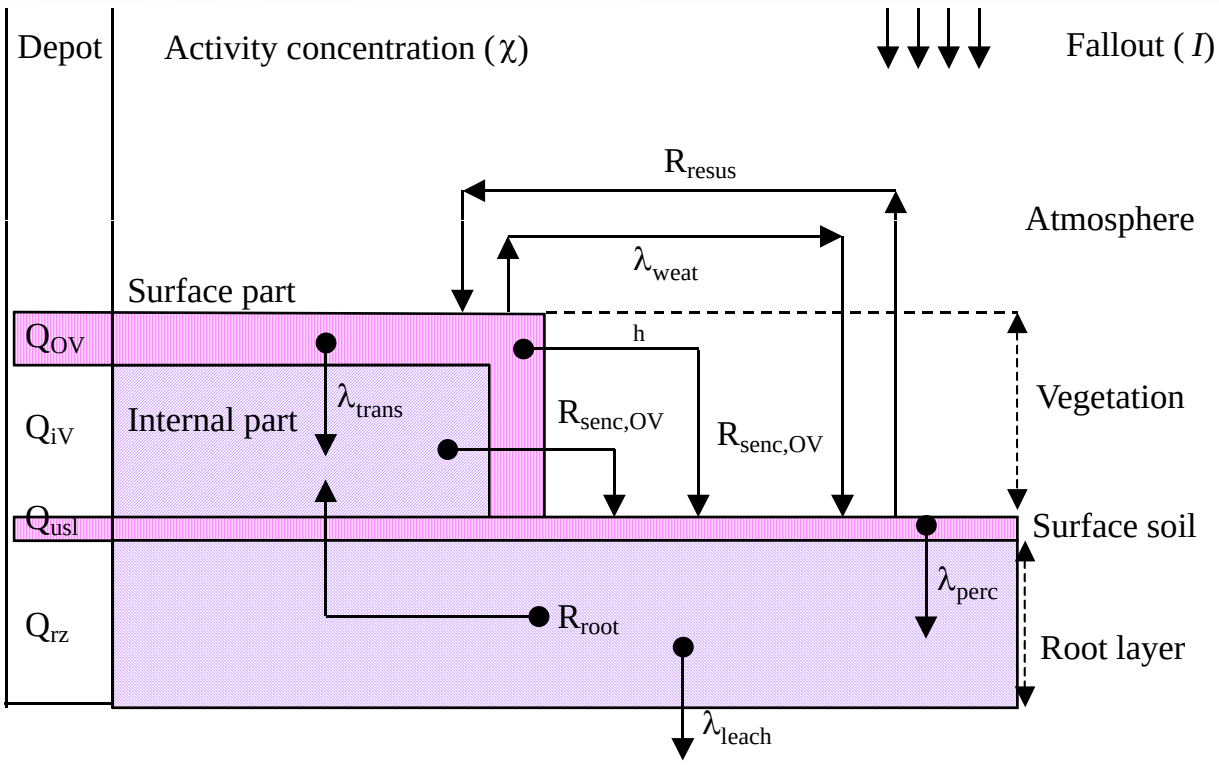
Intermediate Results: Monthly Air Concentration

Average monthly integral surface air activity concentration, Ci/m^3 month



Calculated data (RATCHET) for Ozersk, Novogorny, and Metlino (Techa) for the period 1949–1950

Intermediate Results: Modeling Iodine in the Environment



Four-dimensional model (analogue to DESCARTES) used to simulate ^{131}I migration through atmosphere-vegetation-soil. Reference: «S.F. Snyder, W.T. Farris, B.A. Napier, T.A. Ikenberry, R.O. Gilbert. 1994. Parameters Used in the Environmental Pathway and Radiological Dose Modules of the Hanford Environmental Dose Reconstruction Integrated Codes. HEDR, Battelle, Pacific Northwest Laboratories, Richland, WA».

Main project results (July 2009):

- Monthly data on releases of noble radioactive gases and ^{131}I from Mayak PA stacks were reconstructed for 1948–2002.
- External effective doses to the Ozersk population were estimated (1948–2002). The derived values of 15-20 mSv are in good agreement with experimental TL measurements in bricks of Ozersk buildings (EC Project SOUL). Absorbed doses to individual organs will be estimated.
- Internal doses to the thyroid due to ^{131}I releases were preliminarily estimated for different age groups of the Ozersk population:
  - inhaled dose only: 0.007–0.01 Gy
  - dose due to ingestion (cow milk, vegetable, etc.): 1–2 Gy
  - for a limited part of children's population (born in 1948–1954) consuming goat's milk from Metlino (Techa): 5–7 Gy

Preliminary results of population dose calculation (1948-2002), Gy

Location	External dose	Thyroid dose (1)	
		Inhalation	Ingestion (milk, vegetables, etc.)
Ozersk	0.01 – 0.015 (2)	0.004 – 0.01	0.5 – 1.5
Metlino (Techa River)	0.10	0.02 – 0.04	3 – 6
Novogorny	0.020	0.015 – 0.025	2 – 4
Kasli / Kyshtym	0.005	0.003 – 0.005	0.3 – 0.8
Production site	0.5	~ 0.2	-

(1) – range represents different age groups of the population
(2) – range represents different city districts

Future Plans

- To complete by the end of 2009 the improvement of doses to Ozersk residents accounting for
  - Age at exposure
  - Models of life style and dietary habits
- To evaluate uncertainties of calculated doses
- To complete all deliverables

Conclusions

- JCCRER Project 1.4 is an important component of the whole set of studies conducted to assess radiation risks in the Southern Urals.
- Activities under the Project are slightly behind schedule, but they will be successfully completed by the end of the year 2009.
- Important results to date:
  - Noble gas releases from Mayak PA stacks resulted in external effective dose of Ozersk residents (~ 20 mSv)
  - I-131 releases from Mayak PA stacks were highly non-uniform in time, and the maximum radiation doses to the thyroid were observed in 1949–1951 and 1954–1955.
  - Internal doses to thyroid gland due to ^{131}I releases were preliminarily estimated for different age groups of the Ozersk population to vary from 7–10 mGy for only inhalation intake up to 1–2 Gy accounting for ingestion intake.

Abstract

JCCRER Project 1.2b - Cancer Morbidity in the Techa River Cohort

Prof. A.V. Akleyev and Dr. L. Yu. Krestinina,
Russia, URCRM
Prof. F.G. Davis,
UIC, USA
Dr. D.L. Preston,
HIC, USA

Project 1.2b under the aegis of the Joint Coordinating Committee for radiation effects research (JCCRER) is implemented jointly by the Urals Research Center for Radiation Medicine, University of Illinois at Chicago and HiroSoft Company.

The priority goal of the current project is to develop improved estimates of radiation effects on the incidence of solid cancer and leukemia in the Chelyabinsk subcohort of Techa River Cohort using the best available dosimetry system and to investigate how various risk and dose uncertainty factors may modify these risks.

The first phase of the DOE project (1997-2000) focused on estimation of completeness and quality information about cancer cases for incidence within the TRC members and was focused on the development of the URCRM cancer registry. The tasks carried out during the second phase (2000-2003) included defining a fixed cohort (known as the Chelyabinsk Oblast subcohort or ChOS) and catchment area for which it was feasible to ascertain comprehensive and accurate data on cancer incidence in which to conduct follow-up. The next contract period (2003-2006) was devoted to extending the follow-up, developing more efficient data collection procedures; improving the diagnostic quality and carrying out preliminary risk analyses. The most recent contract period (2006-2009) was devoted to continuing data collection by means of better linkage to the improved tumor registry of the Chelyabinsk Oblast Oncology Dispensary; investigation of the feasibility of extending the catchment area within Chelyabinsk Oblast and publication of reports describing radiation effects on the risk of all solid cancers and breast cancer.

During this time a Techa River subcohort numbering about 18 thousand persons has been identified resident in Chelyabinsk Oblast (Chelyabinsk Subcohort) and analyses have focused on cases identified in a catchment area of 5 raions in Chelyabinsk Oblast

and Chelyabinsk city over a 46 year period from 1956 through 2002. In this proces methods for following-up the cohort have been developed, a cause-of-death registry in collaboration with NCI investigators and a cancer incidence registry in collaboration with the Chelyabinsk Oncology Dispensary have been established.

In parallel with the on-going epidemiological research, efforts were made to improve the model for estimation of doses received by members of the Techa River Cohort; in 2000 the dosimetry system TRDS-2000 was created.

The plans for the next project phase include extending the follow-up period; continuing to collect cancer information in the entire Chelyabinsk Oblast; improving the quality and completeness of the cancer incidence data by developing more efficient and effective methods to obtain cancer information on cohort members from the Oncology Dispensaries in this region. An assessment of the availability or non-radiation related cancer risk factors for control in radiation risk estimates is planned and analysis will incorporate the revised dosimetry estimates with consideration of dose uncertainties as they become available. We have proposed to expand the scope of this project to continue assessment of radiation effects on non-cancer mortality risks in the ETRC. The discontinued European Union SOUL project on this topic has provided some indication of radiation effects on total non-cancer mortality, primarily due to radiation-associated increases in cardiovascular disease mortality. Since mortality data are routinely obtained by the URCRM with support from NCI, we propose focusing on evaluating the quality of the noncancer cause of death information and providing risk estimates based on extended follow-up with the latest dosimetry.

The results of analyses conducted have been published including a methods paper (1); papers on solid cancer risk analysis (2); a breast cancer risk paper (3); a review of the incidence of all types of cancer in the Techa River cohort (published in a Russian journal) (4). In addition, a paper on leukemia risk analysis (5) was submitted for publication in July 2009, and a manuscript on analysis of organ-specific cancer risks is being was prepared for publication (6). Current data support a clear increase in risk that is consistent with a linear dose response with exposure to low level chronic radiation exposure for both solid tumors and leukemias.

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RADIATION EFFECTS RESEARCH

2009

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WASHINGTON D.C.

Project 1.2b (2006-2009) : Cancer Morbidity in the Techa River Cohort

Principle Investigators:

Russia: URCRM
Prof. A.V. Akleyev,
Dr. L. Yu. Krestinina

USA:
Prof. F.G Davis, UIC
Dr. D,L Preston, HIC

Specific Aims

- Obtain comprehensive data on cancer incidence for members of the Chelyabinsk oblast subcohort using the best available dosimetry system
- Investigate how cancer incidence varies with radiation dose

Exposure

- Radioactive releases from 1949-1956
- External exposures: gamma rays from contamination of shoreline and flood plains
- Internal exposures from consumption of water, milk and food contaminated with ^{137}Cs, ^{90}Sr and other radionuclides
- Soft tissue dose estimates up to 0.45 Gy (mean 0.04 Gy)

Why is this Population Important?

- Low-dose, low-dose-rate environmental
- exposure
- General population with over 45 years
- follow-up
- Individualized dose estimates (Project 1.1)
- Risk estimates contribute to radiation
- protection standards

Progress: 1995-2006

Techa River cohort formed:

approximately 29,800 people

Incidence data compiled:

5 raions of Chelyabinsk Oblast & Chelyabinsk city

Follow-up methods developed:

18,400 CO residents with follow-up through 2002 (46 years)

Vital status compiled jointly with NCI

Incident cancer cases ascertained:

1,836 solid cancers for period 1956-2002

Solid Cancer Incidence*

- Follow-up: 1956 – 2002
- Population: Chelyabinsk Oblast subcohort resident in original catchment area (Techa River raions) or Chelyabinsk city

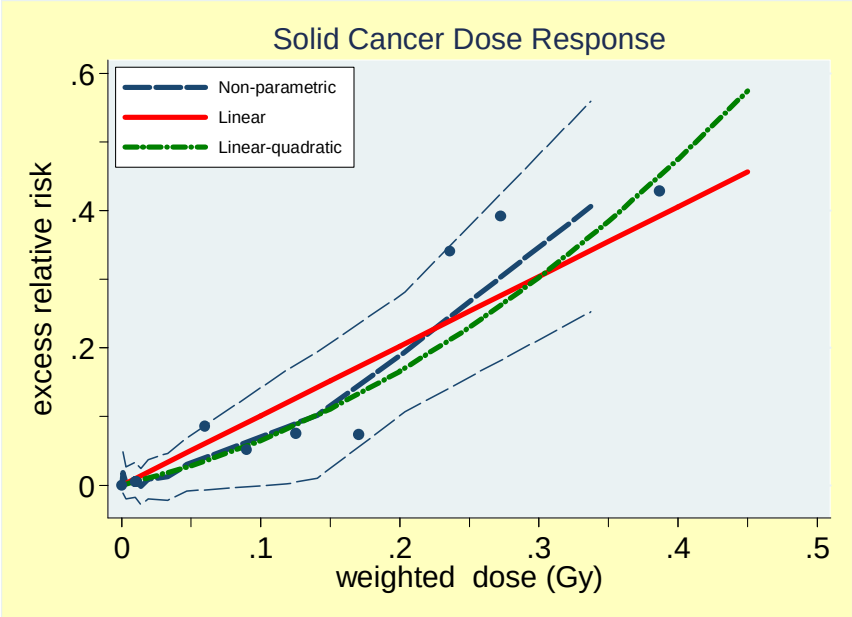
Alive, no cancer	**4,151**	
Solid Cancer	**1,846**	
Dead, no solid cancer	**6,504**	
Dead, cause unknown	**787**	*12%*
Lost to follow up	**4,932**	**28%**
Unknown vital status	*1,397*	
Migrants	*3,535*	
Total	**17,433**	

- **Histological / Visual** **60% overall** **80% after 1990**
- **DC only** **19% overall** **11% after 1990**

*** Int. J Epidem**

Solid Cancer Incidence

Dose	PY	Cases	Excess	AF
< 0.01	236,872	1018	4.6	0%
-0.05	148,888	555	13.8	2%
-0.1	18,033	65	4.1	6%
-0.2	26,529	107	13.2	12%
-0.3	5,756	26	4.8	18%
0.3+	10,510	65	18.1	28%
Total	446,588	1836	58.7	**3%**



- Significant dose response
  - Linear ERR @ 100 mGy 0.1 95% CI (0.03; 0.19)
  - No evidence of curvature (P = 0.4)

Solid Cancer Results to Date

- Evidence of dose-response for solid cancers
- ERR is increased for low dose-low dose rate environmental exposures

- Techa River Incidence - 10% increase at 0.1 Gy
- Nuclear Worker Study - 9% increase at 0.1 Gy
- Atomic Bomb Survivors - 5% increase at 0.1 Gy

Work in Progress

- Extend follow-up and expand catchment area (all of Chelyabinsk Oblast)
- Improve quality, completeness and efficiency of data collection
- Conduct radiation risk estimation

Improving Case Ascertainment

- Collaboration with Chelyabinsk Oblast Oncology Dispensary (ChOOD)
  - Electronic system designed to facilitate linkage with ChOS
  - Developing record linkage tools
- Cancer Registry Includes cases for 2006 - 2008

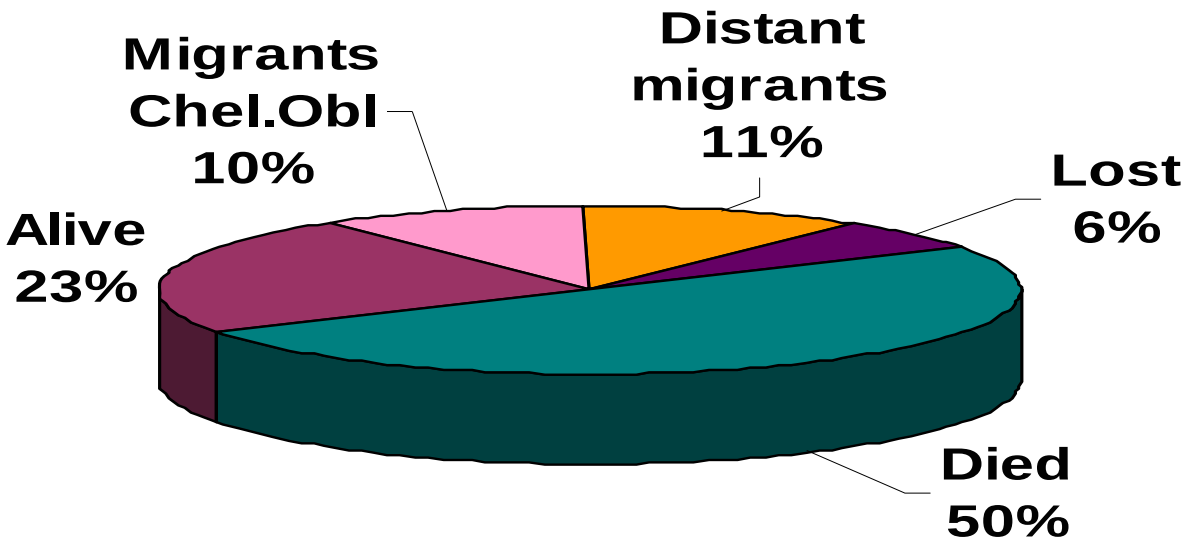
  ~13,000 cases processed per year
  - Used for all newly ascertained cases
- Ongoing development
  - Inclusion of data for cases diagnosed prior to 2006
  - Improved record linkage procedures

Cancer incidence cases

Data as of	Start of project	Current analysis data	July 2009
Period of follow-up	1956-2005	1956-2005	1956-**2008**
Current catchment area cases	2060	2085	2225
Other Chelyabinsk oblast cases	214	223	239
Total Chelyabinsk oblast cases	2274	2308	2464

Extended Follow-up Through 2005

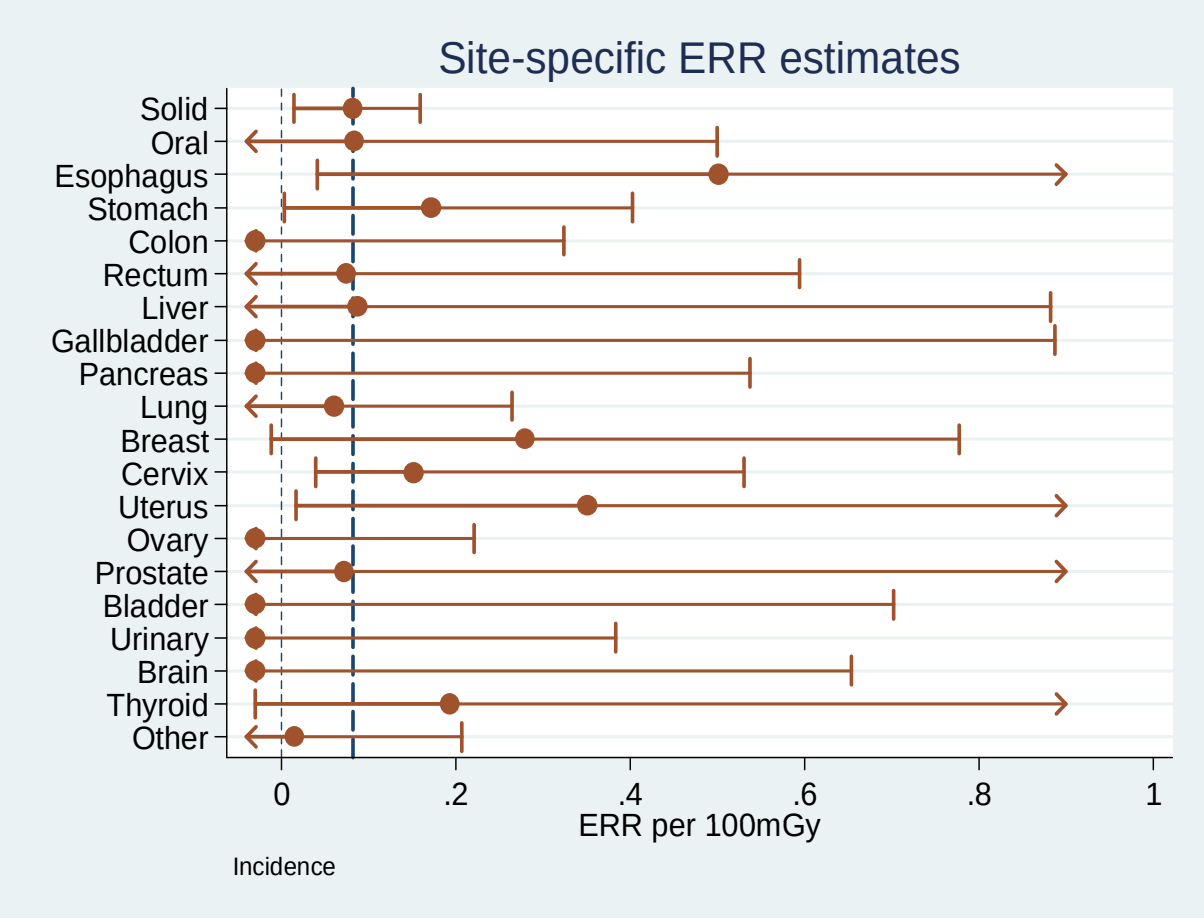
Chelyabinsk subcohort (n=17,444)
Vital status as of 31.12.2005



Cancer incidence structure (1956-2005)

All solid cancers (5 raions + Chelyabinsk city)	1991	100%
Stomach	352	18%
Lung	322	16%
Skin (non-melanoma)	167	8%
Cervix uteri	140	7%
Breast	113	6%
Oral cavity	101	5%
Esophagus	101	5%
Other	695	35%
Haemoblastoses	94	100%
Leukemia	64	68%
Leukemia (1953-2005) in the 2 Oblasts, total	93	
CLL excluded	70	75%

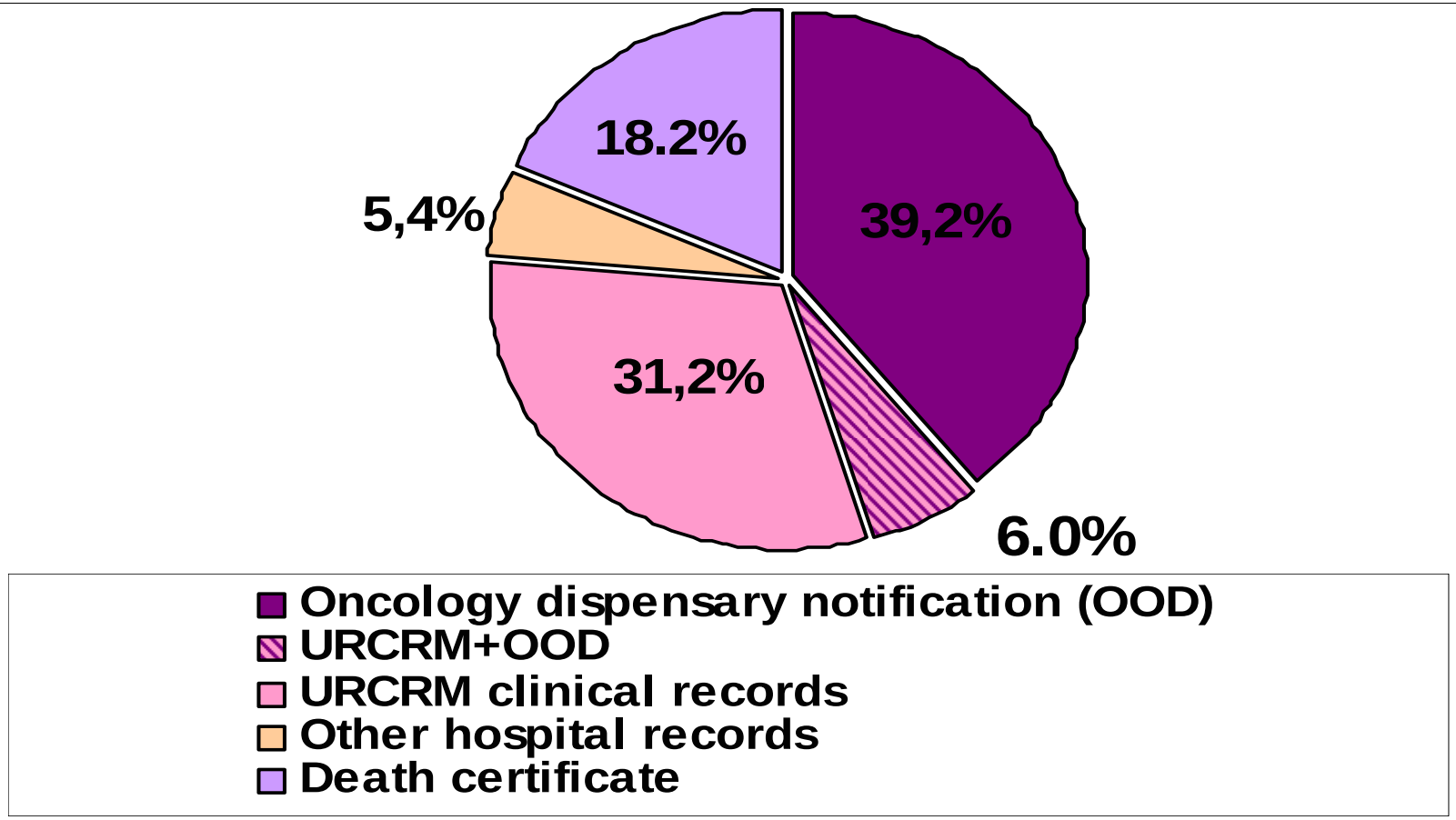
Solid cancer site-specific risks



There is significant excess risk for incidence of all solid cancers

Site -specific risk estimates are quite variable and very uncertain

Leukemia 1953-2005

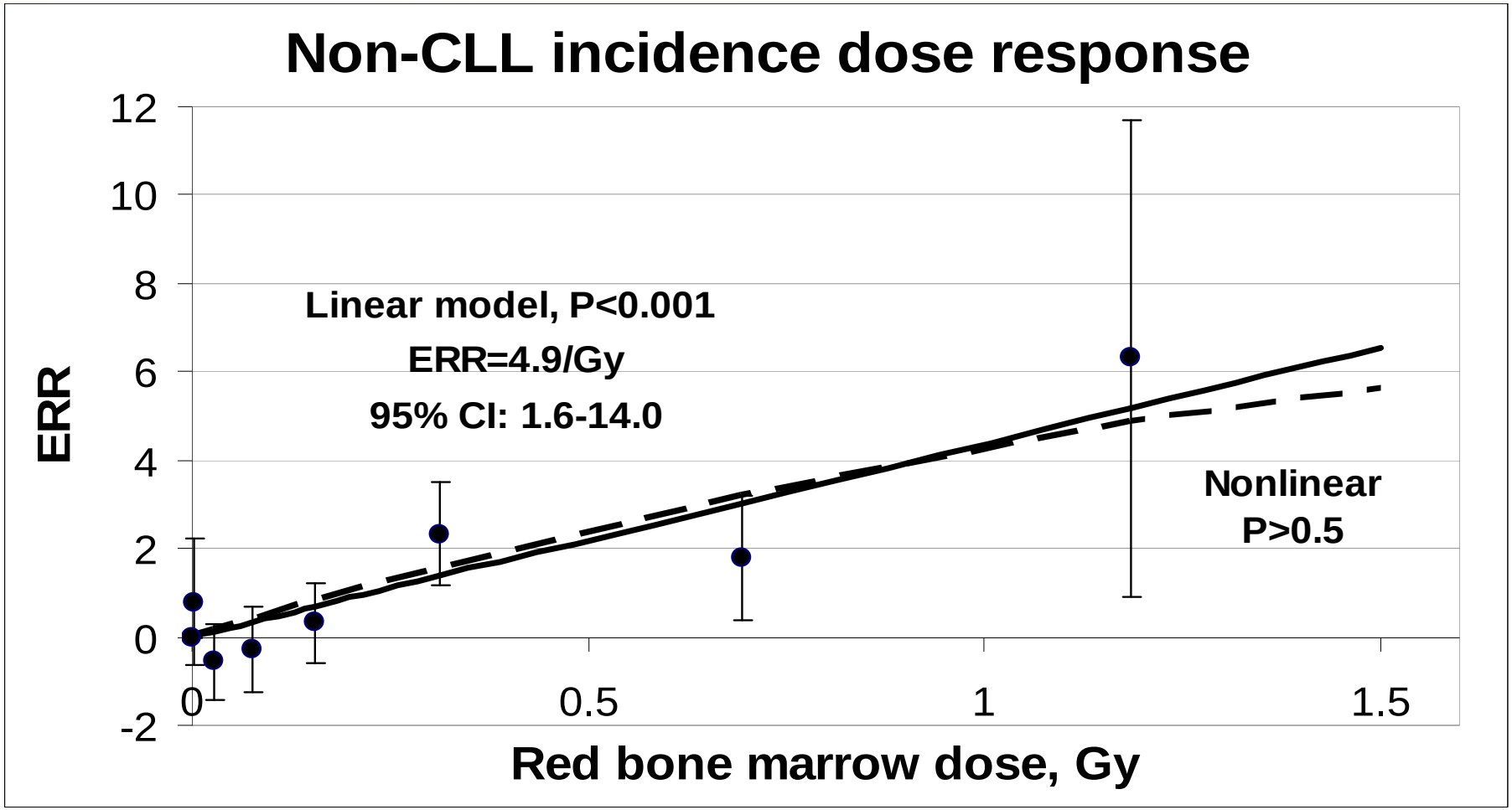


Leukemia 1953-2005

Dose (Gy)	PY (1000's)	Non-CLL		CLL
		Cases	Excess	Cases
<0.01	104	6	0	5
– 0.1	137	3	1	3
– 0.2	171	8	4	5
– 0.5	254	31	14	5
– 1	141	15	17	5
1 +	25	7	5	5
Total	**832**	**70**	**41**	**23**

- non-CLL ERR/Gy 4.9 (95% CI 1.6; 14)
- CLL ERR /Gy < 0 (Upper 95% CI 1.4)

Leukemia excluding chronic lymphatic leukemia



Leukemia Results

- Leukemia incidence (ERR) is increased by 49% at 0.1 Gy, 95%CI: 0.2-1.4; p<0,001
- Atomic Bomb Survivors (48% increase at 0.1 Gy)
- Consistent with strong dose-response relationship and ERR for solid cancer mortality which increased by 0.85% at 0.1 Gy

Priorities

- Analyses based on TRDS 2009 doses
  - Solid cancer and leukemia risk estimates
  - Site-specific risk estimates
  - Impact of changes in dose estimates
  - Impact of non-radiation risk factors (smoking, alcohol)
- Assess impact of dose uncertainties
  - Medical diagnostic exposures
  - Uncertainty in individual dose estimates

Abstract

JCCRER Project 2.2 - Estimation of Risk of Stochastic (Cancer) Effects of Occupational Radiation

Principal investigators:
Mikhail Sokolnikov,
SUBI
Ethel Gilbert,
NCI
Other investigators:
Dale Preston, *Hirosoft*; Elaine Ron, *NCI*; Nina Koshurnikova, *SUBI*

Workers at the Mayak facility were exposed to both external gamma radiation and internal plutonium. In contrast to Japanese A-bomb survivors (the basis for current radiation risk estimates) exposures were protracted over time and thus more similar to exposures of interest for radiation protection purposes. Unlike nuclear workers in other countries, doses are large enough that risks from both external and plutonium exposure can be estimated with reasonable precision. Thus, studies of Mayak workers fill important gaps in radiation research and protection.

The Mayak Worker Registry, developed in the mid-1980's under the direction of Dr. Nina Koshurnikova, currently consists of about 26,000 workers hired in the period 1948 through 1982 either in the nuclear reactor complex (exposed to external radiation), radiochemical plant and plutonium production plants (exposed to both external radiation and plutonium) or in the auxiliary plants (limited potential for exposure). About 25% of the cohort is female. Vital status is known for 94% of the workers. As of March 31, 2009, about 13,300 of the 26,000 persons had died, 3,089 of them from cancer.

The objectives of project 2.2 are to expand and improve the quality of the data, and to evaluate dose-response relationships. Updating vital status and ascertaining cause of death is a continuing effort. Under 2.2, the original registry has been expanded to include workers in the auxiliary plants and workers initially hired in the years 1973-1982. In addition, data on tobacco and alcohol use, pre-Mayak non-radiation exposures, and medical diagnostic procedures have been extracted from medical records. Additional detail on occupational history has also been obtained.

Dose-response analyses are based on annual and cumulative external and internal (plutonium) organ doses, which have been improved under project 2.4. Dose-response relationships for exposure to plutonium have been demonstrated and quantified for mortality from cancers of the lung, liver, and bone, the three major sites of plutonium deposition (Sokolnikov et al. 2008, Int. J. of Cancer). Dose-response relationships for external radiation exposure have been demonstrated for mortality from leukemia; lung cancer, and all cancers other than lung, liver, and bone cancer (Shilnikova et al. 2003, Radiation Research).

Future work will focus on dose-response analyses based on updated mortality data and Doses-2008, which incorporates the latest improvements in both external and internal doses under project 2.4. Analyses of cancers of specific sites will be conducted as will analyses of lung, liver and bone cancer (including estimation of lifetime risks from plutonium). Future analyses will further evaluate the role of smoking (including interactions), and also incorporate data on alcohol use, pre-Mayak exposures and dose from medical procedures. Finally, it is hoped that information on dosimetry uncertainties can be incorporated into dose-response analyses.

Joint Coordinating Committee for Radiation Effects Research

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JOINT COORDINATING COMMITTEE FOR RADIATION EFFECTS RESEARCH

2009

7TH INTERNATIONAL U.S. - RUSSIAN MEETING

WASHINGTON D.C.

Mayak Worker Epidemiology

Ethel S. Gilbert
National Cancer Institute
United States

Mikhail Sokolnikov
Southern Urals Biophysics Institute
Russian Federation

Mayak Worker Cohort

- 26,000 workers hired 1948-82
- 25% female
- 13,300 deaths
- 3,100 deaths from cancer

- Exposed to both external radiation and to plutonium

- Protracted low dose rate exposure similar to that of interest for radiation protection

Mayak Nuclear Facility

Plant	Exposures
Reactor	External
Radiochemical	External + Plutonium
Plutonium	External + Plutonium
Auxiliary	Little potential

Studies for quantifying risks of radiation exposure at low doses and dose rates

- A-bomb survivors in Hiroshima and Nagasaki
  - Wide range of external doses at high dose rates
- Medically exposed persons
  - Mostly acute high dose exposure
- Nuclear workers outside of Russia
  - Low doses and dose rates
  - Limited statistical power and strong potential for confounding

Example: Mayak workers

Mean external dose (Gy)

Mayak workers	0.54
IARC 15-country nuclear worker study	0.02

Mean internal plutonium dose to the lung (Gy)

Mayak workers	0.19
Sellafield workers (UK)	0.01

Gaps Filled by Mayak Worker Cohort

- Large protracted external doses
  - Doses much larger than those received by nuclear workers in other countries
- Substantial exposure from internally deposited plutonium
  - No other human data that are adequate for estimating cancer risks from plutonium
- Both male and female workers exposed

Aims of project 2.2

- Expand and improve the quality of the Mayak worker data
  - Continually update of vital status
  - Added auxiliary plant workers and workers initially employed 1973-82
  - Extracted data from medical records on smoking, alcohol consumption, pre-Mayak exposures, and medical diagnostic procedures.

- Evaluate dose-response relationships

Dose-response analyses

- Based on annual and cumulative external and internal doses developed and improved under Project 2.4

- Analyses today based on Doses-2005 and mortality data through Dec. 31, 2003

Objectives of Analyses

- Quantify the excess relative risk (ERR) as a function of dose
- For linear model:

  Risk = Baseline [1 + ERR x dose]

- Evaluate the shape of the dose-response function
  - Especially interested in risks at low dose
- Evaluate possible modification of risk by
  - sex
  - attained age
  - age at hire

Results: Internal Plutonium Dose

- Analyses adjusted for external dose
- Highly significant dose-response for lung, liver and bone cancer
- For lung and liver cancer, well described by linear function.

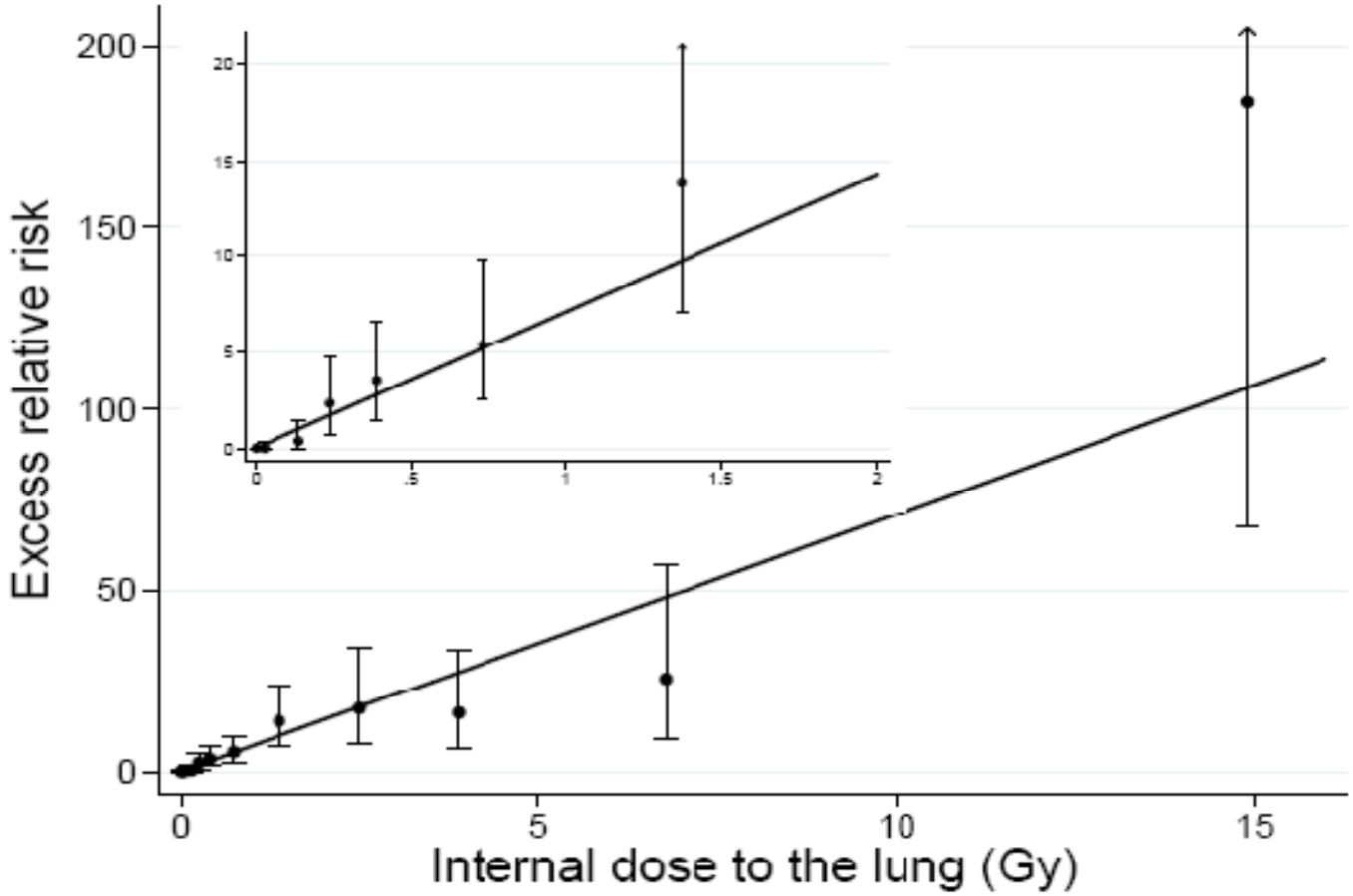
Sokolnikov et al., Int. J. of Cancer, 2008

Lung cancer: Plutonium dose-response

Lung Dose (Gy)	RR (95% CI)	Deaths
0	1.0	139
>0 - .1	0.98 (<1 - 1.3)	111
.1-	1.4 (<1 – 2.4)	16
.2-	3.3 (1.7 – 5.8)	14
.3-	4.5 (2.4 – 7.7)	14
.5-	6.4 (3.5 - 11)	15
1-	15 (8.1 - 25)	16
2-	18 (8.3 – 35)	8
3-	17 (7.1 – 35)	7
5-	27 (10 - 59)	6
10+	186 (69 – 466)	8

Estimates for males.
Estimates for females are a factor of 2.1 higher

Sokolnikov et al. 2008


Excess relative risk
200
150
100
50
0
0
5
10
15
Internal dose to the lung (Gy)
20
15
10
5
0
0
.5
1
1.5
2

Liver cancer: Plutonium dose-response

Dose to liver (Gy)	RR (95% CI)	Deaths
0	1.0	14
>0 – 0.2	1.03 (<1 - 1.8)	9
0.2-	1.5 (<1 - 3.2)	2
1-	4.0 (1.2 - 13)	3
3-	16 (3.3 – 58)	3
5-	43 (12 – 134)	7
10+	36 (4.5 – 196)	2

Estimates for males
Estimates for females are a factor of 11 higher

Sokolnikov et al. 2008

Bone cancer: Plutonium dose-response

Dose to bone surface (Gy)	RR (95% CI)	Deaths
0	1.0	5
>0 - 1	0.9 (<1 – 4.3)	3
1-	0.0 (0.0 – 8.7)	0
5-	0.0 (0.0 – 61)	0
10+	82 (17 – 338)	3*

*Doses of bone cancer deaths were 21, 37, and 85 Gy

Estimates for both sexes.

