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Current trends of radioprotection in Italy

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Abstract

Radiation protection is expressed in a series of principles, recommendations, requirements, prescriptions, technologies and operating methods, evaluations aimed at protecting the population. Protection from the effects of radiation is based, at a general level, on the isolation of the environment and humans from radioactive sources, on the adoption of design, construction and technological solutions, as well as on the identification of behaviours and prescriptions, suitable for reducing the individual and collective exposure to an appropriate extent. Three general principles of radiation protection have been defined in order to reduce the risk of stochastic damage: justification, optimization, and dose limits. The legislative decree 101/2020 acknowledges the innovations that have occurred over the last twenty years, showing awareness of the legislative evolution of the health professions. The new legislation overcomes the paradigm that concerns working on delegation, thanks also to the use of protocols, both in reference to the justification and optimization process.

Keywords

safety, radiology, dose limits, guidelines

Introduction

The existence of an efficient, reliable and transparent radiation protection system is an indispensable precondition in every industrial country. All activities which imply radiological risks should be carried out in compliance with

the basic principles and current legislation on the protection of workers, population and environment, in order to protect them from harmful effects. Radiation protection is expressed in a series of principles, recommendations, requirements, prescriptions, technologies and operating methods, evaluations aimed at protecting the population (individuals in general, workers, subjects undergoing medical diagnostics or treatment practices, using ionizing radiation).

Protection from the effects of radiation is based, at a general level, on the isolation of the environment and humans from radioactive sources, on the adoption of design, construction and technological solutions, as well as on the identification of behaviours and prescriptions, suitable for reducing the individual and collective exposure to an appropriate extent. The determination of the criteria and procedures to be applied for this purpose is being studied by numerous national and international institutions, among which the most authoritative is the International Commission for Radiological Protection (ICRP), an autonomous scientific commission founded in 1928 composed of some of the leading international experts in the field. The ICRP recommendations are based on the fundamental assumption "there is no dose, however small, with no associated risk".1,2 From this assumption derives the need for a conceptually complex protection system. In fact, the ICRP recommends individual exposure limits, determined in relation to the risks normally accepted in conventional industry and the nominal risk coefficient it assesses, but compliance with the aforementioned limits cannot satisfy the prevention needs, since it cannot to exclude the possibility of stochastic damage, even if not detectable even on a statistical basis, nor to ensure that their incidence is reduced to a reasonable extent.

Radiological protection principles

Three general principles of radiation protection have been defined in order to reduce the risk of stochastic damage: justification, optimization, and dose limits.

The Principle of Justification

Any new application and use of radioactive materials involving risk for individuals, population and environment, must be justified. According to this principle, the exposure to ionizing radiation is justifiable only if the benefits deriving from the practices that generate the additional doses outweigh the set of statistically foreseeable adverse effects.

The Principle of Optimization

The optimization principle establishes that – once the justification has been proven – the exposure of the population must be kept as low as reasonably achievable (ALARA principle = As Low As Reasonably Achievable) also taking into account economic and social factors.

The Principle of Application of Dose Limits

The total dose to any individual, from regulated sources in planned exposure situations other than medical exposure of

patients, should not exceed the appropriate limits recommended by the Commission. Dose limits are determined on the basis of nominal risk coefficients.

The individual dose limits, recommended by the ICRP in terms of overall effective dose, are implemented by the basic Italian radiation protection law (Legislative Decree 230/95) in:

- for individuals of the general population: 1 mSv / year;
- for workers exposed for professional reasons: 100 mSv in 5 years with a maximum of 50 mSv / year.

Diagnostic and interventional procedures expose patients to ionizing radiation. Medical exposure of patients is intentional, voluntary and consensual and the three principles take on an important value in medicine to avoid unnecessary or unproductive radiation exposure.

The dose limits recommended by the ICRP is a useful tools for patient's safety. The risk resulting from exposure to ionizing radiation is never zero and the principles of justification and optimization are not sufficient to the protection of the individual, therefore dose limits have been established.

