

Revision and consolidation of Euratom Basic Safety Standards PART 2: Planned exposure situations



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Kaare Ulbak
National Institute of Radiation Protection
Denmark

Preparing a draft revised and consolidated EU-BSS

- Commission Radiation Protection Unit in Luxembourg (D4)
- Article 31 Expert Group
 - WP BSS
 - WP Exemption and Clearance
 - WP Natural Sources
 - WP Graded Approach
 - WP Recast
- First consolidated draft text:
June 2009
- Final Draft and Opinion:
February 2010

http://ec.europa.eu/energy/nuclear/radiation_protection/article_31_en.htm

**Opinion of the Group of Experts established under Article 31 of the Euratom treaty
on the
Revised Basic Safety Standards for the protection of the health of workers and the
general public against the dangers arising from ionising radiation.**

24 February 2010

1. The European Commission has undertaken the simplification of Community legislation in the area of radiation protection and has proposed the consolidation into a single text of the following Directives:

- Council Directive 96/29/Euratom of 13 May 1996, laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation,
- Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure.
- Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency.
- Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas.
- Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources.

Radiation Sources

Radiation Generators

Radioactive Material including
Radioactive Substances

Radioactive Sources

Sealed Sources

High activity
Sealed Sources

Orphan Sources

Radioactive Waste

Naturally occurring
radioactive material

Radiation Sources

Radiation Generators

Radioactive Material including

Definition: An entity that may cause radiation exposure

- such as by emitting ionising radiation or by releasing radioactive material
- and can be treated as a single entity for protection and safety purposes

High activity
Sealed Sources

Orphan Sources

Radioactive Waste

Naturally occurring
radioactive material

Structure of the new Euratom Basic Safety Standards

Preamble

Title I Subject Matter and Scope

Title II Definitions

Title III System of Protection

Title IV Responsibilities for Regulatory Control

Title V Requirements for Education, Training and Information

Title VI Justification and Regulatory Control of Planned Exposure Situations

Title VII Protection of Workers, Apprentices and Students

Title VIII Protection of Patients and Other Individuals Submitted to Medical Exposure

Title IX Protection of Members of the Public

Title X Protection of the Environment

Title XI Final provisions

17 Annexes



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Principles - protection infrastructure

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Specific operational requirements

System of protection - Dose limits



Occupational exposure

- Explicit age limits for exposed workers (18 years)
- Effective dose limit
 - 20 mSv in any single year
 - 5-years averaging may be authorised for certain situations specified in national legislation
- Equivalent dose limit for the lens of the eye
 - 20 mSv in any single year
 - 5-years averaging may be authorised for certain situations specified in national legislation

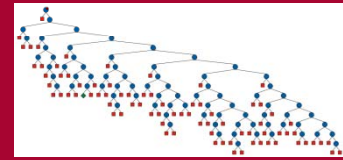
System of protection - Dose limits



Public exposure

- Effective dose limit
 - 1 mSv in any single year
- Equivalent dose limit for the lens of the eye
 - 15 mSv in any single year
 - *31-Expert Group June 2011: Keep provisionally mainly for reasons of consistency with the Int.-BSS*

System of protection - Optimisation



Dose constraints

... where appropriate dose constraints may apply to organ doses (in terms of equivalent doses), as a precautionary measure to allow for uncertainties on health detriment below the threshold for deterministic effects

Where dose constraints are introduced to restrict any protracted accumulated exposure, these shall be established in terms of annual effective dose or equivalent dose to an organ

Responsibilities for Regulatory Control (1/2)

Institutional infrastructure

- Competent authority
 - Communication to the Commission
 - Publication by the Commission
- Recognition of services and experts
 - Occupational health services
 - Dosimetry services
 - Radiation protection experts
 - Medical physics experts
 - Specify the recognition requirements and communicate these to the Commission
- Radiation protection officer
 - Tasks within undertakings, necessary means, reporting directly to the undertaking



Responsibilities for Regulatory Control (2/2)

Institutional infrastructure

- Inspections
 - Systematic inspection programme
 - Findings available to the public
 - Information to relevant parties of lessons learned from inspection and from incidents and accidents
- Enforcement



Requirements for education, training and information

Legislative and administrative framework

- Recognised services and experts
- Information and training of exposed workers, apprentices and students
- Information and training of workers potentially exposed to orphan sources
- Information and training of emergency workers
- Education, information and training in the field of medical exposure



