Role of Medical Physicists in Government

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My early government experience 1970’s

State “public health physicist” (Florida, Broward County Health Dept)
Radiation safety inspections
Radioactive material licenses (Medical, Industrial)
Medical X-rays (cone collimators, direct fluorescent screens)
Environmental Monitoring
Emergency Response

Dept Army health physicist (Aberdeen Proving Ground, MD)
Reactors
Environmental Surveys
Medical Physics (Medical Centers, Hospitals, Clinics)
Environmental and Emergency Response

Transitioned from Health Physics to Medical Physics

- Health physicists historically involved with radiation safety across a broad spectrum, including medical applications.
- Medical physicists are involved with medical applications, which are increasingly more complex.
- Today some MP’s are not necessarily interested in radiation safety. Focusing more on imaging, dosimetry, and computer applications.

Federal Agencies with Physicists

- Department of Defense – Hospitals and Medical Centers
- Department of Energy – Radiation Emergency Assistance Center
- Department of Homeland Security
  - Customs Border Patrol (rubidium incident)
- Nuclear Regulatory Commission
- Environmental Protection Agency
- Dept of Health and Human Services
  - Food and Drug Administration
  - National Institutes of Health
  - Centers for Disease Control and Prevention
What do we, as medical physicists do?

- Develop standards (voluntary, mandatory)
- Develop and review quality control tests
- Review medical products for approval that emit radiation (electronic or radioactive material).
- Develop phantoms and testing protocols (QC)
- Understand imaging as a science.
- Assure all aspects of radiation safety - for the consumer, for the patient, for workers.

Radiation Interpreters

Sometimes I think we are like lawyers, explaining terms only we understand.

The term "dose" is a real example....

Since dose limits have not been adopted in a timely, standard manner, audiences vary!

- 1975 FDA’s RDRC* Dose limits - rem
- 1977 ICRP* promulgates effective dose equivalent, H.
- 1980’s R to air kerma, rad to Gy; rem to Sv; mCi to MBq.
- 1991 NRC** adopts H for radiation dose
- 1991 ICRP replaces H with effective dose, E.
- 1993 NCRP*** adopts E.
- 2004 ICRP proposes new w,’s, modifying how E is calculated.
- 2008 ICRP adopts new w,’s.
- 2009 NRC considers adopting E

*Radioactive Drug Research Committee (CFR 21 361.1)
**International Commission on Radiological Protection
***National Council on Radiation Protection and Measurements

Food and Drug Administration

We have a wide area of radiation related responsibilities.

Unlike National Institutes of Health’s 27 institutes, FDA has three major medical product Centers, ....
FDA consists of many Centers

- Center for Drug Evaluation and Research (CDER) – Radiopharmaceuticals and imaging drugs (x-ray, ultrasound, MRI)
- Center for Devices and Radiological Health* (CDRH) – Medical Devices – accelerators, brachytherapy sources, consumer radiation products, etc.
- Center for Biologics Evaluation and Research (CBER) – Blood Irradiators
- Center for Food Safety and Nutrition* (CFSAN) – Food irradiators, Food Protective Action Guides (PAG)

*Medical or Health Physicists officially employed

Center for Devices and Radiological Health

Authority to regulate electronic and medical radiation products under 3 separate statutes

- Radiation emitting electronic products- includes consumer, non-medical electronic products.
- Medical Devices
- Mammography

Health hazards from non medical products must be evaluated as part of our public health mission.

This often become an issue of accurate dosimetry.

What is a Personnel Security Screening System (People Scanner)?

X-ray backscatter system
Quick review of authorities which give us the responsibility

Radiation Emitting Electronic Products (Radiation Control for Health and Safety Act of 1968)*

- Mandatory Emission Performance Standards
- Consumer and Medical Products
- Microwave ovens, lasers
- X-rays (medical and security products)

* Center for Devices and Radiological Health

Medical Device Act of 1976*

- 510 (k) – predicate device, substantial equivalency
- Class I – Minimal controls
- Class II- Special controls
- Class III
  - High risk devices
  - May require clinical trials for premarket approval (PMA).

