Application of quality management systems in research organisations (technology centres and universities)
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V. Bibliography
This document is addressed to staff working in research centres who are unaware of the basic aspects of quality systems.

The purpose of the document is to provide practical information about what quality systems are and about the standards or benchmarks which might be applicable to universities, technology centres and other organizations which carry out R&D&i (research, development and innovation) projects. It is thus intended to help its target audience to decide whether implementing a quality system would be useful by setting out the benefits that such systems can bring, the issues which will need to be dealt with, the effort required, some of the foreseeable difficulties, ideas for overcoming them, etc.

It does not profess to provide in-depth analysis of the standards or benchmarks or of their requirements, although some of the most significant ones will be discussed and highlighted.
Introduction

1.-introduction

reasons for implementing a QMS
objectives and fields of application

2.-basic issues of the reference standards

ISO 9000
ISO 17025
Principles of GLP
UNE 166000

3.-implementing a QMS

issues to be dealt with
(involvement of management,
system of documents,
complaints, internal audits, ...)

4.-Conclusions
What is a quality management system?

A quality management system (hereinafter QMS) is defined as an organizational structure consisting of procedures, processes and resources which are set up to systematically achieve quality objectives.

In other words, it is a set of components which interact or are mutually connected and are organised in a way that makes it possible to consistently (and not randomly) attain a series of established objectives.

As in any organization, in this set of components people (and their assigned functions and responsibilities) play a key role when it comes to achieving an objective. This means that appropriate staff training and qualification together with high levels of motivation are essential and constitute the basis of any system.

They are thus a necessary but not sufficient condition for attaining goals. In fact, people carry out actions, and the way in which these actions are focussed, the order in which they are done, how they are performed and so on, are also key factors making for efficacy (successfully achieving targets) and efficiency (doing so at the lowest possible cost).

All of this calls for resources of various kinds (people's time, investment in equipment, training, materials, etc.) which must be provided.
Reasons for implementing a QMS

Companies and institutions decide to implement a QMS for a variety of reasons, although they can basically be classified into two main groups: (1) a wish to improve and (2) a wish for formal recognition.

Indeed, it is a widely held opinion that the work systems and activities carried out as part of a good QMS enable significant improvements to be made in the operations it covers in the organization (institution or company) which has implemented it.

There are a number of aspects to this improvement. Thus there will be a change for the better in:

- the EXCELLENCE of work done, which translates into more innovative projects, more reliable analysis and reports, meeting more deadlines, etc.

- the EFFICIENCY of activities, in other words doing them at a lower cost, which boosts the organization’s profitability.

- the increase in CUSTOMER SATISFACTION (private companies which hire services or commission projects, institutions which fund projects, society in general, etc.).

It would seem obvious that improving in any respect is a basic objective of any organization. Nonetheless, in many cases the fundamental reason for implementing a QMS is the wish or need for recognition by a third party.

Indeed, at times this recognition is a wish whose purpose is to drive corporate reputation. However, in most cases it is made into an obligation either explicitly by legislation or implicitly by the market. This is the case, for instance, with ISO 17025 accreditation for laboratories, where the law states that only accredited laboratories can perform “official product control”. Furthermore, there is also a tendency among companies which need external laboratories to analyse their products to give preference to those which are accredited. In other words, laboratories find themselves “forced by their market” to get the accreditation if they want to do business.

In all cases, recognition leads to an increase in activity, which means business for some organizations (companies and so on) and fulfilling their mission for others (institutions, government, etc.).

In addition to the foregoing there is also something else which is quite evident in all organizations which have implemented a good QMS: their employees’ job satisfaction rises as they see how the new system enables them to work better with enhanced efficiency and reliability.
Behind any organization, whether it is a company, a technology centre, a university or government, there is always a customer who has to be satisfied or who requires recognition.

The concept of the customer has traditionally been associated with private companies which produce goods or services. In public sector organizations, however, it has not been so evident and hence people working in them do not have as strong a culture or focus on meeting customer needs.

By contrast, technology centres, whose survival depends to a great extent on the quality of the analysis, teaching, technological support and research services they provide, have identified their customers and are in most cases clearly customer driven.

Nevertheless, and at least in Spain, universities appear to be beyond good and evil, despite the policies put in place in recent years designed to build links between them and the business world and the competition for funding awards for the projects they want to carry out.

Who are the customers of a university or technological centre? On many occasions they will be the companies that pay directly for the services they receive and seek prestige and capacity (resources, knowledge, experience, etc.) in these organizations. At other times, the customer is a regional, national or European institution which decides which projects to fund and with how much money. In all cases, the customer’s needs have to be met (putting forward good ideas and proposals, getting useful results, etc). And then of course there is always the internal customer, the staff who carry out the projects or other partner departments or centres, and who have expectations that also have to be met.
Reference documents and standards

The implementation of a QMS should always be a strategic decision for the organization concerned.

Once top management in the company or institution has decided to embark on this course, the first thing that has to be chosen is the benchmark or document (hereinafter the “standard”) on which implementation is to be based.

Indeed, a reference guide for carrying out such a complex activity seems essential. There are a number of widely respected domestic and international standards which can be used for this purpose, each of which has different objectives and fields of application which need to be known before choosing one or the other. Examples include:

- International Standard ISO 9001
- International Standard ISO 17025
- Principles of Good Laboratory Practice (OECD document)
- Spanish Standards UNE 166001 and UNE 166002

The ISO standards are elaborated by the International Organization for Standardization, the world’s largest developer and publisher of International Standards, a network of the national standards institutes of 163 countries, one member per country.

The Principles of Good Laboratory Practice have been elaborated by the OECD (Organization for Economic Cooperation and Development), an intergovernmental organization of 30 countries, committed mainly to market economy, and also one of the largest publishers in the field of economics and public policy. Its interest in avoiding technical barriers to trade led to the publication of these Principles.

The Spanish Standards have been elaborated by AENOR, an organization dedicated to the development of standardization and certification, designated by the Spanish government to carry out these activities, and present at international forums to guarantee Spanish participation in the development of international standards.

A review of these five standards with respect to their fields of application and their objectives is given below. We hope this will prove to be useful when choosing the one that is most appropriate for the specific needs of an organization.
ISO 9000 Family of International Standards. Objectives and field of application

The ISO 9000 family is a set of standards which furnish an international consensus on management best practice to enable an organization to deliver products and services which meet customers’ quality requirements. It is made up of four standards:

- ISO 9000:2005. Fundamentals and vocabulary. This sets out the definitions of the terms used across all the standards together with a description of the 8 principles of quality and an introduction to QMS.

- ISO 9001:2008. Requirements of a QMS. This is the one of greatest interest from the “objectives and field of application” viewpoint in this document. It focuses on the effectiveness of a QMS in meeting customer requirements and is used when an organization has to demonstrate its ability to regularly provide products and services which meet requirements and seeks to increase customer satisfaction.

This standard makes it possible to assess (either internally or by a third party) an organization’s ability to meet the customer, legal and regulatory requirements applicable both to its products (in the broad sense of the term including services and so on) and to the organization itself. Consequently it is intended for contractual, regulatory or certification use.

- ISO 9004:2009. “Management for the sustained success of an organization. A quality management approach”, provides guidance to organizations (regardless of size, type and activity) to support the achievement of sustained success (defined as the ability to achieve and maintain its objectives in the long term)

It is not intended for certification, regulatory or contractual use

- ISO 9011:2002. Guidelines for auditing quality and/or environmental management systems, which contains guidelines for verifying the system’s ability to achieve quality objectives.

We will focus our attention basically on ISO 9001, although we will also talk about the quality management principles and the fundamentals of the quality management systems established in ISO 9000
International Standard ISO 17025. Objectives and field of application

This standard is applicable to all organizations performing tests or calibrations. This includes first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification.

It specifies the general requirements for the COMPETENCE to carry out tests and/or calibrations, including sampling, performed using standard methods, non-standard methods, and laboratory-developed methods. However, it does not cover compliance with regulatory and safety requirements on the operation of laboratories.

Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognising the competence of laboratories.

Any laboratory which meets the requirements of ISO 17025 will be operating under a quality management system for its testing and calibration activities which also complies with the ISO 9001 standard. Nonetheless, some technical competence requirements are only covered by ISO 17025.

In short, this standard is the benchmark in technical competence recognition for organizations performing tests or calibrations.
Principles of Good Laboratory Practice. Objectives and field of application

The Principles of Good Laboratory Practice should be applied to the non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs as well as food additives, feed additives, and industrial chemicals. These test items are frequently synthetic chemicals, but may be of natural or biological origin and, in some circumstances, may be living organisms.

The purpose of testing these test items is to obtain data on their properties and/or their safety with respect to human health and/or the environment.

Non-clinical health and environmental safety studies covered by the Principles of Good Laboratory Practice include work conducted in the laboratory, in greenhouses, and in the field. The purpose of these Principles of Good Laboratory Practice is to promote the development of quality test data. Comparable quality of test data forms the basis for the mutual acceptance of data among countries. If individual countries can confidently rely on test data developed in other countries, duplicative testing can be avoided, thereby saving time and resources. The application of these Principles should help to avoid the creation of technical barriers to trade, and further improve the protection of human health and the environment. In other words, common principles for GLP facilitate the exchange of information and prevent the emergence of non-tariff barriers to trade, while contributing to the protection of human health and the environment.

