

EN 15267 - A new unified testing and approval scheme for automated measuring systems

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Summary

This paper describes the developing scheme for testing and certifying automated measuring systems (AMS) for measuring stack emissions and ambient air quality. The scheme will be applied through four standards to be published by the Committee for European Normalisation (CEN). The third standard in the series (prEN 15267-3) has been received a positive vote within the CEN member states and will be published later this year. The other parts of prEN 15267 are planned for publication in 2008.

EN 15267 is a new CEN standard in four parts, for testing and certifying automated measuring systems (AMS). The new standard applies to AMS for both stack emissions and ambient-air monitoring. CEN developed EN 15267 because there has been a growing need for a unified set of standards for testing and certifying AMS, to support the requirements of EC Directives and the quality assurance standard, EN 14181, for AMS which measure stack emissions. This paper will focus on the scheme through the standards for AMS which measure stack emissions; although the approaches and requirements described in prEN 15267-1 and prEN 15267-2 can be applied to other technologies. The following aspects of the scheme are described in this paper:

- The monitoring requirements of EC Directives for incineration and large combustion plant.
- The background to testing and certification in Europe – and why there has been a need for type-testing and approval.
- The type-testing and approval schemes in the UK, Germany, France and Italy, and how they led to the development of EN 15267.
- EN 15267 and the requirements of EN 14181 – QAL1 and QAL3.
- prEN 15267-1 – Arrangements for testing and certification.
- prEN 15267-2 – Requirements for an AMS manufacturer's management system.
- prEN 15267-3 – Performance specifications and test procedures for AMS for measuring stack emissions.
- prEN 15267-4 – Performance specifications and test procedures for AMS for measuring ambient air quality

Introduction – the need for standards

Many industrial process operators have to continuously monitor the emissions from their chimney stacks. For example, the Large Combustion Plant Directive (2001/80/EC)(LCPD) specifies that certain process operators must measure emissions of sulphur dioxide (SO₂), oxides of nitrogen (NO_x) and particulate matter (PM), whilst the Waste Incineration Directive (2000/76/EC)(WID) can require process operators to continuously measure at least the emissions hydrogen chloride (HCl), carbon monoxide (CO) and total organic carbon (TOC) in addition to the same determinands required by the LCPD.

The systems which continuously measure stack-emissions are known as *Automated Measuring Systems* (AMS). The LCPD and WID specify performance requirements for AMS, both directly and indirectly.

- **Directly** – the WID and LCPD specify a requirement for accuracy and precision as 95% confidence intervals, expressed as a percentage of emission limit values (ELVs). The Directives also specify requirements for data availability, which in turn means that AMS must meet these availability requirements.

- **Indirectly** – the Directives specify the use of CEN, ISO, national and other non-native national and international standards for monitoring. Many of these standards contain performance specifications for AMS, as well as requirements for the test procedures to verify the performance of AMS.

Additionally, the Directives specify requirements for the quality assurance of AMS, such as calibration using a reference method, and an annual surveillance test. In order to provide for these quality assurance requirements, CEN developed EN 14181, which specifies four levels of quality assurance (known as QALs). The first of these, QAL1, states that AMS must meet the uncertainty budgets specified in the Directives; another standard, EN ISO 14956, describes a procedure to calculate the QAL1 uncertainty value, whilst type-approval and certification schemes can provide the data for these calculations. EN 14181 also specifies requirements for the allowable drift and variations in precision for an AMS during use; this requirement is known as QAL3, and again, type-testing and approval schemes can provide the means to support QAL3.

Quality assurance of monitoring systems

Historically, when process operators bought AMS for measuring stack emissions, there was no independent proof that the AMS would be suitable for the intended use. Although many operators and regulators were satisfied with the data that AMS produced, there were still many cases where AMS did not meet either the users' requirements, or even the claims that manufacturers made. So there was a clear need for a scheme to verify the performance of AMS.

The world's first verification and approval scheme for AMS was the German type-approval scheme, administered by the German environmental regulator, the Umweltbundesamt (UBA). UBA specified the requirements for AMS in a federal document, whilst approved test laboratories would perform the type-testing. A type of AMS has to meet standards for specified performance characteristics, such as:

- Lack of fit.
- Resistance to variations in environmental conditions.
- Effects of interfering substances on the measurements.
- Effects of influencing quantities, such as stack-gas flow and changes in voltage supply.
- Detection limit.
- Availability.
- Zero and span drift during a three-month field-test.
- Accuracy against a reference method.

