Ensuring the quality of analytical measurements – current support and future challenges

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Abstract – Established in 1989, the aim of Eurachem is to provide a focus for analytical chemistry and qualityrelated issues in Europe. The main objectives are establishing a system for the international traceability of chemical measurement results and the promotion of good quality practices. Eurachem currently has 36 member countries and is effectively a 'network of networks'. A requirement of membership is the establishment of a national Eurachem network which supports the dissemination of Eurachem's aims and outputs. Eurachem also has liaison arrangements with a number of European and international organisations. In 2019, Eurachem marked its 30th anniversary. While the network is 'badged' as a focus for analytical chemistry in Europe, in recent years the audience for Eurachem activities has become much broader than analytical chemists making measurements in a laboratory setting. Interest in quality assurance now extends across a broad range of disciplines and measurement environments. This paper will review Eurachem's achievements over the past 30 years and look forward to some of the challenges ahead.

Keywords – Method validation, Measurement uncertainty, Metrological traceability, Sampling, Testing, Guidance.

I. INTRODUCTION

Established in 1989, Eurachem is a network of European organisations which aims to provide a focus for analytical chemistry and quality related issues. The main objectives are establishing a system for the international traceability of chemical measurement results and the promotion of good quality practices. It provides a forum for the discussion of common problems and for developing an informed and considered approach to both technical and policy issues.

Figure 1 illustrates a typical 'measurement cycle', starting with a client's problem or issue which leads to a request for a measurement to be undertaken. Fundamental to ensuring the quality of measurement results is an understanding of the analytical requirement – what does the client need to be measured and why? The interface

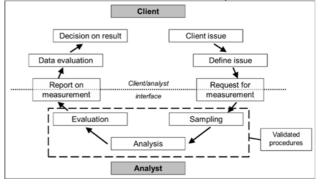


Fig. 1. The measurement cycle

between the client and the analyst is therefore critical to establishing a clear understanding of the analytical requirement. Eurachem produces authoritative guidance to support laboratories in ensuring measurement quality throughout the measurement cycle. Historically the focus was mainly on the analysis part of the cycle, with guides covering metrological traceability, method validation, measurement uncertainty and proficiency testing. However, Eurachem guides also cover other important aspects of the measurement cycle, including sampling and interpretation of results against limits.

This paper describes how Eurachem is structured, how it supports analytical laboratories in ensuring the quality of their measurement results and reviews the impact of Eurachem activities. The paper also includes a forward look to some of the challenges ahead.

II. MEMBERSHIP AND STRUCTURE OF EURACHEM

A. Membership

Full membership of Eurachem is open to countries within the European Union and the European Free Trade Association (EFTA), and the European Commission. It is also open to European countries recognised by the EU and EFTA as accession states, and European countries having

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an Association Agreement with the European Union. Associate Membership is open to other European countries with a good analytical chemical infrastructure, or countries near to Europe who have strong economic relations with Europe and who have a good analytical chemical infrastructure [1]. In addition to the European Commission, Eurachem has 35 member countries as shown in Figure 2. A full lists of members is available on the Eurachem website [2]. Of the 39 countries with a population of greater than 0.1 million that would be eligible for full Eurachem membership, 33 are currently members.



Fig. 2. Full and associate members of Eurachem shown in green

Eurachem is effectively a 'network of networks'. A requirement of membership is the establishment of a national Eurachem network which supports the dissemination of Eurachem's aims and outputs. This network can take a number of forms including (but not limited to): a national Eurachem network established explicitly for the purpose; an existing national association or organisation which expands its remit to cover Eurachem activities; a committee/sub-committee under the auspices of an existing organisation such as a national chemical society.

The Eurachem Memorandum of Understanding, signed by all Eurachem members, is the fundamental document which contains Eurachem's constitution and sets out its strategies, aims and objectives. It also describes the rights and responsibilities of the members [3].

