Radiation Doses in Radiology:
Influence of Standards and Regulations

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Disclaimer statement

The opinions expressed in this presentation may not necessarily reflect the official position of the Food and Drug Administration or the Department of Health and Human Services.
The critical path towards mandatory standards (regulation)

- Education - professional forums, publications.....
- Consensus for Good Practice
- Voluntary Standards
- Mandatory Standards (Regulations)
- Enforcement.
- Litigation (regulator of last resort).
Many ways to educate and regulate via standards

• Reimbursement standards
  – Centers for Medicare and Medicaid Services (CMS)- “reasonable and customary”
  – Insurance Companies

• Product Standards
  – Food and Drug Administration (FDA)- “safety and efficacy”
  – Testing Laboratories

• Professional standards
  – Licensing/ Registration (States)
  – Certification (Professional Boards)
  – Accreditation
    • Joint Commission on the Accreditation of Healthcare Organizations (JCAHO)
    • American College of Radiology (ACR)
Standards and Regulations on Medical radiation dose

Historically, controlling or limiting patient radiation dose was interpreted as interfering with the practice of medicine, but that has changed.

What is a “high” dose? “...know it when we see it”.... paraphrasing Supreme Court Justice Potter Stewart.

What is a reasonable dose?
“As low as reasonably achievable” (ALARA)

• If ALARA were followed, especially in medicine…

• the question of “high” dose would be mute.

• The highest doses are in therapy, yet we rarely need to question these values, other than the accuracy of the radiation dose.

• So “high” or “low” is relative to the imaging and medical task.
Mammography

• In the next few slides I will discuss mammography as a comprehensive example….

• education, a general consensus as to good practice,

• voluntary standards, and finally

• regulatory (Mandatory) Standards, with the Mammography Quality Standards Act of 1992 (MQSA).
Mammography Dose Metrics

- 47 Roentgen- entrance skin exposure (74)
- 14 mGy mean glandular dose (74)
- 3 mGy limit for “standard” phantom (85/92)
- 1.8 mGy (2009)
- Mean glandular dose is the standard dosimetric quantity in mammography.
Dose and Image Quality Trends in Mammography

- Mean Glandular Dose
- Phantom Score (w/o artifact subtraction)
The “Standard” FDA, ACR Mammography Phantom (~4.2 cm compressed breast)
Standard phantom image used to assess optimal performance of entire imaging chain, over time.
Nationwide Evaluation of X-ray Trends (NEXT)

Collaborative program where periodic surveys are conducted to determine radiation associated for a set of widely used exams (mammography, chest, abdomen, fluoroscopy, CT, pediatric).

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

Program uses standard, patient equivalent phantoms.
Phantoms used in the Nationwide Evaluation of X-ray Trends (NEXT) survey program

Fluoroscopy

CT Head phantom
Standardization was essential for NEXT

• Primarily a scientific exercise, establishing baseline data to demonstrate program efficacy over time.

• Measured air kerma (Entrance Skin Exposure) for several diagnostic x-ray exams. Also measured some simple metrics related to image quality.

• Phantoms’ equivalence to average patient was logical, but required some extra effort.

• We did not calculate organ doses, but organ doses could be calculated from these measurements.
Reference Levels as standards

- NEXT data generated distribution of exposures
- State of Illinois and CRCPD* - Exposure limits
- Presidential Directive (Carter)- 1978 Exposure Limits for Federal Facilities
- ICRP 26 (1977) - Reference, investigation, intervention levels - not limits!
- ACR – 2008 Diagnostic Reference Levels
- Exam specific “action level” for follow-up investigation, usually the 75th percentile. Not intended as a mandatory dose limit.

* Conference of Radiation Control Program Directors
Nuclear Medicine
Organ dose standardization

• It was the SNM*’s Medical Internal Radiation Dose (MIRD) committee and the Oak Ridge National Laboratories that made the calculation of radiation organ doses a reality, …..

• This concept is the basis for radiation risk assessment today.

