

Basic Safety Standards Directive – Transposition and Implementation – an overview

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Radiation protection in Europe

Treaty establishing the European Atomic Energy Community (Euratom Treaty) – 1957

Basic safety standards

- Health protection of public, workers and patients against dangers arising from ionising radiation
- Ensure application

English edition

DIRECTIVES

Chapter on Health and Safety Article 31

ISSN 1977-0677 Official Journal L 13 of the European Union Volume 57 Legislation 17 January 201-II Non-legislative acts

Legally binding requirements for EU Member States

Transposed into national legislations



* Council Directive 2013/59/Euratom of 5 December 2013 laving down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealin Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom an 2003/122/Euraton



2014 version of the BSS

Council Directive 2013/59/Euratom covers provisions from five previous Euratom Directives

- Basic Safety Standards, Directive 96/29/Euratom, **1996**
- Medical Exposures, Directive 97/43/Euratom, **1997**
- Public Information, Directive 89/618/Euratom, **1989**
- Outside Workers, Directive 90/641/Euratom, **1990**
- Control of high-activity sealed radioactive sources and orphan sources, Directive 2003/122/Euratom, 2002







Basic Safety Standards Directive

Legally binding requirements on

- Protection of workers, members of the public, patients
- Regulatory control of practices
- Medical applications

. . .

- Emergency preparedness and response
- Natural radiation sources including Radon
- Existing exposure situations
- Monitoring of radioactive discharges
- Environmental monitoring programme
- Safety and control of high-activity sealed sources
- Legacy existing situations & contaminated sites



ISSN 1977-06

BSS – recall some dates



Official Journal of the European Union		L 13
English edition	Legislation	Volume 57 17 January 2014
Contents	I Non-legislative acts	
	DIRECTIVES ★ Council Directive 2013/59/Euratom of 5 December 2013 laying de protection against the dangers arising from exposure to ionis Directives 89/618/Euratom, 90/641/Euratom, 96/29/Eurat 2003/123/Euratom	own basic safety standards for sing radiation, and repealing om, 97/43/Euratom and





CHAPTER X

FINAL PROVISIONS

Article 106

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 6 February 2018.

2. When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

3. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.



BSS – Final provisions

Official Journal L 1 of the European Union				
English edition	Legislation	Volume 57 17 January 2014		
Contents	II Non-legislative acts			
	 DIRECTIVES Council Directive 2013/59/Euratom of 5 December 2013 laying down protection against the dangers arising from exposure to ionising Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 2003/122/Euratom 	basic safety standards for radiation, and repealing 97/43/Euratom and 1		

Status of BSS transposition checks

European Union Member States

- Transposed BSS requirements into national legislations
- Notified transposing legislation in Themis database



European Commission

- Phase 1: Checking completeness finalised
 - Notified legislation of 27 Member States checked for completeness
 - Infringement procedures launched for 26 Member States
 - Cases closed for 25 Member States 1 case still pending
 - Phase 2: Checking compliance close to completion
 - Notified legislation of 26 Member States checked for compliance
 - Infringement procedures launched for 12 Member States so far
 - Cases closed for 4 Member States more to follow
- Phase 3: Monitoring Implementation ongoing, permanent
 - Studies initiated by the Commission
 - Areas of interest identified during completeness and conformity checks



Interesting topics within the BSS

A few observations on the transposition of the requirements on

- Medical exposures
- Non-medical human imaging
- Emergency preparedness and response
- Radon
- NORM activities
- Existing exposure situations
- Building materials
- High activity sealed sources
- Experts and Services Education and training





Medical applications

Challenges

- Patient radiation exposure
 - Varying MS adoption of Diagnostic Reference Levels (DRLs)
 - Communication of *relevant information* to referrers and patients
- Accidental or unintended exposures
 - Varying MS definition of 'significant event' (reportable to the CA)
 - Lacking definition of *clinically significant* (information to patient)
- Persisting *implementation challenges*
 - Clinical audit, justification of imaging (CT), MPE availability, E&T
- New implementation challenges
 - Rapid technology development dosimetry, quality control, Artificial Intelligence
 - New radionuclide therapies individual treatment planning and verification







SAMIRA activities on RP in Medicine

Steering Group on Quality and Safety (SGQS):

- MS health and RP authorities
- draws conclusions from studies and activities
- supports implementation of recommendations in MS



EU-JUST-CT (justification of CT)

Recent / Ongoing Studies

BSSD Equipment

MARLIN (accidents)

EU-REST (staffing, E&T)

#EUCancerPlan

#EUSamira

SAMIRA Action Plan (europa.eu)

Key activities in 2024

Q&S KPIs study

Medical devices study

Acceptability criteria study

DRL Workshop, 17-18 June

EU4Health programme grants

- SAMIRA preparatory Joint Action (direct grants to Member States)
- Clinical audit campaigns to improve quality and safety of medical radiation applications
- Radiation safety and quality of CT of children, adolescents and young adults



Non-medical human imaging

Challenges

- Defining a (relevant / up-to-date) list of justified practices
- Shifting borderline between non-medical human imaging with / without medical equipment
- Dose constraints in the context of public dose limit
- Specific *DRLs* for non-medical human imaging with medical equipment
- Criteria for *individual implementation* (of justified non-medical human imaging practices)



Emergency Preparedness and Response

Challenges

- International cooperation transposition and implementation of Article 99 BSS often too generic
- Cross-border coordination of *protective measures* **and** *public information*
- Inclusion of all elements required in an emergency management system, e.g. transition from emergency exposure situation to an existing exposure situation
- Inclusion of *all elements* required in an emergency response plan.



