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COMMENTARY

Effect of the New Italian Legislative Measures on the Eye Lens Protection of Radioexposed Workers

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Abstract:

Introduction:

Legislative Decree no. 101, published on 31 July 2020 in the Italian Official Gazette, the official journal of the Italian Government, sets out the provisions of Directive 2013/59/Euratom, which establishes the basic safety rules for protection against the risks arising from occupational exposure to ionizing radiation.

Methods:

The main purpose of the legislator was to improve the safety of workers exposed to radiation, updating the previous laws adopted by the Italian government 25 years earlier. Many strategies have been attempted in the past to increase the level of protection of these categories of workers. Still, it is too early to evaluate the effectiveness of the proposed measures.

Results:

Medical professionals play a leading role among other figures involved in the field of occupational radiation protection. To achieve a reliable and detailed evaluation of the risk assessment, which in Italy must be reported in a specific mandatory report called the "Risk Assessment Document", the legislator has assigned differentiated but coordinated tasks to all the actors involved with different responsibilities in radiation protection.

Conclusion:

The drastic reduction of the dose limits for the crystalline lens is a tool for more effective protection of workers against exposure to ionizing radiation.

Keywords: Italian radiological system, Lens opacities, Eye lens protection, Radio-exposed workers, Legislative Measures, Legislative Decree.

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1. INTRODUCTION

Legislative Decree no. 101, issued on 31 July 2020 and published in the Official Gazette of the Italian Republic no. 201 on 12 August 2020, has recognized the indications provided in Directive 2013/59/Euratom, much later than in other European countries [1, 2]. The European Directive establishes basic safety rules for the protection against the risks arising from occupational exposure to ionizing radiation. Among the Italian regulations, Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom have been repealed, and the new law provides for a necessary reorganization of the sectoral legislation according to art. 20, sub. 1, letter a) of Legislative Decree no. 117, adopted on 4 October 2019. Many changes were brought to this legislation, aiming to improve the safety of workers exposed to radiation (radiologists, radiation safety officers, radiology technicians, radiology nurses, nuclear doctors, chemotherapists, radiotherapists, radiochemists, workers at nuclear power plants, research laboratories, and food processing plants, *etc.*) by refining previous laws in terms of classification review, reassessment radiation limits and management of workers' health surveillance procedures.

Too little time has passed since the enactment of the law and its effectiveness in improving environmental protection and preventing the onset of radiation-induced health effects to be able to ascertain its real effectiveness; however, this new

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law brings a new clear point of view to physicians who are involved in the health surveillance of workers exposed to ionizing radiation hazards. Given the complexity of the matter, we believe that an in-depth explanation of this new decree may be useful for occupational physicians.

2. EYE LENS PROTECTION

Eye lens has been recognized as a critical target of ionizing radiation since 1903, when the first case of cataract was reported in a human subject [3]. In 2011, the International Committee on Radiological Protection (ICRP), following a re-analysis of data on the onset of cataracts among A-Bomb survivors and Chernobyl clean-up workers, classified the lens as one of the most radiosensitive tissues in the human body. In the same year, ICRP has recognized a threshold dose of 0.5Gy regardless of dose rate for the onset of lens opacities and vision-impairing cataracts. Radiosensitivity of the eye lens is attributable to the the presence of epithelial cells located in the equatorial area that continuously proliferate throughout the entire life that are. These cells can easily be damaged by ionizing radiation, resulting in abnormal proliferation, differentiation and migration of lens cells. Moreover, oxidative stress and denaturation of lens proteins can contribute to the onset of lens opacities. Lens damage usually occurs sometime after exposure (months in case of acute exposure, years for fractionated doses) and has previously been considered a typical deterministic effect. However, recent findings have shown that lens opacities can also occur in individuals exposed to low doses of ionizing radiations (<100mSv) regardless to rate, raising doubts on the deterministic nature of radiation-induced cataracts. All types of lens opacities are radio-inducible but the posterior subcapsular cataract has sown a stronger association with radiations exposure in published studies. In the Mayak plant workers, the risk of cataracts in aggregate increased with the dose > 0,25Gy [4]. In a large cohort of US radiologist technicians (mean cumulative dose < 60mSv), the risk of self-reported cataract increased linearly with the 5-year lagged cumulative dose for the entire dose range [5]. Those doses are well above the typical level received by the interventional radiologists and cardiologists, who can be considered the most exposed operators in the radiological department. In a recent review, a significantly increased risk of work-related cataracts has been found in healthcare workers exposed to ionizing radiation, primarily in interventional cardiologists and radiologists [6].

