POLICIES AND CONCEPTS

Relevant accreditation policies and concepts in EU-, EFTA- and NAFTA- and other regions

Accred Qual Assur (1997) 2:36–39
© Springer-Verlag 1997

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Accreditation and quality assurance in Swiss chemical laboratories

Introduction

Although "Swiss made" is still an accepted label for quality and reliability, it has been recognized that labelling alone, without independent scrutiny and proof of adherence to sound quality practices, may not be sufficient to instill customer confidence in products and services. In recent years, Swiss industry has gone through a drive to introduce standardized internationally recognized quality systems in production and testing. At the same time, institutions were established which provide accreditation and certification services. The drive was hastened by the development of the European common market, which seeks to promote trade through agreements on mutual recognition of test results of accredited laboratories, resulting in a reduced need for repeated testing.

The importance of chemistry and analytical chemistry

Although the Swiss chemical industry takes only second place with respect to exports (25%) – after the machine/metals/electronics industry – it shows the highest balance of trade and is extremely ex-

port oriented (>85%). Concentration on production of pharmaceuticals and specialty chemicals implies strong commitment to research and development as well as quality assurance and hence reliance on analytical chemistry. Many other industries, from metal working and finishing to agriculture, food processing, health care, etc., rely on analytical chemistry for R and D, process control and quality assurance.

In recent years, analytical chemistry has gained additional importance because of the demands for environmental protection imposed by legislation and because of advances in medical diagnostics and clinical chemistry. In addition to industry, commerce, private laboratories, state (cantonal) chemical laboratories and environmental protection laboratories, government research and testing laboratories and institutes rely on analytical chemistry for R and D and quality assurance. Among analytical chemists, it is generally accepted that quality assurance is necessary and beneficial, regardless of the scheme chosen by the laboratory.

Pillars of analytical quality assurance

Private and public organizations from various disciplines contribute to quality assurance in chemical analysis:

- education and training by institutions of higher learning (universities, technical colleges) and trade schools
- professional associations
- quality associations
- standards organizations.

Education and training

The high professional standing and quality of analytical work of all levels of personnel – from chemist to laboratory technician – are founded on the many chemistry departments of universities, technical colleges and trade schools. In recent years, there has been a shortage of Swiss trained analytical chemists, partly due to the disappearance of analytical chairs. The importance of analytical chemistry to many disciplines and quality assurance has now been recognized, and some improvements have been initiated. Some chairs have been re-established. In addition, centers of excellence in analytical chemistry ("Kompetenzzentrum") have been created at the Swiss Federal Institute of Technology, Zurich and at the University of Geneva as a focus for analytically oriented chairs and departments. Important goals of these centers are collaboration, e.g. with industry and users of analytical chemistry, and education and training, e.g. in matters of quality assurance.

Professional societies make important contributions to education and training. The Section of Analytical Chemistry (SACH) of the New Swiss Chemical Society (NSCG) is the main rallying point for analytical chemistry. In its seminars, quality assurance has become a regular topic. Strong links, important for analytical chemistry, education and training, and quality assurance exist between these societies and IUPAC, FECS/WPAC.

The Swiss Association for Food and Environmental Chemistry ("Schweizerische Gesellschaft für Lebensmittel und Umweltchemie") is dedicated to analysis, testing, and quality assurance in food chemistry. There is close cooperation with the European section of AOAC. The many members of the Swiss Union of Laboratory Medicine (SULM) play an important part in Swiss health care. SULM

has recently created a quality standard for medical analytical laboratories; its criteria are based on the European standard EN 45001. Participation in proficiency tests and round robin tests is required for registered laboratories.

Standardization – quality assurance and testing

The Swiss Association for Standardization (SNV) provides links to ISO and CEN through cooperation in international and national technical committees, developing new and harmonized quality standards and guides. The Swiss Committee for Testing and Certification SAPUZ (Schweizerischer Ausschuss für Prüfung und Zertifizierung) is a technical committee of the Swiss Association for Standardization. SAPUZ was created as a mirror organization of the European Organization for Testing and Certification (EOTC) in order to create firm European links for technical harmonization of quality requirements and free trade. Representatives of industry and trade, government agencies, the research establishment and testing community, quality associations, and accreditation and certification boards cooperate in various technical committees (see Fig. 1), such as "Calibration", "Inspection", "Testing", the latter representing EUROLAB-CH and EURACHEM-CH. Especially important to analytical chemistry is cooperation in EURACHEM – a focus for analytical chemistry in Europe. An important task of EURACHEM-CH is to seek consensus and provide advice in seminars on quality assurance in chemical laboratories.

The collaboration of all parties concerned with quality assurance, accreditation and certification within the transparent network of SAPUZ provides good communications and results in cohesive policies. Various well-attended semi-

nars on quality assurance in analytical chemistry have helped to promote quality assurance and accreditation of analytical laboratories.

Promotion and use of quality systems

The Swiss Society for the Promotion of Quality (SAQ, Schweizerische Arbeitsgemeinschaft für Qualitätsförderung) is active in the area covering quality systems (ISO 9000 series), total quality management (TQM) and environmental management systems (ISO 14001). Education and training are the main activities of SAQ; it offers modular courses in quality management and awards the SAQ diploma "Quality System Manager".

Some companies producing industrial chemicals have introduced quality systems according to the ISO 9000 series and have sought certification by Swiss certifiers. Companies which produce pharmaceuticals or specialty chemicals used as raw materials for pharmaceuticals or which perform analytical work have to adopt a quality system which complies with the rules of GMP ("good manufacturing practice") and GLP ("good laboratory practice"). Testing of pharmaceuticals, pesticides and industrial chemicals, including analytical work, must comply with the GLP principles if the data are to be submitted to regulatory authorities. There are cases where companies have adopted both systems (ISO 9000 and GMP for production; EN 45001 and GLP for testing). A harmonization and convergence of quality systems would be welcomed.

