Radiation Protection in Medicine

sponsored by the National Council on Radiation Protection and Measurements

Tuesday, January 28, 2020

7:15 am

Kathryn D. Held

National Council on Radiation Protection & Measurements and Massachusetts General Hospital/Harvard Medical School

President of NCRP; Associate Radiation Biologist in the Department of Radiation Oncology, Massachusetts General Hospital and Associate Professor of Radiation Oncology (Radiation Biology) at Harvard Medical School. Dr. Held was a member of Scientific Committee (SC) 1-22 on Radiation Protection for Astronauts in Short-Term Missions and Phase I of SC 1-24 on Radiation Exposures in Space and the Potential of Central Nervous System Effects and an advisor to several NCRP committees.

Radiation Biology for Radiation Protection in Medicine [Continuing Education Lecture]

A good understanding of basic radiation biology concepts and new information and research approaches is critical for understanding and applying radiation protection in medicine. In recent years there has been a plethora of new thoughts and data derived using "modern" molecular biology techniques that impact the application of biology knowledge to radiation protection approaches for patients and medical workers, particularly in the low dose and low dose rate arena. In addition to knowing "classic" concepts such as acute and delayed effects on irradiated normal tissues, sparing by low dose rates and radiation carcinogenesis, a medical and health physics practitioner should now be familiar with concepts such as bystander effects, genomic instability, DNA damage repair fundamentals, and genomics and proteomics. This lecture will provide an overview of important radiation biology fundamentals relevant to protecting patients and medical workers exposed to radiation, as well as an introduction to newer findings that could impact future approaches to protection. The lecture will complement the talks to be given in the NCRP Symposium on Radiation Protection in Medicine.

Plenary, 8:25-9:30 am

Donald L. Miller

Center for Devices & Radiological Health, U.S. Food & Drug Administration

Dr. Miller, an interventional radiologist, is Chief Medical Officer for Radiological Health at the U.S. Food and Drug Administration's Center for Devices and Radiological Health. He is a member of NCRP's Board of Directors, chairs Program Area Committee 4, and serves on several NCRP scientific committees. He has been a member and Vice-Chair of International Commission on Radiological Protection Committee 3. Dr. Miller was previously Professor of Radiology at the Uniformed Services University in Bethesda, Maryland.

Overview of NCRP Activities (Emphasis on Radiation Protection in Medicine)

The National Council on Radiation Protection in Medicine (NCRP) was chartered by Congress in 1964 but had its beginnings in 1929, as the U.S. Advisory Committee on X-Ray and Radium Protection. NCRP's mission is to support radiation protection by providing independent scientific analysis, information and recommendations that represent the consensus of leading scientists. The Council consists of up to 100 individuals, selected for their scientific expertise, who are elected to six-year terms. They serve on scientific committees and review all NCRP documents prior to publication. NCRP produces reports, commentaries, and statements. These documents originate in program area committees (PACs) or Council committees (CCs). PACs provide expertise in specific areas of radiation protection: epidemiology and biology, operational radiation safety, security and safety, medicine, environment and waste, dosimetry and measurements, and risk communication and outreach. CCs include members from each PAC and deal with general or overarching issues in radiation protection. CCs produced NCRP Report No.180 (*Radiation Protection Guidance for the United States*) and are developing a commentary on meeting the needs of the nation for radiation protection. This presentation describes recent NCRP publications and introduces current NCRP work, with special emphasis on the work of PAC 4 (Radiation Protection in Medicine). As shown by NCRP Report No. 160 (*Ionizing Radiation Exposure of the Population of the United States*), radiation use in medicine is now responsible for approximately one-half of the total radiation exposure of the U.S. population.

Session 1: Radiation Protection in Medicine: Safety-Related Issues

Kathryn D. Held & Jerrold T. Bushberg, *Co-Chairs*

10:00 am

Keith J. Strauss

University of Cincinnati School of Medicine

Research: development of configurations of imaging equipment that achieves diagnostic image quality at well managed radiation doses during pediatric imaging of children. Professional organizations: American Association of Physicists in Medicine, American College of Radiology, Society for Pediatric Radiology, International Electro-Technical Commission, International Atomic Energy Agency, National Council on Radiation Protection and Measurements, Radiological Society of North America, Image Gently® Alliance.

Gonadal Shielding During Abdominal & Pelvic Radiography (NCRP Scientific Committee 4-11)

Gonadal shielding during abdominal and pelvic radiography for adults and children has been considered good practice for more than 60 y. However, the efficacy of gonadal shielding has recently been questioned. Recent data on the limited effectiveness of gonadal shielding is presented for both males and females, but especially females. First, since automatic exposure control (AEC) capability of current equipment has replaced most manual techniques, the dose to the gonads and surrounding abdominal organs can increase when the shields cover the AEC sensors. In addition, the International Commission on Radiological Protection has revised tissue weighting factors with the colon, stomach, and bone marrow unchanged at 0.12 while reducing this factor for the gonads from 0.2 to 0.08. Thus, gonadal shielding and the impact of AEC are focused on protecting a less sensitive organ while actually increasing the radiation dose to more sensitive surrounding organs. Discontinuing a “good practice” is difficult when patients and/or their parents, regulatory agencies, and medical professionals (radiologic technologists, physicians, medical and health physicists) expect consistency and tradition. This presentation includes recommendations and guidance on the actual merits of gonadal shielding for all relevant professionals. These individuals are custodians for patients and or their parents for understanding that their imaging experience is evolving to deliver the best possible care.

10:25 am

Stephen Balter

Columbia University

Professor of Clinical Radiology (physics) and Medicine at Columbia University. He is an international authority on most aspects of medical fluoroscopy. Dr. Balter is a member of the NCRP Council. He served as the char of NCRP Report No.168 and NCRP Statement No. 11. Dr. Balter is currently responsible for fluoroscopy guided imaging (FGI) quality and radiation management in a clinical service that performs over 10,000 FGI procedures per year.

Patient Radiation Management in Interventional Fluoroscopy

Image-guided interventional medical procedures often require fluoroscopy (FGI) for their completion. This can result in the delivery of substantial amounts of radiation to the patient. FGI patients are accepted for a procedure when the benefits of that procedure are expected to outweigh the associated risks (radiation and others). Radiation use poses a stochastic risk and may also induce tissue reactions. Optimization involves complex interactions between patient characteristics, the capabilities of available fluoroscopes, and the operator. FGI differs from most imaging procedures (*e.g.*, computed tomography) in that the operator continually interacts with the fluoroscope during the procedure, and that changes in the patient’s condition will influence the operator’s options. Unfortunately, about 10 major tissue reactions occur each year around the world. Most of these are not justified and are attributable to operator factors. NCRP Report No. 168 (*Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures* - 2010) and Statement No. 11 (*Outline of Administrative Policies for Quality Assurance and Peer Review of Tissue Reactions Associated with Fluoroscopically-Guided Interventions* - 2014) provide necessary detailed guidance. This presentation will review key guidance elements and present data demonstrating considerable radiation use reduction in the past decade.

10:50 am

Alan G. Lurie

University of Connecticut School of Dental Medicine

Professor and Chair of Oral and Maxillofacial Radiology (OMFR) at the University of Connecticut Dental School. He is Past President of the American Academy of Oral and Maxillofacial Radiology, Past Director and President of the American Board of Oral and Maxillofacial Radiology, and founding and Past Chair of the Image Gently® in Dentistry Group. With 100+ publications in refereed literature, he Co-Chaired NCRP SC-45, preparing Report No. 177, *Radiation Protection in Dentistry and Oral & Maxillofacial Imaging*. He is dental and OMFR representative on NCRP.

Radiation Protection In Dentistry and Oral & Maxillofacial Radiology (NCRP Report No. 177)

Diagnostic imaging is essential in dentistry. Doses range from low to very low, benefits to patients can be immense, and safe techniques are well known but widely ignored. Doses range from very low with properly executed intraoral, cephalometric and panoramic imaging to higher than multidetector computed tomography (MDCT) with conebeam computed tomography (CBCT). Benefits are substantial: imaged dental disease, often obscured from direct vision by size and anatomy, can pose a mortal threat to the patient. Additionally, imaging is often central in planning complex dental procedures. NCRP Report No. 177 addresses the methods by which safety and diagnostic efficacy in dentistry are maximized. Safe imaging in dental environments is straight-forward; the means for minimizing dose and maximizing diagnostic efficacy have been widely and inexpensively available for decades. Digital receptors and rectangular collimators, coupled with stable receptor holding and directional devices, reduce patient dose by some

80 % over traditional techniques but are infrequently used. Digital panoramic equipment reduces doses markedly. For CBCT imaging, selection criteria are critical in defining appropriate fields-of-view and equipment presets. It is treacherous to discuss risk in oral and maxillofacial radiology. There are between one and two billion dental x-ray examinations annually, the majority being intraoral examinations, with steady increases in panoramic and CBCT. Radiation carcinogenesis from conventional imaging is unlikely, although large field-of-view, high-resolution preset CBCT can be comparable in carcinogenesis risk to craniofacial MDCT. Uncertainties in risk estimation from low doses, coupled with the huge numbers of dental images taken annually and the rapid growth of CBCT imaging dictate that safe oral and maxillofacial imaging is in the interests of patients, staff, and members of the public. “As low as reasonably achievable” practices and linear non-threshold risk modeling continue to be prudent and appropriate.

11:15 am

Steven G. Sutlief

Banner MD Anderson Cancer Center

Medical physicist at the Banner MD Anderson Cancer Center. His interests include quality assurance. He currently chairs an American Association of Physicists in Medicine (AAPM) Working Group and Task Group, is a Council member of the NCRP, and serves as an associate editor for *Medical Physics*. He graduated from the University of Washington in high energy physics, where he received further training in medical physics. Dr. Sutlief is a fellow of the AAPM.

Program Components for Error Prevention in Radiation Therapy (NCRP Scientific Committee 4-10)

Considerable efforts have been made in recent years to refine principles of quality and safety in radiation therapy. The intent of this NCRP statement project is to provide a short guidance document for external assessment of a radiation therapy department in terms of quality and safety. The statement will be of value to external reviewers as a guide for quality and safety assessment, to radiotherapy departments as a source of practice improvement initiatives, and to facilities for the assessment of accreditation readiness. Three themes of the statement are the assessment of documentation, metrics, and processes as indicators of quality and safety. Documentation is an essential tool for demonstrating quality and encompasses physician and physicist peer review, commissioning of new modalities and equipment, machine and patient quality-assurance records, and policies and procedures. Metrics include staffing levels, participation in remote dosimetry programs such as by the Imaging and Radiation Oncology Core Houston Quality Assurance Center, incident reporting participation, and the presence of in-service continuing education. Process techniques that aid safety include time outs, sterile cockpit, and shared authority to halt a procedure. This document differs from quality and safety initiatives and reports from professional organizations in that its scope specifically targets external review.

11:40 am

Lisa R. Bruedigan

Texas Department of State Health Services

Radiation Unit Manager, Surveillance Section in the Radiation Control Program. She has 38 y of experience with radiation protection with 22 y at the Texas Department of State Health Services. Ms. Bruedigan is a Texas Conference of Radiation Control Program Directors (CRCPD) member and served on CRCPD’s Board of Directors for 3 y. She currently serves on several CRCPD committees and is their liaison to the American College of Radiology.

The Role of the Conference of Radiation Control Program Directors & State Radiation Control Programs in Radiation Protection in Medicine

The state radiation control programs regulate the use of radiation producing machines in medicine. The Conference of Radiation Control Program Directors (CRCPD) is a partnership of the state radiation control programs whose mission is to promote consistency in addressing and resolving radiation protection issues, encourage high standards of quality in radiation protection programs, and provide leadership in radiation safety and education. State programs are challenged with the exceedingly difficult task of maintaining regulations that adequately protect patients, workers and caregivers as innovations in technology result in new ways to use ionizing radiation for improved diagnostic, interventional and therapeutic purposes. The goals of CRCPD include providing up-to-date guidance and suggested state regulations on the safe use of ionizing radiation in medicine in an effort to assist the states with the development of standards and policy based on sound science and professional consensus.

12:05 pm

Julie K. Timins

Has practiced Radiology and Nuclear Medicine in New Jersey in various settings: Nuclear Medicine Chair at a Veterans Administration Hospital, Staff Radiologist at Robert W. Johnson University Hospital and an inner-city hospital, and mammography in an outpatient facility. She chairs the New Jersey Commission on Radiation Protection. Dr. Timins served on the NCRP Board of Directors. She has been active in American College of Radiology, Radiological Society of New Jersey, and American Association for Women Radiologists.

Evaluating and Communicating Radiation Risks for Studies Involving Human Subjects: Guidance for Researchers & Institutional Review Boards (NCRP Scientific Committee 4-7)

Because of the need for a comprehensive approach guiding human studies research involving radiation, NCRP is developing a guidance document: “Evaluating and Communicating Radiation Risks for Studies Involving Human Subjects: Guidance for Researchers and Institutional Review Boards.” This report is targeted to those developing research protocols and to members of Institutional Review

Boards. There are widely varying levels of knowledge about ionizing radiation and radiological procedures among members of the public, medical professionals, and even among radiologists. The report addresses these knowledge gaps, starting with a history of international and national guidance on human studies research in general, and specifically research involving ionizing radiation. The fundamental principles of radiation biology are discussed, the basic quantities and units used in describing radiation dose are defined, and the basic principles of radiation protection are presented. Regulatory requirements for research are summarized, with links to the relevant regulations in the reference section. Imaging modalities and image-guided interventional procedures are described, including which *do* and which *do not* employ ionizing radiation. There is discussion of radiation therapy and radionuclide therapy. The need to distinguish between the radiation related to the research protocol and radiation encountered in standard patient care is examined. Estimation of radiation dose and radiation risk, and optimization of radiation dose are addressed. There is a discourse on ethics in human studies research, followed by the elements necessary for informed consent.

Session 2: Radiation Protection in Medicine: Doses, Dosimetry and Low Dose Considerations

Kathryn D. Held & Donald L. Miller, *Co-Chairs*

2:00 pm

David C. Spelic

U.S. Food & Drug Administration

Physicist with FDA. He received his PhD in physics in 1994, and shortly thereafter joined the Agency, where he supported activities directed at mammography quality. Dr. Spelic presently conducts numerous medical x-ray imaging activities including standards development, collaborations with professional organizations, and the review of premarket submissions from x-ray device manufacturers.

Radiological Health at FDA: A Review of Programs & Findings, Past & Present

FDA has a long history of radiological health activities directed at medical x-ray imaging. Beginning with two benchmark studies of population exposures conducted in the United States during 1964 and 1970, the Agency has conducted a number of activities that document the state of clinical practice in diagnostic radiology, including both medical and dental x-ray imaging. Studies have focused on specific imaging modalities, including general radiography, fluoroscopy, mammography, computed tomography, and dental imaging, providing a series of snapshots over time that permit a study of trends in the state of practice. One such effort — the Nationwide Evaluation of X-ray Trends, a collaboration begun in 1972 with the Conference of Radiation Control Program Directors — continues to this day. This presentation provides a summary of past and present radiological health activities at the Agency and discusses how those activities have contributed to broader collaborative efforts aimed at documenting and improving the quality of diagnostic x-ray practice.

2:25 pm

Mahadevappa Mahesh

Johns Hopkins University School of Medicine

Professor of Radiology and Cardiology at the Johns Hopkins University School of Medicine, Baltimore, Maryland.

Dr. Mahesh's research interests are in medical imaging, particularly in areas of computed tomography (CT), interventional fluoroscopy, and digital mammography and in the assessment of patient dose and risks from medical x-ray imaging including CT.
Dr. Mahesh is currently associate editor for the *Journal of American College of Radiology* and Consultant to the Editor for *RadioGraphics*. He serves in a number of leadership roles, including as Chair of Physics Commission and member of board of chancellors for the American College of Radiology, Treasurer and

Executive Committee member for the American Association of Physicists in Medicine, and is member of the Radiation Control Advisory Board for the State of Maryland.

Dr. Mahesh is also an NCRP Council member and served as Vice Chair for NCRP SC 4-9 that wrote NCRP Report No.184.

Medical Radiation Exposure of Patients in the United States (NCRP Report No. 184)

NCRP Report No. 160 (2009) demonstrated the rapid and dramatic increase in diagnostic and interventional patient medical radiation exposures between early 1980 up to 2006. The report led to the examination of medical radiation exposures by many groups both in the United States and internationally. NCRP Scientific Committee 4-9 formed in 2016 was charged to prepare a report to evaluate changes in medical x-ray exposure since NCRP Report No. 160. The charge to the committee was to assess the number and types of medical x-ray procedures, the average per caput and collective effective doses, and the changes since 2006. Even though NCRP Report No. 160 was published in 2009, the data were as of 2006. Similarly, the new report (NCRP Report No. 184), recently released, reports data as of 2016. From the onset, the committee members agreed to report effective dose values only for the various medical x-ray procedures and decided not to include organ doses and not include radiation therapy procedures. The publication of new tissue weighting factors (ICRP Publication 103) was accounted and the committee decided to compute collective effective doses using both ICRP Publications 60 and 103 weighting factors. This was done in order to compare the final results with those of NCRP Report No. 160 and to examine the impact of tissue weighting factors. Even though the largest contributor to collective dose among medical radiation exposure is from computed tomography, the estimated annual individual effective dose was similar to NCRP Report No. 160. Overall, the 2016 estimates for collective effective dose (S) and effective dose per capita (E_{US})

indicates a decline from 2006 by ~15 to 20 %. Details of the estimated S and E_{US} for each modality are presented and the details on how the number of procedures and the effective dose for each modality is estimated is discussed in this presentation.

2:50 pm

R. Craig Yoder

Directed Landauer's technical activities relating to radiation dosimetry, particularly for applications in radiation protection from 1983 through his retirement in 2015. Additionally, he oversaw subsidiary and partner businesses located in Australia, Brazil, China, France, Japan, Mexico, Sweden and Turkey.

An internationally known expert in radiation monitoring, Dr. Yoder led Landauer's transition from film and thermoluminescent dosimetry technology to optically stimulated luminescence, an assignment that required strategic planning and direction in areas spanning scientific research, product development, manufacturing, laboratory operations, and marketing. From 1993 to 2001, he was Vice President of Operations and managed Landauer's manufacturing and analytical laboratory activities in addition to overseeing research and development programs.

Dr. Yoder is a member of NCRP and former President of the Council on Ionizing Radiation Measurements and Standards. He has served on several national and international committees to develop dosimetry standards. He was a member of a National Research Council's committee that examined the accuracy of film badge measurements made during atmospheric nuclear weapons testing.

Estimating Lung Doses to Medical Workers in the Million Person Study (NCRP Scientific Committee 6-11)

NCRP Report No. 178 presents an 11-step process to guide the radiation dose reconstruction process to be applied to the worker groups comprising the epidemiological Million Person Study (MPS). Medical radiation workers make up a large group of individuals occupationally exposed to low doses of radiation (and are a sub-cohort of the MPS), who have been monitored with the use of personal dosimeters when potentially exposed to ionizing radiation, and the measurements have generally been maintained. For epidemiologic studies, it is often assumed that the average dose over the entire organ or tissue (organ dose) is the quantity of interest in the analysis. However, the derivation of organ doses for the medical worker cohort members from monitoring data poses difficult problems because of, among other factors: often extreme inhomogeneity of exposure over the body of personnel for any given procedure type as organs or tissues may only be partially irradiated, for example when medical personnel wear lead aprons; differing degrees and methods of radiation protection; inconsistent wearing of dosimeters by personnel (*i.e.*, at times choosing not to wear dosimeters in order to avoid investigations), combined with poor information, as well as high variability, on the workloads of physicians and technologists (*i.e.*, the number of procedures of a given type conducted monthly or annually); and changing technology and medical procedure protocols. NCRP Scientific Committee 6-11 was charged with the task of describing an optimum approach for using personal monitoring data to estimate lung and other organ doses along with specific precautions applicable to epidemiologic study of medical radiation workers, recognizing many associated uncertainties.

3:15 pm **Break**

3:45 pm

Lawrence T. Dauer

Memorial Sloan Kettering Cancer Center

Associate Attending Physicist specializing in radiation protection at MSKCC in the Departments of Medical Physics and Radiology. He is a Council and Board member of NCRP and served as a member of the ICRP Committee 3, Protection in Medicine.

Evaluation of Sex-Specific Differences in Lung Cancer Radiation Risks & Recommendations for Use in Transfer & Projection Models (NCRP Scientific Committee 1-27)

Recent results from the study of Japanese atomic-bomb survivors, exposed briefly to radiation, find the risk of radiation-induced lung cancer to be nearly three times greater for women than for men. Because protection standards for astronauts are based on individual lifetime risk projections, this sex-specific difference limits the time women can spend in space (NCRP Commentary No. 23, 2014). The National Aeronautics and Space Administration (NASA) requested that NCRP evaluate the risk of radiation-induced lung cancer in populations exposed to chronic or fractionated radiation to learn whether similar differences exist when exposures occur gradually over years contrasted with the acute exposure received by the Japanese atomic-bomb survivors. In response to NASA, NCRP initiated an epidemiologic study of ~150,000 medical radiation workers (~50 % women) and additional U.S. Department of Energy worker cohorts within the Million Person Study. These studies are viewed in the context of other studies of reasonable quality with estimates of radiation-induced lung cancer when radiation is given gradually over time (*e.g.*, studies of tuberculosis patients, indoor radon, Mayak workers, scoliosis patients). An extensive and comprehensive review is needed of all epidemiologic studies and animal experiments, as well as mechanistic models. In addition, an evaluation of the factors affecting transfer of risk modelling and incorporation within lifetime risk projection are required. NCRP is evaluating the current risk projection model used by NASA for lung cancer life-time risk projection and examine whether the new data on low dose rate exposures and sex-specific lung cancer risks will be such as to recommend modifications.

4:10 pm

Angela Shogren
U.S. Environmental Protection Agency
Public Affairs Specialist at EPA's Center for Radiation Information and Outreach. Ms. Shogren is an NCRP Council member and represents EPA as a radiation risk communication expert in a working group led by the World Health Organization.

Radiation Risk Communication in Medicine (NCRP Program Area Committee 7)
Medical professionals feel confident prescribing and performing necessary procedure for patients, but when associated radiation risks are raised, many healthcare professionals may not feel adequately prepared to address patient concerns. Effectively communicating radiation risks to patients is often an afterthought in medical education or merely touched on during general patient communication training. There are two main radiation risk communication pathways in medicine — professional-centered communication (between two or more medical professionals) and patient-centered communication (between a medical professional and a patient). There are many ways to communicate radiation risk in medicine; no “one size fits all” script, delivery, or approach. When communicating with patients or other health professionals, it’s imperative to understand the subject’s background, risk perception, and unique situation.

4:35 pm

Kimberly Applegate
University of Kentucky
Member of NCRP and on the Main Commission of the International Commission on Radiological Protection as the Chair of Committee 3, focusing on radiation protection in medicine. Dr. Applegate is a retired professor of radiology and pediatrics at the University of Kentucky in Lexington. Dr. Applegate is a leader in radiology— Dr. Applegate’s policy and research work, including 200 publications, has resulted in an improved understanding of the structure, process and outcomes of how pediatric imaging is practiced, including the volume of ionizing imaging in children, the variation in radiation dose in pediatric computed tomography, and the standardization of practice for both children and adults. She has worked collaboratively around the world to improve practice.

From its start in 2007 to the present, she has worked on the Steering Committee for the Image Gently® Campaign to improve safe and effective imaging care of children worldwide. Dr. Applegate has received a number of awards that include the 2019 American Association of Physicists in Medicine’s Honorary Membership and the American Association for Women in Radiology’s Marie Sklowdoska Curie Award for her unique roles in leadership and outstanding contributions to the advancement of women in the radiology professions.

The ICRP & Its Role in Guidance, Communication, & Collaboration
The International Council for Radiation Protection (ICRP) is an independent, not-for-profit organization with a mission to advance for the public benefit the science of radiological protection, in particular by providing recommendations and guidance on all aspects of protection against ionizing radiation. Founded in 1928, it currently comprises a community of more than 250 globally-recognized experts in radiological protection (RP) science, policy, and practice from more than 50 countries. Committee 3 addresses protection of persons and unborn children when ionizing radiation is used in medical diagnosis, therapy, and biomedical research—and since 2017—protection in veterinary medicine. ICRP Committee 3 has a wide mandate in radiation protection and its members have expertise in diagnostic radiology, radiation oncology, nuclear medicine, medical physics, epidemiology and biostatistics, regulatory application of RP, process and quality improvement, and human and veterinary medicine. We work together with ICRP committees, and we collaborate with a number of organizations including radiology, medical physics, and regulatory bodies.

Discussion

5:00 pm

Kathryn D. Held
President, NCRP

NCRP—Focus on Radiation Protection in Medicine

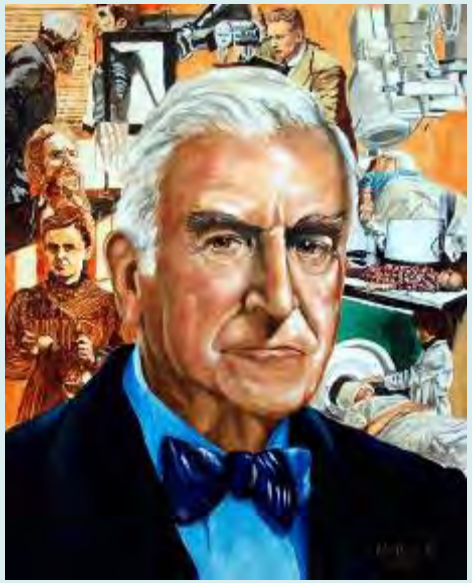
Donald L. Miller, MD, FSIR FACR
Chair, Program Area Committee 4
Member, NCRP Board of Directors

A Long History

1929: U.S. Advisory Committee on X-Ray and Radium Protection

1946: U.S. National Committee on Radiation Protection

1964: National Council on Radiation Protection and Measurements chartered by Congress (Public Law 88-376)



NCRP Status

- 501(c)(3) non-profit corporation
- Although chartered by Congress, NCRP has never received direct funding from Congress

Congressional Charter

- Object and purpose of NCRP:
- To collect, analyze, develop and disseminate in the public interest information and recommendations, and to develop basic concepts about, radiation protection and radiation measurements, quantities and units

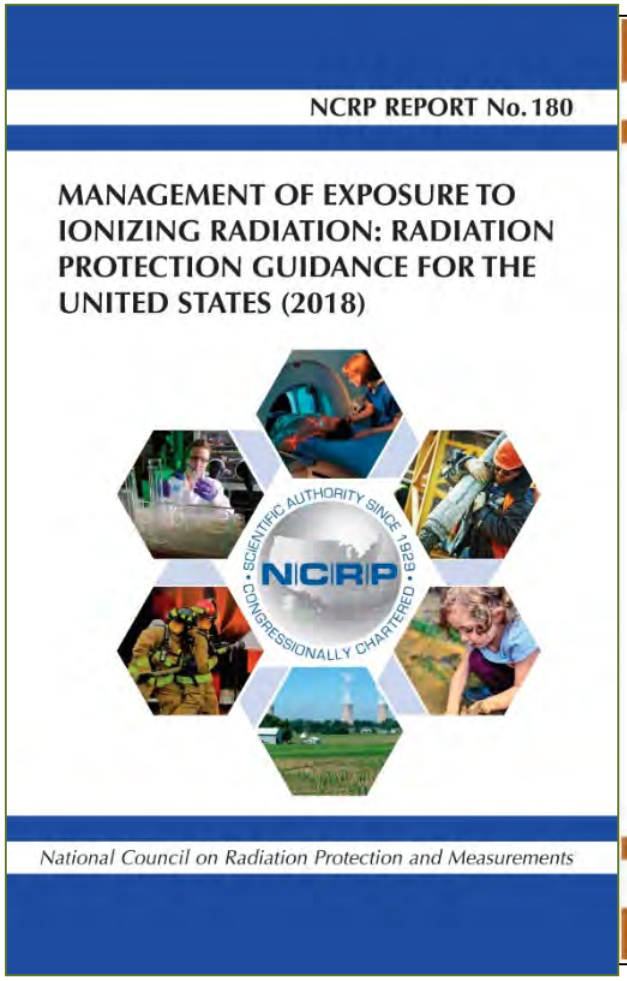
Our Mission

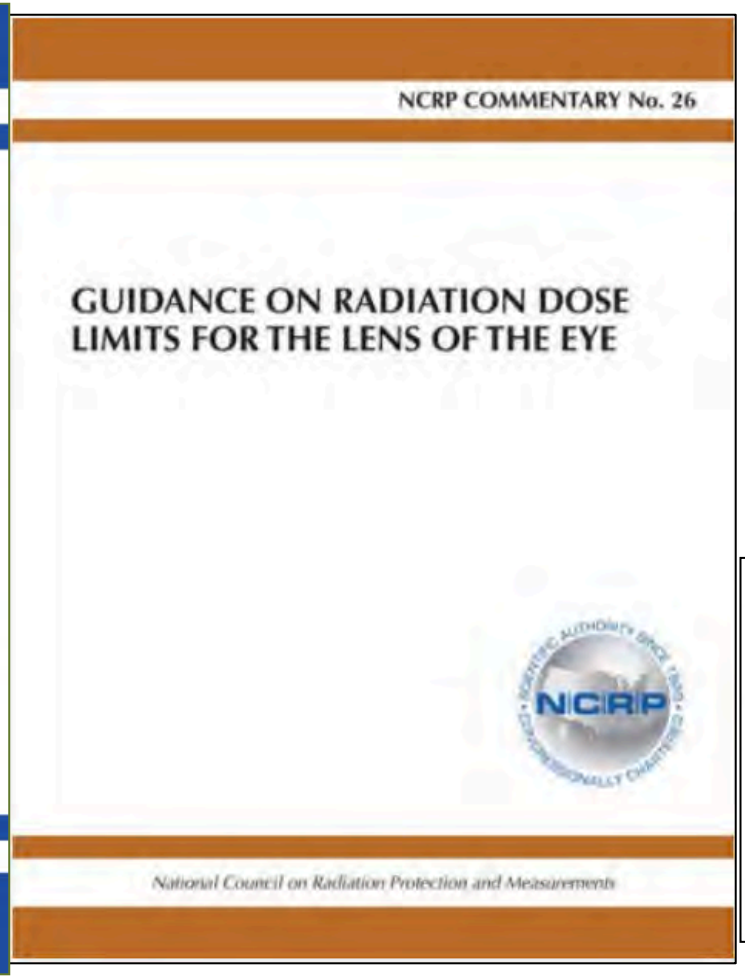
To support radiation protection by providing independent scientific analysis, information, and recommendations that represent the consensus of leading scientists

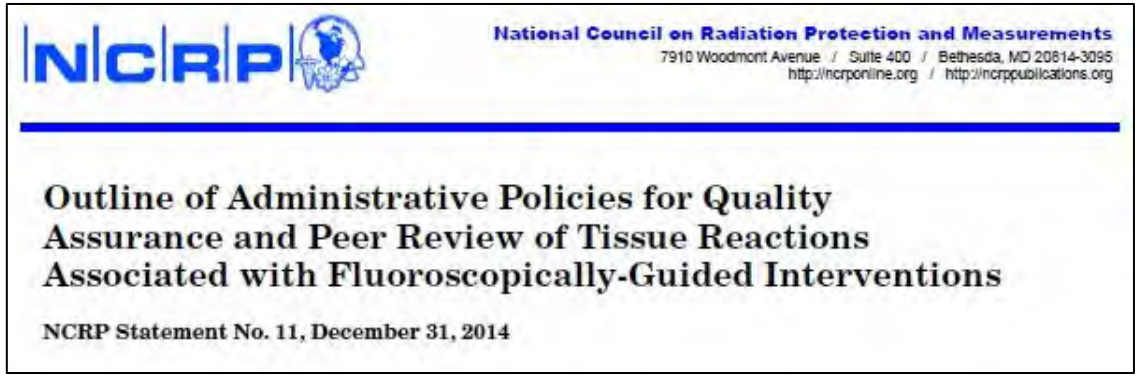
NCRP Council

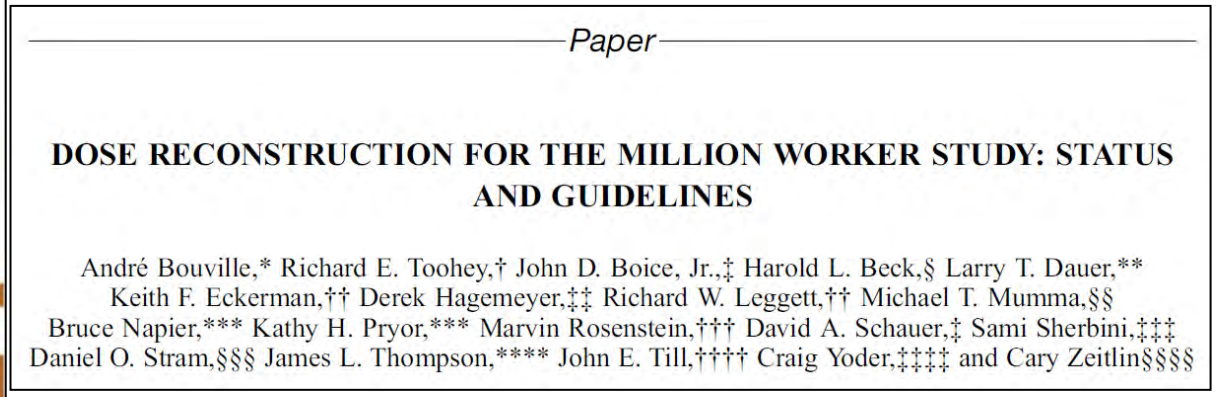
- Consists of up to 100 individuals
- Elected to six year terms
- Selected for their scientific expertise
- Serve on Scientific Committees
- Review most documents produced by NCRP
- Members of Program Area Committees (PACs)

Reports, Advice, Research



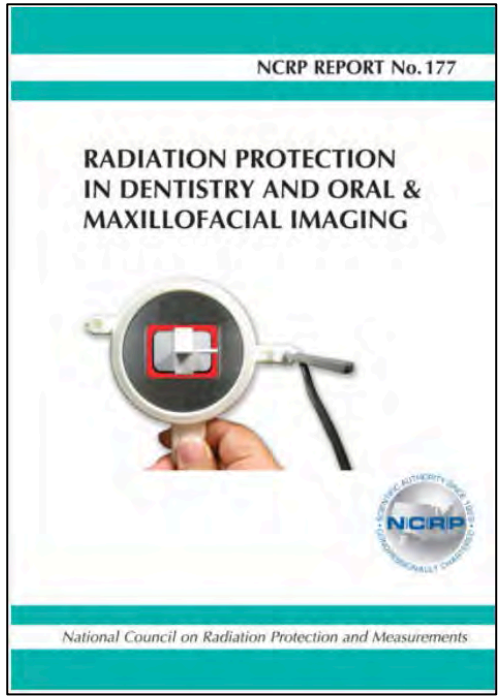


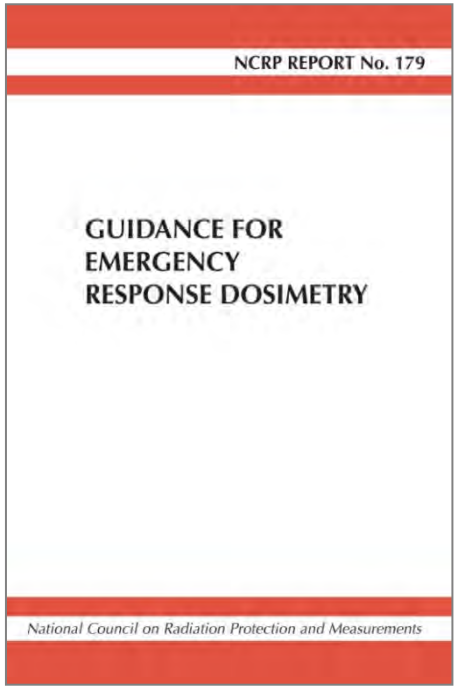


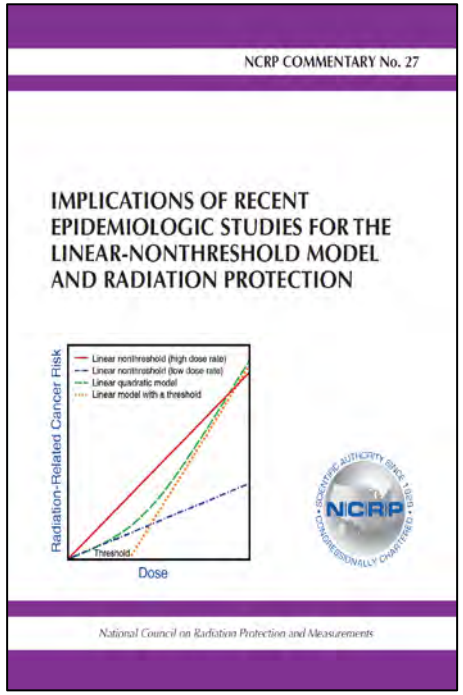


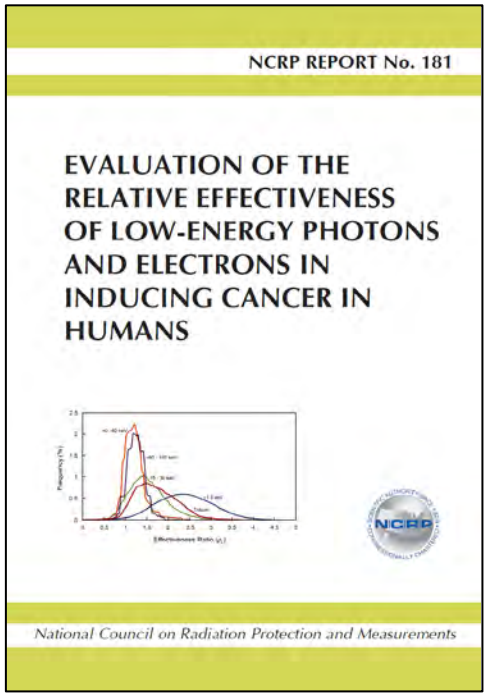
Recently Completed Documents (2017-2019)

- Report No. 177 – Radiation Protection in Dentistry and Oral & Maxillofacial Imaging
- Report No. 179 – Guidance for Emergency Response Dosimetry
- Commentary No. 27– Recent Epidemiologic Studies and Implications for LNT
- Report No. 181 – Biological Effectiveness of Low-LET Radiations



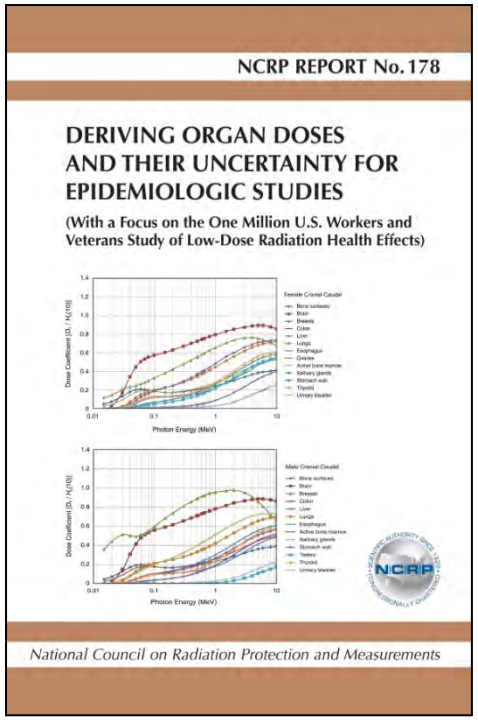


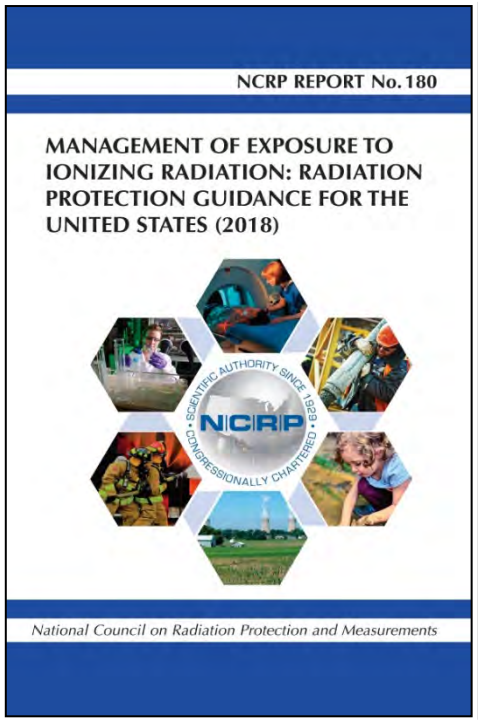


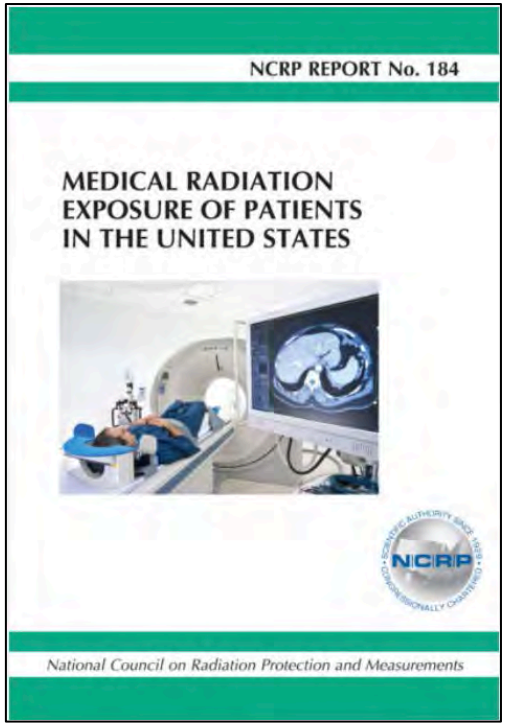


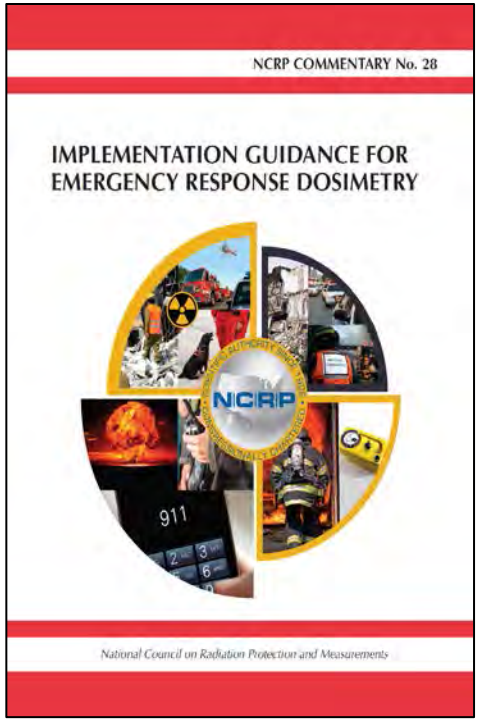
Recently Completed Documents (2017-2019)

- Report No. 178 – Deriving Organ Doses and their Uncertainties
- Report No. 180 – Radiation Protection Guidance for the United States
- Report No. 184 – Medical Radiation Exposure of Patients in the United States
- Commentary No. 28 – Implementation Guidance for Emergency Response Dosimetry









NCRP Annual Meetings

Chair, Fred A. Mettler, Jr.
Co-Chairs, Jerrold T. Bushberg &
Richard J. Vetter

Fifty-Fifth
Annual Meeting Program

NCRP Meeting the Challenge at 90: Providing Best Answers to Your Most Pressing Questions About Radiation

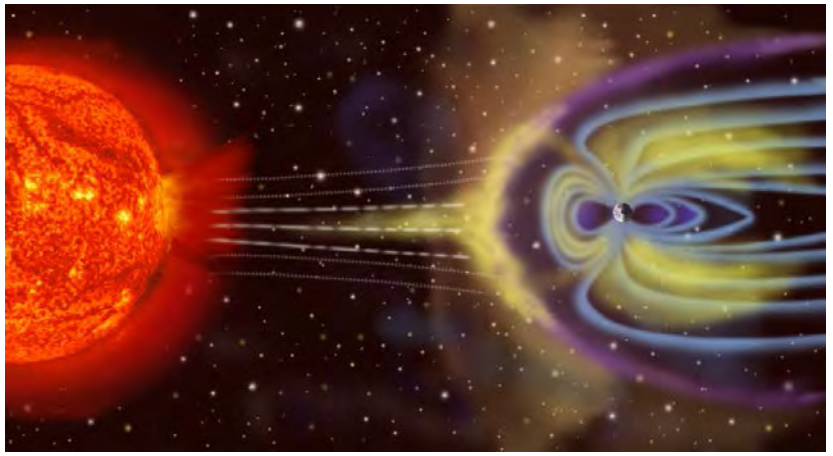
April 1–2, 2019

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

2020 Annual Meeting
March 23-24, 2020

Radiation & Flight: A Down-to-Earth Look at Risks

Jacqueline P. Williams &
Cary Zeitlin, *Co-Chairs*



NCRP Partners With and Participates in Meetings of Other Organizations

Active Partnerships

- Image Gently Alliance
- Conference of Radiation Control Program Directors
- Health Physics Society
- Radiation Research Society

Partnerships with International Organizations

INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

- Two Council Members are on the Main Commission
- NCRP is a Liaison Organization

UNSCEAR

Eight Council Members are on the U.S. Delegation to the United Nations Scientific Committees on the Effects of Atomic Radiation (UNSCEAR)

IRPA 16

RADIATION HARMONIZATION

standing united for protection

ICRU

One Council Member is on the International Commission on Radiation Units and Measurements (ICRU)

National Study of One Million U.S. Radiation Workers and Veterans

Manhattan Project	360,000
Atomic Veterans	115,000
Nuclear Utility Workers	150,000
Industrial Radiographers	115,000
Medical & other	>250,000

Funding from DOE, DOD, NRC, NASA, CDC

Program Area Committees (PAC)

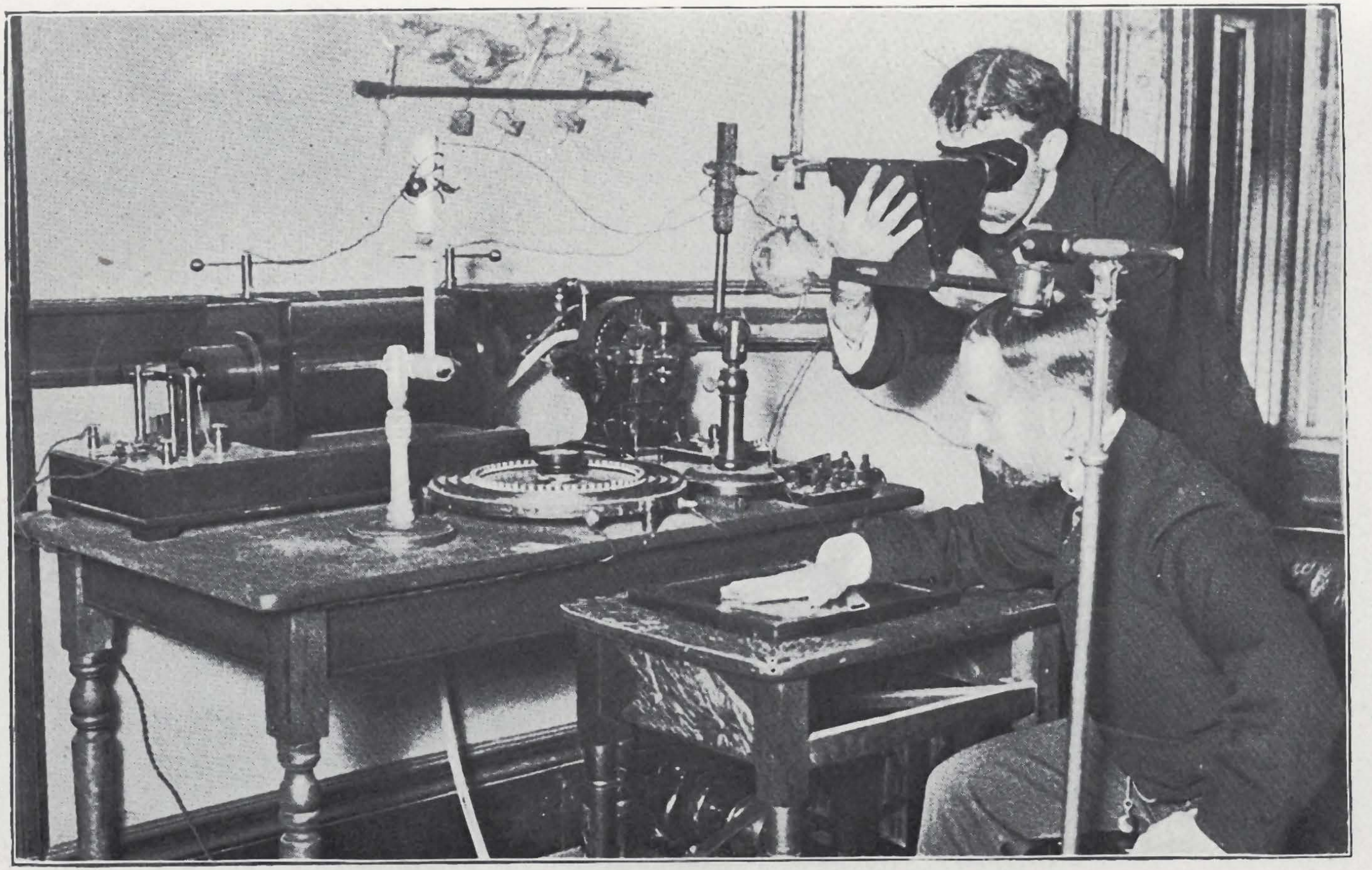
- PAC 1 - Epidemiology & Biology
- PAC 2 - Operational Radiation Safety
- PAC 3 - Security & Safety
- PAC 4 - Medicine
- PAC 5 - Environment & Waste
- PAC 6 - Dosimetry & Measurements
- PAC 7 - Risk Communication & Outreach

Two Council Committees (CCs)

- CC-1 – Radiation Protection Guidance for the US (Report No.180; 2018)
- CC-2 – Meeting the Needs of the Nation for Radiation Protection (WARP: Where Are the Radiation Professionals?)

