Medical Devices
Radiation Safety

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Health Technology Task Group
Radiological equipment has changed a bit since the early days...
First Co-60 Unit (1951)  
Cs-137 Teletherapy (1960’s)

External Beam Therapy

Orthovoltage X-Ray (1990’s)

Linac with IGRT (200s)
Brachytherapy

Manchester Applicator

Ra Needles 1929

1950 - 1960

Cs-137 1970 - 1980

Ir-192

LDR HDR 1990

HDR 2000

Miniature X-Ray Tube

Electronic Brachytherapy
## Global Annual Number of Radiological Exams and Treatments per 1,000 People

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>X Rays</td>
<td>562</td>
<td>420</td>
</tr>
<tr>
<td></td>
<td>(1,607)</td>
<td>(1,230)</td>
</tr>
<tr>
<td>Nuclear Medicine</td>
<td>5.1</td>
<td>5.6</td>
</tr>
<tr>
<td></td>
<td>(19)</td>
<td>(19)</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>0.8</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>(2.4)</td>
<td>(1.9)</td>
</tr>
</tbody>
</table>

(Data for HCL I)

UNSCEAR 2008
Annual per Caput Effective Dose (mSv) for the United States Population

1980

UNSCEAR 2008

2006
Radiation Risks

Contamination Pathways

- Absorption
- Inhalation
- Ingestion

▲ External
▲ Internal
Deterministic Effects

Radiation effects for which generally a threshold level of dose exists above which the severity of the effect is greater for a higher dose.

Stochastic Effects

Radiation effects, generally occurring without a threshold level of dose, whose probability is proportional to the dose and whose severity is independent of the dose.
Effects of Cell Death

Probability of Death

100%

Dose (mGy)

D

Co-60 Radiotherapy Overexposure Panama 2000-2001

Haemorrhagic rectal mucosa 2 days before death
Whole body response: adult

Acute irradiation syndrome

- 1-10 Gy
- 10-50 Gy
- > 50 Gy

BMS (bone marrow)
GIS (gastro intestinal)
CNS (central nervous system)

Lethal dose 50 / 30

Chronic irradiation syndrome

- Whole body clinic of a partial-body irradiation
- Mechanism: Neurovegetative disorder
- Similar to a sick feeling
- Quite frequent in fractionated radiotherapy
Skin Injuries

Interventional Radiology Over-Exposure, USA 1991

Radiodermatitis. 7 year old patient. Four months after a cardiac ablation. E. Vano, L. Arranz et al. BJR, 1998

Radiodermatitis. 17 year old patient. Two years after 2 cardiac ablations. E. Vano, L. Arranz et al. BJR, 1998

January 1992
Effects in the Eye

- Eye lens is highly radiosensitive.
- Coagulation of proteins occur with doses greater than 2 Gy.
- There are 2 basic effects:

<table>
<thead>
<tr>
<th>Effect</th>
<th>Sv single brief exposure</th>
<th>Sv/year for many years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detectable opacities</td>
<td>0.5-2.0</td>
<td>&gt; 0.1</td>
</tr>
<tr>
<td>Visual impairment (cataract)</td>
<td>5.0</td>
<td>&gt; 0.15</td>
</tr>
</tbody>
</table>

Deterministic Effects

Radiation effects for which generally a threshold level of dose exists above which the severity of the effect is greater for a higher dose.

Stochastic Effects

Radiation effects, generally occurring without a threshold level of dose, whose probability is proportional to the dose and whose severity is independent of the dose.