We conduct research

With many other stakeholders
Nationwide Evaluation of X-ray Trends (NEXT) 1973 - current

- Collaborative federal/state program (CRCPD) which conducts surveys of patient dose from several diagnostic x-ray imaging exams
  - Chest
  - Abdomen/Spine
  - Mammography
  - CT
  - Fluoroscopy

1985 mammography survey conducted as a Nationwide Evaluation of X-ray Trends (NEXT) survey.

Program uses *standard* patient equivalent phantoms.

Collaborative program where an exam specific annual survey is conducted to determine radiation associated for a set of *standard* diagnostic exams (mammography, chest, abdomen, fluoroscopy, CT, pediatric).

Phantoms used in the Nationwide Evaluation of X-ray Trends (NEXT) survey program

- Fluoroscopy
- CT Head phantom

Understand the clinical issues, evaluate or develop phantoms for image quality and/or radiation dosimetry
Dose and Image Quality Trends in Mammography

Mammography Quality Standards Act of 1992

- Assures quality by establishing mandatory standards for:
  - Quality control of equipment
  - Personnel
  - Image quality and dosimetry

Leading edge image research

- FDA
  - CDRH’s Office of Science and Engineering laboratories (OSEL)
- National Cancer Institute of the NIH

Variability in radiologist drawn boundaries
How are radiolabeled and contrast drugs (gadolinium-MRI, iodine-x-ray, bubbles-US) regulated by FDA's Center for Drug Evaluation and Research?

Basic Research: Radioactive Drug Research Committee (non-IND human research, not for diagnostic, therapeutic, safety, or efficacy)

- Formally codified in 21 CFR 361.1 (1975)
- Allows human research with radioactive drugs without an IND:
  - Research must be basic
  - RDRC must review and approve protocol
  - There is no clinically detectable pharmacologic effect from the administered drug
  - and radiation dose limits are met

Medical Isotope (Radiopharmaceutical) Clinical Trials

- Center for Drug Evaluation and Research (CDER)
- Center for Biologics Evaluation and Research (CBER)

What does it take to get a drug approved?

Research Phase

- Clinical Research under an Investigational New Drug (IND) Application
  - Phase I- Safety "n ~ 20 – 80"
  - Phase II- Efficacy "n < several hundred"
  - Phase III- Large scale studies for benefit – risk, dosing, and physician labeling information "n ~ several hundred to several thousand"
How are drugs approved?
New Drug Application (NDA)

- NDA Process:
  http://www.fda.gov/cder/regulatory/applications/nda.htm#Related%20Topics:
- Application Fee for NDA ~ $1 M

What does it take to get a drug approved?
Manufacturing Standards

- Quality and purity of product
- Good Manufacturing Practice (GMP)
- Chemistry, Manufacturing & Controls (CMC)

Manufacturing Responsibilities

Pharmaceuticals: Good Manufacturing Practice (GMP) – 21 CFR Parts 210, 211, 212 (proposed), 600-680

Medical Devices: Quality System (QS) regulations – 21 CFR Part 820

Guidance for Industry and FDA Current Good Manufacturing Practice for Combination Products
http://www.fda.gov/cder/guidance/CCMPCombination.htm

Licensing

- FDA does not license radioactive materials
- Radioactive materials licensed by the Nuclear Regulatory Commission (NRC) or
- Radioactive materials licensed by Agreement States (36 states with formal “agreements” with the NRC
- FDA approves biological products by via the Biological Licensing Application (BLA)
- FDA approves radiolabeled drugs via the New Drug Application (NDA)
- www.fda.gov/cder/guidance/5645fnl.htm
Medical physicists are essential for these many responsibilities.

We are often the most knowledgeable regarding radiation safety and imaging criteria.

