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H.M.J. Goldschmidt (✉)
Department of Clinical Chemistry
and Hematology, St. Elisabeth Hospital,
PO Box 10111, 5000 JC Tilburg,
The Netherlands
e-mail: H.M.J.Goldschmidt@ckchl-mb.nl

H.O. Goldschmidt
Dr. Schaepmanlaan 11,
5615 EA Eindhoven, The Netherlands

DISCUSSION FORUM

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Helene Felber

Chemical measurement laboratories caught in a battle between different forces: Accreditation requirements versus economic pressure – Is there a way out?

Abstract In order to meet the requirements of ISO/IEC 17025 and other regulations, accredited laboratories are forced to put more and more effort into quality assurance activities, which result in an increase in their costs. On the other hand, laboratories face increasing pressure due to international competition and, in order to succeed on the market, they must produce results in a short

time at low cost. This is certainly a dilemma. Moreover, most young people who apply for a job as an analytical chemist are not well prepared to solve these problems efficiently. Therefore this dilemma also poses a challenge for universities and colleges to get closer to the practical needs of chemical measurement laboratories.

Keywords Analytical chemistry · Validation · Measurement result · Accreditation · Education

Introduction

Due to the globalization of the economy, service laboratories are confronted with increasing competition (Fig. 1). In order to succeed on the market, service laboratories have to produce more results in a shorter time at lower cost. At the same time they must provide results of an adequate quality as required by accreditation, which involves additional effort. Although accreditation provides a formal guarantee that a laboratory is able to produce reliable results it does not provide a real competitive advantage. Therefore, service laboratories are very much dependant on well-educated

staff members who are able to comply with these contradictory needs of the market.

International competition

The "Chemische Rundschau" [1] gives an overview of the analytical services available in Germany and Switzerland, presenting about 30 Swiss and more than 200 German laboratories. About 35 Swiss laboratories are organised in the Swiss society of private service laboratories (GSDL) [2]. It may be worth noting that the majority of the Swiss laboratories are small enterprises employing 5–30 staff members. Some examples of costs versus income indicate the competitive situation of service laboratories. While in 1995 a Swiss laboratory specializing in textile analysis offered the determination of an azo dye in a fabric for 100 Euro, it can request only 40 Euro for the same analysis today. This is a price decrease of 60% in 5 years. Ten years ago, around 50 Euro had to be paid for a metal determination in water in a well-established laboratory offering environmental analyses. Today the same determination is available for about 20 Euro (in some European countries a metal determination can be obtained for less than 10 Euro).

This price deterioration is partly due to developments in instrumentation and automatization, but the major driving force is the increasing competition between service laboratories. At the same time laboratories are facing increasing costs, making the situation even more drastic. Although the official Swiss salary index [3] increased by only about 3% at the beginning of the 1990s, and has remained more or less constant for the last 5 years, salary increases of 1 to 2% and of even up to 4% have occurred in the field of analytical chemistry. The costs for infrastructure have increased by about 1–2% per year. Although the price of analytical instruments has decreased over the last decade, the cost of state-of-the-art techniques is still high, driving the overall costs of a laboratory up. This is due to the fact that the actual lifetime of instruments has become shorter and that more instruments and automatization techniques are necessary to produce more data.

However, the major cause of increasing expenses over the last decade has been the implementation of quality assurance. It was about 10 years ago when the first laboratories were accredited in Switzerland. Since then they have spent more and more time and effort in improving their quality. Interviews at several well-established laboratories have revealed that laboratories have very different ways of quantifying these efforts, ranging from 50–500,000 Euro per year. While some laboratories calculate only the additional costs caused by the accreditation itself, others take into account all

technical efforts which are necessary to obtain a reliable result. For example, a laboratory for environmental analysis declared that two-thirds of its measurements of metals were used for quality purposes. This included measurements for validation, regular intercomparisons or simply repetitions.