Radon

European Indoor Radon Map, November 2021



Arithmetic means over 10 km x 10 km cells of long-term radon concentration in ground-floor rooms. (The cell mean is neither an estimate of the population exposure, nor of the risk.)

BSS Directive defines for the first time a legally binding framework for radon protection

- Major challenge *National radon action plan*
- National reference level(s)
- Addressing radon in workplaces
- Dose coefficient(s)



≤ 300 Bq/m³

European Commission, Joint Research Centre (JRC), Directorate G - Nuclear Safety & Security, REM project



Nº 193 Radon in workplaces

Radon in workplaces

 Background material published in the Radiation Protection Series of the European Commission as RP N°193

https://op.europa.eu/en/publication-detail/-/publication/93cc4aff-47c5-11ea-b81b-01aa75ed71a1/languageen?WT.mc_id=Searchresult&WT.ria_c=37085&WT.ria_f=3608& WT.ria_ev=search

https://energy.ec.europa.eu/topics/nuclear-energy/radiationprotection/scientific-seminars-and-publications/radiationprotection-series-publications_en





Study on national radon action plans

Objective

Protection

• Review and evaluation of *national radon action plans* established in EU Member States

The study provided

- Overview of the *development* and *content* of national radon action plans
- Evaluation of the *practical implementation* of the actions set out in these action plans
- Identification of *challenges* related to practical implementation
- Identification of *best practices*
- Assistance to the European Commission in the *conformity assessment of plans*

Final report published in the European Commission's Radiation Protection Series as RP 199 Review and evaluation of national radon action plans in EU Member States according to the requirements of Council Directive 2013/59/Euratom - Publications Office of the EU (europa.eu)





Status of National Radon Action Plans in Europe



BSS Directive requirements had a very positive effect on the development of radon policies and strategies in Europe

- 27 EU Member States plus Switzerland, Norway and the United Kingdom have established National Radon Action Plans
- Radon action plans currently in varying stages of implementation in practice
- Indoor radon measurement campaigns planned / started in many Member States

Status May 2024



NORM activities

Challenges

Activities involving naturally occurring radioactive material (NORM)

- Identification of NORM activities of concern
- NORM *activity specific* regulation
- NORM Legacy cites connection to existing exposure situations





Building materials – Basic Safety Directive



Challenges with implementation

- Identification of building materials of concern *national list*
 - Natural materials
 - Materials incorporating NORM residues
- Procedures to determine radionuclide content & activity concentration index
- Procedure to inform of the competent authority



Construction products – related developments

Construction Products Regulation (EU/305/2011)

- Market instrument Objective: prevent barriers for trade of construction products
- *CE marking* based on *common* assessment system
- Dangerous substances Member States to define list of construction products for which radioactivity content may be of concern
- Revised CPR in preparation (EP voted in favour)

European Committee for Standardisation – CEN

CEN/TC 351 Working Group 3 on "Radiation from construction products"

- CEN/TS 17216 Construction products: Assessment of release of dangerous substances

 Determination of activity concentrations of radium-226, thorium-232 and potassium-40
 in construction products using semiconductor gamma-ray spectrometry" published 2018
- EN 17637 Construction products: Assessment of release of dangerous substances Dose assessment of emitted gamma radiation published 2022





Existing exposure situations





Issues with existing exposure situations

- Programmes on existing exposure situations
 - Identification and evaluation

- Mainly through *empowerment* of the *competent authority*
- Strategies for appropriate management
 - Strategies often developed only for *radon*
 - Generic requirements
 - Mainly through *empowerment* of the *competent authority*
- Implementation of strategies
 - Mainly through *empowerment* of the *competent authority*



High-activity sealed sources

Most of the current BSS Directive requirements were already included in Council Directive 2003/122/Euratom (HASS Directive)

Challenges with the transposition of Council Directive 2013/59/Euratom

- Specific requirements for *licensing* of high-activity sealed sources not transposed
 - Often covered by general requirements on licensing
- Detection of orphan sources and metal contamination
 - Scrapyards are encouraged to have detectors, but not all main transit points
 - Requirements on training and information of staff not always implemented
- Financial security for orphan sources not well implemented in some MS

Study on "Control of radioactive sources in the European Union" (2019 – 2023) – to be published

EU inventory of high-activity sources;

- Identified practices related to the control of high-activity sources;
- Level of implementation of the BSS Directive source control articles in EU MSs & UK;
- Incidents and accidents involving radioactive sources occurred in EU & the UK