Medical Physicist Responsibilities not limited to ionizing radiation

- Safety
  - Ionizing Radiation
  - Non-Ionizing
    - Microwave (Ovens, cell phones, radiowaves)
    - Visible light (lasers, ultraviolet)
    - Thermal effects
    - Ultrasound
    - Magnetic
  - Beneficial Uses of Radiation
    - Medical
    - Security

Radiation Safety

- Fluoroscopy
- Computed tomography
- Nuclear medicine
- Radiation dose
  - Organ dose tables
  - Testing protocols
  - Dose assessment

Patient radiation safety

Fluro Skin necrosis  CT hair loss  Cardiac damage?
Organ Dose Methodology
Oak Ridge National Labs/ NIH Grants

Early standard reference mathematical models-
- 1969- Medical Internal Radiation Dosimetry (MIRD) Committee- nuclear medicine organ doses using standard reference organs (Snyder et al)
- 1975- This model modified for external x-ray beam sources (FDA- Rosenstein)
- German GSF- 1982 (Kramer et al) Concept of voxel phantoms
- British NRPB- 1985 (Jones et al)
- mathematical, realistic, stylistic, dynamic, computational models…ICRP Pub 110 (Apr 2009).


U. S. Food and Drug Administration (FDA)
Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging

1. Support informed clinical decision making (justification) - develop and adopt appropriate use criteria for CT, fluoroscopy, and nuclear medicine procedures
2. Promote safe use of medical imaging devices (optimization) – develop nationally recognized diagnostic reference levels for medical imaging procedures that use radiation
3. Increase patient awareness (communication) – provide patients with tools to track their personal medical imaging history
The Technetium-99m Generator
Brookehaven National Lab - 1958
Ideal nuclide
$T_{1/2} = 6$ hours
$\gamma = 140$ keV
http://www.bnl.gov/bnlweb/history/Tc-99m.asp

How are standards developed?

Three phases in regulating
- Educational
- Voluntary consensus standards
- Regulatory (mandatory standards)

The evolutionary path in standards development
- Education - professional forums, publications....
- Consensus for Good Practice
- Voluntary Standards
- Mandatory Standards (Regulations)
- Enforcement - Violation, lack of qualification.
- Fear of Litigation (regulator of last resort).
We do research, educate, standardize, and enforce.

Typical Doses - Adults (E)

<table>
<thead>
<tr>
<th>Radiation Source</th>
<th>Effective Dose (E)</th>
<th>Equivalent to # of chest x-rays</th>
<th>Equivalent</th>
<th>Lifetime</th>
<th>Cancer Mortality Risk</th>
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</thead>
<tbody>
<tr>
<td>Background</td>
<td>3 mSv</td>
<td>150</td>
<td>1 year</td>
<td>1.0 10^-6</td>
<td></td>
</tr>
<tr>
<td>Medical</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Chest x-ray</td>
<td>0.10 mSv</td>
<td>2.4 days</td>
<td>1.5 10^-6</td>
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<tr>
<td>Upper GI x</td>
<td>0.01 mSv</td>
<td>1 year</td>
<td>1.8 10^-6</td>
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<tr>
<td>CT abdomen</td>
<td>0.15 mSv</td>
<td>3.3 years</td>
<td>3.0 10^-6</td>
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<tr>
<td>Upper GI barium</td>
<td>0.1 mSv</td>
<td>4 months</td>
<td>3.5 10^-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PET-CT</td>
<td>0.1 mSv</td>
<td>3.5 years</td>
<td>5.0 10^-5</td>
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<td></td>
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<tr>
<td>PET-FDG</td>
<td></td>
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<tr>
<td>Regulator Limits</td>
<td></td>
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</tr>
<tr>
<td>Individual Gen pop</td>
<td>1 mSv</td>
<td>4 months</td>
<td>6.1 10^-6</td>
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</tr>
<tr>
<td>Worker</td>
<td>0.5 mSv</td>
<td>187 years</td>
<td>2.3 10^-6</td>
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</tr>
<tr>
<td>Emergency Worker</td>
<td>0.05 mSv</td>
<td>187 years</td>
<td>2.3 10^-6</td>
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</tr>
</tbody>
</table>

*ICRP 60 risk coefficients