Testing of AMS takes place in two stages, beginning with a set of laboratory tests, which are then followed by a series of field tests where the AMS measures emissions on an industrial stack over at least three months. A manufacturer has to submit two identical AMS for testing, and both the AMS must pass all of the tests. As there are many types of industrial process, the testing is performed on one of two types of very demanding process. If an AMS is suitable for testing on a demanding process, then based on years of practical experience, UBA considers it suitable for most (if not all) other types of process. An AMS is typically approved for the following processes:

- If the AMS is tested on an incineration process, then the AMS is approved for all types of process.
- If the AMS is tested on a large combustion plant, then it the AMS is approved for all types of process except incineration.

If the testing is successful, then the test laboratory submits a report to UBA and recommends approval. UBA then publishes a list of approved equipment in a federal publication and on its website. Most importantly, industrial operators for processes such as incineration and large combustion plant can be assured that the approved AMS are suitable.

Test laboratories have to meet strict requirements in order to perform the testing. Currently UBA specifies these requirements through several standards, such as EN ISO/IEC 17025, and VDI 4203 Part 1. The performance specifications and test requirements for AMS are specified in VDI 4203-2. Although UBA has approved several test laboratories for this type of work, most of the testing in Germany is performed by TÜV laboratories in Cologne and Munich.

Meanwhile, in the late 1990's, the Environment Agency for England and Wales developed its own Monitoring Certification Scheme (MCERTS). In many ways, this scheme was very similar to the UBA type-approval scheme, although there were a few differences in the performance specifications, and the approach to design changes of AMS. In the German scheme, if an AMS made any design changes to the AMS, then the manufacturer would have to tell the test laboratory about the changes. If the test laboratory decided that the changes were significant, then the AMS may have to go through more testing to verify the effects of the changes.

Under MCERTS, design changes are controlled through applying EN 45011. The Environment Agency appointed an external certification body accredited to EN 45011 to manage the scheme. MCERTS requires AMS manufacturers to keep a detailed record of any design changes to AMS and to notify the certification body when there are changes. The certification body then decides if these changes are significant and whether the AMS has to go through more testing. Additionally, the certification body audits manufacturers every one to two years, to determine whether the manufacturer has an effective procedure for controlling the impact of design changes, and whether the manufacturer can make all AMS to meet the required performance standards.

However, despite the similarities between the German and British schemes, many process operators and manufacturers were confused, especially regarding the need for testing in both Germany and the UK. This in turn led to Germany and the UK working together to align their respective schemes, and to allow for mutual recognition in order to eliminate the need for duplicate testing. In some cases, manufacturers of AMS needed to have a few supplementary tests in order to gain approval both in Germany and certification in the UK for the same AMS; however, the alignment and mutual recognition eliminated the need for complete retesting of AMS that were already approved. The Environment Agency and UBA signed an agreement of mutual recognition in 2002.

Meanwhile, both CESI in Italy and Ineris in France also began to work on national type-testing and approval schemes. CESI started to operate the MCERTS scheme in Italy, under license from the Environment Agency, whilst Ineris developed a scheme whose scope included both AMS and continuous ambient-air monitoring systems (CAMS). Germany had also been operating a type-testing and approval scheme for CAMs.

Also earlier this century, all the countries involved in type-testing and the approval of AMS started working together through the Committee for European Normalisation (CEN) to unify the many standards for type-testing and approval, and to provide the framework for an international scheme within the EC. This work has been carried out in CEN TC 264 WG22.

Objectives of the CEN standards for testing and certification

When WG22 began its work programme, it had several major objectives. These were to:

- Provide a means for AMS to meet the requirements of the LCPD and WID, as well as any other types of installation regulated by national regulators.
- Provide a means of testing and certifying AMS for measuring both stack emissions and ambient air quality.
- To meet the QAL1 and QAL3 requirements of EN 14181.
- To provide the means for a system which would allow an AMS to be tested and certified in one country, and this certification would be recognised throughout the EC.

WG22 will fulfil these objectives by publishing five related standards (Table 1).

Table 1: The four standards being produced by WG22.

Standard	Scope
prEN 15267-1	The broad requirements for testing and certification. This standard describes how certification schemes would work in CEN member states.
prEN 15267-2	Quality assurance of manufacturing processes for AMS, and specifically the control of design changes. This standard expands on the requirements of ISO 9001.
prEN 15267-3	Performance standards and test requirements for the AMS which measure stack emissions.
prEN 15267-4	Performance standards and test requirements for the AMS which measure ambient air quality. As other CEN standards specify these requirements in detail, prEN 15267-4 is a bridging document between these other standards, and prEN 15267-1 and prEN 15267-2.