Given the lack of a certain threshold dose, lens monitoring in the radiation-exposed operators is a crucial issue with regard the radiological protection. This is the reason why the protection of the lens with adequate shielding is very important today. In a recent review, the effectiveness of lens protection devices has been evaluated. When correctly used, lead glasses determine a 35-95% reduction in the eye [7].

3. THE "NEW HEALTH SURVEILLANCE"

Together with numerous amendments to the previous legislation, the new Italian law n. 101/2020 reorganizes the sector of health surveillance of workers exposed to potentially harmful effects of ionizing radiation. As a major regulatory innovation, it redefines the figure of the doctor responsible for the health surveillance of exposed workers and his activities (the so-called "Authorized Physician"). The Italian response to the need for harmonization is a useful paradigm, but it requires some consideration in terms of application and medium- and long-term effects on exposed workers. In Italy, since 1994, the health surveillance for most occupational hazards involves the occupational medicine specialist (the so-called "competent doctor"). Before the entry into force of law 101/2020, the competent doctor was also in charge of the occupational screening of workers exposed to a level of ionizing radiation lower than 6 mSv/year ("B-category" workers). On the other hand, in order to be authorized to perform the health surveillance of the most exposed subjects (above 6 mSv/year: "A-category" workers), the occupational physician was required to specific radiation protection training, certified by the Italian Ministry of Labour as "Authorized Physician."

According to the new Italian law 101/2020, the health surveillance of workers exposed to ionizing radiation (therefore, regardless of their risk classification) is carried out exclusively by an Authorized Physician and no longer by a Competent Doctor [1]. The rationale behind this choice - which implements specifically articles 32 and 44 of the Directive 2013/59/EURATOM - is the priority need to comply with the provisions of the Directive, where it is stated that the risk assessment must be entrusted to a doctor "...whose capacity to act in that respect is recognized by the competent authorities" (Dir. EURATOM 59/2013) [2]. In the Italian context, only the "authorized physician" responds to this definition, as his/her skills are certified on the basis of an official qualification conferred by the Ministry of Labour. The 101/2020 law in paragraph 2 draws up a transitional scheme: an extension of 24 months - from the entry into force of the decree - is granted to the competent doctors already in charge of radiation protection for category B workers. During this time frame, all "competent doctors" who intend to continue to perform the health surveillance of radiation-exposed workers should obtain the title of authorized medical [1].

Another update that substantially changes the role of the designated doctor is inserted in paragraph 1 of the art. 134, in the second part, the engagement letter of the authorized doctor and the corresponding declaration of acceptance must be kept by the employer and presented on request to the health authorities. It is reasonable to imagine that the rule was inserted in place of the communication to the Provincial Department of Labor stated by the previous legislation. The provision of art. 138, decree n. 101/2020, dedicated to the list of authorized doctors, is connected with the new definition of competent/authorized doctor: in particular, paragraph 2 refers to a subsequent decree (which does not appear to have been issued to date) dedicated to the methods and requirements of registration in the register of authorized doctors, as well as periodic updating. Regarding the updating, during the transitional period and until a new regulation is performed, the professional updating of the authorized medical is carried out through compliance with the provisions of Article 38, paragraph 3 of Legislative Decree no. 81 of 2008 [8]. The regulation for medical examinations is also well constructed. Preventive medical examination issued by law 101/2020, which is expressly aimed at the formulation of an assessment

