

# RADIATION PROTECTION REQUIREMENTS FOR MEDICAL APPLICATION OF IONIZING RADIATION IN THE REPUBLIC OF MACEDONIA

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**Abstract** – In this paper, the regulatory infrastructure in radiation protection in the Republic of Macedonia is presented. The national radiation protection requirements for the medical application of ionizing radiation are reviewed for both occupational exposed persons and patients undergoing a medical treatment with ionizing radiation and their compliance with the international standards is considered. The gaps identified on the national level are presented and steps for overcoming such gaps are analyzed.

**Keywords** – radiation protection, ionizing radiation, medical exposure

## 1. INTRODUCTION

Legislative and regulatory framework in radiation protection and safety in the Republic of Macedonia is established with the Law on ionizing radiation protection and safety [1] adopted in 2002 and amended in 2007. This Law [1] establishes a competent authority, the Radiation Safety Directorate (RSD), as an independent governmental institution for carrying out the administrative and professional activities in the field of radiation protection and safety, and nuclear security. The principle functions and activities of the RSD are determined with the Law [1] as following: establishing radiation protection and safety requirements through development of regulations, guides and other acts; licensing practices involving ionizing radiation sources; performing inspections and enforcing the regulatory requirements; maintaining a national register on ionizing radiation sources, occupational exposed persons and nuclear material; establishing intervention levels and undertaking interventions in a case of emergency; establishing institutional and international cooperation on matters within the competence of the RSD etc. Therefore, the radiation protection and safety requirements in different applications of ionizing radiation sources, including the medical application, are to be established and enforced by the RSD.

Pursuant to the Law [1], the Radiation Safety Commission, as an advisory body to the RSD in relation to radiation protection issues, has been established by the director of the RSD consisting of representatives from different institutions determined

in Article 5 of the Law [1]. Moreover, under the current legislation, technical services are clearly separated from the regulatory functions and activities of the RSD. Namely, the Law [1] recognizes the Republic Institute of Public Health Protection (now, Institute of Public Health) as a technical service provider to the RSD. However, the RSD is also given the possibility to give authorization (as prescribed in Chapter II-a of the Law [1]) to other technical service providers for performing different technical services that are required for enforcing the Law itself.

## 2. RADIATION PROTECTION IN MEDICAL APPLICATION OF IONIZING RADIATION

Ionizing radiation sources in the Republic of Macedonia are used in medicine in both diagnostic and therapeutic procedures within different practices: diagnostic and interventional radiology (involving CT's, mammography units, conventional radiography units, fluoroscopy units, dental X-ray units, angiography units etc.), radiotherapy (involving linear accelerators, ortovoltage unit, Co-60 teletherapy unit, LDR brachytherapy unit with Ir-192) and nuclear medicine (diagnostic and therapeutic with I-125, Tc-99m, I-131 etc.). While performing the practice itself, the main responsibility for ensuring radiation protection is given to the legal entity according to Article 13, paragraph 3 of the Law [1]. But, however, according to Article 17 of the Law [1] each person employed or temporary engaged by the legal entity performing practice involving ionizing radiation is obliged to implement the radiation protection and safety requirements set forth in the

Law [1] and the regulations adopted pursuant to this Law.

According to the Law [1], no legal entity could start a practice involving ionizing radiation (including the medical application of ionizing radiation) unless licensed by the RSD. For that purpose, the legal entity should submit license application to the RSD in accordance with [2] in order to demonstrate the compliance with the regulatory requirements. Verification of the fulfillment of all the regulatory requirements is then done during the control and assessment of the license application and with inspection within the licensing process as prescribed with [2]. No license is needed to be granted by the RSD if the legal entity performs a practice involving ionizing radiation source that is exempted or if the radiation exposure is excluded from regulatory control in accordance with [3].

In addition to the Law [1], the regulations [2] and [4] to [7] adopted pursuant to this Law cover some specific radiation protection requirements for the occupational exposed persons as well as some specific radiation protection requirements in connection to the medical exposure. Furthermore, in reference to the medical application of ionizing radiation, some of the regulations inherited from the Former Yugoslavia are still applicable such as [8], [9] and [10].

### 2.1. Basic principles of radiation protection

The Law [1] promotes the three basic principles of radiation protection – justification, optimization and limitation of doses in accordance with the IAEA Basic Safety Standards No. 115 [11] and the Council Directive 96/29 [12]. Therefore:

- No license shall be issued by the RSD according to Article 9 of the Law [1] for a practice involving ionizing radiation that is not justified taking into account all the social, economic and other relevant factors;
- Each legal entity performing a practice involving ionizing radiation shall ensure that the occupational protection and safety is to be optimized in accordance with the ALARA principle; and
- The total dose received by any person shall not exceed the dose limits set in [4] taking into account all the exposure pathways and all the sources of exposure with the exception of the doses incurred within the medical exposure.

