

Fiftieth Annual Meeting Program



NCRP: Achievements of the Past 50 Years and Addressing the Needs of the Future







March 10-11, 2014

Hyatt Regency Bethesda One Bethesda Metro Center 7400 Wisconsin Avenue Bethesda, MD 20814



Front cover: Past and current Presidents of NCRP [top to bottom]:

Lauriston S. Taylor, 1929 – 1977 Warren K. Sinclair, 1977 – 1991 Charles B. Meinhold, 1991 – 2002 Thomas S. Tenforde, 2002 – 2012 John D. Boice, Jr., 2012 –

NCRP Mission:

To support radiation protection by providing independent scientific analysis, information and recommendations that represent the consensus of leading scientists.

Please visit the NCRP website, http://NCRPpublications.org, for a complete list of publications. Reports and commentaries are available in both PDF and hardcopy formats unless otherwise noted. Book reviews of NCRP publications are also available at this website. Contact NCRP's Executive Director, James R. Cassata (cassata@ncrponline.org), for more information.

Introduction

NCRP: Achievements of the Past 50 Years and Addressing the Needs of the Future

Fiftieth Annual Meeting of the National Council on Radiation Protection and Measurements (NCRP)

The program will celebrate the 50th year since our Congressional charter in 1964. Notable contributions to radiation protection policies and programs will be recalled, but the speakers will focus primarily on important challenges and opportunities to address the needs of the nation for the future. Presentations will be given by leading experts in each of the seven areas of protection to be covered with ample opportunities to ask questions verbally or textually.

- Session one addresses basic radiation protection criteria, epidemiology, radiobiology and risk. It includes presentations on integrating basic radiobiological science and epidemiological studies, challenges for radiation protection in space exploration, and the biological effectiveness of x and gamma rays as a function of energy.
- Session two covers nuclear and radiological security and safety concerns. The challenges facing an appropriate medical response to terrorist events involving improvised nuclear or radiological dispersal devices will be presented. After the emergency crisis has ended and the first responders have left, decision making for late-phase recovery following a nuclear incident with widespread radioactive contamination will be discussed.
- Session three explores both current and emerging issues in operational and environmental radiation protection. Specific topics include radiation safety and security of sealed sources (and how to protect the cowboys in the field), radiation safety associated with technologically-enhanced naturally-occurring radioactive material in the oil and gas industry (with a focus on fracking), and radiation safety in the burgeoning area of research and applications in nanotechnology.
- Session four focuses on radiation measurement and dosimetry. The first presentation emphasizes the continuing need for dosimetry and measurements in

radiation protection. This will be followed by a presentation of the complex dosimetry needs and practical approaches being applied to the ongoing epidemiologic study of one million U.S. radiation workers and veterans.

- Session five opens with possibly the most important issue in radiation protection today and in medicine in particular (*i.e.*, the protection for patients in diagnostic and interventional medical imaging). Following are presentations on protection of patients in radiation therapy and radiation protection of the developing embryo, fetus, and nursing infant.
- Session six covers the topics of radiation education, risk communication, outreach, and policy.
- Two concluding presentations address historical trends in radiation protection, policy and communications from 1964 to the present and the role played by national and international organizations in guiding and influencing U.S. radiation protection standards and regulations.

In addition, there will be two featured speakers: Dr. Jerrold T. Bushberg the Warren K. Sinclair Keynote Speaker and Dr. Fred A. Mettler, Jr. is the Lauriston S. Taylor Lecturer.

Program Chair and NCRP Honorary Vice President, Kenneth R. Kase, will synthesize and summarize the diverse topics covered, and will expand on the opportunities and challenges in science, operations, and communications faced as we strive to address the needs of the nation in the 21st century.

NCRP President, John D. Boice, Jr., will close the 2014 Annual Meeting by briefly summarizing NCRP's perspective on future needs in radiation protection and mission obligations in accordance with our Congressional charter.

Monday, March 10, 2014

Opening Session

8:15 am	Welcome	
	John D. Boice, Jr.	
	President, NCRP	

Eleventh Annual Warren K. Sinclair Keynote Address

8:30 am Science, Radiation Protection, and the NCRP: Building on the Past, Looking to the Future Jerrold T. Bushberg University of California, Davis

Basic Criteria, Epidemiology, Radiobiology, and Risk (PAC 1)

Kathryn D. Held, Session Chair

- 9:15 am Integrating Basic Radiobiological Science and Epidemiological Studies (Why and How?) R. Julian Preston U.S. Environmental Protection Agency
- 9:40 am Radiation Safety and Human Spaceflight: Importance of the NCRP Advisory Role in Protecting Against Large Uncertainties Francis A. Cucinotta University of Nevada Las Vegas
- 10:05 am Biological Effectiveness of Photons and Electrons as a Function of Energy Steven L. Simon National Cancer Institute

10:30 am	Q&A

10:50 am Break

Nuclear and Radiological Security and Safety (PAC 3 & 5)

John W. Poston, Sr. & Jill A. Lipoti, Session Co-Chairs

- 11:10 am Response to an Improvised Nuclear Device or a Radiological Dispersal Device: Models, Measurements, and Medical Care C. Norman Coleman National Cancer Institute
- 11:35 am Decision Making for Late-Phase Recovery from Nuclear or Radiological Incidents (What's Next After the First Responders Have Left?) S.Y. Chen Illinois Institute of Technology

12:00 pm	Q&A
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12:15 pm Lunch

Operational and Environmental Radiation Protection (PAC 2 & 5)

Carol D. Berger & Ruth E. McBurney, *Session Co-Chairs*

- 1:45 pm Radiation Safety of Sealed Radioactive Sources Kathryn H. Pryor Pacific Northwest National Laboratory
- 2:10 pm Pennsylvania's Technologically-Enhanced Naturally-Occurring Radioactive Material Experiences and Studies of the Oil and Gas Industry David J. Allard Pennsylvania Department of Environmental Protection

Program Summary

2:35 pm Radiation Safety in Nanotechnology (Does Size Matter?) Mark D. Hoover National Institute for Occupational Safety and Health

3:00 pm Q&A

Radiation Measurement and Dosimetry (PAC 6)

Wesley E. Bolch, Session Chair

- 3:20 pm Framework and Need for Dosimetry and Measurements: Quantitation Matters Raymond A. Guilmette Lovelace Respiratory Research Institute
- 3:45 pm Dose Reconstruction for the Million Worker Epidemiological Study Andre Bouville National Cancer Institute
- 4:10 pm **Q&A**
- 4:25 pm Break

Thirty-Eighth Lauriston S. Taylor Lecture on Radiation Protection and Measurements

5:00 pm Introduction of the Lecturer Milton J. Guiberteau

> On the Shoulders of Giants: Radiation Protection Over 50 Years Fred A. Mettler, Jr. New Mexico Federal Regional Medical Center

6:00 pm Reception in Honor of the Lecturer Sponsored by Landauer, Inc.

Tuesday, March 11

8:15 am NCRP Annual Business Meeting9:15 am Break

Radiation Protection in Medicine (PAC 4)

Donald L. Miller, Session Chair

- 9:45 am Protection of Patients in Diagnostic and Interventional Medical Imaging Kimberly E. Applegate Emory University School of Medicine
- 10:10 am Protection and Measurement in Radiation Therapy Steven G. Sutlief University of Washington Medical Center
- 10:35 am Protection of the Developing Embryo and Fetus from Ionizing Radiation Exposure Robert L. Brent Alfred I. duPont Institute Hospital for Children

11:00 am Q&A

Radiation Education, Risk Communication, Outreach, and Policy (PAC 7)

Julie E.K. Timins, Session Chair

11:20 am Historical Trends in Radiation Protection, Policy and Communications: 1964 to the Present Paul A. Locke The Johns Hopkins University Bloomberg School of Public Health

NCRP: Achievements of the Past 50 Years and Addressing the Needs of the Future

11:45 am U.S. Radiation Protection: Role of National and International Advisory Organizations and Opportunities for Collaboration (Harmony not Dissonance) Michael A. Boyd U.S. Environmental Protection Agency

12:10 pm Q&A

Summary: NCRP for the Future

John D. Boice, Jr., Session Chair

- 12:25 pm Capturing Opportunities and Meeting Challenges in Radiation Protection Kenneth R. Kase Honorary Vice President, NCRP
- 12:50 pm Closing Remarks John D. Boice, Jr. President, NCRP
 - 1:00 pm Adjourn

Monday, March 10

Opening Session

8:15 am	Welcome
	John D. Boice, Jr., <i>President</i>
	National Council on Radiation Protection and Measurements

Eleventh Annual Warren K. Sinclair Keynote Address

8:30 am

Science, Radiation Protection, and the NCRP: Building on the Past, Looking to the Future Jerrold T. Bushberg University of California, Davis School of Medicine



This year, NCRP celebrates 50 y of service to the Nation and the radiation protection community under its Congressional charter signed into law in 1964. However, the history of NCRP and its predecessor organizations date back to 1929, 34 y after the discovery of x rays and radioactivity. While the technology transfer that led to beneficial applications of these discoveries was likely one of the most rapid and profound in modern history, the development of consensus based safety standards to protect against the adverse effects of radiation (which were all too apparent to the many early radiation pioneers) was more gradual. Some members of the international community of scientists working with these sources were keenly interested in advancing and communicating proper radiation protection principles and practices. What would become NCRP was originally established in 1929 as the U.S. Advisory Committee on X-Ray and Radium Protection whose mission was to provide a U.S. consensus of scientific opinion on radiation protection matters to the newly formed International X-Ray and Radium Protection Committee, the predecessor of the International Commission on Radiological Protection (ICRP).

Dr. Lauriston S. Taylor chaired the Advisory Committee and served as the first official U.S. representative to ICRP. After World War II, development and utilization of new radiation technology in medicine and industry accelerated rapidly. In 1946 membership of the Committee was enlarged and its scope broadened to assure their activities would remain relevant. With these and other changes the Committee was renamed the National **Committee on Radiation Protection** (NCRP). In 1959, President Eisenhower issued an executive order establishing the Federal Radiation Council (FRC) to provide regulatory guidance on radiation protection at a national level. In recognition of NCRP's role in providing scientific advice and guidance on radiation protection policies and practices to FRC and others federal agencies, Congress chartered the NCRP in 1964 (Public Law 88-376) as "The National Council on Radiation Protection and Measurements" an independent, nonprofit organization to provide scientific guidance on radiation protection. Key elements of the NCRP charter include responsibilities to: (1) collect, analyze, develop, and disseminate in the public interest information and recommendations

about radiation protection, measurements, quantities and units; (2) provide a means by which other scientific organizations with related interest and concerns may cooperate for effective utilization of their combined resources; (3) develop basic concepts about radiation quantities, units, and measurements and their application to radiation protection; and (4) cooperate with the ICRP and other international and national organizations. A set of bylaws was developed that included the election of a President and other officers of the corporation. 75 members of Council (later increased to 100 in 1997) comprised of scientific experts in a broad range of disciplines with relevance to radiation protection, and a Board of Directors. Since the establishment of its Congressional charter, NCRP has had five productive decades as evidenced by the publication of 174 reports and 90 other documents, including commentaries, statements, and conference proceedings (57 of these documents were published in the last 10 y). In addition, many of the current U.S. radiation protection standards can trace their origin to recommendations made in these NCRP publications (e.g., Report No. 116). Together, these reports have provided guidance and recommendations on a broad array of topics relevant to the science of radiation protection.

The majority of the work of NCRP is accomplished through its scientific committees (SC). The SCs are organized under program area committees (PACs) or advisory committees which help identify important radiation protection issues and topics for which a report by a SC composed of relevant subject matter experts would be of value. These committees include (PAC 1) Basic Criteria, Epidemiology, Radiobiology, and Risk, (PAC 2) Operational Radiation Safety, (PAC 3) Nuclear and Radiological Security and Safety, (PAC 4) Radiation Protection in Medicine, (PAC 5) Environmental Radiation and Radioactive Waste Issues,

(PAC 6) Radiation Measurements and Dosimetry, the recent (PAC 7) Radiation Education, Risk Communication, Outreach, and Policy, and an Advisory Panel on Nonionizing Radiation. Some NCRP reports have provided the basis for much needed change in the use of radiation sources. For example, NCRP Report No. 160 (2009) updated one of NCRP's most cited publications which details the doses to the U.S. population from all sources of ionizing radiation with particular attention to those sources that contribute the largest shares to the public and the radiation worker. This Report revealed that the most significant increase in the average per capita annual dose to the U.S. population in the last 30 y was due to the increased availability and use of radiation in medicine (primarily computed tomography and cardiovascular nuclear medicine). While many lives have been saved by advancements in imaging technology, it is clear that this is now the single most controllable source of radiation exposure in the United States and that continued improvement in justification and optimization are important to keep these exposures as low as diagnostically acceptable (ALADA). ALADA is proposed as a variation of the acronym ALARA (as low as reasonably achievable) to emphasize the importance of optimization in medical imaging.

Using the lessons from the past to help guide our future, NCRP has embarked on a number of initiatives (both scientific and operational) to assure Council and staff will be well prepared to continue its exemplary service to the Nation. Examples of operational initiatives include:

- improvements in NCRP's utilization of the expertise of Council members;
- modifications to our committee structure to improve efficiency and allow for greater cross-discipline communications;

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- enhancements to our web presence and the use of social media to keep up with trends in information access;
- collaborate with other organizations to encourage young scientists to become engaged in professional development of scientific disciplines related to radiation protection;
- developing a deeper understanding of the radiation protection challenges faced by NCRP's federal agency sponsors; reviewing current radiation protection guidance for the United States;
- closer coordination with our national and international partners; and
- rightsizing and timely preparation of reports and streamlining the Council report review process.

Council members and any other interested parties are encouraged to contact NCRP leadership with any suggestions for improving NCRP's ability to fulfill its mission.

NCRP has recently broadened its scope to respond to some of the pressing needs of today's radiation protection environment. NCRP's role in the WARP initiative (Where are the Radiation Professionals: A National Crisis?) to help address the rapidly diminishing workforce of radiation professionals and NCRP's engagement in epidemiological research to extend our knowledge of the potential health effects of low dose radiation by way of the Million Worker Study are just a few of such visionary activities.

While many advances have been made, there are still many questions of importance to radiation protection that have not been fully resolved despite years (sometimes decades) of effort. NCRP will play an important role in helping to develop a consensus view regarding complex issues such as:

 estimating and effectively communicating the health risk from "low dose" radiation;

- implications of nontargeted effects, the concerns about sensitive subpopulations;
- biological effectiveness of low energy photons;
- challenges of applying justification and optimization in diverse environments such as medical imaging and environmental remediation of contaminated sites;
- long-term storage and monitoring of high level radioactive waste
- practical considerations and benefits from harmonization of units and dose limits;
- risks of space travel;
- implications of nanotechnology in radiation safety; and
- many others that will no doubt extend far into the 21st century.

These uncertainties will continue to influence the cost and benefits derived from the ever expanding use of radiation in everything from medical imaging and cancer treatment to manufacturing and homeland security. There will be a continuing need for NCRP to identify the principles upon which radiation protection is to be based and to provide guidance on best practices for the practical application of those principles for the many beneficial uses of radiation in society. The unique and invaluable resource that is NCRP is in large part due to the selfless dedication and numerous contributions of its Council and SC members. The multidisciplinary composition of these leading experts' and their collective input on complex questions provides a unique synergy that result in a comprehensive and well balanced approach to addressing current and future radiation protection challenges. Subsequent presentations covering a broad range of relevant topics will review sentinel accomplishments of the past as well as current work and future challenges that are in keeping with NCRP's mission to advance the science of radiation protection in the public interest.

Basic Criteria, Epidemiology, Radiobiology, and Risk (PAC 1)

Kathryn D. Held, Session Chair

9:15 am

Integrating Basic Radiobiological Science and Epidemiological Studies (Why and How?) R. Julian Preston

U.S. Environmental Protection Agency



On the one hand, there is a guite extensive set of epidemiology studies conducted for a range of different exposure scenarios and in some cases at doses that can be considered to be in the low dose range (<100 mGy). There are uncertainties associated with these studies, for example with the dosimetry, potential confounding factors, and models used for extrapolation to effects at environmental doses and for chronic exposures. On the other hand, there is extensive literature on the effects of radiation at the animal and cellular levels. In addition, there is an expanding knowledge of the underlying mechanisms of disease formation (both cancer and noncancer). Here also there are uncertainties associated with the ability to extrapolate from these studies to predict adverse health outcomes in radiation-exposed human populations. A significant concern is that these two areas of study have rarely been linked to support each other - to enhance low dose/low dose-rate extrapolation and reduction of uncertainty in risk estimates. A significant reason for this is that basic radiobiology research generally has not been designed to support the risk assessment process but rather it is used post facto in an attempt to provide such support. In general, this is not a very satisfactory approach. It is proposed that there be an area of research that uses experimental designs that would provide specific types of data to support the epidemiology and thereby would enhance the radiation risk assessment process.

Such an approach is one that can be adapted from that used for chemical exposures and that was developed largely because there are very few epidemiological data available especially at environmental exposure levels and for which risk assessment is required by the U.S. Environmental Protection Agency, for example. The approach is based on the concept of adverse outcome pathways (AOP) for the formation of adverse health outcomes. The AOP conceptual framework is considered to be a logical sequence of events (so called key events) or processes within biological systems which can be used to understand adverse effects and refine the current risk assessment practice. This approach shifts the risk assessment focus from traditional apical endpoints (e.g., cancer and cardiovascular disease) to the development of a mechanistic understanding of a chemical's effect at a molecular and cellular level for potentially predicting disease outcome, at a qualitative and quantitative level. This approach has been developed into one whereby key events can be used to describe low-dose responses for induced cancer — the Key Events Dose Response Framework (KEDRF). In addition, more recent efforts are designed to provide quantitative predictions of lowdose response in a Q-KEDRF approach. This general approach can be applied also to the estimation of radiation-induced cancer at low doses and dose rates based on the current knowledge of key events for the development of these cancers. It is

also possible that a similar approach could also be used for noncancer effects.

The need for developing such a key eventbased approach for risk estimation is to further knowledge of the key events in radiation-induced carcinogenesis and to provide information on the dose response for these. It is proposed that the key-event approach be used in conjunction with enhanced radiation epidemiology data to reduce overall uncertainty in low dose/ low-dose rate cancer and noncancer risk estimates.

9:40 am

Radiation Safety and Human Spaceflight: Importance of the NCRP Advisory Role in Protecting Against Large Uncertainties

Francis A. Cucinotta University of Nevada Las Vegas

Long-duration space missions present unique challenges for radiation safety due to the complexity of the space radiation environment, which includes high charge and energy (HZE) particles and other high linear energy transfer (LET) radiation such as neutrons, the nature of space missions, and the distinct characteristics of astronauts compared to ground-based radiation workers. For 25 y NCRP has provided important guidance to the National Aeronautics and Space Administration (NASA) on radiation safety. NASA reviews past NCRP recommendations, how these recommendations have been implemented, and the major challenges for the future where the role of NCRP should continue to be pivotal to the success of NASA's goals for space exploration. Recommendations by NCRP have guided NASA in the development of a risk-based system for radiation protection that limits individual occupational radiation exposures to a lifetime 3 % fatality risk. Based on NCRP recommendations, NASA has implemented gender and age-at-exposure specific dose to risk conversion factors as the basis for radiation limits. Because of the much higher exposure of astronauts compared to ground-based workers, this approach places the risk estimates rather than dose as the primary quantity in safety programs. Methods have been developed to estimate uncertainties in risk estimates and the 95 % confidence level applied to

the limiting risk due to the large uncertainties in estimating cancer risks from HZE particles. NASA also reviews NCRP recommendations related to spaceflight dosimetry, acceptable risk, and goals for research in space radiobiology.

More than 50 y after the initial missions into low-Earth orbit, spaceflight may seem routine. However in reality space exploration is in its infancy with the most important goals to be realized in the future. Similarly how to protect individuals from long-term space exposures remains a primary challenge for space flight and one where new knowledge is needed to enable missions. Similar to occupational safety on Earth which has improved over recent decades, spaceflight safety has improved with NASA now projecting <1 in 270 probability of loss of crew (LOC) for current spaceflights. In 2010 the NASA Aerospace Safety Advisory Panel recommended that <1 in 750 LOC risk is achievable through smart technology investments. Such improvements in other areas of safety should inspire NASA to maintain the 1 in 33 fatality limit for space radiation exposures that was recommended by NCRP in 1989. However to achieve exploration goals for Mars and farther destinations within acceptable radiation risks will require new knowledge to significantly reduce the uncertainties in estimates of cancer risks and to address emerging

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issues for noncancer risks. In-flight and late effects to the central nervous system are an emerging area of critical importance based on ground-based experiments at particle accelerators simulating space radiation. Qualitative differences in the biological effects of HZE particles compared to terrestrial radiation remains the largest uncertainty and hinders the development of effective countermeasures. This presentation will highlight the major challenges in these areas and likely roles for NCRP guidance in helping NASA prepare for the future.

Biological Effectiveness of Photons and Electrons as a

Function of Energy Steven L. Simon National Cancer Institute



An unresolved question in evaluating the risk of cancer in humans from exposure to low linear-energy transfer (LET) radiation (i.e., photons and electrons) is the dependence of the biological effectiveness on energy. This dependence is relevant for estimating risks of cancer from exposure to low-LET radiation at the lower energies used in mammography as well as certain sources of occupational and public exposure. Because of the broad importance of this topic to the basic responsibilities and interests of NCRP, the Council created a scientific committee (SC 1-20) to evaluate this question. Other expert groups and investigators have also considered this question, and several have concluded that the biological effectiveness of lowerenergy low-LET radiation based on radiobiologic data and biophysical considerations may be two or more times greater than for higher-energy low-LET radiation. However, biological systems used in the experiments and biophysical analysis provide only indirect evidence and may not be strictly applicable to cancer in humans, particularly considering that there are many types of cancer. Epidemiologic studies that, in theory, could demonstrate that lower-energy photons and electrons are biologically more effective than highenergy photons are inherently difficult to conduct when very large study populations and highly accurate estimates of cancer risks are required to observe a

presumably small effect. Because of the enormous complexity of the phenomena that are involved in the development of cancer following exposure to ionizing radiation, it is unlikely that any single area of study can provide a clear understanding of the relative biological effectiveness of different energy radiations. For these various reasons, an important aspect of the evaluation by SC 1-20 is the combined assessment of multiple lines of evidence and their related uncertainties. SC 1-20 is basing its analysis on five different lines of evidence:

- · microdosimetric calculations;
- studies of damage to DNA, including theory, calculations, and experimental data;
- radiobiologic studies in cellular systems;
- radiobiologic studies in animal systems; and
- human epidemiologic studies.

Accordingly, the Committee has developed a means of assessing a probability density function (PDF) of the biological effectiveness for selected energies (photons of energy ~1.5 keV, ~15 to 30 keV, ~40 to 60 keV, ~50 to 150 keV, and the spectrum of electrons produced in beta decay of tritium) using all available information from the different lines of evidence. Methods for this purpose have been drawn from the field of probability assessment

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that utilizes the elicitation of expert input and the synthesis of data from multiple sources of information *via* Bayesian analysis. In this context, the PDF is intended to represent the current state-of-knowledge about the relative biological effectiveness of the specified low-LET radiations. While the most recent publications in radiation research will provide SC 1-20 with only very limited data that previous expert groups and other investigators did not evaluate, the derivation of a composite PDF based on multiple lines of evidence may provide a unique contribution that can be used to assess the uncertainty in estimates of radiation-related cancer risk. This presentation will summarize the current status of the analysis by SC 1-20.

10:30 am **Q&A**

Break

10:50 am

Nuclear and Radiological Security and Safety (PAC 3 & 5)

John W. Poston, Sr. & Jill A. Lipoti, Session Co-Chairs

11:10 am

Response to an Improvised Nuclear Device or a Radiological Dispersal Device: Models, Measurements, and Medical Care C. Norman Coleman National Cancer Institute



Prior to September 11, 2001, largely because of the ending of the Cold War, there was limited attention given to preparedness for a nuclear detonation or large-sized radiation incident other than ongoing programs related to nuclear power plants. To address potential threats, the U.S. government developed 15 National Planning Scenarios of which No. 1 was a 10 kt nuclear detonation and No. 11 a radiological dispersal device.

The U.S. health and medical response is under Emergency Support Function No. 8 with the U.S. Department of Health and Human Services as the lead agency in collaboration with interagency partners. Four key aspects of the planning have been:

- building on the best possible science;
- developing research and development programs (mostly through the National Institute of Allergy and Infectious Diseases, the Biomedical Advanced

Research and Development Authority, and the U.S. Department of Defense);

- publishing in the peer review literature; and
- making the information understandable and usable for responders who may not have sophisticated training in the radiation sciences.

The knowledge and expertise needed ranges from radiation physics, physical models of detonations, radiation normal tissue injury, medical countermeasure development, mass casualty planning, triage/scarce resource allocation, radiation epidemiology, information management and technology and emergency management. In the aggregate, what we call "REMS" (Radiation Emergency Management System) has been developed which is a complex system that is continuously evaluated and improved. NCRP: Achievements of the Past 50 Years and Addressing the Needs of the Future

Health and medical planning and response for radiological and nuclear incidents have been helped by contributions from NCRP. Indeed, both the research and service missions of the federal agencies have expanded, providing new opportunities for investigation and implementation by government, academia, and the private sector. Furthermore, international collaborations have been strengthened and there have been spin-offs that could benefit cancer treatment. This presentation will review how the REMS approach was

developed and how it is continuing to evolve. The radiation teams were involved in responding to the disaster in Japan in 2011, the experience from which has lead to the proposal of a "Medical Decision Model" for effectively managing rapidly evolving radiological and nuclear incidents. Newer issues for consideration are estimating and potentially mitigating risk from radiation-induced cancer and developing a comprehensive "National Concept of Operations."

Decision Making for Late-Phase Recovery from Nuclear or Radiological Incidents (What's Next After the First **Responders Have Left?)**



S.Y. Chen

Illinois Institute of Technology

In the United States, effort on radiological emergency preparedness has focused primarily on initial responses to an incident; the guidance on the more complex, longterm issues relating to the late-phase recovery has been lacking. It is clear from the recent major accidents at Chernobyl (Ukraine 1986) and Fukushima (Japan 2011) nuclear power plants that the magnitude of the radiological impact can affect extended areas and last for many years, thus making planning for recovery a necessary component to the overall response. Similar challenges likewise may be encountered in the illicit incidents involving the use of radioactive or nuclear material such as those could be posed by a radiological dispersal device (RDD) or improvised nuclear device (IND). In 2010 NCRP established a scientific committee (SC 5-1) to prepare a comprehensive study that establishes the framework of and recommends an approach to optimizing decision making in late-phase recovery from major nuclear or radiological incidents. The study, to be published as

NCRP Report No. 175, addresses all relevant dimensions in all aspects of longterm recovery: health, environmental, economic, psychological, cultural, ethical, and socio-political. Consistent with the recommendations by the International Commission on Radiological Protection, NCRP considers optimization to be the fundamental approach to decision making in late-phase recovery for balancing the multiple factors in situations involving wide-area contamination. The Report describes optimization as an iterative process that consists of a series of steps, all of which involve deliberations with stakeholders as a necessary element for a community-focused recovery. Above all, the Report elicits a new paradigm that specifically addresses a long-term approach to managing the challenging radiological conditions experienced by the communities. In conclusion, the Report makes a series of recommendations aimed at enhancing and strengthening late-phase recovery efforts following a major nuclear or radiological incident.

12:00 pm

11:35 am

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12:15 pm

Lunch

Operational and Environmental Radiation Protection (PAC 2 & 5)

Carol D. Berger & Ruth E. McBurney, Session Co-Chairs

1:45 pm

Radiation Safety of Sealed Radioactive Sources

Kathryn H. Pryor Pacific Northwest National Laboratory



Sealed radioactive sources are used in a wide variety of occupational settings and under differing regulatory/licensing structures. The definition of a sealed radioactive source is not consistent among U.S. regulatory authorities and standardsetting organizations. Potential problems with sealed sources cover a range of risks and impacts. The loss of control of high activity sealed sources (radiography, medicine) can result in very high or even fatal doses to members of the public who come in contact with them. Sources that are not adequately sealed, and that fail, can cause spread of contamination and potential intake of radioactive material. There is also the possibility that sealed sources may be (or threatened to be) used for terrorist purposes and disruptive opportunities.

Until fairly recently, generally-licensed sealed sources and devices received little, if any, regulatory oversight, and were often forgotten, lost, or unaccounted for. None-theless, generally licensed devices can contain fairly significant quantities of radioactive material (e.g., 500 mCi of ¹³⁷Cs, 1,000 mCi of ²⁴¹Am), and there is some dose potential associated with activities of this magnitude if a device is treated in a way that it was never designed.

Industrial radiographers use and handle large, high-dose sealed sources in the field with a high degree of independence and minimal regulatory oversight. Failure to follow operational procedures and properly handle radiography sources can and has resulted in serious injuries and death. Industrial radiographers have experienced a disproportionately large fraction of incidents that result in unintended exposure to radiation.

NCRP has not previously provided overarching guidance on the radiation safety aspects of the fabrication, certification, use and control of sealed radioactive sources. Program Area Committee 2, Operational Radiation Safety, is preparing a report to provide comprehensive guidance on the radiation safety of sealed radioactive sources from "cradle to grave." Recommendations will be provided on the definition of a sealed radioactive source, design and fabrication, acquisition, safe handling, storage, tracking, and control of sealed sources. The report will also present a set of "lessons learned" regarding what has gone wrong with sealed sources, what caused those events, and what could be done to prevent them in the future.

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2:10 pm

Pennsylvania's Technologically-Enhanced Naturally-Occurring Radioactive Material Experiences and Studies of the Oil and Gas Industry David J. Allard

Pennsylvania Department of Environmental Protection



This presentation will provide an overview of the Commonwealth of Pennsylvania's experiences and ongoing studies related to technologically-enhanced naturallyoccurring radioactive material (TENORM) in the oil and gas industry. It has been known for many years that Pennsylvania's geology is unique, with several areas having relatively high levels of natural uranium and thorium. In the 1950s a few areas of the state were evaluated for commercial uranium production. In the late 1970s scoping studies of radon in homes prompted the Pennsylvania Department of Environmental Protection (DEP) Bureau of Radiation Protection (BRP) to begin planning for a larger state-wide radon study. The BRP and Oil and Gas Bureau also performed a TENORM study of produced water in the early 1990s for a number of conventional oil and gas wells. More recently BRP and the Bureau of Solid Waste developed radiation monitoring regulations for all Pennsylvania solid waste disposal facilities. These were implemented in 2001 prompting another evaluation of oil and gas operations and sludges generated from the treatment of conventional produced water and brine,

but mainly focused on the disposal of TENORM solid waste in the state's Resource Conservation and Recovery Act Subtitle D landfills. However since 2008, the increase in volumes of gas well wastewater, and levels of ²²⁶Ra observed in the unconventional shale gas well flow-back frac water, has compelled DEP to fully re-examine these oil and gas operations. Specifically, with BRP in the lead, a new TENORM study of oil and gas operations and related wastewater treatment operations has been initiated. This study began in early 2013, and will examine the potential public and worker radiation exposure and environmental impact, as well as re-evaluate TENORM waste disposal. This presentation will summarize conventional and unconventional oil and gas well operations, geology and respective uranium/ thorium content, radium content in oil and gas wastewater, treatment solids, radon in natural gas, the scope of other TENORM issues in the state, regulatory framework, national regulations and guidance, as well as, provide an overview of past and status of ongoing TENORM studies in the Commonwealth.

2:35 pm

Radiation Safety in Nanotechnology (Does Size Matter?) Mark D. Hoover National Institute for Occupational Safety and Health



NCRP has established Scientific Committee 2-6 to develop a report on the current state-of-knowledge and guidance for radiation safety programs involved with nanotechnology. Nanotechnology is the understanding and control of matter at the nanoscale, at dimensions between ~1 and 100 nm, where unique phenomena enable novel applications. In recent years manmade nanoparticles, including those that are radioactive, have been developed and incorporated into a wide variety of engineered nanomaterials. Applications are being found in a broad range of medical, industrial, educational and consumer products; their use is rapidly expanding. In some cases, radiation is being used to create or alter materials at the nanoscale. Nano-engineered structural materials, metals, coatings, coolants, ceramics, sorbents and sensors may be particularly enabling in radiation-related applications.

Areas of interest for the report include programs where radiation or radioactivity are being used to characterize or alter materials at the nanoscale, to radiolabel nanomaterials for tracking or evaluation of physicochemical and biological behavior, or to use nano-formulated materials in situations involving radiation or radioactivity. The focus is on operational information of practical value to radiation safety officers, operational health physicists, dosimetrists, workers, management, and regulators. Knowledge gaps regarding information needed to implement appropriate radiation safety programs in these settings will be identified.

Questions of interest include how traditional health physics program practices may need to be modified to provide adequate safety for working with radioactive nanomaterials or working with radiation in nanotechnology applications. To the

extent possible, the report will provide guidance on contamination control, engineered and administrative controls, personal protective equipment including respiratory protection, training, waste disposal, and emergency response. The report will also provide specific guidance on conducting internal dosimetry programs if radioactive nanomaterials are being handled. Possible differences in the biological uptake and in vivo dissolution or translocation of radioactive nanoparticles, compared to more commonly encountered micrometer-sized particles, may impact the design and conduct of dosimetry programs. In particular, how nanometer-sized particles are addressed in current respiratory tract and systemic dosimetry models will be evaluated. Model parameters and considerations including deposition efficiency, total and regional retention patterns, and cells and tissues at risk; dose calculation methods; and the potential for multifactorial biological effects from radiation, chemical, and physical particle properties of the nanoparticles are also being considered. It is intended that the report will also inform the broader nanotechnology knowledge infrastructure community.

3:00 pm

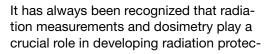
Q&A

Radiation Measurement and Dosimetry (PAC 6)

Wesley E. Bolch, Session Chair

3:20 pm

Framework and Need for Dosimetry and Measurements: Quantitation Matters Raymond A. Guilmette Lovelace Respiratory Research Institute



tion programs for workers and the public particularly as they relate to mitigating potential health risks from exposure to radiation. NCRP has always devoted significant resources to these scientific disciplines in terms of its published reports, and it is anticipated that this emphasis will continue. This includes focus on both external and internal radiation exposure as well as radiation and radioactivity measurement methodology. NCRP, as part of its management of scientific activities, has designated Program Area Committee (PAC) 6 to focus on both radiation measurements and dosimetry (membership comprises all authors).

This presentation will briefly describe how radiation measurements and dosimetry were addressed historically in terms of NCRP activities and reports, how the emphases have changed over the years, and how NCRP has worked effectively with other radiation protection organizations such as the International Commission on Radiological Protection to leverage its expertise in advancing the science of measurements and dosimetry, particularly the latter. For example, recent reports have focused on the state-of-theart in radiation dose assessment as well as elucidating methodologies for evaluating uncertainties in assessing radiation doses from exposure to both external and internal sources of radiation.

Currently the activities of PAC 6 in dosimetry have focused on working with other PACs, bringing its dosimetry and measurement expertise to address larger radiation protection issues, such as radiation protection issues relating to exposure to

Dose Reconstruction for the Million Worker

radioactive nanoparticles, contributing to the development of comprehensive dose assessment methods to deal with the wide range of exposures encompassed by various populations (*e.g.*, those being studied in the Million Worker Study) and performing a quality assurance function for dose assessments (*i.e.*, Operation Tomodachi) performed by other agents and agencies.

Moving forward, it is clear that the needs for expertise in radiation measurements and dosimetry will not diminish, but will continue to be associated with larger scope projects in which measurements and dosimetry play pivotal roles. Thus it is anticipated that collaborations with other PAC activities will continue. In addition, there are also initiatives in which PAC 6 is playing a lead role. These include:

- developing guidance on frameworks for licensing biophysical devices and/ or biological and pharmacological endpoints for biomarkers of radiation exposure and radiation-induced disease;
- elucidating data collection strategies and dose assessment methods for following up potentially exposed members of the public;
- revising the classic NCRP Report No. 58 on radioactivity measurements; and
- exploring emerging issues in measurement and dosimetry relating to medical radiation treatments and diagnostics.



The primary aim of the epidemiologic study of one million U.S. radiation workers and veterans (the Million Worker Study) is

to provide scientifically valid information

Epidemiological Study

National Cancer Institute

Andre Bouville

on the level of radiation risk when exposures are received gradually over time, and not acutely as was the case for Japanese atomic-bomb survivors. The primary

Abstracts: Monday, March 10

outcome of the epidemiological study is cancer mortality but other causes of death such as cardiovascular disease and cerebrovascular disease will be evaluated. The success of the study is tied to the validity of the dose reconstruction approaches to provide unbiased estimates of organ-specific radiation absorbed doses and their accompanying uncertainties. The dosimetry aspects for the Million Worker Study are challenging in that they address diverse exposure scenarios for diverse occupational groups being studied over a period of up to 70 y. The dosimetric issues differ among the varied exposed populations that are considered: atomic veterans, U.S. Department of Energy workers exposed to both penetrating radiation and intakes of radionuclides, nuclear power plant workers, medical radiation workers, and industrial radiographers. While a major source of radiation exposure to the study population comes from external gamma- or x-ray sources, for certain of the study groups there is a meaningful component of radionuclide intakes that require internal radiation dosimetry measures.

Scientific Committee 6-9 has been established by NCRP to produce a report on the comprehensive organ dose assessment (including uncertainty analysis) for the Million Worker Study. The Committee's report will cover the specifics of practical dose reconstruction for the ongoing epidemiologic studies with uncertainty analysis discussions and will be a specific application of the guidance provided in NCRP Reports Nos. 158, 163, 164, and 171. The main role of the Committee is to provide guidelines to the various groups of dosimetrists involved in the various components of the Million Worker Study to make sure that certain dosimetry criteria are respected: calculation of annual absorbed doses in the organs of interest, separation of low- and high linear-energy transfer (LET) components, evaluation of uncertainties, and quality assurance and quality control. It is recognized that the Million Worker Study and its approaches to dosimetry are a work in progress and that there will be flexibility and changes in direction as new information is obtained, both with regard to dosimetry and with regard to the epidemiologic features of the study components.

This presentation focuses on the description of the various components of the Million Worker Study, on the available dosimetry results, and on the difficulties that have been encountered. It is expected that the Committee will provide its report in 2016.

4:10 pm

4:25 pm Break

Q&A

NCRP: Achievements of the Past 50 Years and Addressing the Needs of the Future

Thirty-Eighth Lauriston S. Taylor Lecture on Radiation Protection and Measurements

5:00 pm Introduction of the Lecturer

Milton J. Guiberteau

On the Shoulders of Giants: Radiation Protection Over 50 Years Fred A. Mettler, Jr.

New Mexico Federal Regional Medical Center

There have been remarkable advances in the knowledge of radiation effects and the philosophy of radiation protection over the last half century. No one single person was responsible for this. Most advances have been due to a number of remarkable scientists and physicians (giants) who laid the groundwork, did research, and who mentored and trained us. I have had the good fortune to interact with many of these giants and get to know them on a personal basis. Over the past 50 y we have seen radiobiology progress from single-hit theory to epigenetic effects,



watched remarkable growth in medical radiation applications, gone from concern about genetic effects to elucidation of specific tumor risks, seen continued spectacular accidents from various causes, gone from Cold War fallout concerns to issues regarding terrorism and expansion of nuclear weapon countries, seen nuclear power expand then wane and grappled with the legacy issues of nuclear waste. Success in the future will depend upon our current group of "giants" and their ability to identify and train the next generation.

6:00 pm

Reception in Honor of the Lecturer Sponsored by Landauer, Inc.



Tuesday, March 11

8:15 am NCRP Annual Business Meeting

9:15 am Break

Radiation Protection in Medicine (PAC 4)

Donald L. Miller, Session Chair

9:45 am

Protection of Patients in Diagnostic and Interventional Medical Imaging Kimberly E. Applegate Emory University School of Medicine



The radiology community (radiologists, medical physicists, radiologic technologists, and interventional proceduralists) has led the educational and awareness efforts to reduce radiation dose to our patients through effective collaborations that bridge traditional specialty silos and reach all stakeholders. These successful collaborations have included both vendors and regulators, with the overarching goal of dose reduction. Dose reduction to patients often raises overall safety awareness and lowers occupational doses as well. It is critical that the entire radiology community continue to act as leaders in these efforts in radiation safety for both employees and patients. In order to be successful, we must understand the current state-of-the-science and the growing, worldwide, multimedia resources that are available to us. There is little time or budget for us to recreate training materials or risk communication information that may already exist.

In order to create a strong environment of radiation protection for patients (and for employees), there must also be a strong health system culture of safety. We will discuss multiple elements and training that create a safety culture. Note that safety is necessary but not sufficient to ensure quality healthcare. Radiology departments and healthcare systems focus on safety culture and metrics often based on external requirements or demands such as from the Joint Commission, regulatory agencies, consumer groups, and payers. Increasingly, radiation metrics are included in determining the quality of an imaging department and overall health system.

Together with the increasingly fast-paced and demanding healthcare environment and sharp focus on quality, it has never been more important to understand how to achieve better quality care for radiology departments. That must begin with radiation protection of our patients. We must measure quality for many customers that include patients, referring providers, and many others. How do we show that we are providing, monitoring, and improving quality service in radiology? This presentation will briefly describe the rationale and methods for using collective learning tools that document radiation protection of patients in diagnostic and interventional imaging. These tools include the use of imaging modality registries such as the **Computed Tomography Dose Index** Registry, peer review of imaging reports, the use of clinical decision support, and guidelines.