Dose limits set by the ICRP and applied by national regulations have the function of protecting workers and individuals in the population, but them do not indicate a threshold beyond which mutation occurs. The occasional exposition of one or more individuals to doses higher than those admissible must be evaluated as an indication of the insufficiency of preventive measures and not necessarily as an indication of biological damage. On the other hand, the primary role for limiting radiation risks for already "justified" activities is delegated to a correct optimization of protection, which usually involves the adoption of design criteria, protection systems and operating procedures such as to contain individual doses within values substantially lower than the aforementioned limits.

Tools for radioprotection

Through a continuous process of adaptation aimed at achieving increasingly advanced objectives of protecting the population and workers, radiation protection has developed over time multiple technical and conceptual tools, which have become increasingly elaborate and effective and are grouped into 4 main categories:3

- *the conceptual tools*, given by the fundamental principles that underlie the radiation protection subject, and define the so-called general radiation protection. In particular, these are the aforementioned principles of justification, optimization and limitation;

- *the technical tools*, given by the set of protection devices and radiation measurement instrumentation (shielding, static and dynamic confinement systems of radioisotopes, means of personal protection, testing or intervention procedures, radiation measurement techniques, dosimetry, etc.) involving the physical sciences, biological and natural

sciences, medicine and public health, engineering, work organization and environmental sciences;

- *regulatory instruments*, which involve the development and updating of standards that include community directives, recommendations, national laws, guides and technical standards, regulations, authorization requirements, instructions and operating procedures;

- *controls and inspections*.

Operative radioprotection

Operational radiation protection favours safety by intervening in a series of specific areas, analysing single technological application and their impact on workers and general population.

A second organizational path provides identification of persons responsibilities and behaviors.[3,4]

- Planning and equipment design. In this level, which operates close to the source, most effective measures can be adopted for the purpose of minimizing the health and environmental impact.

- Organization and management. It is the highest hierarchical level in which the actions of operational radiation protection interventions.

- Information and training. The sphere of individual behaviours must be based on the awareness of individuals, and therefore on an intense program of information and formation.

- Limitation and control of worker exposure. Once the structural and organizational tools have been ensured and the right individual and collective behaviours have been induced, the level of radiation protection intervention is transferred to the control and limitation of exposure. This goal is pursued by implementing operational measures (area limitation, access control), techniques and exposure limitation devices (shields, hoods, boxes and gloves, etc. - equipment, protective monitoring and alarm systems) and technical control of doses (external and internal dosimetry).

- Limitation and control of radioactive waste. In the general economy of radiation protection, particular attention is paid to the production and management of radioactive waste, which is perhaps one of the main vehicles through which exposure to radioactivity can affect workers and especially the public.

- Limitation and control of public exposure. This is the level of intervention closest to the population in general.

- Emergency planning and management. Emergency situations can arise in any installation and equipment that uses radioactive substances. These unforeseen events can have dire consequences. After identifying the possible (even if unlikely) emergencies, actions are planned and responsibilities are defined to be prepared in case unexpected events occurs.

- Preparation and management of the instrumentation. The correct execution of an operational program of radiation protection is necessarily based on the availability, correct arrangement and efficiency of a complex system of instruments and surveillance and measurement equipment, which requires intense programs of selection, installation, functional control, calibration, maintenance and efficiency check.

An efficient radiation protection system is essential to ensure that the management of all activities with risk from ionizing radiation takes place in conditions of adequate safety.

The radiation protection system must offer to workers, population and environment a guarantee of control and risk reduction at technically, socially and scientifically acceptable levels.

The structural and functional hierarchy of the entire system is clearly identified, correctly structured and unitary and the competent figures in the various functions and responsibilities are previously well-established.

Finally, the entire system must be characterized by a high degree of transparency in order to offer public opinion the guarantee of efficiency, reliability and independence as well as an image of technical-scientific authority.[5]

Radiation protection in Italy

Very recently, in Italy, the union between health and safety has been enunciated by the Legislative **Decree 31 July 2020, n. 101**.