B. Liaisons

European and international organisations, as shown in Table 1. Liaison links can be formal or informal. Formal liaisons involve a formal arrangement, such as a membership arrangement, memorandum of understanding, working group membership or other agreement to facilitate cooperation. Informal liaisons operate via informal monitoring arrangements; typically an existing member of the organisation concerned provides Eurachem with updates on activity and may provide the respective organisation with updates on Eurachem activity. Table 1 includes both types of liaison.

Table 1. European and international liaisons.

| European and international liaisons |
|---|
| Consultative Committee for Amount of Substance: |
| Metrology in Chemistry and Biology (CCQM) |
| Cooperation on International Traceability in Analytical |
| Chemistry (CITAC) |
| Codex Committee on Methods of Analysis and |
| Sampling (CCMAS) |
| Codex Inter-Agency meeting (IAM) |
| European Cooperation for Accreditation (EA) |
| EA Advisory Board (EAAB) |
| EA Laboratory Committee (EA-LC) |
| EA/Eurolab/Eurachem PT Working group |
| European Chemical Society (EuChemS) |
| EURAMET Technical Committee on Metrology in |
| Chemistry |
| EUROLAB a.i.s.b.l. |
| International Laboratory Accreditation Cooperation |
| (ILAC) |
| ILAC Accreditation Issues Committee |
| ILAC Laboratory Committee |
| ISO Reference Materials Committee (ISO-REMCO) |
| ISO TC69 SC6 - Measurement methods and results |
| International Union of Pure and Applied Chemistry |
| (IUPAC) |
| Joint Committee on Traceability in Laboratory |
| Medicine (JCTLM) |
| Nordic methods committee on food analysis (NMKL) |
| Europe Section of AOAC International (AOAC-E) |

C. Working Groups

Eurachem's technical activity is carried out by its Working Groups. Working Group activities typically involve producing technical guidance and initiating or contributing to international workshops and other events. Eurachem currently has the following active working groups:

- Education and Training
- Measurement Uncertainty and Traceability
- Method Validation
- Proficiency Testing
- EEE Proficiency Testing "Proficiency Testing in Accreditation"
- Qualitative Analysis
- Reference Materials
- Uncertainty from Sampling

Any Eurachem member country may nominate expert members to a Working Group and the Working Group Chair may invite other experts to attend.

A number of the working groups are formed jointly with CITAC.

III. DELIVERING EURACHEM'S AIM AND OBJECTIVES

The key activities undertaken by Eurachem to achieve its key objectives are the publication of authoritative guidance and the organisation of international workshops and training events.

A. Eurachem guidance documents

Eurachem produces three types of guidance documents:

- Eurachem Guide: normally comprising 10 A4 pages or more, containing recommendations on good practice;
- Supplementary guidance: issued in the form of a short document containing recommendations on good practice, usually illustrating or amplifying the provisions of a published Eurachem Guide;
- Information Leaflet: normally a two page document, introducing a Eurachem Guide or providing information on a topic of interest.

All Eurachem guidance documents are freely available on the Eurachem website.

To ensure that Eurachem publications reflect current best practice, are widely accepted and are reviewed regularly, a detailed procedure for the development of Eurachem guidance has been prepared [4].

Translation of guidance documents is encouraged. Eurachem members are entitled to prepare translations of Eurachem guidance in their own language and to distribute them via their own national Eurachem network.

Table 2. Eurachem guidance documents.

| Title | Type* | |
|---|-------|--|
| Quality assurance, accreditation and terminology | | |
| Guide to quality in analytical chemistry: An aid to accreditation | G | |
| Accreditation for microbiological laboratories | G | |
| Quality assurance for research and development and non-routine analysis | G | |
| Terminology in analytical measurement: Introduction to VIM 3 | G | |
| ISO/IEC 17025:2017 – A new accreditation standard | L | |
| You talk, we understand – The way out of the tower of Babel (An introduction to terminology in measurement) | L | |