It is likely that CEN will publish prEN 15267-3 this year, whilst the remaining standards will most likely be published during 2008.

prEN 15267-1 - framework standard

This will be a framework document for certification schemes in CEN member states. It describes the processes of testing, certification and assessment, as well as the responsibilities of the different organisations potentially involved in testing and certification. The organisations involved in certification would be:

- Manufacturers of AMS.
- Test laboratories.
- A competent body, such as a national environmental regulator.
- Certification bodies.

The competent body could be either a national regulator, or a certification body, if the regulator has delegated responsibility for managing a scheme to a third party. The standard proposes that the certification process should comply with EN 45011. If the competent body were a regulator, the standard does not require the regulator to be accredited to EN 45011. Although WG22 has written this framework standard for certifying AMS which measure stack emissions and ambient air quality, the model could apply to the certification of any environmental technologies.

This standard also deals with design changes to AMS, and what the organisations involved in certification have to do, if the manufacturer makes design changes. Part 2 of EN 15267 then focuses on the management-system requirements that a manufacturer must apply in order to quality assure manufacturing and design changes of AMS. Annex 1 describes the content of prEN 15267-1.

prEN 15267-2 – Uniformity in manufacturing

If a manufacturer produces an AMS to meet performance specifications, then it is important for the manufacturer to have a management system which assures that all AMS of the same type meet the performance specifications. In other words, the manufacturer shall have a quality assurance and control system to produce AMS consistently. Furthermore, manufacturers typically make many design changes to AMS during their design lives. Therefore there is a need to ensure that when manufacturers change the design of an AMS, that these changes do not affect the certification. Therefore prEN 15267-2 describes a procedure for recording, assessing and controlling design changes to AMS.

Most, if not all AMS manufacturers, have a management system which conforms to the requirements of ISO 9001:2000. This quality assurance standard specifies requirements for design control, as well as the processes which affect manufacturing. Therefore prEN 15267-2 follows the same model as ISO 9001 and expands on its requirements to specifically cover AMS manufacturing, and design control. WG22 based prEN 15267-2 on ISO 9001 also because it is envisaged that an AMS manufacturer's regular certification body for ISO 9001 management systems would be able to assess the manufacturer to prEN 15267-3 as well. Importantly, prEN does not specify that a manufacturer's management system must be certified to ISO 9001, but states that certification is a means of demonstrating compliance and so avoiding duplicate assessments.

prEN 15267-3 – Performance specifications for AMS which measure stack emissions, and the requirements for testing

This standard is covered in detail in the presentation by Dr Wolfgang Jockel. prEN 15267-3 both unifies and updates all the performance requirements of existing AMS for stack emissions, and also provides the means for compliance with QAL1 and QAL3 of EN 14181. The scope of the standard applies mainly to AMS which measure emissions from sites regulated by the LCPD and WID, although the scope can apply to AMS which measure emissions from other types of regulated installation.

The scope of prEN 15267-3 includes AMS for monitoring gaseous emissions, dust and flow rates. WG22 is now writing a simpler, related standard for dust-monitoring AMS which measure emissions from processes not regulated by the WID and LCPD.

prEN 15267-3 is in two main parts; the first core part specifies the performance specifications which AMS must achieve during the laboratory tests and field tests. The second core part of the standard then specifies the requirements for testing. Any test laboratory wishing to evaluate AMS must become accredited to ISO 17025, prEN 15267-3 and any reference-method standards employed during the field tests. The field tests themselves must comply with the major requirements of EN 14181.

prEN 15267-4 – Performance specifications for AMS which measure ambient air quality, and the requirements for testing

This standard is a framework standard which links existing standards for AMS which measure ambient air quality, to prEN 15267-1 and prEN 15267-2. CEN has already published standards which are reference methods for continuously measuring the pollutants in ambient air which EU member states must measure. These CEN standards include both performance standards and test procedures. The Air Framework Directive for ambient air quality specifies that AMS for the main pollutants must be uncertainty requirements and be type-approved. Therefore prEN 15267-4 provides the connection between the CEN reference methods for ambient quality, and prEN 15267 for testing and certifying AMS.

The CEN scheme and verification.

Annex 2 shows a potential model for a verification scheme which could include different levels of verification, type-approval and certification. In this model, the testing and approval of an environmental technology could take place in two stages; the main components of these stages are described in Table 2:

Stage	Process	Description
Stage 1	Verification, or: Type-testing	Environmental technology is tested to verify a manufacturer's claims. These claims could be based on the manufacturer's own specifications, a regulatory requirement, or a combination of regulatory requirements and claims. Environmental technology is tested according to the requirements of a published national, international or regulatory standard. In other

Stage	Process	Description
		words, the environmental technology is a type which is designed to conform to the requirements of a published specification.
Stage 2	Assessment of manufacturing consistency and design control	The purpose of this assessment is to assess that a manufacturer can make items of environmental consistently, and ensure that any design changes do not degrade the performance (based on the initial testing).

