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# The scope and limitations of a QA system in research

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**Abstract** The article analyses the scope and limitations of quality systems for research centres in the light of the problems involved, foreseen advantages, and growing need created in the context of the globalisation phenomenon. Some propositions are put forward concerning the development of possible quality assurance strategies for research activities.

**Key words** Quality system · Research · Research and development · Quality assurance

## Introduction

The quality assurance (QA) system for laboratory services and research and development (R&D) in the industrial sector is now universally accepted and widely applied. However, the QA approach to research (basic and applied) and to R&D in academic research centres remains a highly controversial issue. An interest for developing a quality system (QS) appropriate for R&D [1–4] is manifested by various sources, such as accreditation bodies, funding organisations and others in whose interest the research is being performed. At the same time, there persists much scepticism, critical reaction and a deep concern amongst some in the scientific community, mainly in academic institutions, with regard to the feasibility and practicality of the present QA system in research activities.

This paper presents a critical evaluation of different issues that contribute to the problems as well as to many advantages related to the implementation of a QS in research facilities. A brief historical background of the evolution in quality concepts is presented. The purpose is to focus on the scope and limitations of extending the existing QA systems to research and R&D in academic scientific centres. Different stages of a research project are discussed in relation to the QA requirements pertinent to each phase. Finally, some comments and propositions concern mainly the topics that require particular attention for adapting the present QA requirements for research. This paper does not cover the applications of QA systems in R&D related to production in the industrial sector.

## Quality systems

### Evolution in quality concepts

Considerable interest developed during the 1950s–1960s to "control the quality" of industrial products at the end of a production chain. Subsequently, the principles of "quality control" were introduced during the entire production chain to produce products of high quality (total QS). The development of QA systems received much attention during the decade from 1970 to 1980 in the interest of establishing a formal structure to satisfy quality criteria, and to establish confidence in the quality of products and services. First the system was based on second-party assessment (interested par-

ty). Subsequently, the procedure involved third-party assessment based on the requirements published in international standards, with a view to develop a uniform system. This constitutes the basis of the present QA systems for laboratory services. Some scientists often tend to link directly the concept of quality control applied in the industrial sector with a relevant QA approach for research facilities. This trend creates many difficulties for recognising the important contribution of a QA system in research activities.

## Essential elements of QSs

The existing QSs developed for laboratory services came into effect as a result of an input from three major sources, as illustrated in Fig. 1. The elements indicated in block 1 laid the grounds for creating the infrastructure for accreditation and certification systems. The international standards (EN 45000 and ISO 9000 series, ISO Guide 25 and good laboratory pratice (GLP) indicated in block 2) provide the basis for a uniform QA system. EN 45001 [5, 6] and ISO/IEC Guide 25 [7] set the requirements for testing laboratories, and cover both quality management (QM) and technical competence (TC) in specified areas. Certification based on ISO 9001 [8] relates primarily to QM in the concept, design, development, production of products and for providing services. GLP [9] is mainly concerned with the planning, performance and recording of studies, and is actually less demanding on TC. Harmonised and validated procedures (block 3) are either available from different standards and the literature, or they are developed in the laboratory to perform the required tests or analysis. Both EN 45001 and GLP emphasise a direct link between QM and TC. These standards are too rigid and detailed to be implemented in their integrity in research activities.

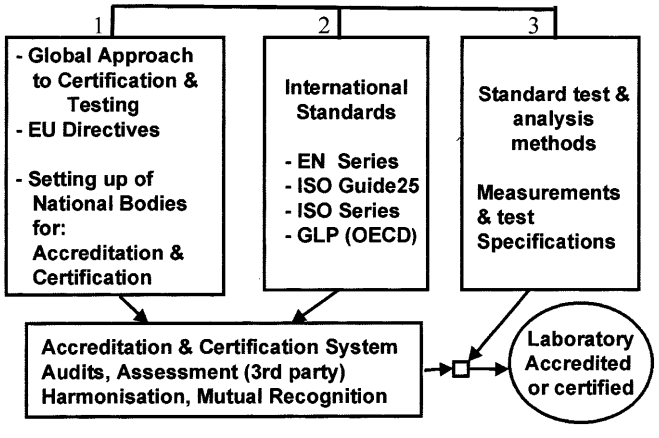


**Fig. 1** Essential components of a quality system

## Research and R&D

Research (basic or applied) is a continuously evolving process based on scientific investigations aimed at discovering new facts (new inventions and innovation of techniques). This is in contrast to the repeated performance of routine tests and measurements with fixed objectives, and by applying the standards and the prescribed procedures. Consequently, these two cases require partially different approaches to the QA system in terms of standardisation, organisation, managerial functions and flexibility.