Program Area Committees (PAC)

- PAC 1 - Epidemiology & Biology
- PAC 2 - Operational Radiation Safety
- PAC 3 - Security & Safety
- **PAC 4 – Radiation Protection in Medicine**
- PAC 5 - Environment & Waste
- PAC 6 - Dosimetry & Measurements
- PAC 7 - Risk Communication & Outreach




CAUTION
THIS MACHINE
HAS NO BRAIN
USE YOUR OWN

PAC 4
Radiation Protection in Medicine

D.L. Miller, Chair
L.T. Dauer, Co-Chair

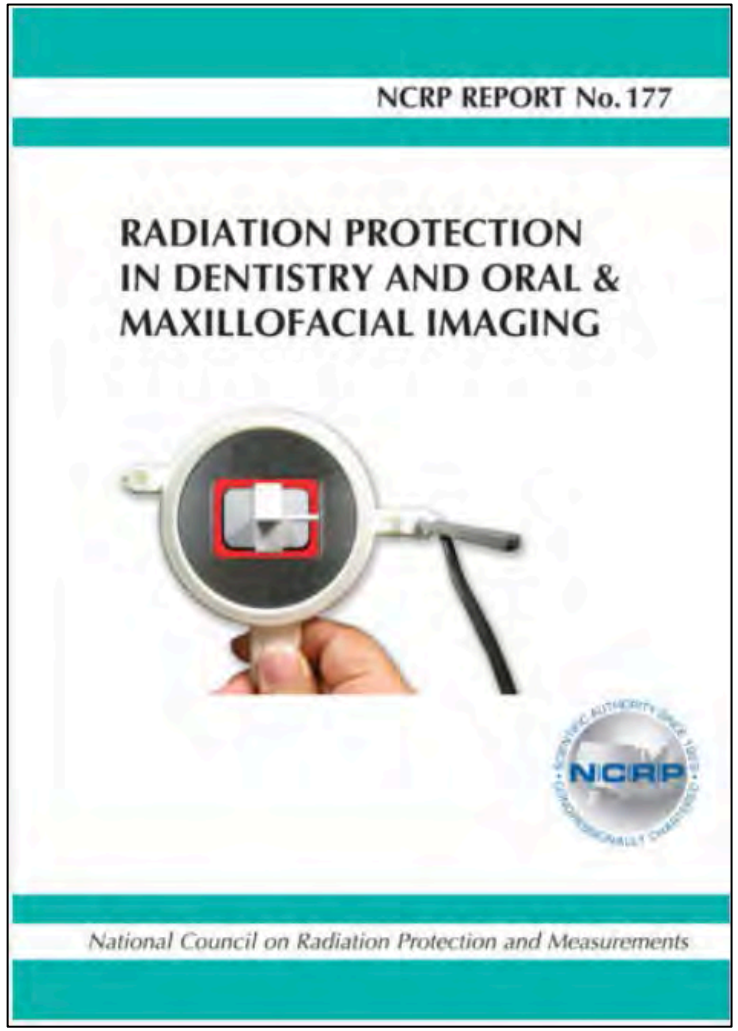
K.E. Applegate
S. Balter
E. Bluth
J.T. Bushberg
A.J. Einstein
D.P. Frush
J.E. Gray
L.A. Kroger
E.M. Leidholdt, Jr.
A. G. Lurie
M. Mahesh
F.A. Mettler, Jr.
W.D. Newhauser
M.M. Rehani
M.J. Rivard
J.A. Seibert
D.C. Spelic
S.G. Sutlief
J.E. Timins
J.P. Winston
S.Y. Woo
P.D. Zanzonico

Current PAC 4 Activities

Scientific Committees (SC)

- SC 4-5: *Radiation Protection in Dentistry* (Report)
- SC 4-7: *Evaluating and Communicating Radiation Risks for Studies Involving Human Subjects: Guidance for Researchers and Institutional Review Boards* (Report)
- SC 4-8: *Improving Patient Dose Utilization in Computed Tomography* (Commentary)
- SC 4-9: Medical Exposure of the U.S. Population (Report No.184, published November, 2019)
- SC 4-10: Program Components for Error Prevention in Radiation Therapy (Statement)
- SC 4-11: Gonadal Shielding During Abdominal and Pelvic Radiography (Statement

SC 4-5 *Co-Chairs:* A. Lurie & M. Kantor



- *Radiation Protection in Dentistry and Oral & Maxillofacial Imaging*, Report No. 177 (2019)
- Update of NCRP Report No. 145 (2003)
- New material: cone beam CT, digital radiography, hand-held dental radiography devices
- Incorporates material from the recent NEXT survey on dental imaging

SC 4-7 *Chair:* J. Timins

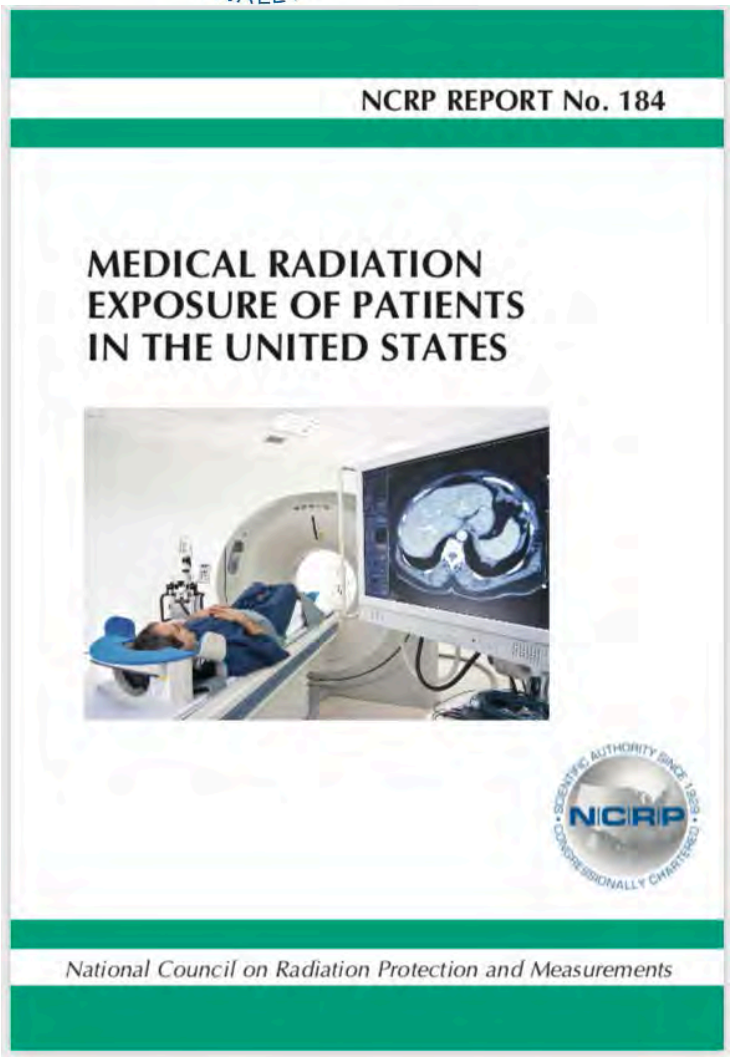
Evaluating and communicating radiation risks for studies involving human subjects: guidance for researchers and Institutional Review Boards

- Guidance for:
  - Researchers who prepare protocols that include radiation exposure to human subjects
  - Reviewing bodies, such as IRBs, that review such protocols
  - Radiation Safety Committees and RSOs

SC 4-8 *Co-Chairs*: M. Kalra, E. Leidholdt, Jr.

- *Improving Patient Dose Utilization in CT*
- Commentary
- Integrated set of recommendations for CT radiation dose optimization and error prevention
- Intended audience: practicing physicians and other healthcare providers, physicists and technologists

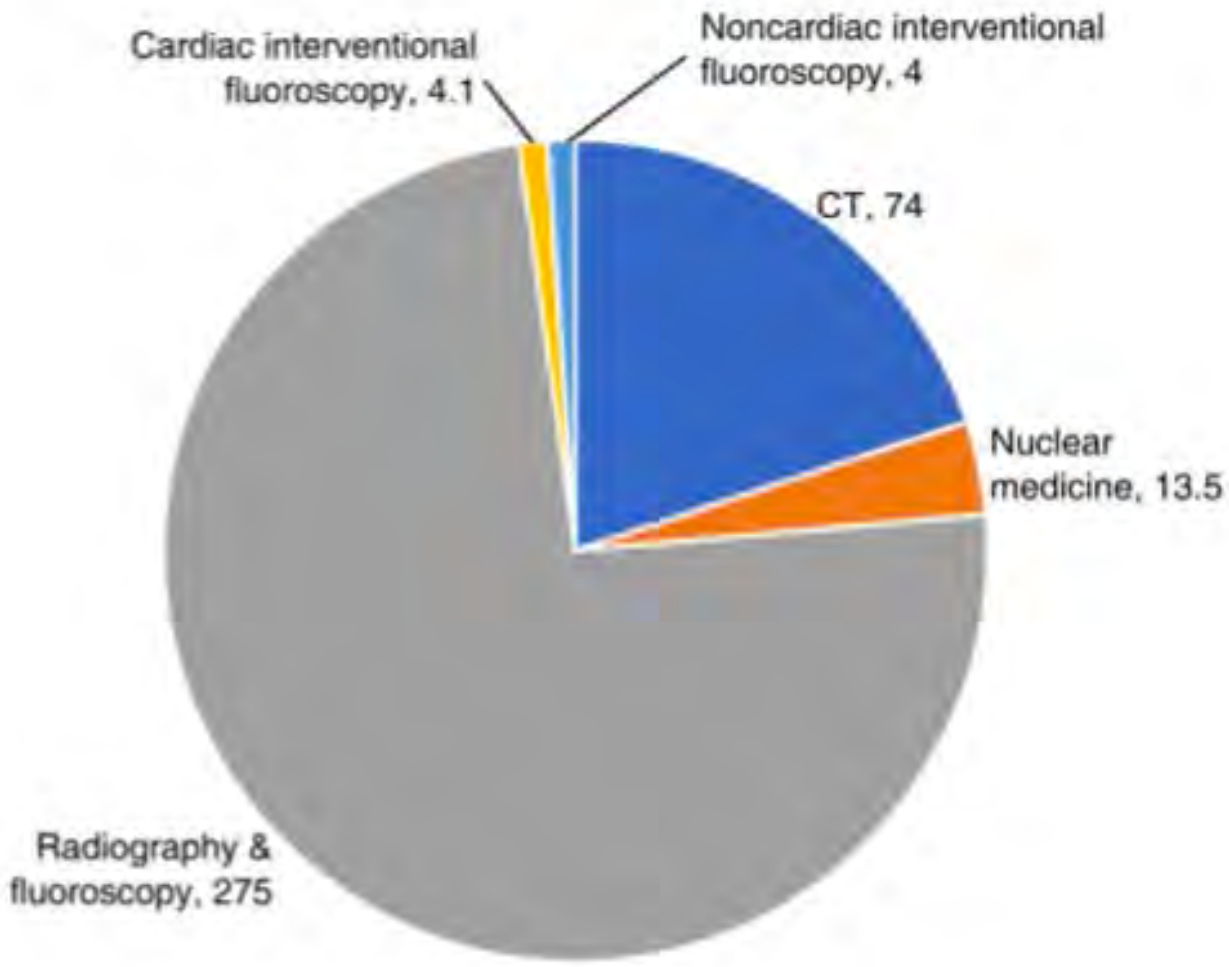
SC 4-9 *Co-Chairs*: F. Mettler, M. Mahesh



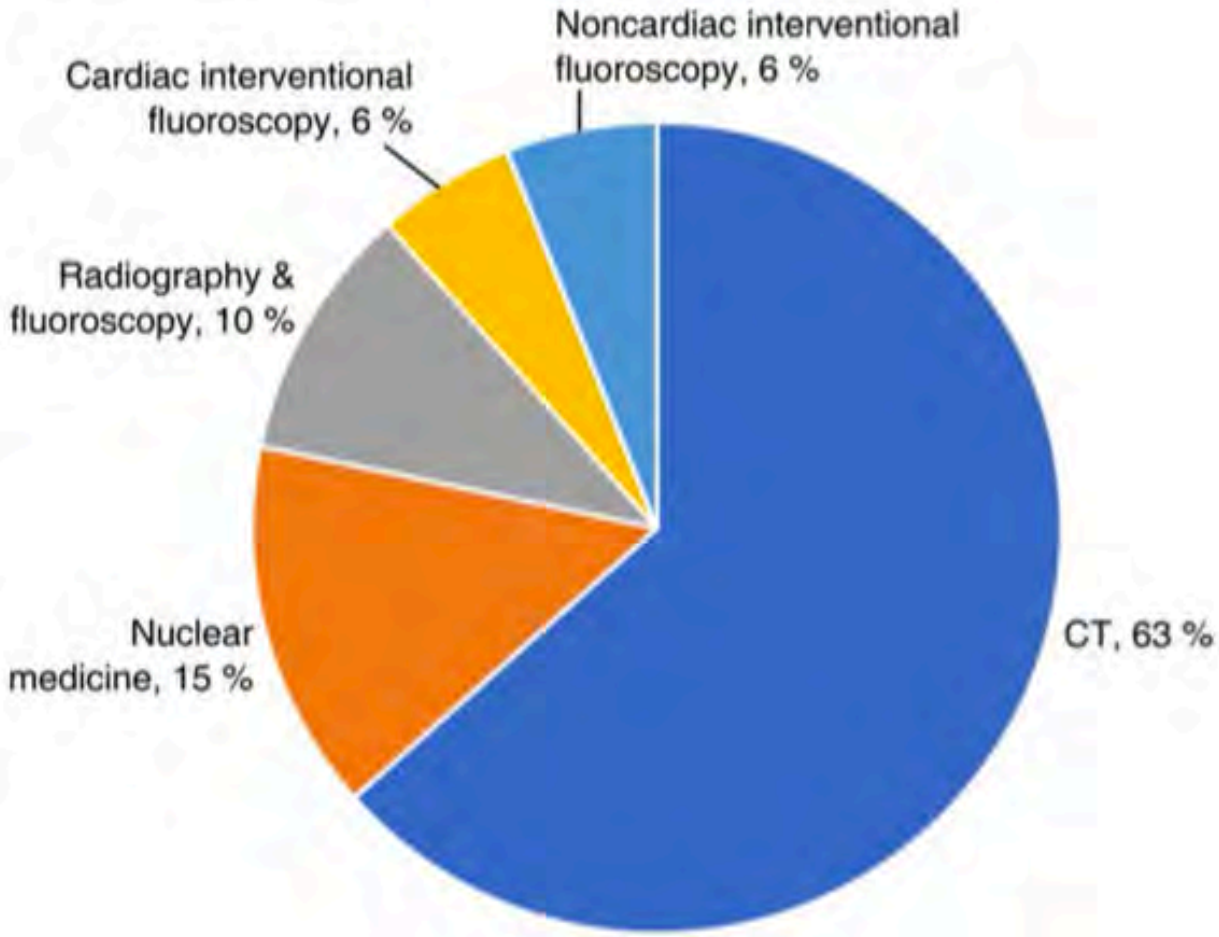
- *Medical Radiation Exposure of Patients in the United States*, Report No. 184 (2019)
- Changes in medical diagnostic and interventional exposure (per caput effective dose) since NCRP Report No. 160
- Radiography, CT, dental, interventional, nuclear medicine, imaging for radiation therapy

Report No. 184

- 10 year update of Report No. 160 (2006 - 2016)
- 25% increase in annual number of CT scans, but estimated U.S. annual *per caput* effective dose (E_{US}) essentially unchanged: 1.4 mSv → 1.5 mSv
- 20% decrease in the annual number of nuclear medicine procedures; 44% decrease in E_{US}
- Overall (not including imaging for XRT), ~20 % decrease in E_{US}: 2.9 mSv → 2.3 mSv



No. of examinations (millions), 2016



% U.S. effective dose, 2016

SC 4-10 *Chair*: S. Sutlief

- *Program Components for Error Prevention in Radiation Therapy*
- Statement
- Guidance on methodologies for error prevention, including prospective and retrospective techniques
- Integrated set of quality and safety recommendations that can be assessed in terms of their successful implementation

SC 4-11 Co-*Chairs*: D. Frush, K. Strauss

- *Gonadal Shielding During Abdominal and Pelvic Radiography*
- Statement
- Recommendations on whether gonadal shielding should continue to be used routinely
- Will address whether changes to existing regulations are needed

Summary

- NCRP chartered by Congress to provide independent scientific advice on matters related to radiation protection and measurements.
- Numerous documents on all aspects of radiation protection, including medicine
- Active development of advice and recommendations to advance radiation protection in medicine

Thank You!

Gonadal Shielding: During Abdominal & Pelvic Radiography (NCRP SC 4-11)

Keith J. Strauss, MSc, FAAPM, FACR

Associate Professor

University of Cincinnati School of Medicine

January 28, 2020

Introduction

- Definition?
- Historical perspective?
- Factors that reduce effectiveness of shields?
  - Scatter radiation
  - Gonads, “Where art thou!”
  - Automatic Exposure Control (AEC)
  - Radio Sensitivity of the gonads?
- Communication
- NCRP Statement from Scientific Committee 4-11

What is Gonadal Shielding

- Placement of a shield, typically Lead equivalent material, on the surface of the patient to directly shadow and protect sensitive organs beneath the shield at some depth in the patient.
- Practice began in the early 1950s.

Historical Perspective

- Radiation doses from diagnostic x-ray examinations are ~ 20 - 25 times less radiation today: 1951 vs 2020
  - Adult KUB: 1951 ~ 11 – 12 mGy[1]
    2020 ~ 0.5 mGy air Kerma
  - Newborn KUB: 1951 ~ 1.4 mGy[2]
    2020 ~ 0.07 mGy air Kerma

[1]Handloser JS, Love RA. Radiation Doses from Diagnostic Studies. Radiology 57: 1951, pp. 252-254.
[2]Billings MS, Norman A, Greenfield MA. Gonad Dose During Routine Roentgenography 69: 1957, pp. 37-41.

Historical Perspective

- Gonadal shielding reduces gonadal doses to less than 10% of original dose![1 – 3]
  - Best information in mid 1950 was in error.

[1]Stanford RW, Vance J. The quantity of radiation received by the reproductive organs of patients during routine diagnostic x-ray examinations. Br J Radiol 1955 May;28(329):266-273.

[2]Ardran GM, Crooks HE. Gonad radiation dose from diagnostic procedures. Br J Radiol 1957 Jun; 30(354):295-7.

[3]Feldman A, Babcock GC, Lanier RR, Morkovin D. Gonadal exposure dose from diagnostic x-ray procedures. Radiology 71; 1958; 197-207.

Current Perspective

- **Suggested State Regulation:**
  - **3701:1-66(G)(2)**

Gonadal shielding . . .

. . . shall be used for human patients,

. . . during radiologic procedures in which the gonads are in the useful beam . . .

Current Perspective

- **Suggested State Regulation:**
  - 3701:1-66(G)(2)

  Gonadal shielding of not less than 0.5 mm Lead equivalent material **shall be used for human patients,** who have not passed the reproductive age, **during radiologic procedures in which the gonads are in the useful beam, . . .**

Current Perspective

- **Suggested State Regulation:**
  - 3701:1-66(G)(2)

  Gonadal shielding of not less than 0.5 millimeter Lead equivalent material shall be used for human patients, who have not passed the reproductive age, during radiologic procedures in which the gonads are in the useful beam, **except for cases in which this would interfere with the radiologic procedure.**

New Paradigm

RADIATION SENSIBILITIES

RICHARD L. MORIN, PHD, DONALD P. FRUSH, MD

Reconsidering the Value of Gonadal Shielding During Abdominal/Pelvic Radiography

Keith J. Strauss, MSc, Eric L. Gingold, PhD, Donald P. Frush, MD

Shielding the gonads, especially when imaging children with ionizing radiation, has been widely accepted as good radiologic practice since it

shield for the ovaries may be less than 20%.

Can a shield be placed accurately over the reproductive organs without

JACR 14(12) December 2017 pp 1635-6

AJR FOCUS ON:

Patient Shielding in Diagnostic Imaging: Discontinuing a Legacy Practice

Rebecca M. Marsh[1]
Michael Silosky

OBJECTIVE. Patient shielding is standard practice in diagnostic imaging, despite growing evidence that it provides negligible or no benefit and carries a substantial risk of increasing patient dose and compromising the diagnostic efficacy of an image. The historical rationale for patient shielding is described, and the folly of its continued use is discussed.

CONCLUSION. Although change is difficult, it is incumbent on radiologic technologists, medical physicists, and radiologists to abandon the practice of patient shielding in radiology.

Patient shielding is an integral part of radiology. Its practice and importance are so deeply ingrained that when a group of radiologic technologists was recently asked what they would do if their institution adopted a policy to not provide patient shielding, 86% of respondents stated that they would shield patients anyway. (One percent of respondents

U.S. Code of Federal Regulations has not changed from the initial wording found in the 1976 version [9]. Patient shielding was—and is—justified as a matter of protection from hereditary risks, not as an overall reduction in stochastic risk. Of importance, 42 years later, no hereditary effects from radiation have ever been observed in humans [10].

AJR: 212 April 2019

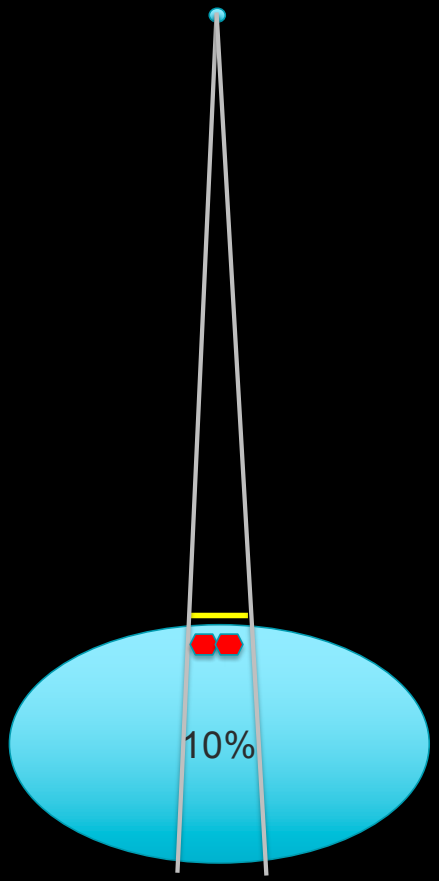
Are Accurately Placed Shields Effective?

- **Male**
  - Flat lead shield reduced dose to the region of testes of of an adult anthropomorphic phantom by 36%.[1]
    - Incorrect measurement of performance of flat shield because shield and gonads not in the primary beam!

[1]Fauber TL. Gonadal shielding in radiography: a best practice? Radiol Tech 88(2) Nov/Dec 2016, 127 – 35.

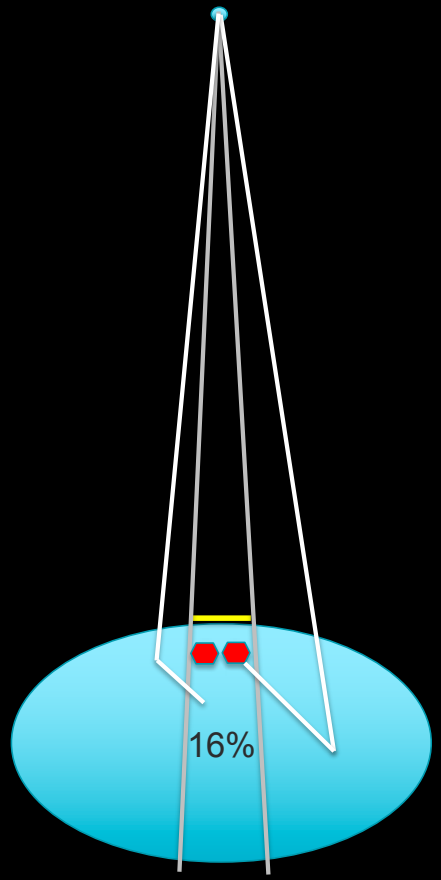
Are Accurately Placed Shields Effective?

- **Simplistic model for males**
  - **1/32” (0.79 mm) of Lead:**
    - **90% or more of primary x-rays attenuated**
- **Location of Testes**
  - **Centered bilaterally and close together**
  - **Near surface close to shield**
- **Testes located within protected region below the shield**



Are Accurately Placed Shields Effective?

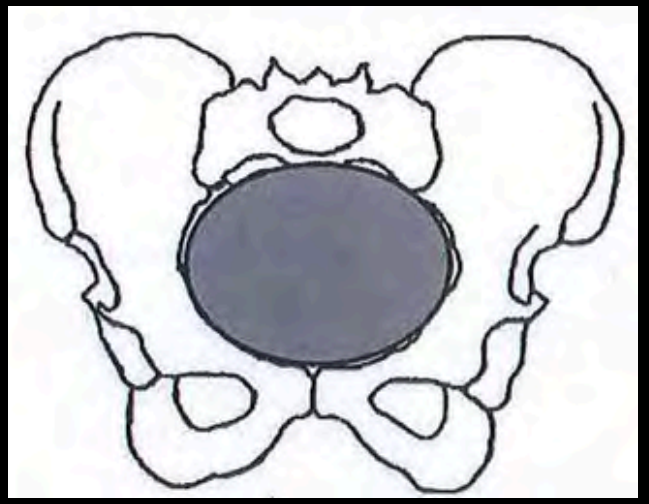
- **Realistic model**
  - 1/32” (0.79 mm) of Lead:
    - 90% or more of primary attenuated
  - **Scatter Radiation**
    - Scatter/Primary Ratio = 2 - 4
    - More scattered than primary x-rays irradiate **testes** for every stopped primary x-ray.
    - Some scatter still reach testes and deliver 16% of the original dose.



Effectiveness of Gonadal Contact Shields

- Female
  - 0 - 80% reduction depending on location of ovaries
  - Scatter x-rays reach gonads and deliver much of the original dose.
  - Varied location of ovaries more than 50% of the time places ovary outside region of primary shielding

[1]Bardo DME, Black M, Schenk K. Location of the ovaries in girls from newborn to 18 years of age: reconsidering Ovarian shielding. Pediatr Radiol (2009)39:253-59



Typical[1]

Effectiveness of Gonadal Contact Shields

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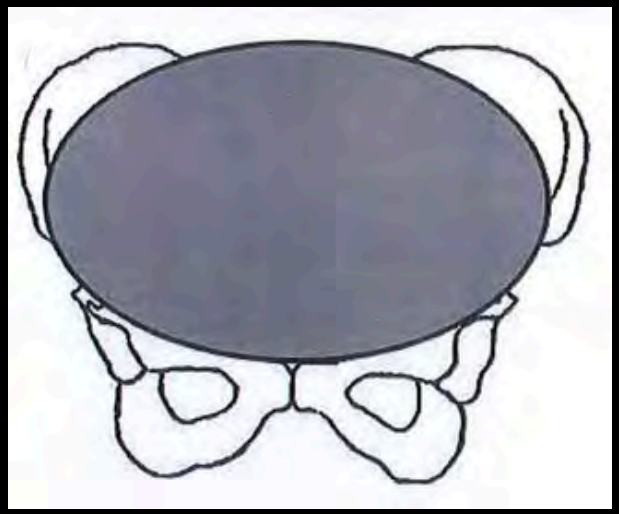

Complete Protection[1]

[1]Bardo DME, Black M, Schenk K. Location of the ovaries in girls from newborn to 18 years of age: reconsidering Ovarian shielding. Pediatr Radiol (2009)39:253-59

Effectiveness of Gonadal Contact Shields

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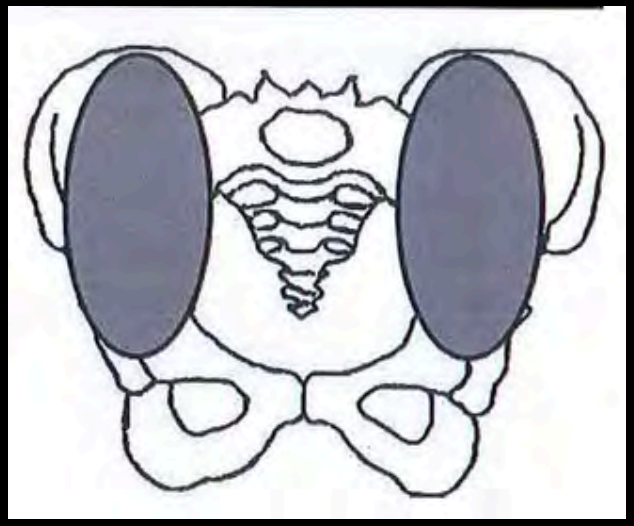
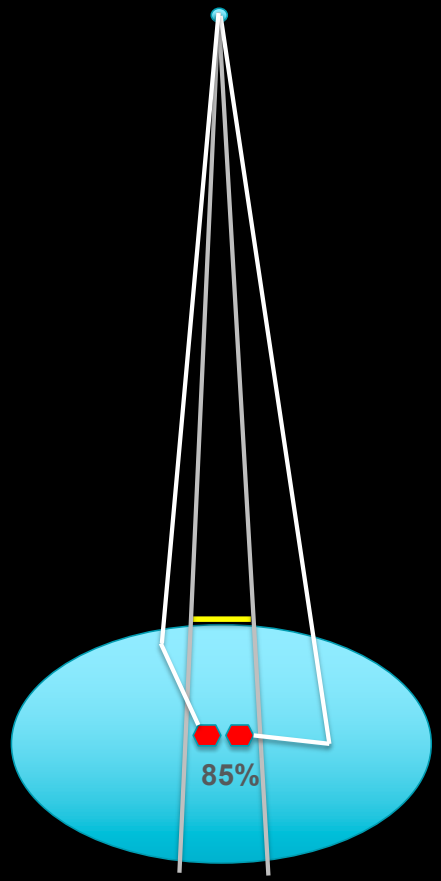


Proposed Improvement[1]

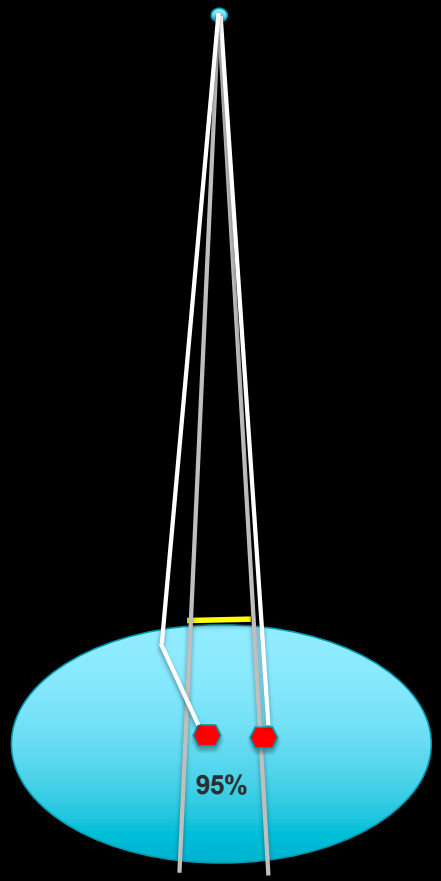
Are Accurately Placed Shields Effective?

- Realistic model for **females**
  - 1/32” (0.79 mm) of Lead:
    - 90% or more of primary attenuated
  - **Scatter Radiation**
    - Scatter/Primary Ratio = 2 - 4
    - Shielding may provide < 10% attenuation
      - Ovaries at a depth below the surface
        - Surface shield less effective at stopping some scatter



Are Accurately Placed Shields Effective?

- Realistic model for **females**
  - 1/32” or (0.79 mm) of Lead:
    - 90% or more of primary attenuated
  - **Scatter Radiation**
    - Scatter/Primary Ratio = 2 - 4
    - Shielding may provide **< 10% reduction**
      - Ovaries at a depth below the surface
      - **Ovaries are typically not centrally located: exposed by primary x-rays**



Optimum Gonadal Shielding

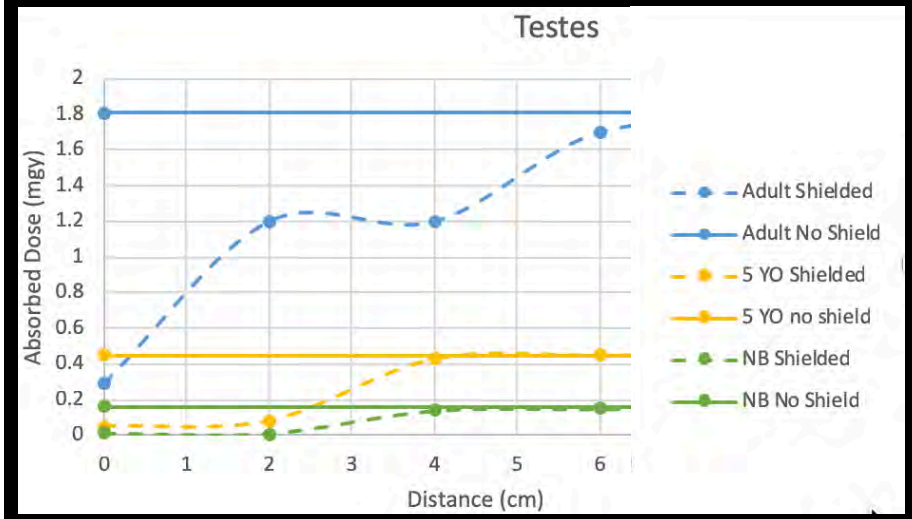
- Center of gonads lies directly below center of shield
- Monte Carlo Simulation of shielded CIRS anthropomorphic ATOM newborn, 5 yo, and adult size
- Standard filtration

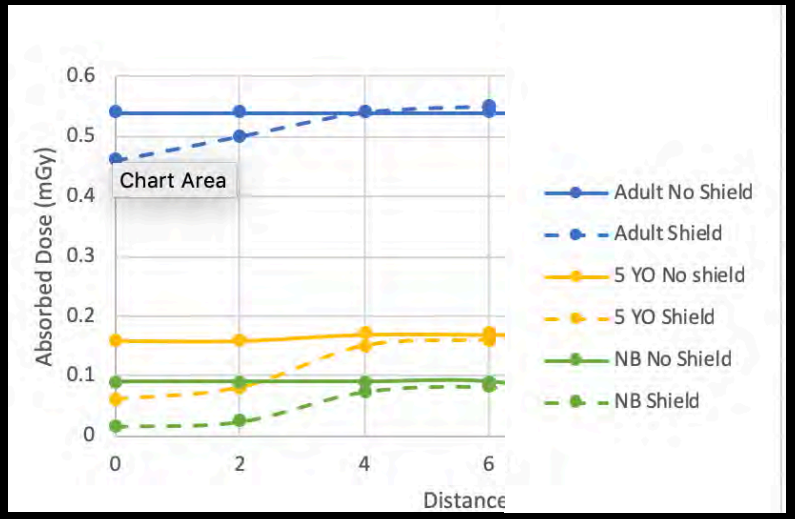
Gonadal Dose (mGy) [% Reduction]

	Testes	Ovary
NB	0.01 [94%]	0.016 [82%]
5 yo	0.05 [89%]	0.06 [63%]
Adult	0.29 [84%]	0.46 [15%]

Routine Gonadal Shielding

- Gonads not fully covered **52%** and **85%** of the time for males and females respectively.



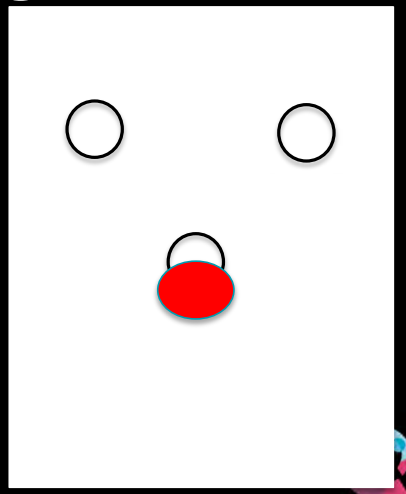


- Gonadal shielding ineffective if shifted **1.5 inches off center!**

[1]Karami V, Zabihzadeh M, Shams M, et.al. Gonadal shielding during pelvic radiography: a systematic review and meta-analysis. Arcg Urab Ned, 2017;20(2): 113 – 123

Impact of Equipment Changes

- Equipment terminates exposure when target dose received by sensor at image receptor
  - Gonadal shield shadowing sensor elevates patient dose
    - Increase dependent on degree of shadowing
      - Measured data suggests that using the Automatic termination feature used with shielding increases Patient dose as much as 25% or more.



Reconsidering the Value of Gonadal Shielding

- Radiosensitivity of organs
  - ICRP 103:
    - Gonadal tissue weighting factor reduced: 0.2 to 0.08
    - Colon, stomach, liver, and bone marrow same at 0.12.
  - Why are we shielding a less sensitive organ at the expense of more sensitive organs?

Reconsidering the Value of Gonadal Shielding

"**Changing a 'tradition' is not easy. . .**
Patients expect . . . the best care possible. Just as care givers need to educate themselves about the true merits of gonadal shielding, they need to help patients understand that their imaging experience should evolve to allow continued deliverance of the best care possible."[1]

[1]Strauss KJ, Gingold EL, Frush DP. Reconsidering the value of gonadal shielding during abdominal/pelvic radiography. J Am Coll Radiol. 2017 Dec; 14(12) pp 1635-6.

Communication

- Conversations should be based on scientific evidence of benefit vs risk
  - Acknowledge potential psychological effect.
  - Perspectives should not assign or imply ‘blame’
    - Gonadal shielding is typically ineffective.
  - Multiple forms of communication may be helpful.
  - Taylor content and language to the relevant audience.
  - Ensure consistent messaging
  - Create an open dialogue

Gonadal Shielding was discontinued at CCHMC 1/1/19

- Because this typically improves patient care:
  - Radiologists want to see ‘blocked’ patient anatomy.
  - Gonadal shielding **increases** instead of **decreases** radiation dose to the patient with AEC use.
  - Gonads are less sensitive to radiation than some other abdominal organs
  - Position of ovaries is variable:
    - Effective positioning of shields is seldom achieved.

Reconsidering the Value of Gonadal Shielding

NCRP Statement from Scientific Committee (SC4-11):

- Gonadal Shielding During Abdominal and Pelvic Radiology
  - Purpose: To provide recommendations and guidance, through an authoritative statement, that addresses newer information and current understanding on possible health effects of gonadal exposures of both adult and pediatric patients.
  - Are changes to existing regulations needed?
  - Technologists are on the front line of this change
  - Communication techniques and resources are required.

Thank you

Keith.strauss@cchmc.org

Patient Radiation Management in Interventional Fluoroscopy

Stephen Balter, Ph.D.

FAAPM, FACMP, FACR, FSCAI, FSIR

Professor of Clinical Radiology (Physics) (in Medicine)

TAM-A.2 2020 HPS Mid-Year Meeting

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

No relevant disclosures

General

- Image guided interventional medical procedures often require fluoroscopy (FGI) for their completion.
  - This can result in the delivery of substantial amounts of radiation to the patient.
- Radiation use poses a stochastic risk and may also induce tissue reactions.
- FGI patients are accepted for a procedure when the benefits of that procedure are expected to outweigh radiation and other risks.

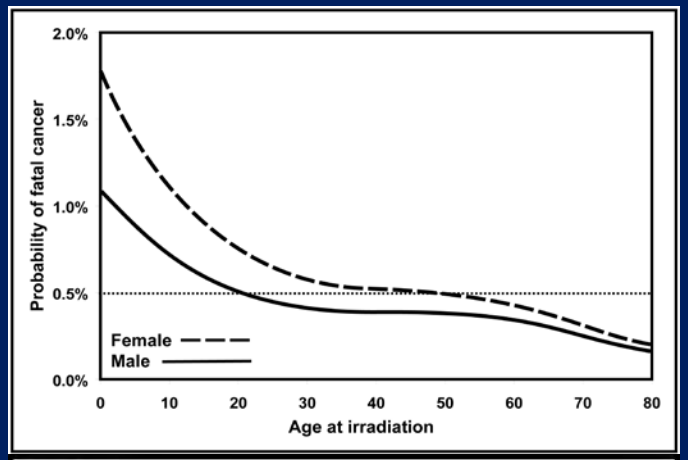
CAUTION

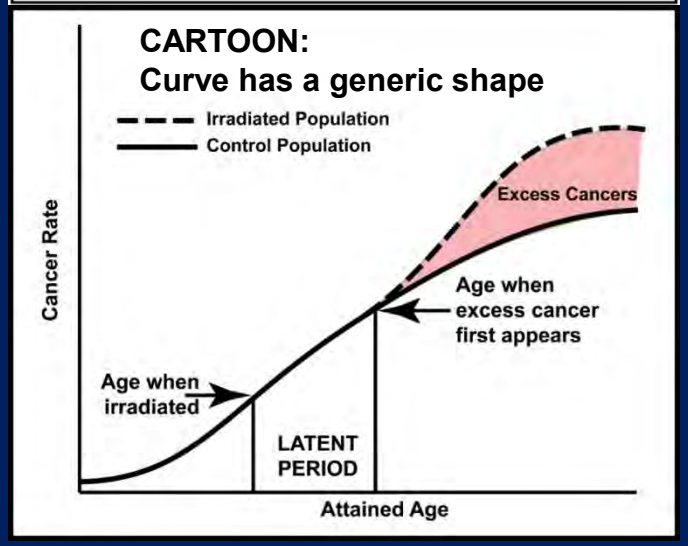
- FDA: “Fluoroscopy is used in a wide variety of examinations and procedures to diagnose or treat patients. Some examples are:
  - Barium X-rays and enemas (to view the gastrointestinal tract)
  - Catheter insertion and manipulation (to direct the movement of a catheter through blood vessels, bile ducts or the urinary system)
  - Placement of devices within the body, such as stents (to open narrowed or blocked blood vessels)
  - Angiograms (to visualize blood vessels and organs)
  - Orthopedic surgery (to guide joint replacements and treatment of fractures)”
- Regulatory confusion has resulted from overly inclusive definitions of FGI
  - putting anything into the patient using fluoro
  - most procedures incur minimal radiation risk

FGI patient risk management goals

- *Provide appropriate medical care.*
  - *Stopping, for any reason, is not always appropriate.*
  - *Overtreating increases risks but not necessarily benefits.*
- FGI has many non-radiation risks.
- Radiation should be regarded as a toxic agent in the same sense as pharmaceuticals.
  - Managing all toxic agents is part of routine patient care.
  - Medically *unavoidable* tissue injuries should be as mild and infrequent as possible.
  - No *unintended* tissue injuries.
  - **Consider stochastic risks**
- **Manage fetal risks**

Cancer risks & Tissue reactions





Tissue Reactions from Single-Delivery Radiation Dose to Skin of the Neck, Torso, Pelvis, Buttocks, or Arms

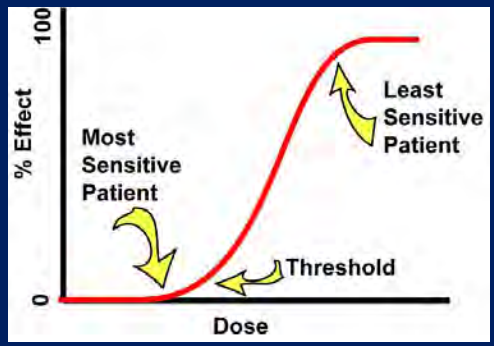
Band	Single-Site Acute Skin-Dose Range (Gy)*	NCI Skin Reaction Grade†	Approximate Time of Onset of Effects			
			Prompt	Early	Midterm	Long Term
A1	0–2	NA	No observable effects expected	No observable effects expected	No observable effects expected	No observable effects expected
A2	2–5	1	Transient erythema	Epilation	Recovery from hair loss	No observable results expected
B	5–10	1–2	Transient erythema	Erythema, epilation	Recovery; at higher doses, prolonged erythema, permanent partial epilation	Recovery; at higher doses, dermal atrophy or induration
C	10–15	2–3	Transient erythema	Erythema, epilation; possible dry or moist desquamation; recovery from desquamation	Prolonged erythema; permanent epilation	Telangiectasia‡; dermal atrophy or induration; skin likely to be weak
D	>15	3–4	Transient erythema; after very high doses, edema and acute ulceration; long-term surgical intervention likely to be required	Erythema, epilation; moist desquamation	Dermal atrophy; secondary ulceration due to failure of moist desquamation to heal; surgical intervention likely to be required; at higher doses, dermal necrosis; surgical intervention likely to be required	Telangiectasia‡; dermal atrophy or induration; possible late skin breakdown;wound might be persistent and progress into a deeper lesion; surgical intervention likely to be required

Note.— Applicable to normal range of patient radiosensitivities in absence of mitigating or aggravating physical or clinical factors. Data do not apply to the skin of the scalp. Dose and time bands are not rigid boundaries. Signs and symptoms are expected to appear earlier as skin dose increases. Prompt is <2 weeks; early, 2–8 weeks; midterm, 6–52 weeks; long term, >40 weeks.

* Skin dose refers to actual skin dose (including backscatter). This quantity is not the reference point air kerma described by Food and Drug Administration (21 CFR § 1020.32 [2008]) or International Electrotechnical Commission (57). Skin dosimetry is unlikely to be more accurate than ± 50%. NA = not applicable.

† NCI = National Cancer Institute.

‡ Refers to radiation-induced telangiectasia. Telangiectasia associated with area of initial moist desquamation or healing of ulceration may be present earlier.



What are the patient's other risks?

Tissue Reactions

Cor. Angioplasty

Coronary Angioplasty

Cardiac Ablation

Coronary Ablation - LATE

Neuroembolization

Renal angioplasty

TIPS placement

FALSE Positive

Time sequence

2 months

6 months

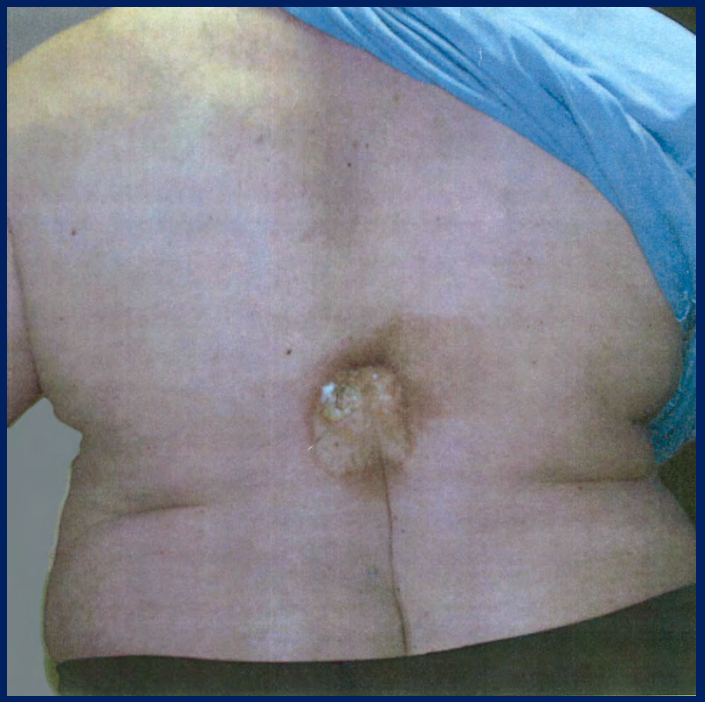
2 years

Source: FDA/CDRH

Experimental Model
Source: J. Hopewell

Diagnosis of a radiation injury

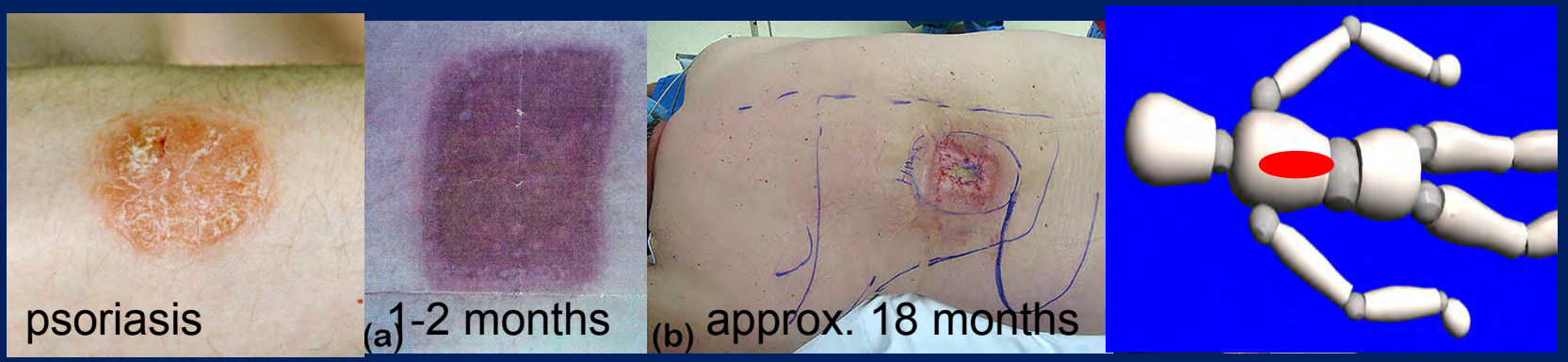
- ***Frequently attributed to other causes.***
- **Interventionalists rarely see patents months after the procedure.**
- **Patients often unaware that radiation is used.**
- **Outside physicians who see skin lesions seldom connect them to radiation.**
  - **Punch biopsy for diagnosis of major injuries can lead to major and difficult to treat infections.**



Using the FDA's web site, this patient finally self diagnosed his lesion as a radiation injury more than one year after the procedure.

Coronary patient's experience

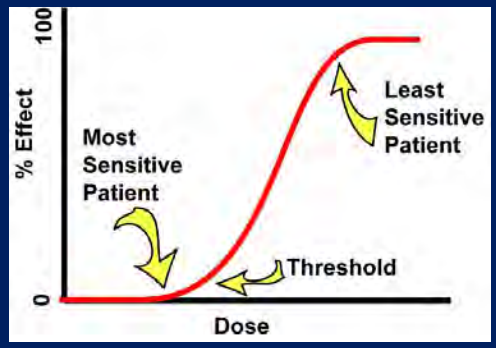
Single procedure. Estimated PSD 20 – 40 Gy.

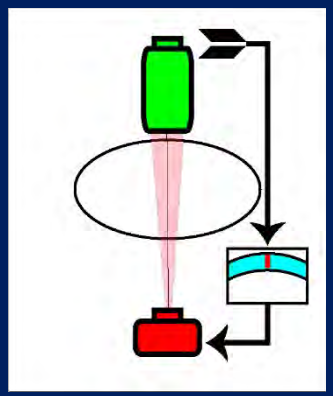


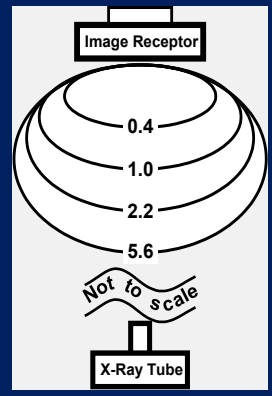
"over 15 months with no more than 2 hours sleep at any one time. The pain is best described as a metal baseball bat stuck in a campfire and pressed in my back just above my left kidney, right beside my spine and pressed to the ribs, with an electrical charge to that bat that you use at random. This was the worst pain you can imagine."

