

Revision of the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the BSS)

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Purpose of presentation

- To provide an overview of draft 3.0 of the revised BSS
- To highlight areas where text of the current BSS has been revised, and where new text has been added
- To highlight areas where there has been considerable discussion as the text has been developed

IAEA Statute

Article III.A.6:

- “To establish or adopt ... in consultation with competent organs of the United Nations and with the specialized agencies concerned, standards of safety for the protection of health and minimization of danger to life and property”

BSS Secretariat



Resolution GC(49)/RES/9A 2005

➡ Review BSS

Resolution GC(50)/RES/(10) 2006

➡ Revision BSS

coordinated by a secretariat

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.

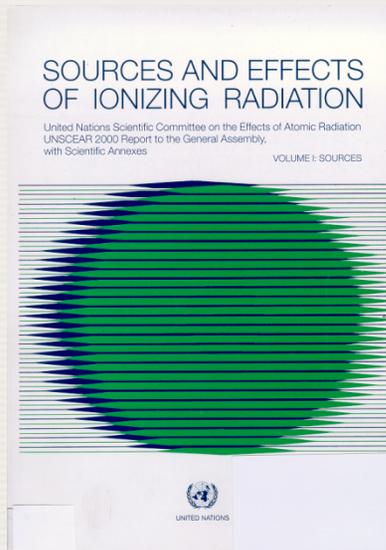
Cosponsorship

- Leads to organizations to provide consistent advice and assistance to the various government agencies of their Member States.
- The expectation that co-sponsoring organizations will apply the co-sponsored safety standards, as appropriate.
- Enhanced exchange of information on the work activities of the co-sponsoring organizations in relation the need for the development, or review and revision of safety standards, and on their experience in the application of the safety standards
- Each cosponsoring organization has its own processes for seeking input from their Member States, and for approval processes of the revised BSS

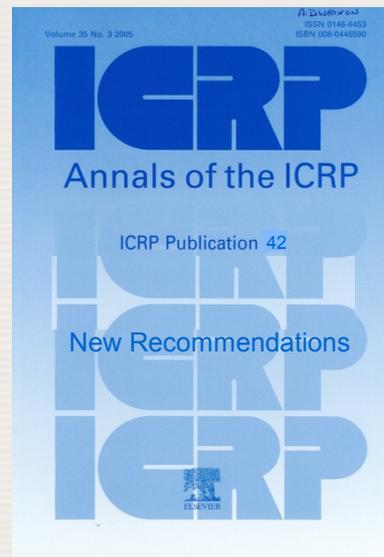
Guidance from RASSC and BSS Secretariat

- Retain BSS role as the international benchmark for radiation safety standards across all fields
- Recognize the need for stability in international standards; so be conservative and justify proposed changes
- Maintain close connection with ICRP
- Keep cosponsors (WHO, PAHO, ILO, NEA, etc) and all Safety Committees fully involved.
- Seek and take note of feedback from Member States on current BSS
- Assist developing countries to participate.

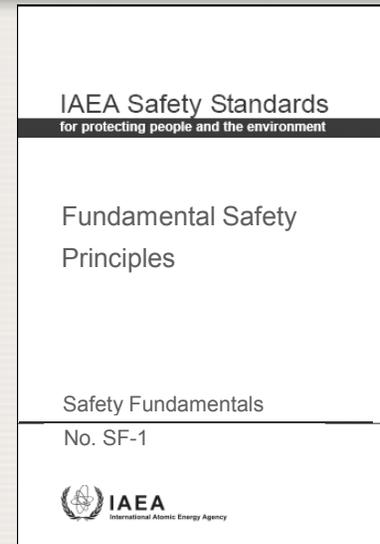
Paradigm to be maintained



Effects of radiation

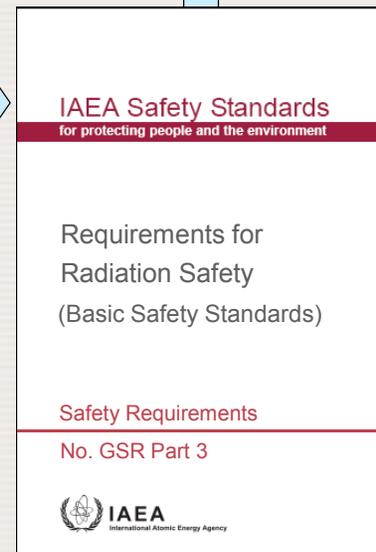


Recommendations for protection



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Essential principles
(moral obligation)



