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DIFFERENCES BETWEEN RESEARCH AND INDUSTRIAL TESTING LABORATORIES IN THE IMPLEMENTATION OF A QUALITY MANAGEMENT SYSTEM.

Martínez Perales, Silvia [1]; Ortiz Marcos, Isabel [1]; Juan Ruiz, Jesús [1]
[1] UPM

Quality management in research testing laboratories has been a widely discussed topic for the last decades, from the late 90s (when ISO 17025 was first published) to our days. The research question that motivates the present work is if still today there is a real difference between research testing laboratories and industrial laboratories in terms of quality management. To this purpose, a field study has been performed in collaboration with RedLab (Red de Laboratorios de la Comunidad de Madrid, Network of Laboratories of the Community of Madrid). Results show that differences between industrial and research laboratories exist in the sample under study, and also that these differences are significant.

Keywords: Quality management system; testing research laboratories; ISO 17025.

DIFERENCIAS ENTRE LABORATORIOS DE ENSAYO INDUSTRIALES Y DE INVESTIGACIÓN EN LA IMPLEMENTACIÓN DE UN SISTEMA DE GESTIÓN DE CALIDAD.

La gestión de calidad en laboratorios de ensayo de investigación ha sido un tema ampliamente discutido desde finales de la década de los 90 (coincidiendo con la primera publicación de ISO 17025) hasta nuestros días. La pregunta de investigación que motiva este trabajo es si todavía hoy existe una diferencia real entre laboratorios de ensayo de investigación y laboratorios de ensayo industriales en materia de gestión de calidad. Con este objetivo se ha realizado un estudio en colaboración con RedLab (Red de Laboratorios de la Comunidad de Madrid). Los resultados muestran que las diferencias entre estos dos tipos de laboratorio de ensayo no sólo existen, sino que además son significativas.

Palabras claves: Sistema de Gestión de Calidad; laboratorios de ensayo de investigación; ISO 17025.

Correspondencia: Silvia Martínez Perales silvia.martinez.perales@alumnos.upm.es

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1. Introduction.

There is an extensive bibliography on the difficulties encountered by laboratories in the field of research and development in applying practices related to quality management. Many of these works date from the 1990s and early 2000s, when the ISO/IEC 17025 reference standard (first published in 1999) was just beginning. These publications (Cammann and Kleibohmer (1997), Mathur-De-Vre R (1997, 2000), Counte and Meurer (2001), Schilling , Cranovsky and Straub (2001), Valcarcel (2003), Verrezen, Vermaercke and Hurtgen (1999), Vermaercke (2000)) called for the development of specific standards for research testing laboratories, which has not happened to date.

Nowadays the testing and calibration laboratories have two fundamental reference standards for Quality Management Systems (QMS): ISO/IEC 17025 and ISO 9001. Numerous authors have analysed the positive influence of having an implemented QMS according to ISO/IEC 17025 on laboratories performance (Cammann and Kleibohmer (1997), Squirrell (2001), Catini et al. (2015), Albano and Faustini (2016), Barradas and Sampaio (2017)) opt for ISO/IEC 17025 as a reference standard for research testing laboratories and recognize that the accreditation of a QMS against ISO/IEC 17025 adds value to the certification against ISO 9001.

Despite the agreement on the benefit of a QMS, its implementation in R & D laboratories has traditionally been a challenge. Although the literature in this regard confirms that the benefit of quality assurance extends to research laboratories, practically all of them recognize the existence of own difficulties in the application to the field of R & D. As an example, in the sector of chemistry, EURACHEM guide promoted quality assurance and suggest good practices, based on the idea that laboratories performing non-routine measurements require a special approach in terms of quality management, different from the one that standards offered by that time (previous to the existence of ISO/IEC 17025 as we know it today).

The challenges for the implementation of a QMS in R & D laboratories identified in the literature are: the validation of the test methods (Vajda et al. (2006), Zapata-Garcia, Llaurado and Rauret (2007)), the excessive rigidity in the processes (Mathur-De-Vre R (1997), Grochau et al. (2010)); the lack of resources for the implementation of a QMS (Grochau, Caten and Forte (2018)), the increase in paperwork (Vajda et al. (2006), Biasini (2012)); the absence of adequate standards for laboratories that carry out R & D activities (Robins, Scarll and Key (2006)); the cost of implantation and maintenance and the lack of staff motivation (Biasini (2012)).