The optimization of the occupational radiation protection should be described in more details within the Radiation Protection Programme in accordance with [1] and [7] which is submitted to, and approved by, the RSD within the licensing process in accordance with [1] and [2]. Within the optimization process of the radiation protection, the legal entities are obliged to use

the dose limits set in [4] but they are also encouraged to use reference levels and dose constraints in accordance with [4].

### 2.2 Occupational radiation protection

The legal entity performing a practice involving ionizing radiation, in accordance with Articles 8 and 13 of the Law [1] must, *inter alia*, ensure:

- Suitable and appropriate facilities and equipment for providing radiation protection;
- Personal protective equipment and monitoring equipment;
- Appropriate qualified and trained personnel;
- Health surveillance for the occupational exposed persons;
- Radiation exposure assessment (through both individual monitoring and workplace monitoring);
- Radiation Protection Programme which contains the Emergency Preparedness Plan and the Quality Assurance and Quality Control Programme;
- Appropriate internal organization and management; and
- Maintaining records in connection with the ionizing radiation sources, occupational exposed persons, radiation protection and safety measures,

which is in line with the IAEA Basic Safety Standards No. 115 [11] and the Council Directive 96/29 [12]. The legal entity should demonstrate compliance with the above mentioned radiation protection requirements in connection with the occupational radiation exposure within the licensing process. A detailed description on how these requirements are met should be given in the Radiation Protection Programme in accordance with [7]. Some specific requirements in connection with the: suitable and appropriate facilities and equipment; qualifications and training of the persons engaged in work with ionizing radiation; health conditions to be fulfilled by any person engaged in work involving ionizing radiation and the health surveillance as well as specific requirements in connection to the individual monitoring, workplace monitoring and records maintaining are given in [4] to [10] and [13].

### 2.3 Radiation protection for medical exposure

The Law [1] defines the medical exposure as exposure incurred by:

- patients as part of their own diagnostic or therapeutic procedures;
- persons, other than those occupationally exposed, knowingly while voluntarily

helping in the support and comfort of patients; and

- volunteers in programs of biomedical research involving their exposure,

which is in line with the IAEA Basic Safety Standards No. 115 [11].

The principles of justification and optimization are also applicable with regard to the medical exposure and they are introduced in the national legislation in accordance with the IAEA Basic Safety Standards No. 115 [11] and the Council Directive 97/43 [14]. The other relevant requirements in relation to the medical exposure set in [11] and [14] are also applicable in the Republic of Macedonia. Namely, according to the Article 20 of the Law [1], each medical exposure should be justified by weighing out the diagnostic or therapeutic benefits it produces, against the radiation detriment it might cause, taking into account the benefits and the risks of available alternative techniques not involving a medical exposure. Article 21 of the Law [1] gives the legal entity responsibility to ensure that:

- no patient is administered a diagnostic or therapeutic medical exposure, unless the exposure is prescribed by a medical doctor or medical doctor-specialist;
- doctors are assigned the primary tasks and obligations of ensuring an overall patient protection and safety in the prescription of, and during the delivery of, medical exposure;
- medical and paramedical personnel is available as needed (includes either health professionals or professionals that have appropriate professional training) to implement the assigned tasks related to the diagnostic and/or therapeutic procedures prescribed by a medical doctor or medical doctor-specialist;
- calibration, dosimetry and quality assurance under supervision of a medical physicist or specialist in medical nuclear physics, during diagnostic and/or therapeutic application of ionizing radiation (including teletherapy, radionuclide therapy and brachytherapy); and
- training of personnel in line with the Law [1] and regulations adopted pursuant to this Law.

Moreover, Article 2 of [9] specifies the medical doctors that could be entitled for prescription and approval of diagnostic and therapeutic procedure involving ionizing radiation. Within the process of justifying the diagnostic and/or therapeutic procedure involving ionizing radiation, according to Article 3 of [9], the medical doctor entitled for the prescription of the procedure shall individually justify the procedure itself taking into account the illness, the characteristics (age, gender etc.) of the individual undergoing the procedure, health benefit for the individual as well as the possible detrimental effects for both the individual and the population. In addition

to this, the medical doctor entitled for approval of the diagnostic and therapeutic procedure involving ionizing radiation, according to Article 6, point 1 of [9] shall determine whether the medical exposure is justified for obtaining the necessary diagnostic information or achieving the needed therapeutic effects taking into account the available alternative techniques which are less risky. The previous diagnostic examinations involving ionizing radiation shall be taken into account with the process of justifying the additional referral of an individual to a procedure involving ionizing radiation where applicable as prescribed in Article 7 of [9]. The medical doctor entitled to approve the medical exposure in accordance with the Article 6, point 3 of [9] is obliged not to allow undergoing diagnostic and therapeutic procedure involving ionizing radiation unless justified. Article 6, point 2 of [9] states that the medical doctor entitled to approve the medical exposure in accordance with the provisions of the same regulation, should determine the conditions for carrying out the procedure so as to ensure that the doses incurred by an individual undergoing the procedure are kept as low as reasonably achievable consistent with the required diagnostic information or the intended therapeutic effects from the procedure.

