The European Union (EU) has more than fifty years of experience in enacting laws on health protection of workers and the general public against the dangers of ionising radiation. This legislation follows from the Euratom treaty, which entrusts the European Commission (EC, ‘the Commission’) to propose basic safety standards (EU BSS) after receiving the opinion of the group of scientific experts referred to in Article 31 of the treaty. After consulting the European Parliament, the Council of Ministers adopted the Euratom BSS Directive (Fig.1), which has to be transposed into the national law of the 28 EU Member States. The Commission has the power to review transposing measures, issue recommendations and take infringement action against Member States.

The revised EU BSS brings several important changes to radiation safety in medical imaging. The Article 31 group’s Working Party on Medical Exposures (WPMED, see the box) was deeply involved in the EU BSS revision, and many of the proposed changes were presented at European and international meetings. The most important amendments - as agreed by the national governments – include:

- The occupational dose limit for the lens of the eye has been reduced from 150 to 20 mSv. This is particularly relevant to interventional radiologists and cardiologists for whom eye protection and dose monitoring should become a standard practice. Medicolegal procedures – now called ‘non-medical imaging exposures’ - have been taken out of the medical chapter and should be treated according to specific new requirements. This includes more rigorous justification and development of national guidelines, specific protocols and DRLs.
- Justification has been reinforced. The term ‘prescriber’ has been replaced by ‘referrer’ in order to emphasise the right of the radiological practitioner to select the appropriate procedure. Patients have to be informed about the benefits and risks of the examination, and radiation dose should be part of the examination report. New requirements have been introduced for exposure of asymptomatic individuals.
- Optimisation has been strengthened. DRLs have to be regularly reviewed and will also cover interventional procedures. Written protocols have to be established for ‘relevant categories of patients’, e.g. children. The involvement of a medical physicist is required in interventional procedures and CT and her/his availability for consultation and advice is required for all other imaging.
- Equipment installed after the EU BSS transposition deadline should meet several requirements for display, reporting and recording of radiation doses.
- Accidental and unintended exposure is subject to recording, analysis and, in some cases, reporting to national authorities. Information about clinically significant accidents should be provided to the referrer and the patient.

The revised EU BSS has to be transposed into the national law and practice of 28 EU Member States not later than four years following its publication. This is a major task requiring leadership from national authorities and involvement of scientific bodies, professional societies, manufacturers and other stakeholders.

European cooperation will facilitate the efficient and transparent implementation of regulatory changes and should bring similar benefit to patients all over Europe. The European Commission has positive experience in taking action to support the implementation of EU legislation (Fig.3), and new initiatives on radiation safety of imaging will soon follow. The European national authorities for radiation protection established the HERCA network in 2007 (http://www.herca.org) and protection of patients is high on their agenda. The key medical professionals have their European societies and federations, which are cooperating on radiation protection issues (http://www.eman-network.eu). Equipment manufacturers are engaged in European-level dialogue with radiation protection regulators (http://www.cocri.org/site/index.php?id=107).

The revision of the EU BSS and its transposition in the following four years should be taken as an opportunity to enhance cooperation and better coordinate action among the different stakeholders. Cooperation on all levels – locally, nationally, regionally and internationally – is the key to success in maintaining, and were necessary, improving radiation protection of patients and health professionals without putting undue burden on regulators, clinicians and industry.

**Summary of the activity of the Working Party on Medical Exposures**

The WP MED is a standing working party of the Group of Experts established under Article 31 (GOE Art31) of the Euratom Treaty. Experts from 12 Member States are involved, and observers from the IAEA and the WHO are usually present. Some of the WP MED experts are also members of ISoP and HERCA allowing for close relations and cooperation with these organisations. The WP MED prepares summaries and proposals for the plenary meetings of the GOE Art31 and proposes topics for action to facilitate the application of the European Directives in medicine. The proposed action may include the development of guidelines or technical documents, and the WP MED helps in the preparation of technical specifications and the follow-up of the work, supporting in the last steps the approval of the produced documents to the EC services and to the plenary of the GOE Art31. The most recent projects dealing with medical imaging have been on ‘Guidelines on Medical Physics Expert, MEDRAPET (Implementation of the Medical Exposures Directive’s Requirements on Radiation Protection Training); Referral Criteria for medical imaging in the European Union (study on the implementation of Council Directive 97/43/ Euratom requirements)’ and ‘Dose Data Med 2 (Population doses from medical exposure). A new project on Diagnostic Reference Levels for Paediatrics has just started.

**Fig. 1:** European Council defines general (nuclear energy) policy & priorities

European Commission proposes

Legislation (regulation / directive / decision) after opinion of:

- European Parliament
- Economic and Social Committee
- Article 31 Group of experts

Council (of Ministers) adopt

Court of Justice controls legality

Court of Auditors controls budget

**Fig. 2:**

**Keeping imaging safe around the world**

**EC - European Commission**

**European Union law and radiation safety in medical imaging**

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The EU legal framework for radiation protection has expanded in the past decades and currently consists of several legal instruments covering different issues. EU legislation on radiation protection of patients was first issued in the 1980s, and revised in the 1990s. The current Medical Exposure Directive (MED) is an elaborate peace of EU law dealing, among others, with the justification and optimisation of radiological procedures, distribution of responsibilities, training of medical staff, procedural aspects and equipment use.

The EU BSS has recently been revised with two main objectives: a) to consolidate the existing legal basis for the protection of workers, patients and general public, and b) to update the legislation in line with the recent scientific, technical and societal developments. The revision and negotiation process took more than five years, and the revised EU BSS was adopted in December 2013 (Fig.2). The revised EU BSS will replace and replace five current Directives, including MED, as of February 2018.

The EU BSS revision, and many of the proposed changes were presented at European and international meetings. The most important amendments - as agreed by the national governments – include:

- The occupational dose limit for the lens of the eye has been reduced from 150 to 20 mSv. This is particularly relevant to interventional radiologists and cardiologists for whom eye protection and dose monitoring should become a standard practice. Medicolegal procedures – now called ‘non-medical imaging exposures’ - have been taken out of the medical chapter and should be treated according to specific new requirements. This includes more rigorous justification and development of national guidelines, specific protocols and DRLs.
- Justification has been reinforced. The term ‘prescriber’ has been replaced by ‘referrer’ in order to emphasise the right of the radiological practitioner to select the appropriate procedure. Patients have to be informed about the benefits and risks of the examination, and radiation dose should be part of the examination report. New requirements have been introduced for exposure of asymptomatic individuals.
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**Fig. 3:** Recent EC projects in the area of radiological safety of medical imaging. The results of this and other work are published as part of the EC Radiation Protection series (http://ec.europa.eu/energy/nuclear/radiation_protection/medical/publications_en.htm).