Basic research represents original experimental and theoretical investigations with the main objective to acquire fundamental knowledge and understanding of facts, without prior considerations for specific applications even though important applications may emerge eventually. The objectives of a basic research project may be precise or vast involving a large number of unknown factors and undefined parameters. Applied research concerns mainly original investigations or improvements upon the existing knowledge in the interest of scientific or industrial applications. A sharp boundary cannot be drawn between basic and applied research. In general, R&D comprises improvements and verification of known facts, testing the feasibility of a project, building a prototype, optimisation of conditions and standardisation of protocols. In general, the R&D processes are based on some available knowledge that may not be exact or sufficient at the start, but nevertheless provides a background for future work in a more precise manner. As a result, it is possible to formulate, within a limited range and predefined criteria, the parameters to be investigated, the methods and techniques to be employed, and the precision or sensitivity required. Therefore, a QA system can be more readily implemented in R&D activities than in basic research that requires an independent and a flexible approach due to a large number of unknown factors and undefined parameters.

## Stages and functional steps in research processes

With a view to examining the manner in which QA can be incorporated in research and R&D, Fig. 2 presents a general structure of the multiple stages and functional steps involved in any research project. These remain valid however simple or complex the programme may be in terms of the diversity of the procedures and methods employed, the extent of activities (duration, resources, collaboration, etc.), the sensitive nature of the objectives and the significance of the research project. These distinct stages, in fact, remain functionally interactive during the evolution of the project. Therefore,

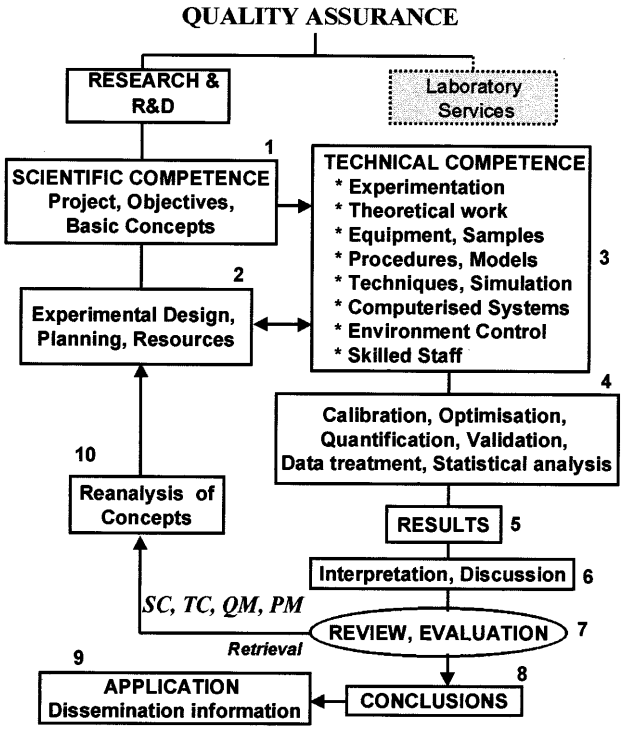


**Fig. 2** Scheme for quality assurance in different stages of a research project

the QA strategies for research need to be adapted according to the objectives of the project, the implications of the results and inventions, and availability of the resources. The scheme is intended to provide guidance for co-ordinating and organising all activities related to the project, and to assist in systematically evaluating the progress. On the contrary, the QA system applied for laboratory services (testing/calibration activities) comprises a linear sequence where each successive step is standardised. The plans to develop a QA approach for research and R&D need to take into consideration: scientific competence (SC), TC and QS.

## Scientific competence

SC, comprising the scientific knowledge (basic concepts, published information) and the intellectual eminence, plays a key role in the accomplishment of any research or R&D programme.

### *QA approach*

The contribution of a QA system in the domain of SC (stages 1 and 2) is mainly concerned with guidance towards a clear and explicitly defined research project.

## Technical competence

For a highly innovative research project, SC alone is not sufficient, but high technical skills are also required to achieve the objectives in accordance with the required specifications. Most commonly employed technical operations are indicated in stage 3, and the steps necessary to ensure and demonstrate the reliability of these operations are summarised in stage 4 of Fig. 2.

