On a Popular Myth: "Scientific Research Cannot be Subject to Quality Management". Think Again! Who Says it Cannot be?

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Abstract. In many scientific research environments the popular belief seems to be that scientific research cannot be subject to so-called "quality" management, at least not down to the research operational level. Examples of popular arguments behind this belief include, "No, but a quality system can cover only routine work", and "No, it is more important to perform the actual research than to waste time adhering to a quality system". This paper considers the above belief for the scenario where the research involves measurements or tests, e.g. by physicists, or other scientists. The realities are that: Researchers, research groups, their employers, and customers, or funders, are investing time, money, and other resources into particular research projects with the expectation of achievement of scientifically valid results, efficiently obtained; and the credibility of researchers, research groups and their managers depend on the scientific validity of their results. Furthermore, product design or development, or service offerings could rely on such results. Consistent achievement and reporting of scientifically valid results will not happen spontaneously, but is more likely achievable by having a suitable scientific management framework down to the research operational level. Ultimately the reporting of scientifically valid measurement or test results depends on a combination of factors, including the following (to name but a few): (1) That collection of valid raw data is achieved as basis to derive results from, (2) that equipment utilised is proven as suitably calibrated and performing correctly, (3) that suitable non routine and routine methods are applied and are documented, (4) that existing or custom written software are proven as providing valid output, (5) that the reporting of the results, e.g. as research reports, or articles, is appropriate, (6) sufficient record-keeping is practiced, and (7) that those who perform the work are either suitably qualified and experienced, or else suitably supervised. Guidance towards a suitable management framework could possibly be taken from ISO/IEC 17025:2005. Although this management system standard has been designed with testing and calibration laboratories in mind, several of its requirements could be useful for guidance for other environments where research involves measurements or tests.

1. Introduction

As much as scientific research and researchers need freedom and flexibility to achieve their research objectives, they also need within each of their research laboratories or research facilities, a framework of good practice and discipline to support their research. Such a framework should address all relevant factors necessary for good research practice, including the principles of scientific method [1], efficiency, etc. One ultimate objective is achievement of consistently valid research results.

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Further, for those research laboratories or facilities at which research involves measurements or tests, guidance to several specific key factors to good laboratory level practice and discipline can be taken from a management system standard like ISO/IEC 17025:2005 [2]. Although this particular management system standard has been formulated for testing and calibration laboratories, many of the factors covered by its requirements, should be recognised as relevant for a much broader range of laboratories (or research facilities).

This paper focuses on, and argues in favour of taking some practical guidance from ISO/IEC 17025. Caution needs to be applied though, for the following reasons:

- Interpretation, adaptation and tailoring to the practical needs of each particular laboratory (or facility) and the laboratory's unique research needs are always necessary.
- ISO/IEC 17025 does not cover all factors of importance to scientific research, but it does cover those factors relevant to results from measurements.
- Taking guidance from ISO/IEC 17025 should not be done to the exclusion of the factors outside of its scope, but should rather be integrated with simultaneous addressing of those other factors, all into the management framework of each particular laboratory and its research applications.
- It should not be taken as being at the exclusion or replacement of a laboratory's existing management framework, but should rather be taken as a tool for checking the laboratory against, with the aim of making improvements where found necessary.

In Figure 1 a representation is given of how the technical management framework of a particular research group or laboratory, meshes with that of its company, and its role regarding research output.

2. The case for having a framework that ensures good practice and discipline

A framework for good laboratory practice and discipline is particularly important considering the following realities:

- Researchers, research groups, their employers, and customers, or funders, are investing time, money, and other resources into particular research projects with the expectation of achievement of scientifically valid results and project deliverables, efficiently obtained.
- The credibility of research groups, their managers, individual researchers, and their track records depend on the scientific validity of their results, as do their continued qualification for contracts or funding.

