Regional Workshop on the International Basic Safety Standards

Session 1: Revised International Basic Safety Standards – overview and key changes

22-25 May 2012, San Jose, Costa Rica

Ian Robinson
Topics

• **General aspects**
  • *IAEA safety standards*
  • *Radiation Protection Framework*
  • *Historical remarks*
  • *Principles of Radiation Protection*

• **International Basic Safety Standards**
  • *Revision Process*
  • *Exposure situations and Schedules*
  • *Challenging issues*

• **Selected IAEA activities in Radiation Protection**
The Safety Standards

Safety Fundamentals (Principles)

Safety Requirements ("Shall" statements)

Safety Guides ("Should" statements)

Supporting publications

Safety Reports

TECDOCs
Cosponsorship of standards

IAEA Safety Standards
for protecting people and the environment

Fundamental Safety Principles

Safety Fundamentals
No. SF-1

IAEA
International Atomic Energy Agency
General aspects

Radiation Protection Framework

UNSCEAR
Scientific basis

ICRP
Protection philosophy, principles and units

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

Requirements for Radiation Safety (Basic Safety Standards)

implemented by Member States

UN transport regulations for radioactive material

ILO convention 115: occupational radiation protection

FAO/WHO
Codex Alimentarius Commission (food contamination guides)

IAEA Safety Standards
for protecting people and the environment

The 2007 Recommendations of the International Commission on Radiological Protection

The 2007 Recommendations of the International Commission on Radiological Protection

UNSCEAR 2006 Report

I A E A

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The IAEA Board of Governors approved the Agency’s Health and Safety Measures on 31 March 1960.

Footnote 1 to the Agency’s Health and Safety Measures (INFCIRC/18) stated that the Agency’s Basic Safety Standards will be drawn up in accordance with the provisions of Article III.A.6 of the Statute and will be based, to the extent possible, on the recommendations of the ICRP.

This statement about being based on the recommendations of the ICRP is made in the introduction to the 1962, 1967, 1977 edition of the BSS, and in the preface to the 1996 edition.
ICRP recommendations
- 1958 (“Publication 1”)
- 1966 (Publication 9)
- 1977 (Publication 26)
- 1990 (Publication 60)
- 2007 (Publication 103)

IAEA Basic Safety Standards
- 1962
- 1967
- 1982
- 1996
- 2011 – Interim edition
ICRP recommendations

• 1958 ("Publication 1")
• 1966 (Publication 9)
• 1977 (Publication 26)
• 1990 (Publication 60)
• 2007 (Publication 103)

IAEA Basic Safety Standards

• 1962
• 1967
• 1982
• 1996
• 2011 – Interim edition
Principles of Radiation Protection

Three fundamental principles of radiation protection are retained!

Justification
Optimization
Dose limitation

The central assumption of a linear dose–response relationship for the induction of cancer and heritable effects continues to underpin ICRP’s recommendations.
Principles of Radiation Protection

• **Justification**

Any decision that alters the radiation exposure situation should do more good than harm.

• **Optimization of Protection**

The likelihood of incurring exposures, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors.
Dose limitation

Dose limits should be set to ensure that no individual faces an unacceptable risk in normal circumstances.

Application of dose limits

The total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits specified in Schedule III of the BSS.
Types of Exposure Situations

Planned exposure situations
situations involving the planned introduction and operation of sources *(including decommissioning, disposal of radioactive waste, rehabilitation)*

Emergency exposure situations
unexpected situations such as those that may occur during of a planned situation, or from a malicious act, requiring urgent attention

Existing exposure situations
situations that already exist when a decision on control has to be taken, such as those by natural background radiation and residues from past practices operated outside the system
Categories of Exposure

**Occupational exposures**

exposure of workers incurred as a result of their work *(with the exception of excluded exposures and exposures from exempt activities; medical exposure; and background)*

**Public exposures**

all exposures of the public other than occupational exposures and medical exposures of patients

**Medical exposures of patients**

incurred by patients as part of their own medical or dental diagnosis or treatment; volunteers helping in the support and comfort of patients; and biomedical research volunteers
Applicability of the fundamental principles according to the exposure situations

Type of exposure situation
- Planned exposure situation
- Emergency exposure situation
- Existing exposure situation

Category of exposure
- Occupational
- Public
- Medical

Principles which are applicable
- Justification Optimisation (DCs) Limitation
- Justification Optimisation (DRLs)
- Justification Optimisation (RLs)

Ref.: ICRP
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During the Board's consideration of measures to strengthen nuclear safety and security, the body approved the revised IAEA Safety Standards on the Safety of Nuclear Power Plants: Design (Safety Standards Series No. NS-R-1), as well as a revision of IAEA Safety Series No. 115, or Draft Safety Requirements: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards.