In addition, with regard to the radiation protection for a medical exposure, according to Article 7 of [7], the legal entity should also ensure:

- written protocols for each standard imaging procedure;
- information and/or instructions for patients, person willingly helping the patients, pregnant women, and/or volunteers knowingly exposed to ionizing radiation for a scientific, medical and biomedical research in relation to the medical exposure and the radiation risks; and
- information and/or instructions for patients undergoing treatment with unsealed radioactive sources and the procedure of providing the information/instructions in relation to the medical exposure and the radiation risks,

which is in line with the IAEA Basic Safety Standards No. 115 [11] and the Council Directive 97/43 [14]. The Law [1] and the same regulation [7] also gives responsibility to the legal entity for ensuring the quality control of the equipment used in the medical exposure and the programme for ensuring the quality control should be described in detail in the Radiation Protection Programme.

Some specific requirements for maintaining records on the procedure undergone by an individual including the assessed dose or the activity and the type of radiopharmaceutical applied and other data needed for patients' dose assessment as well as requirements related to the conditions to be fulfilled when applying unsealed sources in nuclear medicine, X-ray equipment in diagnostics and sealed sources in radiotherapy are set in [9].

Within the process of optimization of the radiation protection of persons that voluntarily participate in medical and bio-medical researches and radiation protection of persons that voluntarily help patients undergoing medical treatment or diagnostic or they are visiting them, article 6, paragraph 2 of [4] promotes use of dose constraints in accordance to the IAEA Basic Safety Standards No. 115 [11] and the Council Directive 96/29 [12]. The aforementioned dose constraints are given in article 16 of [4] in accordance with the IAEA Basic Safety Standards No. 115 [11].

The legal entity should demonstrate compliance with the above mentioned radiation protection requirements for medical exposure within the licensing process. A detailed description on how these requirements are met should be given in the Radiation Protection Programme in accordance with [7].

### 3. CONCLUSION

The legislative and regulatory framework in the field of radiation protection (for both occupational radiation protection and radiation protection for medical exposure) in the Republic of Macedonia is established, generally, in line with the international safety standards and the EU acquis. But, however, the established framework should be improved mainly through adoption of new regulations that fully transpose the EU acquis into the national legislation, in particular, the Council Directive 97/43 [14]. Namely, definition of the medical exposure given in the Law [1] does not include the exposure of individuals as part of: their occupational health surveillance; health screening programmes; and medico-legal procedures and therefore, no specific requirements regarding such exposures have been developed so far. However, procedures established by the legal entity in case of such exposures should be described in detail in the Radiation Protection Programme in accordance with [7]. In order to facilitate better implementation of the regulatory requirements for radiation protection in medical application of ionizing radiation, it is necessary to foresee preparation and adoption of guides and manuals that are intended to specifically address how some of the provisions set in the Law [1] and the regulations adopted pursuant to this Law, are to be implemented by the legal entities.

Moreover, the knowledge of the persons involved in work with ionizing radiation in the field of radiation protection and safety is recognized as an important issue. Therefore, a specific regulation has been adopted by the RSD with regard to the type of training and the training curriculum to be provided for the radiation protection officers and the occupational exposed persons. This regulation [13] establishes the system of training necessary for ensuring an appropriate knowledge in radiation protection and safety for all persons involved in work

with ionizing radiation. But however, the implementation of this regulation [13] is subject to delayed implementation. Namely, this regulation [13] does not specify any institution for providing such trainings which is to be specified in the Law according to the national legal system.

In order to comply with the international standards, the following issues were also identified as needed to be addressed on the national level:

- the necessity for establishment of quality control criteria;
- the establishment of diagnostic reference levels; and
- the optimization of imaging protocols.

Therefore, with regard to the establishment of the quality control criteria, a specific regulation is under preparation by the RSD in line with the RP 91 [15] and IAEA TECDOC Series No. 1040 [16]. Other regulation under preparation by the RSD also establishes the diagnostic reference levels on the national level in line with IAEA Basic Safety Standards No. 115 [11] and RP 109 [17].

The RSD is aware of the existing gaps in the field of radiation protection in medical application of ionizing radiation. Their overcoming represents a challenge for the RSD which could be achieved through: amending and supplementing the existing Law and preparation and adoption of new regulations, guides and manuals in the field in line with the international standards and the EU acquis; enhancing the institutional cooperation; preparation and implementation of specific national projects; promotion of the safety culture as well as further strengthening the control over the ionizing radiation sources in the Republic of Macedonia.

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