In simple terms, the model consists of two stages; the first stage consists of laboratory testing to verify the performance of environmental technology. The testing could be based on a manufacturer's claims (which is termed *verification* here), or based on a published standard (which is called *type-testing* here). Therefore the scope of the testing will determine whether the process is verification or type-testing; there will be cases when either verification or type-testing are suitable or preferable. At the end of successful testing, the manufacturer will receive a test report.

The second stage in the proposed model is optional; this stage examines manufacturing processes, for two reasons. Firstly, the manufacturing processes should ensure that a manufacturer can produce multiple items of environmental technology consistently (so that the 1000th item of a product performs to the same specifications as the 1st item manufactured). Secondly, the manufacturer controls design changes so that the environmental technology still performs to at least the same specifications. Stage 2 is optional, and could be underpinned by standards such as ISO 9001, and EN 45011.

Once a manufacturer's technology has been tested successfully, a competent body could then issue a certificate. The scope of the certificate would describe the parameters tested. If the technology has been tested for verification, then the manufacturer would receive a verification certificate. If the technology was tested for conformity with a published standard, then the manufacturer would receive a type-approval certificate. The certificate could also state whether the manufacturer chose Stage 1 alone, or Stages 1 and 2. In some cases, manufacturers would have to go for both states due to regulatory requirements, but in all other cases, manufacturers could have the choice of Stage 1 only, or both stages.

Conclusions

Within the EC, there are currently four national schemes for verifying the certifying the performance of AMS. These schemes are similar, and EC member states have developed these schemes to improve the quality of monitoring data, meet the requirements of laws, and satisfy the specifications within national and international standards for monitoring. Now, EC member states are working within CEN to develop a series of European standards for AMS. These standards, which will be in the EN 15267 series, describe a uniform framework for testing and certifying AMS. The EN 15267 standards will be published during the next two years and will include performance specifications for AMS which measure gases, dust and flow rates. As well as unifying many varied standards for the performance and testing of AMS, the framework in the EN 15267 series will also help to reduce trade barriers in the EC, as testing and certification in one EC member state should mean recognition in all other CEN member states. Lastly, the scheme described by EN 15267 could fit within a wider model being developed by the EC for verifying environmental technology.

References

- EN ISO/IEC 17025 (2005). General requirements for the competence of testing and calibration laboratories. ISO, Geneva, Switzerland.
- EN 14181 (2004). Stationary source emissions. Quality assurance of automated measuring systems. CEN, Brussels, Belgium.
- EN 45011 (1998). General requirements for bodies operating product certification systems. CEN, Brussels, Belgium.
- prEN 15267-1 (2006). Air Quality – Certification of Automated Measuring Systems (AMS) – Part 1: General aspects.

prEN 15267-2 (2006). Air Quality – Certification of Automated Measuring Systems (AMS) – Part 2: Minimum requirements for product quality assurance, initial assessment and on-going surveillance.

prEN 15267-3 (2006) . Air Quality – Certification of Automated Measuring Systems (AMS) – Part 3: Performance standards and procedures for testing the performance of AMS of stationary source emissions.

prEN 15267-4 (2006). Air Quality – Certification of Automated Measuring Systems (AMS) - Part 4: Performance standards and procedures for testing the performance of AMS of ambient air quality

ISO 9001 (2000). Quality management systems – requirements. ISO, Geneva, Switzerland.

Performance Standards for Continuous Emission Monitoring Systems (2007). Performance standards and test procedures for gaseous emissions, particulates, temperature, pressure and flow rate. Version 3. Environment Agency.

Uniform Practice in monitoring emissions (2005). Circular from the Federal Environment Ministry of June 13, 2005 – IG I 2-45053/5 - Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, Germany.

VDI 4203 Part 1 (2001). Testing of automated measuring systems – General concepts. VDI, Dusseldorf, Germany.

VDI 4203 Part 2 (2003). Testing of automated measuring systems - Test procedures for measuring systems of gaseous and particulate emissions. VDI, Dusseldorf, Germany.

Details of the Environment Agency's MCERTS scheme are available at www.mcerts.net .

Details of German Federal Environment Agency's type-approval scheme are available at <http://www.umweltbundesamt.de/luft/messeinrichtungen/mg-bestimmung.htm> .

Annex 1

prEN 15267-1 - Air Quality – Certification of Automated Measuring Systems (AMS) – Part 1: General Aspects.