Unless specifically exempted by national legislation, these Principles of Good Laboratory Practice apply to all non-clinical health and environmental safety studies required by regulations for the purpose of registering or licensing pharmaceuticals, pesticides, food and feed additives, cosmetic products, veterinary drug products and similar products, and for the regulation of industrial chemicals.
The Asociación Española de Normalización (AENOR – Spanish Standardisation Association) has drawn up two standards (in addition to one about "definitions" - UNE 166000:2006 – and one giving general guidelines for drawing up projects - UNE 157001:2002) that are specifically applicable to R&D&i management. They are:

**ISO 166001:2006. R&D&i project requirements**

This standard is applicable to R&D&i projects regardless of their complexity, duration or technological field.

It aims to:

- facilitate the systematisation of research, development and innovation activities in the form of R&D&I projects.

- help define, document and prepare R&D&i projects, improve their management, as well as communication with the interested parties.

**UNE 166002:2006. R&D&i management system requirements**

This standard is meant to be applied to all sorts of organizations, regardless of their type or size, which, after a previous diagnosis of their R&D&i situation, wish to:

- establish the basic grounds to initiate their R&D&i activities

- define, implement, update and improve an R&D&i management system in accordance with their policy

- demonstrate fulfilment of the requirements of this standard before a third party and/or certify their R&D&i management system

This standard does not aim to establish the requirements needed for an organization to set up its own R&D&i policies, but once these have been created the implementation of a management system following the scheme proposed in this standard will provide the following advantages:
-promotion of R&D&i activities

-provision of guidelines for the effective organization and management of R&D&i

-analysis of the internal and external technological situation

-identification and assessment of the threats and opportunities created by technological evolution

-definition of the basic objectives of R&D&i activities

-selection and management of an appropriate R&D&i project portfolio

-ensuring that no activities which can be generated by the organization’s own technology and patents are lost, activities through which additional benefits can be obtained through technology transfer or tax relief

-promotion of R&D&i as a competitiveness differential factor, and consideration of it as such in corporate reputation schemes

-assistance in the planning, organization and control of R&D&i units, resulting in a saving of resources and in the improvement of the motivation and implication of employees

To simplify, the UNE 166001 standard focuses on project management, while the UNE 166002 standard deals with managing the organization’s project portfolio.
Introduction

In Brief

There are many REASONS FOR IMPLEMENTING a QMS which are intertwined and interconnected:
- a wish to improve
- a wish or need for recognition
- increase staff satisfaction
- increase customer satisfaction
- greater effectiveness / efficiency
- growing the business / requirement for doing business
- legal requirement

This is not either an exhaustive nor a closed list of reasons. Each organization will have to choose their own.

There are a number of reference standards that may be of interest to Research Centres and Universities when thinking of implementing a QMS.

**ISO 9000 Family of Standards**, and more specifically ISO 9001, is focused on the effectiveness of a QMS in meeting customer requirements. It is intended for contractual, regulatory or certification use.

**ISO 17025**, Applicable to all laboratories performing tests or calibrations. It can be used by third parties (e.g. Accreditation bodies) to recognise competence to perform them.

**Principles of Good Laboratory Practices**, whose main purpose is the development of quality test data, are applicable to all non-clinical health and environmental safety studies required by the regulations for the purpose of registering or licensing pharmaceuticals, pesticides, additives, veterinary drug products, … and for the regulation of industrial chemicals.

**UNE 166000 Family of Standards**, applicable to either R&D&i projects (regardless of their complexity, duration or technological field) or the organizations performing R&D activities.
Basic issues of the reference standards

1.-introduction

reasons for implementing a QMS
objectives and fields of application

2.-basic issues of the reference standards

ISO 9000
ISO 17025
Principles of GLP
UNE 166000

3.-implementing a QMS

issues to be dealt with
(involvement of management,
system of documents,
complaints, internal audits, ...)

4.-Conclusions
General considerations

We have just reviewed the objectives and field of application of the various reference standards which may help when it comes to deciding which of them best meets an organization’s needs when implementing a QMS.

It is now time to look at the requirements set out in these standards with the objective of providing an overview of what each one calls for and hence an idea of where implementation efforts should be focused.
ISO 9000 family of standards. Basic issues

The ISO 9000 family of standards have been developed to assist organizations of all types and sizes, to implement and operate effective QMS.

Next the most relevant issues of two of them are described:

**ISO 9000:2005**

This standard is important because it establishes basic issues of QMS, whose proper knowledge is essential for the success in the implementation and the organization itself.

The principal issues in the standard are the following:

1. **It describes the Quality Management Principles**, that can be used by top management in order to lead the organization towards improved performance:
   - Customer Focus, understanding their current and future needs, meeting their requirements and even striving to exceed their expectations.
   - Leadership, as a way to establish unity of purpose and direction of the organization, fully involving people in achieving the organization’s objectives
   - Involvement of People at all levels and at the most, which enables their abilities to be used in the benefit of the organization.
   - Process approach, as a way of managing activities and resources to achieve more efficiently the desired results
   - System approach to management, identifying, understanding and managing interrelated processes, which contributes to the organization’s effectiveness and efficiency in achieving its objectives
   - Continual improvement as a permanent objective of the organization
   - Factual approach to decision making, that is, analysing data and information to make effective decisions
   - Mutually beneficial supplier relationships, to enhance the ability of both to create value.
2. It establishes the fundamentals of quality management systems

Specifically the standard covers the following sections:

-Rationale for quality management systems

The quality management system approach encourages organizations to analyse customer requirements, define the processes that contribute to the achievement of a product which is acceptable to the customer, and keep these processes under control. A quality management system can also provide the framework for continual improvement.

-Requirements for quality management systems and requirements for products

Requirements for quality management systems are specified in ISO 9001. They are generic and applicable to any kind of organization. The requirements for products are generally established by customers (at times by the organization or legislation).

-QMS approach

The standard proposes an approach to developing and implementing a quality management system consisting of several steps (determining expectations of customers, establishing the quality policy and objectives, determining processes and responsibilities, etc.) that creates confidence in the capability of its processes and the quality of its products, and provides a basis for continual improvement, which can lead to the success of the organization.

-The process approach

This consists of the systematic identification and management of the processes employed within an organization and their interaction. Processes are defined as the set of activities that uses resources to transform inputs to outputs.

Process-based management increases the effectiveness of organizations, in other words, their ability to achieve their goals.

-Quality policy and quality objectives

They provide a focus to direct the organization.

-Role of top management within the QMS

Through its leadership, top management can create an environment where people are fully involved and in which a QMS can operate effectively.

-Documentation
Generation of documentation should not be an end in itself but should be a value-adding activity. Each organization determines the extent of documentation required and the media to be used.

- Evaluating quality management systems

Evaluation of a QMS can encompass a range of activities, such as auditing, management reviews and self-assessments.

When doing this it should be asked whether processes have been identified and appropriately defined, whether responsibilities have been assigned, whether procedures have been implemented and whether processes are effective in achieving the required results. The answers will determine the result of the evaluation.

- Continual improvement

Improvement is a continual activity based on feedback from many sources including customers, audits and data analysis. Its aim is to increase customer satisfaction and the success of the organization.

- Role of statistical techniques

The use of statistical techniques can help in understanding variability in processes. They can also assist in decision making and promote continual improvement.

- Quality management systems and other management systems

The QMS is that part of the organization's management system that focuses on the achievement of quality results. However, there are other objectives of the organization (funding, the environment, health and safety, etc.) and other management systems, all of which can be integrated using common elements.

This can facilitate planning, allocation of resources and evaluation of the overall effectiveness of the organization.

- Relationship between quality management systems and excellence models

The approaches given in the ISO 9000 family of standards and in organizational excellence models (for instance, EFQM) are based on common principles, but their scopes of application are different.

Assessment criteria in excellence models provide a basis for an organization to compare its performance with the performance of other organizations.

3. It defines the terms used in quality management systems, which is important in ensuring the systems are understood and that everyone is talking the same language.
All requirements of this international standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provide.

Do not affect the organization’s ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

Its implementation creates confidence in the process capability and quality of its products, and provides a basis for continuous improvement, which can lead to increased customer satisfaction and success of the organization.

We review the requirements below, numbered in the same order as indicated by the standard where they begin to be set down at section 4:

**4.- Quality Management System**

4.1.- General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of the ISO 9001.

The organization shall:

- Determine the processes needed for the quality management system and their application throughout the organization, as well as, the interaction of these processes.

- Determine criteria and methods needed to ensure that both the operation and control of these processes are effective.

- Ensure the availability of resources and information necessary.

- Monitor, measure and analyse these processes.

- Implement actions necessary to achieve planned results and continual improvement of these processes.

4.2.- Documentation requirements

The QMS documentation shall include:
-Documented statements of a quality policy, quality objectives, quality manual, documented procedures and records to ensure the effective planning, operation and control of its processes.

