Physica Medica (2009) **25**, 161–165

available at www.sciencedirect.com

ScienceDirect

journal homepage: http://intl.elsevierhealth.com/journals/ejmp

ORIGINAL PAPER

The European federation of organisations for medical physics policy statement No. 13: Recommended guidelines on the development of safety and quality management systems for medical physics departments☆

Stelios Christofides*

Medical Physics Department, Nicosia General Hospital, 215 Old Nicosia Limassol Road, Strovolos, Nicosia 2029, Cyprus

Received 12 October 2008; accepted 13 November 2008
Available online 6 December 2008

KEYWORDS
Policy statement;
Medical physics;
Safety and quality management;
Recommended guidelines

Abstract This EFOMP Policy Statement outlines the way in which a Safety and Quality Management System can be developed for Medical Physics Departments. The Policy Statement can help Medical Physicists to eliminate or at least minimize accidents or incidences due to improper use or application of medical technology on one hand and on the other to guarantee a safe, effective and efficient usage of new highly complicated and sophisticated technologies and procedures.

Preamble

The rapid advance in the use of highly sophisticated equipment and procedures in the medical field increasingly depends on information and communication technology. In spite of the fact that the safety and quality of such technology is vigorously tested before it is placed on the market, it often turns out that the safety and quality is not sufficient when used under hospital working conditions. To improve safety and quality for patient and users, additional safeguards and related monitoring, as well as measures to enhance quality, are required.

Furthermore a large number of accidents and incidents happen every year in hospitals and as a consequence a number of patients die or are injured [1–4]. Medical Physicists are well positioned to contribute towards preventing these kinds of events.

☆ Disclaimer Note: EFOMP Policy statement No.13 has been approved by EFOMP Council in Krakow (Poland) on 20 September, 2008. Hence this paper has not been subjected to standard peer review, being an official policy statement of the European Federation of Organisations for Medical Physics.

* Tel.: +357 22 603136; fax: +357 22 603137.
E-mail address: cstelios@cytanet.com.cy

1120-1797/$ - see front matter
doi:10.1016/j.ejmp.2008.11.002

This EFOMP Policy Statement outlines the way in which a Safety and Quality Management System can be developed for Medical Physics Departments. The Policy Statement can help Medical Physicists to eliminate or at least minimize accidents or incidences due to improper use or application of medical technology on one hand and on the other to guarantee a safe, effective and efficient usage of new highly complicated and sophisticated technologies and procedures.

Introduction

Although in recent years much effort has been expended on developing accreditation [5] and Continuous Professional Development schemes [6,7] for the Medical Physicist, there is still a need for additional guidelines to improve safety and quality.

Many guidelines have been developed and published for Quality Control and Quality Assurance for the individual Medical Physics procedures used in all the areas of Medical Physics [8—18]. Although these ensure the accuracy, reproducibility and repeatability of the various procedures and operation of the various equipment and systems and so contribute to the safety of the patient, they are not focussed enough on safety to ensure a safe usage of a modern health-care delivery service for the benefit of the patient.

This guideline for the development of a Safety and Quality Management System for Medical Physics Departments is a new tool to fill the safety gap. Safety, Accreditation, Continuous Professional Development, Quality Control and Quality Assurance procedures and systems are parts of a Safety and Quality Management System and play a major role in ensuring safety for the patient.

Aims and objectives

The aim of this policy statement is to encourage Medical Physicists to implement a Safety and Quality Management System fin their departments.

Through a Safety and Quality Management System a Medical Physics Department will achieve the following objectives:

a) Increase the safety of the patient undergoing diagnostic and therapeutic procedures related to medical physics
b) Increase the safety, quality and efficiency of the medical physics services
c) Increase its profitability
d) Introduce the concept of improvement and upgrading of the medical physics services.

The Appendix gives an introduction to Safety and Quality Managements Systems and how these can be applied to a Medical Physics Department.

Recommendations

All National Member Organisations should encourage the Medical Physics Departments in their country to implement a Safety and Quality Management system for their operations.