of suitability for the specific task, in relation to the risk of ionizing radiation. As paragraph 3 explains, specialistic and laboratory investigations, as well as a full worker's medical history, are necessary to obtain a non-general assessment, unlike what was previously read. Formerly, the aim was to assess the general state of the worker's health: a generic expression that previously had led to a risk of misinterpretation. Now, instead, we will be able to refer to the specific risk [9, 10]. The form of the communication of the suitability judgment has also changed. Law 101/2020 requires that the communication is made in writing, electronically, to the employer, his delegate, and the worker. It is, therefore, excluded the previous practice that admitted the oral communication of the result of the evaluation [1]. On the other hand, the provision of paragraph 7 is far more uncertain: it establishes that in the process of assessment of suitability, the doctor will have to take into account the guidelines recognized within the National Health Service, as required by law no. 24 of 8 March 2017. This will probably allow scientific associations to provide to help with the practical activities of authorized doctors. Regarding periodic and special medical examinations, the most important change relates to the frequency of periodic examinations of category A workers. Even though previously the deadline was six months, a high but at least annual frequency of periodic visits is now permitted. The authorized medical must indicate the reasons that allow to extension of the validity of the judgment of suitability beyond the six months of the previous discipline. All kind of radioexposed worker shall remain free to request an extraordinary examination,subject to the assessment of the authorized medical who considers it to be related to occupational risk. Most exposed workers such as those performing interventional maneuvers (radiologists, cardiologists) and operators working in nuclear medicine should benefit from these legislative changes. The rule of paragraph 3 seems to consider this as the only viable form of extraordinary visit so the assumptions previously included in the category of extraordinary visits would be excluded: for example, the ones performed for a worker returning to work after pregnancy or after an accident. Finally, art. 136 decree n. 101/2020, paragraph 7, clarifies the purpose of the examination carried out before the termination of the employment relationship: in fact, the employer provides to subject the worker to a medical examination. On that occasion, the authorized medical shall provide the worker with information about the opportunity to undergo medical examinations, even after he has ceased to work, on the basis of his health status and the development of scientific knowledge. They are periodic health checks designed to monitor the health conditions related to exposure and therefore, require periodic monitoring over time.

4. LENS DOSE

Articles 133 and 146 of Legislative Decree no. 101/2020 draw up a new discipline regarding dose limits for the lens. We will focus only on this limit, omitting to deepen the hypotheses concerning other limits contemplated by the law.

Art. 133, entitled "Classification of workers and workplaces for the purposes of radiation protection and physical surveillance (directive 2013/59 / EURATOM, articles 9, 36; legislative decree March 17, 1995, n. 230, article 82)", provides in paragraph 1, that "exposed workers" are classified as persons who, due to work, are likely to exceed one or more of the following values in a year: a) 1 mSv of effective dose; b) 15 mSv equivalent dose for the lens; c) 150 mSv equivalent dose for the skin, calculated on average on any 1 cm^2 of skin, regardless of the exposed surface; d) 50 mSv equivalent dose for the extremities [2]. Paragraph 3 describes as Category A exposed workers who, on the basis of the investigations carried out by the radiation protection expert, are susceptible to a higher exposure, in a calendar year, to one of the following values: a) 6 mSv effective dose; b) 15 mSv equivalent dose for the lens; c) 150 mSv of equivalent dose for the skin as well as for hands, forearms, feet and ankles (with the evaluation methods established in the aforementioned paragraph). Therefore, the equivalent dose for the lens set at 15 mSv is, in both hypotheses, a sufficient and coincident condition to fall into the category of exposed workers or category A exposed workers.

The major novelty, as mentioned above, concerns the dose limit: in art. 146 (Dose limits - directive 2013/59 / EURATOM, articles 9, 10, 11; legislative decree March 17, 1995, no.230, article 96), we read that the dose limits for exposed workers are established, according to the letter a), in a 20 mSv effective doses in one calendar year [2]. And without prejudice to compliance with the effective dose limit referred to in the letter a), further equivalent dose limits are established in a calendar year: 1) 20 mSv for the lens; 2) 500 mSv for the skin; this limit applies to the average dose, on any 1 cm^2 surface, regardless of the exposed surface; 3) 500 mSv for the ends. Therefore, the legislator has significantly lowered the dose limit for the lens, passing from the previous indication of 150 mSv to the current one of 20 mSv. This is the same limit set for the population as well [11 - 13]. Paragraph 7 of the same art. 147 specifies in fact that "the exposure limits for individuals in the population are established in a) 1 mSv of effective dose per calendar year; b) without prejudice to compliance with the effective dose limit referred to in the letter a), the following equivalent dose limits are established in a calendar year: 1) 15 mSv for the lens; 2) 50 mSv for the skin, calculated on average on 1 cm^2 of skin, regardless of the exposed surface". For now, we limit to describe the current regime, which drastically reduces the limit value, considerably expanding the number of radio-exposed workers and, therefore, introducing a powerful tool for protection and prevention.

This issue has been the topic of various studies, and the recommendation from the ICRP to reduce the lens equivalent dose limit for occupational exposure from 150 mSv/year to 20 mSv/year dates to 2012 [14]. This is a limit suggested by the results of research on the prevention of radio-induced cataracts, which has a hypothesized nominal threshold of 0.5 Gy for acute or prolonged exposure. The existing limit of 15 mSv/year appeared protective enough, as it is highly unlikely that an unexposed individual may receive a higher lens dose [14, 15].

