

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

NCRP PAC 4: Radiation Protection in Medicine

Donald L. Miller, MD FSIR FACR
Center for Devices and Radiological Health
FDA

1

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Overview

- NCRP and PAC 4
- Recent PAC 4 publications
- Reports in preparation

2

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

NCRP and PAC 4

3

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Program Area Committees (PACs)

- PAC 1 Basic Criteria, Epidemiology, Radiobiology, and Risk
- PAC 2 Operational Radiation Safety
- PAC 3 Nuclear/Radiological Security and Safety
- **PAC 4 Radiation Protection in Medicine**

4

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Program Area Committees (PACs)

- PAC 5 Environmental Radiation and Radioactive Waste Issues
- PAC 6 Radiation Measurements and Dosimetry
- PAC 7 Radiation Education, Risk Communication, Outreach, and Policy

5

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

PAC 4 Responsibilities

Radiation protection in medicine

- Radiation protection of patients in medical, dental, and chiropractic practice
- Examining and evaluating techniques and procedures to eliminate unnecessary radiation exposure to the patient
- Examining and evaluating training of medical personnel in radiation protection

6

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

PAC 4

25 members:

- Radiology
 - Diagnostic radiology
 - Interventional radiology,
 - Pediatric radiology
 - Nuclear medicine
- Medical physics
- Health physics

- Radiation oncology
- Cardiology
 - Interventional cardiology
 - Nuclear cardiology
- Dentistry
- Occupational and environmental medicine

7

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Recent PAC 4 publications

8

<p>FDA U.S. Food and Drug Administration Protecting and Promoting Public Health www.fda.gov</p> <p style="text-align: right;">NCRP National Council on Radiation Protection and Measurements 1115 North 17th Street, Rosslyn, VA 22209-4138 Tel: 703/291-7100 Fax: 703/291-7101 www.nrcrp.org</p>	
<p>NCRP REPORT No. 172</p>	<p>NCRP REPORT No. 174</p> <p>Outline of Administrative Policies for Quality Assurance and Peer Review of Tissue Reactions Associated with Fluoroscopically-Guided Interventions</p> <p>NCRP Statement No. 12, December 11, 2014</p> <div style="display: flex; justify-content: space-between; font-size: small;"> <div style="width: 45%;"> <p>Stephen Baker, PhD, Chairman Georgia Institute of Technology Atlanta, Georgia</p> <p>James T. Bushong, PhD University of California, Irvine Irvine, California</p> <p>Charles E. Chambers, MD Medical College of Wisconsin Milwaukee, Wisconsin</p> <p>Steven M. Kishikawa, Jr., PhD US Department of Health and Human Services Washington, DC</p> </div> <div style="width: 45%;"> <p>Donald G. Miller, MD US Food and Drug Administration Washington, DC</p> <p>John P. Minkin, MD University of Wisconsin Madison, Wisconsin</p> <p>James S. Pridmore, MD, Oncologist University of Wisconsin Madison, Wisconsin</p> <p>John D. Stroh, PhD, NCRP Executive Director Washington, DC</p> </div> </div> <p>PRECONCEPTION AND PRENATAL RADIATION EXPOSURE: HEALTH EFFECTS AND PROTECTIVE GUIDANCE</p> <p>Introduction</p> <p style="font-size: x-small;">This report recommends the quality assurance and peer review (QA/PR) policies for tissue reactions due to fluoroscopically-guided interventional (FGI) procedures provide specific advice to reduce the risk and for investigation of adverse clinical cases. However, these recommendations do not provide a basis for determining whether or not patients are in compliance. This document provides a review for QA/PR and an investigation of adverse clinical cases.</p> <p style="font-size: x-small;">This document is intended to clarify recommendations given in the National Council on Radiation Protection and Measurements (NCRP) Report No. 160, Radiation for Diagnostic and Fluoroscopically-Guided Interventional Radiology Procedures (NCRP 2010). It provides detailed recommendations for QA/PR, FGI, and FGI procedures. It also provides a review of the literature on the health effects of FGI and the impact of professional and non-professional radiation protection programs on the health effects of FGI. The document is intended to provide guidance on the implementation of professional and non-professional radiation protection programs.</p> <p style="font-size: x-small;">NCRP Report No. 160 emphasizes that the safe performance of FGI procedures requires careful attention to the use of current occupational and public dose limits, which are based on the average annual whole-body effective dose. It also provides guidance on controlling the use of FGI procedures in the workplace. The document provides guidance on the use of FGI procedures in the workplace and on the use of FGI procedures in the workplace. The document provides guidance on the use of FGI procedures in the workplace and on the use of FGI procedures in the workplace.</p> <p style="font-size: x-small;">This report was developed by the National Council on Radiation Protection and Measurements (NCRP) and is intended to provide guidance on the use of FGI procedures in the workplace. It is not intended to be used as a substitute for professional judgment or as a basis for determining whether or not patients are in compliance. It is intended to provide guidance on the use of FGI procedures in the workplace and on the use of FGI procedures in the workplace.</p>
<p>REFERENCE LEVELS AND ACHIEVABLE DOSES IN MEDICAL AND DENTAL IMAGING: RECOMMENDATIONS FOR THE UNITED STATES</p> <p style="text-align: center;">NCRP</p>	<p style="text-align: center;">NCRP</p>