| Proficiency testing | |
|--|---------|
| Selection, use and interpretation of | G |
| proficiency testing (PT) schemes by | 0 |
| laboratories | |
| Proficiency testing schemes and other | L |
| interlaboratory comparisons | L |
| How can proficiency testing help my | L |
| laboratory? | L |
| Selecting the right proficiency testing | L |
| scheme for my laboratory | L |
| Proficiency testing – how much, and how | L |
| often? | L |
| Pre- and post-analytical proficiency testing | L |
| Use of surplus proficiency test items | L |
| How to investigate poor performance in | L |
| proficiency testing | L |
| | L |
| PT schemes for sampling | |
| Measurement uncertainty and method valida | |
| Quantifying uncertainty in analytical | G |
| measurement | C |
| Measurement uncertainty arising from | G |
| sampling | C |
| Use of uncertainty information in | G |
| compliance assessment | 0 |
| Setting target measurement uncertainty | G |
| The fitness for purpose of analytical | G |
| methods: A laboratory guide to method | |
| validation and related topics | C |
| Planning method validation studies | S |
| Blanks in method validation | S |
| Harmonised guidelines for the use of | G |
| recovery information in analytical | |
| measurements | T |
| Information leaflet for lab customers | L |
| concerning the quality of chemical analyses | т |
| Use of uncertainty information in | L |
| compliance assessment | т |
| Using repeated measurements to improve | L |
| the standard uncertainty | т |
| Treatment of an observed bias | L |
| Setting target measurement uncertainty | L |
| Traceability and reference materials | C |
| Metrological traceability in chemical | G |
| measurement | 0 |
| The selection and use of reference materials | G |
| Traceability of analytical results | L |
| *G: Eurachem guide; S: supplementary guidar | nce; L: |
| information leaflet | |

The guidance documents currently available are listed in Table 2. A number of the guides have been produced in collaboration with other organisations such as CITAC.

Eurachem also maintains a reading list of key references in the areas of:

- Metrology and terminology
- Traceability of measurement
- Uncertainty of measurement
- Statistics
- Validation of analytical methods
- Reference materials
- Proficiency testing
- Internal quality control
- Quality assurance and accreditation

The list is available on the Eurachem website [5].

B. Eurachem workshops

Eurachem generally organises two international workshops per year. Often a workshop is run in conjunction with the General Assembly which takes place in May each year. Since 2010, Eurachem has organised 18 workshops, as shown in Table 3. The preferred structure of a Eurachem workshop is to include a mixture of invited lectures and short communications, as well as poster sessions and breakout sessions. The breakout sessions provide an opportunity for people from different sectors to discuss particular technical issues in detail.

Although the workshops are primarily aimed at participants from European countries, the audience is becoming increasingly global. For example, the workshop on 'Uncertainty from sampling and analysis for accredited laboratories' held in Berlin in November 2019 attracted an audience of over 130 from 37 different countries.

| Торіс | Year |
|-------------------------------------|-------------|
| Accreditation issues | 2019, 2020 |
| Data – Quality, analysis, integrity | 2018 |
| Decision making | 2010 |
| Internal quality control | 2012 |
| Measurement uncertainty | 2011, 2017, |
| | 2019 |
| Method validation | 2016, 2019 |
| Metrology and quality assurance | 2011, 2013, |
| | 2014 |
| Proficiency testing | 2011, 2014, |
| | 2017 |
| Quality assurance in the university | 2020 |
| curriculum | |
| Validation, traceability and | 2012 |
| measurement uncertainty | |

Table 3. International workshops since 2010.

Due to the Covid-19 pandemic, Eurachem held its first virtual workshop in July 2020. The workshop 'Quality Assurance Elements for Analytical Laboratories in the University Curriculum' was due to take place in Bucharest in May 2020. The Eurachem Executive Committee felt that it was important to continue with as many activities as possible, even while face-to-face meetings are not possible. Eurachem-Romania, in collaboration with the University Politehnica of Bucharest, organised a successful two-day on-line workshop which was attended by approximately 80 participants from 23 countries. The on-line event successfully delivered the key features of a Eurachem workshop, including poster presentations and breakout sessions.

Copies of presentations and posters from Eurachem workshops are made freely available on the Eurachem website [6].