### *QA approach*

The QA system can play a very significant role in the domain of TC in research and R&D; there are many common links with the QA system developed for testing and analysis. The QA concepts applied to TC for laboratory services (validation of methods, equipment maintenance, calibration and quantification, training of personal, environment control, and safety-related factors) are equally important for all technical procedures employed in research and R&D. These are necessary to ensure the reproducibility and reliability of the results obtained, and to reduce the possibility of artefacts. However, the QA approach must be fitting and scaled to the requirements necessary for research activities.

## Quality system

The QS concerns the organisational structure of a laboratory including QM and project management (PM).

The functions of QM are to determine, plan and implement the quality policy in compliance with the objectives set in stages 1–3 of Fig. 2. The quality policy defines the acceptable limits for calibration and verification, optimisation of conditions, and validation of methods. In research processes, validation of results often constitutes a serious problem due to non-availability of the reference or comparative data from the literature.

PM is a key issue in a QS for research and R&D. It has important functional roles to efficiently co-ordinate all the necessary activities involving SC and TC within the general framework of QM, and the strategic planning. Furthermore, PM is essential for maintaining a balance between flexibility and creativity, and to encourage the motivation of personal at all levels. Efficient PM can introduce appropriate and timely remedies to solve problems (efficient problem-solving strategies), save time and reduce overall cost. It is important to designate a qualified person responsible for PM.

*QA approach*

As in the case of TC, the level of detailed prescriptions for the requirements of a QS (e.g. record keeping, communication procedures, controlled documents) need to be restricted in a rational manner to maintain the necessary flexibility and a favourable working environment.

For research and R&D programmes, the QA system may be considered as a "utility tool" to ensure and demonstrate the "soundness" of the research work, including the basic concepts and objectives, the technical skills, the methods used and the experimental design. The review and evaluation step (stage 7) is crucial for systematically analysing the results obtained with respect to the set objectives, the pre-defined targets and the relevant quality criteria. It may be noted that the acquisition of data (stage 5) can eventually become a "routine research" procedure once the method is developed according to the criteria set in stages 1–4 of Fig. 2.

### Flexibility in research and R&D

An important factor necessary for successfully integrating a QA system in research practices lies in maintaining a certain degree of flexibility within the framework of a structured organisation, and planned management. Flexibility implies the ability to alter and adapt the research plans and experimental procedures on the basis of the scientific and technical knowledge acquired. The need for flexibility arises because all the resulting phenomena and observations in the research processes cannot be defined completely or predicted precisely. Therefore, the results obtained may deviate significantly from those expected on the basis of the objective set initially, and necessitate changes in the experimental design. The unexpected or erroneous results, and all unpredictable events need further exploration; the unexpected results often provide a valuable contribution to the advancement of science. A profound knowledge of the scientific background and technical aspects related to the project are required, to introduce flexibility and efficiency during the evolution of the research project via the retrieval steps from stage 7 to stage 10 in Fig. 2. In addition, the flexible procedures encourage the creativity and dynamism of the staff engaged in various research activities. The inspiration and motivation of the research scientists cannot manifest under the obligation to follow a set protocol, step-by-step.

## Quality in research

It is pertinent to point out that the general concepts of quality in research practices are not a new revelation for any research scientist. The integration of the intrinsic quality criteria has long been considered as a normal step in a spirit of scientific discipline. What is new and controversial is to consolidate the intrinsic quality of the working procedures in structured and pre-planned managerial functions of the QA system, to identify and demonstrate "soundness" of the research work.

In general terms, quality implies a level of goodness or excellence that provides satisfaction. However, in the context of a QS, it specifically refers to achieving well-defined objectives in compliance to the pre-set conditions. Many research scientists often indiscriminately employ these two meanings. The concept of quality in research and R&D is difficult to define in a single term. It can imply: reliability of the basic scientific and technical aspects of the project (stages 1–3 in Fig. 2), appropriate choice of the quality criteria for the operations indicated in stage 4, scientific value of the results (originality and novel exploitations), achieving the objective in relation to the available resources and pre-defined terms (cost, delay, etc.) and an efficient QS (QM, PM). A combination of all these aspects is referred to as the "quality profile" of the project. A full knowledge of the scientific principles and technical details related to the project as a whole is important to achieve a high "quality profile". Finally, the dissemination of information, number and quality of publications (e.g. prestige of the scientific journals, citation index), international recognition, conference papers etc. all reflect the importance and the quality of research projects.