NCRP: Achievements of the Past 50 Years and Addressing the Needs of the Future

Goals and objectives:

- provide the current state-of-the-science regarding cancer risk from medical procedures using ionizing radiation;
- understand the three basic radiation protection principles for patients and for radiation workers;
- recognize key methods to build a safety culture in radiology;
- understand both qualitative and quantitative metrics in a radiology safety program;
- provide examples of quality assurance and improvement projects based on a safety event and that promote a culture of safety; and
- understand the radiation dose reduction goals and educational materials for all stakeholders involved in imaging children (Image Gently[®]), in imaging adults (Image Wisely[®]) and in efforts to more appropriately use testing (Clinical Decision Support and the Choosing Wisely[®] Campaign).

10:10 am

Protection and Measurement in Radiation Therapy Steven G. Sutlief

University of Washington Medical Center



From its inception, NCRP has contributed much to the field of radiation therapy. Guidance from NCRP encompasses radiation protection of workers, prenatal exposure, risk of damage to normal tissues, reference dosimetry, neutron contamination in therapeutic beams, and facility shielding. Radiation protection of the patient, staff, and members of the public must be reassessed with the introduction of each new technology into radiation therapy, which in turn underscores the need to improve our basic scientific understanding.

Radiation protection concerns include secondary cancers due to radiation to uninvolved tissues, damage to the fetus, damage to implantable electronic devices (e.g., pacemakers and implantable cardioverter defibrillator), and protection of staff and members of the public near radiation therapy equipment.

These concerns must be addressed in ways appropriate to the technology in use. Technological developments in radiation therapy include brachytherapy using either superficial application or temporary or permanent implantation, therapy with radioactive drugs, conventional and conformal external beams (photons or electrons), higher energy beams (≥10 MV) where neutrons contribute, intensity modulated radiation therapy and volumetric arc therapy, small field delivery (*via* stereotactic radiosurgery or stereotactic body radiation therapy), total body irradiation and total skin electron therapy, specialized equipment (such as Tomotherapy[®], CyberKnife[®], and ⁶⁰Co with onboard magnetic resonance imaging), and particle therapies using protons or heavier ions.

This in turn leads to consideration of the science underlying radiation protection and measurement. Scientific concerns include dose risk, both in terms of prompt effects (normal tissue morbidities such as moist desquamation and impaired salivary function) and delayed effects such as secondary cancers and cardiovascular disease. A second underlying scientific concern is dose calculation, which includes absolute dosimetry, extra-focal and leakage radiation, and neutron contamination in beam therapy. A third concern involves dose measurement, both in the case of brachytherapy sources and external beam. A final concern is the engineering of safety and shielding, which

includes equipment design, personal shielding, and facility shielding.

Historical milestones include the formation of several radiation protection organizations in the late 1920s, including the predecessor of NCRP. Through the efforts of these organizations and other professional societies, guidance has been offered to the user community and members of the public on the issues listed above. During the ensuing years, refinements were made both to the quantities used in radiation protection and to the dose limits for workers and members of the public. Most of the primary concerns were identified early in the history of radiation protection and now undergo periodic revision.

Current trends in radiation protection are driven by the rapid commercial development of new radiation therapy technologies, improved science of normal tissue susceptibilities to radiation, and the evolving technology of implantable devices. Foremost among current technological advancements are the use of image guidance and wider availability of proton therapy. Other recent developments include intra-arterial delivery of radioactive microspheres for treating liver lesions, radiolabeled monoclonal antibodies for treating certain lymphomas, and the very recent introduction of therapeutic radiopharmaceuticals incorporating alphaemitting radionuclides.

Future developments will likely include increased use of imaging for assessment and treatment positioning and wider clinical use of molecularly-based disease assessment and treatment strategies. While the conformity of radiation dose continues to undergo incremental refinements, greater gains may be made by assessing patient-specific radiation biology for the purpose of patient selection, so that radiation is given only to those patients likely to benefit from it, as well as broader use of monoclonal antibodies or coupling of radiotherapy with immunotherapy.

This presentation will review historical trends in radiation protection and measurement, describe the current status, and suggest future directions likely to be most fruitful.

Protection of the Developing Embryo and Fetus from Ionizing Radiation Exposure Robert L. Brent Alfred I. duPont Institute Hospital for Children



Scientific knowledge has increased and public concerns have changed in the 37 y since NCRP Report No. 54, *Medical Radiation Exposure of Pregnant and Potentially Pregnant Women* (1977) was published. The scope of Report No. 174, *Preconception and Prenatal Radiation Exposure: Health Effects and Protective Guidance* (2013) covers both ionizing radiation and nonionizing sources. The ionizing radiation sources discussed consist predominantly of low linear-energy transfer radiation.

• Gamete radiation: There is no convincing direct evidence of germline mutation manifest as heritable disease in the offspring of humans and attributable to ionizing radiation, yet radiation clearly induces mutations in microbes and somatic cells of rodents and humans, and transgenerational effects in irradiated drosophila and mice are established. It would be imprudent to ignore the possibility of human germcell mutation, especially since progress in human genetics and genomics promises quantum improvements in being able to address the issue in the future.

• Pregnancy risks from ionizing radiation: The background rate for major

10:35 am

congenital malformations is ~3 % (i.e., in the absence of radiation exposure about 3 of every 100 children born have a recognizable major birth defect). Pregnancy loss (spontaneous abortion, miscarriage) in women who know they are pregnant occurs in 15 % of pregnancies with a wide standard deviation. Doses to the embryo estimated to be in the range of 0.15 to 0.2 Gy during the preimplantation and presomite stages may increase the risk of embryonic loss. However, an increased risk of congenital malformations or growth retardation has not been observed in the surviving embryos. These results are primarily derived from mammalian animal studies and are referred to as the "all or none phenomenon." The potential tissue reactions of ionizing radiation (previously referred to as deterministic effects) are congenital malformations, mental retardation, decreased intelligence quotient, microcephaly, neurobehavioral effects, convulsive disorders, growth retardation (height and weight), and embryonic and fetal death (miscarriage, stillbirth). All these effects are consistent with having a threshold dose below which there is no increased risk. Based on animal studies, the no-adverse-effect level (dose to the embryo or fetus) in humans is estimated at 0.2 Gy for anatomical congenital malformations during a very short period during early organogenesis, and is higher for most other tissue reactions. Doses to the embryo or fetus due to radiation exposure to the maternal chest, extremities, neck and head from diagnostic x-ray procedures do not exceed 0.1 Gy and are thus less than the noadverse-effect level for any of the previously mentioned tissue reactions.

- Radiation carcinogenesis: The risk of cancer in offspring that have been exposed to diagnostic x-ray procedures while in utero has been debated for 55 y. High doses to the embryo or fetus (e.g., >0.5 Gy) increase the risk of cancer. Most pregnant women exposed to x-ray procedures and other forms of ionizing radiation today received doses to the embryo or fetus <0.1 Gy. The risk of cancer in offspring exposed in utero at a low dose such as <0.1 Gy is controversial and has not been fully resolved. Nevertheless, diagnostic imaging procedures utilizing ionizing radiation that are clinically indicated for the pregnant patient should be performed because the clinical benefits outweigh the potential oncogenic risks.
- Mitigation of ionizing radiation risk for pregnant or potentially-pregnant women: Prior to any medical ionizing radiation exposure, it is important to assess if the woman is pregnant, or if there is the possibility that she may be pregnant. The conventional methods of pregnancy assessment range from verbal communication to a highly-sensitive biochemical assay of human chorionic gonadotropin produced by the developing placenta. Nevertheless, women should be considered potentially pregnant if she thinks she may be pregnant.
- Communicating benefits and risks: Women exposed to radiation during pregnancy and members of their families often seek counseling about the associated radiation exposure and present with various levels of anxiety. In such circumstances it is important that the counselor be well versed in the potential adverse consequences associated with the various levels of radiation exposure.

11:00 am

Radiation Education, Risk Communication, Outreach, and Policy (PAC 7)

Julie E.K. Timins, Session Chair

Historical Trends in Radiation Protection, Policy and Communications: 1964 to the Present

Paul A. Locke The Johns Hopkins University Bloomberg School of Public Health

The past 50 y have seen substantial developments in radiation epidemiology, technology, dosimetry, regulations and protection efforts. During the last five decades, radiation communication has also evolved, growing more sophisticated as communication science and practice have advanced and matured. This talk will cover the trends in radiation protection over the past 50 y, illustrated by progress in science and practice of risk communication and changes in societal expectations, and examine challenges that confront radiation risk communication in the future.

Early radiation communication efforts largely adopted a paternalistic approach, featuring experts whose purpose was to educate members of the public about the risks and benefits of radiation. Based on studies in communication and research, this model has been largely replaced by a more collaborative process, structured around discussions among radiation



experts, stakeholder groups, and community representatives. Concurrently, communications technology since the mid-20th century has been transformed by, among other things, the explosion in cellular devices and the rise of social media. These have been both a boom and challenge for radiation risk communication efforts.

This talk will examine the ways in which risk communication has transformed since NCRP was chartered by the U.S. Congress. From the mid-20th century focus on mitigating potential nuclear attacks and civil defense to the early 21st century focus on preparedness, medical radiation, and response to the accident at Fukushima, the type, nature and technology of communications has changed greatly. NCRP and its members should be prepared for addressing both emerging issues of radiation protection and new, innovative ways of communicating about radiation benefits, risks and policies.

11:45 am

11:20 am

U.S. Radiation Protection: Role of National and International Advisory Organizations and Opportunities for Collaboration (Harmony not Dissonance) Michael A. Bovd



The early history of radiation protection recommendations in the United States is intertwined with similar efforts in Europe. At the second International Congress of Radiology in Stockholm in 1928, Rolf Sievert was chosen to chair the new

U.S. Environmental Protection Agency

International X-Ray and Radium Protection Committee, which later became the International Commission on Radiological Protection (ICRP). One of the seven members elected to that first committee was 26 y old Lauriston Taylor. The following year, Dr. Taylor became the first chair of the U.S. Advisory Committee on X-Ray and Radium Protection, which would eventually become the National Council on Radiation Protection and Measurements (NCRP), the organization he led until 1977.

Our knowledge of radiation-related health risk has evolved and improved over time. As indicated by the names of the early organizations, the first recognized threats from radiation exposure came from radium and x rays. Early radiation protection advice concentrated on preventing observed deterministic effects (e.g., skin erythema). In the 1950s, concern had shifted to preventing genetic effects, which were thought to be possible at doses lower than the levels associated with observable tissue damage. Major epidemiological studies, such as the Life Span Study (LSS) of Japanese atomicbomb survivors, failed to show evidence of genetic effects, but did show excess cancers in people exposed to a few hundred millisieverts. More recent follow-up of the LSS cohort and other large epidemiological studies have shown positive dose response correlations around, and in some cases below, 100 mSv, so that cancer risk is now the limiting factor in setting radiation protection regulations. Both the U.S. National Academy of Sciences (NAS) and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) recommend using a linear nothreshold model for estimating excess cancers at low doses. More recently, scientists have begun to explore noncancer endpoints, such as circulatory disease, and to suggest that these effects too might result from exposures to moderate doses of radiation. Science continues to be a driving force in the evolution of the system of radiation protection.

The considerable degree to which the system of radiation protection is practiced consistently around the world is largely attributable to the longstanding coordination and collaboration between NCRP and ICRP. There is a familiar organizational flowchart which characterizes, somewhat ideally, how radiation protection science forms the basis of recommendations, and how the recommendations eventually become regulations or guidance. In this scheme, the state-of-the-science is collected and reviewed by organizations of recognized experts, most notably UNSCEAR and, in the United States, NAS. UNSCEAR publications and the NAS Biological Effects of Ionizing Radiation (BEIR) reports are definitive sources of current information on radiation exposures of the public and their associated health risks. These publications alert ICRP and NCRP when there is a need to modify their radiation protection recommendations. New recommendations, in turn, are incorporated by the International Atomic Energy Agency (IAEA) through revisions to the IAEA Basic Safety Standards (BSS). National authorities that receive funding from the IAEA are required to adopt the BSS in their national regulations. Although the United States does not fall in this category, our regulations and guidance remain broadly consistent with the BSS.

There are many exceptions to this flowchart and many nations tailor the flow path to their unique needs. In the United States, the path from new science and recommendations to new regulations must follow the process laid out in the Administrative Procedure Act, which provides the public an opportunity to review and comment on proposed regulations before they are adopted. Federal agencies must be given statutory authority to issue regulations, and their regulations will reflect the requirements of the particular statute they are using. For that reason, there is a certain degree of dissonance across the many U.S. federal and state radiation protection regulations. Both the U.S. Environmental Protection Agency and the U.S. Nuclear Regulatory Commis-

Abstracts: Tuesday, March 11

sion have announced plans to revise key ICRP and NCRP into U.S. regulations. A radiation protection regulations in the result of achieving this desirable goal coming years. These rulemakings may would be more harmony in the practice of provide an opportunity for incorporating radiation protection, both nationally and many of the latest recommendations of internationally. Q&A 12:10 pm **Summary: NCRP for the Future** John D. Boice, Jr., Session Chair 12:25 pm **Capturing Opportunities and Meeting Challenges in Radiation Protection** Kenneth R. Kase Honorary Vice President, NCRP This summary of the 2014 Annual Meeting technologies, preparing for the improbable but possible event, industry and medicine; captures the opportunities presented during the Warren K. Sinclair Keynote and in education, communication and policy. The challenges include identifying the Address and the six scientific sessions most important aspects of radiation proincluding the subsequent questions and tection and measurement, prioritizing answers. It captures the important issues them in accordance with the NCRP misthat emerge in these opportunities and sion and gaining support for the activities discusses the challenges that they bring of the NCRP to address these issues in to radiation protection. These opportunithe fulfillment of its charter. ties arise in the basic sciences; in operational areas such as emerging 12:50 pm **Closing Remarks** John D. Boice, Jr. President, NCRP

1:00 pm

Adjourn

25

Program Committee

Kenneth R. Kase, Chair Honorary Vice President, National Council on Radiation Protection & Measurements

John D. Boice, Jr., Co-Chair President, National Council on Radiation Protection & Measurements

Jerrold T. Bushberg, Co-Chair University of California, Davis Senior Vice President & Chairman of the Board, National Council on Radiation Protection & Measurements

James A. Brink Massachusetts General Hospital

S.Y. Chen Illinois Institute of Technology

Raymond A. Guilmette Lovelace Respiratory Research Institute

Kathryn D. Held Massachusetts General Hospital **Donald L. Miller** U.S. Food & Drug Administration

John W. Poston, Sr. Texas A&M University

Kathryn H. Pryor Pacific Northwest National Laboratory

Richard E. Toohey *M.H. Chew & Associates*

Paul A. Locke Johns Hopkins University

Registration

Monday, March 10, 2014	7:00 am – 5:00 pm
Tuesday, March 11, 2014	7:00 am – 11:00 am

Register online: http://registration.ncrponline.org/

2015 Annual Meeting

Changing Regulations and Radiation Guidance: What Does the Future Hold? Donald A. Cool, Chair Ruth E. McBurney & Kathy H. Pryor, Co-Chairs

> March 16–17, 2015 Bethesda, Maryland



David J. Allard is the Director of Pennsylvania's Department of Environment Protection (DEP) Bureau of Radiation Protection; responsible for the accelerator, x ray, environmental surveillance, nuclear safety, radiological emergency response, radioactive materials, decommissioning/site cleanup, low-level waste and radon programs within the Commonwealth. He is the Governor's official liaison to the U.S. Nuclear Regulatory Commission, and a Commissioner for the Appalachian States Low-Level Radioactive Waste Compact Commission.

Mr. Allard received a BS in Environmental Sciences from the State University of New York - Albany and an MS in Radiological Sciences and Protection from the University of Massachusetts - Lowell. He is certified by the American Board of Health Physics, a Fellow of the Health Physics Society, and the Conference of Radiation Control Program Directors' official liaison to NCRP.

Prior to joining DEP in February 1999, he was a consultant to the U.S. Department of Energy on environmental and occupational radiation protection for 8 y. Mr. Allard has been involved in the various aspects of governmental, industrial, reactor, medical and academic radiation protection for 36 y. He serves as a member or advisor on several national radiation protection committees, has authored numerous professional papers and reports, and lectures frequently on a wide variety of radiation protection topics and concerns.



Kimberly E. Applegate is a professor of radiology and pediatrics and director of practice quality improvement in radiology at Emory University in Atlanta. At Emory University, she chairs the Radiation Control Council which reviews policy, clinical and research activities involving the use of ionizing radiation. Kimberly is dedicated to service in organized radiology-she is the President of the Association for University Radiologists (AUR) Research and Education Foundation, Past President of AUR, and served on multiple medical boards and editorial boards. Dr. Applegate has published over 140 peer-reviewed papers and book chapters, and presented scientific papers and lectures at medical and scientific assemblies around the world. In 2007, Dr. Applegate was elected to both the NCRP and the Steering Committee of the American College of Radiology (ACR), and began work on the initial Steering Committee for the Image Gently® Campaign to reduce radiation exposure in children. The Campaign has received a number of awards and collaborates internationally to change imaging practice. She is the national and international outreach chair for this campaign. In 2010, she co-edited the book, Evidence-Based Imaging in Pediatrics, to promote appropriate use of medical imaging in infants and children. Most recently, she co-authored the ICRP Publication 121, Radiological Protection of Paediatric Diagnostic and Interventional Radiology. She has long had an interest in the development of imaging guidelines, chairing this process for ACR, and collaborating with the World Health Organization and the International Atomic Energy Agency on international guideline development. Dr. Applegate is the ACR Vice Speaker and member of its Executive Committee.



Carol D. Berger is Certified by the American Board of Health Physics, a Fellow member of the Health Physics Society, and has over 35 y experience in nuclear activities with emphasis in strategic planning, radiation dosimetry, instrumentation, and applied health physics. She is Past-President of the American Academy of Health Physics (AAHP), a past member of the Panel of Examiners for the American Board of Health Physics, Past President and Past Secretary of the East Tennessee Chapter of the Health Physics Society, and Past Director and Treasurer of the Baltimore-Washington Chapter of the Health Physics Society. She is a recognized expert in the fields of external and internal dosimetry, having participated on several American National Standards Institute, American Society for Testing and Materials, and NCRP committees for establishing dosimetry and radiation safety standards. Prior to her current position as President of Integrated Environmental Management, Inc., an Small Business Administration-registered womanowned business with offices in Maryland and Ohio, she served as a senior technical consultant for

IT Corporation, head of the Radiation Dosimetry Group at Oak Ridge National Laboratory, adjunct teaching staff at Oak Ridge Associated Universities, and was a member of the Health Physics and Dosimetry Task Group for the President's Commission on the Accident at Three Mile Island. Dr. Berger is the third recipient of the Joyce B. Davis Memorial Award for professional achievement and ethical behavior in the practice of health physics, given by AAHP.



John D. Boice, Jr. is the President of NCRP, Bethesda, Maryland, and Professor of Medicine at Vanderbilt University School of Medicine, Nashville, Tennessee. He is an international authority on radiation effects and currently serves on the Main Commission of the International Commission on Radiological Protection and as a U.S. advisor to the United Nations Scientific Committee on the Effects of Atomic Radiation. During 27 y of service in the U.S. Public Health Service, Dr. Boice developed and became the first chief of the Radiation Epidemiology Branch at the National Cancer Institute. Dr. Boice has established programs of research in all major areas of radiation epidemiology, with major projects dealing with populations exposed to medical, occupational, military and environmental radiation. These research efforts have aimed at clarifying cancer and other health risks associated with exposure to ionizing radiation, especially at low-dose levels. Boice's seminal discoveries and over 460 publications have been used to formulate public health measures to reduce population exposure to radiation and prevent radiation-associated diseases. He has delivered the Lauriston S. Taylor Lecture at the NCRP and the Fessinger-Springer Lecture at the University of Texas at El Paso. In 2008, Dr. Boice received the Harvard School of Public Health Alumni Award of Merit. He has also received the E.O. Lawrence Award from the Department of Energy - an honor bestowed on Richard Feynman and Murray Gell-Mann among others - and the Gorgas Medal from the Association of Military Surgeons of the United States. In 1999 he received the outstanding alumnus award from the University of Texas at El Paso (formerly Texas Western College). Dr. Boice recently launched the Million U.S. Radiation Workers and Veterans Study to examine the lifetime risk of cancer following relatively low-dose exposures received gradually over time.



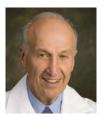
Wesley E. Bolch is Professor of Biomedical Engineering and Medical Physics in the J. Crayton Pruitt Family Department of Biomedical Engineering at the University of Florida (UF). He serves as Director of the Advanced Laboratory for Radiation Dosimetry Studies at UF. Dr. Bolch earned his BSE degree in environmental engineering in 1984, his ME and PhD degrees in radiological physics in 1986 and 1998, respectively, from the University of Florida. He has been certified by the American Board of Health Physics since 1994 and licensed in Radiological Health Engineering by the Texas Board of Professional Engineers since 1992. In 2011, Dr. Bolch was elected Fellow of both the Health Physics Society and the American Association of Physicists in Medicine. He has been a member of the Society of Nuclear Medicine's Medical Internal Radiation Dose (MIRD) Committee since 1993, a member of NCRP since 2005, and a member of Committee 2 of the International Commission on Radiological Protection (ICRP) since 2005. Within the latter, he serves as C2 Secretary and Leader of the ICRP Task Group on Dose Calculations. He has published over 160 peer-reviewed journal articles, coauthored/edited 14 books/book chapters, and served as coauthor on two NCRP reports, two ICRP publications, and two MIRD monographs. Dr. Bolch has managed a broad research program including (1) National Cancer Institute and U.S. Department of Energy funded projects to construct high-resolution models of the skeleton to support dose-response studies in radionuclide therapy and radiation epidemiology, (2) National Institute of Biomedical Imaging and Bioengineering funded projects to develop scalable nonuniform rational B-spline-based and voxel-based computational phantoms of adult and pediatric patients and associated software for organ dose assessment in nuclear medicine, computed tomography, interventional fluoroscopy, and radiotherapy, (3) private company funded projects to develop stereotactic kilovoltage x-ray treatments for age-related macular degeneration and glaucoma, and (4) Centers for Disease Control and Prevention funded projects in stochastic modeling of worker inhalation and gamma-ray exposures following radiological accidents and potential terrorist events.



Andre Bouville was born and educated in France. He came to the United States in 1984 to work for the National Cancer Institute (NCI). His initial assignment was to estimate the thyroid doses received by the American people from ¹³¹I released by the nuclear weapons tests that were conducted at the Nevada Test Site in the 1950s. This study led to the assessment of doses from nuclear weapons tests conducted at other sites all over the world, as well as to a large number of dosimetry studies related to the Chernobyl nuclear reactor accident. He was the head of the Dosimetry Unit of the Radiation Epidemiology Branch at NCI until he retired at the end of 2010. Throughout his career, Dr. Bouville actively participated in the preparation of scientific reports under the umbrella of international organizations, notably the United Nations Scientific Committee on the Effects of Atomic Radiation, the International Commission on Radiological Protection, the International Commission on Radiation Units and Measurements, the World Health Organization, the International Atomic Energy Agency, and the Nuclear Energy Agency. Regarding U.S. organizations, Dr. Bouville was a member of NCRP for 12 y, became a Distinguished Emeritus Member in 2011, and is currently Chair of Scientific Committee 6-9 on the dosimetry for the Million Worker Study. He has served on numerous National Academy of Science committees, is a Lifetime Associate of the National Academies, and is currently a member of the Committee on the analysis of cancer risks in populations near nuclear facilities. For all his achievements, Dr. Bouville was a recipient of the Presidential Rank Meritorial Award in 2003.



Michael A. Boyd is a senior health physicist in the U.S. Environmental Protection Agency (EPA) Office of Radiation and Indoor Air/Radiation Protection Division (RPD) and has been with EPA since 1988. As a member of RPD's Center for Science and Technology, Mr. Boyd manages the development of new federal guidance documents. He is also the co-chair of the Federal Guidance Subcommittee of the Interagency Steering Committee on Radiation Standards (ISCORS). Mr. Boyd is a recently elected member of the International Commission on Radiological Protection Committee 4. He chairs the Health Physics Society's International Collaboration Committee and is on the Bureau of the Organisation for Economic Co-operation and Development/Nuclear Energy Agency's Committee on Radiation Protection and Public Health. He has a BS in Biology and MS in Public Health from the University of North Carolina at Chapel Hill.



Robert L. Brent is the Distinguished Professor, Louis and Bess Stein Professor of Pediatrics, Radiology and Pathology at the Jefferson Medical College, Director of the Clinical and Environmental Teratology Laboratories at the Alfred I. duPont Hospital for Children in Wilmington, Delaware. Robert Brent was born in Rochester, New York in 1927, received his AB (1949); MD with honor (1953), a PhD (1955) in radiation biology and embryology and Honorary DSc degrees from the University of Rochester and the Jefferson Medical College. From 1944 to 1954 he worked in the cosmic ray research laboratories of the physics department and as a research associate in the genetics and embryology divisions of the Manhattan Project of the University of Rochester, where he began his studies on the teratogenic effects of ionizing radiation. As a graduate student he was appointed the Head of the embryology section of the medical school's atomic energy facility. He was the first research (1953) and clinical fellow (1954) of the March of Dimes involved in congenital malformations research. He spent his army tour at the Walter Reed Army Institute of Research as Chief of Radiation Biology (1955 to 1957).

He came to Jefferson in 1957 and has received every award that Jefferson can offer a faculty member, and for having received continuous federal research funding as a principal investigator for his entire research career. In 1989, he was named the third Distinguished Professor in Jefferson's 188 year history.

He was elected to NCRP in 1973. In 2006 he delivered the L.S. Taylor Lecture, having already received the highest honor of the Teratology Society and the Health Physics Society. He was elected to the Institute of Medicine of the National Academy of Sciences in 1996. He was the editor of "Teratology" for 17 y, and

has been invited to China five times and to Japan seven times as a Visiting Lecturer and has had invited lectureships in 27 countries. In 1994 he was selected by the Chinese government as the President of the first International Congress on Birth Defects in China. Dr. Brent will receive the John Scott Award of the American Philosophical Society on November 22, 2013 for his research pertaining to the environmental causes of birth defects but especially for his early research that indicated that the embryo was less vulnerable to the carcinogenic effect of ionizing radiation than the child or adult.

Dr. Brent's greatest recognition has come from his research, publications and lecturing. He is the most frequently consulted authority on the effects of radiation on the embryo and is frequently consulted about other possible teratogenic exposures. His research on the effects of radiation on the embryo demonstrated the no-effect dose for congenital malformations, established that radiation effects on the embryo were due to the direct effects of the radiation, and demonstrated some of the characteristics of the "all-or-none period" of embryonic development.

His writings in the field of litigation concerning the proper role of an expert witness were important. As one of the defense experts in the Bendectin litigation, his testimony contributed to the famous Daubert decision that allowed judges to reject the testimony of junk scientists. His publications include six books and monographs, five movies, 458 publications, and over 400 abstracts.



James A. Brink is Radiologist-in-Chief at Massachusetts General Hospital (MGH). He earned a BS degree in Electrical Engineering at Purdue University and an MD at Indiana University before completing his residency and fellowship at Massachusetts General Hospital. He joined the faculty at the Mallinckrodt Institute of Radiology at Washington University School of Medicine where he rose to the rank of Associate Professor prior to joining the faculty at Yale University in 1997. Promoted to Professor in 2001, Dr. Brink was appointed Interim Chair in 2003 and Chair of the Yale Department of Diagnostic Radiology in 2006. On February 1, 2013, Dr. Brink left Yale to serve as Radiologist-in-Chief at MGH. While he has broad experience in medical imaging, including utilization and management of imaging resources, he has particular interest and expertise in issues related to the monitoring and control of medical radiation exposure. Dr. Brink is a fellow of the Society for Computed Body Tomography/Magnetic Resonance and a fellow of the American College of Radiology (ACR). For ACR, he serves on the Executive Committee and Board of Chancellors as Chair of the Body Imaging Commission, Chair of the Imaging Communication Network, and Co-Chair of the Global Summit on Radiology Quality and Safety. For the American Roentgen Ray Society, Dr. Brink is a member of the Executive Council and immediate Past President. For NCRP, Dr. Brink is the Scientific Vice President for Radiation Protection in Medicine, and chaired the NCRP scientific committee that defined diagnostic reference levels for medical imaging in the United States (NCRP Report No. 172, 2012). For the International Society of Radiology, Dr. Brink serves as Chair of the International Commission for Radiology Education, and for the Radiological Society of North America, he serves as Co-Chair of the Image Wisely® initiative, a social marketing campaign to increase awareness about adult radiation protection in medicine.



Jerrold T. Bushberg is the is the Senior Vice President of NCRP, and Clinical Professor of Radiology and Radiation Oncology, University of California (UC) Davis School of Medicine. He is an expert on the biological effects, safety, and interactions of ionizing and nonionizing radiation and holds multiple radiation detection technology patents. Dr. Bushberg is a fellow of the American Association of Physicist in Medicine and is certified by several national professional boards with specific subspecialty certification in radiation protection and medical physics. Prior to coming to the UC Davis Health System as technical director of nuclear medicine, Dr. Bushberg was on the faculty of Yale University School of Medicine where his research was focused on radiopharmaceutical development. Dr. Bushberg has served as an advisor to government

agencies and institutions throughout the nation and around the world on the biological effects and safety of ionizing and nonionizing radiation exposure. He has worked for the U.S. Department of Homeland Security, the World Health Organization, and the International Atomic Energy Agency as a subject matter expert in radiation protection and radiological emergency medical management. Dr. Bushberg has responsibility for medical postgraduate education in medical physics, radiation (ionizing and nonionizing) protection, and radiation biology. The third edition of the textbook, *The Essential Physics of Medical Imaging*, authored by Bushberg, Seibert, Leidholdt, and Boone, is used extensively by radiology residency programs throughout the United States.



S.Y. Chen is currently Director of Professional Master of Health Physic Program at the Illinois Institute of Technology (IIT), Chicago. Prior to joining IIT, he was Senior Environmental Systems Engineer and also served as the Strategic Area Manager in Risk and Waste Management in the Environmental Science Division at Argonne National Laboratory, Argonne, Illinois. He received his BS in nuclear engineering from National Tsing Hua University in Taiwan and obtained his MS and PhD in nuclear engineering from the University of Illinois at Champaign-Urbana. Dr. Chen's professional interests include radiation protection, human and environmental health risk, and nuclear accident analysis; with special expertise in environmental cleanup, radioactive material disposition management, and nuclear waste transportation. Dr. Chen has been a NCRP Council member since 1999, and served on its Board (2004 to 2011). He currently serves as NCRP Scientific Vice President on Environmental Radiation and Waste Issues (since 2004). Dr. Chen has served on the U.S. Environmental Protection Agency's Science Advisory Board/Radiation Advisory Committee since 2009. He is a long-time member of the Health Physics Society and of the American Nuclear Society. He was elected to Fellow by the Health Physics Society in 2013, and is a Certified Health Physicist by the American Board of Health Physics. While at Argonne, Dr. Chen developed an integrated risk assessment program that addresses the broad-based issues to support federal risk-based policies. Dr. Chen had served on numerous capacities at NCRP, including chairing Scientific Committee (SC) 87-4 which led to the publication of Report No. 141, Managing Potentially Radioactive Scarp Metal, and also chairing SC 5-1, Decision Making for Late-Late Phase Recovery from Nuclear or Radiological Incidents. He served as Chair of NCRP 2005 Annual Meeting Program Committee, Managing the Disposition of Low-Activity Radioactive Materials, and as Co-Chair of NCRP 2013 Annual Meeting Program Committee, Radiation Dose and the Impacts on Exposed Populations.



C. Norman Coleman received his BA in mathematics, *summa cum laude*, from the University of Vermont in 1966 and his MD from Yale University in 1970. He is board certified in three specialties - internal medicine from the University of California San Francisco, medical oncology from the National Cancer Institute (NCI), and radiation oncology from Stanford University. He served in the U.S. Public Health Service at the National Institutes of Health [O-4 (retired)]. He was Assistant and tenured Associate Professor of Radiation and Medical Oncology at Stanford and from 1985-1999 and he was Professor and Chairman of the Harvard Medical School Joint Center for Radiation Therapy. Since 1999, he has been Associate Director, Radiation Research Program and Senior Investigator, with a molecular radiation therapeutics laboratory in the Radiation Oncology Branch of NCI. Since 2004 he has also been a Senior Medical Advisor in the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services. His focus is on radiological and nuclear preparedness and planning but the programs apply to all hazards. This includes the Scarce Resources for a Nuclear Detonation project and participation at the U.S. Embassy in Tokyo during the Japan disaster in March 2011. Among his honors are the Gold Medal from the American Society for Radiation Oncology and the 2011 Samuel J. Heyman, Service to America Homeland Security Medal.



Francis A. Cucinotta is a Professor of Health Physics at the University of Nevada, Las Vegas. Dr. Cucinotta received his PhD in nuclear physics from Old Dominion University. He worked at the National Aeronautics and Space Administration (NASA) Johnson Space Center from 1997 to 2013 as the Radiological Health Officer, Space Radiation Project Manager and Chief Scientist. Dr. Cucinotta developed the astronaut exposure data base of organ doses and cancer risk estimates for all human missions from Mercury to the International Space Station (ISS), and developed risk models for acute, cancer and circulatory diseases. He was NASA's manager for the construction of the NASA Space Radiation Laboratory (NSRL), and NSRL Operations from 2003 to 2012. Dr. Cucinotta worked on radiation safety in NASA's mission control for the Space Shuttle and ISS programs in 1989 and 1990, including during the October of 1989 solar event, and from 2000 to 2006. Dr. Cucinotta has published over 300 journal articles, numerous book chapters, and over 100 NASA technical reports on nuclear and space physics, radiation shielding, DNA damage and repair, biodosimetry, systems biology, and risk assessment models. He has won numerous NASA awards for his efforts in research, mission safety, and research management. Dr. Cucinotta is currently the President of the Radiation Research Society, and a Council Member of NCRP.



Raymond A. Guilmette received a BS in nuclear engineering from Rensselaer Polytechnic Institute and an MS in environmental health sciences and a PhD in radiological health from New York University. For almost 40 y, he has been studying the metabolism, biokinetics, dosimetry, biological effects of internally-deposited radionuclides, developing methods for removing radionuclides from the body (decorporation), and studying the mechanisms of deposition, clearance and retention of inhaled materials. Most of this research was performed at the Lovelace Respiratory Research Institute (LRRI) (formerly the Inhalation Toxicology Research Institute), where he worked for 23 y. From 2000 through 2007, he was team leader for internal dosimetry at the Los Alamos National Laboratory, assessing radiation doses for workers who were exposed to radionuclides associated with the nuclear weapons industry. In 2007, he returned to LRRI as director of the Center for Countermeasures Against Radiation where he is evaluating the efficacy of chemical compounds designed to decorporate radionuclides as well as drugs designed to ameliorate the effects of acute radiation syndrome from large external radiation doses. He is a past president of the Health Physics Society, received its Distinguished Scientific Achievement Award in 2002, and has given several honorary lectures (Newell Stannard Memorial Lecture, 2006; G. William Morgan Lecture, HPS, 2009; inaugural Patricia W. Durbin Memorial Lecture, Lawrence Berkeley National Laboratory, 2010). He is a member of scientific committees of the International Commission on Radiological Protection, NCRP (also a board member), the International Agency for Research on Cancer, U.S. Environmental Protection Agency, and the U.S. National Academies of Science.



Kathryn D. Held is an Associate Radiation Biologist in the Department of Radiation Oncology, Massachusetts General Hospital (MGH) and Associate Professor of Radiation Oncology (Radiation Biology) at Harvard Medical School (HMS). At MGH, Dr. Held leads a team that is involved in research on molecular mechanisms for the induction of bystander effects by high energy particles in cells and tissues, characterization of proton beam induced DNA damage responses, development of a cancer screening platform for personalized radiation medicine, mechanisms for regulation of DNA damage response by cell-cell communication, and development of novel agents for mitigation of radiation-induced pulmonary injury. Dr. Held also teaches radiation biology to radiation oncology medical and physics residents and graduate students at MGH/HMS and the Massachusetts Institute of Technology. Dr. Held earned her PhD in biology from the University of Texas, Austin. She has served on review panels for numerous federal agencies including the National Institutes of Health, the National Aeronautics and Space Administration (NASA), and the U.S. Army Medical Research and Material Command programs and other organizations such as the Radiological Society of North America, is on the Editorial Boards of Radiation Research and the International Journal

of Radiation Biology, and has served on committees for the National Academy of Science/National Research Council, NASA, and the American Society of Radiation Oncology. She has been a President of the Radiation Research Society and is currently on the Board of Directors and Vice President of Program Area Committee 1 of NCRP, having served as Chair of the Program Committee for the 2011 NCRP Annual Meeting on Scientific and Policy Challenges of Particle Radiations in Medical Therapy and Space Missions.



Mark D. Hoover is a senior research scientist in the Division of Respiratory Disease Studies at the Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), in Morgantown, West Virginia. Dr. Hoover is coordinator of the NIOSH Exposure Assessment Cross-Sector Research Program, as well as a critical area leader in the NIOSH Nanotechnology Research Center. NIOSH is the leading U.S. federal agency conducting research and making recommendations to prevent work-related illness, injury, disability and death. Prior to joining NIOSH in 2000, Dr. Hoover was an aerosol scientist for 25 y at the U.S. Department of Energy's Lovelace Respiratory Research Institute in Albuquerque, New Mexico, where his activities included the design and operation of the U.S. test facility for radiation instrumentation for air sampling and monitoring. He earned a BS in mathematics and English in 1970 from Carnegie Mellon University and an MS and PhD in nuclear engineering in 1975 and 1980 from the University of New Mexico. He is board certified in the comprehensive practice of health physics and in the comprehensive practice of industrial hygiene. Dr. Hoover has served as chairman or contributor to the development of many national and international standards; is the cofounder of the U.S. Air Monitoring Users Group; is a past chairman of the American International Health Alliance Nanotechnology Working Group; and is author or co-author of more than 190 open literature publications. He is co-editor of the 2011 CRC Press handbook on Radioactive Air Sampling Methods; chair of NCRP Scientific Committee 2-6 on Radiation Safety Aspects of Nanotechnology; project leader for preparation of the International Electrotechnical Commission technical report on Radiation Instrumentation Issues for Airborne Materials Including Nanoparticles; and the co-lead editor for preparation of a new monograph on Nanoinformatics Principles and Practices. Special emphasis areas for Dr. Hoover's work include a graded approach to exposure assessment and characterization of nanoparticles in the workplace, development of a prototype Nanoparticle Information Library, and promotion of opportunities to apply performance-based occupational exposure limits or control banding approaches to nanotechnology. Detailed information about the NIOSH exposure assessment research program and the NIOSH nanotechnology health and safety research program can be found at http://www.cdc.gov/niosh/programs/expa/ and http://www.cdc.gov/niosh/topics/nanotech.



Kenneth R. Kase is Honorary Vice-President of NCRP. He was a member of the Council for 24 y, served as Senior Vice President for 9 y, and for 12 y as Scientific Vice President and Chair of Scientific Committee 46 for Operational Radiation Safety. He also was a member of Committee 4 of the International Commission on Radiation Protection from 1997 to 2001. Dr. Kase completed his term as President of the International Radiation Protection Association (IRPA) in May 2012. He served as Vice-President from 2004 to 2008, and chaired the International Congress Program Committee for the 2000 International Congress on Radiation Protection (IRPA 10) in Hiroshima, Japan.

Kenneth Kase began his career in Health Physics at Lawrence Livermore National Laboratory, California, in 1963 and moved to Stanford Linear Accelerator Center (SLAC) in 1969. In 1975 he received a PhD from Stanford University and was appointed to the faculty of Radiation Oncology at the Harvard Medical School. He was appointed Professor of Radiation Oncology at the University of Massachusetts Medical School in 1985. In 1992 he returned to Stanford and was appointed Associate Director of SLAC and Director of the Environment, Safety and Health Division in 1995. He retired from that post in 2001 and from SLAC in 2005. Currently he is associated with Lyncean Technologies, Inc., a research and development firm in Palo Alto, California. He is married to Grady and has two daughters and 6 grandchildren.

Throughout his career Dr. Kase has been active in research activities related to radiation physics and radiation protection, particularly in radiation measurements and the operation of particle accelerators. He has published over 75 papers in peer reviewed journals, co-authored one book, and edited three others on radiation dosimetry.

Dr. Kase served on the Board of Directors of the Health Physics Society (HPS) from 1989 to1992 and 2002 to 2005 and as President of the HPS in 2003 to 2004. He served on the Board of Directors of the American Association of Physicists in Medicine (AAPM) from 1984 to 1991, and as AAPM Treasurer from 1986 to 1991. Dr. Kase also has been an associate editor of *Health Physics, Medical Physics*, and *Radiation Research*.



