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RESEARCH ARTICLE

# Safety in radiation oncology: transposition of directive 2013/59/EURATOM in the Spanish Radiation Oncology Departments—recommendations for its adequate and effective application

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## Abstract

**Introduction** The Official Journal of the European Union published on January 17, 2014 the Council Directive 2013/59/EURATOM of December 5, 2013, which establishes basic safety standards for the protection against the dangers derived from the exposure to ionizing radiation, and should have been transposed to the regulations of the member countries of the European Union.

**Methods** We carried out and exhaustive review of the Directive, to highlight its aspects referred to radiotherapy, in order to issue recommendations for its adequate and effective application in Spain.

**Recommendations for its transposition** A series of recommendations are issued, from highest to lowest organizational level: Legislative, Scientific Societies, Healthcare Centers, Radiation Oncology Departments, Radiation Oncologists and Patients.

**Conclusions** The implementation of what the transposition of the Directive to our legal order implies, besides the implication of the professionals, Centers and Administration, a need and a consumption of resources. If not enough are allocated, there is a risk that the innovation and improvement that the transposition would imply in order to raise the level of patient safety and the quality of Radiation Oncology in Spain will remain a paper tiger and, as the Romans said, "Non progredi est regredi", that is, when it does not go forward, it goes backwards.

**Keywords** Patient safety · Transposition Directive 2013/59/EURATOM · Recommendations for its application in Spain · Spanish Radiation Oncology Departments

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## Introduction

The Official Journal of the European Union published on January 17, 2014 the Council Directive 2013/59/EURATOM of December 5, 2013 [1], which establishes basic safety standards for the protection against the dangers derived from the exposure to ionizing radiation, and derogates Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

It establishes uniform basic safety standards against the risks derived from ionizing radiation, applicable to the protection of the health of persons subject to occupational, medical, and general population exposure, and should have been transposed to the regulations of the member countries of the European Union before February 6, 2018.

It regulates the exposure to ionizing radiation in the medical field, to improve the safety of patients, health

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professionals and equipment, such as occupational and population exposures.

In addition, it replaces the previous directives that regulated the safety standards against exposures to ionizing radiation, including those occupational, that gave rise, among others, to the Regulation on Sanitary Protection against Ionizing Radiations [2] and to the Instruction IS-33 of the Nuclear Safety Council [3] on radiological criteria for protection against exposure to natural radiation.

Regarding patients, no dose limits are established for medical exposures, but it does specify their right to information on the risks and benefits of both diagnostic and therapeutic procedures involving the use of ionizing radiation and establishes that the health professionals are the ones who have the responsibility to inform the patient about them.

The European Commission funded the ACCIRAD project to develop a guide on risk management in external radiotherapy. The result was the publication RP 181 [4], which, in its chapter 5, contains recommendations on the implementation of the Directive for the healthcare centers and for the member states.

## Materials and methods

We carried out a detailed and exhaustive review of the Directive, to highlight aspects of it referred to radiotherapy.

It begins with a series of considerations. The ***number 29*** specifies that:

"A *high level of competence and a clear definition of responsibilities and tasks* among *all professionals* involved in medical exposure are fundamental to ensure adequate protection of patients undergoing medical radiodiagnostic and radiotherapeutic procedures.

This applies to *medical doctors*, dentists and other health professionals entitled to take clinical responsibility for individual medical exposures, to *medical physicists and to other professionals* carrying out practical aspects of medical radiological procedures, such as radiographers and *technicians* in radiodiagnostic medicine, nuclear medicine, and *radiotherapy*".

Besides, the ***number 30*** specifies that:

"Accidental and unintended medical exposures are a source of continuing concern. Although for medical devices post-market surveillance is required under Council Directive 93/42/EEC [5], it is the role of the competent authority in radiation protection to address the prevention of accidental and unintended medical exposure and the follow-up in case of their occurrence.

In this respect, *the role of quality assurance programs, including a study of risks in radiotherapy, to avoid such incidents should be emphasized*, *and recording, reporting, analysis and corrective action should be required in such cases*".

***Article 56, paragraph 1***, on **Optimization** says:

"Member States shall ensure that all doses due to medical exposure for radiodiagnostic, interventional radiology, planning, guiding and verification purposes are kept as low as reasonably achievable consistent with obtaining the required medical information, taking into account economic and societal factors.

