

Federation of European Chemical Societies (FECS)

Working Party on Analytical Chemistry (WPAC)

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European Analytical Column 21 (June 1994)

Quality assurance and accreditation

1 Introduction

The WPAC pays full attention to the subjects education, quality assurance and international student competitions, next to the organisation of Euroanalysis conferences and support of analytical special congresses.

It has grown to a tradition that once a year the Analytical Column is dedicated to the activities around quality assurance and accreditation in Analytical Chemistry.

Much information can be extracted from the annual report of the study group on "Quality assurance and accreditation" (Chairman Bauke te Nijenhuis, The Netherlands). The main topics covered in 1993 will be described also in this column.

2 Eurachem

WPAC's clear involvement in Eurachem, originally an EC/EFTA organisation to improve the quality and international comparability of analytical measurements, led already to participation as an observer of several non EC/EFTA countries to the work of Eurachem, such as Czech Republik, Hungary, Poland, Russia, Slovak Republik and Slovenija.

More European countries have announced to join Eurachem. In the last Eurachem committee meeting, held in The Netherlands, it was decided "to upgrade" the observer status to associate members, thus recognizing the important active contribution of East European countries to the goals of Eurachem.

The status of the prime tasks of Eurachem today are:

– The definitive guide: "Accreditation for Chemical Laboratories as a guidance document on the interpretation of the EN 45000 series of standards and ISO/IEC Guide 25" is available now.

A guide for microbiological laboratories and for R&D laboratories is under consideration.

– A most successful workshop on European Cooperation in Proficiency Testing with several WPAC-delegates as attendees was held in Noordwijkerhout (The Netherlands) in November 1993.

– WPAC member countries have given most valuable input to the programme on Education and Training in Quality Affairs on both national and European level.

– A discussion paper on Calibration and Traceability drafted by Ron Walker gives valuable information on Primary, Certified and Working Reference Materials, but needs further consideration and improvement.

3 Accreditation of analytical laboratories

Analytical chemists are confronted with a variety of norms and guidelines, depending on the type of work of the laboratory. The importance of analytical chemistry can be demonstrated by the fact that in Europe about 3% of the gross national product is spent on chemical analysis. Certainly, since the initiation of the open European market, the quality of chemical analytical results has to comply with international norms. Results have to be comparable and traceable. The quality of results can be guaranteed if laboratories meet the requirements of independently fixed internationally accepted quality norms. Depending on their situation laboratories are confronted with norms such as EN 45000-series, ISO-9000-series, ISO/IEC Guide 25, GLP etc. Especially when laboratories work in different fields, different norms might be applied. It was the general feeling in the laboratory world that these norms in essence do not differ much, but that the differences are related to the interpretation by auditors.

So, in view of this feeling, in The Netherlands, a Eurachem study group has compared current norm systems and prepared a report on their findings. (H.A. van't Klooster, H.A. Deckers, C.J. Baijense, I.J.B. Meuwssen and M.L. Salm. Quality assurance in Analytical Chemical Laboratories, Eurachem The Netherlands, September 1993).

The main working conclusion is that, after careful one-by-one comparison of the norms and guidelines EN-45001, ISO/IEC Guide 25, ISO 9002 (9003), OECD/GLP, FDA/GLP and EPA/GLP, norms are highly congruent and only differ in minor points related to the application area. Differences also occur as a result of interpretation and culture in the application area.

The overall conclusion is that the differences established cause no insuperable hindrance to reaching one consistent and worldwide accepted system of quality assurance rules for the laboratory.

Actions are under way by which ISO/IEC Guide 25, after the uptake of amendments, will grow to a worldwide norm for laboratories. Guidelines as mentioned above for analytical chemical laboratories have to be developed for the various working areas where this new norm is valid.

4 Quality and education

Installation of quality systems asks for professional capabilities and continuous training and education.

This will be the driving force for the analytical profession and will be the basis for the recognition of the importance of the analytical chemist. As a consequence, WPAC pays continuous attention to Quality and Education.

Presentations on this subject were given already in the 2nd FEICHEM conference on Education in Analytical Chemistry. On the occasion of Euroanalysis VIII WPAC organized a buffet luncheon meeting on Education where not only the progress in Education matters was reported, but also the need for Education in Quality was underlined.

Several member countries, such as Austria, The Netherlands and the United Kingdom have already developed

(postacademic) courses for universities and polytechnics with the final option to make the contents part of the normal curriculum of all chemistry students.

A separate chapter in the Textbook based on the WPAC Eurocurriculum currently in production by VCH-publishers (Managing Editor: R. Kellner) will be dedicated to quality matters.

5 Working programme

WPAC will continue its strong attention in the field of Quality Assurance and Accreditation as a key issue for the future of Analytical Chemistry and its substantive role in society.

WPAC will proceed in the promotion of cooperation all over Europe and uses Eurachem as an important means for the introduction of harmonized analytical principles for the whole of Europe.

WPAC advises all European member organisations to install or to support national Eurachem organisations in order to be capable of influencing national and European policies of economic origin with respect to the whole executive field of Analytical Chemistry.

WPAC states that Quality Assurance and Education in AC are of equal importance for a balanced development of executive Analytical Chemistry which should result in teaching programmes with a strong focus on quality matters.

Harmonized accreditation systems are of utmost importance for Society and Analytical Chemistry. WPAC strives after one uniform, generally accepted norm for accreditation and certification of analytical laboratories, most probably based on ISO/IEC Guide 25.

WPAC considers assessment and registration of analytical chemists as qualified persons as a logical continuation of its vision and considers the concept of European Chemist as an worthwhile step in this direction.