Sokolnikov et al. 2008

Summary: ERR per Gy for plutonium dose

	Males	Females
Lung:	7.1 (4.9 – 10)	15 (7.6 – 29)
Liver:	2.6 (0.7 – 6.9)	29 (9.8 – 95)
Bone:	0.8 (<0 – 5.2)	3.4 (0.4 – 20)

Sokolnikov et al. 2008

Summary: Shape of plutonium dose-response

	Power of dose (η)
Lung:	1.0 (0.8 – 1.2)
Liver:	1.3 (0.8 – 1.8)
Bone:	2.1 (0.8 – 3.8)

Power function: $\beta\ dose^{\eta}$

Summary: Estimated excess cases from external and plutonium exposure

Cancer	Obs.	Back-ground	External excess	Plutonium excess
Lung	681	424 (62%)	58 (9%)	199 (29%)
Liver	75	42 (56%)	6.3 (8%)	27 (35%)
Bone	30	13 (43%)	3.0 (10%)	14 (47%)
Total	786	479 (61%)	68 (9%)	239 (30%)

Sokolnikov et al. 2008

External Dose: Solid cancers

- Analyses adjusted for plutonium exposure
- Statistically significant increase in solid cancer risk with dose ($p < .001$)
- Remained statistically significant when lung, liver, and bone cancers were excluded

Shilnikova et al., Radiation Research, 2003

External Dose: Leukemia

- Statistically significant increase in leukemia risk with dose ($p < .001$)

Years since dose received	ERR* per Gy
3 - 5 years	7.6 (3.2, 17)
5 + years	0.45 (0.1, 1.1)

*Excess relative risk

Shilnikova et al. 2003

External Dose: Site-specific cancers

- Statistically significant dose-response for lung cancer (Sokolnikov et al. 2008)
- Estimated ERR per Gy for other solid cancers (such as stomach, female breast) compatible with those for the combined category of all solid cancers.
- Small numbers limit conclusions

Future Work

- Dose-response analyses using extended follow-up and Doses-2008
  - Update previous analyses
  - Site-specific cancers
  - Interaction of smoking and radiation
  - Estimates of lifetime risk from plutonium

Future Work

- Utilize data on
  - Smoking
  - Alcohol consumption
  - Occupational exposure before Mayak
  - Radiation exposure from diagnostic medical procedures
- Uncertainties in dose estimates

Smoking in Mayak workers

- Smoking data obtained from medical records
- 75% of males and 4.2% of females reported smoking
- RR for lung cancer by smoking status

	Males	Females
Non-smoker	1.0	1.0
Smoker	9.4 (6.2-15)	4.7 (2.1-9.1)
Unknown	4.7 (2.7-8.3)	1.5 (0.8-2.6)

Liver Cancers by Self-Reported Alcohol Consumption

	Male	Female	Total
Alcohol consumption			
No	3	17	19
Yes	45	5	50
Unknown	3	2	6
Total	51	24	75

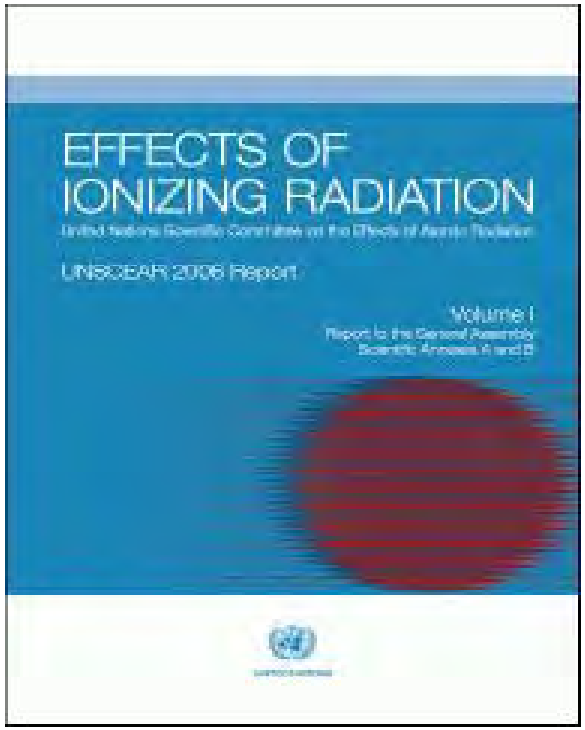
Uncertainties in Plutonium Dosimetry

- Imprecision in urine measurements
- Uncertainties in when plutonium exposure occurred and form of plutonium
- Uncertainties in biokinetic models and parameter values used to estimate deposition and clearance in organs of the body
- Models can only approximate behavior of plutonium in a given individual

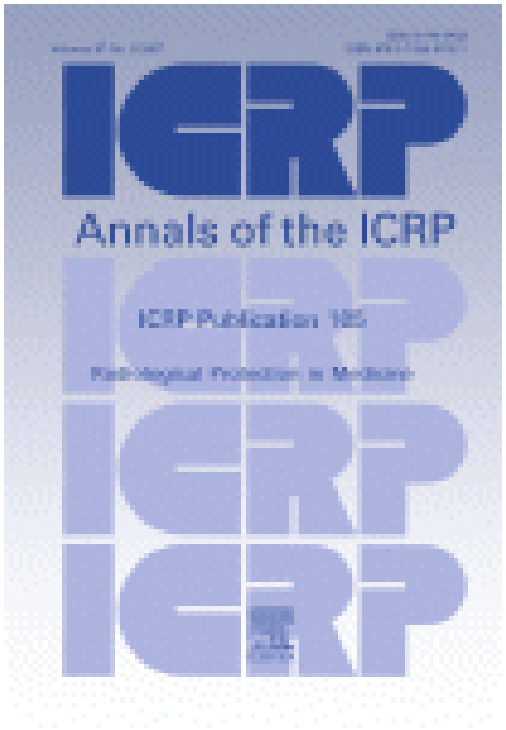
International Impact

BEIR VII, NRC/NAS

UNSCEAR,
United Nations



International Commission
on Radiological Protection



Abstract

JCCRER Project 2.4 – Mayak Worker Dosimetry

M.V. Gorelov,
Mayak Production Association
V.V. Khokhryakov,
Southern Urals Biophysics Institute
R.I. Scherpelz,
Pacific Northwest National Laboratory

The overall goal of JCCRER Project 2.4, "Mayak Worker Dosimetry," is to provide an electronic database containing radiation doses and associated uncertainties to individual Mayak Production Association (MPA) workers for each year of employment for analysis by Project 2.2 (Mayak Worker Epidemiology) researchers to evaluate the association of health effects with protracted radiation exposure compared to acute exposures that were typical of the Japanese atomic bomb survivors.

The project has two general components: external dosimetry and internal dosimetry.

External dosimetry evaluations start with recorded worker dosimeter measurements, or with coworker data for workers with no dosimeter records. The dosimeter readings are corrected for energy and angular response, and workplace-specific correction factors are used to evaluate absorbed dose to individual organs. Doses are evaluated for gamma, neutron and beta exposures. Doses are also evaluated for worker exposure from medical X-ray procedures.

Internal dosimetry evaluations use bioassay data including urine samples and autopsy data to evaluate doses to organs from inhaled plutonium. Lung models have been derived to be applicable to the specific conditions of plutonium inhalation at Mayak facilities.

The results of the internal and external dose evaluations have been compiled in several versions of the Mayak Worker Dosimetry System database. The most recent version, MWDS-2008, was released this fiscal year. This database contained doses for approximately 26,000 Mayak workers. Documentation for the database is currently being prepared
.

The current efforts of Project 2.4 are directed toward MWDS-2011, the next version of the database. This version will include improved uncertainty estimates for all doses; improved biokinetic models for estimating internal doses from inhaled plutonium and other radionuclides, and improved estimates of organ doses from external neutron radiation.

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WASHINGTON D.C.

Project 2.4

Mayak Worker Dosimetry

Project 2.4 Investigators

External Dosimetry

Mayak Production Association:
- Evgeny Vasilenko
- Mikhail Gorelov
- Mikhail Smetanin
- Valery Knyazev
- Igor Teplyakov
- Peter Zharov
- Alexander Sabaev

Robert Scherpelz, PNNL
Daniel Strom, PNNL

Internal Dosimetry

Southern Urals Biophysics Institute
- Victor Khokhryakov
- Klara Suslova
- Vladimir Vvedensky
- Valentin Khokhryakov
- Sergey Romanov

Scott Miller, University of Utah
Alan Birchall, Health Protection Agency
Daniel Strom, PNNL

Project 2.4 Goals

Provide an electronic database

- Containing external doses to Mayak workers
  - Occupational
  - Medical
- Containing internal doses to Mayak workers
- Suitable for analysis by Project 2.2 epidemiologists

  Evaluating the association of health effects with radiation exposure
- Database documentation
  - Methodology
  - Technical basis
  - Limitations

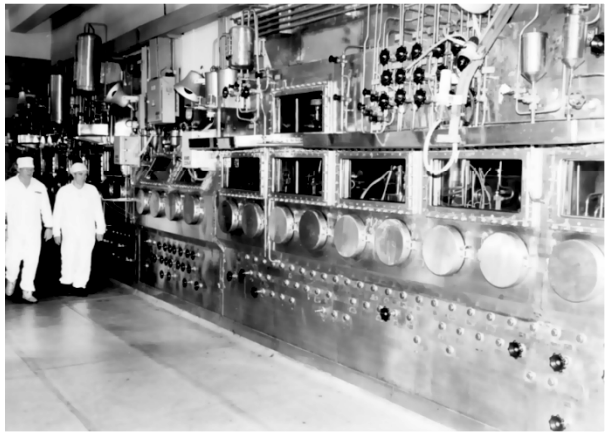
Background

- Mayak site began operation in 1948
- Mayak workers received significant occupational doses until mid-1950's
- External exposures were protracted rather than acute
- Intakes of plutonium were significant in early years of operation
- This study provides a unique and important dataset for health effects research

Main cohort under investigation
Workers hired in 1948 - 1972

Reactor production

Radiochemical production

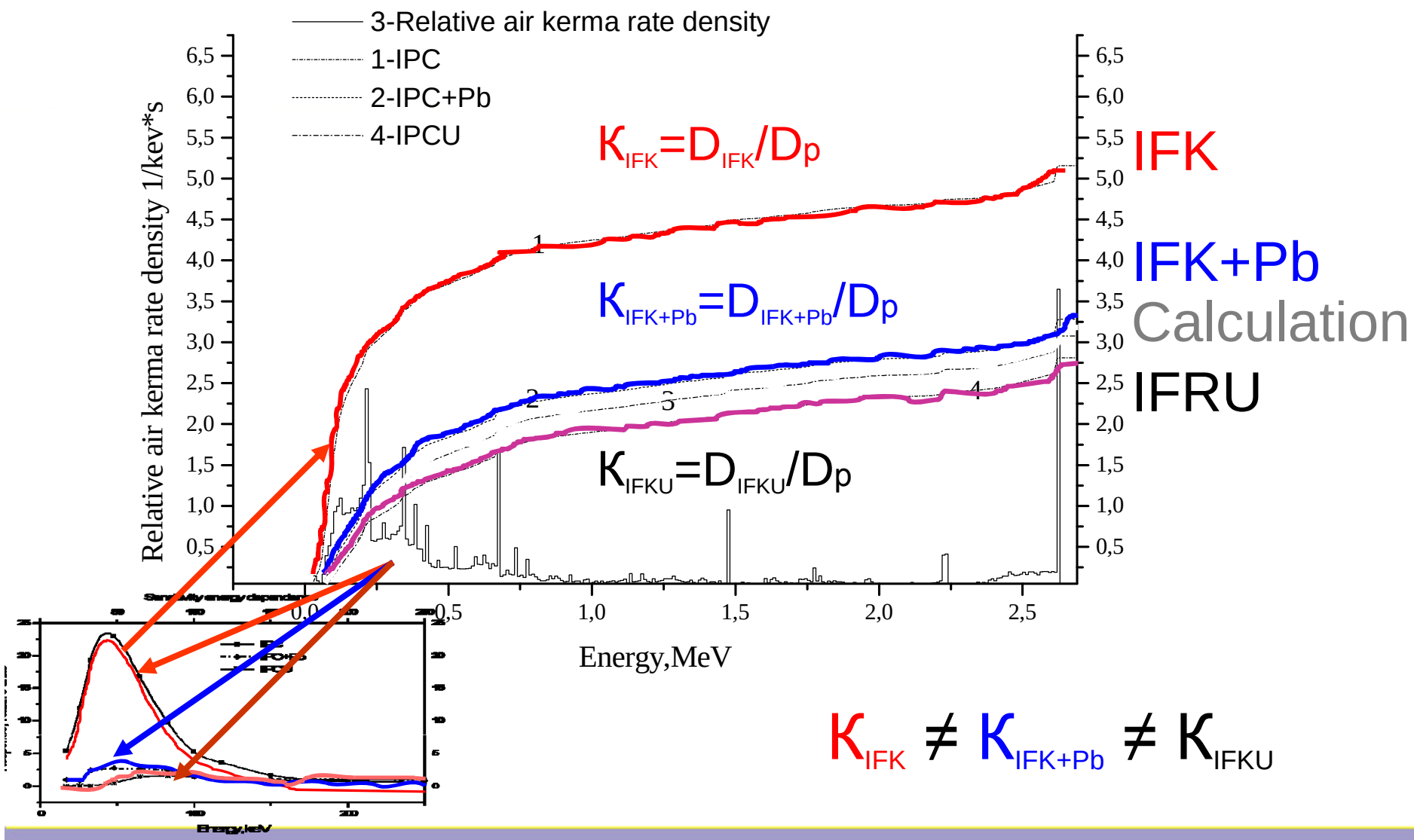


Plutonium production

External Dosimetry: Current Work

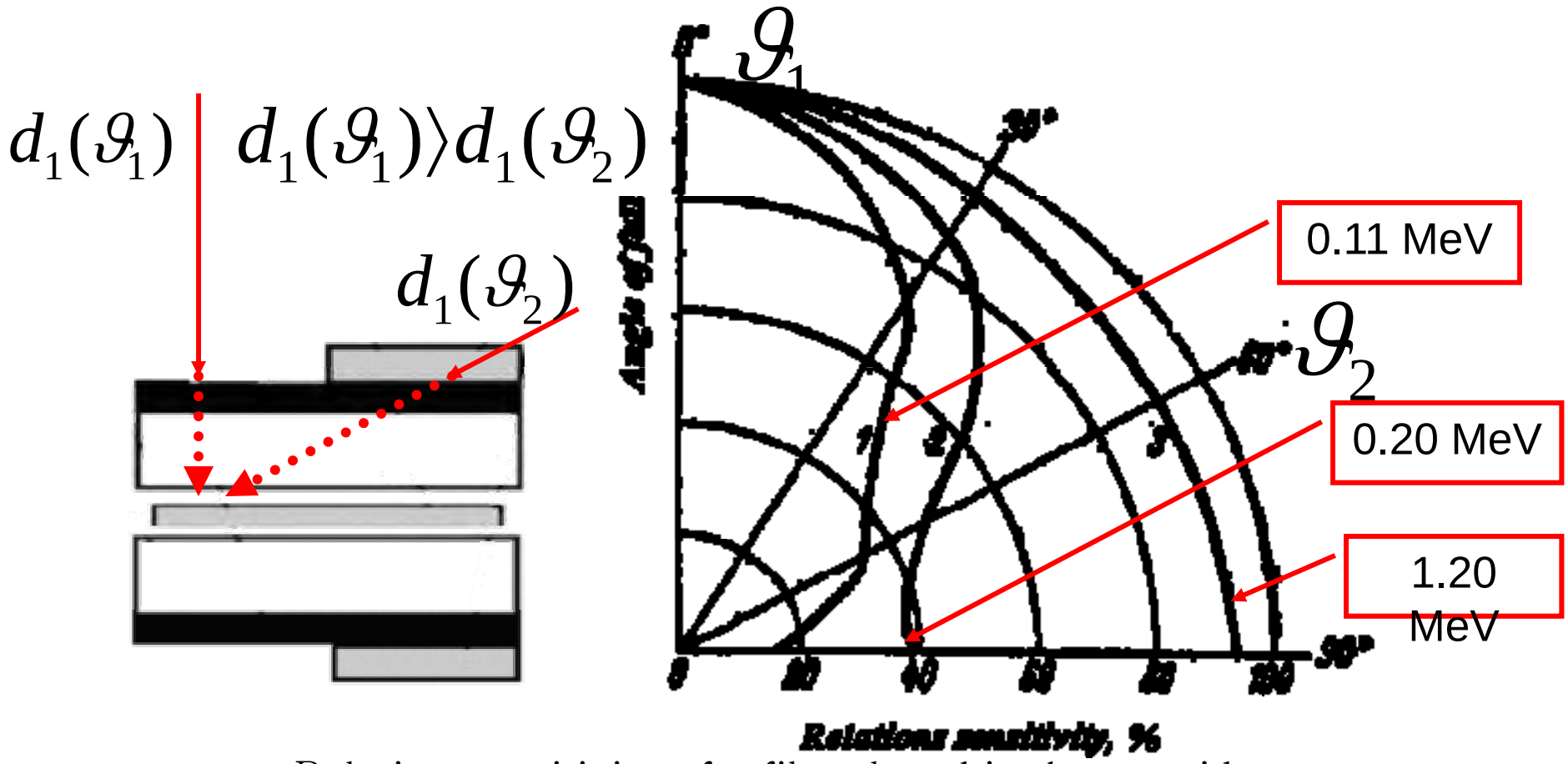
(Mikhail Gorelov, MPA)

Film badge energy response



$$K_{IFK} \neq K_{IFK+Pb} \neq K_{IFKU}$$

Film badge angle response

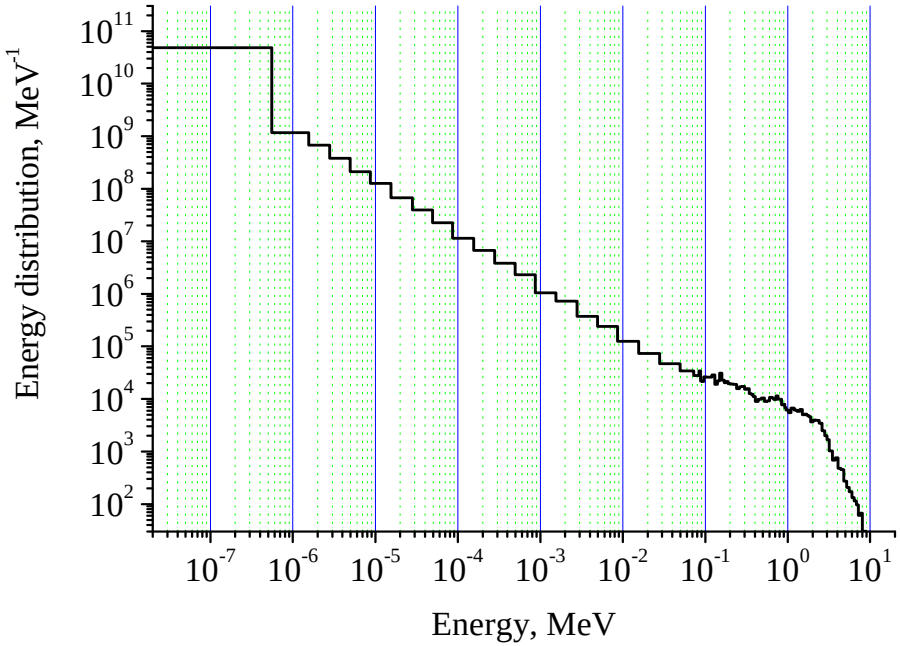


Relative sensitivity of a film placed in the cartridge NBS, at various angles of fall and energy of gamma-radiation
for 0.11 MeV; 0.20 MeV; 1.20 MeV

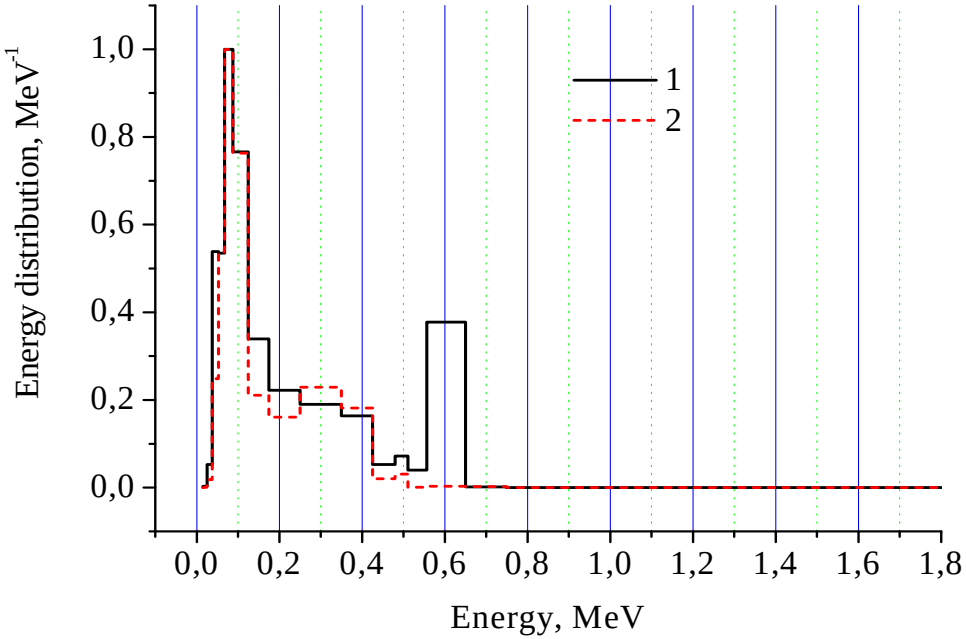
Neutron exposure

Spectrum calculation at workplaces

Neutron radiation



Photon radiation

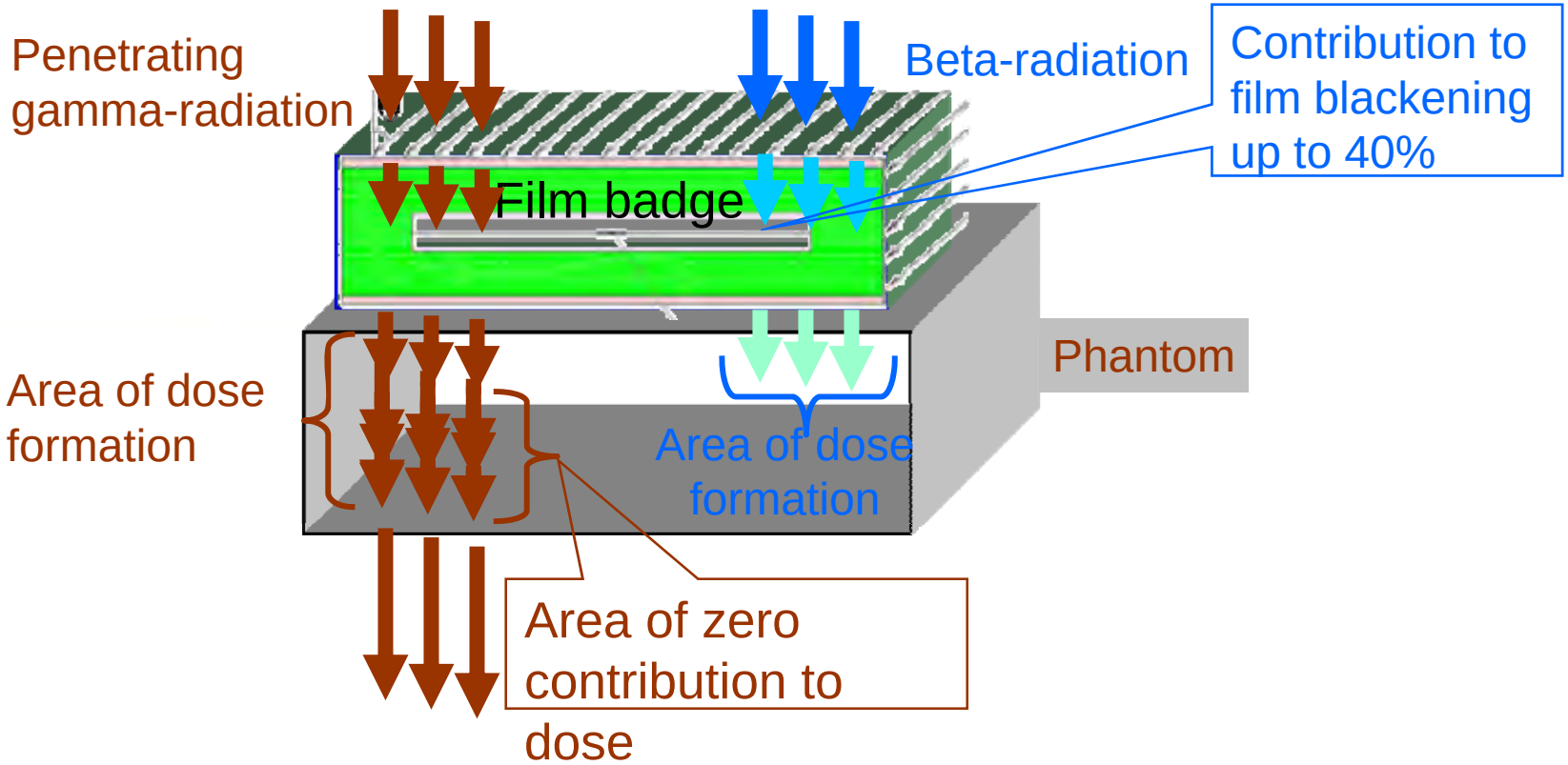


Calculation of dose relation coefficients

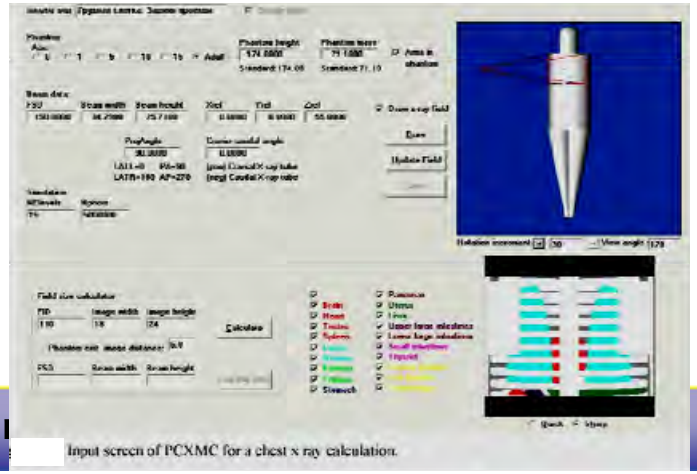
$K_1 = D_{1\,n} / D_{1\,\gamma}$ $K_2 = D_{2\,n} / D_{2\,\gamma}$ $K_3 = D_{3\,n} / D_{3\,\gamma}$

$K = F$(P, t, exposure scenario…)

Effect of hard beta-radiation



Medical exposure



Input screen of PCXMC for a chest x ray calculation.

Stage I 1997-1999 DOSES 1999

Database contained individual archive gamma-doses for a cohort of 18,850

Stage II 1999-2000 DOSES 2000

Doses 1999

+ Individual gamma-doses improved with the account for photon spectra at workplaces and film badge energy response
+ Preliminary results of individual neutron dose reconstruction
+ Preliminary results of individual dose uncertainty estimation

Stage III 2001-2005 DOSES 2005

Doses 2000

+ Individual gamma-doses verified with the account for spectrum and angle photon distribution at workplaces and spectrum and angle film badge response considering phantom effect:
  absorbed dose in air;
  dose gamma-equivalent, Hp(10).
+ Reconstructed individual absorbed photon doses to 18 target organs.
+ Improved estimates of neutron doses :
  dose neutron equivalent, Hp(10).
+ Reconstructed photon doses to personnel not subjected to individual dose monitoring.
+ Reconstruction of individual non-routine doses.
+ Uncertainties of gamma, neutron and organ doses to 18 target organs

Stage IV 2006-2008 MWDS 2008

MWDS 2008

1. Extension of the cohort
2. Off-site doses
3. Doses to target organs due to X-
   procedures and uncertainties in
   their estimates
4. Improvement of methods for
   individual gamma-dose
   reconstruction to workers
5. Improvement of methods for
   individual neutron-dose
   reconstruction to workers
6. Assessment of contributions
   and s
   indivi
7. New a
   indivi
   Expos
   releases. JCCRER Project 1.4

Number of workers :

1. Total – 18831 / 25940
2. Male – 14072 / 19542
3. Female – 4759 / 6398

Number of records:

1. Occupational histories - 65505 / 80859
2. Annual doses - 250443 / 299027
3. Daily doses - 725746

Production structure:

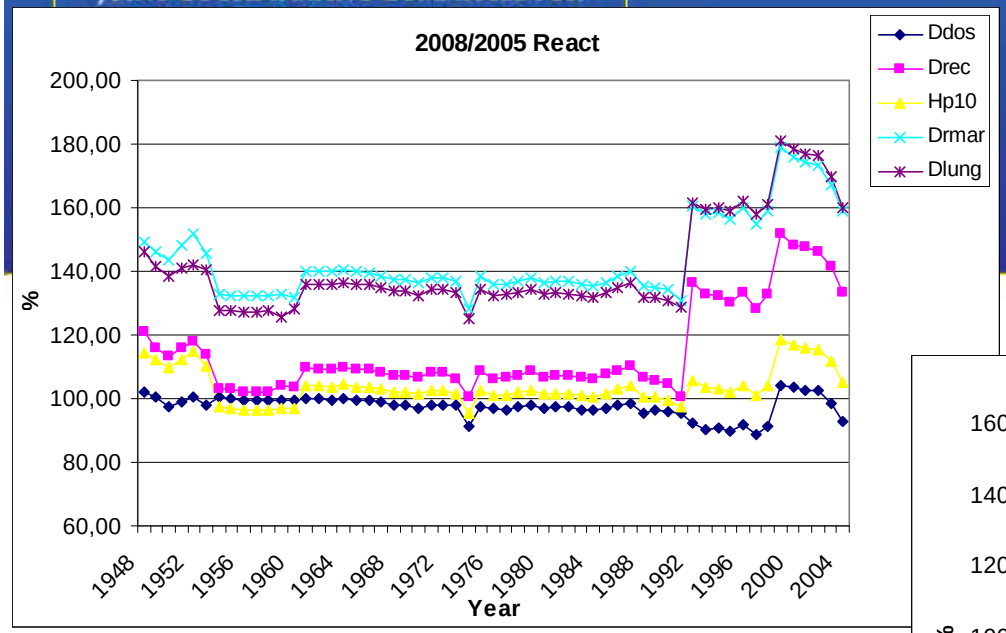
1. Number of productions - 3 / 3
2. Number of shops - 241 / 268
3. Number of areas - 693 / 761
4. Number of workplaces - 8141 / 10774
5. Number of exposure scenarios- 11 / 140

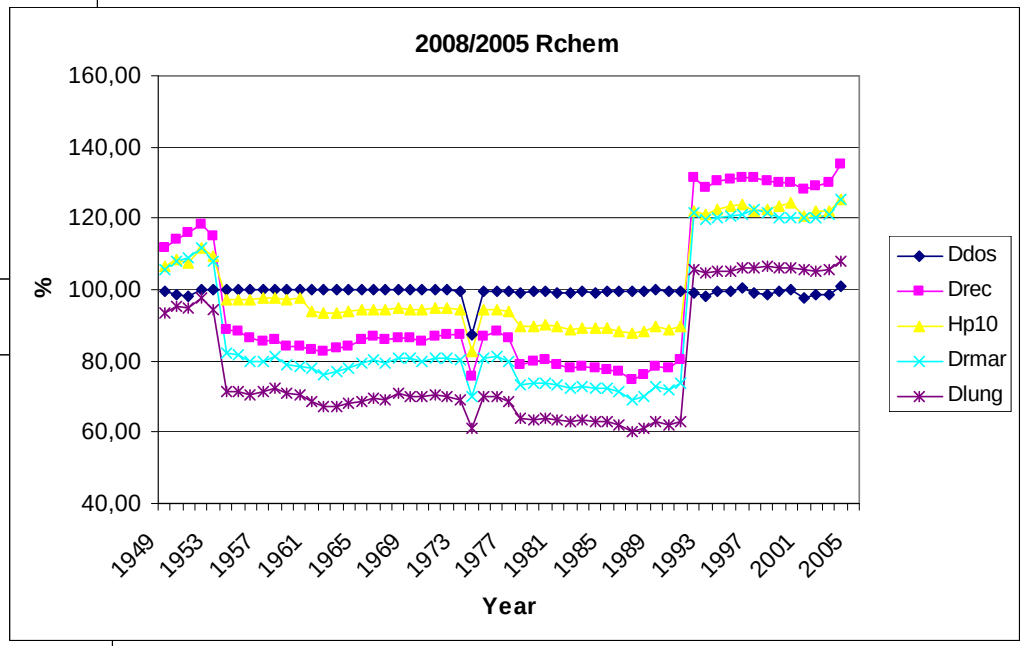
1. Work duration - 372.2 / 558.6 thousand person-yrs
2. Dosimetric monitoring duration - 279.5 / 412.3 thousand person-yrs
3. Measured overall dose - 11522 / 14826 person-Gy
4. Overall corrected dose
4. Overall dose Hp(10) 12989 person-Sv

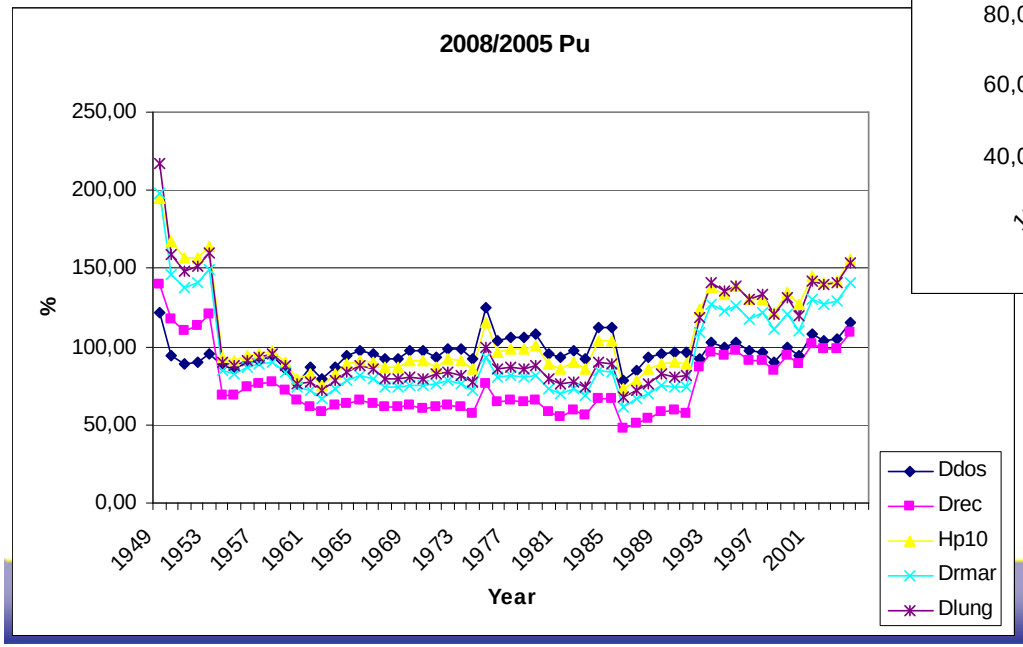
Data for Project 2.2 epidemiologists

Annual doses	- archival γ;dose - point estimate, maximum and minimum absorbed γ dose in air; - point estimate, maximum and minimum γ dose equivalent; - point estimate, maximum and minimum n dose equivalent; - B dose.
Annual γ – doses to organs	- point estimate, maximum and minimum dose to 18 target organs
Annual n – doses to organs (LET≤1)	- point estimate, maximum and minimum dose to 18 target organs
Annual n – doses to organs (LET>1)	- point estimate, maximum and minimum dose to 18 target organs
Total annual n – doses to organs	- point estimate, maximum and minimum dose to 18 target organs
Annual organ doses (medical exposure)	- point estimate, maximum and minimum dose to 18 target organs
Occupational history information	- Time period - Plant - Shop - Area - Occupation

Dose characteristics MWDS-2008 vs DOSES-2005



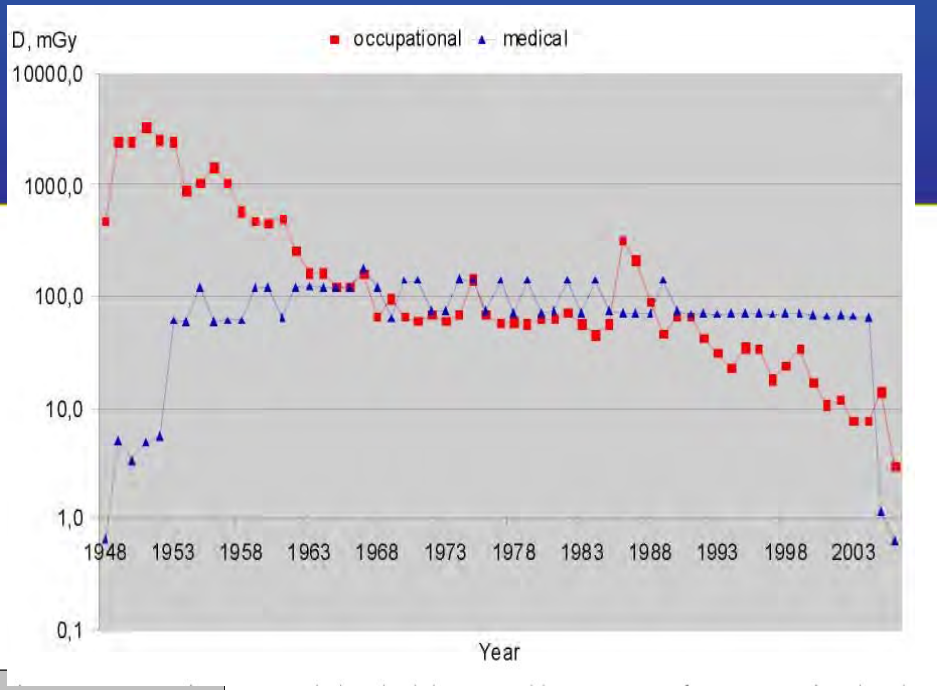


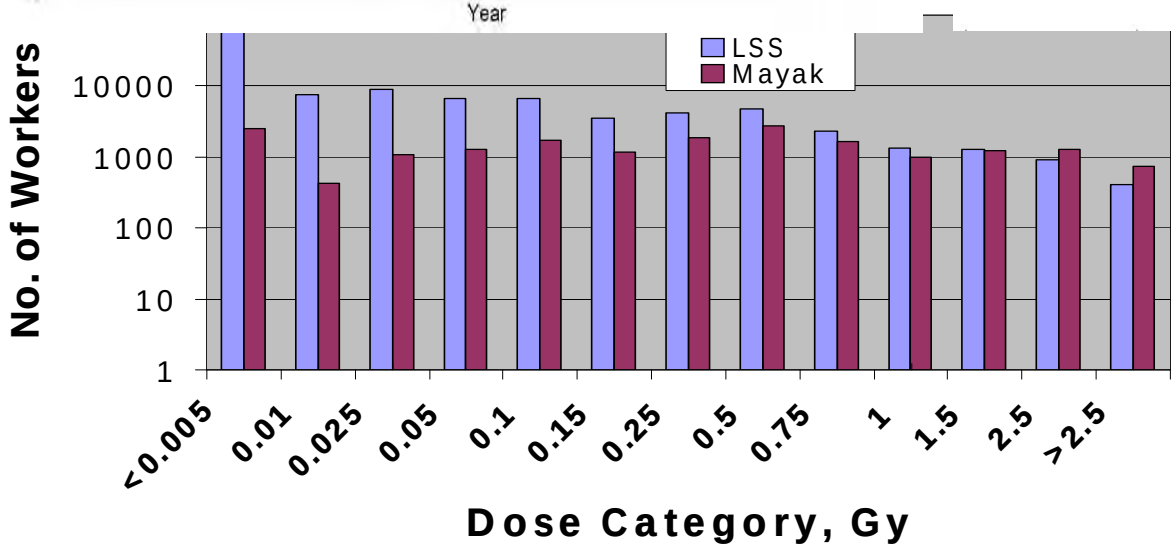


Occupational and medical exposure to RBM

Average annual absorbed dose to RBM due to occupational and medical exposure

Maximum annual absorbed dose to RBM due to occupational and medical exposure





Comparison of accumulated absorbed dose to liver for LSS and MWC

*Life Span Study data courtesy of Radiation Effects Research Foundation

Internal Dosimetry: Current Work

(Victor Khokhryakov, SUBI)

Status of Dosimetry Cohort

Mayak PA workers examined with biophysical method

Production Facility	Year of initial contact (number in cohort)					
	1948-1953 (I)	1954-1958 (II)	1959-1963 (III)	1964-1972 (IV)	1973 - 1977 (V)	1978 - 2009 (VI)
Plutonium	728	489	634	683	504	502
Radiochemical	1315	785	583	408	648	714
Reactors	147	43	40	13	54	0
Sum	2190	1317	1257	1104	1206	1216