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Report No. 172 (2012)

- *Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States*
- Defines purposes and values of Diagnostic Reference Levels (DRL) and Achievable Doses (AD)
- Provides numerical values for U.S. DRLs and ADs

10

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Diagnostic Reference Level

- QA/QI tool for controlling radiation dose
- Designed to reduce the risk of stochastic effects
- DRL value = 75th percentile of survey data
- When doses exceed the DRL value the reasons should be investigated.

11

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Diagnostic Reference Levels

- DRL values *are not*:
 - An indicator of optimum performance
 - Dose limits
 - Regulatory (*use of the DRL process may be*)
- DRL values *do not apply* to individual patients or individual cases

12

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Achievable Dose

- A dose that serves as a goal for optimization efforts and is achievable with standard techniques and technologies in widespread use, while maintaining clinical image quality adequate for the diagnostic purpose.
- AD value = 50th percentile of survey data (median)

13

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Report No. 174 (2013)

- *Preconception and Prenatal Radiation Exposure: Health Effects and Protective Guidance*
- General misconception that any amount of ionizing radiation is much more detrimental to the embryo or fetus than is actually the case
- Diagnostic radiological procedures necessary for the care of the mother, embryo, or fetus can be performed at any time during pregnancy

14

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Report No. 174

- Increased risks to the embryo or fetus *have not* been observed below a weighted uterine dose of **0.1 Gy** for

– mental retardation	– impaired school performance
– birth defects	– convulsive disorders
– growth retardation	– embryonic or fetal death
– neurobehavioral effects	

15

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Statement No. 11 (2014)

- *Outline of Administrative Policies for Quality Assurance and Peer Review of Tissue Reactions Associated with Fluoroscopically-Guided Interventions*
- Structured recommendations for QA processes for review of radiation use in fluoroscopically-guided interventional (FGI) procedures

16

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Statement No. 11

- Provides Tables that summarize
 - Model policies and processes for the management of radiation dose for FGI procedures
 - Essential elements of a QA-peer review program
 - Criteria for evaluation of tissue reactions relative to recognized practice parameters
 - Outcomes and actions after QA-peer review evaluation of a clinically important tissue reaction.

17

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Reports in Preparation

18

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

- Scientific Committee 4-5, Chairs: Alan Lurie and Mel Kantor. *Radiation Protection in Dentistry*
- Scientific Committee 4-7, Chair: Julie Timins. *Evaluating and Communicating Radiation Risks for Studies Involving Human Subjects: Guidance for Researchers and Reviewing Bodies*
- Scientific Committee 4-8, Chair: Manudeep Kalra. *Improving Patient Dose Utilization in Computed Tomography*

19

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Radiation Protection in Dentistry

- Update of NCRP Report No. 145, Radiation Protection in Dentistry (2003)
- Intended as comprehensive, self-contained guide for dental facilities
- New material: cone beam CT, digital radiography, hand-held dental radiography devices
- Data from 2014-2015 NEXT dental survey

20

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Radiation Risks: Guidance for Researchers and IRBs

- Guidance for researchers and IRBs in preparing and reviewing research protocols that include radiation exposure to human subjects
- Cites relevant regulatory requirements
- Discusses estimation of radiation dose and risk in research protocols

21

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Radiation Risks: Guidance for Researchers and IRBs

- Discusses the ethical considerations involved in human studies research
- Provides advice on presenting radiation risk information to subjects as part of the informed consent process

22

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Improving Patient Dose Utilization in CT

- Integrated set of recommendations for CT radiation dose optimization and error prevention
- Intended audience: practicing physicians and other healthcare providers, physicists and technologists

23

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Possible Future Topics

- Program Components for Error Prevention in Radiation Therapy
- Radiation Effects on Implantable and Other Medical Devices
- Radiation Protection for PET-CT and other Multimodality Imaging Systems

24

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Summary

25

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov


- In NCRP, PAC 4 has oversight of activities in the field of radiation protection in medicine
- 25 members, with diverse areas of expertise, including medical physics
- Three recent publications of interest:
 - Diagnostic Reference Levels and Achievable Doses
 - Preconception and Prenatal Radiation Exposure
 - QA and Peer Review of Tissue Reactions Associated with FGI

26

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

- Work in progress:
 - Radiation Protection in Dentistry
 - Evaluating and Communicating Radiation Risks for Studies Involving Human Subjects: Guidance for Researchers and Reviewing Bodies
 - Improving Patient Dose Utilization in Computed Tomography
- Several possible topics for future reports

27

 U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

Thank You!

Questions?

[donald.miller@ fda.hhs.gov](mailto:donald.miller@fda.hhs.gov)

28