Cancer

Heritable Effects
Scale of Radiation Exposures

- Bone scan
- CT scan
- Annual Background
- Typical Radiotherapy Fraction

Cancer deaths/year/1M people vs. Dose (mGy)

- Natural cancer mortality
- Additional cancer deaths due to radiation
Genetic (Heritable) Effects (Mutations)

Fruit Fly Experiments

Absorbed dose (Gy) vs. Frequency (%)
Genetic Effects

▲ Ionizing radiation is known to cause hereditary mutations in many plants and animals

BUT

▲ Intensive studies of 70,000 offspring of the atomic bomb survivors have failed to identify an increase in congenital anomalies, cancer, chromosome aberrations in circulating lymphocytes or mutational blood protein changes.
ICRP Detriment-Adjusted Nominal Risk Coefficient for Cancer and Heritable Effects  
(ICRP 103, 2007)  
($10^{-2} \text{ Sv}^{-1} – \text{Percent per Sievert}$)

<table>
<thead>
<tr>
<th>Exposed Population</th>
<th>Cancer Induction</th>
<th>Heritable Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole</td>
<td>5.5</td>
<td>0.2</td>
</tr>
<tr>
<td>Adult</td>
<td>4.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Problem</td>
<td>Country</td>
<td>Year</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Co-60 Mis-calibrations</td>
<td>USA</td>
<td>1974-1976</td>
</tr>
<tr>
<td></td>
<td>Germany</td>
<td>1986-1987</td>
</tr>
<tr>
<td></td>
<td>UK</td>
<td>1988</td>
</tr>
<tr>
<td></td>
<td>Costa Rica</td>
<td>1996</td>
</tr>
<tr>
<td>Hardware / Software</td>
<td>Canada &amp; USA</td>
<td>1985-1987</td>
</tr>
<tr>
<td>Linear Accelerators</td>
<td>USA</td>
<td>1987-1988</td>
</tr>
<tr>
<td></td>
<td>Spain</td>
<td>1990</td>
</tr>
<tr>
<td></td>
<td>Poland</td>
<td>2001</td>
</tr>
<tr>
<td>Treatment Planning</td>
<td>USA</td>
<td>1987-1988</td>
</tr>
<tr>
<td></td>
<td>Panama</td>
<td>2000</td>
</tr>
</tbody>
</table>
4. REPORTED ACCIDENTAL EXPOSURES WITH NEW TECHNOLOGIES

4.1. Events related to beam output and calibration

4.1.1. Calibration problems of small-fields

4.1.2. Intra-operative radiation therapy beam calibration issues

4.1.3. Beam output drift in tomotherapy

4.2. Issues related to treatment preparation

4.2.1. Problems with dynamic wedges

4.2.2. Computer problems with intensity modulated radiation therapy

4.2.3. Errors in imaging for radiation therapy treatment planning

4.2.4. Treatment set up errors from virtual simulation markers

4.2.5. Digitally reconstructed radiograph errors

4.3. Events related to patient data management

4.3.1. Errors when using “record and verify” systems

4.4. Events related to treatment delivery and treatment verification

4.4.1. Significant radiation exposure from electronic portal imaging

4.4.2. Errors with stereotactic radiosurgery field size
621 Radiotherapy Mistakes (NYT)*
New York State, 2001 - 2008

<table>
<thead>
<tr>
<th>Nr. Patients</th>
<th>Cause of overexposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>133</td>
<td>Beam-shaping devices error</td>
</tr>
<tr>
<td>284</td>
<td>Wrong target</td>
</tr>
<tr>
<td>50</td>
<td>Wrong patient</td>
</tr>
<tr>
<td>1</td>
<td>Faulty calculation</td>
</tr>
<tr>
<td>2</td>
<td>Lack of tests after machine repair</td>
</tr>
</tbody>
</table>

* The information presented is that reported in the New York Times (NYT) by Walt Bogdanich in January 2010. No independent verification for accuracy has been performed.
2 Radiotherapy Mistakes (NYT)*
New York City, 2005
(Patients died in 2007)

<table>
<thead>
<tr>
<th>Cancer Site</th>
<th>Cause of overexposure</th>
<th>Comments / Consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tongue</td>
<td>Multileaf collimator for IMRT did not work. Open field instead. (Varian)</td>
<td>3 of 5 fractions given. Severe morbidity. Physicist checks RX Dose given : 7 times prescribed Hospital and Varian sued Varian modifies software</td>
</tr>
<tr>
<td>Breast</td>
<td>Wedge not in the beam.</td>
<td>27 of 28 fractions given. Morbidity appears at the end. Dose given: 3.5 times prescribed</td>
</tr>
</tbody>
</table>
## Radiotherapy Mistakes (NYT)*
### Other USA States