Jill A. Lipoti was the Director of Water Monitoring and Standards at the New Jersey Department of Environmental Protection until her retirement in 2013. From 1989 to 2010, she directed the activities of the Radiation Protection Programs for New Jersey, with responsibility for the x ray, radioactive materials, nuclear emergency response, environmental monitoring, radon, and nonionizing programs, involving regulation and licensure of professionals. She received the Edward J. III Excellence in Medicine Award in 2009 for her work in reducing patient radiation dose from x rays. Dr. Lipoti served as the New Jersev Commissioner to the Atlantic Interstate Low-Level Radioactive Waste Compact. Dr. Lipoti was elected to the Board of Directors and as Chairperson for the Conference of Radiation Control Program Directors (CRCPD), a nonprofit organization representing all 50 states. In 2000, she received the Gerald S. Parker Award of Merit, the CRCPD's highest award. Dr. Lipoti was elected to NCRP in 2001 and has served on the Board of Directors, Program Area Committee 5 on Environmental Radiation and Radioactive Waste Issues, and on Scientific Committee 5-1, Approach to Optimizing Decision Making for Late-Phase Recovery From Nuclear or Radiological Terrorism Incidents. She served as a member and chair of the Radiation Advisory Committee of the Environmental Protection Agency's Science Advisory Board (SAB) and also served on the SAB's Committee on Science Integration for Decision Making. She served on the Food and Drug Administration's Technical Electronic Product Radiation Safety Standards Committee. Dr. Lipoti served on the National Academies committee to write a report on Uranium Mining in Virginia under the Board on Earth Sciences and Resources. Dr. Lipoti received the Distinguished Alumni George H. Cook Award, Cook College, Rutgers University. She received her PhD in Environmental Science from Rutgers University in 1985. She has traveled to Uganda and Ethiopia on missions for the International Atomic Energy Agency.



Paul A. Locke, a public health scientist and attorney, is an Associate Professor at the Johns Hopkins University Bloomberg School of Public Health in the Department of Environmental Health Sciences, Division of Molecular and Translational Toxicology. He holds an MPH from Yale University School of Medicine, a DrPH from the Johns Hopkins University Bloomberg School of Public Health, and a JD degree from Vanderbilt University School of Law.

Dr. Locke's research and practice focus on how decision makers use environmental health science (toxicology, radiobiology, epidemiology) in regulation and policy making and how environmental health sciences influence the policy-making process. His areas of study include radiation risk communication, designing and evaluating radiation protection initiatives and radiation policies, radon risk reduction, safe disposal of high level radioactive waste, and use of computed tomography as a diagnostic screening tool. Dr. Locke directs the School's Doctor of Public Health program in Environmental Health Sciences.

Dr. Locke was a member of the National Academy of Sciences (NAS) Nuclear and Radiation Studies Board from 2003 to 2009. He has served on seven National Academy committees, and is currently a member of an NAS committee that is tasked with providing an assessment of lessons learned from the Fukushima

nuclear accident for improving the safety and security of nuclear plants in the United States. He is also a member of the Board of Directors of NCRP. He was program committee chair of the NCRP's 2010 annual meeting entitled "Communication of Radiation Benefits and Risks in Decision Making." Dr. Locke is admitted to practice law in the State of New York, the District of Columbia, the Southern District Court of New York, and the United States Supreme Court.



Ruth E. McBurney is the Executive Director of the Conference of Radiation Control Program Directors. In that position, she manages and directs the administrative office for the organization. Prior to taking that position in January 2007, she was the Manager of the Radiation Safety Licensing Branch at the Texas Department of State Health Services, culminating 25 y of service in the Texas Radiation Control Program, most of which involved licensing and standards development. Ms. McBurney has served on the U.S. Nuclear Regulatory Commission's Advisory Committee on the Medical Use of Isotopes and the U.S. Food and Drug Administration's National Mammography Quality Assurance Advisory Committee. She is currently serving as a Member of NCRP, and is also on the Board of Directors. She served as a consultant to the International Atomic Energy Agency in the categorization of radiation sources and recently served on a committee of the National Academy of Science regarding replacement technologies for high-risk radiation sources. She has also been a U.S. delegate to the International Radiation Protection Association's 10th, 11th, 12th, and 13th Congresses.

Ms. McBurney holds a BS in Biology from Henderson State University in Arkansas and an MS in Radiation Sciences from the University of Arkansas for Medical Sciences. She is also certified in comprehensive health physics by the American Board of Health Physics.



Fred A. Mettler, Jr. is currently Professor Emeritus and Clinical Professor at the Department of Radiology at the University of New Mexico School of Medicine. He was chairman of the department for 18 y from 1994 to 2003. He is currently in the Radiology and Nuclear Medicine Service at the New Mexico Federal Regional Medical Center.

He graduated with a BA in Mathematics from Columbia University and in 1970 he received his MD from Thomas Jefferson University. He performed a rotating internship at the University of Chicago and subsequently completed a Radiology and Nuclear Medicine Residency at Massachusetts General Hospital. He received an MS in Public Health from Harvard University in 1975. He is a fellow of both the American College of Radiology and the American College of Nuclear Physicians. He is board certified in both radiology and nuclear medicine.

Dr. Mettler has authored over 360 scientific publications including 20 textbooks, and holds four patents. The books are on *Medical Management of Radiation Accidents, Medical Effects of Ionizing Radiation and Radiology* and *Nuclear Medicine*. He was a Scientific Vice President of NCRP and remains a member. He has chaired several committees for the Institute of Medicine/National Research Council and is a member of the Nuclear and Radiation Studies Board of the National Academies. He is also an academician of the Russian Academy of Medical Sciences. Dr. Mettler has been listed in "The Best Doctors in America" since 1994 as an expert in both nuclear medicine and radiation injury. He has been a certifying examiner for the American Board of Radiology for 30 y.

He was the United States Representative to the United Nations Scientific Committee on the Effects of Atomic Radiation 28 y. He is an Emeritus Commissioner of the International Commission on Radiation Protection (ICRP). He was the Health Effects Team Leader of the International Chernobyl Project. He has served as an expert on radiation effects and accidents for the Centers for Disease Control and Prevention,

the World Health Organization, the International Atomic Energy Agency, the International Agency on Research on Cancer, and for the Costa Rican, Peruvian, Panamanian, Polish governments. He was a coauthor of the NCRP and ICRP reports on radiation protection during radiological terrorism and has been a member of multiple subgroups on radiological terrorism for the U.S. Department of Homeland Security. He is currently a health advisor to the Japanese Cabinet for the Fukushima nuclear disaster.



Donald L. Miller is the Chief Medical Officer for Radiological Health in the Office of In Vitro Diagnostics and Radiological Health of the Center for Devices and Radiological Health at the U.S. Food and Drug Administration (FDA). He received a BA in molecular biophysics and biochemistry from Yale University and an MD from the New York University School of Medicine. He completed his residency and fellowship at the New York University Medical Center. Dr. Miller, an interventional radiologist, is a Fellow of the Society of Interventional Radiology and of the American College of Radiology and an Honorary Member of the American Association of Physicists in Medicine. He is Vice-Chair of Committee 3 of the International Commission on Radiological Protection and serves as a consultant to the International Atomic Energy Agency and the World Health Organization. He served as Vice-Chair of NCRP Report No. 168 and Consultant for NCRP Report No. 172. He currently serves as Co-Chair of NCRP Program Area Committee 4 and a member of the Nominating Committee. Prior to joining FDA, Dr. Miller was a Professor of Radiology and Radiological Sciences at the Uniformed Services University of the Health Sciences and an adjunct investigator at the National Cancer Institute. His research interests have centered on radiation protection in medicine.



John W. Poston, Sr. is a Professor in the Department of Nuclear Engineering and Associate Director of the Nuclear Power Institute. He has been at Texas A&M University since 1985 and served for 10 y as the Department Head. Prior to coming to Texas A&M, he was on the faculty at the Georgia Institute of Technology and, earlier, at the Oak Ridge National Laboratory and the Babcock & Wilcox Company in Lynchburg, Virginia. He is a Fellow of the American Nuclear Society, the Health Physics Society, the American Association for the Advancement of Science, and a Distinguished Emeritus Member of NCRP. Currently, he serves as the NCRP Vice President for Program Area Committee 3, Nuclear and Radiological Security and Safety.



R. Julian Preston recently retired as the Associate Director for Health for the National Health and Environmental Effects Research Laboratory of the U.S. Environmental Protection Agency (EPA). He also served as Director of the Environmental Carcinogenesis Division at EPA and as senior science adviser at the Chemical Industry Institute of Toxicology. He has been employed at the Biology Division of the Oak Ridge National Laboratory and has served as associate director for the Oak Ridge-University of Tennessee Graduate School for Biomedical Sciences. Dr. Preston's research and current activities have focused on the mechanisms of radiation and chemical carcinogenesis and the approaches for incorporating these types of data into cancer risk assessments. Dr. Preston was chair of Committee 1 of the International Commission on Radiological Protection (ICRP), a member of the ICRP Main Commission, and a member of the U.S. delegation to the United Nations Scientific Committee on the Effects of Atomic Radiation. He is an associate editor of Environmental and Molecular Mutagenesis, Mutation Research, Chemico-Biological Interactions, and Health Physics. Dr. Preston has had more than 200 peer-reviewed papers and chapters published. He received his BA and MA from Peterhouse. Cambridge University, England, in genetics and his PhD from Reading University, England, in radiation genetics. He has served on the National Research Council's Committee to Assess the Scientific Information for the Radiation Exposure Screening and Education Program and the Task Group on the Biological Effects of Space Radiation.



Kathryn H. Pryor has been a member of Program Area Committee (PAC) 2 since 2007 and a member of NCRP since 2010. She has served on Scientific Committees 2-4, 2-5, 2-7, 1-19, and 6-9. Ms. Pryor is currently on the NCRP Board of Directors and is Scientific Vice President of PAC 2. She received her BS in Biology in 1979 and MS in Radiological Sciences in 1981, both from the University of Washington.

Ms. Pryor currently holds the position of Chief Health Physicist at the Pacific Northwest National Laboratory (PNNL) in Richland, Washington, and has provided management and technical support to the PNNL Radiation Protection Division since 1992. She also served as the Chief Radiological Engineer for the design of the Pit Disassembly and Conversion Project. Ms. Pryor has previously held radiation protection technical support positions at the San Onofre Nuclear Generating Station and the Trojan Nuclear Plant, and was the Radiation Safety Officer at the University of Southern California Health Sciences Campus.

Ms. Pryor is a Fellow member of the Health Physics Society (HPS) and served as President-Elect, President, and Past President from 2010 to 2013. She is certified in comprehensive practice by the American Board of Health Physics (ABHP), and served on the ABHP both as a member and Chair from 1998 to 2002. Ms. Pryor was awarded the William McAdams Outstanding Service Award by ABHP in 2007 and the John P. Corley Meritorious Service Award by the Columbia Chapter of HPS in 2003.



Steven L. Simon received a BS in Physics from the University of Texas, an MS in Radiological Physics from the University of Texas Health Sciences Center in Dallas, and a PhD in Radiological Health Sciences from Colorado State University. Early in his career, he worked in medical physics and was the first treatment planner for clinical trials of treatments of solid tumors with negative pi-mesons at the Los Alamos Physics Meson Facility. Later specializing in environmental radioactivity, he directed the first nationwide monitoring program of the Marshall Islands for residual contamination from nuclear testing. He also participated in the radiological monitoring of numerous other nuclear test sites worldwide including Johnston Island, French Polynesia, and Algeria and has lead, or participated in, health risk studies of fallout exposures in Utah, the Marshall Islands, and Kazakhstan. In 2000, Dr. Simon joined the National Cancer Institute's Radiation Epidemiology Branch as an expert in dose reconstruction and presently heads the Dosimetry Unit in that group. Steve is a member of NCRP and has been an Associate Editor of *Health Physics* for 20 y. In 2011 during the Fukushima crisis, Steve was deployed by the U.S. Department of Health and Human Services to the U.S. Embassy in Japan to assist with the protection of American citizens.



Steven G. Sutlief received his PhD in experimental particle physics from the University of Washington and subsequently completed a post-doctoral fellowship in radiation therapy medical physics at the University of Washington with research in intensity modulated radiation therapy. Since then he has been chief medical physicist at the Veterans Affairs (VA) Puget Sound Health Care System in Seattle and an affiliate faculty member in the University of Washington School of Medicine. He actively participates in the American Association of Physicists in Medicine, where he has served on many committees and on several task group reports. Dr. Sutlief has worked to advance radiation therapy within the VA, including agency-wide radiotherapy equipment modernization, radiotherapy device interconnectivity, consultation for the VA National Health Physics Program, participation in several investigations, and development of qualification standards for therapeutic medical physicists. He has coauthored 45 articles and book chapters related to therapeutic medical physics. Dr. Sutlief developed and taught the physics curriculum for the Bellevue College Medical Dosimetry program. He has served as a consultant to the International Atomic Energy Agency and as a member of the Radiation Oncology planning group for the Integrating the Healthcare Enterprise. Recently Dr. Sutlief was a Co-organizer for the AAPM Summer School on Quality and Safety in Radiation Therapy and was a faculty member for the Veterans Health Administration Biennial Conference on Radiation Oncology. He is currently an NCRP Council member.



Julie E.K. Timins is a Diagnostic Radiologist, board certified in General Radiology and in Nuclear Medicine. Her medical practice has been varied, including Chair of Nuclear Medicine at the Veterans Administration Hospital in Lyons, New Jersey; 10 y as Staff Radiologist at Robert Wood Johnson University Hospital, New Brunswick, New Jersey; 11 y in an inner-city hospital in Jersey City; and over 4 y in a suburban outpatient imaging facility specializing in Mammography and Women's Imaging in Morristown, New Jersey. Dr. Timins is Chair of the New Jersey Commission on Radiation Protection, and sits on the New Jersey Radiologic Technology Board of Examiners. She served on the NCRP Board of Directors, and received a Commendation for Outstanding Service on the 2010 Annual Meeting Program Committee - "Communication of Radiation Benefits and Risks in Decision Making." She is past president of the Radiological Society of New Jersey and recipient of that organization's Gold Medal Award. Active in the American College of Radiology, of which she is a Fellow and former member of the Council Steering Committee, Dr. Timins currently sits on the Commission on Quality and Safety as Vice-Chair for Practice Guidelines and Technical Standards. She is a recipient of the Advisory Committee Service Award of the U.S. Food and Drug Administration, in recognition of distinguished service on the National Mammography Quality Assurance Advisory Committee. The American Association for Women Radiologists has honored Dr. Timins with the Professional Leadership Award for Mid Career/Senior Faculty and the President's Award. In appreciation of service as an Affiliate Member of the Conference of Radiation Control Program Directors, she was presented with the Board of Directors Award for Outstanding Achievement in the Field of Radiation Protection, for participation on the H-30 Task Force and development of the White Paper on Bone Densitometry.



Richard E. Toohey received his PhD in physics from the University of Cincinnati in 1973. He spent the first part of his career at Argonne National Laboratory in both research and operational health physics. He recently retired from Oak Ridge Associated Universities, where he served as director of the Radiation Internal Dose Information Center, as Senior Health Physicist for the Radiation Emergency Assistance Center/ Training Site, Director of Dose Reconstruction Programs, and Associate Director of the Independent Environmental Assessment and Verification Program. He is currently employed by M.H. Chew and Associates. He is certified in comprehensive practice by the American Board of Health Physics, was the 2008 to 2009 President of the Health Physics Society, is a member and director of NCRP, Treasurer of the International Radiation Protection Association, and Chair of the Scientific Advisory Committee for the U.S. Transuranium and Uranium Registries. His specialties are internal radiation dosimetry, dose reconstruction, and radiological emergency response. Dr. Toohey has 125 publications in the open literature, and is a retired Lt. Colonel, U.S. Army Reserve.

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- U.S. Navy
- U.S. Nuclear Regulatory Commission

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Centers for Disease Control and Prevention National Cancer Institute U.S. Department of Energy

Contributors

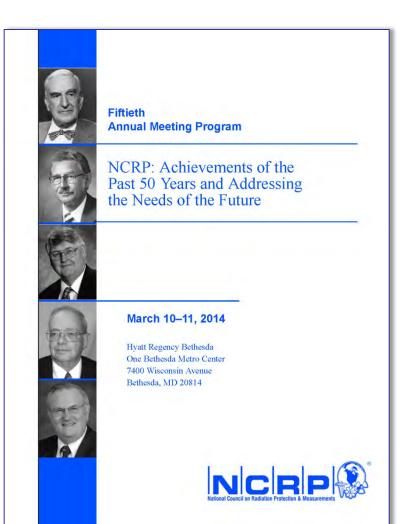
American Academy of Health Physics American Academy of Oral and Maxillofacial Radiology American Association of Physicists in Medicine American Board of Radiology Foundation American College of Radiology Foundation American Dental Education Association American Roentgen Ray Society American Society for Radiation Oncology American Society of Radiologic Technologists Council on Radionuclides and Radiopharmaceuticals Health Physics Society Landauer, Inc. Lillian and Robert Brent Fund **Radiation Research Society** Radiological Society of North America Society for Pediatric Radiology Society of Nuclear Medicine and Molecular Imaging

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Welcome to NCRP 50th Annual Meeting John D. Boice, Jr., President









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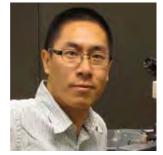
Initiatives that Worked

- Written questions & published answers
- Live Webinar & available after
- Brief bios & photos in Program
- Proceedings to be published 2014
- Video clip introductions for each article
- Free access to 2013 Proceedings thanks NCI!
- Brief "email" <5 min survey after meeting
- Reception line for Taylor Lecturer
- NCRP/RRS Scholars "Program" 2nd
- Contact me for ways to improve future topics

NCRP / RRS Scholars Travel Award Recipients









- Jason D. Domogauer Rutgers-New Jersey Medical School
- Roy Kong Kwan Lam City University of Hong Kong
- Ianik Plante
 NASA Johnson Space
 Center

Integrating Basic Radiobiological Science and Epidemiological Studies (Why and How?)

> R. Julian Preston Expert, US EPA Research Triangle Park, NC

> > NCRP, March 2014

The Aim

To provide a context whereby a greater role is established for the incorporation of basic radiobiology data into the development of radiation risk estimates and to thereby reduce the uncertainty in these estimates for use in radiation protection.

The Present Situation

The calculation of radiation risk estimates for cancer and noncancer diseases relies almost exclusively on epidemiological data from radiation exposed populations, especially the Japan atomic bomb survivors. A number of these epidemiological data sets are very comprehensive but despite this there are quite large uncertainties associated with the calculated risk estimates.

Risk Assessment

The general approach for calculating risk estimates at low doses (<100mGy) and low dose rates (<5mGy per hour) for radiation-induced diseases is to extrapolate from epidemiological data obtained over a range of acute doses (medium to high) to predict levels at these low dose levels. A dose and dose-rate effectiveness factor (DDREF) is then applied to account for reductions in effect of low compared to high dose and low compared to high dose rates.

Extrapolation Models

- For cancer, extrapolation from effects at high/medium doses to predict effects at low doses is currently accomplished using the liner-no threshold (LNT) model.
- For noncancer effects extrapolation from effects at high/medium doses is used to calculate estimates of 'practical' threshold doses defined at the level of 1% incidence.
 (See ICRP Report No. 118 for details)

Uncertainties

These include:

- Dosimetric uncertainties;
- Epidemiological and methodological uncertainties;
- Uncertainties from low statistical power and precision;
- Uncertainties from inadequate modeling of radiation risk data;
- Transport of (or generalizing) risk estimates to different populations;
- Model used for extrapolation;
- DDREF value used for risk reduction at low doses and dose rates; and
- Quality factor used for high LET effects.

Solutions for Reducing Uncertainty

- It might be possible to reduce some of these uncertainties by conducting enhanced epidemiology studies particularly at low doses and low dose rates for situations where individual doses are well characterized. However, this is a quite daunting task and will be limited in its overall application.
- Alternatively or in addition, greater use can be made of the extensive radiobiology data from laboratory animal and cellular studies. These can, for example be incorporated into some informative form of biologicallybased dose-response model or to enhance the current extrapolation approach to risk estimation.

Use of Radiobiology Data

To date, there has been rather limited use of radiobiology data in the cancer risk assessment process and relatively little in the noncancer risk assessments, apart from laboratory animal studies. For cancer, this use has been largely in the estimation of DDREF and Quality Factors, although additional data have been considered for enhancing the "comfort level" for risk estimates.

Risk Assessment for Chemicals

A plausible approach can be provided by considering how risk assessment is conducted for environmental chemicals for which there are limited or no human cancer data. Use is made of laboratory animal and in vitro data for developing extrapolation models, including biologically-based dose-response models. The parameters for such models are based on a set of key events that are essential for defining an adverse outcome pathway leading for example to cancer induction.

Biologically-Based Dose-Response Models (BBDR)

BBDR models combine the use of epidemiology, laboratory animal studies and cellular and molecular data in order to parameterize the model. The selection of data relies on a knowledge of the key events that lead to cancer development in response to radiation. The challenge in simple terms is to:

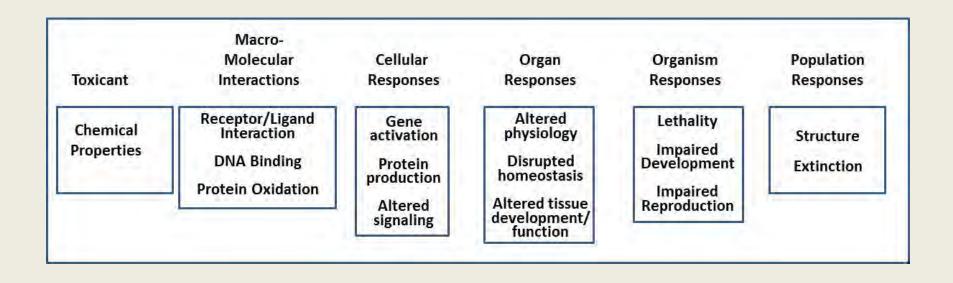
- i. Understand a sufficient amount of the relevant biology
- ii. Acquire enough knowledge to parameterize the model
- iii. Develop the computational model

The requirements will clearly differ depending on whether the model is used to support ongoing research or is to be used in a regulatory setting.

Definitions

- A "key event" is an empirically observable precursor step that is itself a necessary element of the mode of action or is a biologically based marker for such an element.
- An "adverse outcome pathway" is an analytical construct that describes a sequential chain of causally linked events at different levels of biological organization that lead to an adverse health effect.

Schematic Representation of the Adverse Outcome Pathway (AOP) illustrated with reference to a number of pathways.



From OECD Website, 2014

Key Events for Tumor Development: DNA-reactive MoA (e.g., Ionizing Radiation)

- Exposure of target cells to ultimate DNA-reactive and mutagenic entity
- Reaction with DNA in target cells to produce DNA damage
- Replication or repair errors from damaged template
- Mutations in critical genes in target cell
- Enhanced cell proliferation
- Additional mutations induced from DNA damage and repair/replication
- Clonal expansion of mutant cells
- Preneoplastic lesions and neoplasms develop
- Malignant behavior

Outputs and Outcomes

The use of this key event/AOP approach is to identify potential biomarkers of a response or bioindicators of the adverse health outcome itself that can be used qualitatively to predict the form of the dose-response curve for the apical endpoint at low doses and low dose rates and quantitatively to estimate the cancer or noncancer risk itself at these low doses and low dose rates.

Research Program

- The need is for the conduct of <u>targeted</u> research aimed at enhancing the risk assessment process at low doses and low dose rates. To do this the approach will be to identify and evaluate informative bioindicators of an apical response (cancer or noncancer) and use these to set parameters for a BBDR model. Based on our current knowledge, this is a viable approach although not a short term venture.
- These research activities have to be viewed in the context of ongoing and proposed epidemiology studies. Any viable approach has to be an integration of the biology and the epidemiology.

What Is Available?

- For key events, the knowledge of the molecular basis for cancer and, to a lesser extent, for noncancer diseases is increasing very rapidly. New techniques such as ultra high speed sequencing are fueling this.
 (Note Hanahan and Weinberg's "Hallmarks of Cancer")
- Predictive biologically-based models have been developed (e.g., Moolgavkar et al., 1979,1981; Little, 2010; Shuryak et al., 2010; Luebeck et al., 2013).
- Recent computational advances make linking molecular/cellular events to adverse outcomes much for readily feasible.

What is Needed?

- Increased knowledge of key events for radiation-induced adverse health outcomes. Are there "radiation signatures" of response?
- Development of adverse outcome pathways
- Identification and evaluation of key events/bioindicators.
- Development of new and improved BBDR.
- Epidemiology studies directed to low dose and low dose-rate exposures.

Radiation Safety and Human Spaceflight: NCRP Role in Protecting Against Large Uncertainties

Francis A. Cucinotta, University of Nevada, Las Vegas

> Presented at the 50th Annual NCRP Meeting. March 10, 2014

Space Radiation Protection

- The Past: In the 1970's, NASA used dose limits from the National Research Council (NRC).
 - DS65 Analysis of A-bomb survivors
 - Career limit of 4 Sv based on estimated doubling dose for cancer death for 35-year males
- By the 1980's, female and career astronauts
 - DS86 and re-assessments ongoing
 - High Charge and Energy (HZE) radiobiology emerging threat





NCRP Role for Space Shuttle and ISS

- In 1989, NCRP recommended age at exposure and gender based dose limits using a 3% fatal cancer risk (<1 in 33 probability of occupational death).
 - NCRP considered comparisons to accidental deaths in the so-called "Safe", "Less-Safe" and "Unsafe" Industries.
 - Astronauts face other risks similar to "unsafe" industries- it would not be appropriate for NASA's radiation limits to be similar to risks in "unsafe" industries.
- Recommended Dose Limits should limit risk similar to "Less-safe" Industries.
- Gender based limits due to increased cancer risk for breast, ovarian, and lung cancers.

NCRP Report No. 132 (2000)

- Report No. 132 noted that the risks in the "less-safe" industries were reduced since the 1980's, however recommended NASA maintain a 3% Limit similar to risk of ground-based Rad workers.
 - National Safety Council now shows <1% Risk for less-safe industries (NSC, 2011)
- NASA estimates current Loss of Crew (LOC) risk for Space missions is 1 in 270.
 - Aerospace Safety Advisory Panel recommends NASA <u>can</u> make investments to reduce LOC to less than 1 in 750
- Is the 1 in 33 radiation limit comparable to LOC (1 in 270) probability when adjusted for life-loss?

Uncertainties in Space Radiobiology Require New Knowledge and Approaches

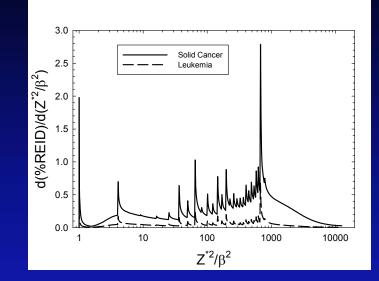
- NCRP Reports 98, 132, 152 noted estimates were highly uncertain for Galactic Cosmic Rays (GCR).
 - Uncertainties too large for application to GCR
 - NRC Reports in 1996, 1999 and 2008 echo concerns
- All experts agreed that knowledge is limited:
 - Unlike other disciplines where the fundamental physiological basis of spaceflight biomedical problems is largely known, the scientific basis of HZE particle radiobiology is largely unknown
 - Differences between biological damage of HZE particles in space vs. x-rays, limits Earth-based data on health effects for space applications

Risk Models- Major Uncertainties for GCR Particle Track Structure Leads to Unique Biological Damage Increasing Uncertainties

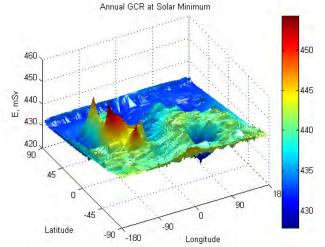


The Present- NASA Space Cancer Risk 2012

- NASA approach is to estimate uncertainties in risk estimates.
 - 95% Confidence in adhering to Risk Limit of 3% Fatality
 - Reviewed by NRC (2008, 2013)
- NSCR-2012 Model:
 - Radiation quality as a Probability Distribution Function (PDF) using track structure theory
 - Revised Low LET Risk coefficients
 - Revised DDREF and Uncertainty
 - Risks for Never-Smokers to represent healthy workers

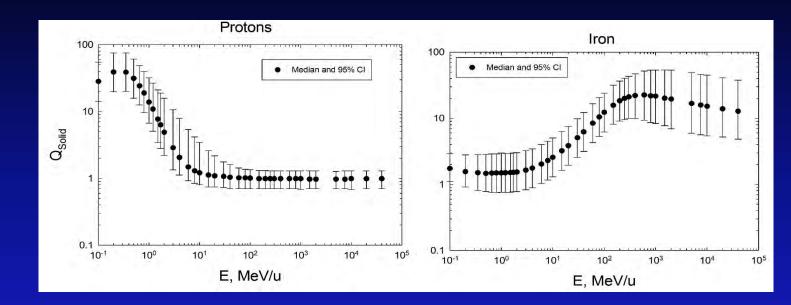


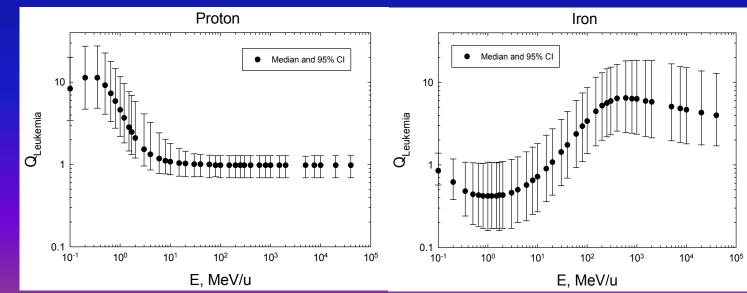
GCR dominate ISS organ risk



GCR doses on Mars

Radiation Quality Uncertainties (95% CL)





S O L I D

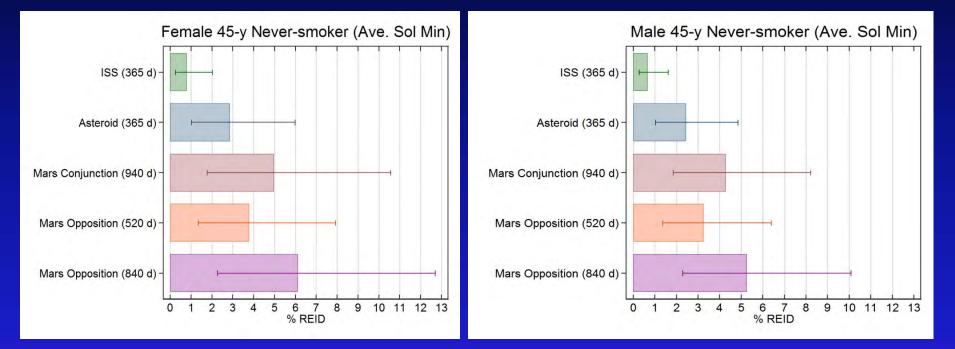


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NSCR-2014 Model

- Circulatory disease risk estimates for GCR.
 - Using Mark Little et al. meta-analysis results
 - RBE model for deterministic effects
 - Open questions on Epi-data and healthy worker effects
- Qualitative Differences:
 - Uncertainties due to HZE particles and neutron likely lead to increase tumor lethality compared to gamma-rays
 - Uncertainties due to Non-Targeted Effects (NTE) modification to low dose response and RBEs
- Improvements on NSCR-2012 Parameters:
 - Bayesian analysis of Quality Factor PDF parameters
 - Analysis of correlations between RBE and DDREF in experimental models
 - New Mars Surface Environment Model

Risk and 95% CI for Exploration Missions: Cancer and Circulatory Diseases (Cucinotta et al., PloS One, 2013)

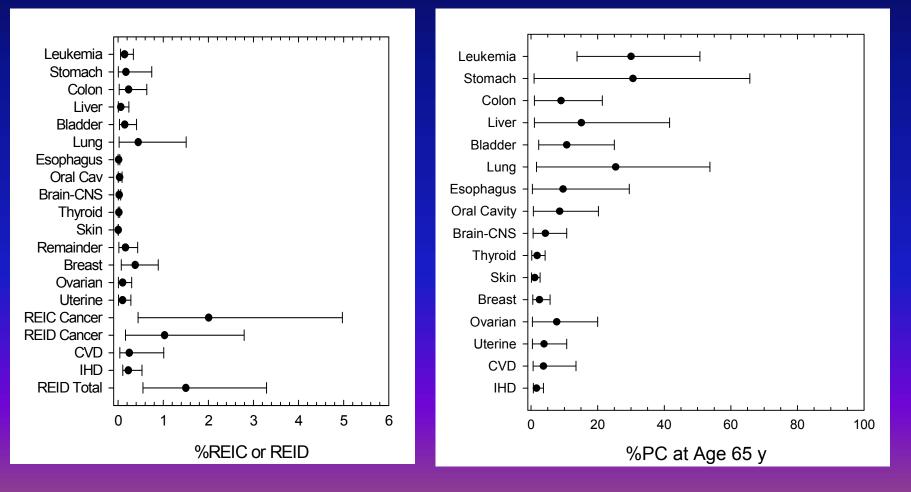


ISS = lower risk because GCR partially shielded by Earth Shadow and Magnetic Field Mars Opposition: 60-d on Mars surface with variable transit time (480 to 720-d) Mars Conjunction: 540-d on Mars surface with 400-d transit time

ISS Mission Risks Females on 2 Missions (Age 40 and 45-y)

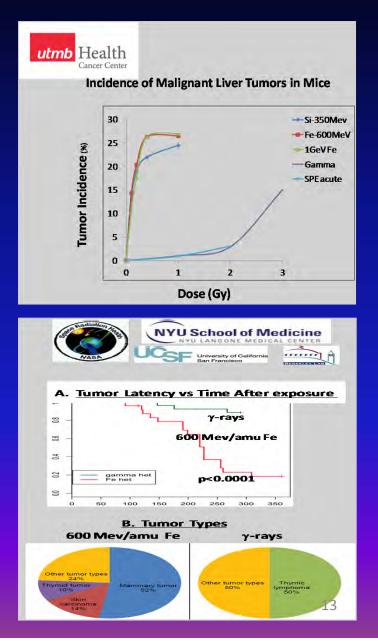
Lifetime Risks

Probability of Causation

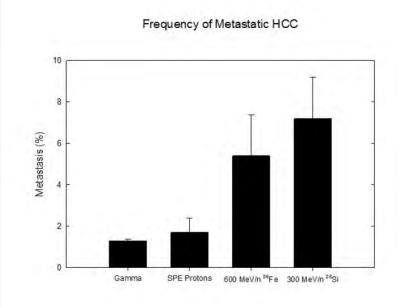


Qualitative Differences in Cancer Risks from GCR

- Risk Models only account for quantitative differences using Quality Factors (QFs)
- Issues emerging from research studies of GCR Solid cancer risks
 - Earlier appearance and aggressive tumors not seen with controls, gammarays or proton tumors
 - Non-linear response at low dose due to Non-Targeted Effects confounds conventional paradigms and RBE estimates
 - SPE (proton) tumors are similar to background tumors
- These issues are called out in NCRP reports and NRC reviews



GCR Heavy ions produce more aggressive tumors compared to controls or X-ray tumors



Funder pathology in Apc^{1638N/+} The definition Quality on Tumor Grade in Color Invasive Carcinoma Tubulovillous adenomas Tubulovillous adenomas

UTMB NSCOR- PI Robert Ullrich Shows much higher occurrence of metastatic Liver (HCC) tumors from GCR Fe or Si nuclei compared to gamma-rays or protons Georgetown NSCOR- PI AI Fornace Shows much higher occurrence of invasive carcinomas tumors from GCR Fe nuclei compared to gamma-rays or protons

Sensitivity of HZE Particles Tumor Lethality

- NSCR model allows effects from particle track to be divided into main track and δ -ray contributions.
- NSCR-2014 considers increased lethality for HZE particles and additional circulatory disease risks.

%REID (F)	%REID (F)	%REID (M)	%REID (M)
Cancer	Total	Cancer	Total
0.69 [0.11, 2.07]	1.03 [0.38, 2.37]	0.52 [0.11, 1.49]	0.86 [0.38, 1.9]
0.78 [0.13, 2.89]	1.12 [0.4, 3.12]	0.59 [0.12, 2.09]	0.93 [0.40, 2.45]
0.87 [0.16, 3.9]	1.21 [0.43, 4.0]	0.65 [0.14, 2.84]	0.99 [0.43, 3.08]
	<i>Cancer</i> 0.69 [0.11, 2.07] 0.78 [0.13, 2.89]	Cancer Total 0.69 [0.11, 2.07] 1.03 [0.38, 2.37] 0.78 [0.13, 2.89] 1.12 [0.4, 3.12]	CancerTotalCancer0.69 [0.11, 2.07]1.03 [0.38, 2.37]0.52 [0.11, 1.49]0.78 [0.13, 2.89]1.12 [0.4, 3.12]0.59 [0.12, 2.09]

Fatal Risk: 1-year ISS Mission for 45-y Male and Females

Conclusions

- Space radiation protection should follow identical principles as ground based radiation protection.
- Differences occur in applications due to:
 - Small specialized group of workers
 - Mission scenarios where workers approach limits requires
 Risk Based approach instead of use of Effective Dose
 - Natures of GCR requires estimates of <u>Quantitative</u> and <u>Qualitative</u> Uncertainties of HZE particles and neutrons
- Expectation of new research results needs to be taken into account in future planning.
- NSCR-2012 and NSCR-2014 are our approach to these problems.

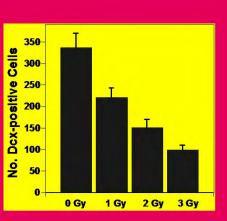
Major Open Questions for Space Radiation Protection

- What is acceptable risk for combined cancer, circulatory and CNS mortality and morbidity risks?
- Will necessary research to reduce uncertainties in quantitative measures (RBE and DDREFs) for protons, HZE particles be completed in timely manner?
- Will knowledge be obtained to understand qualitative differences in Solid Cancer Risks from HZE particles?
 - Increased Tumor Lethality
 - Non-Targeted Effects

CNS Radiation Injury for GCR < 0.5 Gy?

- NASA studies have seen effects in hippocampus, neostratium and pre—frontal cortex
- Apoptosis and overt loss of cellular constituents is minimal (most brain cells are not actively dividing)
- Late effects predominant and may arise from:
 - Loss of progenitor populations (neurons & glia)
 - Persistent inflammation
 - Persistent oxidative changes
- Interdependency of neural elements for normal function (e.g. supporting glia and vasculature) must be recognized





Reduction in neurons (neurodegeneration) for increasing Fe doses in hippocampus (J. Fike, UCSF)



Oxidative Stress (Lipid peroxidation:4-Hydroxynonenal) is Increased in Mouse Hippocampus 9 Months After 2 Gy of ⁵⁶Fe Irradiation

Major Open Questions- continued

CNS Risks

- Are there acute risks to memory and cognitions with mission impacts?
- Does GCR contribute to Alzheimer's disease and other late effects?
- What leads to gender differences in lung, circulatory, and other risks?
- How can the scientific basis for assessing individual radiation sensitivity be accelerated?

Individual Radiation Sensitivity?

- "Evaluation of genetic susceptibility to radiationinduced cancer and the influence of prior radiation exposure (*e.g.,* from medical therapy) should be given consideration as factors..., however at this time it is not possible to make accurate predictions of future risks associated with genetic susceptibility."
- "There have been extensive laboratory studies on the role of genetic susceptibility in radiation sensitivity of cellular and tissue model systems. However, with the exception of a relatively small fraction of the human population that is known to have innate genetic susceptibility to cancer from radiation exposure, it is difficult if not impossible at this time to use the available information to make predictions on the role of genetic factors for the small corps of astronauts."



POTENTIAL IMPACT OF INDIVIDUAL GENETIC SUSCEPTIBILITY AND PREVIOUS RADIATION EXPOSURE ON RADIATION RISK FOR ASTRONAUTS

NCRP. 2011



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- Much thanks to the various NCRP and Committees that have supported NASA, including Bill Beckner, John Boice, Charlie Meinhold, Dave Schauer, and Tom Tenforde.
- Special note of appreciation to Michael Fry who has been instrumental over several decades of service in the support of safety of human spaceflight.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Response to an nuclear detonation or radiological dispersal device: models, measurements and medical care

C. Norman Coleman, MD Associate Director, Radiation Research Program, Division of Cancer Treatment and Diagnosis National Cancer Institute, NIH Senior Medical Advisor Office of the Assistant Secretary for Preparedness and Response Department of Health and Human Services

NCRP: Achievements of the past 50 years and addressing the needs of the future



Presentation is the opinion of the presenter and does not represent NCI, NIH, ASPR, DHHS or USG conclusions or policy.