Table 1. Comparison of dose limits in different countries.

-	Effective Dose	Lens	Skin	Extremities
Italy	20 mSv	20 mSv	500 mSv	500 mSv
USA	50 mSv	150 mSv	500 mSv	500 mSv
Canada	50 mSv	50 mSv	500 mSv	500 mSv
Australia	20 mSv	150 mSv	500 mSv	500 mSv
Germany	20 mSv	20 mSv	500 mSv	500 mSv
India	30 mSv	150 mSv	500 mSv	500 mSv
UK	50 mSv	20 mSv	500 mSv	500 mSv

5. DISCUSSION

5.1. Comparison of Dose Limit with Other Countries

Every country in the world has different dose limits for its workers, especially for the effective dose and the lens equivalent dose. The USA is the country with the highest level of lens equivalent dose, which is 150 mSv [16]. The Australian government, for the equivalent dose has chosen the same level of 150 mSv [17], while 20 mSv is the Australian effective dose limit, which is lower than the 50 mSv limit used in the United States. Some other countries have the same effective dose limit of 50 mSv used by the American governments, for example Canada and the United Kingdom, but the former has an equivalent dose for the lens of 50 mSv [18], which is higher than the dose limit of 20 mSv for the lens of the British regulation. India has set an effective dose limit of 30 mSv, although Indian legislation sets a limit of 150 mSv for the equivalent dose to the lens [19]. Italy is not the only country that has chosen a limit of 20 mSv for both the effective dose and the equivalent dose to the lens. Germany, for example, has adopted the same dose limits, which are laid down in Legislative Decree no. 101/2020 of the Italian Republic [20]. All the countries considered above have the same limit of 500 mSv for the equivalent dose to the skin and extremities (Table **1**).

5.2. Other forms of Protection from Radon and Activities Exposed to NORM

A further innovation introduced by the decree concerns, as anticipated, the protection from radon exposure in the workplace. A new reference level is set at 300 Bq/m^3 for work activities carried out in underground environments and basement workplaces. The same value was indicated in 2020 by the legislator, also for the protection from radon in living environments, thus ensuring a better uniformity of evaluation which will undoubtedly improve the effectiveness of the verification and protection [1]. We also underline that the reference level indicates a dose or concentration value of activity in the air (in the case of radon) that doesn't represent a "threshold", but it is a value above which it is not advisable to verify the exposure and it is therefore necessary to take protective measures, which, however, in compliance with the optimization principle, must also be taken below this level.

We specify the scope of application of the new discipline, intended, as already mentioned, for work activities that occur in underground environments, but also in spas, in basement workplaces and on the ground floor if located in priority areas (appropriately defined in art. 11), or if carried out in "specific workplaces" to be identified as part of the provisions of the National Radon Action Plan [1, 21 - 23].

In these workplaces, measurement of the annual average radon concentration in the air is required. If the concentration is below 300 Bq/m3, new measurements can be carried out every eight years. If this limit is exceeded, corrective measures must be taken to reduce the level below the reference value within two years. A new assessment must be made of the effectiveness of the measures taken. The measures adopted are considered successful if the assessment of the concentration is less than 300 Bq/m3; in this case, measurements must be repeated every four years. If, on the other hand, the radon concentration is still higher than the specified limit, it is necessary to proceed with the assessment of the annual effective doses. This operation must be carried out by the radiation protection expert, who must issue a specific report at the end of the measurement, for which the reference level is 6 mSv per year. Therefore, a new figure of the radon remediation expert is introduced, a professional with specific training in the field, certified by specific university training or refresher courses of a duration of sixty hours, on the design, implementation, management and control of corrective actions to reduce radon concentrations in the environment. This person must work in close collaboration with the authorized occupational physician, since these duties are closely linked to those provided for by Legislative Decree No. 81/2008 and must therefore be included in the risk assessment document. Finally, the issue of protection against gamma radiation from materials containing radioisotopes of natural origin (NORM) should be mentioned [24]. The aforementioned discipline is included in Chapter II of Title IV, which is dedicated to "practices involving the use of materials containing radionuclides of natural origin": the lexical change, consisting in the passage from the term "work activity" to that of "practice", constitutes the first element of novelty and the first strengthening of the protection. In fact, the activities which, according to art. 20 of the Legislative Decree, within twelve months of the entry into force of the Decree (*i.e.* within the period that has just expired, *i.e.* August 27, 2021) or of the commencement of the practice, are obliged to have the measurements of the activity concentrations of the materials present in the production cycle and in the processing residues carried out by specific recognized organizations. In the event that the measurements are higher than the exemption levels described in Annex II, a radiation protection expert must be appointed to implement the radiation protection requirements prescribed for the protection of workers in accordance with art. 22, which clarifies how the

results of the assessments made by the radiation protection expert must be included in the risk assessment document.