### Need for a QA system in R&D

In response to the changing trends in working practices and the requirements for transparency, the need for a QA system in R&D is becoming increasingly apparent [10–14]. The needs are largely created by the globalisation phenomenon, i.e. socio-economic factors (efficiency, cost-effectiveness, client satisfaction, transparency, etc.), that emphasise competitive and productive scales, and require the criteria and definable "indices" for an objective evaluation. Speedy evolution and the availability of highly complex and sophisticated technology, such as computerised methods, automation, the rapid means of communication can also impose very different concepts for planning a research programme than those conventionally employed in the past. Therefore, the application of a QA system can be very important to ensure the reliability of results. This is particularly important since results are no longer evaluated purely for their academic or research interest, or for their scientific value. They are generally regarded in a much wider perspective concerning their far-reaching or immediate impact in many vital sectors (health, ethics, environ-

ment, commercial interests, and even their influence on politics). Finally, a better relationship has developed between many research centres (e.g. universities and academic centres, government institutions) and industry which has already widely adopted formal QS. This may well become a major driving force for the motivation of academic institutions to adopt a QA system in research and R&D performed according to specific requirements, and for the competitive contract-based projects.

### Advantages of QA in research and R&D

The multiple advantages of implementing a QA system in research and R&D activities are emerging as the exploitation of results assumes new dimensions in a globalising world. During the progress of research activities, the implementation of a QA system can facilitate the exploitation of SC and the technical resources available. It also allows an integration, with maximum efficiency, of all "support facilities" available from the research unit and the organisation as a whole. A research project, carried out within the framework of a QA system, can ensure comparable quality criteria for different operations and the results obtained at various interlinked stages. After completion of the project, a suitably adapted QA system provides important advantages by maximising the value of research work in the context of eventual exploitation of the results and inventions, and to establish confidence between all parties concerned (e.g. the sponsors, multicentre research groups, and those exploiting the results). If formal recognition of the research centres becomes a necessity, then a QA system can provide the means for objectively evaluating the laboratories in a consistent manner, and avoid multiple evaluation exercises according to varying schemes and different guidelines.

### Potential difficulties

The difficulties involved in implementing a QA system for research and R&D arise mainly from a number of inherent characteristics specific to the research processes, as well as to the very nature of the existing standards. Furthermore, research is often done in a wide range of organisations such as: government institutions, universities, industrial and public organisations. These organisations have very different interests and objectives concerning science and technology, health and safety issues, marketing and commercial profits.

#### *Nature of the research activities*

Research is a continuously evolving process, and can vary widely in complexity ranging from simple exploration of ideas and hypotheses to investigating specifically defined and complex problems. The unexpected results, unpredictable events and intriguing questions arising during the progress of research work require further exploration. This often leads to uncertainties in fixing the targets, and to comply with the pre-planned time schedule and resources.

#### *Nature of the existing quality standards*

Many difficulties for implementing a QA system in R&D have arisen from the limitations imposed by the excessively normative approach of the existing standards [5–8]. Due to the rigid requirements, these standards lack a flexible approach. In fact, any minor deviation from the prescribed procedures is regarded as non-compliance. Furthermore, some of these standards include a very limited reference to SC.

#### *Problems related to QA in research*

Earlier we discussed some practical problems involved in adopting QA strategies for research and R&D facilities. These were attributed to the characteristics of the research processes as well as to the very nature of the existing standards. Additionally, as a third dimension to the problem, there are certain setbacks originating from the views that are deep rooted in some ideological and philosophical convictions, such as:

1. Research is regarded as an intellectual activity in the interest of advancement of science and technology. A long-standing tradition of the scientific discipline is established whereby quality is considered as an integral part of all theoretical and experimental investigations, motivated mainly by the scientific rigour and precision. Therefore, quality criteria are considered unquestionable and the need for a QA system is generally reproached.
2. The external pressure exerted by the QA system is regarded as a serious constraint, time consuming and demanding in terms of developing the infrastructure and changing habits. There is an expression of fear, in certain cases, that the external pressure of a QA system could undermine the scientific prestige of the research groups.
3. Specialised research groups generally tend to work within fairly closed circles.

## Comments and propositions

The questions concerning the compatibility of a QA system (associated with an excessively normative approach, a structured organisation and demanding man-

agerial functions) with the research activities (requiring independence, flexibility and an incentive for creativity) raise many controversies over the potential of a QA system in research and R&D. Therefore, this section presents some additional comments on certain topics with relevant propositions, in the interest of eventually adapting the existing QA system for research and R&D. Some of these topics have been discussed previously [11].

