



European
Commission

Accidental and Unintended Medical Exposures in Council Directive 2013/59/Euratom

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Energy





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Euratom BSS

- **Binding law** for the EU Member States
- First adopted **1959**
- Supplementing acts
 - ✓ **Medical** – 1984, **1997**
- Regular update ... 1996, 2013

Euratom Treaty

- Rome, 25 March 1957
- Basic Safety Standards (BSS)
 - ✓ Proposal by the **Commission**
 - ✓ Opinions – GoE, EESC
 - ✓ Consultation – Parliament
 - ✓ **Adoption - Council**

Council Directive 2013/59/Euratom

- **Revision and consolidation**
- Latest science (ICRP 103)
- Operational experience
- All exposure situations and categories of exposed



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Година 57
17 януари 2014 г.

Съдържание

II Незаконодателни актове

ДИРЕКТИВИ

★ Директива 2013/59/Евратом на Съвета от 5 декември 2013 година за определяне на основни норми на безопасност за защита срещу опасностите, произтичащи от излагане на йонизиращо лъчение и за отмяна на директиви 89/618/Евратом, 90/641/Евратом, 96/29/Евратом, 97/43/Евратом и 2003/122/Евратом 1

Поправки

★ Допълнение 74

Цена: 7 EUR

BG

Актовете, които заглавия се отпечатват със светли шрифтове, са актове по жечушо управление на самостоятелната политика и имат кратък срок на действие.

Заглавията на всички останали актове се отпечатват с полупечер шрифтове и се пределят от звездичка.

Article 4: Definitions
(3) Accidental exposure
(63) Potential exposure
(99) Unintended exposure

Article 29: Authorisation procedure
Annex IV: license application
(e) Safety assessment
(i) identify AUEs

Article 63: Accidental and unintended exposures
(a) General
(b) Study of risk in RT
(c) Internal recording & analysis
(d) Information to patients, MDs
(e) Reporting to the CA
(f) Dissemination of information

● Recital

- » (30) Accidental and unintended medical exposures are a source of continuing concern. Whereas for medical devices post-market surveillance is required under Council Directive 93/42/EEC, ***it is the role of the competent authority in radiation protection to address the prevention of accidental and unintended medical exposure and the follow-up in case of their occurrence.*** In this respect, the role of quality assurance programmes, including a study of risks in radiotherapy, to avoid such incidents should be emphasised, and recording, reporting, analysis and corrective action should be required in such cases

● Article 5 Definitions

(3) "accidental exposure" means an exposure of individuals, other than emergency workers, as a result of an accident

(63) "potential exposure" means exposure that is not expected with certainty but may result from an event or sequence of events of a probabilistic nature, including equipment failures and operating errors

(99) "unintended exposure" means medical exposure that is significantly different from the medical exposure intended for a given purpose.

Article 63: Accidental and unintended exposures

- Member States shall ensure that:
 - (a) all reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure;
 - » Unchanged from 97/43/Euratom
 - » The rest of the article is new

Article 63:

- Member States shall ensure that:

(b) for radiotherapeutic practices the quality assurance programme includes a ***study of the risk*** of accidental or unintended exposures

Article 29:

(2) In the ***case of licensing*** ... Member States shall take into account the indicative list in Annex IX

...

(e) ***Safety assessment*** of the activities and the facility in order to:

- identify ways in which potential exposures or accidental and unintended medical exposures could occur;
- estimate, to the extent practicable, the probabilities and magnitude of potential exposures

Article 63: Accidental and unintended exposures

- Member States shall ensure that:
 - (c) for all medical exposures the undertaking implements an *appropriate system* for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, ***commensurate with the radiological risk posed by the practice***

Article 63: Accidental and unintended exposures

- Member States shall ensure that:
 - (d) arrangements are made to inform the referrer and the practitioner, and the patient, or their representative, about clinically significant unintended or accidental exposures and the results of the analysis

Article 63: Accidental and unintended exposures

- Member States shall ensure that:
 - (e) (i) the undertaking declares as soon as possible to the competent authority the occurrence of ***significant events as defined by the competent authority***
 - (ii) the results of the investigation and the corrective measures to avoid such events are reported to the competent authority within the time period specified by the Member State

Article 63: Accidental and unintended exposures

- Member States shall ensure that:
 - (f) mechanisms are in place for the timely dissemination of information, relevant to radiation protection in medical exposure, regarding lessons learned from significant events

Article 96

- Member States shall require the undertaking to:
 - (a) implement, as appropriate, a recording and analysis system of significant events involving or potentially involving accidental or unintended exposures;
 - (b) promptly notify the competent authority of the occurrence of any significant event ... as defined by the competent authority for medical exposure, including the results of the investigation and the corrective measures to avoid such events.



