

# IMPLEMENTATION OF A QUALITY SYSTEM IN THE ACADEMIC ENVIRONMENT AND IN RESEARCH AND DEVELOPMENT LABORATORIES

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*Abstract: An operational quality system is one of the opportunities to demonstrate the technical competence of laboratories in the academic environment. The International Standard ISO/IEC 17025 includes many requirements to such a quality system. A new approach has been developed in which these requirements have been prioritised, taking into account the specific aspects of work and organisation of e.g. a university laboratory. Basic and complimentary requirements have been distinguished, resulting in an initial reduction of the total number of items to be implemented. In addition, a modular system for implementation is suggested, to accommodate the awareness building and training of employees.*

*Keywords: Quality assurance, ISO/IEC 17025, academic laboratories*

## 1 INTRODUCTION

The increasing globalization of trade has resulted in the development of tools to increase the mutual acceptance of products and their specifications. International accepted standards such as the ISO/IEC 17025, have been developed for the operation of testing laboratories, and to give objective evidence of their technical competence and the quality of their tests. This implies the implementation of a system for quality assurance of the managerial and technical activities. For international acceptance, laboratories seek for accreditation for compliance of their quality system with the standard.

Quality systems enhance the efficiency and effectiveness of operations and reduce costs. Such operational characteristics are equally beneficial to laboratories at universities and research and development laboratories. It is part of the learning process if students have to repeat work because of wrong hypotheses; it is a waste of time and resources if this is due (as often occurs) to improper preparation, carelessness during the work or by interfering activities of others. In addition, university laboratories are increasingly consulted and asked for measurements that are too complicated to be done at routine laboratories. Industrial customers may set high demands to demonstration of the quality of these tests, to ensure comparability. This requires not only demonstration of competence, but also assurance on calibration, validation of the method, evaluation of measurement uncertainty and proper documentation.

However, it has often been noticed that in academic and research establishments some skepticism exists about the value of quality management for the scientific goals. It is feared that a too formal quality management approach would restrict scientific freedom and progress, and would increase bureaucracy. Some scientists interpret their academic freedom as freedom to non-commitment, which may have far-reaching negative consequences for trackability and assurance of the other operations in the laboratory.

Still, things go wrong in laboratories and experiments have to be repeated. There are several reasons for this, varying from the use of non-validated methods and the utilization of equipment without having the knowledge on its principles of operation, to poor documentation and poor planning. Universities have, in general, a doubtful reputation if it comes to planning and reporting in time.

This paper presents a pragmatic approach [1] for the introduction and implementation of quality assurance in the academic environment, taking into account the special aspects of these laboratories. The feasibility of quality systems within the academic environment has been demonstrated already several years ago [2]. This new approach is based on the direct experience of over a decade with the development, implementation and operation of quality systems in the academic environment (universities and other research and development laboratories [2-3]).

## 2 NEW APPROACH

The basic idea behind the new approach is that it is often not necessary for university laboratories to implement a quality system in full compliance with the ISO/IEC 17025, but that customers require some form of evidence on technical competence for the work to be performed. Therefore, the requirements of the international standard were carefully examined, prioritized and dissected in three categories, viz. (i) Basic organizational requirements, (ii) Technical requirements and (iii) Management requirements. These categories match quite well with the three stages that can be distinguished in scientific research, viz. preparation, execution and review:

**Stage I. Preparation.** The activity to be performed is discussed, defined and organized and planned. This sets the 'Basic Organizational Requirements' to ensure the existence of a minimal organizational structure that is capable of supporting the introduction of the technical requirements. These requirements deal with

- Accommodations and Environmental Conditions
- Organization and Quality System
- Document Control and Control of Records
- Nonconformity Control, Cause Analysis, Corrective and Preventive Action

**Stage II. Execution.** The scheduled activities are carried-out as planned. The emphasis lies now with the applied methods (e.g. if they have been validated prior to use), the fitness of the instrumentation and the skills of its employees. The 'Technical Requirements', once implemented, will ensure the effectiveness, efficiency and quality of the results of the work. These requirements deal with

- Personnel
- Testing, calibration and validation methods
- Equipment
- Measurement uncertainty and traceability

**Stage III. Review.** It has to be demonstrated how the work was actually done, in principle in conformity with the action plan but e.g. also why and how was deviated from this plan and if the documentation and records are well maintained. To this end, 'Requirements to management' are set; once implemented, these requirements will ensure that the quality system formed by the requirements in stages I and II is functioning properly and efficiently. This all can be effectuated via Internal Audits and Management Review

The relevant clauses of the ISO/IEC 17025 have been prioritized into Basic and Complimentary Items (see Figure 1 and Table 1):

- **Basic Items** – these are considered to be the minimum requirements needed to give objective evidence on its technical and managerial capabilities. Typically these requirements deal with the existence of procedures, statements of compliance, client-related policies and the way work is being carried out.
- **Complimentary Items** – these are derived from the remaining Clauses of the ISO/IEC 17025. Though they are mandatory ("...shall...") in the context of ISO/IEC 17025, there is a less urgent need to implement them if a laboratory is not seeking for formal accreditation.



