MINUTES

Meeting of Program Area Committee 4
on Radiation Protection in Medicine
Sunday March 15, 2015; 9:00 AM
Old Georgetown Room
Hyatt Regency Bethesda
Bethesda, Maryland

Attendees: D. Miller, J. Brink, M. Kalra, M. Mahesh, K. Applegate, L. Kroger, S. Sutlief, S. Langhorst, J. Bushberg, J. Gray, S.Y. Woo, T. Siebert, R. Goans, S. Balter, E. Leidholdt, E. Samei, W. Newhauser, D. Frush, L. Dauer, J. Timins

Review of minutes from March 9, 2014 — Miller

The minutes were reviewed and approved.

NCRP Update — Boice, Kase

John Boice addressed the importance of PACS. NCRP is restructuring the PACS to build from the foundation of the organization, rather than from the top down. PAC4's co-chair leadership model has been extended to other PACS, and PAC4's approach of prioritizing many ideas has been promoted as best practice among the other PACS. Guidance for PAC function and membership has been provided to the PAC chairs. Members can only be on one PAC, although they can be liaisons to other PACS. Costs are an important consideration to PAC membership. PAC members are asked to provide a brief bio and portrait. This is useful for fund-raising.

In his fourth year as President of NCRP, John continues to seek funding for all research efforts in the organization. It's critical that we fulfill our charter to address radiation issues that are most important to the U.S. public. House Bill 35 calls for a strategy for low-dose radiation research, and it is now in the Senate. This increased attention on radiation protection requires more radiation protection workers to meet these challenges. New York City government has reached out to NCRP to provide guidance for nuclear terrorism protection.

Partnership with the American College of Radiology (ACR) has been enhanced through an in-person meeting with the ACR Board Chair, Vice-Chair and CEO. This is focused, in part, on helping with communication with the lay press, including Consumer Reports (CR). John will accompany ACR leaders on an in-person visit to CR in Yonkers, New York, next month. Additional discussions are underway regarding a new edition of the Radiation Primer.

Ken Kase reported on a Council Committee (CC-1) focused on Radiation Protection Guidance for the U.S., replacing Report 116. PAC4 will have an important role to play in advising about medical exposures, including a discussion about justification and appropriate use. A section will also focus on the ethical basis of our recommendations. Quantities, units and measurements will also be addressed, more so than in Report 116.

Dose assessment, dose effectiveness and weighting factors will also be addressed, including organ-specific bioeffects.

Status of PAC 4 Activities & Publications — Brink

The statement on tissue injuries has been completed (S. Balter will report on this). The dental report is nearly ready for PAC review (J. Gray will report on this)

SC 4-8 (Dose Utilization in CT) — Kalra

Michael McNitt-Gray and John Boone have been invited as consultants for this commentary (drafting is being conducted without a staff consultant). CT utilization and trends will be covered by M. Mahesh (see Attachment 1, table of covered topics). E. Samei will cover image quality and CT dose utilization, M. Kalra will cover appropriate use and practical applications in specific body regions. D. Frush will cover unique aspects in pediatric CT. Dose metric tracking, dose reporting and dose reference levels will be covered by M. Mahesh. E. Leidholdt will cover error prevention in CT from radiation perspective. M Mahesh will discuss how to review CT protocols routinely. E. Leidholdt will cover diagnostic reference levels for CT. Finally, M. Kalra will address FAQs in CT. Completion of the commentary draft is expected by April 3, 2015. A new title may be necessary to reflect the breadth of content included. The pending DRL publication from the University of California might be included in the DRL section of the commentary. It may be valuable to consider a separate commentary or report on training approaches and requirements.

SC 4-5 (RP in Dental Imaging) — Gray

This is a complete revision of Report 145 (see Attachment 2). Target audience is broad; most difficult audience to engage are the primary care dentists. New sections are drafted for CBCT, digital radiography and hand-held units. No formal guidelines exist for these technologies on safe and effective use in the US. Every dental practitioner acts as an independent radiologist. New information will be presented on the use of high-speed film and under-processing of intraoral dental film. Administration and training will also be addressed. The draft is expected to be distributed to PAC 4 and subject matter experts fro review by 5/15/15. Distribution of the draft to Council and FDA for review is expected by 6/30/15. The completed report is expected by 9/15/15. Notably absent among sponsors is the American Dental Association. There was some discussion about trying to re-engage the American Dental Association for their endorsement.

SC 4-6 (Tissue Injury Statement) — Balter

This statement has been completed and was aimed at administrators with the objective to provide guidance for the detection and management of tissue injuries from fluoroscopically guided procedures (see Attachment 3). “Practice parameters” was chosen as the appropriate designation for the content in this statement, and the essential information is contained in five tables that can be posted in relevant locations. The statement has been made available through many outlets, including the Image Wisely home page. It would be helpful to communicate to The Joint Commission (TJC) that these are quality assurance and sentinel event driven processes, not dose driven processes. Dr. Bushberg recommended that the group draft a letter to TJC for Dr. Boice’s consideration indicating the elements of performance that we would like to see TJC adopt. It was felt that NCRP has a better chance of effecting change in TJC than other specialty based societies that may be seen as self-serving.

SC 4-7 (Evaluating & Communication Rad Risks) Timins

This report will provide guidance for researchers and IRBs for studies involving human subjects (see Attachment 4). A group of interested experts have been assembled and the group had an in-person meeting in February, 2015. The final draft is expected in 3 to 6 months. The background will include an historical perspective and issues specific to human research. Basic radiobiology will be reviewed to inform a framework for radiation protection. Dose definitions and dose metrics will be reviewed as well. The concepts that underpin the IRB, RSC, and RDRC will be reviewed, including the interaction between the IRB and RSC. Modality-specific information will be provided, as will information about image-guided interventional procedures. Details will be provided regarding clinical trials involving radiotherapy. Radiation risk, including uncertainties in risk estimation, will be addressed in this report. Finally, the principles of informed consent will be discussed with a focus on radiation protection and ethics.

SC 1-23 (Cataracts) Dauer

"Guidance on Radiation Dose Limits for the Lens of the Eye" is the commentary produced by SC 1-23 (see Attachment 5). The goal is to have the report completed by the end of March, 2015. Membership on the scientific committee was broad-based, with representatives from Europe and Ophthalmology. Several (more than 60) other reports on this topic were reviewed and helped inform this commentary. The commentary includes a review of the biology of the lens, including quantification of lens changes. Guidance documents on radiation dose were reviewed, and recommendations were included. Meta-analysis of various sources suggest a crude estimation of ~1 Gy as a possible threshold, but there was tremendous variability in this estimate. Shielding strategies are discussed in detail, and specific recommendations are given.

Working Potential PAC 4 activities Miller

D. Miller led the discussion regarding four potential projects under consideration.

Diagnostic and therapy dose to implantable devices Sutlief

Should this be limited to just radiation therapy devices, or just cardiac devices? Last year, we decided to include all device types (see Attachment 6). A discussion ensued regarding the scope – should this include just the impact of radiation on device function, or should it include issues related to the radio-opacity of the device (for detection and guidance)? The group was reminded that NCRP's mission is about radiation protection, and issues related to materials and device placement are probably beyond the scope of this report. Stakeholders should include anyone who uses fluoroscopic guidance. PAC 4 members were surveyed on a 10-point scale for their enthusiasm – it averaged 8.1.

Error prevention in radiation therapy Sutlief

Motivated in part by several articles in the New York Times, this report would be focused on broad issues related to error prevention in radiation therapy (see Attachment 7). An 'Incident Learning System' would be described that allows errors to be reported in a non-punitive fashion for best practice development. Failure mode / effects analysis and process mapping can also inform practitioners about vulnerabilities in radiation therapy practices and systems. Regulatory agencies may look to NCRP to justify a scientific approach to quality and safety in radiation therapy. This report scope was retooled to provide more benchmarking information for best practice definition. S. Sutlief feels that an 8 page statement is too short; a 30 page commentary would be more appropriate. However, a full report would have the full force of the Council behind it because it goes

through Council review. PAC 4 members were surveyed on a 10-point scale for their enthusiasm about a full report – it averaged 7.0. The group was re-polled about their enthusiasm for a statement – it averaged 8.6.

Requirements for CT organ dose calculators Samei/Bolch

This report would be focused on "methods and uncertainties associated with organ dose estimation in CT" (see Attachment 8). The challenges and limitations of effective dose prompt consideration of organ dose as the primary metric of interest for dose monitoring systems. But, there is no standard or reference for the calculation of organ dose. A guideline from the NCRP would be very help inform physicists on the best methods for organ dosimetry. The report could also discuss the impact of external factors such as contrast media on organ dose estimation. Specific methods and their associated uncertainties would also be addressed in this report. Finally, a reference dose database could be included. E. Samei recommends that this be written as a commentary, but others felt that this topic could certainly justify a full report. PAC 4 members were surveyed on a 10-point scale for their enthusiasm about a commentary focused on CT – it averaged 9.3. The group was re-polled about their enthusiasm for a full report on all imaging modalities – it averaged 8.6.

