The implementation of a quality management system (QMS) in a public research centre employs 57 people including researchers, technicians and administrative staff. This system is based on the scheme of regional accreditation of industrial research laboratories which was inspired by ISO 9001:2008 and ISO 17025:2005 and set up by the regional authority. The overall aim of the management system is to monitor all of the industrial research and services which the centre offers to external users, such as government, private and public bodies and companies, and to guarantee that final products, usually technical reports and prototypes, respond to their needs. The accreditation applies to all of the activity of the research centre except for basic research. In this article the critical factors influencing the success of the implementation of the management system are outlined together with benefits and opportunities. Weak points and problems are analysed, and the actions which were undertaken in order to prevent and manage problems are described.

Introduction

The implementation of QMSs in public research centres is still rare, principally because of the widespread belief that quality assurance and control tend to limit researchers’ freedom, but also because there are no widely acknowledged international standards or guidelines for research laboratories to follow.

In recent decades standards and schemes developed by various organizations have proliferated, each one with its own specifications. Thus the French Atomic Energy Commission [1], the American National Standards Institute [2], the U.S. Department of Energy [3] and EURACHEM, the European network of organizations concerned with analytical measurement [4], have all published guidelines and standards for quality in basic and applied research, but none of them has been generally accepted.

However, the market demands confirmation of the ability of public and private research laboratories to provide professional research and innovation services to external clients. This confirmation can be given if research laboratories operate according to a quality system, and some national and regional accreditation bodies do already offer institutional accreditation (IA) procedures for R&D laboratories to guarantee certain predetermined criteria or standards to external users.

In 2010 in Italy, Emilia Romagna’s regional authority set up a system for the IA of industrial research laboratories. The aim of the authority was to support the R&D of regional enterprises and encourage them to cooperate with external research centres, something which they could do to a greater extent. IA shows that public and private research
laboratories are able to respond professionally to the needs of external clients, public and private, who need support for research and innovation.

In this paper we describe the process of the implementation of a QMS which complies with the requirements of IA, and we report difficulties and opportunities related to its application in a public research centre. Before we start the presentation it is advisable to point out the meaning of the terms “certification” and “institutional accreditation”. Certification is the provision, by an independent body, of written assurance (a certificate) that the product, service or system in question meets specific requirements. In that context, accreditation refers to the formal recognition by a specialized body (an accreditation body) that a certification body is competent to carry out certification in specified business sectors. In simple terms, accreditation is the certification of the certification body. Institutional Accreditation is instead a process implemented by local or national governments, which assures that a body satisfies given requirements. If requirements are met, accredited status is granted. The first IA program was established in the USA in 1917 in order to verify that healthcare organisations meet specific quality requirements, and it later spread worldwide. IA systems are usually used in the areas of healthcare and education, and they can have different objectives, criteria and assessment processes.

Background

The Institute of Science and Technology for Ceramics (CNR ISTEC) is a public research centre belonging to the Italian National Research Council. Due to the shrinkage of government funds in the last decade, and since it is not reasonable to expect the trend to reverse soon, CNR ISTEC’s activities have been increasingly oriented to the market, and the Institute’s resources are now mostly dedicated to industrial research and laboratory services in co-operation with, or funded by, public and private stakeholders. The European Community, national and regional research funding programmes, research contracts paid for by private companies, and research services on behalf of third parties are the source of most of CNR ISTEC’s financial support. The Institute employs about 30 researchers, 7 laboratory technicians and about 20 temporary researchers and Ph.D. students.

In 2010 Emilia Romagna’s regional authority invited CNR ISTEC to apply for IA of its industrial research laboratories [5]. The IA programme was set up by the region in order to ensure the ability of public and private research laboratories to satisfy the needs of external clients, public and private, who require research and innovation services. In particular, IA guarantees to external users: professional services in terms of results, cost, delivery time, confidentiality protection and client satisfaction; the research centre’s ability to plan and implement tailored industrial research projects; the centre’s technical expertise on specific products and technologies; appropriately equipped laboratories and suitable instrumentation. Accredited bodies become members of the High Technology Network (HTN) of Emilia-Romagna, which brings together certified academic institutions and public research centres located throughout the region, and which can provide the production system with expertise, tools and resources.