Causes of tissue reactions

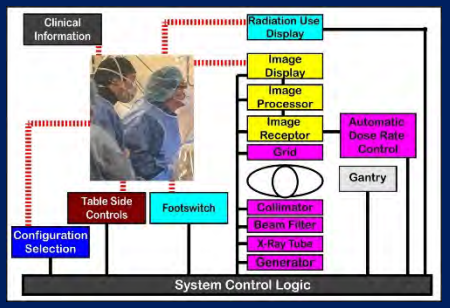
- **Patient Factors**
  - Anatomy
  - Lesions and treatments
  - Physiological variability
- **Technical Factors**
  - Inappropriate equipment
  - Poor maintenance and/or QA
- **Operator Factors**
  - Improper Configuration
  - Improper Mode Selection
  - Improper geometry
  - *Unconcerned about radiation.*
  - *Inattention to radiation use!*







Operator Training is Important



- **Risk based**
  - Minor fluoro guided procedures
  - General fluoroscopy
  - Operators performing ***any*** procedure with more than 5% having $K_{a,r}$ exceeding ??? Gy
- **Training formats**
  - Didactic
  - Hands On
  - Equipment Specific
- **JC training is part of 'staff competence'**

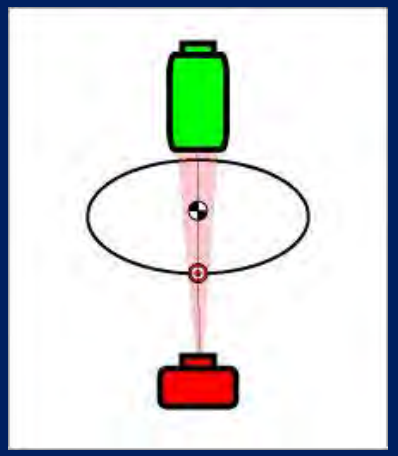
  Staff competence is assessed and documented once every three years, or more frequently as required by hospital policy or in accordance with law and regulation.
  - Local regulatory requirements
  - Facility judgement

Radiation metrics

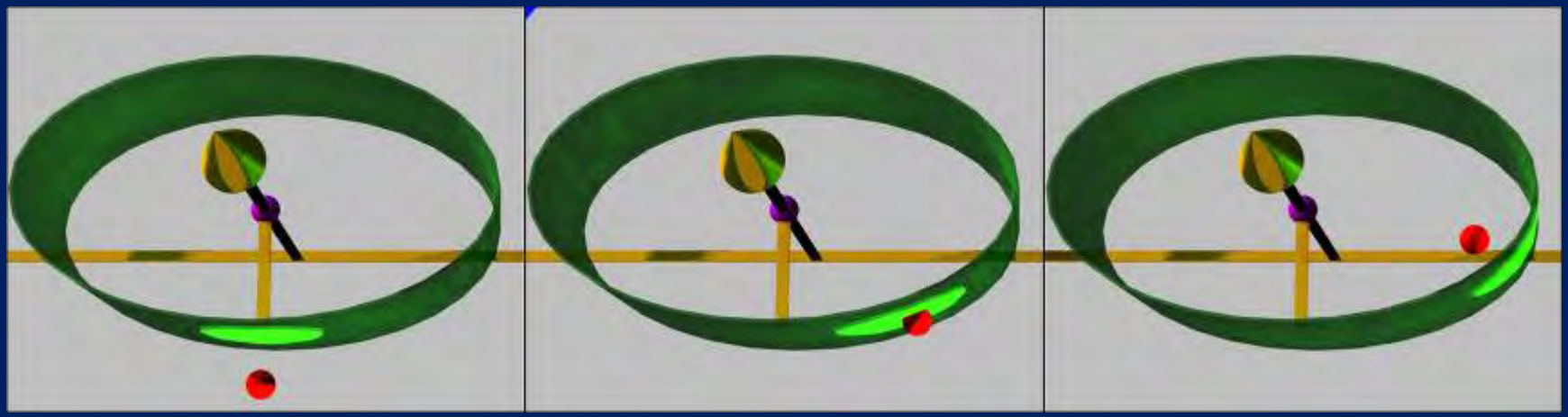
- Peak Skin Dose (PSD) [work in progress]
  - Maximum delivered to a zone on the skin (including backscatter).
- Reference Point Air Kerma ($K_{a,r}$)
  - IEC 60601-2-43 compliant systems; FDA regs
  - Current state-of-art: Lacks collimation, beam motion, and SSD
- Skin Dose Maps [work in progress]
- Air Kerma Area Product (P_{KA})
  - Most interventional systems have this capability
  - Almost impossible to use to estimate PSD
  - Useful stochastic risk, operations, and QA
- ~~Fluoroscopy Time and Image Count~~
  - Poor: Lacks patient size, collimation, beam motion, and SSD

Reference Point Air Kerma ($K_{a,r}$)

Labeled mGy on most systems
NOT skin dose

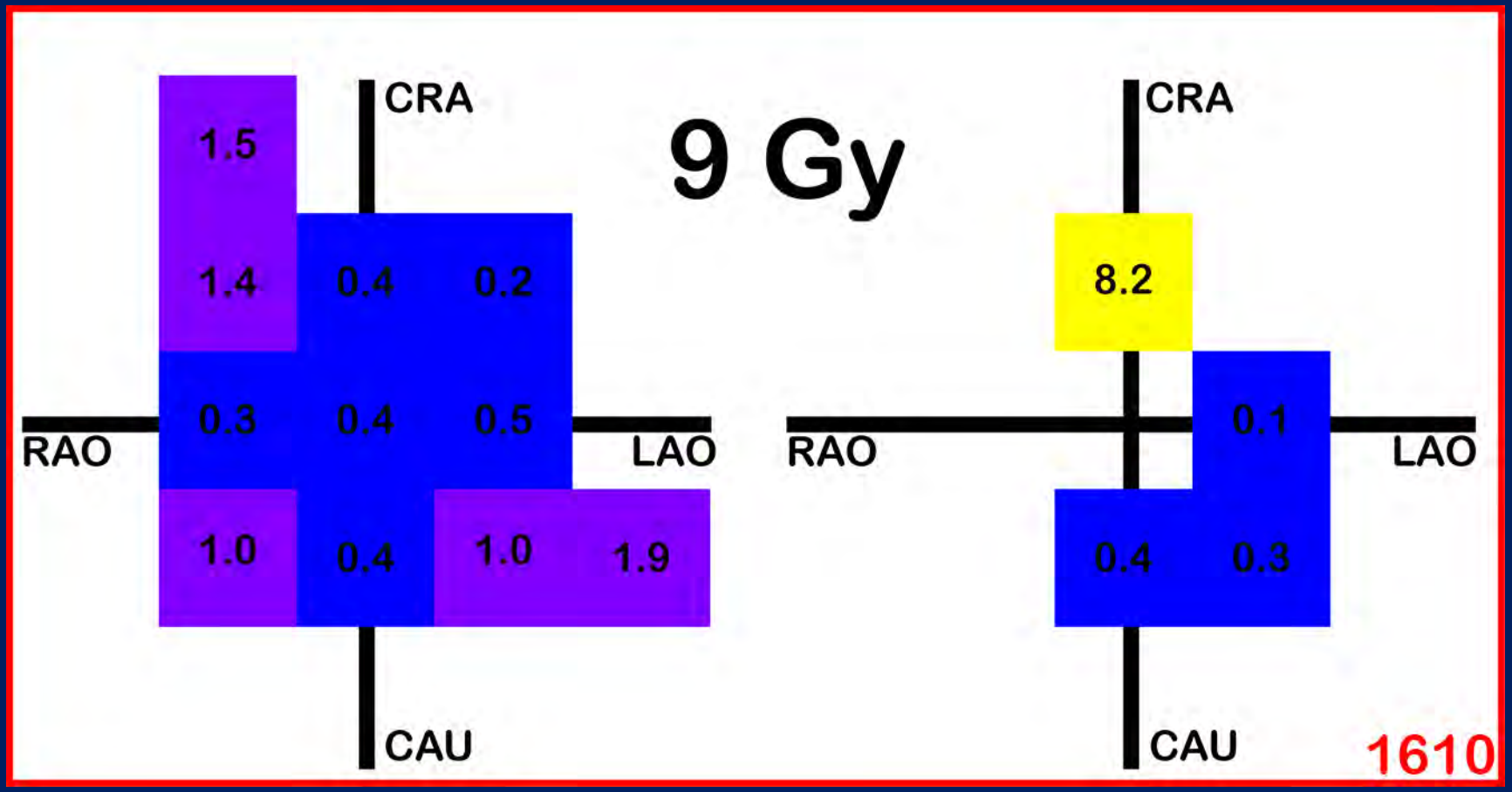


Should be calibrated by QMP
ref TG-190; JC 2019



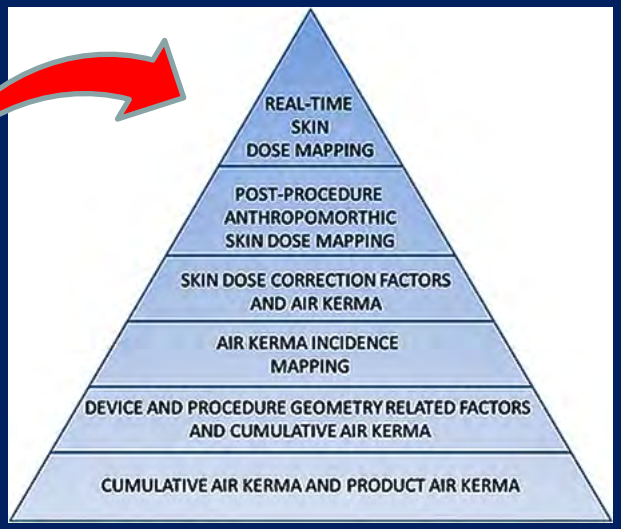
$K_{a,r}$ maps

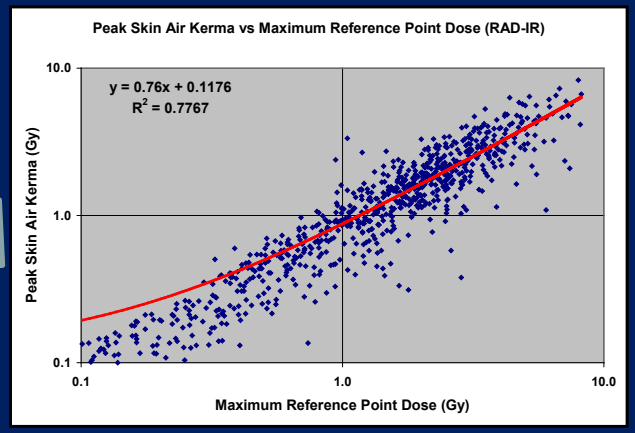
- Relative to beam angle

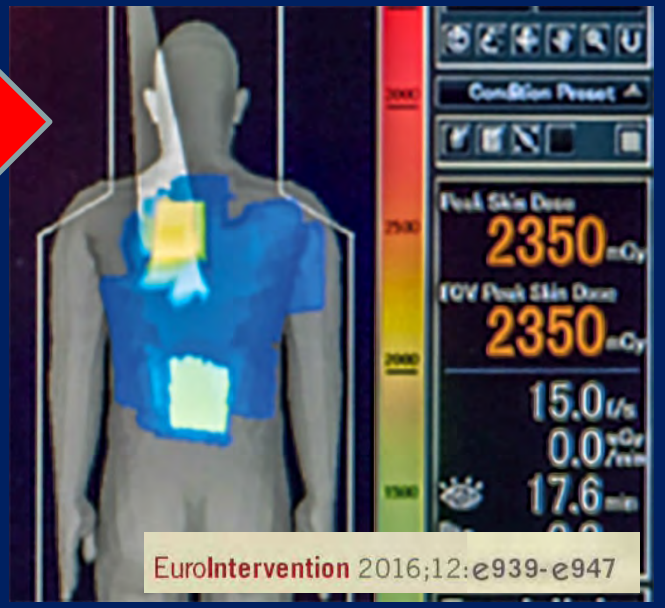


$K_{a,r}$ or dose map?

- $K_{a,r}$ has been available since 2000



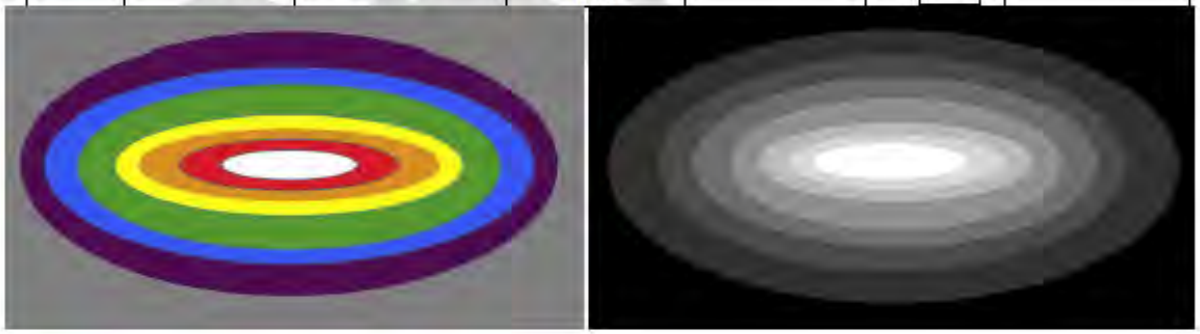




- Some dose map implementations are now available.
- International standard (IEC) requirement is expected in 2019.

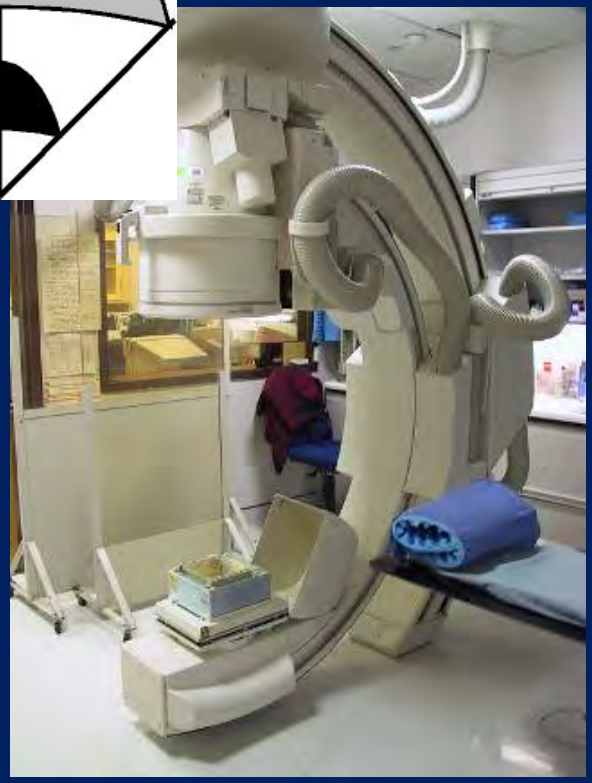
Skin Dose Map Coding Draft – Sep 2019

Step	Skin Dose Range (mGy)	Target Color	RGB Values	CIELab Values	Target Greyscale	Greyscale RGB
0	0-100	Grey	128, 128, 128	52, 00, 00		0, 0, 0
1	100-1000	Violet	092, 000, 080	19, 45, -22		45, 45, 45
2	1000-2000	Blue	000, 084, 241	42 ,42 ,-83		75, 75, 75
3	2000-3000	Green	000, 154, 048	55 ,-56, 44		110, 110, 110
4	3000-5000	Yellow	255, 251, 000	96, -20, 94		145, 145, 145
5	5000-8000	Orange	239, 144, 000	68, 28, 74		185, 185, 185
6	8000-12000	Red	255, 000, 000	53, 80, 67		215, 215, 215
7	>12000	White	255, 255, 255	100, 00, 00		255, 255, 255

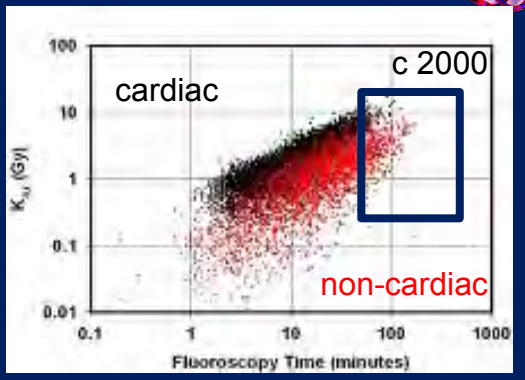


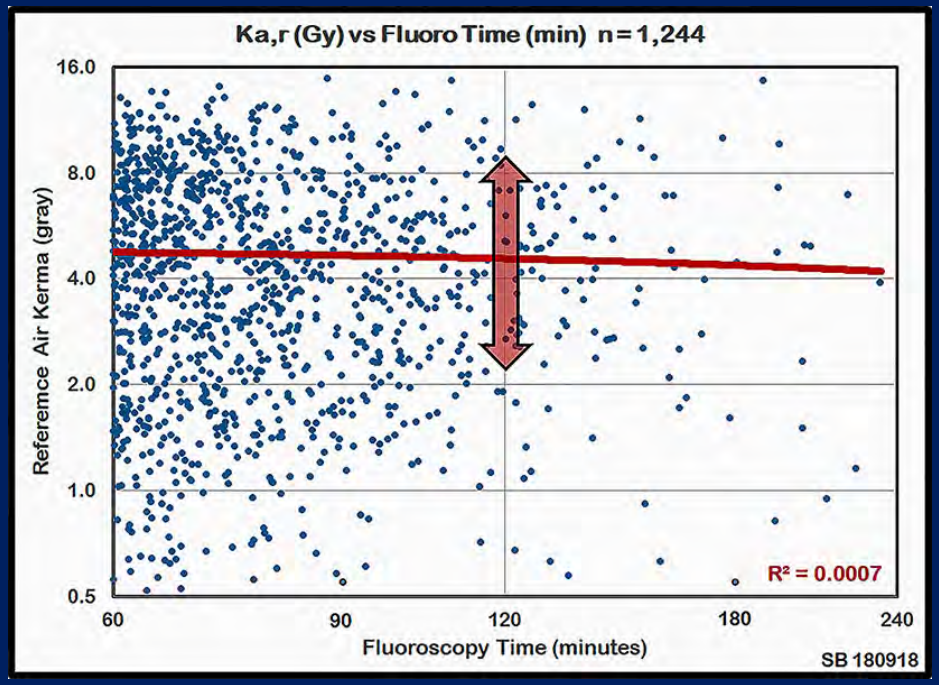
Air Kerma Area Product (KAP, DAP)

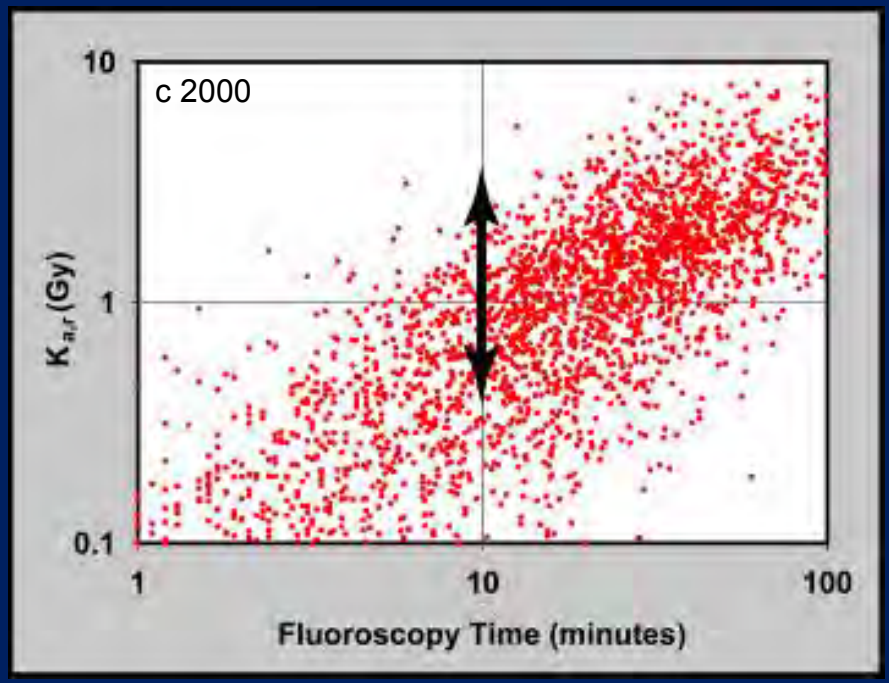
- Does not reflect influences of:
  - field size,
  - beam geometry, or
  - beam motion
- Indicator of
  - patient's stochastic risk
  - scatter intensity in lab
- *NOT a direct indicator of possible tissue reaction.*



~~Fluoroscopy Time~~







1,244 --- 60-minute plus
Cath-lab procedures
R^2 = 0.00007 CUMC Data

≈ 2,100 (c 2000)
Non-cardiac interventions
R^2 = 0.50 RAD-IR I

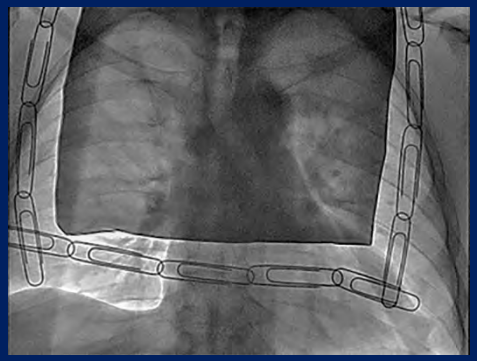
Substantial Dose Procedure (SDP)

- Threshold value used to trigger extended post-procedure education and clinical follow-up.
- Almost no injuries should be observed below the substantial dose level.
- Major injuries occasionally occur, usually well above the substantial dose level.
- Recommend: $K_{a,r}$ = 5,000 mGy for patients without radiation risk factors.

  This value was pragmatically selected to screen for potential skin injuries.

Before a procedure

- Radiation Injury Risk Factors
  - Weight > 150 kG (chest / abdomen / pelvis)
  - Planned procedure
  - Radiation history
    - Previous angioplasty
    - Previous or planned RT to chest
    - Examine patient's back !



- Potential Substantial Dose Patient
  - Appropriate additional discussion of injury risk as part of consent process.
  - Reduce Substantial Dose trigger based on radiation history.

Radiation portion of checklists

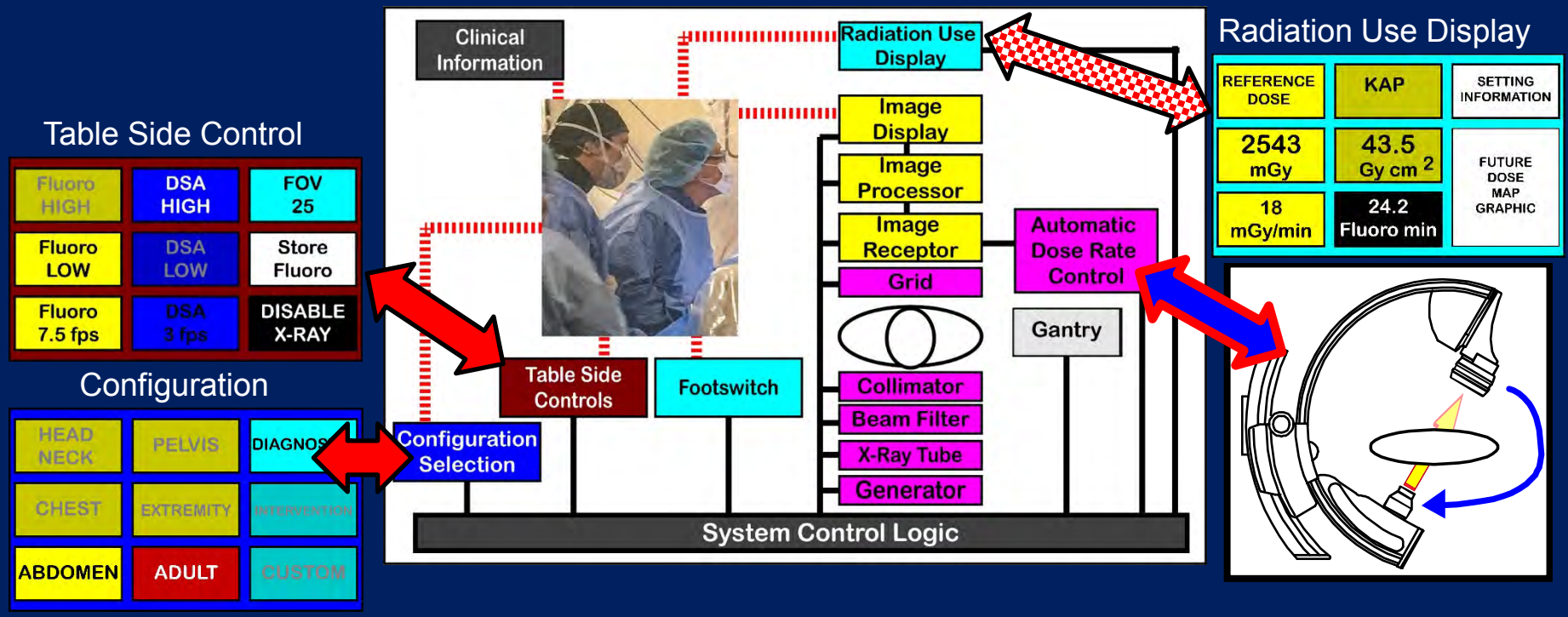
TIME-OUT

- ✓ Machine is configured for the planned procedure.
- ✓ Correct patient name on X-ray machine.
- ✓ All in room are wearing correct PPE & dosimeters.
- ✓ X-ray production enabled after time-out.

POST PROCEDURE

- ✓ X-ray production disabled as soon as complete.
- ✓ All available dose information recorded.
- ✓ Patient given SDP instructions if necessary.

Operator is part of the control system



Operators may escalate dose rate selection
to 'burn through' perceived sub-optimum image quality.

Notifications (NCRP-168)

TABLE 4.7–Suggested values for first and subsequent notifications and the SRDL.

Dose Metric	First Notification	Subsequent Notifications (increments)	SRDL
$D_{skin,max}$	2 Gy	0.5 Gy	3 Gy
$K_{a,r}$	3 Gy	1 Gy	5 Gy[a]
P_{KA}	300 Gy cm^2 [b]	100 Gy cm^2 [b]	500 Gy cm^2 [b]
Fluoroscopy time	30 min	15 min	60 min

[a]See additional discussion concerning the value 5 Gy in Section 4.3.4.2.
[b]Assuming a 100 cm^2 field at the patient's skin. For other field sizes, the P_{KA} values should be adjusted proportionally to the actual procedural field size (*e.g.*, for a field size of 50 cm^2, the SRDL value for P_{KA} would be 250 Gy cm^2).

JC 2019: The hospital identifies radiation exposure and skin dose threshold levels, that if exceeded, trigger further review and/or patient evaluation to assess for adverse radiation effects.

CUMC: Substantial Dose Procedures

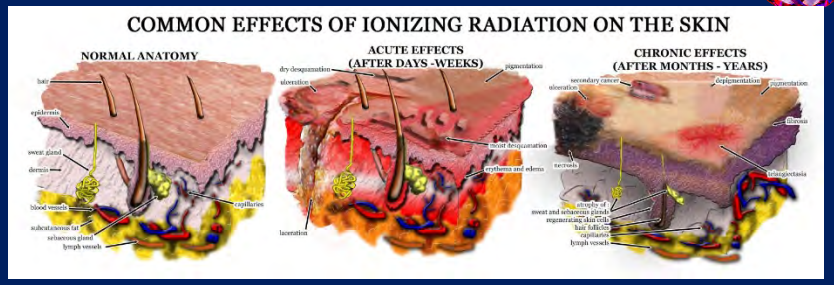
- $K_{a,r}$ > 5,000 mGy – Less if clinically warranted.
  - Lab provides 'hand-off' data:
  - Patient receives discharge radiation instructions.
  - Patient calls if a possible reaction is observed.
  - Clinic visit with operator is scheduled if staff can't absolutely rule out radiation.
- CUMC QA follow-up $K_{a,r}$ > 7,000 mGy
  - Proactive 30 – 40 days post procedure.
  - So far, all patients contacted by QA with skin changes have already called us.
  - Continuing follow-up of these patients.

JC 2019: The hospital reviews and analyzes instances where the radiation exposure and skin dose threshold levels identified by the organization are exceeded.

CUMC: SDP discharge instructions

- Have a family member look at patient's back 30 days from now.
- Call us (lab's 24-hour clinical emergency number) if there is a discolored (red) patch the size of a hand.

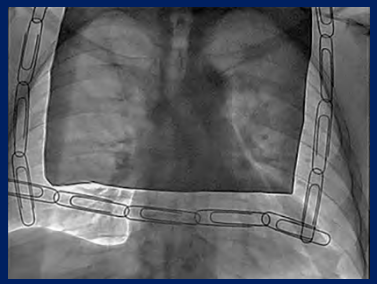
Staged procedures



- **Biology**
  - DNA repair complete in 24 hours.
  - Skin cell death in approximately 30 days.
  - Skin cells replaced in approximately 60 days.
  - Skin microvasculature damaged at higher tissue doses.
  - Use of standard radiobiology dose summation only works if the same tissue is irradiated by different fractions.
- **Minimum "routine" interval**

  4 – 6 weeks for different anatomy.

  8 – 12 weeks for same anatomy.



- **Check patient's back before proceeding.**

  All visible skin changes should be marked so that their locations can be seen on fluoro.

Follow-up policies

Outline of Administrative Policies for Quality Assurance and Peer Review of Tissue Reactions Associated with Fluoroscopically-Guided Interventions

NCRP Statement No. 11, December 31, 2014

- Operator is responsible for at least one year.
  - Can be delegated if necessary.
- Anything is radiogenic until proven otherwise.
  - Initial telephone triage.
  - Visit with operator who performed procedure unless radiation is ruled-out.
  - Specialist referral (if needed) by the operator who performed the procedure.
- NCRP Statement 11 Essentials
  - Interventional-service based peer review (PR criteria provided)
  - All metrics shall be recorded; 100% collection and tracking of radiation data
  - Dosimetry analysis – at least annual
  - Patient follow-up based on exceeding SRDL
- Peer review findings (Statement 11)
  - Unavoidable – No action required
  - Optimization might have improved the situation
  - Did not meet recognized practice parameters

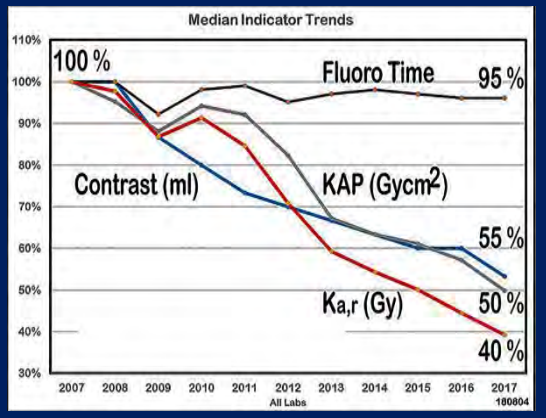
JC Radiation Use Documentation

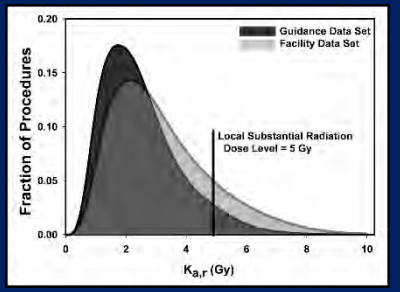
JC 2019: The cumulative-air kerma or kerma-area product are documented in a retrievable format. … such as a picture archiving and communication system.

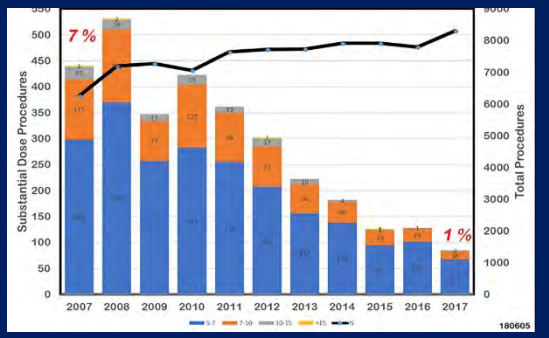
- **Not ‘file and forget’**
  - **Documentation limited to text inserted into individual case reports may not be acceptable.**
  - **May imply that facilities perform statistical audits**
- **Data automation is nontrivial**
  - **Older systems without RDSR or equivalent outputs**
  - **Great variability in the ability of ‘PACS’ to capture and store RDSR or other digital dose data.**
  - **Few if any current PACS have any Radiation Use analytic capability.**

CUMC IC patient dose tracking

- Our equipment mix not support 100 % automated dose tracking.
  - Some data entered in EMR by monitoring person.
  - All data entered in lab logbook daily by X-ray techs.
- Dosimetry collected and combined with EMR data weekly.
- Weekly substantial dose report:
  - Entire report to leadership team.
  - **Individual physicians report of their own SDP cases.**
- Periodic review at clinical QA
  - Reported or potential radiation injuries.
  - Overall statistics.







Physicians usually respond immediately

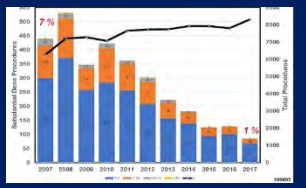
- Typically via return email
- Two recent examples:
  - 5800 mGy:
    Unfortunately, patient was very sick and passed away.
  - 7600 mGy:
    Thx, Patient and MD aware.

Protocols and protocol audits

- Many systems are computer controlled.
  - Delivered with tens to hundreds of protocols
  - Few protocols used on any individual unit
- Adjusted after delivery and over time.
  - Applications tuning to meet local taste.
  - Changing clinical requirements.
  - Software upgrades.
- Audit Tools
  - NEMA XR-27 provides technical data.
  - Clinical inputs and feedback are needed.
  - Exam nomenclature should be standardized.

Tissue reaction results CUMC IC

- Tissue Reactions: Known cases down from 1- 3 per year before 2010 to a single case after 2014.
  - SDP from ≈ 500/y in 2006 to ≈ 80/y in 2019,
  - All known reactions were grade 1 or grade 2 and were self-reported by patients at the 30-day call.
  - Unaware of any major (grade 3-4) reactions in our series.
  - Recently saw a returning patient with an unhealed injury seven years post procedure. Reported multiple biopsies and skin scraping by dermatology over this interval.
- Follow Up: Successful in directly telephoning over 80% of the ≥7 Gy patients treated in the last five years.
  - No additional injuries were identified by these calls, or by a review of available CUMC medical records of all patients above 7 Gy (2006-2017).
- We continue to see a few patents per year from OSH with tissue-reactions.

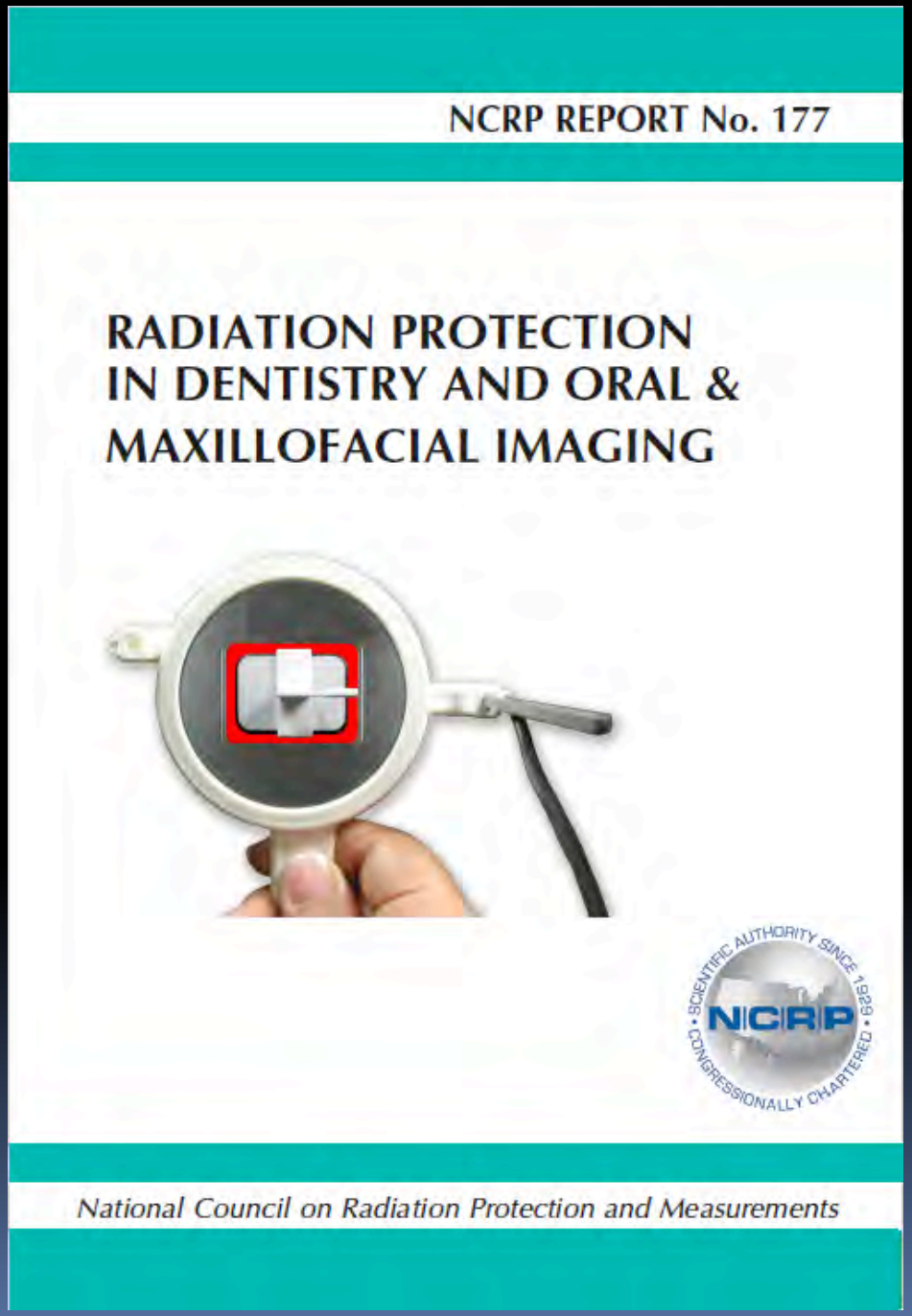


Clinical radiation decisions

- Patient should expect to benefit from each procedure.
- When a fluoro procedure is performed, both patient and staff are exposed to risks.
- There is no regulatory patient dose limit!

  Radiation must be used responsibly
- Operator should have sufficient real time information to evaluate benefits of continuing considering radiation and other risks.

  Injuries are almost always avoidable



NCRP Report No. 177 Radiation Protection in Dentistry and Oral & Maxillofacial Imaging Published December, 2019

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HIGHLIGHTS: EXECUTIVE SUMMARY I

The purpose of this Report is to enhance radiation safety in dentistry and to reinforce published, well-known dose-reduction methods that are not yet being widely applied in the day-to-day practice of dentistry.

This Report updates the information in NCRP Report No.145, adds new content on digital imaging, handheld x-ray devices, and CBCT, and makes 62 recommendations for reducing radiation doses to patients, operators and the public while maintaining or improving image diagnostic efficacy, all in the context of the ALARA principle.

HIGHLIGHTS: EXECUTIVE SUMMARY II

Recommendations grounded in NCRP Report No. 145:

- Rectangular collimation (Cover of Report No. 177)
- Selection Criteria for every imaging examination
- Fastest imaging receptor possible
- Thyroid collars
- Optimal technique factors
- Elimination of ANSI speed group D film

HIGHLIGHTS: EXECUTIVE SUMMARY III

Recommendations for digital, handheld and CBCT imaging:

- Selection Criteria for CBCT examinations
- Smallest FOV and optimal technical factors for minimizing dose and maintaining diagnostic efficacy for CBCT examinations
- Use only FDA-cleared units for imaging, especially for hand-held imaging
- Embrace Image Gently campaign principles and recommendations for imaging children

HIGHLIGHTS: EXECUTIVE SUMMARY IV

Recommendations for education, training and quality assurance in the dental office:

- Establishment of QA and QC protocols and procedures for all aspects of image acquisition are the responsibility of the dentist, with assistance from a qualified expert when needed
- Education and training of dental students, residents, dentists and staff in safe and effective use of imaging technology is to be conducted by trained professionals and other qualified experts, and is not within the expertise of salespersons.

Effective Doses: Intraoral Images

Individual Images:

Rectangular collimation
ANSI E/F-Speed Film or Digital Receptor
5 μSv per image

Round collimation
ANSI D-Speed Film
50 μSv per image

Full Mouth Series: ~ 14-18 periapical + 2-4 bitewing

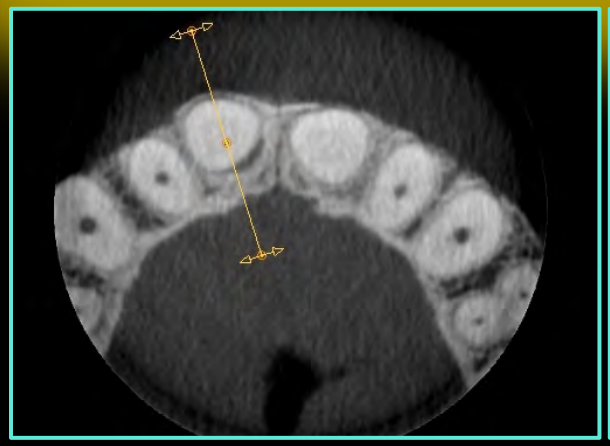
Rectangular collimation, E/F or Digital Receptor
17-35 μSv

Round collimation, D-speed film
388 μSv

Effective Doses: Panoramic Images

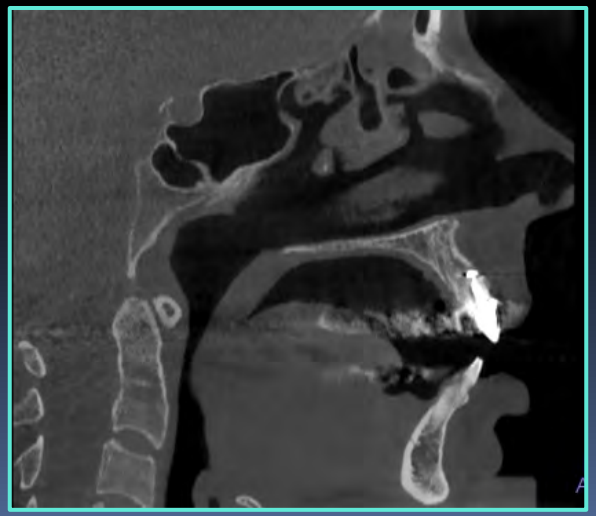
Rare earth film/screen: 24 μSv
Digital receptor: 9 μSv

Effective Doses: Conebeam CT (CBCT) Images



Small Volume CBCT

19 μSv with lowest presets (resolution)
650 μSv with highest presets



Large Volume CBCT

68 μSv with lowest presets
1073 μSv with highest presets

(MDCT Head ~1100 μSv)
(MDCT Mandible ~ 425 μSv)
(MDCT Jaws ~ 700 μSv)

BENEFITS: Traditional Imaging

Bitewing

Periapical

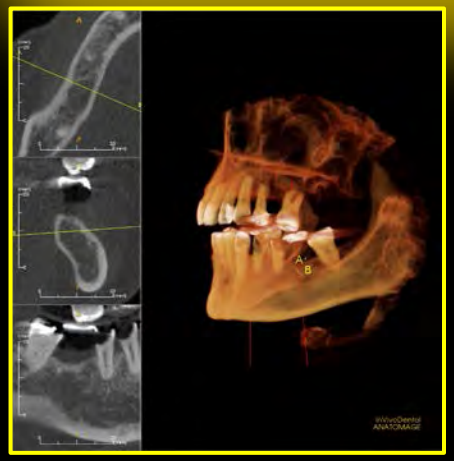
Carious Lesion Detection
Marginal Bone Loss (Periodontal Disease)
Periapical Pathology (Abscess, Granuloma, Cyst)

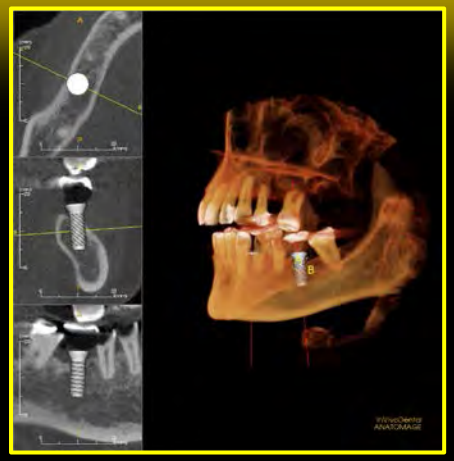
Panoramic: third molars, bone lesions, trauma

Lateral Cephalometric

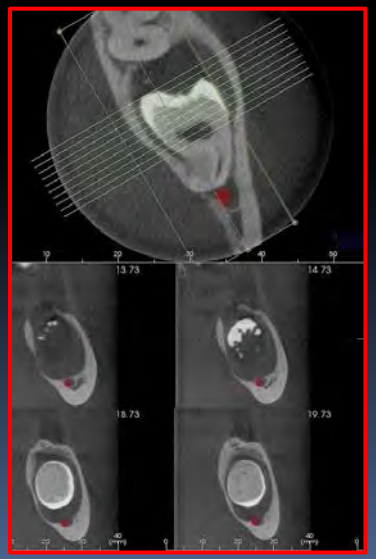
Orthodontic Treatment
Orthognathic Surgery

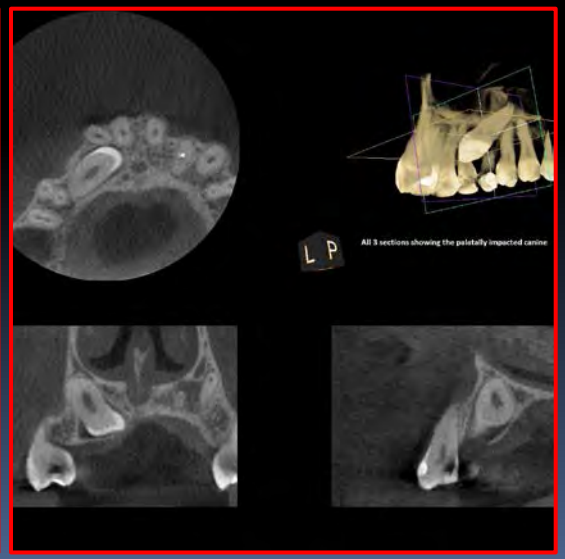
BENEFITS: CBCT



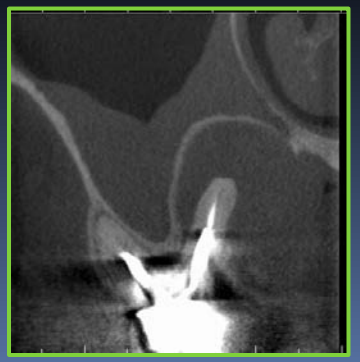


Implant Treatment Planning:
Vascular anomalies
Implant simulations
Implant site characteristics





Oral Surgery, Orthodontics:
3rd molar vs IAC
Impacted tooth location
Orthognathic Surgery



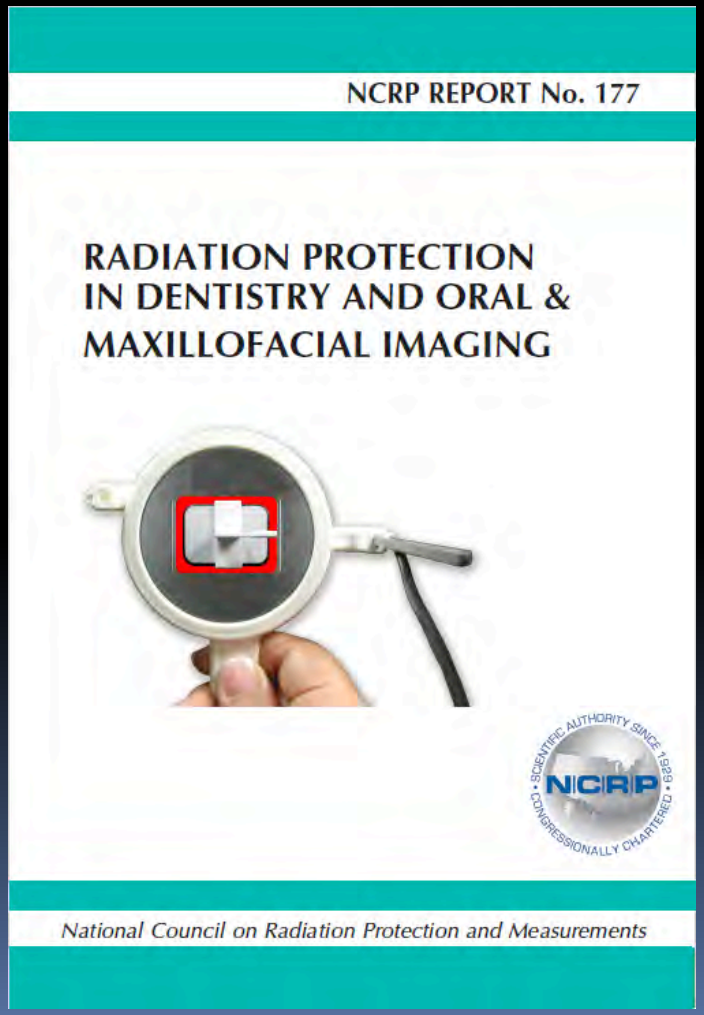
Endodontics:
Dx and definition of root canal problems

SAFETY: Conventional Imaging

Recommendations for conventional imaging from NCRP Report No. 145 that, unfortunately, have to be strongly restated in NCRP Report No. 177 as they are not being widely observed:

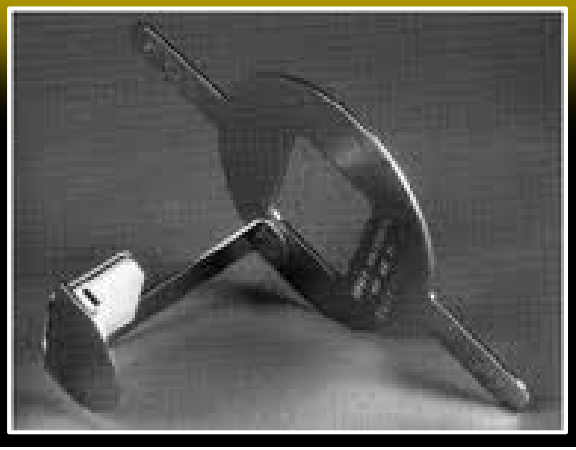
- ***Rectangular collimation for intraoral imaging***
- Fastest image receptor possible; elimination of D-Speed film
- Thyroid shielding
- Selection Criteria

NCRP Reports 145 and 177 SAFETY: Rectangular Collimation of Intraoral Imaging



Recommendation 39: "Rectangular collimation of the x-ray beam ***shall*** be routinely used for periapical and bitewing radiography, and ***should*** be used for occlusal radiography when imaging children with Size 2 receptors. Receptor-holding devices ***shall*** be used whenever possible"

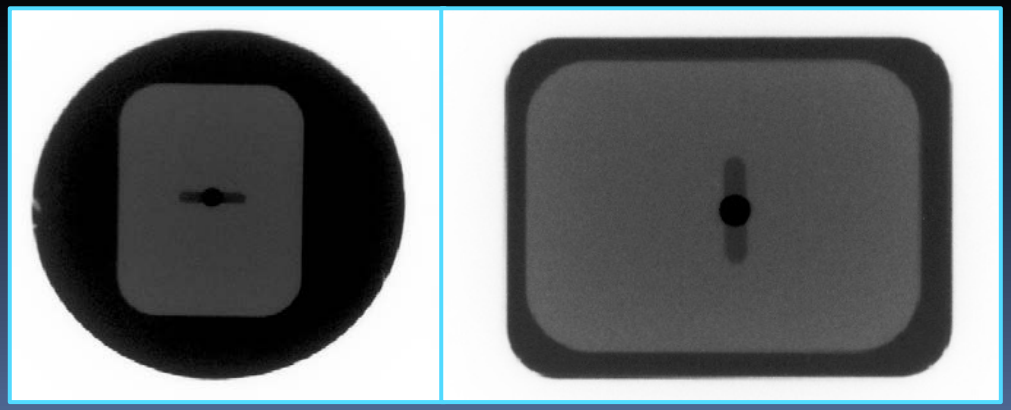
SAFETY: Rectangular collimation is the standard of care for intraoral imaging



Original “Precision Instrument”

XDR ALARA Rectangular Collimator

Round Collimation Rectangular collimation



RINN Universal Rectangular Collimator

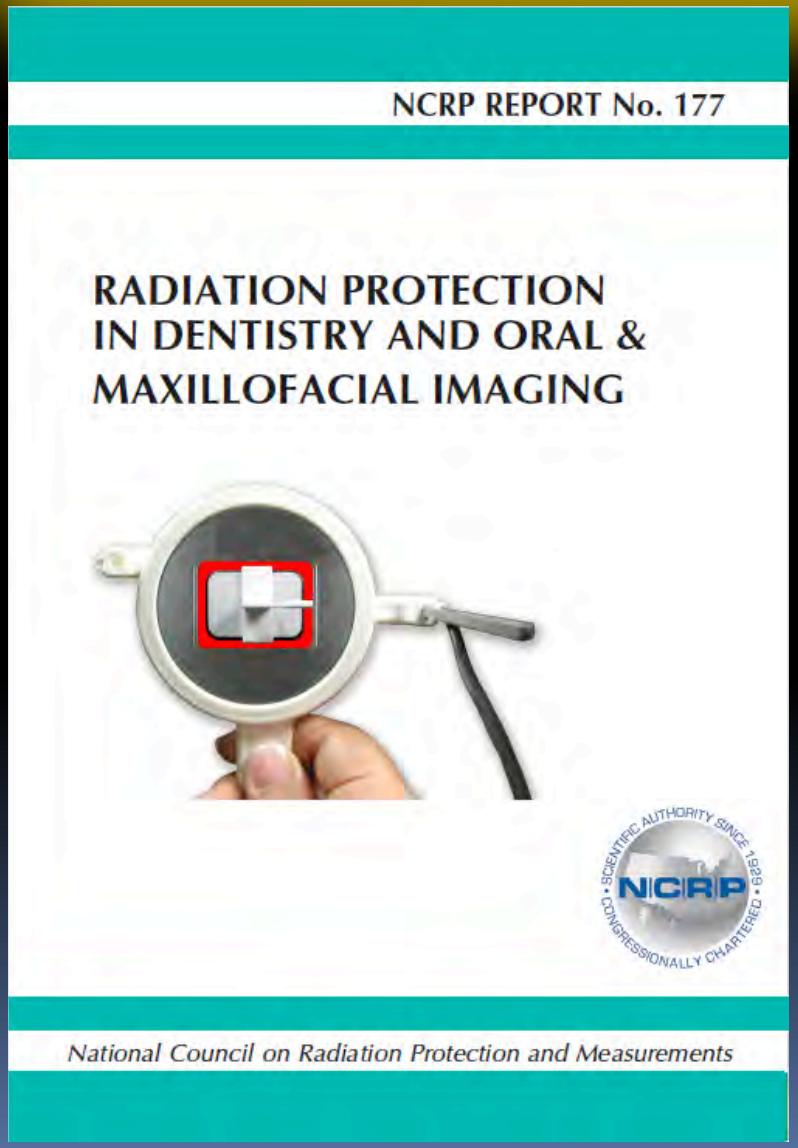
Average Air Kerma per 2 Bitewing Examination (Adapted from the 2014-15 NEXT Survey)

Rectangular collimation:	F-speed film, DR or CR	= 1.0 mGy (Adult) 0.6 mGy (Pediatric)
Round collimation:	F-speed film, DR or CR	= 2.0 mGy (Adult) 1.2 mGy (Pediatric)
	D-speed film	= 3.0 mGy (Adult) 2.1 mGy (Pediatric)

Total number of intraoral examinations in the USA/year is:
Approximately 500-million.

Thus, with most intraoral examinations consisting of 2-20 images, the total number of images annually is well over 1-billion.

