ARTÍCULO ORIGINAL

Quality Management System and Quality Assurance Programs in Radiotherapy in the Light of Regulations Applicable in México

Johnatan Peña-Ramírez,[1,3,*] Héctor Mendoza-Nava,[1,2,*] Miguel Valle-González,[3] Jonathan Elizalde-Cabrera,[4] Verónica Vélez-Donis,[3] Steven Rodríguez-Cubillos,[1,3] Ariel Carrera-Martínez,[3] Raúl Guzmán-Trigueros

Abstract

Radiotherapy Quality Management Systems (QMS) and Quality Assurance (QA) Programs have been proposed as an effective tool to ensure consistency between medical prescription and safe delivery of treatment to patients with minimal exposure to staff. In recent years in Mexico, there has been an increase in the acquisition of modern medical linear accelerators for the delivery of highly sophisticated radiotherapy treatments with specific QA requirements. This makes it necessary to review the current regulatory framework on Quality Management, to know if regulatory requirements are sufficient for the establishment, implementation and development of Comprehensive Quality Systems (QS) in radiotherapy centres. The objective of this work is to review the current national regulations in radiotherapy QMS, in particular those referring to standard procedures, human and physical infrastructure, and the implementation of QS in the practice of health care institutions. Results show a first approach to the implementation of quality management systems and quality assurance programs in radiotherapy centres.

KEY WORDS

Mexico, teletherapy, medical physicists, regulation, survey.

Sistemas de Manejo y Programas de Aseguramiento de la Calidad en Radioterapia a la Luz de las Regulaciones Aplicables en México

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Resumen

Los Sistemas de Gestión de Calidad (SGC) y Programas de Aseguramiento de Calidad (AC) en radioterapia se han propuesto como una herramienta efectiva para garantizar la coherencia entre la prescripción médica y la entrega segura del tratamiento a pacientes, con una exposición mínima al personal. En los últimos años, en México se ha incrementado la adquisición de aceleradores lineales médicos modernos para la entrega de tratamientos de radioterapia altamente sofisticados con requisitos específicos de aseguramiento de la calidad. Esto hace necesario revisar el actual marco normativo en materia de Gestión de la Calidad, para averiguar si los requisitos normativos son suficientes para el establecimiento, implantación y desarrollo de Sistemas Integrales de Calidad (SC) en los centros de radioterapia. El objetivo de este trabajo es revisar la normativa nacional vigente referente a los SGC relacionados a procedimientos estándar, infraestructura humana y física, y la implementación de SC en la práctica clínica de las instituciones de salud. Los resultados muestran un primer acercamiento de la implantación de los sistemas de gestión de la calidad y programas de aseguramiento de la calidad en los centros de radioterapia.

PALABRAS CLAVE

México, teleterapia, física médica, regulación, encuesta.

[1]Universidad Autónoma del Estado de México, México. [2]Instituto Nacional de Investigaciones Nucleares, México. [3]Hospital Regional de Alta Especialidad de Ixtapaluca, México. [4]Instituto Nacional de Cancerología, México.
[*]Corresponding author: jpenar006@alumno.uaemex.mx, hector.mendoza@inin.gob.mx

Introduction

Quality is an issue of great importance in the field of radiotherapy (RT). The purpose of quality is to provide a safe treatment that avoids inappropriate radiation exposures to patients and work personnel. The absence of Quality Assurance (QA) programs in RT can lead to clinical accidents.[1-3] Sometimes, these accidents have been the reason for the modification or creation of new regulations.[4] Quality is defined by the International Organization for Standardization (ISO) as "the ability to satisfy customers, and by the intended and uninformed impact on relevant stakeholders".[5] In the field of health, this term is complex because, unlike a physical product, health service is intangible and depends on the processes of the service.[6] The World Health Organization (WHO) states that quality must be effective, safe and people-centred.[7]

Quality assurance in RT is defined by WHO as "all those procedures that ensure consistency of the medical prescription and the safe fulfilment of that prescription as regards dose to the target volume, together with minimal dose to normal tissue, minimal exposure of personnel, and adequate patient monitoring aimed at determining the result of treatment".[8] Similarly, Quality Management System (QMS) is defined by International Atomic Energy Agency (IAEA) as "The set of actions necessary to ensure that a product conforms to certain quality standards".[9]

The current approach of QMS and QA programs in RT involves the creation of continuous improvement programs, quality control of equipment, models of failure modes and risk analysis that maximize the quality of patient care and safety of patients and staff.[1,3,10-12] International organizations such as WHO, IAEA, and the American Association of Physicists in Medicine (AAPM) have published recommendations for implementing QMS and QA programs in RT centres.[8,13-17] The aim of these is not only to provide technical recommendations but also to standardize these quality programs.