Experts – RPE, MPE, RPO

Review and analysis of the transposition and implementation of the Basic Safety Standards provisions on Radiation Protection Expert (RPE), Radiation Protection Officer (RPO) and Medical Physics Expert (MPE) in EU MS

The aim of the study is to assess

- Availability and adequacy of the legislative and administration framework ensuring the provision of appropriate radiation protection education, training and information in the radiation protection field
- Set-up of the practical implementation of the BSS provisions on RPE, RPO and MPE, including related education and training requirements
- Recognition criteria in all EU Member States

Key data

- Duration: December 2022 December 2024
- Contractor: Consortium NucAdvisor, SCK CEN, EUTERP, EFOMP, ENEN
- Final Workshop Luxembourg, 3 4 October 2024





Dose coefficients for workers

- BSS Directive requires *individual monitoring* of *exposed workers*
- Assessment of exposure using dose coefficients published by ICRP
- In 2014, dose coefficients for internal exposure based on ICRP Publication 103 were still to be developed and published by ICRP
- ICRP Publications on Occupational Intakes of Radionuclides: Part 1 -5, completed in 2022
- Commission asked the Article 31 Group of Experts to establish an Opinion on the use of this updated set of dose coefficients adopted on 28 June 2023
- Commission recommendation (Euratom) 2024/440 of 2 February 2024 on the use of dose coefficients for the estimation of the effective dose and equivalent dose for the purposes of Council Directive 2013/59/Euratom

Official Journal of the European Union	EN L series
2024/440	6.2.2024
COMMISSION RECOMMENDATION (EU) 2024/440	
of 2 February 2024	
on the use of dose coefficients for the estimation of the effective dose and equivalent dose for the purposes of Council Directive 2013/59/Euratom	



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(notified under document C(2024) 563)

Commission Recommendation 2024/440 of 2 February 2024

Legal basis

- The Commission can 'make recommendations' in different ways including to develop a Commission Recommendation on Dose Coefficients under the Euratom Treaty (Article 33) to support the implementation of certain BSS requirements.
- This would ensure a common application of the dose coefficients for occupational exposure in Member States.

		EN
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		6.2.2024
C.	Official Journal of the European Union 2024/440	
_	RECOMMENDATION (EU) 2024/440	
	of 2 February 2024 of 2 February 2024 on the use of dose coefficients for the estimation of the effective dose and equi purposes of Council Directive 2013/59/Euratom (notified under document C(2024) 563)	valent dose for the
	THE EUROPEAN COMMISSION.	atom Treaty'), and in particular
	Having regard to the Treaty establishing the European Atomic EARS, Article 292 of the IT Article 33, second paragraph, and Article 106a thereof referring to Article 292 of the IT European Union,	tom Treaty,
	Having consulted the group of experts referred to in Article 24, and a	

COMMISSION RECOMMENDATION 2024/440 of 2 February 2024 on the use of dose coefficients for the estimation of the effective dose and equivalent dose for the purposes of Council Directive 2013/59/Euratom (published in the OJ)

"...Member States should use the ICRP Publications on Occupational Intakes of Radionuclides: Part 1-5 (ICRP Publications 130, 134, 137, 141 and 151), and all the dose coefficients therein, in the estimation of the effective dose and equivalent dose from internal exposure for the purposes of Directive 2013/59/Euratom..."

EUR-Lex - 32024H0440 - EN - EUR-Lex (europa.eu)

EU radiation protection legislation - European Commission (europa.eu)

Future system of radiological protection

Initiative by the International Commission on Radiological Protection (ICRP)

- ICRP engaged in a process to review and possibly revise the current system of radiological protection laid down in *ICRP Publication 103*
- Council Directive 2013/59/Euratom the BSS Directive based on ICRP Publication 103
- 10 years after the publication European Union Member States transposed and implemented BSS Directive
- Large and unique experience with the implementation of the current system of radiological protection
- Offer this valuable experience to ICRP for their consideration
- European Commission and its Article 31 Group of Experts in close contact with ICRP

European Commission is closely following this ICRP review/revision process of the system of radiological protection as well as scientific and technological developments in radiation protection as these may have an impact on any future BSS Directive



ONAL COMMISSION ON RADIOLOGICAL PROTECTION



Article 31 Group of Experts

Article 31 Group of Experts

- > Advise European Commission
- Follow scientific developments
- Identification of issues topical discussions
- Development of guidance material

Working Parties

- Medical Applications
- Research Implications on Health and Safety Standards
- Natural Radiation Sources
- Dose Constraints

Collaboration with

HERCA, ICRP, IAEA, WHO, OECD/NEA, IRPA, UNSCEAR Norway, Switzerland, UK





Official Journal

of the European Union

Legislation

Non-legislative act

L 13

Résumé

Transposition and implementation of the Basic Safety Standards Directive

- Completeness checks of BSS finalised
- Conformity checks close to completion
- Identified issues with new or strengthened requirements (Radon, NORM, building material, medical applications, non-medical human imaging, emergency preparedness and response, high-activity sealed sources, experts and services...)
- Focus now: Practical Implementation
- Future of the system of radiological protection European experience valuable input to process started by ICRP





Thank you for your attention

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