SAFETY: Thyroid Shielding



Recommendation 19:
"Thyroid shielding ***shall*** be provided for patients when it will not interfere with the examination"

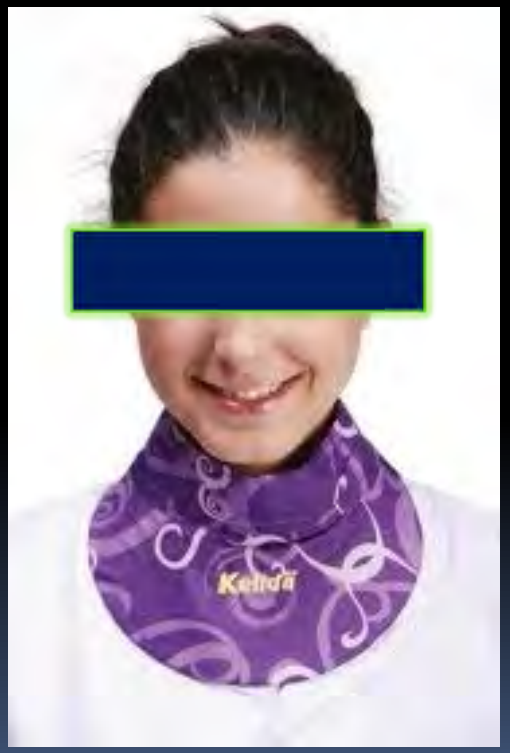
Effective Doses to Thyroid in Dental Imaging

Full mouth series (18 exposures)	177 – 550 μSv
Single intraoral exposure	6 μGy* (Absorbed)
Panoramic exposure	25 – 67 μSv

Thyroid collars reduce the thyroid absorbed dose from intraoral imaging in children by 75%*

GOOD

NOT so good



Data from Health Physics Society, 2008 and from *Fontana et al, Health Phys, 118:136, 2020

Images from Google Images

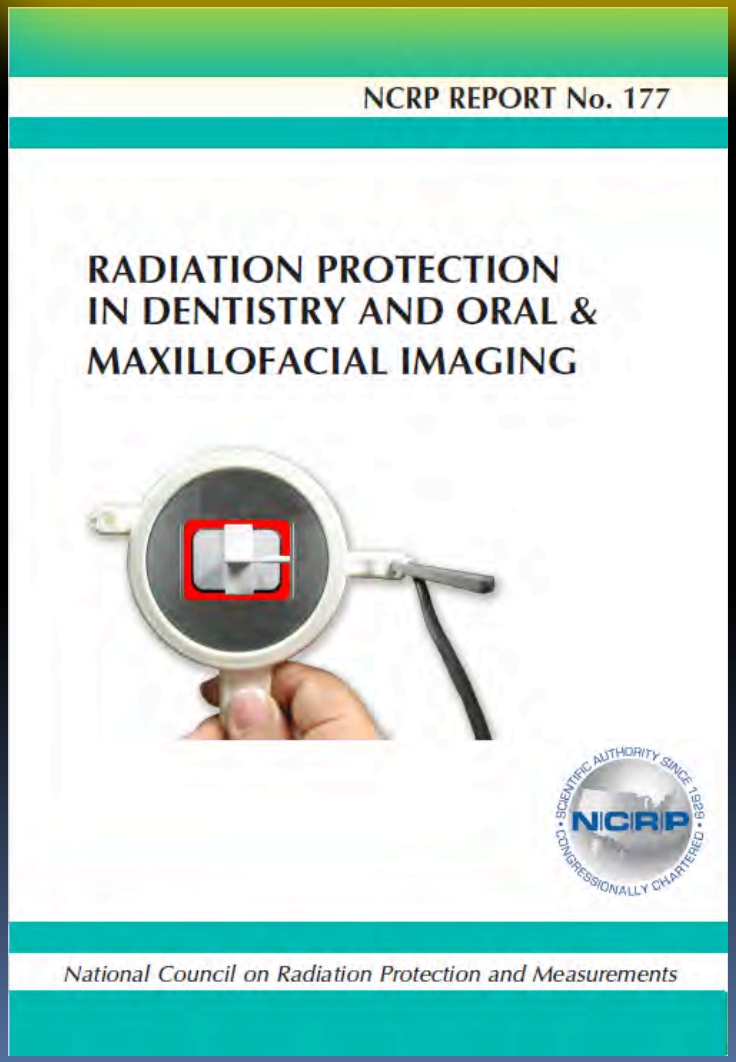
SAFETY: Conventional Imaging

New recommendations for conventional imaging from NCRP Report No. 177:

Hand Held Devices for Intraoral Imaging

Digital Imaging

SAFETY: Hand Held Intraoral Imaging



SAFETY: Hand Held Intraoral Imaging

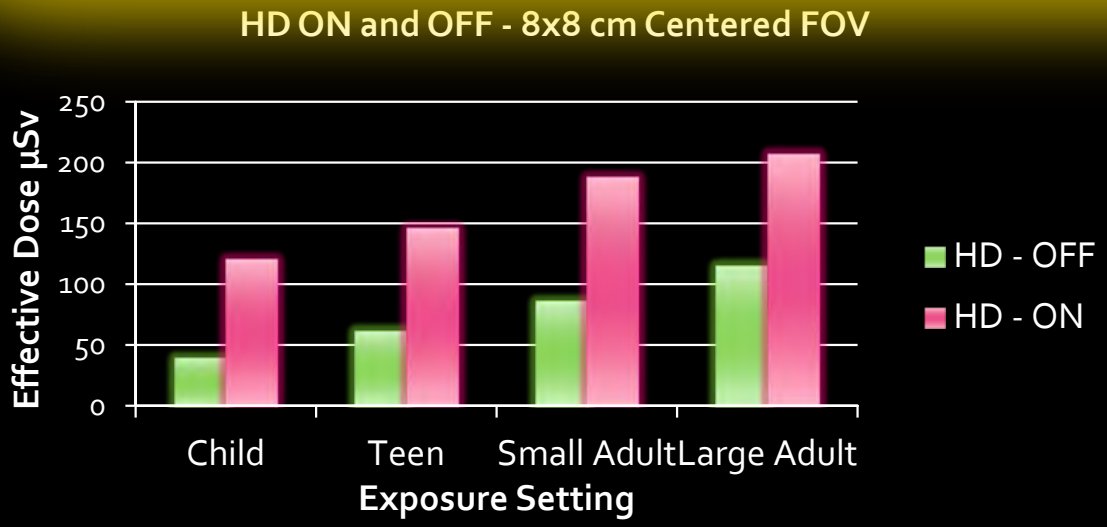
Recommendation 43:
Operators of handheld x-ray equipment ***shall*** have the physical ability to hold the system I place for multiple exposures.

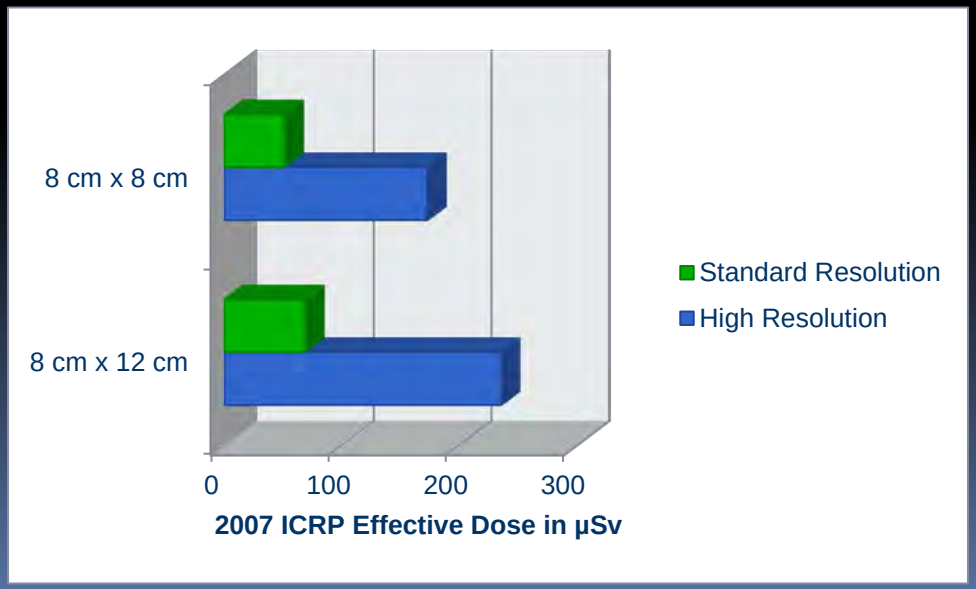
Recommendation 44:
Operators ***shall*** store handheld x-ray equipment so that it is not accessible to members of the public when not in use.

Recommendation 45:
The operator of a U.S. Food and Drug Administration (FDA)-cleared handheld x-ray unit ***shall not*** be required to wear a personal radiation protective garment.

Recommendation 46:
Rectangular collimation ***shall*** be used with hand-held devices whenever possible

SAFETY: CBCT Imaging

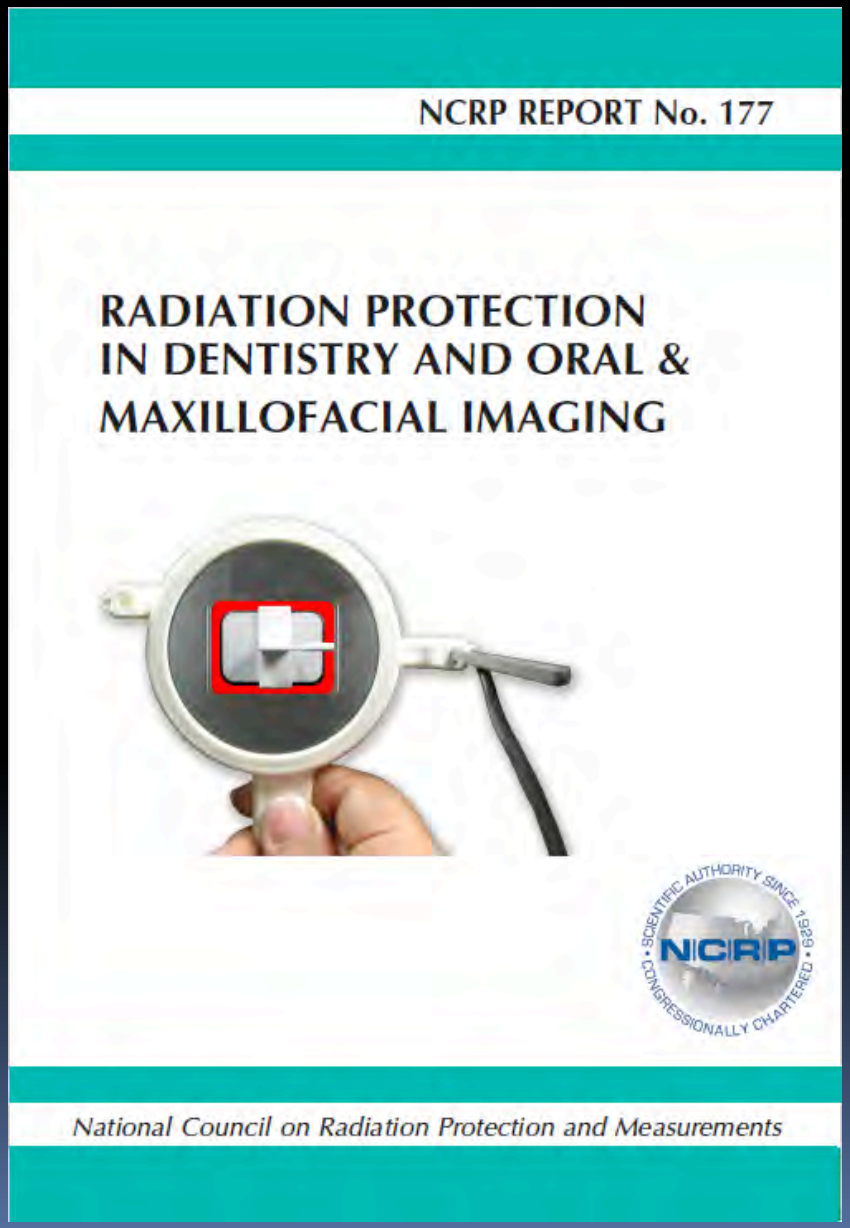




Increasing voxel size, reducing field of view and not using high resolution settings significantly reduces the dose. Many machines already have these options

Ludlow, DMFR, 2015
Orthophos XG 3D (above) and NewTom VGi

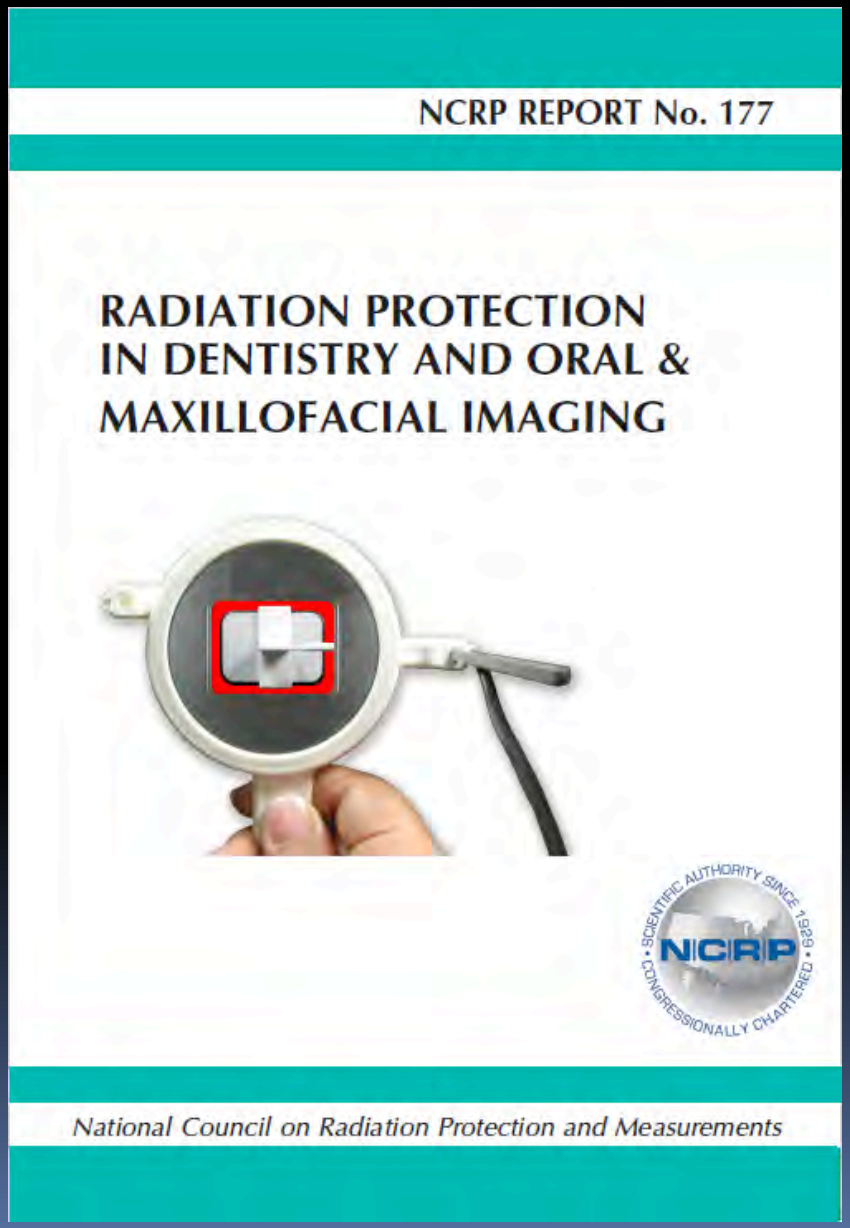
CBCT Safety in Dentistry and OMFR Imaging



Recommendation 52:
Cone-beam computed tomography (CBCT) ***should*** be used for cross sectional imaging as an alternative to conventional computed tomography (CT) when the radiation dose of CBCT is lower and the diagnostic yield is at least comparable.

Recommendation 53:
Cone-beam computed tomography (CBCT) examinations ***shall*** use the smallest field-of-view (FOV) and technique factors that provide the lowest dose commensurate with the clinical purpose.

CBCT Safety in Dentistry and OMFR Imaging



Recommendation 54:
Cone-beam computed tomography (CBCT) examinations ***shall not*** be obtained solely for the purpose of producing simulated bitewing, panoramic or cephalometric images.

Recommendation 55:
Cone-beam computed tomography (CBCT) examinations ***shall not*** be used as the primary or initial imaging modality when a lower dose alternative is adequate for the clinical purpose, and ***shall not*** be used for routine or serial orthodontic imaging.

Risk Considerations

Selection Criteria – Risk/Benefit

- Potential benefit of exam
- Numbers of exams
- Ages of patients

Doses and Acquisition Techniques

- Conventional DMF Examinations
- Conebeam CT Examinations

Risk Conclusions

- For conventional omf imaging, benefits should be high, and doses and risks to individuals are extremely low, possibly negligible to individuals, but numbers of such images annually is enormous (>1billion).

- For CBCT omf imaging, benefits should be very specific and high, and doses are generally modest but can equal or exceed those of MDCT H/N imaging, with attendant comparable risks.

- Risks are beset with uncertainties at such exposure levels; however, prudent practice, that considers both bystander effect and adaptive response, as well as interactions and sensitive subpopulation risks, demands practicing omf imaging using ALARA principles and LNT risk modeling.

Critical Recommendations for Safe and Effective Dentomaxillofacial Imaging (NCRP No. 177)

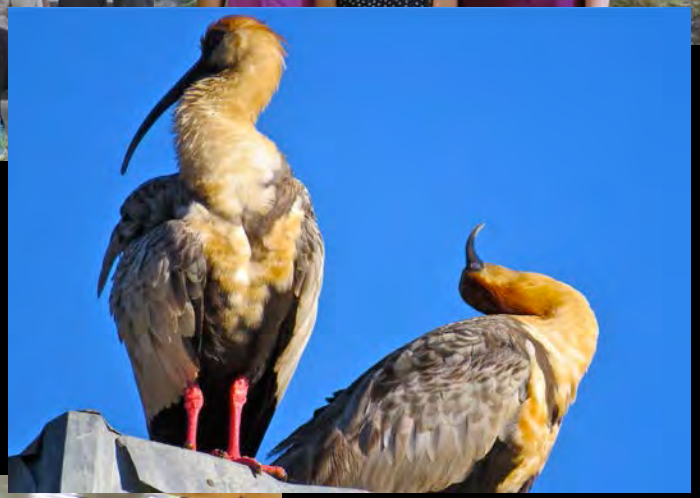
- Use rectangular collimation for all intraoral exposures unless there are anatomic constraints
- Always have a good reason for imaging (selection criteria)
- Use fastest receptor & eliminate ANSI D-speed film

IMAGE WISELY®
Radiation Safety in
Adult Medical Imaging

- Use thyroid shielding for all imaging imaging where feasible
- Use smallest FoV & lowest dose acquisition parameters for Conebeam CT, commensurate with the diagnostic task. Conebeam CT units must have lowered exposure parameters available for use with children
- Better education for dentists and medical physicists on safe use of diagnostic imaging in dentistry

IMAGE WISELY®
Radiation Safety in Adult Medical Imaging

Thank You



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Humanitarian Dentistry Service Trips

NCRP SC 4-10:
PROGRAM COMPONENTS FOR ERROR PREVENTION IN RADIATION THERAPY

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BANNER MD ANDERSON

SUZANNE EVANS, MD; ED LEIDHOLDT, PHD; LUKASZ MAZUR, PHD;

WAYNE NEWHAUSER, PHD; BRUCE THOMADSEN, PHD; SHIAO WOO, MD

NCRP SC 4-10: PROGRAM COMPONENTS FOR ERROR PREVENTION IN RADIATION THERAPY

- NCRP SC 4-10 is a writing project to generate an 8-page statement on indicators of quality and safety within a radiation oncology department that can be assessed by an external reviewer.
- Future milestones:
  - Funding
  - Multidisciplinary approach to the selection of safety indicators
  - Refinement of material to fit constraints of an NCRP statement

PURPOSE

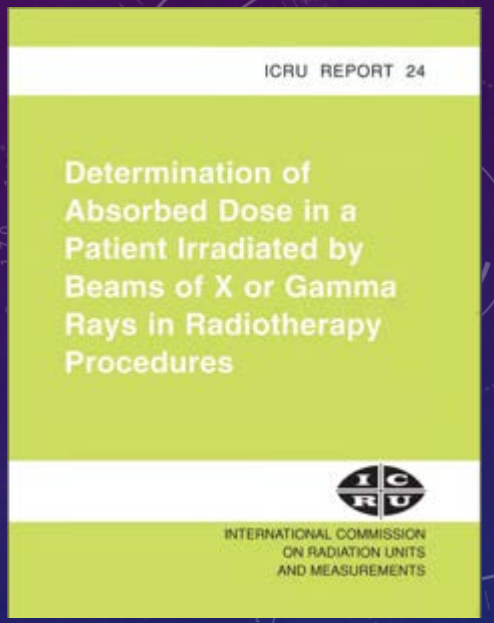
- To enumerate the necessary program components for error prevention in radiation therapy.
- The proposed Statement will provide guidance concerning the methodologies for error prevention, including prospective and retrospective techniques.
- The intent is to provide an integrated set of quality and safety recommendations that can be assessed in terms of their successful implementation.

THE CHALLENGE

- The challenge is to progress from a consensus-based set of requirements to a scientifically-based set of recommendations.
- The Task Group 100 report (published July 2016) "constitutes the AAPM's endorsement of a paradigm shift in the approach to quality management in radiation oncology."
  - The traditional quality management approach placed a strong emphasis on quality control of equipment.
  - While this … will continue to serve an important role, the risks from the clinical process may be a more significant factor in modern radiotherapy.
- The recommendations in Safety Is No Accident (published 2012, 2019) provide an updated framework for achieving the goal of improving the quality and safety of the care we deliver.

Halvorsen, 2016 https://doi.org/10.1002/acm2.12753

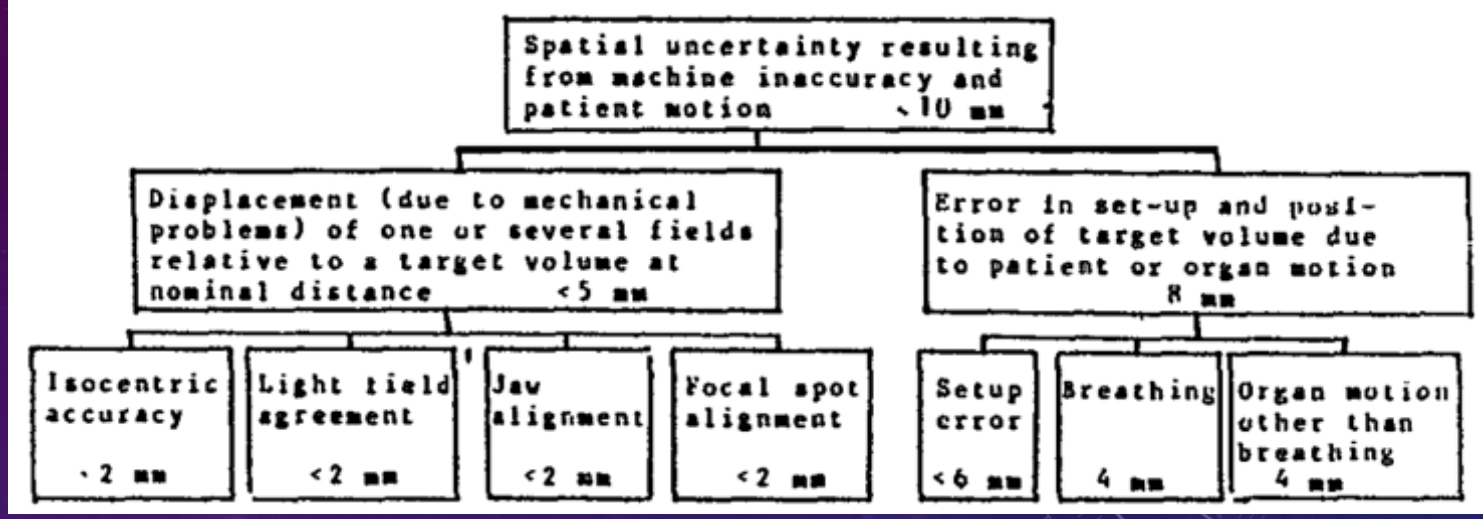
OLD SCHOOL: 1976 IRCU 24: DETERMINATION OF ABSORBED DOSE…

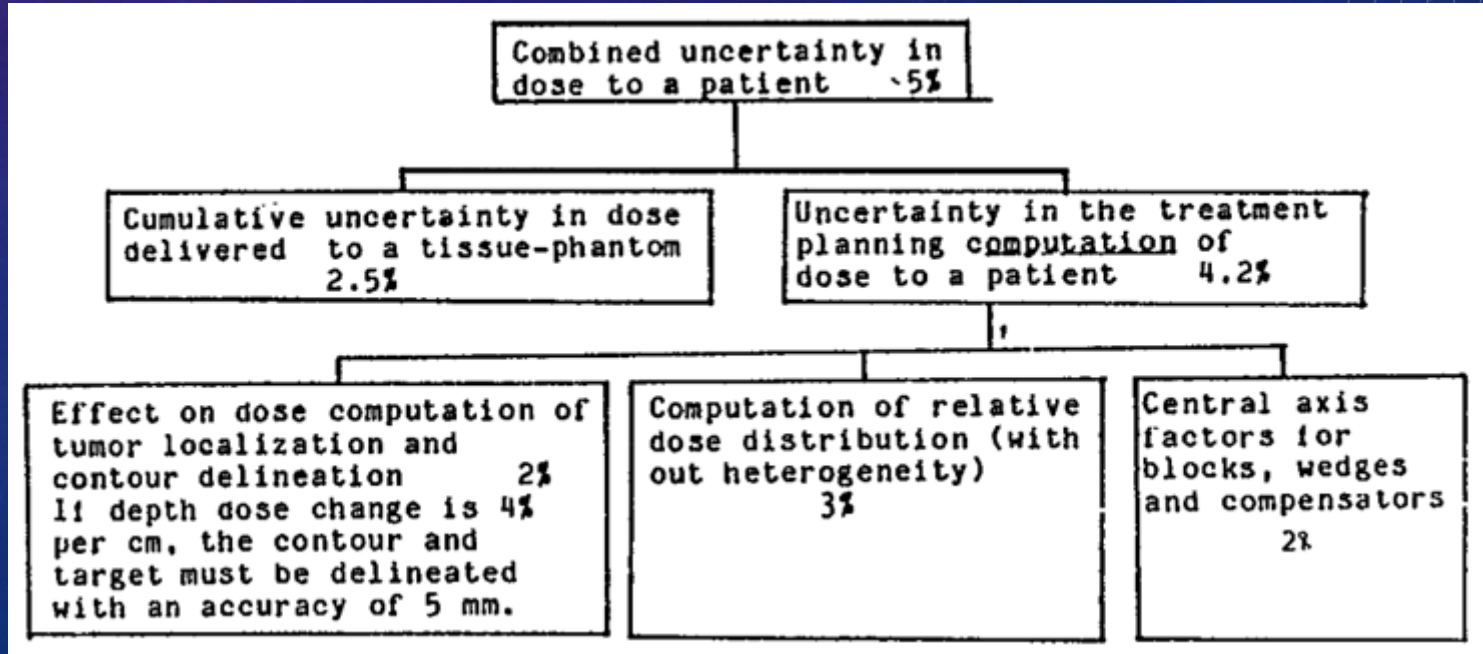


- Published 1976
- "The conclusion which emerges is that although it is too early to generalize, the available evidence for certain types of tumor points to the need for an accuracy of ±5% in the delivery of an absorbed dose to a target volume if the eradication of the primary tumor is sought. Some clinicians have requested even closer limits such as ±2%, but at the present time it is virtually impossible to achieve such a standard." p46

OLD SCHOOL: 1984 AAPM REPORT 24

- AAPM report 24 (1984) refers back to the 5% deviation threshold recommended in ICRU Report 24 and describes how the uncertainties in individual components of radiotherapy combine to that 5% accuracy.
- This report was updated in AAPM TG-40 (1994) and AAPM TG-142 (2008).





OLD SCHOOL: AAPM TG-40 PERSPECTIVE

AAPM TG-40 Table II was frequently referenced for regulatory purposes.

Follow-up report TG-142 (2008) stated:

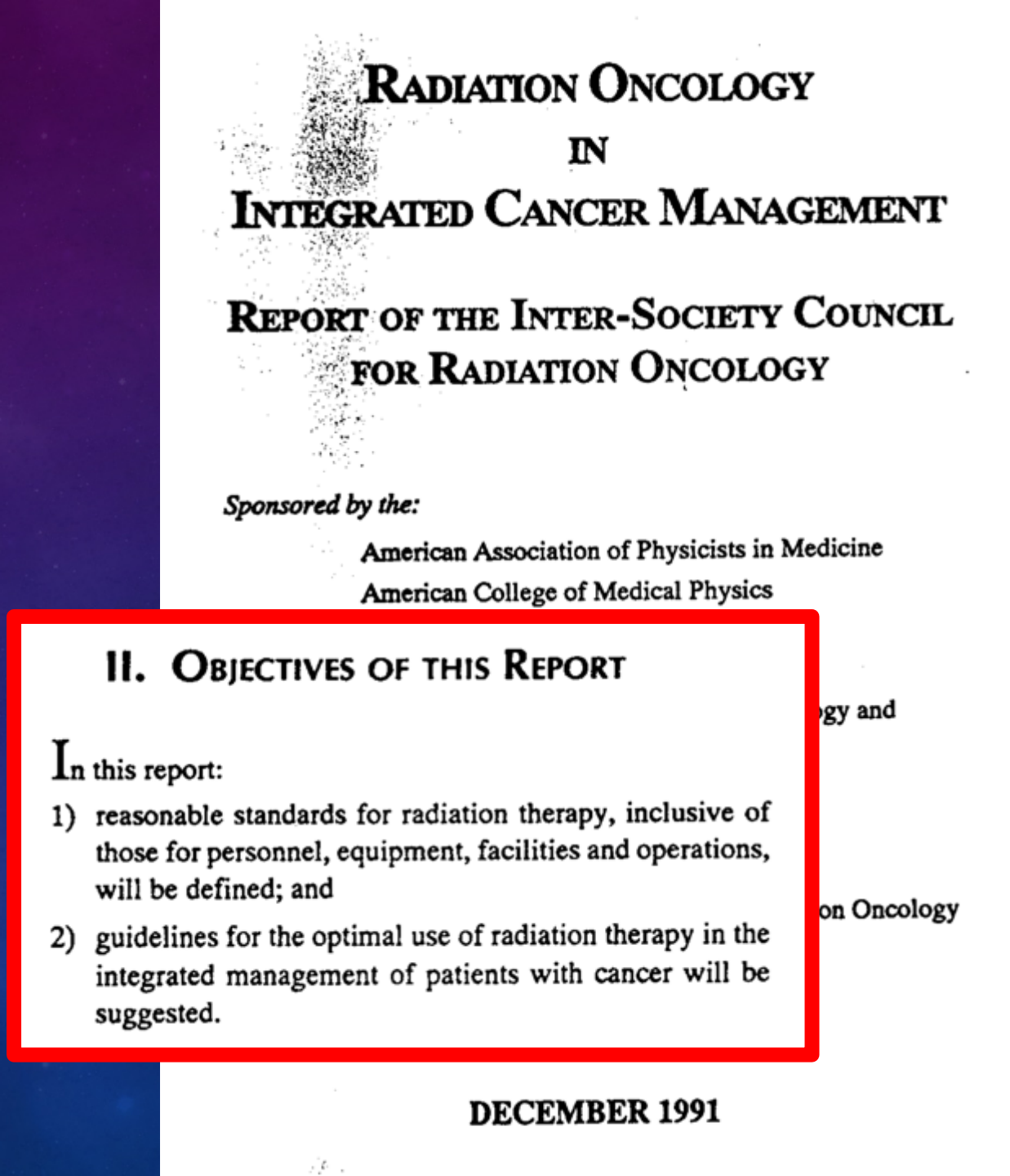
- We reiterate the recommendations of TG-40 that the QA program should be flexible enough to take into account quality, costs, equipment condition, available test equipment, and institutional needs.
- However, we do recommend using the tests and frequencies outlined in the tables that follow until methods such as TG-100 supersede this report.

TABLE II. QA of medical accelerators.

Frequency	Procedure	Tolerance[a]
Daily	Dosimetry	
	X-ray output constancy	3%
	Electron output constancy[b]	3%
	Mechanical	
	Localizing lasers	2 mm
	Distance indicator (ODI)	2 mm
	Safety	
	Door interlock	Functional
	Audiovisual monitor	Functional
Monthly	Dosimetry	
	x-ray output constancy[c]	2%
	Electron output constancy[c]	2%
	Backup monitor constancy	2%
	x-ray central axis dosimetry parameter (PDD, TAR) constancy	2%
	Electron central axis dosimetry parameter constancy (PDD)	2 mm @ therapeutic depth
	x-ray beam flatness constancy	2%
	Electron beam flatness constancy	3%
	x-ray and electron symmetry	3%
	Safety Interlocks	
	Emergency off switches	Functional
	Wedge, electron cone interlocks	Functional
	Mechanical Checks	
	Light/radiation field coincidence	2 mm or 1% on a side[d]
	Gantry/collimator angle indicators	1 deg
	Wedge position	2 mm (or 2% change in transmission factor)
	Tray position	2 mm
	Applicator position	2 mm
	Field size indicators	2 mm
	Cross-hair centering	2 mm diameter
	Treatment couch position indicators	2 mm/1 deg
	Latching of wedges, blocking tray	Functional
	Jaw symmetry[e]	2 mm
	Field light intensity	Functional
Annual	Dosimetry	
	x-ray/electron output calibration constancy	2%
	Field size dependence of x-ray output constancy	2%
	Output factor constancy for electron applicators	2%
	Central axis parameter constancy (PDD, TAR)	2%
	Off-axis factor constancy	2%
	Transmission factor constancy for all treatment accessories	2%
	Wedge transmission factor constancy[f]	2%
	Monitor chamber linearity	1%
	x-ray output constancy vs gantry angle	2%
	Electron output constancy vs gantry angle	2%
	Off-axis factor constancy vs gantry angle	2%
	Arc mode	Mfrs. specs.
	Safety Interlocks	
	Follow manufacturers test procedures	Functional
	Mechanical Checks	
	Collimator rotation isocenter	2 mm diameter
	Gantry rotation isocenter	2 mm diameter
	Couch rotation isocenter	2 mm diameter
	Coincidence of collimetry, gantry, couch axes with isocenter	2 mm diameter
	Coincidence of radiation and mechanical isocenter	2 mm diameter
	Table top sag	2 mm
	Vertical travel of table	2 mm

OLD SCHOOL: 1991 BLUEBOOK

- 1991 Bluebook #5: The prior bluebook "has become the backbone of quality assurance programs in radiation therapy."
- The 1991 Blue Book states its objective as generating reasonable standards.



RADIATION ONCOLOGY
IN
INTEGRATED CANCER MANAGEMENT

REPORT OF THE INTER-SOCIETY COUNCIL FOR RADIATION ONCOLOGY

Sponsored by the:

American Association of Physicists in Medicine
American College of Medical Physics

gy and

on Oncology

DECEMBER 1991

II. OBJECTIVES OF THIS REPORT

In this report:

1) reasonable standards for radiation therapy, inclusive of those for personnel, equipment, facilities and operations, will be defined; and
2) guidelines for the optimal use of radiation therapy in the integrated management of patients with cancer will be suggested.

RECENT MILESTONES IN RADIATION THERAPY Q&S

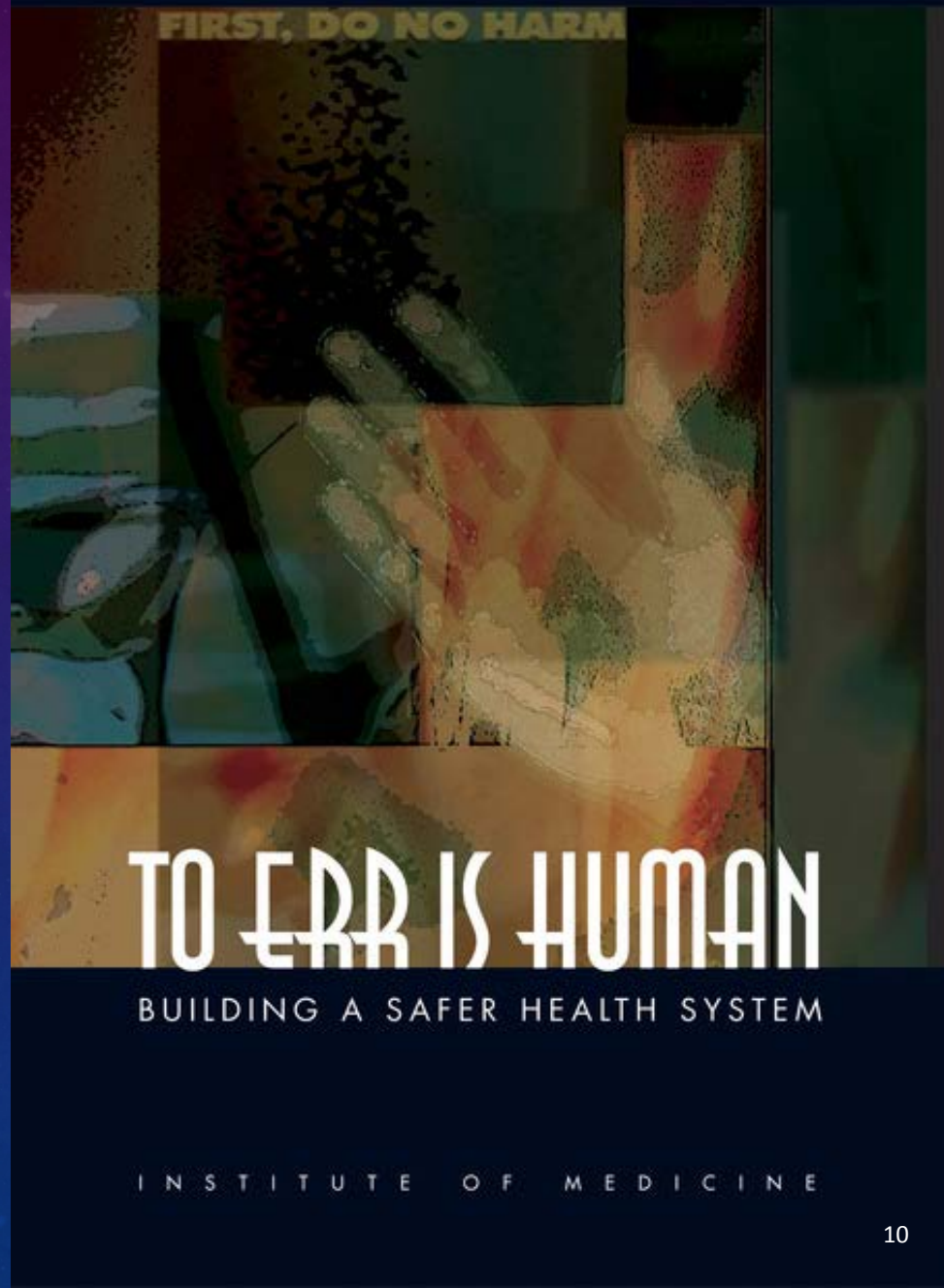
- 1999 IOM “To Err is Human”
- 2010 Walt Bogdanich NYT articles
- 2010 Safety Summit
- 2012 Safety is no Accident
- 2016 AAPM TG-100

IOM: TO ERR IS HUMAN - 1999

- “Preventable adverse events are a leading cause of death in the United States.
- When extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, the results of [the Colorado/Utah and Harvard] studies imply that at least 44,000 and perhaps as many as 98,000 Americans die in hospitals each year as a result of medical errors.”

Note that no mention is made of harm in radiation therapy:

- 0.2% misadministration rate, back-of-the-envelope calculation based on NYT information, Ford and Terezakis 2010



NEW YORK TIMES ARTICLES - 2010

- In a two-year period starting mid-2009, Walt Bogdanich published two dozen articles on radiation in medicine
- The most prominent of the articles was about a patient over-irradiated when the treatment beam was uncollimated during stereotactic radiosurgery.
- Other articles: state registration of medical physicists, danger of complex technology, prostate brachytherapy, CT, …

June 20, 2009

At V.A. Hospital, a Rogue Cancer Unit

A unit in Philadelphia operating with virtually no outside scrutiny botched 92 of 116 prostate cancer treatments over a span of more than six years.

By WALT BOGDANICH

Dec. 28, 2010

THE RADIATION BOOM

A Pinpoint Beam Strays Invisibly, Harming Instead of Healing

A fast-growing form of radiation therapy injures patients when its pinpoint beam is allowed to spread too far.

By WALT BOGDANICH and KRISTINA REBELO

Feb. 26, 2010

At Hearing on Radiation, Calls for Better Oversight

A dozen witnesses told a House subcommittee that more needed to be done to assure that radiation continues to help, not harm, patients.

By WALT BOGDANICH

Feb. 4, 2010

Medical Group Urges New Rules on Radiation

The American Society for Radiation Oncology issued a six-point plan that it said would improve safety and quality and reduce the chances of errors in medical radiation.

By WALT BOGDANICH

Jan. 26, 2010

THE RADIATION BOOM

They Check the Medical Equipment, but Who Is Checking Up on Them?

Loose regulation of medical physicists has allowed problems to enter a part of the process meant to make health care safer.

By WALT BOGDANICH and KRISTINA REBELO

Jan. 23, 2010

THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

While new technology saves the lives of countless cancer patients, errors can lead to unspeakable pain and death.

By WALT BOGDANICH

SAFETY IN RADIATION THERAPY: A CALL TO ACTION- 2010

Medical Physics Letter

Improving patient safety in radiation oncology[a)]

William R. Hendee[b)]
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(Received 17 October 2010; revised 6 November 2010; accepted for publication 10 November 2010; published 14 December 2010)

- As the complexity of treatment devices increases, control over the devices should be simplified.
- Radiation therapist workstations should be designed according to principles of human factors engineering.
- Return control to the point of care.
- Provide improved early warnings.
- Vendors should quickly and intelligibly address concerns reported by physicists and other members of the treatment team.
- User Groups
- The billing process should be simplified, and the radiation therapist should not be burdened with billing duties while overseeing patient treatments.
- Develop recommended staffing levels.
- Radiation therapy facilities should employ techniques such as failure mode effects analysis (FMEA) to identify potential sources of error and root-cause analysis (RCA) to identify and correct errors when they occur.
- Error reporting systems should be developed in radiation therapy.
- A covenant and commitment to safety should be expected of the treatment team.
- Any member of the treatment team can declare a Time Out.
- Checklists should be employed.
- Audits should be performed.
- Facility accreditation should be attained
- Standard operating procedures should be available and revised as necessary.
- Patient safety should be a competency
- Safety champions should be present
- Treatment team qualifications must be consistent and recognized nationally.
- The FDA review process should be improved.

ASTRO TARGET SAFELY INITIATIVE (5 COMPONENTS) 2010

I. Create an anonymous national database for error reporting (ROILS)

II. Enhance and accelerate radiation oncology practice accreditation (APEx)

III. Expand the educational training programs to include intensive focus on quality and safety (”Safety is No Accident”)

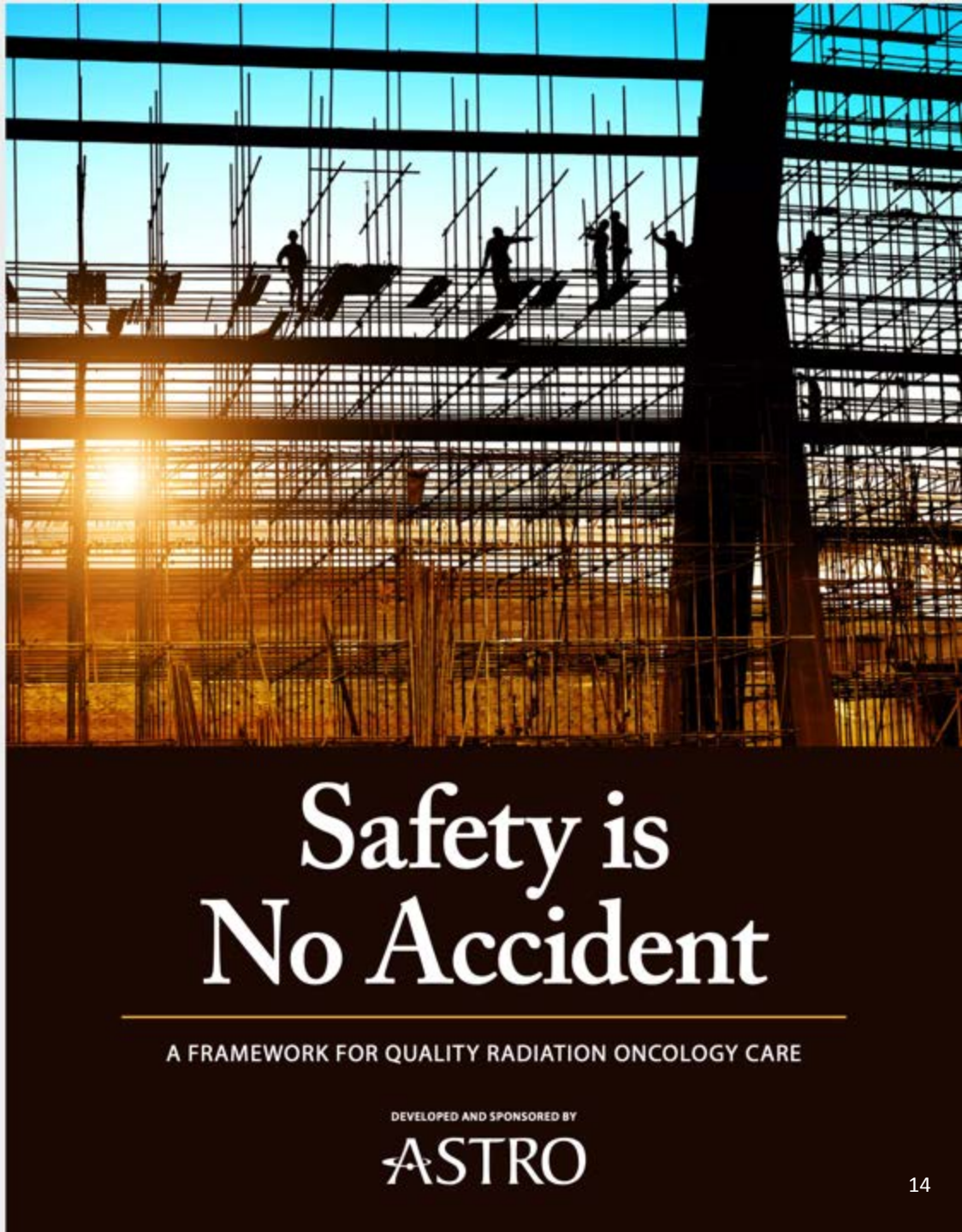
IV. Develop tools for cancer patients to use in discussions with their radiation oncologists; and

V. Accelerate the development of the IHE-RO program (IHE-RO)

SAFETY IS NO ACCIDENT - 2012

Chapters:

- The Process of Care in Radiation Oncology
- The Radiation Oncology Team
- Safety
- Quality Management and Assurance in Radiation Oncology



AAPM TG-100 - 2016

- "[This Report] is emphatically not intended for prescriptive or regulatory purposes."
- "The licensing branches will have to work with licensees in developing amendments that are consistent with the proposed risk-based quality management methods and the transition to these new methods."
- "Regulators are invited to familiarize themselves with TG-100 principles, learn how to evaluate radiation therapy quality management programs developed using risk-based approaches, and how to determine if the programs provide the expected measure of safety."

The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management

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(Received 13 May 2015; revised 13 March 2016; accepted for publication 14 March 2016; published 15 June 2016)

The increasing complexity of modern radiation therapy planning and delivery challenges traditional prescriptive quality management (QM) methods, such as many of those included in guidelines published by organizations such as the AAPM, ASTRO, ACR, ESTRO, and IAEA. These prescriptive guidelines have traditionally focused on monitoring all aspects of the functional performance of radiotherapy (RT) equipment by comparing parameters against tolerances set at strict but achievable values. Many errors that occur in radiation oncology are not due to failures in devices and software; rather they are failures in workflow and process. A systematic understanding of the likelihood and clinical impact of possible failures throughout a course of radiotherapy is needed to direct limit QM resources efficiently to produce maximum safety and quality of patient care. Task Group 100 of the AAPM has taken a broad view of these issues and has developed a framework for designing QM activities, based on estimates of the probability of identified failures and their clinical outcome through the RT planning and delivery process. The Task Group has chosen a specific radiotherapy process required for "intensity modulated radiation therapy (IMRT)" as a case study. The goal of this work is to apply modern risk-based analysis techniques to this complex RT process in order to demonstrate to the RT community that such techniques may help identify more effective and efficient ways to enhance the safety and quality of our treatment processes. The task group generated by consensus an example quality management program strategy for the IMRT process performed at the institution of one of the authors. This report describes the methodology and nomenclature developed, presents the process maps, FMEAs, fault trees, and QM programs developed, and makes suggestions on how this information could be used in the clinic. The development and implementation

ACCREDITATION PROGRAMS

Current Radiation Oncology Accreditation Programs

- American College of Radiology
- American College of Radiation Oncology(ACRO)
- ASTRO Accreditation Program for Excellence (APEx®)

Accreditation programs have several common elements

- Staffing levels
- Staffing qualifications and certification
- Physician practice (consultation, follow up, …)
- Quality Improvement (review mechanisms)

ACR PRACTICE PARAMETERS, TECHNICAL STANDARDS

- Radiation Oncology
- Radiation Oncology Physics for External Beam Therapy
- 3-D External Beam Radiation Planning and Conformal Therapy
- Intensity Modulated Radiation Therapy (IMRT)
- Image-Guided Radiation Therapy (IGRT)
- Monitoring of Image-Guided Radiation Therapy (IGRT)
- Stereotactic Body Radiation Therapy
- Medical Physics Performance Monitoring of Stereotactic Body Radiation Therapy (SBRT)
- Brain Stereotactic Radiosurgery
- Total Body Irradiation
- Performance of Proton Beam Radiation Therapy
- Electronically-generated, Low-energy radiation Sources (ELS)
- Low-Dose-Rate Brachytherapy
- Low-Dose-Rate Brachytherapy Physics
- High-Dose-Rate Brachytherapy Physics
- Transperineal Permanent Brachytherapy of Prostate Cancer
- Therapy with Radium-223
- Benign and Malignant Thyroid Disease with I-131 Sodium Iodide
- Selective Internal Radiation Therapy (SIRT) or Radioembolization with Microsphere Device Brachytherapy Device (RMBD) for Treatment of Liver Malignancies
- Unsealed Radiopharmaceutical Sources
- Radionuclide-Based High-Dose-Rate Brachytherapy Revised
- Radioembolization with Microsphere Brachytherapy Device (RMBD) for Treatment of Liver Malignancies

ACR ACCREDITATION PROGRAM (1987)

Two representative standards:

Practice Parameter for Radiation Oncology

- Process of Radiation Therapy
- Qualifications and Responsibilities of Personnel
- Equipment Requirements
- Quality Assurance
- Continuing Education
- Quality Improvement

Technical Standard for External Beam Physics

- Qualifications of Personnel
- Responsibilities of Personnel
- Equipment
- Quality Management Program
- Clinical Practice
- New Procedures
- Documentation
- Peer Review

ACRO ACCREDITATION (SINCE 1995)

Section II-D of the Manual for ACRO

Accreditation covers practice review:

- Practice Demographics
- Process of Radiation Therapy
- Clinical Performance Measures
- Policies and Procedures
- Physical Plant
- Radiation Therapy Personnel
- Radiation Therapy Equipment
- Radiation Therapy Physics
- Continuous Quality Improvement
- Safety Program
- Education Program

Section II-D-9 covers Continuous Quality Assurance:

- Chart review:
- General practice review
- New procedure review
- Incident report review
- Morbidity and mortality review
- Outcome studies review
- Radiation oncologist peer review
- Record maintenance and data collection

APEX ACCREDITATION PROGRAM 2015

- **Pillar One: The Process of Care (SINA Ch. 1)**
  - Standard 1: Patient Evaluation, Care Coordination and Follow-up
  - Standard 2: Treatment Planning
  - Standard 3: Patient-specific Safety Interventions and Safe Practices in Treatment Preparation and Delivery
- **Pillar Two: The Radiation Oncology Team (SINA Ch. 2)**
  - Standard 4: Staff Roles and Responsibilities
  - Standard 5: Qualifications and Ongoing Training of Staff
  - Standard 6: Safe Staffing Plan
- **Pillar Three: Safety (SINA Ch. 3)**
  - Standard 7: Culture of Safety
  - Standard 8: Radiation Safety
  - Standard 9: Emergency Preparation and Planning
- **Pillar Four: Quality Management (SINA Ch. 4)**
  - Standard 10: Facility and Equipment
  - Standard 11: Information Management and Integration of Systems
  - Standard 12: Quality Management of Treatment Procedures and Modalities
  - Standard 13: Peer Review of Clinical Processes
- **Pillar Five: Patient-centered Care (SINA Ch. 4.2 partially)**
  - Standard 14: Patient Consent
  - Standard 15: Patient Education and Health Management
  - Standard 16: Performance Measurement and Outcomes Reporting

STATE REGULATIONS

Example: 10 NY-CCT 16.24 - Quality assurance programs for the use of radiation for therapy in humans

- Adopt and maintain a quality assurance manual
- Adopt and maintain a radiation treatment manual
- All equipment used in planning and administering radiation therapy is calibrated and maintained
- Audits shall be conducted at intervals not to exceed 12 months by an authorized medical physicist
- Accreditation in radiation oncology

Example: CRCPD Suggested State Regulations, Part X (2009) Item 7.t.iii:

- Full calibration shall include measurement of all applicable parameters required by Table II of "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy: AAPM Report No. 46," prepared by Committee Task Group 40 and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47" prepared by Radiation Therapy Task Group 45. Although it shall not be necessary to complete all elements of a full calibration at the same time, all applicable parameters (for all energies) shall be completed at intervals not exceeding twelve (12) calendar months, unless a more frequent interval is required in Table II.