This annex describes the contents of the draft standard prEN 15267-1.

Introduction

The certification of AMS supports the requirements of certain European Union (EU) Directives which require, either directly or indirectly, that AMS comply with performance specifications, uncertainty budgets and testing requirements. These Directives include the *Directive on the limitation of emissions of certain pollutants into the air from large combustion plants (2001/80/EC)*, the *Directive on the incineration of waste (2000/76/EC)* and the *Framework Directive on ambient air quality assessment and management (96/62/EC) and the associated daughter directives (99/30/EC, 2000/69/EC, and 2002/3/EC)*.

The responsibility for approving AMS for monitoring ambient air quality under Directive 96/62/EC lies with the national competent authority or a body designated by the Member State. No explicit requirement for approving AMS for monitoring emissions from stationary sources is defined in the relevant EU Directives, although the competent authorities in some CEN Member States have such arrangements in place.

In some CEN Member states the competent authority delegates the responsibility for approval of AMS to a Certification Body accredited to EN 45011 by national accreditation bodies. In some Member States the competent authority cannot be accredited by external bodies; in others they may be. These approaches have built up over many years and reflect the different administrative and legal arrangements that exist in CEN Member States. In order to recognize these different approaches, prEN 15267-1 uses the collective term: “Relevant Bodies” when referring to competent authorities and certification bodies. The terms: “competent authority” and “certification body” are only used where it is necessary to be specific for the purpose of clarity in the way in which a requirement applies under the different approaches.

The European Standard EN 45011:1989 specifies general criteria that a certification body operating product certification shall follow if it is to be recognized at a national or European level as competent and reliable in the operation of a product certification system, irrespective of the sector involved. It is intended for the use of accreditation bodies concerned with recognizing the competence of certification bodies. (EN45011 is identical to ISO/IEC Guide 65:1996). EA-6/01 published by the International Accreditation Forum (IAF) provides guidelines on the application of EN 45011. The purpose of EA-6/01 is to harmonise the worldwide application of EN 45011 / ISO/IEC Guide 65 by accreditation bodies as an important step towards mutual recognition between certification bodies under the IAF Multilateral Agreement (MLA).

EN 45011 recognizes that these general criteria may have to be supplemented when applied to a particular sector; prEN 15267-1 provides guidance on the application of EN 45011 to the certification of automated measuring systems (AMS) for monitoring ambient air quality and emissions from stationary sources. It is Part 1 of a four part series of CEN Standards which specify common requirements for the certification of AMS in CEN Member States.

The draft standard prEN 15267-1 defines common procedures and requirements for the certification of AMS that should facilitate mutual recognition by these relevant bodies and thereby minimise administrative and cost burdens on AMS manufacturers seeking certification in multiple CEN Member States. It also describes the roles and responsibilities of manufacturers, test laboratories, certification bodies (for quality management systems) and relevant bodies under

these procedures.

A1. Scope

The scope of the proposed standard, prEN 15267-1, applies to the product certification of AMS for monitoring emissions from stationary sources and ambient air quality.

Product certification of AMS consists of the following sequential stages:

- Stage 1: Performance testing of an AMS.
- Stage 2: Initial assessment of the AMS manufacturer's quality management-system.
- Stage 3: Certification.
- Stage 4: Post-certification product-surveillance.

A2. Principles

A2.1 Stage 1: Performance testing of the AMS

Performance evaluation consists of a combination of laboratory and field testing. Laboratory testing is designed to assess whether an AMS can meet, under controlled conditions, the technical requirements of the relevant performance specification. Field testing, over a minimum three month period, is designed to assess whether an AMS can continue to work and meet the relevant performance specification in a real application. For emissions monitoring, AMS field testing is carried out on an industrial installation representative of the intended application for the AMS for which the manufacturer seeks certification. For ambient air monitoring AMS field testing is carried out at sites as specified in the Framework Directive on ambient air quality assessment and management (96/62/EC), and the associated daughter directives (99/30/EC, 2000/69/EC, and 2002/3/EC).

An AMS is tested to evaluate its performance against specified requirements in an applicable European Standard for the performance and testing of AMS. The testing is carried out by a test laboratory accredited to EN ISO/IEC 17025 and the test procedures specified in the applicable Standard.

The applicable standard for AMS for monitoring emissions from stationary sources is prEN 15267-3, and the applicable standard for AMS for monitoring ambient air prEN 15267-4. These two standards contain performance specifications and test procedures for AMS.

A2.2 Initial assessment of the AMS manufacturer's quality management system

An AMS typically undergoes design changes during its production life and it is essential to ensure that after such changes, the AMS still meets the required performance specifications. Therefore, in order to help meet this requirement the manufacturer controls the quality assurance of production and design of the AMS using a quality management system which meets the requirements of ISO 9001:2000 and the supplementary requirements specified in prEN 15267-2.