Already in the first article a sort of **principle of "beneficence"** is set out:

- possible health damages due to a determinate practice should never prevail benefits for individuals or for the community;

- radiation protection from occupational exposure of individuals should be optimized in order to keep individual doses to a reasonably achievable minimum.

In order to further guarantee the appropriateness of exposures, alongside the principle of optimization, the new directive also introduced the principle of justification, according to which unjustified exposure is prohibited and all types of practices involving medical exposures must be justified. All exposures should be carried out under the clinical responsibility of the specialist doctor, at the reasoned request of the prescribing doctor.

The **health-safety-prevention** link, already enunciated by the Italian **Legislative Decree n. 81/2008**, is further emphasized by reiterating the obligations of both employers and workers, through the training and information.

Article 162 shows the evolution towards interdisciplinarity:

- **Paragraph 2**: health professionals who work in areas directly related to medical exposure must follow training courses on patient radiation protection as part of the continuing education.

- **Paragraph 4**: the specific credits in the field of radiation protection must represent at least 10% of the total credits foreseen in the three-year period for specialist doctors, general practitioners, family pediatricians, medical radiology

health technicians, nurses and pediatric nurses and at least 15% of the total credits foreseen in the three-year period for medical physics specialists and for medical specialists and dentists who carry out complementary activities

- **Paragraph 5**: for the organization and preparation of continuing education course programs and the choice of teachers, the accredited ECM providers make use of bodies, institutions, associations and scientific societies which include among their purposes, in addition to patient radiation protection, one of the following sectors: radiodiagnostics, radiotherapy, nuclear medicine or medical physics, and which are more representative in the individual specialties

The importance of the formative obligation finds its motivation in Article 159 **"Responsibility"**:

- **Paragraph 3**: the practical aspects for the execution of the procedure or part of it are defined in the context of the procedures governed by the guidelines, for the specialist doctor or the medical radiology technician, or for the nurse or for the pediatric nurse, each within their respective professional skills

- **Paragraph 8**: the specialist doctor, the specialist in medical physics and health professionals directly involved in medical-radiological procedures participate in the optimization process, each within their own competences, in accordance with the procedures defined by the guidelines

The **concept of responsibility** also extends to particular protection **during pregnancy and lactation**. The prescribing doctor and the specialist must investigate a possible state of pregnancy of the patient and in the case of administration of radiopharmaceuticals if the affected woman is breastfeeding.

In the event that the diagnostic investigation or therapy cannot be postponed, the specialist doctor informs the woman or her representative of the risks to the unborn child. In the event that it is necessary to proceed with the exposure, the specialist doctor and the medical radiology technician, within their respective competences, must pay particular attention to the optimization process concerning both the mother and the unborn child.

One of the most important changes concerns the verification of the congruity of the classifications – considering the reduction of the dose limit equivalent to the lens – and the identification of the measures to be taken to avoid exceeding this limit.

It is also important that the employer becomes aware of the fact that the methods of assessing a risk already taken into consideration before the entry into force of Legislative Decree 101/2020 have changed. The main changes may concern:

- the dosimetric levels adopted for the classification of exposed workers;
- the values used to verify compliance with the dose limits;
- the devices and measures for the protection of workers;
- the methods of surveillance and assessment of the dose equivalent to the lens.

A further element is constituted by the expansion of the field of action of the dose limits for:

- occupational exposure
- public exposure

(art. 5, Annex XXV, art. 122), to be evaluated in the individual situations.

Conclusions

The legislative decree 101/2020 acknowledges the innovations that have occurred over the last twenty years, showing awareness of the legislative evolution of the health professions. Interesting and stimulating is the passage regarding training in radiology, an increasingly multi-professional setting. The new legislation first of all overcomes the paradigm that concerns working on delegation, thanks also to the use of protocols, both in reference to the justification and optimization process; finally, the typical and confidential skills of the various radiological professionals are recognized.

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