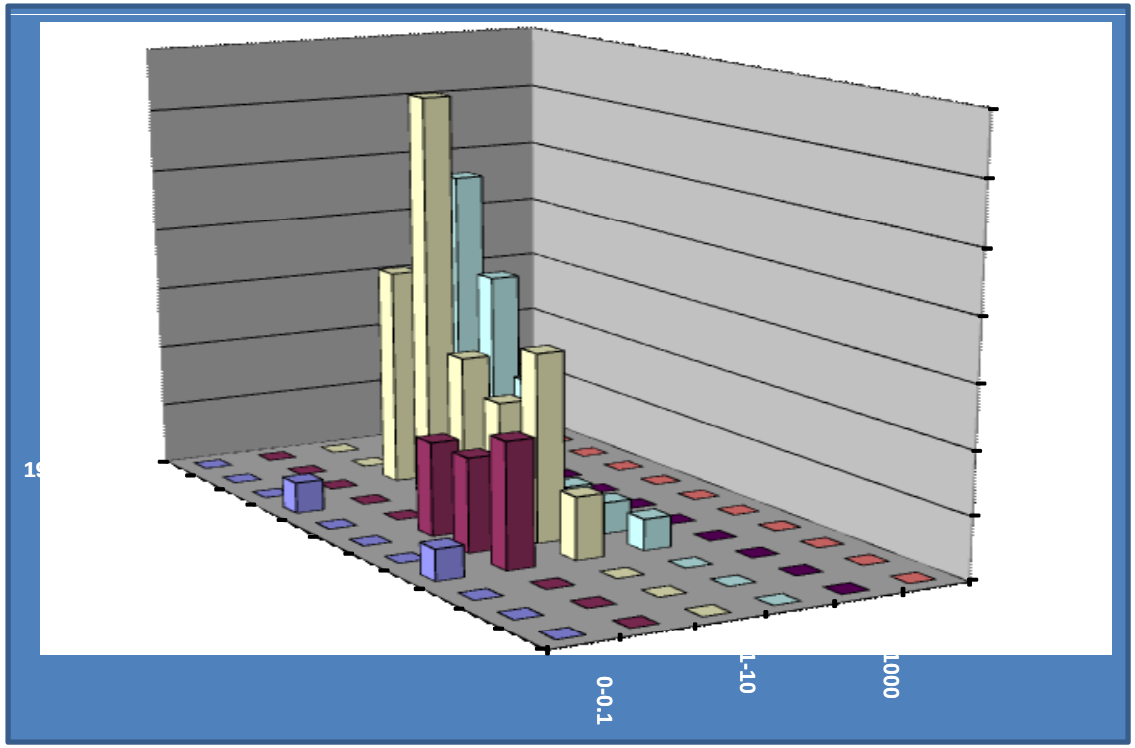
Verification of Model MWDS-2008

Relation of organs and tissues content X_g calculated by urine bioassays according to the MWDS-2008 model to autopsy organs content

S,%	N	Lungs	Lung lymph nodes	System	Body
0,3	14	X_g=1,00 σ_g =3,64	X_g =0,81 σ_g =4,97	X_g =0,84 σ_g =1,87	X_g =0,71 σ_g =2,32
1,0	76	X_g =1,06 σ_g=3,27	X_g =0,80 σ_g =4,72	X_g =0,90 σ_g =1,77	X_g =0,81 σ_g =1,77
3,0	48	X_g =1,54 σ_g =2,96	X_g =1,71 σ_g =3,68	X_g =1,15 σ_g =2,32	X_g =1,14 σ_g =2,30

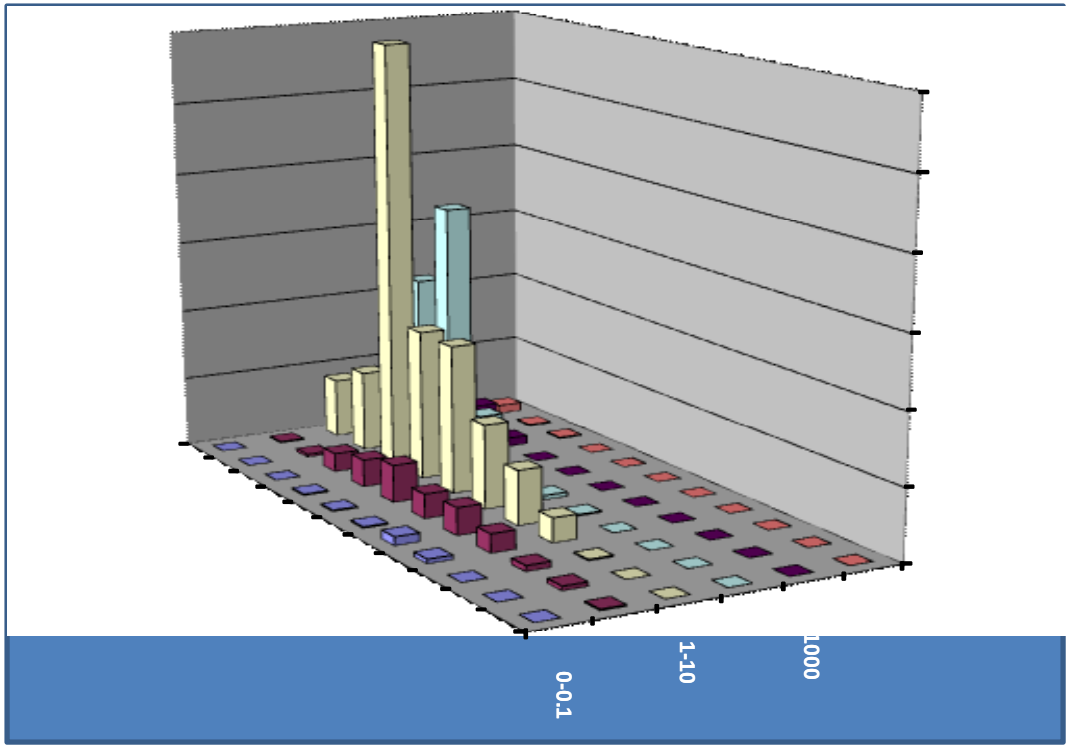
MWDS-2008

Distribution of quantity of professional workers by levels of accumulated absorbed lung doses due to the contact starting year, cGy (transportability S=0.3)



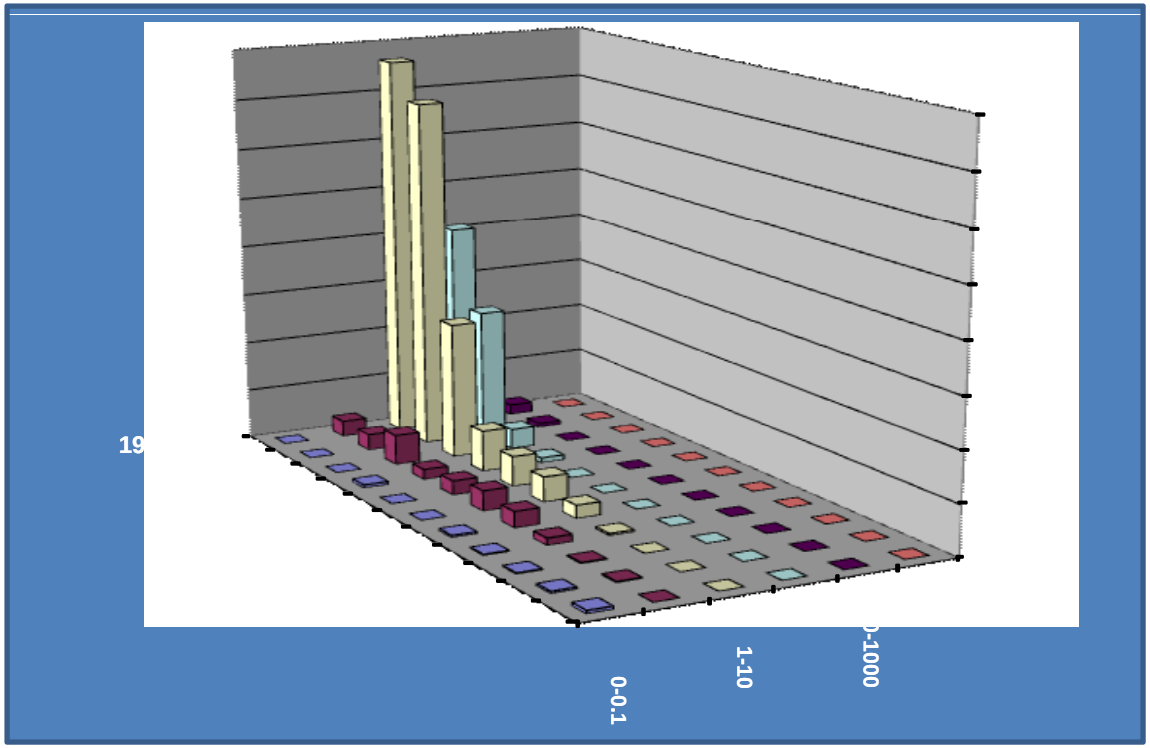
MWDS-2008

Distribution of quantity of professional workers by levels of accumulated absorbed lung doses due to the contact starting year, cGy (transportability S=1)



MWDS-2008

Distribution of quantity of professional workers by levels of accumulated absorbed lung doses due to the contact starting year, cGy (transportability S=3.0)



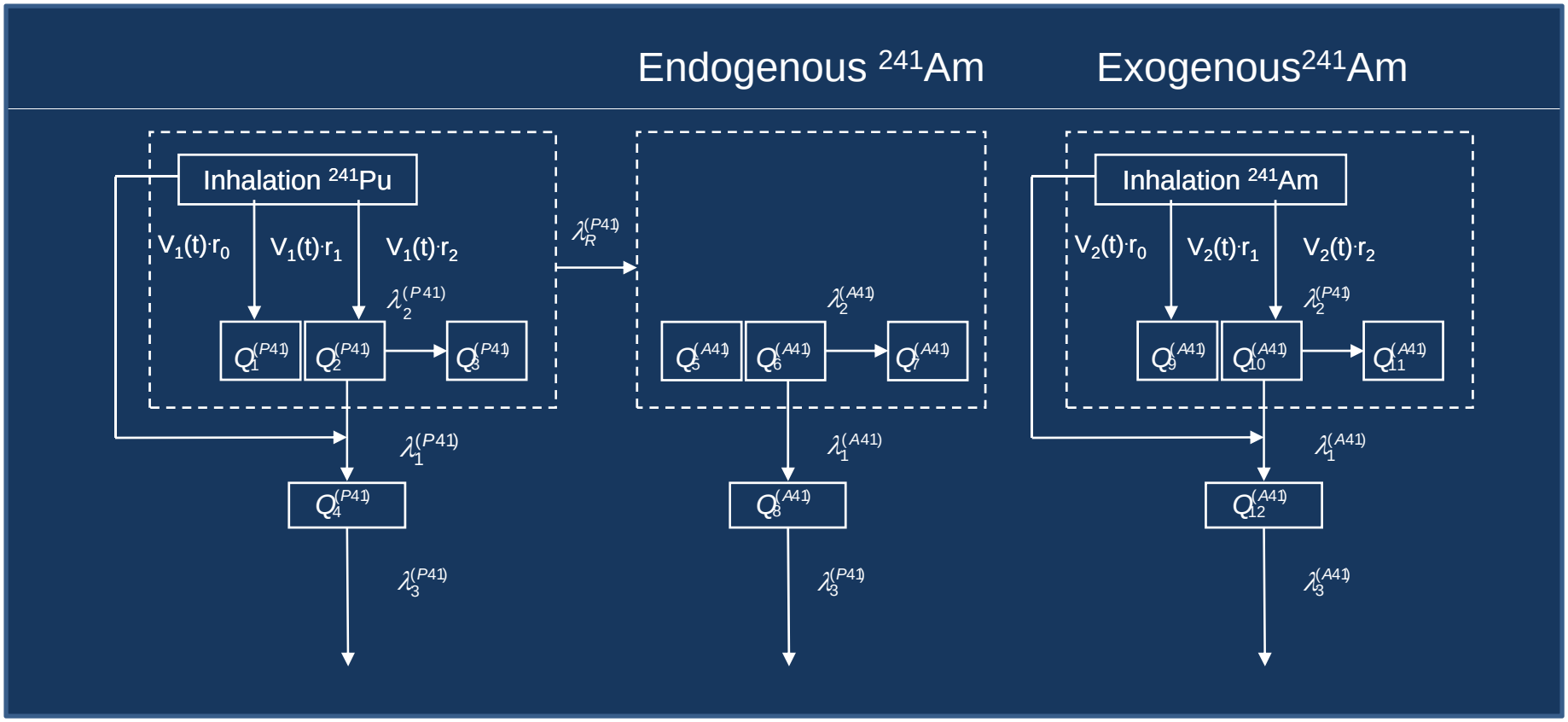
Radionuclide Composition of Aerosols

Distribution of total alpha activity by radionuclide

Nuclide	Range
Radiochemical production plant	
^{238}Pu	from 42% to 71%
^{239}Pu	from 20% to 22%
^{241}Am	from 7.5% to 33%
Plutonium production plant	
^{238}Pu	within (1 to 2)%
^{239}Pu	from 19% to 96%
^{241}Am	from 2.3% to 78%

^{241}Am Metabolism

Model D-Am$_2$



^{241}Am Metabolism

Verification of D-Am_2 Model

	Organ/Tissue		Correlation coefficient
Foundry	Lung	0,913	0,83
	Lymph nodes	1,64	0,74
	Lung + Lung nodes	1,18	0,85
	Systemic	0.993	0,93
	Lung	0,823	0,88
	Lymph nodes	1,05	0,44
	Lung+Lung nodes	0,999	0,79
	Systemic	0,903	0,91
Radiochemical	Lung	0,763	0,62
	Lymph nodes	0,695	0,30
	Lung + Lung nodes	0,895	0,65
	Systemic	0,833	0,82

Studies of ^{238}Pu Metabolism

Fraction of ^{238}Pu activity in total Pu for Mayak PA workers' urine

Characteristics	Cohorts				
	I 1948-53	II 1954-58	III 1959-63	IV 1964-72	V 1973-82
Radiochemical production plant					
Number of examinations of them > MDA	79 25	49 19	30 11	19 4	79 13
^{238}Pu / Σ $^{238+239}$Pu,% Range Mean , M ± σ	0.4–10.9 3.2±3.4	1.7–75.4 17.8±22.5	8.4–84.1 45.5±27.4	7.9–64.9 37.7±29.2	4.0–95.0 53.1±21.8
Plutonium production plant					
Number of examinations of them > MDA	46 7	30 8	23 4	20	86
^{238}Pu / Σ $^{238+239}$Pu,% Range Mean, M ± σ	0.6–10.0 5.2±4.2	0.7–2.0 1.2±0.4	1.6–6.6 3.1±2.4		

Project 2.4: Future Directions

(Bob Scherpelz, PNNL)

External Dosimetry: Current and Future Directions

- Document MWDS-2008

- Develop the MWDS-2011 Database
  - Improved phantom for organ dose assessment
  - Improved calculation of neutron doses
  - Improved beta doses (7 mg/cm^2)
  - Improved uncertainty assessment

Internal Dosimetry Modeling Directions

- Utilize IMBA and WeLMoS methods to:
  - Incorporate Bayesian uncertainty estimates into dose estimates
  - Investigate the impact of different internal models
  - Harmonize dose estimates based on urinalysis and autopsy

- These directions are under initial exploration
  - New participation of Dr. Alan Birchall

Internal Dosimetry Future Directions

- Documentation of MWDS-2008
- Collect more bioassays and autopsies
- Development of the ^{241}Am metabolism and dosimetry model
- Studies of ^{238}Pu metabolism and dosimetry
- Harmonize dose assessments based on
  - Urinalysis
  - Autopsy data
- Studies of chemical and physical properties of industrial aerosols
- Merge Project 2.5 into Project 2.4

JCCRER Project 2.5

Raymond Guilmette, Ph.D.

Principal Investigator

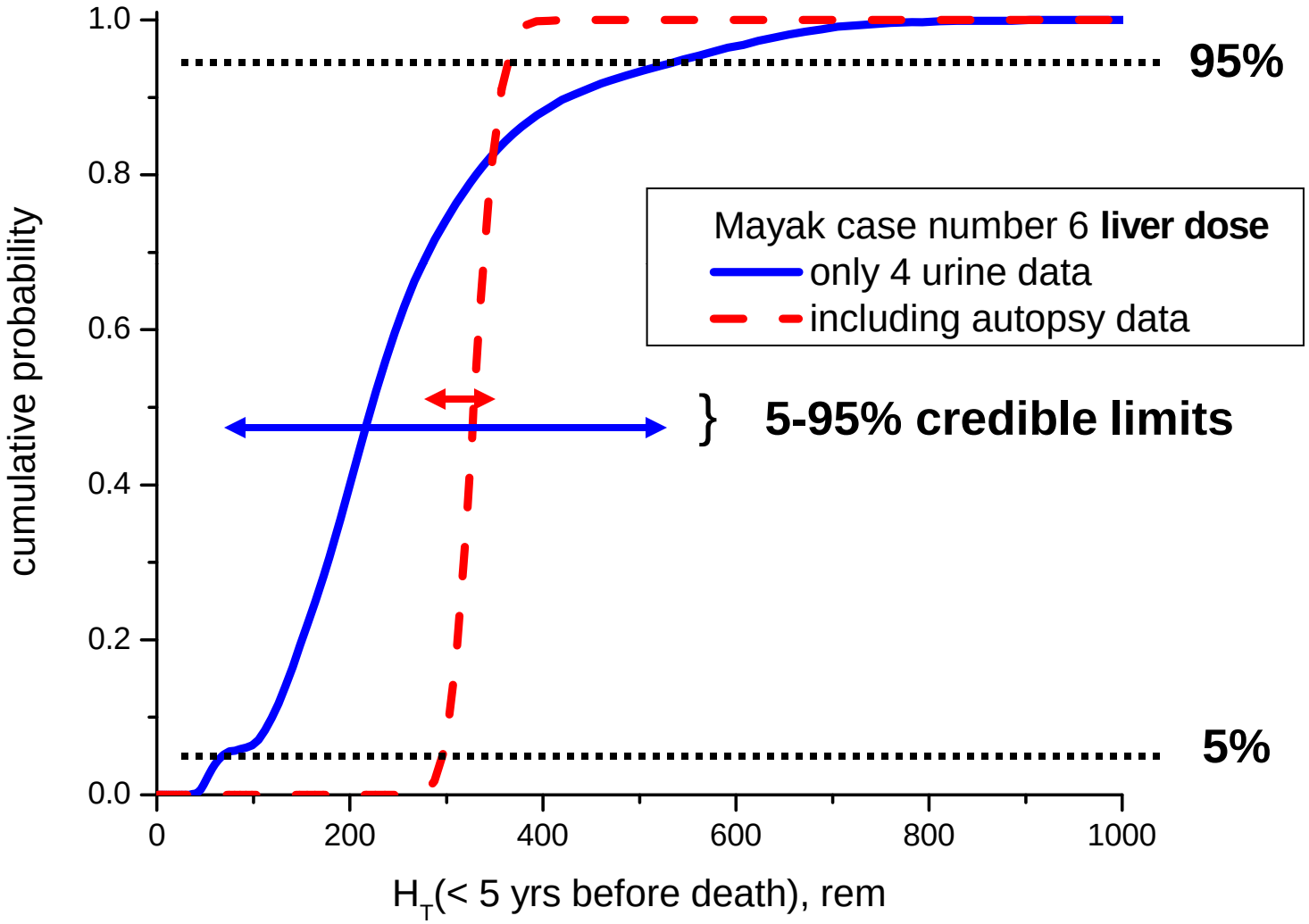
Sergey Romanov, Ph.D.

Principal Investigator

The Bayesian Difference

- The definitive portrait of uncertainty: Bayesian inference produces a *probability distribution* for the quantities of interest (such as dose), rather than a single “best estimate.”
- Measurements have a context: *Prior knowledge* about the population being sampled is rigorously incorporated into the process of measurement interpretation.

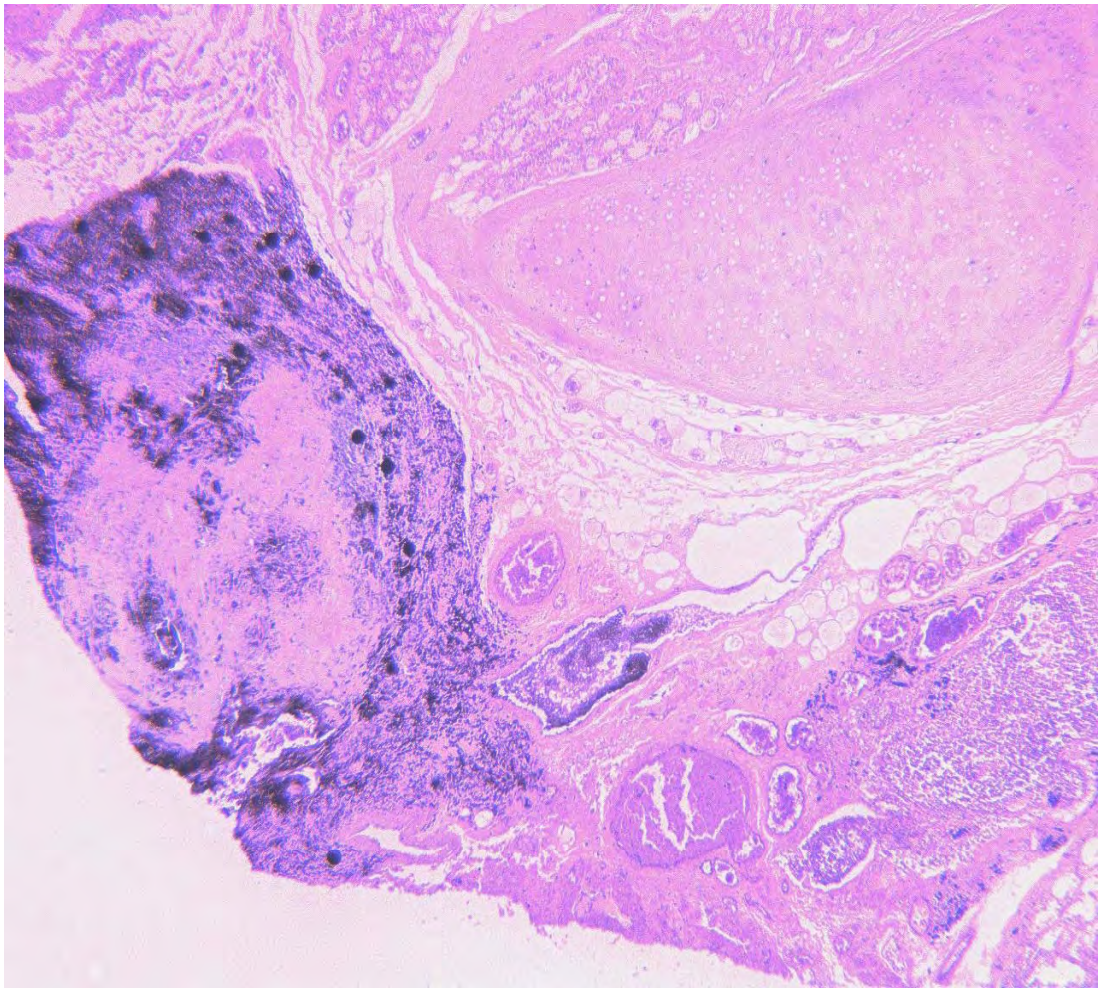
CUMULATIVE PROBABILITY DISTRIBUTION OF ABSORBED LUNG DOSE



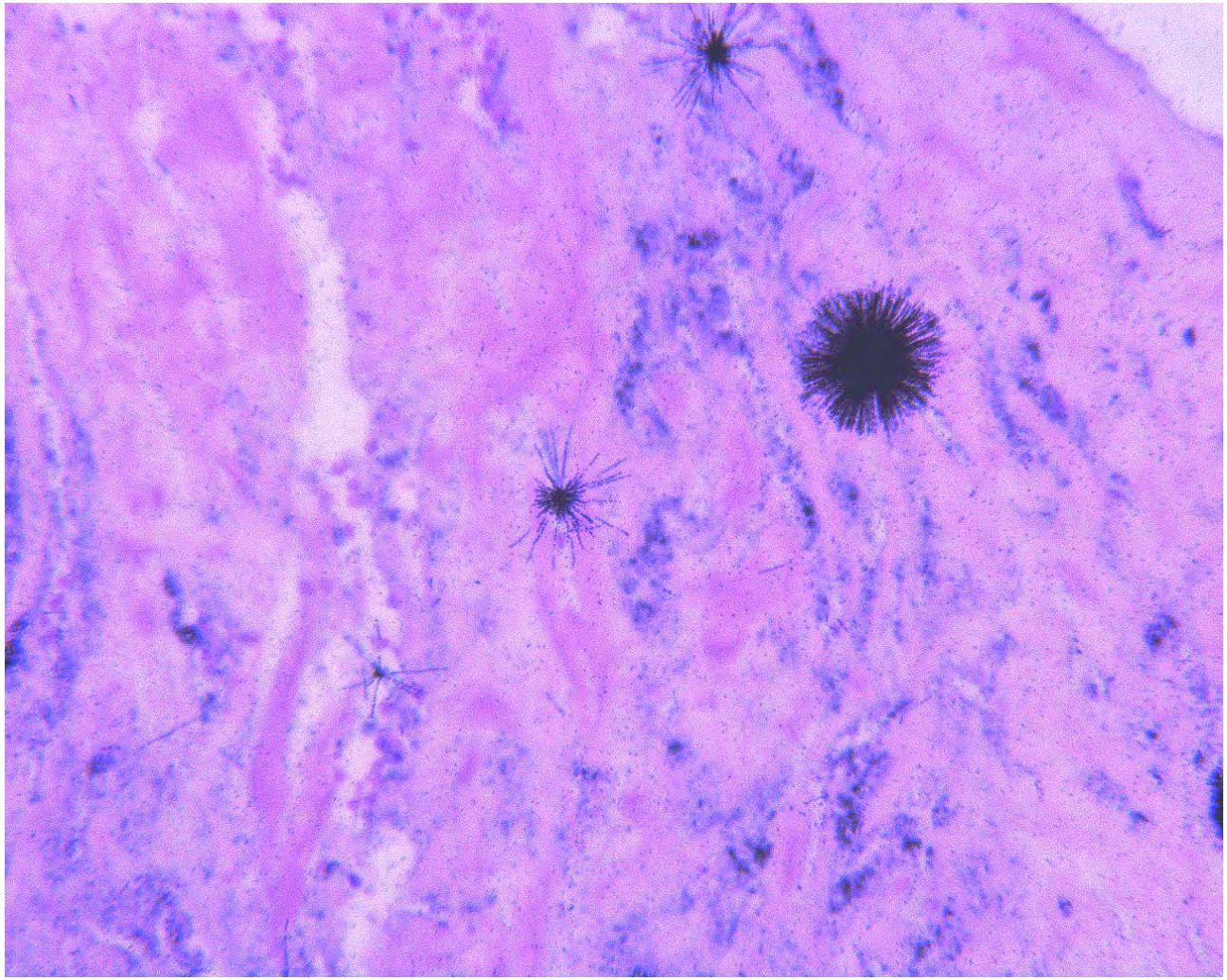
Why such uncertainties?

- ✓ Microdistribution Pu in lung
- ✓ Fixed Pu fraction in the lung
- ✓ Early biokinetics (rapid absorption to blood associated with solubility)
- ✓ Particle sizes (submicron aerosols?)

Pu particles in the non-parenchymal scar



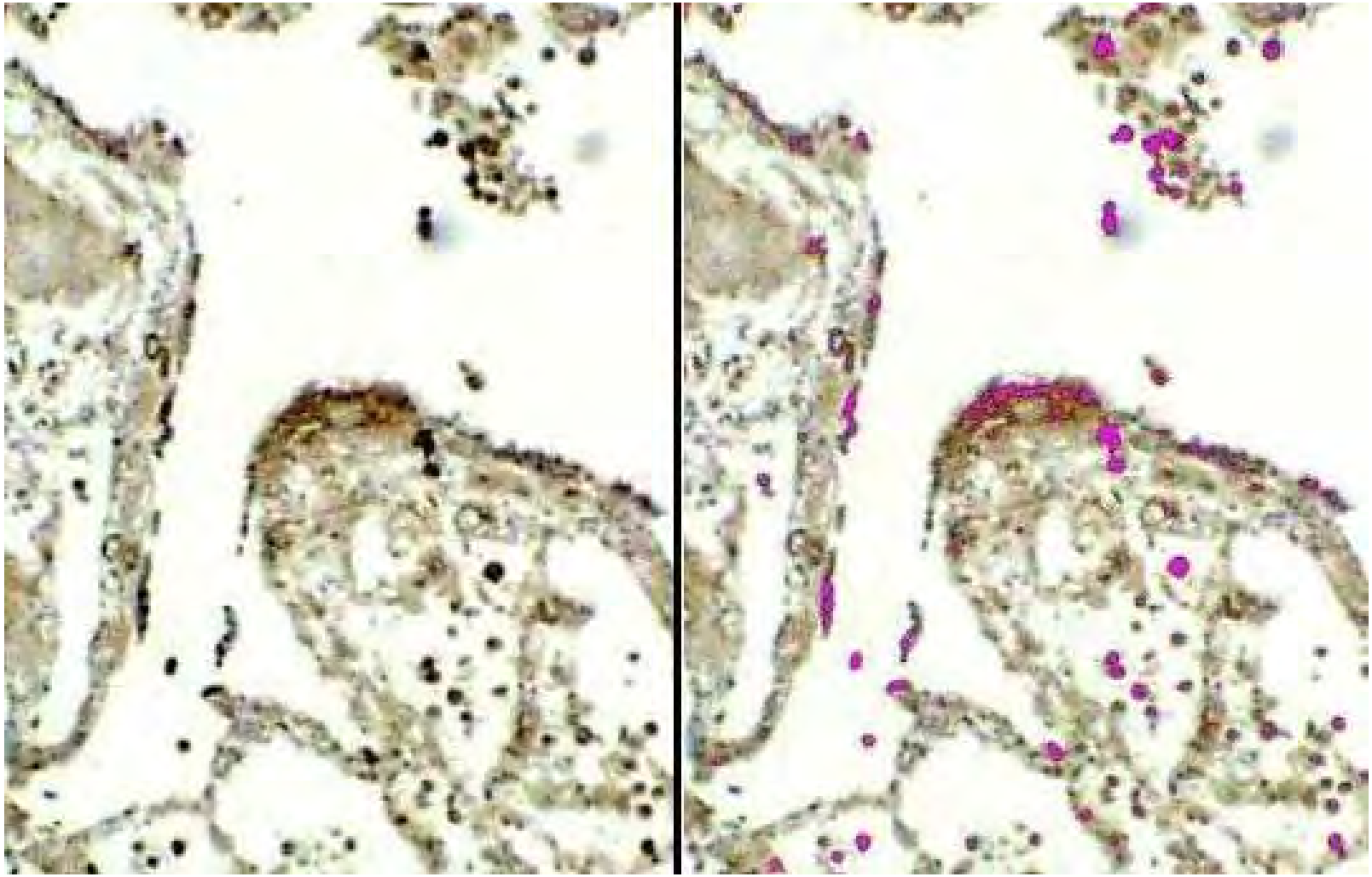
Pu particles in the non-parenchymal scar (higher magnification)



PHASE III PROJECT GOALS

- **To use Monte Carlo computational methods to calculate regional alpha-particle radiation dose and dose-rate patterns in the parenchymal regions of the lung to evaluate the extent and magnitude of nonuniformity of radiation dose delivered to the lung.**

IMMUNOHISTOCHEMICAL STAINING OF CLARA CELLS IN BRONCHIOLES



Why such uncertainties?

- ✓ Microdistribution Pu in lung
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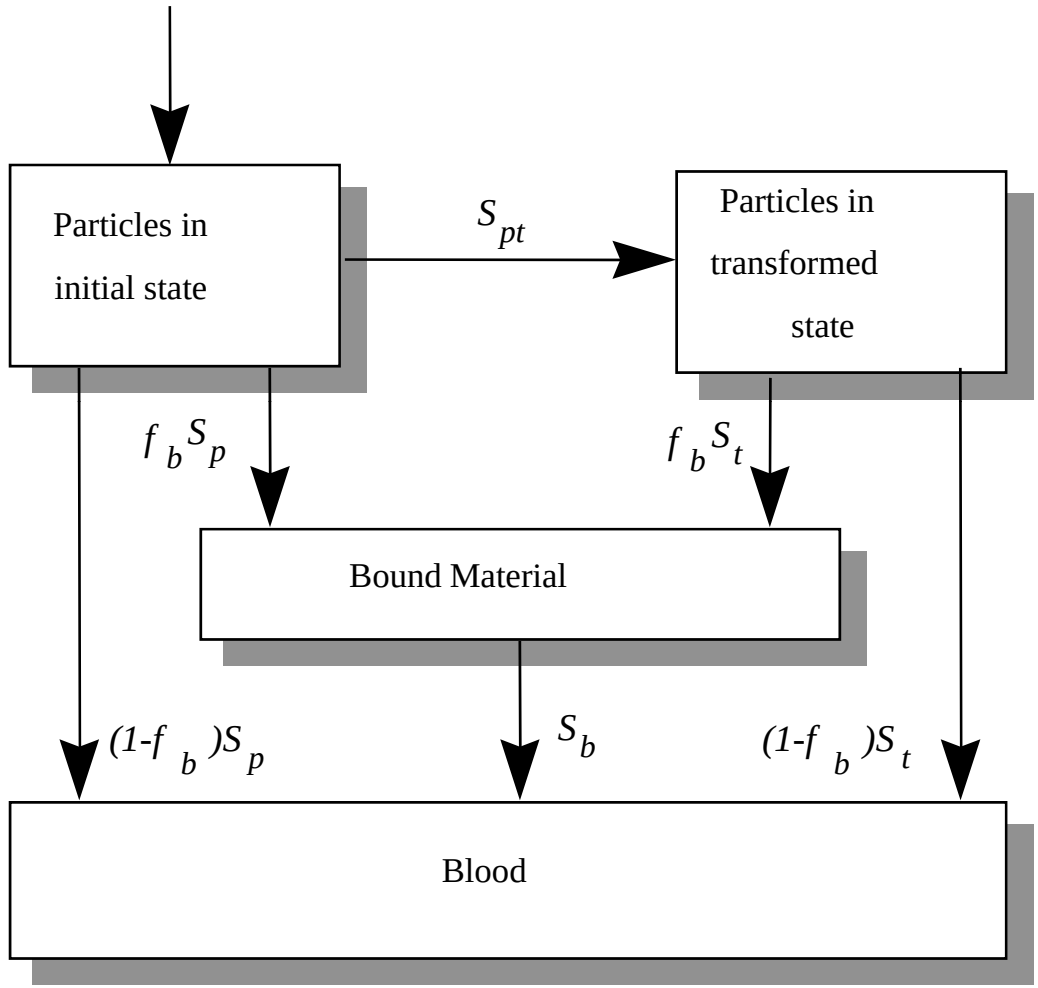
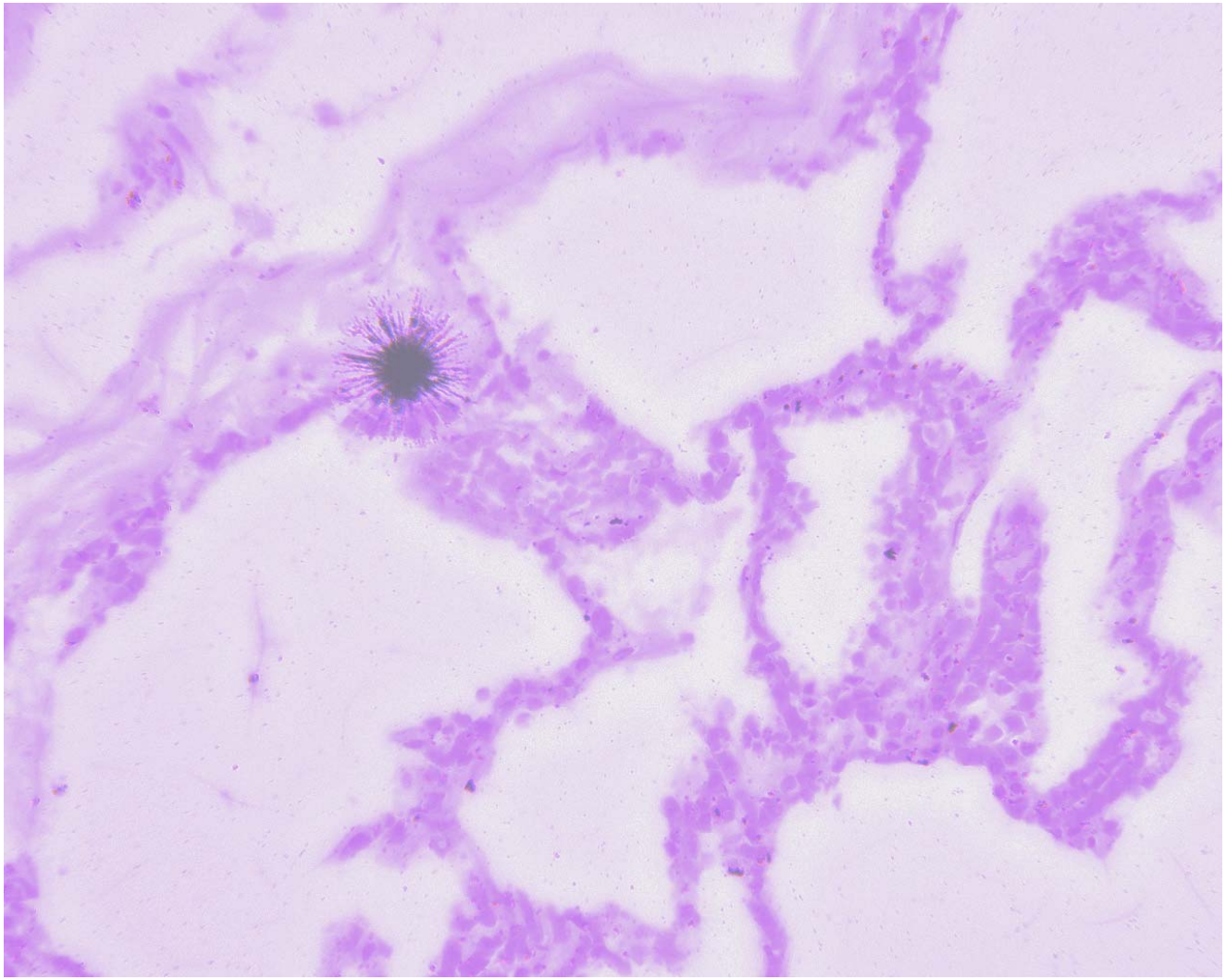
BLOOD ABSORPTION - HRTM



Pu particle in the parenchymal scar



VALIDATION STUDIES FOR AEROSOL DATA FROM MAYAK WORKPLACES

In Vitro Solubility

- **Comparison of dialysis vs. SUF vs. PSF solvents**
- **In vitro analysis of contemporary filters**
- **In vitro analysis of archived filters**

IN VITRO SOLUBILITY

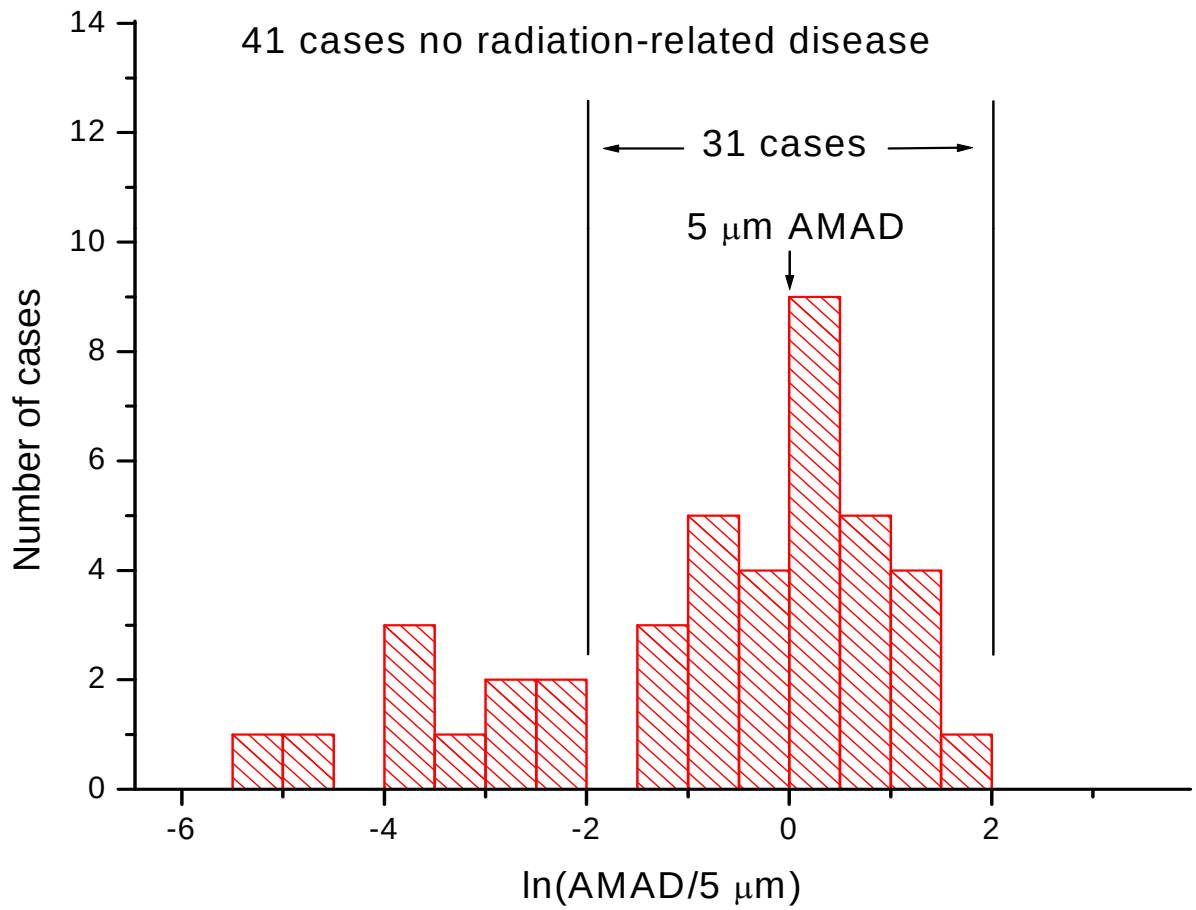
- **Studies on new filters with Pu nitrate show:**
  - **S = 3% for Ringers solution (traditional SUBI)**
  - **S = 21% for SUF (LRRI solvent, pH 7.4)**
- **Affects lung dose estimate for rapid dissolved fraction by 4x**
- **More samples being analyzed for both particle size and solubility**

VALIDATION STUDIES FOR AEROSOL DATA FROM MAYAK WORKPLACES

Particle Size

- **Russian studies (1980s, 1990s) measured solubility, resulting in Khokhryakov transportability factor, S, and average particle size of 1 µm AMAD**
- **Track-etch autoradiography of archived air sample filters. Results in progress.**
- **Expert judgment of processes and environment**
- **Comparison with fitted results**

AMAD FITS FOR 41 MAYAK CASES WITHOUT RADIATION DISEASE



JCCRER 2.5 APPROACH

- **Use data from good worker cases to build knowledge base that can be applied to cases with little data.**
- **Bayesian statistical methods**
  - **Build prior probability distributions**
  - **Obtain posterior distributions of dose with uncertainties**

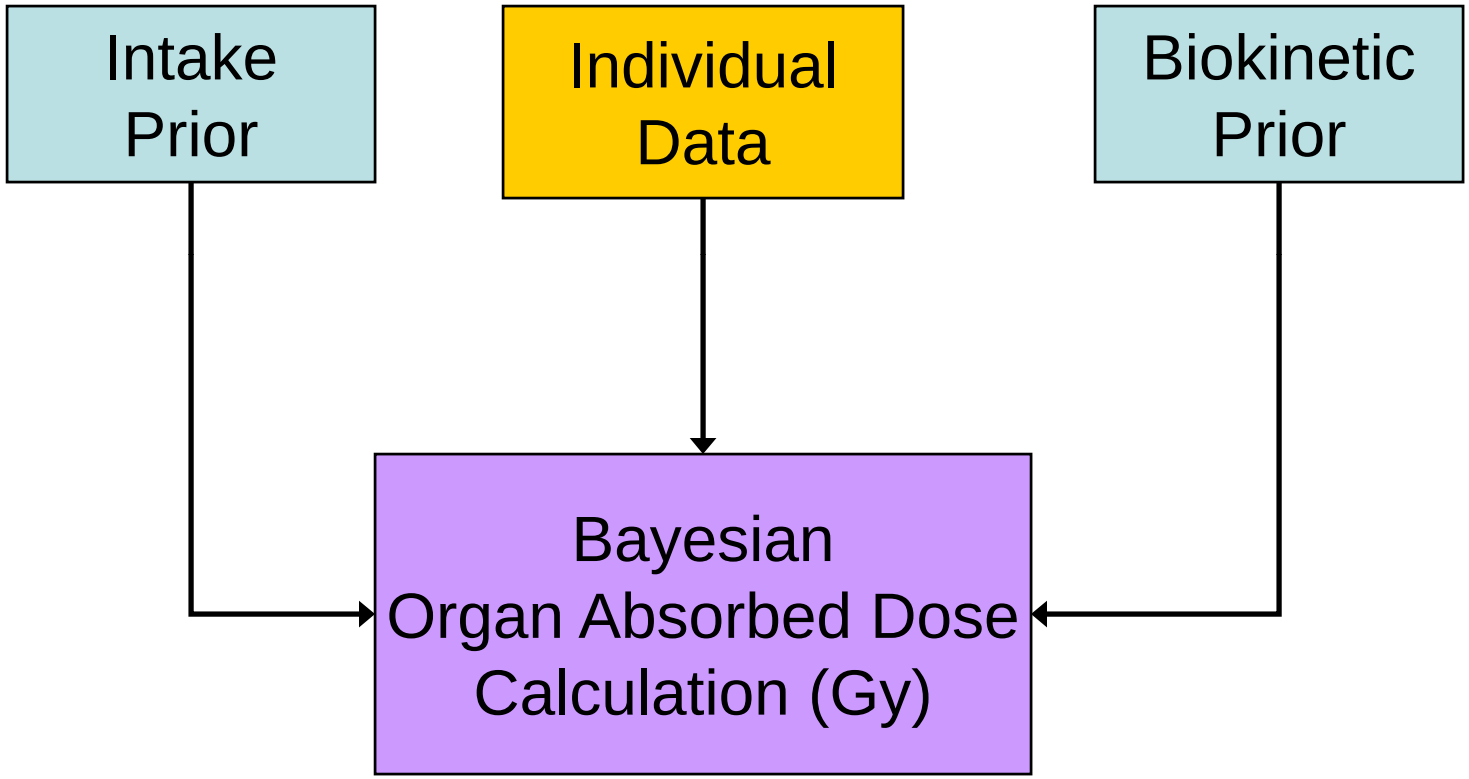
MAYAK TEST DATASET

Individual-specific information was collected on 112 Mayak workers with no radiation-related disease.

