International System of Radiation Protection

Madan M Rehani, Ph.D.
Radiation Protection of Patients Unit, IAEA & European Society of Radiology, Vienna
madan.rehani@gmail.com
Why International System?
Bad & Good example of international systems
Why International system?

- You work in country A and dose limit is 20 mSv/yr, another country 50 mSv, yet another 100 mSv, and also 10 mSv. Result - confusion.
- One month leave for all occupationally exposed
- Badge over lead apron or under lead apron
- Person sitting in the room next to X-ray room wants to be labelled as “occupationally exposed”
- Separate areas for attendants in NM dept
• How to frame regulations?..... Let these be consistent with UK.....No..No...with USA.  ... Oh no..it should be India, S. Africa...no Europe...
• Is there some Harmonised set of regulation?
Organisations in the Cosmic Scheme

Basic Scientific Studies

Scientific Evaluations (UNSCEAR, BEIR etc.)

ICRP Recommendations

Regional (EC, PAHO, NEA) & Topical (ILO, WHO, FAO) Standards

International Safety Standards: BSS (IAEA)

National Regulations

Demonstration of Compliance

Industry Standards (ISO, IEC)
The Basis for the International Safety Standards

UNSCEAR (*)
RADIATION EFFECTS

ICRP (**) PRINCIPLES AND RECOMMENDATIONS

STANDARDS (IAEA)

(*) United Nations Scientific Committee on the Effects of Atomic Radiation
(**) International Commission on Radiological Protection
A matter of interpretation
International Radiation Safety Standard

- Is it mandatory?
  - No

- Then what is legally applicable?
  - National

- What is the role of International Standards?
  - Robust, sound standards that countries can adopt
  - Where national regulations are lacking, international standards provide acceptable system for legal authorities
  - Since it is based on WIDE consensus, most countries tend to adopt it. Essential for seeking IAEA assistance
What people know MOST

ICRP--- Dose limits
IAEA--- Iran, Iraq actions
UNSCEAR---??
What you think that they do?

ICRP

• Establishes principles of radiation protection
• Provides protection philosophy

IAEA

• Has programs for promoting
  • Nuclear medicine, radiotherapy and medical physics
  • Radiation protection of patients
UNSCEAR was established by the General Assembly of the United Nations in 1955.

Its mandate in the United Nations system is to assess and report levels and effects of exposure to ionizing radiation.

Governments and organizations throughout the world rely on the Committee's estimates as the scientific basis for evaluating radiation risk and for establishing protective measures.
The original committee was composed of senior scientists from 15 designated UN Member States, namely Argentina, Australia, Belgium, Brazil, Canada, Czechoslovakia, Egypt, France, India, Japan, Mexico, Sweden, the UK, the USA and the USSR.

Currently 21 countries

Last report 2010

HQ in Vienna

Meeting once every year
<table>
<thead>
<tr>
<th>ICRP</th>
<th>IAEA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Independent Charity</strong></td>
<td><strong>Independent international organisation under UN family</strong></td>
</tr>
<tr>
<td>Established to advance for the public benefit the science of Radiological Protection, in particular by providing recommendations and guidance on all aspects of protection against ionising radiation</td>
<td><strong>Pillars: Safety and Security; Science and Technology; and Safeguards and Verification.</strong></td>
</tr>
</tbody>
</table>
• **Headquarter in Vienna**
• **2400 staff from > 90 countries**
• **Director General, 6 Deputy DG, Directors, SH, UH**
Committee 3, Protection in Medicine: develops recommendations and guidance on the protection of patients, staff, and the public against radiation exposure in medicine.

- Respond to new challenges in radiological protection.
- Improve dissemination of ICRP recommendations and guidance.
# Membership of the International Commission on Radiological Protection