Background

In Mexico, radiation therapy is practised in most states through 110 RT centres with 171 high-voltage equipment and 70 brachytherapy sources.[18] In recent years, the acquisition of modern LINACs for the administration of highly sophisticated treatments with specific QA requirements has increased. This makes it necessary to review the current regulatory framework on Quality Management, to know if the regulatory requirements are sufficient for the establishment, implementation and development of Comprehensive Quality Systems (QS) in radiotherapy centres.

Materials and Methods

The review of the regulatory framework included the Reglamento General de Seguridad Radiologica (RGSR);[19] NOM-012-STPS-2012, Condiciones de seguridad y salud en los centros de trabajo donde se manejen fuentes de radiación ionizante;[20] NOM-033-NUCL-2016, Especificaciones técnicas para la operación de unidades de teleterapia: Aceleradores lineales;[21] NOM-002-SSA3-2017, Para la organización y funcionamiento de los servicios de radioterapia;[22] and Ley de la Infraestructura de la Calidad.[23]

Implementation of QS in health care institutions was carried out through an anonymous survey of RT centers in the country with LINAC equipment. The survey was sent to radiation safety officers, thus eliminating the uncertainty of an institution answering the same questionnaire twice. The data collection time was two months and integrated the eight regions of the country classified as Northwest, Northeast, West, East, North Central, South Central, Southwest and Southeast. This research protocol was presented to an ethics and re-

search committee at the Hospital Regional de Alta Especialidad de Ixtapaluca. Quality indicators already reported,[24-26] were integrated into the survey.

Results and discussion

The RGSR was issued in 1988 and concerns all regarding radiation safety. This regulation states that any facility that uses ionizing radiation (IR) must have a Radiation Safety Report containing, among other things, a quality assurance program; risk analysis and emergency plans. Although the RGSR establishes essential guidelines related to radiation safety, it remains unchanged since its publication, although the International Commission on Radiological Protection (ICRP) has updated the annual dose limit values for workers exposed to IR; and radiation, organ and tissue weighting factors.[27,28]

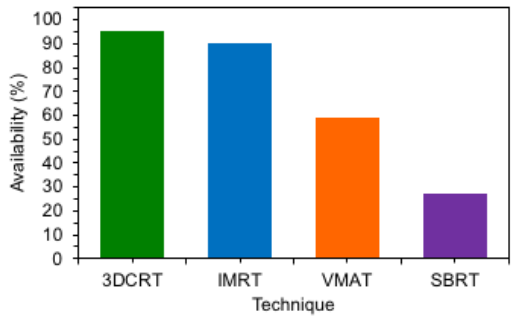
Regarding current national regulations, NOM-012-STPS-2012 establishes the importance of risk prevention for workers, infrastructure and the environment who use IR. An approach to incident learning would help complement this regulation. On the other hand, NOM-033-NUCL-2016 establishes the technical specifications to operate LINACs and establishes a set of tests to verify the performance of the safety, mechanical and dosimetry systems. Currently, this set of tests is used as a quality control program in RT centres. It is relevant to mention that this regulation is focused on equipment with Three-Dimensional Conformal Radiation Therapy (3DCRT) capabilities. Therefore, it can be complemented by adding quality control tests to provide Intensity Modulated (IMRT) and Stereotactic Body Radiation Therapy (SBRT) treatments. Moreover, this regulation does not include verification tests to Treatment Planning Systems (TPS).

Regarding NOM-002-SSA3-2017, it establishes the criteria and characteristics that every radiotherapy centre must have to provide a service with safety and quality. This regulation states that medical physicists are responsible for developing and implementing QA programs for the physical aspects of the medical use of IR. Despite this, there is no national reference document that standardizes the implementation of QMS and QA programs in RT.