Justification and regulatory control of planned exposure situations

Non-medical exposure of humans

- Identification of practices
- Justification: General, particular application, individual exposure (type A)
- Authorisation, optimisation, dose constraints
- Informed consent (except law enforcement)

Type A (Medical staff and equipment)

- Employment purposes
- Immigration purposes
- Insurance purposes
- Physical development and age
- Concealed object within the body

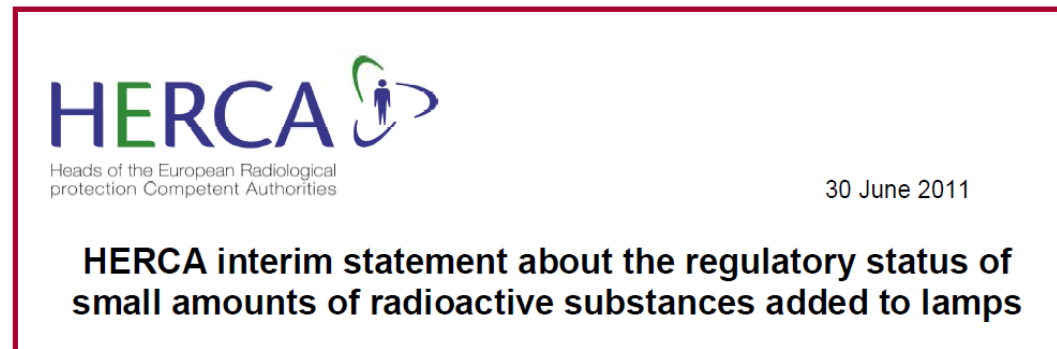
Type B (Non-medical staff and equipment)

- Concealed objects on or attached to the body
- Concealed humans as part of cargo-screening
- Other legal or security purposes

Justification and regulatory control of planned exposure situations

New type of apparatus or products

- Relevant information to competent authorities (Annex)
- Justification (Annex)
 - Type approval / Consumer products
- Information of the competent authorities of other Member States



- European and international standards (IAEA/EU/NEA working group)

