International Basic Safety Standards for Protection against Ionizing Radiation and its relevance for occupational radiation protection in medical applications. Current IAEA activities

Rodolfo Cruz Suarez
Radiation Safety and Monitoring Section
Division for Radiation, Waste and Transport Safety
Department of Nuclear Safety and Security
International Atomic Energy Agency
Outline

2. Current situation of the BSS.
4. ISEMIR project.
5. Outreach approaches.
6. IRPA Regional in LA conclusions.
7. IDOS conclusions.
8. Future activities.
UNSCEAR Global Occupational Exposure

Annual effective dose (mSv)

- Nuclear industry
- Defence
- Medicine
- Coal mining
- Other mining
- Aircrew
- Other workplaces

Man-made sources

Natural sources
Medical exposures

Relative Contributions to Global Radiation Doses

Medical uses of radiation per year:
- About 4 billion X-ray examinations
- About 35 million nuclear medicine examinations
- About 8 million radiation therapy treatment courses

An increasing slice of the pie

2008

1980s

Natural background radiation
Medical uses of radiation
All other (global fallout, Chernobyl accident, nuclear power production)

Up to 50% of X-ray examinations lack proper justification or optimization
Skin injuries occur in interventional procedures

The future:
Medical uses of radiation
- Will increase significantly
- Will become more complex

IAEA
IAEA Safety Functions (Article III.A.6)

“Facilitate and service international conventions and other undertakings”

“To establish or adopt… [in consultation …] standards of safety for protection of health & minimization of danger to life and property”

“…and to provide for the application of these standards…”
Hierarchy of Safety Standards

Fundamentals

underlying principles - aimed at politicians and regulatory authorities

Requirements

specify obligations and responsibilities ("shall" statements)

Guides

recommendations to support requirements ("should" statements)
Radiation Protection Paradigm to be maintained

- IAEA, WHO, ILO, FAO etc.
  - Safety standards
  - Protection programmes

UNSCEAR
Scientific basis

ICRP
Protection philosophy, principles and units

ICRP
Annals of the ICRP

FAO/WHO
Codex Alimentarius Commission (food contamination guides)

UN transport regulations for radioactive material

ILO convention 115: occupational radiation protection

IAEA, WHO, ILO, FAO etc.

implemented by Member States

IAEA

recommendations

levels trends

effects risks
International Standards for Radiation, Transport & Waste Safety

Committees & the Commission on Safety Standards + BSS Secretariat*

*participants include:
FAO, IAEA, ILO, OECD/NEA, PAHO, WHO
EC, UNEP, ICRP, IRPA

review 2005/6

plan for revision
Nov 2006

revision 2007-09

approval 2010/2011?

MEMBER STATES

IAEA Safety Standards
for protecting peoples and the environment

Requirements for Radiation Safety
(Basic Safety Standards)

Safety Requirements
No. RS-R-1
Resolution GC(49)/RES/9A  2005  =>  Review BSS
Resolution GC(50)/RES/(10)  2006  =>  Revision BSS

**Objectives:**

- To support and facilitate the revision by ensuring that the interests, views and responsibilities of each cosponsoring organisation are fully taken into account
- To provide a forum for cosponsor organisations to inform each other of developments that may need to be taken into account
- To coordinate the approval process of the cosponsoring organisations for the revised BSS

The IAEA secretariat has the overall responsibility for the revision of the BSS. The IAEA will chair meetings of cosponsoring organisations, which will generally be held in Vienna.
New structure

The structure of the revised BSS follows from the new recommendations of ICRP

- **three exposure situations**
  - Planned
  - Emergency
  - Existing

- **three categories of exposure**
  - Occupational
  - Public
  - Medical
Revision of International BSS – draft 4.0

New format (CSS - 2008)

• Overarching discrete requirements expressed as “shall” statement, allocated a discrete number, written in plain language, with clear and short sentences.

• Associated with overarching requirements are so-called associated requirements which are considered as an integral part of the safety requirements.