An independent body was commissioned to perform the auditing and inspections which were demanded by the accreditation programme, and the relative costs were paid by the regional authority.

The benefits of getting IA were immediately clear to the managers of CNR ISTEC. First of all, membership of the HTN would enable CNR ISTEC to play a prominent role in regional research policies. Secondly, HTN members would have the exclusive right to apply for regional funds for their activities.

Nature of the IA Scheme

The function of IA is to certify the organization’s competence to carry out industrial research and technology transfer for external users. The IA scheme mainly looks at the organizational aspects of research laboratories regarding their relationship with their clients: the presentation of research results, intellectual property rights, standard research contracts and customer satisfaction. To become accredited, the organization must implement a management system in accordance with the requirements.

The IA scheme regards the possession of ISO 9001:2008 [6] or ISO 17025:2005 [7] certification as an important element in the attainment of accreditation. Indeed, IA specific requirements are similar to ISO 17025, which deals with the ability of laboratories to carry out tests and/or calibrations, or to ISO 9001:2008, which states requirements for a quality management system aimed at demonstrating that products are fit for purpose, and enhancing customer satisfaction.
The specific requirements of IA are therefore described below, and similarities with the above-mentioned ISO specifications are highlighted.

The basic principles of IA involve the implementation of a QMS related to: management and internal responsibilities, which must be defined and communicated; the areas of expertise of staff, which have to be ensured, maintained and improved by identifying relevant training needs and providing appropriate training; equipment, which must be identified, recorded and periodically calibrated or maintained; services to clients, which must be exhaustively defined and communicated to external users in terms of the kind and field of expertise offered by the research centre.

IA assures that the relationship with clients is regulated through written procedures: contract conditions and intellectual property rights policy must be clearly explained and negotiated with the customer; ethical and confidentiality obligations have to be formally stated and publicised. Finally, customer satisfaction must be measured and the results used to make improvements.

Regarding product realisation, IA says that it must be planned, controlled and registered, and that the traceability of documents, records, experimental data and operators has to be assured.

An annual improvement plan must be prepared, and the organization must conduct internal audits, at planned intervals, to determine whether the QMS has conformed to IA requirements, and whether the improvement plan is being implemented correctly.

The organization must define and monitor indicators which demonstrate the suitability and effectiveness of the QMS. A written procedure must be set out for the annual meeting in which the research centre’s management review the system. During this annual meeting, data are presented and analysed in order to guarantee efficiency and continuously improve the QMS.

So far we have highlighted the similarities of the IA scheme and the ISO standards. The most substantial difference between them is that there is no process approach in IA, so there is no requirement to document the processes within the organization and their interaction. IA does not expressly require either written quality manuals and or written documents which follow management procedures: purchasing, preventive and corrective actions, buildings and work environment.

**QMS Implementation**

The decision of the management of CNR ISTEC to apply for IA was taken in 2010 and in a short time a project manager was appointed.

Although not required by IA, CNR ISTEC chose to meet its requirements through a process approach, as required by ISO 9001:2008, and to effectively manage the process of providing industrial research services for external users by establishing a QMS and preparing a quality manual.

Therefore, the overall scope of the QMS is to monitor all of the institute’s activities of industrial research and services for external users, such as government, private and public bodies and companies, and guarantee that final products, usually technical reports and prototypes, respond to their needs.

In spite of the lack of expertise in internal quality assurance, CNR ISTEC did not need to engage external consultants, as it had access to its own in-house experts, Q-Campus, a network of certified CNR research institutes with the role of supporting fellow institutes in the implementation of their QMSs. The cooperation of Q-Campus was invaluable in terms of expertise and helpfulness. Furthermore, Q-Campus members donated their time, free of charge, helping to keep the accreditation costs low.

The implementation phase consisted of the following steps:

- process analysis, the existing processes were identified and analysed;
- comparison of the existing processes with IA requirements;
- process optimization;
- drafting of the procedures;
- testing on small groups;
- revision of the procedures;
- implementation of the procedures;
The structure of the QMS follows the main process chain of a project, beginning with contact requests and quotations, and ending with the delivery of the final reports and prototypes. Management elements, e.g. internal audits and management reviews, and non-project elements, e.g. marketing, complete the system.