-The quality manual shall include the scope of the QMS, a reference of the documented procedures and a description of the interaction between the processes.

-Documents required by the quality management system shall be controlled: The documents shall be approved prior to issue, review and update as necessary, re-approved. The changes and the current revision must be identified. Documents shall remain legible and readily identifiable and available at points of use. External origin documents shall be identified and their distribution controlled.

-Control of records. These are a special type of document and are established to provide evidence of conformity to requirements and of the effective operation of the quality management system.

-Records shall remain legible, readily identifiable and retrievable.

-Document procedure must be defined to establish its control.

5.- **Management responsibility**

5.1.- **Management commitment**

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

-Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements.

-Establishing the quality policy and the objectives ensuring their review.

-Ensuring the availability of resources.

5.2.- **Customer focus**

Top management shall ensure that customer requirements are determinate and are met with the aim of enhancing customer satisfaction.

5.3.- **Quality policy**
Top management shall ensure that the quality policy is appropriate to the purpose of the organization, includes a commitment to comply with the requirements and continually improve the effectiveness of the QMS.

The policy provides a framework for establishing and reviewing quality objectives, and in reviewed for continuing suitability.

The policy shall be communicated within the organization.

5.4.- **Quality management system planning:**

The quality objectives shall be measurable and consistent with the quality policy. The planning of the QMS is carried out in order to meet the general requirements of this standard as well as the quality objectives.

5.5.- **Responsibility, authority & communication:**

- **Responsibility and authority:** top management shall ensure that they are defined and communicated within the organization

- **Management representative:** top management shall appoint a member of the organization’s management who has the responsibility to ensuring that processes needed for the QMS are established, implemented and maintained, reporting to top management on the performance of the QMS and any need for improvement and ensuring the promotion of awareness of customer requirements throughout the organization

- **Internal communication:** Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the QMS.

5.6. **Management review**

Top management shall review the organization's QMS to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives.

- **Review input:** this should include the results of audits, customer feedback, process performance and product conformity, status of preventive and corrective actions, follow-up actions from previous management reviews, changes that could affect the QMS, and recommendations for improvement.
- Review output: this should include any decisions and actions related to improvement of the effectiveness of the QMS and its processes, improvement of product related to customer requirements, and resource needs.

6. Resource management

6.1. Provision of resources

The organization shall determine and provide the resources needed to implement and maintain the quality management system and continually improve its effectiveness, and to enhance customer satisfaction by meeting customer requirements.

6.2. Human resources

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

In this respect, the organization shall determine the necessary competence for personnel and provide training to achieve it, and evaluate the effectiveness of the actions taken.

Management shall ensure that its personnel are aware of the relevance and importance of their activities.

Appropriate human resource records must be kept.

6.3 and 6.4. Infrastructure and work environment

The organization shall determine, provide and maintain the infrastructure and work environment needed to achieve conformity to product requirements or service provision.

7. Product realization

7.1. Planning of product realization

Planning of product realization shall be consistent with the requirements of the other processes of the QMS.

The organization shall determine requirements, processes, documents and resources specific to the product together with required verification, validation, monitoring, inspection and test activities and the criteria for product or service acceptance.
7.2. Customer-related processes:
- Determination of requirements related to the product: the organization shall determine requirements specified by the customer, those necessary for specified or intended use, and any statutory, regulatory or other requirements.
- Review of requirements: this shall be conducted prior to the organization's commitment to supply a product to the customer. The organization shall ensure that product requirements are defined, contract or order requirements differing from those previously expressed are resolved and documents are amended when requirements are changed.

7.3. Design and development:
- Planning: the organization shall determine the design and development stages (including the review, verification and validation of each one), responsibilities and authorities and ensure planning output is updated as the design and development of the product progresses.
- Input: this shall include functional and performance requirements and applicable statutory and regulatory requirements (complete and not in conflict with each other), as well as information derived from previous similar designs. These inputs shall be reviewed for adequacy.
- Outputs: the outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release. Design and development outputs shall provide appropriate information for purchasing, production and service provision and specify the characteristics of the product that are essential for its safe and proper use.
- Review: systematic reviews shall be performed to evaluate the ability of the results to meet requirements, identify any problems and propose necessary actions.
- Verification: verification shall be performed to ensure that the design and development outputs have met the design and development input requirements.
- Validation: design and development validation shall be performed to ensure that the resulting product is capable of meeting the requirements for the specified application. Validation shall be completed prior to the delivery of the product.
- Control of changes: changes shall be identified and records maintained. The changes shall also be reviewed, verified, validated and approved before implementation.

7.4. Purchasing:
-Purchasing process: the organization shall ensure that the purchased product conforms to specified purchase requirements. It shall evaluate and select suppliers based on their ability to supply the product in accordance with the organization's requirements.

-Purchasing information: the organization shall describe the product to be purchased.

-Verification of the purchased product: the organization shall establish and implement the inspection or other activities necessary for ensuring that the purchased product meets specified purchase requirements.

7.5. Production and service provision:

-The organization shall plan and carry out production and service provision under controlled conditions, including the availability of information that describes the characteristics of the product, the availability of work instructions, the use of suitable equipment, the use of monitoring and measuring equipment, the implementation of monitoring and measurement, and the implementation of product release, delivery and post-delivery activities.

-The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

-Identification and traceability: the organization shall identify product status and monitor it throughout product realisation.

-Customer property: the organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product (including intellectual property and personal data).

-Preservation of product: the organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. Preservation shall include identification, handling, packaging, storage and protection.

7.6. Control of monitoring and measuring equipment

Equipment shall be calibrated and have identification in order to determine its calibration status. It shall also be protected from damage and deterioration during handling, maintenance and storage.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed.
8. Measurement, analysis and improvement

8.1. General

The organization shall plan and implement the monitoring, measurement, analysis and continual improvement processes needed to demonstrate conformity to product requirements and the conformity of the QMS.

8.2. Monitoring and measurement:

- Customer satisfaction: the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements.

- Internal audit: the organization shall conduct internal audits at planned intervals to determine whether the QMS is effectively implemented and maintained, and whether it conforms to the planned arrangements and to the requirements of the standard. An audit programme shall be planned, taking into consideration the status and importance of the processes. The audit criteria, scope, frequency and methods shall be defined. The auditors shall be objective and impartial. The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected non-conformities.

- Monitoring and measurement of processes: the organization shall apply suitable methods that demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken to ensure the conformity of the product.

- Monitoring and measurement of product: the organization shall monitor and measure the characteristics of the product, at appropriate stages of the product realization process, to verify that product requirements have been met.

8.3. Control of non-conforming product

The organization shall ensure that a product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

8.4. Analysis of data

The organization shall collect and analyse appropriate data to demonstrate the effectiveness of the QMS and to evaluate where continual improvement can be made.
The analysis of data shall provide information relating to suppliers, customer satisfaction, conformity to product requirements, and characteristics of processes and products, including opportunities for preventive action.

8.5. Improvement

-Continual improvement: the organization shall continually improve the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

-Corrective action: the organization shall take action to eliminate the causes of non-conformities in order to prevent recurrence.

-Preventive action: the organization shall determine action to eliminate the causes of potential non-conformities in order to prevent their occurrence.
ISO 17025. Basic issues

The ISO 17025 standard focuses closely on laboratories’ technical competence in tests and calibrations. Consequently, much of it is taken up by technical requirements which are specific to this standard.

Nonetheless, this technical competence would not be possible if the management requirements set out in the standard were not also met by laboratories. These requirements are fully aligned with those included in the ISO 9001 standard.

The foregoing can be seen in the review below, which follows the numbering used in the standard:

4. Management requirements

4.1. Organization

- It must comply with legal requirements.
- It must carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard.
- The management system shall cover work carried out in all the facilities used by the laboratory to provide its services.
- The responsibilities of key personnel in the organization shall be defined in order to identify potential conflicts of interest, especially when the laboratory is part of an organization performing activities other than testing and/or calibration.
- The laboratory shall have managerial and technical personnel who have the competencies needed to carry out their duties and responsibilities in the quality system.
- It shall have policies and procedures.
- It shall ensure the protection of its customers' confidential information.
- It shall appoint a member of staff as quality manager.

4.2. Quality Management System

- The laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities.
- It shall document its policies, procedures and instructions to the extent necessary to assure compliance with quality requirements.
- It shall have a quality manual.
- The laboratory management's commitment to good professional practice is fundamental.
- Quality objectives shall be established.
- All staff members must be involved with the management system.

4.3. Document control

The laboratory shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), as well as those held on computer media.

Quality system documents must be updated and distributed to ensure that the system is valid and all personnel act in accordance with what has been agreed.

Obsolete documents must be assured against unintended use by the organization’s personnel.

Procedures must be modified to reflect changes in the organization or in legislation and when improvements are introduced which entail a modification in one or more documents in the management system.

4.4. Review of requests, tenders and contracts

The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts with customers to ensure that requirements are adequately defined, documented and understood by both parties before offering any service, and that the laboratory has the capability to perform the work in question.

