THE TRANSPOSITION OF COUNCIL DIRECTIVE 2013/59 INTO ITALIAN LAW

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ABSTRACT

By the European Directive no. 2013/59 Euratom, the European Union has aimed to provide Member States with updated instructions in order to prevent damages possibly arising from radiations in health care, work and social settings. Among the most relevant amendments, the authors have found: a) the introductions of new defining criteria; b) the updating of some dosage related standards, such as the one about the threshold absorbed by the crystalline lens; c) a new set of rules for the measurement of emissions from devices and data management; d) a greater degree of clarity in ascribing liability to anyone involved in utilizing ionizing radiation-emitting devices. The paper outlines the Italian legislative state of affairs by delving into all relevant aspects of the current legislation, what has been put in place in the process of enacting the European Directive and the measures that could be suitable for future improvement.

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Background

In order to better comprehend the current situation concerning the adoption by Italy of the European Directive no. 2013/59, we proceeded by introducing some elements about ionizing radiation, namely what they are and their physical and biological effects, then we analyzed the legal framework in force in Italy now, with a close focus on the European context. Through this analysis, the concept of ionizing radiations was clarified, especially in health care settings, along with their effects on health; medico-legal aspects derived from exposure were considered as well. In addition, we examined the European Directive no. 2013/59 and tried to expound upon the innovation brought by the document, compared to the previous legislative situation in Italy, and the reasons why it has not been transposed yet.

As it is well-known, ionizing radiations are sources of energy that may be potentially harmful to living organisms, and to human beings in particular, since they have the capability of detaching electrons from atoms or molecules. In so doing, they generate ionized particles with an electric charge and capable of interacting with organic matter. Ionizing radiations can be subdivided into those which spread as electromagnetic waves and a different type, which are produced as subatomic particles: X-rays, gamma rays, as well as part of ultraviolet up to a certain wavelength fall within the former category, whereas alpha and beta particles belong to the latter. The source of emission marks the difference between those two categories: a natural source such as cosmic rays, or man-made sources, which may serve various purposes (military-grade nuclear weapons, medical therapeutic or diagnostic applications)[(1)].

Main text

Effect of ionizing radiation and medico legal aspects

Irrespective of the emission source, the relevance of ionizing radiations and their interactions with living organisms is determined by their potential to alter DNA, thus compromising its mechanisms and leading to stochastic induction of cancer[2,3,4]. Cell membrane damage is possible as well, and that may in turn engender free radical formation and imbalances in water homeostasis within the cells. It should be noted, however, that ionizing radiations have been increasingly used in health care: from radiation therapy as cancer treatment to nuclear medicine, in addition to several diagnostic procedures.

Harmful health effects of exposure to ionizing radiation can be grouped in two general categories: deterministic effects and stochastic effects; the former manifest themselves with a specific threshold for each effect, have short latent periods and a degree of severity which is directly proportional to the dose; stochastic damages, on the other hand, entail somatic or genetic mutations, occur regardless of the threshold (according to the linear no-threshold model), and have long latent periods, non-specific effects and random exposure.

From a medico-legal perspective, it is quite significant to establish a causal relationship between prior exposure to ionizing radiations and the biological effects that can be observed. It is somewhat complex to make an association between those two elements, because of the multiple factors at play: age and gender of the individuals involved, type of radiation, duration and intensity of exposure, body parts that were exposed[5].

Given the lack of certainty, from a legal standpoint, as to the causal relationship between radiation exposure and the risks presumably arising from it, the methods that are used to define such a relationship are based on probability theory criteria: based on available scientific evidence, therefore, it is possible to ascribe a certain degree of plausibility to a causal hypothesis. Probabilistic Causation (PC) is defined to be the relationship between excess relative risk (which is in turn described as the relation between excess mortality for a given cause and the natural cancer risk) and the excess relative risk plus one. In other words, the probabilistic causation standard estimates the risk ratio, which is ascribable to the cause that is being considered, through an assessment of overall likelihood, and represents a "sensible way to face the issue of assessing the plausibility that prior exposure to Ionizing Radiations (IR) may be responsible for the onset of cancer", and has been adopted by INAIL[6] as well as the Medico-legal Council of the Italian Ministry of Defence[7] to face litigation stemming from cancer incidents following exposure to ionizing radiations. In Italy, the standard or method based on PC has become a valuable benchmark that doctors can rely on, both during the assessment and decision-making stages in cases of alleged occupational disease (under DPR 1124/65) and as an assessment tool in order to thoroughly evaluate whether workers with pre-existing cancer-related conditions are fit to take on a given occupation.