BSS - process of revision

September 2005 IAEA General Conference agree the Agency should

“…undertake a review of the BSS taking account of developments in radiation protection, knowledge and guidance, including to the extent possible the advice and information provided by ICRP and UNSCEAR.”
The IAEA secretariat has the overall responsibility for the revision of the BSS.

Significant added value coming from the BSS Secretariat

IAEA > 60 meetings in total

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Basic Safety Standards

Three exposure situations
- Planned exposure situation
- Existing exposure situations
- Emergency Exposure situations

Three categories of exposure
- Occupational exposure
- Medical exposure
- Public exposure

Protection and Safety requirements of the BSS apply to all facilities and activities

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)

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# Basic Safety Standards

<table>
<thead>
<tr>
<th>Exposure Category</th>
<th>Planned</th>
<th>Emergency</th>
<th>Existing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occupational</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Public</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Medical</td>
<td>✔️</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>
1. INTRODUCTION

2. GENERAL REQUIREMENTS FOR PROTECTION AND SAFETY

3. PLANNED EXPOSURE SITUATIONS
   - Scope
   - Generic requirements
   - Occupational exposure
   - Public exposure
   - Medical exposure

4. EMERGENCY EXPOSURE SITUATIONS

5. EXISTING EXPOSURE SITUATIONS
   - Schedule I Exemption & clearance
   - Schedule II Categories for sealed sources in common practices
   - Schedule III Dose limits for planned situations
   - Schedule IV Criteria for use in emergency preparedness & response
• 52 overarching requirements

• The requirements associated with the overarching requirements are considered as an integral part of the safety requirements.

• In the revised BSS, these are all “shall” statements.
Scope

These standards apply to all situations involving exposures that are amenable to control. Exposures deemed to be unamenable to control are excluded from the scope of these Standards.

(For example, it is generally accepted that it is not feasible to control 40K in the body and cosmic radiation at the surface of the earth.)
Protection of the Environment

*Man is an integral part of the environment*

- Prevention of radiological effects on flora and fauna
- Ensure the sustainable use of natural resources – now and in the future
  - Agriculture
  - Forestry
  - Fisheries
  - Tourism
Objective

To establish basic requirements for protection of people and the environment from harmful effects of ionizing radiation and for the safety of sources

Aimed at

Governments
Regulatory bodies
Principal parties
Health authorities
Professional bodies
Providers of specialized services (TSO)
Interface between safety and security

- **1.41**: Reference to nuclear security series of publications
- **2.27**: The government shall ensure that infrastructural arrangements are in place for the interfaces between safety and security of radioactive sources.
- **3.32**: The safety assessment shall include: (f) the implications for protection and safety of security measures, and of any modifications to security measures
Government  
To establish and maintain a legal, regulatory and organizational framework

Regulatory body  
To establish or adopt regulations and guides

Principal parties  
To keep the prime responsibility for protection and safety

Other parties  
Specified responsibility for protection and safety
Responsibilities of government / regulatory body

- Revised BSS contains requirements on government and regulatory bodies consistent with the text of the revised Safety Requirements GSR Part 1 “Governmental, Legal and Regulatory Framework for Safety”.

- Included in BSS to retain comprehensive character
- BSS to be a stand-alone document
Responsibilities of other parties

- Prime responsibility for safety – registrants & licensees
- List of principal parties has been enlarged from current BSS:
  - Registrants and licensees, and those responsible for notified practices
  - Employers – occupational exposure
  - Radiological medical practitioners - medical exposure
  - Designated persons or organizations to deal with emergency exposure situations or existing exposure situations
- Requirement on principal parties to ensure that all personnel engaged in activities relevant to protection and safety are appropriately educated, trained, and qualified …
Management Requirements

- Requirements on management systems (quality assurance), human factors and safety culture have been updated

(...commensurate with the complexity of and radiation risks associated with the activity)
Graded approach

GENERAL requirements

The application of the requirements for the system of protection and safety shall be commensurate with the radiation risks associated with the exposure situation.