In addition to the international Eurachem workshops, a key activity of member countries is the organisation of local training events. Information on the activities of the national networks is shared at the annual General Assembly meeting and reported in the Eurachem newsletter [7].

IV. IMPACT OF EURACHEM ACTIVITIES

A formal review of the impact of Eurachem activities was undertaken in 2014 on the occasion of the 25th anniversary of the formation of Eurachem [8]. The review considered a number of areas.

A. Eurachem members (coverage of European countries) and liaisons

The current Eurachem membership and liaisons are described in section II.

B. Impact on accreditation

As mentioned in section II, Eurachem maintains close cooperation with EA as a liaison and as a member of the EA Laboratory Committee. The permanent EA, Eurolab and Eurachem Working Group: EEE Proficiency Testing – "Proficiency Testing in Accreditation" has produced a number of guidance documents (full details can be found at <u>https://www.eurachem.org/index.php/euwgs/eee-pt</u>).

Eurachem also maintains liaison with the International Laboratory Accreditation Cooperation, ILAC, in particular through the ILAC Laboratory Committee. In addition, auditors from accreditation bodies have attended several Eurachem workshops.

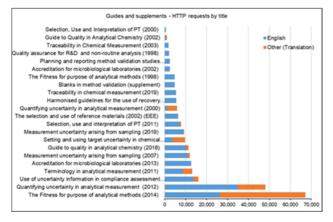
Impact on accreditation can also be assessed by identifying references to Eurachem in documents published by national accreditation bodies. The review undertaken in 2014 found that of the 34 EA member websites that were available for searching, 20 EA members were found either to include reference to Eurachem guidance in at least one of their own published documents or to hold one or more Eurachem guidance documents on their website [8].

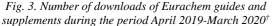
C. Material produced by Eurachem – Guides and leaflets

The guidance documents produced by Eurachem are summarised in Table 2. This comprises 12 Guides, 2 supplements and 15 leaflets. Many of these have been translated by Eurachem national members or - in the case

of languages not covered by the Eurachem membership, – other experts. Full details are available in the publications section on the Eurachem website.

To track the use of guidance documents, visits to the Eurachem website (<u>www.eurachem.org</u>) and document downloads are monitored. Figures 3 and 4 summarise the downloads of guides and leaflets, respectively, during the period April 2019-March 2020. Figure 3 shows all of the guides currently available on the website. This includes earlier editions which are available in the publications archive.





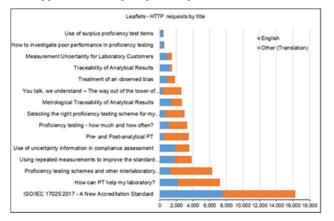


Fig. 4. Number of downloads of Eurachem leaflets during the period April 2019-March 2020^{\dagger}

D. Conferences and workshops

The international workshops organised by Eurachem are discussed in section III. In addition to the events organised by Eurachem and the national networks, Eurachem representatives also participate in conferences organised by other organisations. For example, in 2018, Eurachem organised satellite workshops at the Biennial National Atomic Spectroscopy Symposium (BNASS

[†]Figures presented in Fig. 3 and Fig. 4 are based on hit counts from raw web log files and therefore include search engine and other automated 'hits'. Language counts are based on file name. Files with different

2018) and at the XXII International Mass Spectrometry Conference (IMSC 2018). Participating in such events provides the opportunity to promote Eurachem activities to new audiences.

E. Standardisation

The impact of Eurachem on international standardisation activities can be assessed by identifying the number of standards (norms) that reference Eurachem guides. A search of the ISO on-line browsing platform (<u>https://www.iso.org/obp/ui/</u>) for 'Eurachem', carried out in August 2020 identified 66 citations across 51 standards. Figure 5 summarises the number of citations per guide.