*For all medical exposure of patients for radiotherapeutic purposes, exposures of target volumes shall be individually planned and their delivery appropriately verified taking into account that doses to non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure*".

***Article 63***, on **Accidental and Unintentional Exposures** says:

"*Member States shall ensure* that:

(a) All reasonable measures are taken to minimize the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure;
(b) *For radiotherapeutic practices the quality assurance program includes a study of the risk of accidental or unintended exposures*;
(c) For all medical exposures *the undertaking implements an appropriate system for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice*;
(d) *Arrangements are made to inform the referrer and the practitioner, and the patient, or their representative, about clinically significant unintended or accidental exposures and the results of the analysis*;
(e) (i) the undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority;(ii) the results of the investigation and the corrective measures to avoid such events are reported to the competent authority within the time period specified by the Member State;
(f) Mechanisms are in place for the timely dissemination of information, relevant to radiation protection in medical exposure, regarding lessons learned from significant events".

## Discussion

Despite the fact that the article whose transposition implies more changes in Centers with Radiation Oncology Departments, both in the radiotherapy process, in their relations with the Competent Authority, and in the

obligations for the Competent Authority itself, is the 63, we cannot ignore the previous considerations number 29 and 30, which specify the need for a high level of competence and a clear definition of responsibilities and functions among all professionals involved in the radiotherapy process.

We must emphasize the importance of radiotherapy quality assurance programs include risk analysis, requiring registration, notification, analysis, and corrective measures of incidents.

We also have to consider that Directive 2013/59/EURATOM has already had a practical impact in our country, specifically in the *Patient Safety Strategy 2015–2020 of the National Health System* [6] published by the Ministry of Health, Social Services and Equality, whose *General Objective 2.8* to promote the safe use of ionizing radiation in clinical procedures, has as its specific objective to promote the detection and prevention of adverse effects by ionizing radiation, especially in radiotherapy and interventional radiological procedures. The document recommends *ensure that Quality Assurance Programs including risk analysis and management of reported incidents, at least at the departmental level, are developed in all departments working with ionizing radiations, especially in those of Radiation Oncology*.

We find, therefore, once again the fundamental importance that is given to the risk analysis, its management (notification, analysis, learning, etc.) and their inclusion in the Quality Assurance Programs in the departments of Radiation Oncology.

## Recommendations for an effective transposition in Spain

It is evident that, although in some Centers and Departments the management of incidents is already implemented, it is not a generalized practice, nor is it carried out uniformly in our country.

Therefore, from our point of view, it is essential to carry out a series of initiatives at various levels, including the legislative and the Competent Authority to which repeatedly refer both the current royal decrees: R.D. 1566/1998, of July 17, establishing the quality criteria in radiotherapy [7] and R.D. 815/2001, of July 13, on the justification for the use of ionizing radiation, for the radiation protection of people during medical exposures [8]. These are our recommendations from the highest to the lowest organizational levels (Table 1):

### At the legislative level

(a) Update/Modification of the current Royal Decrees, including the need to perform proactive analysis and risk management of accidental or unintentional exposures. It would be desirable, in addition, the inclusion of other modifications in accordance with national and international recommendations on patient safety, especially not just listing the various professional categories involved in the radiotherapy procedure, but clearly defining the competencies and responsibilities of each of them, and also establishing minimum ratios for each

**Table 1** Recommendations by organizational level

| | |
|---|---|
| Legislative | Update/modification of the current Royal Decrees<br>Define deadline for all Radiation Oncology departments to perform the risk analysis<br>Define what type of event should be communicated<br>Define to whom the event should be communicated (competent authority)<br>Define the maximum communication time of one event<br>Create an event communication system secure and confidential<br>Modify training programs (MIR, FIR) including Patient Safety & QualityTo audit the RO departments centrally to guarantee unified criteria and equity |
| Scientific societies | Promote training update in Patient Safety & Quality among its members |
| Healthcare centers | To ensure implication of center management and head of department in promoting safety culture<br>Create a local incident learning system compatible with that of the competent authority<br>Define how the incident communication will be made and whose responsibility is to do so |
| Radiation oncology departments | Update and modify their Quality assurance programs including proactive risk analysis<br>Create its own map of processes and risks, prior to carrying the risk analysis<br>Create an intradepartmental program of registration and analysis of events<br>Consider the creation of a Patient Safety Commission to perform and update the proactive risk analysis, investigate incidents and design and implement preventive/corrective measures<br>Define which staff will be part of its Commission and evaluate its repercussions regarding clinical tasks<br>As a consequence with the increase in tasks that will occur, a real adaptation of the human recourses needed must be carried out |
| Radiation oncologists and patients | The radiation oncologist responsible for the patient and the patient himself must be truly informed of the clinical impact of each event that implies accidental or unintentional exposure |