Faced with these difficulties, the authors have proposed different approaches. At the beginning of the research on QMS in R & D laboratories, Mathur-De-Vré identified in 1997 four aspects to be taken into account in the implementation: project management (PM), scientific component (SC), quality management (QM) and technical competence (TC). In 2000, Vermaercke identified four factors that, from his point of view, are critical for the success of the implementation of a quality assurance system in R & D: simple and flexible documentation, modular architecture and non-redundant, self-sustainable and with contribution of added value. Fabregas et al. proposed in 2010 a series of stages for the implementation of ISO 9001 in medical research laboratories: analysis of the standard, staff training, editing and implementation of procedures, internal audit, external audit and certification. In this line, Grochau and Caten also suggest general steps for implementing a QMS in testing laboratories, including the definition of the scope of the QMS itself (in terms of tests and staff), calculating costs, establishing the management and technical requirements and defining indicators (among others). On the other hand, Biasini identified the increase of resources and the support of external experts as success factors. Bongiovanni et al. proposed in 2015 a model for quality management in a biomedical research laboratory, based on the management of four work

packages (management of knowledge, management of experimental procedures, QMS for a research laboratory and management of multivariate tests).

It is significant that the difficulties in the implementation of QMS in R & D laboratories reported by authors at the end of the 90s remain 30 years later, despite the fact that in this period of time ISO/IEC 17025, reference standard for testing and calibration laboratories, has emerged and evolved and the laboratories themselves have been maturing in their management systems. The suspicion is that ISO/IEC 17025 approach does not seem to adapt to the activity of laboratories that carry out testing activities that imply a certain degree of innovation.

Although all the test laboratories have the ultimate goal of carrying out measurements, it is necessary to recognize that under the term "test" there are many types of activities with different degrees of complexity. The execution of a "repetitive" and according to a "predefined method" test does not require an adaptation or research work by the laboratory. This is the case, for example, of laboratories that carry out tests against standards that are part of European Directives for certification or homologation. On the contrary, the execution of a "non-repetitive" and according to "non-predefined particular methods" test requires a total adequation of work done by the laboratory, since many aspects may require a definition and validation for the execution of the test (procedure, facilities, fixtures, measurement chain, among others). It could be said that the execution of non-repetitive and non-standardized tests correspond to the definition of “project” established by PRINCE 2. These are real research projects that may start time before the final realization of the test, produce changes in the organization (new facilities, equipment, personnel qualification, test methods, management system, new know-how) and necessarily require the involvement of multidisciplinary teams, including engineers doing “test-oriented” engineering and specialists in the subject matter of the test with the know-how to validate test methods and estimate uncertainties. In this case, questions around the test, such as the test procedure, the test setup or the uncertainty estimation are also a result of the testing activity themselves (for example, as a deliverable in a project or programme).

2. Methodology

In this context, the research question that motivated the present work was: is there a real difference between research testing laboratories and industrial laboratories in terms of quality management?

For a field study on this topic, the access to an important number of laboratories was possible thanks to a collaboration with RedLab (Red de Laboratorios de la Comunidad de Madrid, Network of Laboratories of the Community of Madrid). This network is an initiative of the General Directorate of Universities and Research founded in 2000 with the aim of bringing together the testing and calibration laboratories belonging to research centers and universities, disseminating their activity and supporting them in matters such as the quality and knowledge management. Currently 340 testing (300) and calibration (40) laboratories operating in Madrid (Spain) are members of this network.

Information was collected by distributing a questionnaire among the laboratories belonging to RedLab through the free access platform Typeform. Participants were asked to answer 40 short questions grouped into seven blocks: information about the participant (block I), information about the QMS implanted in the laboratory (blocks II and IV), information about the tests carried out in the laboratory (block III), information on the critical points of the QMS (block V), assessment of the QMS (block VI), benefits of the QMS (block VII). The questions were

posed in different formats depending on the type of response expected: free text, form with a single answer, multiple answer form, numerical answer (0-10).

As a previous step to the analysis of the received responses it was necessary to review the collected data in order to identify and eliminate incomplete and duplicated responses. After this, an analysis of the relevance of the information obtained was done, based on two criteria: the participants professional profile and the experience of the laboratories on quality management. For the latter, it was considered that four years is the period of time in which the experience of the laboratory with the QMS is relevant, since in this period a laboratory has typically covered the closing milestones of a plan to assure the quality of the results , update of personnel technical competence records, closure of the calibration / verification plan (taking into account that 12 and 24 months are typical intervals between calibrations), closure of a maintenance plan for equipment and facilities, celebrations of several management reviews (taking into account that 12 months is a typical interval between meetings), holding several internal audits and holding an external follow-up audit (in the event that the laboratory has external recognition).