## as of July 1st 2013

### Main Commission

<table>
<thead>
<tr>
<th>Committee</th>
<th>Members</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects</td>
<td>William Morgan (Chair)</td>
</tr>
<tr>
<td></td>
<td>Tamara Azizova</td>
</tr>
<tr>
<td></td>
<td>Nobuhiko Ban</td>
</tr>
<tr>
<td></td>
<td>Simon Bouffler</td>
</tr>
<tr>
<td></td>
<td>Ranajit Chakraborty</td>
</tr>
<tr>
<td></td>
<td>Wolfgang Dörr</td>
</tr>
<tr>
<td></td>
<td>Michael Hauptmann</td>
</tr>
<tr>
<td></td>
<td>Dominique Laurier</td>
</tr>
<tr>
<td></td>
<td>Preetha Rajaraman</td>
</tr>
<tr>
<td></td>
<td>Werner Rühm</td>
</tr>
<tr>
<td></td>
<td>Sisko Salomaa</td>
</tr>
<tr>
<td></td>
<td>Alice Sigurdson</td>
</tr>
<tr>
<td></td>
<td>Dan Stram</td>
</tr>
<tr>
<td></td>
<td>Quanfu Sun</td>
</tr>
<tr>
<td></td>
<td>Margot Tirmarche</td>
</tr>
<tr>
<td></td>
<td>Richard Wakeford</td>
</tr>
<tr>
<td>Doses</td>
<td>John Harrison (Chair)</td>
</tr>
<tr>
<td></td>
<td>Michael Bailey</td>
</tr>
<tr>
<td></td>
<td>Volodymyr Berkovskyy</td>
</tr>
<tr>
<td></td>
<td>Luiz Bertelli</td>
</tr>
<tr>
<td></td>
<td>Wesley Bolch</td>
</tr>
<tr>
<td></td>
<td>Doug Chambers</td>
</tr>
<tr>
<td></td>
<td>Marina Degteva</td>
</tr>
<tr>
<td></td>
<td>Akira Endo</td>
</tr>
<tr>
<td></td>
<td>John Hunt</td>
</tr>
<tr>
<td></td>
<td>Chan Hyeong Kim</td>
</tr>
<tr>
<td></td>
<td>Richard Leggett</td>
</tr>
<tr>
<td></td>
<td>Jizeng Ma</td>
</tr>
<tr>
<td></td>
<td>Dietmar Noßke</td>
</tr>
<tr>
<td></td>
<td>François Paquet</td>
</tr>
<tr>
<td></td>
<td>Nina Petoussi-Henss</td>
</tr>
<tr>
<td></td>
<td>Frank Wissmann</td>
</tr>
<tr>
<td>Medicine</td>
<td>Eliseo Vañó (Chair)</td>
</tr>
<tr>
<td></td>
<td>Kimberly Applegate</td>
</tr>
<tr>
<td></td>
<td>Michel Bourguignon</td>
</tr>
<tr>
<td></td>
<td>Lawrence Dauer</td>
</tr>
<tr>
<td></td>
<td>Sandor Demeter</td>
</tr>
<tr>
<td></td>
<td>Keon Kang</td>
</tr>
<tr>
<td></td>
<td>Pek-Lan Khong</td>
</tr>
<tr>
<td></td>
<td>Reinhard Loose</td>
</tr>
<tr>
<td></td>
<td>Pedro Ortiz Lopez</td>
</tr>
<tr>
<td></td>
<td>Colin Martin</td>
</tr>
<tr>
<td></td>
<td>Donald Miller</td>
</tr>
<tr>
<td></td>
<td>Madan Rehani</td>
</tr>
<tr>
<td></td>
<td>Katrine Åhlström-Riklund</td>
</tr>
<tr>
<td></td>
<td>Pierre Scalliet</td>
</tr>
<tr>
<td></td>
<td>Baorong Yue</td>
</tr>
<tr>
<td></td>
<td>Yoshiharu Yonekura</td>
</tr>
<tr>
<td>Implementation</td>
<td>Jacques Lochard (Chair)</td>
</tr>
<tr>
<td></td>
<td>François Bochud</td>
</tr>
<tr>
<td></td>
<td>Mike Boyd</td>
</tr>
<tr>
<td></td>
<td>Analia Canoba</td>
</tr>
<tr>
<td></td>
<td>Kun-Woo Cho</td>
</tr>
<tr>
<td></td>
<td>Donald Cool</td>
</tr>
<tr>
<td></td>
<td>Mark Doruff</td>
</tr>
<tr>
<td></td>
<td>Eduardo Gallego</td>
</tr>
<tr>
<td></td>
<td>Toshimitsu Homma</td>
</tr>
<tr>
<td></td>
<td>Michiaki Kai</td>
</tr>
<tr>
<td></td>
<td>Jean-François Lecomte</td>
</tr>
<tr>
<td></td>
<td>Senlin Liu</td>
</tr>
<tr>
<td></td>
<td>Ann McGarry</td>
</tr>
<tr>
<td></td>
<td>Anne Nisbet</td>
</tr>
<tr>
<td></td>
<td>Deborah Oughton</td>
</tr>
<tr>
<td></td>
<td>Thiagan Pather</td>
</tr>
<tr>
<td></td>
<td>Sergey Shinkarev</td>
</tr>
<tr>
<td></td>
<td>John Shinkarev</td>
</tr>
</tbody>
</table>