As a guideline for the implementation of such a system they may use the steps discussed in Appendix (1—8).

Firstly they should acquire all the Safety and Quality Management Standards, as these will help them understand the concept and purpose of a Safety and Quality Management System.

It is advisable to start implementation of their Safety and Quality Management System in stages. For example they may start by developing such a system for their operations in Radiotherapy. After being satisfied that this system is working and meeting the set aims and objects, then they may proceed to implement a similar system for their Nuclear Medicine or their Diagnostic Radiology operations.

It is wise to start from the simplest operation so that it can be used as a pilot project to learn from, before applying it to a bigger and more complicated operation.

Once they are confident that their Safety and Quality Management System is operating satisfactorily, they are encouraged to have it accredited by an external accreditation body. With this procedure they will have feedback from outside their organisation so helping to improve it even further.

It should be understood from the beginning that a Safety and Quality Management System is a dynamic system that should continuously be improved and modified to meet the evolving needs and demands of the hospital environment.

Summary

The Guidelines presented here constitute a set of general requirements on the design and setting up of a Safety and Quality Management System for Medical Physics Departments.

EFOMP recommends that National Member Organisations encourage the Medical Physics Departments in their countries to set up a Safety and Quality Management System for their operations. As a starting point they may use the steps discussed in Appendix of this policy statement.

A Safety and Quality Management System is a dynamic system that needs to be modified continuously in order to meet the demands and needs of the hospital environment. The ultimate goal is the improvement of the safety of the patient and good medical practice in diagnosis and treatment.

Acknowledgements

The Author acknowledges the help of the EFOMP Officers in compiling this document. A special acknowledgment is due to Ir. Herman J. van Kleffens of the Eindhoven University of Technology for his constructive comments on the final draft of the Policy Statement.

Appendix

The ISO family of safety and quality management standards

The materials required to set up a Safety and Quality Management System are mainly the International

Table 1 Relevant ISO 9000 standards and guidelines.

Standard	Title
ISO 9000: 2005	Quality management systems — Fundamentals and vocabulary
ISO 9001: 2000	Quality management systems — Requirements
ISO 9004: 2000	Quality management systems — Guidelines for performance improvements
ISO 10002:2004	Quality management — Customer satisfaction — Guidelines for complaints handling in organisations
CEN/TS15224: 2005	Health Services — Quality Management Systems — Guide for the use of EN ISO 9001:2000.
IWA 1:2005	Quality management systems — Guidelines for process improvements in health service organisations
IWA 4:2005	Quality management systems — Guidelines for the application of ISO 9001:2000 in local government
ISO 10012:2003	Measurement management systems — Requirements for measurement processes and measuring equipment
ISO/TR 10013:2001	Guidelines for quality management system documentation
ISO 10015:1999	Quality management — Guidelines for training

Organisation of Standards (ISO) 9000 series of standards [19] and related guides to their application. The ones relevant to the present situation are listed in Table 1. Other relevant standards and Guidelines that may be useful are listed in Table 2.

From a management point of view, the greatest value will be gained from the ISO 9000 standards when the entire set of standards is used in an integrated manner. Using the standards in this way also enables you to relate them to other management systems (e.g. environmental) and other quality management strategies (such as awards and Total Quality Management) The relevant environmental standards are listed in Table 3.

The philosophy of Quality Management is that each organisation is a unique entity and must develop its own unique Quality Manual, which includes its Quality Policy, Procedures, Work Instructions and all the Forms to be used, and must cover all the activities of the organisation.

An appropriate Certification Body should certify a Safety and Quality System. This will ensure the continuous implementation of the system as well as its dynamic evolution through the semi-annual or annual inspections by the Certification Body.

The basic steps in setting up a Safety and Quality Management System for a Department in the Clinical Environment may be the following:

1. Identify what are the goals that your department wants to achieve. Typical goals may be:
   - Be more efficient and profitable
   - Deliver better services
   - Improve patient safety
   - Achieve patient satisfaction
   - Increase patient throughput
   - Improve communication and moral in the department
   - Reduce costs and liabilities
2. Identify what others expect of you. These are expectations of interested parties such as:
   - Patients
   - Suppliers
   - Shareholders
   - Society
   - Employees
   - Pressure groups
3. Establish your current status. You may use one or more of the following methods:
   - Self assessment
   - Assessment by an external organisation
   - Patient feedback
4. Obtain the ISO 9000 family of Standards and the relevant Guidelines.