Once the validity and relevance of the responses was confirmed, the participants were assigned to the “industrial testing laboratories” group or the “research testing laboratories” group based on the kind of tests performed. Laboratories declaring the execution of “repetitive” tests under “predefined methods” were assigned to the “industrial testing laboratories” group. Those declaring the execution of “non-repetitive” and according to "non-predefined methods” were assigned to the “research testing laboratories” group.

Finally, the results obtained from both groups were analysed. Two types of analysis were performed: a descriptive quantitative analysis and a statistical analysis based on p-value contrast and t-statistics for the comparison between the two groups.

3. Results

3.1 Preliminar analysis

378 people accessed the questionnaire at the free platform Typeform. 115 complete and valid responses were collected, corresponding to testing and calibration laboratories. After eliminating responses from calibration laboratories and duplicated responses, the final simple consisted of 88 responses, corresponding to 88 participants from testing laboratories that submitted a complete response. Two of them declared not to have an implemented QMS, so the analysis was finally done over 86 participants.

Figure 1 shows the position of the participants in the field study. Professionals who completed the questionnaire declared to have a position directly related to quality management, with a high percentage of laboratory managers and quality assurance managers (76,74% of the total sample). The rest of participants declared to have a position also involved with quality assurance tasks, including testing engineers and technical responsibles.

The distribution of the number of years that the QMS has been implanted in the testing laboratories participating in the study is shown at figure 2. 80,23 % of the participants declared to have a QMS implanted for more than four years which, in accordance to the established criteria, means a complete knowledge on quality management aspects.

Most of the laboratories (62,16%) declared to have a QMS recognised by a third party, being ENAC (Spanish National Accreditation Body) or a certifying organization.

Figure 1: Participants position

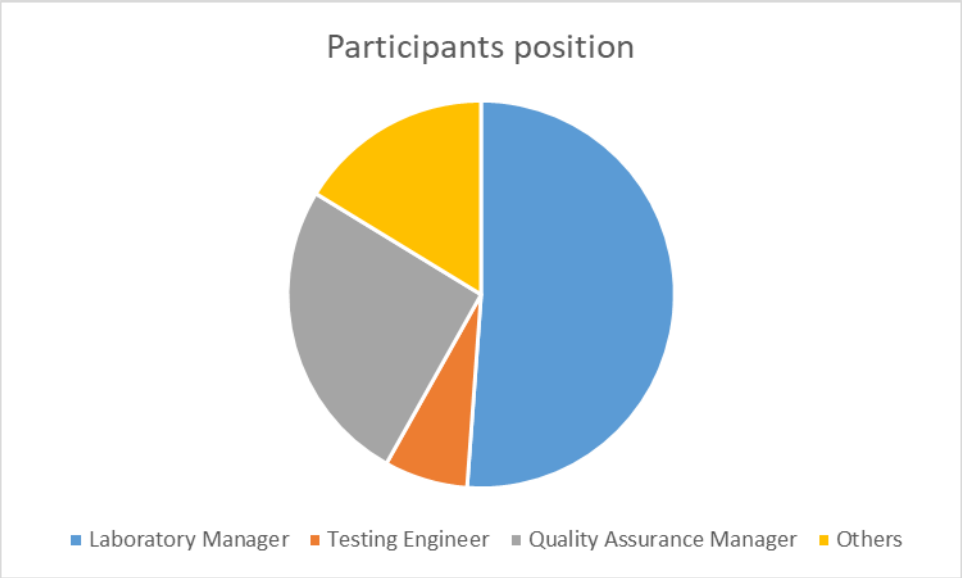
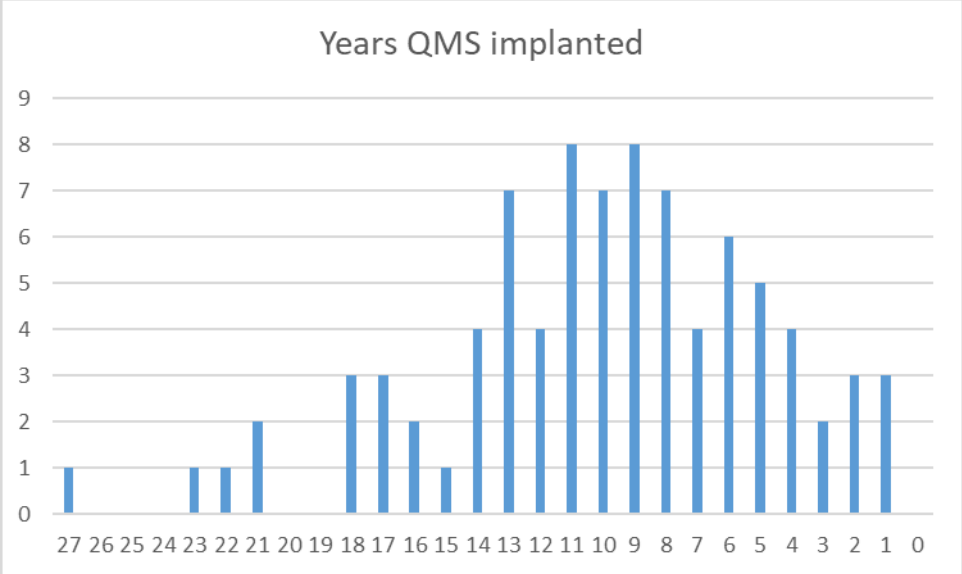


