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

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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.

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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 rigorously 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.
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 newly 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.

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**Aims and objectives**

The aim of this policy statement is to encourage Medical Physicists to implement a Safety and Quality Management System in 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 Management 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**

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**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.

<table>
<thead>
<tr>
<th>Standard</th>
<th>Title</th>
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<tbody>
<tr>
<td>ISO 9000: 2005</td>
<td>Quality management systems — Fundamentals and vocabulary</td>
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<tr>
<td>ISO 9001: 2000</td>
<td>Quality management systems — Requirements</td>
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<tr>
<td>ISO 9004: 2000</td>
<td>Quality management systems — Guidelines for performance improvements</td>
</tr>
<tr>
<td>ISO 10002:2004</td>
<td>Quality management — Customer satisfaction — Guidelines for complaints handling in organisations</td>
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<tr>
<td>IWA 1:2005</td>
<td>Quality management systems — Guidelines for process improvements in health service organisations</td>
</tr>
<tr>
<td>ISO 10012:2003</td>
<td>Measurement management systems — Requirements for measurement processes and measuring equipment</td>
</tr>
<tr>
<td>ISO/TR 10013:2001</td>
<td>Guidelines for quality management system documentation</td>
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<tr>
<td>ISO 10015:1999</td>
<td>Quality management — Guidelines for training</td>
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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.

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<tr>
<th>Standard</th>
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<tr>
<td>ISO 13485:2003</td>
<td>Medical devices — Quality management systems — Requirements for regulatory purposes</td>
</tr>
<tr>
<td>ISO 13488:1996</td>
<td>Quality systems — Medical devices — Particular requirements for the application of ISO 9002</td>
</tr>
<tr>
<td>ISO 15189:2003</td>
<td>Medical laboratories — Particular requirements for quality and competence</td>
</tr>
<tr>
<td>ISO/TS 19218:2005</td>
<td>Medical devices — Coding structure for adverse event type and cause</td>
</tr>
<tr>
<td>ISO 22870:2006</td>
<td>Point-of-care testing (POCT) — Requirements for quality and competence</td>
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Without the staff support one will never be able to implement a system. It is necessary to develop a safety and quality system. IWA 1:2005 provides guidance for quality systems, for each service provided by the Medical Physicist. 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

Recommended guidelines on the development of safety and quality management systems