The dataset includes:

- **Detailed individualized occupational history**
- **Bioassay and postmortem tissue measurements**
- **Pu air concentration data as annual averages**
- **Data on workplace-specific physicochemical form**
- **Smoking history**
- **Health status**

DOSE ASSESSMENT STRATEGY



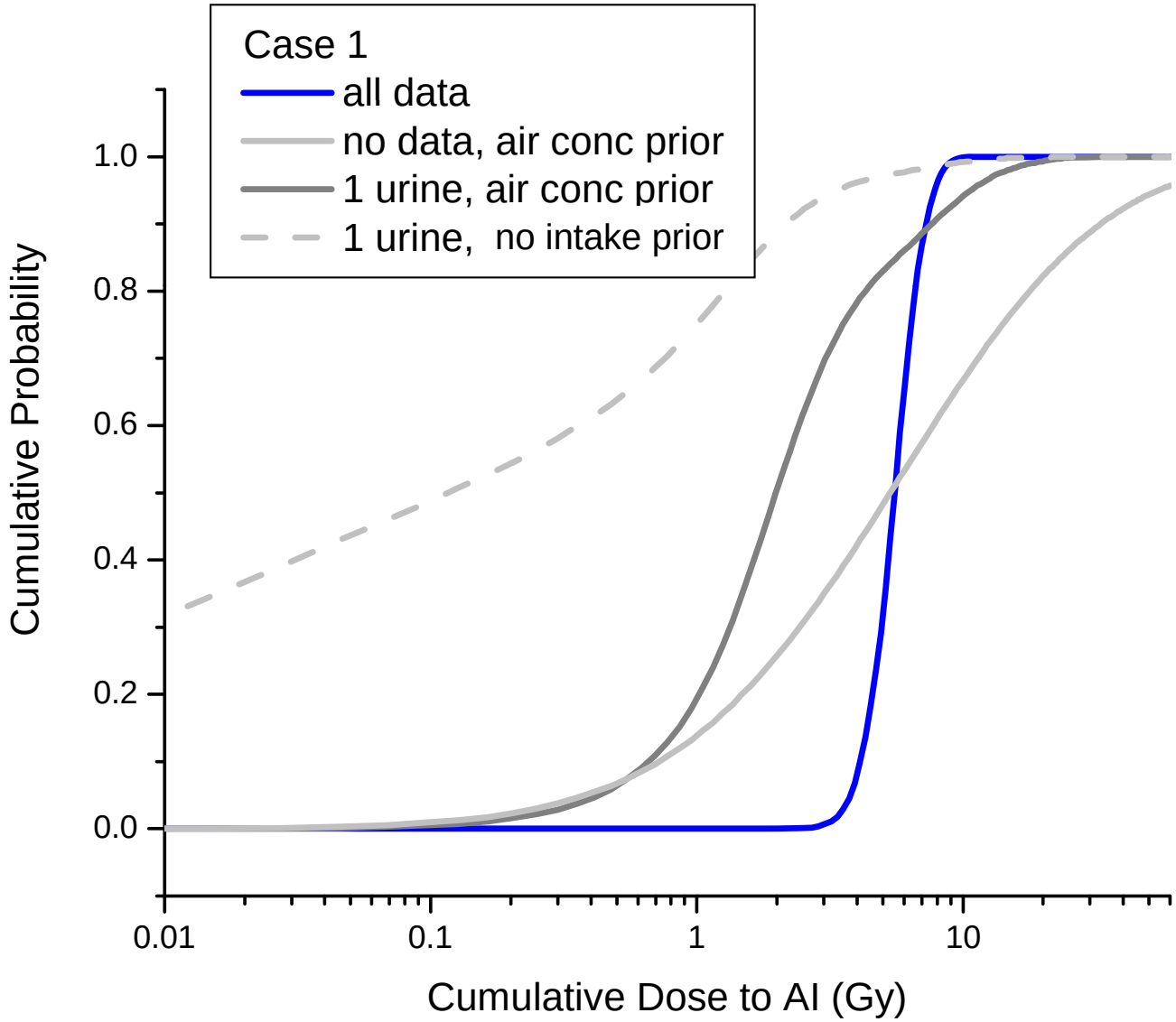
INTAKE PRIOR FORMULATION

- **Need:**
  - **Pu air concentration**
  - **Particle size**
  - **By location and time**
- **Have:**
  - **Yearly average Pu concentration**
  - **Some particle size data (consistent with HRTM)**
  - **Most work locations have data**

BIOKINETIC PRIOR FORMULATION

- **Need:**
  - **Reasonable models for inhalation, ingestion, wound, systemic Pu**
  - **Solubility**
  - **Worker bioassay data**
- **Have:**
  - **[ICRP 66, Doses-2005], [ICRP 30, ICRP 99], NCRP 156, [ICRP 67, Leggett 2005, Luciani and Polig 2000]**
  - **Plant-specific solubility (Khokhryakov S values)**
  - **Tissue data for > 1,200 workers**
  - **Urine bioassay data**

CUMULATIVE PROBABILITY DISTRIBUTION OF ABSORBED DOSE



The work performed under financial support of Office of International Health Programs of the U.S. Department of Energy and Federal Medico-Biological Agency of Russian Federation.

Thank you for your attention!

Abstract

JCCRER Project 2.8 - Radiobiological Tissue Repository of the Mayak PA Workers Exposed to Radiation

Evgenia N. Kirilova,
Southern Urals Biophysics Institute, Ozyorsk, Russia
Christopher A. Loffredo,
Lombardi Cancer Center, Georgetown University, Washington DC USA

Objective: To expand the Radiobiological Tissue Repository (RTR) by the continuing enrollment of Mayak workers exposed to low-level radiation, and the collection and annotation of human biological materials for research purposes.

Background: The RTR was established at the Southern Urals Biophysics Institute (SUBI) of the Federal Medical Biological Agency (FMBA) under DOE Project 2.8. As of September 1, 2009, over 1.1 million biological samples from 7,888 registrants have been placed into storage at the RTR. It consists of several components:

1. *Biorepository of Autopsy Tissues*: tissue samples of internal organs, cerebrum, endocrine glands, reproductive organs, blood-forming/lymphoid and bone tissues that were sampled at the autopsies of 940 workers of the Mayak PA, who died in 1951-2009, including 70 residents of Ozyorsk who were never occupationally exposed to ionizing radiation sources (a comparison group). The specimens are stored as formalin-fixed, paraffin blocks and slides with tissue sections. Catalogues of malignant tumors of the lung, pleura, and digestive organs are continuously maintained.
2. *Biorepository of Surgical/Biopsy Tumor and Non-Tumor Tissues*: these specimens were collected at surgical interventions and/or diagnostic biopsy from 655 individuals (403 workers of the Mayak PA, and 252 individuals from the comparison group).
3. *Biorepository of Blood and its Components*: these specimens consist of blood cells of various types (suspensions of leukocytes, lymphocytes, immortalized B-lymphocytes, erythrocytes), plasma and serum, and extracted DNA from 4,082 registrants (3,492 workers of the Mayak PA, and 590 individuals from the comparison group).

.

4. *Biorepository of Other Tissues:* these specimens consist of buccal epithelial cells, bone marrow, lymphoid tissue cells, cells and supernatant of induced sputum, bone tissue, which were collected from 2,211 registrants.

In order to successfully organize and maintain the RTR, several challenges have been overcome. This required addressing a complex set of organizational, methodological, regulatory and ethical issues. Collection and storage of these unique biological materials, as described above, provides a resource to the scientific community for investigating radiation health effects in workers and other persons. Collection of occupational and dosimetry data, medical and socio-demographic information, and verified external and internal dose accumulations of the RTR registrants are essential elements of the data annotation of each specimen. Systematization of the data has been achieved for the RTR specimens. This in turn has allowed us to create meta data resources, such as a catalogue of malignant tumors of various sites. Finally, we have developed and tested protocols for the approval and implementation of transfers of stored specimens samples to researchers in different countries.

Work under the Project in 2009-2010: We are continuing to collect biological specimens and data from workers and from the population of Ozyorsk (as a comparison group). We recently developed and implemented methods for the collection of saliva. We are going to establish the database of blood and its components, a log of research results obtained based on the blood bank, and the conversion of the tumor tissue catalogues into searchable electronic format. A monograph on the Experience of Establishing the Radiobiological Repository is being written at this time, and we anticipate its completion by the end of the year. The RTR data base of specimens and annotated data is being converted from an older software system into Microsoft Access, which will allow enhanced search and reporting capabilities. Finally, we are in the process of a complete review of all protocols at the RTR to assess and achieve compliance with the recently released guidelines of the U.S. National Cancer Institute's Best Practices for Biological Repositories.

Joint Coordinating Committee for Radiation Effects Research

(JCCRER)

7TH International U.S. - Russian Meeting

2009

September 16 - 17, 2009
Washington D.C.

JOINT COORDINATING COMMITTEE FOR RADIATION EFFECTS RESEARCH

2009

7TH INTERNATIONAL U.S. - RUSSIAN MEETING

WASHINGTON D.C.

DOE Project 2.8

Establishment of the Russian Radiobiology Human Tissue Repository of the Mayak PA Workers Exposed to Radiation

Evgenia N. Kirillova

Southern Urals Biophysics Institute (SUBI), Ozyorsk, Russia

Christopher A. Loffredo

Lombardi Cancer Center, Georgetown University, Washington, DC, USA

Principal Investigators

RUSSIA:	1999-2008	K. Muksinova
	2008-2009	E. Kirillova
USA:	1999	R. Katren
	2000-2005	R. Neta
	2006-2008	B. Fountos
	2008-2009	C. Loffredo

Project Tasks

- **Expansion and maintenance of the Repository**:
  - collection of samples of the autopsy, biopsy, tumor and non-tumor tissues, blood and its components, genetic material from workers of the Mayak PA and their offspring, supernatant and induced sputum cells;
  - collection of the demographic, occupational, dosimetry and medical information on registrants.
- **Monitoring of storage conditions and assessment of biospecimen integrity: ongoing quality control**.

Project Tasks (continued)

- **Transfer of biospecimens on requests of researchers from different countries for investigating effects of protracted exposure.**
- **Update of the RRHTR website and databases.**
- **Conversion of catalogues of malignant tumors to electronic format.**
- **Verification of doses: adjustment of the data on accumulated doses from external γ-rays, and ^{239}Pu body burden and absorbed doses from internal α-radiation (*Doses-2005, 2008).***

Productivity

As of September 1, 2009:

over **1.1 million** biological specimens from **~7,888** registrants have been placed into storage at the Repository.

Autopsy Tissue Bank

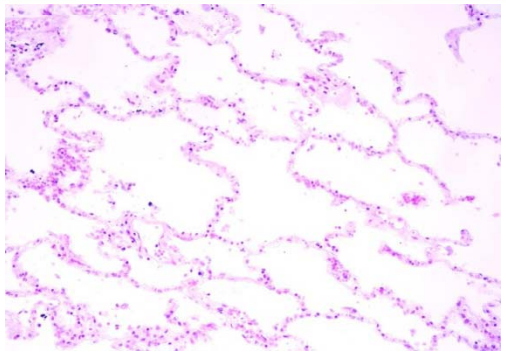
- Tissue samples of internal organs, cerebrum, endocrine glands, reproductive organs, blood-forming/lymphoid and bone tissues that were sampled at the autopsies (**940** individuals):
  - **870** workers of the Mayak PA, who died in **1951-2009**; and
  - **70** residents of Ozyorsk, who were never occupationally exposed to ionizing radiation sources (*a comparison group*);
- Autopsy tissues are stored as formalin-fixed, paraffin blocks and slides with tissue sections.
- Catalogues of malignant tumors of the lung, pleura and digestive organs are updated and maintained.

Surgical/Biopsy Tissue Bank

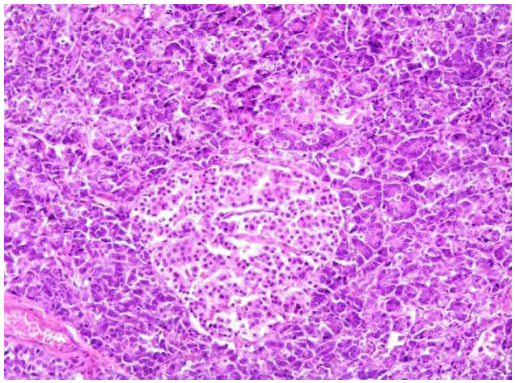
Specimens collected at surgical interventions and/or diagnostic biopsy from **655** individuals:

- **403** workers of the Mayak PA; and
- **252** individuals from the comparison group.

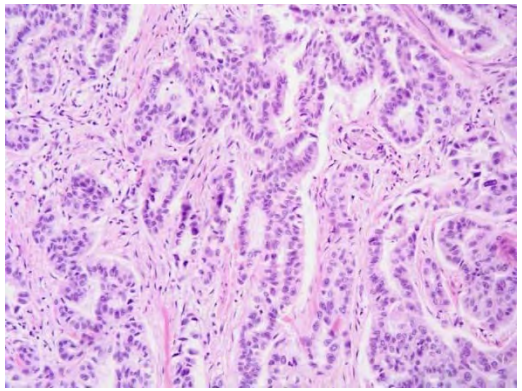
Integrity of the Autopsy Tissue Samples Stored in Formalin



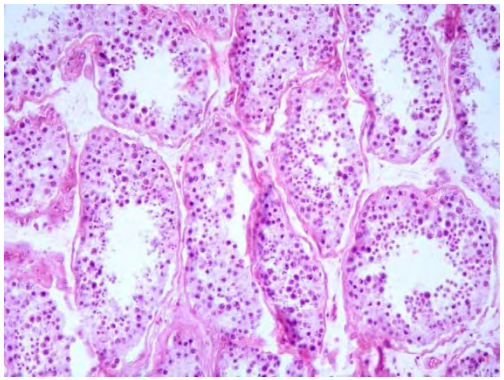
Histological slide of the ***Lung*:**
27 years of storage in formalin



Histological slide of the ***Pancreas*:**
27 years of storage in formalin



Lung Adenocarcinoma:
27 years of storage in formalin



Histological slide of the ***Testicle:***
40 years of storage in formalin

Storage of Biomaterial at -78˚C, -152˚C

Storage of the Autopsy Tissues

Repository of Blood and Components

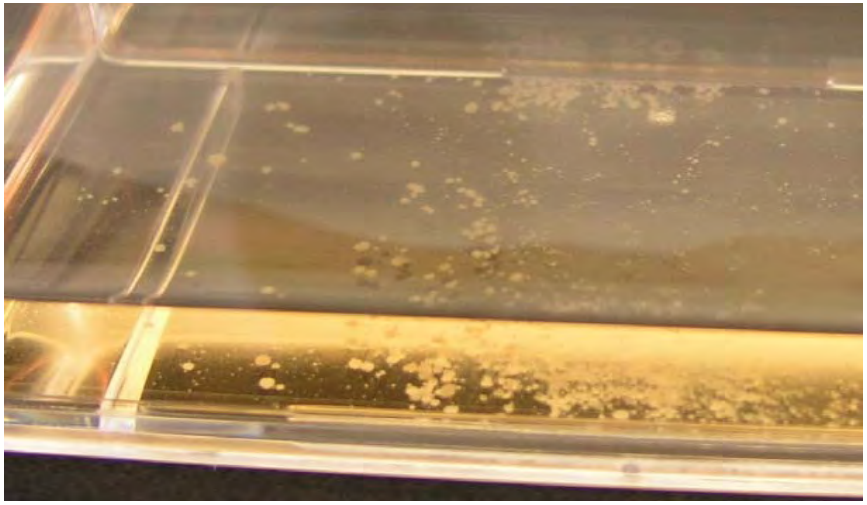
Cells of various types:

suspensions of leukocytes, lymphocytes, immortalized B-lymphocytes, erythrocytes; plasma and serum; and extracted DNA from **4082** registrants, including:

- **3422** workers of the Mayak PA; and
- **590** individuals from the comparison group.

Monitoring of the Biospecimen Integrity

Lymphocytes stored for 36 months at -78°C in cell suspension, x1000



12-day culture of immortalized B-lymphocytes stored for 48 months at -160°C

Bank of Other Tissues

Biospecimens of:

buccal epithelial cells,

bone marrow and lymphoid tissue,

cells and supernatant of sputum,

bone tissue

Collected and stored from

2,211 registrants.

Work Plan for 2009-2010

- **Continuing collection of:**
  - blood and its components, including DNA, from the Mayak PA workers and from the population of Ozyorsk (*controls*), and information on them (**400-450** individuals);
  - extracted DNA from the offspring of exposed parents in the first and second generation (**100** individuals);
  - autopsy (**10-20** individuals) and biopsy (**60-70** individuals) tissue specimens;
  - induced sputum specimens (**50-60** individuals).

- Development and implementation of methods for the collection and storage of saliva from workers of the main facilities.

Work Plan (2)

- Verification of absorbed doses from external and internal exposure to the whole body and organs of the Mayak workers, and entry of information into the database (*Doses-2005, Doses-2008*).
- Establishment of the database of blood and its components with inclusion of our own research results obtained based on the Blood Bank.
- Completion and publication of a monograph on the Bank of Blood and its Components.
- Preparation of a monograph on the Experience of Establishing the Radiobiology Human Tissue Repository.
- Conversion of the Tumor Tissue Catalogues into electronic format.

Work Plan (3)

- Conversion of the RRHTR database of specimens and annotated data from an older software system into Microsoft Access, which will allow enhanced search and reporting capabilities.

- Complete review of all protocols at the RRHTR to assess and achieve compliance with the recently released guidelines of the U.S. National Cancer Institute's Best Practices for Biological Repositories.

Acknowledgments

- This work is performed with the support of:
  - **U.S. Department of Energy, Office of International Health Studies (HS-14)**
  - **Federal Medical Biological Agency (FMBA) of the Russian Federation**

  in the framework of the *JCCRER Program*

- Our special acknowledgement and thanks to:

  Dr. Barrett N. Fountos

Abstract

U.S. Department of Energy - Russian Collaboration in Emergency Management Under Direction 3 of the U.S. - *Russia Agreement on Cooperation in Radiation Effects Research*

Nuclear Safety Institute of the Russian Academy of Sciences (IBRAE RAS), State Atomic Energy Corporation (Rosatom), and Ministry of Emergency Situations (EMERCOM)

Vince McClelland,
Director, Office of International Emergency Management and Cooperation (IEMC) within the Office of Emergency Operations of DOE/NNSA

Since 1999, Russian agencies have collaborated with the Office of International Emergency Management and Cooperation Program (IEMC) within the Office of Emergency Operations of DOE/NNSA to conduct activities under Direction 3 of the U.S. - *Russia Agreement on Cooperation in Radiation Effects Research*. Direction 3 involves multiple Russian agencies including IBRAE, Rosatom, and EMERCOM to carry out projects to enhance emergency preparedness and response capabilities, reduce the risk of nuclear and radiological events, and reinforce emergency management planning and preparedness. Successful projects include technical enhancements, communications, analysis, training and exercises, the establishment of Emergency Response Management and Training Centers in St. Petersburg and Moscow; development of Portable Analysis Laptop systems for onsite radiation safety experts and responders; and facility risk assessments conducted at four facilities in Russia.

Current projects include: (1) Development of the MIPK Training Center (Moscow) to improve training systems for Rosatom emergency response team leaders; (2) Plume Modeling to develop internationally harmonized software capabilities of the RECASS NT system; (3) Public Emergency Information Tutorial to train nuclear facility personnel in public notification during a radiological accident; (4) Source Control Project to reduce risk by incorporating ISO 14000 principles; and (5) development of the Emergency Technical Training Center in St. Petersburg for radiation experts at Rosatom.

A series of exercises have been conducted under Direction 3 to verify the effectiveness of emergency plans, procedures, and decision making. Beginning with an exercise at the Bilibino Nuclear Power Plant in 2002, the series has continued with exercises at the NIIAR Research Reactor (2003); ARCTIC 2005 (Murmansk); “Large City” Table-top 2006 (Moscow); and ARCTIC 2008 ("Zvezdochka” Shipyard, Arkhangelsk). All exercises have included a public information component which has led to a series of awareness publications: (1) Risk and Safety: Industrial North – Nuclear Technologies and Environment (2004); (2) Emergency Public Information Manual (2004); (3) ABC of Radiation Protection (2005); (4) Keeping the Public Informed in Radiological Emergency (2006); and (5) Risk and Safety: The Far East – Nuclear Technologies and Environment (2008).

Continuing activities include: (1) the “Arctic-10” exercise to be conducted at Nerpa shipyard in July 2010; (2) emergency response equipment upgrades at the Zvezdochka facility; (3) customization of the NOSTRADAMUS and TRACE WIN, computer based assessment and plume modeling tools for three additional radiation facilities (in addition to the 13 facilities currently equipped); (4) the development of computer based training for improved emergency public information communications; (5) risk assessment, incorporating ISO 14000 methods analyzing the transportation of radioactive sources at the Scientific and Research Institute of Atomic Reactors (SSC RF NIIAR) under the Source Control Project; and (6) the development of a technical plan for improvement of radiation monitoring and emergency response capabilities for facilities in the Far East region.

Cooperation under Direction 3 has been mutually beneficial and progress has been made in institutionalizing emergency management planning, training, and response and establishing sound emergency management policy. Proposals for further cooperation and additional activities to advance the goals of Direction 3 are already in discussion with Russian counterpart.

Joint Coordinating Committee for Radiation Effects Research

(JCCRER)

7TH International U.S. - Russian Meeting

2009

September 16 - 17, 2009
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JOINT COORDINATING COMMITTEE FOR
RADIATION EFFECTS RESEARCH

2009

7TH INTERNATIONAL U.S. - RUSSIAN MEETING

WASHINGTON D.C.

Office of Emergency Operations

Activities Under Direction 3

U.S. - Russia Agreement on Cooperation in Radiation Effects Research

Overview

- Emergency management cooperation began in March 1999
- Successful projects in a range of activities to include technical enhancements, communications, analysis, training and exercises
- Office of Emergency Operations continues to work with IBRAE, Rosatom, EMERCOM, and other Russian agencies to maintain and reinforce a sound program of emergency management planning, preparedness, training, and exercises

Areas of Cooperation

- Training Centers development
- Conduct of drills, training, and exercises on emergency preparedness
- Development and improvement of radiation accident response capabilities, including technologies and procedures
- Source Control Project
- Community Radiation Safety Information

Current Projects

- Development of the MIPK Training Center (Moscow)
- Plume Modeling
- Public Emergency Information Tutorial
- Source Control Project
- Emergency Technical Training Center

Current Projects (cont.)

- The NERPA - 2010 exercise “Arctic-10”
- Zvezdochka Equipment Modernization
- NOSTRADAMUS/TRACE WIN
- Exercise Simulations
- EMERCOM Reference Books
- ROSHYDROMET - Plume modeling

Key Accomplishments - Exercises

Exercises	Dates
Bilibino Nuclear Power Plant	**2002**
NIIAR Research Reactor	**2003**
ARCTIC 2005 (Murmansk)	**2005**
“Large City” Table-top 2006 (Moscow)	**2006**
“Northwest” Joint RER Field 2006, 2007 (St. Petersburg)	**2006, 2007**
ARCTIC 2008 ("Zvezdochka” Shipyard, Arkhangelsk)	**2008**
Spent nuclear fuel shipment Angarsk Electrolysis chemical complex (Baykal)	**2009**

Key Accomplishments - Publications

- Risk and Safety: Industrial North – Nuclear Technologies and Environment
- Emergency Public Information Manual
- ABC of Radiation Protection
- Keeping the Public Informed in Radiological Emergency
- Risk and Safety: The Far East – Nuclear Technologies and Environment

Key Accomplishments

- Established Centers with specific missions:
  - Emergency Technical Response Training Center in St. Petersburg
  - Emergency Management Training Center in Moscow
  - EMERCOM's National Crisis Situation Management Center in Moscow
- Portable Analysis Laptop systems developed for technical support for onsite radiation safety experts and responders
- Facility Risk Assessments conducted at 4 facilities

Planned Activities

- Exercises: “Nerpa 2010”
- Source Control Project
  - transportation of radioactive sources at the Scientific and Research Institute of Atomic Reactors (SSC RF NIIAR)
  - Risk assessment, incorporating ISO 14000 methods
- Technical improvements and plans for radiation facilities in 2 regions
- Equipment/Enhancements

Proposals

- Joint Radiation Search Exercise in the U.S.
- Maritime Demonstration in Russia
- Invitation to Observe the U.S. National Level Exercise (NLE) in May 2010
- Consequence management activities:
  - US and Russian CM teams to exercise in contaminated zone
  - Test equipment, procedures and systems for CM response

Conclusion

- Cooperation has been mutually beneficial
- Progress has been made in institutionalizing emergency management planning, training, and response with Russian partners
- Cooperation has contributed to establishing sound emergency management policy
- Work will continue to ensure improvements in these areas as well as sustainability

Abstract

Epidemiologic Studies of Cancer Risk and Chronic Radiation Exposure from the Mayak Nuclear Facility

Principal Investigators:
Elaine Ron and Ethel Gilbert,
NCI
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SUBI

Other Investigators:
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Dale Preston, *Hirosoft*

The aim of this project is to conduct epidemiologic studies of cancer risks related to protracted occupational and environmental radiation exposures from the Mayak nuclear facility in the South Urals. The project fills important gaps in radiation research and protection by providing quantitative risk estimates based on updated and improved epidemiologic and dosimetric data. Specifically, the goals are to quantify cancer mortality risk among nuclear workers, to assess thyroid cancer incidence in relation to I-131 exposure among the offspring of Mayak workers and the dose-response for leukemia and solid cancer in relation to exposures received *in utero,* to evaluate thyroid cancer and other thyroid diseases among Ozyorsk residents exposed to atmospheric emissions of radioactive isotopes, and to estimate cancer mortality risk among individuals exposed to environmental radiation from nuclear waste discharges into the Techa River. The studies of cancer mortality in the Mayak nuclear workers and the Techa River residents are coordinated with JCCRER epidemiology projects 2.2 and 1.2b, respectively and the JCCRER dosimetry projects 2.4-2.5 and 1.1, respectively. Results from the Mayak worker cohort are described separately under JCCRER project 2.2.

The offspring cohort includes over 72,000 individuals who were born between 1934 and 1988, and who lived in Ozyorsk before their 15th birthday for at least one year in the period 1948-1988. This cohort is of interest because many of the parents were employed at the Mayak facility and received occupational radiation exposure. Roughly

17,000 offspring had preconception paternal exposure, 4,300 had preconception maternal exposure and 3,300 were exposed *in utero*. Given the wide range of maternal uterine doses, this cohort presents a unique opportunity to study cancer incidence and mortality among persons exposed *in utero*. Vital status for cohort members is currently known for 91% of the cohort and cause of death is known for 92% of the 7,900 deceased subjects; 813 cohort members died of cancer and 69 of leukemia. There were approximately 2,200 deaths under age 15 including 76 solid cancer deaths and 33 leukemia deaths. Current work on this cohort is focused on improving data quality and statistical analyses. In the future, we also plan to pool the *in utero* exposed cohort with a similar group of *in utero* exposed members of the Techa River cohort.

Because it is estimated that children born in Ozyorsk in the 1950s received significant chronic iodine-131 doses to the thyroid from Mayak's frequent atmospheric releases. NCI and SUBI initiated programs to evaluate thyroid cancer and other thyroid diseases in this population. During the pilot screening program 900 people were screened; 581 were born in Ozyorsk during 1952 and 1953, the years of large I-131 atmospheric releases, and 313 people of the same age who moved to Ozyorsk after 1967, when exposures had been reduced substantially. We found a significantly higher prevalence of nodular disease in the exposed group (20.7%) compared with the non-exposed (14.4%) group (relative risk= 1.4, 95% CI 1.1; 1.9). Risks were larger for solitary nodules and for nodules ≥10 mm in diameter. The screening program recently was expanded to include 360 people who were born in 1954 or 1955, years of moderate radioiodine exposure. We plan to work with members of JCCRER project 1.4 to estimate thyroid doses so that we can conduct dose response analyses for all screened individuals. We also are evaluating thyroid cancer incidence among members of the Mayak offspring cohort.

The Techa River cohort includes 29,873 people born before 1950 who lived in the 41 Techa riverside villages between 1950 and 1960. These villagers received chronic low-dose-rate external radiation exposures from gamma-fields on the contaminated river bank and flood plain soil and internal exposures from the ingestion of radionuclides in river water and food stuffs. At the end of follow-up, 14,380 (48%)of cohort members died in the study catchment area and the cause of death was known for close to 90% of these deaths (1,860 solid cancer deaths and 61 deaths from leukemia, including 12 cases of chronic lymphatic leukemia (CLL)). Dose-response analyses were based on 5-year lagged cumulative TRDS-2000 stomach dose for solid cancers and 2-year lagged cumulative red bone marrow dose for leukemias. After excluding 18 bone cancers because of potential effects of 90Sr exposure on these cancers and adjusting for the effects of age, gender, ethnicity, birth cohort and residence in Kurgan Oblast on baseline cancer rates, there was a highly significant linear solid cancer mortality dose response ($P < 0.001$), with the excess relative risk (ERR) per Gy estimated as 0.9 (95% CI: 0.2; 1.7). The ERRs per Gy estimated from a linear dose-response model for all leukemia deaths and after exclusion of the 12 deaths from chronic lymphocytic leukemia are 4.2 (95% CI 1.2; 13) and 6.5 (95% CI 1.8; 24), respectively. There is no evidence of significant non-linearity in the dose-response for non-CLL leukemia deaths ($P > 0.5$).

These data provide clear and compelling evidence of increased risks for both solid cancer and non-CLL leukemia associated with chronic radiation exposure. Complementary data on cancer incidence are provided under JCCRER project 1.2b.

National Cancer Institute

NCI-Funded Epidemiologic Studies of Cohorts Exposed to Chronic Radiation from Mayak Operations

Elaine Ron

Radiation Epidemiology Branch

DCEG, NCI

JCCRER meeting

September 17, 2009

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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Background

- NCI began collaborative research program to evaluate radiation-related cancer mortality with SUBI, URCRM and RERF in 1995
- Expanded program currently conducted through NCI contracts with SUBI and URCRM
- Program is closely coordinated with other groups (DOE, EC)

Program Goals

- Quantify solid cancer and leukemia mortality radiation risks in Mayak Worker and Techa River Cohorts
- Evaluate the dose-response for leukemia and solid cancer in persons exposed *in utero* in Ozyorsk offspring
- Assess cancer risks among persons exposed to preconception radiation in Ozyorsk offspring
- Evaluate thyroid cancer and other thyroid diseases in Ozyorsk residents

Specific Aims

- Improve study methods and data quality
- Analyze and interpret data
- Prepare summary manuscripts and meeting presentations
- Provide epidemiologic training

Contributions: Gaps Filled

- Protracted external and internal doses
- Unique exposures to plutonium and strontium
- Protracted I-131 in childhood
- In utero and preconception exposure
- Exposure at early ages
  - Ozyorsk offspring
  - 40% of Techa Cohort under age 20 at entry
- Chronic exposure to females
  - 25% Mayak workers
  - 58% Techa cohort

Cohorts Exposed from Mayak Operations

- Mayak workers (26,000)
- Techa River cohort (30,000)
- Mayak offspring (72,000)
- Ozyorsk residents (2,000)

Techa and Mayak Cohorts

	Techa River	Mayak Workers
Subjects	29,756	25,939
Entry period	1950-1960	1948-1982
Follow-up	1950-2005	1948-2005
Person years	900,990	933,090
Lost to follow-up	23%*	5%
Mean dose, Gy	0.03	0.54 (external)
Total deaths	16,619	11,537
Cancer deaths	2,203	2,729

*70% of these are distal migrants

Techa Solid Cancer Data

Site	Total
Oral Cavity	42
Esophagus	108
Stomach	505
Colon	58
Rectum	82
Liver	71
Pancreas	58
Lung	393
Breast	77
Uterine corpus	130
Cervix	90
Ovary	55
Prostate	29
Bladder	52
Kidney	34
Brain & CNS	43
Other solid	283
Total	*2110*

- Number of cancers for specific sites relatively small
- Lung and stomach cancers most common for men
- Stomach, uterus, and breast most common for women

Techa Cohort: Solid Cancer Risks

Dose (Gy)	PY	Cases	Fitted Values		AR%
			Back.	Excess	
< 0.01	651,892	1,462	1,455.5	4.6	0.3%
- 0.05	166,549	411	402.0	8.5	2.1%
- 0.1	20,520	47	44.6	2.6	5.4%
- 0.15	25,067	68	65.8	7.1	9.7%
- 0.3	15,811	38	30.1	5.7	15.9%
0.3 +	21,151	84	62.4	21.2	25.3%
Total	900,990	2,110	2,060.4	49.6	2.4%

Mayak Offspring Cohort

- Lived in Ozyorsk as children (n=72,111)
  - Born between 1934-88
  - Lived in Ozyorsk for >1 year before age 15
  - 53,872 born in Ozyorsk
- *In utero* exposure (n=3,347)
- Parental occupational exposure (n=22,213)
  - Maternal preconception (n=4,426)
  - Paternal preconception (n=17,787)
  - Maternal & paternal (n=2,527)

Mayak Offspring Cohort

	Year of Birth				
	1934-47	1948-59	1960-73	1974-88	Total
People	5,764	25,433	19,535	21,379	72,111
Vital status at age 15					
% known	94	85	98	99	93
# deaths	37	1,291	438	413	2,179
cancer deaths	1	27	19	29	76
Current vital status					
% known	82	82	96	98	90
# deaths	1,505	4,395	1,517	826	8,243
cancer deaths	301	402	103	49	855

Mayak Offspring Cohort Deaths

- 8,243 current deaths
  - Cause known 91%
  - 855 cancer deaths
  - 71 leukemia deaths
- 2,179 deaths <15 yr
  - Cause known 96%
  - 76 cancer deaths
  - 33 leukemia deaths

Mayak Offspring Cohort
In Utero and Preconception Exposure

Preliminary		Preconception	
Dose, Gy	In Utero	Maternal	Paternal
0	50,525	49,446	36,085
<0.1	2,636	3,638	15,759
0.1-0.5	593	744	1,932
0.5+	118	44	86
Exposed	3,347	4,426	17,787
Mean	0.09	0.06	0.04
Median	0.015	0.013	0.008

Ozyorsk Thyroid Diseases

- Mayak released large quantities of radionuclides into atmosphere
- I-131 thyroid doses expected to be high in Ozyorsk between 1949-54
- Children living in Ozyorsk at that time received especially high doses

Why Are These Studies Important?