Figure 1. Structure of items in ISO/IEC 17025 (according to new approach)

Table 1 – Overview of the minimum requirements to quality management at universities and research and development laboratories

REQUIREMENTS		Total number of items	
ISO/IEC 17025 Clause	Stage I - Basic Organizational Requirements	Recommended Basic Items	Complimentary Items
5.3	Accommodation and environmental conditions	5	7
4.1	Organization	9	5
4.2	Quality System	14	-
4.3	Document Control	14	-
4.9	Non-conformity control	8	-
4.10	Corrective action	7	2
4.11	Preventive action	2	1
4.12	Control of Records	14	-
	<b>Stage II – Technical Requirements</b>		
5.2	Personnel	11	8
5.4	Testing, calibration and validation methods	29	6
5.5	Equipment	19	-
5.6	Measurement traceability	12	4
	<b>Stage III – Management Requirements</b>		
4.13	Internal Audits	7	-
4.14	Management review	4	-
	<b>TOTAL</b>	<b>155</b>	<b>33</b>

The remaining Clauses of the International Standard are summarized in Table 2. This does not imply that these clauses are not important or not relevant. Laboratories, expecting a growth in external 'routine' services may benefit from the requirements as laid down in Clauses 4.4 and 4.7. Laboratories, involved in e.g. legal metrology or serving forensic institutes may prefer to fulfil the requirements of Clause 5.9 during Stage II of the research being carried out. At the first sight, it may even seem odd that the requirements of Clause 5.9 have not been selected in Table 1. However, this Clause is more applicable to routine services than to research and development, and to some extent, insight in the quality of the results will be obtained via the method validation, complying with the requirements in Clause 5.4 during Stage II.

Table 2 - List of items that are not included in the new approach

ISO/IEC 17025 Clause	Requirements that are not included in the approach	Items in Clause
4.4	Contract Review	9
4.5	Subcontracting of tests and calibrations	4
4.6	Purchase of services and supplies	9
4.7	Customer services	2
4.8	Complaints	2
5.1	Technical requirement – general	2
5.7	Sampling	7
5.8	Handling of testing and calibration items	13
5.9	Assuring the quality of test results	8
5.10	Results report	28
	<b>TOTAL REMAINING NUMBER OF ITEMS</b>	<b>84</b>

### 3 IMPLEMENTATION OF THE NEW APPROACH

Introduction of a quality system requires an action plan with a triangular interaction between 'hardware' (the physical means of an organization), 'software' (the amount of information) and 'humanware' (representing the individual who has to work as efficient and effective as possible). Implementation of a quality system is most difficult with the permanent staff since any change in the style of working and organization, no matter how simple, always meet with resistance, comparable to the repulsive forces if a foreign object is implanted in a human body. Fact is that a traditional style of working may have to be abandoned and that, inevitably, some paperwork and bureaucracy has to be introduced. Moreover, scientists often have difficulties to accept that careful planning and documentation contributes to a higher efficiency of work and savings of resources. Repetition of work is often interpreted as a part of the research, to which they are entitled being an academic. The introduction and implementation of the quality system should therefore be parallel to an identification of current deficiencies on the respective topics, such as repetition of work, poor trackability of operations, irritations and waste of resources.

Laboratory managers should be well aware of the importance of awareness building in a structured manner, which may include lectures in sequential modules on the quality principles, the modern view on management of laboratories, harmonization of work etc.

Lectures on the introduction of this style of working may be done via the following sequence:

**Module 1 – Quality Principles** – This Module starts with awareness training. Examples of 'disasters' in research (preferentially in the laboratory's own history) should be reviewed. Basic quality concepts are presented in this module, as well as their application to products and services. The concepts of internal *vis-à-vis* external clients are also explained. This Module ends with an identification of the laboratory's own driving forces to implement a quality system.

**Module 2 – Modern Management Vision** – This module explains the interaction between Man, Machine and Information. The objective is to provide an overview of the organization in which people work and to show them where they are located within the context of this organization. Fishbone diagrams are a useful tool in this. Such factors are essential for the development of motivation for innovation and change.

**Module 3 – 5 S Program** – Prior to the introduction of any new system or model, it is worthwhile to assess the current status, and to identify the current waste of time or materials. The 5S approach<sup>1</sup> is an adequate tool in it. The 5S philosophy focuses on effective workplace organization and standardized work procedures. It simplifies the work environment, reduces waste and non-value activity while improving quality efficiency and safety. This module is highly interactive and enhances the awareness that quality management relates to every component and person in the organization. It is the onset of a culture in which people realize that this should be based on "what can we do to prevent that it happens again?" rather than on 'who's to blame for it?'. This Module may end with the awareness that it is meaningful to document the style of working via working instructions/procedures.

