Radiation Protection Guidance for Diagnostic and Interventional X-ray Procedures, OMB Review, and Roll-Out to Professionals

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Requirements (Mandates)

- 1959 – FRC to advise President on radiation health matters
- 1959 – DHEW (DHHS) to intensify its radiological health efforts
  - Collection, analysis, and interpretation of data
  - Areas include environmental radiation levels such as natural background, radiography, medical and industrial use of isotopes and x-rays, and fallout
  - Secretary can advise the President and the general public.
  - ↑FDA + PHS budgets from $1.0M to $3.2M
- 1970 – EPA to "advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States."
- 2010 – FDA to strengthen oversight of CT

1976 FGR9 (Rationale)

- X-rays contributed 90% of manmade radiation (11% of total)
- Increased use (faster than population from 1964–1970)
- Potential for dose reduction: protecting patient → greatest control of population exposure
- Bottom line: Following guidance would save dose and money

Rationale for Update: FGR No. 9 Outdated

- Shift from film screen to digital imaging
- Additional modalities and newer technologies
- Newer radiation protection concepts, methods
- Negative events

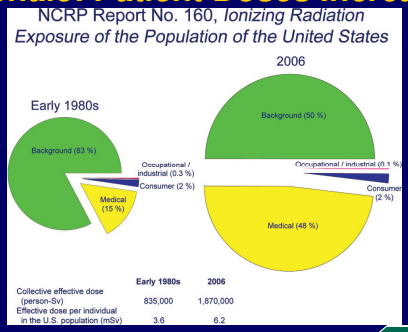
Rationale: Overexposure Potential

Appropriate exposure | Over exposure

Challenges in Medicine

Rationale: Patient Doses Increasing

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



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

Rationale: Protect Children

Image Gently Alliance:
Keep it simple
Invite all stakeholders
Listen and learn
Collaborate

ISCORS Established Medical Workgroup

- Identified US agencies that use x-rays, promote health, or issue radiation guidance
- Assembled expert writing group
- Authored sections by specialists collaborating with external experts
- Developed FGR-14 as a "toolbox" for guidance in all modalities

Authors

- Federal agencies
  - DHHS, EPA, DoD (Army/Navy/Air Force), OSHA, VA
- Commonwealth of PA
- Physicians (radiology, pediatric radiology, cardiology, internal medicine), dentists, veterinarians
- Medical physicists, health physicists, radiologic technologists

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Basic Message

The fundamental objective in performing an x-ray examination is to obtain the required diagnostic information with only as much radiation dose as is required to achieve adequate image quality.

Guidance

- The appropriate examination is performed
- Appropriate equipment and technique factors are used
- Equipment is functioning properly and calibrated
- Equipment is operated only by competent personnel
- The patient is prepared appropriately

What is Included

- *Recommendations ("should")*
- Imaging using X-rays
  - Radiography, CT, fluoroscopy, bone densitometry
  - Medicine, dentistry, veterinary medicine
- Special patient populations
  - Pregnant, pediatric, research studies
- Occupational radiation protection

What is Not Included

- *Requirements/mandates ("shall", "must")*
- Radiation oncology
- Nuclear medicine (except hybrid modalities)
- Ultrasound
- MRI

Contents

- Radiation safety concepts and standards
- Requesting and performing studies
- Technical QA
- Specific guidance by modality
  - Equipment
  - Testing and QA
  - Personnel
  - Procedures
- Imaging informatics
- Recommendations for agency/facility actions

OMB Review

- 10/7/11 EPA submitted draft to OMB
- 11/21/11-4/10/12 OMB interagency review
  - Review 30d ↑ 141d
  - ~300 comments, 14 submitters
- 4/11/12-7/9/12 WG addressed comments
  - 14 conf calls, 30 hr
- 7/9/12 EPA submitted new draft/responses
- 7/16-20/12 OMB comment period for submitters
- 7/31/12 Additional OMB comments
- Next ?

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OMB Review Comments

- Cost to implement
- Dose metrics
- Reference levels
- Screening program oversight
- Lead aprons
- Hand-held x-ray generators
- Informed consent plus templates
- Editorial: terminology, acronyms, abbreviations, definitions, units of measure

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Prep for Rollout: Status and Outreach

- Federal review (DoD, DOL, EPA, HHS, VA, PA)
  - 6/2011 EPA Deputy Assistant Administrator OAR briefed
  - 7/2011 briefings by ATSDR+FDA, meetings of DHHS+EPA
  - 8/2011 Rollout preparation for FRN
- State, county, city, tribal reviews
  - Coordinated through CRCPD, ASTHO, NACHO
- Other stakeholder review
  - Physicians, physicists, technologists, regulators, manufacturers