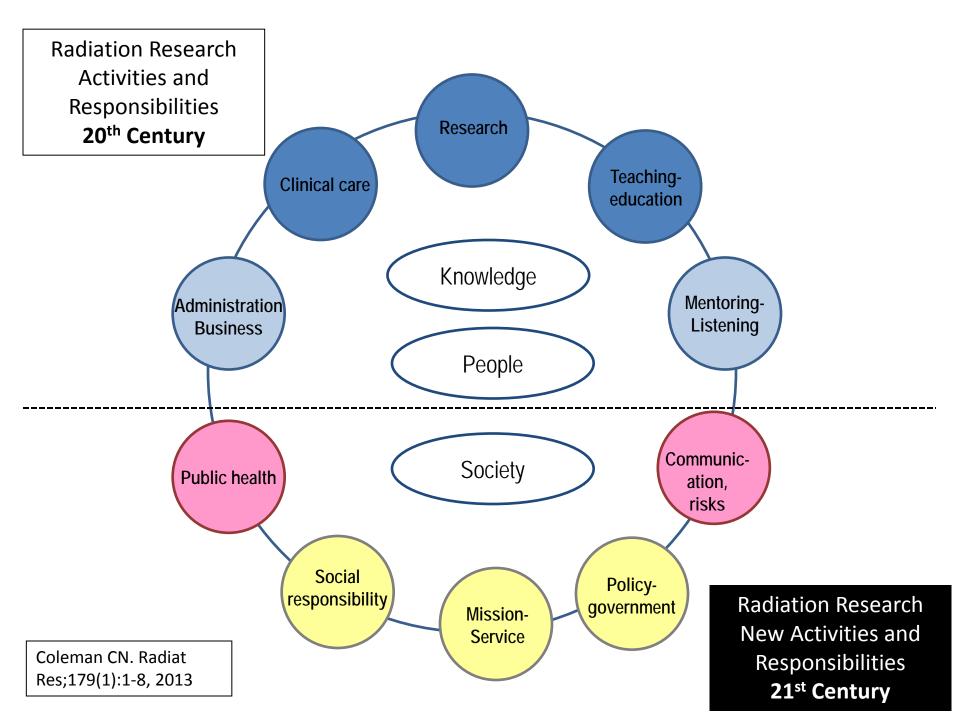
The challenge, request from the Assistant Secretary (ASPR) in 2004: prepare the U.S. for medical response rad/nuc National Planning Scenarios

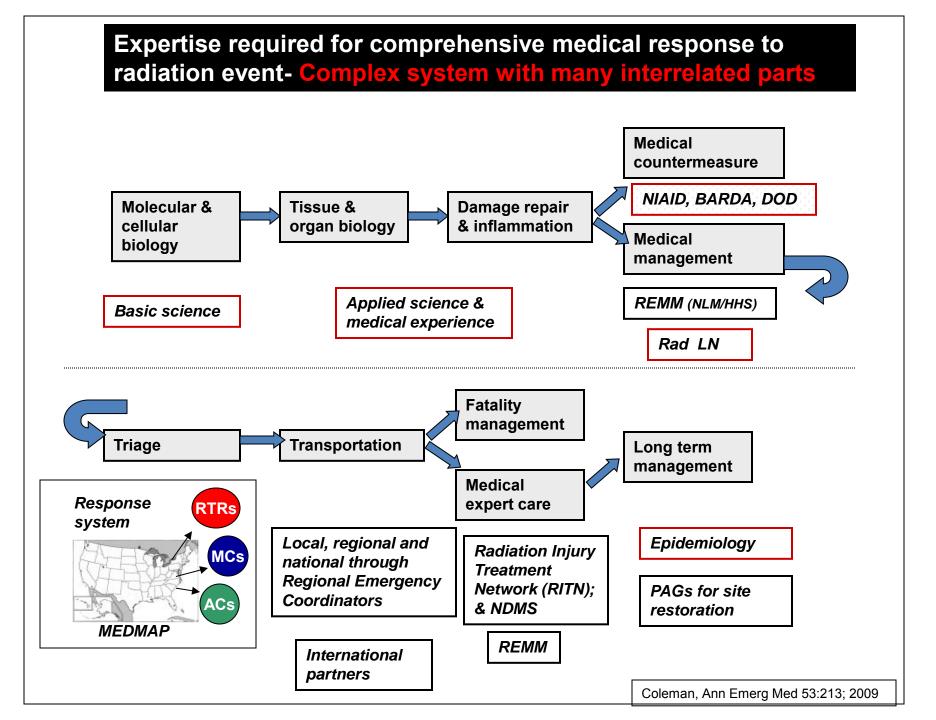
	: Nuclear Detonation – nprovised Nuclear Device	
Casualties	Hundreds of thousands	
Infrastructure Damage	Total within radius of 0.5 to 3 miles	
Evacuations/Displaced Persons	 100,000 in affected area seek shelter in safe areas (decontamination required for all before entering shelters) 250,000 instructed to shelter in place as plume moves across region(s) 1 million+ self-evacuate from major urban areas 	* * * * * * * * * * * * * * * * * * * *
Contamination	Various levels up to approximately 3,000 square miles	
Economic Impact	Hundreds of billions of dollars	
Potential for Multiple Events	No	
Recovery Timeline	Years	

Scenario 11: Radiological Attack – Radiological Dispersal Devices

Casualties	180 fatalities; 270 injuries; 20,000 detectible	
	contaminations (at each site)	
Infrastructure Damage	Near the explosion	
Evacuations/Displaced Persons	10,000 evacuated to shelters in safe areas (decontamination required prior to entering shelters) 25,000 in each city are given shelter-in-place instructions Hundreds of thousands self-evacuate from major urban areas in anticipation of future attacks	
Contamination	36 city blocks (at each site)]
Economic Impact	Up to billions of dollars	
Potential for Multiple Events	Yes	
Recovery Timeline	Months to years]

WE had a problem that our country asked us to help solve....





REMS - Radiation Emergency Management System

- Built around Nuclear Detonation and the effects
 - Most difficult rad/nuc problem partly subsumes solutions for others
- Playbook- pre-scripted steps for planning and preparedness
 - Federal and State/local planners- distinct but need similar "sheet of music"
- Medical management- Just-in-time, comprehensive, easy-to-use (algorithm "ACLS-like" approach)- REMM (Radiation Emergency Medical Management)
 - ASPR <-> NLM, (Specialized Information Services, CHEMM, etc.)
- Requirements, tools, diagnostics and CONOPS
 - MedMap- situational awareness- planning and response
- Taking care of people- guidelines, triage,
 - co-locating space, staff and stuff
 - Building capacity and capability
- Built upon,
 - Modeling (multi-agency)- DHS, DTRA, Nat'l Labs, BARDA
 - Collaboration with state/local/regional/tribal; PHEMCE- HHS
 - Science- basic \rightarrow preclinical \rightarrow advanced *product* development
 - Multiagency, NCI/DOE, NIAID (CMCR), BARDA, DOD=



Nuclear detonation damage zones





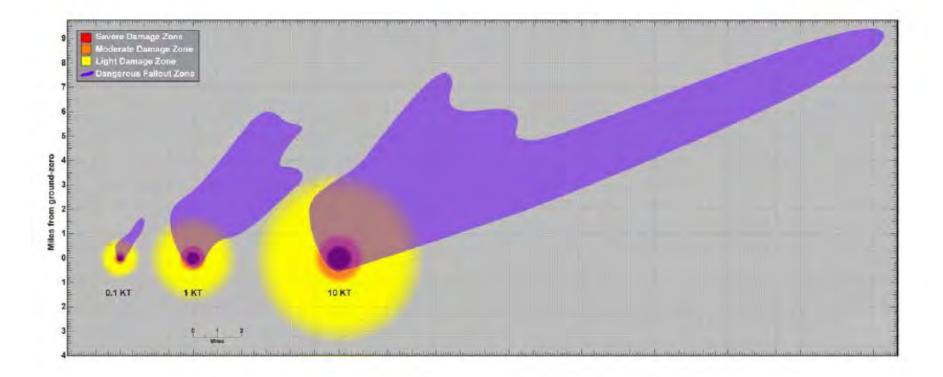


Figure 1.6: Representative dangerous fallout (DF) zones for 0.1KT, 1.0KT and 10 KT in which an early and direct threat from fallout radioactivity exists. A radiation *exposure rate* of 10 R/h is used to bound this zone. The DF zone will begin to shrink immediately and decrease relatively quickly over time.

ASPR: Resilient People. Healthy Communities. A Nation Prepared.



Radiation Syndromes:

Management depends on dose, which is manifest in organ dysfunction!



Acute Radiation Syndrome (ARS) and Delayed Effect of Acute Radiation Exposure (DEARE)

- Continuum of injuries- Multi-organ injury
- Time to clinical manifestation depends on organ system and dose
- Phases: Prodrome →Latent → Manifest < There is time

Organ syndromes

- Hematological (>2 *Gy)
- Gastrointestinal (>6 Gy)
- CNS/Cardiovascular (>10 Gy)
- Cutaneous (>6 Gy)
- Combined injury

few days to 2 months

few days to a week

immediate

few days to weeks

immediate

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Distribution of casualties from



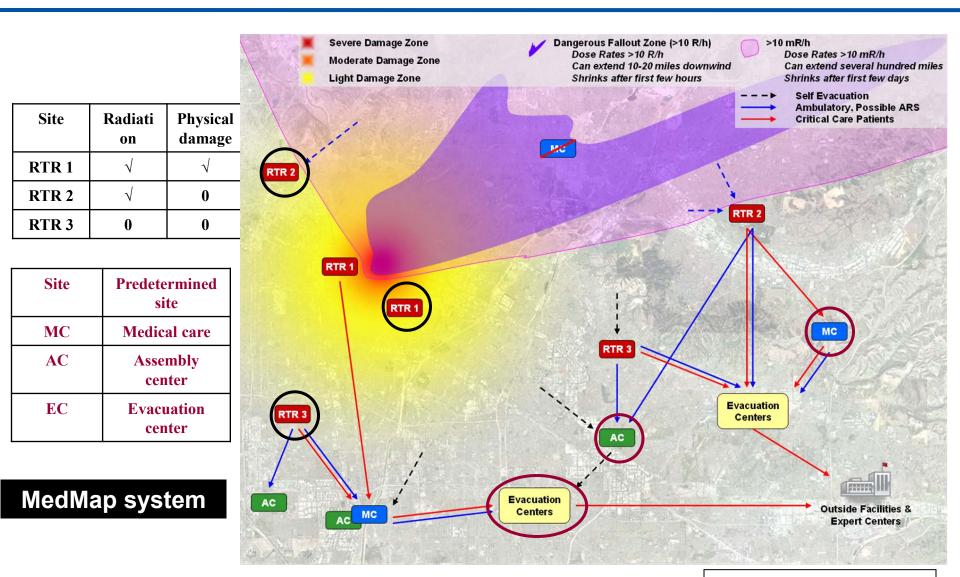
BUILT SERVICES Nuclear Detonation modeling (from a series of models) (from a series o

Injury	Category	Composite			
Туре		50%ile	85%ile	95%ile	
Trauma (ISS Score)	Mild (1-9)	20,000	53,000	80,000	
	Moderate (10-14)	34,000	118,000	121,000	
	Severe (>15)	14,000	63,000	143,000	
Radi-ation (Dose in Gy)	Mild 0.75-1.5 Gy	4,000	23,000	72,000	
	Moderate 1.5-5.3 Gy	6,000	25,000	41,000	
	Severe 5.3-8.30 Gy	3,000	6,000	12,000	
	Expectant >8.30 Gy	5,000	16,000	47,000	
Com- bined Injury (Rad Dose > 1.5 Gy)	Trauma and/or Burn (Mild – Severe)	2,000	20,000	45,000	

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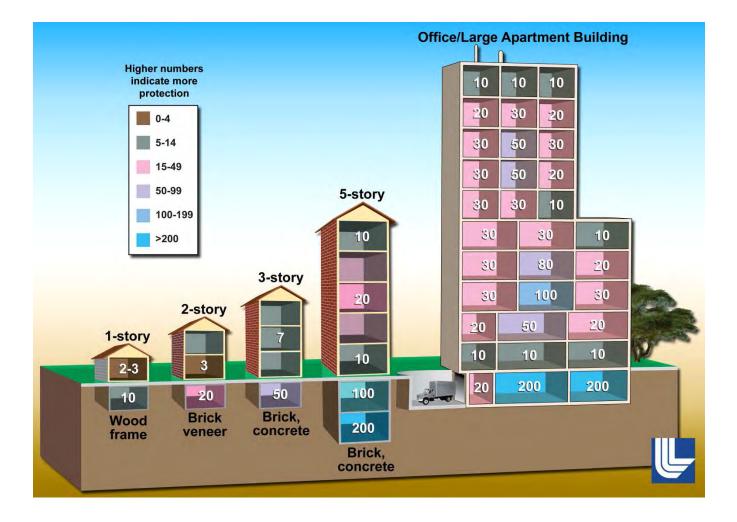
BARDA modeling, & Casagrande, Buddemeier

Structural, radiation and medical response ASSISTANT SECRETARY FOR zones (based on situational awareness)



ASPR: Resilient People. Healthy Communities. A Nation P Hrdina, Coleman, Knebel

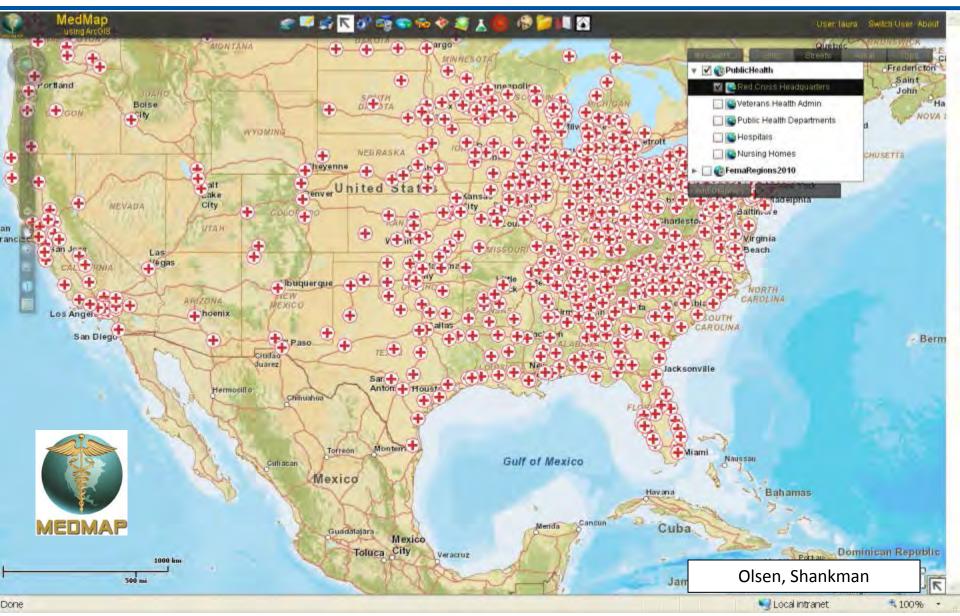
Building protection factors: Shelter-in-place for early hours



Buddemeier et al



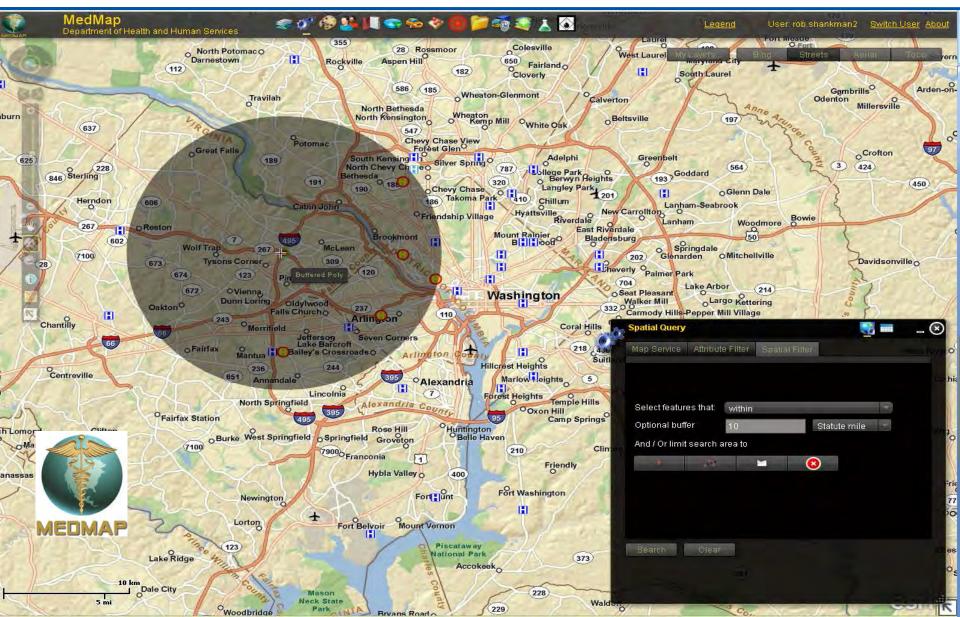
MedMap- Multiple Layers and Tools ASSISTANT SECRETARY FOR Rapid Situational Awareness





Spatial Queries





U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

RADIATION EMERGENCY MEDICAL MANAGEMENT

Guidance on Diagnosis & Treatment for Health Care Providers

REMM



WHAT KIND OF EMERGENCY?

INITIAL EVENT ACTIVITIES

PATIENT MANAGEMENT TOOLS & GUIDELINES

WHAT KIND OF EMERGENCY?

- Radiological Dispersal Devices: Dirty Bomb, Other Dispersal Methods
- Radiological Exposure Devices: Hidden Sealed Source
- Nuclear Explosions: Weapons, Improvised Nuclear Devices
- Nuclear Reactor Accidents
- Transportation Accidents
- Discovering an Event

INITIAL EVENT ACTIVITIES

- Onsite Activities
- Triage Guidelines
- Hospital Activities

OTHER AUDIENCES

- First Responders in the Field
- Mental Health Professionals
- Hospitals
- Public Information Officers
- Radiation Safety and Protection
- Preplanning
- Practices and Drills
- Pet Owners

ABOUT THIS SITE

- What Are the Goals of This Site?
- Who Produced This Site?
- Disclaimers
- List of Consultants
- Join the REMM ListServ
- Contact us: Provide Site Feedback
- Download REMM to Your Computer/Mobile Device
- System Requirements: Allow Pop-ups, Download Adobe Reader®, more ...

PATIENT MANAGEMENT

- Choose Appropriate Algorithm: Evaluate for Contamination/Exposure
- Contamination
- Exposure (Acute Radiation Syndrome)
- Exposure + Contamination

MANAGEMENT MODIFIERS

- Radiation + Trauma Burn Triage and Treatment
- Mass Casualty
- Psychological Issues
- Specific Populations

TOOLS & GUIDELINES

- Dose Estimator for Exposure
- Template for Hospital Orders
- Use of Blood Products
- Follow-up Instructions
- Population Monitoring
- Management of the Deceased
- Develop a Radiation Response Plan .
- Equip an Emergency Department for Decontamination

REFERENCE/DATA CENTER

- Training and Education
- Dictionary
- Animations, Illustrations, Photos 10
- Emergency Contacts 28
- Abbreviations
- Understanding Radiation
- Sources of Radiological/Nuclear Info

REMM.nlm.gov

FEATURES

SEARCH

- Planning guidance for response to a nuclear detonation, 1/2009 (Homeland Security Council)
- Population Monitoring in Radiation Emergencies: A Guide for State and Local Public Health Planners, 8/2007 (HHS/CDC)
- Medical Countermeasures Against Radiological and Nuclear Threats (NIH/NIAID)

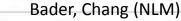
QUICK LINKS

- New Users: Where Do I Start?
- What's New on REMM
- Patient Management Algorithms 協議
- Print Algorithms & Tables
- Isotopes of Interest
- Countermeasures
- Decontamination Procedures
- Dose Estimator for Exposure
- Manage ARS Subsyndromes
- Multi-organ Dysfunction Syndrome
- Cutaneous Radiation Syndrome
- Time/Dose Effects in ARS
- Time Phases of ARS.
- Strategic National Stockpile
- Animations, Illustrations, Photos I
- Dictionary
- Emergency Contacts 2
- Download REMM (6/2009) 4
- Download Mobile REMM (6/2009)

OTHER WEB RESOURCES

MEDICAL MANAGEMENT **GUIDELINES**

Just-in-time, user-friendly





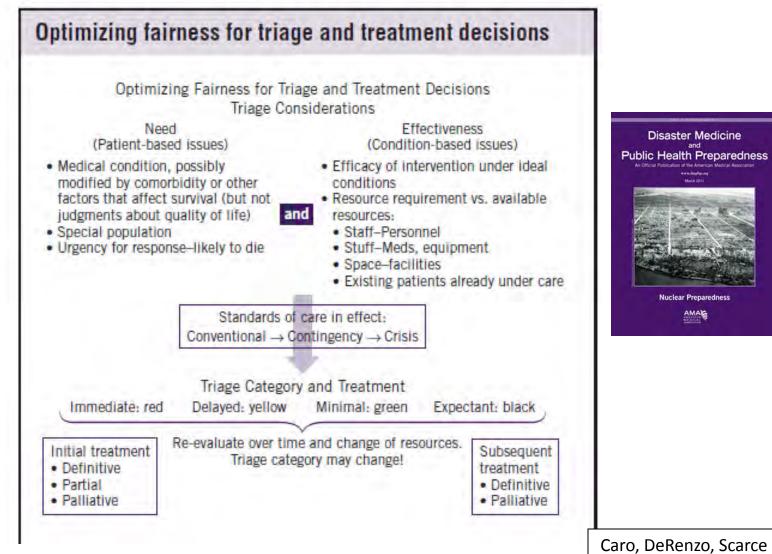
Judy

Bader



Overarching ethical principal for triage: Fairness

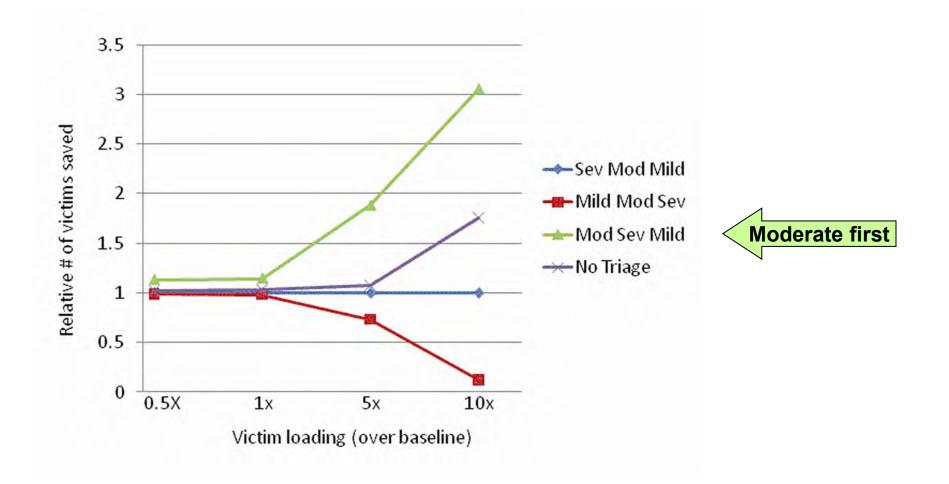




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Caro, DeRenzo, Scarce Resources project

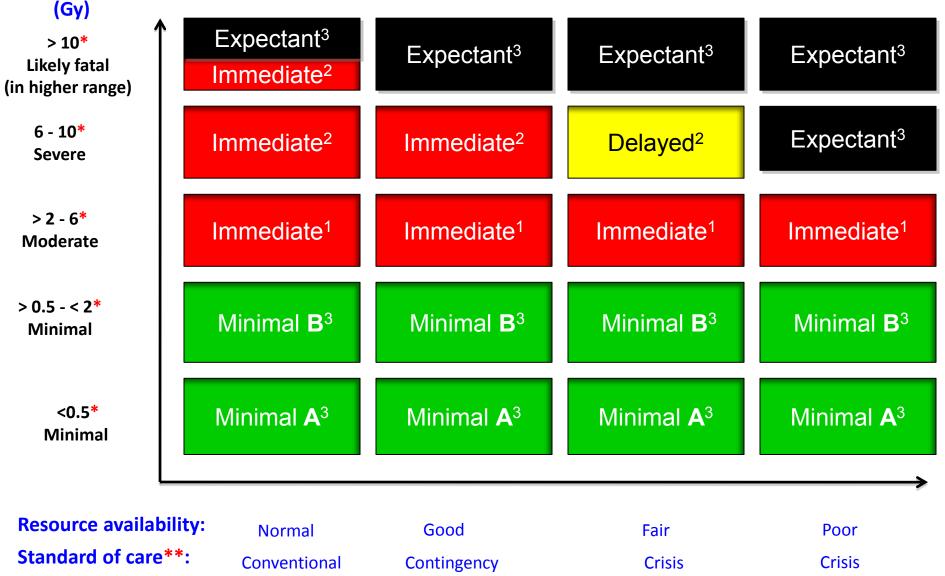




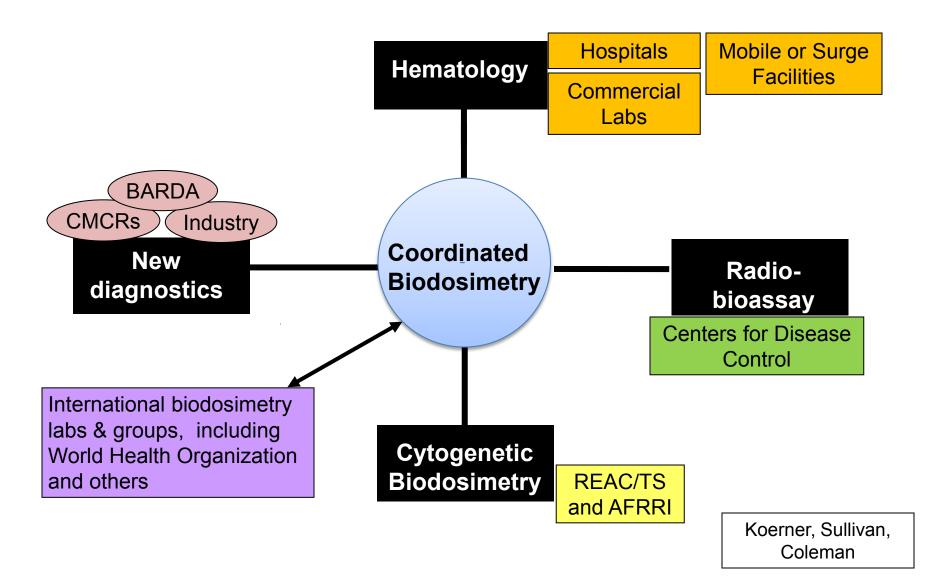
ASPR: Resilient People. Healthy Communities. A Nation Prepared.

Casagrande

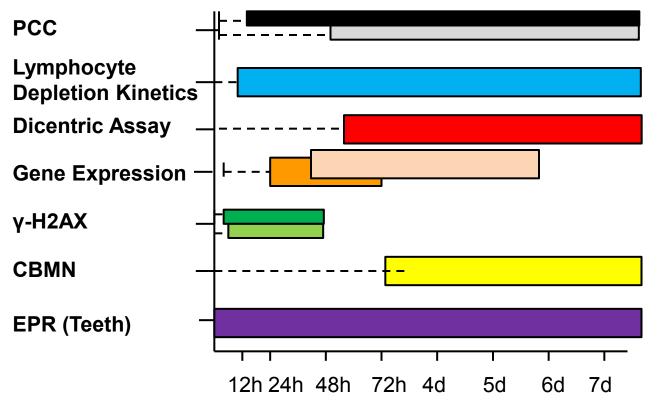
Triage category affected by radiation dose and resource availabilityRadiation Dose*RADIATION ONLY



What dosimetry methods could be used today and where are they located?



Comparison of retrospective dosimetry assays -Time assays give results

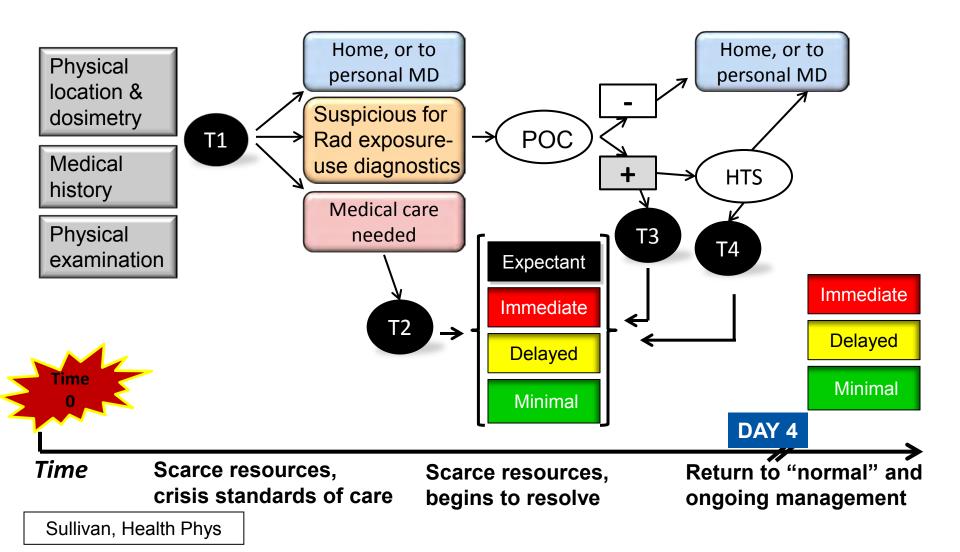


Time after detonation

--Time for sample preparation and analysis

Sullivan, Health Phys

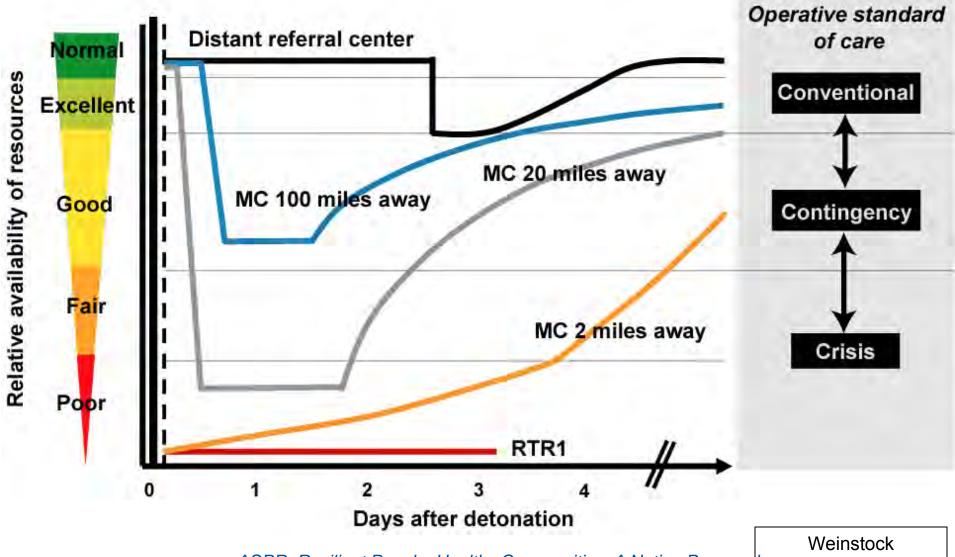
Incorporation of medical triage model with coordinated biodosimetry model



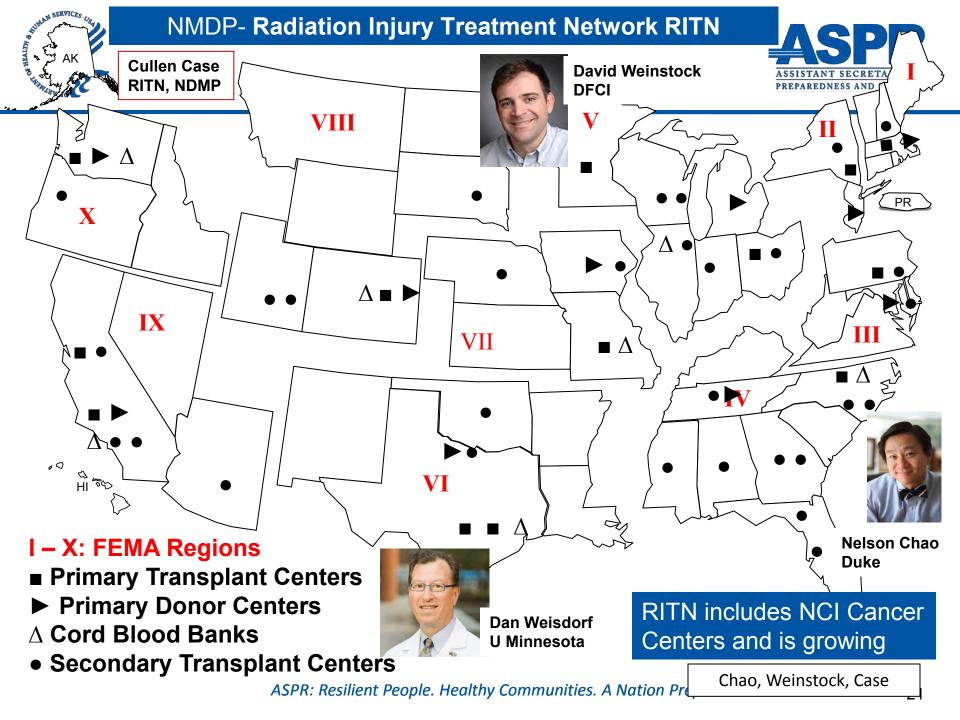


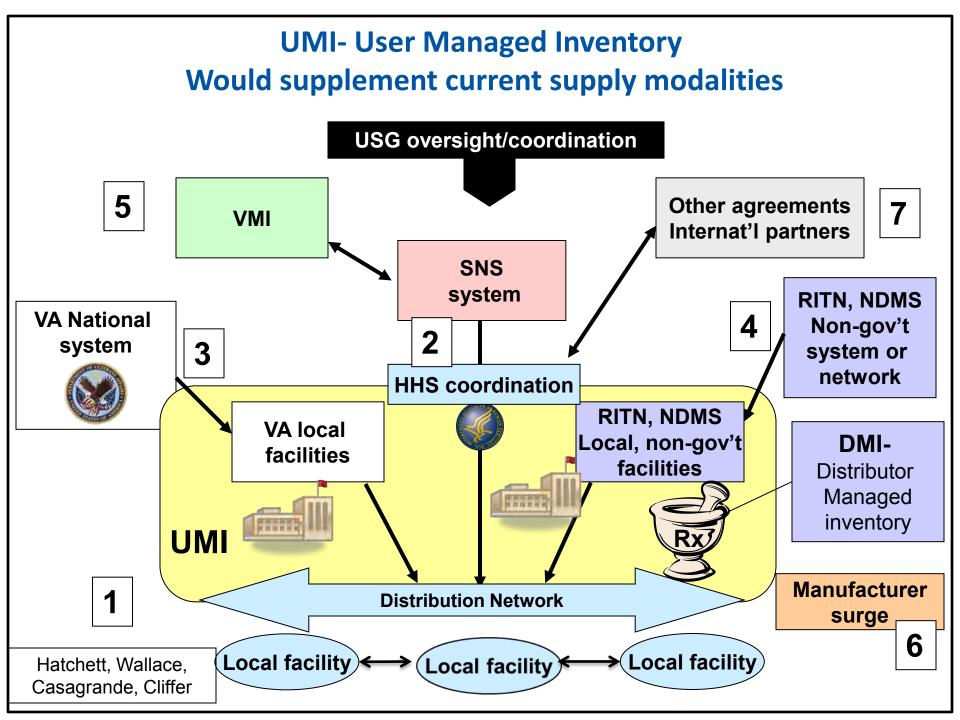
Standards of care will vary by location and time after incident





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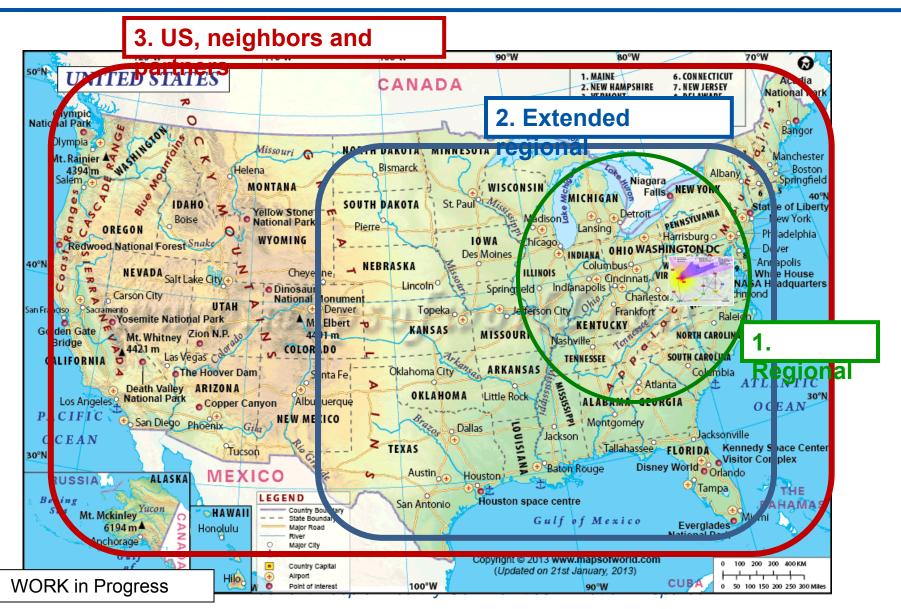




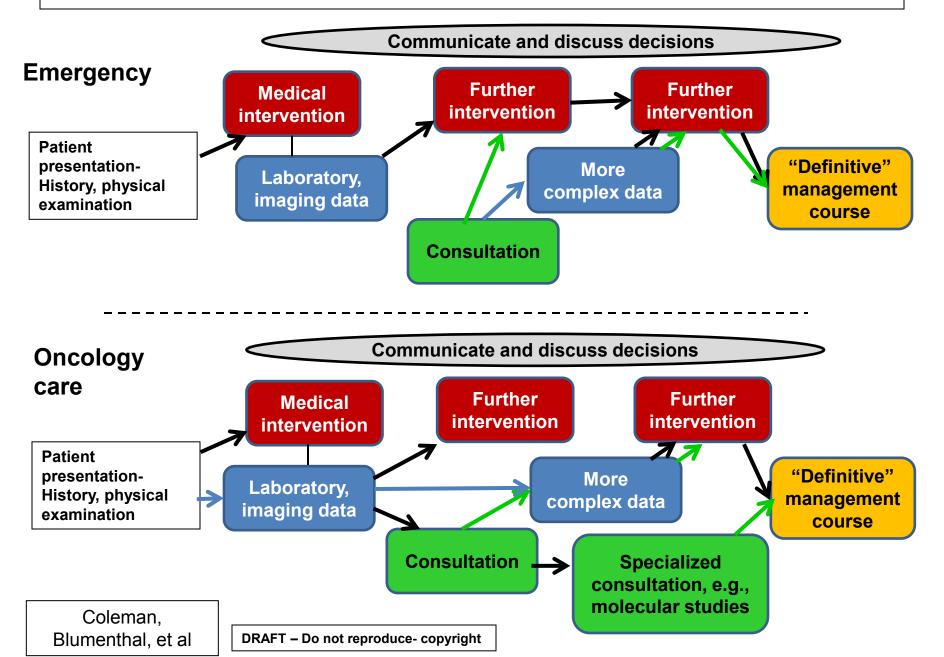


Expanded CONOPS for IND response (For any mass casuality- "MedMap 3.0"

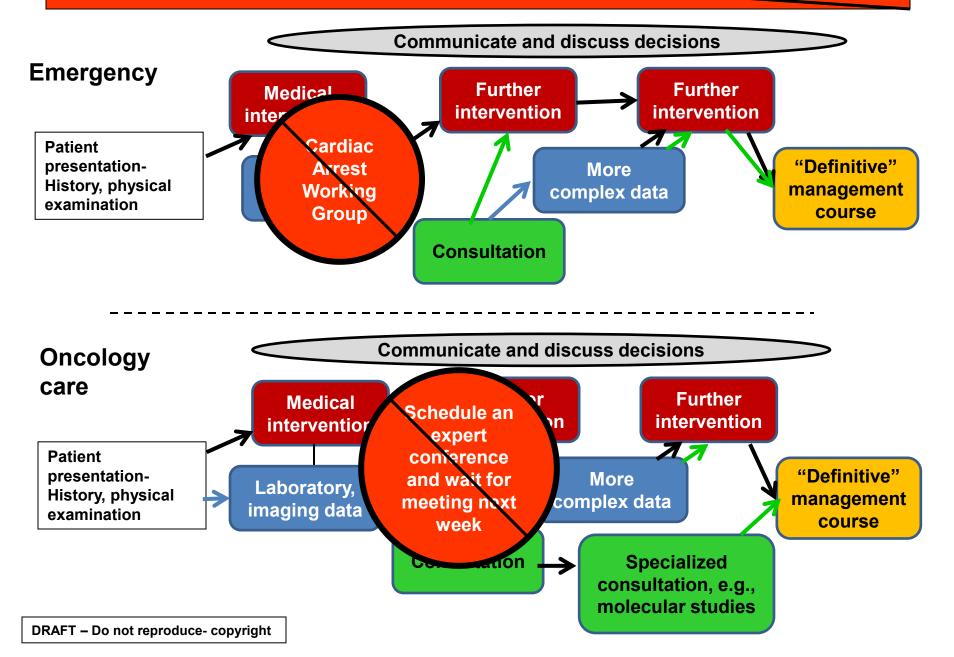




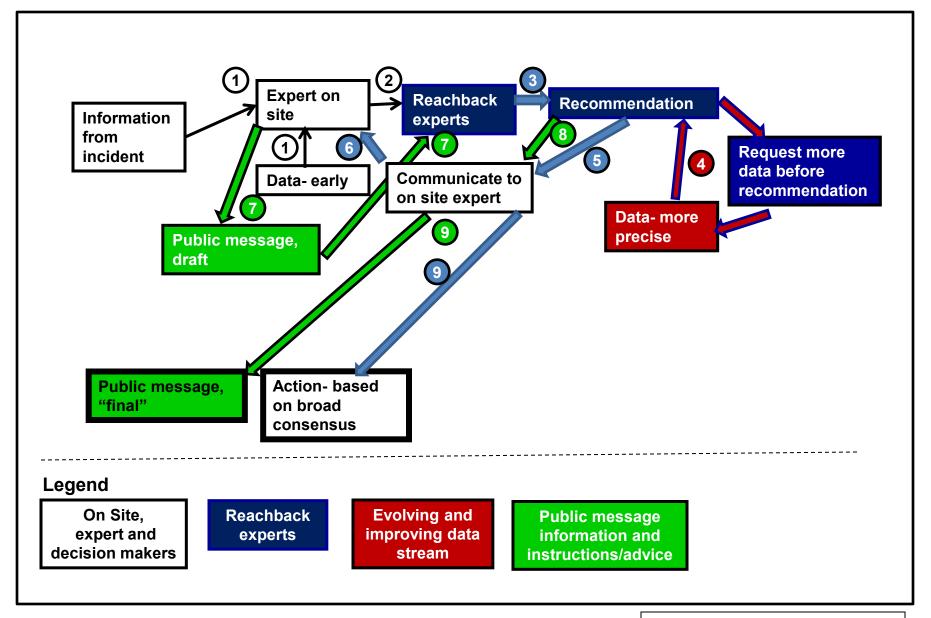
Medical decision process, in urgent setting