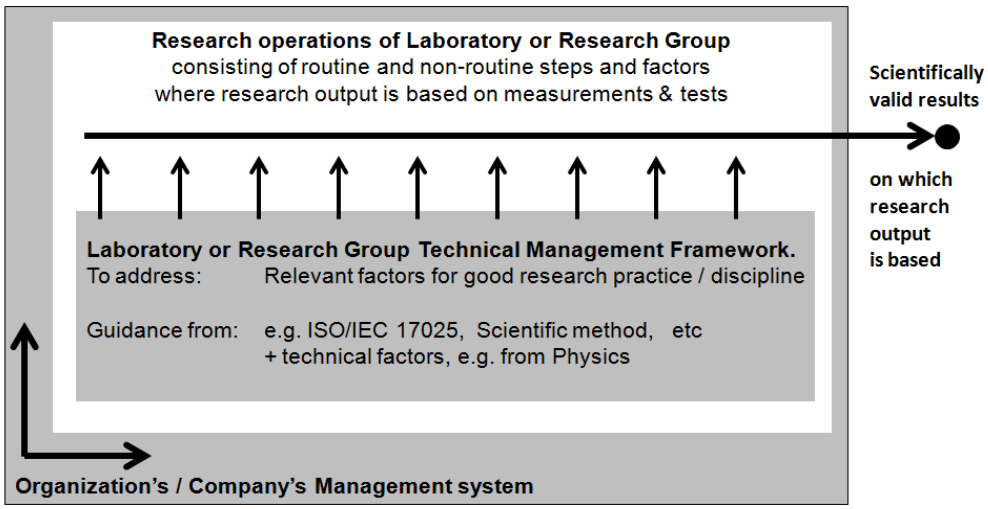

Figure 1. Diagrammatic representation of how the technical management framework of a particular research group or laboratory meshes with that of its company, and its role regarding research output.

- Constraints on time, funds, availability of enough researchers or assistants, availability of a sufficient skills base, and constraints on available equipment and other resources make compromises necessary, sometimes risking validity of results.
- Experienced scientists, under the above-mentioned constraints, are heavily burdened.
- Young scientists enter the working environment or research scene armed with some theoretical knowledge and some skill to apply it, but do not come armed with an understanding of where their knowledge and skills fit within a framework of good laboratory practice and discipline.
- Product design or development, or testing, or service offerings, could rely on research results.
- Although some companies or institutions that do scientific research have management systems in place that conform to the more generic ISO 9001:2008 [2] management system standard, often the company's management system covers only administrative and higher-level management processes, but covers little or nothing down to the research operational level.

Consistent achievement of, and reporting of scientifically valid results will not happen spontaneously, but is achievable where a research laboratory or research facility, applies a framework for good laboratory practice and discipline.

From a company or organizational point of view such a framework is a management "system", more specifically down to the research operational level, it is a "laboratory management system", or "scientific management system", or "technical management system". In "quality" language some may prefer to call it a "quality management system", but although the title of this paper contains the term "quality management", the term will be mostly avoided further on owing to gross misconceptions that exist about "quality management".

3. ISO/IEC 17025, common sense and laboratory practice

Since ISO/IEC 17025 is a standard it sets requirements related to key factors affecting validity of measured results. None of the requirements contain anything unusual or surprising. In fact, the requirements cover logical, common sense, practical, good laboratory practice. So, if it is logical and common sense, why is it then necessary for research laboratories (or facilities) to consider such a standard for guidance? The following are good reasons to consider it:

- Common sense and logic does not automatically translate into practice. Therefore a managed, structured, pro-active, designed approach is necessary.
- It promotes critical consideration and definition of the laboratory's own scope of capabilities, and the ranges and limitations of each capability. A statement of scope of capabilities can include explicit definition of support capabilities. It is around this defined scope of capability that a laboratory's management system should be designed.
- The way in which the requirements are organised by the standard inherently promotes systems thinking applied to the laboratory's (or facility's) capabilities and its management system. This provides a basis, e.g. for breaking down budgeting, capital expenditure, designing a record system, document system, training plans, scheduling, equipment commissioning, maintenance, calibration, etc.
- The requirements promote due diligence and critical consideration on each of the factors affecting validity of measured results, as applicable to the particular laboratory's operations..
- The requirements promote finding a suitable balance between the laboratory's objectives, resourcing, management commitment, and readiness for sub-tasks of key importance (e.g. to measurements for a laboratory's research operations).
- Like a golden thread running through the standard, it promotes documenting of procedures, also for sufficient record-keeping of various factors, and for particular planned, scheduled activities like maintenance, calibration, training, quality assurance processes, etc.

4. Factors affecting validity of measurements and reported results: Taking some guidance from the technical requirements of ISO/IEC 17025

While scientific research can generally involve more than just measurements and more than just their transformation into reported results, measurement does constitute an important part of physics research. In other branches of natural science, other typical terms used (instead of "measurement"), include "chemical analysis", "pathological analysis", etc. ISO/IEC 17025 sets a number of specific technical and non-technical requirements aimed at ensuring the technical competence of a laboratory (or facility) to produce valid measured results and associated valid reporting. It needs to be understood that being a standard ISO/IEC 17025 sets requirements. It does not necessarily provide answers on the specific needs of each laboratory. However, the requirements do occur in a structured framework, and they promote critical consideration of each factor.