The Swiss Accreditation System

The Swiss Accreditation System (SAS) was established as part of the Swiss Federal Office of Metrology (OFMET) which has granted

recognition to calibration laboratories since 1985. The SAS is Switzerland's official accreditation body. As a governmental organization, it is based on the accreditation and designation ordinance. This ordinance introduces a new chapter on designation (notification) of organizations responsible for the assessment of the conformity of products in the regulated field. Accreditation will play an important role in the designation process, and the Swiss Accreditation Service is expected to play an active part within the designation process.

According to the ordinance mentioned above, the managing director of OFMET grants accreditation after a comprehensive assessment performed by the SAS and an examination of the assessment reports by an independent accreditation board. This board, appointed by the Swiss government, currently consists of nine members, representing the Swiss industry, federal and cantonal administration, and universities. SAS assessments are directed by its own staff members, who are also responsible for the assessment of the quality system of the applicant. SAS leading assessors, possessing a broad technical education and wide industrial experience, are extensively trained in quality management. For the technical part of the assessments, SAS engages technical experts with a broad experience in the required field. These technical assessors receive additional training provided by SAS before being engaged in the assessment of applicants.

Once an organization is accredited, it will be surveyed by the SAS regularly. The SAS performs its technical duties for the benefit of the Swiss economy. It strives to perform its duties correctly, efficiently and quickly, at a high level of quality. It operates in accordance with all standards of the SN EN 45000 series and the corresponding ISO Guides.

SAPUZ

Schweizerischer Ausschuss für Prüfung und Zertifizierung
Swiss Committee for Testing and Certification

SAPUZ-Special Committee «Testing»

■ Chairman:

Dr. P. Radvila, EMPA St. Gallen

National Delegates to

■ EUROLAB

Prof. F. Eggimann, EMPA
Dr. J. Heyner, SEV-ASE

■ EURACHEM

Dr. P. Radvila, EMPA St. Gallen
PD Dr. Ursula Spichiger, ETHZ

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The SAS participates very actively in the activities of the international organisations of standardisation such as ISO and CEN/CENELEC as well as within organisations dealing with accreditation such as the European Co-operation for Accreditation of (calibration and testing) Laboratories (EAL) and the European Co-operation for the Accreditation of Certification Bodies (EAC). The SAS also actively contributes to the International Laboratory Accreditation Co-operation (ILAC) and the International Accreditation Forum (IAF). The performance of the Swiss Accreditation Service is highly valued and recognized by the members of the EAL and EAC Multilateral Agreements. After a comprehensive assessment of its performance, the signatories of these multilateral agreements are ready to promote the recognition of the accredited bodies in Switzerland in their own countries.

The SAS has signed all the existing Multilateral Agreements (MLA) for mutual recognition of reports and certificates and will also be engaged in establishing bi- or multilateral agreements for mutual recognition with accreditation bodies outside Europe. In addition to its multinational activities, the SAS is actively collaborating with the national accreditation scheme of Austria and the DAR in Germany. A harmonized training scheme for technical assessors within the German-speaking area, a common training scheme for interested parties in eastern Europe, and harmonized technical application documents are the results of the "D-A-CH collaboration".

On the national level, the SAS is actively working within the Swiss Association for Testing and Certification (SAPUZ).

The SAS participates in various technical committees of SAPUZ, such as the committees for calibration, testing, inspection, quality management and environmental

management. The collaboration within the network of SAPUZ is an excellent opportunity to measure the value of the SAS services and to evaluate their contribution to the Swiss economy. As a result, a rapidly growing infrastructure of more than 250 accredited bodies is available in Switzerland, providing the following types of services in almost every technical sector: calibration, testing, and certification of products, quality systems, ecomanagement systems and personnel inspections.

Addresses of accredited laboratories and bodies, together with the services they provide, are published and updated in the Index of the Swiss Accreditation Service (SAS). In addition, the scope of each accredited body is individually registered. This and other requested information may be at

The Swiss Accreditation Service
Swiss Federal Office of Metrology
Lindenweg 50
CH-3084 Wabern
Tel. +41 31 323 35 11
Fax +41 31 323 35 10

or at one of its subsidiaries:

The Swiss Accreditation Service
SAS/OFMET
Agence pour la Suisse romande
c/o EPFL
CM Ecublens
CH-1015 Lausanne

The Swiss Accreditation Service
SAS/OFMET
c/o EMPA Dübendorf
Überlandstr. 129
CH-8600 Dübendorf

The GLP program in Switzerland

Since the chemical industry in Switzerland is of great importance, a well-established infrastructure to monitor compliance with the OECD principles of good laboratory practice (GLP) is available in Switzerland. About 70 industrial and private laboratories, in both the pharmaceutical and environmental protection areas, are confirmed by the three Swiss GLP monitoring authorities to comply with the Swiss GLP principles.

The Swiss GLP monitoring program is fully in line with the OECD principles and officially recognised by all OECD member countries. Since a number of laboratories are interested in complying with the GLP Principles and in accreditation according to the EN 45001 standard, a collaboration between the GLP panel and the Swiss Accreditation Service has recently been established. The aim of this collaboration is to conduct joint or coordinated assessment and surveillance visits where requested by a laboratory. Rules and procedures for such combined assessments are under discussion.

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