PLANNED exposure situation

…..commensurate with the characteristics of the practice or the source within the practice, and with the magnitude and likelihood of the exposures.
Planned exposure situations

Scope

• Practices
  • Production and supply of rad. material & devices that contain/generate radiation; generation of NP and other activities in nuclear fuel cycle; use of radiation or rad. material for industry, medical etc; **mining and processing or raw materials**

• Sources with practices
  • Facilities that contain rad. material / radiation generators e.g. nuclear installation, medical radiation facilities, rad. waste management facility, mineral extraction & mineral processing facilities
  • Individual sources of radiation

• Occupational, medical and public exposure

• Natural sources
  • **Material containing natural radionuclides above specified level:**
    • (U/Th decay chains > 1 Bq/g; K-40 > 10 Bq/g)
  • Radon (Rn-220 and Rn-222) and their progeny
    • (i) in workplace where radon levels above reference level
Justification

• ....provisions are in place for justification of any type of practice, …, and shall ensure that only justified practices are authorized.

Optimization of protection and safety

• Registrants and licensees shall ensure that protection and safety is optimized
• Dose constraints
  • Tool for optimization
  • Are not limits
  • Set or approved by the government or regulatory body

Dose limits

• Comply with dose limits specified in Schedule III
  • Dose limit for lens of eye has been reduced for workers and for apprentices
Protection of the environment

- ... as required by the regulatory body, have an appropriate prospective assessment made for radiological environmental impacts, ...

- Definition of Environment:

The conditions under which people, animals and plants live and develop and which sustain all life and development; especially such conditions as affected by human activities
Planned exposure situations

Human imaging for purposes other than medical diagnosis or treatment

- There was a need to “size” the problem
- There was a need to develop a consistent and comprehensive approach, using the ICRP RP principles

- Two types of exposures:
  - Those carried out by medical staff using conventional radiological equipment e.g. exposures for occupational, legal or insurance purposes without reference to clinical indications
  - Exposures by non-medical staff e.g. security screening, screening of cargo
Human imaging for purposes other than medical diagnosis or treatment

...justification of any type of practice and for review of the justification, as necessary, and
...ensure that only justified practices are authorized.
...ensure that the use of ionizing radiation for human imaging for purposes other than medical diagnosis, medical treatment or biomedical research shall be subject to the system of protection and safety.

- Justified practices to be subject to regulatory control
- Regulatory body to establish requirements for regulatory control
- Government is to establish dose constraints procedures conducted using medical radiological equipment
- Requirements for public control apply to procedures for the detection of concealed objects – public dose limit
- Persons to be informed of alternative technique
- Equipment to meet applicable standards
Practices deemed **not** to be justified:

- performed for occupational, legal or health insurance purposes, and is undertaken without reference to clinical indication
- deliberate addition of radioactive substances (or by activation) in food, feed, beverages, cosmetics
- frivolous use of radioactive substances in commodities, toys, jewelry;
- human imaging for art or publicity purposes;
- human imaging for theft purposes;

**Exceptional circumstances for other applications considered**
Radiation generators and radioactive sources

• Requirements taken from CoC for sources

  • Licensees sharing inventory records with reg. body
  • Reg. body require sealed sources to be categorized
  • Manufacturer of r/a source or device to ensure that source and device are marked with trefoil symbol
  • Licensees ensure sealed sources are identifiable and traceable
  • Licensees ensure that r/a sources are stored safely
  • Licensees ensure arrangements for safe management and disposition of disused r/a sources
Occupational Exposure

- Requirements on government or the regulatory body
  - Establish and enforce requirements that require protection and safety be optimized and that occupational exposure is limited
- Employers, registrants and licensees to establish and use constraints as part of the optimization of protection and safety
- The requirements on licensees, registrants, workers, are essentially unchanged
- Requirements for “special circumstances” (relaxation of dose limit) have been removed – complicated, and no longer needed
- Requirements regarding pregnant workers, expanded to also cover breast feeding women
**Occupational Exposure**

**Requirements for**
- Responsibilities of regulatory body
- Monitoring and recording of exposures
- Responsibilities of employers and licensees
- Compliance by workers
- Classification of (work) areas
- Local rules and personal protective equipment
- Monitoring of the workplace
- Assessment of occupational exposure
- Workers’ health surveillance
- Information, instruction and training
- Conditions of service
- Special arrangements – pregnant women, breast-feeding women, person under 18 years of age

*essentially unchanged*
Public exposure

Requirements on government or the regulatory body
• Establish and enforce requirements that require protection and safety be optimized and that public exposure is limited
• Establish or approve constraints for dose and risk

Requirements on registrants and licensees are essentially unchanged.