Radiation Protection for PET and multimodal systems Leidholdt

This report would include an overview of radiation protection in multimodality systems, including doses to staff, departmental design, shielding, operational radiation safety, qualifications and training of the operators, and protection of patients and care-givers (see Attachment 9). Optimization of doses to patients could be included as well. Related topics might include PET-CT for CT simulation and novel PET tracers. A few references are available to provide some guidance, and it was noted that several additional publications are in the pipeline. As such, a statement from NCRP might be in order. But, the group felt that a commentary would be more appropriate, perhaps in one year's time, after pending publications appear in press. PAC 4 members were surveyed on a 10-point scale for their enthusiasm about a commentary – it averaged 8.2.

Discussion of future activities All

E. Samei initiated a discussion about effective dose, and possible alternatives to it, including the potential for a 'risk index' or 'effective risk index'. The group was intrigued and generally supportive of this concept. E. Samei agreed to produce a scoping document on this topic. A poll will be deferred until a scoping document can define more clearly what this report or commentary might contain.

M. Kalra reiterated his interest in a separate report or commentary on training requirements. It was pointed out that ICRP has a very detailed document on training requirements. If we pursue a document regarding training, perhaps we should include details regarding the workforce initiative (WARP).

K. Applegate suggested that NCRP consider a report on pediatric diagnostic reference levels, particularly given the 'new' data that may be provided by the ACR Dose Index Registry.

Details regarding the results of our polling of potential projects are included in Attachment 10.

Attachment 1

Chapter #	Title		Pages	Lead	Partners	Partners		
1	CT utilization and trends	Submitted for review	2	M. Mahesh	*	*		email
2	CT scanner settings and scan parameters		5	M. Mahesh	M. Kalra	*		email
3	CT dose descriptors: Applications and Limitations		2	M. Mahesh	E. Leidholdt	*		email
4	Image quality in CT		5	E. Samei	*	*		phone
5	General concepts for CT radiation dose utilization		8	E. Samei	*	*		
6	Appropriate use and Stepwise designing of CT protocols	Outline	6	M. Kalra		*		
7	Understanding aspects of dose utilization in chest CT	50%	6	M. Kalra		*		
8	Specific aspects of dose utilization in head and neck CT	50%	6	M. Kalra		*		
9	Specific aspects of dose reduction in abdominal CT	50%	6	M. Kalra		*		
10	Unique aspects of CT dose utilization in cardiac CT	Outline	6	M. Kalra	M. Mahesh		consultant	
11	Unique aspects of dose reduction in pediatric CT		6	D. Frush	*	*		call him
12	Dose metric tracking, dose reporting and reference dose levels in CT		5	M. Mahesh	D. Frush	E. Leidholdt		
13	Error prevention in CT from radiation perspective	Submitted for review	4	E. Leidholdt	*	*	out	KA
14	How to review CT protocols routinely		6	M.Mahesh	M. Kalra			
15	Reference Dose Levels (DRLs) for CT		6	E. Leidholdt			out	
16	Frequently asked questions in CT dose utilization	30%	10 (max 20)	M. Kalra	All authors	ALL		
	SUBTOTAL PAGES		83					
	Reference pages		25					
	Table of content		2	Ready				
	Contributors		2	list committee members				
	Executive summary		2					
	Preface		4 (8 max)					
	TOTAL PAGES		118					

NCRP SC 4-5
Radiation Protection in Dentistry

Complete Revision of NCRP 145 (2003)
With New Sections on CBCT, Digital Radiography, and Hand-Held Dental Units

Joel Gray, Ph.D.
NCRP Staff Consultant

SC 4-5 Members

Alan G. Lurie, *Co-Chair*
Mel L. Kantor, *Co-Chair*
Mansur Ahmad
Veeratrishul Allareddy
John Ludlow
Edwin T. (Ted) Parks
Eleonore D. Paunovich
Robert Pizzutiello
Robert A. Sauer
David C. Spelic
David A. Smith, *NCRP Executive Director*
Joel E. Gray, *NCRP Staff Consultant*

SC 4-5 Consultants

Edwin M. Leidholdt
Donald L. Miller
W. Doss McDavid
Madan Rehani

Target Audience

- **Primary care dentists**
- **Dental and maxillofacial radiologists**
- **Head and neck radiologists**
- **ENT physicians**
- **Medical physicists**
- **Radiographers and imaging technologists**
- **Dental assistants and hygienists**
- **Dental radiologic technicians**
- **Equipment manufacturers and suppliers**
- **State regulators**
- **Relevant federal agency representatives**

New Topics



Need?

- **CBCT, digital radiography, and hand-held x-ray units in wide use**
- **No formal guidelines on safe and effective use in US**
- **Every dental practitioner acts as an independent radiologist**
- **CBCT installed as "plug and play" devices**
  - **Perceived not as CT but exotic panoramic units**
  - **Many states classify same as intraoral units**

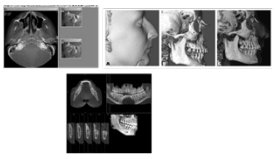
Topics

- All topics covered in NCRP 145
- CBCT including patient selection criteria
- Digital radiography
- Hand-held x-ray units
- Use of high-speed film
- Under-processing of intraoral dental film
- Organizations and their roles, e.g., Image Gently®

CBCT, Digital Radiography, and Hand-Held X-Ray Units

- General information
- Equipment and facilities, protection of patients and staff, measurements and dose
- Administrative and regulatory considerations
- Education and training
- Summary and conclusions
- References
- Glossary
- Appendices

Cone Beam CT



Cone Beam CT Effective Dose

Modality	Effective Dose (μSv)
Intraoral Bitewing	1.5
Panoramic	24
CBCT	48 – 1,073
CT Scan (dental program)	534 – 2,100

Concerns About CBCT

- Need referral criteria—being used inappropriately
- CBCT units in wide use— 5,000 today; 15,000 projected in five years (only dental)
  - Others– ENT, extremity, ???
- No formal guidelines on safe and effective use in US
- Every dental practitioner acts as an independent radiologist
- CBCT installed as "plug and play" devices
  - Perceived not as CT but exotic panoramic units
  - Many states classify same as intraoral units

Computed Radiography

- Photostimulable phosphor plate
- Use similar to film
- Plate placed in laser scanner to obtain digital image

- One unit can support several rooms

Digital (or Direct) Radiography

- Charge-coupled device (CCD) or complimentary metal oxide semiconductors (CMOS)
- Digital data directly through USB cable to computer
- Relatively costly, one or two rooms

Adoption of Digital Radiography

- Digital radiography is *NOT* replacing *film* radiography as rapidly as in medical imaging
- 25% to 45% of dental facilities using digital intraoral imaging (depending on state)
- 5% to 35% of those using digital use CR (depending on state)

Hand-Held X-Ray Units

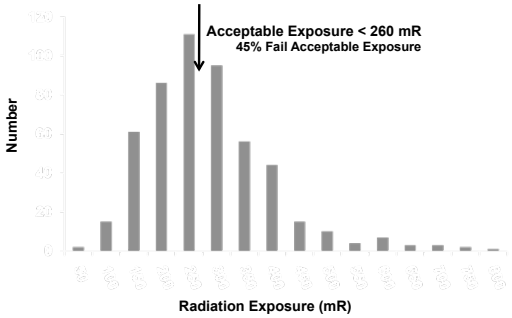
- Minimal concerns with appropriate design and use
- 15,000 in use today in US
- Original concern— Holding x-ray tube
- Not all hand-helds are created equal!
- No formal guidelines on safe and effective use in US

All Hand-Helds Not Created Equal

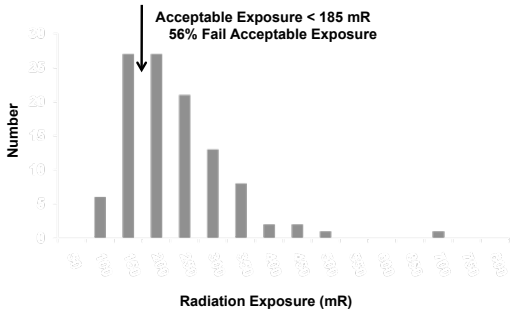
Dental Intraoral Skin Doses

- D-speed film– 2 mR (17.4 µGy)
- F-speed film– 1 mR (8.7 µGy)
- Computed radiography (PSP) plates– 1 to 1.25 mR (8.7 to 10.9 µGy)
- Direct radiography (CCD or CMOS)– 0.5 to 1.0 mR (4.35 to 8.7 µGy)

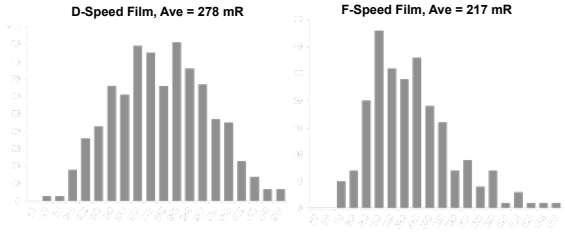
Patient Radiation Exposure (mR) D-Speed Film



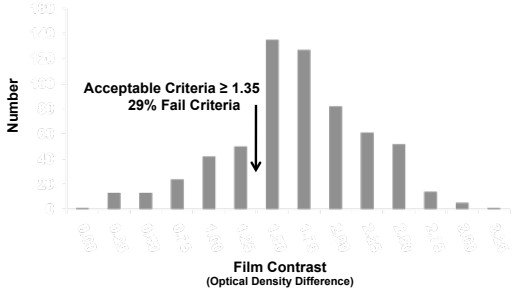
Patient Radiation Exposure (mR) E-F-Speed Film



