Abstract

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Patient Safety in Medical Imaging: View from the European Commission

The European Union (EU) has a long and successful history of dealing with radiation protection of patients. The EU has adopted specific legislation under the Euratom Treaty and has undertaken different actions to support its implementation. Other EU policy areas, such as safety of medical devices, patient electronic records, etc. are relevant to this topic but not further discussed in this article.

The 28 EU Member States regulate patient safety in medical imaging in accordance with specific legislation issued under the EURATOM Treaty. "Medical exposure" Directives were first issued in 1984 and subsequently updated in 1997 and 2013. The most recent update, Council Directive 2013/59/Euratom, modernises and consolidates the European radiation protection legislation. The new Directive repeals previous European legislation, including Directives 96/29/Euratom "Basic Safety Standards" and the 97/43/Euratom "Medical Exposure".

The most important legal changes introduced by Council Directive 2013/59/Euratom include:

(i) strengthening the justification principle and expanding it to asymptomatic individuals,

(ii) more attention to interventional radiology,

(iii) new requirements for dose recording and reporting,

(iv) better definition of roles and responsibilities,

(v) new set of requirements for preventing and following up on accidents, etc.

By February 2018, the 28 EU Member States have to bring into force laws, regulations and administrative provisions to ensure compliance with the Council Directive 2013/59/Euratom. Starting in 2014, the European Commission will facilitate the exchange between Member States to help timely and co-ordinated national action. At a later stage, i.e. in 2017-2018, the Commission will exercise its legal powers and verify the national legal provisions and, where necessary, issue recommendations or open infringement cases.

The Commission provides support for practical implementation of the legal requirements through financing European studies and guidance. Further action to support practical implementation will be defined soon. This will be done together with European associations and networks of regulators, professional and scientific stakeholders.