Requirements to be reviewed include test methods to ensure that they are capable of meeting customer expectations.

4.5. Subcontracting of tests and calibrations

When a laboratory subcontracts work to another laboratory, whether because of temporary or unforeseen reasons or on a continuing basis, it must ensure that the subcontractor laboratory is competent for the work in question.

In these cases a laboratory is working on behalf of another and the customer must be advised and, when appropriate, give their approval.

4.6. Purchasing services and supplies

The laboratory shall have a procedure for the selection and evaluation of providers and subcontractors based on the quality of their products or services, so that only those which
ensure compliance with established requirements become designated providers or subcontractors of the organization.

Procedures shall exist for the purchase and reception of orders to ensure that they are received in suitable condition for use in the laboratory’s activities.

4.7. Service to the customer
The laboratory shall be willing to cooperate with customers or their representatives in clarifying the customer’s request.
The laboratory shall ensure confidentiality to other customers.
There must be suitable channels to ensure this communication can take place.

4.8. Complaints
The laboratory shall have a policy and procedure for the resolution of complaints received from customers.
Complaints shall be analysed and suitable measures shall be taken to make sure they do not recur.

4.9. Control of non-conforming testing and/or calibration work
The laboratory shall have a policy and procedures to identify and resolve incidents which may occur during the laboratory’s normal operations.
Corrective measures shall be adopted when non-conforming work ceases to be occasional or when it is deemed to be of sufficient significance.
Appropriate authorities for implementing solutions shall be designated.

4.10. Improvement
The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

4.11. Corrective action
Corrective action shall be taken in the event of serious or repeated nonconformities and shall be geared towards dealing with the cause of the non-conforming work so that it does not recur. The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

4.12. Preventive action
Needed improvements and potential sources of non-conformities shall be identified and action plans shall be monitored to reduce the likelihood of the occurrence of such non-conformities and to take advantage of the opportunities for improvement.

4.13. Control of records

Technical records (original observations and test data) and management records (including audits, management review, corrective and preventive action, etc.) shall be legible and stored in secure facilities for the established retention time.

The records shall make it possible to repeat the test or calibration and measures shall be taken to prevent the loss or change of original data.


As in ISO 9001, planned internal audits shall be carried out regularly (usually once a year) by trained and qualified personnel who are independent of the activity to be audited.

4.15. Management reviews

It establishes the same requirements as ISO 9001 and also includes other specific ones, such as the need for review input data to include the results of interlaboratory comparisons or proficiency tests, quality control, etc.

5. Technical requirements

Technical requirements cover those factors which in the case of a laboratory contribute to the accuracy, reliability and validity of its testing and calibrations. These factors are:

Below is a brief description of the requirements for each one of them.

5.2. Personnel

The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates.

The laboratory management shall formulate education goals and schedule training based on needs.

It shall maintain job descriptions, including the functions and responsibilities of each one.

5.3. Accommodation and environmental conditions.
Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.

Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.

5.4. Test and calibration methods and method validation.

The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, and preparation and all the stages in precise testing or calibration.

When the customer does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international or national standards or in relevant journals or as specified by the manufacturer of the equipment.

The methods shall be validated before use. The customer shall be informed as to the method chosen.

The introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources.

When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration.

The method developed shall have been validated appropriately before use.

Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. In other words, it entails checking that an activity is suitable for its intended purpose.

A laboratory performing its own calibrations and/or tests shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.

When, as is usually the case, computers or automated equipment are used for the acquisition and processing of test and/or calibration data, the laboratory shall ensure that:

- computer software is documented and validated as being adequate for use
- procedures are established and implemented for protecting the data
- computers and automated equipment are maintained

5.5. Equipment

The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations.

In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of the standard are met.
Calibration programmes shall be established for key quantities or values of the instruments where these properties have a significant effect on the results.

5.6. Measurement traceability.
The laboratory shall have an established programme and procedure for the calibration of its test and calibration equipment.
The laboratory shall have a procedure for the calibration of its equipment including its reference standards.

5.7. Sampling.
The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances for subsequent testing or calibration. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken.
Sampling plans shall be based on appropriate statistical methods.
The validity of the test and calibration results shall be assured.

5.8. Handling of test and calibration items
The laboratory shall have a system for identifying test and/or calibration items.
The identification shall be retained throughout the life of the item in the laboratory.
The identification system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents.

5.9. Assuring the quality of test and calibration results
The laboratory shall have quality control procedures for monitoring the validity of tests and/or calibrations undertaken.
The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results.

5.10. Reporting the results
Results shall be reported in a test report or a calibration certificate.
The test report or calibration certificate shall include all the information requested by the customer and necessary for the interpretation of the test and/or calibration results and all information required by the method used.
The test report or calibration certificate shall include:
   - a title
   - the name and address of the laboratory
- unique identification of the test report or calibration certificate
- the name and address of the customer
- identification of the method used
- a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated
- the date of receipt of the test or calibration item(s) and the date(s) of performance of the test or calibration
- reference to the sampling plan (where applicable) and to the procedures used by the laboratory
- the test or calibration results with, where appropriate, the units of measurement
- the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate
Good Laboratory Practices. Basic issues

The principles of Good Laboratory Practices (GLPs), as revised in 1997, sponsored and published free of charge by the Organization for Economic Co-operation and Development (OECD), establish criteria for the performance of non-clinical health and environmental safety studies, and constitutes a quality system concerned with the organisational process and the conditions under those studies are planned, performed, monitored, recorded, archived and reported. Its main purpose is to promote the development of quality test data.

This quality system is very much focused on the technical aspects relevant for conducting the studies, although it also emphasizes the responsibilities of different people who take part in it.

It is worth pointing out that this QMS uses a very specific vocabulary (not existing in other standards) that is necessary to know, and has to do with:

- the organization of a test facility
- the non-clinical health and environmental safety study
- the test item

Next, a brief review of the established requirements in the GLP document is done:

1. Test facility organization and Personnel

Very detailed responsibilities are established in connection with:

- Test facility Management: responsibilities are broken down in 17 specific sections with the general objective of assuring compliance with the principles of GLP in the test facility (that is, the persons, premises, and operational units necessary for conducting the study)

- Study Director: breaks down his responsibility for the overall conduct of the study and for its final report in 9 specific sections

- Principal Investigator: he is a representative of the Study Director on which some phases of the study have been delegated

- Study Personnel
2. **Quality Assurance Programme (QAP)**

To assure that studies performed are in compliance with the Principles of GLPs, a documented QAP must be carried out by individuals who are familiar with the test procedures and are not involved in the conduct of the study.

The QAP must:

- verify that the study plan contains the information required
- conduct inspections on the Study, the Facility and the Process, to determine if all studies are conducted according to GLPs
- inspect the final reports

The Quality Assurance personnel must prepare and sign a statement, to be included with the final report, specifying detailed information about the QAP carried out for the relevant study.

3.- **Facilities**

The test facility should be suitable (in size, construction, location and design) to assure proper conduct and validity of the study.

In this respect requirements are established for the test system facilities, for handling test and reference items, for archive and waste disposal.

4.- **Apparatus, material and reagents**

Apparatus should be of appropriate design and adequate capacity, and periodically maintained and calibrated according to standard operating procedures.

Reagents should be properly labelled, and some information (concerning preparation, stability, …) available on request.

5.- **Test systems (physical, chemical and biological)**

Detailed requirements are established for biological systems in connection with proper conditions for the storage, housing, handling, acclimatising and isolation (when applicable) as well as with information and records related to them.
6.- Test and reference items

In the same way, requirements on receipt, handling, sampling, storage (including stability) and characterisation, are established for reference and test items, including records that must be maintained.

7.- Standard Operation Procedures (SOPs)

Written SOPs are intended to ensure the quality and integrity of the data generated by the test facility.

They should be available for:

- test and reference items,
- apparatus, materials and reagents,
- record keeping, reporting, storage and retrieval,
- test system
- quality assurance

8.- Performance of the study

Requirements are established on

- the Study Plan
  - must be written prior to the initiation of the study
  - approved by the Study Director, the Test Facility Management and the Sponsor (if applicable) and verified by Quality Assurance personnel
  - amendments should be justified and approved
  - deviations from the study plan should be described, acknowledged and dated
  - it should contain information
    - about the identification of the study, the test item and reference item
    - concerning the sponsor and the test facility
    - dates of approval (by signature) and the proposed ones for experimental starting and completion
- test methods
- records to be retained
- issues (where applicable)

- the Conduct of the study.
  - should be in accordance with the study plan, traceable through a unique identification, which should be carried by all items, specimens
  - all data generated, in paper or straight in the computer, should be recorded directly, accurately and legibly. If changed, reasons must be given and the previous entry must not be obscured.
  - data should be signed or initialled and dated

9.- Reporting of study results

A final report, signed and dated by the Study Director indicating the extent of compliance with the principles of GLP, should be prepared for each study.