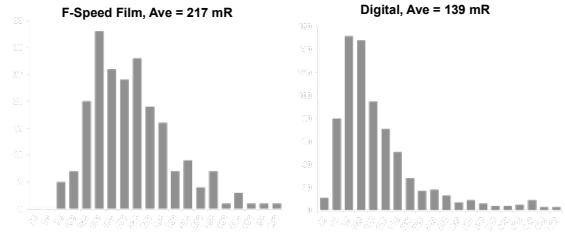
Entrance Exposure D- vs F-Speed Film



Film Contrast ⇨ Processing Quality



Entrance Exposure F-Speed Film vs Digital



NCRP Report No. 17X

RADIATION PROTECTION IN DENTISTRY

NCRP

Contents

Status of SC 4-5 Report

Presently, relatively complete draft
5/15/15 Draft to PAC 4 and SMEs for review
6/30/15 Draft to Council and FDA for Review
9/15/15 Completed NCRP Report to FDA

SME = Subject Matter Expert

Funding

American Academy of Oral and Maxillofacial Radiology (AAOMR)
American Association of Physicists in Medicine
American Board of Radiology Foundation (ABRF)
American Dental Education Association (ADEA)
US Food and Drug Administration

NCRP
National Council on Radiation Protection & Measurements

NCRP Statement No. 11

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

Overview
February – March 2015

National Council on Radiation Protection and Measurements
7910 Woodmont Avenue / Suite 400 / Bethesda, MD 20814-3095
http://ncrponline.org / http://ncrppublications.org

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

Stephen Balter, Ph.D., *Chairman*
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American Association of Physicists in Medicine
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Joel E. Gray, Ph.D., *Staff Consultant*

Objective

Managing FGI procedures should be a medical event driven process instead of an exclusively dose driven process.

- Processes must be in in place to detect and respond to FGI skin reactions.
- Radiation utilization and all detected tissue reactions are to be managed by the facility's usual medical event Quality-Assurance / Peer Review processes.
- Sentinel events are determined by QA/PR, not dose.
- Not detecting reactions might be considered a SE.

Target Audiences

- Hospital Quality-Assurance / Peer-Review (QA/PR) committees
- Professional organizations
- Regulatory bodies
- (Joint Commission)
- Legal system ?

Format Enhancements

- Professional affiliations of writing group members
- Glossary
- Extended references
- Key information from NCRP-168 was duplicated

ORGANIZATION

- Introduction
- Background
- Quality-Assurance / Peer-Review
- Conclusions
- Essential information is in five tables (designed to facilitate cut and paste)

Lexicon Choices

- Standard of Care
- Best Practices
- Appropriate Use
- Practice Parameters

TABLE 1—*Substantial radiation dose levels (NCRP, 2010).*[a]

Dose Metric	SRDL Value[b]
Peak skin dose ($D_{skin,max}$ or PSD)	3 Gy
Cumulative air kerma at a reference point ($K_{a,r}$)	5 Gy
Air kerma-area product (P_{KA}) (assuming a 100 cm^2 field at the reference point)	500 Gy cm^2
Fluoroscopy time (only if PSD, $K_{a,r}$, and P_{KA} are not available)[c]	60 min

[a]The radiation dose level that is intended to trigger follow-up for an FGI procedure, in order to ensure detection of any clinically-relevant injury in an average patient.
[b]These criteria apply to radiation dose values at the end of a procedure.
[c]Facilities performing potentially high-dose FGI procedures ***shall*** measure dose metrics and ***should not*** rely on fluoroscopy time alone. NCRP Report No. 168 states that fluoroscopy time ***should not*** be used as the only dose indicator during potentially high-dose FGI procedures.

TABLE 2—*Policies and processes for services performing FGI procedures.*

1. When appropriate, the informed consent process includes discussion and documentation of the potential for skin injury.
2. A complete set of dose metrics is included in the report for every FGI procedure, in addition to inclusion in the medical record in any other locations that the facility deems appropriate.
3. Upon procedure completion, the responsible physician documents, in the medical record, the clinical necessity for exceeding any SRDL.
4. Patients are promptly informed when substantial amounts of radiation (Table 1) were used for their procedures, and why it was necessary.
5. Patients receive follow-up, documented in the medical record, to determine whether tissue reactions occurred.
6. The results of patient follow-up are reported to and reviewed by the interventional service's QA-PR committee.
7. If a tissue reaction is identified, or suspected, the patient ***shall*** be referred to an appropriate provider for management.

TABLE 3—*Essential elements of a QA-PR program for managing radiation use in all FGI procedures.*

1. Each interventional service ***shall*** have its own QA-PR program, a component of which is the evaluation of radiation management for all FGI procedures (Jones and Pasciak, 2012; Stecker *et al.*, 2009).
2. All available metrics that describe the total radiation dose from the case ***shall*** be recorded in the procedure report and the patient's medical record for every procedure.
3. Radiation dose data ***shall*** be collected and tracked for all FGI procedures.
4. Interventional services ***shall*** have policies and processes to ensure that when an SRDL is exceeded, appropriate documentation and follow-up are provided.
5. The interventional service's summary patient radiation dose metrics for all cases of every FGI procedure ***shall*** be analyzed periodically and at least annually. These data ***shall*** be compared to current published data.
6. Patient follow-up ***shall*** be based on exceeding an SRDL.

TABLE 4—*Criteria for a QA-PR committee to determine whether a procedure with a clinically important tissue reaction meets recognized practice parameters for radiation management.*[a]

1. The procedure was justified clinically.
2. When applicable, the timing of this procedure with respect to previous procedures was reviewed.
3. When applicable, the pre-procedure physical examination included inspection of relevant areas of the patient skin for evidence of previous radiation injury.
4. If a tissue reaction was considered possible, the potential for a tissue reaction was included as part of the informed consent process.
5. Use of radiation during the procedure was appropriate.[b]
6. After the procedure, the patient was advised of possible tissue reactions; appropriate follow-up was arranged and performed (NCRP, 2010).

[a]For procedures performed on an emergent basis, some or all of the pre-procedural steps may have been limited or omitted due to clinical necessity.
[b]A qualified medical physicist should be consulted to analyze the distribution of radiation dose, contributing technical parameters, and related factors.

TABLE 5—*Possible outcomes of a QA-PR analysis of an FGI procedure that resulted in a clinically important tissue reaction.*

1. The tissue reaction was detected and, likely, was unavoidable. No action required.
2. While clinical or technical optimization might have reduced the severity or improved the detection of the tissue reaction, overall practice parameters were still met. Methods for optimization of radiation use are available and should be implemented.
3. Radiation use did not meet recognized practice parameters. A clinically important tissue reaction was potentially avoidable, its severity could have been minimized, or it was not detected. Corrective action is required.

NCRP ***recommends*** that, regardless of the PSD, a sentinel event ***shall not*** be considered to have occurred when a skin tissue reaction results from one or more FGI procedures, if all FGI procedures that irradiated the affected skin were performed in accordance with recognized practice parameters.

NCRP SC 4-7

Evaluating and Communicating Radiation Risks for Studies Involving Human Subjects:

Guidance for Researchers and Institutional Review Boards

Supported by the CDC and NRC

SC 4-7 COMMITTEE MEMBERS

• Julie Timins, Chair	Michael Grissom, Staff Consultant
• Jerrold Bushberg	Patricia Fleming
• Linda Kroger *	Edwin Leidholdt, Jr.
• Donald Miller `	Robert Reiman *
• J. Anthony Seibert	Steven Sutlief

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 IRB bodies and other groups on the process of reviewing protocols that involve radiation exposure to human subjects

SCOPE OF REPORT

- Basic information on radiobiology and radiation dose metrics
- Regulatory requirements for institutional supervision of research
- Identification of experimental studies utilizing ionizing radiation
- Distinguishing between radiation required for standard patient care and that incurred specifically by research study design
- Assessment of proper utilization of radiation in a research protocol
- Estimation of radiation dose
- Estimation of radiation risks including adjustments for specific populations (e.g., young children versus terminally ill adults)
- Optimization of radiation dose
- Important elements of informed consent for protocols involving ionizing radiation, including appropriate risk language
- Templates for informed consent

Report Timeline

- Originally submitted Aug. 14, 2013
- Approved by NCRP BOD Jan. 20, 2014
- 1st Conference Call April 7, 2014
- 7th Conference Call Jan. 12, 2015
- Face-to-Face Meeting at UC Davis, Sacramento Feb. 9-10, 2015
- Final Draft – Potentially 3-6 months

REPORT STRUCTURE

1. Executive Summary
2. Introduction
3. Basics of Radiobiology and Radiation Dose
4. Regulatory Requirements for Institutional Supervision of Research
5. Identification of Experimental Studies Utilizing Ionizing Radiation
6. Distinguishing Between Radiation for Standard Patient Care and Research
7. Estimation of Radiation Dose
8. Estimation of Radiation Risk
9. Optimization of Radiation Dose
10. Key Elements of Informed Consent
11. Conclusions and Recommendations

Appendix A. Templates for Informed Consent

2. Introduction

2.1 Purpose of Report

2.2 Background

- **2.2.1** History of Guidance for Research Involving Human Subjects and Informed Consent
- **2.2.2** Issues Specific to Research Involving Ionizing Radiation to Human Subjects
- **2.2.3** Scope of the Report