### Scientific Secretariat

<table>
<thead>
<tr>
<th>Committee</th>
<th>Members</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Christopher Clement (Scientific Secretary)</td>
</tr>
<tr>
<td></td>
<td>Michiya Sasaki (Assistant Scientific Secretary)</td>
</tr>
<tr>
<td></td>
<td>Lynn Lemaire (Executive Assistant)</td>
</tr>
<tr>
<td></td>
<td>Ian Steadman (Intern)</td>
</tr>
</tbody>
</table>

### Committee 5

<table>
<thead>
<tr>
<th>Committee</th>
<th>Members</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environment</td>
<td>Carl-Magnus Larsson (Chair)</td>
</tr>
<tr>
<td></td>
<td>David Copplestone</td>
</tr>
<tr>
<td></td>
<td>Jordi Vives i Batlle</td>
</tr>
<tr>
<td></td>
<td>Jacqueline Garnier-Laplace</td>
</tr>
<tr>
<td></td>
<td>Kathryn Higley</td>
</tr>
<tr>
<td></td>
<td>Li Jianguo</td>
</tr>
<tr>
<td></td>
<td>Almudena Real</td>
</tr>
<tr>
<td></td>
<td>Kazuo Sakai</td>
</tr>
<tr>
<td></td>
<td>Per Stand</td>
</tr>
<tr>
<td></td>
<td>Alexander Ulansovky</td>
</tr>
</tbody>
</table>

---

*Complete ICRP Membership, including the Main Commission, Scientific Secretariat, Committees, Task Groups and Working Parties, totals over 200 experts in radiological protection science and policy from more than 30 countries*
Chairperson
Dr. Claire Cousins, UK

Main Commission Chair + 12 members

C1- Radiation Effects Dr William F Morgan, US

C2- Doses from Radiation Exposure Dr John Harrison, UK,

C3- Protection in Medicine Dr Eliseo Vano, Spain

C4- Application of ICRP Recommend. Dr Jacques Lochard, FR

C5-Prot. of the Environment Dr Carl-Magnus-Larsson, Australia
ICRP C3 (September 2013) (Protection in Medicine)

• Eliseo Vañó (Chair)
• Kimberly Applegate
• Michel Bourguignon
• Lawrence Dauer
• Sandor Demeter
• Keon Kang
• Pek-Lan Khong
• Reinhard Loose

• Reinhard Loose
• Pedro Ortiz Lopez
• Colin Martin
• Donald Miller (Vice Chair)
• Madan Rehani (Secretary)
• Katrine Åhlström-Riklund
• Pierre Scalliet
• Baorong Yue
• Yoshiharu Yonekura
Committee 3 Protection in Medicine

Committee 3 is concerned with protection of persons and unborn children when ionising radiation is used for medical diagnosis, therapy, or for biomedical research; also, assessment of the medical consequences of accidental exposures.

Summaries of Committee 3 Meetings:
- Beijing, 2004
- Geneva 2005
- San Francisco 2006
- Berlin 2007
- Mallorca 2008
- Porto 2009
- Hong Kong 2010
- Washington DC 2011
- Vienna 2012
ICRP C3: 15 publications in 10 years
## Ethical Basis for the ICRP System

<table>
<thead>
<tr>
<th><strong>Utilitarian ethics</strong></th>
<th><em><em>Deontological</em> ethics</em>*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Judge actions by the consequences</strong></td>
<td><strong>Some duties are imperative</strong></td>
</tr>
<tr>
<td><strong>Justification</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Do more good than harm</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Optimisation</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Maximise good &gt; harm</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Limitation</strong></td>
<td></td>
</tr>
<tr>
<td><strong>No individual unduly harmed</strong></td>
<td></td>
</tr>
</tbody>
</table>
Changes in occupational Dose Limit (ICRP)

mSv/yr

Year

1931 | 1947 | 1977 | 1990
Past ICRP Recommendations

• **At first**: Occupational exposures in medicine
  
  *Avoid deterministic harm*

1928: Working hours limited (~1000 mSv)
1934: ~500 mSv

• **Then**: Occupational exposures

1950: ~150 mSv

• **Now**: Exposures

  …*and minimise stochastic harm*

1956: 50 mSv; 5 mSv
1959: Publ. 1; 1964: Publ. 6
1966: Publ. 9, reduce doses if readily achievable
1977: Publ. 26, …if reasonably achievable
1990: Publ. 60: 20 mSv, 1 mSv
Tissue Weighting factor $W_T$ (ICRP 103 vs 60)

- Breast, gonads, and the treatment of remainder tissues.

