STRATEGIC BUSINESS PLAN
ISO/TC 158

EXECUTIVE SUMMARY

ISO/TC 158 prepares written standards as tools for the industry, laboratories, assessment bodies, regulators and governments. These provide a harmonized basis for the preparation and use of calibration gases and gas mixtures by metrological institutes and (calibration) gas suppliers. As the work of ISO/TC 158 is mainly concerned with the calibration of gases and gas mixtures, the total market is limited for this document to the calibration gas market, although the standards' direct influence is on the whole gas market. The overall turnover of the "suppliers" is estimated at around 200 billion US $ and their employability exceeds 150 000 persons worldwide. However, only a small part of these figures relates directly to calibration gases.

ISO/TC 158 has become more market oriented and advocates the consistent use of a coherent set of International Standards targeting Good Analysis Practice in organizations dealing with gas analysis. The committee acts as a knowledge centre in the field of gas analysis, with specific expertise in uncertainty calculations and handling of calibration gases. The committee is also an active intermediary between suppliers and users of calibration gases.

To support the prime objective of the TC to produce standards for the production of calibration gases and gas mixtures, it provides standards to harmonise and enhance quality control and handling of products and proper evaluation of uncertainty. Thereby it aids its target audience in mitigating risks related to producing quality data that are not sound and harmonized worldwide, and ascertain a smooth and reliable worldwide transaction of industrial and other gases.

ISO/TC 158 has provided many common standards of metrological traceability and quality control methods for gas analysis. These standards support the liaison TCs, such as ISO/TC 146, ISO/TC 193, ISO/TC 197, etc., to draft analytical method standards in their own fields, and have made outstanding contributions in solving some practical problems. As preparation of calibration gas mixtures at lower concentrations with smaller uncertainties of target components has become increasingly important over the years, ISO/TC 158 will respond to the needs from climate change, energy gases, health and life sciences, and advanced manufacturing, in order to provide metrological traceability and ensure the measurements reliability.

ISO/TC158 is pro-active in standardization of new production techniques for calibration gas mixtures. This manifests itself in the two-yearly organization of the International Gas Analysis Symposium and Exhibition, a means for the whole (calibration) gas users community to identify market requirements and to learn about the latest developments.

1. INTRODUCTION

1.1 ISO technical committees and business planning

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure which forms part of a major review of business. The aim is to align the ISO work programme with expressed business environment needs and trends and to allow ISO/TCs to prioritize among different projects, to identify the benefits expected from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

1.2 International standardization and the role of ISO

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: ISO (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of IEC (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of ITU (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 164 countries (organizations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the International Standard.

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry). ISO and its Technical Committees are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction is that the IWA is developed by ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.

2. BUSINESS ENVIRONMENT OF THE ISO/TC

2.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal and social dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of this ISO/TC, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards.

Preparation of calibration gas mixtures with low fractions of targeted components has become increasingly important over the years. Regulations with respect to, e.g., emissions, climate monitoring, energy gases push the technology and methods used for calibration gas mixture production and quality assurance to their limits. As a side effect, there is an increased demand for high-purity gases, both for calibration purposes but also for direct use in the industry (e.g., semi-conductor industry) and end-users (e.g., hydrogen for fuel cell applications). Consequently, calibration gas mixtures need to be developed with smaller uncertainties of the component fractions than before. In this environment, ISO/TC 158 standards fulfil the needs of the market, and create a base for metrologically traceable and comparable measurements and ensure quality.

Political, economic, social, technical, legal and international factors that either directly require some or all of the standardization activities proposed by the ISO/TC, or significantly influence the way these activities are carried out, are the following:

- Air pollution control
- Greenhouse gas emission monitoring
- Air quality measurements (e.g., depletion of ozone-layer).
- Emission control of stacks and vehicles (e.g., Clean air act (USA), AutoOil (EU) and Kyoto Protocol)
- Determination of Volatile Organic Components (VOC's, emission from all sorts of products)
- Clean air environments and HACCP/OHSAS related regulations or demands (semiconductor, pharmaceutical and food industry)
- High-precision measurements (e.g., energy deliverance, open gas markets)
- In- or at-process analysis (e.g., process control, risk management)
- Industrial safety control
- Customized measurements in the field under various conditions (LNG, upstream)
- Conformity assessment of biomethane and biogas
- Conformity assessment of hydrogen (e.g., for fuel cell applications)
- Conformity assessment of CO_2 for Carbon Capture Utilisation and Storage (CCUS)