Justification and regulatory control of planned exposure situations

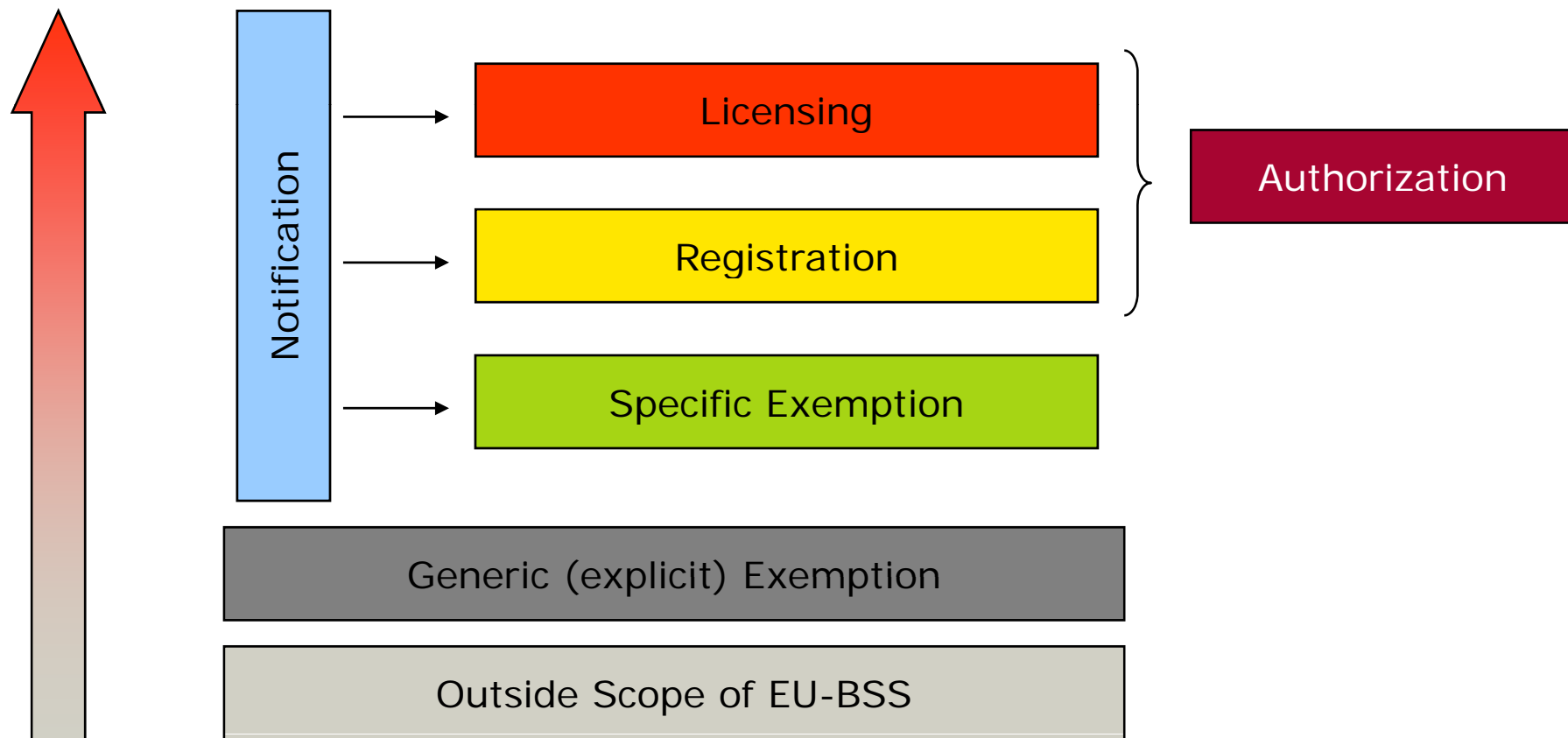
Graded approach

- Working Party of the Article 31 Expert Group

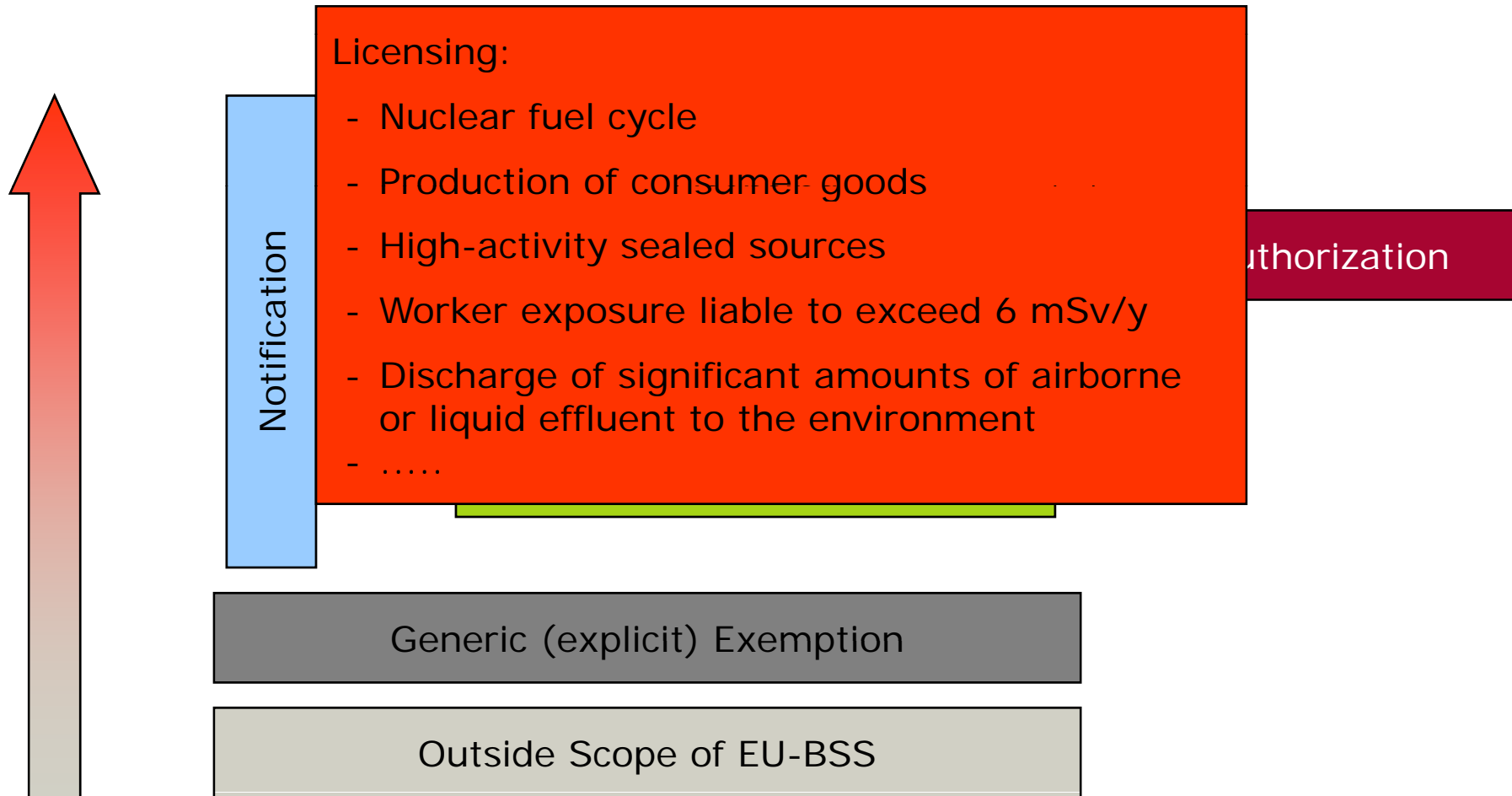


Member States shall require any notified practice to be subject to regulatory control commensurate with the magnitude and likelihood of exposures resulting from the practice, and commensurate with the extent by which regulatory control may have an impact on reducing such exposures or improving the safety of the installations

