

BRAZILIAN JOURNAL OF RADIATION SCIENCES 06-02-B (2018) 01-09



Radiological protection and certification for medical professionals in Brazil

Castro Luz^a C.P.V., Sá^a L.V., Delgado^a J.U.

^a Instituto de Radioproteção e Dosimetria, 22783-127, Rio de Janeiro, RJ, Brasil camille@ird.gov.br

ABSTRACT

Radiation protection is supported by three pillars: justification, optimization and dose limitation. The safe use of ionizing radiation is governed by the limits of public and occupational exposure, justification and optimization for medical exposures. In Brazil there are at least 200,000 professionals working in medical facilities that involve the use of ionizing radiation. There are standards in radiation protection that establish the obligation of the performance of certified professionals in the facilities through pre-established criteria. The certification in radiation protection assesses the skills, knowledge and competence of the professionals. A survey, classification and detailed analysis of the mandatory requirements by the regulatory body for professional performance in this area were carried out as well as the competencies and skills required in the radiation protection standards in force in the country. The results obtained in this evaluation demonstrated that the certification process of these professionals aims at higher quality and optimization of the medicals procedures performed. The direct beneficiaries of this process would be the practitioners themselves and patients of medical practices involving the use of ionizing radiations. Certifying medical professionals in radiation protection would meet the demand of national standards that require a quality control of those involved in medical treatments using ionizing radiations.

Keywords: radiation protection, certification, regulatory body, medical professionals.

ISSN: 2319-0612 Accepted 2018-07-23

1. INTRODUCTION

Radiological protection aims the use of ionizing radiation to the public benefit, covering all exposures incurred by people and the environment, always protecting human beings and the ecosystem of possible undesirable effects [1]. For this, the radiation protection (RP) is based on three basic principles: justification, optimization and dose limitation. The safe use of ionizing radiation is governed by public and occupational exposure limits and by individual monitoring of workers. These limits are based on international recommendations from IAEA (International Atomic Energy Agency) and ICRP (International Commission on Radiological Protection) besides national standards. CNEN (National Nuclear Energy Commission) is the Brazilian Regulatory Body responsible for stablished radiation protection standards in Brazil within the framework of the use of ionizing radiation in nuclear medicine practices, radiation therapy and individual monitoring [2].

There are at least 200,000 professionals in Brazil who work in medical facilities involving the use of ionizing radiation, including interventionists, nurses, medical physicists, pharmacists, and technicians in radiation therapy and radiology. The resolution no. 453 from Brazilian Ministry of Health, published in 1 June 1998 [3], has the approved technical regulation in the country to establish "basic guidelines for radiological protection in medical and dental diagnostic radiology", and "rules on the use of diagnostic X-ray in the national territory and other matters" [3]. Chapter 3 of this regulation requires on the implementation of an organizational structure with the definition of the responsibilities of the Radiation Protection Supervisors (RPS), technical responsible (RT), and physics in diagnostic radiology, technicians and auxiliaries of the radioactive facilities. Also establishes the obligation of certification for RT, RPS and X-ray technicians in diagnostics for acting on the facilities through pre-established criteria. Certification in the area of radiation protection assess the skill, knowledge of each professional and aims to improve quality and optimization of medical procedures performed. The direct beneficiaries would be professionals and patients of medical practices involving the use of ionizing radiation. This certification of the medical professionals would meet the standard

requirements that demand the fulfillment of the quality control of all personnel involved in medical treatment or diagnosis procedures using ionizing radiation.

The certification process for professionals consists of a third party giving written assurance that the competence of a personal complies with specified requirements so that the latter can perform a function. These requirements are usually specified in standards that regulate the practice. In Brazil the requirements for radiation protection (RP) certification are related to the standards from CNEN, the resolution n° 453 from the Ministry of Health, and RDC n° 20 [4] and 38 [5] from ANVISA (National Agency of Sanitary Surveillance)

It is important to point out the difference between certification and qualification of a professional to practice a profession. Qualification of a professional consists of providing education, qualification, training and even professional experience to a person to pursue their profession [6]. Unlike certification, qualification in Brazil is provided by the MEC (Ministry of Education) through the registration of graduation or technical courses. The post-graduation courses, whether *lato sensu* or *stricto sensu*, are also not considered certification scheme for a professional, but specialization courses [7].

In Brazil the certification process must be carried out by a certifying body accredited by the National Institute of Metrology, Quality and Technology (INMETRO) that evaluate its competence in the work in front of the requirements required in a qualification standard. INMETRO is the only representative of Brazil in the Agreement of Mutual Recognition of the International Conference of Accreditation of Laboratories (ILAC) since 2000 [8]. It is INMETRO that defines the criteria requirements for bodies operating certification of persons in the country [9]. Currently there is no body certifying persons in the RP area that is accredited by INMETRO. There are some class associations that provide *certification* for your affiliates, such as the Brazilian College of Radiology and Diagnostic Imaging (CBR). However, these organizations are not bodies operating certification of persons in the RP accredited by INMETRO [10].