*Society of Nuclear Medicine
Monte Carlo Computer Models

Enabled the calculation of organ doses for a standard 70 kg human model from input data such as radioactivity and biodistribution for a specific radionuclide; later adopted for external x-ray sources.
Early standard reference mathematical models-

- 1969- Medical Internal Radiation Dosimetry (MIRD) Committee- nuclear medicine organ doses using standard reference phantom with 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).
These phantoms represent different ages, sizes, they may have scalable organ dimensions, different body geometries (prone, supine, upright, and some are dynamic (respiratory or cardiac cycles).
Adult Reference Computational Phantoms


Phantoms based on medical images of real people, organ masses adjusted to ICRP (Pub 89- 2002) adult Reference Male and Reference Female.

Organ doses can now be calculated from all sources!
Science caused changes in regulatory concepts …

In the 70’s….as we developed the ability to calculate organ specific radiation absorbed dose, regulatory concepts shifted away from the (1) whole body dose to (2) organ/tissue doses.

One legacy example of this two tier system which still exists today, promulgated in 1975, is FDA’s radioactive drug research program…..
Radioactive Drug Research Committee
Radiation Dose Limits*

<table>
<thead>
<tr>
<th>Organ or System</th>
<th>Single Dose</th>
<th>Annual and Total Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole body</td>
<td>0.03 Sv (3 Rem)</td>
<td>0.05 Sv (5 Rem)</td>
</tr>
<tr>
<td>Active blood-forming organs</td>
<td>0.03 Sv (3 Rem)</td>
<td>0.05 Sv (5 Rem)</td>
</tr>
<tr>
<td>Lens of the eye</td>
<td>0.03 Sv (3 Rem)</td>
<td>0.05 Sv (5 Rem)</td>
</tr>
<tr>
<td>Gonads</td>
<td>0.03 Sv (3 Rem)</td>
<td>0.05 Sv (5 Rem)</td>
</tr>
<tr>
<td>Other organs</td>
<td>0.05 Sv (5 Rem)</td>
<td>0.15 Sv (15 Rem)</td>
</tr>
</tbody>
</table>

Based on 1975 Nuclear Regulatory Commission’s occupational dose limits

*21 CFR 361.1 (b) (3)

Radiation doses from x-ray procedures that are part of the research study shall also be included.

For research subjects under 18 years of age at his last birthday, the radiation dose does not exceed 10 percent of adult dose.
This disparity between whole body and organ dose limits was finally addressed by the International Commission on Radiological Protection (ICRP) in 1977!...32 years ago.
ICRP’s dose and phantom standards.

- 1977 - ICRP (Report 26) introduced effective dose equivalent, H.
- 1990 - modified in Report 60 to effective dose, E.
- 2008 - E updated in Report 103.
- 2009 - Publication 110 – Adult Reference Computational Phantoms
Effective Dose* (E)

“Risk based metric, relating partial body irradiations (individual organ or tissue, limited x-ray field) to uniform whole body irradiation.”

The effective dose (E) is the sum of the weighted equivalent doses in all the tissues and organs of the body.

\[ E = \sum T W_T H_T \]

Where:

- \( W_T \) is the weighting factor for tissue T, and
- \( H_T \) is the individual tissue or organ dose for tissue T

*International Commission on Radiological Protection (ICRP Report 60, 1990)
Effective Dose, a Worldwide standard

- **Advantages**
  - Allows comparison of radiation dose (detriment) from different sources
  - Single metric

- **Limitations**
  - Single metric, creates potential for people to ignore underlying organ doses, which are important for medicine and specific safety situations.
  - Ignores age and gender, so comparisons between populations of different age and gender is problematic
  - It is a radiation protection metric, not rigorously scientific, not originally designed for medicine.
### Tissue Weighting Factors ($w_t$)