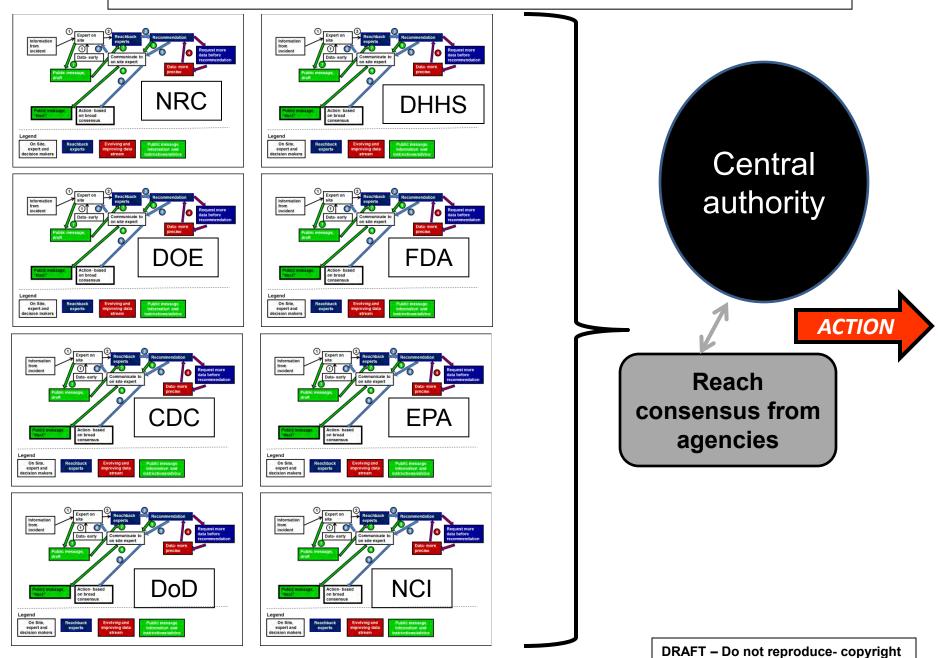
Medical decision process, in urgent setting



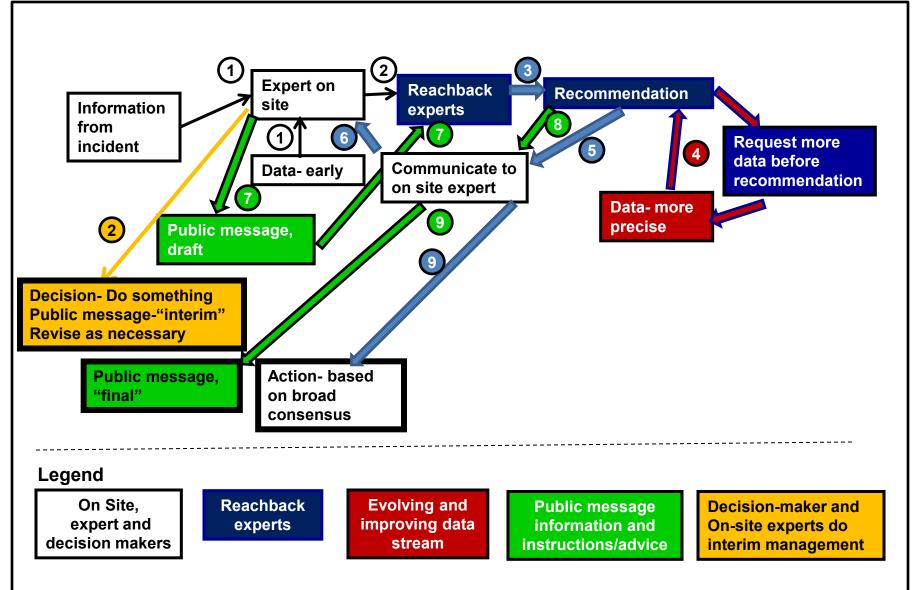
Agency decision and communication process (example)

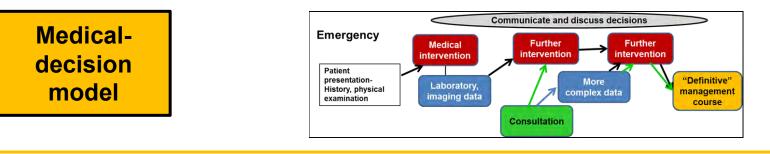


Coordinate advice and message all agencies (8 or more)

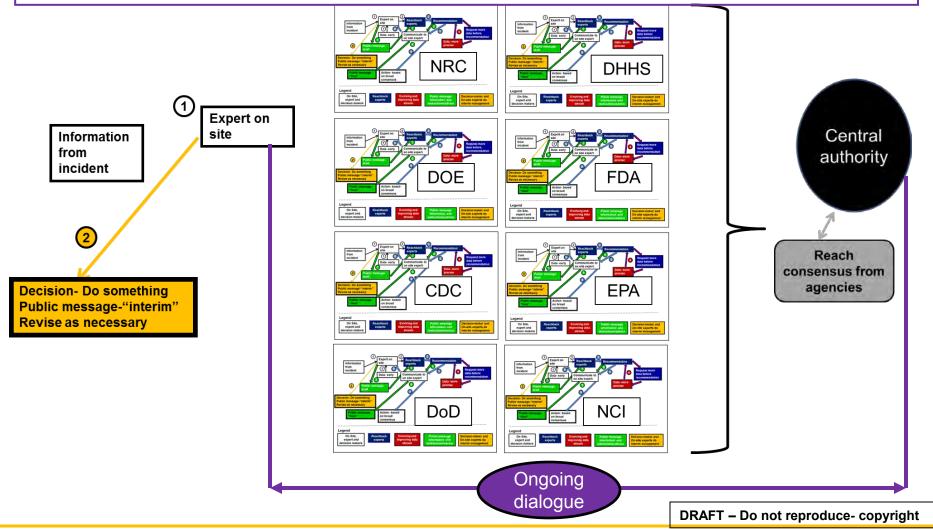


Agency decision and communication process with interim decisions made "on-site" (example)





Incident managed on site --- ongoing agency advice --- revised & final decisions



A Practical Guide for Decision-makers

U.S. Department of Health and Human Services Assistant Secretary for Preparedness and Response

Medical Planning and Response Manual for a Nuclear Detonation Incident:

A Practical Guide for Decision-makers

DELIBERATIONAL DRAFT - DO NOT CITE

March 2013

Provides a common baseline in understanding for various allied response disciplines from senior operational responders, to emergency managers, public health advisors and leaders, and local, State, and Federal executives

> Koerner, Murrain-Hill, Sullivan, Coleman

















- Cancer risk
- Low vs higher vs really high dose
- Cancer care
- Molecular targets
- Immunological effects
- Radio-protectors
- Medical radiation
- Prevention
- Screening, susceptible populations
- Terrorism- intentional exposure

- Carcinogenesis
 mechanisms
- Tissue injury
- Stress response
- Adaptive response
- HZE particles
- Particle therapy
- Biomarkers/ diagnostics
- Environmental exposure, food
- Industrial accidents
- Industrial exposure







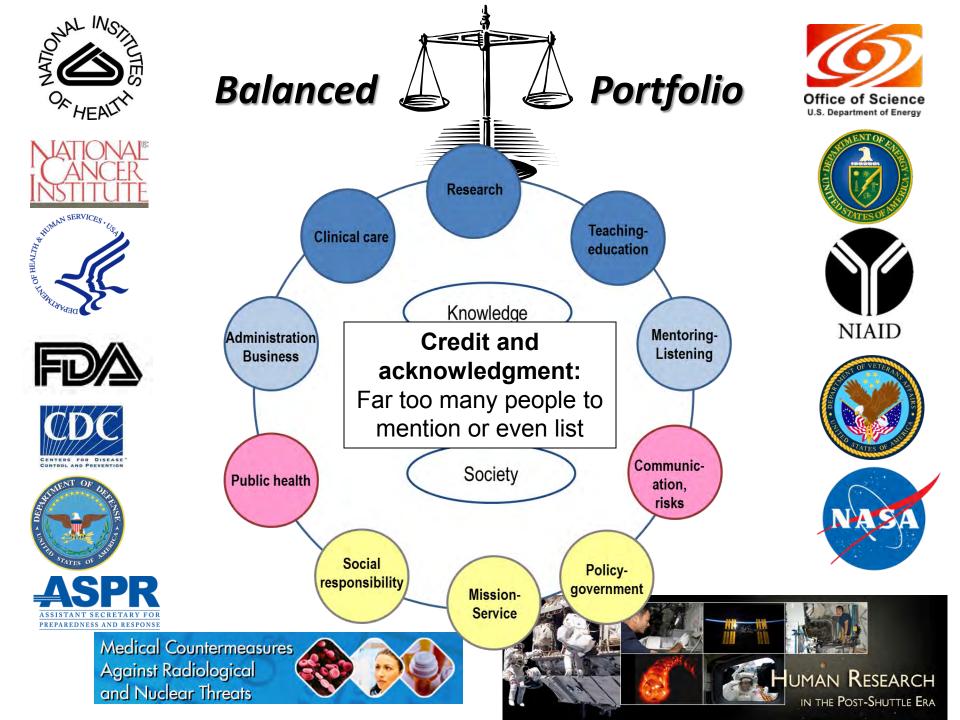




Creating new models and overall "systems" approach

- **REMS** (integrated systems approach to nuke/rad)
- Improve IND models (work with BARD, Nat'l labs- more realistic models)
- Nuclear Detonation Planning Guidance (zoned approach to response across government)
- Civilian playbook (specific to civilian health emergency response planners)
- **REMM, CHEMM** (just-in-time tools in the hands of responders)
- Novel triage algorithms (Scarce Resources- ethical models)
- **MedMap** (GIS based planning and incident management; new- MedMap 3.0national CONOPs planning and response capability)
- RTR System (exposure-based medical response)
- User-Managed Inventory (new concept local/regional hospitals, RITN)
- **Dual-utility** (emphasize agents/diagnostics that also have routine use)
- **RITN** (Radiation Injury Treatment Network- working with academic network)
- Radiation Laboratory Response Network (LRN for rad)
- Novel biodosimetry and medical countermeasures (based on molecular biology and radiation biology- point of care and high throughput)
- International collaborations (working across borders and regulations)
- Medical-decision incident management model (novel approach- uses expert reach-back but avoids "paralysis by analysis"
- Decision-makers guide (novel tools for local authorities to manage)

DRAFT – Do not reproduce- copyright



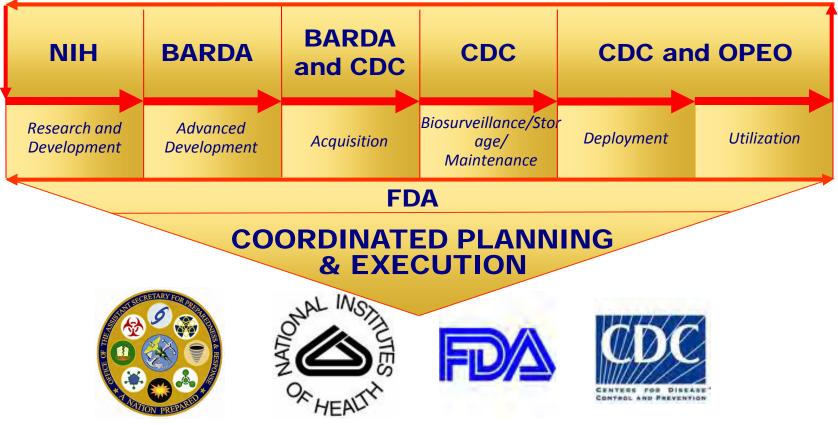


HHS Public Health Emergency Medical Countermeasures Enterprise Science based: Content & Process



Science \rightarrow Products \rightarrow CONOPS \rightarrow Playbooks \rightarrow Diagnosis & Treatment Tools \rightarrow Network of SMEs \rightarrow Constant improvements

Goal- When disaster hits- we help you with "WHAT DO I DO!!!"



ASPR: Resilient People. Healthy Communities. A Nation Prepared.

Decision Making for Late-Phase Recovery from Nuclear or Radiological Incidents (*What's Next After the First Responders Have Left?*)

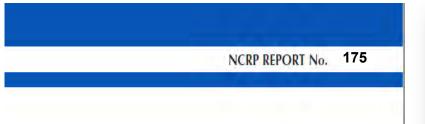
NCRP Fiftieth Annual Meeting

NCRP: Achievements of the Past 50 Years and Addressing the Needs of the Future

> Bethesda, MD March 10, 2014

S.Y. Chen, Ph.D., CHP Illinois Institute of Technology Chicago, IL







S.Y. Chen, *Chairman* **SC 5-1** Illinois Institute of Technology,

In 2008, DHS issued Protective Action Guides (PAGs) for Radiological Dispersal Device (RDD) and Improvised Nuclear Device (IND) incidents, providing recommendations for protection of public health in the early, intermediate, and late phases of response to an RDD or IND incident.

The current Report, expanded to include nuclear reactor accidents, provides a basic framework and approaches to implementing and optimizing decision making during late stage recovery for large-scale nuclear incidents.

DECISION MAKING FOR LATE-PHASE RECOVERY FROM NUCLEAR OR RADIOLOGICAL INCIDENTS

2014



SC 5-1: Decision making for late-phase recovery from nuclear or radiological incidents





Standing: B Buddemeier (LLNL), J MacKinney (DHS, Consultant), M Noska (FDA, Consultant), D Allard (PA, Advisor), A Wallo (DOE), K Kiel (Holy Cross), J Edwards (EPA, Advisor), A Nisbet (HPA, Advisor), J Cardarelli (EPA, Consultant), D Barnett (JHU), & S Frey (Staff Consultant)
Seated: V Covello (CRC), SY Chen (IIT, Chairman), H Grogan (Cascade, Advisor), J Lipoti (NJ), & D McBaugh (Dade Moeller)

Radiological and nuclear incidents involving terrorism: RDDs and INDs

Potential Sources:

- Radiological Dispersal Device (RDD) refers to any method used to deliberately disperse radioactive material in the environment in order to cause harm.
- Improvised Nuclear Device (IND) refers to any device incorporating radioactive materials designed to result in a nuclear explosion.



Recent nuclear accident at Fukushima, Japan presents a serious challenge to response



An earthquake initiated a series of events leading to Fukushima nuclear accident in 2011.

Accident at the Fukushima Nuclear Power Station

Report 175 expanded from terrorist events to include nuclear power plant accidents since the Fukushima accident of 2011.

Although health effects from Fukushima are minor the economic impacts have been devastating

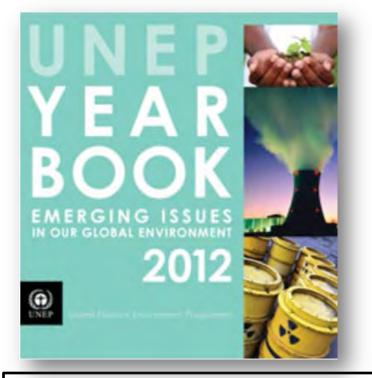


Health risk assessment

from the nuclear accident after the 2011 Great East Japan Earthquake and Tsunami based on a preliminary dose estimation



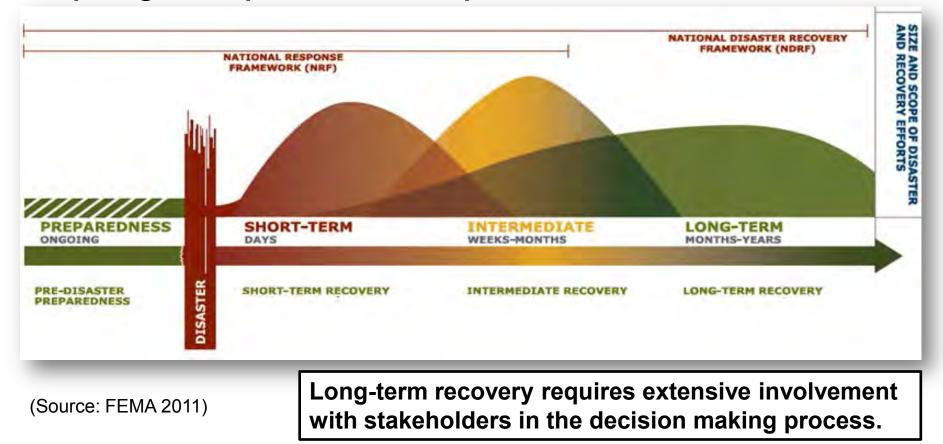
"With respect to Japan, this assessment estimates that the lifetime risk for some cancers may be **somewhat elevated above baseline rates** in certain age and sex groups that were in the areas most affected" (WHO 2013)



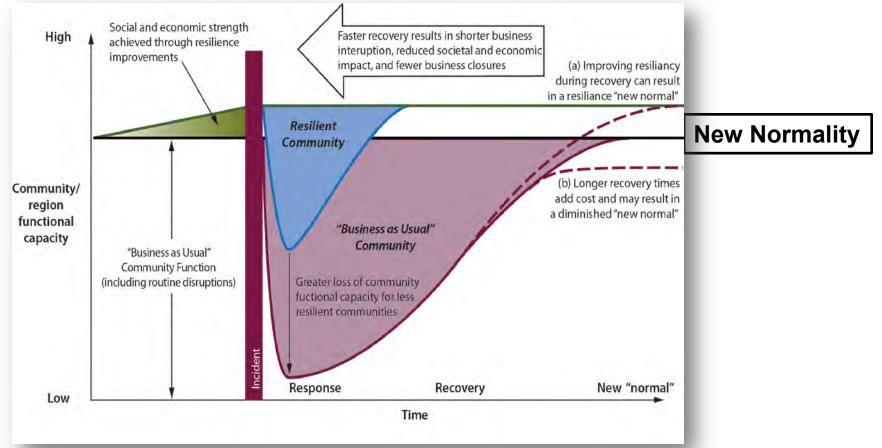
"With huge economic damage, this event is considered not only tragic in terms of its human toll; it is the *most economically devastating disaster in history*" – United Nations Environmental Programme (UNEP 2012).

All responses culminate in long-term recovery

Preparing for response in various phases:



Late-phase recovery: a challenging journey back to new normality



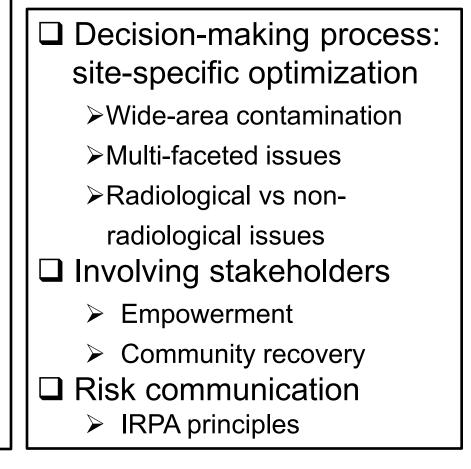
Model: Dr. Mary Ellen Hynes, DHS (2001); Blair Ross, ORNL; CA RRI 2008 ©

Recovery from a nuclear or radiological incident is contingent on proper remediation of contamination (Source: NCRP).

Late-phase recovery: major issues in wide-area radiological contamination

Recovery considerations

- Local economic viability
- Major infrastructures
- Repatriating displaced populations
- Returning to a "*new normality*" in the most expedient manner
- Remediation strategy
 - Future land uses
 - Priority of remediation
 - Resources and technology



Late-phase recovery: addressing a broad scope of issues

□ DHS PAG Guidance (2008) (Updated PAGs pending from EPA)

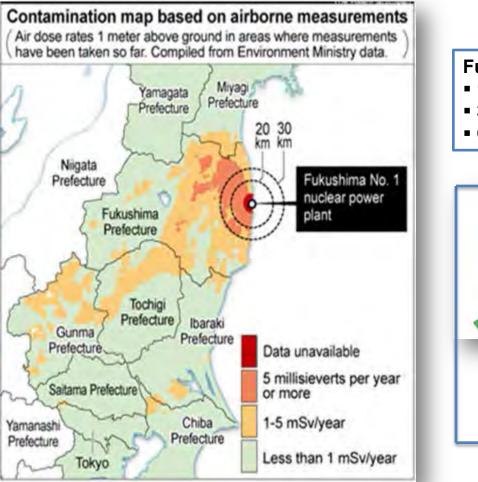
- An "optimization" process in lieu of a pre-determined Protective Actions Guideline (PAG)
- Existing statutory processes as starting point
- **G** Further
 - Long-term potential *health consequences* are not the only consideration
 - Other priority issues include the *local economy, employment, critical infrastructures, public services* which demand urgent attentions
 - Decisions toward cleanup require careful deliberation through the **optimization process** for competing priorities of the society
 - Stakeholder is an integral part of the decision-making process

Optimization: a key principle to radiation protection

Radiation protection principles: Justification, Optimization and Protection of Individuals (ICRP)

The **principle of optimization** requires that, the likelihood of exposure, the number of people exposed, and the magnitude of individual doses "should all be kept as low as reasonably achievable, *taking into account economic and societal factors...*" (ICRP 2007)

Addressing wide-area contamination: the unprecedented impacts



- Fukushima cleanup level at 1 mSv/y:
- 13,000 km², or
- 3% of Japan's land mass,
- Costs at \$15.6 B



State of Connecticut

(Contamination area near Fukushima. Source: The Asahi Shimbun 2011)

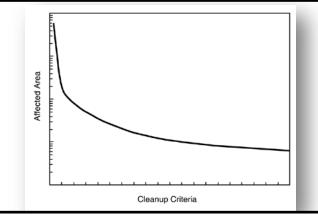
Weighing the difficulty options: cleanup vs. waste generation



Estimated radioactive waste volume from cleanup of nearby prefectures surrounding Fukushima NPP is 29x10⁶ m³, or about 1 billion ft³. This *has exceeded* the US commercial LLW disposal capacities combined. Some *adaptive management strategy* is needed.



Temporary storage of contaminated material - examples from clean-up demonstration tests



Waste volume is *directly proportional* to the rigor in cleanup.

(Source: ICRP 2012)

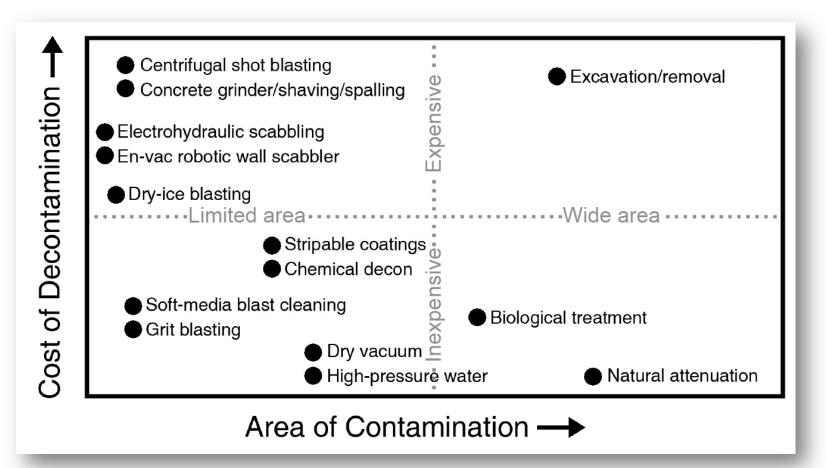
Recovery requires adaptation of technology to various contamination situations



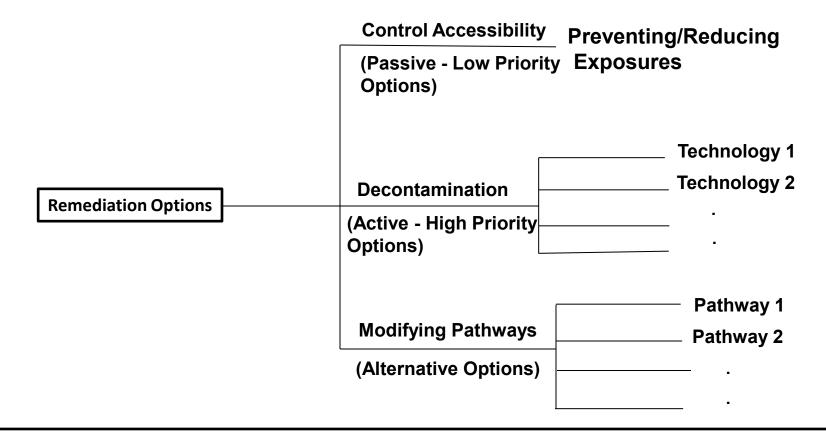
High pressure water cleaning of Mowing and removal of sludge paved road

Removal of crushed stones and topsoil, and cover with clean soil

Existing technology may not adequately address the remediation needs



Various remediation options support optimization approach for managing long-term exposures



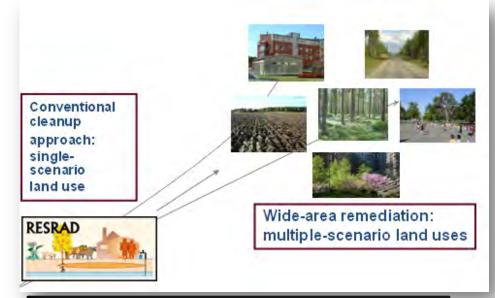
Dose reduction takes many forms in remediation strategy: from *passive approach* to active cleanup to help achieve an optimized result (Source: NCRP).

A new paradigm in remediation: site-specific optimization

Addressing wide-area remediation:

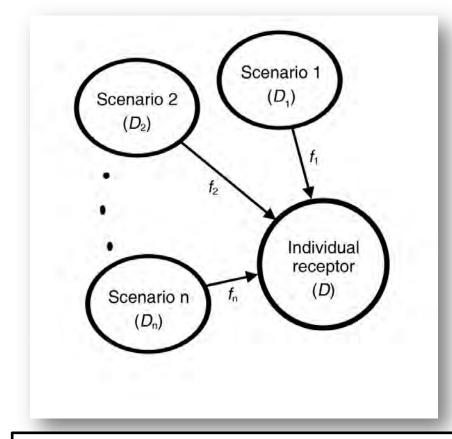
- A departure from conventional cleanup approach
- Complex decision making with iterative, graded approach in environmental remediation
- Remediation also entails effective deployment of applicable technology
- Realism vs conservatism
- Cost-benefit analysis, plus other factors, play a vital role in optimizing decision making

Wide-area issues: *individual dose* vs *multiple exposure scenarios*



The optimization approach aims at dose reduction through long-term management strategy.

Individual dose involves multiple land-use exposure scenarios



A challenge to the concept of *critical group:* an individual-related exposure from multi-scenarios with contamination.

$$D = \sum_{i} f_i x D_i$$

- D = dose received by the individual receptor
- f_i = occupancy frequency for Scenario i
- D_i = dose received for Scenario i
 - = function (contamination
 level, pathways)

It must be recognized that dose assessment should account for *elevation* of *background radiation*.

Risk communication: essential for gaining trust from stakeholders

- Risk communication is as important as the risk assessment itself.
- Even when radiation doses are low, risk communication and outreach are essential to help the public, media, authorities.
- Scientists must be willing to communicate their work to other scientists, regulators, and the public.
- Be available
- Town meetings
- Focus Groups
- Dialogues
- Engage, Empower



Partnering with stakeholders in decision making



Active participation by stakeholders is an absolute necessity throughout the late-phase recovery process.

In preparing for response to large scale catastrophes, the U.S. Federal Emergency Management Agency (FEMA) began to develop a concept that involves the "*whole community*" in the response effort.

(Source: NCRP)

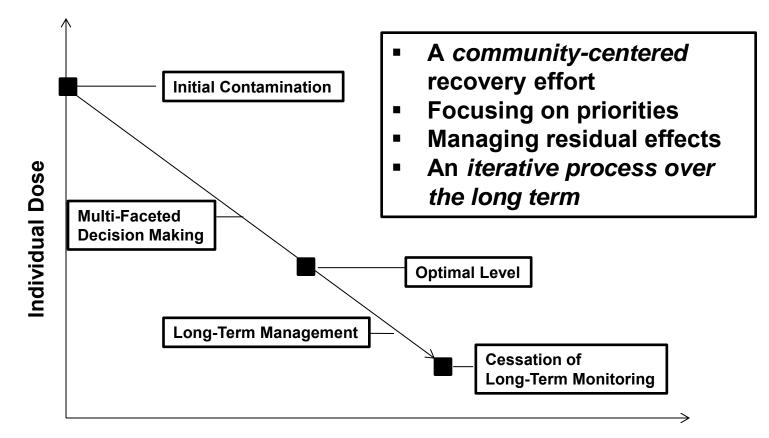
Long-term recovery: monitoring the residual impacts

Population Monitoring

Controlling Residual Contamination



Optimization: a strategy that includes long-term monitoring and management



Time of Late-Phase Recovery

Summary and highlights (1)

A decision for late-phase recovery may involves multi-faceted issues

- A major nuclear or radiological incident may cause widespread contamination in affected areas
- An expedient recovery is predicated by effective and timely remediation
- Remediation may involve highly complex societal issues that warrant a *deliberate, comprehensive decision process*
- Site-specific optimization requires a flexible, adapted and *iterative approach*
 - Policies must be conducive to addressing the community needs
 - Facilitating expedient remediation with careful planning and ample resources
 - Avoiding strict approach to bringing the community back to normality (one cannot "*regulate*" an incident)

Summary and highlights (2)

□ Recovery effort must focus on the community

- It requires a "whole community" effort to achieve effective recovery
- A collective decision to return the community to a "*new normality*" following recovery
- Stakeholder must be representative and is also empowered throughout the decision making process
- Effective communication is essential to facilitate a well coordinated recovery effort based on consensus

□ Late-phase recovery entails a long-term process

- It takes a well planned management strategy to address issues in widespread contamination
- Remediation requires an approach that includes *long-term* monitoring and management of residual contamination

Summary and highlights (3)

- Preparing for or responding to a major incident entails broad base knowledge and a continuous learning process
 - Developing broad knowledge base by learning lessons from the past incidents
 - Continuously keeping vigilance and accumulating experience by conducting exercises/drills against potential incident scenarios
 - Identifying knowledge gaps such as in remediation technology and conducting necessary research and development
 - Developing a *global information repository* for the latephase recovery

Thank You!

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Radiation Safety of Sealed Radioactive Sources

Kathryn H. Pryor, CHP Chair, PAC-2 Operational Radiation Safety

March 10, 2014

Sealed Sources – Perception and Reality

- What do you think of when you hear the term "sealed source"?
 - Radioactive material double-encapsulated in stainless steel?



• PAC-2 Sealed Source Report

Sealed Sources – Perception and Reality

• An Industrial Radiography camera?



• A well-logging source?



Sealed Sources – Perception and Reality

How about a check source?



• A vial containing radioactive material?



An electroplated alpha source?



Sealed Sources – Perception and Reality

How about a mylar-covered source?



What Exactly is a Sealed Source?

- Sealed source definitions vary
 - NRC definitions encased in a capsule designed to prevent leakage or escape
 - DOE definition contained in a sealed capsule, sealed between layer(s) of non-radioactive material, or firmly fixed to a non-radioactive surface by electroplating or other means intended to prevent leakage or escape
 - ANSI-HPS/ISO definition sealed in a capsule or having a bonded cover, the capsule or cover being strong enough to prevent contact with and dispersion of the radioactive material under the conditions of use and wear for which it was designed.

Definitions

- Common element
 - Sealed, encapsulated, or otherwise fixed to preclude release of radioactive material under conditions of intended use
- Differences are in the degree of "sealing"
 o Encapsulation, bonded cover, fixed in a matrix, electroplated onto a substrate
- Consider conditions of intended use

 Environmental conditions temperature, pressure
 Mechanical conditions vibration, shock, puncture

Standards - Source Classification

- ANSI/HPS N43.6-2007 and ISO 2919:1999
 - Establish classification system (Class 1 to 8) based on test performance; specify general requirements, performance tests, production tests, marking and certification
 - Performance test criteria for temperature, external pressure, impact, vibration, puncture, bending
 - The ability to meet performance criteria does not mean that the source will maintain its integrity if continuously exposed to the maximum rated conditions over time

Common Perspective

- "Sealed source mindset"
 - The term "sealed source" implies a certain robustness of design and construction
 - More concerned with external radiation hazards during normal use
 - Lack of understanding of source/device design
 - Loss of integrity and spread of contamination is not expected



Issues

- Sealed sources can cause problems if they are lost, stolen and/or damaged
 - External radiation hazards some high activity sources can cause injury or death
 - Leakage or failure can cause spread of contamination
 - In the hands of the wrong people, could be used in terrorist activities
- Sealed sources don't have to be high activity sources to cause major headaches
 Failure of relatively "small" sources can result in significant contamination spread

Generally Licensed Sources/Devices

- Manufactured and distributed under a specific license; used under a general license
 - Examples include tritium exit signs, industrial gauges, gas chromatographs, smoke detectors, in vitro test kits
- Industrial GL devices regulated under 10 CFR 31.5 (e.g. detecting, measuring, gauging, controlling)
 - Some GL devices can contain fairly significant quantities of radioactive material (e.g., 20 GBq Cs-137; 37 GBq Am-241)
 - Requirements for leak testing, shutter testing, transfer, records, registration of higher activity devices



• PAC-2 Sealed Source Report





Generally Licensed Devices

- Problems -
 - \circ No specific license \rightarrow low level of regulatory oversight
 - GLs are expected to report transfer, disposal, leakage, loss or mechanical failure of devices to NRC or states
 - Lack of understanding on the part of the GL's regarding requirements, hazards of devices





Generally Licensed Devices

- Incidents subject of numerous NRC information notices and regulatory issue summaries
 - Contamination events resulting from improper device disassembly (by manufacturers or service providers)
 - o Fixed gauge shutter failures stuck in open position
 - Damage to devices by running over them with trucks
 - Improper disposal leading to spread of contamination
 - o Theft of devices from vehicles



• PAC-2 Sealed Source Report





Industrial Radiography Sources

- Regulated under 10 CFR 34 (and corresponding agreement state regulations)
- Small, high activity sources in shielded cameras; engineered controls to reduce personnel exposure
- Radiographers are required to complete formal training and obtain certification





Industrial Radiography Sources

- Problems
 - Work locations are frequently at temporary job sites
 - Low level of regulatory oversight in the field
 - Radiographers and assistants don't reliably wear their dosimeters; perform required surveys or have functioning audible indicators on survey instruments
 - Sources can produce very high doses in short amount of time if something goes wrong



PAC-2 Sealed Source Report



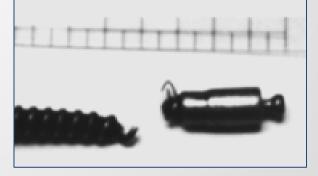
Industrial Radiography Sources

- Incidents –NRC event report database contains many Industrial Radiography-related examples
 - Sources stuck or left in exposed position; equipment damaged; failure to survey; failure to wear dosimeters; failure to inform state or NRC of work in their jurisdiction; failure to secure or maintain control of source
- Accidents many are well known and publicized
 - o Mishandling sources when disconnected or stuck in guide tube
 - Frequently the result of loss/theft of source; end up impacting members of the public



Photos courtesy of REAC/TS (left, center) • PAC-2 Sealed Source Report





"Small" Sources Can Cause Big Problems

- June 2007 PNNL event Failure of in-house fabricated Pu-238 source
- Contaminated three workers, two adult family members and one child; two separate buildings, items in two homes; three personal vehicles
- Contamination spread continued for 1 week before discovery
- Workers had visited gas stations, grocery stores, traveled across the state, stayed in hotels and friends' homes, eaten in restaurants, etc.



• PAC-2 Sealed Source Report

A Big Mess

- Final doses from intakes maximum of 3 mSv to worker, 0.3 mSv to family member
- Clean-up generated lots of rad waste

 From homes clothing, bedding; from offices –
 computers, desks, file cabinets
- Contaminated 3 personal vehicles

 Too difficult to fully decontaminate
 Sent to a waste processing vendor





The Culprit: Pu-238 Source

- ²³⁸Pu source 144 MBq (3.9 mCi or 0.2 mg)
- In-house fabrication challenging
 - Electrodeposited thick layer of metallic Zn and ²³⁸Pu on a stainless steel disk; covered with an Al foil, SS washer and sealed with super glue
 - Planned to use source under vacuum in instrument



• PAC-2 Sealed Source Report

Source Configuration

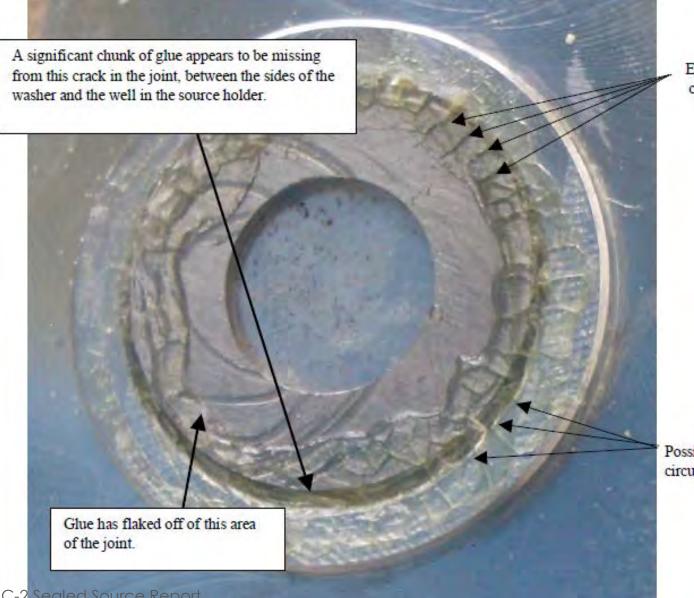
aluminum holder w/well

stainless steel disk Zn/Pu deposition aluminum foil stainless steel washer super glue ~0.7 mm vent hole

Causes

- Source design and fabrication
 - No written/approved design specifications
 - No description of limitations on conditions of use (e.g., temperature)
 - Zn-Pu deposition turned out to be friable over time
- Source was used on a different project by staff unfamiliar with its design
 - Taped face down on a jig for testing
 - Repeatedly cycled to 40 degrees C; not designed for this temperature; super-glue barrier cracked due to thermal expansion mismatch of materials
- Researchers required to perform precautionary contamination surveys at end of source use; not consistently performed due to "sealed source mindset"

Glue Barrier Cracking



Examples of radial cracking

Possible evidence of circumferential cracking

SC 2-7 Sealed Source Report

- Purpose and scope
 - NCRP has previously only provided limited guidance on select aspects of sealed source use or in specific occupational settings
 - Provide "cradle to grave" recommendations on radiation safety aspects of sealed sources and devices
 - Address source use in different occupational settings
- Audience individuals with responsibility for any aspect of sealed source program/use; regulatory authorities



PAC-2 Sealed Source Report

SC 2-7 Sealed Source Report

- Proposed Report Contents
 - o Definitions, categorization
 - o Design, fabrication
 - o Acquisition, receipt
 - Source use general considerations, specific occupational settings
 - Leak testing, inspection and inventory
 - o Transportation
 - o Disposal
 - Special considerations for delicate sources
 - o Emergency Response
 - o Lessons Learned
- Status Currently working on first draft of report
 - Target date for technical peer review Fall 2014
 - Target date for Council review Spring 2015

Members of PAC-2, SC 2-7

- Ed Bailey
- Carol Berger
- Mary Birch
- John Frazier
- Eric Goldin
- Dave Myers

- John Poston, Sr.
- Kathy Pryor
- Glenn Sturchio
- Joshua Walkowicz
- Jim Yusko

James Thompson, Technical Consultant

Radiation Safety in Nanotechnology (Does Size Matter?)

Fiftieth Annual Meeting Program NCRP: Achievements of the Past 50 Years and Addressing the Needs of the Future Bethesda, Maryland

March 10, 2014

Mark D. Hoover, PhD, CHP, CIH

304-285-6374

mhoover1@cdc.gov

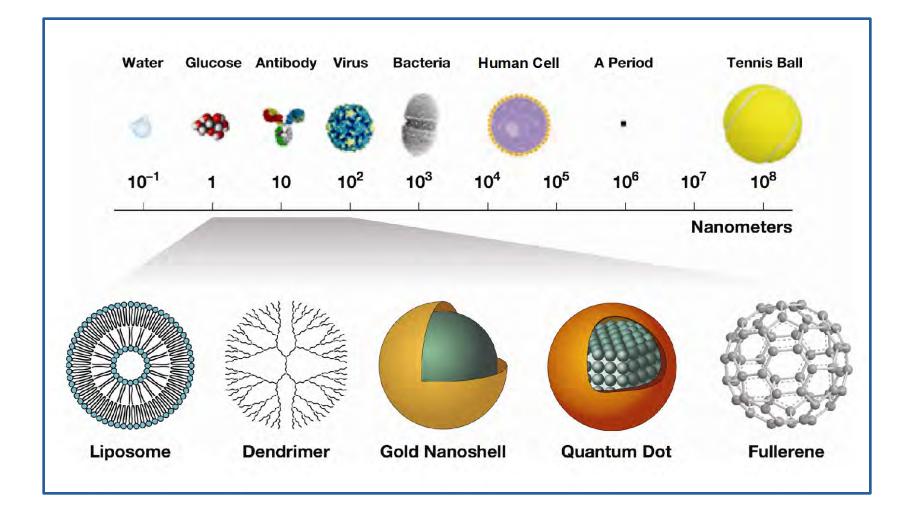
National Institute for Occupational Safety and Health Morgantown, West Virginia

The findings and conclusions in this presentation are those of the author and do not necessarily represent the views of the National Institute for Occupational Safety and Health. Mention of company names or products does not constitute endorsement.