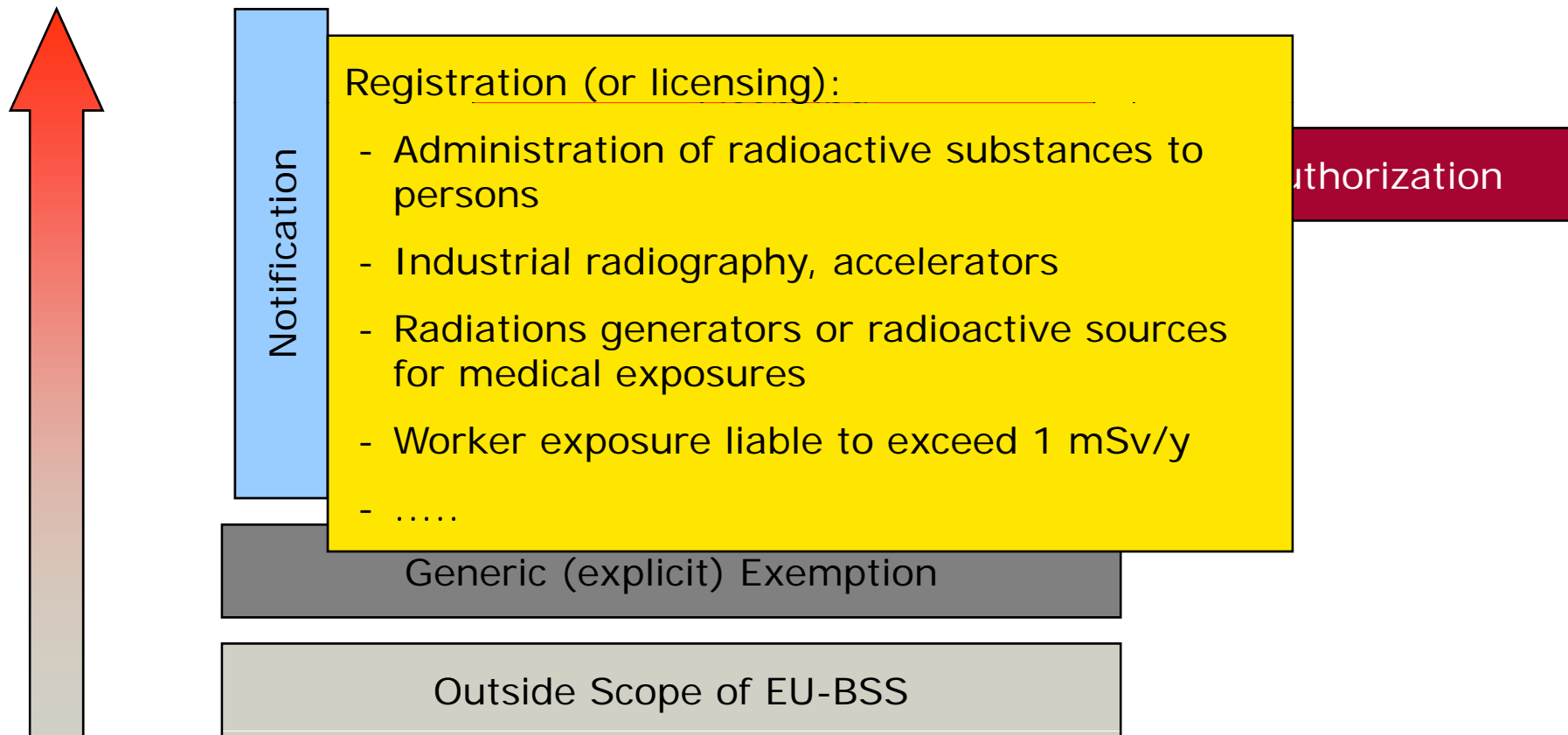
Regulatory Control - Graded Approach



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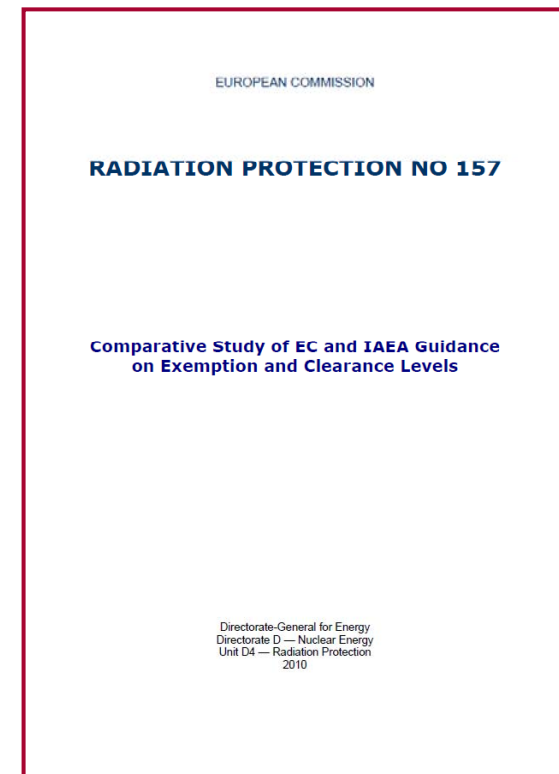
Regulatory Control - Graded Approach



Release from regulatory control

Exemption and clearance

- No general clearance levels in 1996 EU-BSS (Recommendations in RP 122)
- IAEA RS-G-1.7
- Working Party of the Article 31 Expert Group
 - Comparative Study
- **IAEA levels used as both exemption and clearance levels in revised EU-BSS**
 - However, do not apply in two cases to natural occurring radionuclides:
 - Residues into building materials
 - Specific risk of groundwater contamination

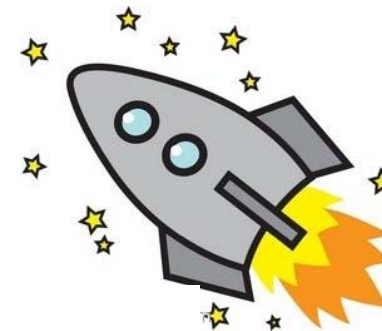


Protection of workers, apprentices and students

Air and space crew

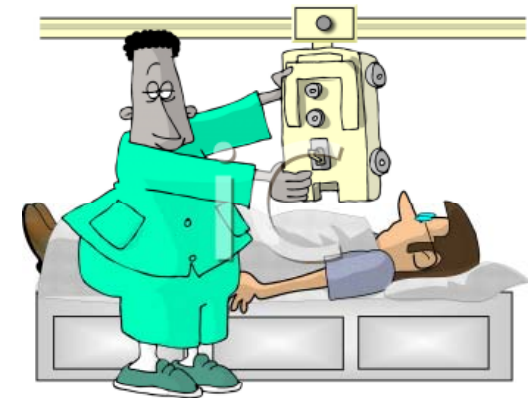
- Exposure of air crew
 - Requirements maintained
 - Regarded as planned exposure situation

- Exposure of space-crew
 - Included in scope of EU-BSS
 - Special authorised exposure



Protection of patients and other individuals

- Remains essential unmodified from the medical exposure directive
- But new emphasis on
 - Justification of **asymptomatic individuals**
 - Information provided for patients
 - Interventional radiology procedures
 - Diagnostic reference levels
 - Dose indicating devices
- New features
 - Detailed consideration of accidental or unintended exposures
 - The role of the quality assurance programme, including risk analysis in radiotherapy, to avoid incidents



Next step

Atomic Questions Group of the Council

No, little or substantial changes to the text ???