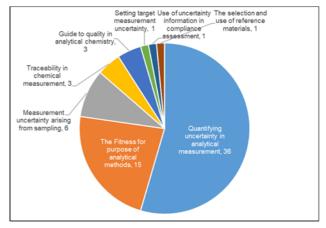


Fig. 5. Number of citations of Eurachem guides in ISO standards. Data obtained from a free text search of the ISO online browsing platform for 'Eurachem' in August 2020

F. Scientific literature

A simple search of Google Scholar was used to identify the approximate number of citations of Eurachem guides in the literature. Searches on the titles of Eurachem guides during August 2020 indicted approximately 2330 citations. By far the most cited guide is the 'Quantifying uncertainty in analytical measurement' (approximately 1300 citations). The next most cited guides are 'The fitness for purpose of analytical methods: A laboratory guide to method validation and related topics' (approx. 590 citations) and 'Measurement uncertainty arising from sampling' (approx. 190 citations).

V. FUTURE CHALLENGES

When Eurachem was founded in 1989, its primary aim, as stated in the Memorandum of Understanding, was to help establish a system of international traceability for chemical analysis. At that time there was limited activity in that area. However, in the intervening years there has

language versions have different file names. All guides are available in English but many guides are also available in other languages.

been significant focus on traceability and quality assurance in analytical chemistry, both by Eurachem and other organisations such as ILAC, CCQM and CITAC. Although much has been achieved there is still much to be done. So what are the likely future challenges for Eurachem?

While Eurachem is 'badged' as a focus for analytical chemistry in Europe, in recent years the audience for Eurachem activities has become much broader than analytical chemists making measurements in a laboratory setting. Interest in quality assurance now extends across a broad range of disciplines and measurement environments. In 2019, Eurachem marked its 30th anniversary with a workshop on the validation of targeted and non-targeted methods. Validation has always been a key area of interest for Eurachem, but the focus on non-targeted methods provided an opportunity to discuss the particular challenges in this area. The boundaries between measurement disciplines are increasingly blurred. Chemical techniques are used in the analysis of biological entities (for example the use of mass spectrometry in the analysis of proteins) and large numbers of quantitative tests are routinely carried out by molecular biologists using techniques such as qPCR and dPCR. The development of international standards for laboratory accreditation [9, 10] has driven interest in quality assurance across a broad range of sectors. A key challenge for Eurachem will be how to meet the needs of this wider audience. Eurachem has produced specific guidance to assist laboratories involved with microbiological testing to achieve accreditation but there may be other sectors where specific guidance would be beneficial [11]. Eurachem will need to continue to keep abreast of changes in the accreditation and regulatory landscapes to ensure that future guidance meets the requirements of the analytical community.

VI. CONCLUSIONS

The aim of Eurachem is to provide a focus for analytical chemistry and quality related issues in Europe. This paper has explained how Eurachem operates and described the key activities undertaken to meet these aims. In formulating guidance Eurachem is aware not only of the key cornerstones of the analytical quality assurance (metrological traceability, method validation, measurement uncertainty, quality control and proficiency testing), but also the wider 'measurement cycle', including, for example, sampling and compliance. Eurachem develops guidance and organises international workshops through a number of active Working Groups. The number of citations of Eurachem guides, both in the scientific literature and international standards, indicates that the guidance is widely accepted and considered to be authoritative.

During these most challenging times, it is pleasing that Eurachem activities are continuing, even when face-toface meetings are not possible. The use of 'virtual' meeting platforms potentially opens up meetings and workshops to a wider audience and is something that will be considered in the future, even when travel becomes possible.

Looking to the future, as the focus on quality assurance increases across a broad range of measurement disciplines, a challenge for Eurachem will be how to meet the needs of this wider audience.

VII. ACKNOWLEDGMENTS

Eurachem is nothing without its active members. I therefore thank all the General Assembly and Working Group members who share their knowledge and give generously of their time, to help Eurachem achieve its aims. I would also like to thank Dr Stephen Ellison for managing the Eurachem website and providing the document download statistics, and members of the Eurachem Executive Committee for their valuable comments on this paper. Preparation of this paper was supported by the UK Department for Business, Energy and Industrial Strategy.

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