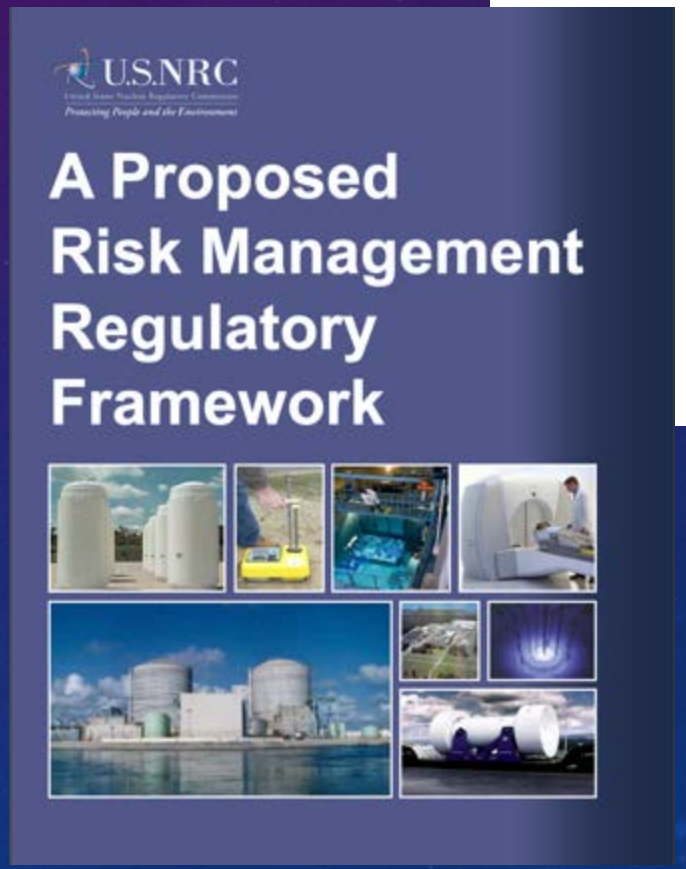
US NUCLEAR REGULATORY COMMISSION

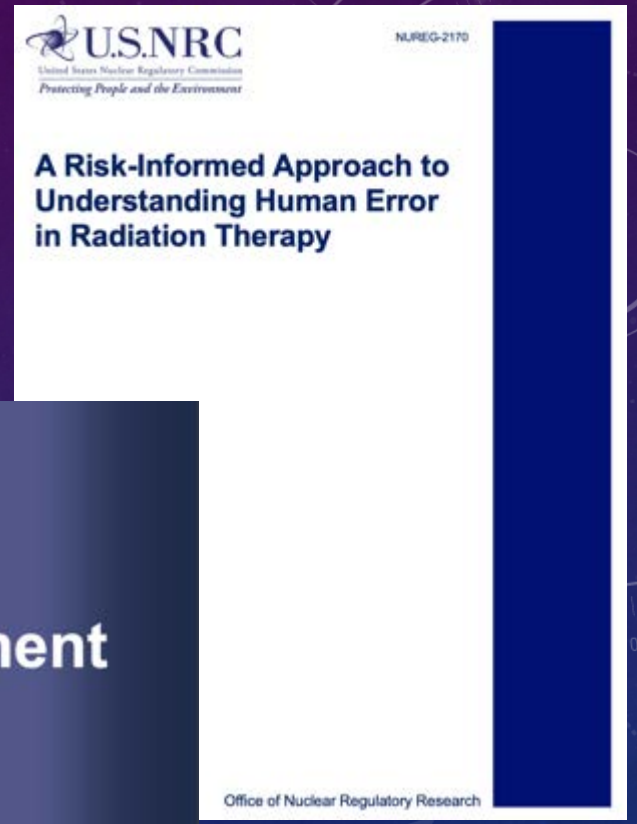
NUREG-2150: A Proposed Risk Management Regulatory Framework (2012)

NRC NUREG-2170: A Risk-Informed Approach to Understanding Human Error in Radiation Therapy (2017)

Four related elements for improving safety:

- Improved understanding of human error in radiation therapy;
- Improved ability to anticipate errors;
- Effective strategies for supporting humans in managing complexity; and
- Methods to evaluate and monitor the effectiveness of corrective actions.





PROBLEMS WITH TRADITIONAL APPROACHES TO QUALITY MANAGEMENT IN RADIATION THERAPY

- Need to address the treatment processes comprehensively
- Excessive demand on physics resources
- Difficulty in developing a QM protocol that covers all permutations in clinical practice
- Delays in establishing accepted QM protocols for emerging technologies and associated processes

From Huq et al, AAPM TG-100 (2016)

MODERN APPLICATIONS

- **Prospective techniques:** Failure Modes and Effects Analysis, Fault Tree Analysis, Plan-Do-Study-Act
- **Human factors:** Crew Resource management, sterile cockpit, safety culture, just culture,
- **Safety Barriers:** Checklists, Redundancies, Rounds
- **Retrospective techniques:** Root Cause Analysis and Incident Learning

DRAFT CONTENT OF THE STATEMENT

- Short document: 8 – 10 pages
- Seven Developers: Four from NCRP Council, Three External
- Solicitations to be made from professional organizations and agencies for liaisons
- Thirteen draft paragraphs
- Five draft tables

DRAFT INDICATORS FOR PROGRAM DEVELOPMENT

- **Quality improvement meetings**
- **Coupling of delivery, imaging, and motion management**
- **Presence of an incident learning system**
- **New process design: Process mapping, FMEA, FTA**
- **Documentation of root-cause analysis (RCA), corrective actions, and monitoring**

DRAFT INDICATORS FOR SAFETY BARRIERS

- **Verbal time outs**
- **Dose calculation check programs**
- **Per-patient pre-treatment dosimetric verification**
- **Treatment plan second check**
- **Weekly chart check**
- **Chart rounds**
- **Time for physics checks and quality assurance**
- **On-treatment imaging verification**
- **Use of tolerance tables**
- **In vivo dosimetry**
- **Checklists**

DRAFT STAFFING, SUPPORT, AND ENVIRONMENT

- **Two therapists per machine for all procedures.**
- **For SBRT procedures, a radiation oncologist present for setup verification.**
- **For SBRT procedures, a medical physicist present throughout.**
- **Does each staff member have assigned tasks during patient treatment?**
- **Are non-critical calls prevented from reaching the control room?**
- **Is the frequency of interruption from staff stopping by kept minimal?**
- **Is the environment free of distractions such as web browsing during treatment?**
- **Safety Culture**
- **Training records**
- **Physician peer review**
- **Physicist peer review**
- **Competency assessment records**

DRAFT EXTERNAL CALIBRATION AND VALIDATION

- **Accredited Dosimetry Calibration Laboratory (ADCL)**
- **IROC OSLDs**
- **IROC onsite visits**
- **Radiation therapy accreditation review**
- **Other accreditation reviews**

DRAFT INDICATORS FOR EQUIPMENT RECORDS

- **Shielding calculation**
- **Shielding survey**
- **Acceptance testing**
- **Commissioning demonstrating customization for clinical use**
- **Ongoing quality assurance records**

THANK YOU

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Radiation Protection in Medicine Perspective of CRCPD / State Radiation Control Programs

Lisa Bruedigan

Health Physics Society Midyear Meeting

January 28, 2020

A Partnership Dedicated to Radiation Protection

Disclaimer

Note: Any Products or manufacturers mentioned or shown in photographs or text of this presentation, does not represent and endorsement by the author, NCRP, or CRCPD.

Conference of Radiation Control Program Directors, Inc. (CRCPD)

Established in 1968, the CRCPD is a 501(c)(3) nonprofit organization, incorporated in the State of Kentucky, with its headquarters office located in Frankfort, Kentucky.

A Partnership Dedicated to Radiation Protection

Purpose

- To provide a common forum for the exchange of information among state and local radiation control programs.
- To provide a mechanism for states to communicate with the federal government on radiation protection issues.

Mission

- To promote consistency in addressing and resolving radiation protection issues.
- To encourage high standards of quality in radiation protection programs.
- To provide leadership in radiation safety and education.

Goal

To keep radiation exposure of the patient, worker, and general public to the lowest practical level, while not restricting the beneficial use of this valuable energy source.

CRCPD Advisory Committee

- American Association of Physicists in Medicine (AAPM)
- American College of Radiology (ACR)
- American Society for Radiation Oncology (ASTRO)

CRCPD Liaisons

Related to Medical

- Health Physics Society & American Academy of Health Physics (Earl Fordham – WA)
- National Council on Radiation Protection
- American Association of Physicists in Medicine
- American College of Radiology
- Society of Nuclear Medicine & Molecular Imaging
- American Society of Radiation Oncology
- American Society of Radiologic Technologists/American Registry of Radiologic Technologists
- Joint Commission

Types of Membership

Director Members

– State & local radiation control program directors

Associate Members

– Staff of radiation control programs in the U.S.

Affiliate Members

– Anyone having an interest in CRCPD and radiation protection

Types of Membership

International Members

– Staff of radiation programs outside U. S.

Emeritus Members

– Former members as approved by Board of Directors

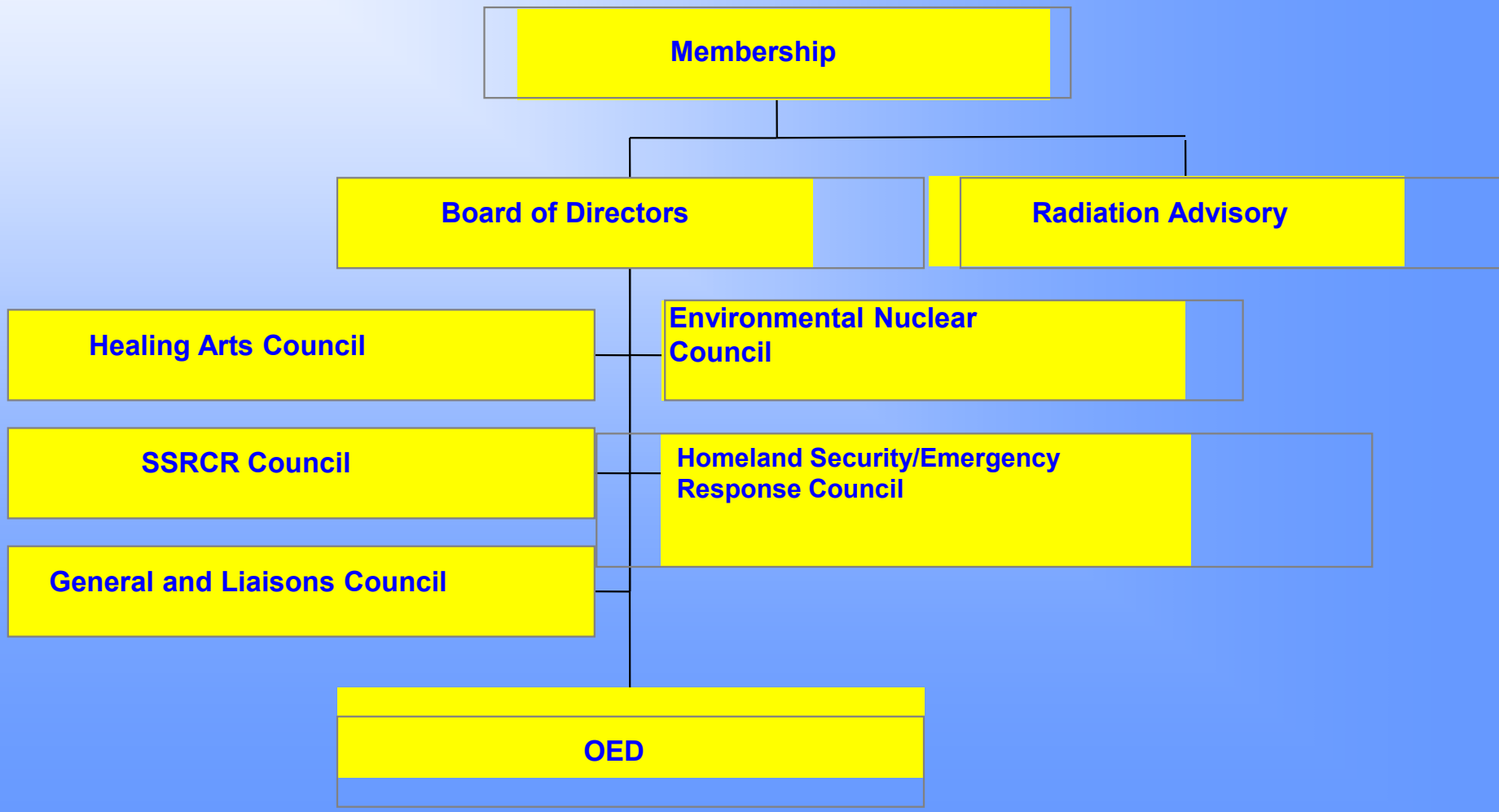
Honorary Members

– Special contribution in radiation protection

CRCPD Members

- Radiation and health physicists
- Regulators
- Radiation control program managers
- Radiation safety officers
- Radiologic technologists
- Radiologists
- Radiation industry professionals
- Public health professionals

CRCPD Organizational Chart



A Partnership Dedicated to Radiation Protection

Responsibilities

Membership

- constitution, bylaws, positions, voting

Board

- policy, budget, committee structure, and direction to Executive Director

Advisory Committee

- advice to Board of Directors

Responsibilities

Office of Executive Director

- Day-to-day operations, assistance to board

Healing Arts Council

- Technical radiation protection issues in the healing arts

Environmental Nuclear Council

- Technical issues relating to the protection of the environment

Responsibilities

SSRCR Council

– Develop and publish *Suggested State Regulations for Control of Radiation*

General and Liaisons Council

– General issues in radiation protection

Homeland Security/Emergency Response Council

– WMD issues and emergency response planning

CRCPD Federal Partners

- Food and Drug Administration (FDA)
- Nuclear Regulatory Commission (NRC)
- Environmental Protection Agency (EPA)
- Department of Energy (DOE)
- Center of Disease Control and Prevention (CDC)
- Federal Emergency Management Agency (FEMA)
- Department of Transportation (DOT)
- Department of Homeland Security (DHS)
- National Institute of Occupational Safety and Health (NIOSH)
- National Institute of Standards and Technology (NIST)
- Department of State
- National Academy of Sciences

Special Services of CRCPD

- Accreditation of regional calibration laboratories
- Recognition of states that license NARM
- Administer a U.S. DOT Exemption for moving contaminated scrap and trash
- Comprehensive program review for state agencies.

Special Services of CRCPD

- Coordinates and brokers the Texas Industrial Radiography Examination to states
- Coordinates and conducts an annual National Conference on Radiation Control
- Coordinates and conducts an annual National Radon Conference

Special Services of CRCPD

- Assist states with orphan radioactive source disposition by direct broker funding for characterizing, packaging, and disposal or transfer to a licensed recipient
- Assist in disposition of unused/disused sealed sources that do not meet other disposal options

Special Services of CRCPD

Provide a website to keep interested parties informed on CRCPD activities, including two limited access sections, “Regulatory Forum” for Director Members and Associate Members to discuss regulatory matters, and “Members Only” for Members to have access to financial matters of the CRCPD.

Numerous CRCPD documents available: www.crcpd.org

CRCPD Councils

- Healing Arts Council
- Suggested State Regulations for Radiation Control (SSRCR) Council
- Environmental Nuclear Council
- Homeland Security / Emergency Response
- General Council

CRCPD & Radiation Protection in Medicine

Healing Arts Council

- Recommend programs and activities for state implementation to reduce x-ray exposure
- Provide guidance for consumers
- Provide patient education in x-rays.

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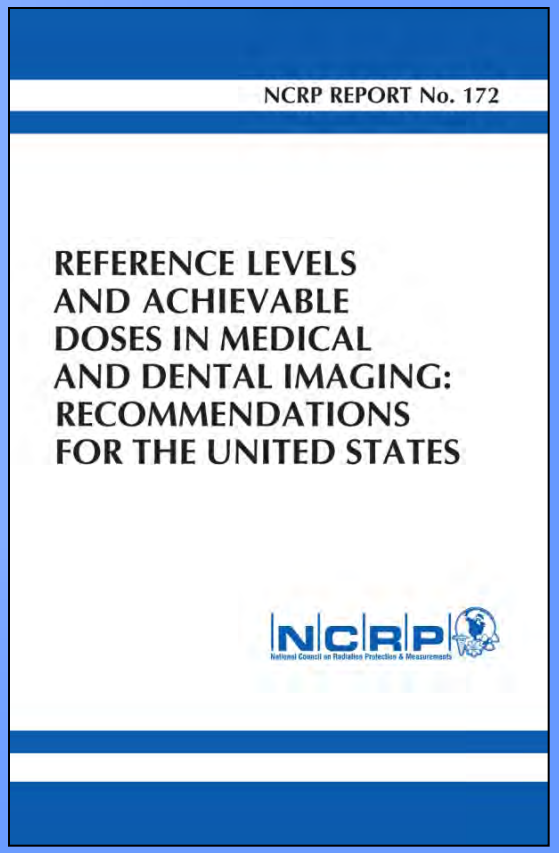
CRCPD
Healing Arts Council

Currently 12 Working Groups

- Nationwide Evaluation of X-ray Trends (NEXT)(H-4)
  - Diagnostic Reference Levels (DRLs)
- Diagnostic X-ray / X-ray Topics and Trends (H-7)
- Medical Events (H-38)
- Cone Beam Computed Tomography (CBCT) (H-44)
- Radiation Therapy (H-48)
- Digital Imaging (H-55)
- Hand Held Radiographic Devices (H-56)

H-4 Nationwide Evaluation of X-ray Trends (NEXT)

- Develops guidance for states in the collection of data for evaluating the trends in X-ray exposure throughout the U.S.
- Assist in the design and implementation of training courses for state NEXT inspectors.



H-55 Quality Assurance in Diagnostic X-ray

Determine the elements of diagnostic X-ray technique that impact image quality and patient exposure to aid facilities in maintaining minimal patient exposure and consistent high quality diagnostic images.

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H-11 Mammography

- Provides clearinghouse for issues related to mammography
- Provides comments on activities under MQSA
- Solicit and synthesize states' comments on MQSA Inspection Program
- Provides states' recommendations in the development of a national inspection program
- Training for state MQSA Inspectors

Suggested State Regulations Working Groups

Suggested State Regulations for Control of Radiation Council (SSR's)

Develop suggested state regulations for the control of radiation in the areas of radiation producing machines registration, use and inspection, and radioactive materials licensing, use and inspection.

Radiation Protection in Medicine & SSR's

- National Issues
- New Technology
- Crisis
- Special Interest Groups
- Moral Consciousness
- Federal Mandates

Radiation Protection in Medicine & SSR's

SR-F Medical Diagnostic & Interventional X-ray

- 2015 Revision removed the suggested requirement for gonadal shielding.
  - a.vi. A sufficient number of protective apparel (e.g., aprons, gloves, collars) and shields shall be available to provide the necessary radiation protection for all patients and personnel who are involved with x-ray operations.
  - a.vii. All protective apparel and auxiliary shields shall be evaluated annually for integrity and clearly labeled with their lead equivalence.

Radiation Protection in Medicine & SSR's

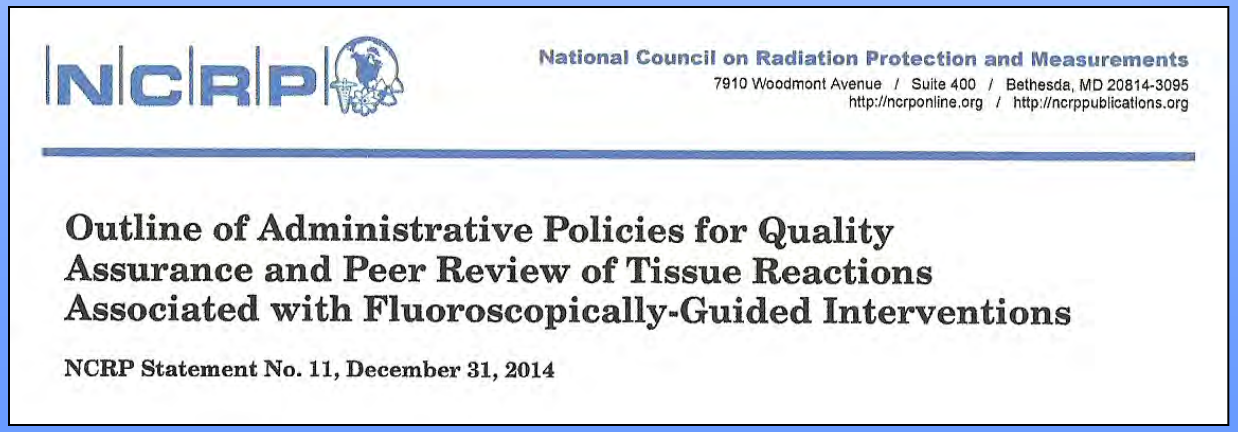
Gonadal shielding

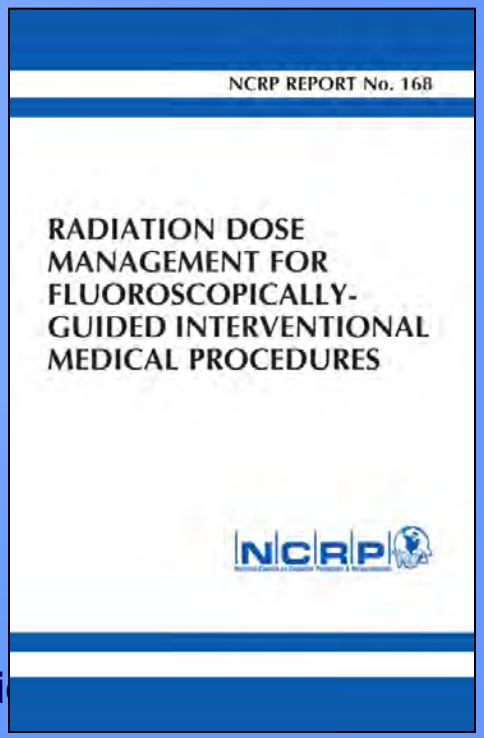
- Pennsylvania 25 Pa. Code 221.11(f)
  - *During diagnostic procedures in which the gonads are in the useful beam, gonad shielding of at least 0.5 mm lead equivalent shall be used for patients except for cases in which this would interfere with the diagnostic procedure.*
- Texas TAC §289.227(i)(13) – updated 5/2013
  - *Gonadal shielding shall be used on patients when the gonads are in or within 5 cm of the useful beam. This requirement does not apply if the shielding will interfere with the diagnostic procedure. Gonadal shielding shall be of at least 0.5 mm lead equivalent material.*
- Louisiana LAC 33:XV603.A.6
  - *Gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.*

Radiation Protection in Medicine & SSR's

SR-F Medical Diagnostic & Interventional X-ray

- 2015 Revision included recommendations from NCRP 168 & NCRP Statement 11





Radiation Protection in Medicine & SSR's

SR-F Medical Diagnostic & Interventional X-ray

- 2015 Revision for Dental Cone Beam Computed Tomography (CBCT)
  - Evaluation by a Qualified Expert
  - Quality Control

Radiation Protection in Medicine & SSR's

SR-F Medical Diagnostic & Interventional X-ray

- 2015 Revision & X-ray Units Specifically designed to be handheld

  Intraoral Hand Held

  - Shall be equipped with a backscatter shield of not less than 0.25 mm lead equivalent and 15.2 cm diameter (6 inches).
  - When operating a hand-held intraoral dental unit, operators shall wear a 0.25 mm lead equivalent apron, unless authorized by the Agency or a certified health or qualified medical physicist.

Radiation Protection in Medicine & SSR's & H-38

H-38 (Medical Events) & SR-X (Radiation Therapy)

- SR-X was last revised 2009
- Therapeutic radiation machine:
  - Involves the wrong patient, wrong treatment modality, or wrong treatment site; or
  - For which, the weekly administered dose differs from the weekly prescribed dose by more than thirty percent (30%); or
  - For which, the total administered dose differs from the total prescribed dose by more than twenty percent (20%) of the total prescribed dose; or
  - For which, the dose differs by fifty percent (50%) or greater for any single fraction of a multi-fraction treatment; or
  - Any equipment failure, personnel error, accident, mishap or other unusual occurrence that causes or is likely to cause significant physical harm to the patient

Radiation Protection in Medicine & SSR's & H-38

H-38 (Medical Events) & SR-F Medical Diagnostic& Interventional X-ray:

- Results in an unintended dose to the skin greater than 2 Gy (200 rads) to the same area for a procedure or series; or
- Results in an unintended dose greater than 5 times the facility's established protocol for a procedure and exceeds 0.5 Gy (50 rads) to an organ or 0.05 Gy (5 rads) total effective dose; or
- Involves the wrong patient or wrong site for the entire diagnostic exam (procedure/service) and exceeds 0.5 Gy (50 rads) to an organ or 0.05 Gy (5 rads) total effective dose* for the procedure ; or
- Involves any equipment failure, personnel error, accident, mishap or other unusual occurrence with the administration of ionizing radiation that exceeds 0.05 Gy (5 rads) total effective dose.

Radiation Protection in Medicine
A Regulator's Perspective

TRAINING!

- Usually largest need
- Limited opportunities
- Limited funds
- Limited staff

Radiation Protection in Medicine
A Regulator's Perspective

Compliance vs. Enforcement

- Are they the same thing?
- Can you have one without the other?

Radiation Protection in Medicine
A Regulator's Perspective

- What really changed during the transition from film/screen to filmless technology?

SCATR Program

An effort to reduce the amount of unused & unwanted radioactive material stored by our licensees.

CRCPD in Cooperation

- the states
- Los Alamos National Lab
- DOE's National Nuclear Security Administration
- Energy Solutions Class A sources variance

A Partnership Dedicated to Radiation Protection

A Partnership Dedicated to Radiation Protection

www.crcpd.org

lisa.bruedigan@dshs.texas.gov

HEALTH PHYSICS SOCIETY
NCRP SC 4-7

Evaluating and Communicating Radiation Risks for Studies Involving Human Subjects:

Guidance for Researchers and Institutional Review Boards

Supported by CDC, AAPM, ACR & SNMMI
and a generous grant from the ABR Foundation

PURPOSE OF REPORT

- To provide guidance to researchers in developing and preparing research protocols that involve exposure of human subjects to ionizing radiation

- To provide guidance to IRBs and other groups on the process of reviewing protocols that involve radiation exposure to human subjects

Knowledge Gaps

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- McBride et al. 2009. “An assessment of ordering physician’s knowledge and attitudes regarding risk from CT associated radiation exposure,” AJR 192(5), A106-A113.

SC 4-7 COMMITTEE MEMBERS

- Julie Timins, Chair
- Jerrold Bushberg
- Linda Kroger
- Donald Miller
- J. Anthony Seibert

Michael Grissom, Staff Consultant

Patricia Fleming
Edwin Leidholdt, Jr.
Robert Reiman
Steven Sutlief

SCOPE OF REPORT

- History; Basics of Radiobiology, Radiation Protection and Dose
- Regulatory requirements for institutional supervision of research
- Identification of studies utilizing ionizing radiation
- Distinguishing between radiation for SOC and for research study
- Assessment of proper utilization of radiation in research
- Estimation of: Radiation Dose; Radiation Risk
- Optimization of Radiation Dose
- Ethical considerations and Informed Consent requirements
- Examples of language for Informed Consent

International Ethical Foundations of Human Research

- International Guidelines for Ethical Review of Epidemiological Studies (CIOMS, 1991)
- Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products (WHO, 1995)
- International Conference on Harmonization Guidelines for Good Clinical Practice (ICH, 1996)
- Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (COE, 1997)
- Medical Research Council Good Clinical Practice in Clinical Trials (MRC, 1998)
- Operational Guidelines for Ethics Committees that Review Biomedical Research (WHO, 2000)
- International Ethical Guidelines for Biomedical Research involving Human Subjects (CIOMS, 2002)
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TRC, 2010)

Regulation of Human Research in the US

- National Research Act, 1974: National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
- The Belmont Report, 1979. 3 Ethical Principles: respect for persons, beneficence, and justice
- DHHS, 1991: Federal Policy for the Protection of Human Subjects: The ‘Common Rule’
- The Office of Human Research Protections, created in 2000

Radiobiology, Radiation Protection & Dose

- Basic Radiobiology
- Framework of Radiation Protection: 3 Principles
  - Justification
  - ALARA - Optimization
  - Dose Limitation – ‘Numeric Protection Criteria’
- Quantities and Units Describing Dose
  - Exposure, Absorbed Dose, Equivalent Dose, Effective Dose, LET, Other Quantities, Administered Activity

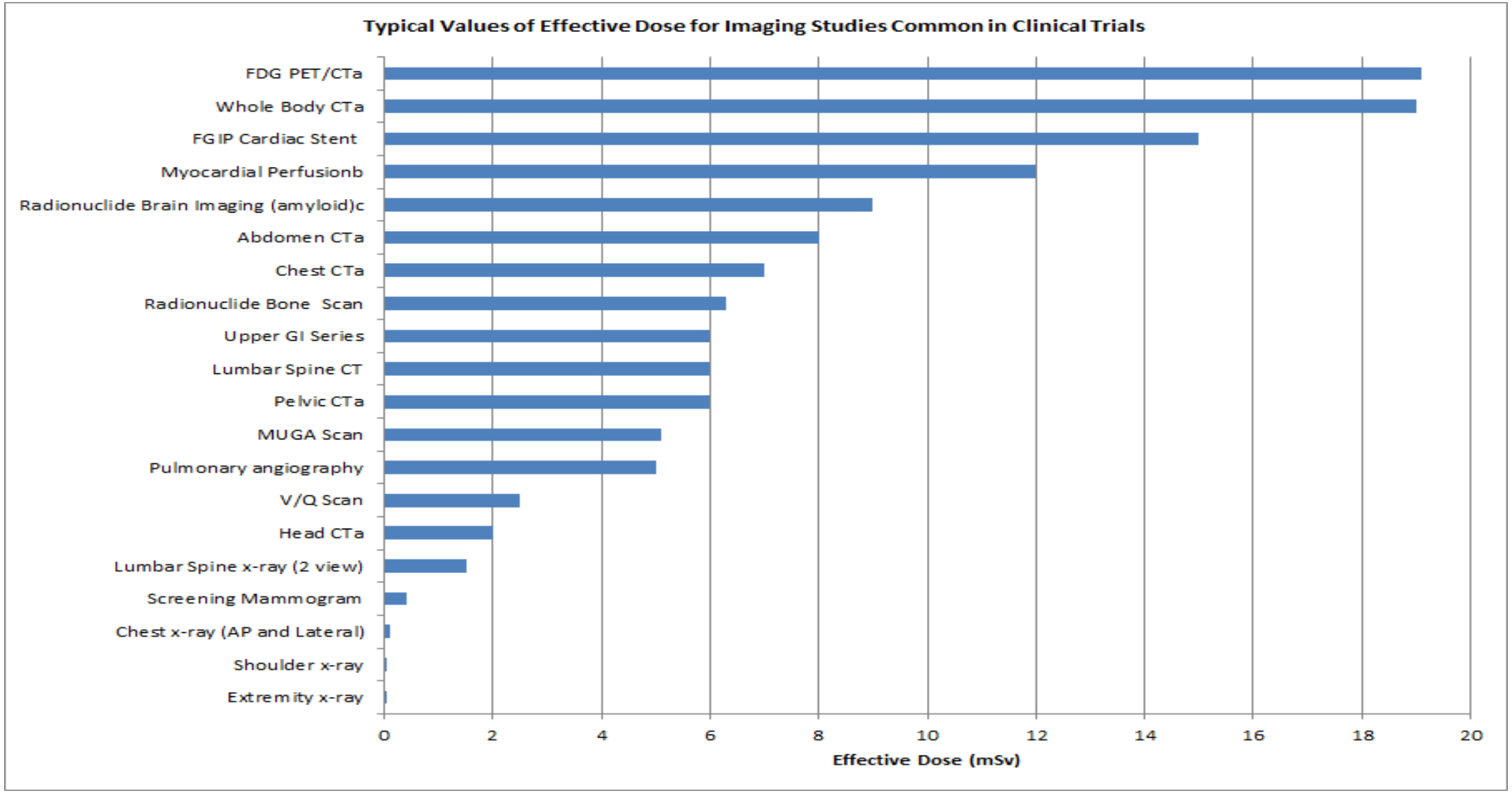
Regulatory Provisions

- Institutional Review Board
- Radiation Safety Committee, Radiation Safety Officer
- Radioactive Materials: NRC, Agreement States
- Electronic Products: FDA
- Investigational Drugs & Radiopharmaceuticals: FDA for IND; Radioactive Drug Research Committee (RDRC)
- Investigational Devices
- Expanded and Early Access to Investigational Drugs & Medical Devices – Compassionate Use, Humanitarian Device Exemption

Standard Diagnostic Imaging Modalities

- Conventional projection radiography
  (e.g., chest x ray, mammography)
- Dual-energy x-ray absorptiometry (DXA)
- Fluoroscopy
- Computed Tomography (CT)
- Nuclear Medicine Imaging (including PET and SPECT)
- Fusion Imaging (PET/CT, SPECT/CT, PET/MRI)
- Ultrasound (Sonography)
- Magnetic Resonance Imaging (MRI)

Effective Dose (mSv) from Common Imaging Procedures



(NCRP 2020)

Image Guidance and Therapeutic Radiation

- Image-Guided Interventions:

  diagnostic and therapeutic procedures,

  with and without ionizing radiation
- Radiation Therapy
- Radionuclide Therapy

Research vs. Standard Patient Care

Standard of Care Definition: NCI, 2014:

“treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals”

Distinguishing Radiation Related to Research

- Typical studies, but required more frequently
- Studies required specifically by research protocol
- Novel radiopharmaceutical or radiation treatment/regimen

IRB should know SOC for study population or solicit advice from clinicians and Radiation Safety Committee or Radiation Safety Officer

Principal Investigator (PI) Responsibilities

- Be knowledgeable about the use of radiation in the study,

  or

- Consult with a knowledgeable medical physicist or other appropriate radiation professional.

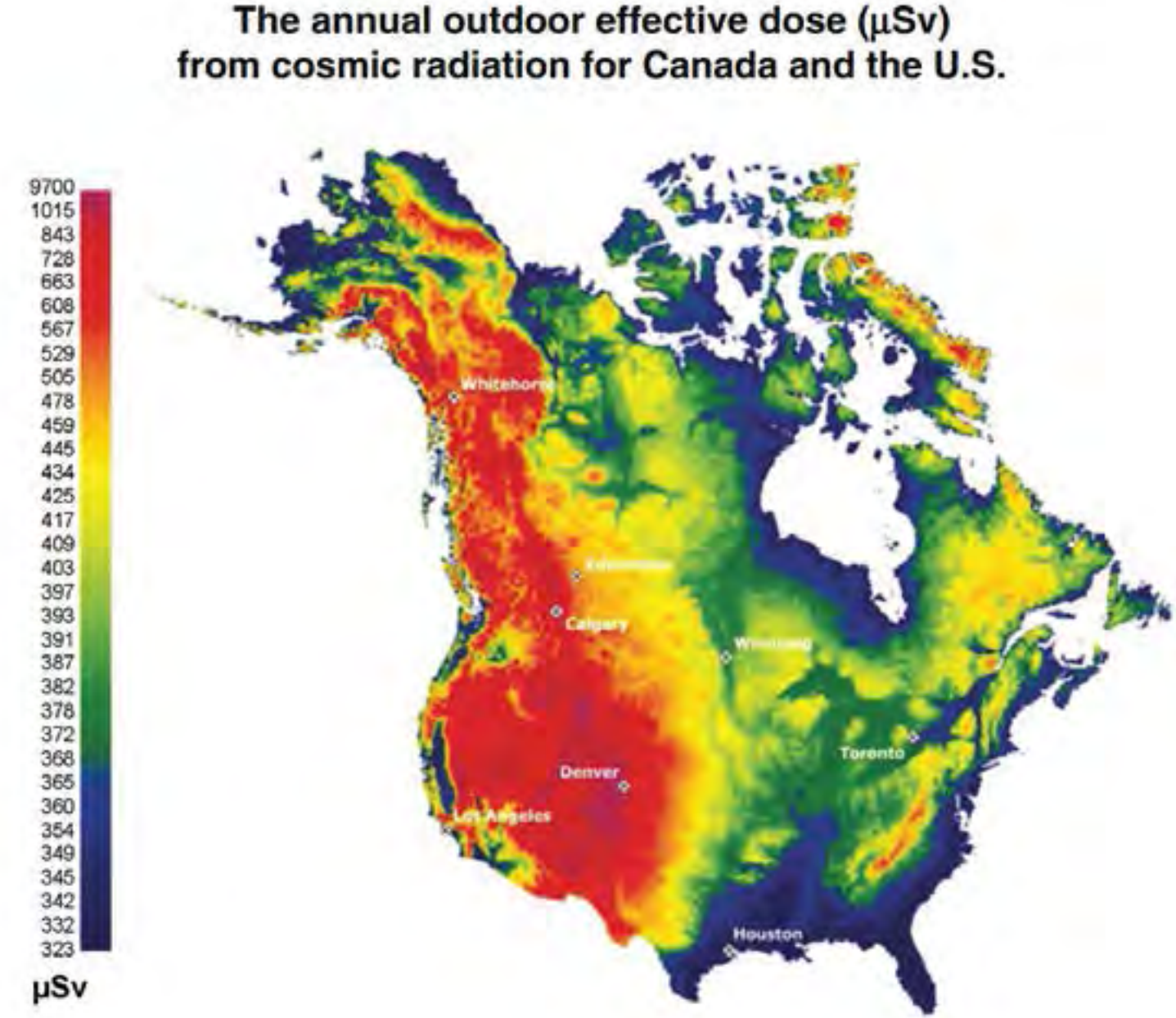
- Should assess the use of exams using radiation against modalities that don’t use ionizing radiation.

Estimating Radiation Dose

- To estimate risk to subjects
- To develop language for informed consent
- To optimize study design, keeping doses ALARA

Discussion per Modality

X-ray, CT, Image-Guided Interventions, Nuclear Medicine, Radiation Therapy



(Grasty and LaMarre 2004)

Estimation of Radiation Risk

- Terminology and Definitions: AR, RR, EAR, ERR, LAR
- Radiation Detriment
- Estimating Cancer Risk: Average Organ Dose
- Uncertainties in Risk Estimates
- Factors Influencing Individual Risk

Radiation Dose in Risk Estimation: Absorbed Dose (D) v. Effective Dose (E)

Mean absorbed dose to a tissue or organ shall be used as the appropriate quantity for estimating the risk of stochastic effects and tissue reactions for human research studies.

Effective dose can be used for prospective dose assessment and as a qualitative indicator of radiation detriment for balancing against expected individual or societal benefit.

Determining Reasonableness

- Efficacy of exam in assessing the clinical trial measure
- Deliver the lowest feasible radiation dose, while considering other (societal, economic and environmental, availability) factors

Consider:

- Are the clinical measures appropriate?
- Are they obtained with lowest dose reasonable?
- Is the estimated radiation risk appropriate in context of other protocol risks and potential benefits?

Ethics in Human Studies Research: Four Principles

- Respect an individual's autonomy - autonomy
- Prevent a harm – non-maleficence
- Provide a good – beneficence
- Act fairly – justice

EC (2000): precautionary principle

Values: human dignity, prudence and honesty

Informed Consent: A Process

- Clear Language
- Issues of literacy and numeracy
- Length reasonable and commensurate with risk
- Communicating Risk, Uncertainty, Latency
- Benchmarks and Circularity
- Children and other vulnerable populations:
  The Common Rule
- Age-appropriate Informed Assent

Informed Consent: Examples of Language

- Adults:
  - Effective Dose <3mSv
  - Effective Dose 3 – 50 mSv
  -Effective Dose 50 – 100 mSv
- Children (under 18 years) – same dose ranges
- Image-Guided Interventions
- Therapeutic Radiation (High Dose), including:
  - External Beam, Brachytherapy, Radionuclide Therapy

Radiological Health at FDA
A Review of Findings, Past and Present

David Spelic
Food and Drug Administration
Silver Spring MD

2020 HPS-NCRP Symposium
Bethesda MD

Radiological Health Efforts: 1950's
of Dade W. Moeller, Public Health Service[1,2,3]

- Survey 1950's : 20 USPHS Hospitals
  - Patient exposures: *"…from approximately 1R for a photofluorographic to about 65 R for an average fluoroscopic examination."*
  - Workers: *"An appreciable fraction of radiologists experience exposures averaging more than 0.1 roentgen per day."* -> today about 80 chest exams/month
  - **15 million chest x-rays**- tuberculosis: ~1 R/exam
- Delivery item: *Guide for the Inspection of Medical and Dental Diagnostic X-ray Installations (1953)* (Ingraham SC, Terrill JG Jr., Moeller DW. PHS, 1953)

Radiation Exposure in the United States

By DADE W. MOELLER, M.S., JAMES G. TERRILL, JR., C.E., M.B., and SAMUEL C. INGRAHAM, II, M.D., M.P.H.

Public Health Reports Vol. 68, No. 1, January 1953

In addition to the operators, a considerable portion of the general population is also exposed to radiations from X-ray machines. Of the 2,500,000 persons seen daily by physicians, a large number have some X-ray diagnostic procedure performed upon them by the physicians, and 82,000 are referred to radiologists. Approximately 25,000,000 X-ray examinations are given annually by radiologists (*1*). Data relative to radiation exposures resulting from these examinations are summarized below:

~ 820 million visits/yr

= 17% of U.S. popul.

Type of examination	*Average radiation dosage (roentgens)*	*Distribution (percent)*
Radiographic	2. 7	51. 88
Photofluorographic	1. 0	33. 64
Fluoroscopic	65. 0	14. 48

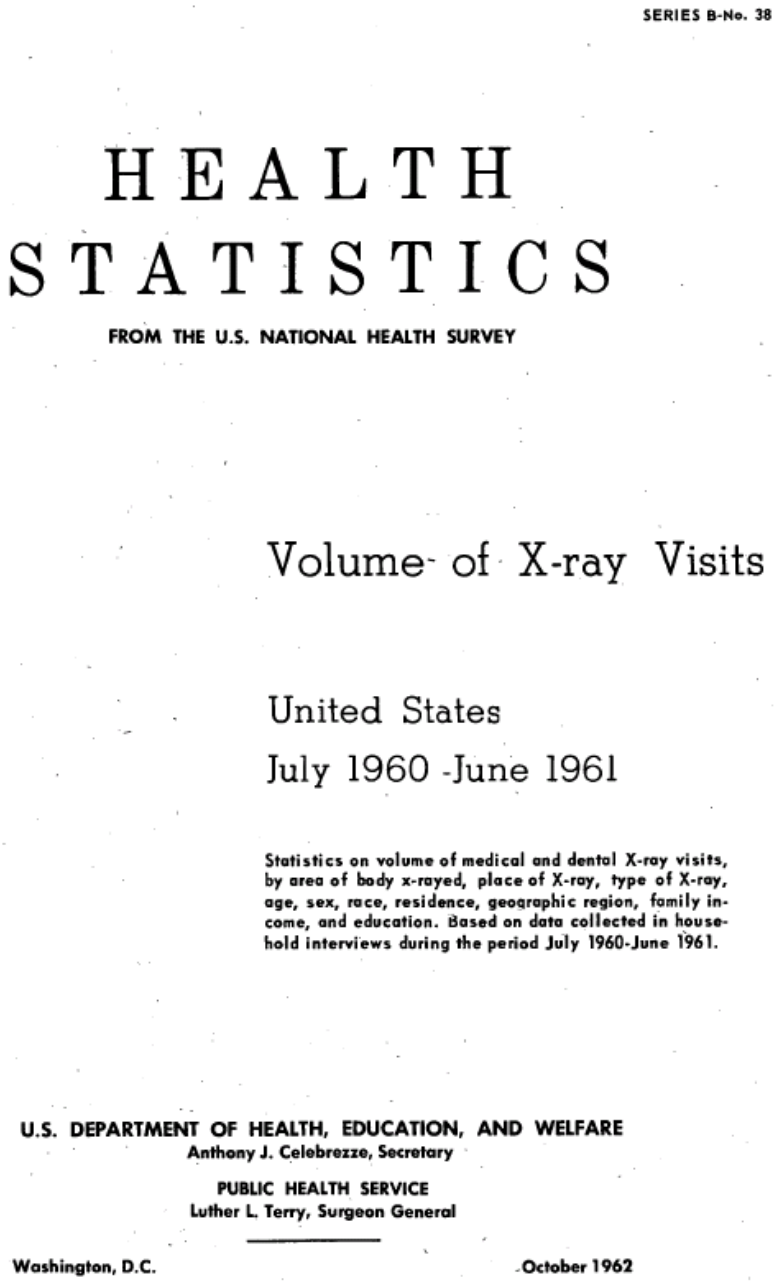
Radiological Health Efforts: 1950's
Public Health Service

- Survey meters- custom modified @ NIH to measure exposure
- Moeller volunteered to be "patient", later used coconut- dental
- Observations: **Medical X-ray**:
  - **X-ray tubes**- really bad or missing collimation, seldom had filtration
  - **Dental:** intraoral exposures typically **exceeded 44 mGy (5R)**
- **Non-medical-** *"Subsequent surveys showed that the exposure to the feet of the customers ranged from 7 to 14 R per 20-second viewing. Exposure rates from scattered radiation ranged up to 1 R per minute."*

More Survey Findings- 1950's

Large-scale Survey: Professional Bureau, *American College of Radiology*[3]:

- 150,000 practicing physicians
- 3,000 certified practicing Radiologists
- 18,000 '*Rotentgen-ray Units*'
- Approximately 30 million x-ray exams / year



SERIES B-No. 38

HEALTH STATISTICS

FROM THE U.S. NATIONAL HEALTH SURVEY

Volume of X-ray Visits

United States
July 1960 -June 1961

Statistics on volume of medical and dental X-ray visits, by area of body x-rayed, place of X-ray, type of X-ray, age, sex, race, residence, geographic region, family income, and education. Based on data collected in household interviews during the period July 1960-June 1961.

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Anthony J. Celebrezze, Secretary

PUBLIC HEALTH SERVICE
Luther L. Terry, Surgeon General

Washington, D.C. October 1962

1957: PHS National Center for Health Statistics initiates the National Health Survey (NHS)

- Goal: To characterize State of US public health.
- Method: Household interviews
- 1960-1961: NHS collects data regarding diagnostic x-ray practice[4]
- 38,000 households visited/125,000 respondents interviewed
- Among their findings[4]:

- 82 million visits to clinical sites for medical x-ray (diagnostic)
-Most frequent exam: chest (51 million)
-49 million dental exams

X-ray Exposure Study- XES
PHS surveys 1964 and 1970[5,6,7]

- 1964 Survey: Planned as extension of U.S. National Health Survey to include capture of X-ray visits:
- **Two components:**
  - Household interview of U.S. population sample
  - Follow-up mail packet to clinical sites- x-ray equipment and exam data, estimation of patient exposure -> dosimetry

- Data regarding x-ray exam history was collected for 31,289 persons / 9653 households (1964)
- Survey was repeated in 1970
  - 22,500 households interviewed/67000 persons

XES surveys: 1964 and 1970

- Scope: Dental & medical x-ray, fluoroscopy, and x-ray therapy
- Film packs: sent to clinical sites- capture beam size and dosimetry[7]
  - Separate film packs for each modality
  - Fluoro: Two packs:
    - large area film recorded patient exam, scanning densitometer records approximately 1386 readings from each film- 1.5 million data points
    - Folding film pack captures beam geometry to infer source-table top distance

Dosimetry[7]

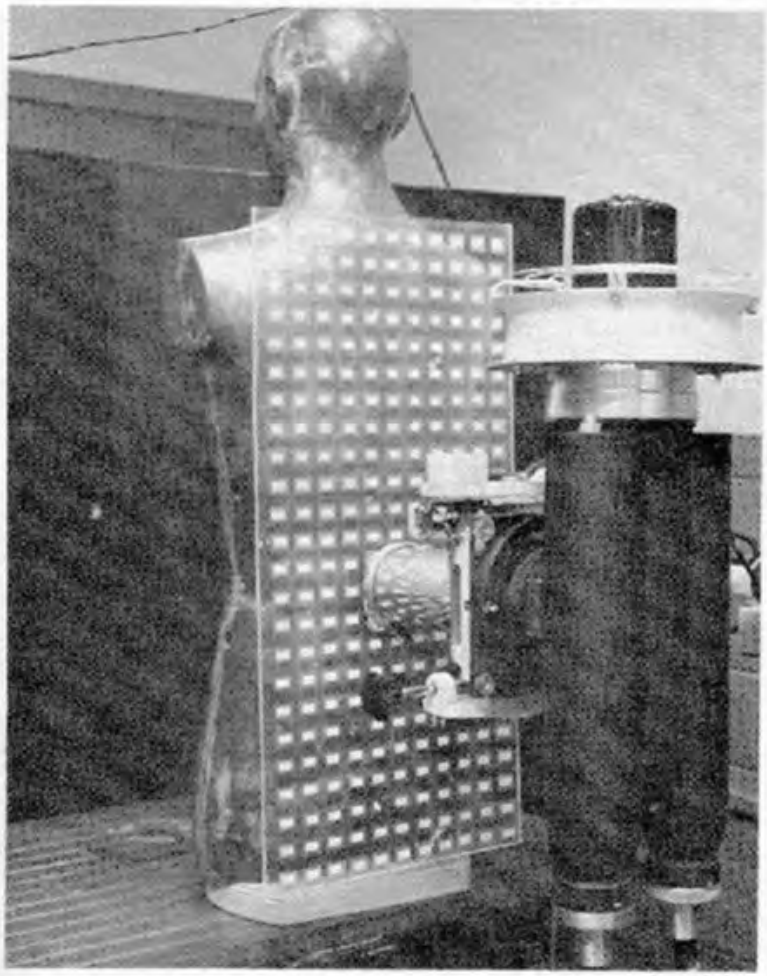


EXHIBIT 18.—The RANDO Phantom, Reference Grid System and X-ray Equipment Used to Determine the Exposure Ratios for the Postero-anterior Position.

- BRH developed models to compute patient exposure
- based on reported x-ray technique, collimation and film packet measurement

- Doses were computed using RANDO phantoms- exposure ratios and scatter were measured for dose calculations.

- Surveyed exams included dental, radiographic, and fluoroscopic procedures.

EXHIBIT 10.—Measuring Beam Size Recorded on Radiographic Film Packs.

BUREAU OF RADIOLOGICAL HEALTH*

John C. Villforth, Director
E. C. Anderson, Deputy Director

DIVISION OF MEDICAL RADIATION EXPOSURE

Arve H. Dahl, Director
Joseph N. Gitlin, Deputy Director

DIVISION OF HEALTH INTERVIEW STATISTICS**

Elijah L. White, Director
Robert Fuchsberg, Deputy Director

1970 X-RAY EXPOSURE STUDY

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PUERTO RICO SURVEY

Michael Gileadi

NOTE: For further information regarding this report, direct all inquiries to: Office of Information, Bureau of Radiological Health, 5600 Fishers Lane, Rockville, Maryland, 20852.

*Key personnel as of the time period during which the Study was conducted.
**National Center for Health Statistics.

No. x-ray exams in U.S. (millions):

1964: 119 DX /53 dental

1970: 212 DX / 67 dental)

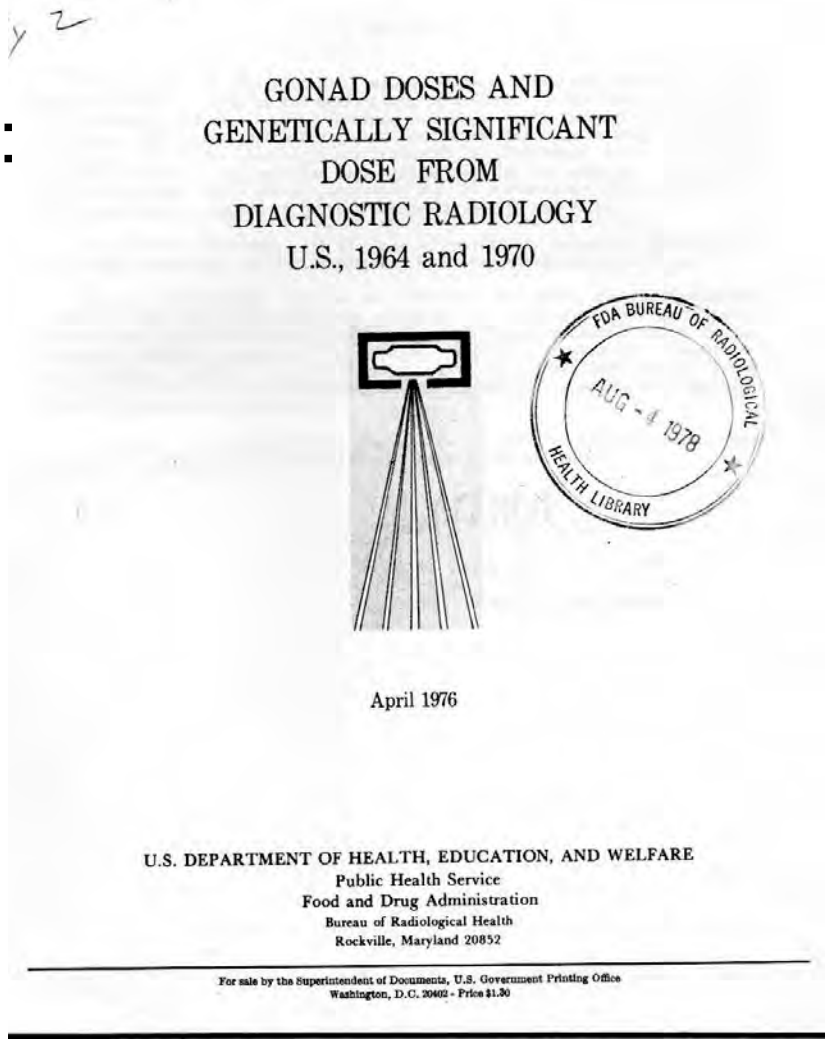
Bureau of Radiological Health: 1960's to 1980's

Lots of radiological training:

- Diagnostic x-ray- 'how to's
- Dosimetry
- Imaging- technology aspects
  screen-film systems

Radiological surveys

- General radiography
- Fluoroscopy
- Mammography
- Dental x-ray



GONAD DOSES AND
GENETICALLY SIGNIFICANT
DOSE FROM
DIAGNOSTIC RADIOLOGY
U.S., 1964 and 1970

April 1976

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Food and Drug Administration
Bureau of Radiological Health
Rockville, Maryland 20852

For sale by the Superintendent of Documents, U.S. Government Printing Office
Washington, D.C. 20402 - Price $1.50

The 1970's – a BUSY time for BRH

DHEW Publication (FDA) 74-8007

A REVIEW of
DETERMINATIONS of
RADIATION DOSE to the
ACTIVE BONE MARROW from
DIAGNOSTIC X-RAY EXAMINATIONS

Bernard Shleien

October 1973

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
FOOD AND DRUG ADMINISTRATION
Bureau of Radiological Health
Rockville, Maryland 20852

HEW Publication (FDA) 77-8029

COURSE MANUAL
for
MACHINE SOURCES
of X RAYS
(GS-461)

Prepared by:

The X-Ray Science and Engineering Laboratory
Oregon State University

Project Director:
E. Dale Trout, Director
X-Ray Science and Engineering Laboratory

•

Project Officer:
James S. Benson
Deputy Director
Bureau of Radiological Health

This work was carried out under PHS Contract Number 223-72-6314.