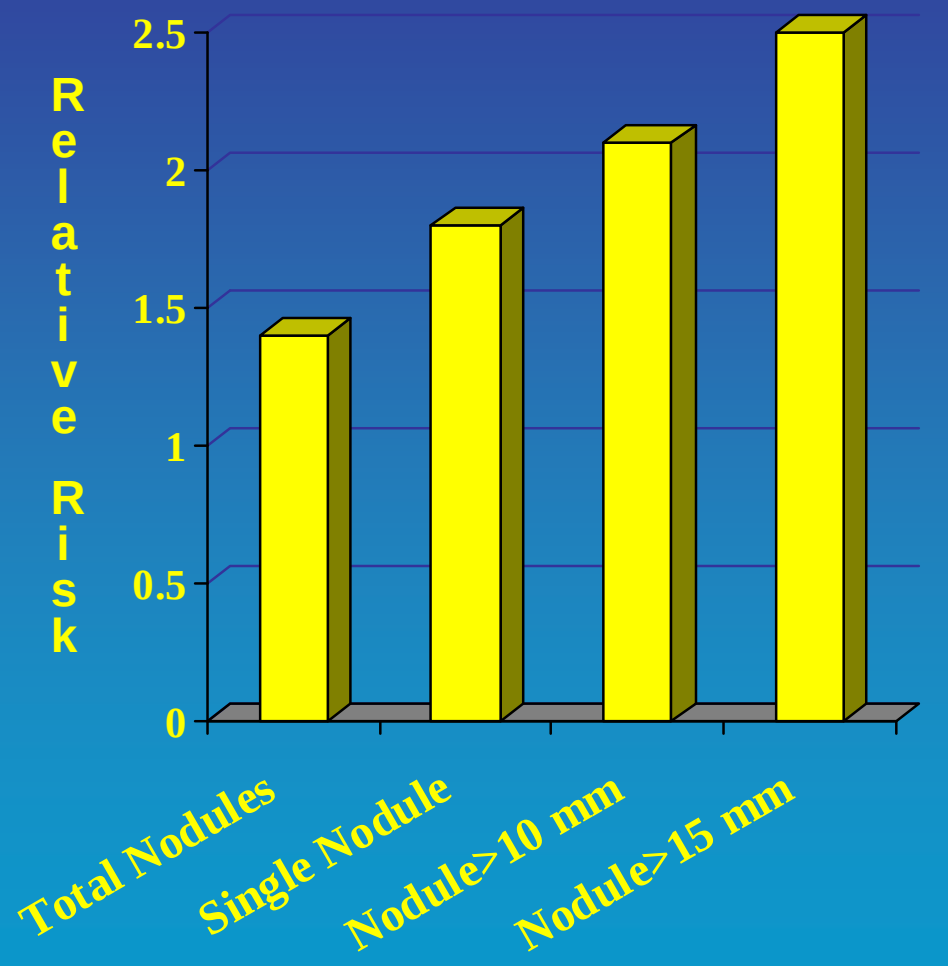
- I-131 is an exposure of public and scientific interest
  - Potential nuclear accidents or terrorism
  - Global fallout
  - Medical use
- Thyroid cancer incidence increasing
  - Some think related to Chernobyl and fallout
- Can learn more about the long-term health effects from childhood exposure to radioactive iodines

Ozyorsk Residents
Pilot Thyroid Screening Examination

- Palpation
- Ultrasound
- Thyroid hormone tests
- Fine needle aspiration and surgery if needed

Pilot Thyroid Screening Project

- Born 1952-1953
- 581 exposed; 313 non-exposed
- Thyroid nodule prevalence higher among ^{131}I exposed persons



Mushkacheva et al, Rad Res, 2006

Expanded Ozyorsk Thyroid Screening Project

	Unexposed		Exposed by year of birth							
	N=313		1950-51 N=356		1952-53 N=647		1954-55 N=375		1956-57 N=252	
	Cases	OR	Cases	OR	Cases	OR	Cases	OR	Cases	OR
Total Nodule	45	1.0	65	1.3	128	1.4	74	1.4	39	1.1
Single	28	1.0	48	1.5	100	1.7	54	1.6	30	1.3
Multi	14	1.0	15	0.9	22	0.8	20	1.2	9	0.8
Tumor	3	1.0	2	0.6	6	1.0	0	--	0	--

Thyroid Screening Project
Summary

- Increased risk of single thyroid nodules
- Complement to studies of external radiation
- Addition to studies of internal radiation
- Need dose estimates to quantify risks

Summary of Results

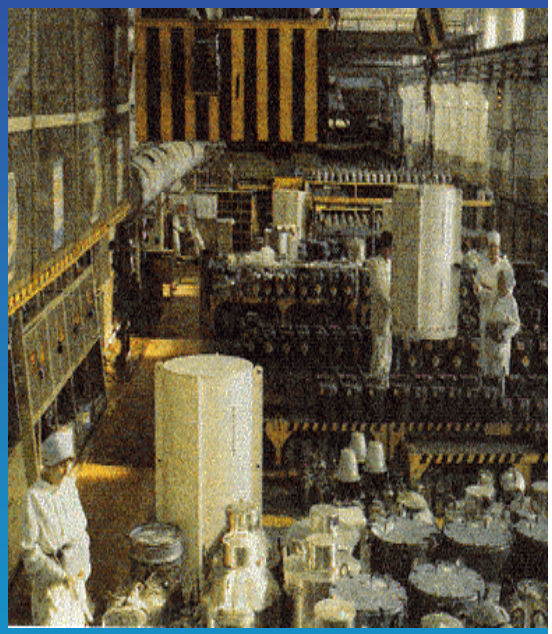
- Techa River Cohort
  - Evidence of low-dose, low-dose-rate effects on cancer mortality risks
  - Levels of risk consistent with LSS data, but possibility of dose bias cannot be ruled out
  - Mortality data suggest ERR increases with attained age
- Ozyorsk Thyroid Screening
  - Association between protracted childhood I-131 exposure and thyroid nodules

Future Directions:
Techa River Cohort

- Dose-response analyses of cancer mortality
  - Extended follow-up and improved dosimetry
  - Site-specific cancers
  - Take into account radiation exposure from medical examinations

Future Directions:
Mayak Worker Cohort

- Dose-response analyses of leukemia and solid cancer mortality (external radiation)
  - Extended follow-up and improved dosimetry
  - Site-specific cancers
- Dose-response analyses of lung, liver and bone cancer (internal radiation)
  - Extended follow-up and improved dosimetry
  - Radiation and smoking interaction
  - Estimate lifetime risk from plutonium
- Evaluate effect of radiation dose from medical procedures
- Feasibility assessment: radiation exposure and preleukemic condition



Future Directions:
Ozyorsk Offspring Study

- Dose-response analyses *in utero* exposure
- Dose-response analyses cancer incidence and mortality
- Dose-response analyses I-131 exposures and thyroid cancer incidence

Recent Publications (1)

- Mayak Worker Cohort
  - Cancer mortality and external exposure (Shilnikova et al. Rad Res, 2003)
  - Internal and external radiation and lung cancer risk (Gilbert et al. Rad Res, 2004)
  - Internal plutonium exposure and lung, liver, and bone cancer (Sokolnikov et al. Int J cancer, 2008)
- Ozyorsk Population
  - Thyroid Screening Study (Mushkacheva et al. Rad Res, 2006)

Recent Publications (2)

- Techa River Cohort
  - Methods paper (Kossenko et al. Rad Res, 2005)
  - Protracted radiation exposure and cancer mortality (Krestinina et al. Rad Res, 2005)
  - Radiation exposure and breast cancer incidence (Ostroumova et al. Br J Cancer, 2008)
  - Leukemia incidence dose response (Krestinina et al. submitted)
- Other
  - Bayesian analysis of site-specific cancer dose-response analyses for Mayak worker and Techa River cohorts (Preston et al. Submitted)

Impact

Article highlighting the Techa River Cohort

Contributions to national and international radiation protection agencies

EPIDEMIOLOGY

Russian Cancer Study Adds to the Indictment of Low-Dose Radiation

A Cold War environmental calamity appears to be the cause of a spate of cancers in the Russian heartland. A landmark study this month by U.S. and Russian scientists blames excess cancers in the Ural Mountains on chronic exposures to radioactivity leaked from a weapons plant a half-century ago.

The study is the latest blow to the notion that there is a threshold of exposure to radiation below which there is no health threat (and there might even be a benefit). The results add weight to last summer's report from the U.S. National Research Council, which backed the hypothesis that radiation is risky even at the smallest doses (*Science*, 8 July, p. 233). Although that conclusion had been inferred from Japanese atomic bomb survivors, the Russian study—along with a recent report revealing an elevated cancer risk in nuclear workers around the globe—provides the strongest direct evidence yet of chronic, low-dose health effects.

Both sets of findings indicate that workplace radiation standards are correct in erring on the safe side. In 1991, the International Commission on Radiological Protection (ICRP) set an annual workplace limit of 20 millisieverts (mSv) per year over 5 years, which assumes there is no safe level. "This is an endorsement of the precautionary approach as a tool for radiation protection," says Lars-Erik Holm, director general of the Swedish Radiation Protection Authority and ICRP chair.

The new data come from villagers downstream from the Mayak weapons complex in the southern Urals, victims of the struggle for nuclear supremacy. From 1949 to 1956, they were exposed to a steady stream of plutonium production byproducts released into the Techa River. After the Soviet breakup, U.S. experts—including atomic bomb radiation expert Dale Preston, now at Hirosoft International Corp. in Eureka, California, and epidemiologist Elaine Ron of the U.S. National Cancer Institute—joined forces with colleagues at the Urals Research Center for Radiation Medicine in Chelyabinsk to scrutinize the health of 25,000 people who lived in 41 villages along the Techa between 1950 and 1952, when radioactivity releases climaxed, and nearly 5000 people who moved to these communities between 1953 and 1960.

The biggest challenge has been getting a handle on individual radiation doses, which remain uncertain. The team has measured strontium-90, the most common downstream radioisotope, in teeth from scores of subjects and conducted whole-body counts of strontium and cesium-137. They have at least one strontium measurement for more than a third of the villagers.

Low-dose risks. A study of cancers in Muslyumovo (*inset*) and other villages near the radionuclide-laden Techa River points up the importance of limiting exposure to radiation in the workplace.

CREDITS: REUTERS (INSET) COURTESY OF A. AKLEYEV

According to death certificates, 1842 villagers died from solid tumors other than bone cancer, the prevalence of which would have been skewed by strontium-90. And 49 died from leukemia, not counting chronic lymphocytic leukemia (CLL), which is not thought to be triggered by radiation. The researchers attributed deaths above the background rate to radiation—46 from solid cancer (2.5%) and 31 from leukemia (63%). The risks increase with estimated dose, the team reports in the November issue of *Radiation Research*. "People were hoping that the risks would be a lot lower," says Lynn Anspaugh, now at the University of Utah, Salt Lake City, who helped with the study's dosimetry.

The figures, although alarming, are in line with the largest study of nuclear power workers ever carried out. A team led by Elisabeth Cardis of the International Agency for Research on Cancer in Lyon, France, pooled data on more than 400,000 plant workers in 15 countries. In this group, 6519 have died from solid cancers and 196 from non-CLL leukemias. The finding suggests that between 1% and 2% of the deaths may be due to radiation, the team concluded in the 29 June issue of the *British Medical Journal*.

It's an "impressive study," says Holm, although he and others flagged a shortcoming: Smoking may account for a large share of deaths attributed to radiation. In the study, the risk of smoking-related tumors—primarily lung cancers—is much higher than for other solid cancers. Cardis points out that the paper acknowledges smoking as a confounding factor. "Although smoking may play a role in the increased risk of all cancers excluding leukemia, it is unlikely to explain all of the increased risk observed," she says. Future publications will address concerns about the study's methods, she says.

Although the Cardis study has been challenged, exhibit B in the low-dose indictment, the Techa River study, provides corroborating evidence. The two studies come to "practically the same conclusion," says Peter Jacob of the Institute of Radiation Protection in Neuherberg, Germany. That means that the 20-mSv standard is unlikely to budge, despite arguments from industry that it is too stringent. The Russian results are "a setback for those who hope for a relaxation of the standards," says Anspaugh. The United States is one of the few nations that does not use the ICRP standard; it permits exposures up to 50 mSv per year.

In practice, most nuclear industry workers are exposed to far less radiation than the ICRP limit. That's a good thing: The average lifetime dose in the Cardis power plant study was only 19.4 mSv, with less than 0.1% of workers receiving more than 500 mSv. Calculations in the Techa study suggest that the vast majority of villagers received less than 50 mSv of lifetime accumulated dose to the stomach. In light of ongoing efforts to refine these estimates, says Urals center director Alexander Akleyev, cancer risks should be viewed as "preliminary." Jacob agrees: "This is not the final word," he says. –RICHARD STONE

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Science, November 2005

Abstract

Research in the Southern Urals Sponsored by the European Commission

Colin Muirhead,
Health Protection Agency Centre for Radiation, Chemical and Environmental Hazards
Clemens Woda, Albrecht Wieser and Peter Jacob,
Helmholtz Zentrum München- German Research Centre for Environmental Health
Institute of Radiation Protection

Researchers in the European Union and the Russian Federation have worked together over many years to investigate radiation exposures to populations in the Southern Urals and associated health effects. In this presentation, we will summarise work that has been conducted since 2005 under the SOUL project*, which is supported by the European Commission (EC) under its 6th Framework Programme. We will also outline plans for continued European-Russian research after 2009, as envisaged in a proposal entitled SOLO which was recently submitted to the EC for support under its 7th Framework Programme. The value of close links between radiation research activities conducted in the Southern Urals with support from the USA and Europe will be stressed.

** SOUL is coordinated by Dr Peter Jacob (Helmholtz Zentrum München, Germany).*

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Joint Coordinating Committee for Radiation Effects Research

(JCCRER)

7TH International U.S. - Russian Meeting

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JOINT COORDINATING COMMITTEE FOR RADIATION EFFECTS RESEARCH

2009

7TH INTERNATIONAL U.S. - RUSSIAN MEETING

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Research in the Southern Urals sponsored by the European Commission Part I – External Dosimetry

Clemens Woda, Albrecht Wieser, Peter Jacob

Helmholtz Zentrum München,

Institute of Radiation Protection, Germany

JOINT COORDINATING COMMITTEE FOR RADIATION EFFECTS RESEARCH
2009
7TH INTERNATIONAL U.S. - RUSSIAN MEETING
WASHINGTON D.C.

SOUL – Southern Urals Radiation Risk Research

(August 2005 – December 2009)

Coordinator: Dr Peter Jacob (HMGU)

Contractors involved:

- Helmholtz Zentrum München, HMGU, Germany
- Health Protection Agency, HPA, UK
- Urals Research Center for Radiation Medicine, URCRM, RF
- Southern Urals Biophysics Institute, SUBI, RF
- Karolinska Institutet, KI, Sweden
- Closed Corporation "Company GEOSPETSECOLOGIA", ZAO, RF
- Istituto Superiore di Sanità, ISS, Italy
- Bundesamt für Strahlenschutz, BfS, Germany
- Technische Universität München, TUM, Germany
- Aristotle University of Thessaloniki, AUTH, Greece
- Leiden University Medical Center, LUMC, The Netherlands
- Westlakes Scientific Consulting, WSC, UK
- Institute of Metal Physics, IMP, RF
- Università di Palermo, UNIPA, Italy

Evaluation of external doses in Mayak-Doses 2005

- Angular and energy characteristics of radiation fields at different workplaces have large influence on organ doses in Mayak-Doses 2005

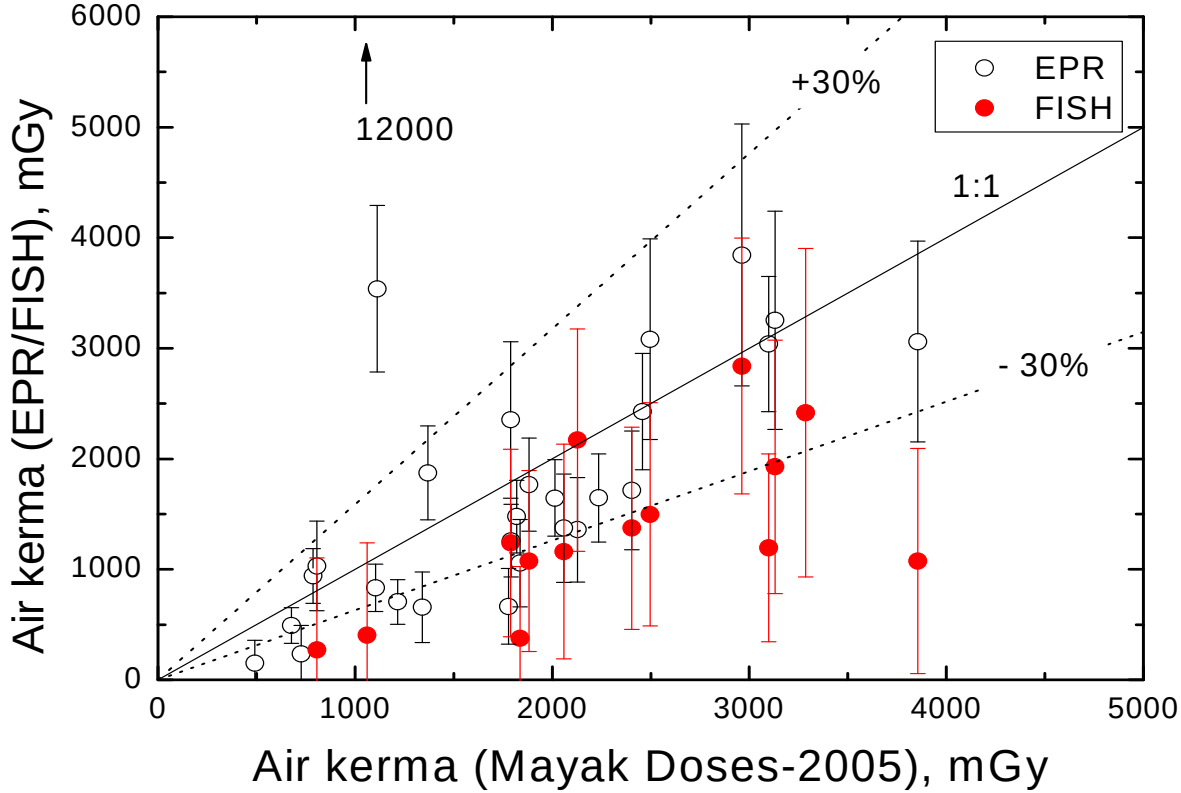
Independent validation of characteristics of radiation fields by

- defining 5 workplace clusters with similar characteristics and 3 time periods with the same type of film badge: 15 groups
- measuring doses in tooth enamel by EPR (220 workers)
- measuring doses to red bone marrow by FISH (69 workers)

$\Rightarrow$ two biodosimeters with different photon energy dependence than film badge

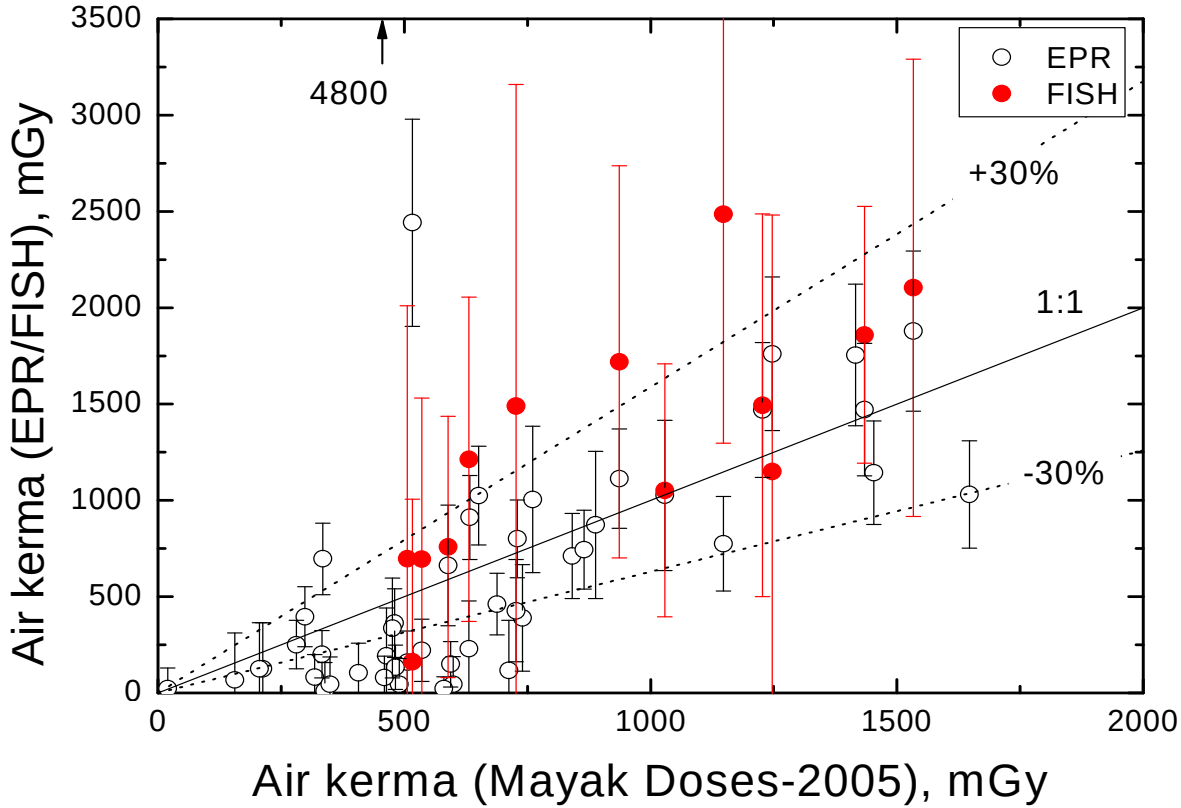
Radiochemical plant, isotropic exposure (cluster 1) 30 workers, main exposure from 1954 - 1960

FISH = (203 ± 730) + (0.48 ± 0.31) × MD05
EPR = (-169 ± 142) + (0.87 ± 0.10) × MD05



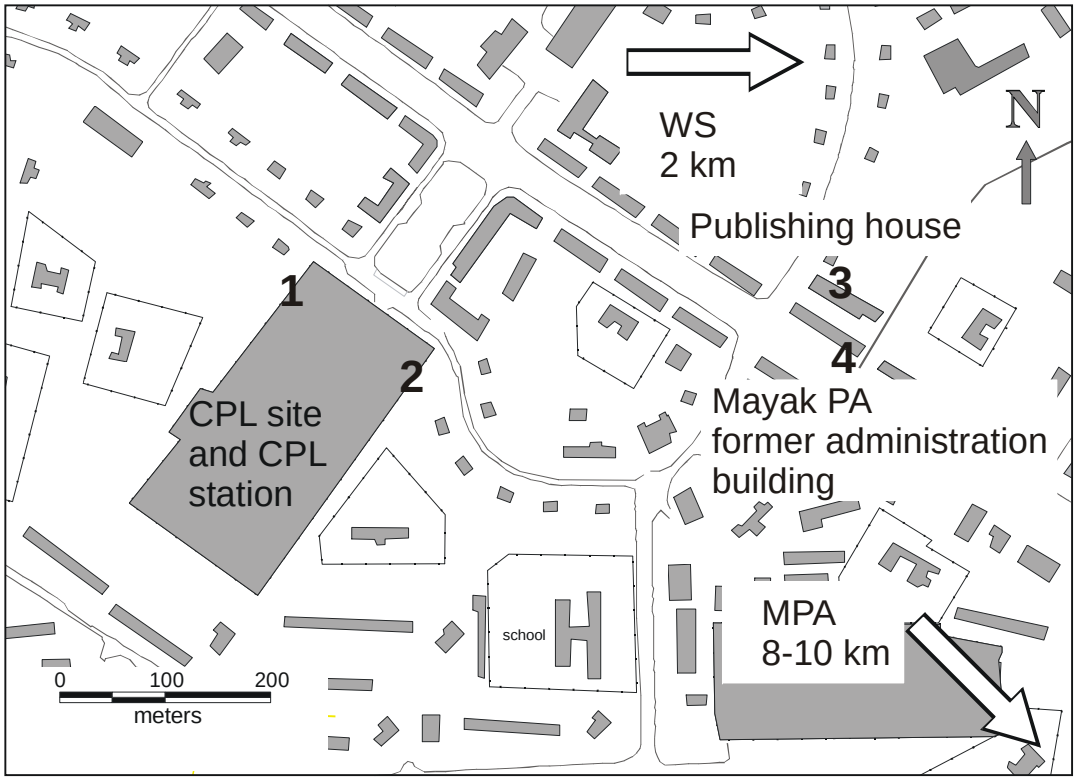
Radiochemical plant, isotropic exposure (cluster 1) 48 workers, main exposure after 1960

FISH = (186 ± 771) + (1.15 ± 0.76) × MD05
EPR = (-107 ± 57) + (0.94 ± 0.09) × MD05



Evaluation of external exposure of population of Ozyorsk due to gaseous releases using luminescence

Brick sampling positions in central Ozyorsk

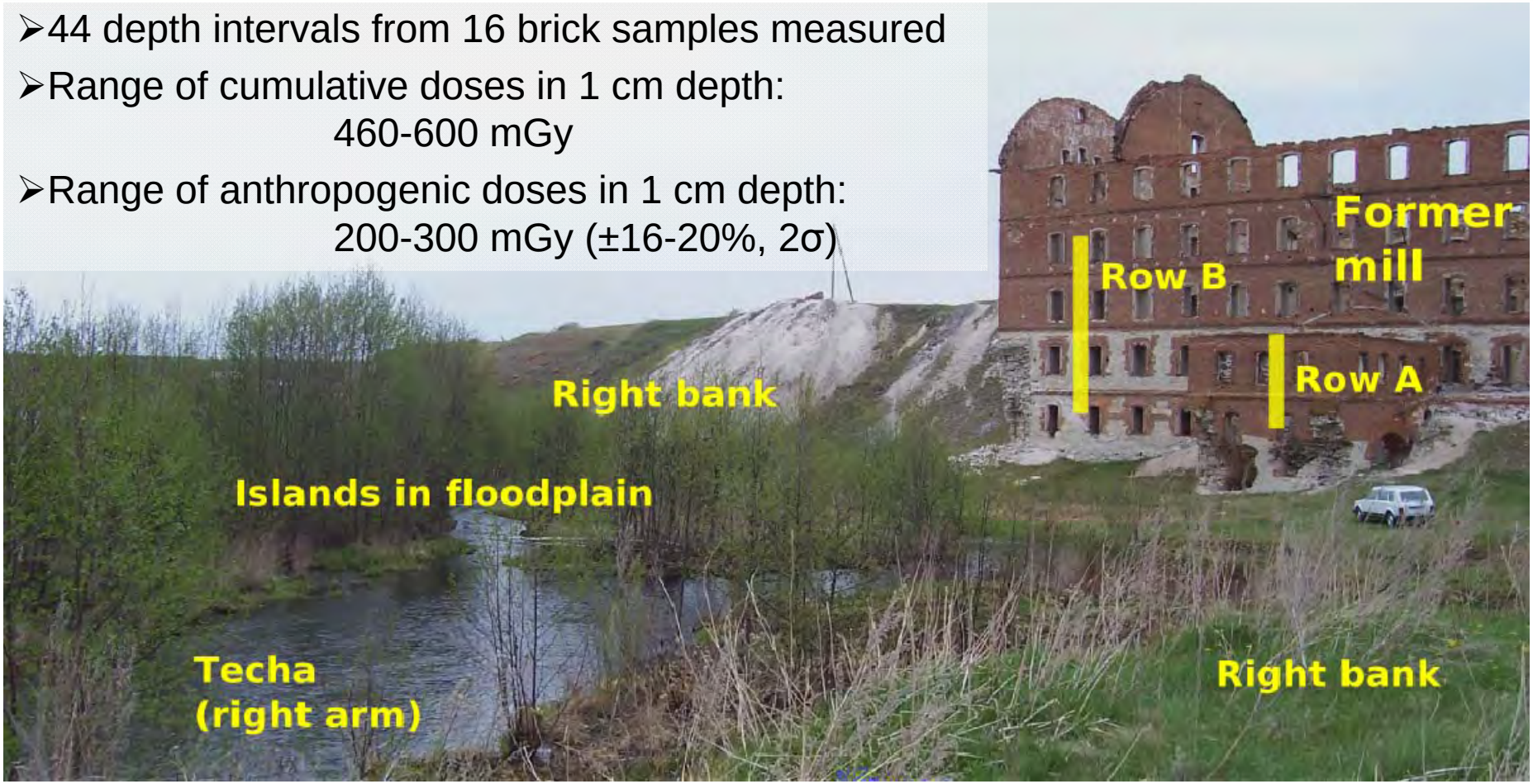


Sample	D_X, mGy	
	TL	OSL
1-1	17 ± 8	13 ± 8
1-2	12 ± 9	2 ± 9
2-1	20 ± 9	19 ± 9
2-2	5 ± 8	-16 ± 7
3-1	---	9 ± 10
3-2	-3 ± 8	-12 ± 8
4	17 ± 11	0 ± 11
Average	10 ± 9	1 ± 9

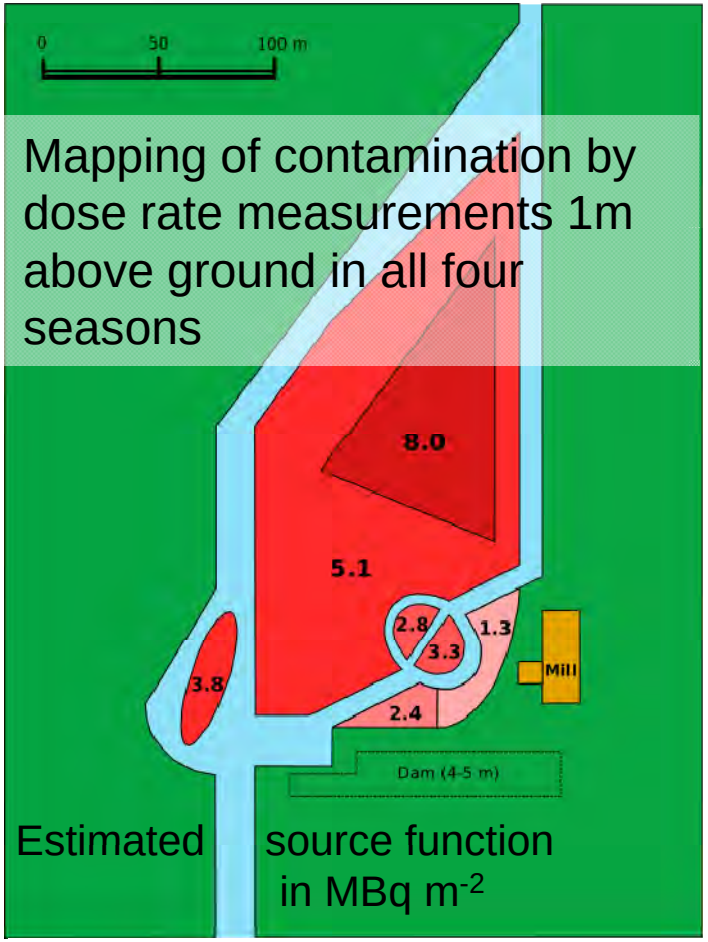
Upper limit for dose in air and for effective dose : 52 mGy and 21 mSv

Evaluation of TRDS external dose estimate using luminescence - Muslyumovo sampling site

- 44 depth intervals from 16 brick samples measured
- Range of cumulative doses in 1 cm depth: 460-600 mGy
- Range of anthropogenic doses in 1 cm depth: 200-300 mGy (±16-20%, 2σ)



Definition of source-detector geometry and photon transport calculations



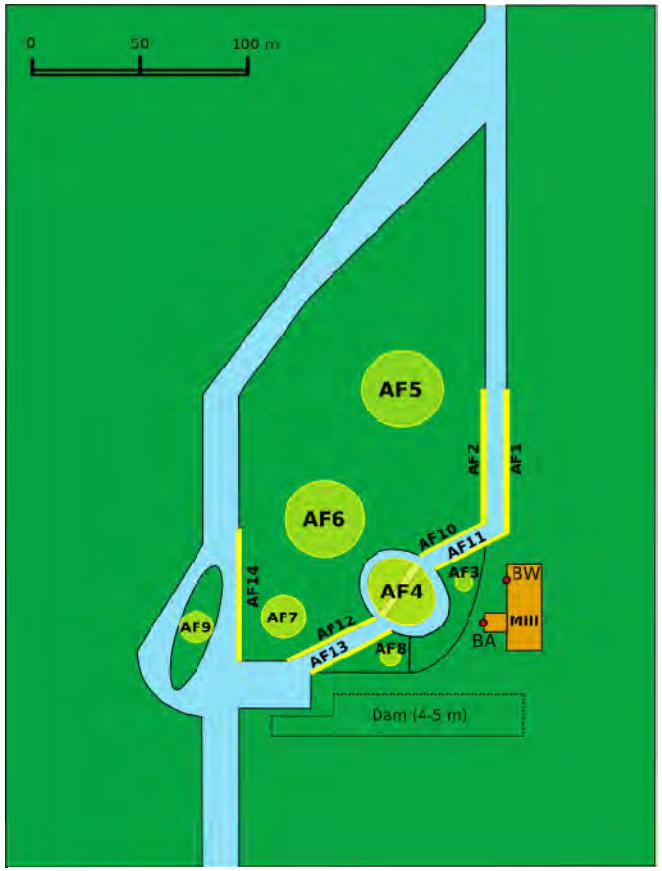
Mapping of contamination by dose rate measurements 1m above ground in all four seasons

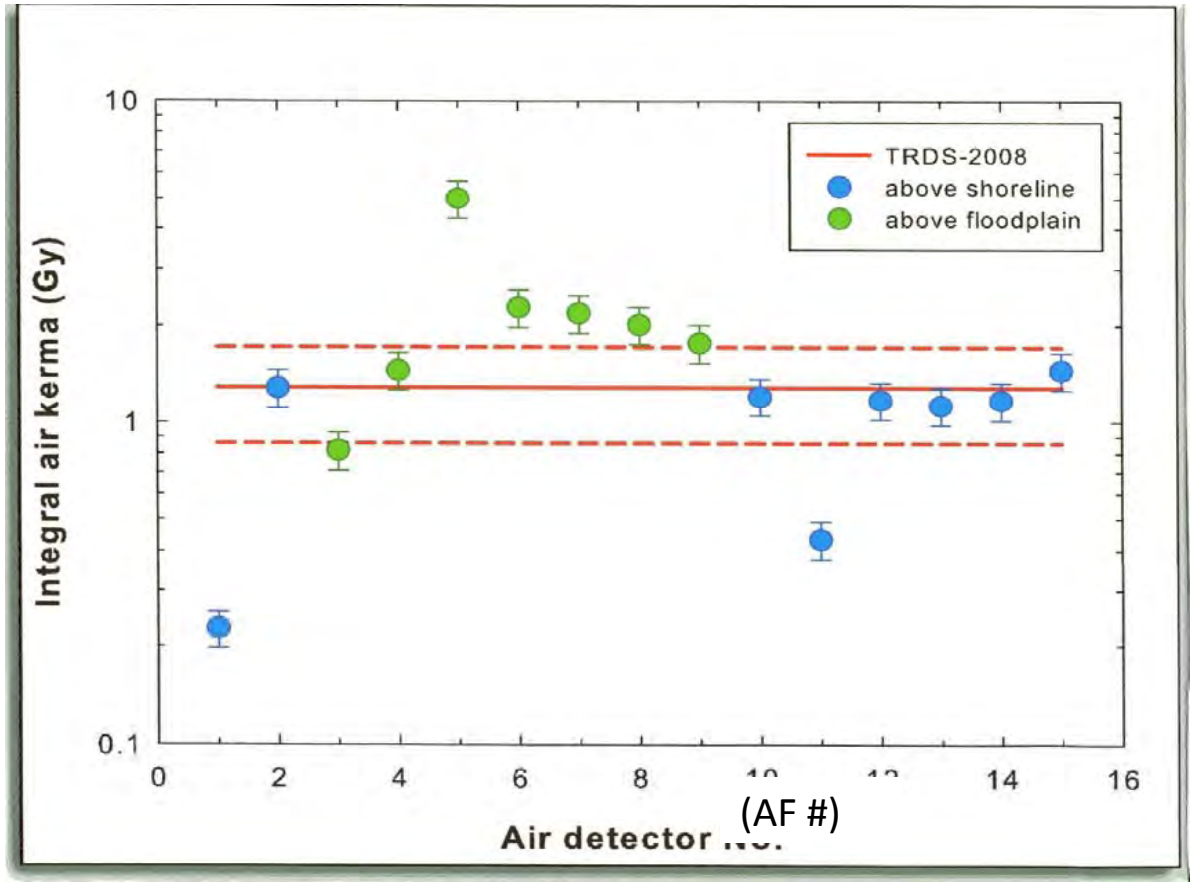
Estimated source function in MBq m^{-2}

Validation: TLD measurements of contemporary anthropogenic gamma dose rates in brick

Ratio of calculated and measured annual doses: 1.10 ± 0.10

Results - integral anthropogenic air kerma from 1950-2007 at air detector positions





A. Ulanovsky

Summary – External Dosimetry in SOUL

- Dosimetry system Mayak-Doses 2005 can have systematic errors
- Accurate evaluation of dosimetry system requires careful assessment of all additional influencing parameters for EPR and FISH-> work in progress
- Evaluation of gaseous releases reveals non-significant exposure of population of Ozyorsk
- Evaluation of external doses in TRDS for Muslyumovo reveals variation of air kerma values at Techa river shoreline and over floodplain of one order of magnitude due to heterogeneous contamination
- Value of integral air kerma used in TRDS-2008 lies approx. in the middle of this range
- Other dosimetry activities in SOUL (work in progress) : evaluation of external doses in TRDS using EPR and FISH, dosimetry for ^{90}Sr in teeth, internal dosimetry, calculation of individual doses for the TROC members

Acknowledgments

- HMGU: A. Ulanovsky, N. Semioschkina, I.Fiedler, E. Verdi
- URCRM: N. Bougrov, M. Degteva, M. Vorobieva
- SUBI: I. Azizova, N. Sotnik
- Mayak: Y. Mokrov, S. Rovny, E. Vasilenko, P. Zharov, M. Gorelov
- IMP: D. Ivanov
- ISS: P. Fattibene
- HPA: A. Edwards, L. Ainsbury
- LUMC: F. Darroudi

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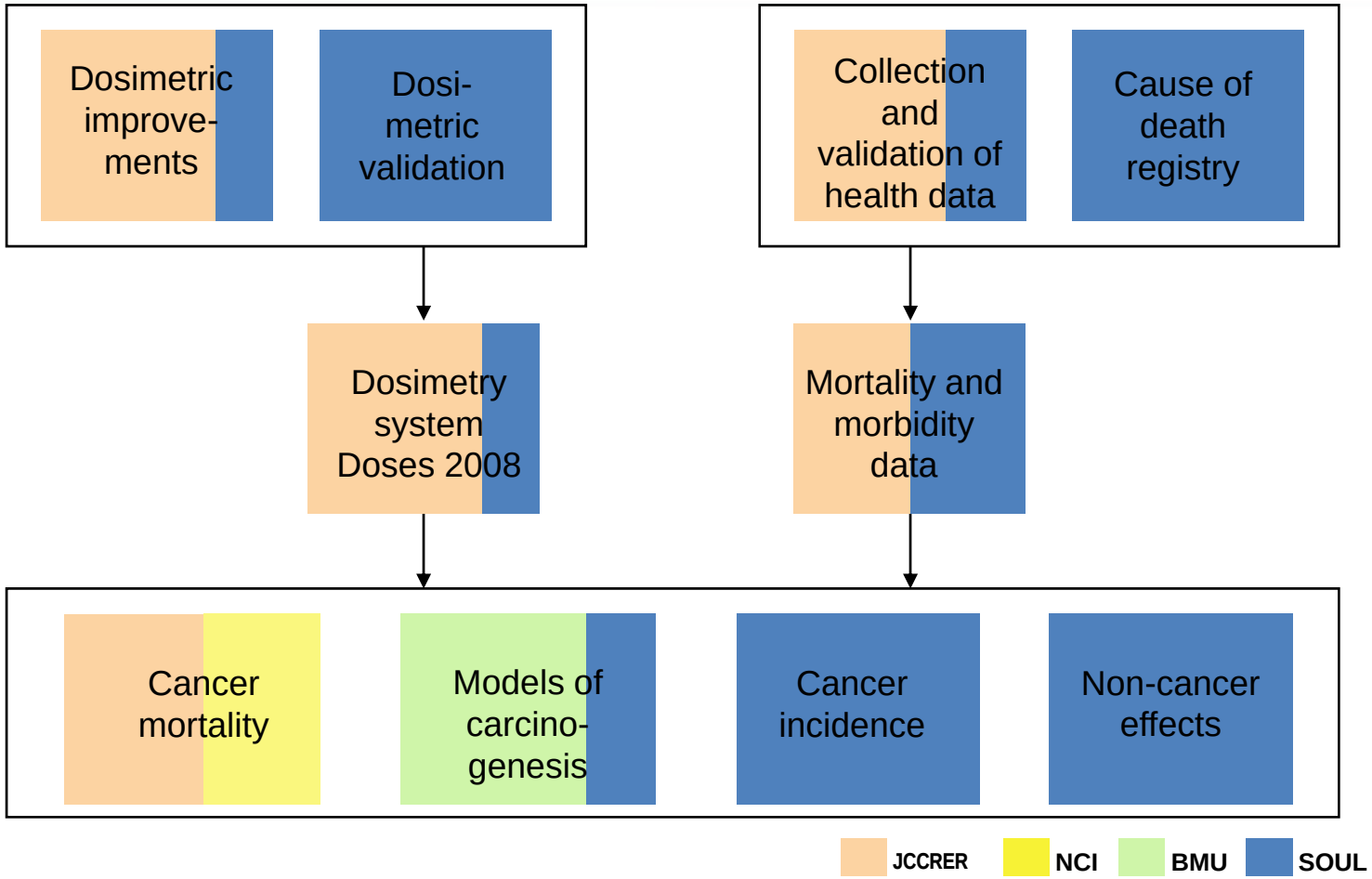
Research in the Southern Urals sponsored by the European Commission
Part II – Epidemiology and Internal Dosimetry

Colin Muirhead

Health Protection Agency, UK

Mayak Worker Cohort



WP 2.1 & WP 2.2 Internal Dosimetry for the Mayak Worker Cohort

Sergey Romanov (SUBI), John Harrison (HPA)

Aims

- To enhance the accuracy and reliability of individual plutonium dose assessment for Mayak workers by developing & validating a new set of biokinetic models incorporated into computer codes
- To validate the best individual organ dose estimates for the members of the Mayak worker cohort