Recently in Mexico, in 2020, the Ley de la Infraestructura de la calidad was approved. One of its main objectives is to promote technological innovation in processes and services to improve the quality of life of people through, among other aspects, evaluations and accreditations. This law is particularly of interest because it evaluates the conformity of NOM-033-NUCL-2016 and provides the possibility of accrediting and certifying not only RT centres but also RT treatment techniques. Currently, the regulatory framework does not include audit programs as a fundamental part to review and improve QS in RT centres. Concerning the survey sent to the country's radiotherapy centres. A total of 22 questionnaires were answered covering the Northwest, North Central, South Central, Southwest and Southeast regions of the country. Results are shown in table 1.

Graph 1

Capacity and availability of TPS for different treatment techniques



Source: Own elaboration.

LINAC availability and planning systems capabilities

Results related to the availability of LINAC equipment show that most RT centres (54.2%) have one teletherapy equipment, followed by two units in 25% and only 20% of the services have more than three equipment. Results also indicate that most RT centres offer 3DCRT with 95.5%. The second treatment technique that most services can offer is IMRT with 90%. Despite this, the current regulatory framework does not indicate QA processes for this technique. Finally, only 27% of them have the infrastructure to provide SBRT treatments (graph 1).

Quality control tests to TPS and LINAC

Results related to quality control tests on LINAC and TPS equipment indicate that, although current regulations do not establish verification tests for TPS, 59% of the centres perform quality control tests on these systems. Similarly, the results show that 73% of the centres complement the tests established in NOM-033-NUCL-2016 to verify the correct performance of the LINACs.

Quality management systems and quality assurance programs

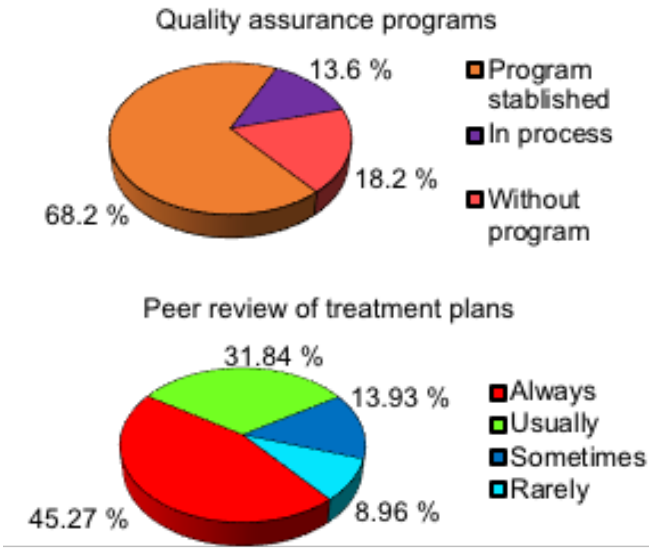
Results regarding the implementation of QA programs and QMS in the RT centres indicate that 68.2% of the services have established a program, 13.6% are in the process of being created and just 18.2% do not have them. In addition, most of these programs are based on IAEA and AAPM recommendations and only 4.5% of the centres consider ISO 9001 standards (figure 1). Highlights of QMS practice include peer review of treatment plans among medical physicists and participation in external postal audits with up to 45.5% and 82% of the RT centres surveyed, respectively (graph 2) and just one RT centre which has already a treatment technique accredited by The MD Anderson institute (table 1). In addition to this, results show that most RT services do not have an internal incident reporting program and Incident Learning System (ILS). Currently, these programs are essential in QMS. Therefore, although there are currently international recommendations available to implement QS, the development of local guidelines is required to guide RT centres to establish and standardize these programs in our country.

The lack of local guidelines and regulatory frameworks is not unique problem for our country but also for others, which in response to this, they have adopted recommendations of international standards to develop QMS in their RT centres. In The Netherlands,[30] RT centers have adapted ISO 9001 standards in response to local regulations requiring the development of QMS. In Poland,[4] regulations have been developed for the implementation of QMS programs in RT, mainly due to radiological incidents such as the one that occurred in Bialystock, 2001. In Canada, Italy and Spain, organizations and researchers have proposed guidelines and quality indicators for the evaluation and implementation of QMS for radiation treatment programs.[24-26,31]

Graph 2

a) Percentage of quality assurance programs established.

b) Medical physicist peer review of treatment plans.



Source: Own elaboration.