Figure 2: Years of QMS implanted



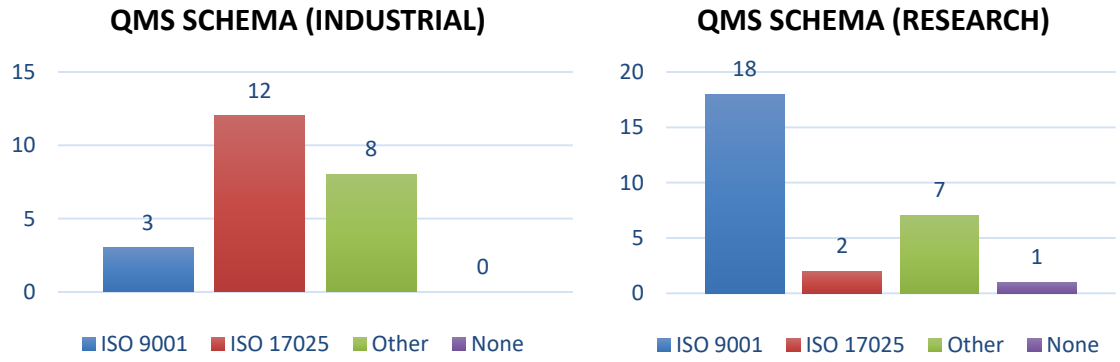
After this preliminar analysis, and taking into account the two defined criteria, the sample under consideration was considered to be valid and relevant for the purpose of the study.

3.2 Results from research testing laboratories and industrial testing laboratories

Since the purpose of this study was the exploration of the differences among research and industrial testing laboratories in terms of quality management, the participants were assigned to the "industrial" group (repetitive, under pre-defined methods tests) or the "research" group (non repetitive, under non-predefined methods tests), according to the type of tests performed. Those laboratories performing tests under different conditions (e.g., non-repetitive tests under pre-defined methods) were considered not to have a clear industrial or research nature, and so were not included in the analysis. After this, 23 participants were assigned to the "industrial" group and 28 were assigned to the "research" group.

48% of the total sample have a QMS based on ISO 9001, and 28% have a QMS based on ISO 17025. Distribution changes if the analysis is done on the two defined groups: for the industrial laboratories, the most used schema is the one based on ISO 17025 (52%), being ISO 9001 for the research group (64%) (figure 3).

Figure 3: QMS reference standard



Regarding the adaptation of the QMS to the laboratory (meaning if the quality management system is tailored to the activity of the laboratory and integrated, or if, on the contrary, it has been implanted as a standard system and is separated from the rest of the activities), 100% of the laboratories from the industrial group declare a level of adaptation better that 5 (in a 0-10 scale). This percentage is lower in the research group: 31% of the participants declare a poor level of adaptation (lower than 5 in the 0-10 scale).

Significant results were obtained when the participants the grade in which quality management requirements for the competence of testing laboratories (as defined by ISO 17025) were met. Participants were asked to value in a 0-10 scale the level of compliance to the standard quality management requirements. Table 1 shows the mean values of the obtained responses from industrial and research groups. Right column shows the difference between means.