NOTE: Manufacturers need to demonstrate compliance with ISO 9001:2000 and the requirements of prEN 15267-2. One means of demonstrating this compliance is through an initial and subsequent assessments of the manufacturer's quality management system, as carried out by a certification body accredited to EN 45012.

A2.3 Certification

The reports from the testing of the AMS and evidence of compliance with ISO 9001:2000 and prEN 15267-2 of the manufacturer's quality management system are reviewed by the relevant body for conformance with the applicable standards and if satisfactory, then the relevant body will issue a certificate of conformance for the AMS.

A3.4 Post certification product surveillance

Following certification, the relevant body ensures that surveillance of the continued manufacturing and performance of certified AMS is carried out periodically

Note: The post-certification surveillance is normally carried out by the certification body, for example, which performed the initial assessment of the manufacturer's quality management system to ISO 9001:2000 and to prEN 15267-2. This applies if the manufacturer chose certification of its management system as a means of demonstrating compliance with ISO 9001:2000 and prEN 15267-2.

A4. Normative References

The proposed standard prEN 15267-1 incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter.

prEN 15267-3	200x	<i>Air Quality – Certification of Automated Measuring Systems (AMS) – Part 3: Performance standards and procedures for testing the performance of AMS of stationary source emissions</i>
prEN 152672	200x	<i>Air Quality – Certification of Automated Measuring Systems (AMS) – Part 2: Minimum requirements for product quality assurance, initial assessment and on-going surveillance.</i>
prEN 15267-4	200x	<i>Air Quality – Certification of Automated Measuring Systems (AMS) - Part 4: Performance standards and procedures for testing the performance of AMS of ambient air quality</i>
EN ISO 9001:2000	2000	<i>Quality management systems, specifications and guidance for use</i>

A5. Definitions

A5.1 Automated measuring system (AMS)

acronym for *automated measuring system*. Entirety of all measuring instruments and additional devices for obtaining a measurement result.

NOTE 1: Apart from the actual measuring device (the analyser), an AMS includes facilities for taking samples (e.g. probe, sample gas lines, flow meters and regulator, delivery pump) and for sample conditioning (e.g. dust filter, pre-separator for disturbing components, cooler, converter). This definition also includes testing and adjusting devices that are required for functional checks and, if applicable, for commissioning.

NOTE 2 Automatic Measuring System is a term sometimes used in continental Europe. The acronyms CEM and CAM, for Continuous Emission Monitoring systems and Continuous ambient-Air-quality Monitoring systems are typically used in the UK and USA.

A5.2 certification body

an accredited body qualified to EN 45012 for the certification of quality management systems and/or EN 45011 for the certification of products.

A5.3 certification range

the lower determinand values over which the instrument is to be tested, bounded by specified upper and lower limits and for which the certified range is fit for the intended application of the AMS. Testing takes place within the certification range.

NOTE 1: The lower limit is typically the detection limit of the AMS and often considered to be zero.

NOTE 2: Generally, the lower the certification range, the better the performance of the AMS. Also an AMS typically performs satisfactorily at higher values over the measurement range.

A5.4 relevant body

organisation or organisations which implement the requirements of EU Directives and regulate installations which must comply with the requirements of applicable European Standards

A5.6 customer complaint

any reported written or verbal complaint made by a customer which concerns the identity, quality, durability, safety, security, conformity or performance of any equipment or protective

A5.7 technical documentation

information for the operation of AMS, such as manuals.

A5.8 legislation

directives, Acts, ordinances and regulations

A5.9 manufacturer

an organisation, situated at a stated location or locations, that carries out or controls such stages in the manufacture, assessment, handling and storage of a product that enables it to accept responsibility for continued compliance of the product its certification and undertakes all obligations in that connection.

NOTE: The term "manufacturer" is used instead of "organisation" as used in EN ISO 9001:2000. For the purpose of prEN 15267-1 standard they are interchangeable.

A5.10 manufacturer's documents

those documents required by a manufacturer but not subject to assessment by a body when making an application for either an type-approval certificate or product/production quality assurance notification. For example: instructions, related drawings, data sheets and sales literature.

A5.11 product

the term "product" covers AMS and software and as defined in 3.4.2 of EN ISO 9000:2000.

A5.12 product surveillance

An evaluation to determine the continued conformity of the certified product with specified requirements. (ISO/IEC Guide 2)

Note: In the context of prEEN 15267-1, product means AMS

A5.13 related drawing

drawing not referenced in the testing report, but used for example, for detailed manufacture of component parts.