**Module 4 – Standardization** – the objective of this module is to define and establish standardized (i.e. harmonized) procedures for all laboratory routines. This will generate a more uniform performance of all activities and a consequent reduction of failures. The difficulty in this step lies with the fact that to some extent harmonization in work is needed to reduce the variation –and hence the sources of error- between workers. Sometimes, e.g. for use of equipment, the manufacturer's manuals can serve as a basis. A specific training program on the drafting procedures and instructions complements this module.

**Module 5 – Introduction of a Quality system** - once the concept of standardization has been implemented, it becomes necessary to define a structure that will support all the procedures and standards that have been established. The definition must comprise a system that ensures quality and must also address the interrelationship between all the different procedures (activities) and standards, and this may be accomplished by simply making the necessary adaptations to the standard that is being employed. At this point it has to become clear that (initially ?) only part of the requirements of the International Standard will be implemented –unless there is a driving force to obtain formal accreditation.

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<sup>1</sup> 5S: A philosophy based on the Japanese words Seiri-Seiton-Seisi-Seiketsu-Shitsuke, sometimes translated into: Sort unnecessary items-Set in order- Shine (clean-up the lab) – Standardize – Sustain.

**Module 6 – Introduction of an Effective Internal Audit system** - although a quality system already provides the internal audit requirement, it is important to underpin this point in a separate module on account of its importance in terms of maintaining an effective Quality System. The employees must learn to accept that the purpose of an audit is to verify that a system is functioning efficiently rather than to look for people to blame. Nevertheless, it is this type of assessment that leads to the identification of a number of non-conformities that are either due to noncompliance with the established procedures, or to poorly trained personnel, or may even result from the need to improve the procedures of a specific process.

**Module 7/8 – Quality Tools** – This Module focuses, amongst others, on the opportunities of non-conformance management. Non-conformities do not *a priori* relate to the findings during internal audits; there may be many situations during work –especially in a research environment- in which for forced or unforced reasons the scheduled path has to be left. Similarly, hypotheses and/or specifications may not be met as expected in the test plan. Non-conformance management, in combination with cause analysis, remedial and corrective actions forms the basis for a systematic elimination of sources of error, and further development of the quality system. Other quality tools that will be discussed in this Module are the assignment of quantified criteria at decision points, the use of control charts and e.g. Pareto analysis.

**Module 8 - Introduction of a Routine Management system** - at this point, all the features that are necessary for the organization to function efficiently are already in place. Whether the laboratory in question is large or small, all that technical managers and operations managers need to do now is define their targets and goals and promote follow-up assessment of the processes by means of the control items. In case the objectives have not been attained, it then becomes necessary to define responsibilities and authority so as to submit the process to corrective action with the use of the tools and methodologies that have been described above. This Module aims to prepare an action plan for implementation of the quality system, identifying the task(s), person(s) involved and deadline for implementation or completion of the first draft written procedure.

Differently from the permanent staff, students have less difficulty in dealing with the requirements of a quality system. Firstly, it's the style of working at the laboratory they selected, and it's a simply matter of 'take it or leave it'. Compliance with the quality system may be put at the same level as compliance with (conventional, hygienic, toxicological, radiological etc.) safety rules. Secondly, being active in a laboratory with an operational quality system is an excellent preparation for a later career in an industrial or private laboratory/environment where such cultures have been implemented as an essential need to 'survive' amongst competition.

## 4 DISCUSSION AND CONCLUSIONS

In many laboratories it may be found that several of the requirements to quality management, as laid down in the clauses of the International Standard ISO/IEC 17025 are already operational, either solely in the practice or both in the practice and as written procedures. However, alleged 'academic freedom' often results in a declining discipline towards commitment to these quality rules. Moreover, the quality management activities are not planned, which typically reflects the academic environment.

The prioritization of the requirements of the international standard ISO/IEC 17025 should not be interpreted as a shortcut to simplify the quest for demonstration of technical competence of academic laboratories, rather as a logistic strategy for attaining a recognition of being a reliable partner for collaboration. In certain cases, it will be the stepping stone towards a quality system in full compliance with the standard.

A quality system introduces, unavoidable, a certain amount of paperwork and some degree of bureaucracy. In return, the laboratory's activities are better documented, reproducible whereas sources of error will systematically be eliminated. The here presented approach is currently implemented in the Mass Spectrometry Laboratory of the Chemistry Department of the Pontifical Catholic University (PUC-Rio), Rio de Janeiro, Brazil. The same approach has also been adopted as a model by the new regional metrology organization (Rio-Metrologia Agency). This organization intends to strengthen the infrastructure of the laboratory services in the State area by implementing laboratory-training programs. A quality system, accredited for compliance with the internationally accepted norms, is already operational since 1992 at the Delft University of Technology [2].

Quality assurance for 'routine' operations is a well-accepted culture in industry, private companies and in several governmental research organizations. In addition, there is an increasing interest and need for implementing quality assurance in the research and development, and non-routine

operations [3-4]. It can not be excluded that the underlying guides will somehow form the basis for a new style of working and education in the 21<sup>st</sup> century, also at universities.

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