Requirements for the content are specifically established in connection with:

- the identification of the study, the test item and the reference item
- the sponsor and the test facility
- the experimental starting and completion dates
- a statement about the Quality Assurance Programme
- the description of materials and test methods
- the results obtained
- the storage of the study plan, samples, items, report, ...

10.- Storage and retention of records and materials

All documents (study plan, final report, ..), records (environmental, inspections, raw data, ...), items (test, reference) and specimens should be retained for the period specified by the appropriate authorities, indexed in archives in such a way to facilitate orderly storage and retrieval.

Only personnel authorised by management should have access to the archives and any movement of material should be recorded
UNE 166000 family of standards. Basic issues

**UNE 166001:2006. R&D&i project requirements**

Below is a brief review highlighting the most significant features of the requirements set out in the Spanish UNE 166001 standard. The number given to each requirement corresponds to the same in the standard:

4.2. **Responsibilities**: The organization shall designate the person who will be responsible for the project and establish his/her functions.

4.3. **Report**: All projects shall be documented in the form of a comprehensive report that shall be correctly identified and monitored. The minimum contents of this report are described below:

- quantitatively or qualitatively measurable objectives, the general methodology for achieving them and the impact and opportunities it provides

- innovation and novelty:

  - state-of-the-art: the starting point is the current state of knowledge (including existing disadvantages and/or limitations)

  - a description of the scientific and/or technical developments proposed in the project

  - a statement of plans to protect the results of the project

  - references to any relevant legislation and anything that may be necessary for the initiation, execution and exploitation of the project (contracts, etc.)

4.4. **Planning**: the structure of the project shall be described including:

- stages, tasks and their interaction, specifying the responsibilities of the participating organizations in each stage and task as well as the expected results

- the risks and critical points that can affect the execution of the work programme to a considerable extent, establishing a series of procedures to implement the changes needed to respond to the identified unforeseen events and risks,
- organizational and staff structure, including their skills
- control of the work programme (project stages and the results relating to them)

4.5. Budget: all the project costs shall be clearly identified, as well as their distribution in timeframes, and their connection with the task breakdown structure. To that end the following shall be established:

- a mechanism to identify what requirements are needed in the project and when these are required
- a system to control the dedication of the people of the organization involved in the project

4.6. Control of the project documentation: a mechanism of control (identification, registration and filing) shall be established along with the length of time documents are kept for (this period is recommended to be at least three years long).

4.7. Project monitoring: the degree of development in the execution of the project shall be described at periodical intervals (e.g. in technical-economic reports) including deviations from the original planning.

In addition to the abovementioned requirements, the standard also lays down guidelines for the EXPLOITATION OF RESULTS of projects in the following respects:

- identifying new products or processes and its possible applications
- defining groups, markets or customers interested in using the results of the project
- deciding whether the results will be protected, and if so, defining the most suitable way to protect them (patent, utility model, etc.)
- in the case of projects involving several participating organizations, the interest of each organization in the ownership and economic exploitation of the results shall be defined in a documented way
- establishing provisional exploitation accounts
- describing the way in which the expected project results contribute to improving the competitiveness of the organization shall be described
This standard, which seeks to systematise R&D&i activities without restricting them by set rules which can limit the imagination and emotional intelligence of researchers, makes it possible to assess the degree of validity of an R&D&i management system.

The standard does not advocate uniformity in the structure of R&D&i management systems, as these will be heavily influenced by factors such as an organization’s specific needs and objectives, the services it provides, its size and structure and so on. It merely lays down some general requirements which are discussed below, using the same system of numbering as the standard:

4.1. R&D&i management system and model

4.1.1. General: the organization shall identify the R&D&i activities to which the R&D&i management system shall be subject, guarantee the availability of the necessary resources, determine the sequence and interaction of these activities and determine the necessary criteria and methods to ensure the effective operation and control of these activities, monitor, measure and analyse these activities and continually improve the efficacy of the system. Mechanisms shall also be established for the protection and exploitation of results.

4.1.2. Documentation:

- R&D&i policy and R&D&i objectives and everything needed by the organization to ensure the effective planning, operation and control of the R&D&i activities must be documented.

- A system shall also be established for appropriate management and control of all documents, including ones coming from outside the organization and records.

4.2. Responsibility of top management: this section receives special attention in the standard and covers the following requirements:

4.2.1. Top management shall provide evidence of their commitment to the development and implementation of the R&D&i management system, as well as to the continual improvement of their effectiveness (e.g. by establishing the policy and objectives, setting up the R&D&i Management Unit, ensuring the availability of resources, etc.).
4.2.2. Interested parties approach with a focus on the demands of providers and customers, the motivation and involvement of employees, legal and regulatory requirements, innovations and technological changes required by the market, etc.

4.2.3. R&D&i policy that is suitable for the organization’s aim and is also communicated and understood, reviewed, etc.

4.2.4. Planning, establishing R&D&i objectives that shall be measurable and consistent with the R&D&i policy, planning the management system to meet them and setting investment policy.

4.2.5. Responsibility, authority and communication. The standard specifies the setting up of two units which have well-differentiated functions:

- The R&D&i Unit which undertakes the R&D&i projects it has been assigned, generates knowledge, develops new technology and improves the existing one

- The R&D&i Management Unit which
  - identifies and analyses problems and opportunities
  - analyses and selects R&D&i ideas
  - plans, monitors and controls the project portfolio
  - carries out the technology transfer
  - monitors and controls documentation of results
  - protects and exploits the results
  - measures, analyses and improves the efficacy of the QMS

The establishment and structure of the units shall enable appropriate project management and implementation. Hence, each project shall consider the need to structure flexible teams that will adapt to projects of different types and sizes and it must be possible to temporarily incorporate external experts to the R&D&i unit and/or subcontract, partially or completely, the project or some of the tasks or stages of the latter.

Top management shall define the authority and responsibility of these Units and also designate one of its members who shall, in addition to other responsibilities, control the R&D&i activities, including ensuring that the necessary activities for the R&D&i management system are established, implemented and maintained, inform top management about the performance of the R&D&i management system and about any improvement need and ensure that awareness of R&D&i activities is promoted within all the organization levels.

4.2.6. Management review, similar to the procedure contained in ISO 9001
4.3. **Resource management**, including:

- determining and providing resources to maintain and enhance the QMS, increase the satisfaction of the interested parties and foster cooperation with external entities that will provide knowledge, methodologies, instruments, funding, etc.
- motivation, competence, awareness and training of human resources
- the necessary infrastructure including working areas, equipment and support services
- the work environment

4.4. **R&D&i Activities**

R&D&i activities are those performed by the R&D&i Unit in order to undertake the R&D&i projects it has been assigned (including those hired externally) and manage the system.

R&D&i activities involve the following factors:

4.4.1. **Tools for carrying out the activities**, namely:

- Technology watch to carry out, in a systematic way, the compilation, analysis, dissemination and exploitation of the scientific or technical information that can be useful for the organization. This includes:
  - Identification of information needs
  - Search, treatment and dissemination of information
  - Information assessment

- Technology foresight and meditation in order to identify new ideas that will enable the provision of guidance for the future development of products and/or processes in the organization

- Creativity, as a mental process contributing to the generation of new ideas, shall be fostered within the organization by promoting the ability to discard the usual structured channels and ways of thinking to reach an idea that will allow to solve a specific problem

- Analysis

- External analysis as an instrument that provides guiding elements in order for an organization to assess the importance of different innovative ideas, comparing them with the external reality (obtaining data on the evolution of markets in their sector, identifying, assessing and proposing opportunities for technological partnerships, etc.)
4.4.2. Identification and analysis of problems and opportunities through analysis and monitoring of scientific and technological results, identifying the barriers jeopardising the use of new knowledge in the organization, analysis of the consistency between the organization's business strategy and the R&D&i projects, etc.

4.4.3. Analysis and selection of R&D&i ideas using a method established for that purpose which shall assess a series of factors that will try to guarantee the success of the idea. Among these factors we find economic, productive, legal and social factors, as well as those of technological nature.

4.4.4. Planning, monitoring and control of the project portfolio which take into account a range of aspects such as review and approval of documents, supervision of global progress, the search for sources of funding, the search for internal and external collaborations, etc.

4.4.5. A technology transfer system that will consider both their own technology and the possibility to integrate external technology, bearing in mind aspects like intellectual and industrial property, creation of joint ventures, etc.

4.4.6. R&D&i product, whose planning and design shall include, where appropriate, the subsequent stages, which will not need to be sequential:

- Basic design
- Detailed design
- Pilot test
- Redesign, demonstration and production
- Marketing
- Change control

4.4.7. Purchasing, including subcontracting, from providers who are selected according to their ability to meet the needs of the R&D&i management unit and are also adequately checked.

4.4.8. Results of the R&D&i process, provided in such a way that they will enable to evaluate that the objectives planned in the R&D&i policy have been effectively fulfilled. The results must be documented, monitored, measured, protected and exploited.
4.5. Measurement, analysis and continual improvement of the execution of R&D&i activities and the R&D&i management system and the perception of the interested parties with regard to the fulfilment of their needs and expectations. Here the standard refers to:

- internal audits
- monitoring and measurement of the R&D&i process
- monitoring and measuring the results of the R&D&i process
- control of the deviations from the expected results
- data analysis
- continual improvement of the system’s effectiveness using a range of tools, including corrective and preventive action, along the same lines as ISO 9001
A Single management system

As we have seen above, the various reference standards have some features in common and others that are different. The same thing happens when organizations bring in management systems whose purpose is not to achieve quality objectives but rather objectives in other areas, such as the environment or health and safety.