BRH
bureau of radiological health

WHO Collaborating Center for Training and General Tasks in Radiation Medicine

(This publication supersedes HEW Publication (FDA) 73-8026, January 1973)

July 1977

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Food and Drug Administration
Bureau of Radiological Health
Rockville, Maryland 20857

Technician checks x-ray emissions from color television receiver using Bureau-developed survey meter as part of overall laboratory product testing program.

Mammography- 1970's

Breast Exposure: Nationwide Trends- BENT [8,9]

Cooperative: FDA's Bureau of Radiological Health and National Cancer Institute with field support provided by state programs.

Objectives

- Characterize patient exposure
- Identify reasons for very high/very low exposures
- Reduce unnecessary exposure via improved QA practices

4 components

- Identified mammo sites completed questionnaire.
- Sites mailed dosimetry card (TLD's) to expose.
  NOTE: approx 10% of mammo units equipped w/ AEC
- Exposures evaluated, follow-up visits -> corrective actions
- Revisit follow-up sites after 1 year

BENT

- Pilot phase: 19 states reported data on 1567 x-ray units
- Exposures ranged from 0.25 R to 16 R !! (2.2 – 140 mGy)
- Nationwide site visits began in **late 1970's**
- Participation: 42 states, P.R., DC, NYC, PHS hospitals, US Army, Navy, Air Force, 3 Canadian provinces.
- **Observations:**
  - Technology in use (% of all units):
    - direct-exposure film (10%)
    - xeromammography (45%)
    - screen-film (S/F) (45%)

- 58% sites using S/F systems needed follow-up for low (29%!) or high (7%) doses[9]
- 22% sites - high HVL, inappropriate kVp for target (W vs Mo)[9]

Preliminary Data As of 3/11/77

TABLE FOUR. Exposure by Type of Image Receptor in BENT Pilot States.

	All Image Receptors	Direct Exposure Film	Film/Screen Combinations	Xerox
No. of x-ray units	435	75	198	162
No. of patients examined in 1 month	18,759	1,071	6,201	11,487
mean exposure (R)	1.49	3.21	0.60	1.80
standard deviation	2.07	3.74	0.74	1.41
minimum	0.00*	0.18	0.00	0.18
1st quartile	0.32	1.10	0.13	0.89
median	0.91	2.00	0.33	1.40
3rd quartile	1.70	3.50	0.74	1.90
maximum	16.60	16.60	5.00	6.90
range (max - min)	16.60	16.42	5.00	6.78

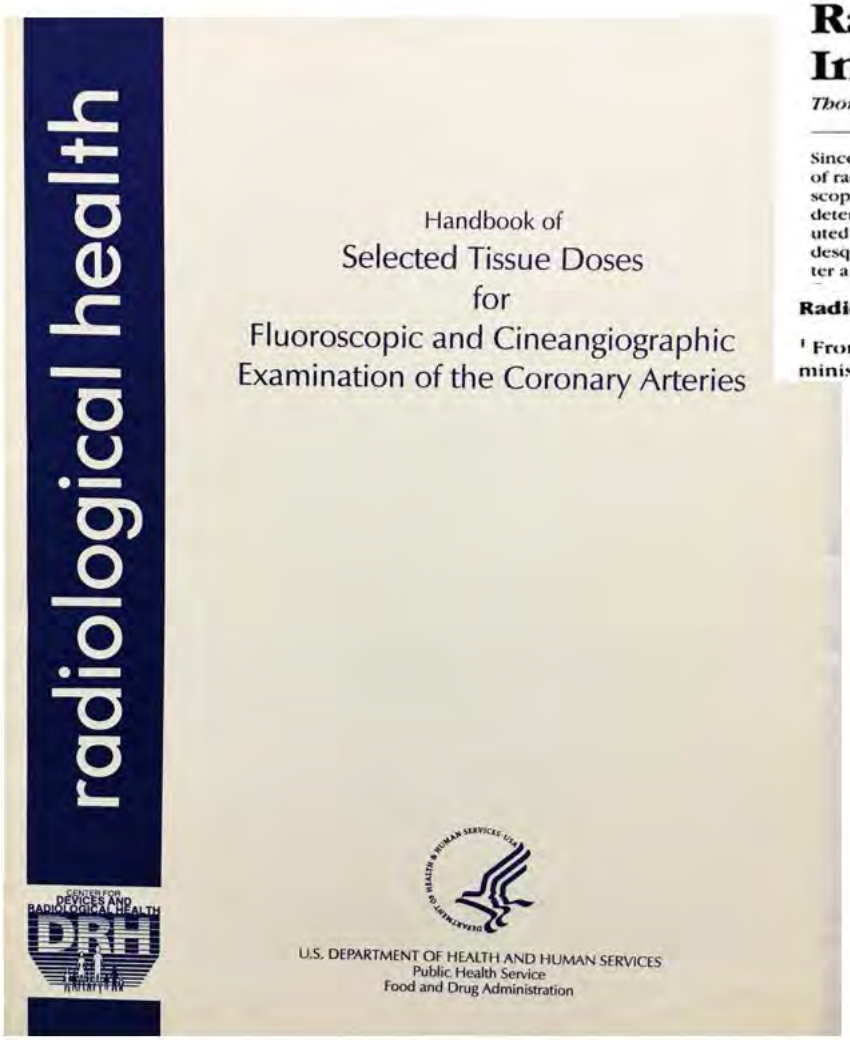
*Actual min value is 0.025 R, stated in FDA report to CRCPD, Seattle 1977

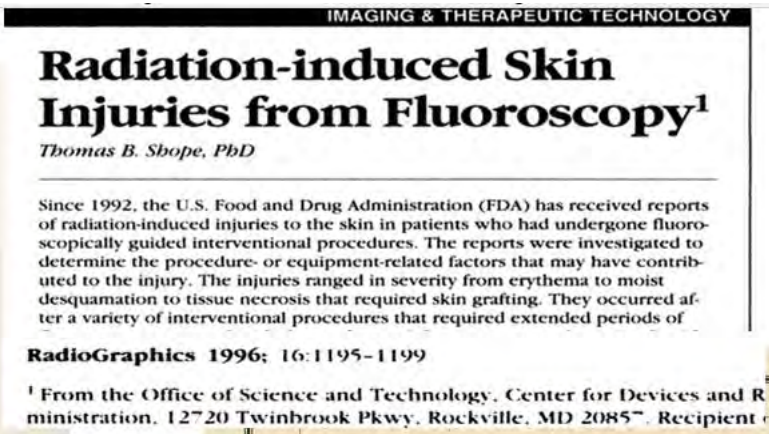
Unit of Exposure: Roentgens free-in-air at the skin entrance site (6 cm above the tabletop or the equivalent plane) from a single craniocaudal view of a "medium-density, medium-size" breast. Backscatter is NOT included.

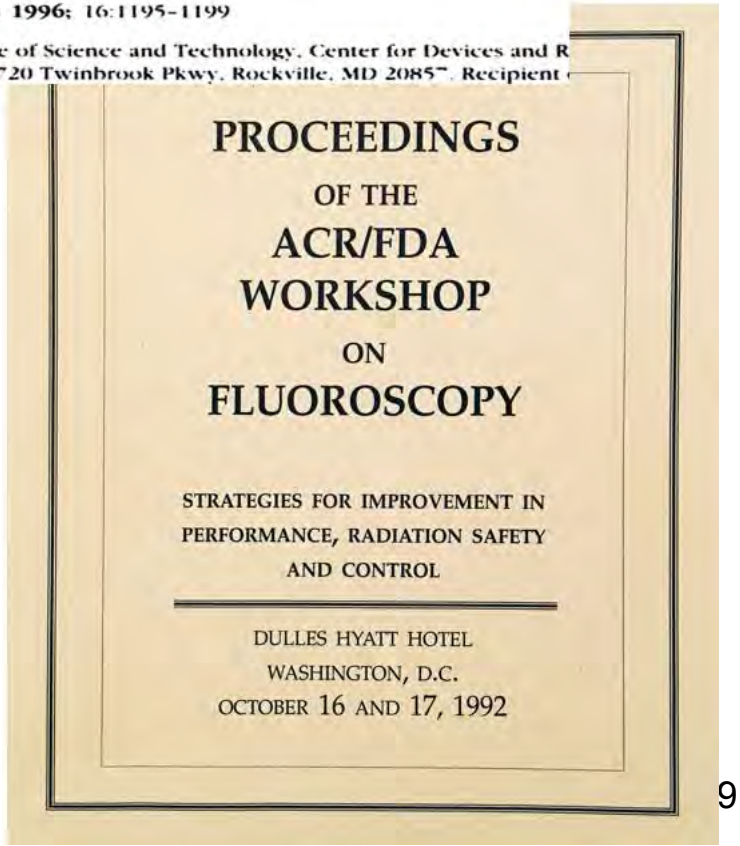
Dental Exposure Normalization Technique: DENT[10]

- Early 1970's: Intraoral exposures up to 44 mGy (5 R) per film;
- Bureau of Radiological Health (BRH)- studies problem, derives optimal range of exposures for radiographs
- Pilot study: 46% of surveyed sites in RI and NH have exposures exceeding recommendations
- BRH develops DENT as a QA process for identified dental offices
- State Rad Health programs conduct site visits, BRH provides equipment, planning support.

Later Activities- 1990's





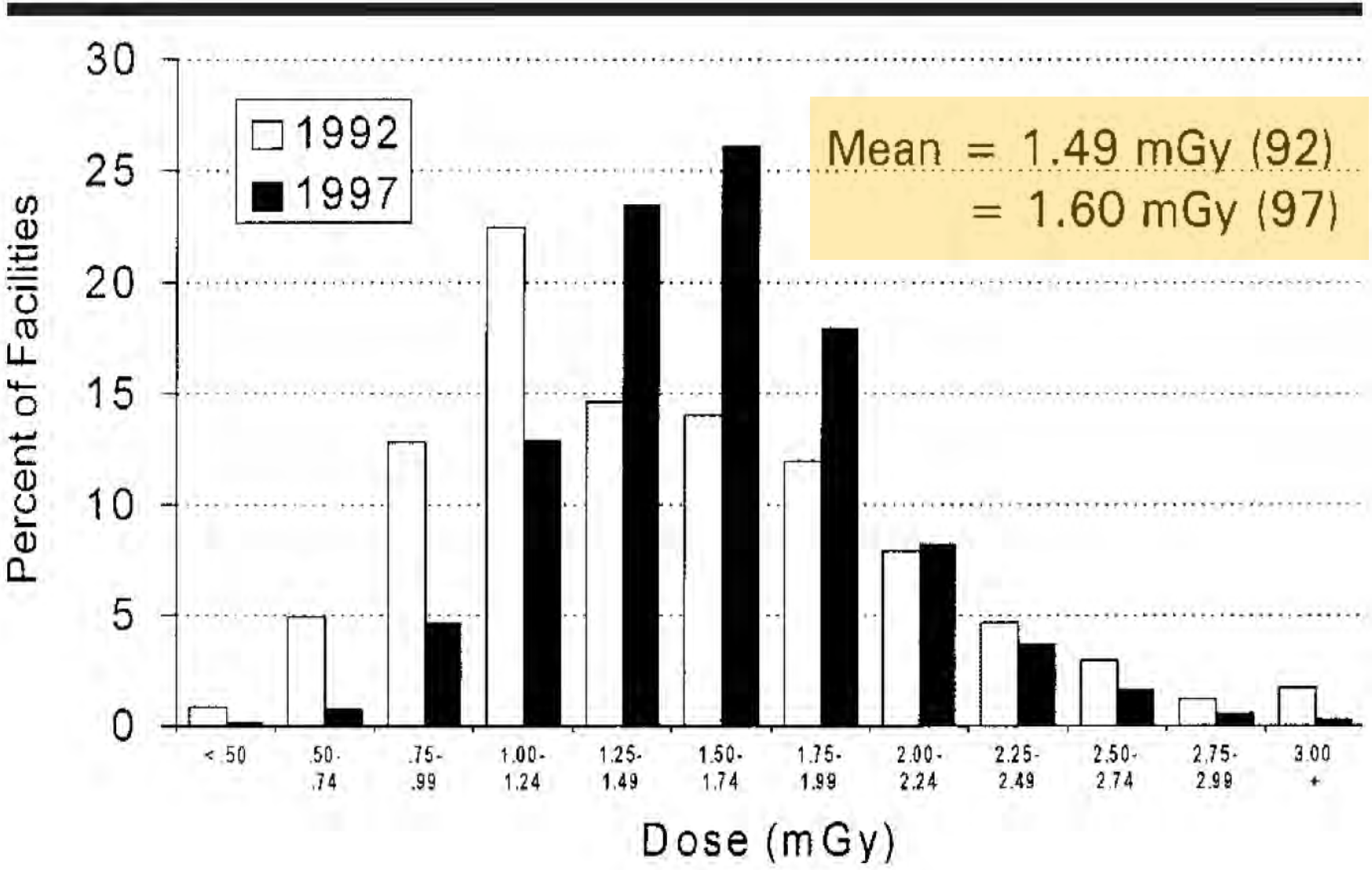


Later / present Agency Radiological Health Activities

- Mammography Quality Standards Act of 1992 (MQSA):
  - enacted in 1992, mandates minimum stds for quality including maximum radiation dose per image*, image quality, staff credentials, and medical outcomes audit, among other requirements
  - Equipment inspection procedures developed based on prior NEXT surveys (85, 88, and 92)

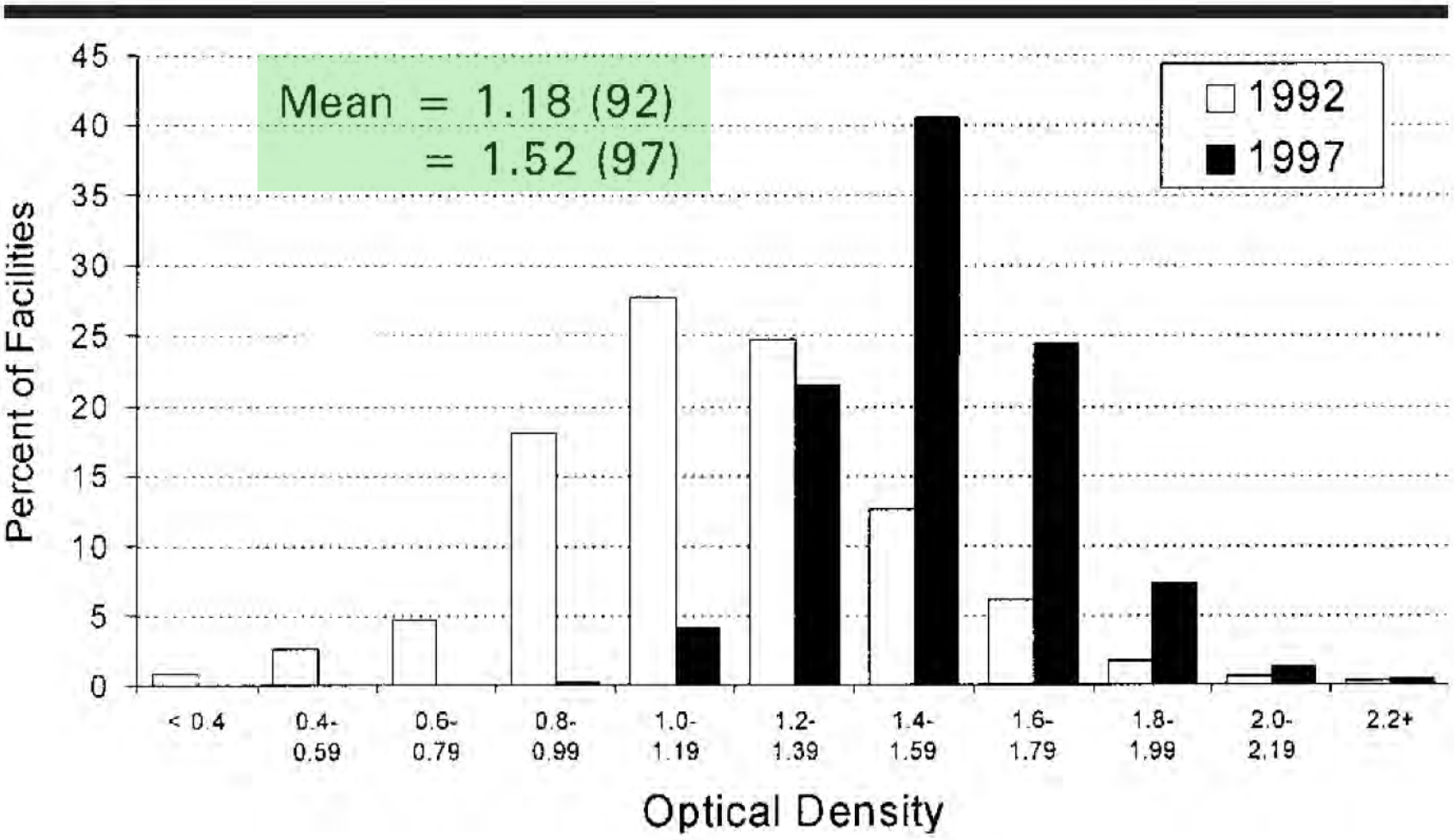
*Specified to a standard breast

Mean Glandular Dose: Pre- and Post-MQSA inspection start



Taken from: Suleiman, et al. Mammography in the 1990s: The United States and Canada. Radiology 210(2), February 1990; pp 345-351.

Higher dose is not necessarily a bad thing…



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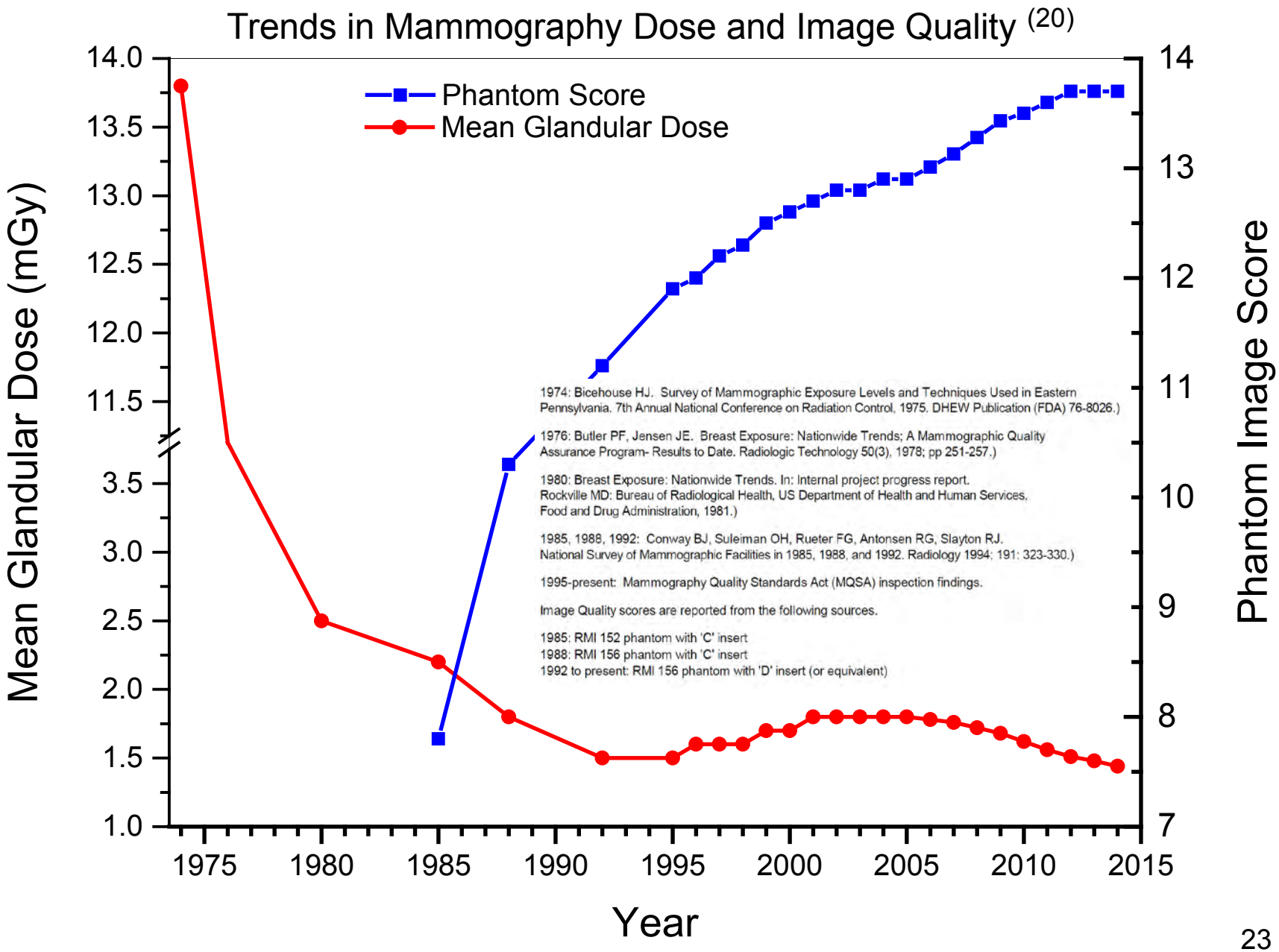
Trends in Mammography Dose and Image Quality (20)
Phantom Score
Mean Glandular Dose
Mean Glandular Dose (mGy)
Phantom Image Score
Year
14.0
13.5
13.0
12.5
12.0
11.5
3.5
3.0
2.5
2.0
1.5
1.0
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12
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1975
1980
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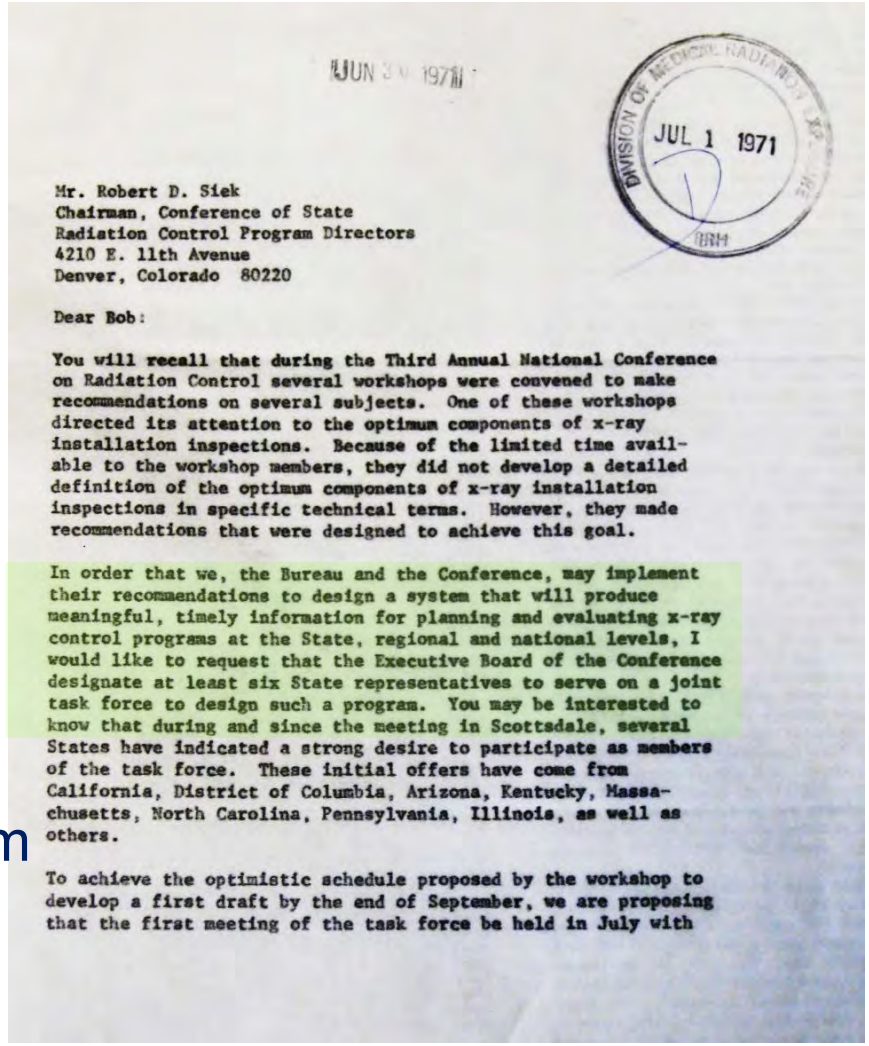
2015
1974: Bicehouse HJ. Survey of Mammographic Exposure Levels and Techniques Used in Eastern Pennsylvania. 7th Annual National Conference on Radiation Control, 1975. DHEW Publication (FDA) 76-8026.)
1976: Butler PF, Jensen JE. Breast Exposure: Nationwide Trends; A Mammographic Quality Assurance Program- Results to Date. Radiologic Technology 50(3), 1978; pp 251-257.)
1980: Breast Exposure: Nationwide Trends. In: Internal project progress report. Rockville MD: Bureau of Radiological Health, US Department of Health and Human Services, Food and Drug Administration, 1981.)
1985, 1988, 1992: Conway BJ, Suleiman OH, Rueter FG, Antonsen RG, Slayton RJ. National Survey of Mammographic Facilities in 1985, 1988, and 1992. Radiology 1994; 191: 323-330.)
1995-present: Mammography Quality Standards Act (MQSA) inspection findings.
Image Quality scores are reported from the following sources.
1985: RMI 152 phantom with 'C' insert
1988: RMI 156 phantom with 'C' insert
1992 to present: RMI 156 phantom with 'D' insert (or equivalent)

Nationwide Evaluation of X-ray Trends-NEXT[12]

- Early 1970's: FDA's BRH and CRCPD initiate effort to characterize state of U.S. diagnostic X-ray practice in a standardized, practice-representative way.
- By 1972 NEXT begins surveying 12 commonly performed exams.
- Surveys continue through 1982.
- 1984- focus on single exam
- patient-equivalent phantoms
- Film processing quality, darkroom fog, and related aspects of diagnostic x-ray practice are characterized.



JUN 30 1971

DIVISION OF MEDICAL RADIATION EXPOSURE
JUL 1 1971
BRH

Mr. Robert D. Siek
Chairman, Conference of State
Radiation Control Program Directors
4210 E. 11th Avenue
Denver, Colorado 80220

Dear Bob:

You will recall that during the Third Annual National Conference on Radiation Control several workshops were convened to make recommendations on several subjects. One of these workshops directed its attention to the optimum components of x-ray installation inspections. Because of the limited time available to the workshop members, they did not develop a detailed definition of the optimum components of x-ray installation inspections in specific technical terms. However, they made recommendations that were designed to achieve this goal.

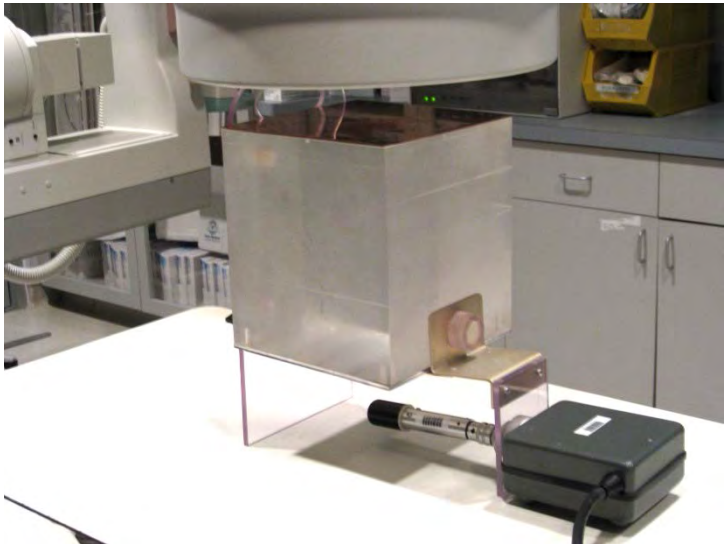
In order that we, the Bureau and the Conference, may implement their recommendations to design a system that will produce meaningful, timely information for planning and evaluating x-ray control programs at the State, regional and national levels, I would like to request that the Executive Board of the Conference designate at least six State representatives to serve on a joint task force to design such a program. You may be interested to know that during and since the meeting in Scottsdale, several States have indicated a strong desire to participate as members of the task force. These initial offers have come from California, District of Columbia, Arizona, Kentucky, Massachusetts, North Carolina, Pennsylvania, Illinois, as well as others.

To achieve the optimistic schedule proposed by the workshop to develop a first draft by the end of September, we are proposing that the first meeting of the task force be held in July with

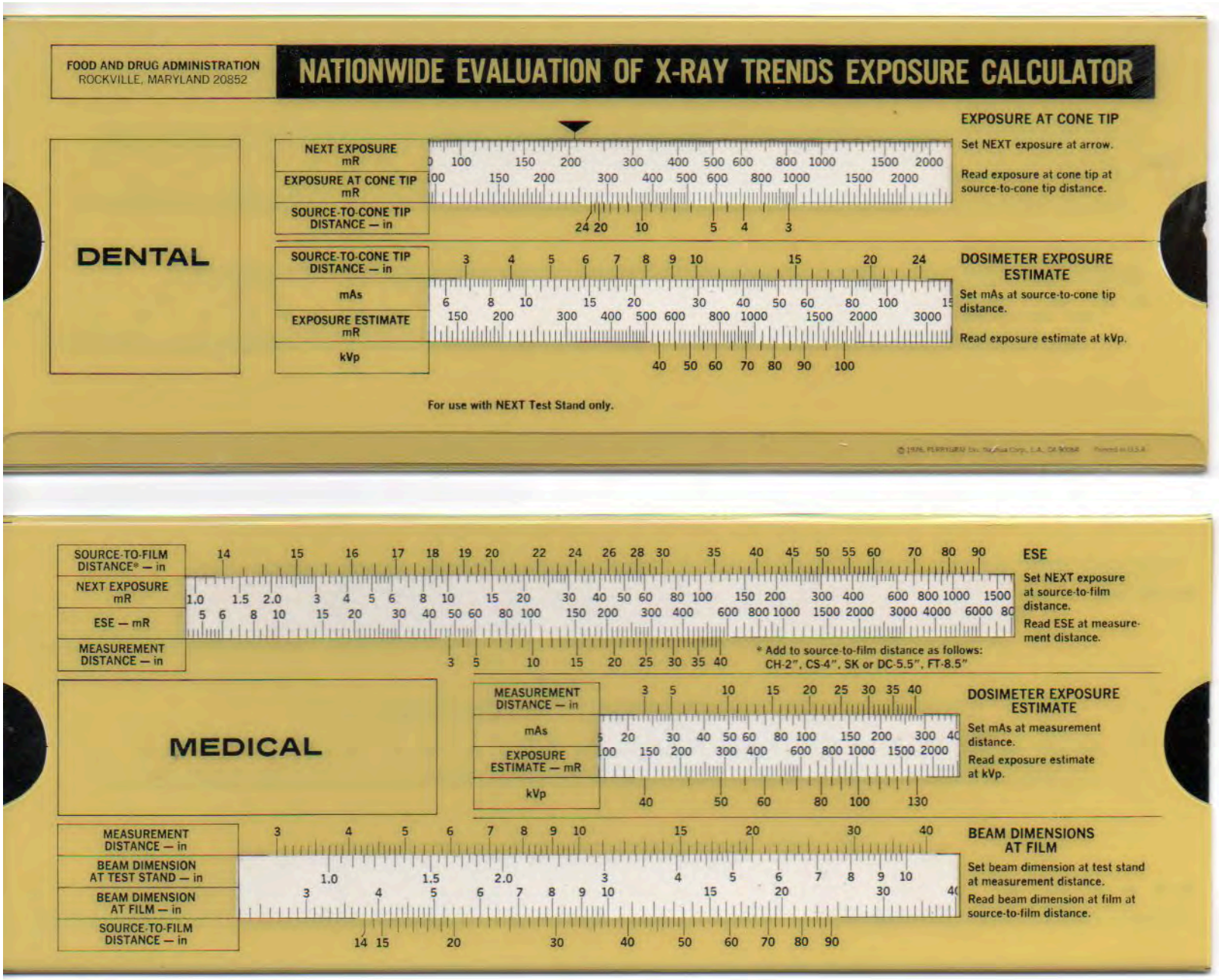
NEXT Surveys

Examination	Survey Years
Chest radiography	1984, 1986, 1994, 2001
Mammography	1985, 1988, 1992
Abdomen and lumbo-sacral (LS) spine radiography	1987, 1989, 1995, 2002
Fluoroscopy {upper GI (91, 96, 03), cardiac cath labs and mobile C-arms (96), *coronary angiography (2008)*}	1991, 1996, 2003, 2008
Computed tomography (CT)	1990, 2000, 2005
Dental radiography	1993, 1999, 2014-15
Pediatric Chest	1998
Chiropractic Imaging	2018-2019

Teamwork



Survey participation- Typical Site Distribution

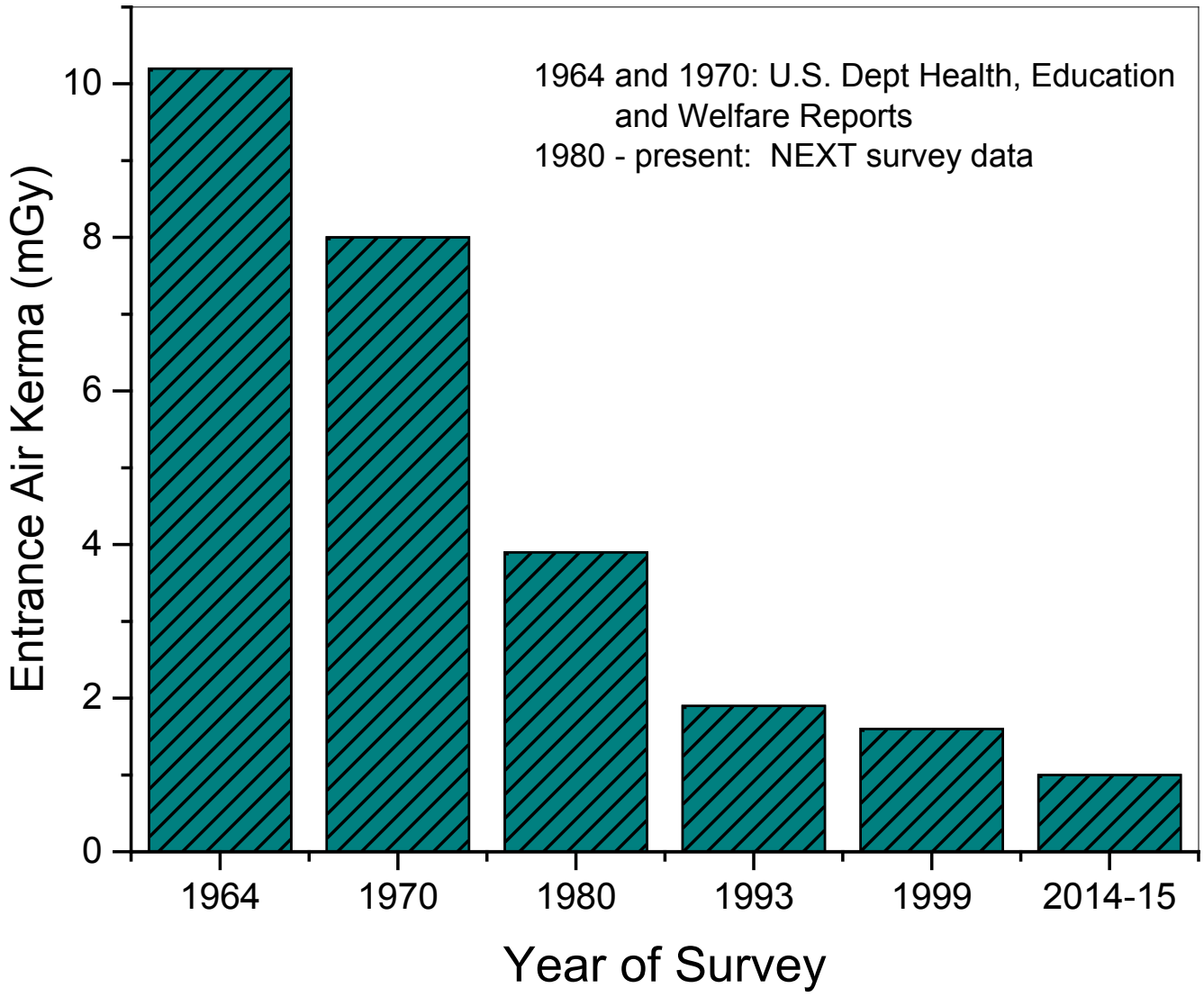

FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852
NATIONWIDE EVALUATION OF X-RAY TRENDS EXPOSURE CALCULATOR
DENTAL
NEXT EXPOSURE mR
EXPOSURE AT CONE TIP mR
SOURCE-TO-CONE TIP DISTANCE — in
EXPOSURE AT CONE TIP
Set NEXT exposure at arrow.
Read exposure at cone tip at source-to-cone tip distance.
SOURCE-TO-CONE TIP DISTANCE — in
mAs
EXPOSURE ESTIMATE mR
kVp
DOSIMETER EXPOSURE ESTIMATE
Set mAs at source-to-cone tip distance.
Read exposure estimate at kVp.
For use with NEXT Test Stand only.
SOURCE-TO-FILM DISTANCE* — in
NEXT EXPOSURE mR
ESE — mR
MEASUREMENT DISTANCE — in
ESE
Set NEXT exposure at source-to-film distance.
Read ESE at measurement distance.
* Add to source-to-film distance as follows:
CH-2", CS-4", SK or DC-5.5", FT-8.5"
MEDICAL
MEASUREMENT DISTANCE — in
mAs
EXPOSURE ESTIMATE — mR
kVp
DOSIMETER EXPOSURE ESTIMATE
Set mAs at measurement distance.
Read exposure estimate at kVp.
MEASUREMENT DISTANCE — in
BEAM DIMENSION AT TEST STAND — in
BEAM DIMENSION AT FILM — in
SOURCE-TO-FILM DISTANCE — in
BEAM DIMENSIONS AT FILM
Set beam dimension at test stand at measurement distance.
Read beam dimension at film at source-to-film distance.

U.S. Estimates- 2014-2015

INTRAORAL X-RAY	
No. Dental sites of all types in U.S.	139,500
No. of Intraoral x-ray units	370,900
No. of Intraoral Exams (adult and Ped)	296 million

CONE BEAM CT	
Estimated No. Dental CBCT units in U.S.	7,340
No. of All CBCT exams: Pediatric Adult and Adolescent	 0.4 million 4.8 million

Trends for Intraoral Air Kerma per Image




FDA
U.S. FOOD & DRUG
ADMINISTRATION

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    1976 (dose): Butler PF, Jensen JE. Breast Exposure: Nationwide Trends; A Mammographic Quality Assurance Program-Results to Date. Radiologic Technology 50(3), 1978; pp 251-257.

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    1995-2006 (dose and image quality): Mammography Quality Standards Act (MQSA) inspection findings.

    Image Quality scores are reported for following phantoms.

    1985: RMI 152 phantom with 'C' insert

    1988: RMI 156 phantom with 'C' insert

    1992 to present: RMI 156 phantom with 'D' insert (or equivalent)
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National Council on Radiation Protection and Measurements

@mmahesh1

Medical Radiation Exposure of Patients in the United States

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Professor of Radiology and Cardiology

Johns Hopkins University School of Medicine

Chief Physicist – Johns Hopkins Hospital

Joint Appointment - Johns Hopkins School of Public Health

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HPS, Mid-Year Meeting *Jan 28-29, 2020 * Bethesda, MD *mmahesh@jhmi.edu

Disclosures

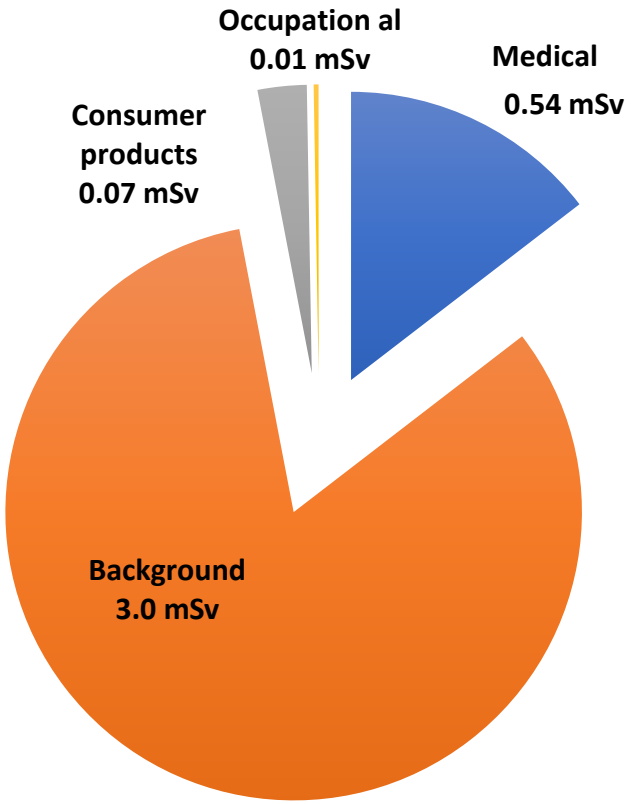
- **Royalties**
  - Lippincott Williams and Wilkins (book)
- **Council Member**
  - National Council on Radiation Protection and Measurements (NCRP)
- **Travel Funding**
  - American College of Radiology (ACR) (Board Member)
  - American Association of Physicists in Medicine (AAPM) (Board Member)

Purpose

- Prepare report to evaluate changes in medical radiation exposures for US population since 2006 (NCRP 160)
- NCRP 160
  - Published officially in 2009
  - Data from 2006
- This report (NCRP 184)
  - Published officially in November 2019
  - Data from 2016

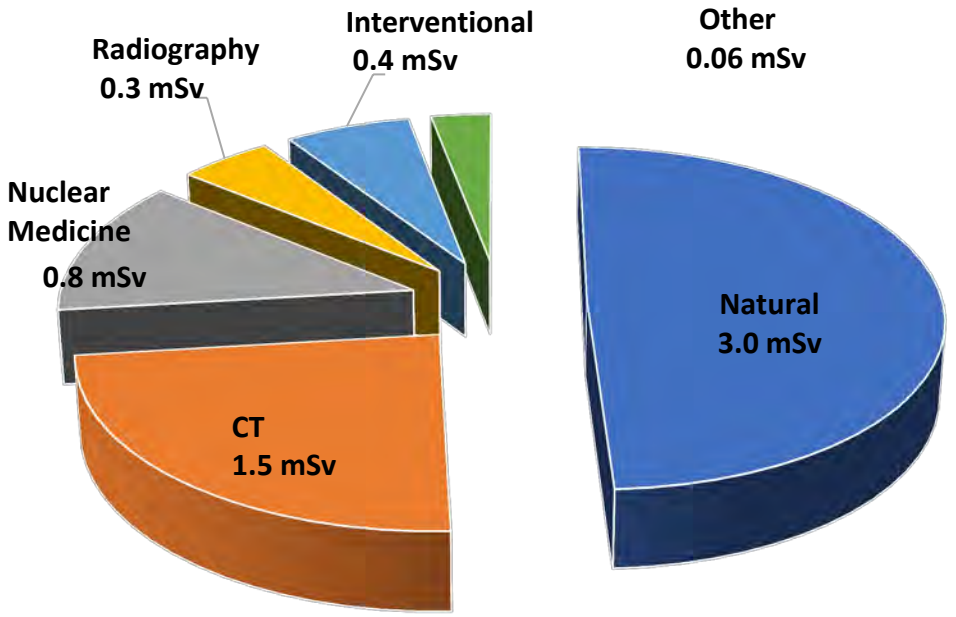
Past: Radiation Exposures to US population

1980



Medical 0.54 mSv per capita
Total 3.6 mSv per capita

2009



Medical 3.0 mSv per capita
Total 6.2 mSv per capita

NCRP Medical Exposure Reports

NCRP REPORT No. 100

EXPOSURE OF THE U.S. POPULATION FROM DIAGNOSTIC MEDICAL RADIATION

Start 1972
Finished 1988
Published 1989

National Council on Radiation Protection and Measurements

17 years

NCRP REPORT No. 160

IONIZING RADIATION EXPOSURE OF THE POPULATION OF THE UNITED STATES

Start 2006
Finished 2008
Published 2009

NCRP 1929 2009

3.5 years

NCRP REPORT No. 184

MEDICAL RADIATION EXPOSURE OF PATIENTS IN THE UNITED STATES

Start Nov 2016
Finished early 2019
Published Nov 2019

National Council on Radiation Protection and Measurements

3.0 years

NCRP PAC 4-9 Committee Members

• Chair	F. Mettler	Univ of New Mexico	(Diagnostic Radiology)
• Co-Chair	M. Mahesh	Johns Hopkins Univ.	(Medical Physics)

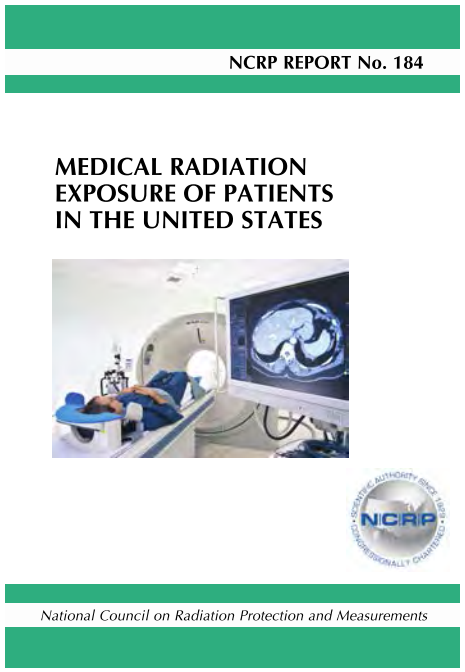
• H. Royal	Wash Univ. St. Louis,	(Nuclear Medicine)
• C. Chambers	Penn. State	(Interventional cardiology)
• D. Miller	U.S. FDA CDRH	(Interventional radiology)
• D. Frush	Duke Univ.	(Pediatric Radiology)
• M. Milano	Univ of Rochester	(Radiation Oncology)
• D. Spelic	U.S. FDA	(NEXT and Dental)
• M B. Chatfield	Exec. VP, Am Coll Radiol.	(Medicare & data sources)
• J. Elee	State of Louisiana	(CRCPD + State data)

- Advisors: A. Ansari, W. Bolch, G. Guebert, R. Sherrier, J. Smith
- R. Vetter, L. Atwell, SciMetrika (literature related) and NCRP staff

NCRP Report 184

U.S. population data are reported in four metrics

- Number and type of diagnostic and interventional medical radiation procedures
- Procedures: Exams vs Scans
  - Scans w multiple exposures (dual-phase studies)
  - 1 exam but 2 scans
- Effective dose (E) per procedure
- Collective Effective Dose (S) per procedure
- U.S. Annual Average Individual Effective Dose (E_{US})*



*allows comparison of the magnitude of medical radiation exposure to that from various non-medical sources

Calculations

- Number of Imaging Procedures (N)
- Effective dose (E) per procedure (mSv)
- Collective Effective Dose (S) (person-Sievert) = E*N
- Average Individual Effective dose (E_{US}) (mSv)
- E_{US} = S/US population*

* 323 million in 2016

What is not included the NCRP 184?