Table 1: Compliance to QMS requirements.

	Mean values		Means difference
	Industrial testing laboratories	Research testing laboratories	
Control of documentation	8,2	6,7	1,5
Outsourcing	7	4	3
Corrective/ preventive actions	7,9	6,4	1,5
Management reviews	8,4	6,5	1,9
Personnel management	7,8	6,4	1,4
Measurement equipment control	8,3	7,3	1
Testing facilities management	8	6,4	1,6
Development/ validation of methods	8,7	6,4	2,3
Estimation of uncertainty	7	5,3	1,7
Control of raw data	8,6	7,3	1,3
Quality assurance of results	8	6,4	1,6
Internal quality assurance	7,8	6,2	1,6
Interlaboratory activities	6,5	3	3,5
Traceability	8,2	6,4	1,8
Test reports	8,6	6	2,6
Lessons learnt management	7	5,4	1,6
Risk management	7,4	4,8	2,6

4. Discussion

A major part (64%) of the research testing laboratories refer to ISO 9001 for the QMS scheme, which is considered to be a relevant result. ISO 9001 is a general purpose standard, that establishes requirements for any kind of organization; for sure, ISO 17025 is the reference standard for quality management in testing laboratories. This fact could be considered as a sign that ISO 17025 does not take into account special needs and nature of research activities, which is in line of findings in the literature review.

Regarding the compliance to standard quality management requirements, it can be observed that research laboratories declare a lower compliance than industrial laboratories for every requirement. Industrial testing laboratories declare a high level of compliance (higher than 7 in any case, except for intercomparison activities), whereas research testing laboratories even fail to meet two of them (outsourcing and intercomparison activities).

In order to check if differences found at this point were relevant, a contrast statistical analysis was done. Results shown at table 2 confirm that differences are significant for a significance level of 0,05.

Table 2. Contrast statistical analysis.

	t-stat	p-valor
Control of documentation	2,70	0,0094
Outsourcing	2,81	0,0071
Corrective/ preventive actions	2,26	0,0280
Management reviews	2,73	0,0088
Personnel management	1,62	0,1111
Measurement equipment control	1,53	0,1317
Testing facilities management	2,44	0,0184
Development/ validation of methods	3,85	0,0003
Estimation of uncertainty	2,04	0,0472
Control of raw data	2,98	0,0045
Quality assurance of results	2,24	0,0296
Internal quality assurance	2,08	0,0430
Interlaboratory activities	3,77	0,0004
Traceability	2,47	0,0172
Test reports	3,35	0,0016
Lessons learnt management	2,10	0,0413
Risk management	3,40	0,0013

Results suggest that research testing laboratories have lower compliance to quality management requirements. Two possible causes are suggested for this. First could be that research testing laboratories have difficulties to meet these requirements, due to complex nature of the research activity, closer to projects than to industrial testing. Second, could be that these requirements do not reflect the real needs of research testing laboratories in terms of quality management, and so these kind of laboratories do not even make the effort to meet them.

5. Conclusions and future research

The field study performed in collaboration with RedLab suggests that there are differences between industrial testing laboratories and research testing laboratories in terms of quality management, which is in line with the findings from the literature review. In the context of the field study (testing laboratories from RedLabs network), research laboratories do not mainly adopt ISO 17025 as the reference standard for the Quality Management System (not the same for industrial testing laboratories), which is surprising taking into account that ISO 17025 is the obvious reference.

Also, testing laboratories declare a lower compliance to quality management requirements, which should be met no matter the research or industrial nature of a testing laboratory.

The deep reason of these findings should be subject to future research. Adequacy of ISO 17025 for research testing laboratories should be reviewed, and alternative models for Quality

Management Systems should be suggested in order to promote the compliance to quality management requirements in research testing laboratories.

6. References

Albano FdM, Faustini LH (2016) The influence of a quality system according to ISO/IEC 17025 on the performance of Brazilian laboratories in proficiency testing in the environmental area. Accreditation and Quality Assurance 21(1):19-23. doi:10.1007/s00769-015-1181-9.

Barradas J, Sampaio P (2017) ISO 9001 and ISO/IEC 17025 Which is the best option for a laboratory of metrology? The Portuguese experience. International Journal of Quality & Reliability Management 34(3):406-417. doi:10.1108/IJQRM-03-2014-0032.