• Draft 4.0 contains 52 overarching requirements currently
Principles of Radiation Protection

**Planned exposure situations**
- justification
- optimization
- dose limitation (+dose constraints & risk constraints)

**Emergency exposure situations**
- optimization
- dose limitation (reference levels)

**Existing exposure situations**
- optimization
- dose limitation (reference levels)
Revision of International BSS – draft 4.0

Responsibility tree

To establish and maintain a legal, regulatory and organizational framework
GOVERNMENT

To establish or adopt regulations and guides
REGULATORY BODY

PRIME responsibility
- Person or organization responsible for facilities and activities
- Principal parties

Specified responsibility
- Other parties
Revision of International BSS – draft 4.0

- **Specific requirements** on responsibilities of regulatory bodies have been **included** (eg Req. 19, 20)
- The requirements on licensees, registrants, workers, are **essentially unchanged**
  - Some rearrangement, consolidation and editing of text
  - Some detailed requirements on monitoring have been removed – more appropriate in a Safety Guide
  - Requirements for “special circumstances” (relaxation of dose limit) have been removed – complicated, and no longer needed
Occupational exposure

- Responsibilities assigned (incl. government and regulatory body)
- Requirements for special circumstances (relaxation of dose limit) deleted
Medical exposure

- Responsibilities assigned for Government and Reg. Body as well as referrers, medical radiological practitioners, medical physicists, radiographers
- Requirements for key personnel on training, education and competence
- Emphasis is placed on key players (in RP) having the appropriate competence to fulfill their role
- Justification is expanded to follow ICRP 73, 103
- Introduction of the radiological review (audit)
- The patient is introduced into the picture
Medical exposures in 2010 versus 1996

Since the early 1990s:
• Increasing use of radiation in medical applications worldwide
  • More machines, etc
  • New technologies and techniques
  • New roles
• Increasing complexity in the planning & delivery of the radiation

Plus:
• 10+ years experience of Member States in trying to implement the BSS

The revised BSS must address all of these
New terms

- Distinguishing the roles of the “referrer” and the “doer”, namely:
  - Referring medical practitioner
  - Radiological medical practitioner
    (Note: these can be the same person, e.g. a dentist, a radiation oncologist)
- Medical physicist (based on IOMP definition)
- Medical radiation technologist
  - Radiographer,…
Education, training and competence

• Crucial to radiation protection
  • Radiological medical practitioner
  • Medical physicist
  • Medical radiation technologist
  • Radiopharmacist

• All definitions have a similar format:
  • A health professional, with education and specialist training in ……., competent to …… .

• Explanatory note to each definition:
  • Competence of persons is normally assessed by the Member State by having a formal mechanism for registration, accreditation or certification of …. 
  • Member States that have yet to develop such a mechanism need to assess …. based either on international accreditation standards or standards from another country …. 

IAEA
Short history to get draft 4.0 revised BSS

• DPP approved end 2006
• January 2007 – Revision process started
• July 2007 – “Technical Meeting”

• Draft 1.0 - July 2008 - 1200 comments
• Draft 2.0 – May 2009 - 500 comments
• Draft 2.5 – Sep. 2009 – 1000 comments
• Draft 3.0 – Jan. 2010 – 1500 MS comments

• Draft 3.5 – Aug. 2010 BSS Secretariat meeting
• Draft 4.0 – Sept. 2010 sent to committees

• December 2010 approved to be sent to CSS (March 2011)
Action Plan for Occupational Radiation Protection

Fourteen proposed actions under headings:

- **ONGOING ACTIONS**
  - ILO Convention 115 (Actions 1-3)
  - The ILO code of practice (Action 4)
  - Co-operation IAEA – ILO (Action 5)
  - Information exchange and Networking (Actions 6, 7)
  - Exposure to natural radiation (Action 11)
  - Protection of pregnant workers (Action 13)
  - Probability of causation (Action 14)

- **CLOSED ACTIONS**
  - Education and Awareness (Actions 6, 8, 10)
  - Holistic approach to workplace safety (Action 12)
Action 6- to develop publicity materials that target groups of workers

Follow up actions to be made:

• finalising the posters;
• providing them in a leaflet or brochure form;
• asking for endorsement by stakeholders such as trade unions;
• making the material available as pdf in the six official languages.
TOPICS

- Industrial Irradiators
- Industrial Radiography
- Radioactive Tracers
- Nuclear Gauges
- Diagnostic Radiology
- Nuclear Medicine
- Radiotherapy
Action 8: To prepare and disseminate suitable information materials to workers’ representatives and labour educators

- to submit the redrafted training handbook with a clear indication of the objectives and target audience;
- to make the new draft available within
- to request members of the Steering Committee to send written comments on the draft document within three months;
- to make the final draft available within 18 months.
Action 10 - Manuals on Radiation Protection