Outline

- Context of the question
- Nanotechnology and radnano
- An informatics approach for the NCRP SC2-6 Report
 - Leaders, cultures, and systems for safety, health, well-being, and productivity
 - Example flaws in decision-making
 - CLEAR communication assessment criteria
 - Relevance and reliability assignment
 - Know versus show alignment
 - Perception versus reality refinement
- Some lessons learned
- The path forward

Relative size of nanoparticles



Nanotechnology

- Definition includes all three of these features:
 - Research and technology development at the atomic, molecular, or macromolecular levels, in the length scale of approximately 1-100 nm.
 - Creating and using structures, devices, and systems that have novel properties and functions because of their small and/or intermediate size.
 - Ability to control or manipulate on the atomic scale.



Myriad nano-enabled products are on the market.



Mercedes-Benz Mercedes CLS-class



Wilson Double Core tennis balls



Eddie Bauer Ruston Fit Nano-Care khakis



ЗМ

3M Adper Single Bond Plus dental adhesive



Smith&nephew

Smith & Nephew Acticoat 7 antimicrobial wound dressing

loda



immuno-suppressant

Wyeth Rapamune

Wyeth*





Kodak EasyShare LS633 camera



NanoOpto subwavelength polarizing beam splitter/combiner

LAUFEN Laufen Gallery washbasin with Wondergliss

SAMSUNG

Samsung Nano SilverSeal Refrigerator

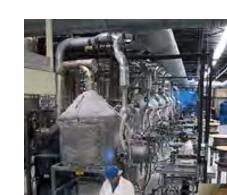




Hummer H2

Nanotechnology: A spectrum of activities













Many similarities to nuclear industries

Some involve other sources of ultrafine aerosols.



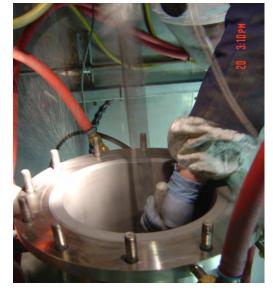
Direct-gas heating units



Propane-fueled vehicles

Examples of potential exposures to nanoparticles













TIOSH

Photos courtesy of Dr. Mark Methner, NIOSH Field Research Team



Image from a task-based personal breathing zone air sample analyzed via transmission electron microscopy (A circled area notes where energy dispersive spectroscopy was done.)



Harvesting of singlewalled carbon nanotubes (SWCNTs) from a Carbon Arc Reactor

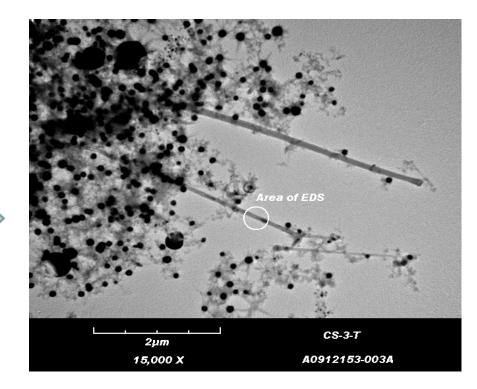
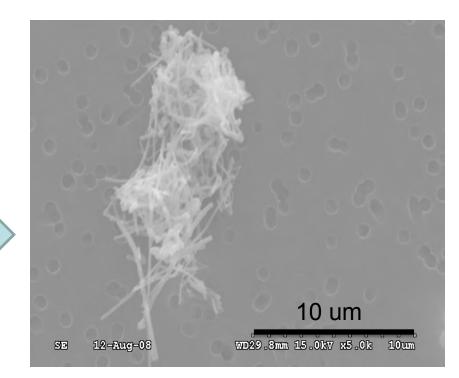




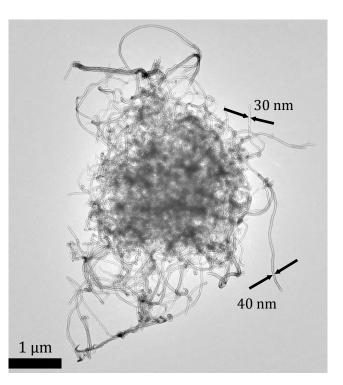
Image from a task-based personal breathing zone air sample analyzed by scanning electron microscopy

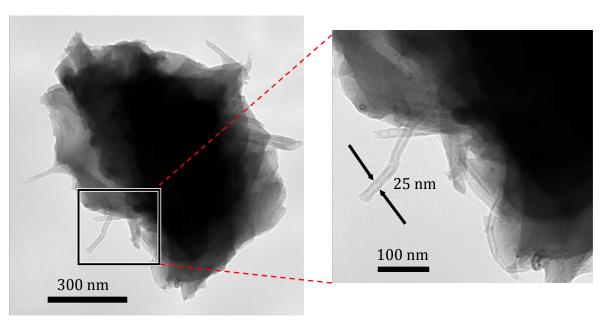


Weighing of multi-walled carbon nanotubes (MWCNT's)



Example of carbon nanotubes in a polymer matrix





Bulk 10-50 nm OD Multi-Wall CNTs

Sanding particle of epoxy containing 2% by weight MWCNTs

RJ Lee Group

> | NANOTECHNOLOGY NTR RESEARCH

Key guidance is available from NIOSH.



www.cdc.gov/niosh/topics/nanotech





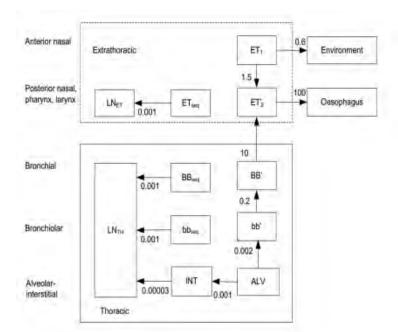
13

3.00um

Nano-enhanced materials and processes are raising issues in radiation-related operations.

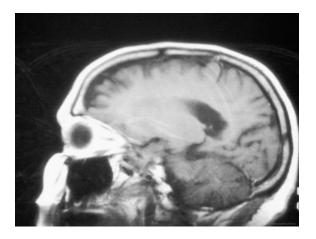


What are the sources of radiation-related nanomaterials?



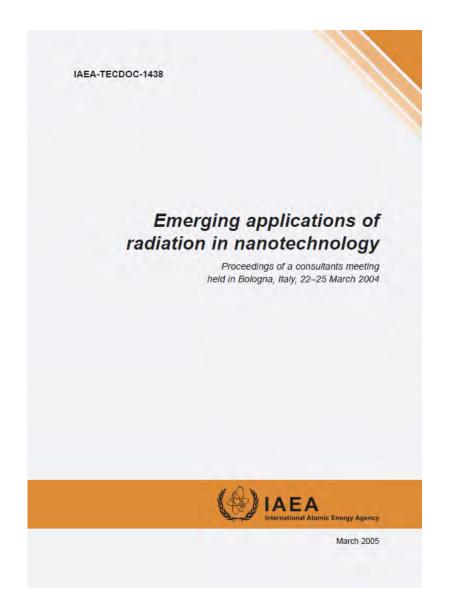


How can exposure be assessed over life-cycle processes?



How should radiation dosimetry be conducted for nanomaterials?

Applications of Radiation in Nanotechnology



- Nano-synthesis methods
- Annealing processes
- Characterization tools
- Aging studies
- Special systems
 - Plasma-focus-based radiation sources

www-pub.iaea.org/MTCD/publications/PDF/te_1438_web.pdf

Applications of Nanotechnology in Nuclear Power Plants (NPPs)



Collaborative Report on the Workshop

Gaithersburg, Maryland June 6-8, 2012

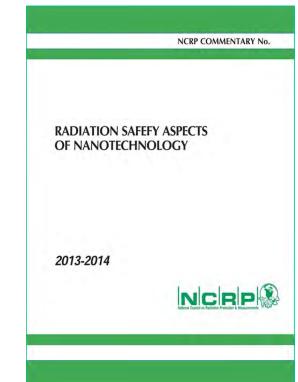


- Nano-enabled materials for components and structures
 - Are carbon nanotubes "the new steel" ?
 - Noble-metal enrichment using Pd for self-healing of cracks
- Coatings and barriers
- Coolants
- Cooling piping
- In-core reactor applications
- Sensors
 - Physical, chemical, radiological
- Separations / Sorbents
- Enhanced concretes
 - Security applications

Objective of the NCRP report on Radiation Safety Aspects of Nanotechnology

- Provide *practical operational information* for
 - management,
 - radiation safety officers,
 - operational health physicists,
 - dosimetrists,
 - workers, and
 - regulators.

SC 2-6 members: Mark Hoover, Dave Myers, Leigh Cash, Ray Guilmette, Wolfgang Kreyling, Günter Oberdörster, Rachel Smith, and Bruce Boecker and Mike Grissom. *With special thanks to John Boice and Jim Cassata.*

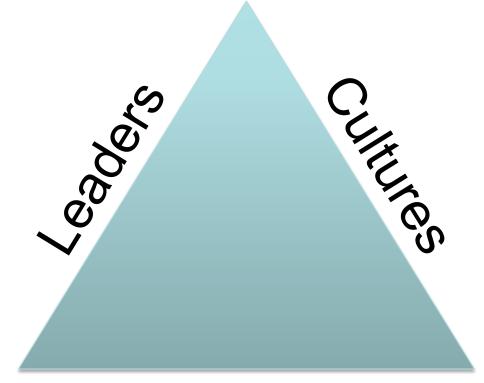


We can view the radnano challenge as "A Nanoinformatics Opportunity" in which:

- Nanoinformatics is the science and practice of determining which information is relevant to meeting the objectives of the nanoscale science and engineering community,
- and then developing and implementing effective mechanisms
- for collecting, validating, storing, sharing, analyzing, modeling, and applying the information, and then confirming that appropriate decisions were made and that desired mission outcomes were achieved.

Adapted from the Nanoinformatics 2020 Roadmap, available at www.nanotechinformatics.org

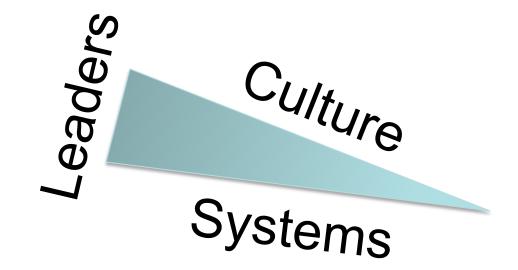
Leaders, cultures, and systems are essential for safety, health, well-being, and productivity



Systems

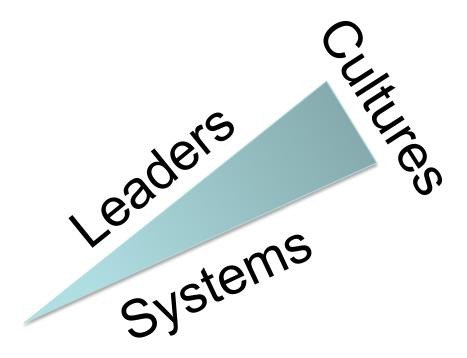
Leaders, cultures, and systems must be built and sustained.

Inadequate leaders diminish safety, health, well-being, and productivity



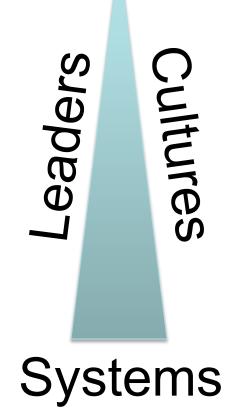
Leaders must be built and sustained.

Inappropriate cultures diminish safety, health, well-being, and productivity



Cultures must be built and sustained.

Inadequate systems diminish safety, health, well-being, and productivity



Systems must be built and sustained.

Example Flaws in Decision-Making

Туре	Attribute
00	Lack of CLEAR objectives
0	Failure to address uncertainty
1	False positive conclusion
2	False negative conclusion
3	Inappropriate decision level
4	Inappropriate evaluation method
5	Equating correlation and causation
6	Inappropriate extrapolation
7	Inadequate documentation
8	Mishap or misconduct

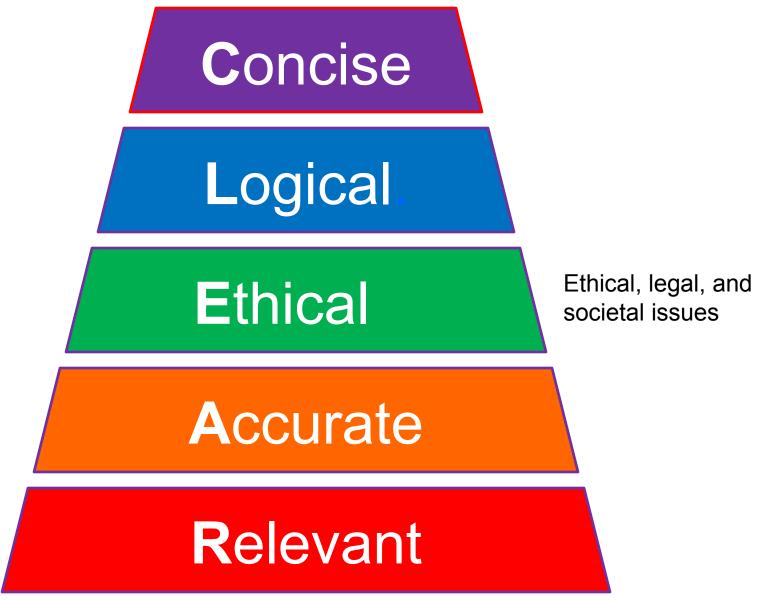
Hoover, Cash, Mathews, Feitshans, Iskander, and Harper (2014)

Communication and Education Message and Audience-Planning Matrix for (insert the current project name)

	Workers	Health and safety practitioners	Managers	Policy makers and regulators	Equipment and facility providers	Materials suppliers	Financiers	Insurers	Legal community	Researchers	Educators	Students	Emergency Responders	Media	Consumers	Society
Literacy and																
Critical																
Thinking Skills																
Real Life																
Examples																
Understanding																
(not rote																
application)																
Continuous																
Improvement																
Modeling																
and Sharing																
Assessment																

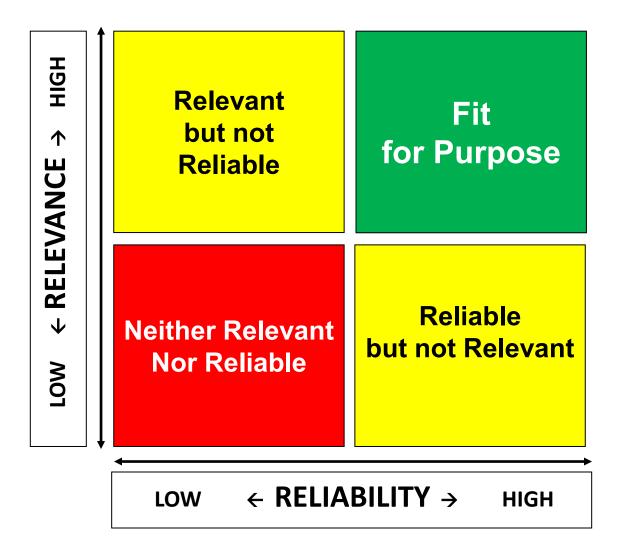
Specific messaging and actions in each element of the matrix must be based on (a) what knowledge and understanding each stakeholder needs and (b) what knowledge and understanding each stakeholder can provide.

CLEAR Communication Assessment Criteria



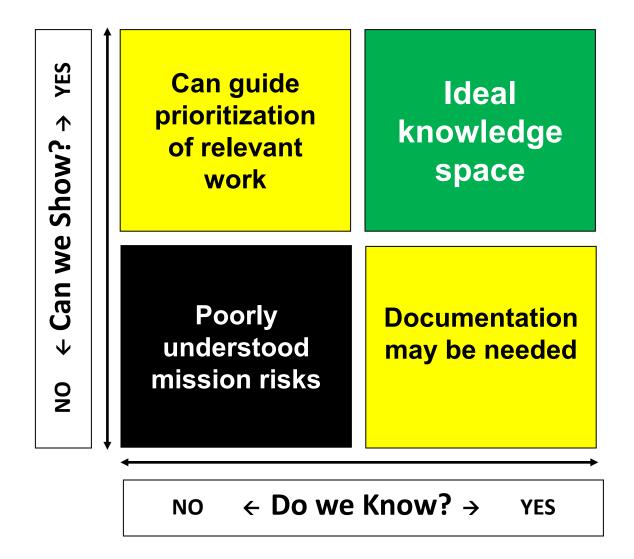
Hoover, Cash, Mathews, Feitshans, Iskander, and Harper (2014)

Relevance-versus-Reliability Assignment

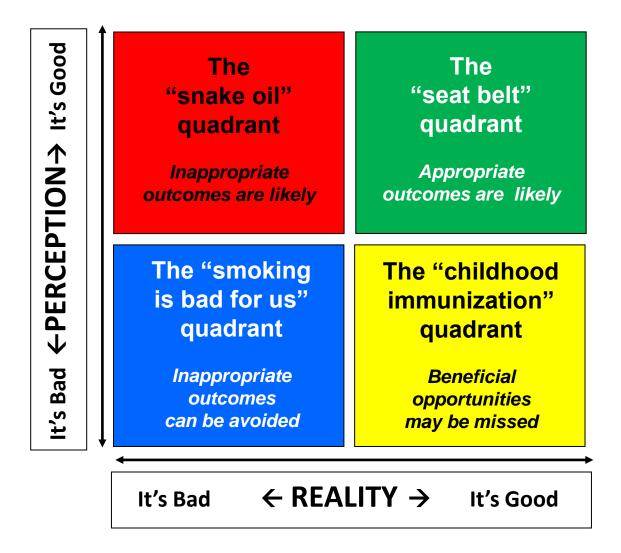


Hoover, Cash, Mathews, Feitshans, Iskander, and Harper (2014)

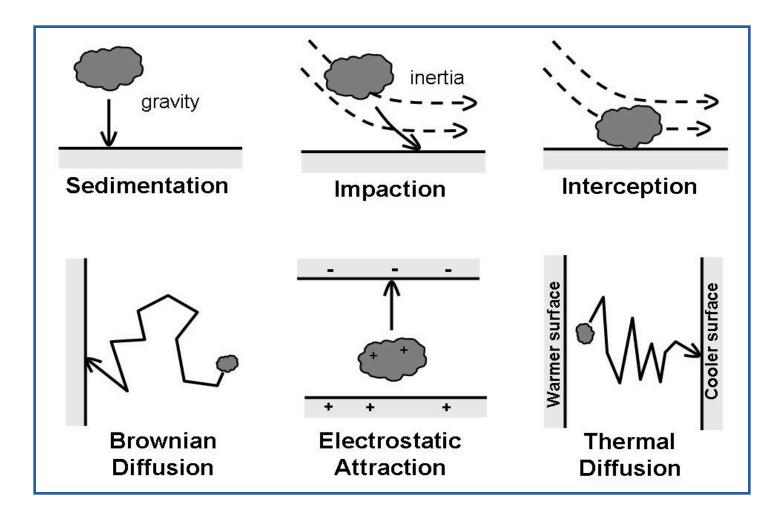
Know-versus-Show Alignment



Perception-versus-Reality Refinement

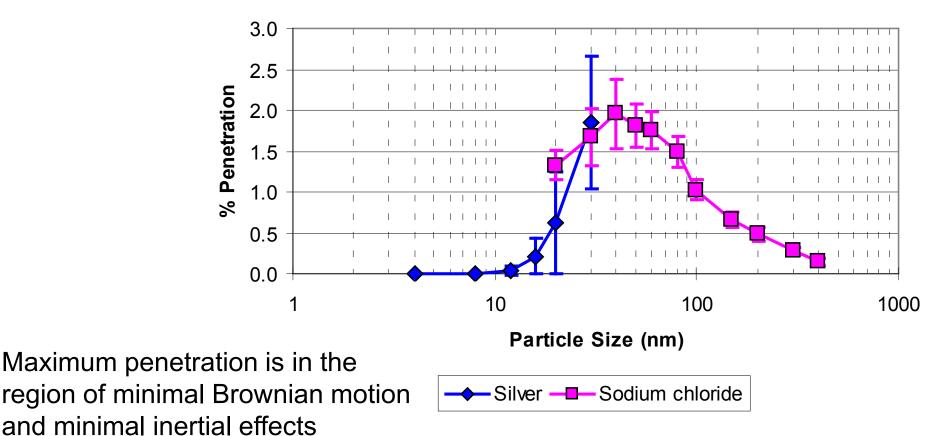


Fundamental mechanisms of particle collection in the environment, in air filtration and air cleaning systems, and in the human respiratory tract



Respiratory protection is efficient for nano-sized particles

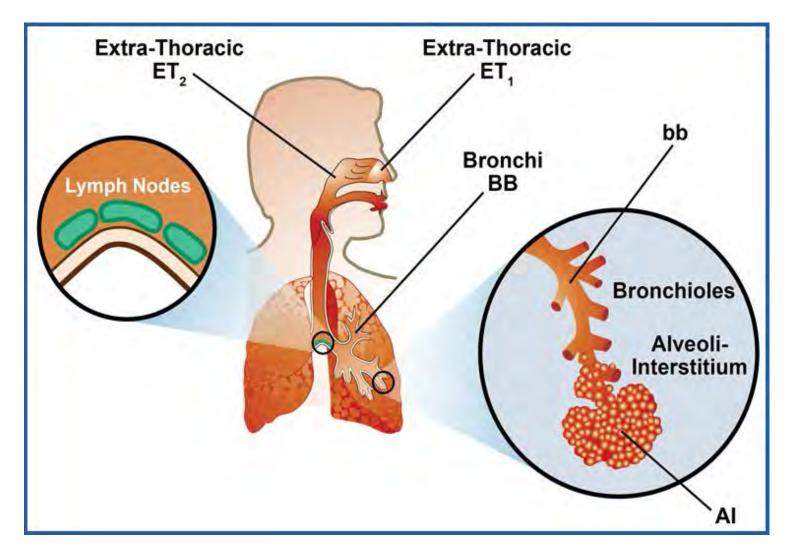
• Example data for N95 respirators



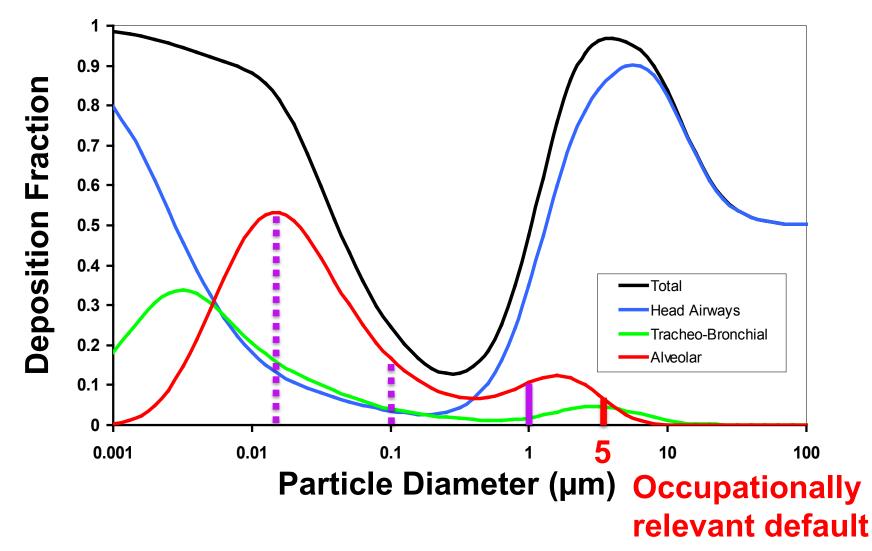
n = 5; error bars represent standard deviations Flow rate 85 L/min; NIOSH Approved N95 (NPPTL)

30

Major compartments of the ICRP Human Respiratory Tract Model (HRTM)

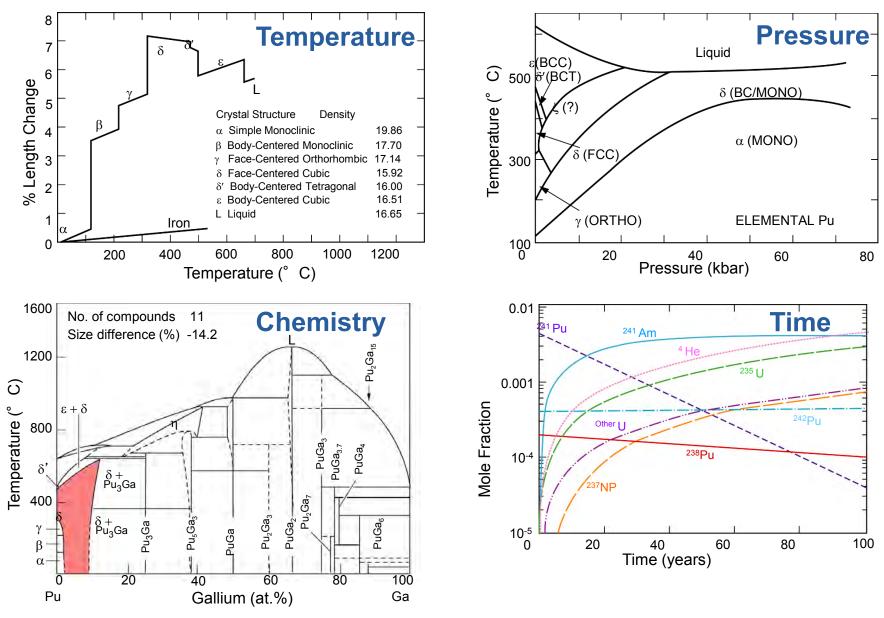


Particle size-dependent deposition in the human respiratory tract



Calculated from the ICRP 66 model for an adult male, light exercise, nose breathing. 32

Factors affecting plutonium



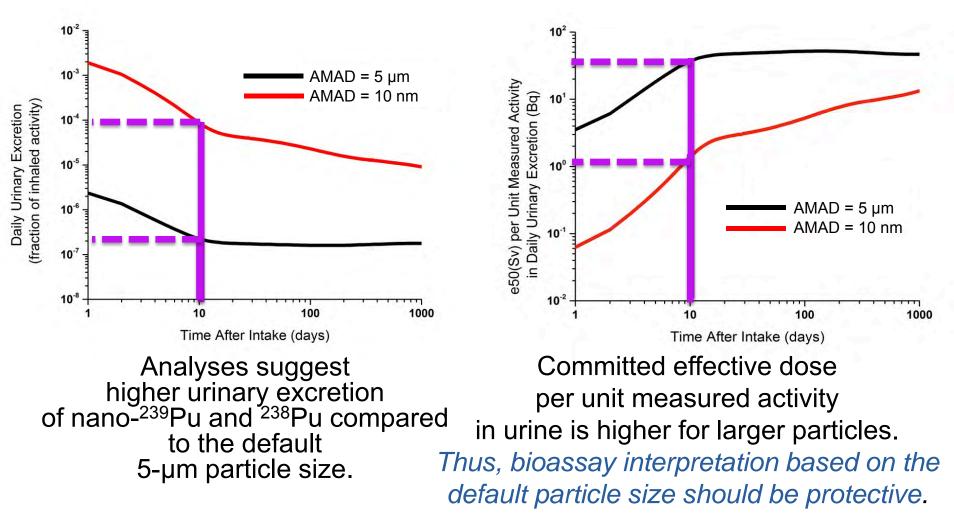
Courtesy of D.L. Clark, Los Alamos National Laboratory

Biokinetic information on nano-PuO₂

- No human data are available
- Biokinetic behavior must be derived from animal experiments
- Smith et al. and Stradling et al. studies in rats are relevant
- ²³⁹Pu and ²³⁸Pu particles were size-fractionated by filtration
 - 10 nm activity median aerodynamic diameter (AMAD)
 - 250 nm AMAD
- The ²³⁸Pu study included a 10 nm AMAD "aged material"
- Animal exposure was by injection and pulmonary intubation
- Animals were serially sacrificed for analysis of plutonium distribution in organs, tissues, urine and feces

Courtesy of L. J. Cash

Bioassay interpretation requires an understanding of particle characteristics



Better characterization of particles will lead to better dosimetry.

Courtesy of L. J. Cash

Four Steps for Community Action to build and sustain leaders, cultures, and systems for safety, health, well-being, and productivity



Hoover et al. (2014) – and the Nanoinformatics 2020 Roadmap

FRAMEWORK AND NEED FOR DOSIMETRY AND MEASUREMENTS: QUANTITATION MATTERS

Raymond A. Guilmette, Ph.D., CRadP, FHPS Lovelace Respiratory Research Institute Ray Guilmette & Associates LLC

PAC 6 MEMBERSHIP

- L. Bertelli, Los Alamos National Laboratory
- W. F. Blakely, Armed Forces Radiobiology Research Institute
- W. E. Bolch, University of Florida
- L. A. Braby, Texas A & M University
- J. F. Dicello, John Hopkins University
- R. A. Guilmette, Lovelace Respiratory Research Institute
- R. T. Kouzes, Pacific Northwest National Laboratory
- S. L. Simon, National Cancer Institute
- J. J. Whicker, Los Alamos National Laboratory
- G. Zeman, Illinois Institute of Technology

PAST

AREAS OF COVERAGE IN MEASUREMENTS AND DOSIMETRY (PAC 6)



AREAS OF COVERAGE IN MEASUREMENTS AND DOSIMETRY (PAC 6)

- Population exposure, U.S.A. (and Canada) from external and internal sources
- Theoretical dosimetry (absorbed dose)
- X- and γ-ray beam dosimetry for radiation therapy
- Microdosimetry and fluence-based dosimetry for space
- Radiofrequency and electromagnetic field exposure/dose
- Radioactivity measurements
- Biokinetic/dosimetric models for radionuclides (lung, wounds, embryo/fetus)
- Radionuclide dosimetry
 - Medical
 - Occupational
 - Public
- Uncertainty and reliability for external and internal dosimetry
- Dose Reconstruction

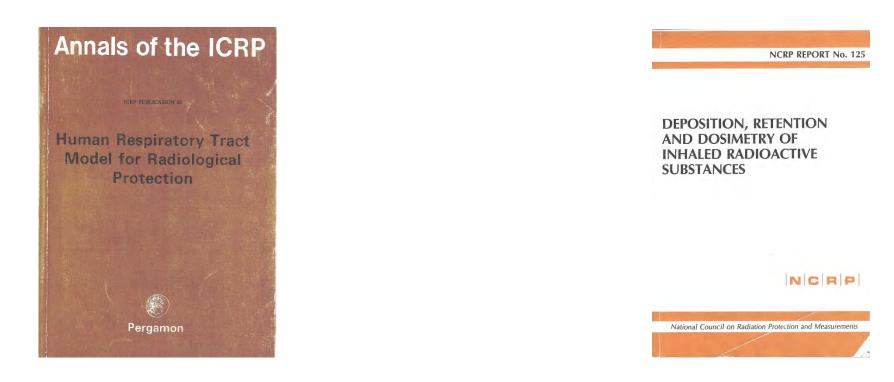
AREAS OF COVERAGE IN MEASUREMENTS AND DOSIMETRY (other PACs)

- Environmental radiation and radioactivity measurements (5)
- Medical management of intakes of radionuclides (4)
- Decorporation of radionuclides (4)
- Bioassay procedures for radionuclide intakes (2)
- Liver cancer dose and risk from radionuclides (1)
- Hot particle exposure, dose and risk (1)
- Research needs (all)
- 48 reports in all

AREAS OF COVERAGE IN MEASUREMENTS AND DOSIMETRY

- Areas on interest for PAC 6 are broad, varied and multidisciplinary
 - Many are focused significantly on measurements and dosimetry
 - Others are integral to the subject matter of other PACs
- Past reports point out the importance of teaming

HUMAN RESPIRATORY TRACT MODELS



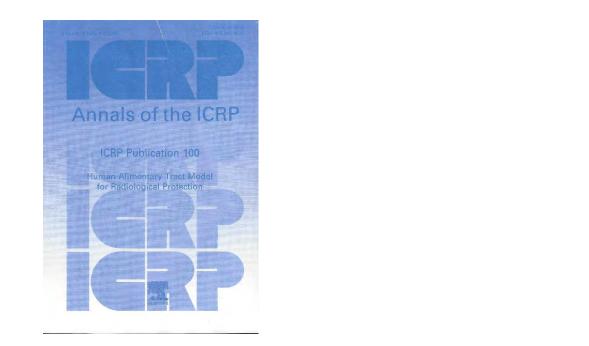
ICRP Publication 66 (1994)

- Accepted regulatory model
- First-order rates for clearance
- Being revised in OIR (2014)

NCRP Report 125 (1997)

- Alternative research tool
- Complex rate functions for clearance
- Nanoparticle deposition different

NCRP-ICRP COOPERATION/COLLABORATION



ICRP Pub. 100 Alimentary Tract Model (2006)

- Comprehensive treatment of clearance/dosimetry of target tissues
- First-order clearance models
- Being incorporated worldwide



NCRP REPORT No. 156

DEVELOPMENT OF A BIOKINETIC MODEL FOR

CONTAMINATED WOUNDS AND PROCEDURES FOR THEIR ASSESSMENT, DOSIMETRY AND TREATMENT

RADIONUCLIDE-

• Treats wounds, lacerations burns

NCRP

- Focus on biokinetics; driver for systemic models
- First-order clearance models
- Only consensus model

NCRP REPORTS SUPPORTING DOSE RECONSTRUCTION PROGRAMS

- In 2004, NCRP initiated a program on radiation dosimetry uncertainties and dose reconstruction for U.S. Department of Defense
- **Need**: Public debate often involved issues that questioned the validity and reliability of the government processes for dose reconstruction
- **Goal**: Establish a stronger scientific foundation for radiation dose reconstruction, including uncertainty analysis.
- The NCRP program resulted in four reports that applied directly to ongoing government radiation compensation programs including:
 - 400,000+ atomic veterans who witnessed one or more of 200+ atmospheric nuclear weapons tests, or were exposed to radiation from the atomic bombs in Japan
 - Energy workers or contractors involved in nuclear weapons production during the Cold War era





NCRP REPORTS SUPPORTING DOSE RECONSTRUCTION PROGRAMS

• Scientific Committee 6

- Report No. 158 Uncertainties in the measurement and dosimetry of <u>external</u> <u>radiation</u> (2007)
- Report No. 164 Uncertainties in internal radiation dose assessment (2009)
- Report No. 163 Radiation dose reconstruction: Principles and practices (2009)
- Scientific Committee 1
 - Report No. 171 Uncertainties in the estimation of <u>radiation risks</u> and probability of disease causation (2012)

PRESENT

SC 1-20. Biological Effectiveness of Low LET Radiation as a Function of Energy (S. Simon, chair)

- Evaluate cancer risk from exposure to low-energy, low-LET (photons and electrons) compared with risks at higher energies, i.e., develop an energy-dependent dose-modifying factor relevant to induction of cancer in humans
- Essential aspect of study is quantitative assessment of uncertainties
- Committee consists of experts in microdosimetry, DNA damage, cellular radiobiology, animal studies, epidemiology, medical physics and radiation protection
- Considering the breadth of data from molecular, cellular, animal and human studies
- Focus on energy range relevant to medical, occupational and other human exposures
 - Mammography
 - Other medical procedures (e.g., CT imaging)
 - Tritium
- Work in progress

SC 2-6 Radiation Safety Aspects of Nanotechnology (M. Hoover, chair, D. Myers, vice chair)

- Provide guidance for development of radiation safety programs involving the use of radioactive nanomaterials
- Operational
 - Engineered and administrative controls
 - Air filtration
 - Air sampling
 - Contamination control
 - Personal protective equipment
 - Training
 - Waste disposal
- Internal dosimetry
 - Biokinetic and dosimetric modeling
 - Bioassay
 - Dose assessment
 - Medical management

SC 2-6 Radiation Safety Aspects of Nanotechnology

- Committee consists of experts in:
 - Nanomaterials
 - Nanotoxicology
 - Operational health physics
 - Internal dosimetry and dose assessment
- Report drafting nearing completion

SC 6-8 Operation TOMODACHI Radiation Dose Assessment Peer Review (J. Till, chair)

- Review DTRA project report on Operation Tomodachi dose assessments of U.S. Forces Japan who were potentially exposed following the Dukushima Daiichi accidents
- Focus on adequacy of assumptions, technical approaches and other factors impacting the accuracy of the dose assessments
- Four-member committee consisted of experts in environmental and personnel dose assessment
- Assessments included individual estimates for external radiation, intakes of radionuclides, dose to the embryo, fetus or nursing infants, and response characteristics of different types of radiation instruments used
- A report summarizing key recommendations from the review of six DTRA reports will be completed in 2014 (No final report required by contract)

SC 6-9 U.S. Radiation Workers and Nuclear Weapons Test Participants Radiation Dose Assessment (A. Bouville, chair, R. Toohey, cochair)

- As part of the NCRP coordination of the "Million Worker Study," this committee is providing guidance on the comprehensive dose assessment requirements and methodologies needed for the diverse study populations
- Charge: practical dose reconstructions for epidemiological studies with uncertainty analysis
 - Strengths and limitations of proposed methods
 - Circumstances of occupation settings
 - Environmental scenarios (e.g., fallout)
 - Intakes of radionuclides
- Best estimates of organ absorbed doses

FUTURE

SCIENTIFICALLY BASED REGULATORY FRAMEWORK FOR RADIATION BIODOSIMETRY

- Need capability to provide early-phase and rapid diagnostic information to medical responders to assess radiation exposure/risk from radiation mass-casualty event
- Federal government funding development of biodosimetry and biomarker technologies
 - Diverse measurement endpoints and devices
 - Point of Care (PoC): initial triage, qualitative (2 Gy threshold), integrated device, easy to use, use in clinics, ERs, temp facilities, << 15 minute time to result, 10⁶ patients in 6 days
 - High-Throughput Device (HTD): injury assessment/treatment, quantitative (0.5 10 Gy), lab instrument with automation, ≤ 24 h time to result, 2,000 per day, 400,000 patients
- Presently FDA has yet to approve an assay or device for radiation dose and injury assessment
- Such applications are expected in next 5 years
- No clear roadmap/framework for use of animal, human radiation therapy and accident data and models to validate biodosimetry/biophysical device protocols

SCIENTIFICALLY BASED REGULATORY FRAMEWORK FOR RADIATION BIODOSIMETRY

- Diverse endpoints being studied:
 - Point of Care
 - Protein expression immunoassay
 - Electron paramagnetic resonance in teeth and nails
 - DNA damage
 - Ocular dosimetry
 - Gene expression (qRT-PCR)
 - Volatile organic compounds in breath
 - High-throughput Device
 - Gene expression, chemical ligation
 - Protein expression immunoassay
 - Cytogenetics (γ-H2AX foci, micronuclei)
- Many variables can confound the dose-response relationship including radiation quality, dose rate/fractionation, sex, intrinsic radiosensitivity (special populations), age, spatial dose distribution (total vs. partial body), combined injury (burns, infection, trauma)

SCIENTIFICALLY BASED REGULATORY FRAMEWORK FOR RADIATION BIODOSIMETRY

- Proposal: develop a NCRP consensus Commentary Report on issues related to radiation biodosimetry and biomarkers
 - Framework for regulatory review of methods and devices
 - Review technical issues related to use of biodosimetry methods
 - Animal models (e.g., "two-animal rule" in lieu of human data)
 - Exposure scenarios regarding heterogeneity of exposure
 - Calibration and use of multiple biomarkers
 - Characterize variability and uncertainty with respect to known confounders
 - Initial 1-year focus on diagnostic biodosimetry for early-phase treatment decision-making

SCIENTIFICALLY BASED REGULATORY FRAMEWORK OF RADIATION BIODOSIMETRY DIAGNOSTICS : RADIATION MASS CASUALTIES

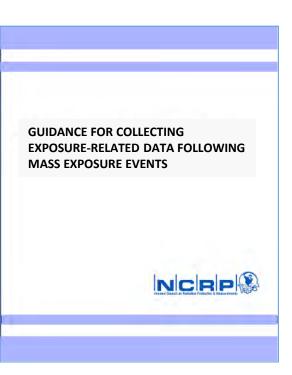
NCRE

PRACTICAL METHODS FOR DATA COLLECTION FOR DOSE RECONSTRUCTION FOLLOWING MASS EXPOSURE EVENTS

- Post 9-11 and Fukushima, programmatic emphasis for consequence management R & D has focused on certain medical countermeasures, dose mitigation strategies, management of contaminated food and land, and strategies to manage acute radiation effects.
- Regarding evaluation of long-term health consequences, little has been done to develop suitable methods to collect necessary data in the aftermath of a mass exposure event.
- Determination of who might be exposed, and the degree of exposure is inherently difficult after a radiation accident or large event for reasons including loss of infrastructure, loss of subjects to follow-up (they are evacuated, taken for medical treatment or move away) and psychological difficulties in memory recall of the traumatic event.
- Health risk studies to determine the true event consequences over and above natural disease incidence require a detailed understanding of the potentially exposed population and collection of exposure-related data to support realistic dose reconstruction of individual organ doses, accounting for age, gender, ethnicity and other variables.
- Data collection as soon as possible after the event is necessary to maximize data collection accuracy and to minimize uncertainties.
- Presently, methods development and planning for cohort identification, data collection and acquisition after such events has been inadequate.