Table 1

Results of the survey applied to radiotherapy centres

Availability of planning systems for different radiotherapy techniques			
3DCRT 95.5%	IMRT 90%	VMAT 59%	SBRT 27%
Established program of a quality management and assurance system			
Yes 68.2%	In the process of creation 13.6%	No 18.2%	
Reference documents to implement QMS and QA Programs			
OIEA/AAPM 90%	National Regulations 82%	ISO 9001 4.5%	
Medical physics peer-review of treatment plans			
Always 45.5%	Usually 32%	Sometimes 14%	Hardly ever 9%
Treatment techniques accredited by international institutions			
Yes 4.5%		No 95.4%	
Participation in IAEA/WHO postal audits or similar			
Yes 82%		No 18%	
Quality control tests complementary to NOM-033-NUCL-2016			
Yes 73%		No 27%	
Quality control tests to Planning Systems (TPS)			
Yes 59%		No 41%	
Internal incident reporting program			
Yes 45.5%	No 41%	In the process of creation 13.5%	
Incident Learning System			
Yes 23%	No 64%	In the process of creation 13%	
Current national regulatory framework is sufficient to stablish QMS and QA programs			
Yes 22.7%	No 22.7%	It can be complemented 54.6	

Source: Own elaboration.

Conclusion

The present review shows that quality management systems and quality assurance programs in radiotherapy are essential tools that prevent possible incidents and allow maximize the resources of services. Currently in Mexico, although radiotherapy services have had the initiative to develop and implement their own QMS and QA programs, these are not standardized due to the lack of a regulatory framework for radiotherapy. As a consequence, although these programs are good, they lack essential aspects such as internal and external audit programs, accreditations, incident reporting

systems and incident learning systems. Hence, development of local guidelines is required to guide RT centres to establish these programs.

In conclusion, this work shows a first approach to the current implementation of quality management systems and quality assurance programs in radiotherapy centres in the country. Complementary studies, with a broader participation of radiotherapy services, can help to have a better understanding and establish the current status of the implementation of QMS and QA programs in the country.

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Conflicts of interest:
None declared.

References

1. International Commission on Radiological Protection. ICRP publication 112. A report of preventing accidental exposures from new external beam radiation therapy technologies. Vol. 39, Annals of the ICRP. 2009.
2. Novonty J. Accidents in Radiotherapy: Lack of Quality Assurance? En IAEA-TECDOC-989 Quality Assurance in Radiotherapy [Internet]. Vienna: IAEA; 1997. Disponible en https://www.iaea.org/publications/search/type/tecdoc-series?keywords=.
3. Fraass BA. Errors in Radiotherapy: Motivation for Development of New Radiotherapy Quality Assurance Paradigms. Int J Radiat Oncol Biol Phys. 2008;71(1 SUPPL.):162-5.
4. Bogusz-czerniewicz M. Quality management system in radiotherapy in the light of regulations applicable in Poland. Wspolczesna Onkol. 2012;16(2):140-6.
5. International Organization for Standarization. ISO 9000:2015 Quality management systems –Fundamentals and vocabulary [Internet]. 2015 [citado el 22 de julio de 2021]. Disponible en https://www.iso.org/standard/45481.html.
6. Mosadeghrad AM. Healthcare service quality: Towards a broad definition. Int J Health Care Qual Assur. 2013;26(3):203-19.
7. World Health Organization (WHO). Handbook for National Quality Policy and Strategy [Internet]. WHO; 2018. Disponible en: http://www.who.int/servicedeliverysafety/areas/qhc/nqps_handbook/en/%0Ahttp://apps.who.int/iris/bitstream/handle/10665/272357/9789241565561-eng.pdf?ua=1.
8. World Health Organization (WHO). Quality assurance in radiotherapy. Geneva: WHO; 1988.
9. Organismo Internacional de Energía Atómica. Aspectos Clínicos de la Garantía de Calidad en Radioterapia: Guía de Gestión de Calidad Clínica. Vienna: IAEA; 2015.
10. Choi WH, Cho J. Evolving clinical cancer radiotherapy: Concerns regarding normal tissue protection and quality assurance. J Korean Med Sci. 2016;31(1):S75-87.
11. Huq MS, Fraass BA, Dunscombe PB, Gibbons JP, Ibbott GS, Mundt AJ, et al. The report of Task Group 100 of the AAPM: Application of risk analy-