Although accreditation provides a formal guarantee of the quality of a laboratory, it does not provide a real advantage in the global competitive market. On the one hand, the number of accredited laboratories has increased very fast and on the other hand, the market is mainly driven by money and, unfortunately, not by quality. Very often quality becomes a relevant factor only after economic damage has been caused by wrong results. Also, data evaluations of the International Measurement Evaluation Programme (IMEP) have shown that there is no significant difference between the results of accredited and non-accredited laboratories. An example for inorganic components in human serum is given in [4].

Another major factor of rising expenses is the continuing education of laboratory staff. Several laboratories complained that young people who apply for jobs are not well prepared to solve the actual problems. They certainly know how to produce numbers well enough, but most of them have never learned how to produce a correct result including all the necessary considerations of validation and quality control. Moreover, they are not at all prepared to do so in an economically compatible way.

In the light of all these developments, it is not surprising that several laboratories have given up their services over the last decade. Many of the remaining laboratories have had to change their services and focus on core activities in order to survive on the market.

Accreditation requirements versus the actual situation of quality management

Although the benefit of accreditation is incontestable, an additional pressure arises for a laboratory. Every accredited laboratory has to prove that its measurement procedures are valid, fit for purpose, and lead to comparable results. Moreover, it must also do its best to obtain results which are traceable to the SI. This requires not only a detailed knowledge of the individual analytical procedures from the chemical point of view, but also the availability of good reference materials and the knowledge of procedures for a correct data treatment. Contrary to former conceptions, new paradigms about the nature of a measurement result have been worked out. Today, there is worldwide agreement among metrologists that uncertainty is an inherent feature of a

measurement and that the result of a measurement is not a single number but a range. In other words, the result of a chemical analysis may be expressed as a number which is stringently accompanied by an uncertainty statement indicating a range. This measurement uncertainty shall be evaluated according to the rules expressed in the *Guide to the Expression of Uncertainty in Measurement* (GUM) [5] and "translated" for chemists by EURACHEM [6].

Although many laboratories put an increasing effort in their quality assurance, there is still a lack of awareness of what a result should look like. Still, a simple repeatability is often falsely quoted as the uncertainty of the number, which is then declared as the result. In addition there is a strong belief in the quality of reference materials. A result often refers to a reference material which does not deserve its name. Unfortunately, the term "reference" or "certified" is by no means a guarantee for the values which are declared on the labels of these materials. In addition, many analysts are not aware that the stated values of many reference materials change with time. This is a serious factor for uncertainty at least for solutions even when handled carefully.

Requirements of the customers

Most results from chemical analyses serve as a basis for decisions. A correct decision however can only be drawn from a correct result. Therefore, from the point of view of the customer, the result must be correct and as inexpensive as possible. As a matter of nature, a correct result comes as a range which may be expressed by a value and an uncertainty. However, the customer is usually not an expert of chemistry who is able to interpret a range, especially when it has to be compared with a specification or a legal limit which normally is expressed as a number without an uncertainty. In other words, many customers expect a single number and do not want to accept an "uncertain result". It happens time and again that a correct result is regarded as a bad result because of its uncertainty. There is still a lack of understanding of what the product of a measurement is. In the *"Guidelines on Assessment and Reporting of Compliance with Specification"* [7] the International Laboratory Accreditation Co-operation (ILAC) has clearly shown how compliance or non-compliance with specified limits can be stated, based on "uncertain measurement results". These guidelines, however, are fairly unknown to customers. As long as there is a misunderstanding of the nature of measurements among the customers and their is pressure on laboratories to report correct results, there is the risk of a fatal new kind of competition: the competition of "low uncertainties".

Requirements of the laboratories versus education

The economical success of an accredited laboratory is very much dependent on the ability of the analysts to produce correct results very efficiently. This not only requires sufficient knowledge of general chemistry; measurement techniques and procedures; validation protocols and data treatment; uncertainty evaluation and traceability of results, but also a sound idea of economical principles. In fact, hardly any student of chemistry has ever heard about subjects like metrology, traceability, uncertainty or economy on leaving university. There is certainly a lack of education regarding the latest developments in analytical chemistry from the point of view of quality assurance in practical life. The concepts developed by metrologists and organisations like EURACHEM, CITAC, EUROLAB, EA and others during the past decade are still unknown.