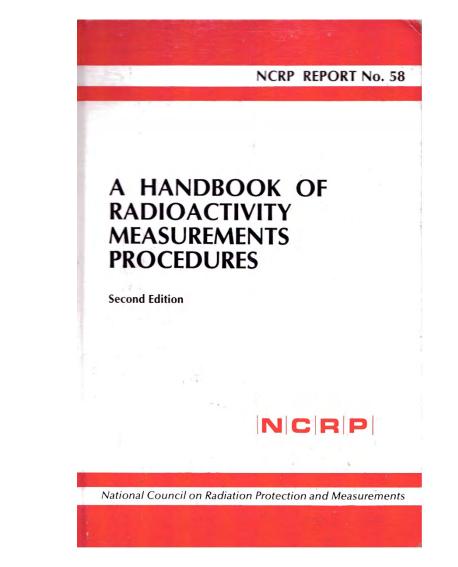
PRACTICAL METHODS FOR DATA COLLECTION FOR DOSE RECONSTRUCTION FOLLOWING MASS EXPOSURE EVENTS

- Goal: develop practical methods for obtaining individual and population information useful for realistic individual dose reconstruction.
- Experts in retrospective dose assessment, biodosimetry, biomarkers and radiobiology, forensics, disaster response, epidemiology, psychology and communication
- Deliverables might be:
 - Protocols for data collection
 - Protocols for dose reconstruction (including uncertainty)
 - Guidance for epidemiological followup



Update of NCRP 58 on Radioactivity Measurements

- Originally published as NBS Handbook 80 (1961), Report 58 issued in 1978
- By 1983, supplies exhausted; 2nd edition (1985)published with substantial revisions
- One of most popular reports (> 13,000 sold)
- Material now dated (no sales last few years)
- Clearly there was a market



Update of NCRP 58 on Radioactivity Measurements

- Focus was on describing instrumentation and its application for measurement
 - Physics of ionization chambers, GM detectors, proportional counters, solid, liquid and gas scintillation counters, semiconductor, Cerenkov counting
 - Application to direct and indirect or comparative measurement of activity
 - Preparation of standard sources
 - Radioassay and identification of radionuclides in environmental, medical and industrial labs
 - Counting statistics
 - Measurement assurance, standards, traceability and uncertainty
- Considerations for updating
 - Is there a need?
 - Is there a market?
 - Are there alternate sources of information? Competition?

Update of NCRP 58 on Radioactivity Measurements

• Preliminary assessment:

- Significant new instrumentation technology in last 30 years
- Scope could be expanded: bioassay, radiochemistry, medical imaging, position sensing, environmental measurements, information processing, measurement quality objectives (MQOs), data quality objectives (DQOs)
- Advantage to have all this varied information in one volume (or two)
- Should be of interest to a wide range of disciplines and customers
- Time to write a proposal!



FUTURE ROLE OF MEASUREMENTS AND DOSIMETRY

- Build on published achievements and products
- Special topics will continue to emerge
- Leverage opportunities to work with other PACs

Protection and Measurement in Radiation Therapy

Steven Sutlief, PhD

VA Puget Sound Health Care System

University of Washington

2014 NCRP Annual Meeting

Outline

Framework	Justification
	Optimization
	Limitation
Past Accomplishments	Occupational Dose
	Shielding
	Equipment/Facility Design
Present Concerns	Pregnancy Dose
	Secondary Malignancies
	Implantable Devices
	Accident Prevention
Future Directions	Molecularly-based disease assessment and treatment strategies
	Continual release of novel delivery strategies
	Tension between best medical practice and regulatory oversight

Radiation Protection Framework

Justification Optimization Limitation

Radiation Therapy and Radiation Protection

Radiation Therapy Radiation Protection

- Optimal conformality
- Optimal targeting
- Optimal fractionation
- Adjuvant therapies

- Damage to normal tissues
- Implantable devices
- Fetal dose
- Imaging dose
- Shielding
- Unintentional dose

The Fundamental Question for Radiation Protection

For staff, the patient, and the public, what is the proper balance between...

Benefits of the radiation technology

versus

Risk due to anticipated and unanticipated radiation exposure?

The Answer: ICRP/NCRP Framework

- **1954:** NCRP Report 22: maximum dose recommendations "for the purpose of keeping the average dose to the whole population as low as reasonably possible"
- **1966:** ICRP 9: Recommendations of the International Commission on Radiological Protection
- 1973: ICRP 22: Implication of Commission Recommendations that Doses be kept As Low as Readily Achievable
- **1977:** ICRP 26: Three Principles: Justification, Optimization, Limitation
- 1990: NCRP Report 107, Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel
- **2004:** Further clarification in NCRP Statement 10

ICRP and NCRP Objectives for Protection

- NCRP 116 says the objectives of radiation protection are "to prevent the occurrence of clinically significant radiation induced deterministic effects by adhering to dose limits that are below the apparent threshold levels and... To limit the risk of stochastic effects, cancer and genetic effects to a reasonable level in relation to societal needs, values, benefits gained and economic factors."
- ICRP 103 states its aim is "to contribute an appropriate level of protection against the detrimental effects of radiation exposure without unduly limiting desirable human actions associated with such exposure."

ICRP/NCRP Protection Objectives

Justification

• The net positive benefit of the activity

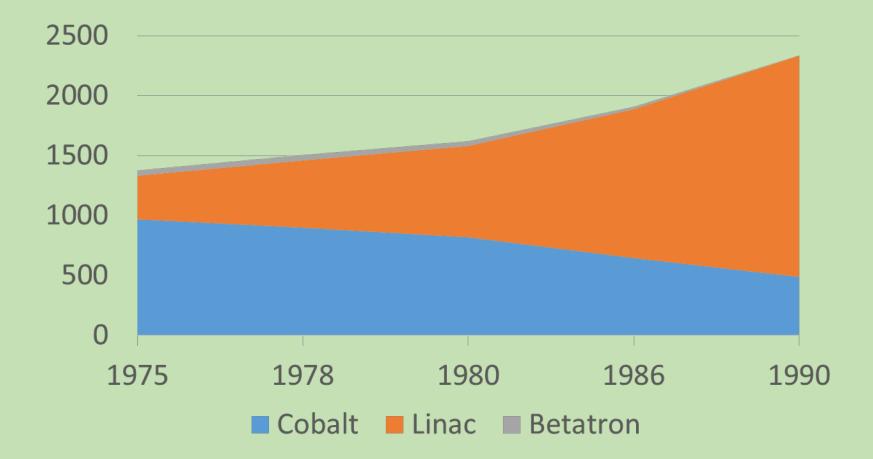
Optimization

• Keeping dose "as low as reasonably achievable, economic and social factors being taken into account"

Limitation

• Impose to limits to individuals

Co-60 & Linacs in the US 1975-1990



Radiation Therapy – the Next 10 Years

More Protons

More Radiosurgery

Adaptive Therapy

Proliferation of US Proton Centers

St Louis, MO PC Seattle, WA PC Sumerset, NJ Hampton, VA U Penn

PC Warrenville, IL

PC Oklahoma City, OK

MD Anderson

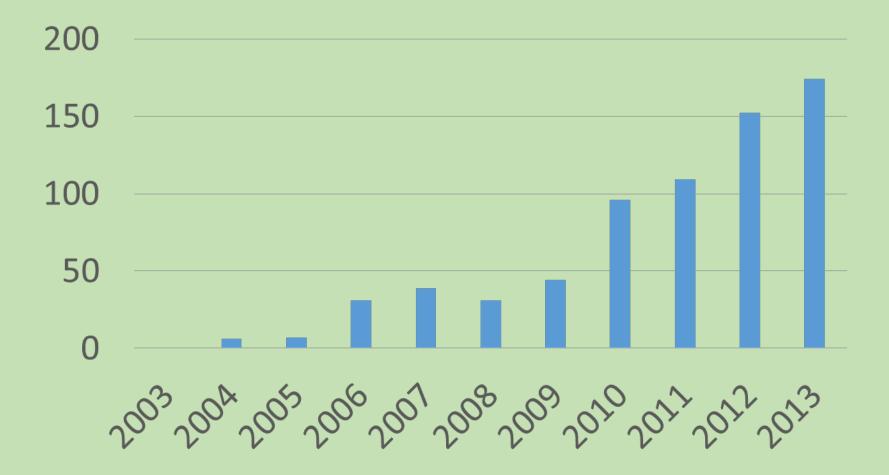
UF Jacksonville

Indiana University

Loma Linda

Harvard Cyclot ron Laboratory /MGH 1961 1990 2004 2006 2009 2010 2012 2013

SBRT Publications per PubMed



ART Publications per PubMed



Past Accomplishments

Occupational Dose Shielding Equipment/Facility Design

Protection of Workers and Public

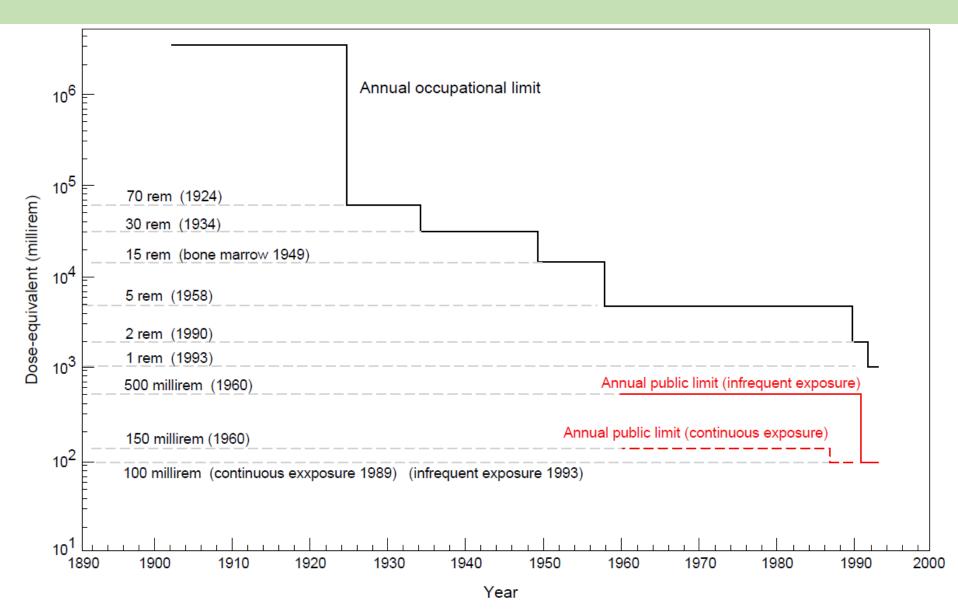
Deterministic vs. Stochastic effects

	Deterministic (prompt effects)	Stochastic effects (delayed effects)
Dose Threshold	Yes	No
Probability Relationship with dose	N/A	Yes
Severity relationship with dose	Yes	No
Examples	Hair loss, radiation sickness	Cancer, Cataracts

Occupational Dose Limits

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

Annual Exposures Limits

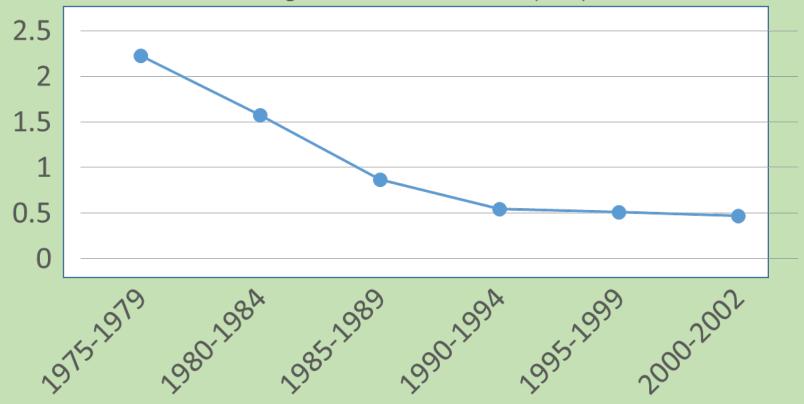


Radiation Protection of Staff

- UNSCEAR 2008 Annex B, p307 says: "the annual activation dose received by staff during typical operations are in the range of 0.7-5 mSv."
- NCRP #116 recommends an occupational dose limit of 50 mSv/yr, while ICRP #103 recommends 20 mSv/yr.
- The doses encountered by workers in radiation therapy are significantly below the occupational thresholds.

World Average Exposure to Radiotherapy Workers

Average Annual Effective Dose (mSv)

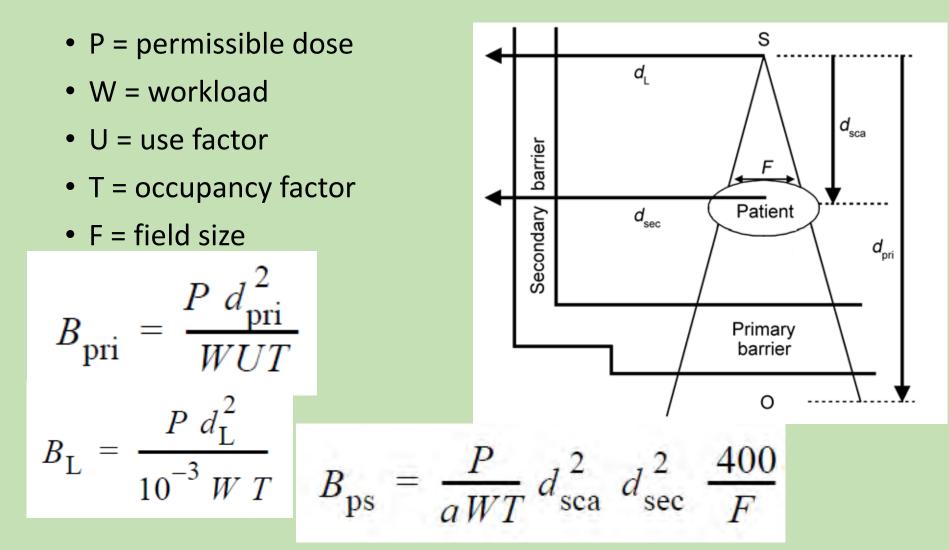


Shielding

Evolution of Shielding Guidance

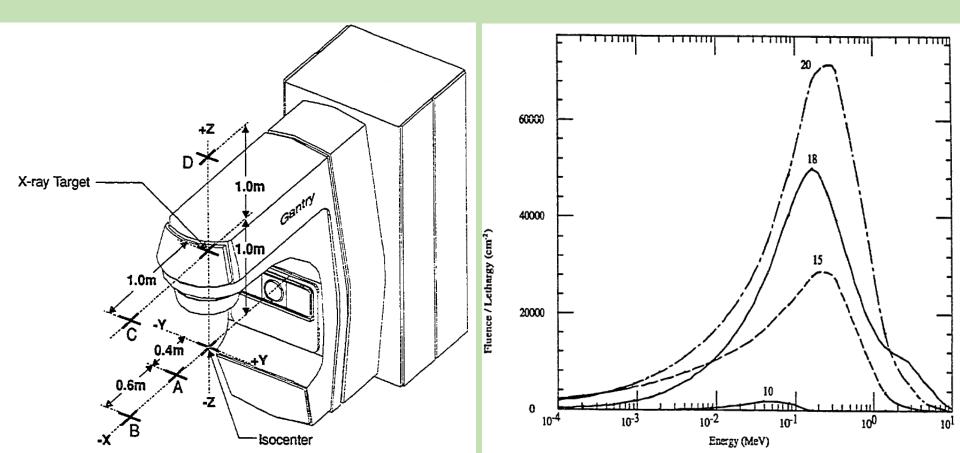
- Initial Guidance for accelerating voltages up to 10 MV maximum
 - NCRP Report No. 49 (1976) Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies up to 10 MeV
- One of the first comprehensive treatments of accelerator radiological-protection concerns
 - NCRP Report No. 51 (1977): Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities
- Neutron exposure from medical equipment used to generate electrons is operated at energies above 10 MeV
 - NCRP Report No. 79 (1984): Neutron Contamination from Medical Electron Accelerators
- NCRP 51 Revision: including source intensities, shielding, dosimetry, and the environmental aspects of particle accelerator operation
 - NCRP Report No. 144 (2003) Radiation Protection for Particle Accelerator Facilities
- Revised guidance including accelerating voltages exceeding 10 MV
 - NCRP Report No. 151 (2005) Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities

Shielding (NCRP 151)

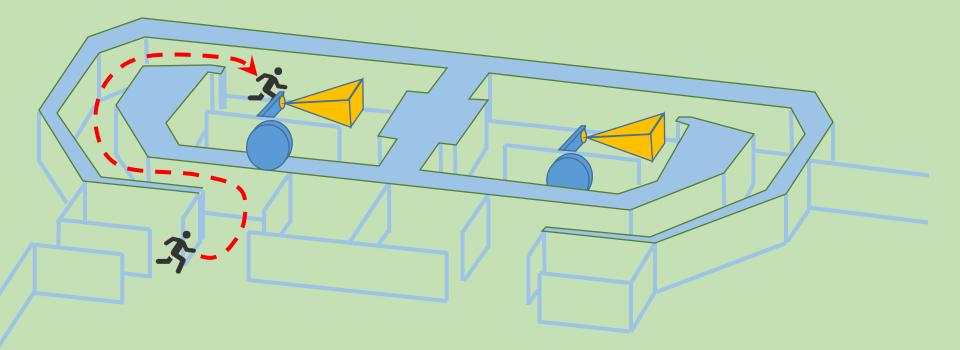


Neutron Dose

- Photo-neutron contamination rises quickly above 10 MeV.
- Concrete is good shielding, but doors are a problem.



Shielding for a 25 MV Linac



Equipment Specification

Equipment Design and Use

- 1968: NCRP Report No. 33, Medical X-Ray and Gamma-Ray Protection for Energies Up to 10 MeV, Equipment Design and Use
- 1989: NCRP Report No. 102 Medical X-Ray, Electron Beam and Gamma-Ray Protection for Energies Up to 50 MeV Equipment Design, Performance and Use
- 1998: INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment, Part 2-1: Particular Requirements for the Safety of Electron Accelerators in the Range 1 MeV to 50 MeV, Rep. IEC 601-2-1, IEC, Geneva (1998).
- 2009, dating back to 1992: CRCPD Suggested State Regulation for Control of Radiation, Part X: Therapeutic Radiation Machines

Sources of Additional Dose in External Beam Radiation Therapy

Source	% of Rx
Radiation Leakage from the Accelerator Head	<0.2%
Secondary radiation generated in patient	<<0.1%
Setup verification imaging (MV & KV, planar & CBCT) Assuming daily CBCT=2.4 cGy/(200cGy/day)	≤1.2%
CT-Simulation Assuming CDTIW = 2.4 cGy, Rx = 20 Gy	≤0.1%

Present Concerns

Pregnancy Dose Secondary Malignancies Implantable Devices Accident Prevention

Exposure of Patients who are Pregnant

- Discussed in AAPM Task Group 36 (1995): Fetal Dose from Radiotherapy with Photon Beams
- ICRP Publication 84 (ICRP, 2000a) covers the exposure of patients who are pregnant and
- ICRP Publication 90 (ICRP, 2003a) covers radiation risks after prenatal radiation exposure.
- ICRP Publication 105 (ICRP, 2007b) also discusses the considerations to be taken into account regarding termination of pregnancy after radiation exposure.

Exposure of Patients who are Pregnant

- ICRP 103 states "Absorbed doses below 100 mGy to the embryo/ fetus should not be considered a reason for terminating a pregnancy."
- Furthermore, "the pregnant patient should receive sufficient information to be able to make informed decisions based upon individual circumstances, including the magnitude of the estimated embryonic/fetal dose and the consequent risks of serious harm to the developing embryo/fetus and risks of cancer in later life."

Pediatric Data from UNSCEAR

- UNSCEAR is the United Nations Scientific Committee on the Effects of Atomic Radiation
- UNSCEAR 2013 Report, Volume II, Scientific Annex B, p56: The switch from 3D Conformal to IMRT replace a higher dose restricted to beam entrance and exit paths to a lower dose spread over a larger volume.
- P41: "The commonly held notion that children might be two-three times more sensitive to radiation than adults is true for some health effect but certainly not for all."

Deterministic Effects	More	Same	Less	Insuff.	Evidence	Comments
Brain	Х				Strong	Neurocognitive reduction
Neuroendrocrine		Х			Strong	Growth hormone suppression
Cataracts	Х				Weak	
Cerebrovascular accident	Х				Moderate	Stroke
Heart	Х				Strong	Prevents growth, valvular abnorm.
Breast hypoplasia	Х				Strong	Most severe during puberty
Lung			Х		Weak	Max Capacity decr. If chest wall growth inhobited.
Thyroid hypofunction		Х			Weak	
Thyroid nodules	Х				Strong	
Thyroid autoimmune				Х		
Kidney		Х			Weak	
Bladder	Х				Strong	Bladder capacity reduced
Testes	Х				Strong	Most severe during puberty
Ovaries			Х		Moderate	Less sensitive at younger age
Uterus	Х				Moderate	Uterine vasculature impaired
Musculoskeletal	Х				Strong	Hypoplasia, deformity, osteochondroma
Immune				Х		
Marrow whole body			Х		Strong	Less available marrow when older

Carcinogenesis Risk: Child versus Adult

From UNSCEAR 2010 Appendix B

	Cancer site	More	No Diff.	Less	Insuff. Data	Evidence
	Oesophagus				Х	
C	Stomach	ERR	EAR			Moderate
	Small intestine				Х	
S	Colon (incidence, mortality)	EAR/	ERR			Weak
	Rectum				Х	
	Pancreas				Х	
	Liver		Х			Weak
	Lung			х		Moderate
	Skin non-melanoma	Х				Moderate
	Breast	Х				Strong
	Uterus				Х	
	Cervix				Х	
	Ovary				Х	
	Prostate				Х	
	Kidney				Х	
	Bladder		Х			Moderate
	Brain	Х				Strong
	Thyroid	Х				Strong
	Parathyroid				Х	
	Hodgkin's lymphoma				Х	
	Non-Hodgkin's lymphoma				Х	
	Myeloma				Х	
	Leukaemia non-CLL	Х				Strong
	Myelodysplasia	Х				Weak

Secondary Cancers

- Per the SEER 2006 data, 17% of all newly diagnosed cancers each year are second cancers.
- The yearly frequency of second cancers exceeds any individual cancer.
- Those under 18 years old are at greatest risk of developing a second cancer, more that twice the rate of those age 18 to 29.
- Epidemiologic Studies Breast cancer, Hodgkin lymphoma, Cervical cancer, and Childhood cancer

Cardiovascular Disease

NCRP Report No. 170 (2011): "Secondary Primary Cancers and Cardiovascular Disease after Radiation Therapy":

- "Late effects, such as iatrogenic SPCs and heart disease, will continue to increase, based on absolute numbers alone, although conceivably at a lower level than those associated with past therapies and methods."
- "Clinical and public-health awareness of these adverse consequences is now prominent, and the development of means to mitigate and ameliorate and to provide counseling, surveillance and supportive care is essential both now and in the future."

Implanted Medical Devices

- Electronic
 - Implantable Cardioverter Defibrillators
 - Heart Pacemakers
 - Cochlear Implants
- Structural
 - Artificial Hips
 - Artificial Knees
 - Spine Screws, Rods, and Artificial Discs (Spinal Fusion Hardware)
 - Metal Screws, Pins, Plates, and Rods (Traumatic Fracture Repair)
- Other
 - Breast Implants
 - IUDs (Intra-Uterine Devices)
 - Coronary Stents
 - Ear Tubes (Tympanostomy Tubes)
 - Artificial Eye Lenses (Psuedophakos)

Accident Prevention

- ICRP 113 favors defense in depth, which "is aimed at preventing equipment failures and human errors and mitigating their consequences should they happen."
- "The Commission has given extensive advice on reducing the probability of potential exposure and preventing accidents in Publications 76, 86, 97 and 98 (ICRP, 1997b, 2000c, 2005b, 2005c)."

How do we make radiotherapy safe?

- US professional societies: ASTRO, AAPM, ASRT, ASMD, ASROA
- US governmental agencies: FDA, States, NRC, EPA
- Related agencies: CRCPD, NCRP, ICRP
- European Agencies: ICRP, ICRU, IAEA

All these bodies have a stake in making radiotherapy safe and effective.

ROILS RADIATION ONCOLOGY INCIDENT LEARNING SYSTEM

Sponsored by ASTRO and AAPM

Benefits of participation:

 Submit information on incidents or near-misses in a confidential, non-punitive environment.

COMING IN 2014

- Track and analyze internal incidents and near-misses.
- Receive reports on events from the national database with information on equipment, technique and dosemetric severity scale.
- Receive quarterly, institution-specific benchmarking reports.

Future Directions

Continual release of novel delivery strategies

Wider clinical use of molecularly-based disease assessment and treatment strategies

Regulatory oversight driving medical practice

New novel delivery strategies

- Flattening Filter Free
- ViewRay system

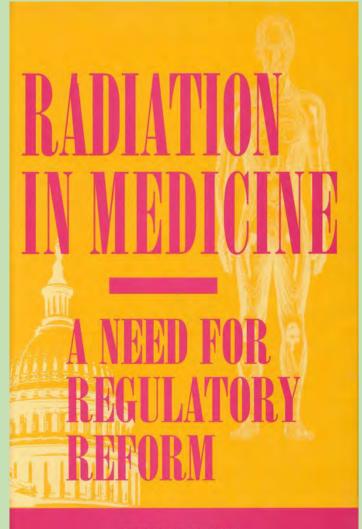


Molecularly-based disease assessment and treatment

 Will there come a point at which we have biomarkers and other tools which let us predict which patients are most suitable for radiation therapy, such that our radiation protection paradigm changes to include the ethical dimension of only giving radiation to those who will benefit?

Regulatory Oversight

- The 1996 IOM report recommended NRC's oversight be shifted to the CRCPD.
- Most departments spend far more effort with NRC compliance than State compliance.
- Conventional external beam Co-60 devices in the US dropped to zero.
- Sales and users have noted the advantages of accelerators, Pd-103, and electronic brachytherapy not being under NRC.



Protection of the Gametes and Embryo/Fetus from Prenatal Radiation Exposure

Robert L. Brent MD, Ph.D., D.Sc.(Hon) Thomas Jefferson University

duPont Hospital for Children Wilmington, DE

NEMOURS

duPont of children



Thomas Jefferson University Robert Brent states that he has no relevant financial relationships to disclose or COIs to resolve pertaining to this presentation

The Birth of NCRP Report 174: 2013

"Preconception and Prenatal Radiation Exposure: Health Effects and Protective Guidance

In 2007 NCRP applied to the CDC to update Handbook 54 which was published in 1977 as Report No. 54. "Medical Radiation Exposure of Pregnant and Potentially **Pregnant Women**". NCRP report 174 was completed and published in 2013 Much of the material for today's presentation was derived from the updated material in NCRP 174 which is 374 pages long and it would be impossible to cover all the material in this presentation.

Protection of the Gametes, Embryo/Fetus from Prenatal Radiation Exposure

• This presentation will include potential radiation health effects on the gamete, embryo and fetus, including review of radiation risks and potential outcomes:

Genetic Diseases.

Stochastic and threshold dose-response relationships of diseases produced by environmental agents*

Phenomenon	Pathology	Site	Diseases	Risk	Definition
Stochastic	Damage to a single cell may result in disease	DNA	Cancer, germ cell mutation	Some risk exists at all doses; at low doses, risk is usually less than the spontaneou s risk	Incidence of the disease increases but the severity and nature of the disease remain the same
Threshold, tissue effects, deterministi c effects	Multipl e cell and tissue injury	Multipl e, variabl e etiolog y, affecti ng many cellula r and organ functio ns	Birth defects, growth retardation , death, toxicity, mental retardation etc.	No increased risk below the threshold dose	Both the severity and incidence of the disease increase with dose

*Brent, 1987, 1990, 1999

Radiation produced genetic disease in the F-1 generation

• There is little to no evidence among the offspring of childhood, adolescent, and young adult cancer survivors; atomic- bomb survivors; residentiallyexposed populations or radiation-exposed workers for an excess of cytogenetic syndromes, single- gene disorders, malformations, stillbirths, neonatal deaths, cancer, or cytogenetic markers that would indicate an excess of heritable genetic mutations in the exposed parents (COMARE, 2004; Nakamura, 2006; Winther and Olsen, 2012).

There are extensive data on mutations induced by ionizing radiation in microbes and somatic cells of rodents and humans. However, these data alone cannot be used to assess mutational risk in human germ cells, possibly because of the biological characteristics of human gametogenesis, compared to that of other mammals and to somatic cells of either humans or other mammals (Sobels, 1993). To accurately assess the influence of ionizing radiation on the genome of human germ cells, it is necessary to conduct studies in human populations.

Why have we not been able to document radiation induced mutagenesis in humans?

Biological filtration (Brent 1992)

- The importance of pure bred strains of experimental animals.
- The specific locus test using pure bred strains of mice
- The rarity of the persistence of induced mutations., necessitating very large populations exposed to high exposures.
- Neel's estimate of the exposure to double the mutation rate from the mouse data is 2 Gy (acute dose, 4Gy protracted dose.

Tissue Effects of the Embryo/Fetus from Pregnancy Radiation Exposure

60 years of animal researh has determined that all of these effects have a NOAEL <0.20 Gy.

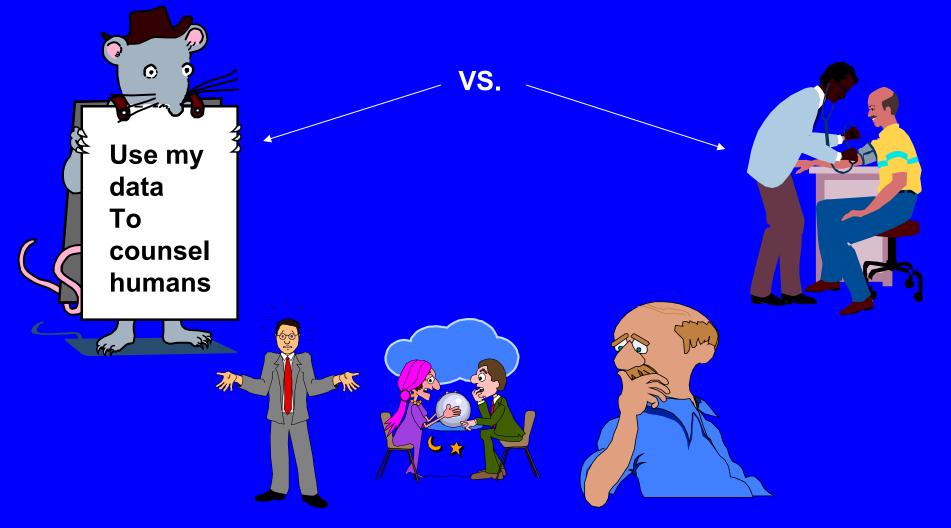
- congenital malformations,
- growth retardation,
- miscarriage and stillbirth,
- "The all or none phenomenon"
- mental retardation and neurobehavioral effects,
- convulsive disorders

bur not cancer risks in the children of mothers exposed to radiation during pregnancy.

Not without controversy

- "The all or None Phenomenon"
- Mental retardation

The All or None Phenomenon



Not without controversy

- "The all or None Phenomenon "
- Irradiation of rats and mice with up to 1.5 to 2 Gy during the pre-implantation and pre-somite development stage results in high embryonic mortality. However, malformation rates in the surviving fetuses at term are similar to the controls,. There was no weight reduction in the surviving rat embryos at term.

The All or None Phenomenon Dogma

In many of Streffer's and his colleague's papers they repeat the mantra:

"The fact that malformations can be induced after exposure to a single cell, the zygote, contradicts the long-standing dogma of teratology that developmental defects are inducible only when the conceptus is exposed during organogenesis".

The All or None Phenomenon Dogma

In many of Streffer's and his colleague's papers they repeat the mantra:

"The fact that malformations can be induced after exposure to a single cell, the zygote, contradicts the long-standing dogma of teratology that developmental defects are inducible only when the conceptus is exposed during organogenesis".

Vindication

 Margaret Adam, a geneticist at the University of Washington published a review article dealing with the "All or None Phenomenon" and concluded, "given the many women exposed to medications or environmental agents before learning of their pregnancies, it would be prudent to continue to counsel pregnant women using "All or None hypothesis" to avoid needless interruption of pregnancy out of unfounded fear of an adverse pregnancy outcome" (Birth Defects A, 2012).

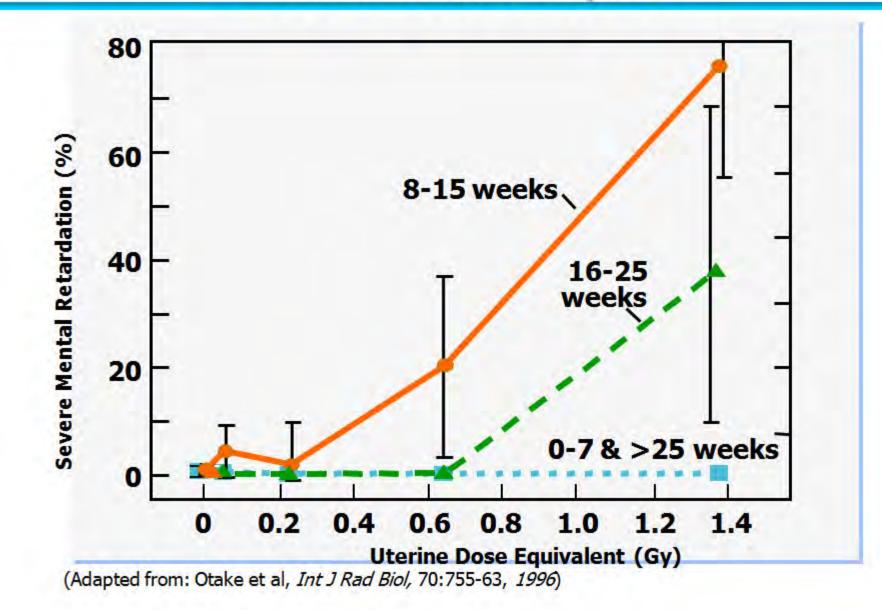
Mental Retardation Otake and Schull, 1984

In 1984 Otake and Schull summarized data from the in utero A-bomb survivors and concluded that mental retardation was not a threshold effect and that exposures in the range of diagnostic radiological procedures could increase the risk of mental retardation (0.1 Gy, 10 rad).

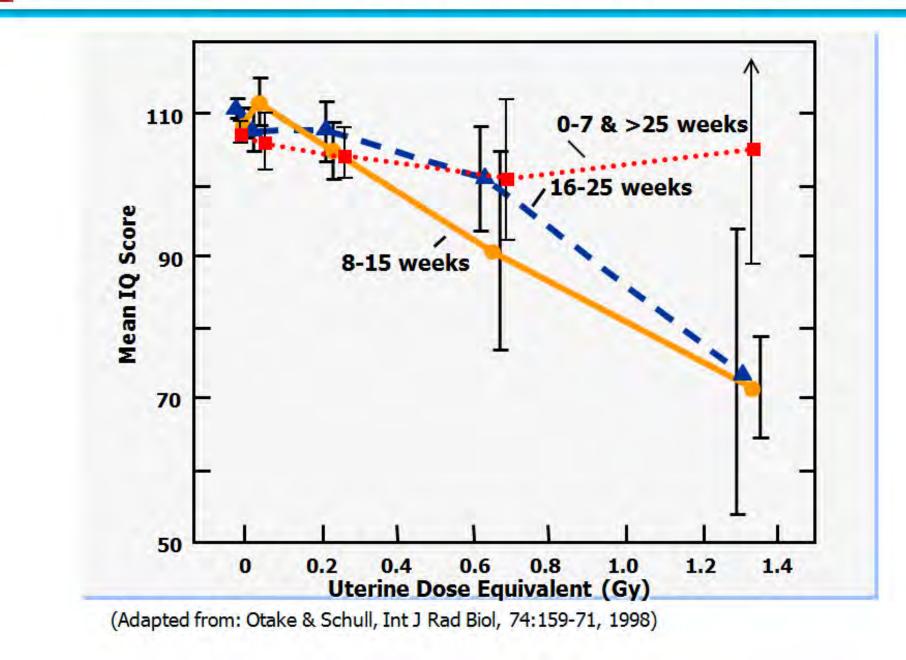
In 1999, Schull presented a re-analysis of his data and indicated that there may be a threshold for mental retardation at 0.54 Gy.



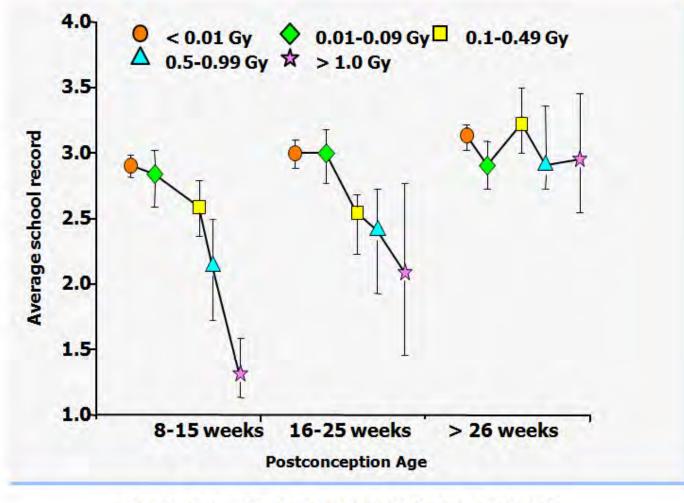
Mental Retardation by Dose and Weeks Postconception



Intelligence Quotient by In Utero Weeks Postconception &



School Performance, In Utero A-bomb Exposure



(Otake & Schull, Int J Rad Biol, 74:159-71, 1998)

Stochastic and threshold dose-response relationships of diseases produced by environmental agents*

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*Brent, 1987, 1990, 1999

Basic Science Plausibility of Why 1 Rad (.01 Gy) Does Not Double the Incidence of Mental Retardation

- **1. Teratogenesis is a threshold phenomenon.**
- 2. In-utero exposure to ionizing radiation indicate that there is approximately a 30 point IQ loss per Gy during the most sensitive period of human brain development, indicating that severe mental retardation would not occur at 0.01 Gy, even if there were not a threshold effect.
- 3. At .01 Gy there are no observable histological effects in the developing brain that could account for severe CNS effects.
- 4. Neurobehavioral evaluations of animals exposed inutero demonstrate a threshold for behavioral effects at the same dose as for other teratologic effects (>0.2 Gy).

New Publications

Brent, RL, Carcinogenic risks of prenatal ionizing radiation. Seminars in Fetal and Neonatal Medicine, June 2014.

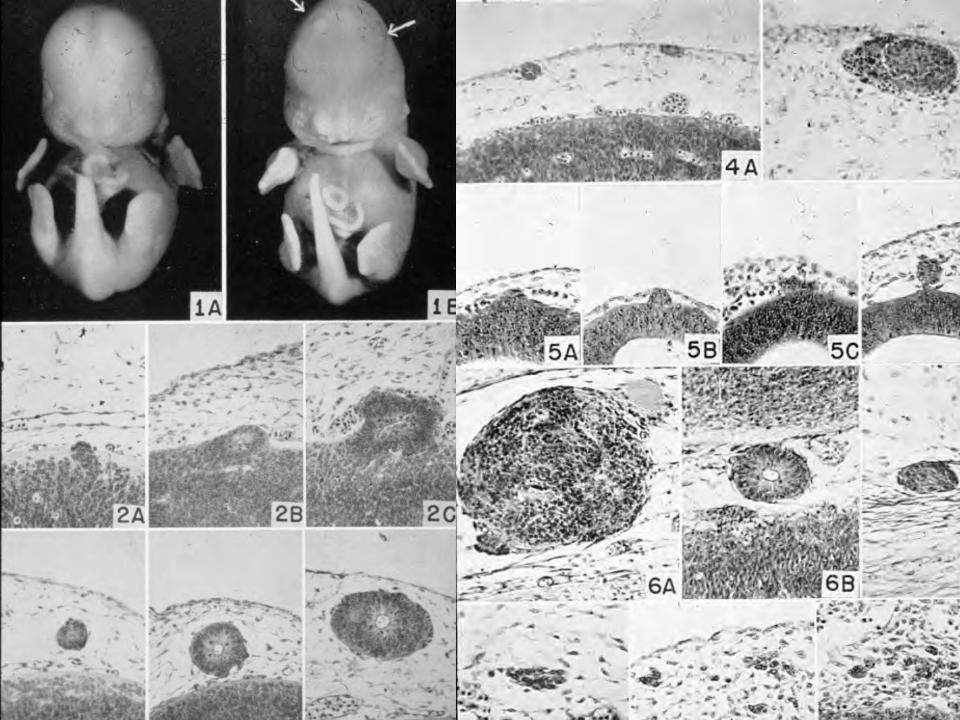
Brent, RL, Counseling families with regard to reproductive risks of environmental toxicants. Seminars in Fetal and Neonatal Medicine, June 2014.

NCRP publication 174. Preconception and Prenatal Radiation Exposure: Health Effects and Protective Guidance, May 24, 2013. pp 372.,7910 Woodmont Ave,, suite 400, Bethesda, MD 20814-3095

The era of the 1940s and 1950s

Research discoveries at the University of Rochester Research publications of Alice Stewart 1956;1958; 1972

Wilson, J.G., Brent, R.L. and Jordan, H.C.: Neoplasia induced in rat embryos by roentgen irradiation. Cancer Research 12: 222-228, 1952; also appeared in U.S.A.E.C.D. U.R.-183, 1951.