Biasini V (2012) Implementation of a quality management system in a public research centre. Accreditation and Quality Assurance 17(6):621-626. doi:10.1007/s00769-012-0936-9.

Cammann K, Kleibohmer W (1997) The need for quality assurance in analytical research and development. Accreditation and Quality Assurance 2(5):262-263. doi:10.1007/s007690050145.

Catini RH, Pires de Souza FJ, Martins Pinhel MdF et al (2015) Application of indicators and quality index as a tool for critical analysis and continuous improvement of laboratories accredited against ISO/IEC 17025. Accreditation and Quality Assurance 20(5):431-436. doi:10.1007/s00769-015-1143-2.

Counte MA, Meurer S (2001) Issues in the assessment of continuous quality improvement implementation in health care organizations. International Journal for Quality in Health Care 13(3):197-207. doi:10.1093/intqhc/13.3.197.

EURACHEM / CITAC working group (1998) Quality Assurance for Research and Development and Non-routine Analysis

Fabregas-Fernandez A, Garcia-Montoya E, Perez-Lozano P et al (2010) Quality assurance in research: incorporating ISO9001:2000 into a GMP quality management system in a pharmaceutical R plus D plus I center. Accreditation and Quality Assurance 15(5):297-304. doi:10.1007/s00769-009-0610-z.

Grochau IH, Ferreira CA, Ferreira JZ et al (2010) Implementation of a quality management system in university test laboratories: a brief review and new proposals. Accreditation and Quality Assurance 15(12):681-689. doi:10.1007/s00769-010-0713-6.

Grochau IH, Caten CA (2012) A process approach to ISO/IEC 17025 in the implementation of a quality management system in testing laboratories. Accreditation and Quality Assurance (17). doi: 10.1007/s00769-012-0905-3

Grochau IH, Caten CA, Forte MM (2018) Motivations, benefits and challenges on ISO/IEC 17025 accreditation of higher education institution laboratories. Accreditation and Quality Assurance. doi: 10.1007/s00769-018-1317-9

International Organization for Standardization. ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories; ISO: Geneva, Switzerland, 2017.

International Organization for Standardization. ISO 9001:2015 Quality Management Systems—Requirements; ISO: Geneva, Switzerland, 2015.

Mathur-De-Vre R (1997) Approach to quality system in research and development. Accreditation and Quality Assurance 2(2):63-68. doi:10.1007/s007690050100.

Mathur-De Vre R (2000) The scope and limitations of a QA system in research. Accreditation and Quality Assurance 5(1):3-10. doi:10.1007/s007690050001.

PRINCE2. (PRojects IN Controlled Environments) https://www.axelos.com/best-practice-solutions/prince2

Robins MM, Scarll SJ, Key PE (2006) Quality assurance in research laboratories. Accreditation and Quality Assurance 11(5):214-223. doi:10.1007/s00769-006-0129-5.
Schilling J, Cranovsky R, Straub R (2001) Quality programmes, accreditation and certification in Switzerland. International Journal for Quality in Health Care 13(2):157-161. doi:10.1093/intqhc/13.2.157.
Squirrell A (2001) ILAC mutual recognition arrangement. Accreditation and Quality Assurance 6(1):37-38. doi:10.1007/s007690000258.
Vajda N, Balla M, Molnar Z et al (2006) On the way to formal accreditation. Accreditation and Quality Assurance 10(11):599-602. doi:10.1007/s00769-005-0068-6.
Valcarcel M, Rios A (2003) Quality assurance in analytical laboratories engaged in research and development activities. Accreditation and Quality Assurance 8(2):78-81. doi:10.1007/s00769-002-0570-z.
Vermaercke P (2000) Sense and nonsense of quality assurance in an R&D environment. Accreditation and Quality Assurance 5(1):11-15. doi:10.1007/s007690050002.
Verrezen F, Vermaercke P, Hurtgen C (1999) Quality assurance in accordance with EN45001 and ISO9001 at the Belgian nuclear research centre SCK center dot CEN. Environmental Radiochemical Analysis(234):318-329.
Zapata-Garcia D, Llaurado M, Rauret G (2007) Exp Grochau IH, Ferreira CA, Ferreira JZ et al (2010) Implementation of a quality management system in university test laboratories: a brief review and new proposals. Accreditation and Quality Assurance 15(12):681-689. doi:10.1007/s00769-010-0713-6.

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