## Standards

None of the existing international standards [5–9], in isolation, are actually suitable to cover satisfactorily the QA strategies for research and R&D activities, even though they all present many relevant features. Generic standards/guidelines for QA in research and R&D (based on these standards) are required in a much wider perspective to formulate suitable QA strategies. It is important to note that a guideline has been developed concerning the application of QA in R&D in non-routine analysis in analytical chemistry [10]; it combines the essential elements of different published standards [5–9]. The guidelines for QSs in R&D at the national level are now available in some countries [1–4].

## Research project

An important aspect of the QA approach to research and R&D consists in providing guidance for preparing a well-formulated research project, setting achievable objectives in relation to the resources available [1, 2, 4, 10]. A clear and explicit description of the project should include:

1. The objectives of the project, scientific basis, technical requirements, expected milestones, resources and terms of contracts, cost, complexities and hazards.
2. The specifications of the experimental design, procedures, equipment maintenance, methods for calibration and validation, and safety requirements. These should be detailed to an appropriate level without describing step-by-step prescriptions.
3. An outline of the QM system including the qualifications and responsibilities of the staff, a description of the proposed review plan and PM; but avoiding excessively pre-planned strategies.

## Recognition schemes

The QA recognition schemes for research and R&D in research laboratories may be either voluntary based on different options or mandatory. Three optional schemes are possible.

1. A declared statement of compliance to an existing national or international guideline/standard.
2. The development and implementation of an Internal Guidance Document (open to verifications) based on published standards [5–9], with a view to provide a "QA plan" specific to the research facility.
3. A formal recognition of the QA system implying accreditation, GLP compliance or ISO certification of the research centre. This involves third-party assessment based on the standards. The need for a mandatory formal recognition of the QA system will depend on the objectives of the research project, and the eventual applications of the results and the knowledge gained in specific areas (e.g. health and safety issues).

## Application fields for QA in research

It is important to first identify the domains of the scientific activity (basic and applied research, R&D), and the organisational level of the research facility that needs to be covered by a QS. In general, the following levels may be considered:

1. The laboratory/facility as a whole for the activities involving many related research areas with common objectives.
2. A laboratory, or a section of it, involved in a well-defined research project employing a single or multiple techniques.
3. A laboratory, or a section of it, concerned with the applications of highly specialised methods or technology for a variety of research problems either within the centre or for the external sources. In certain cases this may eventually lead to a "routine research" activity.
4. Only the QM system of the research facility.

The relevant choice would depend on the objectives, the nature and the complexity of various research activities, the resources available, the size of the research unit and the number of persons employed.

## Research and R&D in universities

The implementation of a QA system in universities presents many special problems arising from their structure, activities and functions. Basic and applied research projects in university research centres often cover a wide range of scientific interests and technical resources. The projects may be multidisciplinary or multifunctional sharing technology, and are often performed under different sponsorships. The functions and responsibilities of the staff are generally varied and diffused, e.g. research and other scientific activities, teaching, and solicitations for expert advice. A further difficulty in adopting a QA system in its integrity in univer-

sity centres concerns compliance to the conditions required for qualifications of the personal. This is an important point in relation to the frequent participation of temporary personal (students and visiting scientists) in the research projects.

An efficient way to adapt the existing QA systems for scientific research in university centres would be to develop an Internal Guidance Document based on the essential elements of the existing standards and covering SC, TC, and the QS with emphasis on QM and PM. A research project should be formulated including specifications related to the field of application for a QA system and the options for the recognition schemes, as discussed in the previous sections. For research projects covered by a QA system, it is important to assign the functional roles and responsibilities at appropriate levels of supervision (e.g. the research director, a competent person responsible for PM, diffused responsibilities), including the role of temporary personal.

### Future needs

Some plausible proposals for future actions concerning a QS for research and R&D activities are summarised as follows:

1. Generic standards or internationally agreed "general QA guidelines" need to be developed in a wider perspective as compared to the existing standards. These standards/guidelines can eventually serve as the basis for formulating a complementary guidance to prepare an Internal Guidance Document for particular cases. A combination of the general standards and specific QA guidelines is essential for maintaining a certain degree of harmonisation, and at the same time to assure flexibility and specificity necessary for different types of research facilities marked by diversity of interests.
2. At the present stage, it is proposed to adopt a voluntary optional scheme for the recognition of a QS. The mandatory formal recognition system may be necessary only in certain selected areas.