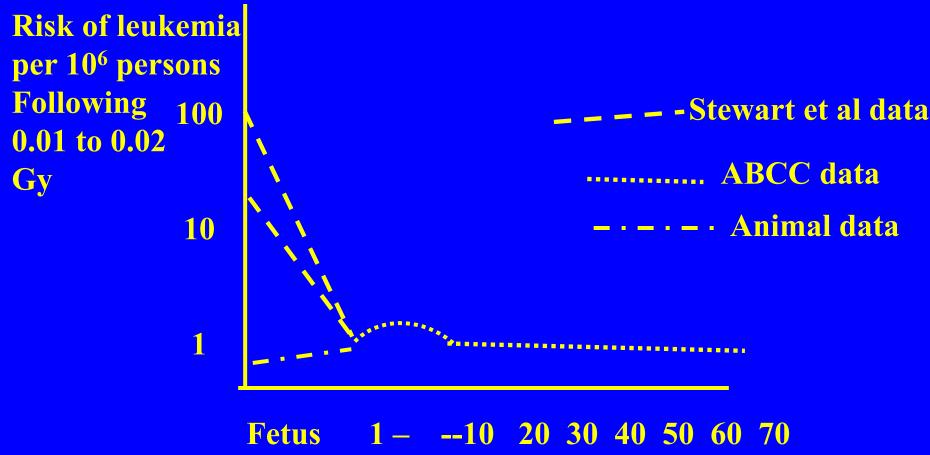
Nakano <u>et al.</u> (2007), Chromosome aberrations do not persist in the lymphocytes or bone marrow cells of mice irradiated in utero or soon after birth . Radiat. Res, 167: 693-702 Nakano et al. (2007) irradiated mice at various stages of pregnancy with 1 or 2 Gy. **Translocation frequencies in the peripheral** blood T cells, spleen cells and bone marrow cells were determined when the offspring were 20 weeks old. The translocation frequency was very low in the mice that were irradiated in utero (0.8 %). The mice that were irradiated during days to weeks after birth had translocation frequencies of 5 %.

R

The Risk of Cancer from In-utero Irradiation (Publications)

Stewart et al. 1956; Stewart et al. 1958; Ford and Patterson 1959; Ager et al. 1965; Graham, Levine et al. 1956; Lillienfeld 1966; Polhemus and Koch 1969; Stewart and Kneale 1970; Stewart 1972, 1973; Hoshino et al. 1965; McMahon 1985; Harvey et al. 1985; Yoshimoto et al. 1988; Graham et al. 1988; Muirhead and Kneale 1989; Rodvall et al. 1990; Thompson et al. 1994; Yoshimoto et al. 1994; Boice and Inskip 1996; Pierce et al. 1996; Delongchamp et al. 1997; Doll and Wakeford 1997; Miller and Boice 1997; NRBP 1998; Boice and Miller 1999; Miller 1999; Brent 1999; Naumburg et al 2001

Risk of leukemia in children following ionizing radiation exposure of pregnant women



Age in years

Numerous in-utero radiation epidemiological studies have been performed that have studied the risk of cancer in the children and adults who were irradiated in utero

Positive associations for an increased incidence of <u>childhood</u> <u>leukemia</u> and <u>cancer</u> following in utero diagnostic radiation exposures have been derived from 40 case control studies. Of the 40 case control studies 24 were not statistically significant. However, the meta analysis indicated a RR of 1.2 to 1.3.

The 17 cohort studies did not find an association.

COURT BROWN, W.M., DOLL, R., and HILL, A.B. (1960). "Incidence of leukaemia after exposure to diagnostic radiation in <u>utero</u>," Br. Med. J. 2(5212), 1539– 1545.

Three famous epidemiologists performed a cohort study of 39,000 plus pregnant mothers exposed to diagnostic radiological studies from 1945-58 at 8 hospitals in the UK. The number of children who died from leukaemia in the exposed group was 9; the expected number was 10.5. The investigators, "concluded that an increase in leukaemia among children due to radiographic examination of their mother's abdomen during the relevant pregnancy is not established."

Interaction between Stewart and Mole

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Kneale and Stewart concluded that first trimester exposures are "Probably 16 times as dangerous as third trimester exposures." Stewart reminded Dr. Mole, "Not to forget that as a result 10% of viable fetuses were involved in these examinations between 1953 and 1970." This resulted in a 5% addition to the number of children who died from malignant diseases."

Remember what Brenner stated as the basis of his risk estimate

"The most scientifically credible approach to risk extrapolation to this dose range is a linear extrapolation from greater doses, which is the assumption implicitly adopted here." (Brenner et al 2001). ***Radiation-related cancer risks at low doses among Atomic Bomb survivors* Pierce and Preston, Radiation Res. 154:178, 2000**

In responding to ICRP application of the RERF data to other radiological exposures, Pierce and Preston stated, "It is important to consider reasons why the A-Bomb survivor results should depart from other radiological expectations."

Linear-no-threshold hypothesis: LNTH

Hermann Muller, Nobel Prize speech in 1946 **Curt Stern 1946; Is the dose-rate unimportant? National Council on Radiation Protection American Nuclear Society Rejection of the universal application of the LNTH Health Physics Society 2010 USA BEIR VII report 2005** French Academy of Sciences, Academie Nationale Med 2005 **UNSCEAR 2000 Calabrese 2011 (Hormesis)**

Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionizing Radiation (Royal College of Radiologists (RCR 2009) and the Health Protection Agency)

Fetal	doses and the risk of childhood ca	ncer
Mammography	0.001 to 0.01 mGy	1 in 1,000,000
CT scan of Pelvis		1 in 1000
CT pelvis, abd, chest	10 to 50 mGy	1 in 200
Background radiation	3 mGy during pregnancy	1 in 3000

Words of Wisdom from the Past and Present

"I am certain that there is too much certainty in the world" -Michael Crichton



• •

Very large risks from *in utero* exposure have been predicted

- Based mostly on the large Stewart-Kneale case-control study of fetal radiation exposure and childhood cancer, it was predicted that an additional 6% of persons would die from cancer after 1 Gy of *in utero* radiation. (Doll & Wakeford, *Br J Radiol*, 70:130-39, 1997)
 - 6% lifetime cancer mortality risk per Gy is:
 - ~3 times as large as the corresponding estimated A-bomb risk after exposure at age 10, or
 - ~6 times as large as estimated risk after exposure at age 30. (Preston et al, *Radiat Res*, 160:381-407, 2003)

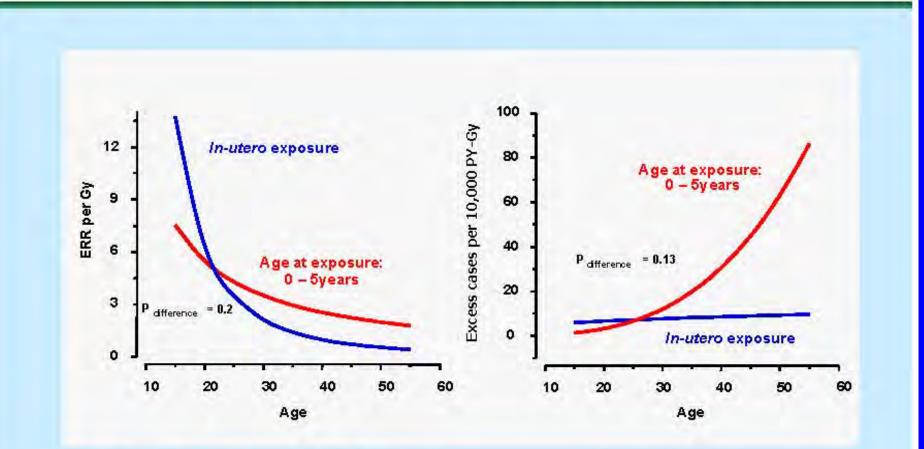
Solid Cancer Incidence in Atomic Bomb Survivors Exposed In Utero or as Young Children

Dale L. Preston, Harry Cullings, Akihiko Suyama, Sachiyo Funamoto, Nobuo Nishi, Midori Soda, Kiyohiko Mabuchi, Kazunori Kodama, Fumiyoshi Kasagi, Roy E. Shore J Natl Cancer Inst 2008;100: 428 – 436

Lifetime risks following in utero exposure may be considerably lower than for early childhood exposure.



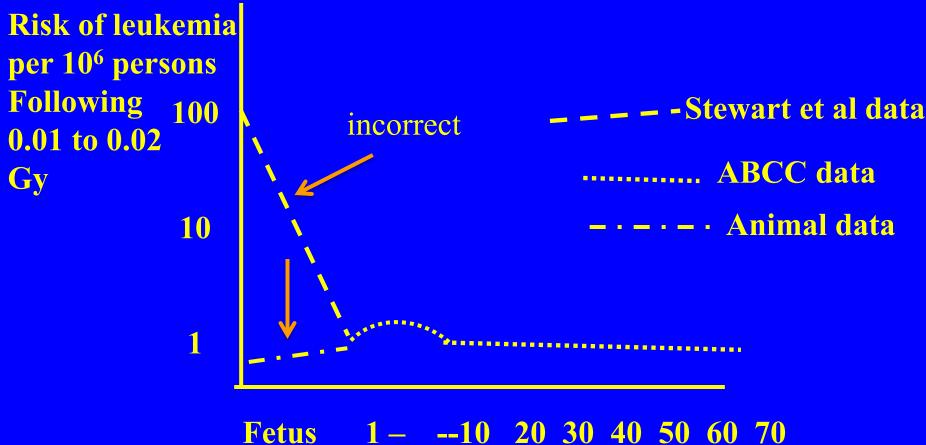
Solid Cancer Risk Patterns for In Utero and Childhood Exposure, A-bomb Survivors



In utero ERR/Gy= 1.0 (95%CI: 0.2, 2.3)

(Preston et al, J Natl Cancer Inst, 2008; 100:428-36)

Risk of leukemia in children following ionizing radiation exposure of pregnant women



etus 1 – --10 20 30 40 50 60 70 Age in years

Carcinogenic Risks <0.01 Gy to the Embryo/Fetus

There is the scholarly, conservative view of Martha Linet who writes that the risk is very small and would not justify canceling a radiological study in a pregnant woman if the study is medically indicated. She also suggests that we wait to determine whether the risk increases based on future data from the Preston et al. study, which stated that "additional follow-up of this cohort is necessary before definitive conclusions can be made about the nature of the risks for those exposed *in* utero." 28

Richard Wakeford has been interested in this subject for decades. We first met many years ago when we were defense experts in litigation between the UK and **Ireland regarding the allegation that the Sellafield** Nuclear Facility was discharging nuclear "waste" that was responsible for an increase in cancer and birth defects in the inhabitants on the East Coast of Ireland. The World Court deliberations ended after 10 years with a defense verdict. One of his most recent publications indicated that 20% of childhood leukemia in the UK may be due to background radiation.⁶⁷ He still is the proponent of the idea that the embryo is more vulnerable to the carcinogenic effects of radiation than the child.

- I Brent) am not one who is reluctant to make • predictions. I agree with Martha Linet regarding the risks of embryonic ionizing radiation. However, I would predict that in the next twenty years we will learn that the risk of cancer from embryonic radiation will be further reduced. At my present age I will not be alive to know the results. I believe that the omnipotential (stem) cells protective effect that was present in the embryo at the time of the radiation will continue to be manifested.
- We may be using umbilical cord blood or other sources stem cells from the recipient to prevent future cancers.

Counseling

- Counseling an Individual Patient
- If a pregnant woman has had a diagnostic radiological procedure that exposed her embryo or has been scheduled for an x-ray that will expose her embryo and is concerned about the increased risk of cancer from the exposure, what is your response?
- Response: The majority of diagnostic radiological studies expose the embryo to less than 0.10 Gy (10 rad). Based on all the studies we have available, the risk of cancer to the embryo is very low and possibly so low that we may never be able to measure the risk

Therefore, diagnostic radiological studies that are considered to be important for optimal patient care should be performed.

It is important to be aware of the background risk of cancer for all individuals, which is 23% for potentially lethal cancers. Fortunately, each year the percentage of cancers that are cured is increasing. The background risk of cancer is hundreds to thousands of times more prevalent than theoretical radiation induced cancer risk.

Health Physics Pregnancy Website, Ask the Expert (ATE)

In 2013 there were thousands of hits on the pregnancy website.

In 2013, one thousand, four hundred and eighty- three (1483) individuals made direct contact for a personal consultation.

"Will I get cancer?"



"I am four months pregnant and my obstetrician was concerned that the pain in my chest was due to a pulmonary embolus. He ordered a CT scan of my chest. Now I am concerned that my fetus and I will get cancer"

The era of the 1940s and 1950s

Research discoveries at the University of Rochester Research publications of Alice Stewart 1956;1958; 1972

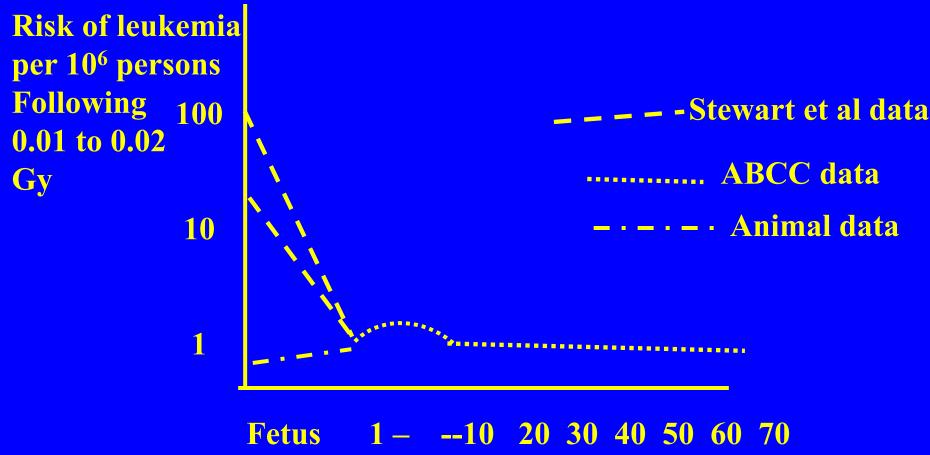
Wilson, J.G., Brent, R.L. and Jordan, H.C.: Neoplasia induced in rat embryos by roentgen irradiation. Cancer Research 12: 222-228, 1952; also appeared in U.S.A.E.C.D. U.R.-183, 1951. Nakano <u>et al.</u> (2007), Chromosome aberrations do not persist in the lymphocytes or bone marrow cells of mice irradiated in utero or soon after birth . Radiat. Res, 167: 693-702 Nakano et al. (2007) irradiated mice at various stages of pregnancy with 1 or 2 Gy. **Translocation frequencies in the peripheral** blood T cells, spleen cells and bone marrow cells were determined when the offspring were 20 weeks old. The translocation frequency was very low in the mice that were irradiated in utero (0.8 %). The mice that were irradiated during days to weeks after birth had translocation frequencies of 5 %.

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The Risk of Cancer from In-utero Irradiation (Publications)

Stewart et al. 1956; Stewart et al. 1958; Ford and Patterson 1959; Ager et al. 1965; Graham, Levine et al. 1956; Lillienfeld 1966; Polhemus and Koch 1969; Stewart and Kneale 1970; Stewart 1972, 1973; Hoshino et al. 1965; McMahon 1985; Harvey et al. 1985; Yoshimoto et al. 1988; Graham et al. 1988; Muirhead and Kneale 1989; Rodvall et al. 1990; Thompson et al. 1994; Yoshimoto et al. 1994; Boice and Inskip 1996; Pierce et al. 1996; Delongchamp et al. 1997; Doll and Wakeford 1997; Miller and Boice 1997; NRBP 1998; Boice and Miller 1999; Miller 1999; Brent 1999; Naumburg et al 2001

Risk of leukemia in children following ionizing radiation exposure of pregnant women



Age in years

Numerous in-utero radiation epidemiological studies have been performed that have studied the risk of cancer in the children and adults who were irradiated in utero

Positive associations for an increased incidence of <u>childhood</u> <u>leukemia</u> and <u>cancer</u> following in utero diagnostic radiation exposures have been derived almost exclusively from 40 case control studies. Of the 40 case control studies 24 were not statistically significant. However, the meta analysis indicated a RR of 1.2 to 1.3.

The 17 cohort studies did not find an association.

COURT BROWN, W.M., DOLL, R., and HILL, A.B. (1960). "Incidence of leukaemia after exposure to diagnostic radiation in <u>utero</u>," Br. Med. J. 2(5212), 1539– 1545.

Three famous epidemiologists performed a cohort study of 39,000 plus pregnant mothers exposed to diagnostic radiological studies from 1945-58 at 8 hospitals in the UK. The number of children who died from leukaemia in the exposed group was 9; the expected number was 10.5. The investigators, "concluded that an increase in leukaemia among children due to radiographic examination of their mother's abdomen during the relevant pregnancy is not established."

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Contributors to NCRP Report 174

Committee: Robert Brent, Roger Harms, Martha Linet, John Mulvihill, Robert Gorson, Linda Kroger, Andrew Maidment, Shiao Woo.

Consultants: Jerold Bushberg, Susan Wiltshire, Joseph Morrissey, Marvin Ziskin

NCRP Secretariat: Marvin Rosenstein, Brian Dodd, Cindy O'Brien, Laura Atwell, James Cassata President of the NCRP: John D. Boice, Jr

For Counselors

With regard to the in-utero population, the finalization of the Preston et al (2008) publication twenty or thirty years from now may provide some definitive answers. Some predict that there may be an epidemic of cancer in the older in utero population.

In the mean time we have to say that we do not have a definitive answer to this question.

Counseling about cancer risks

The more recent studies indicate that the embryo/fetus is less vulnerable to the carcinogenic effects of radiation compared to the child or adult. With exposures of pregnant women below 0.10 Gy, the embryo may not be at increased risk. Whether or not there is a threshold, the carcinogenic risks are estimated to be very low and would indicate that a clinically indicated diagnostic test should be performed in a pregnant woman.

More Headlines

Headline in the NY Times "Reckless Full-Body Medical Scans"

"A new study finds that scans impart radiation doses comparable to those received by atomic-bomb survivors in Hiroshima and Nagasaki"

Solid Cancer Incidence in Atomic Bomb Survivors Exposed In Utero or as Young Children

Dale L. Preston, Harry Cullings, Akihiko Suyama, Sachiyo Funamoto, Nobuo Nishi, Midori Soda, Kiyohiko Mabuchi, Kazunori Kodama, Fumiyoshi Kasagi, Roy E. Shore J Natl Cancer Inst 2008;100: 428 – 436

Lifetime risks following in utero exposure may be considerably lower than for early childhood exposure. U.S. Radiation Protection: Role of National and International Advisory Organizations and Opportunities for Collaboration (Harmony Not Dissonance)

Michael Boyd U.S. Environmental Protection Agency

Overview

- A brief history of ICRP and NCRP recommendations and how they compare
- Examples where U.S. regulations differ from ICRP/NCRP recommendations and some reasons why
- A review of the ideal flow chart for moving from science to radiation protection regulations
- Opportunities for better collaboration leading to harmony, not dissonance

Origin of the ICRU, ICRP, and NCRP

- 1925 First International Congress of Radiology (ICR) in London established what was to become the ICRU
- 1928 ICRP originated at Second ICR in Stockholm as the International X-ray and Radium Protection Committee (IXRPC)
 - First radiation protection recommendations adopted
 - Consensus on a tolerance dose for x-rays (~700 mGy/yr)
- 1929 Advisory Committee on X-ray and Radium Protection formed under sponsorship of U.S. National Bureau of Standards

Evolution of the NCRP

- 1929 1946 Advisory Committee on X-ray and Radium Protection
- 1946 1956 National Committee on Radiation Protection
 - Name change reflected the increasing scope
- 1956 1964 National Committee on Radiation Protection and Measurements
- 1964 Present National Council on Radiation Protection and Measurements (50th anniversary)
 - Congressionally chartered in 1964

Influence of Lauriston Taylor

- From 1928 through most of the 20th century, Lauriston Taylor played an important role in the activities of the organizations now known as ICRU, ICRP and NCRP
- Close collaboration between NCRP and ICRP helps to explain why U.S. and international radiation protection recommendations have tended to remain in harmony, even when U.S. regulations have not kept up with them

Recommendations: NCRP and ICRP

NCRP Report No. 17 (1954)

- "Protection against Radiations from Radium, Cobalt-6o, and Cesium" (also known as NBS Handbook 54 or the "1949 Report" for the Tri-Partite Conference held in Chalk River, Canada)
- 300 mR/week (~ 3mSv per week or 150 mSv/yr)
- Maximum permissible "amounts in body" for Ra = 0.1 μCi (3.7 kBq), Co-6o = 3 μCi (111kBq), and Cs-137 = 90 μCi (3.33 MBq)
- ICRP Recommendations (1954)
 - o.3 rem per week (basis for MPCs for critical organ)
 - Doses to public should be 10x lower (first public dose limit)

An Example of Collaboration

- K. Z. Morgan chaired the committees of both NCRP and ICRP that resulted in:
 - ICRP Publication 2 (1959)
 - National Bureau of Standards (NBS) Handbook 69 abridged version of ICRP 2
 - NCRP Report No. 22 NBS Handbook 69 with an addendum

 ICRP 2 (Permissible Dose for Internal Radiation) provided a consistent method for implementing RP recommendations across U.S. agencies and among international community

Recommendations: NCRP and ICRP

NCRP Amendments (1957)

- 0.3 rem per week not to exceed 3 rems per quarter
- Maximum accumulated dose = (Age 18) x 5 rems
- Maximum prospective annual permissible dose equivalent = 5 rems (50 mSv)
- ICRP Recommendations (1957)
 - Occupational dose limit of 5 rems/yr (50 mSv/yr)
 - Public dose limit of 500 millirems/yr (5mSv/yr)

NCRP Recommendations

NCRP Report No. 39 (1971)

- "Basic Radiation Protection Criteria"
- Includes fetal dose limit of 0.5 rem
- Introduces quality factor (QF) and dose equivalent (DE)
- NCRP Report No. 91 (1987)
 - Includes discussion of stochastic risk
 - Adopts effective dose equivalent as introduced by ICRP in Publication 26 and adopts SI units
 - Recommends 50 mSv per year occupational limit and 1 mSv public dose limit
 - Endorses ALARA along with justification and limitation

NCRP Recommendations

NCRP Report 116 (1993)

- Generally consistent with ICRP Publication 60 (1990); uses same tissue and radiation weighting factors to calculate effective dose
- Reflects latest science from NAS BEIR V and UNSCEAR (i.e., risk-based recommendations)

Notable differences with ICRP Pub. 60

- Retains 50 mSv/yr occupational limit, but sets lifetime limit of 10 mSv/yr; ICRP recommends 20 mSv/yr (avg.)
- Equivalent dose to embryo-fetus should not exceed 0.5 mSv/month; ICRP recommends 2 mSv total

U.S. Radiation Protection Standards

- 1955 Atomic Energy Commission (AEC) proposes standards for radiation protection (final rule 10 CFR 20 in 1957)
- 1959 Federal Radiation Council (FRC) established by Executive Order
- 1959 ICRP issues Publications 1 and 2
- 1960 FRC issues general guidance for radiation protection and AEC revises Part 20

1977 – An Instance of Bad Timing (Dissonance?)

- EPA used ICRP 2 methodology for
 - 1976 drinking water standards (40 CFR Part 141)
 - 1977 uranium fuel cycle regulations (40 CFR Part 190)
- ICRP issued Publication 26 in January 1977!

U.S. Agencies Respond to ICRP 26

- NRC begins major revision to 10 CFR 20
- EPA issues Federal Guidance Report No. 11 (September 1988)
 - DCFs for inhalation and ingestion for over 800 radionuclides based on ICRP Pub. 30
- EPA issues air emission standards for radionuclides – 40 CFR Part 61 (1989)
 - Public dose limit of 100 μSv/yr ede
 - No more than 30 μSv/yr ede from iodine

1990 – More Bad Timing

- ICRP Publication 60 adopted Nov. 1990
- May 1991 NRC issues new standards for radiation protection based on ICRP 26
- January 1994 EPA issues spent fuel and high level waste disposal standards
 - Include 150 µSv/yr ede limit for public exposure based on ICRP 26 dosimetry

U.S. Agencies Respond to ICRP 60

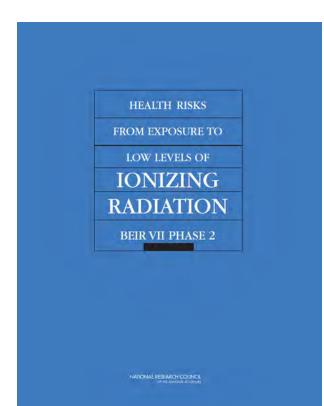
- NRC allows licensees, upon request, to use updated dosimetry such as ICRP Publication 68
- DOE issues worker protection standards in 2007 based on ICRP Publication 60
- EPA Yucca Mountain disposal standards (2008 amendments) use dosimetry based on ICRP Publication 72

From Science to Regulations

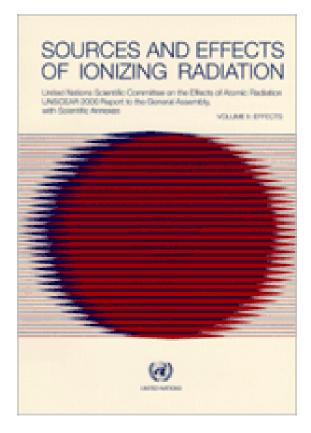
- Step 1 Collect and interpret the scientific literature (NAS BEIR and UNSCEAR reports)
- Step 2 Develop radiation protection recommendations based on the science (NCRP and ICRP)
- Step 2 ½ Update the Basic Safety Standards (IAEA, but not binding on the U.S.)
- Step 3 Develop or update RP regulations as necessary (EPA, NRC, State RP agencies, etc.)

Step 1 – BEIR VII and UNSCEAR

NAS BEIR VII (2005)

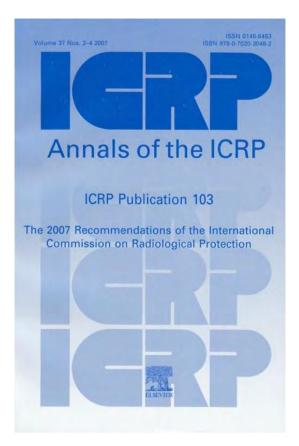


UNSCEAR 2000 REPORT, VOL. 2



Step 2 – ICRP and NCRP Recommendations

ICRP PUBLICATION 103



NCRP REPORT 116



LIMITATION OF EXPOSURE TO FONIZING RADIATION



Step 2 ¹/₂ – IAEA Basic Safety Standards (2011)

IAEA Safety Standards

for protecting people and the environment

Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards INTERIM EDITION

General Safety Requirements Part 3 No. GSR Part 3 (Interim)



Step 3: U.S. RP Regulations

- U.S. Nuclear Regulatory Commission
 - IO CFR Part 20
 - IO CFR 50 Appendix I
- U.S. Environmental Protection Agency
 - 40 CFR Part 190
 - Other dose-based standards found in Clean Air Act regulations, Safe Drinking Water Act MCLs, and various waste managment standards

ICRP Publication 103 (2007)

- Moves from process-based to situation-based system
 - Planned exposure situations
 - Emergency exposure situations
 - Existing exposure situations
- Distinguishes between source-related protection using constraints and reference levels and individual-related protection using dose limits

Opportunities for Harmonization

- Expected new rulemakings offer opportunities for selectively incorporating ICRP Publication 103
 - EPA has issued ANPR for updating 40 CFR 190
 - NRC staff developing technical basis for updating 10 CFR 20
- U.S. is making progress moving towards SI as preferred system of units

NCRP Proposal to Update Report No. 116

- NCRP Report 116 largely compatible with ICRP Publication 60
- ICRP Publication 103 was issued in 2007
- Historically, NCRP issues recommendations that tailor ICRP publications to U.S. applications
- A timely revision to Report No. 116 could lend support to U.S. agencies' achieving more harmony with international RP regulations
- The Fukushima accident exposed weaknesses due to our current "dissonance" with the global RP community

Opportunities for Collaboration

- Staff from U.S. agencies are collaborating on the technical underpinnings of these new proposed rulemakings by
 - Participating on subcommittees of the Interagency Steering Committee on Radiation Standards (ISCORS),
 - Participating on NCRP committees and ICRP task groups, and
 - Staying current with reports of the NAS, UNSCEAR, and the scientific literature

Thank you for your attention!

- Useful references for this presentation:
 - A Brief History of Radiation Protection Standards, William C. Inkret, Charles B. Meinhold, and John C. Taschner, Los Alamos Science, Number 23, 1995
 - The History of ICRP and the Evolution of its Policies, R.H. Clarke and J.Valentin, published in ICRP Publication 109, 2009

Fiftieth Annual Meeting Program

Summary Session





NCRP: Achievements of the Past 50 Years and Addressing the Needs of the Future



Kenneth R. Kase

National Council on Radiation Protection & Measurements



50th Annual Meeting

Bethesda MD -- March 11, 2014







From 2003: Radiation Protection at the Beginning of the 21st Century—A Look Forward

> 3 central themes (T. Tenforde):

- Facilitate improved communication,
- Coordinate the development of the basis for radiation health protection guidance and recommendations, and
- Achieve consistency in meeting the needs of federal, state and public organizations.



- NCRP could move in new directions in developing radiation safety recommendations (e.g. relating dose to something other than fatal cancer risk),
- Consider making recommendations about estimates of risk, but not specifying dose limits,
- Apply the principle of justification also to the removal of an existing source of radiation,
- Deliver an understandable product accepted by stakeholders.



From 2013: Implications of Radiation Dose and Exposed Populations on Radiation Protection in the 21st Century

- Radiation protection guidance should keep in step with
 - Increase in population exposures,
 - Changes in size of the population exposed,
 - Possibility of nuclear incidents,
 - Development of new scientific knowledge,
 - Development of new technologies.



As the needs for radiation protection change in the 21st century there is a need for constant improvements, constant vigilance, continued guidance and more radiation protection scientists.

2014 – Fiftieth Annual Meeting



NCRP: Achievements of the Past 50 Years and Addressing the Needs of the Future

Eleventh Annual Warren K. Sinclair Keynote Address

Science, Radiation Protection, and the NCRP: Building on the Past, Looking to the Future Jerrold T. Bushberg University of California, Davis School of Medicine





Current important questions:

- Estimating and effectively communicating the health risk from "low dose" radiation,
- Implications of non-targeted effects,
- Concerns about sensitive subpopulations,
- Biological effectiveness of low energy photons,
- Justification and optimization in diverse environments,
- Long term storage and monitoring of high level radioactive waste,
- Risks of space travel,
- Implications of nanotechnology.

Thirty-Eighth Lauriston S. Taylor Lecture on Radiation Protection and Measurements On the Shoulders of Giants: Radiation Protection Over 50 Years Fred A. Mettler, Jr. New Mexico Federal Regional Medical Center





Success in the future will depend upon our <u>current group of "giants"</u> and their ability to <u>identify and train the next</u> <u>generation</u>.



Basic Criteria, Epidemiology, Radiobiology, and Risk

Kathryn D. Held, Session Chair





Radiation Safety and HumanSpaceflight: Importance of theNCRP Advisory Role in ProtectingAgainst Large UncertaintiesFrancis A. CucinottaUniversity of Nevada Las Vegas

Integrating Basic Radiobiological

U.S. Environmental Protection Agency

Science and Epidemiological

Studies (Why and How?)

R. Julian Preston



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Biological Effectiveness of Photons and Electrons as a Function of Energy Steven L. Simon National Cancer Institute and SC 1-20 ≻A key event based approach for risk estimation could be used with radiation epidemiology data to reduce uncertainty in low dose/low-dose rate cancer and non-cancer risk estimates. (SC 1-21)

New knowledge is needed to reduce the uncertainties in risk estimates to achieve exploration goals for Mars and beyond.
 Qualitative differences in the biological effects of HZE particles compared with terrestrial radiation and effects to the central nervous system are areas of critical importance.

 The Committee has developed a means of assessing a probability density function (PDF) of the biological effectiveness for selected energies.
 A composite PDF based on multiple lines of evidence may provide a way to assess uncertainty in estimates of radiation-related cancer risk.

Nuclear and Radiological Security and Safety John W. Poston, Sr. & Jill A. Lipoti, *Session Co-Chairs*



Response to an Improvised Nuclear Device or a Radiological Dispersal Device: Models, Measurements, and Medical Care C. Norman Coleman *National*

C. Norman Coleman National Cancer Institute Newer issues for consideration are estimating and potentially mitigating risk from radiationinduced cancer and developing a comprehensive "National Concept of Operations."



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Decision Making for Late-Phase Recovery from Nuclear or Radiological Incidents (What's Next After the First Responders Have Left?) S.Y. Chen Illinois Institute of Technology

>Recommendations are needed aimed at enhancing and strengthening late-phase recovery effort following a major nuclear or radiological incident. (Draft Report of SC 5-1 is in review.)

Operational and Environmental Radiation Protection

Carol D. Berger & Ruth E. McBurney, Session Co-Chairs





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Radiation Safety of Sealed Radioactive Sources Kathryn H. Pryor Pacific Northwest National Laboratory

A new report from PAC 2 (SC 2-7) will provide a set of "lessons learned" regarding what has gone wrong with sealed sources, what caused those events, and what could be done to prevent them in the future.

Pennsylvania's Technologically-Enhanced Naturally-Occurring Radioactive Material Experiences and Studies of the Oil and Gas Industry David J. Allard Pennsylvania Department of Environmental Protection

➤New information concerning TENORM related to oil and gas well operations, geology, the respective uranium/thorium and radium content in oil and gas wastewater, treatment solids and radon in natural gas may lead to future work.



Radiation Safety in Nanotechnology (Does Size Matter?) Mark D. Hoover National Institute for Occupational Safety and Health and SC 2-6

>Knowledge gaps regarding information needed to implement appropriate radiation safety programs in these settings will be identified and questions arising from the report related to nanometer-sized particles in current respiratory tract and systemic dosimetry models may require further work.

Radiation Measurement and Dosimetry

Wesley E. Bolch, Session Chair



Framework and Need for Dosimetry and Measurements: Quantitation Matters Raymond A. Guilmette Lovelace Respiratory Research Institute and PAC 6 >Develop guidance on frameworks for licensing biophysical devices and biological and pharmacological endpoints for biomarkers of radiation exposure and radiation-induced disease.

>Explore emerging issues in measurement and dosimetry relating to medical radiation treatments and diagnostics.



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Dose Reconstruction for the Million Worker Epidemiological Study Andre Bouville National Cancer Institute ≻The report will stimulate approaches to dosimetry that will require flexibility and changes in direction as new information is obtained, both with regard to dosimetry and with regard to the epidemiologic features of the study components. (SC 6-9)

Radiation Protection in Medicine

Donald L. Miller, Session Chair



Protection of Patients in Diagnostic and Interventional Medical Imaging Kimberly E. Applegate *Emory University School of Medicine*

>Provide the current state of the science regarding cancer risk from medical procedures using ionizing radiation.



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Protection and Measurement in Radiation Therapy Steven G. Sutlief University of Washington Medical Center Suggest future directions likely to be most fruitful.



Protective Guidance from Radiation Risks to the Gametes, Embryo, Fetus and Nursing Infant Robert L. Brent Alfred I. duPont Institute Hospital for Children > The NCRP has issued Report No. 174. Have all the questions been answered?

Radiation Education, Risk Communication, Outreach, and Policy

Julie E.K. Timins, Session Chair



Historical Trends in Radiation Protection, Policy and Communications: 1964 to the Present Paul A. Locke The Johns Hopkins University Bloomberg School of Public Health >Prepare to address both emerging issues of radiation protection and the new, innovative ways of communicating about radiation benefits, risks and policies.



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U.S. Radiation Protection: Role of National and International Advisory Organizations and Opportunities for Collaboration (Harmony not Dissonance) Michael A. Boyd U.S. Environmental Protection Agency

>New rulemaking should provide the NCRP an opportunity for updating fundamental radiation protection guidance for incorporation into U.S. regulations.

Capturing Opportunities and Meeting Challenges in Radiation Protection



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View from 25th (1989) – Future Role of NCRP in Radiation Protection

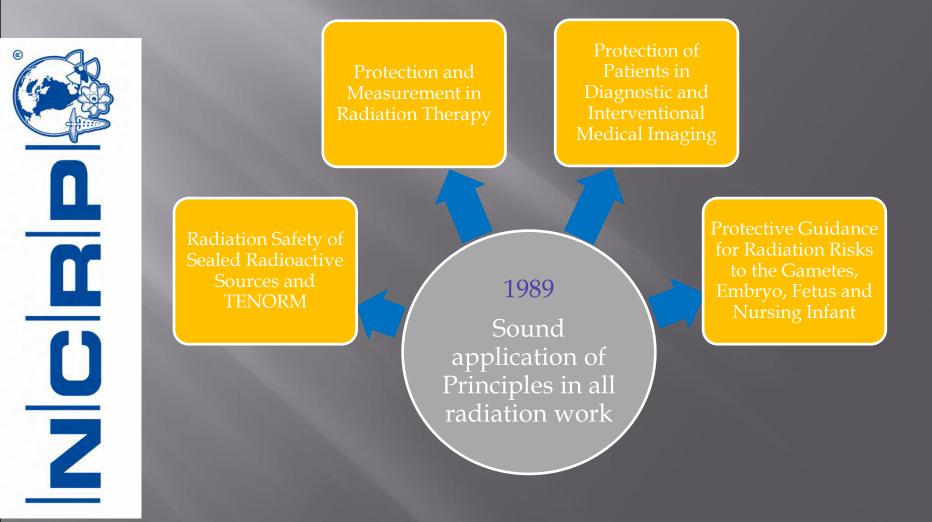
- Radiation research, effects, mechanisms, epidemiology,
- Sound application of Principles in all radiation work,
- Improve measurement and dosimetry techniques,
- Study and report on public exposure, reduce where appropriate,
- Accident prevention and preparedness,
- Recommendations for regulation to achieve adequate control,
- Develop better public understanding of radiation as a hazard in the context of other hazards.



Integrating Basic Radiobiological Science and Epidemiological Studies

1989

Radiation research, effects, mechanisms, epidemiology Biological Effectiveness of Photons and Electrons as a Function of Energy



1989

Improve

measurement

and dosimetry

techniques

Dose

Reconstruction for

the Million Worker

Epidemiological

Study



Framework and

Need for

Dosimetry and

Measurements



Improvised Nuclear Device or an Radiological Dispersal Device: Models, Measurements, and Medical Care

1989

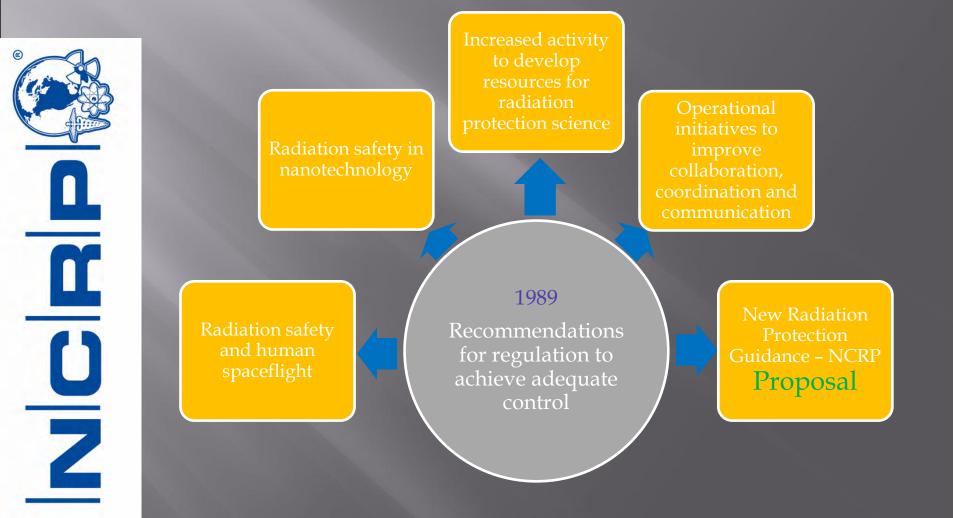
Accident prevention and preparedness Decision Making for Late-Phase Recovery from Nuclear or Radiological Incidents



Radiation education, risk communication, outreach, and policy

1989

Develop better public understanding of radiation as a hazard in the context of other hazards



What Else?



NCRP can rely on the strength of its multi-disciplinary personnel resources

There is a need to elucidate the ethical principles for radiation protection – ICRP/IRPA Workshop, 17-18 July 2014 in Baltimore following the HPS Meeting

What Else?



Proposal : Radiation Protection **Guidance for the United States**

Purpose: To update and expand NCRP Report 116 on Radiation Protection Guidance for the United States.

Question: Considering that ICRP published revised recommendations in 2007, what new considerations is NCRP ready to address?

Issues for a Revision of the Basic Radiation Protection Recommendations



- A Rational and consistent specification of detriment
 - Non-cancer effects such as cardiovascular disease
 - Effect of age at exposure
 - Effect of gender
 - Genetic susceptibility
 - Severity and Treatability of the radiation effect
 - Threshold

Issues for a Revision of the Basic Radiation Protection Recommendations



Assessing Risk and Dose

- Effect of age at exposure
- Effect of gender
- Genetic susceptibility
- Risk versus dose
- Biologically-based models
- Energy dependent radiation weighting factors
- Weighting factors for specific radionuclides or classes of radionuclide emitters
- Skin dose and hot particles
- A revision of NCRP Report No.115 (Risk Estimates for Radiation Protection)

Issues for a Revision of the Basic Radiation Protection Recommendations



- Regulatory Issues
 - Risk versus dose
 - ALARA (Optimization)
 - Threshold
 - Energy dependent radiation weighting factors
 - Weighting factors for specific radionuclides or classes of radionuclide emitters
 - Units
 - Reporting and recording doses and units
 - Patient protection