<table>
<thead>
<tr>
<th>State</th>
<th>Year</th>
<th>Nr. Patients</th>
<th>Cancer Site</th>
<th>Cause of overexposure</th>
<th>Overdose (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florida</td>
<td>2005</td>
<td>77</td>
<td>Brain</td>
<td>Linac miscalibration</td>
<td>50</td>
</tr>
<tr>
<td>Louisiana</td>
<td>2005</td>
<td>1</td>
<td>Prostate</td>
<td>Wrong CT scan for TPS</td>
<td>100 (38 fractions)</td>
</tr>
<tr>
<td>Texas</td>
<td>2004</td>
<td>1</td>
<td>Prostate</td>
<td>EBT + Brachy : No dose prescription, no post-implant calcs</td>
<td>?</td>
</tr>
<tr>
<td>Ohio</td>
<td>2006</td>
<td>1</td>
<td>Breast</td>
<td>Incorrect magnification factor</td>
<td>100</td>
</tr>
</tbody>
</table>
# Radiotherapy Mistakes

## Veterans Affairs Hospitals

<table>
<thead>
<tr>
<th>Location</th>
<th>Year</th>
<th>Nr. Patients</th>
<th>Cancer Site</th>
<th>Cause of overexposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Philadelphia, Pennsylvania</td>
<td>2002 - 2008</td>
<td>97</td>
<td>Prostate</td>
<td>Incorrect placement of I-125 seeds, No dosimetry</td>
</tr>
<tr>
<td>East Orange, New Jersey</td>
<td>2006</td>
<td>56</td>
<td>Prostate, Head &amp; Neck, Lung, Breast, 2 Others</td>
<td>No staff training in IMRT, No experience, No QC, QA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>36 overirradiated, 20 had “errors”</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
"Medical Radiation: An Overview of the Issues"
Subcommittee on Health
February 26, 2010
Radiation-Emitting Products

Home > Radiation-Emitting Products

Spotlight
- CDRH FY 2010 Strategic Priorities
- CDRH Ombudsman Annual Report - Calendar Year 2009
- Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging
- Guidance for Industry and FDA Staff: Acceptable Media for Electronic Product User Manuals
- Exemptions From Electronic Product Regulations

Radiation-Emitting Products and Procedures
- Medical Imaging, Surgical & Therapeutic
- Home, Business, & Entertainment
- Radiation Safety
- Radiation Dose Reduction, Nationwide Evaluation of X-Ray Trends (NEXT), Electromagnetic Compatibility (EMC)
- Mammography Quality Standards Act and Program
- Regulations, Guidance, Facility Certification and Inspection

Electronic Product Radiation Control Program
- Getting a Product to Market, Regulations, Guidance
- News and Events (Radiation-Emitting Products)
- Program Updates, New Documents
- Resources for You (Radiation-Emitting Products)
- Consumers, Health Care Providers, Regulated Industry
- FDA Radiological Health Program
- Standards, Monitoring, Education, Research

Recalls & Alerts
- Consumer Safety Alert: Internet Sales of Laser Products
- Alerts and Notices
- Report a Problem
- List of Device Recalls
NRC NEWS
U.S. NUCLEAR REGULATORY COMMISSION
Office of Public Affairs Region III
2443. Warrenville Road
Lisle IL 60532

No. III-10-005
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Prema Chandrathil 630-829-9663

March 17, 2010
E-Mail: opa3@nrc.gov
Web site: www.nrc.gov

NRC PROPOSES $227,500 FINE AGAINST DEPARTMENT OF VETERANS AFFAIRS

The Nuclear Regulatory Commission has proposed a $227,500 fine against the Department of Veterans Affairs (DVA) for violations of NRC regulations associated with an unprecedented number of medical errors identified at the Veterans Affairs Medical Center in Philadelphia (VA Philadelphia).

Medical errors at VA Philadelphia involved the incorrect placement of iodine-125 seeds to treat prostate cancer. Out of 116 procedures performed between 2002 and 2008, 97 were executed incorrectly.