While the non-technical requirements are as important as the technical requirements, this paper will focus on the technical requirements. The technical requirements are broadly classified into nine main factors. They are also represented in Figure 2. For full detail the reader is advised to consult ISO/IEC 17025:2005 [2]. The nine main factors are briefly mentioned and described below (with some interpretation applied).

4.1. Persons who perform measurements

This factor includes requirements on the ability and competence of each person to perform specific designated tasks or subtasks, and to function within the laboratory's management framework. Further, not only qualifications and training matter, but also demonstrated skill. Supervision must be provided where necessary, e.g. for those persons still under training.

4.2. Methods and procedures used for measurements, data analysis and calculation of results

Each procedure or method must be documented (as briefly or elaborately as demanded by the complexity of the particular measurement and by how tight their uncertainties are) to promote consistent performance of the measurement. Routine procedures should be particularly easy to document. Non-routine procedures may be more difficult to document, but not necessarily impossible. The collection of raw data is covered under this factor, as well as data analysis and calculation of results, estimation of measurement uncertainty, method validation, and data integrity. Existing or custom written software must be validated as providing correct output.

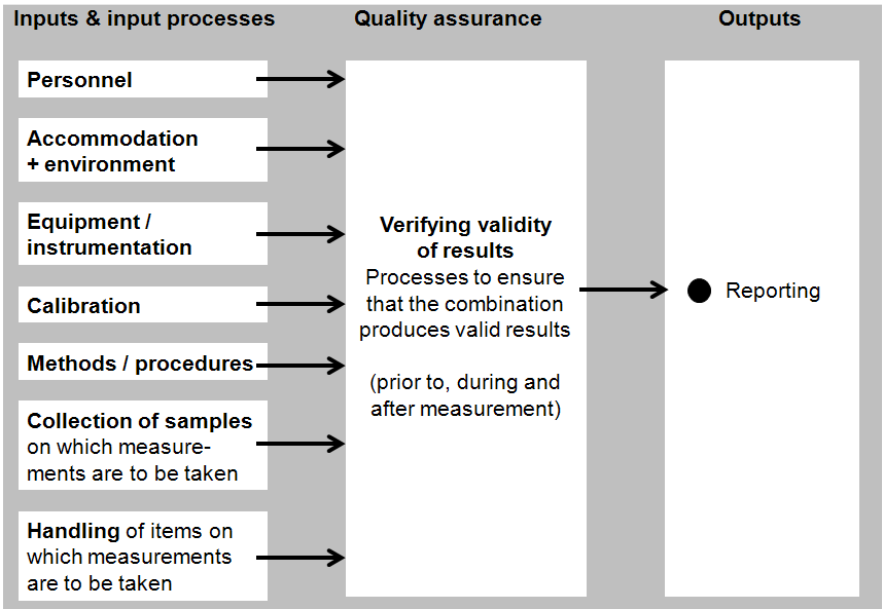

Figure 2. A representation of main technical factors covered by ISO/IEC 17025:2005.

4.3. Accommodation or facilities at which the work is done and environmental conditions
Under this factor requirements are set for accommodation or facilities. It must provide the necessary infrastructure, facilitate correct performance of measurements and limit adverse influences. Relevant environmental conditions must be controlled if necessary and feasible, and monitored if necessary.

4.4. Equipment and instrumentation used
This factor includes requirements that the appropriate equipment be available, the ranges and accuracy of each, be appropriate, that control over use of equipment be such as to ensure continued correct performance, and a requirement for equipment maintenance programmes.

4.5. Measurement traceability (calibration) affecting the measurements
For measurements that require measurement traceability to the International System of Units, or to some other measurement standards, appropriate equipment calibration programmes must be in place, or other means of establishing measurement traceability.

4.6. Collection of samples
In cases where measurements are done on some samples collected, the samples must be collected in a way that ensures representative, valid results.

4.7. Handling of items on which measurements are to be done
This factor includes requirements regarding transport, receipt, handling, protection, storage, retention or disposal of items, their identification and checking of their functionality.

4.8. Verifying validity of results
The standard includes requirements regarding quality control precautions be in place to ensure checking on the validity of measurements and results, typically implemented as verifications before, during and after measurements.