The use of calibration gas mixtures is essential in situations where small measurement deviations have a major impact. Striking examples are control of alcohol abuse in traffic by breath analysers, natural gas analysis, or emission measurements of engines and plants. In the international natural gas market the caloric value should be known with a relative uncertainty of a few per mill, as it concerns large quantities in which small deviations imply differences of millions of dollars in trade. The measurement of background levels of greenhouse gases is pivotal to understanding changes in the Earth's climate. Long-term observations based on accurate and stable standards ensure that data meets the requirements of WMO-GAW compatibility goals and environmental policy makers. For all these applications ISO/TC 158 also produces guidance documents for handling of the calibration gases and for determination of uncertainty budgets when measuring.

For calibration gas mixtures and certified standard mixtures the needs are global. Especially for certified standard gas mixtures traceability is still very important. Also the implementation of international agreements such as the Mutual Recognition Arrangement between the signatory countries of the metre convention relies on standards developed by this TC. The same metrological principles are applied from NMIs to end users, creating transparency in the sector and harmonization of quality assurance requirements. The standards also contribute to the smooth

and harmonized implementation of standards such as ISO 9001, ISO/IEC 17025 and ISO 17034 in organisations.

The metrology institutes deliver the reference standard gases and gas mixtures to both gas users and gas suppliers. The later ones use these reference standards to make large amounts of calibration gases. These gases are supplied worldwide by worldwide acting manufacturers. The overall turnover of these manufacturers is estimated at around 200 billion US $ and their employability exceeds 150 000 persons worldwide, of which only a small part of this relates directly to calibration gases.

2.2 Quantitative Indicators of the Business Environment

The following list of quantitative indicators describes the business environment in order to provide adequate information to support actions of the ISO/TC.

The major product influenced by the standards are calibration gas mixtures. The production of these gases is based on the following methods:

- weighing or gravimetric methods,
- static volumetric methods, and
- dynamic gravimetric or volumetric methods.

Of increasing importance have become methods and approaches for the assessment of the purity of high-purity gases, be it for ‘zeroing’ analysers, for end users applications (e.g., hydrogen for fuel cell applications, gases for the semi-conductor, food, and pharmaceutical industry). The TC aims to make available best practices developed over the years in calibration gas mixture preparation and quality assurance for these applications, including state-of-the-art methods for evaluating measurement uncertainty in support of (1) setting up traceable calibration methods by users of calibration gas mixtures and (2) conformity assessment and the development of specifications for industrial production of gases.

The overall growth for calibration gases within the sector is around 8% per annum. This is also based on the fact that developing and Eastern Europe countries are establishing their own national metrological institutes. These institutes open new markets within their countries. Moreover, the demand of a larger gamma of gas mixtures (especially in the medical and environmental control areas) directly delivered ‘in the bottle’, increases the market for calibration mixtures.

Specialty gas companies rely on the metrological institutes in the various countries for their calibration standards. In other words, these companies rely on their metrological institutes’ use of ISO standards to produce their primary calibration standards.

Customers of ISO/TC 158 standards are the metrological institutes, their customers for sales of primary and secondary standards (i.e. the gas mixture suppliers) and the next customers in line as cited above. To obtain secure uniform analysing gas mixtures the work of ISO/TC 158 is of vital importance. Furthermore, our standards are cited normatively in standards from, e.g., ISO/TC 193 Natural Gas and ISO/TC 146 Air Quality.

3. BENEFITS EXPECTED FROM THE WORK OF THE ISO/TC

An increasing number of economic and technical motives exist that require knowledge of the composition of gas mixtures more accurately. Due to these, the need for calibration gases has increased. Especially within the medical field, environmental control, greenhouse gas monitoring and for specialised gas mixtures the market is thought to be increasing. These specialised gases are more and more custom-made, and require new production technologies or the introduction of liquid components in a gas mixture.