2. MATERIALS AND METHODS

The methodology adopted here was to carry out a detailed analysis of CNEN standards CNEN- NN-6.01 [11], CNEN-NN-3.01 [12], CNEN-NN-3.05 [13], CNEN-NN-6.10 [15], CNEN-NN-7.01 [16], regulations from Ministry of Health no. 453 [3] and ANVISA RDC / n° 20 [4] and n° 38 [5], with a view to the certification of professionals working in radiotherapy, radiodiagnosis and nuclear medicine. In this way, the minimum regulatory requirements in the country with regard to certifications for performance of medical professionals using ionizing radiation were evaluated.

Also were analyzed the knowledge and skills required of certified professionals in the light of the specific radioprotection standards, emphasizing the requirements related to training and experience for professionals cited in the reference documents.

3. RESULTS AND DISCUSSION

From the detailed analysis of the Brazilian standards that deal with radiological protection in medical field it was possible to evaluate the necessary requirements to professional certifications. The observations found, showed in table 1, were:

- The certification of radiological protection officers (RPO) is currently regulated and conducted by CNEN, having established processes for the practices of radiotherapy and nuclear medicine, but no for radiology. For this practice, the qualification of professionals is defined by regulation no. 453/98, however for such qualification and proof of knowledge mentioned, there is not a Brazilian institution that offers this service;
- For certification of the qualification and proof of professional knowledge in the area of radiology cited in articles 3.36 and 3.32 (no. 453/98), also there is not a Brazilian institution that offers this service. When considering about of 36,000 facilities [14], with two technicians on average by equipment, there are 72,000 technicians or technologists working currently in this area without their respective qualification certification. The same is true for

- dentistry, considering the operation of approximately 45,000 equipment installed [14], there is a need for at least 46,000 technicians or auxiliaries to be certified;
- For nuclear medicine CNEN-NN-3.05 standard [13] defines the requirements and qualifications for physicians (RT) and RPO, as well as the sufficient number of professionals at the upper and middle level, who are appropriately qualified to perform their duties. This standard also stipulates that there should be a specialist physicist, but does not specifically refer to the medical physicist (MP) in nuclear medicine; does not even mention its attribution in the planning of doses in radionuclide therapy, a function worldwide attributed to MP. There is a discrepancy between the numbers of MP certificates in radiotherapy in relation to the specialty in nuclear medicine;
- For radiotherapy the professionals' assignments in the area of treatment planning and equipment quality control are well defined in CNEN and ANVISA standards; there was no repressed demand in the sector for the certification of professionals in this area.
- It was observed that there are professionals who work in nuclear medicine, radiotherapy or radiology who do not have their qualification and certification required by current regulations. One can mention the radiopharmacist, which is present in nuclear medicine services, in the radionuclide and radiopharmaceutical production sites and in centralized or industrial radiopharmacies. Radiologists and dentists, although cited in the standards, are not certified in radiation protection by CNEN or any other institution established for that purpose. There is no certification process implemented in the country for the RT, responsible for maintenance of the equipment, even this professional being required in the CNEN and ANVISA RDC 20 [4] standards for radiotherapy. The number of professionals working in this sector is not registered in any organization leading to no professional quantification or statistical study can be carrying out or published in the literature. However, the importance of certifying the competence, qualification and skills of these workers is undoubtedly a priority;
- The design of the radiative installation, whether in radiology, nuclear medicine or radiotherapy, plays an important role in the radiological protection of workers and the surrounding public. These projects are now conducted by physicists, engineers and architects, but have presented serious conceptual problems of calculation, especially in those

aspects involving radiation protection, which has delayed the licensing process. As an example, CNEN-NN-6.10 [15] mentions the professionals responsible for the design of shielding calculations in order to grant authorization to build the radioactive facility. However, today there is no estimate of the number of professionals working in this area, nor at least if the basic requirements to be met to certify the professional are stipulated;

- CNEN-NN-6.01 [11] mentions the professional for self-contained cell irradiators, which can also be operators of blood irradiators in hospitals and gamma cells in a research laboratory. It is known, however, that the number of professionals working in this area is also not registered and their certification by qualification is not established; and
- The regulatory agency in the PR area in Brazil, CNEN, only performs Radiation Protection Officers (RPO) certification by CNEN-NN-7.01 [16] which requires college level qualification, in a process of personnel certification who is not yet accredited by INMETRO.

Table 1: Certifications in radiation protection required by Brazilian standards.