3. Basics of Radiobiology and Radiation Dose

3.1 Basic Radiobiology

- **3.1.1** Biological Effects, Tissue Reactions and Stochastic Effects
- **3.1.2** Radiation Risks to the Patient, Fetus and Family Members
- **3.1.2.1** Radiation Effects to the Patient
- **3.1.2.2** Radiation Effects to the Fetus
- **3.1.2.3** Risk from Radiopharmaceuticals to the Nursing Infant
- **3.1.2.4** Radiation Risk to Family Members

3.2 Framework for Radiation Protection

3.3 Dose Definitions

- **3.3.1** Exposure
- **3.3.2** Absorbed Dose
- **3.3.3** Effective Dose

3.4 Dose Metrics

4. Regulatory Requirements for Institutional Supervision of Research

4.1 Introduction to IRB, RSC and RDRC

- **4.1.1** Institutional Review Board
- **4.1.2** Radiation Safety Committee and RSO
- **4.1.3** Research Involving Drugs, Devices and Radioactive Materials

4.2 Interaction between RSC and IRB

- **4.2.1** Regulation of Radioactive Materials
- **4.2.2** Regulation of X-ray Equipment

4.3 Investigational New Drug (IND) Applications

- **4.3.1** Radioactive Drugs and the Role of the RDRC
- **4.3.2** New Drug App (NDA) & Abbreviated New Drug App (ANDA)

5. Identification of Experimental Studies Utilizing Ionizing Radiation

5.1 Diagnostic Imaging Modalities

- **5.1.1** Radiography
- **5.1.2** DXA
- **5.1.3** Fluoroscopy
- **5.1.4** CT
- **5.1.5** Nuclear Medicine
- **5.1.6** Ultrasonography
- **5.1.7** MRI
- **5.1.8** Fusion Imaging

5.2 Image-Guided Interventions

- **5.2.1** Types of Experimental Studies
- **5.2.2** Patient Radiation Dose Estimates for Interventional Procedure

5.3 Assessing Clinical Trials Involving Radiotherapy

6. Distinguishing Between Radiation for Standard Patient Care and Research Studies

6.1 Imaging Studies Indicated in Standard Patient Care

6.2 Imaging Studies Requiring Greater Frequency by Research Protocol

6.3 Special Studies Required by Research Protocol

6.4 Determining Reasonableness of Studies Required by Research Protocol

6.5 Replacement of Ionizing Radiation Studies by Non-ionizing Radiation Studies

6.6 Device or Treatment Oriented Research Protocol within Accepted Standards

7. Estimation of Radiation Dose

7.1 Introduction
7.2 X-ray Imaging
7.3 Nuclear Medicine and Other Procedures using Unsealed Radioactive Materials
7.4 Radiation Oncology
7.5 Radiation Dose in Perspective

8. Estimation of Radiation Risk

8.1 Introduction
8.2 Uncertainties in Risk Estimates
8.3 Factors Influencing Individual Risk at Time of Exposure
8.4 Use of the Quantity Effective Dose in Risk Estimations
8.5 Second Cancers Following Radiotherapy

9. Optimization of Radiation Dose

9.1 Methods to Improve Dose Utilization and Efficiency
9.2 Dose Optimization in CT
- **9.2.1** Technological Advances that can Reduce Dose
- **9.2.2** Optimization of CT Imaging Protocols

9.3 Dose Optimization in Fluoroscopically-guided Procedures
9.4 Dose Optimization in Nuclear Medicine
9.5 Radiation Oncology and Radionuclide Therapy Optimization Methods

10. Key Elements of Informed Consent

10.1 Basic Ethical Considerations in Human Studies Research
10.2 The Principle of Autonomy and the Rule to Seek Informed Consent
10.3 The 'Informed' Part of Informed Consent
- **10.3.1** Clear Language
- **10.3.2** Address Different Reading Levels in Affected Populations
- **10.3.3** Keeping Length of Document Reasonable and Commensurate with Radiation and Overall Protocol Risk

10. Key Elements of Informed Consent (cont)

10.4 Informational Issues Concerning Uncertainty and Latency Unique to Ionizing Radiation Research
- **10.4.1** Informed Consent for Studies Involving Diagnostic Exams
- **10.4.2** Informed Consent for Studies Involving Image-guided Interventions
- **10.4.3** Informed Consent for Studies Involving Therapeutic Radiation
- **10.4.4** Benchmarks and Circularity in Communicating Information on Radiation Dose

10.5 The 'Consent' Part of Informed Consent, Intentionality and Voluntariness
- **10.5.1** Established Methods for Studies Involving Children and Intellectually Handicapped
- **10.5.2** Research Involving Randomized Trials and Blind Research Groups
- **10.5.3** Voluntariness and Controlling Influences

10.6 Other Ethical Elements and Concerns

Needed Text

Bullet Items for Each Section

11. Conclusions and Recommendations

Appendix A – Templates for Informed Consent

1. Executive Summary

Guidance on Radiation Dose Limits for the Lens of the Eye

Status of NCRP SC 1-23 Commentary

-MEDICAL-

LAWRENCE T. DAUER & ELEANOR BLAKELY

NCRP 51st Annual Meeting:
Changing Regulations and Radiation Guidance:
What Does the Future Hold?
16-17 March 2015
Bethesda, MD

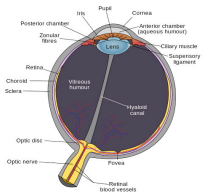
Guidance on Radiation Dose Limits for the Lens of the Eye

Status of NCRP SC 1-23 Commentary

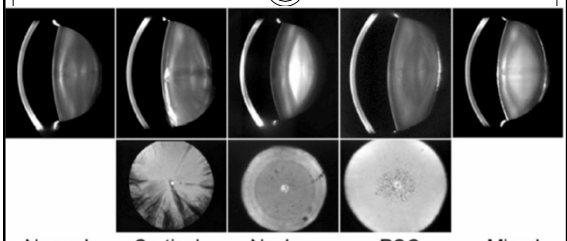
- SC 1-23
- CORE QUESTIONS
- CURRENT NCRP GUIDANCE
- OTHER RECENT REVIEWS
- EYE BIOLOGY & LENS EFFECTS
- EPIDEMIOLOGY
- POPULATIONS/PROTECTION
- DRAFT CONCLUSIONS
- DRAFT RECOMMENDATIONS

Guidance on Radiation Dose Limits for the Lens of the Eye

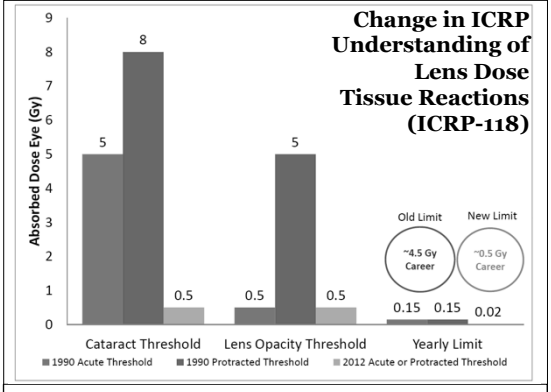
Status of NCRP SC 1-23 Commentary



Cataract Types



NCRP SC-123, Fig 4.3



NCRP SC 1-23

Members

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

Consultants

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

NCRP Staff Consultant

- Michael Grissom

Purpose

- 01/14/14 1st teleconference.
- NCRP Commentary by early 2015.

U.S.NRC

Guidance on Radiation Dose Limits for the Lens of the Eye

Status of NCRP SC 1-23 Commentary

CORE QUESTIONS

SC 1-23 Core Questions

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

Guidance on Radiation Dose Limits for the Lens of the Eye

Status of NCRP SC 1-23 Commentary

CURRENT NCRP GUIDANCE

NCRP
National Council on Radiation Protection & Measurements

Objectives of Radiation Protection

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

NCRP-116 (1993)

Principles of Radiation Protection

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

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

Occupational Dose Limits (mSv)

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

Relevant NCRP Documents

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

NCRP National Council on Radiation Protection & Measurements

Guidance on Radiation Dose Limits for the Lens of the Eye

Status of NCRP SC 1-23 Commentary

OTHER RECENT REVIEWS

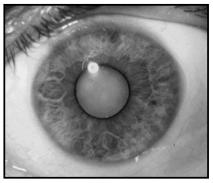
Other Recent Lens of Eye Reviews

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

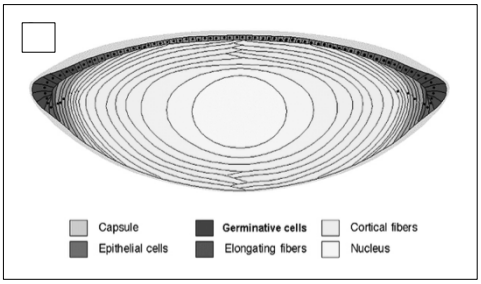
Guidance on Radiation Dose Limits for the Lens of the Eye

Status of NCRP SC 1-23 Commentary

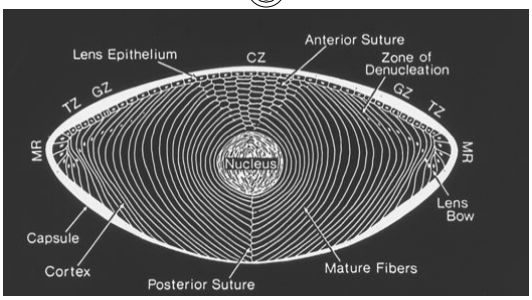
EYE BIOLOGY & LENS EFFECTS



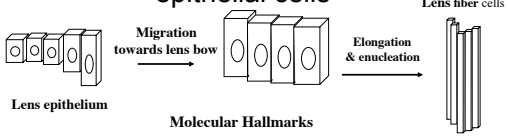
Cross-section of Human Lens



Cross-section of Human Lens



Normal Differentiation of Lens epithelial cells



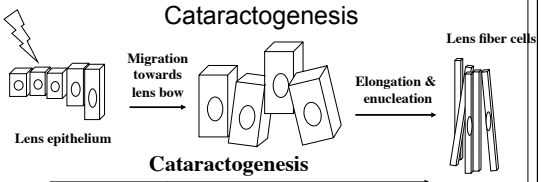
Molecular Hallmarks

Differentiation genes
Apoptosis sensitivity
Cyclin-dependent kinase inhibitors CDKIs

Cyclin-dependent kinases
E2F1/Rb

Blakely, 2014

Underlying Mechanism of Radiation-induced Cataractogenesis



Cataractogenesis

Etiology still not fully known – multifactorial.