The global liberalisation of the natural gas market leads to an increase in the number of places where gas owners change. International trade increases. Also the ongoing energy transition leads to new demands and new applications for calibration gas mixture. Measurement uncertainty of gas measurements gets more important. Also the chemical industry yields more and more residual products that are transported from site-to-site instead of burning them off. These transactions from one company to the other (also enlarged by reshuffling of ownership of plants by take-overs and merges within the industrial world) need accurate measurements. Calibration of these measurements needs to be done on-site, sometimes relying on multivariate gas composition evaluation.

Furthermore, governmental organisations rely on calibration gases for measurements of transactions and upholding of regulations (i.c. alcohol abuse or air emissions). Specific need for more accurate gas mixtures within this field is growing. Moreover, increasing technological and environmental requirements demand lower level elemental analysis, resulting in improved and/or complex calibration gases and measurement equipment. The developments of high accuracy, SI-traceable, gaseous reference materials of greenhouse gases drive the uncertainties towards the compatibility goals of the WMO GAW Programme.

The socio-economic attention to quality control and product reliability have an impact as well. Companies, especially (internal) laboratories, pay more and more attention to reliability (precision and trueness) of the chosen measurement methods. In the semi-conductor industry for example, even a minor deviation in the indication of hygrometers, that check the contents of water vapour within the used gases, can end in massive damage because of production loss.

The previously mentioned fact that more countries are establishing their own national metrological institutes, gives an enlarged amount of suppliers of primary gas standards. These new institutes and countries should rely on ISO experience, where they in the past might have developed new methods of producing calibration gases. These politico-social changes give new directions for the future work of ISO/TC 158.

The availability of the standards gives producers and legal authorities a general idea of the requirements and possibilities, where it allows upcoming institutes and markets to develop an internationally accepted production of gases. Multinational companies can buy their standard and calibration gases in the country the plant is based, saving transport costs. Markets in non-Western countries are opened for calibration gas production.

The work of ISO/TC 158 so far has been of major importance. The market lacked an international set of standards describing the methods of producing calibration gases. Now that almost all production methods are described, updating them to the market needs will remain important in the near future. For calibration gas mixtures a broader field of use and new markets will become available. Key standards like ISO 6142 and ISO 6143 have been in place without major change, thus contributing to a sustainable quality infrastructure for calibration gas mixtures and clear requirements with respect to metrological traceability of measurement results in the sector.

New developments and ideas, and the sharing of its expertise is accumulated by the TC in its regularly organized International Gas Analysis Symposium and Exhibition. This event has

become a sequel event, unique in the gas and calibration world where researchers, industrials, laboratory workers and calibration gas users meet each other with a focus on international standardization. The event is also used to test new standardization ideas in and to extract new directions for standardization from the work field. More than 200 participants have attended each of symposiums held in 2015, 2017, 2019, 2022, and 2024.

4. REPRESENTATION AND PARTICIPATION IN THE ISO/TC

4.1 Membership

Countries/ISO member bodies that are P and O members of the ISO committee

4.2 Analysis of the participation

Suppliers of gases and gas mixtures, manufacturers of calibration gases, metrology institutes, research institutions and test laboratories are well represented in this ISO Technical Committee. On the other hand, the market becomes more-and-more customer-driven. Although these customers (such as Shell, Ford, Philips, Pfizer or ABB) do not have the calibration gas expertise, their needs are the basis for further work. ISO/TC 158 has experience with several market events, such as the international gas symposium and exhibition and the gas users network, for identifying and accommodating these needs.

Regarding active membership there is an emphasis on experts from European countries. As many of the organisations from industry operate globally, the interests of other geographic regions are represented in part indirectly. Nevertheless, the TC undertakes efforts to make itself known to a broader audience, for example by presenting its activities and results at the International Gas Analysis Symposium and Exhibition and international meetings, such as those of the National Metrology Institutes. Also the participation in research and development projects through its members or as stakeholder contributes to making the participation wider.

In the past years, both the number of O- and P-members have shown a slight increase.