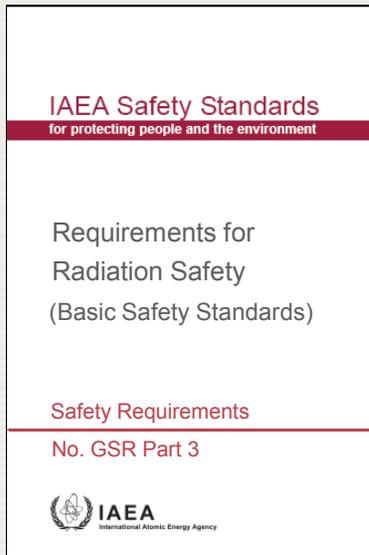
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Essential requirements
(legal obligation)



*indicative covers only

Comprehensive character of BSS



- Regulatory control of exposure
- Occupational and public exposure from practices
- Safety of sources
- Safety of radioactive waste
- Medical exposure
- Existing exposure
- Emergency preparedness
- Rehabilitation
- Basis for safe transport

The essential protection and safety requirements of the BSS underpin all circumstances of exposure to radiation

Revised BSS – draft 3.0

1. INTRODUCTION

2. GENERAL REQUIREMENTS FOR PROTECTION AND SAFETY

Implementation of radiation protection principles
Responsibilities of government
Responsibilities of the regulatory body
Responsibilities of other parties
Management requirements

3. PLANNED EXPOSURE SITUATIONS

Scope
Generic requirements
Occupational exposure
Public exposure
Medical exposure

4. EMERGENCY EXPOSURE SITUATIONS

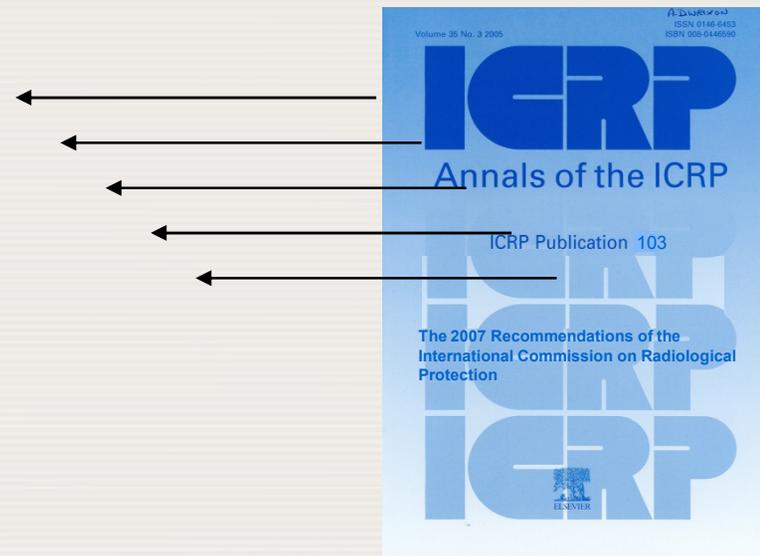
Scope
Generic requirements
Public exposure
Exposure of emergency workers
Transition from an emergency exposure situation to an existing exposure situation

5. EXISTING EXPOSURE SITUATIONS

Scope
Generic requirements
Public exposure
Occupational exposure

SCHEDULES

Schedule I EXEMPTION AND CLEARANCE
Schedule II CATEGORIZATION OF SEALED SOURCES
Schedule III OSE LIMITS FOR PLANNED EXPOSURE SITUATIONS
Schedule IV CRITERIA FOR USE IN EMERGENCY PREPAREDNESS AND RESPONSE



Some general issues

- New structure of BSS
- New format for Safety Requirements
- Protection of the environment
- Interface between safety and security

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

New format (CSS - 2008)

- Overarching discrete requirements expressed as “shall” statement, allocated a discrete number, written in plain language, with clear and short sentences.
- The conditions associated with the overarching requirements are considered as an integral part of the safety requirements.
 - In draft 3.0, the conditions are written as “shall” statements while in other Safety Requirement publications, written as “has to”
- Improve user-friendliness
- Draft 3.0 contains 52 overarching requirements? Too many? Too few?