one, for the proper functioning of the departments. It is well known that workload is a determining factor in the burnout of the professionals [9] and, consequently, in the deterioration of safety in medicine [10].

(b) Define the deadline for all the Radiation Oncology departments to have carried out an initial risk analysis.

(c) Define what type of event should be communicated. There are many ways to define what a "significant event" is, according to the intention and available resources for the notification and learning system. Thus, if what is intended is co-responsibility in taking measures to prevent serious events from recurring, the level of notification can be one, while if it is intended is to learn from any event (regardless of its consequences), the level can be other. On the other hand, if resources are scarce, the threshold for notification should be limited, while if resources are sufficient, lessons from events can be managed, analyzed and disseminated with a lower threshold for reporting. In many notification systems, the obligation to notify is established from a dose deviation between the planned treatment and the treatment actually given. However, the definition of a significant event exclusively in terms of dose deviation has limitations:

- There is no direct correlation between a dose deviation and the consequences, since these depend on many other factors, such as the patient's clinical situation, the location, the dose level, and other medical treatments such as chemotherapy, surgery, etc.
- If there is no dose deviation, but with a significant geographical error in the location where it is delivered, it can lead to serious consequences.
- It would be difficult to determine how and where to define the dose deviation. Is it defined as a deviation of the maximum, average or minimum dose? Is it defined in relation to the target volume, to the organs at risk, or both?
- An infradosification, not compensated may have very serious consequences for the patient due to lack of tumor control. Considering that the effects and thresholds for overdosing and underdosing can be very different, the deviation considered significant would be different towards a higher dose or a lower dose. At this respect, scientific societies should establish recommendations for the management of non-scheduled treatment interruptions.
- The level of dose deviation is defined for the complete treatment or for a fraction? If it is defined for a fraction, should it be communicated if the deviation is compensable?

One option is the use of the severity scale CTCAE [11] (Common Terminology Criteria for Adverse Events) and that those clinical consequences of grade 2 or higher are considered significant, as long as they are the result of an accident or non-intentional exposure, i.e., that they are not a consequence of normal treatment. The problem is that there are effects that can take a long time to appear or that can be masked by the disease progress. Therefore, it seems advisable to additionally establish notification levels for deviations (in percentage of dose and/or displacement in mm) between the treatment plan and the dose delivered in reality.

(d) Define to whom the event should be communicated. We consider that the term "Competent Health Authority" must be specified, since, leaving the term as it is in the current legislation, we do not really know who will be responsible for the management of significant events, especially the dissemination of lessons learned from its analysis, that should be transmitted to all Spanish professionals.

(e) Define the maximum communication time of an event (we consider that the term "as soon as possible" must be specified).

(f) Establishment of a confidential and secure event communication system for who notifies, and to ensure the adequate dissemination of the lessons learned.

(g) Regarding training, include contents referring to Patient Safety and Quality in the training programs (MIR and RFIR) of professionals involved in the use of ionizing radiation, especially on risk analysis.

(h) Considering that, without an audit and accreditation system, it is impossible to know if the regulations and provisions are being adequately applied, we propose that audits be carried out in an effective manner. This possibility is already included in the Royal Decrees currently in force [7, 8]. Our proposal, in order to guarantee the equality and uniformity of criteria in their realization for all Spanish autonomous autonomies, is that they should be carried out by the Ministry of Health with the cooperation of the Professional Societies involved in the radiotherapy process.