In some cases you may need to use only one or two specific standards, but it is advisable to have the documents listed in Tables 1 and 2.

5. Apply the standards that best suit the management system for your department.

Start with ISO 9000:2005 for the fundamental principles and terminology and then ISO 9001:2000 for the requirements.

6. Use sector specific and general guidance.
   - For the application of ISO 9001:2000 use IWA 4:2005
   - For improvements in health service organisations use IWA 1:2005

Table 2 Other useful standards and guidelines.

Standard	Title
ISO 13485:2003	Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 13488:1996	Quality systems — Medical devices — Particular requirements for the application of ISO 9002
ISO/TR 14969:2004	Medical devices — Quality management systems — Guidance on the application of ISO 13485: 2003
ISO 15189:2003	Medical laboratories — Particular requirements for quality and competence
ISO/TS 19218:2005	Medical devices — Coding structure for adverse event type and cause
ISO 22870:2006	Point-of-care testing (POCT) — Requirements for quality and competence

Table 3 Relevant environmental standards.

Standard	Title
ISO 14001:2004	Environmental management systems — Requirements with guidance for use
ISO 14004:2004	Environmental management systems — General guidelines on principles, systems and support techniques
ISO 14031:1999	Environmental management — Environmental performance evaluation - Guidelines
ISO/TR 14032:1999	Environmental management - Examples of environmental performance evaluation (EPE)
ISO 14040:1997	Environmental management — Life cycle assessment — Principles and framework
ISO 14041:1998	Environmental management — Life cycle assessment — Goal and scope definition and inventory analysis
ISO 14042:2000	Environmental management — Life cycle assessment — Life cycle impact assessment
ISO 14043:2000	Environmental management — Life cycle assessment — Life cycle interpretation
ISO/TR 14047:2003	Environmental management — Life cycle impact assessment — Examples of application of ISO 14042
ISO/TR 14049:2000	Environmental management — Life cycle assessment — Examples of application of ISO 14041 to goal and scope definition and inventory analysis
ISO 14050:2002	Environmental management — Vocabulary

- For management system documentation use ISO/TR 10013:2001

7. Do you need to demonstrate conformance? If not, go to 8 below. If you need to show conformance for various purposes, for example:
   - Contractual requirement
   - Market reasons
   - Regulatory requirements
   - Risk management
   - To set a clear goal for your internal quality development (motivation),

   then:
   - Use ISO 19011:2003 for guidance in auditing of Quality Management Systems
   - Use ISO 9001:2000 specific requirements.
8. Continue to improve your system.

Review the effectiveness and suitability of your management system. IWA 1:2005 provides guidance for quality improvement.

The basic ingredient for a successful Safety and Quality system is the absolute support of all the staff of the department or organisation in which the safety and quality management system is being developed and implemented. Without the staff support one will never be able to implement a system. It is necessary to develop a safety and quality culture from within the department.

All the staff must feel that they are part of the system and that their input is appreciated and taken into consideration in the development and evolution of the system. With staff involvement, the staff will consider the safety and quality system as theirs and they will feel proud of their achievement and they will work with zeal to continuously improve it.

A safety and quality system must be developed over time, starting from the basics. Each staff member should write down in detail what he or she does and how he or she does it. In this way the staff will develop a description of their activities and a set of instructions will be developed to ensure carrying out their work as required. This activity will help to develop the Work Instructions and Procedures of the Manual with the help and contribution of the staff members themselves.

The idea behind a documented Safety and Quality System is that the staff work according to the quality manual and protocols that have been developed. There is a long tradition of producing guidelines and protocols to define good practice for the task of a Medical Physicist, but focussed on individual tasks, not as a part of a unified safety and quality system. The requirement of following the manual might help to produce more practical guidelines and also lead to more discipline in carrying out what it was promised by the policy statement of the department or organisation.