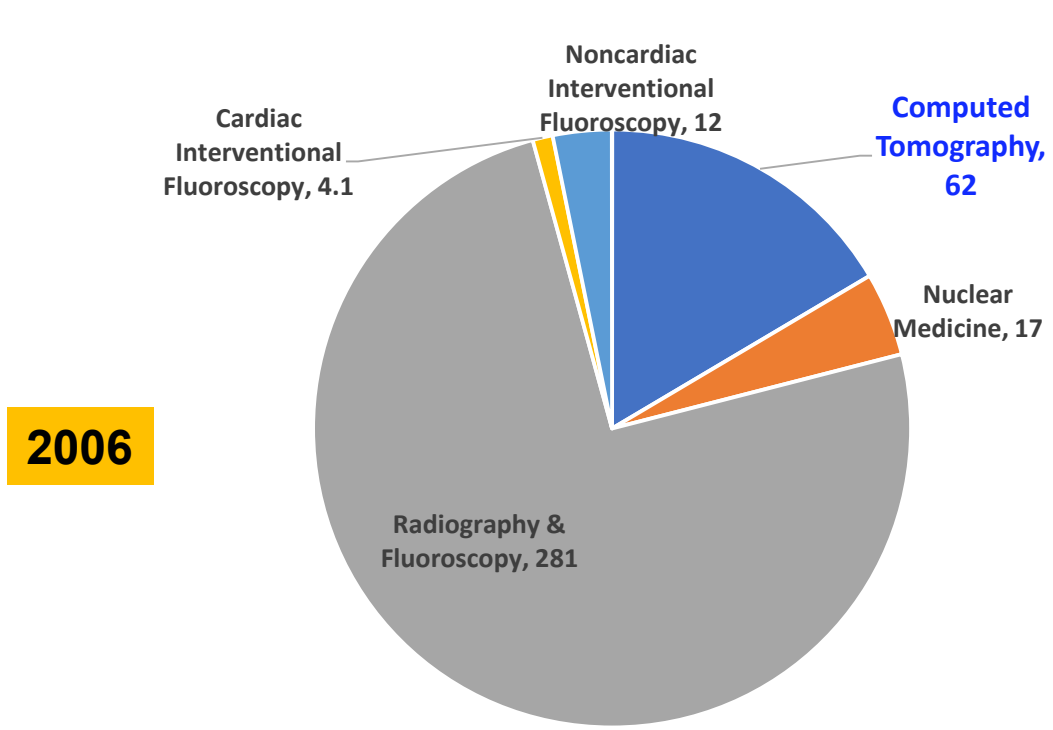
- Discussion of benefits or risks
- Discussion of appropriateness in medicine
- Radiation therapy treatment doses

Major and minor data sources

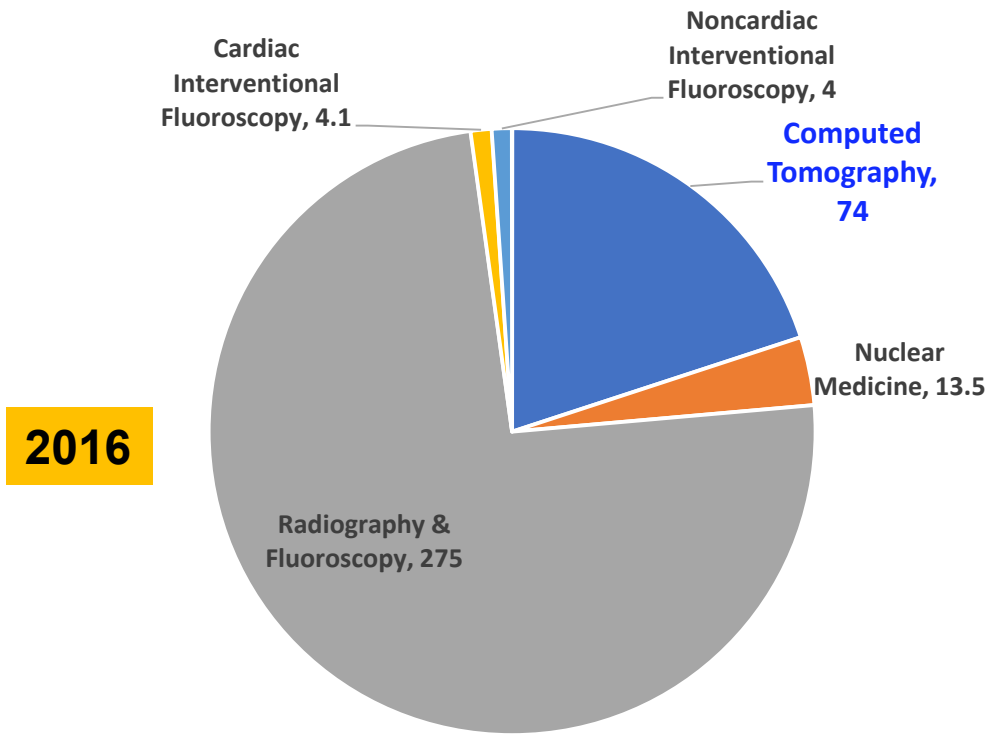
- Commercial (IMV Benchmark)
- Medicare payment data (2003-2016)
- VA Health Care System
- US FDA
- CRCPD
- State radiation programs
- Large hospitals
- American College of Radiology
- Industry sources
- Literature

Results

Number of Procedures: 2006 vs 2016



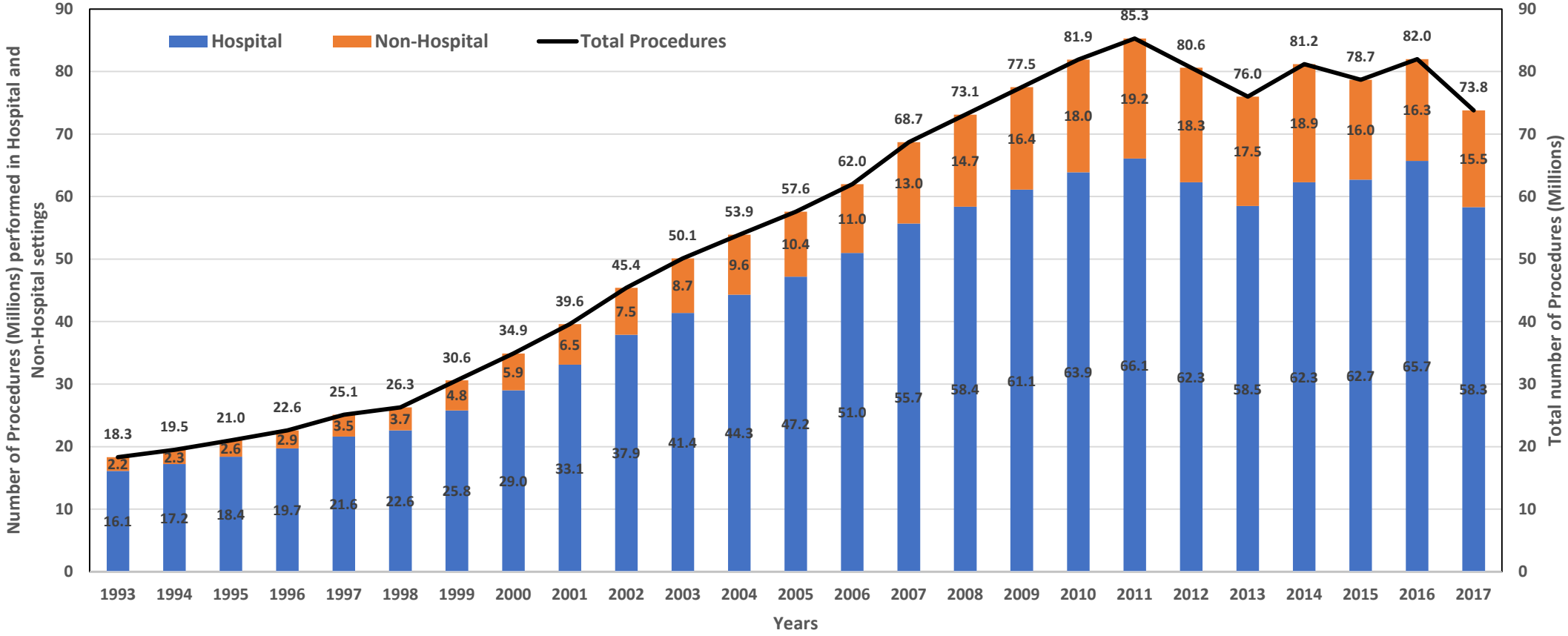
Total: 377 million



Total: 371 million

NCRP 184

Number of CT procedures*

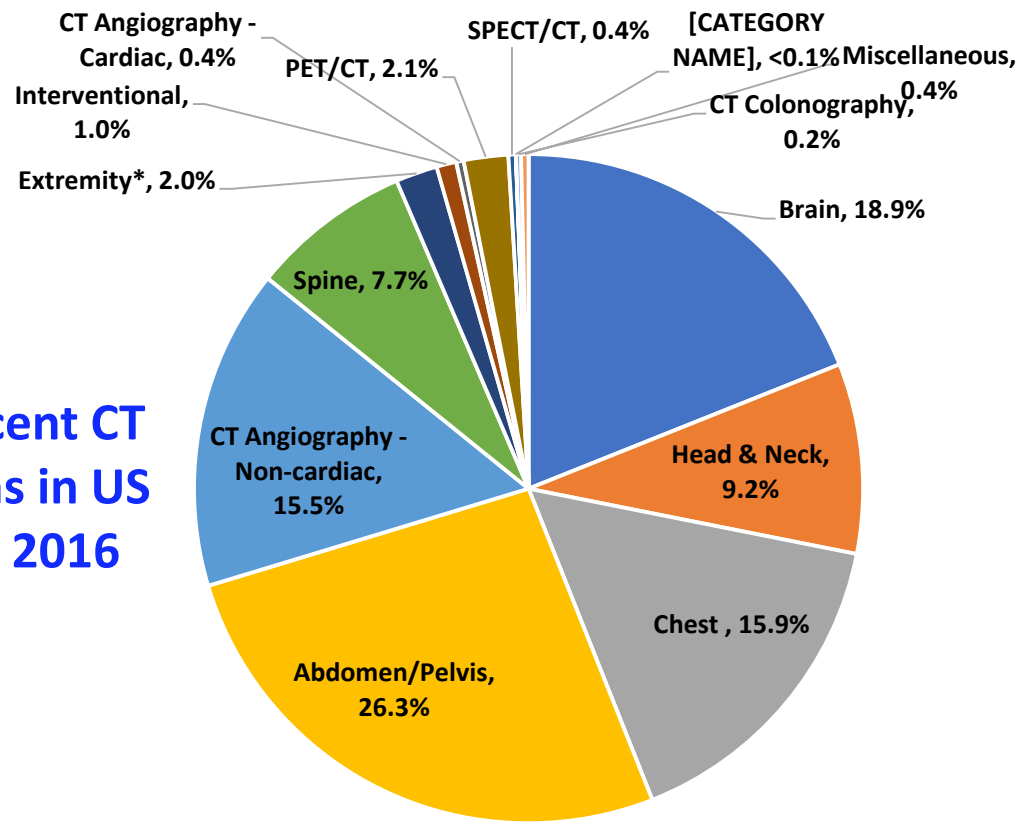


* 2018 IMV Report

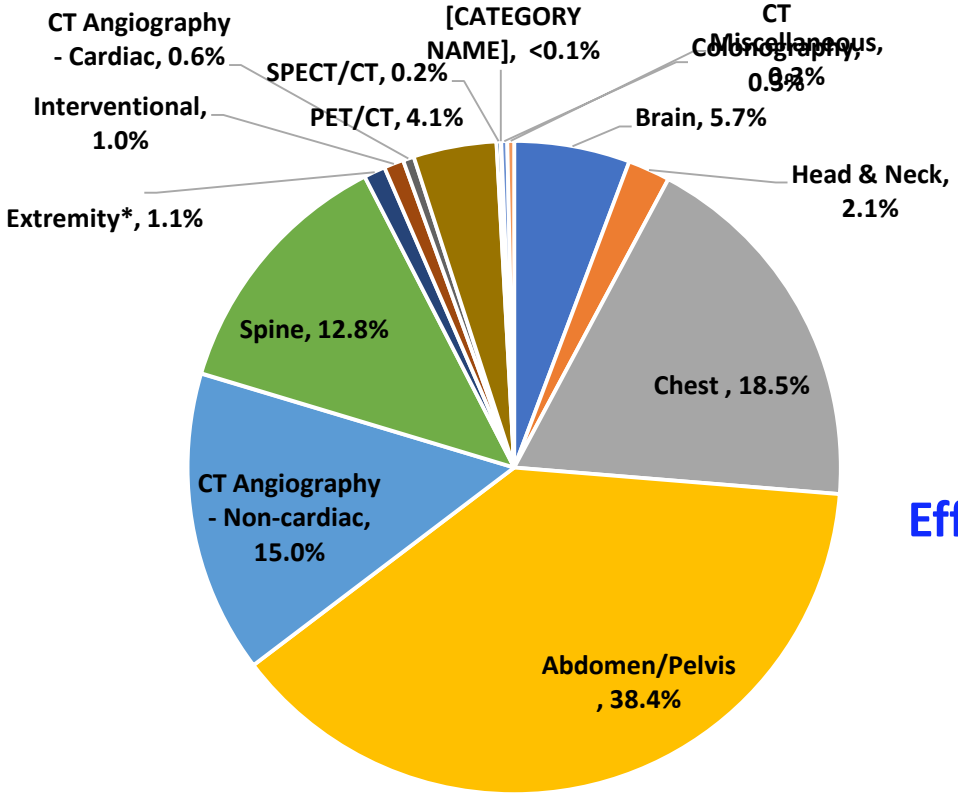
Increased by ~20% over 10 years!

NCRP 184

CT: Procedures vs Collective Dose*



Percent CT scans in US for 2016



Percent Collective Effective Dose

Collective Effective Dose
Effective Dose per Person

444,000 person-Sv
1.37 mSv

* For 2016 using ICRP 103 w_Ts

NCRP 184

E_{US} for CT

1.45 mSv (2006) vs 1.37 mSv (2016)

- CT procedures increased from 62 million (2006) to 74 million (2016)
- CT scans increased from 67 million (2006) to 84 million (2016)
- US population increased from 300 million (2006) to 323 million (2016)
- Average Individual Effective Dose (E_{US}) for CT decreased by ~6% per person in the United States

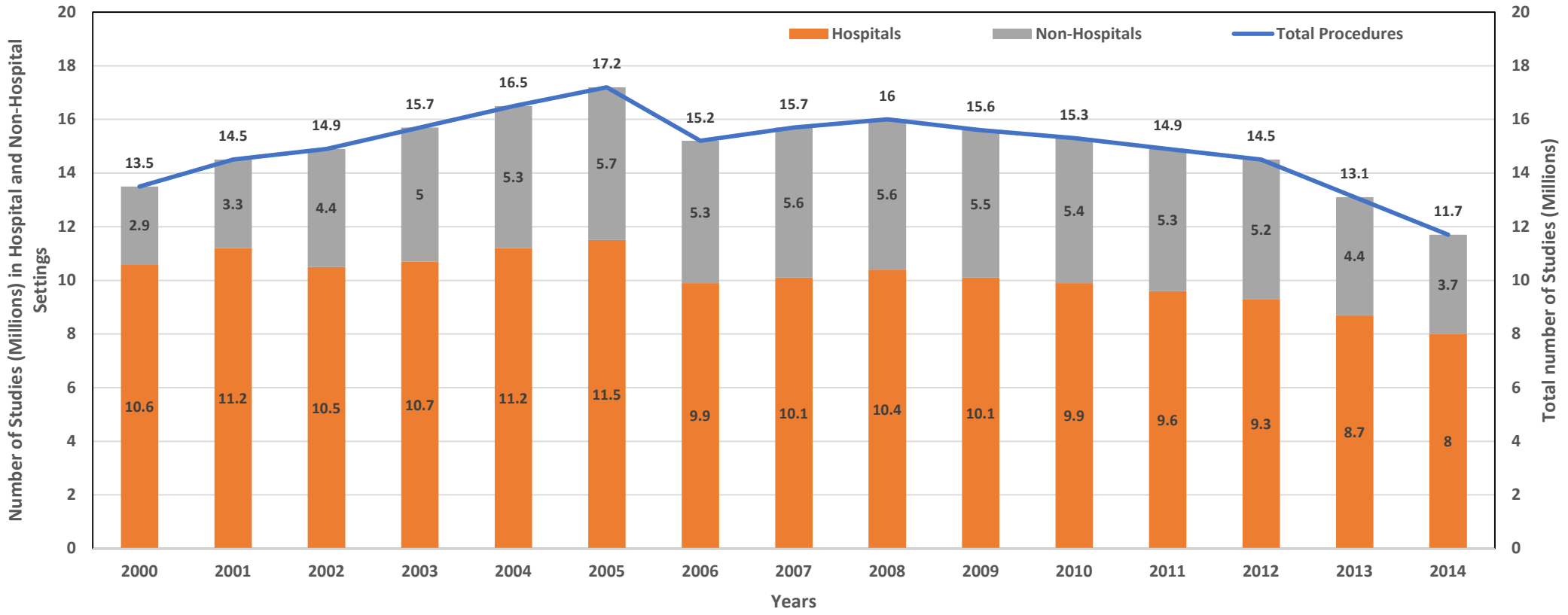
Probable causes for decrease in CT dose

- CT procedures higher by ~20 % than in 2006
- US population higher by 23 million than in 2006
- Decrease in effective dose per CT procedure is real!

- All this contributes towards ~6% reduction in individual effective dose

1.46 mSv (2006) vs 1.37 mSv (2016)

Number of Nuclear Medicine Procedures



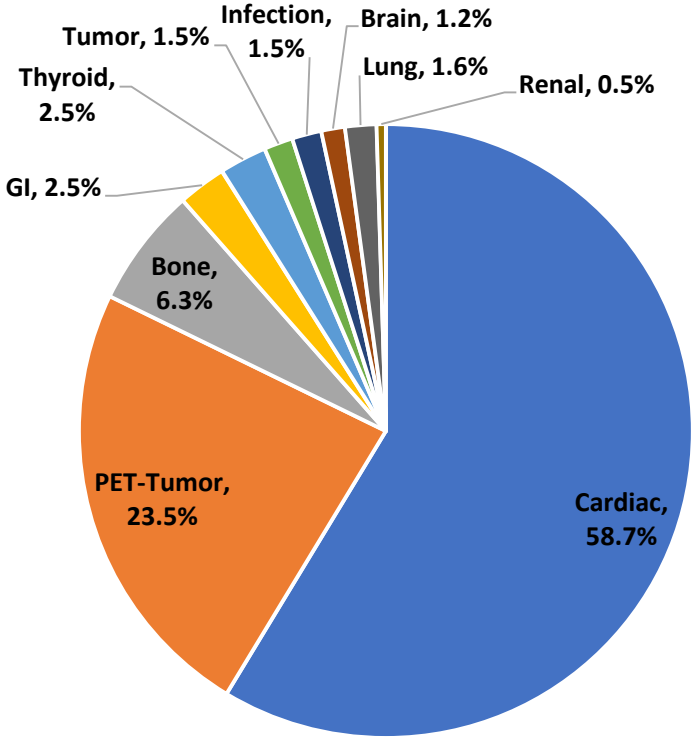
* 2015 IMV Report

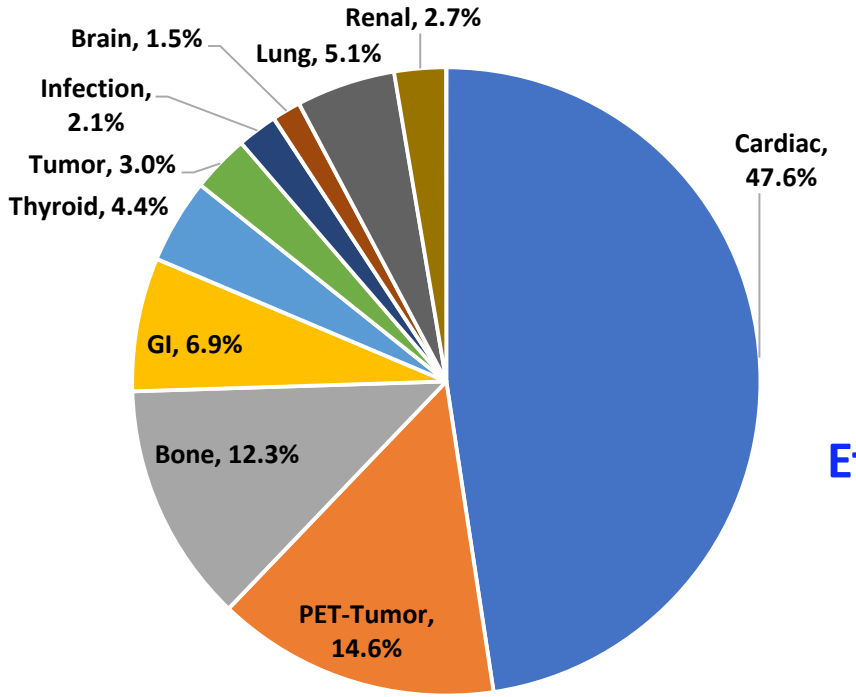
Decreased by ~20% over 10 years!

NCRP 184

Nuclear Medicine: Procedures vs Collective Dose*

Percent Nuclear Medicine Procedures in US for 2016





Percent Collective Effective Dose

Collective Effective Dose 106,000 person-Sv

Effective Dose per Person 0.32 mSv

* For 2016 using ICRP 103 w_Ts

NCRP 184

E_{US} for Nuclear Medicine

0.73 mSv (2006) vs 0.32 mSv (2016)

- Nuclear Medicine procedures decreased from ~17 million (2006) to 13.5 million (2016)
- However, there was substantial increase in PET/CT scans
- While US population increased from 300 million (2006) to 323 million (2016)
- Average Individual Effective Dose (E_{US}) for NM decreased by ~56% per person in the United States

Probable causes for decrease in NM dose

- Decrease in number of procedures: 20% lower than 2006
- Use of radioactivity injected after optimized for weight
- Use of new models to estimate effective dose

- All 3 together may have contributed towards >50% reduction in individual effective dose

0.73 mSv (2006) vs 0.32 mSv (2016)

Impact of Tissue Weighting Factors
ICRP 60 vs ICRP 103

- **Effective dose per person estimated using both ICRP 60 and 103 weighting factors, in order to compare results with NCRP 160**
- **Effective dose per procedure**
  - **Decrease for procedures that includes pelvis region**
  - **Increase for procedures that includes chest region**

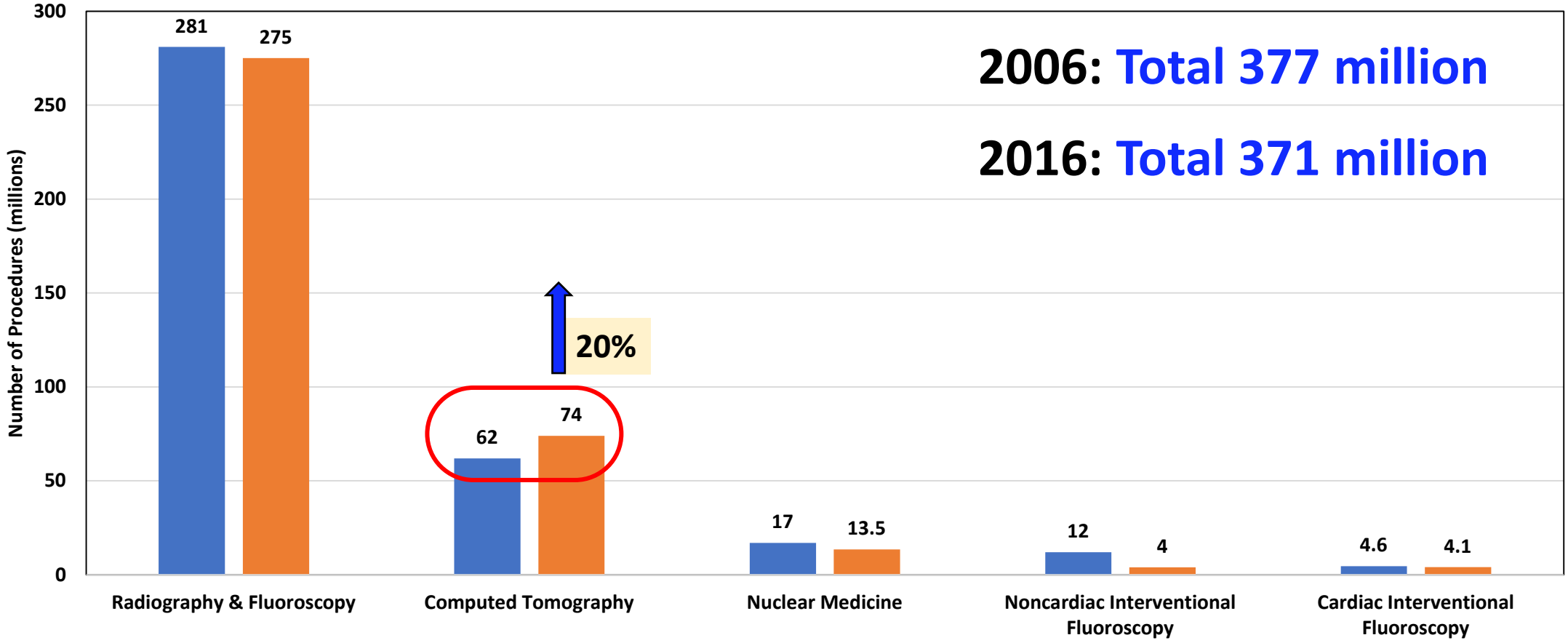
Effective doses for CT exams

(Impact of ICRP 103)

Type of CT Scan	Eff dose (mSv) ICRP 60	Choice of E_{103}/E_{60}	Eff dose (mSv) ICRP 103
Brain	1.9	0.84	1.6
Head & Neck	1.4	0.87	1.2
Chest CT	5.4	1.14	6.1
Cardiac CT	7.6	1.14	8.7
Abdomen & Pelvis	8.7	0.88	7.7
CT Colonography	7.5	0.88	6.6
Spine	9.2	0.96	8.8
CT Angiography (non-cardiac)	5.4	0.94	5.1
Interventional	5.2	0.96	5.0
PET-CT	10.0	1	10.0

NCRP 184

Number of Procedures: 2006 vs 2016



NCRP 184

Estimated Procedures, Collective Effective Doses and Average Individual Effective Dose by modality for 2016*

	Procedures (millions)	%	S (person-Sv)	%	$\underline{E}_{US}$ (mSv)
Computed Tomography	74	20	440,000	63	1.37
Nuclear Medicine	13.5	4	106,000	15	0.32
Radiography & Fluoroscopy	275	74	71,000	10	0.22
Cardiac Interventional Fluoroscopy	4.1	1	42,000	6	0.13
Non-cardiac Interventional Fluoroscopy	4.0	1	40,000	6	0.12
Total	371		703,000		2.16

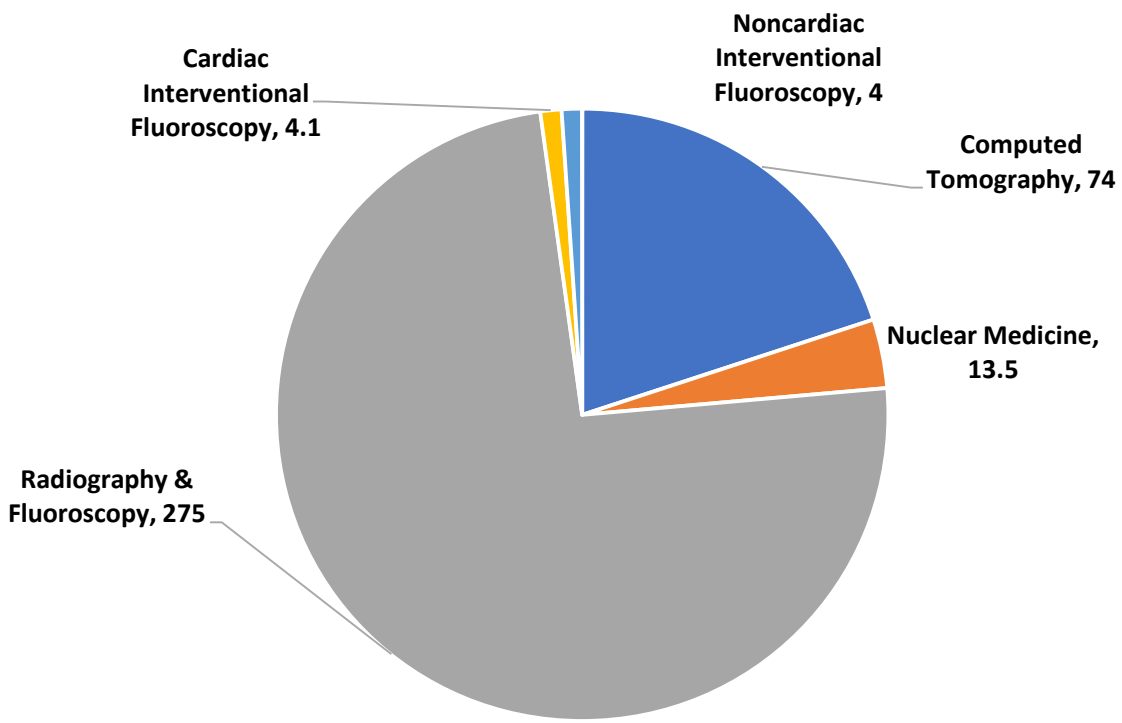
24%

78%

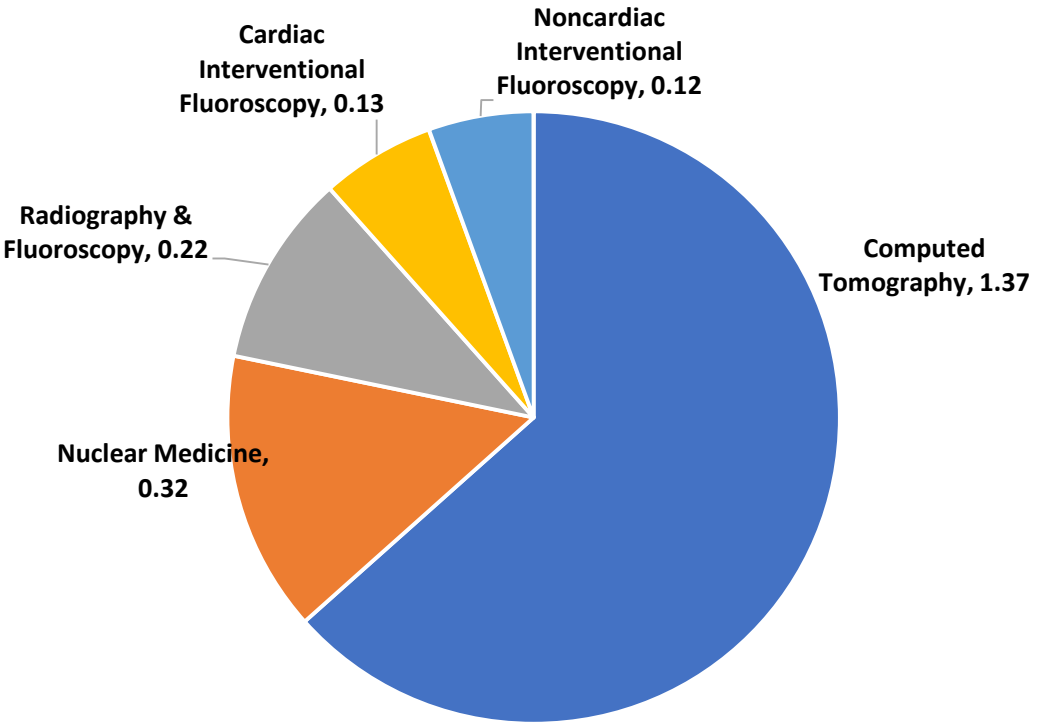
* Based on ICRP 103 tissue-weighting factors

NCRP 184

Number of Procedures vs Average Individual Effective Dose* for US population in 2016



Procedures (Millions)

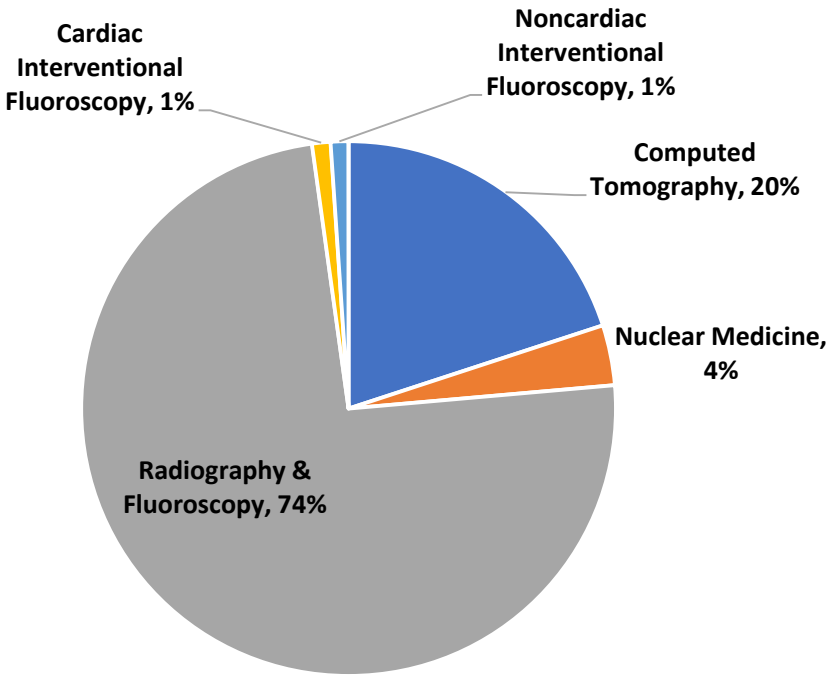


Average Individual Effective Dose (mSv)

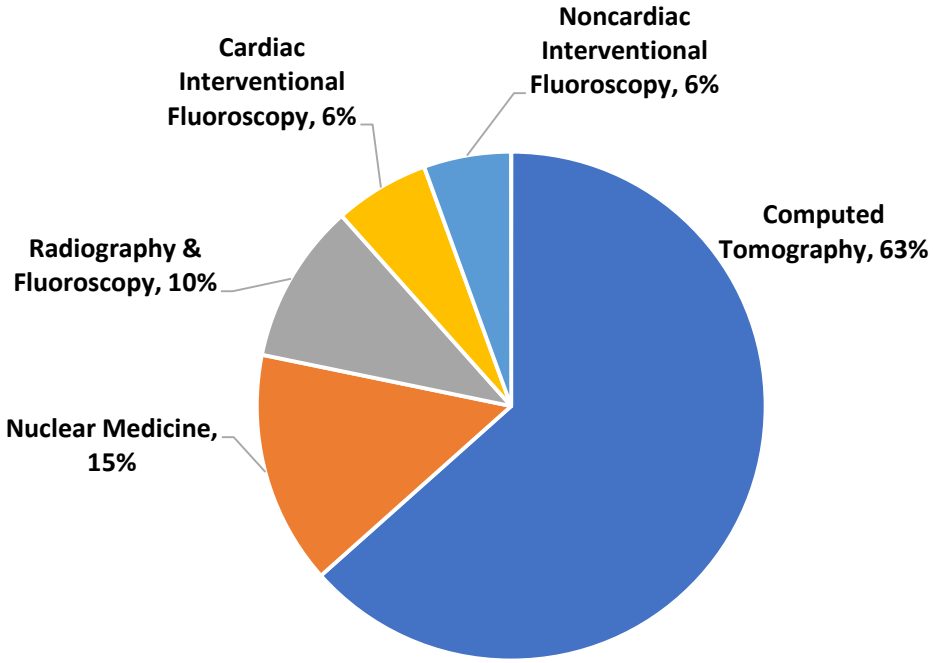
*using ICRP 103 tissue weighting factors

NCRP 184

Perecent Procedures vs Average Individual Effective Dose for US during 2016



% Radiation Imaging Procedures in US during 2016



% Average Effective Dose per capita for US population in 2016

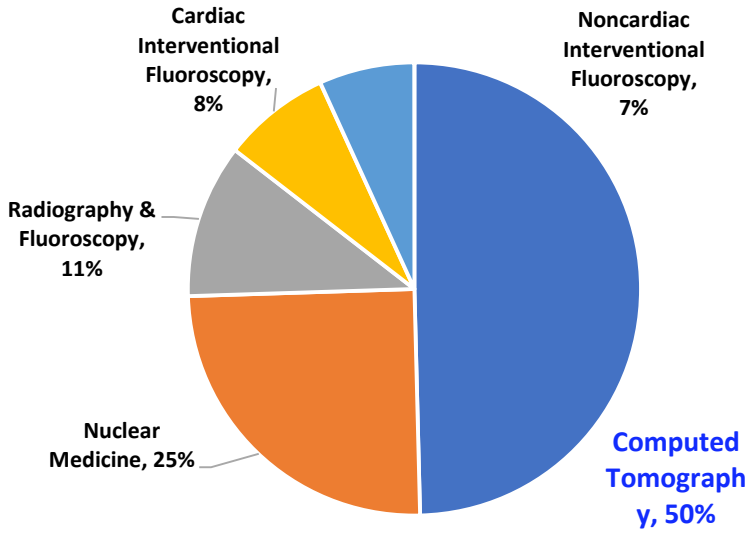
*using ICRP 103 tissue weighting factors

*values are not per patient, but per person in the US population

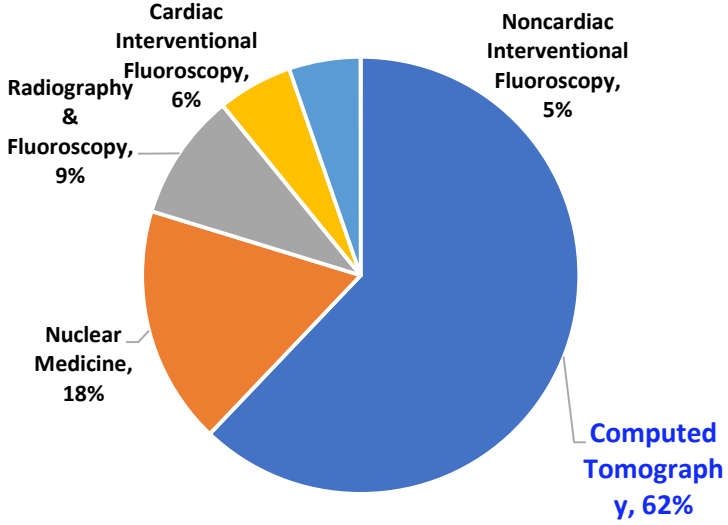
NCRP 184

Results

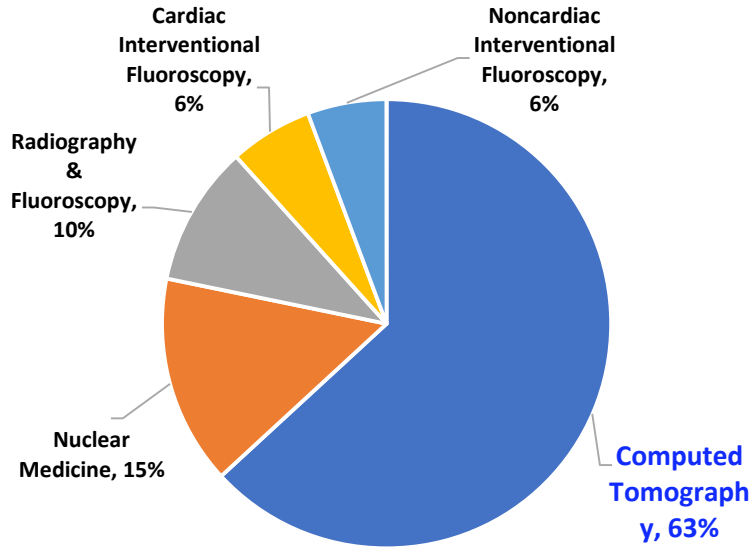
2006_{ICRP60}
885,000 person-Sievert
2.92 mSv/person



2016_{ICRP60}
755,000 person-Sievert
2.33 mSv/person



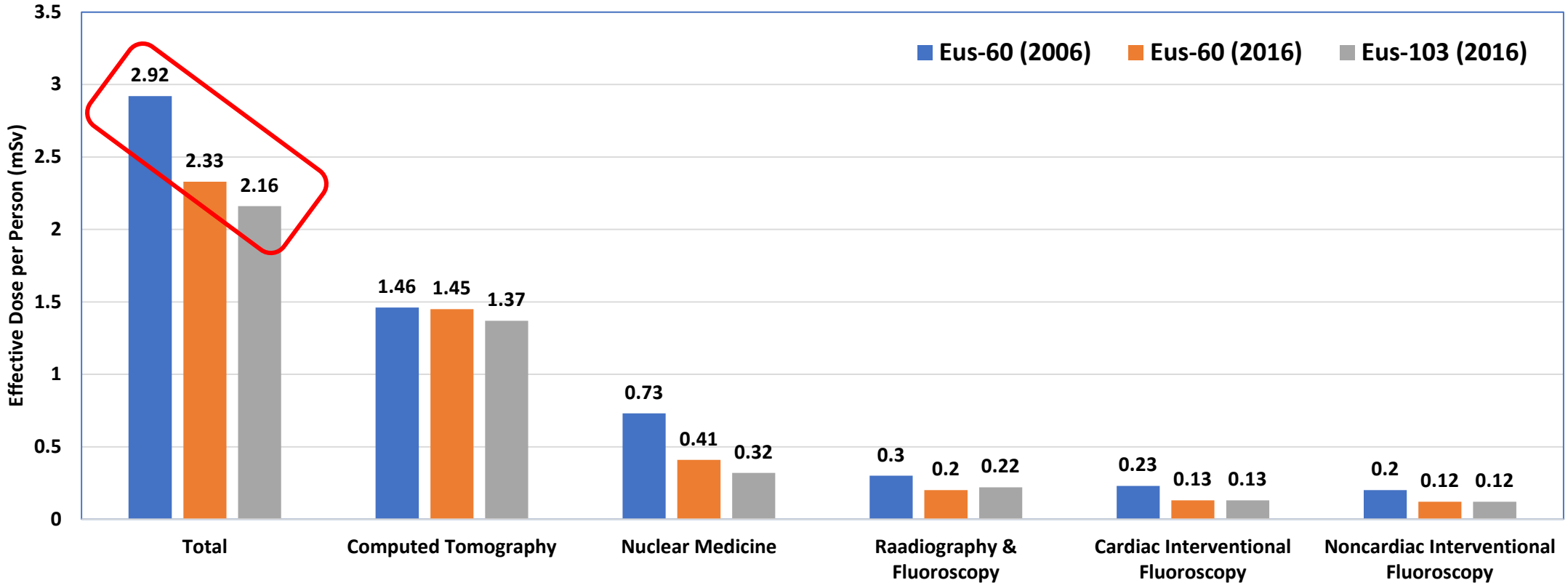
$2016_{ICRP103}$
717,000 person-Sievert
2.16 mSv/person



NCRP 184

Average effective dose per person for US Population*

(Comparison between 2006 and 2016 computed with ICRP publications 103 and 60 Tissue Weighting Factors)

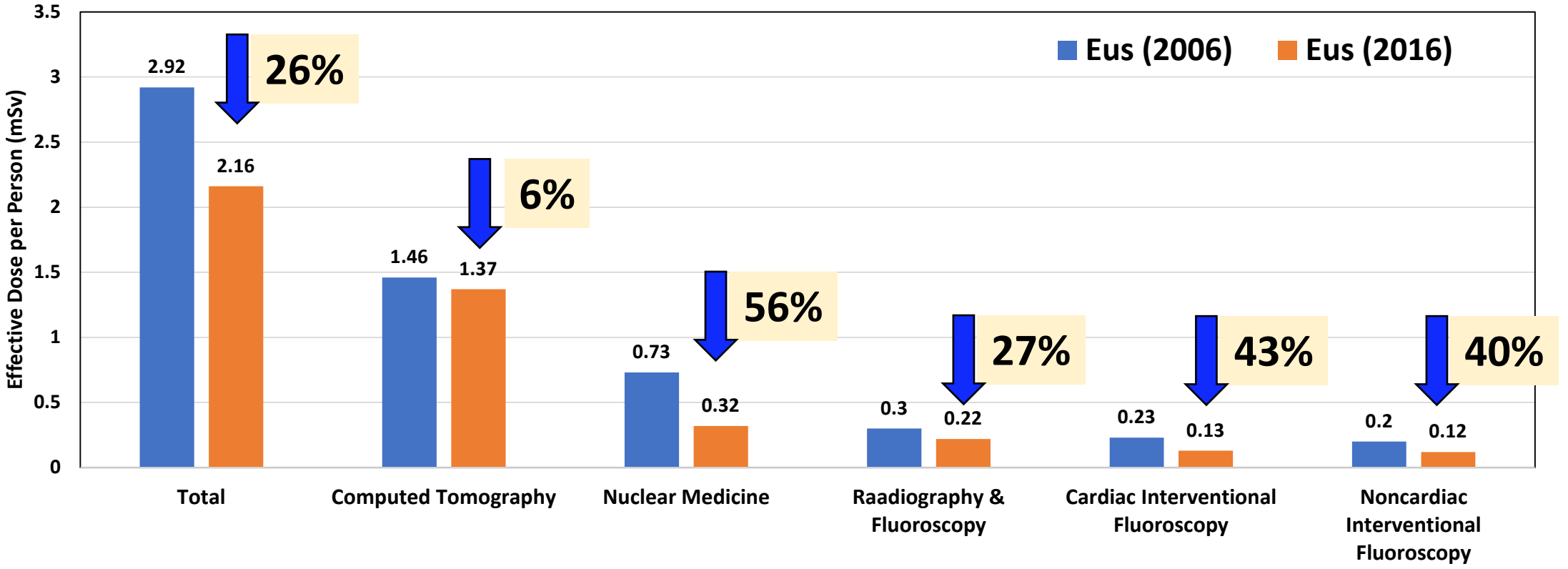


*values are not per patient, but per person in the US population

NCRP 184

Average effective dose per person for US Population*

2006 vs 2016



*values are not per patient, but per person in the US population

NCRP 184

Limitations

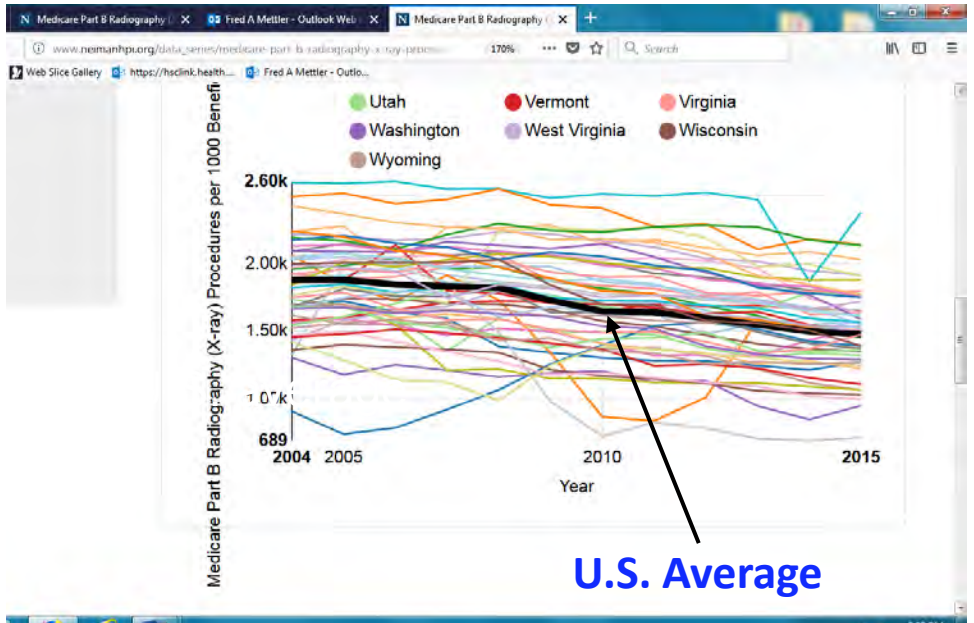
- Effective dose values varies widely
- Used published Diagnostic Reference Levels (DRLs), and other dose values published in literature
- In the report for CT, the ACR DIR data was used for CT dose computation – and cross verified with published results

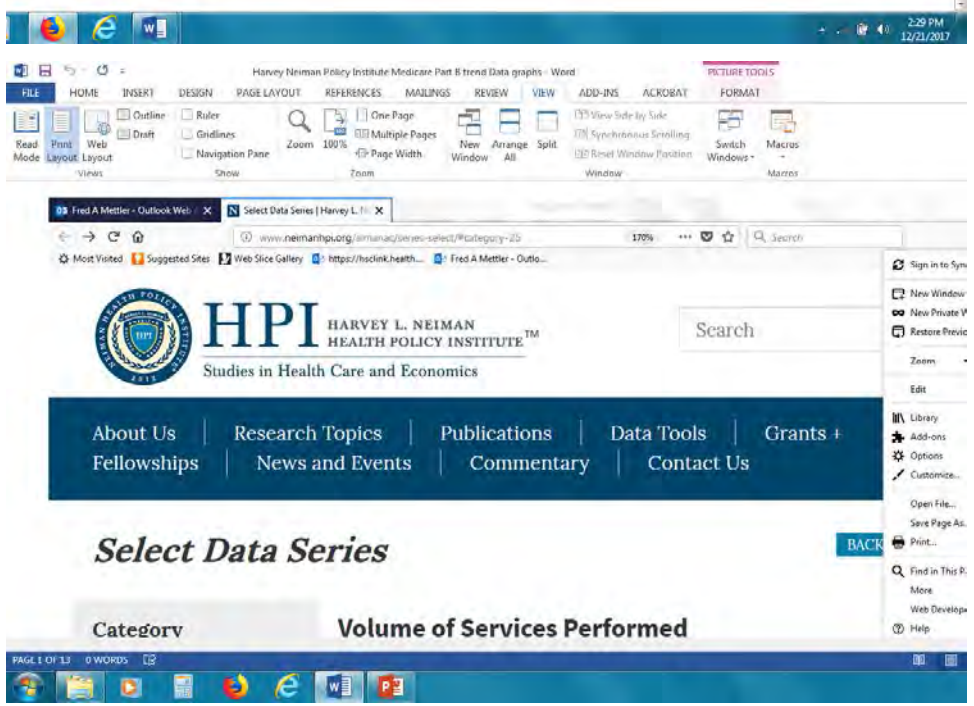
Challenges

- Tissue weighting factors changed from the time NCRP 160 was published
- ICRP 103 published in 2007
- Not very detail procedure numbers available for interventional procedures
- Doses per interventional procedures varies by a wide margin

Trend & Challenges in radiography

- Wide differences in data based on scanners
- Counts by more than just procedure types for meaningful measurement of exposure was not readily available
- Radiography done in locations where procedures/counts are not always accessible/reliable, such as dentist offices and chiropractor offices contribute to uncertainty in numbers





Summary

Decrease in Medical Radiation Exposure to Patients in the United States may be due to:

- **Advances in medical imaging technologies**
- **Optimization of imaging protocols and accreditation of modalities**
- **Increase awareness about radiation by Image Gently®, Image Wisely®, Choosing Wisely® and others**
- **Medical community can continue to leverage benefits of radiological procedures for patients in the United States while lowering dose**

Key Messages

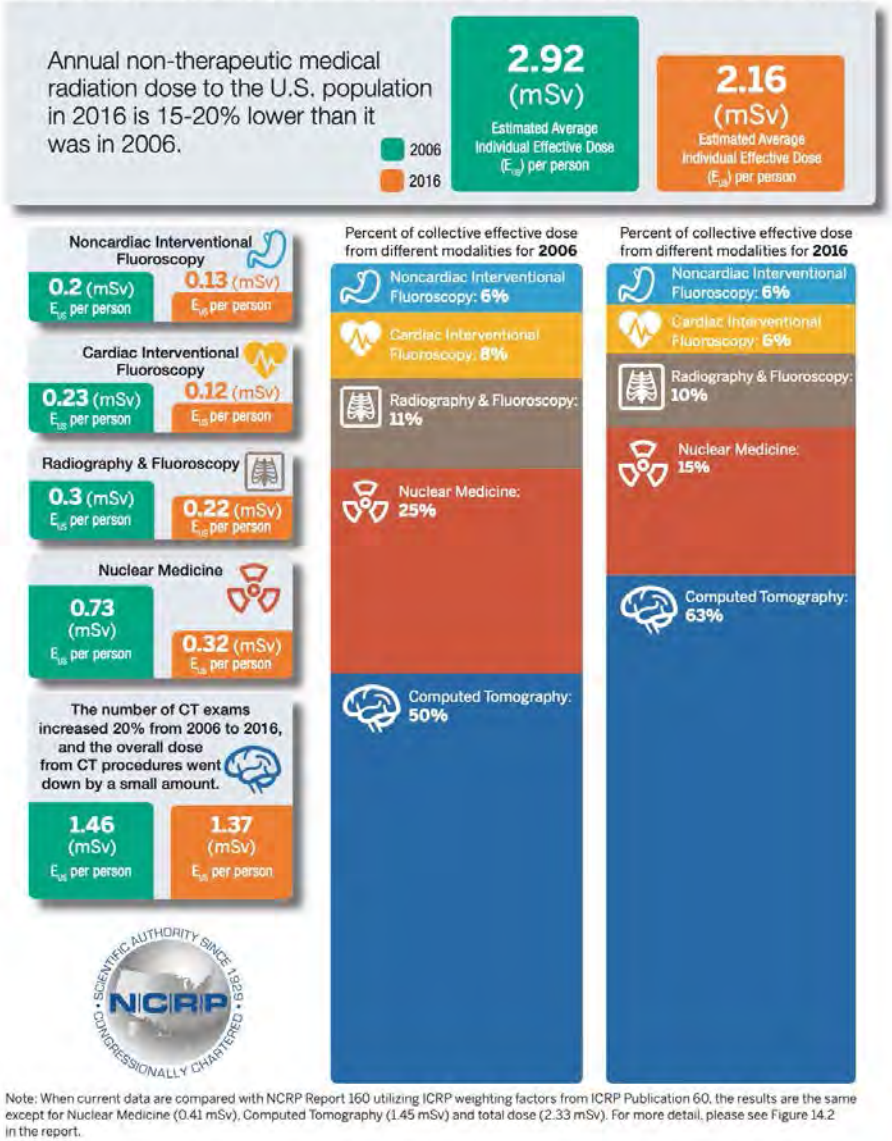
Compared to 2006 (NCRP 160), 2016 data (NCRP 184) demonstrates that medical radiation dose to US population

- **Decreased by ~15-20% across all x-ray imaging modalities**
- **Decreased by >50% for Nuclear Medicine, predominantly due to decrease in procedures**
- **Decrease by ~6% for Computed Tomography, in-spite of 20% increase in CT procedures**

The Dream Team

NCRP PAC 4-9

U.S. Medical Radiation Doses Are Decreasing



Note: When current data are compared with NCRP Report 160 utilizing ICRP weighting factors from ICRP Publication 60, the results are the same except for Nuclear Medicine (0.41 mSv), Computed Tomography (1.45 mSv) and total dose (2.33 mSv). For more detail, please see Figure 14.2 in the report.

NCRP 184

Estimating Lung Doses to Medical Workers

Craig Yoder, Ph.D.
Lawrence Dauer, Ph.D.
John Boice, Sc.D.
Helen Grogan, Ph.D.

Topics to be Discussed

- Role of medical workers in the Million Person Study (MPS).

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Topics to be Discussed

- Role of medical workers in the Million Person Study (MPS).
- Approach recommended in NCRP Report 178.
- Factors influencing the estimate of average or mean organ/tissue dose, D_T.
- Radiation exposure scenarios for medical workers.
- Issues encountered using personal monitoring results.

Role of Medical Workers

- Cohort containing large percentages of females.
- Atomic bomb survivor data indicates a near three fold increase in lung cancer for females.
- Impacts NASA risk analyses for extended space travel such as to Mars.

NCRP Report 178 Guidance

- Establish an annual estimate of the mean organ dose, D_T, using conversion coefficients that relate the personal dose equivalent, $H_P(10)$ to D_T.
- Establish radiation exposure scenarios that permit the use of the coefficients.
  - Radiations and energies;
  - Geometries of exposure;
  - Use of radioprotective shielding, e.g. leaded aprons.

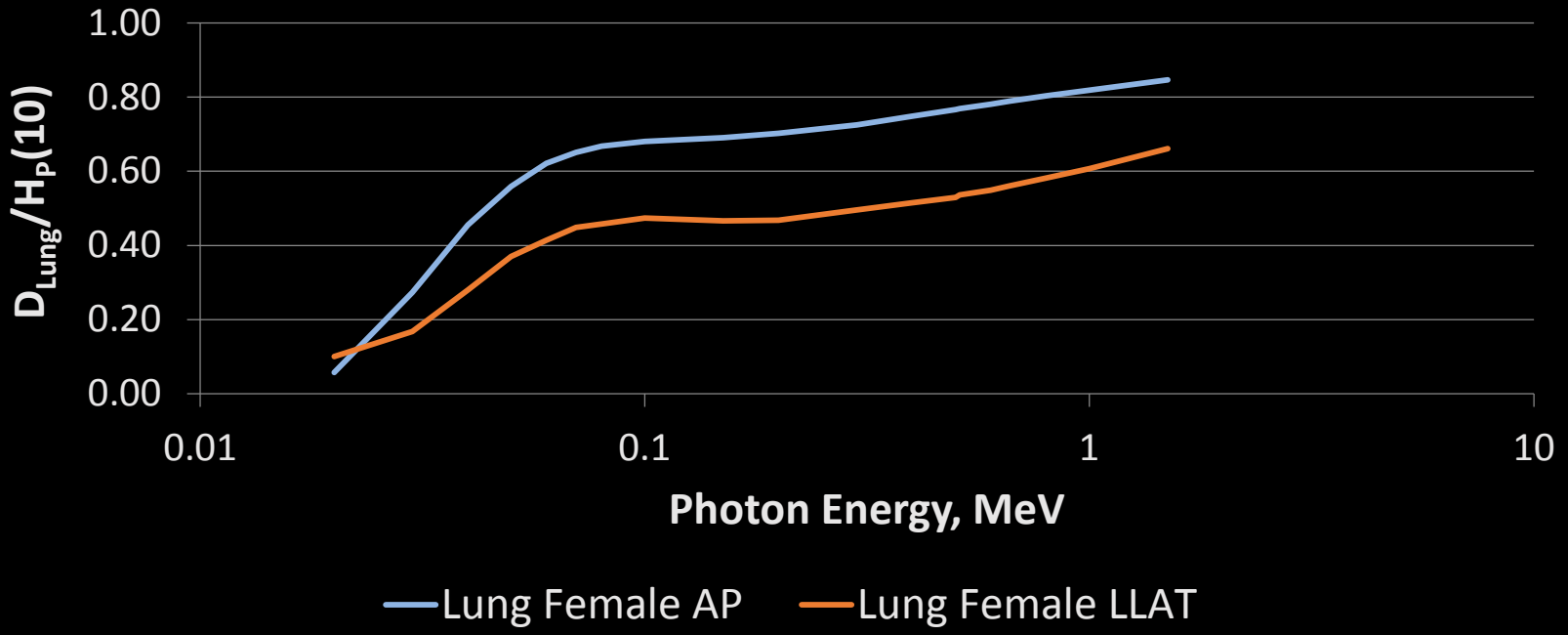
Selection of the Medical Worker Group

- Selection based on accumulated dosimeter values.
- Timeframe extends from 1968 through 2015
- Annual dose values from 1977 through 2015
- Evidence of an unknown selection bias for the lowest exposed subjects.