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

Cyclin dependent kinases E2F1/Rb

Blakely, 2014

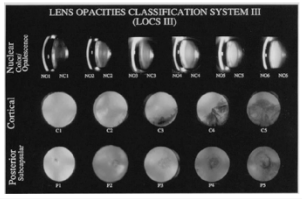
Review and Summary of Eye Biology & Lens Effects

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

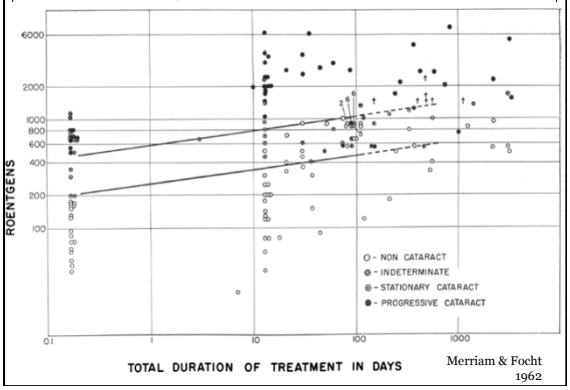
Guidance on Radiation Dose Limits for the Lens of the Eye

Status of NCRP SC 1-23 Commentary

EPIDEMIOLOGY



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



Merriam & Focht 1962

More Recent Reviews of Radiation Cataractogenesis Epidemiological Studies

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

- General Conclusions:
  - Strong likelihood of an association between exposure to ionizing radiation and initiation or development of various opacifications and/or cataracts.
  - Recognize large uncertainty.
  - A lower threshold or no threshold *may* be an appropriate model for radiation cataractogenesis risk.

Populations Evaluated (>60 publications)

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

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

Quality of Epidemiological Studies (EPRI, 2014)

- Quality score according to methodology strengths and weakness
  - Typical approach when evaluating available epidemiologic evidence for outcomes due to exposures (as does the EPA, e.g., Wartenberg et al, 2010).
  - 0 for expected good design.
  - +1 for strengths.
  - -1 for evident shortcomings.
- 9 Tier 1 – most informative.
- 15 Tier 2 – important.
- 34 Tier 3 – unreliable.

Quality Evaluated On:

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

Odds Ratio Meta-analysis

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

Odds Ratio Meta-analysis

- Recognizing several limitations and questions, the meta-analysis results of these 4 study populations:
  - PSC OR=1.45 at 1 Gy (95%, 1.15-1.85).
  - Cortical OR=1.37 at 1 Gy (95%, 1.20-1.56).
  - Mixed OR=1.75 at 1 Gy (95%, 1.26-2.46).
  - Nuclear OR=1.07 at 1 Gy (95%, 0.5-2.0).
- Likelihood of an association between exposure to ionizing radiation at ~1 Gy and initiation or development of PSC, mixed, and/or cortical cataracts.

Threshold Evaluations

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

Guidance on Radiation Dose Limits for the Lens of the Eye

Status of NCRP SC 1-23 Commentary

POPULATIONS / PROTECTION

Members of the Public – per ICRP

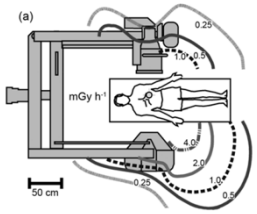
- Equivalent Dose for Lens of Eye Limit of 15 mSv/y.
- Effective Dose Limit of 1 mSv/y.
- ICRP-118 – no new limit for public exposure to lens of the eye, as the Commission judged that the existing limit was adequately protective, and therefore a reduction could impose unnecessary restrictions.
- Highly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

Occupational: Populations / Protection

- Medical
  - Interventional Radiology and Cardiology
  - Radiopharmacy, Radiochemistry, Nuclear Medicine
  - Other workers
  - Patients
- Nuclear Facilities
- Industrial Radiography
- Astronauts / Pilots
- Engineering, Safe Work Practices, Administrative Controls
- PPE
  - Screens, Goggles, Leaded Glasses
  - Face Shields
  - Respirator Face Shields
  - Bubble Suit Masks
- Monitoring Lens Dose

FGI IR/IC Protection Controls (NCRP-168)

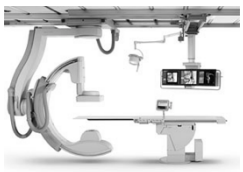
- Engineering
  - Equipment
  - Structural Shielding
  - Equipment Shielding
- Safe Work Practices
  - SOPs
  - 10 Commandments/Pearls
- Administrative
  - Training/Credentialing
  - Expectations
- PPE (aprons/collar/ glasses, etc.)



NCRP-168

Operator Training / Credentialing

- Equipment design and shielding help…BUT
- Training and Credentialing needs improvement.
- Europe leads in operator training.
- As of 2011, only 27 states enacted legislation regarding radiation education for FGI operators



Shielding Strategies for FGI LDE reduction

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

Thornton et al 2010 JVIR

How to Measure LDE?

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

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

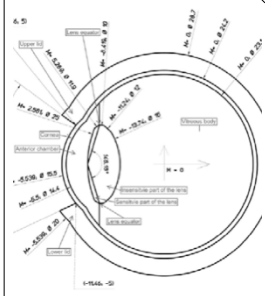
?What if Leaded Glasses are worn?

Practical LDE Dosimeter Choices
– Starts with actually wearing them!

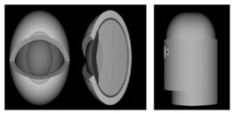
- DDE dosimeters (Whole Body) $H_p(10)$:
  - On trunk or waist far from eyes.
  - Underestimate at low photon energies (too thick)
  - Under lead apron if in use.
- SDE dosimeters (Extremity) $H_p(0.07)$:
  - Must be worn facing the beam/scatter
  - Worn near eye (note NCRP-168 factor of ~1 at collar)
  - OK for photons, overestimates for beta (too thin)
- LDE dosimeters (Eye) $H_p(3)$ – exist?:
  - Must be worn facing the beam/scatter
  - Only type OK for photons and beta.

Behrens, Oct. 2012, IAEA

ICRP External Dose Factors for Lens of Eye



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



Guidance on Radiation Dose Limits for the Lens of the Eye
Status of NCRP SC 1-23 Commentary

DRAFT CONCLUSIONS

SC 1-23 Draft Conclusions

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

SC 1-23 Draft Conclusions

- What effects do LET, dose rate, acute and/or protracted dose delivery have on cataract induction and progression?
  - Although different studies have looked at many of these factors independently, there is still very little evidence upon which to base an answer to this question.
  - Mechanistic evidence is perhaps stronger in some instance (e.g., differential effect of increased radiation ionization qualities enhancing the induction and progression of opacities).
  - More high-quality epidemiological and mechanistic studies are required. Need for better dosimetry and scoring methods.

SC 1-23 Draft Conclusions

- How should detriment be evaluated for cataracts?
  - Cataracts are not life threatening but may affect individuals' ability to carry out their occupations or other daily tasks.
  - ICRP lowered dose limit for lens could be interpreted as putting lens opacities on equal footing with diseases affecting mortality. Many authors question appropriateness of this.
  - NCRP SC 1-23 encourages NCRP-168 recommendation that until there is sufficient evidence available to accurately reassess current dose-limit values, it is prudent to regard eye exposures in much the same way as whole-body exposures (*i.e., ensure exposures are consistent with ALARA principles*). This includes careful justification and optimization in exposure situations including radiation doses to the lens of the eye.

SC 1-23 Draft Conclusions

- Based on current evidence, should NCRP change the recommended limit for the lens of the eye at this time?
  - Current epidemiology and biology studies indicate an association between exposure to ionizing radiation and initiation or development of PSC, cortical and/or mixed visually-impairing cataracts for various exposure situations, perhaps even at lower doses than previously considered for lens dose limits.
  - However, the data are limited and have large uncertainties.
  - Not yet possible to quantitatively estimate threshold values.
  - At this time there is no sufficient justification to make a change in the current NCRP recommended lens of eye occupational dose limit of 150 mSv/y.