Protection of the environment

- 1.26 (not a requirement): The system of protection and safety in these Standards generally provides appropriate protection of ecosystems in the human environment against harmful effects of radiation exposure. Nevertheless, international trends in this field show an increasing awareness of the vulnerability of the environment. Trends also indicate the need to be able to demonstrate (rather than to assume) that the environment is protected against effects of industrial pollutants, including radionuclides, in a wider range of environmental situations, irrespective of any human connection with them. This is normally accomplished through an environmental assessment, which identifies the target(s), defines the appropriate criteria for protection, assesses the impacts and compares the results of the available protection options. The methods and criteria for these radiological assessments are being developed and will continue to evolve.
- Requirements: 3.9(e), 3.15(d), 3.131 (d): ‘appropriate assessment made of the potential impacts on the environment’

Interface between safety and security

- 1.30: reference to nuclear security series
- 2.28: The government shall ensure that adequate infrastructure arrangements for interface between safety, security and accounting and control of sources are clearly established.
- 3.31: The safety assessment shall include: (f) the protection and safety implications of security measures and any of their modifications
- 3.50: When choosing a location to use or store a radiation generator or radioactive source, registrants and licensees shall take into account: (a) Factors that could affect the safety and security of the radiation generator or radioactive source

Section 1: Introduction

- Standard format for Safety Standards
 - Background
 - Links to Safety Fundamentals, ICRP, system of protection and safety, some explanatory material
 - Level of detail
 - Objective
 - Scope
 - Structure

Section 2. GENERAL REQUIREMENTS FOR PROTECTION AND SAFETY

- Chapter 2 contains requirements that are applicable to all 3 exposures situations (planned, emergency, existing)
- The three radiation protection principles apply to all three exposure situations (dose limits only apply to planned exposure situations) and are included in Chapter 2.

Responsibilities of government

Responsibilities of regulatory body

- The preamble to SS115 - 1996 - these Standards are based on the presumption that a national infrastructure is in place enabling the Government to discharge its responsibilities for radiation protection and safety. Etc
- The text of the paragraphs in these two parts of section 2 (2.13-2.39) are consistent with the text of the revised Safety Requirements GS-R-1 “*Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety*”.
 - Included to retain comprehensive character of the BSS

Responsibility of other parties

- List of principal parties enlarged to include:
 - Radiological medical practitioners in the case of medical exposure
 - Designated persons or organizations to deal with emergency exposure situations or existing exposure situations
- Ensure all personnel engaged in activities relevant to protection and safety are appropriately educated, trained, and qualified ...

Management Requirements

- Requirements on managements systems (quality assurance) and safety culture have been updated to take account of the Safety Requirements GS-R-3: Management Systems for Facilities and Activities published in 2006

Section 3. PLANNED EXPOSURE SITUATIONS

GENERIC REQUIREMENTS

- Scope
 - List of practices has been expanded for clarity
 - Sources with practices
 - Natural sources
 - Public exposures to discharges or to radioactive waste arising from a practice involving natural sources
 - Occupational exposure to radon required by or directly related to work
 - Occupational exposure to radon in an existing exposure situation where the annual average activity concentration remains above the reference level established ..
 - Exposure to material, other than .., in any relevant activity where the activity concentration in the material of any radionuclide in the uranium or thorium decay chains is greater than 1 Bq/g or the activity concentration of K-40 is greater than 10 Bq/g.
(NEW)