This provided input to the development of *Mayak Doses-2008*

WP 2.4
Non-cancer effects in the Mayak worker cohort

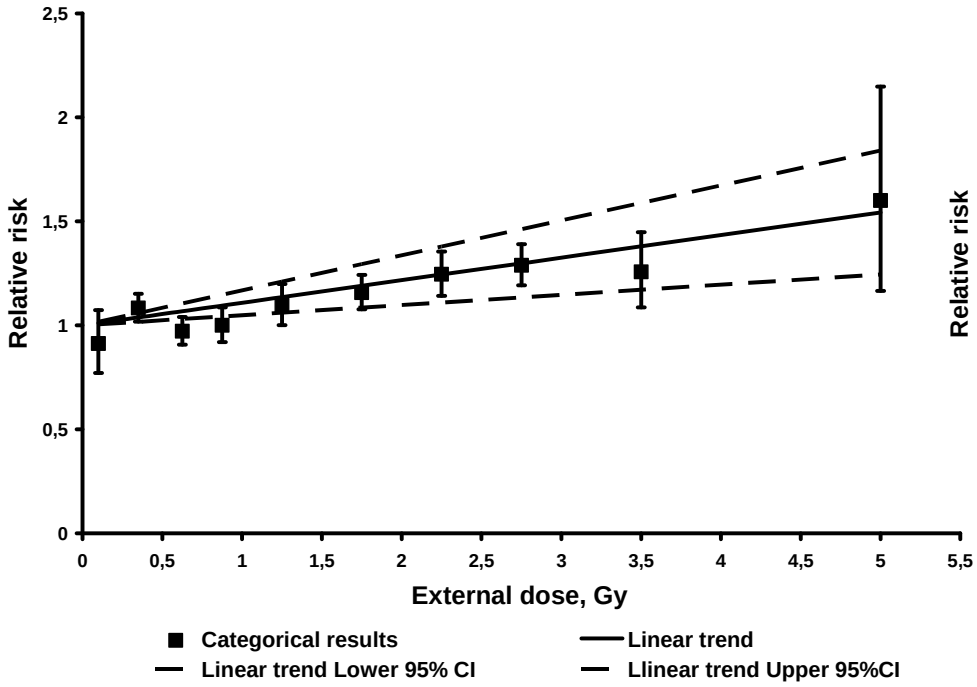
Tamara Azizova (SUBI), Colin Muirhead (HPA)

Workers hired 1948-58	Number	%
Number of workers included in the cohort	12210	100.0
Females	3552	29.1
Vital status known as of 31 December 2000	10789	88.4
Died	5685	52.7
Autopsy performed	1948	34.3
Cause of death known	5317	93.5
Medical documentation (morbidity data)	11597	95.0

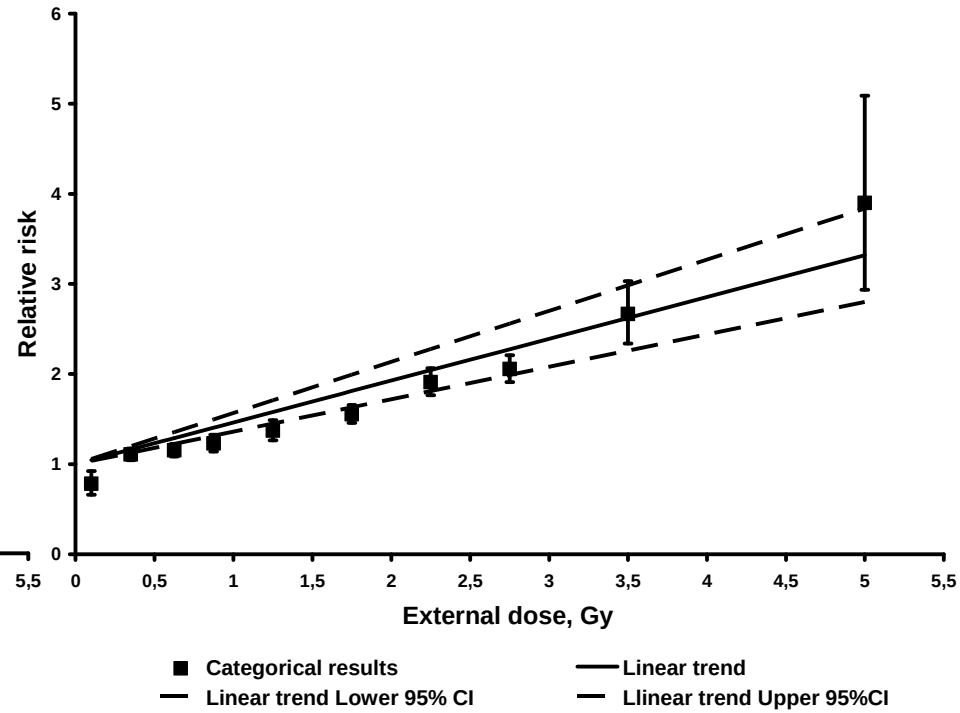
Annual external dose, annual internal dose (30%)
smoking, alcohol consumption, obesity, hypertension

WP2.4: Excess relative risks (ERR) for morbidity among Mayak workers in relation to external dose

Ischemic heart disease
0.11 (95% CI 0.05-0.17) Gy^{-1}



Cerebrovascular disease
0.46 (95% CI 0.36-0.57) Gy^{-1}



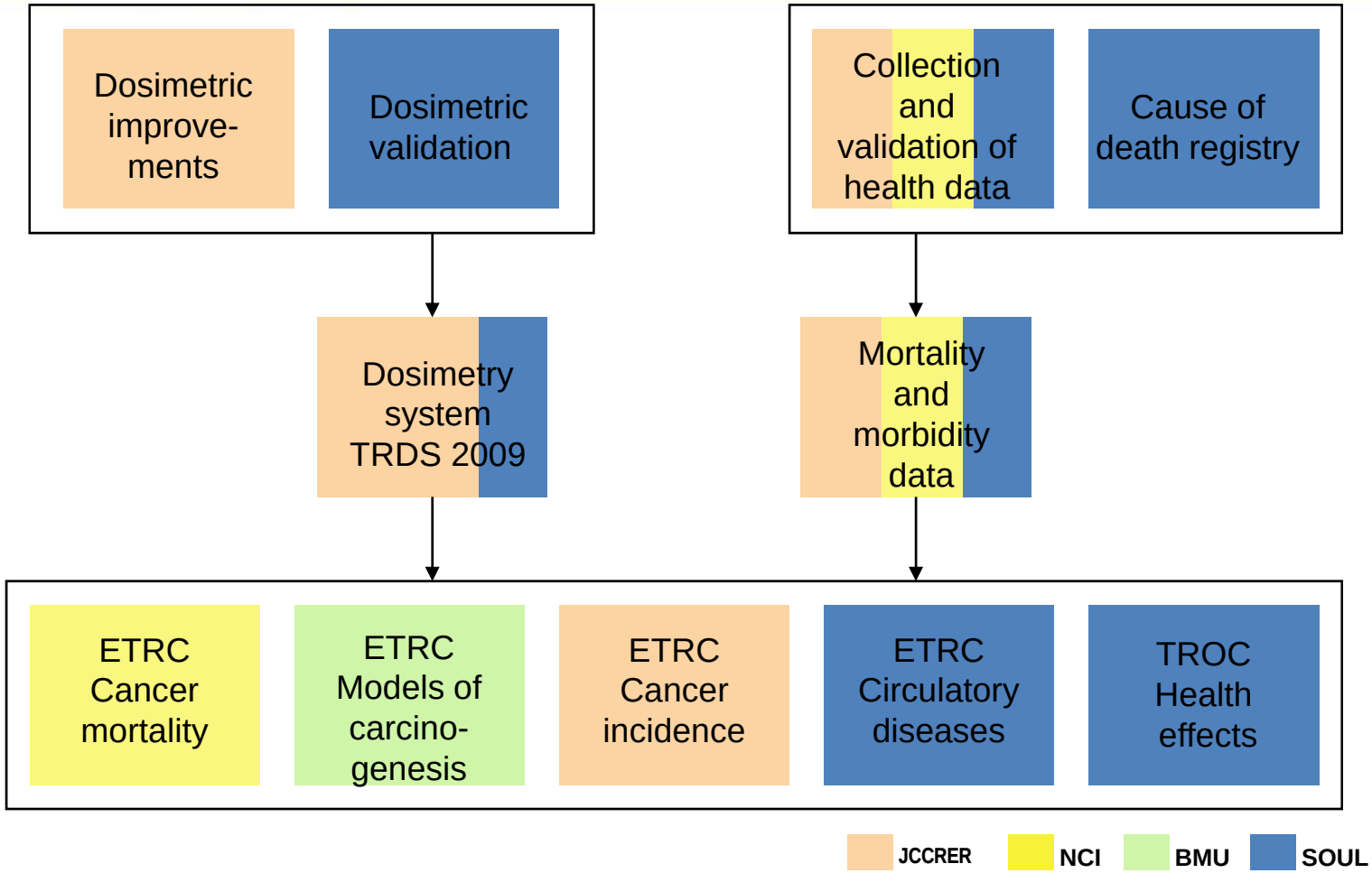
WP 2.5
Cancer Incidence in the Mayak Worker Cohort

Nina Koshurnikova (SUBI), Keith Binks (WSC)

Group	All workers 1948-1982	No plutonium exposure	Plutonium dose and monitored	Potential plutonium dose
Total	22327	5118	6067	11142
Males	16639 (75)	3981 (78)	4262 (70)	8396 (75)
Females	5688 (25)	1137 (22)	1805 (30)	2746 (25)
Lung[1] cancers	453	89	231	133
Liver[1] cancers	53	7	27	19
Bone[1] cancers	37	8	10	19
Other Solid[1] cancers	1413	276	526	611
Leukaemia[1] exc. CLL	55	9	12	34

[1]First cancers only excluding non-melanoma skin cancer events

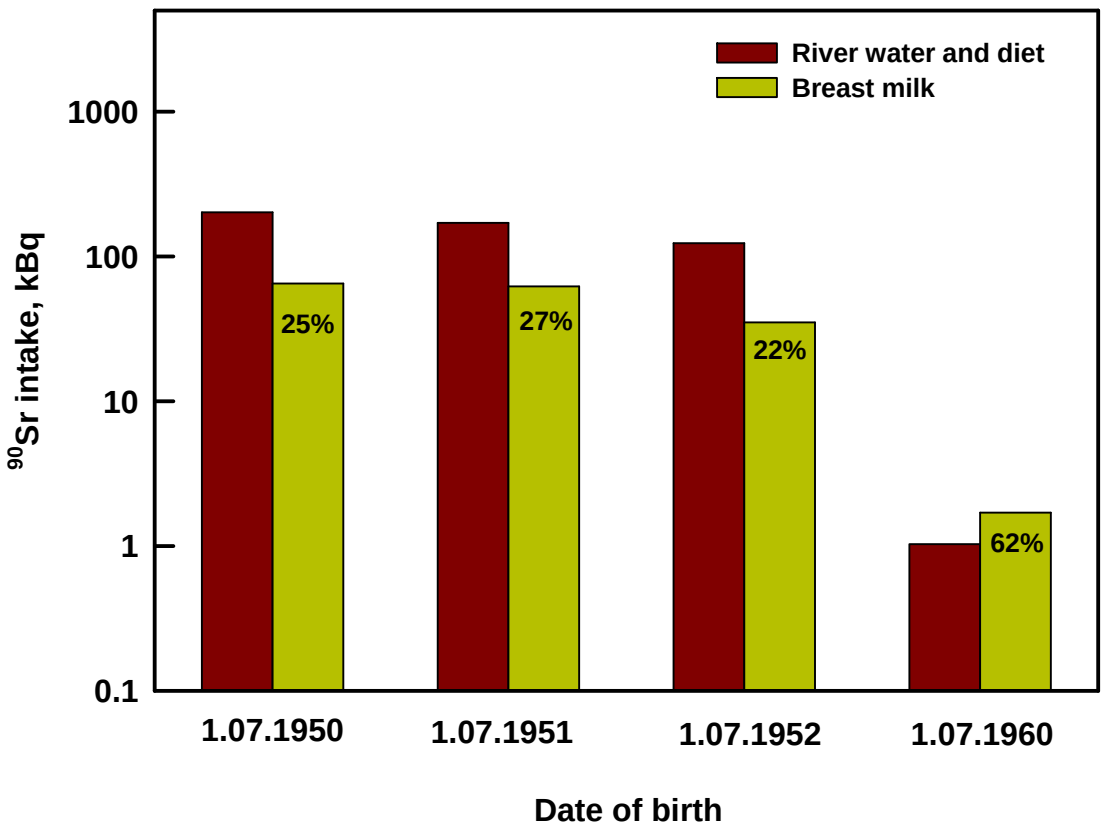
Techa River Cohorts



WP 3.3 Internal dosimetry (fetal and infant) for Techa River offspring cohort

John Harrison (HPA)

Evgenia Tolstykh (URCRM)



Intake of ^{90}Sr during the first year of life for children born in Muslyumovo in different calendar years

Percentages indicate the contribution of ^{90}Sr ingested with breast milk to total intake

WP 4.2 Health effects in the Techa River Offspring Cohort

Alexander Akleyev (URCRM) Per Hall (KI)

Dose distribution for offspring born in 1950 - 1955

Fetal dose (mGy)	n	%	Postnatal dose (mGy)	n	%
0.0	560	15	0.0	181	5
0.0 - 1.0	683	18	0.0 - 1.0	955	25
1.0 - 2.5	587	15	1.0 - 2.5	799	21
2.5 - 5.0	554	14	2.5 - 5.0	591	15
5.0 - 10	411	11	5.0 - 10	451	12
10 - 25	601	16	10 - 25	426	11
25 - 50	269	7	25 - 50	175	5
50 -	196	5	50 -	283	7
Total	3.861		Total	3.861	

Vital status known for >80% of non-migrants and local migrants

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WP 4.3 Non-cancer mortality in the Extended Techa River Cohort

Per Hall (KI) Alexander Akleyev (URCRM)

Structure of major causes of death for ETRC members including local migrants during 1950 through 2003 by gender

	Men		*Women*		*Total*	
Disease	n	%	n	%	n	%
Infectious and parasitic diseases	336	*5.0*	184	*2.4*	520	*3.6*
Neoplasms	1,145	*17.0*	1,097	*14.6*	2,242	*15.7*
Diseases of the circulatory system	2,971	*44.0*	4,604	*61.1*	7,575	*53.0*
Diseases of the respiratory system	618	*9.2*	467	*6.2*	1,085	*7.6*
Diseases of the digestive system	203	*3.0*	181	*2.4*	384	*2.7*
Symptoms, signs, and ill-defined conditions	158	*2.3*	303	*4.0*	461	*3.2*
Injury and poisoning	1,076	*15.9*	373	*5.0*	1,449	*10.1*
All causes	6,748	*100*	7,531	*100*	14,279	*100*
Total age-standardized mortality rate, per 10,000 person-years (95% CI)	18.3 (17.9-18.7)		9.6 (9.4-9.8)		12.7 (12.4-12.9)	

SOLO – Epidemiological Studies of Exposed Southern Urals Populations

- Proposal submitted to EC in April 2009 for 4-year project (coordinated by HPA) to follow on from SOUL
  - *Contract negotiation in progress*

Key elements of SOLO:

- To develop improved modelling modules of external dosimetry
- To continue studies of cancer incidence and non-cancer morbidity & mortality among Mayak workers
- Subject to feasibility studies that will consider, *inter alia*, data compatibility, to conduct pooled analyses of:
  - *Mortality & cancer incidence among plutonium workers at Mayak & Sellafield (UK);*
  - *Cancer following in utero irradiation in the offspring of Mayak female workers and the Techa River female population*

International liasion

- Discussions between researchers from the Russian Federation, USA and Europe have taken place in periodic workshops (eg. Chelyabinsk, 2005; Bad Griesbach, 2007) and telephone conferences for International Groups on Epidemiology and Dosimetry

- US representation (Lynn Anspaugh & Elaine Ron) on SOUL's Scientific Advisory Board

- Important to maintain close links between those involved in Southern Urals radiation research programmes

Abstract

U.S. Civilian Research and Development Foundation (CRDF): Supporting JCCRER Collaboration

Shawn T. Wheeler,
Vice President for Global Operations & Program Support Services U.S. Civilian Research & Development Foundation (CRDF)

Objective: To expand the Radiobiological Tissue Repository (RTR) by the continuing enrollment of Mayak workers exposed to low-level radiation, and the collection and annotation of human biological materials for research purposes.

Background: The RTR was established at the Southern Urals Biophysics Institute (SUBI) of the Federal Medical Biological Agency (FMBA) under DOE Project 2.8. As of September 1, 2009, over 1.1 million biological samples from 7,888 registrants have been placed into storage at the RTR. It consists of several components:

1. *Biorepository of Autopsy Tissues*: tissue samples of internal organs, cerebrum, endocrine glands, reproductive organs, blood-forming/lymphoid and bone tissues that were sampled at the autopsies of 940 workers of the Mayak PA, who died in 1951-2009, including 70 residents of Ozyorsk who were never occupationally exposed to ionizing radiation sources (a comparison group). The specimens are stored as formalin-fixed, paraffin blocks and slides with tissue sections. Catalogues of malignant tumors of the lung, pleura, and digestive organs are continuously maintained.
2. *Biorepository of Surgical/Biopsy Tumor and Non-Tumor Tissues*: these specimens were collected at surgical interventions and/or diagnostic biopsy from 655 individuals (403 workers of the Mayak PA, and 252 individuals from the comparison group).
3. *Biorepository of Blood and its Components*: these specimens consist of blood cells of various types (suspensions of leukocytes, lymphocytes, immortalized B-lymphocytes, erythrocytes), plasma and serum, and extracted DNA from 4,082 registrants (3,492 workers of the Mayak PA, and 590 individuals from the comparison group).

.

4. *Biorepository of Other Tissues:* these specimens consist of buccal epithelial cells, bone marrow, lymphoid tissue cells, cells and supernatant of induced sputum, bone tissue, which were collected from 2,211 registrants.

In order to successfully organize and maintain the RTR, several challenges have been overcome. This required addressing a complex set of organizational, methodological, regulatory and ethical issues. Collection and storage of these unique biological materials, as described above, provides a resource to the scientific community for investigating radiation health effects in workers and other persons. Collection of occupational and dosimetry data, medical and socio-demographic information, and verified external and internal dose accumulations of the RTR registrants are essential elements of the data annotation of each specimen. Systematization of the data has been achieved for the RTR specimens. This in turn has allowed us to create meta data resources, such as a catalogue of malignant tumors of various sites. Finally, we have developed and tested protocols for the approval and implementation of transfers of stored specimens samples to researchers in different countries.

Work under the Project in 2009-2010: We are continuing to collect biological specimens and data from workers and from the population of Ozyorsk (as a comparison group). We recently developed and implemented methods for the collection of saliva. We are going to establish the database of blood and its components, a log of research results obtained based on the blood bank, and the conversion of the tumor tissue catalogues into searchable electronic format. A monograph on the Experience of Establishing the Radiobiological Repository is being written at this time, and we anticipate its completion by the end of the year. The RTR data base of specimens and annotated data is being converted from an older software system into Microsoft Access, which will allow enhanced search and reporting capabilities. Finally, we are in the process of a complete review of all protocols at the RTR to assess and achieve compliance with the recently released guidelines of the U.S. National Cancer Institute's Best Practices for Biological Repositories.

Joint Coordinating Committee for Radiation Effects Research

(JCCRER)

7TH International U.S. - Russian Meeting

2009

September 16 - 17, 2009
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U.S. Civilian Research and Development Foundation (CRDF)

Supporting JCCRER Collaboration

Who We Are

CRDF was established in 1995 as an independent, non- governmental organization, headquartered in Arlington, VA, with four overseas offices in Azerbaijan, Kazakhstan, Russia and Ukraine with a fifth office in Jordan opening in late 2009.

A unique, public-private partnership, CRDF promotes international science and technology collaboration through grants, technical resources and training.

CRDF operates with funding from a wide array U.S. government agencies, private foundations, foreign organizations, and companies.

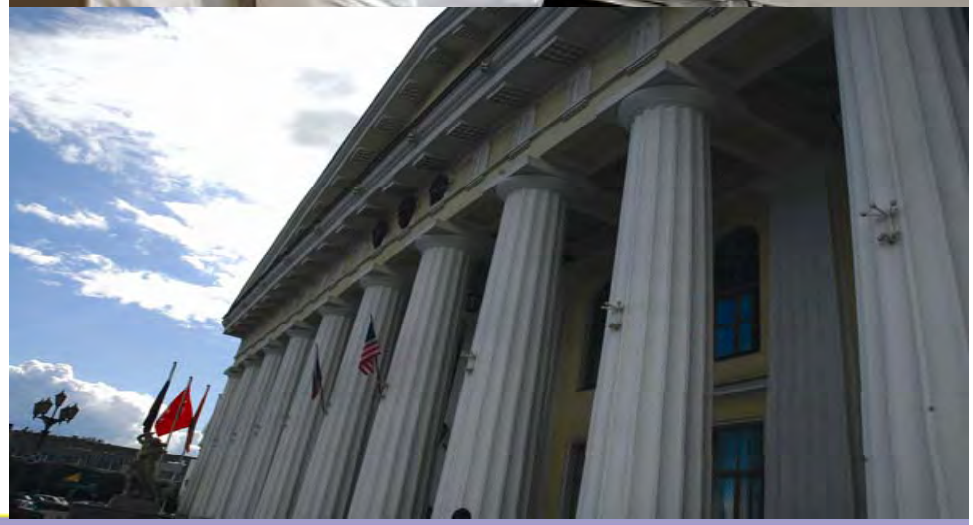
What We Do

CRDF fosters international scientific cooperation to harness nations' economic potentials; solve societal challenges; promote security, and improve human conditions.

How We Do It

- **Cooperative Research**: CRDF enables and promotes cross-border research collaborations to address critical global issues (ex. health, environment, energy, and security).

- **Higher Education & Infrastructure**: CRDF is helping to build solid foundations of knowledge economies by transforming and reinvigorating educational institutions around the globe to best prepare the next generation of scientists and engineers.



How We Do It

- **Innovation**: Scientific research can be the primary engine of economic development. CRDF works to catalyze successful international science and technology-based business partnerships.

- **Security & Threat Reduction**: Through direct engagement of scientific communities CRDF helps nations develop secure science to address the challenges of the future.

How We Do It

- **Services and Support**: CRDF provides project management, information technology solutions and support services that enable organizations to establish and maintain international partnerships, leverage limited resources, broaden R&D capabilities and reduce the obstacles and risks of international collaboration.

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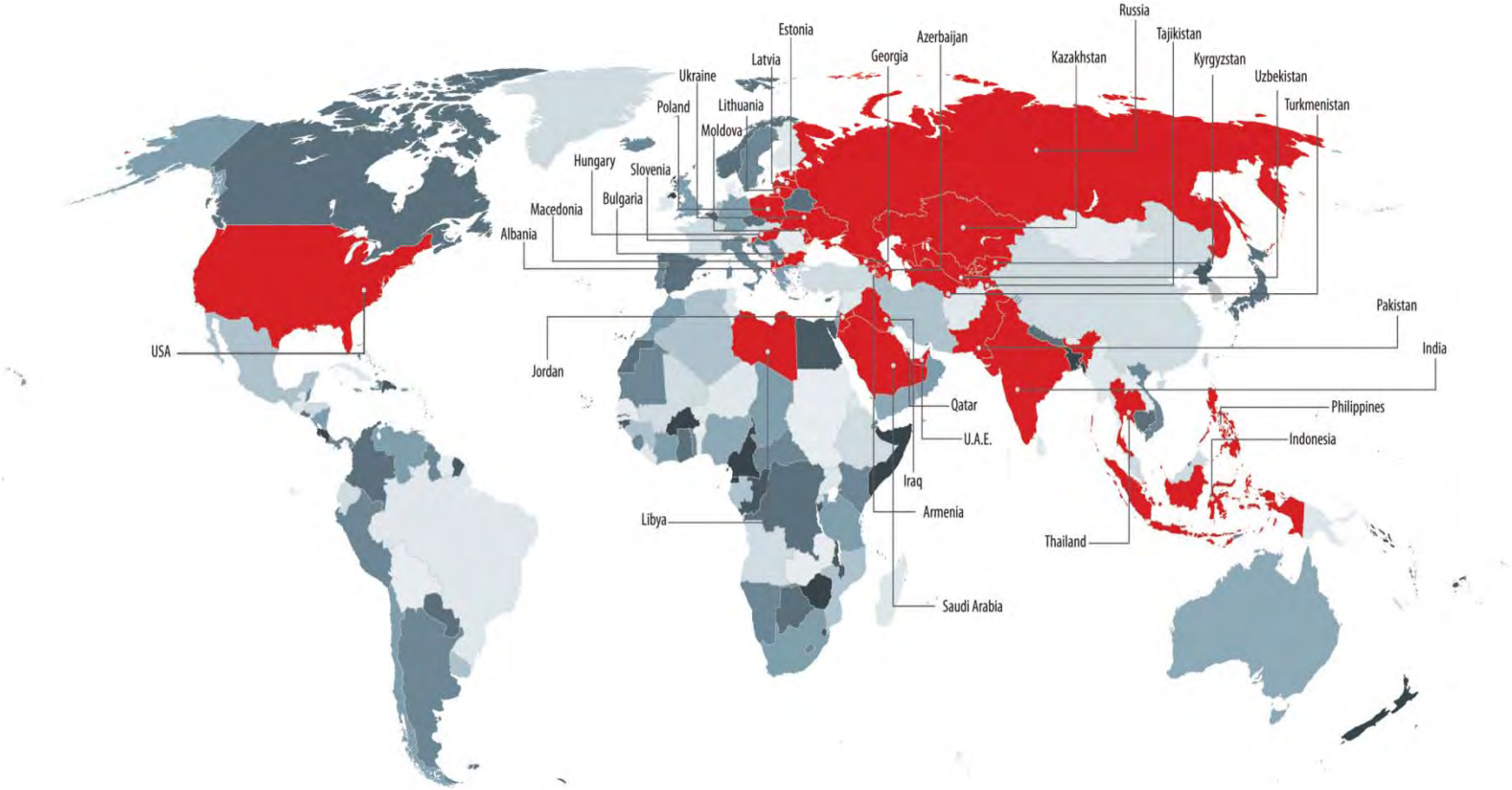
Where We Work



Who We Serve

CRDF has worked on behalf of or in partnership with hundreds of funders and clients, including:

CRDF & Russia

CRDF Russia Office located in the Shemyakin and Ovchinnikov Institute of Bioorganic Chemistry in Moscow. Satellite representatives in St. Petersburg & Vladivostok

СРДФ
техинновации

CRDF TechInnovation is a for-profit subsidiary established by CRDF to provide project management, professional training in innovation management, technology commercialization and other services.

CRDF & Russia

- Since 1995 CRDF has:
  - Awarded over 1,800 grants
  - Engaged more than 20,000 Russian scientists & engineers
  - Invested over $60M in funding from CRDF, $18M from the Russian Government, $9M from Russian institutions and $10M from U.S. industry.
- CRDF has facilitated over 1,100 projects on behalf of other organizations totaling over $186M.

CRDF & Russia

Major Initiatives:

- HIV/AIDS Public Health Centers of Excellence
- Basic Research & Higher Education
- Innovation & Entrepreneurship
- Climate Change Research

CRDF & JCCRER

CRDF has been proud to support DOE in its JCCRER efforts since 1998 beginning with the transfer of scanning and microfilm equipment to DOE's Russian partners. Since that time our support for DOE has expanded and to date CRDF has facilitated the transfer of over $8M in funds and equipment in support of JCCRER activities.

CRDF Supporting Research on Health Effects of Radiation

In addition to our long-standing support of DOE's activities under JCCRER, CRDF has also supported the efforts of the International Consortium for Research on the Health Effects of Radiation, Fred Hutchinson Cancer Research Center, and the Institut de Radioprotection et de Sûreté Nucléaire in their research efforts in the Russian Federation.

Peace and Prosperity Through International Science Collaboration

1530 Wilson Boulevard, Third Floor

Arlington, Virginia 22209

Telephone: 703-526-9720

www.crdf.org

JCCRER 2009 Roster of Registrants[1]

English	Organization	Russian
Alexander Akleyev	Urals Research Center for Radiation Medicine (URCRM)	Александр Васильевич Аклеев
Isaf Al-Nabulsi	U.S. Department of Energy (DOE)	Исаф Аль-Набульси
Matthew Aptaker	Civilian Research and Development Foundation (CRDF)	Мэтью Эптэйкер
Michael Ardaiz	U.S. Department of Energy (DOE)	Майкл Ардейз
Judith Ann Bamberger	Pacific Northwest National Laboratory (PNNL)	Юдит Энн Бэмбергер
Yana Barbotko	Federal Medical Biological Agency (FMBA)	Яна Барботько
Alan Birchall	Health Protection Agency	Элан Берчел
Diana Clark	U.S. Department of Energy (DOE)	Диана Кларк
Mary E. Clark	U.S. Environmental Protection Agency (EPA)	Мери Е. Кларк
Denise Clarke	U.S. Department of Energy (DOE)	Денис Кларк
Francis Cucinotta	National Aeronautics and Space Administration (NASA)	Фрэнсис Кусинота
Faith Davis	University of Illinois at Chicago	Фэйт Дэйвис
Ray Daniels	Defense Nuclear Facilities Safety Board (DNFSB)	Рэй Даниелс
Marina Degteva	Urals Research Center for Radiation Medicine (URCRM)	Марина Олеговна Дёгтева

[1] Names are listed alphabetically based on their English spelling

English	Organization	Russian
William Eckroade	U.S. Department of Energy (DOE)	Вильям Экроуд
Danny Fields	U.S. Department of Energy/ National Nuclear Security Administration (NNSA)	Дэнни Филд
Barrett Fountos	U.S. Department of Energy (DOE)	Баррет Фаунтос
Lesley Gasperow	U.S. Department of Energy (DOE)	Лесли Гэсперoу
Ethel Gilbert	National Cancer Institute (NCI)	Этель Гилберт
Evgeny Goloborodko	Federal Medical Biological Agency (FMBA)	Евгений Владимирович Голобородько
Mikhail Gorelov	Mayak	Михаил Васильевич Горелов
Kathy Halvey Gibson	U.S. Nuclear Regulatory Commission (NRC)	Кэти Хэлви Гибсон
Terry Hamilton	Lawrence Livermore National Laboratory (LLNL)	Тэрри Хамильтон
Ann Heinrich	U.S. Department of Energy/ National Nuclear Security Administration (NNSA)	Энн Хайнрих
Vincent Holahan	U.S. Nuclear Regulatory Commission (NRC)	Винсен Холахан
William Jackson	U.S. Department of Energy (DOE)	Вильям Джэксон
André Jouve	European Commission (EC)	Андре Жув
Evgenia Kirillova	Southern Urals Biophysics Institute (SUBI)	Евгения Никитовна Кириллова
Mikhail Kiselev	Russian JCCRER Co-Chair Federal Medical Biological Agency (FMBA)	Михаил Филиппович Киселёв
Liudmila Krestinina	Urals Research Center for Radiation Medicine (URCRM)	Людмила Юрьевна Крестинина

English	Organization	Russian
Arina Kuzmova	Civilian Research and Development Foundation (CRDF)	Арина Кузьмова
Olga Lazareva	Southern Urals Biophysics Institute (SUBI)	Ольга Лазарева
Alexey Lebedev	Urals Research Center for Radiation Medicine (URCRM)	Алексей Лебедев
Patricia Lillis-Hearne	Armed Forces Radiobiology Research Institute	Патрисия Лиллис-Хирн
Christopher Loffredo	Georgetown University	Кристофер Лофредо
Mary Lisa Madell	U.S. Department of Health and Human Services (DHHS)	Мэри Лайза Мэйдел
Sergey Mikheenko	State Atomic Energy Corporation (ROSATOM)	Сергей Григорьевич Михеенко
Charles Miller	U.S. Department of Health and Human Services (DHHS)	Чарльз Миллер
Scott Miller	University of Utah	Скотт Милер
Vitaly Minchenko	Embassy of the Russian Federation	Виталий Минченко
Douglas Minema	Defense Nuclear Facilities Safety Board (DNFSB)	Дуглас Майнема
Ashley Minton	Link Technologies, Inc. (DOE)	Эшли Минтон
Yuri Mokrov	Mayak	Юрий Геннадьевич Мокров
Eric Monares	Link Technologies, Inc. (DOE)	Эрик Монарес
Colin Muirhead	Health Protection Agency	Колин Мурхэд
Bruce Napier	Pacific Northwest National Laboratory (PNNL)	Брюс Напье

English	Organization	Russian
David Pawel	U.S. Environmental Protection Agency (EPA)	Дэвид Поуэл
Gerald Petersen	U.S. Department of Energy (DOE)	Джеральд Питерсен
Glenn Podonsky	U.S. JCCRER Co-Chair U.S. Department of Energy (DOE)	Гленн Подонски
Craig Postlewaite	U.S. Department of Defense (DOD)	Крэг Постелвэйт
Dale Preston	Hirosoft International	Дэйл Престон
Joel Rabovsky	U.S. Department of Energy (DOE)	Джоэл Рабовский
Glen Reeves	Northrop Grumman	Глен Ривз
Sergey Romanov	Southern Urals Biophysics Institute (SUBI)	Сергей Романов
Elaine Ron	National Cancer Institute (NCI)	Рон Элен
David Rush	Prof. Emeritus, Tufts University	Дэйвид Раш
Frank Russo	U.S. Department of Energy/ National Nuclear Security Administration (NNSA)	Фрэнк Руссо
Michael Ryan	Health Physics Journal	Майкл Райен
David Schauer	National Council on Radiation Protection & Measurements (NCRP)	Дэйвид Шауэр
Robert Scherpelz	Pacific Northwest National Laboratory (PNNL)	Роберт Шерпелц
Sara Schonfeld	National Cancer Institute (NCI)	Сара Счонфилд
Natalia Shandala	Federal Medical Biophysical Agency (FMBC)	Наталия Шандала

English	Organization	Russian
Sergey Shinkarev	Russian JCCRER Executive Committee Co-Chair Federal Medical Biophysical Agency (FMBC)	Сергей Шинкарев
Daniela Stricklin	National Academies	Даниэла Стриклин
Mikhail Sokolnikov	Southern Urals Biophysics Institute (SUBI)	Михаил Соколников
Ali Tabatabai	Link Technologies, Inc. (DOE)	Али Табатабаи
Oleg Volosov	Federal Medical Biological Agency (FMBA)	Олег Волосов
Joseph Weiss	U.S. Department of Energy (DOE)	Джозеф Вайс
Shawn Wheeler	Civilian Research and Development Foundation (CRDF)	Шон Вилер
Elizabeth White	U.S. Department of Energy (DOE)	Элизабет Вайт
Clemens Woda	Helmholtz Zentrum Munchen	Клеменс Вода
Patricia Worthington	U.S. JCCRER Executive Committee Co-Chair U.S. Department of Energy (DOE)	Патрисия Уортингтон
Jeanette Yarrington	U.S. Department of Energy (DOE)	Дженет Йэрингтон
Larissa Zagaytova	U.S. Department of Energy/ National Nuclear Security Administration (NNSA)	Лариса Загайтова
Alexandra Zeigler	Link Technologies, Inc. (DOE)	Алекс Цейглер
Joey Zhou	U.S. Department of Energy (DOE)	Джои Джоу

AGREEMENT BETWEEN
THE GOVERNMENT OF THE UNITED STATES OF AMERICA
AND
THE GOVERNMENT OF THE RUSSIAN FEDERATION
ON COOPERATION IN RESEARCH ON RADIATION EFFECTS
FOR THE PURPOSE OF MINIMIZING THE CONSEQUENCES
OF RADIOACTIVE CONTAMINATION ON HEALTH AND THE ENVIRONMENT

The Government of the United States of America and the Government of the Russian Federation (hereinafter referred to as the "Parties"):

Desiring to establish close and long-term cooperation in the field of studying the radiation effects upon the health and the environment for the purpose of minimizing the effect of radioactive contamination;

Noting the benefits to humanity of increased scientific understanding of the radiation effects upon the health and the environment;

Have agreed as follows:

Article I

The purpose of this Agreement is to establish a framework for cooperation between the participating organizations of the parties, as determined pursuant to Article IV of this Agreement, in research on radiation effects for the purpose minimization of the consequences of radioactive contamination on health and the environment.

Article II

The areas of cooperation under the Agreement may include, but are not limited to, the following:

1. Health effects studies including epidemiologic and other health-related studies of workers and community members potentially exposed to ionizing radiation;

2. Information and data management activities including information development and exchange of experience in radiation effects, data preservation, and database and information system development;

3. Environmental studies including the identification and modeling of deposition, dispersion, and ecological transport of radionuclides and other hazardous contaminants as necessary to study and reconstruct doses to human populations and to assess the impact of radioactivity on the environment. Development and application of dosimetric systems and methodologies for retrospective reconstruction of doses to human populations.

4. Health communication of risk assessment including distribution of public health information pertaining to radiological contamination and measures to reduce present and future human exposure to radionuclides and associated hazardous substances;

5. Policy analysis including review of radiation detection and reporting mechanisms, as well as evaluation of safeguards to minimize radiation effects on human population;

6. Scientific research to develop information which can assist in minimization of the consequences of radioactive contamination on the environment and health;

7. Other areas of cooperation as may be mutually agreed by the Parties.

Article III

1. To implement this Agreement, there shall be established a Joint Coordinating Committee for Radiation Effects Research (the "JCCRER").

2. The JCCRER shall consist of an equal number of representatives from each Party. All decisions taken by the JCCRER shall be by mutual agreement of the Parties.

3. The JCCRER will decide on its membership and meeting schedule. Generally, it will be convened once a year, alternatively in the United States and Russia, unless agreed otherwise. Times, places and agendas for meetings will be agreed upon in advance by the Parties.

4. The JCCRER will, within the framework of its jurisdiction, coordinate and review all aspects of cooperation under this Agreement and shall take such action as is appropriate for this Agreement's effective implementation.

5. The JCCRER may organize, establish and arrange working groups, conferences and seminars of specialists for joint

discussion and study of specific topics related to the purposes of this Agreement. Specific projects and programs for radiation effects research, exchanges of scientific and technical safety information, personnel and equipment, and procedures for addressing and resolving questions of such matters as payment of costs under this cooperation, and patent and/or publication rights for joint activities administered under this Agreement may be developed separately by the JCCRER in accordance with the laws and regulations of the Parties.

6. The JCCRER shall generally establish on an annual basis a program of cooperation to be implemented during the following year.

7. The Executive Agents responsible for coordination of this Agreement shall be, for the United States of America, the United States Department of Energy, and for the Russian Federation, the State Committee of the Russian Federation for the Social Protection of Population and Rehabilitation of Regions Affected by Chernobyl and Other Radiation Catastrophes.

Article IV

The forms of cooperation to be approved by the JCCRER under this Agreement may include the following:

1. Joint data collection and information exchange, as well as experimental, developmental, demonstrational and design work by technical personnel at appropriate facilities and sites of the two countries;

2. Exchanges of appropriate instrumentation, equipment and materials for projects;

3. Exchange of technical specialists for participation in agreed activities;

4. Exchange of appropriate scientific and technical information, documentation and results of research;

5. Organization of seminars and other meetings on agreed topics; and

6. Such additional forms of cooperation, as mutually agreed.

Article V

1. Cooperation under this Agreement will be conducted according to the plans and programs of the following principal establishments and organizations, as agreed to pursuant to Article III.5:

In the United States of America:

-- the Department of Energy;
-- Nuclear Regulatory Commission;
-- Department of Defense;
-- Department of Health and Human Services;
-- Environmental Protection Agency; and other government departments and nuclear industry establishments and organizations, as appropriate;

in the Russian Federation:

-- State Committee of the Russian Federation for the Social Protection and Rehabilitation of Regions Affected by Chernobyl and Other Radiation Catastrophes;
-- Ministry of the Russian Federation for Atomic Energy;
-- Ministry of Health of the Russian Federation:
-- Ministry of Agriculture of the Russian Federation;
-- State Committee on Sanitary and Epidemiological Surveillance of the Russian Federation;

-- Federal Service of Russia on Nuclear and Radiation Safety;

-- Russian Federal Service for Hydrometeorology and Environmental Monitoring;

-- Federal Service of Russia on Forest Economy;

-- Russian Ministry of Defense;

-- Russian State Committee for Civil Defense Affairs, Emergencies and Elimination of Consequences of Natural Disasters;

-- Russian Academy of Sciences, and other interested Russian ministries, departments, and organizations.

2. Each Party may adjust the list of its principal establishments and organizations participating in this cooperation, and shall inform the other Party of any such adjustments through the State Committee of the Russian Federation for the Social Protection of Population and Rehabilitation of Regions Affected by Chernobyl and Other Radiation Catastrophes and the United States Department of Energy.

Article VI

1. Provisions for the protection and allocation of intellectual property are set forth in the Annex to this Agreement and form an integral part of this Agreement and apply to all activities carried out hereunder.

2. For purposes of this Agreement, the obligations of Article III of the Annex shall also apply to "Confidential Information". Confidential information means information containing know-how, trade secrets, or technical commercial, or financial information that:

- has been held in confidence by its owner;
- is not generally known or available from other sources;
- has not been made available by its owner to other parties without an obligation concerning its confidentiality; and
- is not available to the receiving Party without obligations concerning its confidentiality.

