

2013/59/EURATOM Directive: from the “Magna Charta” to the clinical practice

Euratom Treaty provides the establishment of uniform safety standards to protect the health of workers and of the general public, in particular Article 30 defines "basic standards" for the protection of the health of workers and the general public against the dangers arising from ionising radiations, in order to harmonize the protection in the Member States.

Since the first time in 1959, the Community revised the basic standards several times to consider the new recommendations of the International Commission on Radiation Protection (ICRP), in the light of new scientific evidence and operational experience.

The last Directive on this topic, 2013/59/EURATOM (ED59-2013) was issued by the European Council in December 2013, repealing previous Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom. It should have been transposed into national legislation by Member States by February 6th, 2018. ED59-2013 considers the recommendations of the ICRP Publication 103 and covers all exposure situations and all categories of exposure, namely occupational, public, and medical.

Three main innovations concerned with medical exposures have been introduced by ED59-2013: the definition of the responsibility and of the optimization process (Article 57), the availability of the information relating to patient exposure (Article 58) and the training and recognition requirements (Article 59) for the individuals involved in the optimization process.

The referrer (*a medical doctor, dentist or other health professional who is entitled to refer individuals for medical radiological procedures to a practitioner*) is responsible of the justification of the medical exposure in conjunction with the practitioner (*a medical doctor, dentist or other health professional who is entitled to take clinical responsibility for an individual medical exposure*) who is responsible for the medical exposure of the patient. The optimization of the medical exposure is a joint responsibility of the practitioner, the medical physics expert and those entitled to carry out the practical aspects of medical radiological procedures.

These three points appear to be particularly relevant when considering that the concept of the multidisciplinary work in radiological procedures has been growing steadily in recent years and, consequently, the attention to the patient's exposure. Radiological procedures are currently performed in the fields of cardiology, gastroenterology, urology, nephrology, orthopaedics-traumatology and neuro and vascular surgery. In this context, the responsibility of the medical exposures involves not only the professionals who traditionally have been working with ionizing radiations (radiologists, nuclear medicine physicians, radiation oncologists), but also those who are rather 'new' in this field. The adequate training claimed by Article 59 aims at guaranteeing that the professionals referred to in the justification and optimization processes are currently updated and informed about patient's radiation protection.

Moreover, particular attention is required for all the radiological procedures performed on pediatric patients, especially in interventional radiology, for which the intrinsic high doses are associated to a three-fold increased risk for stochastic effects due to the age of these patients.

In this context, the harmonization of the protection against the dangers arising from ionising radiations is of utmost importance across European Countries.

Thus, it seemed of interest to acquire information on the transposition of the ED59-2013 into the national legislation of the Member States to provide a general overview of the situation across Europe: thanks to the collaboration of Medical Physics Experts from different European countries, data on the date of transposition, the reference of the legislation and website of publication were collected.

Each Member State transposed the ED59-2013 in a unique or in several steps. The Table below lists how and when the transposition took place. The national transposition is the essential step, to translate the “theory” into clinical practice, according to the local habits but always respecting the “major statements”.