## Conclusions

In research and R&D, the conformity to a QA system is intended to demonstrate the "soundness" of the research work, from the initiation to the final stage of a project as shown in Fig. 2. Whereas, the aim of the existing QA system for accreditation of testing laboratories is to guarantee that the prescribed procedures are employed correctly, and hence there is confidence in the reliability, validity, viability, traceability and reproducibility of the results. Research and R&D activities in scientific centres differ fundamentally from laboratory services in their basic concepts, objectives and functions; therefore they require partially different approaches to the general requirements of a QA system.

The QA system can help to establish confidence in the reliability and credibility of all the scientific data obtained and in their conclusions. This is particularly important when multiple parties have interest in the research project, for example: sponsors, regulatory bodies, decision-making authorities that are not necessarily specialists in the field, scientists participating in the multicentre programmes, and those exploiting the results. A major problem in accepting QA strategies for research and R&D lies in the fact that an incentive for implementing a QA system is put into perspective prior to any consensus on a general infrastructure associated with the scope and the modalities for applications. A consequence of this situation is the proliferation of a number of general guidelines [1–4] at national levels, and in certain specific areas [10, 15].

The development of a QA system for research and R&D in scientific institutes requires international or national standards, as well as an Internally Developed Guidance and a specific "QA plan" for projects in specific scientific domains. The recognition scheme (mandatory or optional), and the field of application for research facilities would be a function of the extent and complexity of the research activities, techniques employed, structure and size of the organisation (laboratory), importance of the personal, and involvement of the group in multicentre projects. It is apparent that the QA approach to research and R&D requires a proficient scientific contribution, that is not equivalent to the concepts of "quality control" commonly applied in the chain of industrial production.

In the opinion of some scientists, a QA system is considered as a serious setback for progress and creativity in research and R&D, while in view of others perseverance to continuously evolve quality in research remains the major driving force for the advancement of science and technology. Yet others claim that QA in R&D is needed to introduce some transparency to demystify research and to reduce the possibility of certain unacceptable behaviour under the pressure of dynamism and strong competition (e.g. false data or wishful conclusions). Whatever the reality, in the near future there may not be any viable alternative in certain domains than to adopt a QA system in some form, largely due to the external pressure from sources such as industry or public authorities.

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## References


1. Cheilan MA, Lachet MB, Minoux MJ, Petit MJC, Piedallu MA, Tuffery MG (1997) Guide expérimental pour la qualité en recherche. Groupe de travail français "Qualité en Recherche", France
2. BELTEST (1998) Accreditation de laboratoires pour les activites de recherche et developpement. Lignes directrices pour l'application des critères généraux d'accréditation: L10-REV0-1998-17. Ministry of Economic Affairs, Belgium
3. NEN 3417 (1992) Quality assurance: additional requirements to NEN-EN45001 for research laboratories. Netherlands Standardisation Institute, Den Haag, The Netherlands
4. DOE-ER-STD-6001-92 (1992) Implementation guides for quality assurance programs for basic and applied research. The United States Department of Energy, Washington DC, USA
5. (1989) EN 45001 General criteria for the operation of testing laboratories. CEN/CENELEC
6. Draft International Standard (1998). ISO/IEC FDIS 17025 General requirements for the competence of testing and calibration laboratories. ISO, Geneva, Switzerland
7. ISO/IEC Guide 25 (1997) General requirements for the competence of calibration and testing laboratories, 5th edn. ISO, Geneva, Switzerland
8. ISO 9001 (1994) Quality system-model for quality assurance in design/development, production, installation and servicing, 2nd edn. ISO, Geneva, Switzerland
9. ENV/MC/CHEM(98)17 (1998) OECD principles of good laboratory practice. Organisation for Economic Co-operation and Development, Paris, France
10. EURACHEM/CITAC (1998) Quality Assurance for research and development and non-routine analysis. (1st edn) Teddington, Middlesex, UK
11. Mathur-De Vré R (1997) Accred Qual Assur 2:63–68
12. Camman K, Kleibohmer W (1998) Accred Qual Assur 3:403–405
13. Petit JC (1999) Accred Qual Assur 4:274–279
14. Petit JC (1999) Accred Qual Assur 4:458–462
15. Bode P, Heydorn K, Innes R, Wood R, Zeisler R (1998) Accred Qual Assur 3:197–202