<table>
<thead>
<tr>
<th>Organ (Tissue)</th>
<th>Reports:</th>
<th>26</th>
<th>60</th>
<th>DRAFT/103</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gonads</td>
<td></td>
<td>0.25</td>
<td>0.20</td>
<td>0.05/0.08</td>
</tr>
<tr>
<td>Breast</td>
<td></td>
<td>0.15</td>
<td>0.05</td>
<td>0.12</td>
</tr>
<tr>
<td>Red BM, lung</td>
<td></td>
<td>0.12</td>
<td>0.12</td>
<td>0.12</td>
</tr>
<tr>
<td>Thyroid</td>
<td></td>
<td>0.03</td>
<td>0.05</td>
<td>0.05/0.04</td>
</tr>
<tr>
<td>Bone surfaces</td>
<td></td>
<td>0.03</td>
<td>0.01</td>
<td>0.01</td>
</tr>
<tr>
<td>Colon, stomach (NC- not calculated)</td>
<td></td>
<td>NC</td>
<td>0.12</td>
<td>0.12</td>
</tr>
<tr>
<td>Bladder, liver, esophagus</td>
<td></td>
<td>NC</td>
<td>0.05</td>
<td>0.05/0.04</td>
</tr>
<tr>
<td>Skin</td>
<td></td>
<td>NC</td>
<td>0.01</td>
<td>0.01</td>
</tr>
<tr>
<td>Salivary glands, brain</td>
<td></td>
<td>NC</td>
<td>NC</td>
<td>0.01</td>
</tr>
<tr>
<td>Remainder</td>
<td></td>
<td>0.30</td>
<td>0.05</td>
<td>0.10/0.12</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
</tr>
</tbody>
</table>
These periodic changes in Tissue Weighting Factors ($w_t$) are important!

Demonstrate that new science is being incorporated periodically.
Effective dose, $E$, allows comparison among modalities

The only standard risk based metric that allows comparison of radiation dose from different sources such as x-ray, CT, nuclear medicine, and other sources.

The next slide, although not perfect, uses $E$, and compares the average dose, when known, or “typical” doses for a variety of exams or sources.

Caveat - even for a known amount of radiation, the dose any individual may receive can vary by a factor of 10 or more for a variety of reasons, such as patient size, geometry, radiation type and quality, and time.
# Typical Doses - Adults (E)

<table>
<thead>
<tr>
<th>Radiation Source</th>
<th>Effective Dose (E)</th>
<th># of chest x-rays</th>
<th>Equivalent time</th>
<th>Lifetime* Cancer Mortality Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>U.S. - 1 year</td>
<td>3 mSv</td>
<td>150</td>
<td>1 year</td>
<td>1.5 $10^{-4}$</td>
</tr>
<tr>
<td>Medical</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chest x-ray</td>
<td>0.02 mSv</td>
<td>1</td>
<td>2.4 days</td>
<td>1.0 $10^{-6}$</td>
</tr>
<tr>
<td>Upper GI fl</td>
<td>3 mSv</td>
<td>150</td>
<td>1 year</td>
<td>1.5 $10^{-4}$</td>
</tr>
<tr>
<td>CT- abdomen</td>
<td>10 mSv</td>
<td>500</td>
<td>3.3 years</td>
<td>5.0 $10^{-4}$</td>
</tr>
<tr>
<td>Tc-99m-lung perf</td>
<td>1 mSv</td>
<td>50</td>
<td>4 months</td>
<td>5.0 $10^{-5}$</td>
</tr>
<tr>
<td>Tc-99m-bone</td>
<td>4 mSv</td>
<td>200</td>
<td>1.3 years</td>
<td>2.0 $10^{-4}$</td>
</tr>
<tr>
<td>PET–FDG</td>
<td>10 mSv</td>
<td>500</td>
<td>3.3 years</td>
<td>5.0 $10^{-4}$</td>
</tr>
<tr>
<td>Regulatory Limits</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individual Gen pop</td>
<td>1 mSv</td>
<td>50</td>
<td>4 months</td>
<td>5.0 $10^{-5}$</td>
</tr>
<tr>
<td>Worker</td>
<td>50 mSv</td>
<td>2500</td>
<td>16.7 years</td>
<td>2.5 $10^{-3}$</td>
</tr>
<tr>
<td>Emergency Worker</td>
<td>500 mSv</td>
<td>25,000</td>
<td>167 years</td>
<td>2.5 $10^{-2}$</td>
</tr>
</tbody>
</table>

*ICRP 60 risk coefficients
Effective dose, E, despite limitations, is a valuable dose standard.

A better metric would also adjust each organ dose for age, sex, and dose rate.

These could be addressed in the future.
Effective dose, E, has not been adopted in a timely, standard manner!

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.
2008  ICRP adopts new $w_t$’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
When should voluntary standards be mandated?