Italian and European legal framework

On 6th February 2018, the deadline expired in order for Italy to transpose into law European Directive Euratom 59/2013, issued by the Council of the European Union on 5th December 2013. Such a directive provides for the establishment of uniform safety standards at the European level, in order to more effectively protect the health of workers and of the general public against the dangers arising from exposure to ionising radiation, while at the same time repealing the previously issued following Directives:

- 89/618/Euratom: "on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency", which in Italy was transposed into law by Legislative Decree n. 230, on 17th March 1995;
- 90/641/Euratom: "on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas", transposed into law by Legislative Decree n. 230, on 17th March 1995;
- 96/29/Euratom," laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation", turned into law by Legislative Decree n. 230, on 17th March 1995;
- 97/43/Euratom, "on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom", transposed into Italian law by Legislative Decree n. 187 on 26th May 2000;
- 2003/122/Euratom, "on the control of high-activity sealed radioactive sources and orphan sources", turned into law by Legislative Decree n. 52, February 6th 2007;

For the sake of clarity, it should be remarked that in Italy the following directives are currently in force: 2006/117 (on the supervision and control of shipments of radioactive waste and spent fuel), 2009/71 (establishing a Community framework for the nuclear safety of nuclear installations), 2011/70 (establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste), all transposed into law by Legislative Decree n. 230, 1995, whose provisions would remain in full force, unchanged by the new regulatory path undertaken by the European Union.

Moreover, it is noteworthy that the proceedings for the transposition of the new directive into Italian law had been started by the inclusion of said directive into the draft bill n. 1758 - Delegating the conversion of European Directives and the fulfillment of other European Union provisions to the Italian Government - 2014 European law transposition" – which in article 10 lays out the basic principles and specific standards for the fulfillment of the above mentioned commitment. Nonetheless, said article has been repealed in the 14th Italian Senate Committee through amendment 10.10: therefore, the overall standards and principles enshrined in article 1, subsection 1 remain valid, as enacted on 2nd July 2015. In order to outline and pass a piece of legislation that would be consistent with the principles spelled out by the European Directive, an expert panel was summoned on 4th April 2014 at the Italian Ministry of Economic Development, made up by representatives from the ministries whose functions would be somehow affected by the new norms (the already mentioned Ministry of Economic Development, in addition to the Ministries of Education and Research, the Environment, Health Care, Labor, the Interiors and the Department of Justice) and from technical government institutions (ISS, ISPRA, INAIL), along with experts appointed on a regional basis. Eventually, the committee was subdivided into thematic groups, in which the ministries dealt with "medical and non-medical exposure", and that was supposed to be the first stage of the conversion process; later on, in fact, a political-institutional phase was meant to take place, followed by a renewal of parliamentary committees and the parliamentary vote itself, without any further scrutiny.

Legislative decree 187/2000: hence, the more medically relevant regulatory aspects, related to protection from ionizing radiations in health care settings, are currently covered by Legislative Decree 187/2000[8]. The chief amendments and changes that were introduced by such regulatory initiative provide a greater degree of specificity in terms of measures for the protection of patients, in keeping with the fundamental principles of radiation protection (justification and optimization), while defining and issuing a set of procedures and dosage limitations that must be met by assistants as well as by those who accompany the patients who are exposed to medical radiations, as specified in annex I, the basic diagnostic levels (LDR) meant to optimize the implementation of imaging and radiodiagnostic examinations or tests, which are mentioned in annex II, and all procedures that are instrumental in rationalizing and fostering scientific research. Possible areas of application of such a decree, as stated in article I, may include all those who will be exposed to medical radiations: patients and accompanying persons, those involved in surveillance, screening or research projects, personnel who may be exposed on account of procedural or medico-legal reasons. Undoubtedly, an effort has been made to protect not only patients, but anyone who may come into contact with radiations under any conditions possible.

The following articles were meant to enforce two fundamental principles: justification and optimization. The former, which is comprised within article 3, dictates that exposure to radiations be limited to circumstances where it is absolutely necessary, according to suitability standards thoroughly defined and priorly laid out by specialists. For any procedure, the advantages must outweigh the disadvantages, taking into account the "cost-benefit" ratio, thus limiting useless exposures that bring no benefit to patients.

The legislative scope of intervention has been broadened to include research and experimentation as well, which is asserted in article 3, subsection 6: "*exposure to medical radiation for research or experimentation purposes shall be assessed by an ethics committee, gathered according to the laws currently in force*".