Rollout: Status and Outreach

- EPA to release via FRN
  - Description of issue
  - Targeted audience
  - Messaging by EPA in collaboration with DHHS
- Key messages in FRN
  - Seeking public comment on draft FGR14
  - 45-day comment period
  - EPA authority to advise Feds on public radiation health matters
  - Final guidance to be issued to Federal x-ray facilities
  - Document is guidance … nothing else
  - Document is adoptable in part or whole by others

Rollout: Status and Outreach

- EPA/DHHS Activities
  - Developing communications plan, web page, FAQs
  - Pre-notifying non-fed stakeholders
  - Preparing FRN, establishing docket
- Time frame
  - 8/6/2012 assumed approval by OMB
  - 8/6/12 – 9/20/12 (45 day public comment period)
  - 11/1/12 (Address public comments and publish)

Rollout: Communications Plan

- Description of issue (FGR9 old, FGR14 new, public comments)
- Targeted audiences
  - Hospital administrators, medical imaging administrators
  - Referring and radiological medical practitioners
  - Medical physicists, health physicists
  - Biomedical engineers, radiological medical technologists
  - Manufacturers
- Recommended activities (web, outreach)
- Key messages

Rollout: Professional Organizations

- AAPM – American Association of Physicists in Medicine
- ACA – American Chiropractic Association
- ACC – American College of Cardiology
- ACEP – American College of Emergency Physicians
- ACGME - Accreditation Council for Graduate Medical Education
- ACOEP – American College of Osteopathic Emergency Physicians
- ACR – American College of Radiology
- ACVR – American College of Veterinary Radiology
- ADA – American Dental Association
- AGA – American Gastroenterological Association
- AHRA – American Healthcare Radiology Administrators
- AMA – American Medical Association
- AOA – American Orthopedic Association
- AOA – American Osteopathic Association

Rollout: Professional Organizations

- AOBR – American Osteopathic Board of Radiology
- AOCR – American Osteopathic College of Radiology
- AORN – Association of PeriOperative Registered Nurses
- APHA – American Public Health Association
- APMA – American Podiatric Medical Association
- ARNA – American Radiological Nurses Association
- ARRT – American Registry of Radiologic Technologists
- ASGE – American Society for Gastrointestinal Endoscopy
- ASIPP - American Society of Interventional Pain Physicians
- ASRT – American Society of Radiologic Technologists
- ASTHO – Association of State and Territorial Health Officials
- AUA – American Urological Association
- AVIR – Association of Vascular and Interventional Radiographers
- CRCPD – Conference of Radiation Control Program Directors

Rollout: Professional Organizations

- HPS – Health Physics Society
- HRS – Heart Rhythm Society
- IAEA – International Atomic Energy Agency
- IRPA – International Radiation Protection Association
- ISCD – International Society for Clinical Densitometry
- NACHO – National Association of County and City Health Officials
- NCRP – National Council on Radiation Protection and Measurements
- NEMA – National Electrical Manufacturers Association
- RSNA – Radiological Society of North America
- SAGES – Society of American Gastrointestinal and Endoscopic Surgeons
- SCAI – Society for Cardiac Angiography and Interventions
- SIR – Society of Interventional Radiology
- SNIS – Society of NeuroInterventional Surgery
- SNM – Society of Nuclear Medicine
- SVS – Society for Vascular Surgery

Recommendations for Agencies

- Ensure infrastructure exists for collecting, storing, and analyzing patient dosimetry data. Planning should address data acquisition, networking, storage, analysis, and security requirements of existing and planned future diagnostic devices.
- Ensure all uses of radiation in medical imaging are justified and optimized.
- The justification of medical exposure for an individual patient should be carried out by the Referring Medical Practitioner, in consultation with the Radiological Medical Practitioner

Recommendations for Agencies

- Promote the development of national reference levels for use as quality assurance and quality improvement tools.
- Only adopt screening programs that have been submitted to rigorous scientific evaluation of efficacy
- Use methods for estimating individual occupational doses based on the goal of assigning accurate doses rather than overly conservative estimates of doses

Recommendations for Facilities

- Justify/optimize diagnostic and interventional x-ray use
- Ensure justification for an individual patient is made by the Referring Medical Practitioner in consultation with the Radiological Medical Practitioner
- Begin radiation dose management before the exam is ordered and extend it until follow-up is complete
- Provide relevant sources of information to the Referring Medical Practitioner at the time or ordering to assist with justification.

Recommendations for Facilities

- Periodically evaluate imaging system performance to optimize dose
- Provide for patient safety through an infrastructure for collecting, storing, and analyzing patient dose data
- Track patient doses
- Use reference levels as quality improvement tool
- Submit radiation dose data for national registry

Questions?

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