In these cases, it is useful to take advantage of common features and combine different management systems or sub-systems into a single system. This can be done when, for instance, an organization performs a number of the activities referred to in this document: analyses and/or calibrations (ISO 17025 to ensure technical competence), non-clinical safety studies (PGLP) and R&D&i projects (UNE 166000).

This can facilitate planning, resource assignment, setting complementary goals and assessing the organization’s overall efficacy.

In this sense it's worth highlighting that different ISO committees are making an effort to align the different ways standards are elaborated and published, in order to facilitate the integration of different quality systems.

That is why it is foreseeable that future quality management standards have identical

- key generic requirements
- main structure
- headings
- section titles and its sequence
- key terms and definitions
Basic Issues of the Reference Standards

In Brief

ISO 9000 describes the Quality Management Principles that can be used by top management in order to lead the organization towards improved performance and establishes the Fundamentals of QMS. Familiarising one self with them is crucial in order to implement an effective QMS.

ISO 9001 establishes generic requirements intended to be applicable to any organization, which are indeed the basis for other reference standards. Management responsibility, resource management, product realization, measurement, analysis and improvement, etc. are among the topics this standard deals with.

ISO 17025, which is fully aligned with the ISO 9001 standard, focuses on technical competence in tests and calibrations, but this competence would not be possible if management requirements set out in the standard were not met by laboratories.

Principles of Good Laboratory Practices, specifically focused on all technical aspects that directly influence the acquisition of data (facilities, test systems, procedures, equipment, performance of the study, quality assurance programme, etc.) and reporting and storage. It also describes very detailed responsibilities of the personnel involved with the studies.

UNE 166001 focuses mainly on technical aspects related to the performance of individual R&D&I projects (planning, budget, documentation, monitoring, report).

On the other hand, UNE 166002 sets down requirements related to quality management systems whose scope is the portfolio of R&D&I projects. This is why it strengthens the responsibility of top management (for example, creating the R&D&I Management Unit), talks about the tools for carrying out the activities (technology watch and foresight, creativity, analysis and selection of ideas, etc.), etc.

The various reference standards have some features in common, and this is why, when implemented, different quality systems are combined into an integrated one.
Implementing a QMS

1.-Introduction

reasons for implementing a QMS
objectives and fields of application

2.-Basic issues of the reference standards

ISO 9000
ISO 17025
Principles of GLP
UNE 166000

3.-Implementing a QMS

issues to be dealt with
(involvement of management, system of documents, complaints, internal audits, ...)

4.-Conclusions
Implementation methodology

We know that there are several ways of tackling the implementation of a QMS, and that the methodology may vary as a result of numerous factors specific to the features of the organization concerned.

Some guidelines can be found in the ISO 9000 standard and there is a lot more information about the subject available on the internet. Nonetheless, we will set out below a methodology which will enable us to view the implementation of a QMS as a process. It should be noted that the proposed steps do not have to be taken in sequential order (a number of them may be carried out at the same time) or even in the suggested order, since, as has been noted above, this will depend on the organization’s features (size, complexity, scope, etc.) and its situation when implementation begins.

The process starts with the possibility of putting in place a QMS, an idea which may be put forward for a number of reasons: due to customer requirements, the inefficiency or inefficacy in the organization as shown by mistakes, complaints, poor results, etc., because it is mandatory and so on.

Experience would suggest that when thinking about putting a QMS in place, one of the first critical tasks is to gain the commitment of management, which should also specify the scope of the system and its initial objectives. As will be discussed below, it is crucial that this commitment is genuine and does not just pay lip service.

Another preliminary step is to analyse the organization’s situation (available resources, qualification levels, need for training or investment, etc.) taking as a reference the standard which is to be used as the basis for the QMS.

Furthermore, QMSs are complex and their development and implementation call for the involvement of the entire organization. This participation will be headed by a number of people with specific responsibilities assigned to them by management who are tasked with leading the implementation and encouraging all staff to achieve objectives.

With these preliminary measures in place, the time has come to draw up a plan which will set out the development milestones and specify what has to be done, who has to do it and within what timeframe, etc. This plan of action will be designed to achieve the objectives set by management.

Once the plan has been mapped out and approved, it then has to be implemented. Actions to be carried out include:

- training and communication for staff in order to engage them with the project and provide them with the technical and/or management skills they need
-investment (in facilities, equipment, standards, etc.) and other expenses (consultancy services, reference materials, intercomparisons, etc.)

-drawing up system documents (a quality manual, a process map with its indicators, procedures, equipment maintenance and calibration plans, quality assessment plans, etc.)

As the system is developed and documented it is also implemented, in other words actions are carried out in compliance with procedures and plans:

- validation of methods
- control of internal and external quality
- verification of facilities
- handling non-conforming work and complaints
- etc.

This implementation will generate a large quantity of data from various sources, such as:

- process measuring and monitoring (indicators created for that purpose)
- product/service monitoring, including non-conforming work and products (i.e. those which do not comply with established requirements) and complaints
- measurements of customer satisfaction
- etc.

After the QMS has been in place for a while, it is audited to make sure it is working properly and this provides further data.

All the information gleaned has to be analysed and the results of this analysis should then be used to enable continuous improvement. Here the organization will need to carry out corrective and preventive measures, in other words, actions which tackle the CAUSES of real or potential non-conforming work or products, in order to avoid recurrence or preclude occurrence respectively.

Finally, the QMS is reviewed by management to check its ongoing advisability, appropriateness and efficacy. These reviews, which are held regularly at planned intervals, include an assessment of the need to make changes and also set new quality objectives.
DEVELOPMENT AND IMPLEMENTATION OF A QMS

1. POSSIBILITY OF IMPLEMENTING A QMS
2. COMMITMENT OF TOP MANAGEMENT
3. SITUATIONAL ANALYSIS
4. IMPLEMENTATION PLAN
   - INVESTMENTS
   - DOCUMENTATION
   - TRAINING & COMMUNICATION
5. IMPLEMENTATION
   - MEASUREMENT & ANALYSIS
   - IMPROVEMENT
6. MANAGEMENT REVIEW
7. QMS IMPLEMENTED
Involvement of management

What do the reference standards require?

The ISO 9000 and 17025 standards are clear and explicit about the need for the involvement of management in a QMS in order to ensure it operates properly. Moreover, experience would also suggest that such engagement is needed.

Through its leadership and actions, top management can create an atmosphere in which staff feel completely engaged. These actions will include:

- laying down the quality policy and objectives and promoting them across the organization to increase awareness, motivation and participation.
- ensuring the QMS has an appropriate focus (customer-driven, etc.)
- ensuring that necessary resources are available
- regularly reviewing the QMS

What are the problems?

In many cases top management is in favour of and supports the implementation and maintenance of a QMS, yet it does not really get involved. This leads to attitudes and actions that slow down implementation and improvement, which result in the QMS being less efficacious and more inefficient. Examples include:

- assigning all responsibility to the Quality Manager
- limited or zero participation by top management in communication actions addressed to the organization’s staff, who consequently do not perceive the QMS as something which is a priority or important and hence become less engaged with it
- putting off decisions about the QMS
- little interest in doing training in quality issues

The foregoing is more marked if the person in charge of the QMS is not extremely close to top management in the organization’s hierarchy.

Some ideas

It is crucial to ensure that top management is GENUINELY committed before beginning to put a QMS in place. Its members, along with other significant figures in the company, need to be provided with training in quality issues. It also has to be decided which specific actions the top management will directly take part in.
Quality policy and objectives

What do the reference standards require?

Quality policy and objectives are specifically set out in ISO 9001 and provide a point of reference to guide the organization and help it to achieve hoped-for results.

The policy needs to dovetail with the organization’s purpose and include a commitment to continuous improvement in the efficacy of the QMS and to ensuring it is communicated and understood across the organization.

The policy provides the framework for establishing quality objectives which, in addition to being consistent with the policy, also have to be measurable and set for relevant functions and levels in the organization.

What are the problems?

The policy becomes nothing but a mere statement of good intentions, grandiloquent words that have no connection with reality. Furthermore, it is not properly transmitted to staff (it may be mailed or framed but it is not explained, discussed or interiorised).

As for objectives, staff do not identify with them (often they do not even know what they are). They are inadequately stated, lack specifics and indicators which would enable them to be monitored, and have no linked actions designed to attain them.

In short, policy and objectives are not worth the paper they are written on and do not fulfil their function.

Some ideas

Include values and guidelines in the policy which people are prepared to battle for and which can be translated into goals and these goals in turn into results. They should be specific and deal with crucial aspects.

Draw up goals that are specific and not generic, and link each one with the actions required to achieve them and the indicators which will measure how much progress is being made towards them.