The performance of a system cannot be improved if it is not measured or compared. Therefore measurable or easily compared performance parameters must be identified, build into the safety and quality system and analysed at set intervals of time. This analysis will give a number of performance indicators that will assist in the improvement of the system and thus its performance.

The challenge of a safety and quality system is to comprehend that the everyday activities are part of the system and should be regarded as part of improvement projects.

The Basic Safety and Quality Management System steps discussed above may sound very bureaucratic and time consuming to the beginner in the concept of Safety and Quality Systems, but the development of procedures and work instructions, as specified in the standards of safety and quality systems, for each service provided by the Medical Physicist is necessary tools to ensure the safety of the patient.

The records that are kept as a part of a Safety and Quality System, help in the analysis of accidents and incidents and thus contribute positively in the continuous development of the procedures and work instructions of the quality system in a dynamic loop, which aims at the perfection of the services delivered to the patient.

References

[1] Eurohealth, Mythbusters, myth: we can eliminate errors in health care by getting rid of 'bad apples'. Eurohealth(2): 29—30. Available from: www.chsrf.ca/mythbusters/pdf/myth15_e.pdf, 2006;12.

[2] Gillin M. Institute of Medicine Report on medical errors. AAPM Newsletter March/April 2000.

[3] International Atomic Energy Agency (IAEA). Lessons learned from accidental exposures in radiotherapy 2000. Safety Reports Series No. 17. Vienna: IAEA; 2000.

[4] International Commission on Radiological Protection. Prevention of accidental exposures to patients undergoing radiotherapy. Publication 86. Exeter: Pergamon Press; 2001.
[5] EFOMP policy statement No 6: ''recommended guidelines on national registration schemes for medical physicists''. Physica Medica 1995;XI(4):157—9.
[6] EFOMP policy statement No 8: ''continuing professional development for the medical physicist.''. Physica Medica 1998;XIV(2):81—3.
[7] EFOMP policy statement No 10: ''recommended guidelines on national schemes for continuing professional development of medical physicists''. Physica Medica:97—101, www.efomp.org, 2001;XVII.
[8] Kutcher GJ, Coia L, Gillin M, Hanson WF, Leibel S, Morton RJ, et al. Report of AAPM TG 40, Comprehensive QA for radiation oncology. Medical Physics 1994;21:581—618.
[9] Thwaites DI, Scalliet P, Leer JW, Overgaard J. Quality assurance in radiotherapy. Radiotherapy and Oncology 1995; 35:61—73.
[10] Leer JW, McKenzie A, Scalliet P, Thwaites DI. Practical guidelines for the implementation of a quality system in radiotherapy. ESTRO Physics for Clinical Radiotherapy booklet no. 4. Brussels: ESTRO; 1998.
[11] International Atomic Energy Agency, Standardized quality audit procedures for on-site dosimetry review visits to radiotherapy hospitals, Izewska J. et al., SSDL Newsletter No.46, Vienna (2002).
[12] World Health Organisation. Quality assurance in radiology. Geneva: WHO; 1982.
[13] British Institute of Radiology. Assurance of quality in the diagnostic X-ray department. London: BIR Publ.; 1988.
[14] BIR Report 18: technical and physical parameters for quality assurance in medical diagnostic radiology. London: BIR Publ.; 1989.
[15] National Council on Radiation Protection (NCRP), Report 99: quality assurance for diagnostic radiology. Bethesda: NCRP Publ.; 1988.
[16] European Commission. European guidelines for quality assurance in mammography screening. Report EUR 14821. 3rd ed.; 2001. Luxembourg.
[17] Busch HP, Jaschke W. Adaptation of the quality criteria concept to digital radiography. Radiation Protection Dosimetry 1998;1—3:61—3.
[18] Busch HP. Dose and quality management in digital radiography. Fortschritte Roentgenstrahlen 2003;175:17—9.
[19] Selection and use of ISO 9000. Available from: http://www.iso.ch.