



Generic Justification of Medical Exposures in Council Directive 2013/59/Euratom

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(331) The principle of justification applies at three levels in the use of radiation in medicine.

- At the second level, a specified procedure with a specified objective is defined and justified (e.g., chest radiographs for patients showing relevant symptoms, or a group of individuals at risk to a condition that can be detected and treated). The aim of the second level of justification is to judge whether the radiological procedure will usually improve the diagnosis or treatment or will provide necessary information about the exposed individuals.

7.1.1. The justification of a defined radiological procedure (level 2)

(332) The justification of the radiological procedure is a matter for national and international professional bodies, in conjunction with national health and radiological protection authorities and the corresponding international organisations. The possibility of accidental or unintended exposures should also be considered. The decisions should be reviewed from time to time, as more information becomes available about the risks and effectiveness of the existing procedure and about new procedures.



Euratom Treaty

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

Euratom BSS

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

Council Directive 2013/59/Euratom

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

Generic Justification in 2013/59/Euratom



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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 текущо управление на съседстващата политика и имат кратък срок на действие.

Заглавията на всички останали актове се отпечатват с полупечат шрифт и се предшестват от звездичка.

European
Commission

Article 5: System of Radiation Protection (a) Justification

Article 19: Justification of practices

1. New types / classes
2. Existing types / classes
4. Medical exposures

Article 55: Justification of medical exposures

1. ... alternative techniques
2. Application
 - (a) new types of practice
 - (e) (bio)medical research
 - (f) screening

Article 77: Transparency

Article 78: Information on equipment

Energy

● Recital

- » (28) In the medical area, important technological and scientific developments have led to a notable increase in the exposure of patients. In this respect, this Directive should emphasise the need for justification of medical exposure ... It should be noted that according to the World Health Organisation ***the concept of health is understood to cover the physical, mental and social well-being of an individual and not merely the absence of disease or infirmity.***
- » (52) Pursuant to Article 106a(3) of the Euratom Treaty, the legislation adopted on the basis of the provisions of the Treaty on European Union and of the Treaty on the Functioning of the European Union should not derogate from the provisions of this Directive, and consequently the ***justification and optimisation principles should apply notably for medical devices*** and construction products ***covered by CE marking.***

- **Article 5 (a):** Decisions introducing a practice shall be justified in the sense that such decisions shall be taken with the intent to ensure that the individual or societal ***benefit*** resulting from the practice ***outweighs the health detriment*** that it may cause.
- **Article 55 (1):** Medical exposure shall show a ***sufficient net benefit***, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, ***taking into account*** the efficacy, benefits and risks of ***available alternative techniques*** having the same objective but involving no or less exposure to ionising radiation.
 - » **ICRP:** only “*positive net benefit*” required, alternative procedures considered only for individual justification (?)



- **Article 19 (1):** Member States shall ensure that new ***classes or types*** of practices resulting in exposure to ionising radiation are justified before being adopted
 - » Unchanged from 96/29/Euratom
 - » Commission proposal (**COM(2012) 242**) only uses "***types*** of practices", "classes or types" re-introduced in WPAQ upon MS proposal
 - » COM(2012) 242: MS shall list the approved types of practices in legislation or administrative acts

- **Article 19 (2):** Member States ***shall consider a review*** of existing classes or types of practices with regard to their justification whenever there is new and important evidence about their efficacy or potential consequences or new and important ***information about other techniques and technologies.***

- » New: information about other techniques and technologies can trigger a justification review
- » COM(2012) 242: Existing types of practices ***shall be reviewed*** as to their justification whenever ...

- **Article 19 (4):** Practices involving medical exposure shall be justified both as a class or type of practice, taking into account medical and, ***where relevant, associated occupational and public exposures***, and at the level of each individual medical exposure as specified in Article 55.
 - » New (rather a clarification?): taking into account the associated occupational and public exposure
 - » COM(2012) 242: similar requirement, not limited to generic justification

- **Article 55 (2):** Member States shall ensure that the principle [of justification] is applied and in particular that:
 - (a) new types of practices involving medical exposure are justified in advance before being generally adopted
 - » Unchanged from 97/43/Euratom (reason for difference in language with 19 (1) – “class or type”, “generally adopted”)
 - (b) ... (individual justification)
 - (c) if a type of practice involving medical exposure is not justified in general, a specific individual exposure of this type can be justified, where appropriate, in special circumstances, to be evaluated on a case-by-case basis and documented
 - » Change from 97/43/Euratom: justification to be documented

- **Article 77. Transparency:** Member States shall ensure that ***information in relation to the justification of classes or types of practices***, the regulation of radiation sources and of radiation protection ***is made available to undertakings, workers, members of the public, as well as patients and other individuals subject to medical exposure***. This obligation includes ensuring that the competent authority provides information within its fields of competence. Information shall be made available in accordance with national legislation and international obligations, provided that this does not jeopardise other interests such as, inter alia, security, recognised in national legislation or international obligations
 - » New requirement. Transparency of justification decisions could be a game changer (personal opinion)
 - » COM(2012) 242: MS shall list the approved types of practices in legislation or administrative acts



- **Article 78 (1):** Member States shall ensure that any undertaking acquiring equipment containing radioactive sources or a radiation generator is provided with adequate information about its potential radiological hazards and its proper use, testing and maintenance, and with a demonstration that the design permits to restrict exposures to a level which is as low as reasonably achievable
 - » New requirement. Result of WPAQ negotiations.
- **Article 78 (2):** Member States shall ensure that any undertaking acquiring medical radiological equipment is provided with adequate information on the risk assessment for patients, and on the available elements of the clinical evaluation
 - » New requirement. Result of WPAQ negotiations.
 - » COM letter to HERCA (May 2016): link to EU medical devices legislation

BSS Transposition



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



By Feb 2018

ADOPTION
National Provisions

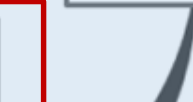


COMMUNICATION to EC
National Provisions

FUTURE AMENDMENTS
of National Provisions

INFINGEMENT
Procedures

CONFORMITY
Checks



Evaluation of national plans – BSS in medicine

- Survey: October 2016
- Workshop: 25-26 Jan 2017

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ПОПРАВКИ

★ Допълнение

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Energy

3 December 2015

**Council conclusions on the Justification of
medical imaging involving exposure to
ionising radiation**

1. STRESSES that, ... Council Directive 2013/59/Euratom contains important changes requiring revision of existing national arrangements by 6 February 2018,
2. INVITES the Commission, when reviewing the implementation of Council Directive 2013/59/Euratom, to pay attention to the legal provisions related to the proper justification of medical radiological imaging,

...

8. SUGGESTS that Member States cooperate in the generic justification of new classes or types of practices involving medical radiological exposure

...

Other elements specific to individual justification, e.g. roles of healthcare professionals, referral guidelines, clinical audit, training, etc. – all addressed to Member States



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[TOPICS](#)

[STATISTICS](#)

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[EVENTS](#)

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[STUDIES](#)

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>