## At the scientific societies level

The scientific societies of the professionals involved in the radiotherapy process are responsible for promoting the training update of their members by holding conferences and courses on Patient Safety and Quality, both specific to each scientific society and multidisciplinary.

In this regard, the Spanish Society of Radiation Oncology has been conducting since 2017 symposiums on these topics.

### At the Healthcare centers level

(a) The participation, leadership and support of the Center management and the head of the department in planning measures to improve the safety of patients in radiotherapy and promote a culture of safety constitute one of their priority responsibilities, and should be ensured.
(b) Each healthcare center with a radiation oncology department must have a local incident learning system. This system must be compatible with that of the Competent Authority, which implies that the latter should be established first. If possible, the structure should also be compatible with international incident learning systems, mainly SAFRON [12], which is the anonymous and voluntary radiotherapy event registration and learning system enabled by the IAEA. The objective of this registry, following the spirit of the Directive, is to learn from mistakes and to put the means so that they do not happen again, without punitive intentions.

In this regard, 97.4% of the Spanish Heads of Department agree with the implementation of a national system, similar to other countries in our environment [13].
(c) Define how the incident communication will be made to the Competent Authority and whose responsibility it is to do so.

### At the Radiation Oncology Departments level

(a) All the Spanish departments must update their Quality Assurance Programs, establishing the necessary modifications and resources so that the proactive risk analysis can be carried out, as well as the analysis of modified events, proposal of corrective measures and dissemination of the lessons learned.
(b) Before carrying out the risk analysis, each department should create its own map of processes and risks. We believe that this aspect should also be included in each Quality Assurance and Control Program in Radiotherapy.
(c) Develop of an intradepartmental program of safe registration and analysis of confidential events.
(d) Management of events communication, design of preventive measures, evaluation of their implementation and results.
(e) Consider the creation of a Patient Safety Commission that performs and updates the proactive risk analysis, investigates the incidents and designs and implements preventive measures.
(f) Define which professionals of the department will be part of the aforementioned commission and evaluate its repercussions (the professionals who perform risk management will do so within their working hours and, obviously, while doing so they will not perform clinical tasks that should be made by other professionals).
(g) Real adaptation of the human resources in the departments must be carried out, consistently with the increase in tasks that will occur.

### At the Radiation Oncologist and patients level

The radiation oncologist responsible for the patient and the patient himself must be informed of the clinical impact of each event that implies accidental or unintentional exposure.

The obligation to offer the patient correct and truthful information of the clinical significance of an event is not clearly established in our legislation, although it could be considered as set forth in Law 41/2002, of November 14, regulator of patient's autonomy and of rights and obligations about information and clinical documentation [14].

In Article 2.6, it establishes that "Every professional involved in the care activity is obliged not only to the correct provision of their techniques, but also to compliance with the duties of information and clinical documentation, and respect for decisions taken freely and voluntarily by the patient". In Article 4.1 states that "Patients have the right to know, on the occasion of any action regarding his health, all available information about it, saving the assumptions excepted by the Law.

In addition, every person has the right to have his or her will to not be informed. The information, which as a general rule will be provided orally and recorded in the clinical record, includes, at least, the purpose and nature of each intervention, its risks and consequences. It adds in point 4.2 that "Clinical information, as a part of all the care actions, it will be true…".

Given that there are patients who may not know how to interpret information about an event without clinical consequences; the intention is that this information is mandatory only when the event entails significant clinical effects.

## Conclusions

We have detailed what are, in our opinion, the implications of the Directive 2013/59/EURATOM transposition, with the corresponding recommendations for its correct and effective implementation in Spain. However, we cannot go beyond fundamental evidence. All the implementation of what the transposition of the Directive to our legal order implies, besides the implication of the professionals, centers and administration, a need and a consumption of resources. Security and Quality cannot be obtained at zero cost.

If sufficient resources are not allocated, there is a risk that, all or a large part of the innovation and improvement that the transposition would imply in order to raise the level

of patient safety and the quality of Radiotherapy in our country, will remain a paper tiger and that, as the Romans said, "Non progredi est regredi", that is, when it does not go forward, it goes backwards.

## Compliance with ethical standards

**Conflict of interest** The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

**Ethical approval** This paper does not involve human pacticipants and/or animals.

**Informed consent** Informed consent in not necessary.

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