The principle of optimization is included in article 4, which reads: "*the probability of incurring exposures, the number of people exposed, and the intensity of individual doses should all be kept as low as reasonably achievable, while still making it possible to obtain the intended diagnostic results and taking into account economic and societal factors as well; the principle of optimization also pertains to the choice of equipment, the suitable achievement of diagnostic outcomes or therapeutic results, the definition of practical aspects, in addition to Legislative*

Decree 187/2000, later amended by law 9/2002 p. 4/16 and programs aimed at guaranteeing and verifying quality standards, the evaluation of doses or activities undergone by patients". A thorough assessment in terms of costs and health benefits has been once again prioritized, therefore the suitability of a given prescription must go in lockstep with the optimization of exposure doses: all of that is meant to achieve the best possible diagnostic or therapeutic outcomes with the least possible damage

Such a procedure, as statted in the decree, also covers the stages prior to diagnostic testing, i.e. the choice of devices, and those following it, with an accurate evaluation of doses incurred by patients. In order to guarantee the highest standards in terms of objectivity and homogeneity when applying the principle of optimization on a national scale, annex II (which is mentioned in subsection 4) encompasses guidelines that identify diagnostic benchmarks to be used as a frame of reference (Diagnostic levels of reference, LDR in Italian) in programs meant to ensure high quality standards of diagnostic radiology and nuclear medicine. LDR thus constitute a valuable means to improve the overall levels of performance: easily achievable values, ascribable to any diagnostic procedure. It should be stressed that through article 39 within law 39/2002, part of article 4, subsection 4 of the above-mentioned legislative decree has been repealed, which indirectly remanded to subsection 5 of article 96 of legislative decree 230/1995 ("*with the decrees and their subsections 1 and 3, exceptional cases my be identified where dosage limitations defined in those same decrees may not be applied*"): Thus, any chance to have exceptions with respect to what previously stated has been ruled out. A great degree of attention has been paid to the medico-legal realm, as asserted in subsection 6, which recommends that doses arising from exposure to radiations for medico-legal purposes must be kept as low as possible.

Furthermore, as far as legal medicine is concerned, article 5 has laid out an important set of criteria in order to determine liability arising from exposure to medical radiations: radiologists, who are tasked with implementing such procedures (which are at times delegated to medical radiology technicians, nurses, or pediatric nurses, according to their respective skills) upon patient demand, will be held liable. Moreover, specialists are responsible for identifying and choosing the most suitable methods and techniques for the achievement of the best diagnostic or therapeutic outcome, and for assessing any possible alternative procedures, in full compliance with the principles of justification and optimization enshrined in articles 3 and 4. The "practitioner" profile is outlined in article 2, subsection 1, as "the professional who, according to the type and organization profile of a given concern, is responsible for the concern itself, meant as the productive unit, the establishment or structure manufacturing and providing goods and services, autonomous from the technical, functional and financial perspectives".

Practitioners are required to hire adequately trained professionals to be put in charge of the radiology department, who need to be certified doctors specialized in diagnostic radiology, radiotherapy, or nuclear medicine (article 2, subsection 2.f); such a profile may coincide with the practitioner him/herself, provided that they are licensed to directly carry out clinical screening procedures (article 2, subsection 2.f). As for the services for which the LDR have been set for any device or procedure, those who are in charge of radiology departments are required to keep track of diagnostic levels relative to all procedures and document the results in a dedicated registry (under article 6, procedures). Such performance tests should be implemnted upon demand of the professional in charge of the department, by physicists in compliance with the provisions set forth by European Guidelines on Quality Criteria for Diagnostic Radiographic Images (EUR 16260, EUR 16261, EUR 16262 and EUR 16263), and later additions and modifications.

The importance of providing thorough information to patients, particularly those involved in clinical scientific research trials, reflected in informed consent, is reasserted in article 5, subsection 6.

From a procedural standpoint, any reference to guidelines published through official government channels, under article 6 of the legislative decree herein analyzed, is even more relevant following the enactment of law n. 24, 8th March 2017 (denominated "Gelli-Bianco"). According to provisions in that legislation (specifically, in art. 590-*sexies*) that deal with liability in health care, health care practitioners are not punishable if they provably comply with guidelines, or in the absence of such guidelines, with best clinical health care practices, taking into account each case's peculiarities.