Carry out specific communication actions geared towards all staff members.
The system of documents

What do the reference standards require?

ISO 9000 states that drawing up documents should not be an end in itself but instead should add value.

Each organization will decide how much documentation it requires and in what form (paper, electronic, etc.), but in general there are the following types of documents:

- Quality Manual: it sets out the general guidelines for the system and includes the quality policy.

- Quality Plans: they specify what/who/when/and which resources should be used for a project, product or process.

- Specifications: they spell out requirements

- Guidelines: they set out recommendations or suggestions

- Procedures and Instructions: they provide information about how to carry out the activities. They must allow for the repeatability of these activities.

- Records: they provide objective evidence of the activities performed and results achieved. They must allow for the reproducibility of these activities.

Normally, the system of documents is represented by a pyramid whose apex is the Quality Manual and from which the rest of the documents emanate.
What are the problems?

QMS documents are usually very long and almost no-one reads them. They also contain lots of cross-references to other documents and updating them is complicated. Very often there is a difference between what actually happens and what is documented in both directions; that is to say, sometimes the document says what should be done but in reality something else is done, and sometimes things are done well but the document does not reflect this.

The list of documents tends to be quite long (depending on the complexity of the organization and the scope of its system of documents, the list may consist of several hundred documents), and almost no-one ever looks at it.

The documentation is associated with bureaucracy.

Some ideas

It is advisable to draw up very simple documents with no paraphernalia which go straight to the point and are consequently short and easy to consult. It might even be a good idea to use “other ways” of documenting procedures (for instance by using video tutorials).

Not everything has to be documented, only those things which if not written down might give rise to mistakes, confusion, ways of doing things which are not the ones the organization wants, etc.

It is useful to run mini training sessions to explain the most important documents to staff members. That way you can be sure they have read and understood them.

Information technology has a key role to play in managing the system of documents and of course in achieving the goal of “zero paper”. Hence it is very important that the organization has a computer application for handling documents.
Complaints and non-conforming work/products.

What do the reference standards require?

Complaints are referred to in a very limited way in both ISO 9001 (extremely ambiguously it says that "effective arrangements must be made for communication with customers about, among other things, complaints") and ISO 17025 (it states that there should be a procedure to deal with customer complaints, including investigating them and taking action).

Both standards have rather more to say about non-conforming work and products, that is to say those which do not meet established requirements. In this case, they require a system to be put in place to identify non-conforming products and which specifies who is responsible for dealing with them and authorising their use, release or acceptance and actions to prevent their unintentional use, for eliminating the non-conformity that has been identified, etc.

In practice, complaints come from customers while non-conforming work and products can be detected in numerous ways (during external or internal quality control, instrument calibration, verification of reports, certificates or specifications, by the customer, etc.). In some cases, they have specific names, for instance deviations (classified in remarks or non-conformities) when they come from internal or external audits.

What are the problems?

Staff attitudes to complaints (when they are directly affected by them) tend to be negative as they think they are "a stain on my record". As a result, they tend not to handle them formally (they don't open a complaint file in the quality system) and are usually quite defensive in dealing with them.

Solutions adopted tend to be one-offs and do not deal with the cause, which means the same complaint can recur. Consequently, they are not sufficiently exploited as a means of improvement.

Some ideas

Establish a culture through training and communication whereby complaints and non-conforming work and products are seen as an opportunity to improve. Solving them should entail a small step forward, a small degree of progress.

Analyse all complaints and non-conforming work and products detected and dealt with over a period of time (for instance in the course of a year) as this will provide an overview of the weaknesses of the QMS.
Corrective and preventive action

What do the reference standards require?

Corrective and preventive action needs to deal with the CAUSE of the non-conformity that has taken place or the potential cause, as it should provide not just a one-off solution to the problem but rather ensure that it does not happen again.

The efficacy of actions that are carried out also needs to be checked.

What are the problems?

On many occasions, dealing with the cause is complex and takes much longer than dealing with a specific incident that has come up and finding a solution for it. This means that management is more complex.

On many occasions, actions are carried out which are not subsequently recorded because they took place some time ago, because this is seen as being mere bureaucracy, etc.

Some ideas

Formulate corrective action very specifically so that it provides a solution in the short to medium term. It is better to make small improvements by tackling very specific issues rather than try to carry out complex corrective action that takes a long time and generates frustration and despondency. If this is not possible, corrective action should be approached as a separate project, for instance through improvement groups, outside standard management structures.
Internal audits

What do the reference standards require?

Internal audits should be carried out at planned intervals (usually every year) by qualified staff who are independent of the activity being audited.

What are the problems?

It can be hard to find an audit team inside the organization which is qualified (technically in terms of the activity to be audited and also in terms of carrying out audits) and impartial.

Some ideas

Internal audits can be carried out by external consultants thus avoiding independence problems.

If the foregoing is not possible (for instance due to its financial cost), it should be borne in mind that impartiality is closely connected with honesty. Hence if internal staff have to be used, priority should be given to demonstrating technical competence over impartiality as this will lead to more effective audits, in other words, ones which can detect non-compliance, faults and improvements in the QMS.

The success of an audit lies in painstaking preparation and being knowledgeable about the activity being audited.
Review of the QMS by management

What do the reference standards require?

Both the ISO 9001 and 17025 standards call for review by management to be planned (to take place on an annual basis as a guideline) and they provide an exhaustive list (which differs slightly between the standards) of the input for the review (audit results, customer feedback, changes which may affect the QMS, recommendations for improvement, etc.).

They also stress the need for results from the reviews, which will include decisions and actions (which must be implemented within an appropriate timeframe) concerning:

- increasing the efficacy of the QMS and its processes
- product improvement in response to customer requirements
- resource needs

What are the problems?

The participation of all relevant staff without this entailing a high cost in terms of working time.

Inefficacy of the review. Decisions are not taken and actions that can lead to improvements are not put forward, usually because there has been no proper preparation for the meeting, data has not been adequately analysed, etc.

Some ideas

Make sure that top management becomes genuinely engaged with this review.

Set up the meeting based on process indicators.

Do not entrust all the review to a single annual meeting. Do it over a number of sessions so that it is “continuous” and check that all relevant aspects have been reviewed over the course of the year.
Staff

What do the reference standards require?

QMS standards require the organization’s staff to have the competencies needed to carry out their tasks (competencies which are based on education, training, experience and skills). Appropriate records must be kept to demonstrate this.

Hence, a system has to be established to identify and meet training needs and evaluate the effectiveness of training that is given.

Furthermore, to ensure the QMS works properly staff need to:
- be familiar with and take on their functions and responsibilities
- be motivated, engaged and aware of the significance of their work in achieving objectives

What are the problems?

Implementing a QMS involves a change in working methods and is generally seen as extra work and more bureaucracy.

The members of an organization will quite frequently pose objections to changes undertaken. They may completely refuse to cooperate and want nothing to do with proposed changes; they may follow the letter but not the spirit of the new regulations, “doing things as they should be done” while deliberately allowing mistakes to be made; or they may acquiesce but with great resentment. These kinds of attitudes are manifestations of “resistance to change”, meaning the negative reaction by individuals or groups in an organization to changes in organizational system parameters.

Some ideas

The key factor in raising awareness about the importance of a quality management system is to generate and increase transparency, information and the degree of staff participation and involvement in the change process. This enables them to understand the reasons for the change and hence reduces resistance to it. This approach essentially assumes that the cause of the resistance lies in erroneous information or poor communication: if employees are given accurate information and misunderstandings are cleared up, resistance will disappear.

It is also important to meet the training requirements established in the standards, especially in terms of knowledge of the QMS.
Putting the functions and responsibilities of staff members into writing (for instance as job descriptions) will help to prevent confusion or vagueness about each person’s activities.
Methods. Validation

What do the reference standards require?

The laboratory should use testing methods which:

- meet customer needs (including normative requirements)
- are suitably documented (in other words can be repeated)
- are readily available to staff who carry out the tests
- are validated, that is to say seen as valid (through examination and the provision of objective evidence) for the specific purpose they are designed for. This usually involves obtaining their values for uncertainty, accuracy, detection and quantification limits, selectivity, linearity, repeatability, reproducibility, matrix effect, etc.

What are the problems?

Validation of methods requires specialised training.

Some ideas

When the laboratory uses standardised methods (previously documented and validated), it may well be the case that it should complement the testing procedure (as on many occasions the standards do not allow for proper repeatability) and carry out validation even though it is not complete (checking that the method is valid in its working conditions, i.e. staff, facilities, equipment, etc.).
Equipment. Maintenance, verification and calibration plan

What do the reference standards require?

Organizations should have all the equipment needed for carrying out tests, calibrations and studies, in other words with the features (accuracy, uncertainty, etc.) required to comply with the specifications of the activity to be performed.

Preventive maintenance, verification and calibration programmes must be mapped out and each item of equipment must be suitably identified (including its use and/or calibration status) and protected against accidental settings.

Calibrations must be carried out using standards that are nationally or internationally traceable.

What are the problems?

A degree of expert knowledge is required to carry out internal calibrations, which means laboratory staff have to be given specialist training.