European Commission

5 Dec 2013
OJ 17 Jan 2014

ADOPTION
Euratom Directive
Council (of Ministers)

- Publication in OJ
- 23 official EU languages

DRAFTING
National Provisions
MS authorities

- Legislation
- Regulation
- Administrative action
- Education and training

By Nov 2017

COMMUNICATION to EC
National Drafts

EC RECOMMENDATIONS
on Transposition Drafts

FUTURE AMENDMENTS
of National Provisions

By Feb 2018

ADOPTION
National Provisions

COMMUNICATION to EC
National Provisions

INFINGEMENT
Procedures

CONFORMITY
Checks

Evaluation of national plans – BSS in medicine

- Survey: October 2016
- Workshop: 24-25 Jan 2017

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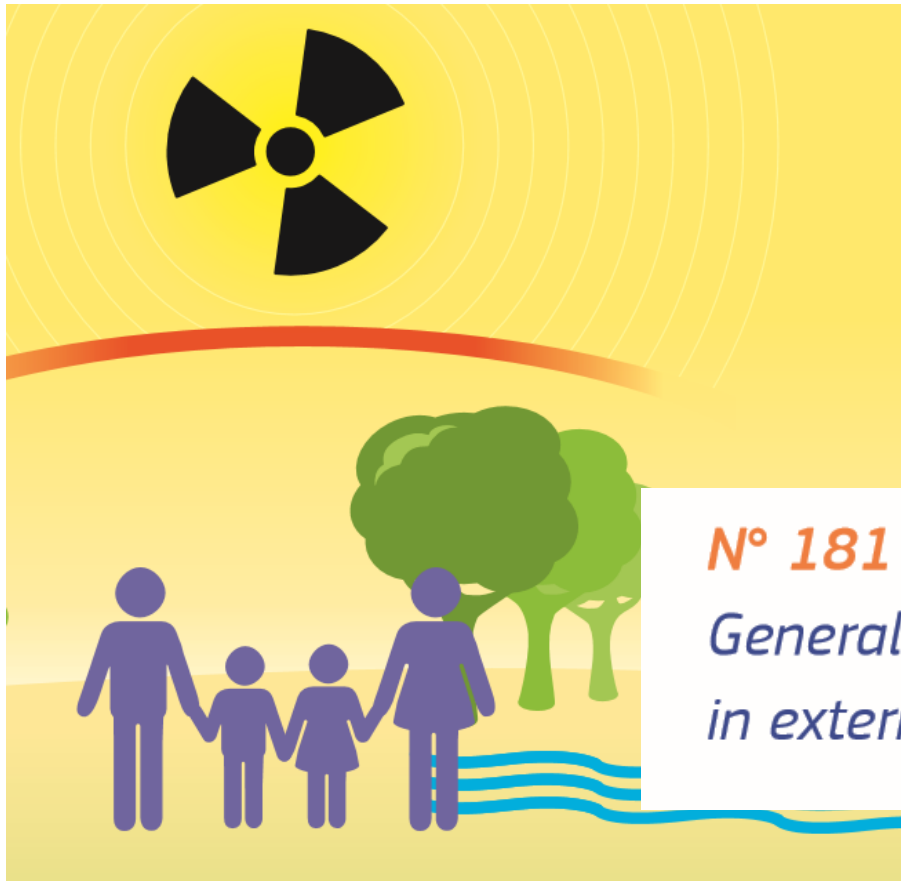
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N° 181

*General guidelines on risk management
in external beam radiotherapy*

Radiation Protection



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Radiation from medical use

The use of radiation in medicine has been an important tool in diagnosing and treating patients for over a century. For instance, radiation is used in x-ray medical imaging and cancer-treating radiotherapy.

Exposure to radiation can harm the health of both patients and medical staff however. With human exposure to ionising radiation in medicine exceeding that of any other man-made source, it is important to have safety standards in place.

<http://ec.europa.eu/energy/en/topics/nuclear-energy/radiation-protection/radiation-medical-use>