Practice	Requirements			
	Worker	Professional qualification	Type of certification ne-cessary	Standard related to RP certification
Radiotherapy	Technical responsible	Doctor Radiotherapist	Certification	CNEN-NN-6.10
Radiotherapy	RPO	University graduate	Certification	CNEN-NN-3.01 CNEN-NN-7.01
Nuclear Medicine	RPO	University graduate	Certification	CNEN-NN-3.05 CNEN-NN-7.01
Nuclear Medicine	Technical responsible	Nuclear Medicine Physician	Registration and / or Certification	CNEN-NN-3.05
Nuclear Medicine	Medical Physicist (MP)	University graduate	Registration	CNEN-NN-3.05
Radiology	RPS	Physics Specialist in radiology or medicine or dentistry	Certification	Regulation 453/98
Radiology	Technical responsible	Medicine or dentistry	Certification	Regulation 453/98
Radiology	Technical of X-ray diagnostic	Radiology technician	-	Regulation453/98

In summary the results of the assessment of regulatory issues in Brazil have shown that there is urgency in the implementation of Radiation Safety Professional certification process in medical field in order to obtain greater safety for patients and workers with the optimization of procedures performed on the premises. Also, it was observed that there is no a national body certifying persons in the PR area accredited by INMETRO [10]. Currently the personnel certification programs of these professionals has been carried out by private associations or institutions, without control of the country's regulatory and accreditation body. Therefore, the number of certified professionals cannot be calculated accurately, nor statistical data can be evaluated in this field.

4. CONCLUSIONS

It has been demonstrated that radiological protection certification for all medical professionals, covering nuclear medicine, radiotherapy and radiology, would meet the demand contained in national and international standards that require a quality control restricted to personnel involved in medical practices that use ionizing radiation. In order to increase the reliability of the safe use of ionizing radiation in Brazil the authors emphasize the need to promote a basic understanding among regulators, CNEN and ANVISA, to review their standards and include the requirement to certify the qualification of these professionals. It was concluded that there is an urgent need for a body certifying persons in the area of RP issues accredited by INMETRO, since the institutions that currently intend to perform this task are not accredited by the only accrediting body in the country.

REFERENCES

- [1] ICRP International Commission on Radiological Protection. **Proceedings of the third international symposium on the system of radiological protection. Annals of ICRP Volume 45 N° 1S**, ICRP, 2016. 380p.
- [2] NAVARRO, MVT. **Risco, radiodiagnóstico e vigilância sanitária,** [online], Salvador: EDUFBA, 2009, 166 p. ISBN 978-85-232-0620-8.

- [3] ANVISA Agência Nacional de Vigilância Sanitária, Secretaria de Vigilância Sanitária, **Diretrizes básicas de proteção radiológica em radiodiagnóstico médico e odontológico, dispõe sobre o uso dos raios-X diagnósticos em todo território nacional e dá outras providências**, Portaria nº 453, Diário Oficial da União 103, 2 de june 1998.
- [4] ANVISA Agência Nacional de Vigilância Sanitária, Regulamento Técnico para o funcionamento de serviços de radioterapia, visando a defesa da saúde dos pacientes, dos profissionais envolvidos e do público em geral, RDC/ANVISA nº 20, 02 de february 2006.
- [5] ANVISA Agência Nacional de Vigilância Sanitária, RDC/ANVISA nº 38, **Aprova** o regulamento para os programas de acesso expandido, uso compassivo e fornecimento de medicamento pós-estudo, 12 august 2013.
- [6] Presidência da República do Brasil, Lei nº 9394, **Estabelece as diretrizes e bases da educação nacional**, 20 december 1996.
- [7] Frauches, C.C., **A pós-graduação** *lato sensu*, **a Lei e as normas do MEC**, ABMES Associação Brasileira de Mantenedoras de Ensino Superior, available in http://www.abmes.org.br/public/documentos/detalhe/352/a-pos-graduacao-lato-sensu-a-lei-e-as-normas-do-mec, 2014.
- [8] Soares, M.A., Costa, H.G. Acordos de reconhecimento mútuo na acreditação de laboratórios, [online], XI SIMPEP Bauru SP, Brazil, 2004.
- [9] INMETRO Instituto Nacional de Metrologia, Qualidade e Tecnologia, norma INMETRO NIT-DICOR-004, **Critérios para a acreditação de organismo de certificação de pessoas**, Rev. 12, june 2016.
- [10] INMETRO Instituto Nacional de Metrologia, Qualidade e Tecnologia, available in http://www.inmetro.gov.br/organismos/resultado_consulta.asp in june 2017
- [11] CNEN Comissão Nacional de Energia Nuclear, norma CNEN NN 6.01, Requisitos para os registros de pessoas físicas para o prepare, uso e manuseio de fontes radioativas, resolução CNEN 005/99, 1999.
- [12] CNEN Comissão Nacional de Energia Nuclear, norma CNEN-NN-3.01, **Diretrizes básicas de proteção radiológica**, resolução CNEN 164/14, 2014.

- [13] CNEN Comissão Nacional de Energia Nuclear, norma CNEN-NN-3.05, **Requisitos de segurança e proteção radiológica para serviços de medicina nuclear,** resolução CNEN 159/13, 2013.
- [14] CNES Cadastro Nacional de Estabelecimentos de Saúde, available in http://cnes.datasus.gov.br/, accessed in june, 2017
- [15] CNEN Comissão Nacional de Energia Nuclear, norma CNEN-NN-6.10, **Requisitos de segurança e proteção radiológica para serviços de radioterapia**, resolução CNEN 214/17, 2017.
- [16] CNEN Comissão Nacional de Energia Nuclear, norma CNEN-NN-7.01, Certificação da qualificação de supervisores de proteção radiológica, resolução CNEN 194/16, 2016.