- The $W_T$ changes in question are:
  - Breast (new 0.12, old 0.05); Increase by factor 2.4
  - gonads (new 0.08, old 0.20); Decrease by factor 2.5
  - remainder tissues (new 0.12, old 0.05 using a new additive system)
2007 recommendations

Tissue weighting factor for breast increased from 0.05 to 0.12 (2.4 times, by 140%) and for gonads decreased from 0.2 to 0.08, by ≈ 60%.

Remainder tissues (new 0.12, old 0.05 using a new additive system)
The Genetic Risk Estimate Is Smaller, But...

Gonad shielding is still imperative in order to keep doses ALARA!
Implementation Takes Time

• ICRP 1977 Recommendations
  International standards 1984
  National standards ~1989

• ICRP 1990 Recommendations
  International standards 1996
  National standards ~2000

• ICRP 2007 Recommendations
  International standards 2012
  …national standards after 2014?
<table>
<thead>
<tr>
<th>ICRP 60</th>
<th>ICRP73</th>
<th>ICRP 103</th>
</tr>
</thead>
</table>
| Nothing of substance | • Introduced  
  • Values of dose constraints to be fixed at the national or local level.  
  • A value in the region of a few mSv per episode is likely to be reasonable, but warns against rigid use. | • Focussed on situations dealing with patients treated with radionuclides  
  • 5 mSv per episode for comforters and carers, except children and pregnant women where 1 mSv |
Accidental and unintended exposures

- Specific recommendations with respect to accidental and unintended medical exposures in the period since ICRP 60.
- The recommendations given in ICRP 103 are based on Publication 76, 86, 97 and 98.
## Accidental and unintended exposures

<table>
<thead>
<tr>
<th>ICRP 60</th>
<th>ICRP 73</th>
<th>ICRP 103</th>
</tr>
</thead>
<tbody>
<tr>
<td>No specific recommendation</td>
<td>Design of equipment</td>
<td>In addition to ICRP 73,</td>
</tr>
<tr>
<td></td>
<td>• Defence in depth</td>
<td>• Incident reporting</td>
</tr>
<tr>
<td></td>
<td>• Calibration</td>
<td>• External beam RT</td>
</tr>
<tr>
<td></td>
<td>• Independent confirmation</td>
<td>• Brachytherapy</td>
</tr>
</tbody>
</table>

---

*ICRP* stands for International Commission on Radiological Protection.
Volunteers for biomedical research

• Reference Publication 62 for ethical aspects and there is recommendation on the need for the ethics committee.
Unjustified exposures

• These recommendations seem to appear for the first time in ICRP 103

Certain exposures should be deemed to be unjustified without further analysis, unless there are exceptional circumstances. These included:

• Radiological examination for occupational, health insurance, or legal purposes undertaken without reference to clinical indications, unless the examination is expected to provide useful information on the health of the individual examined or in support of important criminal investigations.

• Medical screening of asymptomatic population groups involving radiation exposure, unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and societal costs, including the radiation detriment.
Patient Consent

• The concept of patient consent is introduced into ICRP 103. The text presents more statements of "fact" or current practice, rather than explicit recommendations with respect to informed consent.

• It states that the patient (or legal guardian) consents to exposure and this decision is made with varying degree of informed consent.
Pregnancy

- The pregnant patient has a **right to know** the magnitude and type of potential effects that might result from *in utero* exposure.

- It is essential to ascertain whether a female patient is pregnant prior to **radiotherapy** and some abdominal interventional procedures.

- Termination of pregnancy at foetal doses above 100 mGy.

- The pregnant patient should receive sufficient information to be able to make an informed decision.
The IAEA is the world’s center of cooperation in the nuclear field.