In detail, the task of the radiation protection expert is to measure the activity concentration of the materials present in the production cycle, the residues and any effluents. If the values measured are below the exemption levels, the practice can be considered to be exempt from the obligation to notify and it is possible to abandon the radiation protection procedure, only having to carry out new measurements every three years. On the other hand, if the results show that the declared values have been exceeded, it is necessary to assess the effective dose to the workers and to the representative person and, if the assessments show that the dose to these subjects does not exceed the exemption values, the activity can be considered to be exempt from the notification obligations and it is possible not to carry out the radiation protection program, although it is necessary to repeat the measurements every three years. Conversely, if the exemption levels are exceeded in terms of dose to the worker and the representative individual, Title XI, which deals with the exposure of workers, must be applied [1].

CONCLUSION

The new discipline introduced by Legislative Decree No. 101/2020 transposed the indications of European Directive 59/2013, proposing an articulated system of protection for workers exposed to ionizing radiation.

The tools used to increase the level of protection of these categories of workers are of a different nature, and it is too early to assess the effectiveness of the proposed measures.

In this new context, medical professionals play a leading role. In this renewed context, medical professionals play a leading role. The figure of the authorized medical stands alongside other figures involved in the occupational radiation protection matter, to whom the legislator has assigned differentiated, but coordinated tasks in order to elaborate a reliable and detailed Risk Assessment Document.

As mentioned above, the drastic reduction in the dose limit for the lens is a tool for more effective protection of workers. It has already been said that the implementation of the Directive is the result of studies that have demonstrated sufficient protection below the codified limits. These data could make it possible to propose to workers exposed to radiation the adoption of more effective protective measures and, for the professionals responsible for measurement, more accurate dosimetric evaluation methods. For example, the guidelines (ISTISAN 15/41) propose the use of a TLD dosimeter as the optimal option.

We have mentioned the creation of a National Radon Action Plan. This is an important novelty that can, under several profiles, increase the effectiveness of the protection of Legislative Decree no. 101/2020. The existence of such a plan will be essential to achieve several objectives. The existence of such a plan will be essential in order to achieve several objectives: firstly, to identify the work activities for which the risk of exposure in the workplace deserves to be measured; secondly, to specify the instruments recognized by the law as appropriate for fulfilling the measurement obligations, and to provide operational models, such as guidelines and procedures, as well as criteria that will make it possible to identify the areas of greatest criticality (the decree clarifies that, if radon concentration data or normalized data are available for the ground floor, the Regions and Autonomous Provinces will define as "priority areas" those in which at least 15% of the buildings exceed the reference value). As regards the so-called NORM industries, moreover, protection is also enhanced through the expansion of the industrial sectors to which the new discipline applies and which had not previously been involved in the legislation dedicated to radiation protection (such as cement factories, geothermal energy, systems for the filtration of groundwater, to name just a few examples; furthermore, two types of activities are to be considered: those relating to the use or storage of materials that contain radionuclides of natural origin and those relating to the production of residues or effluents that contain radionuclides of natural origin. With regard to the latter, Legislative Decree 2020 also precisely regulates the disposal of residues produced by the NORM industries, introducing a distinction between "exempt" and "non-exempt".

Residues are "exempt" when their radiological content is lower than the general removal levels, *i.e.* they are considered to be of no radiological relevance and are excluded from the scope of the radiation protection system. They must be managed, disposed of in the environment, recycled or reused, with prior authorization, in accordance with the general regulations on atmospheric emissions or waste management, pursuant to Legislative Decree no. 152 of 3 April 2006. On the other hand, "non-exempt" residues must be disposed of in authorized landfills in accordance with art. 26 of Legislative Decree 101/2020 and in the manner indicated in Annex VII.

ABBREVIATION

ICRP = International Committee on Radiological Protection

CONFLICT OF INTEREST

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