sis methods to radiation therapy quality management. Med Phys. 2016;43(7):4209-62.
12. Symonds P, Mills JA, Duxbury A. Walter and Miller's TEXTBOOK OF RADIOTHERAPY Radiation Physics, Therapy and Oncology. Eighth. El Sevier; 2019.
13. International Atomic Energy Agency. Quality assurance in radiotherapy. Proceedings of the Working Meeting on National Programmes: Design, Harmonisation and Structures jointly organized by the International Atomic Energy Agency and the International Society for Radiation Oncology and held in. Vienna: IAEA; 1997.
14. International Atomic Energy Agency. Commissioning And Quality Assurance Of Computerized Planning Systems For Radiation Treatment Of Cancer [Internet]. Vol. 430, Technical reports series No. 430. Vienna: IAEA; 2004. Disponible en: https://www.iaea.org/publications
15. Klein EE, Hanley J, Bayouth J, Yin FF, Simon W, Dresser S, et al. Task group 142 report: Quality assurance of medical acceleratorsa. Med Phys. 2009;36(9):4197-212.
16. International Atomic Energy Agency. Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement [Internet]. Vienna: IAEA; 2007. Disponible en: https://www.iaea.org/publications.
17. Hanley J, Dresser S, Simon W, Flynn R, Klein EE, Letourneau D, et al. AAPM Task Group 198 Report: An implementation guide for TG 142 quality assurance of medical accelerators. Med Phys. 2021.
18. International Atomic Energy Agency. DIRAC Directory of Radiotherapy Centres [Internet]. 2018 [citado el 30 de junio de 2021]. Disponible en https://dirac.iaea.org/.
19. Comisión Nacional de Seguridad Nuclear y Salvaguardias. Reglamento General de Seguridad Radiológica [Internet]. México; nov 22, 1998. Disponible en https://www.gob.mx/cnsns/documentos/reglamento-general-de-seguridad-radiologica.
20. Secretaría del Trabajo y Prevensión Social. NORMA Oficial Mexicana NOM-012-STPS-2012, Condiciones de seguridad y salud en los centros de trabajo donde se manejen fuentes de radiación ionizante. México; 2011.
21. Secretaría de Energía. NORMA Oficial Mexicana NOM-033-NUCL-2016, Especificaciones técnicas para la operación de unidades de teleterapia: Aceleradores lineales. México; 2016.
22. Secretaría de Salud. NORMA Oficial Mexicana NOM-002-SSA3-2017, Para la organización y funcionamiento de los servicios de radioterapia. México. 2017.
23. Ley de Infraestructura de la Calidad. México; jul 1, 2020 p. 1-63.
24. Canadian Partnership for Quality Radiotherapy, Canadian Association of Radiation Oncology, Canadian Organization of Medical Physics, Canadian Association of Medical Radiation Technologists. Quality Assurance Guidelines for Canadian Radiation Treatment Programs [Internet]. 2015. Disponible en: http://www.cpqr.ca/wp-content/uploads/2013/09/QRT2015-12-03.pdf.
25. Cionini L, Gardani G, Gabriele P, Magri S, Morosini PL, Rosi A, et al. Quality indicators in radiotherapy. Radiother Oncol. 2007;82(2):191-200.
26. López Torrecilla J, Marín i Borràs S, Ruiz-Alonso A, Jaen Olasolo J, Vázquez de la Torre ML, Bóveda Carro E, et al. Quality indicators in radiation oncology: proposal of the Spanish Society of Radiation Oncology (SEOR) for a continuous improvement of the quality of care in oncology. Clin Transl Oncol. 2019;21(4):519-33.
27. International Commission on Radiological Protection. The 2007 Recommendations of the International Commission on Radiological Protection. Ann ICRP. 2007;(37):1-337.
28. International Commission on Radiological Protection. 1990 Recommendations of the International Commission on Radiological Protection. Ann ICRP [Internet]. 1991;21(1-3):1-201. Disponible en: http://www.ncbi.nlm.nih.gov/pubmed/2053748.
29. Gobierno de México. Ley Reglamentaria del Artículo 27 Constitucional en Materia Nuclear. México; feb 4, 2012.
30. Leer JWH, Corver R, Kraus JJAM, Togt JC v.d., Buruma OJS. A quality assurance system based on ISO standards: experience in a radiotherapy department. Radiother Oncol. 1995;35(1):75-81.
31. Gabriele P, Maggio A, Garibaldi E, Bracco C, Delmastro E, Gabriele D, et al. Quality indicators in the intensity modulated / image-guided radiotherapy era. Crit Rev Oncol Hematol. 2016;108:52-61.