A5.14 relevant body

a competent authority or a certification body, nominated by a competent authority or Member State, that carries out the certification of AMS in accordance with the procedures and requirements of prEN 15267-3.

A5.15 reference drawing

drawing referenced in the testing report (e.g: in the schedule or the report)

A5.16 technical file

a record of the reference drawings and design changes to the reference drawings

A5.17 test laboratory

the laboratory which evaluates the AMS against the performance standards.

A6. Roles and responsibilities

The roles and responsibilities of the AMS manufacturer, the test laboratory, the certification body (for quality management systems), and the relevant body are described below.

Note: An organisation can perform more than one role as defined in the Scope of prEN 15267-1, if it is suitably accredited. For example, a single organisation could perform all four of the stages as defined in the scope.

A6.1 Roles and responsibilities of the manufacturer

The manufacturer shall:

- Make the initial approach to a test laboratory and/or relevant body for performance testing of an AMS.

NOTE: Whether a test laboratory or relevant body is approached first it is advisable that, with the agreement of the manufacturer, they inform the other so that the scope of the testing and the intended application (i.e. ambient air monitoring, type of industrial installation) for which certification is to be sought can be decided in consultation. When the scope and application have been agreed, testing may proceed.

- Submit two AMS for performance testing to a test laboratory and provide all necessary information for testing.

Note: The manufacturer can submit more than two AMS of the same type, to complete the testing faster by running the laboratory and field testing in parallel

- Establish, maintain and operate a certified management system, meeting the requirements of ISO 9001:2000 and prEN 15267-2 .
- Provide evidence to the relevant body of continued certification of the management system to ISO 9001:2000 and the supplementary requirements of prEN 15267-2.
- Ensure quality assurance and control of manufacturing such that all certified AMS continue to meet the applicable performance specifications.
- Control and assess design changes, and keep detailed records of changes to the AMS within a technical file for each certified AMS in accordance with the requirements of prEN 15267-2.

Note: The assessment may include complete or partial re-testing of the changed AMS. The manufacturer may seek the advice of a test laboratory and the relevant body regarding the need for complete or partial re-testing, following design changes. Any re-testing may be carried out by the manufacturer or, at the manufacturer's request, by a test laboratory.

- If an AMS requires partial or complete re-testing, then the manufacturer shall record the methods and results of re-testing in the technical file, as specified in ISO 9001:2000.

- Notify a test laboratory and/or the relevant body of changes to the AMS, if the manufacturer has defined this, or to the complete AMS.

A6.2 Roles and responsibilities of the test laboratory

The test laboratory shall:

- Establish, maintain and operate a quality system accredited to EN ISO/IEC 17025, where the scope of accreditation includes the applicable standards for monitoring and testing.
- For the testing of AMS for measuring stationary sources, each test laboratory's scope of accreditation shall include prEN 15267-3, plus applicable standards which elaborates EN ISO/IEC 17025 for application to stack emission measurements which form part of the field testing of AMS. For the testing of AMS for monitoring ambient-air quality, each test laboratory's scope of accreditation shall include prEN 15267-4.
- Evaluate AMS conformity with the performance specifications defined in applicable European Standards, by testing in accordance with the requirements specified in those standards.
- Guide the manufacturer on the suitability of the AMS for different applications (i.e. ambient air monitoring, industrial installations) and measurement ranges in accordance with the requirements defined in the applicable standard.
- If required and on behalf of the manufacturer, make applications to the relevant body for the certification of AMS.
- If requested by the manufacturer, evaluate any design changes to the AMS and notify the relevant body of such changes if they affect the original certification and advise the manufacturer and relevant body if any re-testing is required.

A6.3 Roles and responsibilities of the certification body (for quality management systems).

If the manufacturer chooses third-party certification as a means of demonstrating compliance with ISO 9001:2000 and prEN 15267-2, then the assessment must be performed by an accredited certification body. This certification body shall:

- Be accredited to EN 45012 for the certification of quality management systems.
- Carry out an initial assessment of the AMS manufacturer's quality management system for conformance with ISO 9001: 2000 and the requirements of prEN 15267-2.

Note: Where a manufacturer is already certified to ISO 9001, the initial assessment should focus only on the requirements of prEN 15267-2.

- Submit a report of the initial assessment to the manufacturer..

A6.4 Roles and responsibilities of the relevant body

The relevant body shall:

- If the relevant body is a certification body, then it shall be accredited to EN 45011 for the certification of AMS in accordance with the requirements of prEN 15267-1.
- If the relevant body is an unaccredited competent authority it shall have in place appropriate procedures for the certification of AMS in accordance with the requirements of prEN 15267-1.
- Provide guidance on the certification arrangement and requirements to the manufacturer,

test laboratory and the certification body (for quality management systems).