As the whole institute had to be certified, we adopted a bottom-up approach aimed at involving all staff members in the planning of the QMS. For this purpose, the director of CNR ISTEC held an initial general meeting, in order to raise staff motivation and awareness. She stated her desire to obtain IA, and invited Q-Campus representatives to explain the meaning and importance of quality assurance and their experience in public research organizations. From the start, the appointed quality manager worked in close collaboration with the users, carrying out personal interviews with key staff members during the analysis of the existing processes in order to highlight best practices and involve people to a greater extent.

The equipment at the Institute was spread out in sixteen laboratories, and for each laboratory a manager was appointed. These laboratory equipment managers were involved in drafting the procedure for equipment management. IA, mimicking the ISO17025, requires a complete history of each piece of equipment. This is carried out by means of detailed records of calibrations, repairs, routine maintenance and performance checks. Every scientific instrument was provided with its own identification card on which calibration and maintenance needs, frequencies, tolerance limits and all maintenance is recorded. In addition, a master list of the available instrumentations was compiled including: identification details, location, laboratory name, calibration dates and frequency, and the name of the person in charge, in order to be able to monitor any piece of equipment at any time.

Researchers, administrative officers and the director’s secretary helped in the mapping of the process of offers, orders and contract management. In addition, the director’s secretary helped in the planning of the staff expertise management process.

Procedure drafts were tested and verified by small groups of volunteers before being submitted for approval. This enabled us to identify mistakes before the procedure was officially adopted. Although not mandatory, a written procedure for document control was established.

The QMS was finally approved and came into effect in June 2011. Staff training, which was regarded as key to the success of the QMS, immediately followed. Specific training was provided for every member of staff, depending on their function, and questionnaires were administered at the end of each class in order to determine what the participants had learned and, if necessary, what still needed to be learned.

QMS documentation is electronically available to all staff on the intranet in an organized and easily searchable database, and QMS records are stored there in separate folders. Every staff member can access QMS data any time they need and from anywhere, using the option of remote user connection. The instrumentation master list, records of quotations, the technical reports database and the active contracts database are available for consultation with full transparency.

The first internal audit took place in autumn 2011, and it gathered relevant information about the implementation of the QMS and its compliance with IA requirements. A QMS revision followed.

The management’s first review meeting took place in early December to discuss the functioning of the quality system and to analyse the industrial research and service work which had been carried out for external users in the period 01/06/2011 - 31/10/2011. The analysis was of turnover, contracts and orders, technical reports which had been issued, scientific publications, projects which had been approved for funding, customer satisfaction results, internal audit results, customer complaints and staff training.

In December 2011, a third party auditor declared that the QMS conformed with IA requirements, and CNR ISTEC obtained IA in February 2012.

**Problems and Success Factors**

- **Cost**
  The cost of accreditation was one of the main causes of disagreement on the project, in particular the cost of maintenance and calibration. It sometimes happens that laboratories calibrate two identical instruments. An alternative would be to share a single calibrated instrument among several operators, thus halving the cost of calibration. In addition, costs can be kept low by, whenever possible, performing internal calibration, instead of contracting out, and...
by being careful not to calibrate more often than is necessary. The frequency of calibration depends on many factors, including instrument sensitivity and usage. In the case of instruments which are seldom used, the frequency of calibration can be reduced. Instruments can even be calibrated just before they are used rather than at set intervals. Taking into account firstly the quality of the final product, and following the above mentioned options, we saved money, improved the condition of the equipment, and carried out monitoring. We did not calibrate every measuring instrument, but only those whose results affect the quality of the final product. The need and frequency of calibration were defined for each individual measuring instrument according to the manufacturer’s recommendations, standards and relevant procedures, instrument past behaviour, overall impact of non-compliances and frequency of use.

- **Slowness**
  People worried about having to deal with additional paperwork, slowness and uncertainty. Bearing in mind that written procedures and forms are required, we tried to be as concise as possible, at the same time keeping the QMS flexible, transparent, participatory and continuously improved without exceeding with details.