- Safety, avoidance of harm, is usually a major justification for such mandatory regulatory standards.
- Often mandated by legal statute.
- When voluntary standards have failed to prevent harm.
For fluoroscopy

When we still observe deterministic effects such as skin erythema and radiation burns, it is obvious education alone is not working.
Fluoroscopy regulatory history

- Professional articles
- ACR/FDA Fluoroscopy Workshop- 1992 ACR/FDA Fluoroscopy Conference held in Reston, VA (October 16 and 17, 1992)
- Two FDA Advisories (1994 and 1995)
- Dose speedometer and odometer regulations (June 2006) 21 CFR 1020
- Sentinel Incident- JCAHO
- Yet radiation burns continue…..
And in Computed Tomography

• We are also observing deterministic effects such as skin erythema (ring around the body) and hair loss.

• Stochastic risks are not trivial, but they represent an abstract level of risk, but deterministic effects are palpable.
Computed Tomography regulatory history

- Professional articles, meetings, workshops
- Voluntary Dose indicators
- Obviously with increasing use, we are observing more adverse events.
Are we repeating history?
Major radiation epidemiologic studies have been medical, except for the LSS

Life Span Study of A-Bomb Survivors (n = 91,228)

Ankylosing Spondylitis (n = 14,106)

Women treated for Cervical cancer (n~150,000)

Canadian Fluoroscopy Study (n= 31,710)

New York State Postpartum Mastitis Study (n = 601)

Massachusetts Fluoroscopy Study (n = 1742)
What do these technologies have in common?

• Widely used, user friendly, and valuable medical technologies.

• Complex technologies, radiation source and anatomy change dynamically. Lack simple relationship between air kerma and absorbed dose. Dosimetry is challenging.

• Very operator (user) dependent.

• Potential to deliver deterministic adverse events.
Radiation Safety Assurance

• Operators must understand radiation safety for their modality, not just how to operate it.

• Current equipment “dose” displays insufficient for safety, we need a “standardized” radiation dose to patient display, for all modalities.
Radiation Source Metrics

Essential for dose calculation, but they are modality specific, radioactivity for nuclear medicine, air kerma, and air kerma rate for fluoroscopy, and CTDI for CT.

These radiation source metrics are not a precise nor an accurate predictor of the final human radiation dose.

Additional factors that will affect the final patient dose estimate are exposure time, patient size, and the specific protocol used.

*Computed tomography dose index
So in order to practice “As low as reasonably achievable” (ALARA)

• You need to know the patient’s dose?

• E, or something similar, representing the dose estimate to the patient, or a computational phantom of similar size, should be the standard for safety.

Without E, how can you compare radiation risk among modalities?

Cardiac imaging is an excellent example where the doses patients receive are not reported in a standard, comparable way. Which cardiac imaging study gives the most dose, fluoroscopic angiography, cardiac uptake studies using Tc-99m, or CTA (CT angiography), an emerging cardiac imaging exam!
E can be determined for all modalities.

- The technology exists today to be part of the solution.
- For each modality using a specified technique or protocol, the dose to a set of phantom(s) representing different patient sizes can be calculated. This data could be stored in a database.
- For any patient using the same specified technique or protocol, the radiation dose can be estimated by matching the patient’s dimensions with the computational phantom.
- A dose estimate, such as E, can be displayed in real time.
- These dose estimates (organ and E) would enable recording of this information in a standard way in a patient’s permanent medical record.
And for the user (operator)

We need to assure that the individuals using these technologies are educated and trained in standard radiation safety practice, specific to these technologies.

Variety of regulatory pathways exist to ensure standard education and training.
In closing (1)

Today, when medically necessary, the radiation associated with any imaging modality that is properly operated and used is safe.

• The radiation dose for each new exam or protocol should always be estimated by qualified personnel.

• Repeat and multiple exams need to be tracked by recording the dose in a patient’s medical record, since patients may often have additional exams.
In closing (2)…

Standard dose estimates for these exams, derived from organ doses should be determined for each patient. A whole body dose surrogate, such as E, should be displayed, which can also be recorded for each patient.

Mandatory standards for patient radiation safety, for those individuals operating imaging modalities capable of delivering deterministic doses, should be required.
FDA
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