It was set up as the world’s "Atoms for Peace" organization in 1957 within the United Nations family.
International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources

Jointly sponsored by FAO, IAEA, ILO, OECD/NEA, PAHO, WHO
IAEA Safety Standards

for protecting people and the environment

Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards
INTERIM EDITION

General Safety Requirements Part 3
No. GSR Part 3 (Interim)
Be Informed About the Safe Use of Ionizing Radiation in Medicine
Information to help health professionals achieve safer use of radiation in medicine for the benefit of patients


3. It is safe to have an X-ray examination of the extremities (feet, legs, hands, arms) in pregnancy, provided the examination is clinically justified and radiation protection principles are observed.

Actions to Protect Patients in:
- Radiology
- Radiotherapy
- Nuclear Medicine
- Interventional Radiology
- Interventional Cardiology
- Other Specialties & Imaging Modalities

Latest News
New Publications on Newer Imaging Techniques released
Download FREE three new publications on radiation protection in newer imaging techniques (PET/CT, Cardiac CT and CT colonography)

Cardiologists' Newsletter
Next issue of the Newsletter of the Asian Network of Cardiologists in Intervention will now be available

Meeting planned to prepare contents for patient information part of this website, Vienna, 4-8 May 2009
Meeting to discuss framework for patient information, draw guidelines and prepare contents

Meeting for Smart Card for long term record of patient doses, Vienna, 27-29 April 2009
The first meeting on this project will be held in IAEA Vienna

10 million hits/y ≈ 200,000 visits/y, 190 countries
• I can’t sit next to him as he is emitting too much radiation

• I submit my resignation as the background level in this organisation is very high.
Exposure which is unamenable to control, is EXCLUDED from the standards e.g. $^{40}$K in the body, cosmic radiation at earth’s surface
Medical exposures & the BSS
Radiation accident

- I am not responsible. My staff in Radiology department is responsible for this.

- BSS lists responsibilities
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, …
Revised BSS & the medical physicist

• The MP has a mandated role in:
  • Therapeutic uses of radiation:
    • The requirements for calibration, dosimetry and QA, including the acceptance and commissioning of medical radiological equipment
      • Are fulfilled by or under the supervision of a medical physicist
  • Diagnostic uses & image-guided interventional procedures
    • The requirements for imaging, calibration, dosimetry and QA, including the acceptance and commissioning of medical radiological equipment
      • Are fulfilled by or under the oversight of or with the documented advice of a medical physicist
      • Whose degree of involvement is determined by the complexity of the radiological procedures and the associated radiation risks
• I want 30 days compensatory leave on account of work with radiation.
• Radiation risk allowance
• Milk, special food
Special compensatory arrangements

Special compensatory arrangements, or preferential consideration with respect to salary, special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits, **shall neither be granted nor be used as substitutes for measures for protection and safety in accordance with the requirements of these Standards.**
International BSS

- Most important document for Member States of the IAEA pertaining to radiation safety regulatory requirements
Does BSS recognize Medical Physicist?

YES
Medical Physicist

A health professional,

• with special education and training in the concepts and techniques of applying physics in medicine, and

• competent to practise independently in one or more of the subfields (specialties) of medical physics.
What is responsibility of the Government?
Governments Responsibilities

The government shall ensure that requirements are established for:

• (a) education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety;

• (b) the formal recognition of qualified experts;

• (c) the competence of organizations that have responsibilities relating to protection and safety.
Responsibilities of Regulatory bodies

• Shall ensure the application of the requirements for education, training,
• Qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety.
Responsibilities of principal parties

- The relevant principal parties and other parties having specified responsibilities in relation to protection and safety shall ensure that all personnel engaged in activities relevant to protection and safety have appropriate education, training and qualification so that they understand their responsibilities and can perform their duties competently, with appropriate judgement and in accordance with procedures.
Is there a requirements for specialization?

Yes, this is “New” in revised BSS
The regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and that they meet the requirements for education, training and competence in the relevant specialty.
Who should assess competence?

- Competence of persons is normally assessed by the State by having a formal mechanism for registration, accreditation or certification of medical physicists in the various specialties (e.g. diagnostic radiology, radiation therapy, nuclear medicine).
• States that have yet to develop such a mechanism would need to assess the education, training and competence of any individual proposed by the licensee to act as a medical physicist and to decide, on the basis either of international accreditation standards or standards of a State where such an accreditation system exists, whether such an individual could undertake the functions of a medical physicist, within the required specialty.
Recap

• Why international system?
• Which parties are involved?
• Consensus of >140 members states, besides co-sponsors
• ICRP, UNSCEAR, IAEA
• Main points in international system of RP (responsibilities, conditions of service, justification, optimization)
Thank You