4.9. Reporting of results
This factor includes requirements that reporting be accurate, clear, and objective, and that relevant conditions and information also be reported.

5. Discussion of some misconceptions about quality management

Earlier in this paper it was stated that the term "quality management" will be mostly avoided in this paper. However, since ISO/IEC 17025 is a "management system standard" misconceptions associated with quality management must be acknowledged, and particularly placed in context.

Quality management systems are often unpopular, and unfortunately with reason. The causes are experiences that people have with some misguided implementations, which also give rise to individuals believing that quality management cannot be applied down to the practical research operational level.

5.1. Misguided implementations of a quality management system
One misguided way of implementation is where excessive focus is placed on processes, procedures and records, i.e. it focuses mostly on "paper". In such cases that is done without consideration for the purpose for having processes, procedures and records, and without balancing the effort with the laboratory's objectives, resourcing, management commitment, and readiness for sub-tasks of key importance, and associated risk and impact. Another misguided way of implementation is where the "quality management system" is introduced as an artificial second management system but serving no real purpose. In such cases it does cost extra effort without adding value. In cases where such problems occur it is likely that the objectives for the management system has not been defined or understood properly, with the consequence that the management system is directionless. In principle a research laboratory or facility should have one management system with clear objectives, including that of ensuring good laboratory practice and discipline.

5.2. Misconception 1: "procedures can cover only routine work"

Rebuttal of misconception: It is acknowledged that it would be a definite mistake to treat non-routine work as if it was routine work. But few research projects consist of purely non-routine work. In fact, many research projects rely on a basis of some routine steps, or some routine methods. Sometimes it is just the results that are unique and new. An example is research on the elastic properties of alloys, via ultrasonic measurement techniques. Steps like the preparation of the alloy samples and the ultrasonic measurements are routine. Furthermore, procedures for non-routine aspects of scientific research can cover the work down to a suitable level. The gap between that, and the actual practical work, and routine steps, can then be mitigated and covered by the research project plan.

5.3. Misconception 2: "A quality management system is typically about generating 'paper', or it involves a lot of effort, or it wastes time, or it costs money, all without adding value"

Rebuttal of misconception: It is acknowledged that misguided implementations could cause these problems and frustrations, often without adding value. But in a purposeful, well-implemented quality management system, paper work, effort and costs should be value-adding. If a laboratory has previously neglected good practice (e.g. calibration, or records, or documenting of procedures) then extra effort, extra time spent and extra cost will generally result from now following good practice.

5.4. Misconception 3: "Considering conformance to ISO/IEC 17025 automatically implies considering laboratory accreditation, e.g. by an accreditation body like the South African National Accreditation System (SANAS)"

Rebuttal of misconception: The decision of a laboratory (or facility) to bring its management system into conformance with ISO/IEC 17025 should be a business decision separate from that of seeking ISO/IEC 17025 accreditation. Accreditation demands full conformance, and also demands conformance to additional requirements as set by the accreditation body (e.g. by SANAS). Accreditation is designed for somewhat more routine operations, and is usually not suited to highly non-routine operations and research operations. Instead, a laboratory (or facility) that decides to bring its management system into conformance with ISO/IEC 17025 should in principle do so for ensuring good practice, particularly towards promoting achievement of valid results from measurements. A non-accredited laboratory has the freedom to conform partially, i.e. conform selectively.

6. Conclusion

On the stated popular myth: "Scientific research cannot be subject to quality management": earlier in this paper the case was stated for needing a framework that ensures good practice and discipline in a research laboratory. It was pointed out that a standard like ISO/IEC 17025 requires common sense to be applied and promotes systems thinking to be applied to laboratory-level (and facility level) operations. Nine key technical factors from it were briefly discussed. These technical factors are also of relevance to scientific research, particularly where measurements or tests are involved. These factors can therefore form part of the basis of a practical quality management system down to the research operational level. Additional important factors to be considered do exist, e.g. the nontechnical factors covered by ISO/IEC 17025, and also factors that are not covered by ISO/IEC 17025.

References

[1] 2003 *Good Research Guide, 2nd edition* (Pretoria: CSIR)

[2] 2005 *ISO/IEC 17025:2005, edition 2, General Requirements for the Competence of Testing and Calibration Laboratories* (International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC))

[3] 2008 ISO 9001:2008, Edition 4 and tech. corr. 1, *Quality Management Systems — Requirements*, International Organization for Standardization (ISO)