Guidance on Radiation Dose Limits for the Lens of the Eye

Status of NCRP SC 1-23 Commentary

DRAFT RECOMMENDATIONS

SC 1-23 Draft Recommendations

- Urgent need for NCRP comprehensive evaluation of overall effects of radiation on the eye. (Begun, ~3y).
- Wait for outcome of re-evaluation of RERF data and work in progress.
- Need for new, high-quality epidemiology and basic research on mechanisms of action.
- On-going opportunity for dose-sparing optimization and the need for more education and more accurate dose assessment for potentially exposed populations.
  - EURADOS/ORAMED
- Need additional information on children effects.
- Longitudinal studies.

Guidance on Radiation Dose Limits for the Lens of the Eye

Status of NCRP SC 1-23 Commentary

NCRP 51st Annual Meeting:
Changing Regulations and Radiation Guidance:
What Does the Future Hold?
16-17 March 2015
Bethesda, MD

LAWRENCE T. DAUER, PHD, CHP

DEPARTMENT OF MEDICAL PHYSICS
DEPARTMENT OF RADIOLOGY
MEMORIAL SLOAN-KETTERING
CANCER CENTER

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Attachment 6

NCRP PAC 4 – Mar 15, 2015

To: Board of Directors

From: John Boice
President

Jerrold Bushberg
Vice President
Chairman of the Board

Re: Request for Approval of NCRP Proposal

Proposal Title: Diagnostic Imaging and Radiation Therapy Dose to Implantable Devices

Funding: Solicitations for support may be sought from the American Society for Radiation Oncology, the American Association of Physicists in Medicine, and other organizations.

Purpose: SC 4-x is proposed as a new NCRP scientific committee to provide guidance on damage pacemakers, implantable cardiac defibrillators, and other implantable devices due to radiation scatter from high radiation fields. The three US makers of pacemakers and ICDs offer varied levels of information to practitioners planning radiotherapy treatment for patients with implanted devices. The published research suffers from two shortcomings: (1) small sample sizes and (2) limited duration of relevance due to continual advances in the miniaturization of implanted devices which make them potentially more susceptible to radiation damage and malfunction. This proposal is to summarize current results, recommend a methodology for future device testing, recommend reporting guidelines for manufactures, and suggest appropriate methods for clinicians to assess risk and take preventative action.

Background: (taken from Sutlief 2015) Implanted devices present several challenges for radiation therapy delivery. They may be susceptible to radiation damage, necessitating monitoring before, during, and after treatment. When placement within the radiation field cannot be avoided, they may perturb the dose distribution, making treatment planning difficult. A list of implantable devices is given in Table 1.

Devices that are not susceptible to radiation damage may still present a challenge to the treatment planner because of perturbations to the radiation field. An additional complication is that a high-density object on the treatment planning CT will have incorrect CT numbers and may produce artifacts that must be removed before performing voxel-based dose calculations. Considerable attention has been given to hip prostheses that impact treatment planning in the pelvic region, such as for prostate cancer treatment (Reft et al. 2003). Breast implants, which do not overly perturb the radiation field, have been extensively investigated in terms of outcome and cosmetic results, both of which are favorable, except in the cases of reconstructive surgery prior to irradiation, where there is greater risk of cosmetic failure (Victor et al. 1998; Hazard et al. 2004).

Of greater interest from a radiation protection perspective is the impact of radiation therapy on implantable electrical devices. The proliferation of devices over the past two decades with ever increasing miniaturization indicates that innovation in this field will present an ongoing concern for radiation protection. Due to their prevalence and critical medical role, pacemakers and implantable cardiac defibrillators have received the most attention for radiation protection. AAPM Task Group 203 is currently looking at the management of radiotherapy patients with implanted cardiac pacemakers and defibrillators. Their report should be published within

the next year. In presentations, the Task Group chairs have recommended a risk-based approach. Some of the concerns identified by this approach are the need for the patient to be seen by cardiac electrophysiology staff before treatment begins, the inaccuracy of treatment planning systems when assessing dose far from the treatment site, the need to favor lower energy beams (e.g., 6 MV is preferable to 15 MV to reduce neutron dose), and the need to obtain in vivo dosimetry verification. Protocols for handling pacemaker and implantable cardiac defibrillator patients have been published by the Dutch Society of Radiotherapy and Oncology (Hurkmans et al. 2012) and by the University of Michigan (Makkar et al. 2012).

There are many other implantable electrical devices of concern with respect to radiation treatment. Cochlear implants have been studied in terms of the risk of device damage, which has not been found to be a concern at clinical doses (Klenzner et al. 2010), and in terms of dose perturbations they create, which are manageable for treatment planning (Gossman et al. 2011). Implanted intrathecal drug delivery is also becoming more common. Although the risk of failure is low, it is prudent to check the device after completion of radiation therapy or if the patient experiences increased pain (Gebhardt et al. 2013). While the subject of non-cardiac implantable devices remains largely unstudied in radiation therapy, a literature search in the context of anesthesiology found the following devices to be of interest: deep brain stimulators, vagal nerve stimulators, sacral nerve or bladder stimulators, phrenic nerve stimulators or diaphragmatic pacemakers, spinal cord stimulators, gastric pacemakers, bone stimulators, and laryngeal nerve stimulators (Venkatraghaven et al. 2009). It is clear that ever-greater concern must be given to these devices as technology evolves (Wilkinson et al. 2005).

Table 1. A list of common implantable medical devices.

- Electronic
  - Implantable cardioverter defibrillators
  - Heart pacemakers
  - Cochlear implants
  - Neuro stimulators
  - Drug delivery devices
- Structural
  - Artificial hips
  - Artificial knees
  - Spine screws, rods, and artificial discs (spinal fusion hardware)
  - Metal screws, pins, plates, and rods (traumatic fracture repair)
- Other
  - Breast implants
  - IUDs (intra-uterine devices)
  - Coronary stents
  - Ear tubes (tympanostomy tubes)
  - Artificial eye lenses (psuedophakos)

Scope: This document will encompass both the perturbative effects of implantable devices on the quality of medical radiation imaging and therapy as well as the effect of radiation on the device and the subsequent risk for the patient. The document will include a summary of current results of damage and risk, recommendation of a methodology for future device testing, recommended reporting guidelines for manufactures, and suggested methods for clinicians to assess risk and take preventative action.

Proposed Outline:

(following the Preface, Table of Contents, Contributors, Executive Summary)

1. Implantable devices and radiation interactions
    a. How implantable devices work
    b. Characteristics of direct and peripheral radiation (particle type, energy)
    c. Secondary neutron damage
2. Types of radiotherapy and radiology delivery situations which present possible damage to implantable devices
    a. Conventional 3D computed radiotherapy
    b. Intensity Modulated Radiation Therapy and Tomotherapy.
    c. Total Body Irradiation
    d. Total Skin Electron Therapy
    e. Brachytherapy (low or high dose rate)
    f. Computed tomography
    g. X-ray
3. Types of implantable devices
    a. Pace makers and pacing leads
    b. Implantable cardioverter defibrillators
    c. Cochlear implants and hearing aids
    d. Neuro-stimulators and spinal cord stimulators
    e. IV infusion controllers
    f. Unclassified prosthetic devices
4. Recommended methodology for future device testing
    a. Variation of radiation quality and secondary neutron production
    b. Testing of leads separate from the pacing device
    c. Standardized metrics for quantifying device failure
    d. Theoretical model for radiation sensitivity for current and future electronic components
5. Recommend reporting guidelines for manufactures
    a. Recommended metrics to be reported
    b. Recommended language for reporting
6. Methods to assess risk and take preventative action
    a. Preventative measures during diagnostic procedures
    b. Peripheral dose assessment
    c. Radiotherapy treatment planning
    d. On-treatment monitoring
    e. Communicating risk to patients

Expected Page Length: Approximately 100 pages.

Committee Members:

Proposed Chairman:

Steven Sutlief Ph.D. FAAPM
Associate Director of Medical Physics
University of California, San Diego
3855 Health Sciences Way
La Jolla, CA 92093

Proposed Scientific Committee Members:

Coen W Hurkmans
Y. Kim
L Walsh
Cynthia McCollough,
[Industry representatives]

Proposed Staff Consultant:

------- --------, Ph.D.

Consultant:

Donald Miller, M.D. (FDA, Co-Chair of NCRP Program Area Committee on Radiation Protection in Medicine)

Representatives from other organizations:* American Society for Radiation Oncology, American Association of Physicists in Medicine, Conference on Radiation Control Program Directors, Other manufacturers

Timeline:

To be determined.

Proposed Meetings:
One (possible two if sufficient additional funds can be raised) face to face meetings with monthly teleconferences/ webinars

Projected Budget Plan: To be developed.

Proposed Budget Option – Implantable Devices (PAC 4)
Direct Costs

Scientific Committee Travel			
Number of SC Members Requiring Travel Funds	Average Cost Per 1.5 Day Meeting	Number of Meetings	Total
8	**$ 1,250**	1	$ 10,000
Staff Consultant			
Hours Allotted	**Cost per Hour**	Number of Consultants	Total
100	**$ 100**	1	$ 10,000
NCRP Staff Costs			
Hours Allotted	**Average Cost per Hour**		Total
100	$ 84		$ 8,400
Total Direct Costs			**$ 28,400**

Indirect Costs (Overhead Rate = 1.0414)

Total Indirect Costs	**$ 29,576**

Total Direct and Indirect Costs	**$ 57,976**
Publications Costs	**$ 1,500**
Amount Secured to Date:	**$ 17,500**
Remaining Funds to be Raised:*	**$ 41,976**

* Remaining funds requirements are somewhat flexible by deleting or adding face to face meetings.