Some ideas

It is highly advisable to use a computer programme to manage equipment. This programme should include data from each unit, the maintenance, verification and calibration plan (including alerts, e.g. units to be calibrated), the operations history, etc.
Internal and external quality control

What do the reference standards require?

One of the cornerstones of ISO 17025 is ensuring the quality of the results of tests and calibrations, and this must be planned by laboratories.

Some authors describe assessing result quality at three levels:

- level 1. Carried out simultaneously with each test (e.g. sterility controls in microbiology, calibration curve standards, etc.)

- level 2. Carried out periodically, for instance by making duplicates, repetitions, using reference material.

- level 3. This involves intercomparison exercises.

The plan must be complete (if it is recognised by a certification organization, it should cover all the certified tests) and must be proportional to the activity performed.

When quality control results are inadequate (they do not meet the preset criteria, for instance a Z-score > 3 in a round-robin test) they should be approached as non-conforming work in order to deal with the problem and its causes.

What are the problems?

When certification is wide-ranging, the direct cost of the quality control plan is normally quite high.

On occasions it is not possible to find intercomparison schemes which include certain types of analysis (e.g. viruses in foodstuffs).

Some ideas

Quality control is one of the basic pillars of confidence in the reliability of results, thus, it should be carried out irrespective of being accredited or not. Laboratories can take advantage of their participation in intercomparison schemes to carry out internal quality control.
Quality is not a priority and the QMS is maintained through audits

One of the most common problems in organizations which have a QMS in place is that the culture of quality and the system itself have not been interiorised by staff or built into their daily operations.

In the most serious cases, quality is seen by the organization’s staff as being the exclusive preserve of the quality department, that is to say quite the reverse of the “quality depends on all of us” concept.

As a result, the QMS is seen as a necessary evil for achieving recognition in the shape of credentialing or certification. Many QMS activities are carried out without staff really knowing why they are being done, and in some cases such as recordkeeping they are seen as being pure bureaucracy.

For the same reasons, QMS activities are stepped up when audit time comes around (normally once a year) and are run down or forgotten about once the audit is over. This means that QMS maintenance is highly ineffective and inefficient.

Preventing or finding a solution to these problems involves implementing a series of actions including the ones set out below:

- the organization’s top management must be heavily involved
- appropriate QMS training and communication is vitally important
- the QMS needs to focus on improvement, and achievements must be transmitted to all staff as feedback that boosts motivation and engagement
- all staff should take part in QMS activities to the extent that they can, and these activities should be built into daily work routines and not seen as something apart or extra
Cost of developing, implementing and maintaining the QMS

It is difficult to estimate the cost of developing, implementing and maintaining a quality system as in most cases, organizations do not have a system in place for assigning these costs which provides reliable data.

The cost will vary a great deal depending on the organization’s features (for instance, its size, complexity and so on), the quality standard to be implemented, the scope of the QMS, etc.

No published information has been found about this topic, but personal experience and knowledge of other organizations and companies make it possible to estimate that the cost of maintaining and improving a QMS comes to around 5-15% of turnover, a figure that with time and the maturity of the system usually falls significantly.

The major costs of developing and implementing a QMS and which did not exist beforehand are as follows:

- external consultants
- special training for implementation project leaders
- staff training
- drawing up documents
- purchasing computer applications
- purchasing equipment (e.g., standards)
- internal audits
- staff time taken up by coordination and monitoring meetings

Once the system is in place there are maintenance costs (which in some cases existed beforehand but have now probably risen) including:

- quality control activities, including taking part in intercomparison schemes
- preventive maintenance of equipment and internal and external calibrations
- annual internal audits
- external certification/accreditation audits
- staff time taken up by continuous learning, improvement groups, review of the QMS by management, handling complaints.
Next some figures are given in order to illustrate the situation in Spain in connection with the QMS. Data have been either informed straight from a number of Institutions or taken from their web sites or published in some articles.

Figures given are referred to QMS implemented and recognised by certification or accreditation boards.

In connection with ISO 9001 it is worth highlighting that:

- according to the magazine Forum Calidad, at the end of 2008, a total of 68,730 certificates had been issued by 23 certification companies (being Bureau Veritas Certification y AENOR the most important ones)

- from the available data an estimation of 4 % correspond to the sector “Engineering and R&D”

- we do not have data concerning the implementation of ISO 9001 in universities or technological centres.

With regards to the activity of analysis and calibration (accredited against ISO 17025)

- the Spanish accreditation board is called ENAC

- at the end of 2008 a total of 732 organizations were accredited (588 for testing and for 144 calibration) for a total of 1,244 accreditations (920 and 324 respectively)

- according to the information obtained from its web site (in a “search by words”), 46 testing labs and 22 calibration labs belong to universities

In connection with GLP

- there is only 1 scheme that can be accredited by ENAC according to the principles of GLP, that is, “studies of pesticide products and industrial chemical substances”

- A total of 23 accreditations have been issued, mainly in connection with field pesticide studies as well as pesticide characterization and residues

- one of the accreditations have been issued for a university
As to R&D&i is concerned, available data are the following:

- 11 organizations have been accredited by ENAC to certify R&D&i projects
- 3 organizations have been accredited to certify R&D&i management systems.

Between them, the number of valid certificates issued by AENOR is:

- Certification of R&D&i management systems: 245
- Certification of R&D&i projects: 108

Most of these (above 95%) belong to private companies, and just a few of them have been issued to Foundations or Technology Institutes.

The scope of certification is widely assorted: water, energy, infrastructure, materials and construction, instrumentation and control, industrial processes, science and technology, …
Implementing a Quality Management System
In Brief

When implementing a QMS the requirements laid out in the reference standards are of great help in order to know what to do. However some difficulties are found along the way, some of technical origin, some related to staff and top management (involvement, attitude, …)

Getting top management really involved is crucial for the success of the implementation of a QMS. Adequate transmission of the quality policy and objectives as well as providing proper training to staff will minimise or eliminate “resistance to change”, so contributing to the effectiveness of the implemented QMS

None of the activities carried out within the QMS must be an end in themselves. They do not have to be done "because it is a requirement laid down in the reference standard". On the contrary, all of them should add value, so the organization must decide what to do and how to do it. In this way the staff will have the perception that documents and records are useful (and not mere “bureaucracy”), they will think that internal audits and the management of complaints are powerful tools for continuous improvement, they will realise that quality control activities raises the confidence in the results obtained, … It is highly feasible that, in this way, the implementation of the QMS will be a priority and its maintenance activities will be carried out steadily.
Conclusions

1. Introduction

Reasons for implementing a QMS objectives and fields of application

2. Basic issues of the reference standards

ISO 9000
ISO 17025
Principles of GLP
UNE 166000

3. Implementing a QMS

Issues to be dealt with (involvement of management, system of documents, complaints, internal audits, ...)

4. Conclusions
The following conclusions may be drawn about the implementation of a QMS in technology centres and universities based on the points discussed in this document:

1. There are a number of reasons for deciding to implement a QMS which can basically be classified into two main groups: a wish to improve (in excellence, efficiency and customer satisfaction) and a wish for recognition. Every organization will have reasons of one or the other of these two kinds depending on their mission and strategy.

2. There are a range of standards with different objectives and fields of application which can be used as the basis for implementing a QMS. Those covered in this document are:

<table>
<thead>
<tr>
<th>Standard</th>
<th>Objective</th>
<th>Scope</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 9001</td>
<td>improve efficacy to satisfy client's requirements</td>
<td>improve quality management in any kind of organization</td>
<td>certifiable</td>
</tr>
<tr>
<td>ISO 17025 Principles of Good Laboratory Practice</td>
<td>technical competence in analysis and calibration promote the development of quality test data for the purpose of registering, licensing or regulating different products and chemicals.</td>
<td>testing and calibration laboratories non-clinical safety and environmental testing of test items contained in food and feed additives, pharmaceutical products, veterinary drugs, ...</td>
<td>accreditable</td>
</tr>
<tr>
<td>UNE 166001</td>
<td>help define, document and prepare R&amp;D&amp;i projects, improve its management</td>
<td>R&amp;D&amp;i projects regardless of their complexity, duration or technological field</td>
<td>certifiable</td>
</tr>
<tr>
<td>UNE 166002</td>
<td>improve the R&amp;D&amp;i results and the procedures of its internal transfer in order to optimise the technological innovation processes of the organization</td>
<td>R&amp;D&amp;i management systems</td>
<td>certifiable</td>
</tr>
</tbody>
</table>

3. The standards lay down management and/or technical requirements which must be met if the organization wishes to achieve recognition from a third party (a credentialing or certification organization).
4. There is some overlap between the requirements in the various standards, and consequently implementation should be carried out from the perspective of an integrated system.

5. Although all the requirements set out in the standards are important, some are considered to be critical when it comes to implementing and maintaining an effective QMS. They include the engagement of management and staff training and motivation.

6. Although implementation time for a QMS will vary a lot between organizations, it normally takes between 1 and 2 years, and maintenance costs can come to around 5-15% of the organization’s turnover.
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