Other aspects that have been also regulated under Decree 187/2000 concern professional training, intended both as the inclusion of targeted courses within the final stages of medical education and as constant professional updates, the regulations on

the choice and maintenance of medical devices, all precautions and recommendations to be followed in cases of pregnant or breastfeeding patients, potential exposures, and any consideration in terms of background exposure.

Euratom Directive 2013/59

Council Directive 2013/59/Euratom provides for the establishment of uniform safety standards meant to protect against occupational, public and medical exposures[9]. As far as the medical exposures are concerned, laid out in subsection VII, important new indications have been introduced in article 58, in addition to the reinforcement of the principles of justification and optimization, under articles 55 and 56 and the attribution of liability, already defined in legislative decree 187/2000. First and foremost, standardized protocols have been introduced, to be specifically applied to each individual procedure and device based on the type of patients that are being treated. Perhaps the most important innovation from a practical standpoint is found in subsection b: the doses of radiations to which the patient was exposed during any procedure must be indicated in the test results. That requirement is instrumental in protecting the patient themselves, and provides the highest possible degree of transparency in terms of data collection; such data must not only be assessed and communicated to patients during the decision-making stages, i.e. for predictive purposes, but indicated after each instance of exposure, in order to reflect and document the suitability of the doses to which the patients were exposed.

A reference , in the same article, to guidelines pertaining to the procedures is made for doctors who prescribe the procedures too: that way, greater emphasis is placed on the thorough assessment that needs to be made prior to the exposure, i.e. upon choosing the proper methodologies based on hard, quantitative data. Besides, data management always needs to be highly readable and transmissible, even when quaint devices are being used. One of the most troublesome points relative to that provision is the very fact that, according to article 60, subsection 3, all devices that were installed after the directive's transposition into Italian law must have meters capable of measuring the doses used, with an exception for devices that were installed before 6th February 2018; however, in light of the impossibility to replace all devices currently in use within a reasonably short time frame, it would perhaps be advisable to include a mandatory term for the replacement of those devices as well.

A further relevant new change that has been introduced by Directive 59 is the one concerning the the limit for equivalent dose for the lens of the eye in occupational exposure[10]: such a limit has been reconsidered in light of new scientific findings by the IRCP (International Commission on Radiological Protection)[11], which have shown a higher level of sensitivity for the lens of the eye to ionizing radiations, especially in presence of conditions such as cataract or clouding. According to the IRCP report, Directive 59, article 9, subsection 3 (a), with regards to occupational exposures, reads: "the limit on the equivalent dose for the lens of the eye shall be 20 mSv in a single year or 100 mSv in any five consecutive years subject to a maximum dose of 50 mSv in a single year, as specified in national legislation;". Consequently, article 40 of the same Directive updates the classification criteria, including within category A" those exposed workers who are liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 15 mSv per year for the lens of the eye"[12].

A document based on common consensus by several Italian scientific societies was signed on 22nd April 2017: in it, while acknowledging the ultimate role of medical physicists in evaluating the level of radiation exposure, recommendations have been put forth and different scenarios have been outlined for the purpose of attaining "*proper data management as to the levels of exposure for diagnostic tests (art. 60, subsections 3 c, d, e, f) and a thorough provision of information about exposure incurred by every patient, with particular reference to article 58 (b) of the Council Directive 2013/59*." The ultimate purpose of the document, signed by 7 societies that were involved in the directive itself, is to bridge the regulatory gap that was created by the failure to transpose into law the Council Directive 53/2013. By the same token, the report has been designed in an attempt to summarize and clarify all the most relevant novelties introduced by the Council Directive, thus providing professionals with practical and updated support for them to better fulfill their duties.

Currently, the reasons behind the failure to produce a commonly shared position regarding the transposition of the Directive are the difficult identification of the authorities that should be in charge, in addition to the creation of a system of sanctions and the absence of extra financial burdens for the national government.

Conclusion

In conclusion, it is arguably desirable to swiftly overcome any snag and setback in the decision-making process, in order to avoid disciplinary procedures from the European Union and to ensure greater safeguards for all those that may incur ionizing radiation exposure.

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Key points:
1. Safety improvements and innovation introduced by the European Directive 2013/59.
2. State of the art in the Italian legislation regarding the adoption of European Directive 2013/59.
3. Medico-legal aspects of health law and radiation.

Abbreviations and acronyms:
EURATOM = European Atomic Energy Community, PC = Probabilistic Causation, IR = Ionizing Radiation, DPR = Decreto del Presidente della Repubblica (Decree of the President of Republic), LDR = Livelli di Riferimento (Basic Diagnostic Levels), ICRP = International Commission on Radiological Protection.

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