Article VII

1. Cooperation under this Agreement will be conducted according to the international obligations, laws and regulations of the Parties and will be subject to the availability of funds.

2. Exchange of specialists and experts shall be governed by mutual agreement of the Parties in each case.

3. Any questions of interpretation and implementation relating to this Agreement shall be resolved by agreement of the Parties.

Article VIII

1. This Agreement will enter into force upon signature and will remain in force for five (5) years, subject to extension of additional five (5) year terms by written agreement of the Parties following joint review at the end of each five-year period.

2. In case of cessation of this Agreement, all joint projects and experiments being conducted at the cessation of

this Agreement may be continued to their conclusion in accordance with the terms of this Agreement.

3. This Agreement may be amended by mutual agreement in writing.

4. Either Party has the right to terminate this Agreement after giving the other Party six (6) months advance written notice.

IN WITNESS WHEREOF, the undersigned, being duly authorized by their respective Governments, have signed this Agreement.

Done at Moscow, in duplicate, this 14th day of January, 1994, in the English and Russian languages, each text being equally authentic.

FOR THE GOVERNMENT OF
THE UNITED STATES OF AMERICA:

Warren Christopher

FOR THE GOVERNMENT OF
THE RUSSIAN FEDERATION:

V. Kozyrev

ANNEX

INTELLECTUAL PROPERTY

Pursuant to Article VI of this Agreement:

The Parties shall ensure adequate and effective protection of intellectual property created or furnished under this Agreement and relevant implementing arrangements. The Parties agree to notify one another in a timely fashion of any inventions or copyrighted works arising under this Agreement and to seek protection for such intellectual property in a timely fashion. Rights to such intellectual property shall be allocated as provided in this Annex.

I. SCOPE

A. This Annex is applicable to all cooperative activities undertaken pursuant to this Agreement, except as otherwise specifically agreed to by the Parties or their designees.

B. For purposes of this agreement, intellectual property shall have the meaning found in Article 2 of the Convention Establishing the World Intellectual Property Organization, done at Stockholm, July 14, 1967.

C. This Annex addresses the allocation of rights, interests, and royalties between the Parties. Each Party shall ensure that the other Party can obtain the rights to intellectual property allocated in accordance with the Annex, by obtaining those rights from its own participants through contracts or other legal means, if necessary. This Annex does not otherwise alter or prejudice the allocation between a Party and its nationals, which shall be determined by that Party's laws and practices.

D. Disputes concerning intellectual property arising under this Agreement should be resolved through discussions between the concerned participating institutions or, if necessary, the Parties or their designees. Upon mutual agreement of the Parties, a dispute shall be submitted to an arbitral tribunal for binding arbitration in accordance with the applicable rules of international law. Unless the Parties or their designees agree otherwise in writing, the arbitration rules of the UNCITRAL shall govern.

E. Termination or expiration of the Agreement shall not affect rights or obligations under this Annex.

II. ALLOCATION OF RIGHTS

A. Each Party shall be entitled to a non-exclusive, irrevocable, royalty-free license in all countries to translate, reproduce, and publicly distribute scientific and technical journal articles, reports, and books directly arising from cooperation under this Agreement. All publicly distributed copies of a copyrighted work prepared under this provision shall indicate the names of the authors of the work unless an author specifically declines to be named.

B. Rights to all forms of intellectual property, other than those rights described in Section II(A) above shall be allocated as follows:

1. Researchers and scientists visiting in furtherance of their education shall receive intellectual property rights under the existing rules of the host institution. In addition, each visiting researcher or scientist named as an inventor shall have the right to national treatment regarding awards, benefits or other compensation, including royalties, in accordance with the existing rules of the host institution.

2. (a) For intellectual property created during joint research, for example, when the Parties, participating institutions, or participating personnel have agreed in advance on the scope of work, each Party shall be entitled to obtain all rights and interests in its own territory. Rights and interests in third countries will be determined in implementing arrangements. The rights to intellectual property shall be allocated with due regard for the economic, scientific and technological contributions from each Party to the creation of intellectual property. If research is not designated as "joint research" in the relevant implementing arrangement, rights to intellectual property arising from the research will be allocated in accordance with Paragraph II(B)(1). In addition, each person named as an inventor shall have the right to national treatment regarding awards, benefits and other compensation, including royalties, in accordance with the existing rules of the host institution.

(b) Notwithstanding Paragraph II(B)2(a), if a type of intellectual property is available under the laws of one party but not the other Party, the Party whose laws provide for this type of protection shall be entitled to all rights and interests worldwide. Persons named as inventors of the property shall nonetheless be entitled to royalties as provided in Paragraph II(B)2(a).

III. BUSINESS-CONFIDENTIAL INFORMATION

In the event that information identified in a timely fashion as business-confidential is furnished or created under the Agreement, each Party and its participants shall protect such information in accordance with applicable laws, regulations, and administrative practice. Information may be identified as "business-confidential" if a person having the information may derive an economic benefit from it or may obtain competitive advantage over those who do not have it, the information is not generally known or publicly available from other sources, and the owner has not previously made the information available without imposing in a timely manner an obligation to keep it confidential.

PROTOCOL

BETWEEN THE GOVERNMENT OF THE UNITED STATES OF AMERICA AND THE GOVERNMENT OF THE RUSSIAN FEDERATION TO EXTEND AND AMEND THE

((Agreement between the Government of the United States of America and the Government of the Russian Federation on Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment)) signed January 14, 1994

The Government of the United States of America and the Government of the Russian Federation (hereafter referred to as the «Parties»),

Having regard to the Agreement between the Government of the United States of America and the Government of the Russian Federation on Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment signed on January 14, 1994 (hereafter «the Agreement)));

Desiring to continue joint activities within the framework of the Agreement to minimize the consequences of radioactive contamination on human health and the environment; and

Noting that Paragraph 1, Article VIII of the Agreement provides for extension of the Agreement by written agreement of the Parties,

Have agreed as follows:

Article I

The term of the Agreement is extended for five years until January 14, 2004, unless terminated earlier in accordance with Paragraph 4, Article VIII of the Agreement.

Article II

The Agreement shall be amended as follows:

1. Paragraph 7, Article III shall be worded as follows:

«7. The Executive Agents responsible for coordination of activities to implement this Agreement shall be,

for the United States of America

- the United States Department of Energy and

for the Russian Federation

- the Ministry of Health of the Russian Federation (on issues of medical-biological research of the effect of radiation on human organs) and the Ministry of the Russian Federation for Civil Defense Affairs, Emergencies and the Elimination of Consequences of Natural Disasters (on issues of implementing measures for rehabilitation of the population and territories that have been subjected to radiation accidents).))

2. Paragraph 1, Article V shall be worded as follows after «in the Russian Federation)):

«- Ministry of Health of the Russian Federation

- Ministry of the Russian Federation for Civil Defense Affairs, Emergencies and the Elimination of Consequences of Natural Disasters
- Ministry of the Russian Federation for Atomic Energy
- Other interested federal bodies of the executive branch and organizations)).

3. Paragraph 2, Article V shall be worded as follows:

«2. Each Party may adjust the list of offices and organizations participating in the implementation of this Agreement, and shall inform the other Party of such adjustments through the Executive Agents responsible for coordination of activities in accordance with Paragraph 7, Article III of the Agreement.))

Article III

The Protocol shall enter into force upon signature.

Done at Washington, this 10 day of March, 2000, in duplicate, in the English and Russian languages, each text being equally authentic.

FOR THE GOVERNMENT OF THE UNITED STATES OF AMERICA	FOR THE GOVERNMENT OF THE RUSSIAN FEDERATION

PROTOCOL

**between the Government of the United States of America
and the Government of the Russian Federation
to Extend and Amend
the Agreement between the Government of the United States of America
and the Government of the Russian Federation
on Cooperation in Research on Radiation Effects for the Purpose of
Minimizing the Consequences of Radioactive Contamination on
Health and the Environment
of January 14, 1994**

The Government of the United States of America and the Government of the Russian Federation, hereinafter referred to as the Parties,

Noting the terms of the Agreement between the Government of the United States of America and the Government of the Russian Federation on Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment of January 14, 1994 (hereinafter the Agreement), and the Protocol of March 10, 2000, between the Government of the United States of America and the Government of the Russian Federation to Extend and Amend the Agreement between the Government of the United States of America and the Government of the Russian Federation on Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment of January 14, 1994,

Desiring to continue joint activities within the framework of the Agreement to minimize the consequences of radioactive contamination on human health and the environment,

Noting that paragraph 1, Article VIII of the Agreement provides for extension of the Agreement by written agreement of the Parties,

Have agreed as follows:

Article 1

To extend the term of the Agreement for five years, until January 14, 2009, unless terminated earlier in accordance with paragraph 4, Article VIII of the Agreement.

Article 2

To amend the Agreement as follows:

1) The second paragraph under paragraph 7, Article III shall be worded as follows:

"for the Russian Federation – the Federal Medical-Biological Agency (on issues of medical-biological research of the effects of radiation on human health) and the Ministry of the Russian Federation for Civil Defense, Emergencies and Elimination of Consequences of Natural Disasters (on issues of implementing measures for rehabilitation of the population and territories affected by radiation accidents)."

2) Supplement paragraph 7, Article III with the following paragraph:

"The Parties shall immediately notify each other through diplomatic channels of a change in agents responsible for the coordination of activities to implement this Agreement."

3) Paragraph 1, Article V, as it relates to the principal cooperating establishments and organizations of the Russian Federation shall be worded as follows:

"in the Russian Federation:
Federal Medical-Biological Agency,
Ministry of the Russian Federation for Civil Defense, Emergencies and Elimination of Consequences of Natural Disasters,
Federal Atomic Energy Agency,
other interested federal bodies of the executive branch and organizations."

Article 3

This Protocol shall enter into force upon the date of signature.

DONE at Moscow, this 4 day of May, 2007, in duplicate, each in the English and Russian languages, both texts being equally authentic.

FOR THE GOVERNMENT OF THE UNITED STATES OF AMERICA

FOR THE GOVERNMENT OF THE RUSSIAN FEDERATION

ПРОТОКОЛ

между Правительством Соединенных Штатов Америки и Правительством Российской Федерации о продлении срока действия и внесении изменений в Соглашение между Правительством Соединенных Штатов Америки и Правительством Российской Федерации о сотрудничестве в области изучения радиационных воздействий с целью минимизации влияния последствий радиоактивного загрязнения на здоровье человека и окружающую среду от 14 января 1994 г.

Правительство Соединенных Штатов Америки и Правительство Российской Федерации, далее именуемые Сторонами,

принимая во внимание условия Соглашения между Правительством Соединенных Штатов Америки и Правительством Российской Федерации о сотрудничестве в области изучения радиационных воздействий с целью минимизации влияния последствий радиоактивного загрязнения на здоровье человека и окружающую среду от 14 января 1994 г. (далее – Соглашение), Протокола между Правительством Соединенных Штатов Америки и Правительством Российской Федерации от 10 марта 2000 г. о продлении срока действия и внесении изменений в Соглашение между Правительством Соединенных Штатов Америки и Правительством Российской Федерации о сотрудничестве в области изучения радиационных воздействий с целью минимизации влияния последствий радиоактивного загрязнения на здоровье человека и окружающую среду от 14 января 1994 г.,

желая продолжить совместную деятельность в рамках Соглашения с целью минимизации влияния последствий радиоактивного загрязнения на здоровье человека и окружающую среду,

отмечая, что в пункте 1 статьи VIII Соглашения предусматривается возможность его продления по письменному согласию Сторон,

согласились о нижеследующем:

Статья 1

Продлить срок действия Соглашения на 5 лет, до 14 января 2009 г., если его действие не будет прекращено раньше в соответствии с пунктом 4 статьи VIII Соглашения.

Статья 2

Внести в Соглашение следующие изменения:

1) в пункте 7 статьи III абзац второй изложить в следующей редакции:

«с Российской Стороны – Федеральное медико-биологическое агентство (по вопросам медико-биологических исследований воздействий радиации на здоровье человека) и Министерство Российской Федерации по делам гражданской обороны, чрезвычайным ситуациям и ликвидации последствий стихийных бедствий (по вопросам осуществления мероприятий по реабилитации населения и территорий, пострадавших в результате радиационных аварий);»;

2) дополнить пункт 7 статьи III абзацем следующего содержания:

«Об изменении органов, ответственных за координацию деятельности по реализации настоящего Соглашения, Стороны незамедлительно уведомляют друг друга по дипломатическим каналам.»;

3) пункт 1 статьи V в части основных учреждений и организаций, осуществляющих сотрудничество с Российской Стороны, изложить в следующей редакции:

«в Российской Федерации:
Федеральное медико-биологическое агентство,
Министерство Российской Федерации по делам гражданской обороны, чрезвычайным ситуациям и ликвидации последствий стихийных бедствий,
Федеральное агентство по атомной энергии,
другие заинтересованные федеральные органы исполнительной власти и организации;».

Статья 3

Настоящий Протокол вступает в силу со дня его подписания.

Совершено в городе Москве « 4 » мая 2007 г. в двух экземплярах, каждый на английском и русском языках, причем оба текста имеют одинаковую силу.

За Правительство Соединенных Штатов Америки

За Правительство Российской Федерации

DRAFT April 24, 2009

PROTOCOL NO. 3

BETWEEN THE GOVERNMENT OF THE UNITED STATES OF AMERICA AND THE GOVERNMENT OF THE RUSSIAN FEDERATION TO EXTEND AND AMEND THE AGREEMENT BETWEEN THE GOVERNMENT OF THE UNITED STATES OF AMERICA AND THE GOVERNMENT OF THE RUSSIAN FEDERATION ON COOPERATION IN RESEARCH ON RADIATION EFFECTS FOR THE PURPOSE OF MINIMIZING THE CONSEQUENCES OF RADIOACTIVE CONTAMINATION ON HEALTH AND THE ENVIRONMENT SIGNED JANUARY 14, 1994

The Government of the United States of America and the Government of the Russian Federation (hereinafter referred to as the "Parties"),

Noting the terms of the Agreement between the Government of the United States of America and the Government of the Russian Federation on Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment of January 14, 1994 (hereinafter referred to as the "Agreement"), and the Protocol between the Government of the United States of America and the Government of the Russian Federation of May 4, 2007, to Extend and Amend the Agreement between the Government of the United States of America and the Government of the Russian Federation on Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment of January 14, 1994,

Desiring to continue joint activities within the framework of the Agreement to minimize the consequences of radioactive contamination on human health and the environment,

Noting that paragraph 1, Article VIII of the Agreement provides for extension of the Agreement by written agreement of the Parties,

Have agreed as follows:

Article 1

To extend the term of the Agreement for five (5) years, until January 14, 2014, with effect from January 14, 2009, unless terminated earlier in accordance with paragraph 4, Article VIII of the Agreement.

Article 2

To amend the Agreement as follows:

1) Paragraph 7, Article III shall be worded as follows:

"The Executive Agents responsible for coordination of this Agreement shall be, for the United States of America, the United States Department of Energy, and for the Russian Federation, the Federal Medical-Biological Agency."

2) Paragraphs 3 and 4 of the Article IV shall be worded as follows:

"3. Exchange of technical specialists, researchers and the experts for participation in agreed activities, including the visits to the secure territories, for which special permission for the entry of foreigners is required. The detailed procedures of visits of U.S. personnel to the secure territories of the Russian Federation, for which special permission for the entry of foreigners is required, shall be developed by the Russian Federation and submitted to the appropriate authorities in both the Russian Federation and the United States of America for approval according to the laws of the Russian Federation and the United States of America;

4. Exchange of appropriate scientific and technical information, documentation and results of research, including databases and biological materials, shall be permitted according to the laws of the Russian Federation and the United States of America. To facilitate the exchanges, detailed procedures will be developed by the Russian Federation and submitted to the appropriate authorities in both the Russian Federation and the United States of America for review and approval;"

3) Paragraph 1, Article V, as it relates to the principal cooperating establishments and organizations of the Russian Federation shall be worded as follows:

"In the Russian Federation:
Federal Medical-Biological Agency;
Ministry of the Russian Federation for Civil Defense, Emergencies and Elimination of Consequences of Natural Disasters;
State Corporation for Nuclear Energy "Rosatom;"

and other interested federal bodies of the executive branch and organizations."

4) Paragraph 1, Article VIII shall be worded as follows:

"This Agreement will enter into force upon signature, with effect from January 14, 2009, and will remain in force for five (5) years. The automatic extension to the next five (5) year period shall be performed unless either Party decides to terminate the Agreement according to Paragraph 4, Article VIII."

Article 3

This Protocol shall enter into force upon the date of signature, with effect from January 14, 2009.

DONE at _____, this_____day of_____, 2009, in duplicate, each in the English and Russian languages, both texts being equally authentic.

FOR THE GOVERNMENT OF THE UNITED STATES OF AMERICA	FOR THE GOVERNMENT OF THE RUSSIAN FEDERATION

DRAFT April 30, 2009

PROTOCOL NO. 3

BETWEEN THE GOVERNMENT OF THE RUSSIAN FEDERATION AND THE GOVERNMENT OF THE UNITED STATES OF AMERICA TO EXTEND AND AMEND THE AGREEMENT BETWEEN THE GOVERNMENT OF THE RUSSIAN FEDERATION AND THE GOVERNMENT OF THE UNITED STATES OF AMERICA ON COOPERATION IN RESEARCH ON RADIATION EFFECTS FOR THE PURPOSE OF MINIMIZING THE CONSEQUENCES OF RADIOACTIVE CONTAMINATION ON HEALTH AND THE ENVIRONMENT SIGNED JANUARY 14, 1994

The Government of the Russian Federation and the Government of the United States of America (hereinafter referred to as the "Parties"),

Noting the terms of the Agreement between the Government of the Russian Federation and the Government of the United States of America on Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment of January 14, 1994 (hereinafter referred to as the "Agreement"), and the Protocol between the Government of the Russian Federation and the Government of the United States of America of May 4, 2007, to Extend and Amend the Agreement between the Government of the Russian Federation and the Government of the United States of America on Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment of January 14, 1994,

Desiring to continue joint activities within the framework of the Agreement to minimize the consequences of radioactive contamination on human health and the environment,

Noting that paragraph 1, Article VIII of the Agreement provides for extension of the Agreement by written agreement of the Parties,

Have agreed as follows:

Article 1

To extend the term of the Agreement for five (5) years, until January 14, 2014, with effect from January 14, 2009, unless terminated earlier in accordance with paragraph 4, Article VIII of the Agreement.

Article 2

To amend the Agreement as follows:

1) Paragraph 7, Article III shall be worded as follows:

"The Executive Agents responsible for coordination of this Agreement shall be, for the United States of America, the United States Department of Energy, and for the Russian Federation, the Federal Medical-Biological Agency."

2) Paragraphs 3 and 4 of the Article IV shall be worded as follows:

"3. Exchange of technical specialists, researchers and the experts for participation in agreed activities, including the visits to the secure territories, for which special permission for the entry of foreigners is required. The detailed procedures of visits of U.S. personnel to the secure territories of the Russian Federation, for which special permission for the entry of foreigners is required, shall be developed by the Russian Federation and submitted to the appropriate authorities in both the Russian Federation and the United States of America for approval according to the laws of the Russian Federation and the United States of America;

4. Exchange of appropriate scientific and technical information, documentation and results of research, including databases and biological materials, shall be permitted according to the laws of the Russian Federation and the United States of America. To facilitate the exchanges, detailed procedures will be developed by the Russian Federation and submitted to the appropriate authorities in both the Russian Federation and the United States of America for review and approval;"

3) Paragraph 1, Article V, as it relates to the principal cooperating establishments and organizations of the Russian Federation shall be worded as follows:

"In the Russian Federation:
Federal Medical-Biological Agency;
Ministry of the Russian Federation for Civil Defense, Emergencies and Elimination of Consequences of Natural Disasters;
State Corporation for Nuclear Energy "Rosatom;"
and other interested federal bodies of the executive branch and organizations."

4) Paragraph 1, Article VIII shall be worded as follows:

"This Agreement will enter into force upon signature, with effect from January 14, 2009, and will remain in force for five (5) years. The automatic extension

to the next five (5) year period shall be performed unless either Party decides to terminate the Agreement according to Paragraph 4, Article VIII."

Article 3

This Protocol shall enter into force upon the date of signature, with effect from January 14, 2009.

DONE at _____, this_____day of_____, 2009, in duplicate, each in the English and Russian languages, both texts being equally authentic.

FOR THE GOVERNMENT OF THE RUSSIAN FEDERATION	FOR THE GOVERNMENT OF THE UNITED STATES OF AMERICA

ПРОЕКТ 30 апреля 2009 года

ПРОТОКОЛ № 3

МЕЖДУ ПРАВИТЕЛЬСТВОМ РОССИЙСКОЙ ФЕДЕРАЦИИ И ПРАВИТЕЛЬСТВОМ СОЕДИНЁННЫХ ШТАТОВ АМЕРИКИ О ПРОДЛЕНИИ СРОКА ДЕЙСТВИЯ И ВНЕСЕНИИ ИЗМЕНЕНИЙ В СОГЛАШЕНИЕ МЕЖДУ ПРАВИТЕЛЬСТВОМ РОССИЙСКОЙ ФЕДЕРАЦИИ И ПРАВИТЕЛЬСТВОМ СОЕДИНЁННЫХ ШТАТОВ АМЕРИКИ О СОТРУДНИЧЕСТВЕ В ОБЛАСТИ ИЗУЧЕНИЯ РАДИАЦИОННЫХ ВОЗДЕЙСТВИЙ С ЦЕЛЬЮ МИНИМИЗАЦИИ ВЛИЯНИЯ ПОСЛЕДСТВИЙ РАДИОАКТИВНОГО ЗАГРЯЗНЕНИЯ НА ЗДОРОВЬЕ ЧЕЛОВЕКА И ОКРУЖАЮЩУЮ СРЕДУ ОТ 14 ЯНВАРЯ 1994 ГОДА

Правительство Российской Федерации и Правительство Соединенных Штатов Америки (далее именуемые Сторонами),

принимая во внимание условия Соглашения между Правительством Российской Федерации и Правительством Соединенных Штатов Америки о сотрудничестве в области изучения радиационных воздействий с целью минимизации влияния последствий радиоактивного загрязнения на здоровье человека и окружающую среду от 14 января 1994 г. (далее - Соглашение), Протокола между Правительством Российской Федерации и Правительством Соединенных Штатов Америки от 4 мая 2007 года о продлении срока действия и внесении изменений в Соглашение между Правительством Российской Федерации и Правительством Соединенных Штатов Америки о сотрудничестве в области изучения радиационных воздействий с целью минимизации влияния последствий радиоактивного загрязнения на здоровье человека и окружающую среду от 14 января 1994 г.,

желая продолжить совместную деятельность в рамках Соглашения с целью минимизации влияния последствий радиоактивного загрязнения на здоровье человека и окружающую среду,

отмечая, что в пункте 1 статьи VIII Соглашения предусматривается возможность его продления по письменному согласию Сторон,

согласились о нижеследующем:

Статья 1

Продлить срок действия Соглашения на пять (5) лет, до 14 января 2014 г., начиная с 14 января 2009 года, если его действие не будет прекращено раньше в соответствии с пунктом 4 статьи VIII Соглашения.

Статья 2

Внести в Соглашение следующие изменения:

1) пункт 7 статьи III изложить в следующей редакции:

«Органами, ответственными за координацию деятельности по реализации настоящего Соглашения, являются:

с Российской Стороны – Федеральное медико-биологическое агентство;

с Американской Стороны – Министерство энергетики Соединенных Штатов Америки.»;

2) пункты 3 и 4 статьи IV изложить в следующей редакции:

«3. Обмен техническими специалистами, исследователями и экспертами для участия в согласованной деятельности, включая визиты на режимные территории, для въезда на которые иностранным гражданам требуется специальное разрешение. Детальные процедуры, описывающие организацию визитов на режимные территории, будут разработаны российской стороной и согласованы ответственными российскими и американскими организациями в соответствии с законами Российской Федерации и Соединенных Штатов Америки.

4. Обмен соответствующей научной и технической информацией, документацией, результатами исследований, в том числе базами данных, биоматериалами, который будет допущен в соответствии с законами Российской Федерации и Соединенных Штатов Америки. Детальные процедуры, упрощающие процедуру обмена, будут разработаны российской стороной, рассмотрены и согласованы ответственными российскими и американскими организациями в соответствии с законами Российской Федерации и Соединенных Штатов Америки.».

3) пункт 1 статьи V в части основных учреждений и организаций, осуществляющих сотрудничество с Российской Стороны, изложить в следующей редакции:

«в Российской Федерации:

Федеральное медико-биологическое агентство,

Министерство Российской Федерации по делам гражданской обороны, чрезвычайным ситуациям и ликвидации последствий стихийных бедствий,

Государственная корпорация по атомной энергии «Росатом»,

другие заинтересованные федеральные органы исполнительной власти и организации;»;

4) пункт 1 статьи VIII изложить в следующей редакции:

«Настоящее Соглашение вступает в силу с даты его подписания и остается в силе в течение пяти лет. Оно автоматически продлевается на последующий пятилетний период, если ни одна из Сторон не решит прекратить действие настоящего Соглашения в соответствии с пунктом 4 статьи VIII.».

Статья 3

Настоящий Протокол вступает в силу со дня его подписания, действует с 14 января 2009 года.

Совершено в _____ _____ 2009 г. в двух экземплярах, каждый на русском и английском языках, причем оба текста имеют одинаковую силу.

ЗА ПРАВИТЕЛЬСТВО РОССИЙСКОЙ ФЕДЕРАЦИИ

ЗА ПРАВИТЕЛЬСТВО СОЕДИНЁННЫХ ШТАТОВ АМЕРИКИ

ПРОЕКТ 24 апреля 2009 года

ПРОТОКОЛ № 3

МЕЖДУ ПРАВИТЕЛЬСТВОМ РОССИЙСКОЙ ФЕДЕРАЦИИ И ПРАВИТЕЛЬСТВОМ СОЕДИНЁННЫХ ШТАТОВ АМЕРИКИ О ПРОДЛЕНИИ СРОКА ДЕЙСТВИЯ И ВНЕСЕНИИ ИЗМЕНЕНИЙ В СОГЛАШЕНИЕ МЕЖДУ ПРАВИТЕЛЬСТВОМ СОЕДИНЁННЫХ ШТАТОВ АМЕРИКИ И ПРАВИТЕЛЬСТВОМ РОССИЙСКОЙ ФЕДЕРАЦИИ О СОТРУДНИЧЕСТВЕ В ОБЛАСТИ ИЗУЧЕНИЯ РАДИАЦИОННЫХ ВОЗДЕЙСТВИЙ С ЦЕЛЬЮ МИНИМИЗАЦИИ ВЛИЯНИЯ ПОСЛЕДСТВИЙ РАДИОАКТИВНОГО ЗАГРЯЗНЕНИЯ НА ЗДОРОВЬЕ ЧЕЛОВЕКА И ОКРУЖАЮЩУЮ СРЕДУ ОТ 14 ЯНВАРЯ 1994 ГОДА

Правительство Соединенных Штатов Америки и Правительство Российской Федерации (далее именуемые Сторонами),

принимая во внимание условия Соглашения между Правительством Соединенных Штатов Америки и Правительством Российской Федерации о сотрудничестве в области изучения радиационных воздействий с целью минимизации влияния последствий радиоактивного загрязнения на здоровье человека и окружающую среду от 14 января 1994 г. (далее - Соглашение), Протокола между Правительством Российской Федерации и Правительством Соединенных Штатов Америки от 4 мая 2007 года о продлении срока действия и внесении изменений в Соглашение между Правительством Соединенных Штатов Америки и Правительством Российской Федерации о сотрудничестве в области изучения радиационных воздействий с целью минимизации влияния последствий радиоактивного загрязнения на здоровье человека и окружающую среду от 14 января 1994 г.,

желая продолжить совместную деятельность в рамках Соглашения с целью минимизации влияния последствий радиоактивного загрязнения на здоровье человека и окружающую среду,

отмечая, что в пункте 1 статьи VIII Соглашения предусматривается возможность его продления по письменному согласию Сторон,

согласились о нижеследующем:

Статья 1

Продлить срок действия Соглашения на пять (5) лет, до 14 января 2014 г., начиная с 14 января 2009 года, если его действие не будет прекращено раньше в соответствии с пунктом 4 статьи VIII Соглашения.

Статья 2

Внести в Соглашение следующие изменения:

1) пункт 7 статьи III изложить в следующей редакции:

«Органами, ответственными за координацию деятельности по реализации настоящего Соглашения, являются:

с Российской Стороны – Федеральное медико-биологическое агентство;

с Американской Стороны – Министерство энергетики Соединенных Штатов Америки.»;

2) пункты 3 и 4 статьи IV изложить в следующей редакции:

«3. Обмен техническими специалистами, исследователями и экспертами для участия в согласованной деятельности, включая визиты на режимные территории, для въезда на которые иностранным гражданам требуется специальное разрешение. Детальные процедуры, описывающие организацию визитов на режимные территории, будут разработаны российской стороной и согласованы ответственными российскими и американскими организациями в соответствии с законами Российской Федерации и Соединенных Штатов Америки.

4. Обмен соответствующей научной и технической информацией, документацией, результатами исследований, в том числе базами данных, биоматериалами, который будет допущен в соответствии с законами Российской Федерации и Соединенных Штатов Америки. Детальные процедуры, упрощающие процедуру обмена, будут разработаны российской стороной, рассмотрены и согласованы ответственными российскими и американскими организациями в соответствии с законами Российской Федерации и Соединенных Штатов Америки.».

3) пункт 1 статьи V в части основных учреждений и организаций, осуществляющих сотрудничество с Российской Стороны, изложить в следующей редакции:

«в Российской Федерации:

Федеральное медико-биологическое агентство,

Министерство Российской Федерации по делам гражданской обороны, чрезвычайным ситуациям и ликвидации последствий стихийных бедствий,

Государственная корпорация по атомной энергии «Росатом»,

другие заинтересованные федеральные органы исполнительной власти и организации;»;

4) пункт 1 статьи VIII изложить в следующей редакции:

«Настоящее Соглашение вступает в силу с даты его подписания и остается в силе в течение пяти лет. Оно автоматически продлевается на последующий пятилетний период, если ни одна из Сторон не решит прекратить действие настоящего Соглашения в соответствии с пунктом 4 статьи VIII.».

Статья 3

Настоящий Протокол вступает в силу со дня его подписания, действует с 14 января 2009 года.

Совершено в _____ _____ 2009 г. в двух экземплярах, каждый на русском и английском языках, причем оба текста имеют одинаковую силу.

ЗА ПРАВИТЕЛЬСТВО СОЕДИНЁННЫХ ШТАТОВ АМЕРИКИ:	ЗА ПРАВИТЕЛЬСТВО РОССИЙСКОЙ ФЕДЕРАЦИИ

Summary of Items Discussed by the JCCRER Executive Committee (EC)
Fifth (5th) JCCRER Meeting
November 6, 2007
Las Vegas, NV

1. Concerning the access to the facilities in the RF and US the parties agreed on the following:

   - Continue to implement Section 5 of the Article 3 of the Agreement the EC representatives will develop a document that clearly determines the procedure of planning, approval and organization of the visits to the facilities in RF (including closed sites) and US by experts responsible for implementation of the projects under the auspices of the Agreement.

   - Define categories of individuals to visit facilities for successful achievement of the purposes of the projects will be identified.

   - Until the above mentioned document is in force the parties will adhere to the existing national requirements and do everything possible to arrange the already planned trips of the US scientists to Russia.

2. Next JCCRER Meeting

   - The parties agreed that the Russian EC will immediately inform the U.S. EC as soon as the Russian JCCRER members are appointed. Thereafter, the parties will immediately start preparation of the JCCRER meeting. The dates of the meeting will be decided later.

3. Functioning of the EC

   - The parties agreed on the following:

     - The EC will continue to conduct the joint meeting or telephone or video conferences at least once every 90 days. For the next EC meeting the parties agreed to develop proposal on the following issues:

       - Expansion of the area of research conducted under the Agreement

       - Information policy of JCCRER in the area of implementation of the Agreement.

Participants

Russian JCCRER Executive Committee Members Present:

Victor Nazarov, Co-Chair, FMBA
Alexander Ivanov, Scientific Research Center – Institute of Biophysics
Tatyana Marchenko, EMERCOM

Russian Institute Directors and Principal Investigators Present:

Evgeny Vasilenko, Mayak PA
Alexander Akleyev, URCRM
Sergey Romanov, SUBI

Russian Interpreters Present:

Ekaterina Muzrukova, Mayak PA
Ekaterina Zaytseva, SUBI
Konstantin Makarov, Mayak PA

U.S. JCCRER Executive Committee Members Present:

Patricia Worthington, Co-Chair, DOE
Patricia Lillis-Hearne, AFRRI
Jerome Puskin, EPA
Francis Cucinotta, NASA
Vincent Holahan, NRC

U.S. Program Manager:
Barrett Fountos, DOE

U.S. JCCRER Member (observer only):

Sher Bahadur, NRC

Signatures:

Patricia Worthington
Co-Chair U.S. JCCRER Executive Committee

Victor Nazarov,
Co-Chair Russian JCCRER Executive Committee

Signed: November 7, 2007

A G R E E M E N T
between the Government of the United States of America

and
the Government of the Russian Federation
on
COOPERATION IN RESEARCH ON RADIATION EFFECTS FOR THE PURPOSE OF MINIMIZING THE CONSEQUENCES OF RADIOACTIVE CONTAMINATION ON HEALTH AND THE ENVIRONMENT

С О Г Л А Ш Е Н И Е
между Правительством Российской Федерации

и
Правительством Соединенных Штатов Америки
о
СОТРУДНИЧЕСТВЕ В ОБЛАСТИ ИЗУЧЕНИЯ РАДИАЦИОННЫХ ВОЗДЕЙСТВИЙ С ЦЕЛЬЮ МИНИМИЗАЦИИ ПОСЛЕДСТВИЙ РАДИОАКТИВНОГО ЗАГРЯЗНЕНИЯ НА ЗДОРОВЬЕ ЧЕЛОВЕКА И ОКРУЖАЮЩУЮ СРЕДУ

MEMORANDUM
of the Sixth International Meeting of the Joint Coordinating Committee For Radiation Effects Research (JCCRER)

Moscow, Russia
2008

Overview

The Sixth international meeting of the Russian and U.S. delegations within the framework of the Intergovernmental Russian-American agreement on "Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment", was held in the Burnasyan Federal Medical Biophysical Center of the Federal Medical-Biological Agency of Russia, Moscow, Russian Federation on October 1-2, 2008. During this sixth meeting of the JCCRER the outcomes of joint projects; main provisions and principles of conducting research under the JCCRER aegis; suggestions on prolongation of the Agreement as well as fundamental principles of the guiding document to delineate procedures for planning, co-ordinating and organizing visits of U.S. personnel participating in the implementation of joint projects with the Mayak Production Association (Mayak PA) and the Southern Urals Biophysics Institute (SUBI) located at the closed administrative-territorial districts ("ZATO") were discussed.

Participants on the American side included:

JCCRER members:

- **Mr. Glenn Podonsky** Chief Health, Safety and Security Officer, Office of Health, Safety and Security, U.S. Department of Energy (DOE), Co-Chair

- **Dr. Charles Miller** Chief, Radiation Studies Branch, National Center for Environmental Health, Centers for Disease Control and Prevention, Division of Environmental Hazards and Health Effects, U.S. Department of Health and Human Services (DHHS)

Executive Committee (EC) members :

- **Dr. Patricia Worthington** Director, Office of Health and Safety Office of Health, Safety and Security, U.S. Department of Energy (DOE), Co-Chair

- **Colonel Patricia Lillis-Hearne** Director, Armed Forces Radiobiology Research Institute, U.S. Department of Defense (DOD)

Participants on the Russian side included:

JCCRER members:

- **Mikhail Kiselev** Deputy Head
Federal Medical-Biological Agency, Appointed Co-Chair;

- **Alexander Agapov** Head of Department
Of Nuclear and Radiation Safety, Organizing and Permitting Activities, State Corporation "Rosatom", Appointed Member

- **Valeriy Shuykov** Deputy Head of Foreign Department
Ministry of the Russian Federation for Civil Defense Affairs, Emergencies and Elimination of Consequences of Natural Disasters (EMERCOM), Appointed Member

Executive Committee (EC) members :

- **Victor Nazarov** Director,
Federal State Enterprise Scientific Practical Center "Farmzazhita", Co-chair;

- **Tatyana Marchenko** Division head
Ministry of the Russian Federation for Civil Defense Affairs, Emergencies and Elimination of Consequences of Natural Disasters (EMERCOM)

Items Approved by the JCCRER:

a.) JCCRER Reaffirmation Statement of Responsibilities and Principles for Doing Work:

On May 4, 2007, Deputy Minister of Foreign Affairs of the Russian Federation Sergey Kislyak and U.S. Ambassador to the Russian Federation William Burns signed the Protocol to extend the joint Agreement on radiation effects research through January 14, 2009.

During the meeting in Moscow on October 1-2, 2008, the JCCRER highly appreciated the atmosphere of trust and understanding in performance of the joint radiation health effects research and confirmed its responsibilities for these joint activities as well as carrying out of the JCCRER principles, that had been approved during the Fourth JCCRER meeting held in St. Petersburg, Russia, on September 13-14, 2000.

The JCCRER confirmed that for conducting the joint research the following principle has been used:

- The Charges of the Joint Scientific Review Group (SRG) placed for consideration during the Fourth JCCRER meeting held in St. Petersburg, Russia, on September 13-14, 2000 and signed by the Co-chairs of the EC;
- Data Access Agreement placed for consideration during the Fourth JCCRER meeting held in St. Petersburg, Russia, on September 13-

14, 2000 and signed by the Co-chairs of the JCCRER

b.) **Ongoing Results and the Scope of the New Researches (Directions 1 and 2):**

The JCCRER approved the results and perspectives of the joint research (Directions 1 and 2). The JCCRER underlined that results of the joint studies published in Russian, U.S. and international journals significantly improved the level of knowledge of the chronic exposure effects and risks of low doses of prolonged exposure of the ionizing radiation. The JCCRER confirmed that published scientific data provide new and important information that can lead to the revision of radiation protection standards. The JCCRER considered preparing, in cooperation with competent Russian and U.S. authorities, an official request to the international organizations, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), World Health Organization (WHO) and the International Atomic Energy Agency (IAEA) to formulate a scientific opinion about the merits of the research on the health effects of prolonged low-dose exposure of large populations conducted under JCCRER aegis in the Southern Urals.

During meeting on October, 1-2 held in Moscow, Russia, the JCCRER Co-Chairs signed the Joint Recommendation on the involvement of international organizations in the evaluation of scientific results of researches on the health effects of long-term, low-dose radiation exposure performed under JCCRER aegis.

c.) **Extension of the Agreement:**

The JCCRER underlined the interest of the both parties in the continuation of the joint cooperation.

During the meeting in Moscow on October 1-2, 2008 the JCCRER Co-chairs signed the Joint Recommendation to extend the JCCRER Agreement for additional five (5) years.

d.) **Planning, Approval and Organization of the Visits:**

The JCCRER notices that the conduct of joint projects suggests the need for periodic collective discussion of both the results and the perspectives of the research as well as peer-reviews. Conducting collaborative research assumes the need for access to primary as well as compiled and secondary data, which according to the data access agreement, could be granted only at the territory of the closed administrative-territorial districts ("ZATO").

At the meeting held in Moscow, October 1-2, 2008, the JCCRER Co-chairs signed the Joint Recommendation about the Planning and Organization of Visits to the Secure Territories of the Russian Federation, for Which Special Permission for the Entry of Foreigners is Required.

e.) Other Items Discussed:
Both parties were informed about the new structure of the JCCRER, the JCCRER EC, and the joint U.S.-Russian SRG.

The JCCRER Charges for the JCCRER EC

The JCCRER charged the Executive Committee with the following actions:

- Prepare the necessary documents for the extension of the JCCRER Agreement,
- Create the Joint Recommendations to involve international organizations in the assessment of the research results in the Southern Urals;
- Develop the Guidelines Document for planning, approval and organization of the visits;
- Ensure the continuation of the work.

Next Meeting:

It was agreed that the next JCCRER meeting would be held in the United States, in 2009 after the signing of Protocol to extend of the JCCRER Agreement.

Signed on this 1st day of October, 2008, in Moscow, Russian Federation

Mikhail Kiselev
Appointed
Russian JCCRER Co-chair

Glenn Podonsky
U.S. JCCRER Co-chair

Joint Recommendation to Amend and Extend the Joint Coordinating Committee for Radiation Effects Research Agreement

The Joint Coordinating Committee for Radiation Effects Research taking into consideration the positive results of the joint research conducted during the time period 2004-2009 and being guided by paragraph 1 of Article VIII of the Agreement between the Government of the Russian Federation and the Government of the United States of America "Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment"

HAVE AGREED AS FOLLOWS:

To extend of the Agreement for more five years. This will be accomplished through the joint Protocol 3 between the Government of the Russian Federation and the Government of the United States of America "Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment"

Mikhail Kiselev
Appointed
Russian JCCRER Co-chair

Glenn Podonsky
U.S. JCCRER Co-chair

Joint Recommendation to Involve International Organizations in the Assessment of Radiation Health Effects Research Results Performed under the Purview of the Joint Coordinating Committee for Radiation Effects Research (JCCRER) Following Prolonged Low-Dose Exposure in the Southern Urals

The JCCRER Co-chairs concluded that results of the research conducted under the purview of the JCCRER during 1994-2009 significantly improved the level of knowledge about the effects and risks of low doses of prolonged exposure to ionizing radiation. Noting the high quality of the research carried out and the large number of articles published in the peer-reviewed U.S., Russian, and international journals,
it was agreed:

1. To prepare, in cooperation with corresponding Russian and U.S. authorities, an official request to the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) to provide a scientific estimate of the results of the effects of radiation exposure in personnel and general public research in the Southern Urals,

2. To prepare an official request to the International Atomic Energy Agency (IAEA) in order to arrange a workshop to develop expert conclusions on health effects of radiation exposure in the Southern Urals.