Vol. 1: General

Vol. 2: Radiology

Vol. 3: Dentistry

Vol. 4: Nuclear Medicine

Vol. 5: Radiotherapy
ACTION 12- DEVELOPING COHERENT APPROACH TO RADIATION AND OTHER RISKS FACTORS AT WORK PLACE

• Chapter 1  Philosophy, principles and system
• Chapter 2  Technical tools for risk assessment, management, communication
• Chapter 3  Examples of managing risks in different activity sectors
• Chapter 4  Examples of regulating and controlling occupational risks in different countries
• Chapter 5  Findings and conclusions
• Glossary
• Annexe
The ISEMIR project

- Information System on Occupational Exposure in Medicine, Industry and Research
  - Based on the experience of a network of Nuclear Power Plant operators
  - A database containing operational occupational doses at a detailed level is very helpful for:
    - Comparing doses for specific occupations and functions
    - Assessing the impact of specific radiation protection actions
    - Following dose trends

A tool for the implementation of ALARA
Occupational dose versus workload

Interventional Cardiologists - annual effective dose vs workload

200 ± 50 procedure per year, 33 ICs
Annual effective dose (mSv):
  Average = 1.94 ± 2.41
  Median = 0.98
  Range: 0 – 10.3
  20% had “zero” dose
Conclusions

• 2009 Survey of RBs showed
  • For a world-wide IC dose database
    • RBs are probably not the best source of dose data
    • Compliance with wearing dosimeters is an issue
  • Compliance with wearing dosimeters is an issue

• Interim results of 2010 Pilot Test show
  • Dose data can be obtained directly from IC facilities
    • Compliance with wearing dosimeters is still an issue

• You are invited to participate in this project:
  • Recruiting interventional cardiology facilities
  • Please visit ISEMIR web pages on IAEA ORPNET website, or
  • Email: John.Le.heron@iaea.org
Occupational Radiation Protection Networks – A medium for communication and exchange of information on Occupational Radiation Protection

http://www-ns.iaea.org/tech-areas/communication-networks/norp/default.asp
Radiation protection of patients—Recent activities

- Activities are related to the International Action Plan for Radiation Protection of Patients
Summary of the Round Table on ORP in Medical Application in LA

• Poor implementation of the RPP.
• Lack of E & T of medical staff.
• Lack of National Dose Registry.
• Lack on Internal Dosimetry in Nuc. Medicine.
• Issue with “Itinerant” workers in medical applications.
• Need of ORAMED results dissemination.
• Increased awareness of the management & medical staff on the risk of deterministic effects from the use of radiation in medical procedures;
• Radiation protection programs must be in place at medical facilities for both worker and patient protection. Individual monitoring of medical staff, specially for extremity dosimetry demonstrates improved protection.
• Diagnostic imaging procedures, in interventional radiology and nuclear medicine, should be optimized.
• International standards, guidance and assistance on capacity building in radiation protection remain abreast of the rapidly developing medical technology and are effectively disseminated, in particular for dosimetry.
IDOS Highlights - Radiation Protection Dosimetry

- Proposal for double dosimetry and eye dosimetry.
- Upgrade and/or creation of National Dose Registry at the National/State level.
- Recommendation needed for the protection and monitoring of “itinerant” medical staff.
- Collaboration with medical and scientific societies and organizations as well as manufacturers of medical equipment.
- Monitor the ORAMED and participation in ISEMIR projects for improving the staff monitoring and optimization of protection.
- Implementation of QMS for monitoring and Medical Physics services.
Future activities

As BSS is approaching finalization:

- Development of a Safety Guide on the use of radiation in medical facilities
- Updating Safety Guides on Occupational Radiation Protection

Development of voluntary reporting systems:

- SAFRAD (Safety in Radiological Procedures)
  - Web-based voluntary educational reporting system
  - To identify circumstances around high dose events in interventional procedures
  - Currently undergoing pilot-studies
- SAFRON (Safety in Radiation Oncology)
  - Web-based voluntary safety reporting system for rt
  - Retrospective incident reporting and sharing
  - Complementing mandatory reporting; linking to other voluntary initiatives
  - Incorporating prospective safety analysis
Future activities

Progressing outreach of balanced information:

• **RPoP website** to be further strengthened
  • Information for health professionals and patients to be updated – and translated to Spanish
  • The use of Social Media to reach more relevant individuals more effectively and timely

• **ORPNET website** to be further strengthened

A major conference is under preparation:

• **International conference** on radiation protection in medicine
  • To be held in Germany towards the end of 2012
  • Follow-up to Malaga Conference in 2001, which set the agenda for the following decade
  • Target: 1000 participants; health professionals; regulators; policy makers; patient organizations
  • To set the agenda for the coming years
THANK YOU

http://www-ns.iea.org/home/rtws.asp