New requirements on:
• Monitoring programmes: A more specific requirement on reporting the results of monitoring programmes and retrospective assessment of doses
• Radioactive Waste: Maintain an inventory of all radioactive waste generated, stored, transferred or disposed of
• Environmental impact from discharges: added to the requirements on discharges to ‘consider the environmental impact, as required by the regulatory body’ (for authorization)
**Dose Limits**

- Apply to **planned exposure situations**
- Apply to occupational and public exposures

<table>
<thead>
<tr>
<th></th>
<th>Occupational Dose Limits</th>
<th>Public Dose Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Dose (Whole Body)</td>
<td>20 mSv/a averaged over 5 years (and 50 mSv/a)</td>
<td>1 mSv/a</td>
</tr>
<tr>
<td>Equivalent Dose (Lens of the Eye)</td>
<td>20 mSv/a averaged over 5 years (and 50 mSv/a)</td>
<td>15 mSv/a</td>
</tr>
<tr>
<td>Equivalent Dose (Skin)</td>
<td>500 mSv/a</td>
<td>50 mSv/a</td>
</tr>
<tr>
<td>Equivalent Dose (Hands and Feet)</td>
<td>500 mSv/a</td>
<td>-</td>
</tr>
</tbody>
</table>
Medical exposure

- Terms and definitions:
  referring medical practitioner, radiological medical practitioner, medical physicist, medical radiation technologist

- Requirements on responsibilities of government and regulatory body
  - Establish diagnostic reference levels
    - The schedule in SS115 on guidance level has been deleted
  - Establish dose constraints for carers and comforters, and for volunteers in biomedical research
  - Establish criteria and guidelines for release of radiotherapy patients

- Requirement that patient be informed of potential benefit and radiation risk of the diagnostic or therapeutic procedure

Planned exposure situations BSS 2011
**Medical exposure**

Justification principle requires a special approach.

- **Overarching justification**: use of radiation in medicine does more good than harm.

- **Next level**: a need for generic justification of a given radiological procedure. This applies to the justification of new technologies and techniques as they evolve.

- **Final level**: the application of the radiological procedure to a given individual has to be considered. The specific objectives of the exposure, the clinical circumstances and the characteristics of the individual involved have to be taken into account through referral criteria developed by professional bodies and the health authority.
Medical exposure

Responsibility

The medical exposure has been justified through consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, or is part of an approved health screening programme.
Emergency exposure situations

- Requirements consistent with ICRP Publication 103 & 109
  - Dose concepts of residual dose, projected dose, received dose

- Integrated and coordinated emergency management system is established and maintained

- Arrangements for protection of public, such as strategies for protection
  - New dose concepts of reference levels for residual dose in range of 20-100 mSv
  - Generic criteria for some protective actions
Emergency exposure situations

- The government shall establish a programme for managing, controlling and recording doses received in an emergency by emergency workers, which shall be implemented by response organizations and employers.
  - Exceed 50 mSv only in exceptional circumstances

- Modified definition of emergency worker: any person having a defined role as a worker in an emergency and who might be exposed while taking actions in response to the emergency.

- Requirement on transition from emergency exposure situation to existing exposure situation
Emergency exposure situation

**Exposure of workers**

Emergency workers = Workers (ILO)
20 mSv/a averaged over 5 years, max 50 mSv/a

Caveats:
- Life saving activities (<500 mSv/a)
- Prevent severe deterministic effects (<500 mSv/a)
- Avert large collective dose (<100 mSv/a)

> 50 mSv/a voluntarily !!! (ILO)
Existing exposure situation

Scope

- Exposure due to contamination by residual radioactive material
- Commodities that incorporate radionuclides
- Radon in dwellings and workplaces
- Exposure of aircrew and space crew to cosmic radiation
Existing exposure situation

Public exposure

- Justification of protective actions and remedial actions
- Optimization of protection
  - Reference levels typically expressed as annual effective dose to the representative person in range of 1-20 mSv
- Requirements from WS-R-3 (remediation) into BSS
Existing exposure situations

Radon in dwellings and other buildings with high occupancy factors for members of the public

- Information gathered on radon levels in dwellings and other buildings of high occupancy
- Dissemination of information
- If significant radon levels, then national action plan
  - *Reference level in general not to exceed 300 Bq/m$^3$*
  - *Optimize protection*
  - *Prevention and mitigation measures into building codes*
  - *Determine if remedial actions are mandatory or voluntary*
Regulatory body to establish specific reference levels for exposure to RN in construction materials, food, feed, drinking water – reference level is not to exceed 1 mSv