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Radiation Therapy Dose to Implantable Devices

This document was originally proposed by S. Sutlief, who had provided an extensive scoping statement. It was given a numerical ranking of 9.1. It was originally intended to cover estimation of dose from radiation therapy and the associated risk to implantable devices. It was to include both in-field and out-of-field devices. It would summarize current results, recommend a methodology for future device testing, recommend reporting guidelines for manufactures, and suggest appropriate methods for clinicians to assess risk and take preventive action. Implantable devices include not only electronic devices such as pacemakers and cochlear implants, but many other devices as well.

The PAC discussed the proposed topic. It was agreed that the report should include a discussion of diagnostic energy ranges also. The title of this proposed Report was revised to "**Diagnostic Imaging and Radiation Therapy Dose to Implantable Devices".** The proposed Chair is S. Sutlief. **New numerical ranking—8.6**

Considerations for audience versus scope

1. Option 1: Only include pace makers and ICDs
    a. Audience
        i. Cardiologists
        ii. Radiation Oncologists (and Radiologists)
        iii. Medical Physicists
    b. Scope
        i. Damage to devices from radiation
        ii. Risk to patients from malfunctioning devices
2. Option 2: Include all implantable medical devices (including structural, non-structural, and other electronic implants as listed earlier)
    a. Audience
        i. Radiologists
        ii. Radiation Oncologists
        iii. Medical Physicists
        iv. Cardiologists
        v. Biomedical Engineers
        vi. Industry
    b. Scope
        i. Perturbation of Images and therapy fields by implantable devices
        ii. Risk to patients from scatter of high energy therapeutic radiation
        iii. Damage to devices from radiation
        iv. Risk to patients from malfunctioning devices

Specialization	Interest	What they want
Radiologists	Electrical devices at risk of interference	Risk pathways, incidence levels, mitigations strategies
Radiation oncologists	All devices subject to high radiation	Risk pathways, incidence levels, mitigations strategies
Medical physicists	Same as radiologists and radiation oncologists	Same as radiologists and radiation oncologists
Cardiologists	Only pace makers and ICDs	Protocol for mitigation and monitoring during radiation therapy
Other physician specialists	Only those pertinent to the specialty (e.g., cochlear implants, neuro stimulators, drug delivery devices)	Risk pathways, incidence levels, mitigations strategies
Industry	Primarily electrical devices at risk of malfunction	Testing standards
Biomedical engineers	All devices	General information

Attachment 7

NCRP PAC 4 – Mar 09, 2014

To: Board of Directors

From: John Boice
President

Jerrold Bushberg
Vice President
Chairman of the Board

Re: Request for Approval of NCRP Proposal

Proposal Title: Program Components for Error Prevention in Radiation Therapy

Funding: Solicitations for support may be sought from the American Society for Radiation Oncology and the American Association of Physicists in Medicine.

Purpose: SC 4-x is proposed as a new NCRP scientific committee to provide guidance for external evaluation of program components for error prevention in radiation oncology. The statement concerns the methodologies for error prevention in radiation therapy, including prospective and retrospective techniques. The intent is to provide an integrated set of recommendations which can be assessed in terms of their successful implementation.

Background: Although a tremendous number of reports on safety in radiation therapy have been published during the last ten years, the guidance is generally piecemeal and lacking overall coherence. A key perspective of this report would be objective characteristics of a safety-focused RT department.

Several contemporary projects overlap with the material to be covered in this Report:

- AAPM 2013 Summer School and proceedings: Quality and Safety in Radiotherapy: Learning the New Approaches in TG 100 and Beyond, June 16-20, 2013. Theme: prospective and retrospective techniques.
- AAPM Task Group No. 100: Method for Evaluating QA Needs in Radiation Therapy, chaired by Saiful Huq. Active dates: 8/1/2003 - 12/31/2013, however this report is still undergoing internal review within AAPM and has not yet gone out for publication. Theme: Application of FMEA and FTA for prospective assessment.
- Safety is No Accident, American Society for Radiation Oncology. 2012. 52 pages. Theme: a long list of recommendations.
- Consensus recommendations for incident learning database structures in radiation oncology. Ford et al, Med Phys. 2012 Dec; 39(12):7272-90.

Scope: This statement describes the necessary program components for error prevention.

Proposed Outline:

1. Paradigms for safety in radiation therapy (Rasmussen schema, mock qualitative methodologies such as FMEA and FTA, role of safety measures within the context of open-chart and closed-chart review).
2. Rationalizing device quality assurance and patient quality assurance to optimize value of safety measures.
3. Recommended policies, procedures, and documentation to demonstrate a safety-focused radiation therapy department.

4. Metrics for gauging the effectiveness of safety measures.

Expected Page Length: Approximately 30 pages

Committee Members:

Proposed Chairman:

Steven Sutlief Ph.D. FAAPM
Associate Director of Medical Physics
University of California, San Diego
3855 Health Sciences Way
La Jolla, CA 92093

Proposed Scientific Committee Members:
Larry Marks, MD (University of North Carolina, Radiation Therapy)
Bruce Thomadsen, PhD (University of Wisconsin, Radiation Therapy)
Peter Dunscombe, PhD (University of Calgary, Radiation Therapy)
Larry Mazur, PhD (University of Radiation Therapy, Radiation Therapy)
[alternate individuals: Barrett Caldwell, Frank Rath, or Nancy Levinson]

Proposed Staff Consultant:
------- --------, Ph.D.

Consultant:
Donald Miller, M.D. (FDA, Co-Chair of NCRP Program Area Committee on Radiation Protection in Medicine)

Representatives from other organizations:* American Society for Radiation Oncology, Amarican Association of Physicists in Medicine, Conference on Radiation Control Program Directors, Other manufacturers

Timeline:
To be determined.

Proposed Meetings:
One (possible two if sufficient additional funds can be raised) face to face meetings with monthly teleconferences/ webinars

Projected Budget Plan: To be developed.

Proposed Budget Option – Error Prevention and Safety In Radiation Therapy (PAC 4)
Direct Costs

Scientific Committee Travel			
Number of SC Members Requiring Travel Funds	Average Cost Per 1.5 Day Meeting	Number of Meetings	Total
8	**$ 1,250**	1	$ 10,000
Staff Consultant			
Hours Allotted	**Cost per Hour**	Number of Consultants	Total
100	**$ 100**	1	$ 10,000
NCRP Staff Costs			
Hours Allotted	**Average Cost per Hour**		Total
100	$ 84		$ 8,400
Total Direct Costs			**$ 28,400**

Indirect Costs (Overhead Rate = 1.0414)

Total Indirect Costs	**$ 29,576**

Total Direct and Indirect Costs	**$ 57,976**
Publications Costs	**$ 1,500**
Amount Secured to Date:	**$ 17,500**
Remaining Funds to be Raised:*	**$ 41,976**

* Remaining funds requirements are somewhat flexible by deleting or adding face to face meetings.

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Error Prevention in Radiation Therapy

This document was originally proposed by S. Sutlief, who had provided an extensive scoping statement. It was originally intended to cover methodologies for error prevention in radiation therapy, including prospective and retrospective techniques. It was intended to provide an integrated set of recommendations. It originally received a numerical ranking of 9.2. The PAC discussed the proposed topic and observed that ASTRO and manufacturers have an initiative to reduce errors. A revision to the original concept was agreed upon.

The document will now be a Statement that describes the necessary program components for error prevention. The new title is "**Program components for error prevention in radiation therapy"**. The proposed Chair is S. Sutlief. **New numerical ranking—9.3**

Attachment 8

Methods and uncertainties associated with organ dose estimation in computed tomography

Ehsan Samei, Wesley Bolch

Prospectus

Characterizing patient-specific radiation dose in CT has emerged as a necessary requirement to practice medical imaging. Amongst various dose metrics, organ dose is generally regarded as one of the best metrics to quantify individual radiation burden. Over the past decade, significant progress has been made to quantify organ dose with various estimation and validation techniques.[1-6] Despite the continuing efforts, there arises a necessity to understand the uncertainties associated with different organ dose estimation methods. The quantification of uncertainty provides a better understanding of the limitations of current dose estimation methods. Furthermore, it substantiates the necessity for a standardized organ dose database for benchmarking purposes.

Organ dose is a measure of the magnitude and distribution pattern of ionization radiation deposited in human body. Since it is impractical to directly measure the dose distributed inside a living body, the best technique is to estimate organ dose by Monte Carlo simulation of the CT acquisition process on representational phantoms. The estimation accuracy is therefore critically dependent on how well the method models the patient and exposure condition, including (a) the patient anatomical characteristics, (b) the x-ray irradiation condition of the scanner, and (c) the administration of iodinated contrast medium used in the exam. Uncertainties are further induced due to variation in the approaches used to model the above factors. Table 1 offers a summary of these factors and their general magnitude of associated uncertainty. These are reflective of the material currently under consideration by AAPM TG246.

The purpose of this report is to provide a comprehensive extension of the initial work of TG246. The report will review the current techniques for estimating organ dose in CT and delineate the main sources of uncertainties associated with organ dose estimation. Here we review several key elements for organ dose estimation and their influence on the estimation error. Finally, the report further offers a database of clinical CT scans under precise irradiation conditions. Validated organ dose values will be provided, estimated considering the exact scanner and anatomical distribution of each patient. It is expected that this database can be used as a reference standard in quantification and reporting of organ doses.