However, there is also a lack of education in analytical chemistry in general. Many universities and colleges do not reflect the importance of analytical chemistry for the economy in their curricula. Analytical chemistry plays a decisive role in many fields, e.g. life sciences, environmental protection, production, forensic science and more. Regarding drugs, anabolic steroids or even alcohol, analytical data are the basis of the decision whether a law has been violated or not. No substance is synthesized without an overall analytical control of every synthetic step. No product can be manufactured without a permanent analytical control of the production process. No product will be established on the market without being accompanied by a series of analytical data, revealing the composition, characterizing the behaviour or underpinning the risk or benefit for man and environment, or any other purpose.

The following numbers underpin the economic importance of analytical chemistry. Recent studies of the Section of Analytical Chemistry (SACH) of the Swiss Chemical Society (NSCG) and the American Chemical Society reveal data showing the requirements of the economy concerning analytical chemistry [8, 9]. Both conclude that about 20% of chemists work exclusively as analytical chemists and probably another 50% produce or at least use analytical data in their specialized fields. This complies with the number of analytical papers, about 20%, referred to per year in Chemical Abstracts. About 60% of the costs of chemical and biological R&D work are estimated to arise from analytical work [8]. Professor H. J. Matthias assumed in his farewell lecture in 1995 that chemists working in the field of product development or production spend 85% of their time on some kind of measurement [10].

Several studies over the past few years have indicated that measurements account for 4–6% of the gross national product in industrial countries, a great part of which involves chemical measurements.

Although the profile of a candidate applying for a job as an analyst has changed a lot, most education programmes at universities or other schools have not followed the current trends in analytical chemistry. Therefore, analytical chemistry still plays a minor role in the academic education of a chemist. This under evaluation is also reflected by the number of professors and assistants teaching analytical chemistry, and in the homepages of academic establishments. In analytical chemistry courses important metrological principles dealing with the aspects of quality, comparability and reliability of results are very poor or not found at all.

But it is not only the academic community that has failed to keep up with the recent developments. This is also true for education of technical assistants in Switzerland. Young apprentices receive a very practical education over 3 years which is normally composed of 1 day per week in school and 4 days in a company. The majority of apprentices are educated in the chemical industry. However many analytical laboratories are small or very small enterprises which are not able to provide adequate education programmes. The official rules for education of technical assistants [11] require only little mandatory analytical work and the quality aspects described above are completely absent. As a consequence, the education focuses on synthesis. Analytical education is poor unless the apprentice is directly engaged in an analytical laboratory.

Is there a way out?

The answer is: yes there is a way out. But this requires not only a lot of additional work but also a change in thinking for many people. First of all, it is absolutely necessary that the universities and other schools adapt their education programmes to the practical needs of the chemical industry. Analytical chemistry should be a mandatory part of any chemist's education including the knowledge transfer of all the above mentioned new developments in metrology and quality assurance. Secondly, a broad clarification of the nature of a result of a measurement is needed. Every customer who receives a result must become aware of the fact that no measurement will lead to a single number but always to a range. This clarification could be a major future topic for international organisations like EURACHEM, EUROLAB, EUROMET, EA or CITAC as well as for national institutions. A simple but practical initia-

tive has recently been started by the Swedish National Testing and Research Institute with an information leaflet designed for its customers [12].

Last but not least, the customer must also be willing to take the responsibility for any decision and not to shift the responsibility to someone else, like to the chemist who provided the number. Ideally the decision to be taken is the product of a cooperation between the customer and the chemist taking all aspects of a limited reliability into account.

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H. Felber
Swiss Federal Laboratories for Materials Testing and Research (EMPA),
Lerchenfeldstrasse 5, 9014 St. Gallen,
Switzerland, www.empa.ch
e-mail: helene.felber@empa.ch
Tel.: +41-71-274 77 92
Fax: +41-71-274 77 88