Food traded internationally as a result of a nuclear or radiological emergency – FAO/WHO - Codex has published guideline values

Drinking water – WHO guidelines
Existing exposure situations

**Exposure in workplaces**

Remediation of contaminated areas
- Controlled as per requirements for planned exposure situations

Radon in workplaces
- Reference level not to exceed 1000 Bq/m3 (*annual average activity concentration*)
- Protection is optimized
- If radon levels remain above reference level, then requirements for occ. exposure in planned exposure situations apply
Existing exposure situation

**Exposure to cosmic rays**

- **Aircrew:**
  - Relevant authority to determine whether:
  - Assessment of exposure is warranted
  - Specific requirements for occupational exposure in planned exposure situations are to apply, particularly for pregnant aircrew

- **Humans in space based activities:**
  - Relevant authority to establish framework of radiation protection, appropriate for this exceptional situation
  - Make all reasonable efforts to optimize protection
  - Dose limitation requirements do not apply to humans in space based activities
Schedules

- Schedule I: Exemption and clearance

Criteria of
- (1) risk low so as to not warrant regulatory control (10 μSv/a) and
- (2) regulatory control would yield no net benefit

- Levels for exemption of moderate quantities of material – Table I-1 with additional radionuclides to the current BSS
- Bulk quantities of material containing radionuclides of natural origin – dose criterion of about 1 mSv/a
Schedules

Schedule I (ctd):

Levels for clearance and for exemption of *bulk* quantities of solid material - *New*
Artificial radionuclides – table I-2

Levels for clearance of material containing r/n of natural origin – table I-3
1 Bq/g for each r/n in U/Th decay chains, 10 Bq/g for K-40
Schedules

- **New**: Schedule II – Categories for sealed sources used in common practices
  - Table same as in Safety Guide RS-G-1.9

- Schedule III – Dose Limits

- Schedule IV – Criteria for use in emergency and response
Challenging issues for discussion during the week

- Justification and optimization in medical applications
- Equivalent DL for the lens of the eyes – occ. and public
- Outside workers
- Contamination of foodstuff – need for a globally harmonized approach
- Occupational exposure to radon
  - Important topic for uranium mining
  - Further evaluation of the impact on NORM
- Implementation of the dose constraints concept in different areas
- Emergency management and rehabilitation of contaminated sites
- Transition from emergency exposure situation to existing exposure situation

Integrated environmental assessment
Thank you for your attention

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Objectives

- to indicate gaps in current approaches to radiation protection in medicine;
- to identify tools to improve radiation protection in medicine;
- to review advances, challenges and opportunities in the field;
- to assess the impact of the International Action Plan on Radiation Protection of Patients, in order to prepare new international recommendations, taking into account newer developments
Goals:

- Improved awareness of good practice in medical radiation protection among individuals and organizations globally
- Justification, improved optimization and safe practice in relation to medical uses of ionizing radiation globally

The International Action Plan for the Radiation Protection of Patients
Development of a Safety Guide: "Safety in Medical Uses of Ionizing Radiation" (DS399)

- Dealing with radiation protection in diagnostic radiology, nuclear medicine, radiotherapy and newer medical imaging technologies, covering all aspects of protection in these practices and ensuring compatibility with the revised BSS

Organization and follow-up of international campaign on effective justification of medical exposures – The 3 A’s

- Awareness, Appropriateness, Audit
- Guidance material, publications and promotion material

Development and promotion of usage of Smart Radiation Tracking for long term recording of radiation exposures of individual patients

- To define harmonized methodology that can be used for development of Appropriateness criteria
- To elucidate areas for possible collaboration in order to
  - maximize efficiency
  - avoid/minimize contradictions
- To consider optimal methods of deploying and utilizing guidelines (TM 6-8 March 2012, Vienna)
SAFRAD is a web-based system for collecting, analyzing and disseminating information on circumstances around higher exposure of patients, initially for interventional procedures.

- Available on rpop.iaea.org

SAFRON is a web-based safety reporting system for radiotherapy - for reporting and learning from incidents and near-incidents; integrating retrospective reporting and prospective risk analysis; integrating with existing systems, complementing national and mandatory systems.

- Prototype is being tested
Protection of Environment

• Integration of radiological protection in Safety Guides
  • Radiological Environmental Impact Analysis (DS 427)
  • Radiological Protection Criteria (DS 432)
  • Regulatory control of discharges (DS 442)

• Revision of SR 19:
  • Generic models for use in assessing the impact of discharges of radioactive substances to the environment
Thank you for your attention