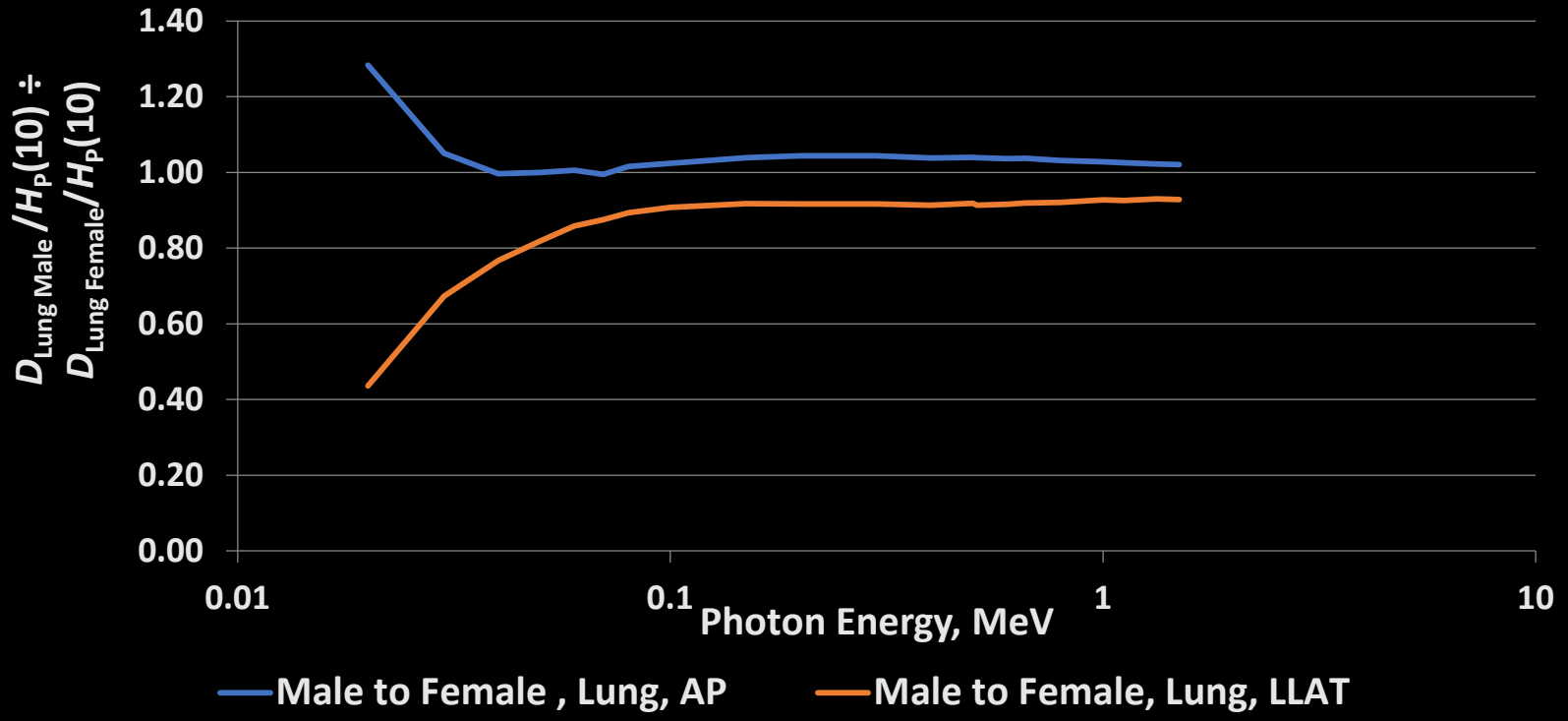
Characteristics

- 101,253 subjects: 51,449 females; 49,804 males.
- 853 female subjects with lung doses above 50 mGy.
- 1,567 male subjects with lung doses above 50 mGy.
- Physicians dominate the higher dose population.

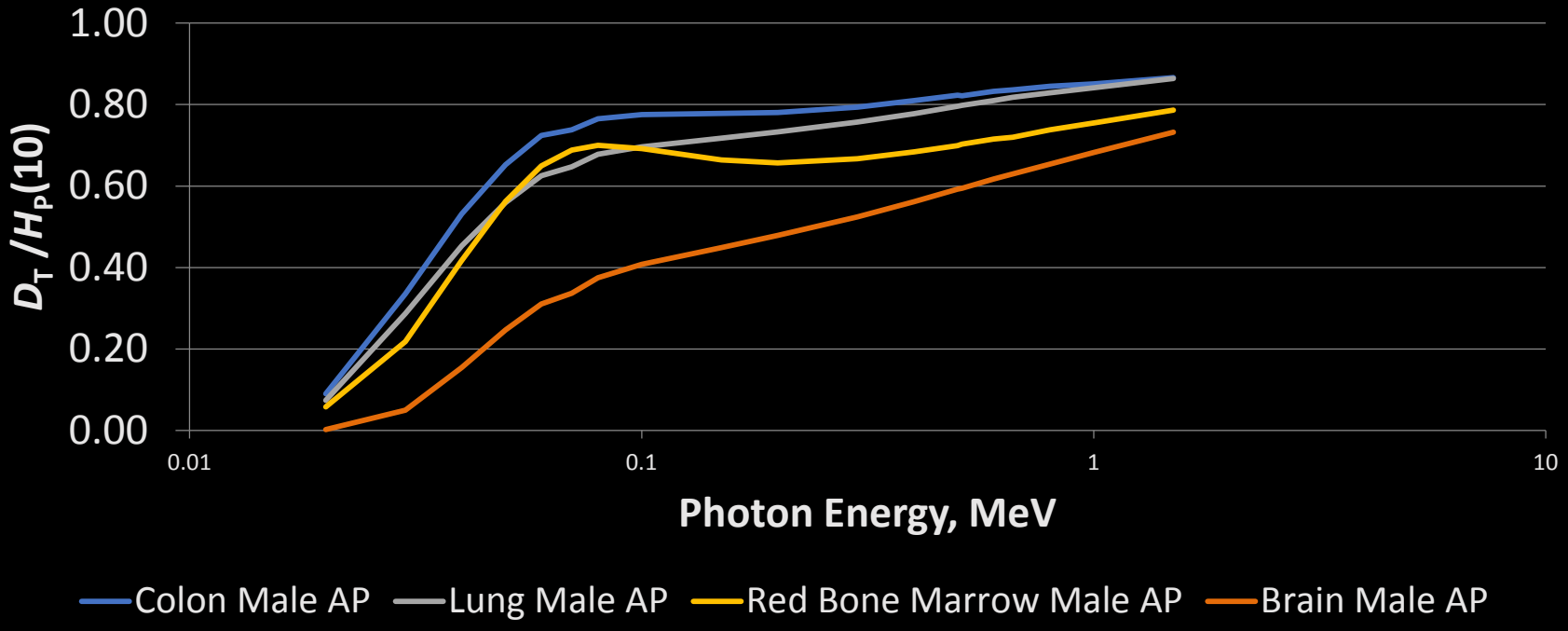
Relationship between Female Lung Dose and $H_P(10)$.



Comparing Male to Female Lung Dose Conversion Coefficients



Relationships between D_T for Other Organs and $H_P(10)$.



Radiation Exposure Scenarios

1. Use of x rays without radioprotective clothing.
2. Use of x rays with radioprotective clothing.
3. Nuclear medicine before and after extensive introduction of Positron Emission Tomography, PET.
4. Radiation therapy with emphasis on brachytherapy sources.

Influence of photon energy specification

- Detailed spectra or mean photon energy yield similar conversion factors. Half Value Layer yields lower values.
- Peak generating voltage potential and exposure assumptions have marginal influence.
- Nuclear medicine and radiation therapy conditions can be combined into a single set of conversion factors.

Accounting for the Effect of Radioprotective Clothing.

- How to estimate $H_P(10)$ under a radioprotective apron?
- Examined paired dosimeter results from under and over apron monitoring from 2009, 2012 and 2015. Protection factor of 20 selected.
- Recent complication from the use of effective dose equivalent formulas allowed for fluoroscopic based procedures.

Conversion Coefficients for Selected Organs

Scenario	Female Lung	Male Lung	Female Red Bone Marrow	Male Red Bone Marrow	Female Brain	Male Brain
X Rays NO Apron	0.45	0.46	0.48	0.43	0.18	0.17
X Rays WITH Apron	0.57	0.56	0.65	0.58	0.32	0.28
Nuclear Medicine/ Radiation Therapy	0.73	0.74	0.71	0.68	0.54	0.53

Personal monitoring data issues.

- Number of institutions involved and relating doses across institutions.
- Using ancillary information to assign workers to radiation exposure scenarios.
- Variations in measured quantities over the time span of interest – 55 years.
- Regulatory requirements and variations.

Closing Comments

- Personal monitoring data from commercial services can be an adequate source of data for medical workers.
- Cohort selection, modelled conversion factors and regulatory effects introduce biases.
- Differences between male and female conversion coefficients are generally modest except for a few organs.

NCRP SC 1-27
Sex-Specific Differences in Lung Cancer Radiation Risks

HPS MIDYEAR
HEALTH PHYSICS SOCIETY, JAN 2020

Lawrence T. Dauer
Associate Attending Physicist
Memorial Sloan Kettering Cancer Center
Department of Medical Physics / Department of Radiology
NCRP Board, Million Person Study Scientific Coordinator

Vanderbilt-Ingram Cancer Center

NCRP · SCIENTIFIC AUTHORITY SINCE 1929 · CONGRESSIONALLY CHARTERED

ORISE

OAK RIDGE National Laboratory

Memorial Sloan Kettering Cancer Center

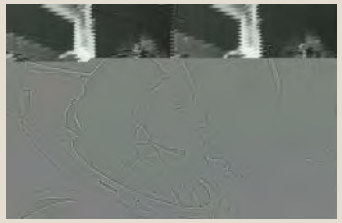
NASA Relevance – Current and Future Missions

Women are Not Able to Spend as Much Time in Space as Men Due to Differences in Lifetime Estimates of Cancer Risk

Kristina Rex interviews Jessica Meir
Jessica was in 2013 Group 21 Astronaut Class

Cancer type – Atomic Bomb Survivors	Female to Male Ratio of ERRs
All solid cancers	2.1
Lung	2.7

Anna Fisher
Nov 1984
First Mom in Space



Boice, *Relevance of the MPS to research needs for NASA and space exploration*. Int J Radiat Biol 2019

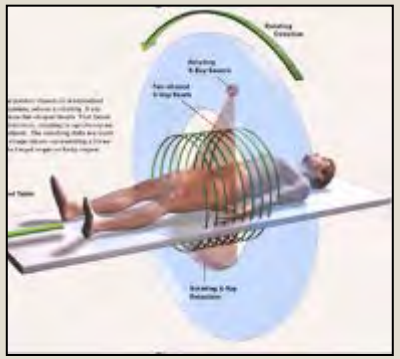
Million Person Study Relevance
U.S. Radiation Workers and Veterans

Acute and High versus Chronic and Low

We know something about the effects of radiation when much is received all at once, but there is a significant gap in knowledge when dose is low and it is received over years.

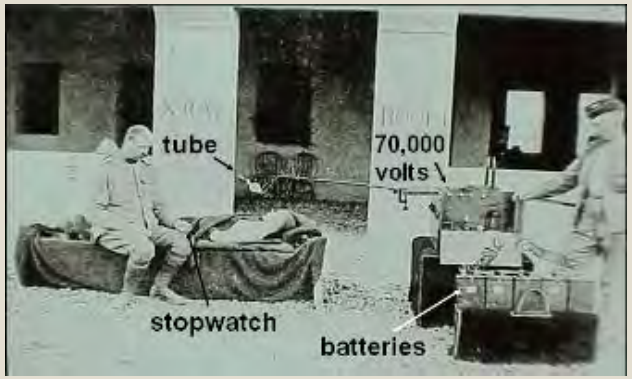
A need to accurately assess risks related to:

Medicine



Accident or Terrorism

Occupation



Environment

Protection Guidelines, Compensation, Risk Assessment/Projection, Representativeness, Specific Relevance, Responsibility to Workers and their Families

MPS Sponsors – A National Effort
Past and Present

Vanderbilt-Ingram Cancer Center

ENERGY.GOV
Office of Health, Safety and Security

UNITED STATES
DEPARTMENT OF VETERANS AFFAIRS

EPA

NATIONAL CANCER INSTITUTE

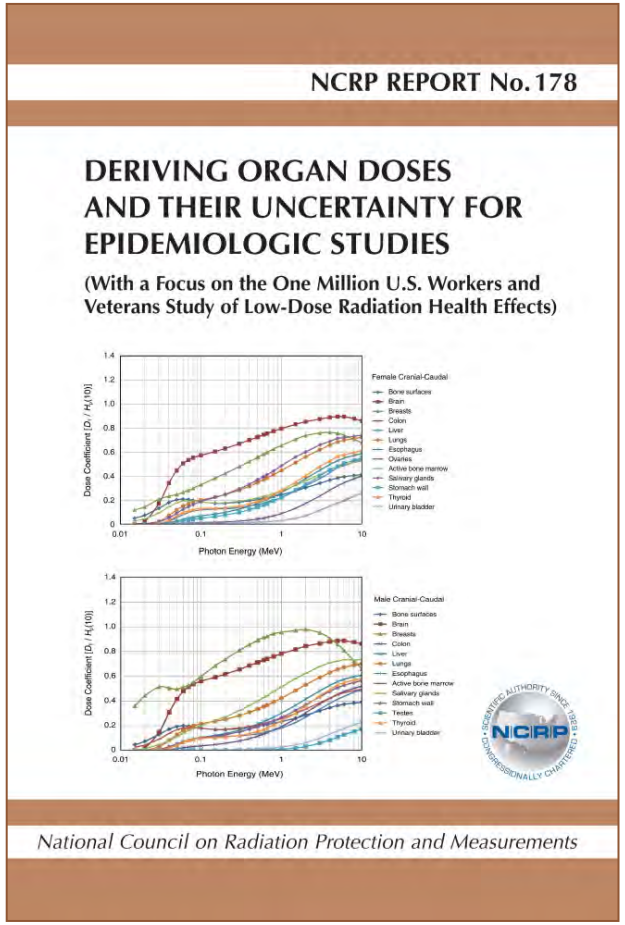
U.S.ARMY

UNITED STATES AIR FORCE

Current: DOE, NASA, CDC, US Navy and in kind from others

NIAID

Dosimetry is Key to Quality Epidemiology



NCRP Report No. 178, *Deriving Organ Doses and Their Uncertainty for Epidemiologic Studies (with a Focus on the One Million U.S. Workers and Veterans Study of Low-Dose Radiation Health Effects)*

André Bouville, *Chair*
Richard E. Toohey
Co-Chair
Lawrence Dauer
Co-Chair



Dose Estimation in Epidemiology

- Estimation of Absorbed Doses (**Gy**) for the organ or tissue of interest (RBM, lung, breast, brain, etc.)
  - External – for the year of exposure.
  - Internal – for the year of exposure and for each of the following 49 years.
  - Addition of External + Internal components of the absorbed dose to the organ or tissue of interest.
- Differences with regulatory way:
  - Aim for realistic dose estimates, not 'lower than limits'.
  - Direct - no use of weighting factors ($\not{W}_R$ and $\not{W}_T$).
  - Annual absorbed doses to organs/tissues with evaluation of uncertainties.

Million Person Study Population

Boice et al. *The Million Person Study, Whence it Came and Why*. IJRB March 2019

Robert Oppenheimer, General Leslie Groves, Enrico Fermi, Hans Bethe, Theodore Hall

Sub-Cohort	Number
DOE - Manhattan Project	~360,000
DOD - Atomic Veterans	115,000
Industrial Radiographers	130,000
Medical & Related	~110,000
NRC – Early Nuclear Utility Workers	~135,000
Other cohorts	+++
TOTAL	>1,000,000

Appropriations Bills (PUBLIC LAW 115–31 & 115-141) – 'line items' that specify support for MPS

One Million People

Papal visit to Philadelphia, 2015

Comparison with Atomic Bomb Survivor Study

External Dose (mSv)	Million Worker Study Preliminary Estimates	Atomic Bomb Survivor Study (Ozasa 2012)
< 5 mSv	6,507,275	38,509
5 -	963,652	29,961
100 -	53,211	5,974
200 -	24,456	6,356
500 -	4,120	3,424
1000 -	1,007	1,763
> 2000	211	624
Total	7,553,932	86,611

~ 83K > 100 mSv, or 4x more high dose subjects.

Women in the Million Person Study

☑ Nuclear Power	5,000
☑ Industrial Radiographers	13,000
☑ Mound	2,000
☑ Los Alamos	6,629
Rocky Flats	5,000
Hanford	8,000
K-25 (ORNL)	9,000
Other DOE	40,000
TEC (Oak Ridge)	13,000
Medical / other	60,000
Total already…	>160,000

Number of adult Japanese female atomic bomb survivors in 1945 ~30,000

Boice et al. *The Million Person Study, Whence it Came and Why*. IJRB 2019

INTERNATIONAL JOURNAL OF RADIATION BIOLOGY
https://doi.org/10.1080/09553002.2018.1547441

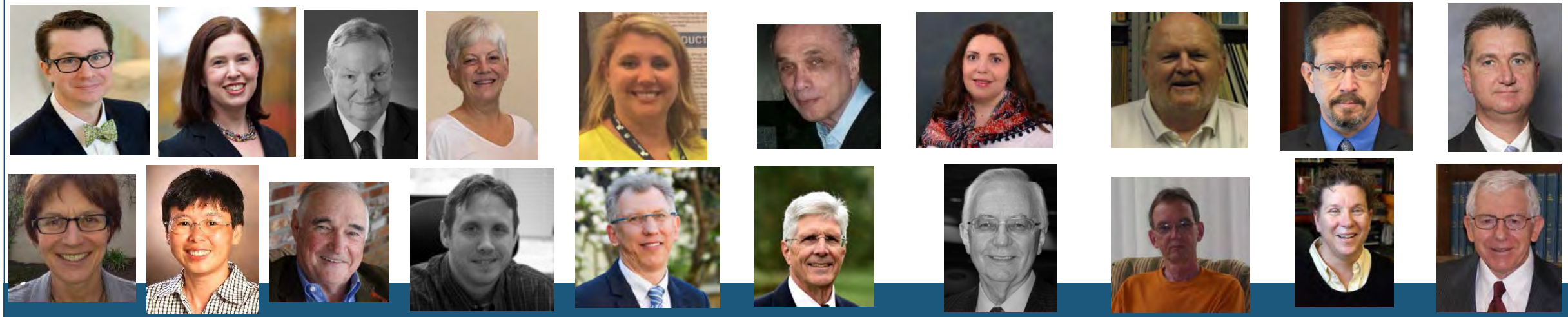
Taylor & Francis
Taylor & Francis Group

ORIGINAL ARTICLE

Sex-specific lung cancer risk among radiation workers in the million-person study and patients TB-Fluoroscopy

John D. Boice, Jr.[a,b], Elizabeth D. Ellis[c], Ashley P. Golden[c], Lydia B. Zablotska[d], Michael T. Mumma[e] and Sarah S. Cohen[f]

[a]National Council on Radiation Protection and Measurements, Bethesda, MA, USA; [b]Division of Epidemiology, Department of Medicine, Vanderbilt-Ingram Cancer Center, Vanderbilt Epidemiology Center, Vanderbilt University School of Medicine, Nashville, TN, USA; [c]Oak Ridge Associated Universities, Oak Ridge, TN, USA; [d]School of Medicine, University of California, San Francisco, San Francisco, CA, USA; [e]International Epidemiology Institute, Rockville, MA, USA; [f]EpidStat Institute, Ann Arbor, MI, USA



Sex-specific Lung Ca Risks at 100 mGy
Hazard Ratio, HR=1.00 no association

Million Person Study To date…	FEMALES	MALES
Cohort	HR at 100 mGy (95% CI)	HR at 100 mGy (95% CI)
Mallinckrodt (U Processing)	na	0.95 (0.81, 1.12)
Atomic Veterans	na	1.04 (0.90, 1.21)
Mound (polonium - Be)	0.86 (0.48, 1.55)	1.01 (0.99, 1.03)
Nuclear Power Plant (NPP)	1.80 (0.86, 3.78)	0.96 (0.90, 1.02)
Industrial Radiographers (IR)	0.69 (0.14, 3.49)	1.09 (1.02, 1.17)
Los Alamos National Lab Pu)	Similar --→	1.05 (0.89,1.23)

Little evidence for an effect for fractionation exposures

Boice *et al*. Sex-specific lung cancer risk. *IJRB* 2019

Lung Cancer Risk following Fractionated (Low-Dose Rate) Exposures

Cohort	Total subjects Both sexes	# Females	Total lung cancers Both sexes	Mean lung dose, mGy	Sex-adjusted ERR at 100 mGy (95% CI)
TB Fluoroscopy Canadian	63,707	31,787	1,178	1,055	0.00 (-0.005, 0.005)
TB Fluoroscopy Massachusetts	13,198	6,538	160	840	-0.02 (-0.04, 0.00)

Little evidence for an effect for fractionation exposures

Boice JD Jr, et al. ***Int J Radiat Biol***. **2019** Jan 7:1-36. [Epub ahead of print]

Sex-Specific Lung Cancer Risk So Far…

Little evidence that chronic occupational exposures increased the risk of lung cancer in these MPS cohorts or among TB-Fluoroscopy patients.

There were no apparent differences in the risk of lung cancer between men and women.

Sex-specific analyses from MPS to date are interpreted cautiously because of the relatively small number of women (n=18,880) studied to date and their relatively low doses.

A much larger study is ongoing of medical radiation workers which include ~60,000 women and ~60,000 men.

Medical Radiation Workers – an important cohort

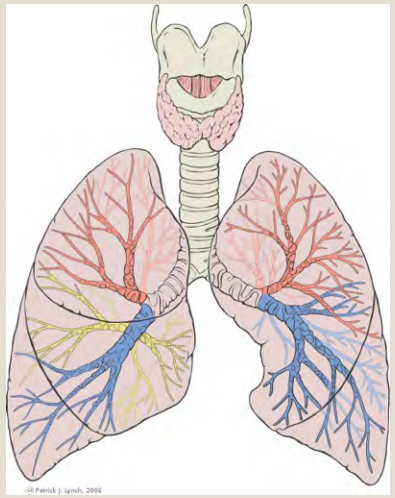
- ~120,000
- ~50% Female/Male
- Radiologists, Technologists, Interventionalists, Cardiologists, Oncologists, Nuclear Medicine, Physicists.
- Near completion.
- Challenging dosimetry (esp. for lead aprons)
- NCRP SC 6-11 Guidance
- MSKCC Pilot (~30K historical workers)

Lifetime mSv	N	%
< 10	29,902	24.5
10-49	77,150	25.2
50-99	34,410	28.1
100-499	25,376	20.8
500-999	1,247	1.0
1000 +	516	0.04

NCRP SC 6-11 Medical Radiation Workers

Dosimetry Guidance for Medical Radiation Workers with a Focus on Lung Dose Reconstruction

Thanks to NASA for financial support



R.C. Yoder, *Co-Chair*
L.T. Dauer, *Vice Chair*
S. Balter
C.N. Passmore
L.N. Rothenberg
R.J. Vetter
M. Mumma, *Advisor*
H.A. Grogan, *Staff Consultant*

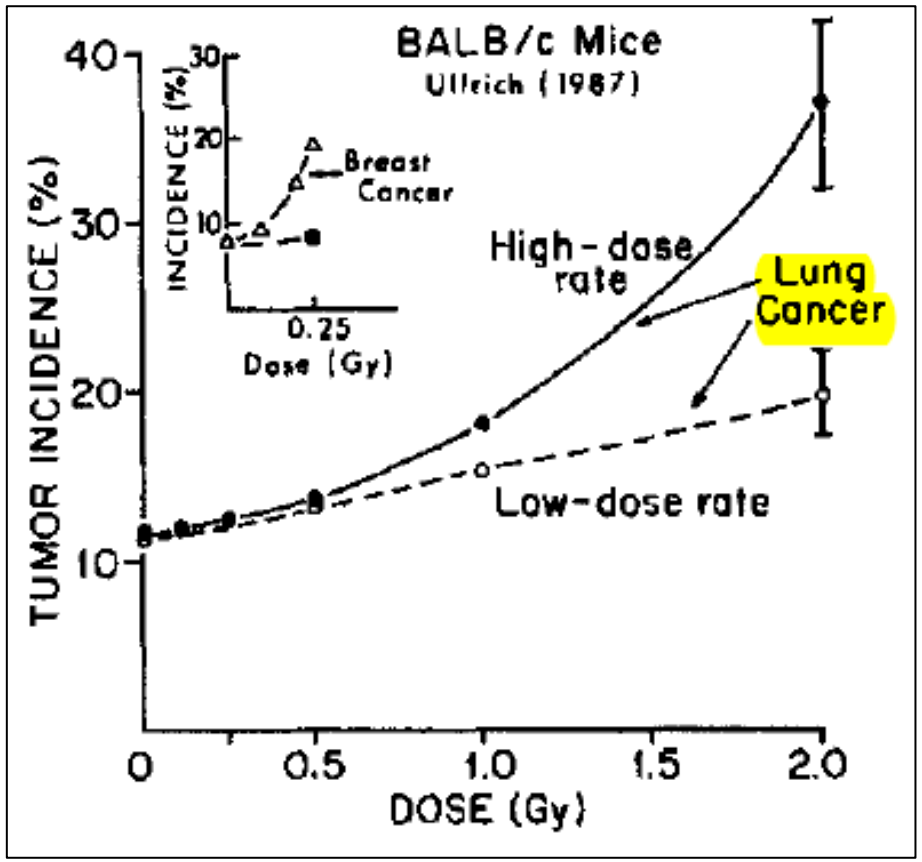
Medical Radiation Workers
Careful Dosimetry Evaluations Essential

Range	Badge Dose Hp(10) [mSv]	Prelim Lung [mGy]	Prelim ABM [mGy]
>0 - <10	17.7 %		
<5		40.9%	36.4 %
5 - <10		18.5 %	19.6 %
10 - <25	29.9 %	27.3 %	28.4 %
25 - <50	15.8 %	9.7 %	10.7 %
50 - <100	20.4 %	2.7 %	3.7 %
>=100		0.9 %	1.1 %
100 - <250	12.2 %		
250 - <500	2.9 %		
500 - <1000	0.7 %		
>=1000	0.3 %		

Other Studies Evaluating Sex-Specific Differences in Lung Ca

Cohort	Reference	Sex-Specific Difference?
US Scoliosis Study	Ronckers et al. 2010	No Effect
Hodgkin Lymphoma	Gilbert et al. 2003	M > F
IARC 15-Country	Cardis et al. 2007	M > F
INWORKS (French, UK, USA)	Richardson et al. 2018	Not Presented
Sellafield (UK Plutonium production)	Gillies et al. 2017	No Difference
Mayak (Russian Plutonium Production)	Gilbert et al. 2004, 2013; Gillies et al. 2017	F > M
Japanese Atomic Bomb Survivors	Ozasa et al. 2012; Cahoon et al. 2017	F > M
Indoor Radon (China, Europe, North America)	Lubin et al. 2004; Darby et al. 2006; Krewski et al. 2006	No Difference, or ~M > F

Importance of Experimental Lung Data



Ullrich et al. Rad Research 1987

The experimental data would predict that an effect of fractionation would be more likely to be detected in the case of induction of lung cancer than breast cancer, and that is what has been found in the epidemiological studies.

RJM Fry. Health Phys 70(6):823-827; 1996

NCRP SC 1-27 Sex-Specific Differences

Evaluation of Sex-specific Differences in Lung Cancer: Radiation Risks & Recommendations for Use in Transfer and Projection Models

M.M. Weil, *Chair*
D.L. Preston
W. Rühm, Advisor
L. Walsh; R. Wakeford
M. Story; L. Dauer
E. Grant; M. Sokolnikov
D. Pawel; D. Hoel
L. Zablotska; J. Huff
S. Blattnig, *NASA Technical Advisor*
M. Rosenstein, *Staff Consultant*








Thanks to NASA, DOE, NCI, and NRC for financial support.

NCRP SC 1-27 Sex-Specific Differences (Overview)

- Introduction
  - Role of Risk Estimates
  - NASA's Current Lifetime Risk Projection Model
  - Astronaut Cohort
- Epidemiology
  - Lung Ca (esp. non-smokers)
  - Radiation-Related Lung Ca Studies
  - Criteria for Evaluating Study Quality and Relevance
- Biological Aspects of Lung Ca
  - Potential Differences Between Men and Women.
- Animal Experiments
  - Relevant to sex-specific differences (esp. Lung Ca)
- Guidelines for Improving Lifetime Risk Projection for Lung Ca
- Findings/Recommendations
- Research Priorities

Thanks to NASA, DOE, NCI, and NRC for financial support.

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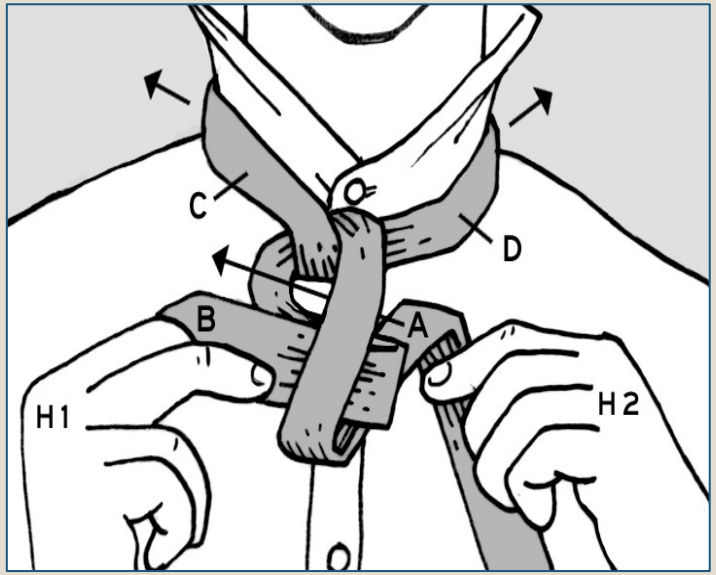

RADIATION RISK COMMUNICATION IN MEDICINE

Angela Shogren

Public Affairs Specialist

U.S. Environmental Protection Agency

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POLL

- Who works in the medical field?
- Have you had to talk about radiation health effects or radiation risks?

HOW SHOULD YOU COMMUNICATE ABOUT RADIATION?

It depends.

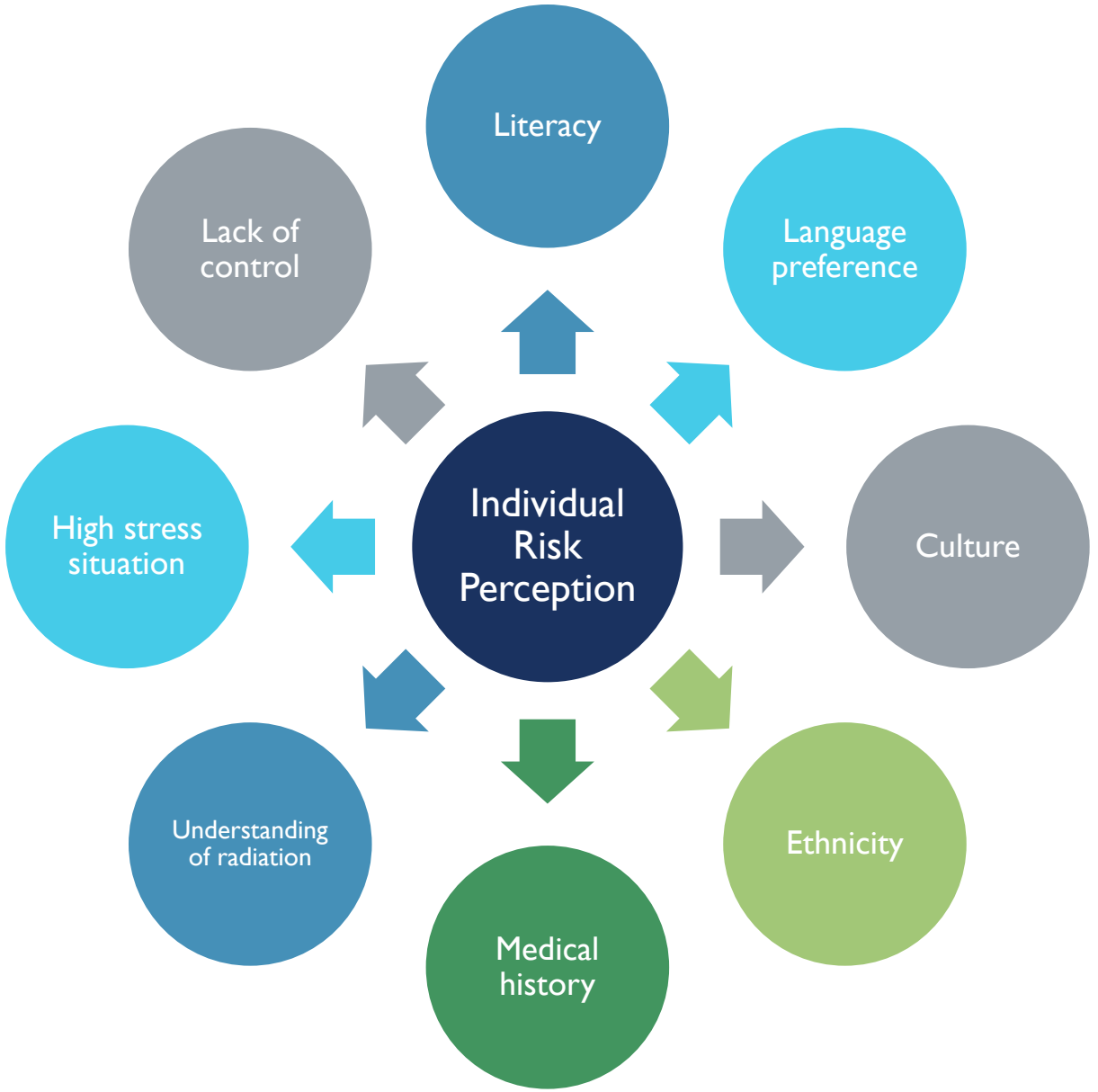
ME

- Connections create trust.
- More than basic medical knowledge.
- Relies on studies, research, and evidence.
- Asks a lot of questions.

HIM

- Needs time to process information.
- Seeks a plan of action and trusts knowledge and confidence.
- Will think through all sides before making a decision.

FACTORS TO TAKE INTO ACCOUNT



HOW DO YOU KNOW YOUR AUDIENCE?

- Non-verbal cues
- Active listening
- Prepare
- Ask!

- How can I help?
- What do you know about the topic?
- Who is involved in the decision making?
- What information can I provide that would be most useful to you? Most useful to any joint decision maker?
- How do you like to get your information? Verbal? In writing? References? Case Studies?

Source: Communicating Radiation Risk: The Power of Planned, Persuasive Messaging (Wieder 2019)

BEST PRACTICES

- Trust is paramount. Set the tone for an open dialogue.
- Be prepared. Anticipate questions/concerns.
- Empathy.
- Use simple terms when possible.
- Ask if they have any questions. Don’t interrupt. Don’t rush.
- Give them what they need.

TOOLS AND RESOURCES (MEDICAL)

- Communicating radiation risks in paediatric imaging information to support healthcare discussions about benefit and risk (WHO): https://www.who.int/ionizing_radiation/pub_meet/radiation-risks-paediatric-imaging/en/
- Image Wisely/Image Gently: https://www.imagewisely.org/Imaging-Modalities/Computed-Tomography/How-to-Understand-and-Communicate-Radiation-Risk

TOOLS AND RESOURCES (EMERGENCY RESPONSE)

- Communicating Radiation Risks (US EPA): https://www.epa.gov/sites/production/files/2017-07/documents/epa_communicating_radiation_risks.pdf
- Communication and Media Tools (US CDC): https://www.cdc.gov/nceh/radiation/emergencies/mediatools.htm
- Nuclear Communicators Toolbox (IAEA): https://www.iaea.org/resources/nuclear-communicators-toolbox

THANK YOU!

Angela Shogren

Public Affairs Specialist

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National Council on Radiation Protection and Measurements (NCRP)
Council Member, Program Area Committee 7 Member

NCRP Special Session 2- Radiation Protection in Medicine: The ICRP and its Role in Guidance, Communication, and Collaboration

Kimberly Applegate, MD, MS
ICRP C3 Chair
University of Kentucky
Professor of Radiology and Pediatrics (retired)

Disclosures

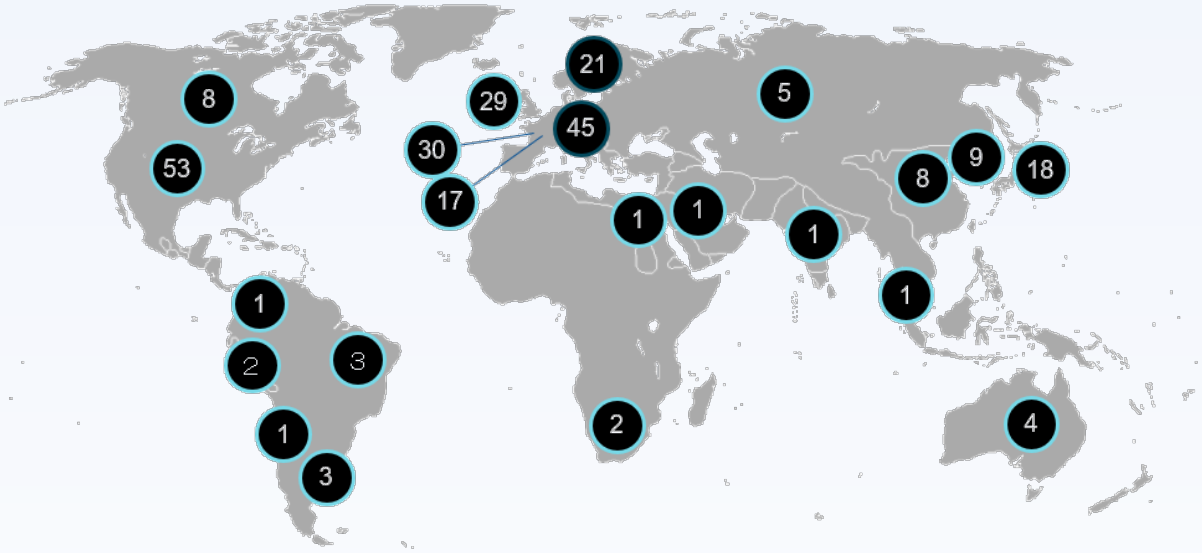
- No financial COI
- Volunteer Member:
  - NCRP
  - European Society of Radiology Radiation Safety Committee
  - FDA MIDAC
  - Image Gently Steering Committee
  - NQF Safety Committee

ICRP Update and Strategic Priorities 2020-2024

Structure


Main Commission
Scientific Secretariat
Committee 1 Effects
Committee 2 Doses
Committee 3 Medicine
Committee 4 Application
TASK GROUPS

ICRP Membership



266 members from 38 countries

as of 12 September 2018, including liaison organisation primary contacts

Scientific Secretariat

Christopher Clement, CN
Hiroki Fujita, JP
Chunsheng Li, CN
Kelsey Cloutier, CN
Lynn Lemaire, CN

Main Commission

Claire Cousins (UK, **Chair**), Jacques Lochard (France, **Vice-Chair**), Kimberly Applegate (USA, **C3 Chair**), Simon Bouffler (UK), Kunwoo Cho (South Korea), Donald Cool (USA, **C4 Chair**), John Harrison (UK, C2 Chair), Michiaki Kai (Japan), Carl-Magnus Larsson (Australia), Dominique Laurier (France), Senlin Liu (China), Sergey Romanov (Russia), Werner Rühm (Germany, **C1 Chair**)

ICRP Committees

Committee 1: Effects

Chair W Rühm ● Vice-Chair A Wojcik ● Secretary J Garnier-Laplace

Assesses knowledge on radiation risk relevant for radiological protection

Committee 2: Dosimetry

Chair J Harrison ● Vice-Chair F Paquet ● Secretary W Bolch

Develops reference models and data, including dose coefficients

Committee 3: Medicine

Chair K Applegate ● Vice-Chair C Martin ● Secretary M Rehani

Develops recommendations to protect patients, staff, and the public

Committee 4: Application

Chair D Cool ● Vice-Chair KA Higley ● Secretary J Lecomte

Develops principles and recommendations on radiological protection

Review, Reflection, and Revision of the Fundamental Recommendations: Proposed General Plan

Last Fundamental Recommendations:
ICRP Publication 103 (2007)

Acknowledgement: Christopher Clement

ICRP Strategic Plan Overview

Remainder of 2017-2021 Term

- **Preparation of strategic priorities**

2021-2025 Term

- **Development of building blocks**

2025-2029 Term

- **Development of revised fundamental recommendations**

ICRP Strategic Priorities and Key Actions

- **Continue to improve the integrated system of RP**
  - Regularly evaluate advances in science, technology, and identify research gaps
- **Strengthen Engagement with Professionals, Policy Makers, and the Public**
  - Engage with all stakeholders using multiple communication methods
- **Ensure ICRP Operates as a Well-Governed and Forward-Looking Organisation**
  - Increase outreach to young professionals

Key Role of ICRP Symposia

ICRP 2021: Focus on launching process, seeking feedback facilitated by paper on areas to be addressed, published in advance

ICRP 2023 & 2025: Presentation and discussion of building blocks, and perhaps a first peek at the shape of the new recommendations at ICRP 2025

ICRP 2027: Presentation/discussion/consultation on draft fundamental recommendations

ICRP 2029: Launch of new fundamental recommendations?

Remainder of 2017-2021 Term: Preparation

- **Minimise establishment of new TGs not related to the revision**
- **Finish TG work now underway not related to the revision**

- **Broadly announce the beginning of the review & revision**
- **Take advantage of opportunities to get input on issues to be addressed**

Based on the 2-day session planned in Rome in Nov 2020:

- **Identify areas needing further work for the revision**
- **Round I of building-block TGs, focusing on fundamental issues**

  (Note TGs 79, 91, 102, 111, 114)

2021-2025 Term: Building Blocks

Enhanced engagement during development

- **Hold open workshops* in connection with TG meetings**
- **Present work-in-progress at conferences and seek feedback**
- **Publish papers in peer-reviewed journals**

Enhanced consultation

- **Extended consultation periods**
- **Open workshops* during consultation**

**** In particular, collaborating with liaison organisations according to the topics***

- **Round II of building-block TGs, focusing on topics that rely on earlier results: Committee 3 work**

2025-2029 Term: “New Pub 103”

- **Complete all building-block TGs**
- **Plan two rounds of consultation on the new fundamental recommendations based on experience of the 2007 recommendations**
- **Hold several regional workshops for feedback during each consultation**
  - Work with liaison organisations to hold workshops
  - Consider special partnership with IRPA to get a broader spectrum of views (previously with NEA)
- **Aim for one consultation period to align with ICRP 2027**

ICRP 2029 → launch of new fundamental recommendations

26 Active Task Groups

TG36 (C2/C3) Radiopharmaceutical Doses

TG64 Cancer Risk from Alpha Emitters

*[**TG79** **(C2)** Use of Effective Dose]*

TG89 (C3) Occupational RP in BrachyTx

TG90 Age-dependent Dose Conversion Coefficients for External Exposures

TG91 Low-dose & Low-dose Rate Exposure

TG93 Update of ICRP *Publications 109* and *111*

TG95 Internal Dose Coefficients

TG96 Computational Phantoms and Radiation Transport

TG97 Surface and Near Surface Disposal

TG98 Contaminated Sites

TG 99 Reference Animals and Plants Monographs

TG102 Detriment Calculation Methodology

[***TG103*** *Mesh-type Computational Phantoms*]

TG105 The Environment in the System of RP

TG106 (C4) Mobile High Activity Sources

TG108 (C3) Optimisation of Protection in Digital Radiography, Fluoroscopy, and CT

TG109 (C3/C4) Ethics in RP in Medicine

TG110 (C3/C4) Veterinary Practice

TG111 (C1/C3) Individual Response to Radiation

TG112 (C4) Reasonableness & Tolerability

TG113 (C2/C3) Dose Coefficients (DR,CT,FL)

TG 114 (C4) Reasonableness & Tolerability

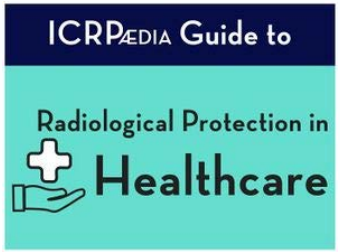
TG 115 (C1) Astronaut RP

TG 116 (C3) RP of imaging during Rad Therapy

TG 117 (C3) RP of PET and PET/CT

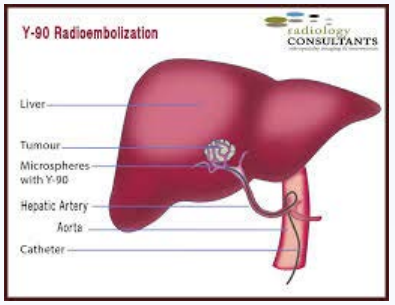
Program of Work

- **Areas of Work**
  - Exposure of Patients and Public, Families & Carers, Biomedical Research Volunteers, and Medical Workers
  - C3 work categories are planned exposures, but also existing and emergency exposure patterns occur.
  - Areas of Focus are Topical Within:
    - Diagnostic ionising imaging, nuclear medicine, and interventional procedures
    - Radiation therapies
    - Veterinary practice
    - *ICRPaedia—stakeholder communication*



Exposure and Protection of P

- *Publication 135*: Diagnostic Reference Levels in Medical Imaging, 2017
- *Publication 140*: Radiological Protection in Therapy with Radiopharmaceuticals, 2019
  - Identified need for continued updates with new agents



- TG 36 (C2/C3): Dose to patients in diagnostic nuclear medicine; current work to update ICRP P128

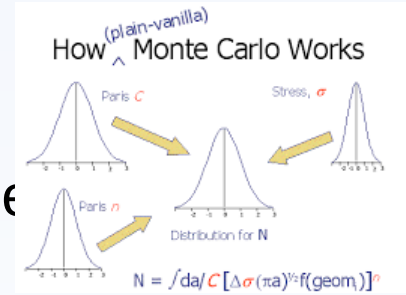
- Suppor quantities in medicir

*TG 108 in Glasgow

- TG 108: Optimisation of RP in digital radiography, fluoroscopy, and CT*

Exposure of Patients (2)

- TG 109 (C3/C4): Ethics in RP for medical diagnosi and treatment*
- TG 111 (C1/C3): Individual response to ionising radiation
- TG 113 (C2/C3): Reference organ and effective dose coefficients for common imaging exams (x-ray, CT, and fluoroscopy)



- **Future Work**
  - NEW Task G se imaging guidance with radiation
  - Task Group to update *Publication 62* on biomedical research (1992)

*TG 109 Geneva, Sept, 2019

Exposure and Protection of Workers

- *Publication 139: Occupational RP in Interventional Procedures, 2018*
- *Publication 140*: Radiological Protection in Therapy with Radiopharmaceuticals, 2019

- *TG 109 (C3/C4): Ethics in RP for medical diagnosis and treatment*
  - Scenario based education and training
  - Plan presentation at IRPA 15 mtg in Seoul
- **Future Work**
  - NEW Task Group 117 on RP for staff, patients, public exposure to PET/CT
  - Task Group review of RP guidance on personal

Exposure and Protection in Veterinary Practice

- *[TG 107 (MC): Advice on Radiological Protection of the Patient in Veterinary Medicine] …led to:*
- TG 110 (C3/C4): RP for veterinary practice
  - New engagement with veterinary imaging

23 ICRP Publications on RP in Medicine since 2000

Publication 84 Pregnancy	**Publication 85** Radiation Injuries Interventional	**Publication 86** Accidents in Therapy	**Publication 87** CT
Publication SG 2 Radiation and your Patient	**Publication 93** Digital Radiology	**Publication 94** Release of Patients	**Publication 97** HDR Brachy-therapy Accidents
Publication 98 Prostate Brachy-therapy	**Publication 102** Multi-detector CT	**Publication 106** Radiopharma-ceuticals	**Publication 112** External Beam RT Accidents
Publication 113 Education and Training	**Publication 117** Fluoroscopy	**Publication 118** Tissue Reactions	**Publication 120** Cardiology
Publication 121 Paediatric Radiology	**Publication 127** Ion Beam Radiotherapy	**Publication 128** Radiopharmaceuti cals Compendium	**Publication 129** Cone Beam CT
Pub 135 DRLs Med Imaging	**Pub 139** Occupational RP Intervent Fluoro	**Pub 140** RP in Therapy with Radiopharmaceuticals	

C3 Working Parties

A. "Update of P62 on biomedical research"
Chair, Keon Kang

B. "RP of Production and Transport in nuclear medicine" (with C4)
Chair, Sandor Demeter

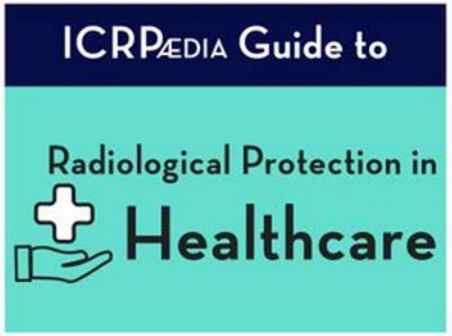
C. "Personal shielding (workers, patients, comforter/carers)"
Chair, Kimberly Applegate

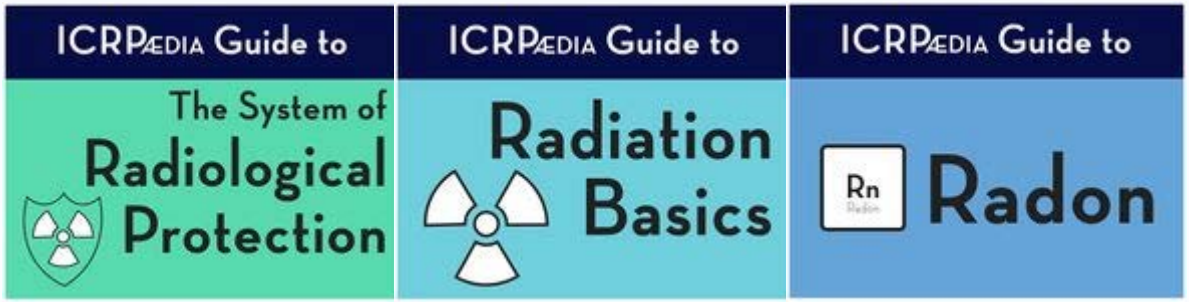
D. "Justification in Medicine"
Chair, Lodewijk Van Bladel

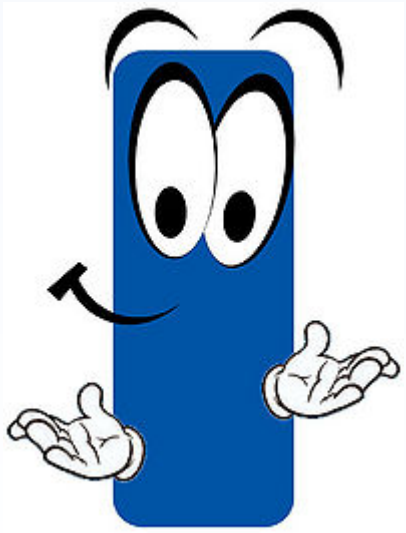
E. "TG 101 proposal to continue updating radiopharmaceuticals in Tx" (with C2)
Chair, Makoto Hosano

ICRPaedia Topics…

- ICRPædia Guide to the Basics of Medical Use of Radiation
- Radiation Basics
- Radon and Lung Cancer Risk
- Cosmic Radiation







http://icrpaedia.org/Main_Page

ADVANCING TOGETHER

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