Assisting IAEA Member States to strengthen regulatory control, particularly in the medical area

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Outline of presentation

• Background on Medical Exposure
• Challenges
• The most relevant IAEA Safety Standards and other key publications
• Assistance Mechanisms
Radiation Use in Medical Area

Medical exposures contribute around 20% of the average annual per caput dose to the global population (medical: 0.65mSv/y natural background: 2.4mSv/y) (UNSCEAR 2008 Report)

Annually, worldwide (UNSCEAR 2001 Report)

• more than 3,600 million X-ray examinations are performed,
• 33 million diagnostic nuclear medicine procedures are carried out, and
• 5.1 million courses of radiotherapy treatments are given
Radiation Use in Medical Area

UNSCEAR 2008:

- Increase in annual collective effective dose
- Increase in mean annual effective dose
- Increase in the frequency of performing procedures

Reasons:

- Increase in the annual frequency of diagnostic medical and dental radiological examinations (mainly in Health Care level I countries)
- Increase in the per caput effective dose per examination (new technologies with higher doses)
- Increase in the annual number of examinations to the world population (NM)
- Increase in the average effective dose per procedure (NM)
- Increase in the global population
"Conventional medicine says take aspirin. In the absence of tort reform, defensive medicine says MRI and Cat Scan."
Justification: medical exposures shall be justified

- for generic justification: Health Authority with Professional Bodies
- for individual patients: radiological medical practitioner and the referring medical practitioner
- a challenge for all Health-Care levels
- tool for implementation: Referral Guidelines
Optimization in Medicine
Optimization: protection and safety is optimised for each medical exposure

- design and operational considerations
- calibration
- dosimetry of patients
- diagnostic reference levels
- quality assurance for medical exposures
- dose constraints
- a challenge for all Health-Care levels
Thus:

- Medical exposure is overwhelmingly the most significant manmade source of exposure to the population from ionizing radiation.

- Inappropriate regulatory control can lead to potential health hazards for patients, staff, and public.
Accidents in Medical Use

- Over the last three decades, at least 3000 patients have been reported to be affected by radiotherapy incidents and accidents. This is likely grossly under-reported.
- Radiation accidents involving medical uses have accounted for more injuries and early acute health effects than any other type of radiation accident, including accidents at nuclear facilities.

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<tbody>
<tr>
<td>Accidents at nuclear facilities</td>
<td>13 deaths</td>
<td>42 early effects</td>
<td>123 early effects</td>
<td>3 deaths</td>
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<tr>
<td>Industrial accidents</td>
<td>0 deaths</td>
<td>8 early effects</td>
<td>61 early effects</td>
<td>3 deaths</td>
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<tr>
<td>Orphan source accidents</td>
<td>7 deaths</td>
<td>5 early effects</td>
<td>98 early effects</td>
<td>19 deaths</td>
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<td>Accidents in academic/research work</td>
<td>0 deaths</td>
<td>2 early effects</td>
<td>22 early effects</td>
<td>0 deaths</td>
</tr>
<tr>
<td>Accidents in medical use</td>
<td>Unknown</td>
<td>Unknown</td>
<td>470 early effects</td>
<td>42 deaths</td>
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Causes of Medical Accidents

• Insufficient radiation protection and radiation safety regulations, or poor application
• Failure to implement radiation protection and radiation safety procedures
• Error due to insufficient knowledge of radiation protection and radiation safety regulations
• Insufficient training
• Lack of adequate quality control

In many cases:

• Lack of legal and regulatory framework for safety
Challenges

• Lack of regulatory framework for safety in many MS
• Lack of capacity at the national level
• Promotion of regulatory requirements
• Implementation of Justification
• Further enhance Optimisation
• Complex equipment, new technologies and techniques, quality control
• Coordination with relevant professional bodies
IAEA Safety Functions

IAEA Functions in Radiation & Waste Safety (Article III.A.6 of the Statute)

- To facilitate and service international conventions and other undertakings
- To establish standards of safety
- To provide for the application of international standards
IAEA Safety Standards for regulatory control of sources

- **Principles**
  - Safety Fundamentals
  - IAEA Safety Standards for protecting people and the environment
  - Fundamental Safety Principles
  - Safety Fundamentals No. SF-1

- **“Shall”**
  - Safety Requirements
  - General Safety Requirements
    - No. GSR Part 1 (Rev. 1)
  - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards
    - General Safety Requirements Part 3
    - No. GSR Part 3

- **“Should”**
  - Safety Guides
    - Building Competence in Radiation Protection and the Safe Use of Radiation Sources
    - SAFETY GUIDE
    - No. RS-G-1.4
    - Regulatory Control of Radiation Sources
    - Safety Guide
    - No. GS-G-1.5
    - Categorization of Radioactive Sources
    - Safety Guide
    - No. RS-G-1.9
IAEA Safety Standards for regulatory control of sources

- IAEA Safety Standards are not legally binding on Member States but may be adopted by them.