Section 3. PLANNED EXPOSURE SITUATIONS **GENERIC REQUIREMENTS**

- Overarching requirements
 - Responsibility of government or regulatory body
 - Exemption and clearance
 - Justification
 - Optimization of protection and safety
 - Dose limitation
 - Safety assessment
 - Human imaging for purposes other than medical diagnosis or treatment
 - Graded approach
 - Applies to all exposure situations – S. 2 or S. 3

Section 3. PLANNED EXPOSURE SITUATIONS GENERIC REQUIREMENTS

- Optimization of protection and safety
 - Dose (and risk) constraints
 - Tool for optimization
 - Are not limits
 - Set or approved by the regulatory body
 - Definition
 - Constraint: a prospective and source related value of individual dose or risk used as a tool in the optimization of protection and safety of the source, which serves as a boundary in defining the range of options in optimization
 - ‘is optimized’ v. ‘be subject to a process of optimization’ – footnote added

Section 3. PLANNED EXPOSURE SITUATIONS **GENERIC REQUIREMENTS**

- Radiation generators and radioactive sources
 - new requirements relating to (3.54 – 3.59):
 - Licensees sharing inventory records with reg. body
 - Reg. body require sealed sources to be categorized
 - Manufacturer of r/a source or device that source itself and container are marked with trefoil symbol
 - Licensees ensure sealed sources are identifiable and traceable
 - Licensees ensure that r/a sources are stored
 - Licensees ensure arrangements for safe management and disposition of disused r/a sources
- From Code of Conduct / S. Guide

Section 3. PLANNED EXPOSURE SITUATIONS **GENERIC REQUIREMENTS**

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

Section 3. PLANNED EXPOSURE SITUATIONS

GENERIC REQUIREMENTS

- 3.18: Human imaging using radiation performed for occupational, legal or health insurance purposes without reference to clinical indication shall normally be deemed to be not justified. If, in exceptional circumstances, the justification of such imaging is to be considered, the requirements of 3.60 to 3.64 shall apply
- 3.19: Human imaging for theft detection purposes shall be deemed to be not justified.
- 3.20: Human imaging using radiation for the detection of concealed objects for security or anti-smuggling purposes shall normally be deemed to be not justified. If, in exceptional circumstances, the justification of such imaging is to be considered, the requirements of 3.60 to 3.63 and 3.65 to 3.67 shall apply
- 3.60 – 3.67: Proposed new paragraphs to strengthen the safety and regulatory control of non-medical imaging practices, by making regulatory control, justification decisions and optimization of protection and safety explicit.

Section 3. PLANNED EXPOSURE SITUATIONS

OCCUPATIONAL EXPOSURE

- Definition of ‘occupational exposure’: Exposure of workers incurred during the course of their work’
- Definition of ‘worker’: any person who works, whether full time, part time or temporarily, for an employer and who has recognized rights and duties in relation to occupational radiation protection
- Specific requirements on responsibilities of regulatory bodies have been included (Req. 19, 20, 3.69-3.73)
 - The regulatory body shall establish and enforce requirements that protection and safety is optimized, and that doses from occupational exposure comply with dose limits
 - The regulatory body shall establish and enforce requirements for the monitoring and recording of occupational exposure in planned exposure situations

Section 3. PLANNED EXPOSURE SITUATIONS **OCCUPATIONAL EXPOSURE**

- 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

Section 3. PLANNED EXPOSURE SITUATIONS

PUBLIC EXPOSURE

- New requirements on government or the regulatory body (Req. 29, 32, paras 3.117-3.123, 3.134-3.135, 3.138):
 - To establish and enforce requirements to ensure public exposure control
 - To establish or approve source related constraints for dose and risk to be used for optimization of protection of the public
 - To establish or approve source related criteria, such as authorized limits for discharge, for the demonstration of compliance.
 - To ensure that environmental monitoring programmes are in place, results are recorded and made available
 - Setting out responsibilities of the regulatory body in relation to authorizing the supply of consumer products to the public

Section 3. PLANNED EXPOSURE SITUATIONS

PUBLIC EXPOSURE

- New requirements on registrants and licensees:
 - Monitoring programmes (Para 3.136): A more specific requirement on reporting the results of monitoring programmes and retrospective assessment of doses
 - Waste (Para 3.130): Requirement expanded to include: Maintain an inventory of all radioactive waste generated
 - Environment impact from discharges (Para 3.131 (d)): New requirement added to the requirements on discharges to 'consider the environmental impact, as required by the regulatory body'