5. OBJECTIVES OF THE ISO/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

5.1 Defined objectives of the ISO/TC

The prime objective of the TC is to produce standards as tools for the production of calibration gases and gas mixtures. This objective is achieved by elaboration of standards on the main three production methods: weighing, static volumetric and dynamic methods. ISO/TC 158 will be the first to develop new or update current standards, to foster harmonization and to avoid unnecessary issues in the supply chain of calibration gas mixtures and pure gases due to the application unharmonised methods having incompatible foundations.
Other general objectives are given below:

- Elaboration of Standards for quality assurance aspects in the use of reference gas mixtures on a continuous basis.
- Providing Standards to determine and quantify (calibration) gas mixtures which will enhance quality control and handling of products and proper determination of uncertainty. This is envisaged at a rate of two deliverables (Standard, Technical Report) per year.
- Production of Standards that are appropriate to avoid the risks of producing quality data that are not sound and harmonized worldwide.
- Elaboration of Standards or guidance documents for a smooth and reliable worldwide transaction of industrial and other gases. This is envisaged at deliverance of own products or joint work with other ISO/TC's at two active work items during the year.
- Pro-active in standardization of new production techniques for calibration gas mixtures.
- Provision of further support to the users of standards, for example in the form of example calculations, software to support a smooth implementation.

New ideas and market potentials to be studied are:

- Sampling of (calibration) gases
- Impact of the isotopic composition on the standards of ISO/TC158
- Requirements for high-purity gases and analytical methods of impurities
- Performance assessment and requirements for gas analysers
- High-end applications for dynamic methods
- High precision GHG standard gases supporting the climate monitoring

5.2 Identified strategies to achieve the ISO/TC's defined objectives

The objectives will be achieved by:

1. providing computational support to existing standards, thereby assisting the readership with the implementation of these,
2. liaise with bodies outside ISO to address specific issues such as the isotopic composition of components in gas analysis to address emerging needs in this area,
3. using terminology, vocabulary and uncertainty calculation basics laid down in its own standard (ISO 7504) and in international accepted guides,
4. organization of a regular informative meeting (the International Gas Analysis Symposium and Exhibition) for the whole (calibration) gas users community to identify market requirements,
5. production of guides and reports for the users on the application of ISO/TC 158 standards in general or in specific fields,
6. request regional standardization organizations, such as CEN, to adopt our standards,
7. liaison and cooperation with relevant international (users) organisations and other ISO technical committees on fields such as natural gas, air quality, petroleum products, medicine, food packaging, chemistry and (road) transportation,
8. collaborate with consortia of research and development projects with activities related to our portfolio of standards,
9. full exchange of information between metrology institutes and manufacturers,

10. encourage the development of new method standards for analysing the impurities in high-purity gases.

6. FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE ISO/TC WORK PROGRAMME

The representation in the TC is worldwide, with the centre of gravity form Europe. With the internationalization and consolidation of the gas industry, mechanisms for the takeup of standards has changed (the international takeup happens partly within industrial organisations, rather than through the traditional ISO and NSB structure.

The representation in NSBs (mirror committees) is also a point of attention. The number of attendees is declining, yet their role is vital in the development and approval of standards and other ISO deliverables. The TC seeks to support these mirror committees to stop the trend and to ensure that on a national level there remains a platform to discuss issues and to provide input and feedback to the TC.

Furthermore, the re-engineering and merge of a lot of companies may diminish the amount and/or time availability of experts.

The final factor that would affect the completion and implementation of the TC’s work programme is lack of funding to support the Committee Manager and Chair.

7. STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF THE ISO/TC

Information on ISO online

The link below is to the TC's page on ISO's website:
ISO TC 158 on ISO Online

Click on the tabs and links on this page to find the following information:
- About (Secretariat, Committee Manager, Chair, Date of creation, Scope, etc.)
- Contact details
- Structure (Subcommittees and working groups)
- Liaisons
- Meetings
- Tools
- Work programme (published standards and standards under development)

Reference information

Glossary of terms and abbreviations used in ISO/TC Business Plans

General information on the principles of ISO's technical work