- **Staff Motivation**
  The motivation of the research centre staff could not be increased through bonus payments and other benefits because they are public employees and earn a fixed salary. In order to reduce their natural resistance to change we informed them of the reasons for the implementation of the QMS, as well as the deriving benefits, and provided process details, a schedule and updates. We also encouraged the involvement of interested parties in the planning of the system by asking them for suggestions, incorporating their ideas and emphasizing their best practices in the management system. In this way the staff members were a little involved in the development of the QMS, felt their initiatives were appreciated and therefore their motivation increased. Moreover, we acted in order to obtain support from staff with specific roles in the QMS, as well as to assign key roles to committed people. The commitment of the management of CNR ISTEC was vital in overcoming problems and barriers, and the quality manager found in the director an essential ally in the solution of conflicts and in creating positive attitude and contagious commitment towards the QMS. There were, however, still isolated cases of employees who found it hard to accept the QMS. When directly asked, there were a few people who claimed that the information which was transparently shared could be used against them. Dealing with them was the hardest part of the job, and the full support of ISTEC management was essential to contain this inappropriate behaviour.

- **Resources**
  The availability of necessary resources and the creation of internal expertise in quality systems were additional critical factors in achieving accreditation. The director gathered and provided the required resources (human, financial, technological, infrastructural) to pursue the goal, and she specified the role, responsibility and authority of everyone involved in the planning of the QMS.

- **External Experts**
  Lastly, the Q-Campus experts provided an external perspective, monitored the implementation of the system, offered advice and experience, and helped to ensure success.

**Conclusions**

Increasing competition in the world market of research requires organizations to take advantage of every opportunity for progress, and research institutes should see the implementation of a QMS as a chance to improve their performance. In this paper we analysed the implementation of a QMS in a public research centre with 57 employees, and described some of the critical factors which influenced its success. The quality management system that was successfully implemented and is maintained, complies with the requirements of IA for industrial research services as set out by the regional authority. IA certifies the excellence of industrial research, which constitutes a large part of the work of the research centre under consideration. Only basic research is excluded from the procedure. The accreditation path was undertaken because of pressure from the regional authority. The aim was not to be excluded from regional research programmes. The centre set up a QMS which meets the requirements of IA, a scheme very similar to ISO 9001:2008. Assuming that a QMS can only be successfully implemented if it is fully supported by the general management, and if every staff member is committed to it, the project benefited from management’s attitude and involvement combined with the in-house experts’ support, and the application of a top down approach together with a bottom up approach was the key to success. The introduction of a QMS in the research centre did not lead, as feared, to increased bureaucracy and reduced space for independent research. It did, in fact, prove to be beneficial. Now, in fact, responsibilities are well defined, roles are
clear, and staff members know the correct way to behave in any situation. Moreover, in most cases morale has improved because of the greater transparency resulting from sharing information. Before the implementation of this system, researchers relied very much on their memory, and therefore, when they were absent from work, data were not accessible. QMS has improved data traceability with, for example, historical reconstructions of data, and the transparency of records, organization and responsibilities.

All staff are now included in annual training programmes. Training activities are recorded, monitored and assessed. Instruments and equipment are scheduled for maintenance and calibration and are constantly monitored to prevent failures and malfunctioning.

The work which was carried out during the setting up of the QMS developed and consolidated knowledge and skills which were formerly lacking in the research centre, including especially experience in quality systems, the deep understanding of the specific standards governing them, and the full comprehension of their purposes and point of view. Such knowledge has already proved to be precious when customers have asked us to develop Quality Plans for them. The gained experience allowed the research centre to quickly make up good quality plans without hiring consultants.

In the near future the management of the Institute will examine the requirements for its own ISO 9001:2008 certification.

Acknowledgements

I wish to thank Sandro Menegatti, David Jafrancesco and Q-Campus, spontaneous network of CNR Institutes for the development of a Quality Culture in the field of scientific research. This would not have been possible without their help.

Thanks are also due to the Emilia Romagna regional authority for bearing the cost of the inspection activities.

Keywords

Quality assurance, research organisations, R&D

References