Section 3. PLANNED EXPOSURE SITUATIONS

MEDICAL EXPOSURE

- 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 (IOMP definition)
 - Medical radiation technologist (ISRRT def'n)

Section 3. PLANNED EXPOSURE SITUATIONS MEDICAL EXPOSURE

Responsibilities of government:

to ensure, as a result of consultation between health authorities, professional bodies and the regulatory body, that:

- There is appropriate authorization for all parties to assume their roles and responsibilities
- DRLs are established
- Dose constraints are established for
 - Carers and comforters
 - Volunteers in biomedical research
- Guidelines and criteria are established for the release of patients after radionuclide therapy

Section 3. PLANNED EXPOSURE SITUATIONS MEDICAL EXPOSURE

- Responsibility of Regulatory Body:
 - Authorization must specify that personnel that take the roles of - Radiological medical practitioners, Medical physicists, Medical radiation technologists, Other qualified experts with specific duties in patient radiation protection
 - Only if they are specialised in the appropriate area
 - Meet respective education, training and competence requirements in radiation protection
 - Are named in an up-to-date list maintained by the licensee

Section 3. PLANNED EXPOSURE SITUATIONS MEDICAL EXPOSURE

- Responsibility on the licensee for the patient to be informed, as appropriate, of the potential benefit of the radiological procedure as well as radiation risk

Section 3. PLANNED EXPOSURE SITUATIONS

MEDICAL EXPOSURE

- Justification
 - General requirement (as in current BSS)
 - Level II (for radiological procedures)
 - Health authority, professional bodies
 - Level III (for individual patients)
 - Radiological medical practitioner, in consultation with the referring medical practitioner when appropriate
 - Particular attention to pregnant, breast-feeding and paediatric patients
 - Use of relevant guidelines in justifying individual radiological procedures (as before)

Section 3. PLANNED EXPOSURE SITUATIONS

MEDICAL EXPOSURE

- Justification
 - Health screening programmes
 - Health authority, professional bodies
 - Asymptomatic individuals – intended for early detection of disease
 - Referrer/practitioner
 - Professional body guidelines
 - Informed re benefits, risks and limitations
 - Exposure of humans for biomedical research is deemed to be not justified unless.... (as before)

Section 3. PLANNED EXPOSURE SITUATIONS MEDICAL EXPOSURE

- Optimization of protection
 - Biggest section
 - Much technical detail removed (to go into SG)
 - Same sub-sections in current BSS retained
 - Design considerations
 - Scope of “equipment” expanded to include: Radiation generators, accelerators, sources, etc, gamma cameras, image intensifiers, etc, Software for delivery of radiation
 - Operational considerations
 - Major consolidation of requirements

Section 3. PLANNED EXPOSURE SITUATIONS MEDICAL EXPOSURE

- Optimization of protection
 - Calibration
 - Medical physicist assigned responsibility
 - Clinical dosimetry
 - Medical physicist assigned responsibility
 - Diagnostic reference levels (DRLs)
 - Strengthened through link made to clinical dosimetry requirements

Section 3. PLANNED EXPOSURE SITUATIONS

MEDICAL EXPOSURE

- Optimization of protection
 - Quality assurance
 - Under the supervision of a medical physicist
 - QC tests to be made:
 - At the time of acceptance & commissioning, prior to clinical use on patients
 - Periodically, thereafter, and
 - After any major maintenance that could affect patient safety
 - Pregnant or breast-feeding women
 - Arrangements in place to afford appropriate radiation protection: signs, procedures in place

Section 4. EMERGENCY EXPOSURE SITUATIONS

- Changes
 - Restructuring the text
 - Deleting certain parts covered in GS-R-2
 - Response actions and criteria
 - Development of the paragraph on transition from emergency exposure situation to existing exposure situation
 - New ICRP recommendations

