

# The revised European Basic Safety Standards Directive and the way forward to strengthening radiation protection in Europe

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## Introduction

The 28 European Union Member States' national systems for radiation protection – although differing in their institutional, administrative and legal structure – are built around the requirements of Council Directive 96/29/Euratom [1], commonly referred to as the European Basic Safety Standards (EU BSS). The recently published Council Directive 2013/59/Euratom [2] – known as the revised EU BSS – contains many important changes in comparison with the 1996 EU BSS and other Euratom legislation, e.g. the Medical Exposure Directive [3].

## National Transposition of EU BSS

The 2013/59/Euratom Directive gives a deadline of February 6, 2018 by which the EU Member States must bring into force the laws, regulations and administrative provisions necessary to comply with its requirements. European legislation defines a process of communication between the Member States and the European Commission, allowing the Commission to effectively exercise its role as 'guardian of the treaties' in relation to the health and safety legislation adopted under the Euratom treaty (Fig. 1):

- » Article 33 of the Euratom Treaty stipulates that the EU Member States shall communicate to the Commission draft transposing measures after they have been internally agreed but before being adopted.
- » The Commission has the right – within three months of an Article 33 submission – to issue recommendations to the submitted draft legal and administrative provisions.
- » According to article 106, paragraph 3, of the 2013/59/Euratom Directive, Member States have to communicate to the Commission the text of the provisions of national law which they adopt in the field covered by the Directive.
- » The Commission performs conformity checks of the adopted national provisions and, in the case of identifying non-compliance with the Euratom provisions, can undertake action against the Member States, including launching an infringement procedure [4].
- » Any future (draft) amendments of national laws and regulations adopted pursuant to the Euratom Treaty and its secondary law are subject to article 33 of Euratom, article 106 of EU BSS and the EU infringement provisions.

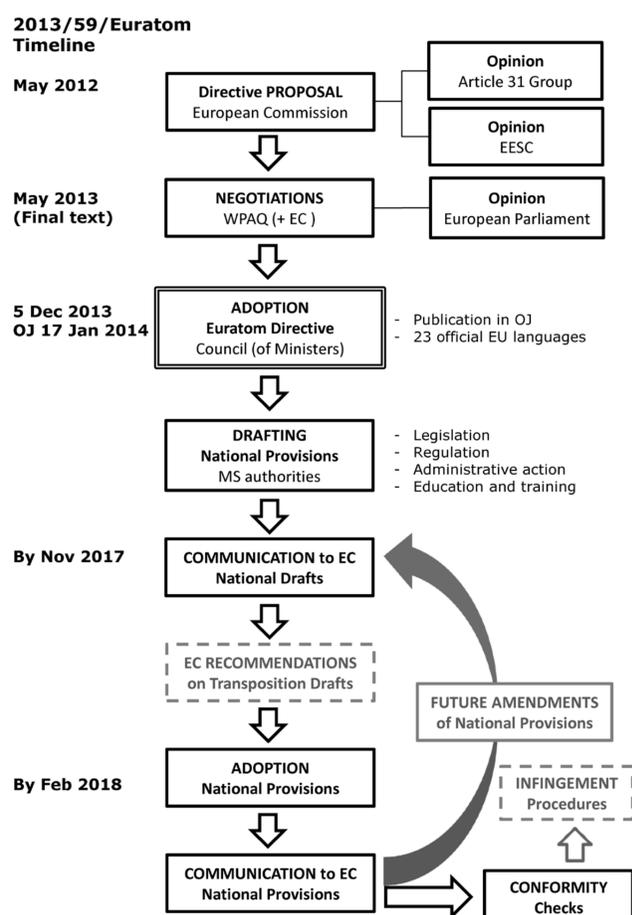


Fig. 1: Euratom timeline

## Commission Action

The above legal provisions define a challenging schedule within which 28 national legal proposals have to be elaborated, submitted to the Commission, reviewed and some of them, possibly, revised. The Commission foresees a series of actions to facilitate this process and to ensure its successful completion within the legally defined deadlines. This will include early establishment of contacts with the responsible competent authorities, collection and continuous update of information about the national implementation plans and activities and exchange of experiences between the EU countries.

In practical terms, the above tasks have been organised into several distinctive projects for evaluation of national transposition and implementation plans in different areas. The work will start with a general survey in late-2014 and a workshop on the national transposition plans in 2015. The general workshop will, among others, identify (up to four) topical areas where further surveys and meetings should be held. The Commission has already identified two topical areas – emergency preparedness and response, and radiation protection in medicine – where similar action should take place.

## Medical Imaging and the European BSS

The 1996 European BSS and the 1997 Medical Exposure Directive provided a solid legal basis for the radiation protection of patients and medical staff. The new European BSS builds upon the existing requirements and introduces important changes which will affect medical imaging in the coming years [5].

Besides ensuring that the Euratom legal requirements are fully and correctly transposed into national law, the Commission provides support for their implementation in practice. Most of this work results in factual reports and guidelines, which are published as radiation protection reports on the Commission website [6]. Most recently, the Commission launched the PiDRL project on diagnostic reference levels for paediatric imaging [7] implemented by a consortium led by the European Society of Radiology.



Fig. 2: Publications on radiation protection by the European Commission

## References

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3. 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, and repealing Directive 84/466/EURATOM. Official Journal L-180 of 09.07.1997, 22.
4. [http://ec.europa.eu/eu\\_law/infringements/infringements\\_en.htm](http://ec.europa.eu/eu_law/infringements/infringements_en.htm)
5. G. Simeonov, European activities in radiation protection in medicine, Proceedings of the International Conference on Radiation Protection in Medicine: Facing Increasing Challenges, 30 May – 2 June 2014, Varna, Bulgaria (in press)
6. [http://ec.europa.eu/energy/nuclear/radiation\\_protection/publications\\_en.htm](http://ec.europa.eu/energy/nuclear/radiation_protection/publications_en.htm)
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