Mikhail Kiselev
Appointed
Russian JCCRER Co-chair

Glenn Podonsky
U.S. JCCRER Co-chair

Joint Recommendation about the Planning and Organization of Visits to the Secure Territories of the Russian Federation, for Which Special Permission for the Entry of Foreigners is Required.

To facilitate regular visits of U.S. personnel working on JCCRER projects to Russian organizations which participate in the projects of the Agreement between the Government of the Russian Federation and the Government of the United States of America "Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment" from January 14, 1994

The JCCRER has agreed as follows:

1. The visits of U.S. personnel, which are necessary for the successful conduct of the joint projects to the secure territories of the Russian Federation, for which special permission for the entry of foreigners is required, have to be conducted in accordance with the laws of the Russian Federation.
2. Rosatom will develop a separate guidelines document, which will delineate detailed procedures of visits of U.S. personnel to the secure territories of the Russian Federation, for which special permission for the entry of foreigners is required. These procedures will be submitted to the appropriate authorities in both the Russian Federation and the United States for approval.

Mikhail Kiselev Appointed Russian JCCRER Co-chair	Alexander Agapov Appointed Russian JCCRER member	Glenn Podonsky U.S. JCCRER Co-chair

С О Г Л А Ш Е Н И Е
между Правительством Российской Федерации
и
Правительством Соединенных Штатов Америки
о
СОТРУДНИЧЕСТВЕ В ОБЛАСТИ ИЗУЧЕНИЯ РАДИАЦИОННЫХ ВОЗДЕЙСТВИЙ С ЦЕЛЬЮ МИНИМИЗАЦИИ ПОСЛЕДСТВИЙ РАДИОАКТИВНОГО ЗАГРЯЗНЕНИЯ НА ЗДОРОВЬЕ ЧЕЛОВЕКА И ОКРУЖАЮЩУЮ СРЕДУ

A G R E E M E N T
between the Government of the United States of America
and
the Government of the Russian Federation
on
COOPERATION IN RESEARCH ON RADIATION EFFECTS FOR THE PURPOSE OF MINIMISATION OF CONSEQUENCES OF RADIOACTIVE CONTAMINATION ON HEALTH AND THE ENVIRONMENT

МЕМОРАНДУМ
Шестого заседания
Объединенного координационного комитета по изучению радиационных воздействий

г. Москва, Россия
2008 г.

Введение

Шестое совместное заседание Российской и Американской делегаций в рамках межправительственного Российско-Американского Соглашения «О сотрудничестве в области изучения радиационных воздействий с целью минимизации влияния последствий радиоактивного загрязнения на здоровье человека и окружающую среду» состоялось в Федеральном медицинском биофизическом центре имени А.И.Бурназяна ФМБА России (г. Москва, Российская Федерация) 1-2 октября 2008 года. Во время Шестого заседания Объединенного координационного комитета по изучению радиационных воздействий (ОККИРВ) были обсуждены итоги выполнения совместных проектов и перспективы развития дальнейших исследований, основные положения и принципы выполнения работ под эгидой ОККИРВ, предложения по продлению Соглашения, а также основные положения руководящего документа о планировании, согласовании и организации визитов американских специалистов, участвующих в выполнении совместных проектов с Производственным объединением «Маяк» и Южно-Уральским институтом биофизики, расположенными в закрытом административно-территориальном образовании (ЗАТО) г. Озерск.

Американская сторона была представлена следующими участниками:

Члены ОКК ИРВ:

- **м-р Гленн Подонски** руководитель офиса по здоровью, безопасности и охране труда Министерства энергетики США, сопредседатель;
- **д-р Чарльз Миллер** начальник Отдела по исследованию воздействия излучения на здоровье, Министерство здравоохранения и социального обеспечения США;

Члены Исполнительного комитета:

- **д-р Патрисия Уорсингтон** начальник Отдела по изучению здоровья Министерства энергетики США, сопредседатель;
- **полковник Патрисия Лиллис-Хирн** Директор Института радиобиологии вооруженных сил, Министерство обороны США;

Российская сторона была представлена следующими участниками:

Члены ОККИРВ:

- **Михаил Киселев** заместитель Руководителя Федерального медико-биологического агентства, назначенный сопредседатель ОККИРВ;

- **Александр Агапов** начальник Департамента ядерной и радиационной безопасности, организационной и разрешительной деятельности Государственной корпорации по атомной энергии «Росатом», назначенный член ОККИРВ;

- **Валерий Шуйков** заместитель Директора департамента международной деятельности Министерства Российской Федерации по делам Гражданской обороны, чрезвычайным ситуациям и ликвидации последствий стихийных бедствий», назначенный член ОККИРВ

Члены Исполнительного комитета:

- **Виктор Назаров** директор Научно-производственного центра «Фармзащита», сопредседатель;

- **Татьяна Марченко** начальник Управления преодоления радиационных аварий и катастроф, Министерство Российской Федерации по делам Гражданской обороны, чрезвычайным ситуациям и ликвидации последствий стихийных бедствий;

Поручения ОККИРВ:

а) **подтверждение обязательств и принципов организации работ**:
4 мая 2007г. Заместитель Министра иностранных дел Российской Федерации Сергей Кисляк и посол США в Российской Федерации Уильям Бернс подписали протокол о продлении совестного соглашения о сотрудничестве в области изучения радиационных воздействий до 14 января 2009 года.
На заседании в г. Москве 1-2 октября 2008 года ОККИРВ высоко оценил атмосферу доверия и понимания при выполнении совместных исследований и подтвердил свои обязательства по поддержке этих совместных работ и принципы их проведения, принятые 13 сентября 2000 г. в Санкт-Петербурге на Четвертом заседании ОККИРВ.
ОККИРВ подтвердил, что при выполнении совместных исследований, стороны будут руководствоваться:

-Уставом совместной группы научного рецензирования, рассмотренным 13 сентября 2000 г. в Санкт-Петербурге на Четвертом заседании ОККИРВ и подписанным сопредседателями Исполнительного комитета;
- Соглашением о доступе к данным, рассмотренным 13 сентября 2000 г. в Санкт-Петербурге на Четвертом заседании ОККИРВ и подписанным сопредседателями ОККИРВ

б) итоги и объем будущих работ по направлениям 1 и 2:

ОККИРВ одобрил итоги и перспективы совместных исследований по направлениям 1 и 2. ОККИРВ отметил, что выполненные и опубликованные в российских и зарубежных журналах результаты значительно расширили уровень знаний в понимании эффектов и рисков воздействия ионизирующей радиации при длительном (хроническом) воздействии малых доз ионизирующей радиации. ОККИРВ подтвердил, что полученные данные служат реальной научной базой для разработки новых стандартов радиационной безопасности. ОККИРВ считает целесообразным подготовить обращение через компетентные органы Российской Федерации и США в международные организации (НКДАР ООН, МАГАТЭ, ВОЗ) по оценке эффектов для здоровья вследствие хронического низкоуровневого облучения больших популяций на основании результатов исследований на Южном Урале, выполненных под эгидой ОККИРВ.

На заседании в г. Москве 1-2 октября 2008 года Сопредседатели ОККИРВ подписали Совместную рекомендацию по вовлечению международных организаций по оценке результатов, выполненных под эгидой ОККИРВ в области изучения эффектов для здоровья вследствие хронического низкоуровневого облучения больших популяций.

в) **продление Соглашения:**
ОККИРВ отметил заинтересованность сторон в дальнейшем продолжении совместного сотрудничества.
На заседании в г. Москве 1 октября 2008 года Сопредседатели ОККИРВ подписали Совместную рекомендацию по продлению и изменению Соглашения между Правительством Российской Федерации и Правительством Соединенных Штатов Америки «О сотрудничестве в области изучения радиационных воздействий с целью минимизации влияния последствий радиоактивного загрязнения на здоровье человека и окружающую среду».

г) планирование, согласование и организация визитов:
ОККИРВ отметил, что выполнение совместных проектов предусматривает периодическое совместное обсуждение результатов и перспектив научных исследований, их рецензирование. При проведении этих работ возникает необходимость в доступе к первичным, компилированным и вторичным данным, который в соответствии с положением о доступе к данным может быть осуществлен участниками совместных проектов только на территории той организации, которая ими владеет и их поддерживает.
На заседании в г. Москве 1-2 октября 2008 года Сопредседатели ОККИРВ подписали Совместную рекомендацию о планировании и организации визитов на режимные территории Российской Федерации, для въезда на которые иностранным гражданам требуется специальное разрешение.

д) другие обсуждаемые вопросы:
Стороны проинформировали о новом составе ОККИРВ, Исполнительного комитета и совместной Группы научного рецензирования.

ОККИРВ поручил ИК:
- организовать работу по подготовке необходимых документов по продлению соглашения; по реализации Совместной рекомендации по вовлечению международных организаций по оценке результатов исследований на Южном Урале, а также регламента, определяющего планирование, согласование и организацию визитов;
- обеспечить непрерывность работ под эгидой ОККИРВ.

О следующем заседании ОККИРВ:

Была достигнута договоренность, что следующее заседание ОККИРВ будет проведено в 2009 году в США после подписания

Протокола о продлении Соглашения в сроки, согласованные Сторонами Соглашения между Правительством Российской Федерации и Правительством Соединенных Штатов Америки «О сотрудничестве в области изучения радиационных воздействий с целью минимизации влияния последствий радиоактивного загрязнения на здоровье человека и окружающую среду» от 14 января 1994 г.

Подписано 1 октября 2008 года в г. Москве

От Российской Федерации	От Соединенных Штатов Америки
Михаил Киселев Назначенный Сопредседатель ОККИРВ	Гленн Подонски Сопредседатель ОККИРВ
Дата	Дата

СОВМЕСТНАЯ РЕКОМЕНДАЦИЯ
по продлению и изменению Соглашения между Правительством Российской Федерации и Правительством Соединенных Штатов Америки «О сотрудничестве в области изучения радиационных воздействий с целью минимизации влияния последствий радиоактивного загрязнения на здоровье человека и окружающую среду»

Объединенный Координационный Комитет по изучению радиационных воздействий, принимая во внимание положительные результаты совместных исследований, достигнутые при выполнении совместных исследований в период с 2004 по 2008 годы, руководствуясь пунктом 1 Статьи VIII Соглашения между Правительством Российской Федерации и Правительством Соединенных Штатов Америки «О сотрудничестве в области изучения радиационных воздействий с целью минимизации влияния последствий радиоактивного загрязнения на здоровье человека и окружающую среду»,

СОГЛАСИЛСЯ О НИЖЕСЛЕДУЮЩЕМ:

Продлить на следующие пять лет срок действия Соглашения. Это будет оформлено совместным Протоколом 3 о продлении Соглашения между Правительством Российской Федерации и Правительством Соединенных Штатов Америки «О сотрудничестве в области изучения радиационных воздействий с целью минимизации влияния последствий радиоактивного загрязнения на здоровье человека и окружающую среду».

От Российской Федерации	От Соединенных Штатов Америки
Михаил Киселев	Гленн Подонски
Назначенный Сопредседатель ОККИРВ	Сопредседатель ОККИРВ
Дата	Дата

СОВМЕСТНАЯ РЕКОМЕНДАЦИЯ
по вовлечению международных организаций по оценке результатов, выполненных под эгидой ОККИРВ в области изучения эффектов для здоровья вследствие хронического низкоуровневого облучения на Южном Урале

Мы, сопредседатели ОККИРВ, отмечаем, что полученные под эгидой ОККИРВ за период с 1994 по 2009 годы результаты научных исследований значительно расширили уровень знаний в понимании эффектов и рисков воздействия ионизирующей радиации при длительном (хроническом) воздействии малых доз ионизирующей радиации. Отмечая высокое качество научных исследований, а также большое количество публикаций в рецензируемых российских и зарубежных изданиях, мы рекомендуем:

1. Подготовить текст совместного обращения в компетентные органы Российской Федерации и Соединенных Штатов Америки, в котором предложить Научному комитету по действию атомной радиации ООН дать научную оценку результатам исследований радиационных воздействий на здоровье персонала и население на Южном Урале.

2. Подготовить обращение в Международное агентство по атомной энергии (МАГАТЭ) о проведении Южно-Уральского форума для выработки согласованных авторитетных заключений о последствиях для здоровья людей, которое можно объяснить воздействием радиационного облучения на Южном Урале.

От Российской Федерации	От Соединенных Штатов Америки
Михаил Киселев Назначенный Сопредседатель ОККИРВ	Гленн Подонски Сопредседатель ОККИРВ
Дата	Дата

СОВМЕСТНАЯ РЕКОМЕНДАЦИЯ
о планировании и организации визитов на режимные территории Российской Федерации, для въезда на которые иностранным гражданам требуется специальное разрешение.

В целях обеспечения регулярных визитов исследователей из США, участвующих в выполнении проектов в рамках Соглашения между Правительством Российской Федерации и Правительством Соединенных Штатов Америки «О сотрудничестве в области изучения радиационных воздействий с целью минимизации влияния последствий радиоактивного загрязнения на здоровье человека и окружающую среду» от 14 января 1994 года (далее – Соглашение),

ОККИРВ СОГЛАСИЛСЯ О НИЖЕСЛЕДУЮЩЕМ:

1. Необходимые для выполнения совместных проектов в рамках Соглашения визиты исследователей из США на режимные территории Российской Федерации, для въезда на которые иностранным гражданам требуется специальное разрешение, должны осуществляться в соответствии с законами Российской Федерации.
2. При участии государственной корпорации по атомной энергии «Росатом» будут разработаны детальные процедуры, описывающие организацию визитов исследователей из США на режимные территории Российской Федерации, для въезда на которые иностранным гражданам требуется специальное разрешение. Эти процедуры будут согласованы с ответственными российскими и американскими организациями.

От Российской Федерации		От Соединенных Штатов Америки
Михаил Киселев Назначенный Сопредседатель ОККИРВ	Александр Агапов Назначенный член ОККИРВ	Гленн Подонски Сопредседатель ОККИРВ
Дата	Дата	Дата

A G R E E M E N T
between the Government of the United States of America
and
the Government of the Russian Federation
on

COOPERATION IN RESEARCH ON RADIATION EFFECTS FOR THE PURPOSE OF MINIMIZING THE CONSEQUENCES OF RADIOACTIVE CONTAMINATION ON HEALTH AND THE ENVIRONMENT

С О Г Л А Ш Е Н И Е
между Правительством Российской Федерации
и
Правительством Соединенных Штатов Америки
О
СОТРУДНИЧЕСТВЕ В ОБЛАСТИ ИЗУЧЕНИЯ РАДИАЦИОННЫХ ВОЗДЕЙСТВИЙ С ЦЕЛЬЮ МИНИМИЗАЦИИ ПОСЛЕДСТВИЙ РАДИОАКТИВНОГО ЗАГРЯЗНЕНИЯ НА ЗДОРОВЬЕ ЧЕЛОВЕКА И ОКРУЖАЮЩУЮ СРЕДУ

MEMORANDUM
of the Seventh International U.S.-Russian Meeting of the Joint Coordinating Committee For Radiation Effects Research (JCCRER)

September 16-17, 2009

Washington, DC, USA

Overview

The Seventh international meeting of the Russian and U.S. delegations within the framework of the intergovernmental U.S.-Russian Agreement on "Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment," was held at the Washington Marriott Metro Center Hotel in Washington, DC, USA, on September 16-17, 2009. Through the JCCRER's efforts, the program has a rich history of accomplishments making significant contributions to science and improving the international scientific community's understanding of the health effects of ionizing radiation. This seventh meeting commemorated the attainment of a major milestone of 15 years of collaborative U.S. and Russian efforts that have resulted in over 200 peer-reviewed publications in U.S., Russian, and international scientific journals. The purpose of this meeting was to promote and advance the goals of the JCCRER by: 1) facilitating the technical exchange of scientific information and results from the research in the Southern Urals jointly conducted by the United States and Russia, by the U.S. National Cancer Institute, and by the European Commission; 2) highlighting program successes and accomplishments; 3) defining common goals and milestones for the coming year; and 4) planning for the future.

During this meeting of the JCCRER, the key topics discussed included the results of the current joint projects in the Southern Urals performed pursuant to JCCRER Direction 1, Population Studies, Direction 2, Worker Studies, and Direction 3, Emergency Response Activities, the status of the extension of the JCCRER Agreement, and the status of the three joint recommendations from the sixth International U.S.-Russian JCCRER Meeting. In addition, the JCCRER discussed how to move forward with the preparation of the guiding document to delineate procedures for planning, coordinating, and organizing visits of U.S. Government personnel and U.S. contractor personnel participating in the implementation of joint projects with the Mayak Production Association (Mayak) and the Southern Urals Biophysics Institute (SUBI) to these organizations located at the closed administrative-territorial districts ("ZATO").

Participants on the American side included:

JCCRER Members:

- **Mr. Glenn S. Podonsky** — Co-Chair, U.S. JCCRER, Chief Health, Safety and Security Officer, Office of Health, Safety and Security, Department of Energy (DOE)
- **Ms. Ellen P. Embrey** — Deputy Assistant Secretary of Defense (Health Affairs), Force Health Protection & Readiness

Department of Defense (DoD)

- **Dr. Charles Miller** — Chief, Radiation Studies Branch

Division of Environmental Hazards and Health Effects
National Center for Environmental Health
Centers for Disease Control and Prevention
Department of Health and Human Services (DHHS)

- **Ms. Elizabeth Cotsworth** — Director, Office of Radiation and Indoor Air

Environmental Protection Agency (EPA)

- **Dr. Richard Williams** — Chief Health and Medical Officer

National Aeronautics and Space Administration

- **Ms. Kathy Halvey Gibson** — Deputy Director

Division of Systems Analysis
Office of Nuclear Regulatory Research
Nuclear Regulatory Commission (NRC)

JCCRER Executive Committee (EC) members :

- **Dr. Patricia Worthington** — Co-Chair, U.S. JCCRER Executive Committee, Director, Office of Health and Safety

Office of Health, Safety and Security
Department of Energy (DOE)

- **Colonel Patricia Lillis-Hearne** — Director, Armed Forces Radiobiology Research Institute

U.S. Department of Defense (DOD)

- **Ms. Mary Lisa Madell** — Director for Europe and Eurasia

Office of Global Health Affairs
Department of Health and Human Services

- **Dr. Jerome Puskin** — Director, Center for Science and Risk Assessment

Office of Radiation and Indoor Air
Environmental Protection Agency (EPA)

- **Dr. Francis Cucinotta** — Chief Scientist, Human Research Program

Johnson Space Center
National Aeronautics and Space Administration (NASA)

- **Dr. Vincent Holahan** — Senior Advisor, Office of Nuclear Regulatory Research

Nuclear Regulatory Commission (NRC)

Participants on the Russian side included:

JCCRER members:

- **Dr. Mikhail Kiselev** — Co-Chair, Russian JCCRER, Deputy Director

Federal Medical Biological Agency (FMBA)

JCCRER Executive Committee (EC) members :

- **Dr. Sergey Shinkarev** — Co-Chair, Russian JCCRER Executive Committee, Department Head

Federal Medical Biophysical Center (FMBC)

- **Dr. Evgeny Goloborodko** — Advisor

Federal Medical Biological Agency (FMBA)

- **Dr. Sergey Mikheenko** — Advisor

State Atomic Energy Corporation (Rosatom)

Items Approved by the JCCRER:

a) JCCRER Reaffirmation Statement of Responsibilities and Principles for Doing Work:

During the meeting in Washington on September 16-17, 2009, the JCCRER highly appreciated the atmosphere of trust and understanding in the performance of the joint radiation health effects research and confirmed its responsibilities for these joint activities as well as carrying out of the JCCRER principles. Those responsibilities and principles had been approved during the Fourth International U.S.-Russian JCCRER meeting held in St. Petersburg, Russia, on September 13-14, 2000.

The JCCRER also confirmed that for conducting the joint research, the following principle continues to be employed:

- The charges of the Joint U.S.-Russian Scientific Review Group (SRG) placed for consideration during the Fourth International U.S.-Russian JCCRER meeting held in St. Petersburg, Russia, on September 13-14, 2000 and signed by the Co-chairs of the EC remain in force.
- The Data Access Agreement placed for consideration during the Fourth International U.S.-Russian JCCRER meeting held in St. Petersburg, Russia, on September 13-14, 2000 and signed by the Co-chairs of the EC remain in force.

b) Ongoing Scientific Results and Scope of the New Research Pursuant to Directions 1 and 2:

The JCCRER approved the results and perspectives of the joint research conducted pursuant to Direction 1, Population Studies and Direction 2, Worker Studies. The JCCRER noted that the results of the joint studies published in over 200 peer-reviewed articles in U.S., Russian, and international journals significantly improved the level of knowledge of both the effects and risks of

chronic, low to moderate doses of ionizing radiation. The JCCRER confirmed that published scientific data provide new and important information that can lead to the revision of radiation protection standards and practices. The JCCRER considered preparing, in cooperation with competent Russian and U.S. authorities, an official request to the international organizations, the United Nations Scientific Committee on the Environmental Effects of Atomic Radiation (UNSCEAR) and the International Atomic Energy Agency (IAEA), to formulate a scientific opinion about the merits of the research on the health effects of prolonged low-dose exposure of large populations conducted under JCCRER aegis in the Southern Urals.

During the meeting in Moscow, Russia on October 1-2, the JCCRER Co-Chairs signed the Joint Recommendation on the involvement of international organizations in the evaluation of scientific results of research on the health effects of long-term, low-dose radiation exposure performed under the auspices of the JCCRER.

During the meeting in Washington on September 16-17, 2009, the JCCRER reiterated its intent to prepare the letters to UNSCEAR and IAEA requesting a review and scientific opinion of the results published to date.

c) **Extension of the Agreement:**

On 4 May, 2008, Deputy Minister of Foreign Affairs of the Russian Federation Sergey Kislyak and U.S. Ambassador to the Russian Federation William Burns signed the Protocol to extend the joint Agreement on radiation effects research through January 14, 2009.

The JCCRER noted that 2009 marked fifteen (15) years of highly successful U.S.-Russian collaboration to make significant contributions in the field of radiation health effects research.

Both sides have worked diligently to renew the Agreement by signing Protocol 3 to amend and extend the Agreement through January 14, 2014.

Noting that during the meeting in Moscow on October 1-2, 2008, the JCCRER Co-chairs signed the Joint Recommendation to extend the JCCRER Agreement for additional five (5) years, during the meeting in Washington on September 16-17, 2009, the JCCRER reiterated its intent that both parties will continue to work together to extend the Agreement through January 14, 2014.

d) Planning, Approval and Organization of the Visits (*this item is submitted to Rosatom for endorsement*):

The JCCRER continues to observe that the conduct of joint radiation health

effects research projects suggests the need for periodic collective discussion of both the results and the perspectives of the research, as well as peer-reviews. Conducting collaborative research assumes the need for access to primary as well as compiled and secondary data, which, according to the data access agreement, could be granted only at the territory of the closed administrative-territorial districts ("ZATO").

At the meeting held in Moscow, October 1-2, 2008, the JCCRER Co-chairs signed the Joint Recommendation for the Planning and Organization of Visits to the Secure Territories of the Russian Federation for Which Special Permission for the Entry of Foreigners is Required.

During the meeting in Washington on September 16-17, 2009, the JCCRER reiterated the importance of the development and implementation of the guidelines delineating the procedures for planning, approval, and organizing visits to the closed administrative-territorial districts ("ZATO").

e) Other Items Discussed:

Both parties were informed about the new structure of the JCCRER, the JCCRER EC, and the joint U.S.-Russian SRG.

Both parties were informed about the role of the SRG in maintaining the integrity and quality of the results of the research through ongoing peer review.

Both parties were informed about the parallel radiation health effects research sponsored by the U.S. National Cancer Institute and the European Commission.

Both parties were informed about the process employed by the U.S. National Council on Radiation Protection and Measurements (NCRP) for reviewing peer-reviewed publications and making recommendations for revising radiation protection standards and practices.

JCCRER Charges for the JCCRER EC

The JCCRER charged the Executive Committee with the following actions:

- Continue to work diligently to prepare the necessary documents for the renewal of the JCCRER Agreement;
- Develop the Guidelines Document for the planning, approval, and organization of the visits to the closed administrative-territorial districts ("ZATO").

- Create the Action Plan to involve international organizations in the assessment of the research results in the Southern Urals; and

- Ensure the continuation of the work.

Next Meeting:

It was agreed that the next JCCRER meeting would be held in the Russian Federation in 2010.

Signed on this 17th day of September 2009, in Washington, DC, United States of America.

Mr. Glenn S. Podonsky U.S. JCCRER Co-chair	Dr. Mikhail F. Kiselev Russian JCCRER Co-chair

Russian Health Studies Program
Peer Reviewed Publications and Outcomes
December 31, 2008

Project Number	Project Name	U.S. PI	Russian PI	Number of Peer-Reviewed Publications	Outcomes
1.1	Techa River Population Dosimetry 1999-2003 2004-2006 2007-2009	Lynn Anspaugh *University of Utah*	Marina Degteva *Urals Research Center for Radiation Medicine*	79	This project provides the foundation for the derivation of radiation risk from studies of the Techa River Cohort. It provides the dosimetry data for Project 1.2b, Techa River Population Morbidity. This study is important because it addresses the question of radiogenic risk from dose received at low dose rates. In addition, this project is providing valuable, new information for improving dose estimation from the intake of ^{90}Sr. Current work is directed to completion of the Techa River Dosimetry System-2009.

Project Number	Project Name	U.S. PI	Russian PI	Number of Peer-Reviewed Publications	Outcomes
1.2a	Data Preservation at URCRM 1997-2005	Donna Cragle *Oak Ridge Institute for Science and Education*	Nikolai Startsev *Urals Research Center for Radiation Medicine*	1	This completed project established a document imaging system at URCRM for preserving valuable medical records of residents of the Southern Urals region exposed to radiation due to the operations of the Mayak facility and environmental releases. These documents contain information from 1951 to the present with details of medical examinations, individual dose measurements, addresses, causes of death, and other data necessary for epidemiologic studies and dose reconstruction. Computer scanning equipment was purchased, installed, and later updated. Scanning, verification, indexing, and creation of a computer database of the scanned documents were completed.

Project Number	Project Name	U.S. PI	Russian PI	Number of Peer-Reviewed Publications	Outcomes
1.2b	Techa River Population Morbidity 1997-2003 2004-2006 2007-2009	Faith Davis *University of Illinois at Chicago*	Alexander Akleyev *Urals Research Center for Radiation Medicine*	25	The combined work of Projects 1.1 and 1.2b addresses the important question of the validity of the dose-response model (linear, non-threshold) used by national and international authorities in the development of radiation-protection standards, particularly as applied radiation delivered at low dose rates. The Extended Techa River Cohort (ETRC) reflects a general population exposed to moderate doses of radiation at low dose rates 50 years ago. The population is relatively large (~30,000) and has been actively followed so that results can be expected within a reasonable time frame. Preliminary results indicate an excess in leukemia and other cancers in this population. Preliminary risk assessment indicates a statistically significant dose dependence of incidence rates, but confounding sources of exposure and potential biases in the collection of the outcome data in this population must be investigated and resolved.

Project Number	Project Name	U.S. PI	Russian PI	Number of Peer-Reviewed Publications	Outcomes
1.4	Reconstruction of Dose to the Residents of Ozersk from Mayak Operations 2003-2004 2005-2009	Lynn Anspaugh *University of Utah*	Yuri Mokrov *Mayak Production Association*	7	This project is concerned with the reconstruction of doses to the residents of Ozersk from the airborne radionuclide emissions from Mayak. Focus is on the emission of ^{131}I and dose to the thyroid glands of children. Data will support an epidemiologic study of thyroid cancer in children sponsored by the National Cancer Institute. This should help resolve the dichotomy between the studies at Hanford (no observed effect) and Chernobyl (large effect). The data also will determine whether these emissions are a confounding factor in the study of the Extended Techa River Cohort (Projects 1.1 and 1.2b).
2.2	Mayak Worker Mortality 1997-2001 2002-2004 2005-2007 2008-2010	Ethel Gilbert *National Cancer Institute*	Mikhail Sokolnikov *Southern Urals Biophysics Institute*	7	This project is the first to demonstrate statistically significant associations between occupational exposure to plutonium (Pu) and lung, liver, and bone cancer. Dose-response analyses based on Mayak Worker Doses 2005 database have been conducted for lung, liver, and bone cancer and express the excess relative risk as a function of plutonium dose, external dose, gender, and attained age. Statistically significant dose-response relationships for external dose have also been demonstrated for leukemia; all solid cancer excluding lung, liver, and bone cancer; and lung cancer.

Project Number	Project Name	U.S. PI	Russian PI	Number of Peer-Reviewed Publications	Outcomes
2.4	Mayak Worker Dosimetry 2001-2003 2004-2006 2007-2008 2009-2011	Scott Miller *University of Utah*	Victor Khokhryakov *Southern Urals Biophysics Institute*; Evgeny Vasilenko *Mayak Production Association*	50	In addition to providing the dosimetric data for Project 2.2, Mayak Worker Mortality, this project has enhanced the understanding of Pu metabolism in the human body and improved the biokinetic models for assessing dose from Pu uptakes. These outcomes will be of direct benefit to DOE in improving the determination of dose to DOE workers from Pu exposure. Additionally, this project has improved the interpretation of worker external dosimetry and developed improved methods of estimating organ doses based on dosimeter results. These improved methods can be applied to the evaluation of worker dose at DOE facilities. This task also developed important relationships for the role of medical x-rays for worker exposure. Researchers prepared the Doses 2005 database for 18,831 Mayak workers employed between 1948 and 1972 and are now finalizing the Doses 2008 database for about 26,000 workers hired between 1948 and 1982.

Project Number	Project Name	U.S. PI	Russian PI	Number of Peer-Reviewed Publications	Outcomes
2.5	Improved Plutonium Dose Assessment Methods for Mayak Workers 1999-2003 2004-2006 2008-2010	Raymond Guilmette *Los Alamos National Laboratory*	Sergey Romanov *Southern Urals Biophysics Institute*	11	The earlier efforts in this project focused on determining the amount and location of long-term-retained Pu in the lungs of Mayak workers. This study was the first to demonstrate very long-term sequestration of Pu particles in human lung parenchyma. Then, this knowledge of Pu distribution in lung was used with state of the art dose assessment methods to modify the human respiratory tract dosimetry models to improve dose assessment. The main objective of the current phase is to obtain new knowledge and to implement additional useful tools that will facilitate the development of a new harmonized Pu dosimetry system, which will eventually replace the Mayak Doses 2005 dosimetry system in Project 2.4, Mayak Worker Dosimetry. This includes addressing several critical issues for lung dosimetry modeling, combining Pu dose estimates with the uncertainties for individual Mayak workers by using available urine bioassay and/or postmortem tissue data together with the Bayesian approach for individual dose assessment, and applying the probability distributions for intake and biokinetic model parameters for assessing the dose for workers monitored for Pu to Mayak workers for whom little or no Pu monitoring data are available.

Project Number	Project Name	U.S. PI	Russian PI	Number of Peer-Reviewed Publications	Outcomes
2.6	Molecular Markers of Lung Cancer in Mayak Workers 2000-2002 2003-2008	Steve Belinsky *Lovelace Respiratory Research Institute*	Vitaly Telnov *Southern Urals Biophysics Institute*	4	The original project demonstrated that the p16 tumor suppressor gene was targeted for inactivation by promoter hypermethylation in plutonium-induced adenocarcinomas of the lung. The current phase of the research is to examine methylation profiles in adenocarcinomas and squamous cell carcinomas of the lung in Mayak workers and controls.
2.7	Radiation Biomarkers 2001-2002 2003-2008	David Brenner *Columbia University*	Tamara Azizova *Southern Urals Biophysics Institute*	5	The feasibility study indicated a statistically significant dose-response between Pu exposure and intra-arm chromosomal aberrations from worker blood samples. This study may lead to the development of a dose-related biomarker of Pu exposure.
2.8	Mayak Worker Tissue Repository 1998-2002 2003-2007 2008-2012	Christopher Loffredo *Georgetown University*	Klara Muksinova *Southern Urals Biophysics Institute*	12	The Mayak Worker Tissue Repository now holds tissues from 1,000 deceased workers, surgical/biopsy tissue samples from 500 donors, and blood DNA, cells, serum samples from 4,800 professionals and residents of Ozersk. In conjunction with medical, occupational, and dosimetry information, data collected in the repository will make possible the conduct of molecular epidemiology studies. Such studies combine epidemiologic with genetic/molecular methods to establish an association between disease and radiation exposure in individuals.

Project Number	Project Name	U.S. PI	Russian PI	Number of Peer-Reviewed Publications	Outcomes
2.9	Database Integration 2001-2005	Dale Preston *Hirosoft International* Eric Grant *Radiation Effects Research Foundation*	Sergey Romanov *Southern Urals Biophysics Institute*; Evgeny Vasilenko *Mayak Production Association*	0	This project is meant to combine databases located in two Russian organizations so as to facilitate researcher access to data. As such, it is not intended to result in publications or influence radiation protection standards.

As of December 31, 2008, U.S. and Russian investigators working on projects funded by the Russian Health Studies Program have generated 201 peer-reviewed publications.

Russian Health Studies Program
201 Peer Reviewed Publications
December 31, 2008

Project 1.1: Techa River Population Dosimetry (79)

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11. Degteva, M.O.; Kozheurov, V.P.; Tolstykh, E.I. Retrospective dosimetry related to chronic environmental exposure. *Radiat. Prot. Dosim.* 79:155–160; 1998.

12. Degteva, M.O.; Vorobiova, M.I.; Kozheurov, V.P.; Tolstykh, E.I.; Anspaugh, L.R.; Napier, B.A. Dose reconstruction system for the exposed population living along the Techa River. *Health Phys.* 78:542–554; 2000.

13. Degteva, M.O.; Kozheurov, V.P.; Tolstykh, E.I.; Vorobiova, M.I.; Anspaugh, L.R.; Napier, B.A.; Kovtun, A.N. The Techa River Dosimetry System: Methods for the reconstruction of internal dose. *Health Phys.* 79:24–35; 2000.

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Project 2.7: Radiation Biomarkers (5)

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Project 2.9: Database Integration (0)

None.

TRAVEL & LODGING INFORMATION

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- Baltimore-Washington International Airport
  www.bwiairport.com
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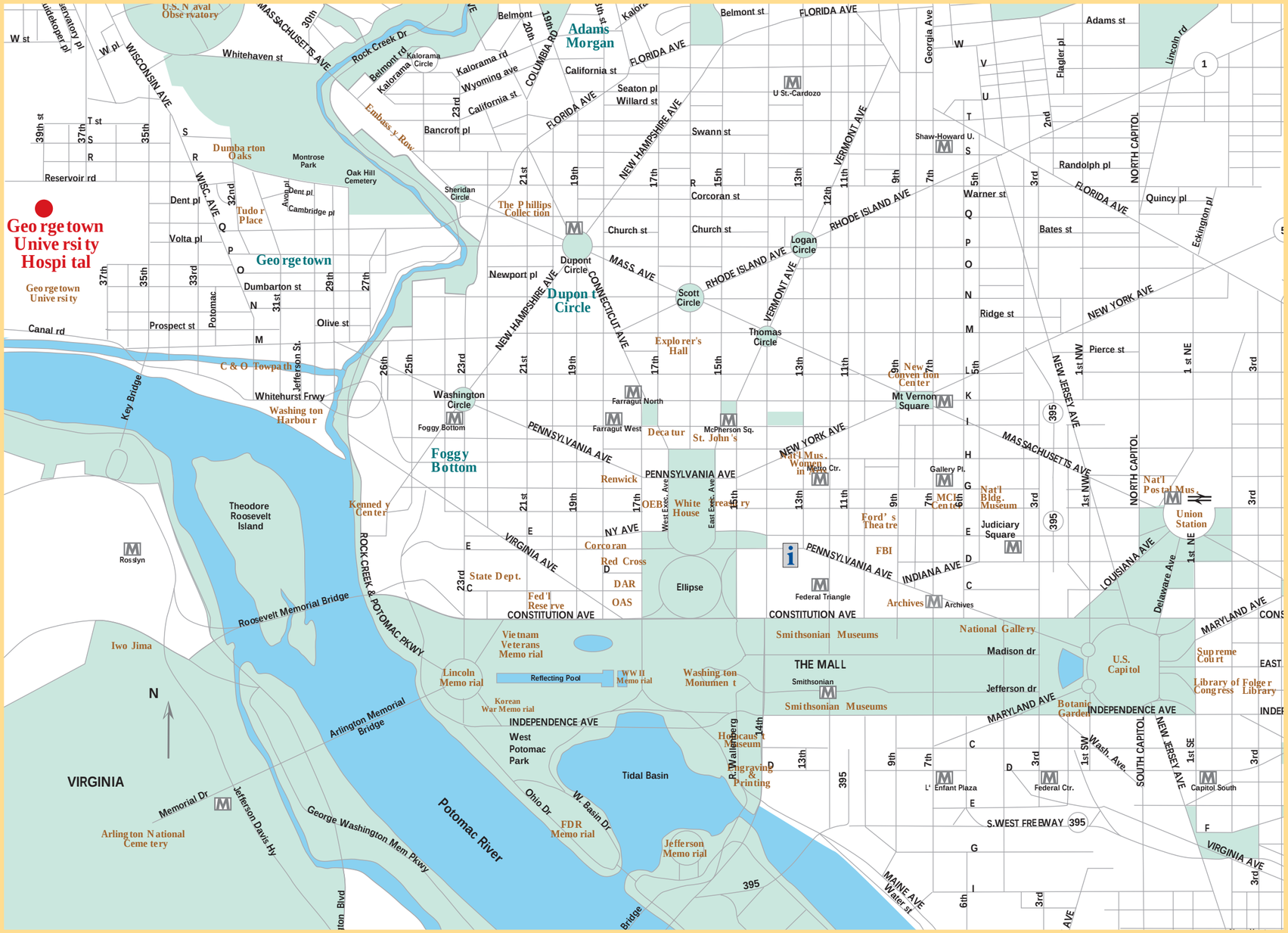

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Take Rhode Island Ave. west until it merges into M St. after Scott Circle. Take M St. to Wisconsin Ave. Turn right onto Wisconsin Ave. Take Wisconsin Ave. to Reservoir Rd. and turn left.

FROM MARYLAND:

From I-270

Take I-270 south toward Washington. Exit Rte. 355/Wisconsin Ave. south towards Bethesda. Take Wisconsin Ave. south 7 miles toward downtown D.C. Turn right onto Reservoir Road.

From I-95

Take I-95 south to I-495 west to Silver Spring. Exit Rte. 355/Wisconsin Ave. south towards Bethesda. Take Wisconsin Ave. south 7 miles towards downtown D.C. Turn right.

From Baltimore-Washington Parkway or Route 50 Westbound

Take BW Parkway or Rte. 50 west to New York Ave. Take New York Ave. until it merges into Massachusetts Ave. (at Seventh St.) Stay on Mass Ave. through underpass to Scott Circle. From the circle take Rhode Island Ave. (west) to M St. Bear right on M St. Follow to Wisconsin Ave. Turn right on Wisconsin Ave. to Reservoir Rd. Turn left.

From Southern Maryland

Take I-295 Washington to I-395 South/Richmond. Exit at 12th St. and stay right. Take 12th St. north to Massachusetts (Mass) Ave. Turn left on to Mass Ave. Stay on Mass Ave. through underpass to Scott Circle. From the circle take Rhode Island Ave. (west) to M St. Bear right on M St. Follow to Wisconsin Ave. Turn right on Wisconsin Ave. to Reservoir Rd. Turn left.

FROM NORTHERN VIRGINIA:

From I-66

Take I-66 east to the Rosslyn-Key Bridge exit. Stay in left lane and follow signs to Key Bridge. Cross Key Bridge and stay in left lane. Turn left onto Canal Road. Stay in right lane. Bear right onto Foxhall Rd. Turn right.

From I-395

Take I-395 north. Exit Washington Blvd. to Rosslyn. Take Washington Blvd. and follow signs to Rosslyn and Key Bridge. Cross Key Bridge. Turn left onto Canal Rd. Stay in right lane. Bear right onto Foxhall Rd. Turn right at Reservoir Rd.

From Route 50 Eastbound

Follow Route 50 east and take the Rosslyn-Key Bridge exit. Follow signs to Key Bridge. Cross Key Bridge and turn left onto Canal Road. Stay in right lane. Bear right onto Foxhall Rd. Turn right at Reservoir Rd.

From George Washington Parkway

Take the GW Parkway south. Exit Key Bridge. Cross bridge and turn left onto Canal Rd. Stay in right lane. Bear right onto Foxhall Rd. Turn right.

TIP FOR NAVIGATING D.C.

Washington D.C. is set-up like a grid, with the Capital Building being the very center and dividing the city into quadrants (NW, NE, etc.). All streets running north and south are numbered and increase as you go away from the Capital. Letters designate streets running east and west and progress the same way.

NOTES