Table 1. Summary of the sources and level of uncertainties in organ dose estimation

Source	Description	Anticipated magnitude of error
Patient modeling	Reflective of how accurately different types of computational phantoms resemble the anatomical structure of the actual patient	3%-66%
Patient representation	Induced by geometry difference between a clinical patient and a matched computational phantom	10%-15%
Field modeling	Induced by how the heterogeneous dose pattern created across patient coincides with an organ	<10% for most organs 10%-33% for the small surface organs
Irradiation modeling	Induced by using simplified tube current profiles (z-dimensional) to approximate organ dose under TCM	0%-20% depending on the method used to model the dose field under TCM
Transport modeling	Caused by the underlying differences in the physical models used by different simulation models.	5-10%
Contrast medium effects	Induced by the photoelectric interaction products of the contrast medium	26-380% depending on organ, injection protocols

Computational phantoms

The estimation uncertainty associated with computational phantoms refers to how accurately a representing model resembles the anatomical structure of the actual patient. Currently, three types of computational phantoms are available for organ dose estimation, namely, stylized phantoms, voxelized phantoms, and hybrid phantoms.

The uncertainties associated with using different types of computational phantoms have been previously reported in several studies. Zhang *et al* assessed the organ dose uncertainties associated with four types of phantoms (ICRP, CT-Expo, XCAT, and IMPACT) for ten body and three neurological CT protocols.[7] With one single dose estimation technique used across all phantoms, the average percentage differences were in the range of 3%-38% for fully irradiated organs and 7%-66% for partially irradiated organs, respectively. Sizable differences were found for organs that located near the scan boundary (e.g. testes for abdominopelvic examination and colon for chest examination). Furthermore, noticeable uncertainties were found for organs with different spatial distribution across phantoms (e.g. breasts for female phantoms). Liu *et al* compared the organ dose differences between RPI and ICRP reference phantoms for chest, abdominopelvic, and chest-abdomen-pelvis protocols.[8] It was found that the ratio between the organ doses for the two types of phantoms were within the range of 0.75-1.16 for the majority of fully irradiated organs. However, significant differences were found for organs near the scan start/end location. In both studies, uncertainties were mainly introduced by variation in organ location and spatial distribution.

The above-mentioned studies highlight the need for phantoms that can realistically mimic human features. However, even in the presence of a library of diverse human models, to achieve accurate dose estimation, a clinical patient needs to be optimally matched to a model in the library. The quality of the matching can significantly impact the organ dose estimation accuracy. Tian *et al* assessed the uncertainties associated with patient matching to tens of computational phantoms for chest and abdominopelvic exams.[9] The matching process was based on patient size estimated from the patient localizer image. The organ dose differences between the matched patient pairs were on average 11% and 15% for chest and abdominopelvic examinations, respectively. The largest uncertainties were again found for small organs near the scan start/end region (e.g. testes for abdominopelvic examination and thyroid for chest examination).

Scanner irradiation condition

The uncertainty associated with scanner irradiation condition refers to how the technique models the scanner radiation, including geometry and physical properties of the CT scanner, scanning collimation, start and end tube angle positions, over-ranging distance, and the tube current modulation (TCM) technique. Furthermore, some levels of uncertainties are associated with Monte Carlo simulation packages used for the estimation. In the following section, we review the underlying basis and the overall magnitude for each of these specific sources of uncertainty.

Mostly associated with spiral CT, the uncertainties associated tube start/end location are mainly induced by the helical trajectory of the CT source, which creates a periodical dose pattern across patient body. Such heterogeneous distribution of the scanner output radiation results in “hot spots” and “cold spots” in different organs. Zhang *et al* studied the effect of tube start/end location under different conditions (e.g. pitch, collimation) for different patient models (infant, small child, adult female, and pregnant patient).[10] It was found that the largest dose variations occur for eye lens, thyroid, breasts, and testes, all of which are at or near the surface of the patient. The uncertainties were in the range of 10%-33% across different phantoms for the small surface organs. Similar results were found by Li *et al*.[11] The uncertainties were generally higher for small peripheral organs (e.g. breast, testes) and for organs on the edge of scan coverage (e.g., gall bladder in chest scan, and breast in the abdominopelvic scan). However, the uncertainties were generally found to be within 10% for the majority of organs.

Another main source of organ dose uncertainties is the modeling of tube current modulation in examinations conducted with automatic exposure control. Modeling TCM requires effective quantification of dose field distribution created by the changing tube current. As the tube current is changing dynamically across patient body habitus, the scanner reported $CTDI_{vol}$ estimated using the average tube current does not reflect the local dose field of a given organ. As illustrated by Schlattl *et al*, there can be significant differences (>50%) when using scanner reported $CTDI_{vol}$ with fixed tube current organ dose coefficients to approximate organ dose.[4] Khatonabadi *et al* and Li *et al* have demonstrated the use of a regional $CTDI_{vol}$ estimated by averaging the tube current values within the organ region to approximate organ dose under TCM.[12, 13] The uncertainties associated with such techniques were found to be generally with 20% for most of the organs, with the expectation of organs located in the pelvic and shoulder regions. With the inclusion of the scattered dose distribution by convolving the TCM profile with the dose rate profile of the scanner,[9] the uncertainties associated with TCM approximation can be reduced to within 10% across different organs.

In addition to the uncertainty associated with geometry and irradiation condition of the scan, there is also uncertainty associated with the statistical fluctuations associated with any Monte Carlo simulation as well as that associated with the underlying differences in the physical models used by different implementations. The latter uncertainties are generally small and within 5-10%. As the organ dose is an average over a large volume of tissue, they generally exceed those associated with the statistical uncertainties, which is normally in 1-2% range. [14]

Contrast

The iodinated contrast medium is widely used in clinical CT exams. At kilovoltage energies, the high photoelectric cross section of iodine result in substantial photoelectric interaction. The high linear energy transfer and short range of the photoelectric interaction products (photoelectrons, characteristic x-rays and Auger electrons) and free radicals produce a localized dose enhancement. Recently, several studies have assessed the dose increase due to the presence of contrast media. In Sahbaee *et al*, organ dose was estimated for uni-phasic and bi-phasic injection protocols. The injection of contrast medium resulted in up to 52% increase of kidney dose and 22% of liver dose.[15] In Tran *et al*, the organ dose increased 361% in kidney, 379% in adrenals, and 266% in spleen compared with non-contrast exam for a standard clinical contrast-enhanced body CT examination.[16] To what extend those enhanced dose values corresponded to increased radiation burden to biological tissue (as opposed to the contrast medium alone) is a topic that requires further investigation. However, the presence of contrast medium and its proximity to biological tissue has a non-negligible effect on organ dose.

Reference Dose Database

As summarized in Table 1, there are multiple sources of uncertainties associated with organ dose estimation in CT. Those are related to the exact correspondence of the patient geometry to the representational model used, the accuracy of the modeling of x-ray irradiation condition, the simplification of irradiation condition associated with TCM, and the uncertainty due to the presence of iodine contrast medium. Given the magnitude of these uncertainties, it is beneficial to establish a reference organ dose database for comparative purpose. This will be a component of this report.

Overall outline:

- The relevance and use of organ dose in medical imaging
- Survey of methods for organ dose estimation
  - Dose estimation techniques
    - Experimental measurements
    - Monte Carlo methods
    - Analytical techniques
  - Dose objects
    - Benchmarking phantoms
    - Anatomically-inspired phantoms
    - Anthropomorphic models
    - Physical vs computational constructs
    - Representation vs matching strategies
- Uncertainties associated with organ dose estimation
  - Phantoms
  - Patient representation
  - Organ location
  - Irradiation modeling
  - Transport modeling
  - Contrast medium effects
  - Estimation uncertainty (simulation and experimental)
- Organ dose estimation in other imaging procedures
  - NM
  - Fluoroscopy
  - Radiography
  - Mammography
- Reference dose database for organ dose benchmarking

Membership:

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Statistics expertise
….

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Attachment 9

Radiation Protection for PET-CT and Other Multi-Modality Imaging Systems (PET-MRI, SPECT-CT, etc.)

Overview
Doses to Staff
Departmental Design
Shielding
Operational Radiation Safety
Qualifications and Training of Operators
Protection of Patients and Carers?
    Optimization of doses to patients

Specific issues:

1. PET-CT as a CT sim
2. Novel PET tracers
3. NRC is new to PET and a potential funding source.
4. Commentary

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Membership:

Kroger and Leidholdt

Members selected from authors of references above

Attachment 10

Implantable Device Report	Rad Rx Report	Rad Rx Statement	Organ Dose CT-Commentary	Organ Dose All imaging-Report	PET/Hybrid Imaging Commentary
7	10	10	10	9	10
9	4	5	9	8	9
6	7	8	8	10	8
7	6	8	10	8	7
10	6	9	10	9	9
8	7	9	10	10	6
8	5	8	9	8	9
6	6	9	10	9	9
9	9	9	9	8	9
9	7	9	9	8	6
8	6	9	10	8	8
8	9	9	10	9	9
7	7	9	9	9	9
8	8	9	7	6	8
9	7	9	9	8	7
8	5	9	9	10	8
10	10	9	10	10	8
8.1	7.0	8.6	9.3	8.6	8.2