- IAEA Safety Standards are binding on IAEA.

- i.e.: IAEA technical assistance in any radiation technology is conditional on the existence of an adequate radiation safety infrastructure.
Other key publications - The Code of Conduct

- The Code of Conduct

  Provides recommendations to States on:

  - Legislation
  - Regulations
  - Regulatory body
  - Import/Export controls

Non-legally binding international instrument based on International Standards

130 countries expressed political support

4th Open-Ended Meeting, 30 May – 4 June 2016
Important Safety Guides in final stage of development:

- DS 399: “Safety Guide on Radiation Protection and Safety in Medical Uses of Ionizing Radiation”
- DS 455: Establishing the Infrastructure for Radiation Safety
- DS 472: Organisation, Management and Staffing of a Regulatory Body for Safety
- DS 473: Functions and Processes of the Regulatory Body for Safety
Other key Publications: TECDOCs

Practical guidance for Regulators:
- TECDOCs 1525 and 1526 under revision to include more medical practices
- TECDOC 1732 on Model regulations
Assistance Mechanisms

Advisory Missions for States with no or little regulatory infrastructure:

Provision of “tailored” regulatory and technical advice and solutions:

- based on the IAEA safety standards,
- taking into consideration experience and good practice
- keep balance between “new technologies” / “realistic solutions”, taking into account the national circumstances and needs:
  - Health care level
  - Financial resources
  - Existing infrastructure
  - Alternatives
Adequate Infrastructure beyond Regulation
Adequate Infrastructure also includes skills to implement New Technologies.

“According to the films, it appears I’ve left an instrument inside you. Luckily, I can fix that in Photoshop.”
Integrated Regulatory Review Service (IRRS): Comprehensive Peer Review by international experts

- for operational and mature regulatory infrastructure
- includes the review of the regulatory oversight of medical facilities and patient protection
Most frequent Recommendations and Suggestions:

• Need for consistency in applying the graded approach for licensing medical facilities

• Development of practice specific regulations and guides, with consultation of relevant professional bodies

• Development of guidance on training required by medical personnel

• Need of specific training for inspectors of medical facilities

• Development and use of diagnostic reference levels
Self-Assessment methodology and Tool - SARIS

• Based on IAEA Safety Standards
• To be used in preparation of an IRRS, and for periodic self–evaluation of the regulatory system
• Includes modules on control of sources and on patient protection
Regulatory Authority information System - RAIS

- to establish and maintain the national register of radiation sources
- to manage all core regulatory functions (Authorization, Inspection, Enforcement)
- RAIS 4.0 is under development
- RAIS is being used by more than 65 MS
Assistance Mechanisms

- Support for **drafting** laws and regulations
- **Review** of draft regulations
- **School** for drafting regulations organized through TC projects and according to needs (12 Schools in the last 6 years)
Assistance Mechanisms

Several training packages for regulatory bodies, including:

- Authorization and Inspection of Radiotherapy, Nuclear Medicine, Radio-diagnostic
- Authorization and Inspection procedures of Cyclotrons
- Organization, Staffing and Competence Management of the Regulatory Body
- Enforcement
- Effective and Sustainable Regulatory Control of Radiation Sources
- Integrated Management System
Assistance Mechanisms

Training packages for health professionals on:

- Radiation protection in:
  - Diagnostic and interventional radiology
  - Nuclear medicine
  - Radiotherapy
  - Cardiology
  - PET/CT
  - Paediatric radiology
  - Digital radiology
  - Doctors using fluoroscopy outside radiology
- Prevention of accidental exposure in radiotherapy
- Downloadable from RPOP website
Assistance Mechanisms

- Control of Sources Network – CSN under GNSSN

- Technical support to Regulators’ Networks
Assistance Mechanisms

- Safety learning databases
  - anonymous
  - voluntary
  - learning from incidents
- SAFRAD
  - covers interventional procedures
- SAFRON
  - covers radiation therapy
  - facilities in MS are encouraged to use and learn from these systems
On-going Challenges

- Lack of regulatory framework for safety in many MS
- Lack of capacity at the national level
- Promotion of regulatory requirements
- Implementation of Justification
- Further enhance Optimisation
- Complex equipment, new technologies and techniques, quality control
- Coordination with relevant professional bodies
"He's been kind enough to stand in for us, until we can afford a new x-ray machine."
Thank You!
“Still, let’s do an x-ray just to be sure.”