Section 4. EMERGENCY EXPOSURE SITUATIONS

- Generic requirements
 - Emergency management system
- Public exposure
 - Preparedness and response to emergency
 - Protection strategies and justified and optimized
 - Reference level – residual dose – 20-100 mSv
 - Generic criteria for particular protective and other actions
 - Default triggers for initiating different parts of response plan – OILs, EALs
 - Response undertaken through timely implementation of arrangements

Section 4. EMERGENCY EXPOSURE SITUATIONS

- Exposure of emergency workers
 - Definition: 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.
 - Programme for controlling doses received by emergency workers
 - Apply requirements for occupational exposure in planned exposure situations using a graded approach
 - Exceed maximum single year dose limit in exceptional circumstances
- Transition from emergency exposure situation to existing exposure situation
 - Arrangements in place for transition

Section 5: EXISTING EXPOSURE SITUATIONS

- OVERVIEW:
 - Existing exposure situations - chronic exposure situations in the current BSS – new ICRP terminology
 - Action level has been superseded by reference level - ICRP
 - Compared with the current BSS, the text of Draft 3.0 is expanded and completely rewritten
- Scope
 - Exposure to natural sources – radon, r/n in commodities
 - Exposure of aircrew to cosmic radiation now included
 - Exposure due to contamination of areas by residual radioactive material from
 - Past activities never regulated or regulated to different standards
 - A nuclear or radiological emergency, after emergency has been declared ended

Section 5: EXISTING EXPOSURE SITUATIONS

- Generic Requirements
 - Specific responsibilities of government, regulatory bodies and other relevant authorities
 - Programme to identify and evaluate existing exposure situations
 - Framework for protection and safety
 - National strategies
 - Establish appropriate reference levels
 - Involvement of stakeholders

Section 5: EXISTING EXPOSURE SITUATIONS

- Public exposure
 - Justification of protective actions/ optimization of protection
 - Reference levels in range of 1-20 mSv
 - Remediation of areas contaminated by residual radioactive material – incorporation of requirements from Safety Req. WS-R-3
 - Living in areas with residual contamination

Section 5: EXISTING EXPOSURE SITUATIONS

- Indoor radon
 - Dissemination of information
 - If significant radon levels, national action plan
 - Reference level in general not to exceed 300 Bq/m³
 - Optimize protection
- Commodities
 - Examples: food, water, construction material
 - Reference level not to exceed 1 mSv/yr

Section 5: EXISTING EXPOSURE SITUATIONS

- Occupational exposure
 - Requirements for public exposure apply, except for:
 - Remediation of contaminated areas
 - Controlled as per requirements for planned exposure situations of section 3
 - Radon in workplaces
 - Reference level not to exceed 1000 Bq/m³
 - Protection is optimized
 - If radon levels remain above reference level, then requirements for occ. exposure in section 3 apply

Section 5: EXISTING EXPOSURE SITUATIONS

- Occupational exposure
 - Exposure to cosmic rays
 - Aircrew:
 - Relevant authority to determine whether:
 - Assessment of exposure is warranted
 - Specific requirements for occupational exposure in planned exposure situations in Section 3 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
 - Levels for exemption of moderate quantities of material – Table I-1
 - Additional radionuclides to the current BSS
 - Levels for clearance and for exemption of bulk quantities of material
 - Values from RS-G-1.7
 - Artificial radionuclides – table I-2
 - Natural radionuclides – 1 Bq/g for U/Th decay chains

Schedules

- Schedule II – Categories for sealed sources used in common practices
 - New Schedule in the BSS. Taken from Safety Guide RS-G-1.9.
- Schedule III – Dose Limits
 - Reference to ICRP publications for dose coefficients
 - More suitable ways of presenting the Tables containing dose coefficients will be explored (e.g. CD-ROM inside the back cover)

Schedules

- Schedule IV
 - Table IV-1: Generic criteria for acute doses at which protective and other actions are expected to be taken under any circumstances to avoid or minimize severe deterministic health effects
 - Table IV-2: Guidance values for restricting exposure of emergency workers

Glossary

- The IAEA Safety Glossary is being updated in parallel with the revision of the BSS.

Thank you for your attention