- Assess test reports and determining whether the test laboratory is appropriately accredited to carry out the tests and whether the data supports the application and scope of certification.
- Verify the evidence that the AMS manufacturer has a management system which is certified to ISO 9001:2000 and the requirements of prEN 15267-2.
- Liaise as appropriate with the relevant national competent authority.
- Issue certificates with an appropriate scope of certification.
- Issue certificates in at least one of the three principal CEN languages; English, French and German.

NOTE: The scope of certification includes the determinands, certification ranges, process applications and any limitations of use.

- Ensure that post-certification surveillance of the on-going manufacturing and performance of certified AMS is periodically carried out.

Note: The post certification surveillance is normally carried out by, for example, the certification body which performed the initial assessment of the manufacturer's quality management system.

A7. Certification procedure

The figure at Annex1 illustrates the main stages involved in obtaining certification of an AMS

A7.1 Performance testing of the AMS,

At the time of application for testing, the manufacturer shall agree with the test laboratory and the relevant body the ranges and applications of the AMS, according to the requirements of European Standards, legislation and the national competent authority, for which certification will be sought.

Note: The manufacturer may approach the test laboratory first and request the laboratory to act on its behalf with the relevant body or vice versa. Whichever route is chosen it is important that all parties are kept fully informed.

The testing shall be carried out according to the requirements of the applicable European Standard. If an AMS fails any of the tests, then the testing shall be halted. If the manufacturer addresses the reasons for any failures and resubmits the AMS, the testing shall be started again from a point in the programme agreed to be appropriate by the test laboratory and the relevant body in consultation with the manufacturer. Details of this re-start shall be recorded in the test report.

Upon completion of the test programme, the test laboratory shall write a report of the testing and issue this to the manufacturer and the relevant body. If the AMS meets the requirements of the applicable European Standard, then the test report shall include a recommendation for certification, stating the applicable ranges, the suitability of the AMS for specified fields of application, and any qualifying remarks.

A7.2 Initial assessment of the manufacturer's quality management system

If the manufacturer chooses third-party certification as a means of demonstrating compliance with ISO 9001:2000 and prEN 15267-2, then the AMS manufacturer shall request a certification body, accredited to EN 45012, to carry out the initial assessment of its quality management system. This assessment shall be made in accordance with the requirements of ISO 9001 and

prEN 15267-2.

Note 1: Where a manufacturer is already certified to ISO 9001 the initial assessment should focus only on the requirements of prEN 15267-2.

The certification body shall submit a report of its initial assessment to the manufacturer who in turn shall make it available to the relevant body as part of its final application for certification.

A7.3 Certification

The relevant body shall review the application, the test report, the assessment of the manufacturer's quality management system and any other supporting documents.

The information to be supplied by the manufacturer when submitting an application shall include:

- the intended certification range and any supplementary ranges,
- determinands and industrial process applications or ambient air monitoring for which certification is being sought ;
- a description of the AMS,
- the results of the performance testing, as required by prEN 15267-3 or prEN 15267-4,
- evidence of compliance of the quality management system, to ISO 9001:2000 and the supplementary requirements of prEN 15267-2.
- the manufacturer's documents and related drawings.

If there is sufficient evidence to certify the AMS, then the relevant body shall issue a certificate of conformance to the manufacturer and add the AMS to its official register of certified AMS.

The certificate shall clearly state:

- A unique identifier for the type of AMS.
- The measurement ranges, minimum certification ranges (and additional certification ranges if applicable) for each certified determinand, against specified performance standards in applicable European Standards.
- The applicable industrial process or ambient air monitoring applications.
- Whether the AMS is suitable for installations under EU Directives for large combustion plant and/or waste incineration
- A specific reference to the performance test-report from the test laboratory.

A7.4 Mutual recognition of certification

If manufacturers, test-laboratories, relevant bodies and certification bodies meet the requirements of the EN 15267 series of standards, then such compliance provides the means for mutual recognition in different countries.

Note: Relevant Bodies in CEN member states are recommended to establish a central register listing certified AMS. The register should provide traceable links to the original certificates and supporting information.

A7.5 Post-certification surveillance of the quality management system

Following certification the relevant body shall ensure that surveillance of the on-going manufacturing and performance of the certified AMS is periodically carried out to determine continued conformance with the applicable European Standard. This surveillance shall involve audits of the quality control of design changes and manufacture of the AMS.

Post-certification surveillance shall be carried out at least every year.

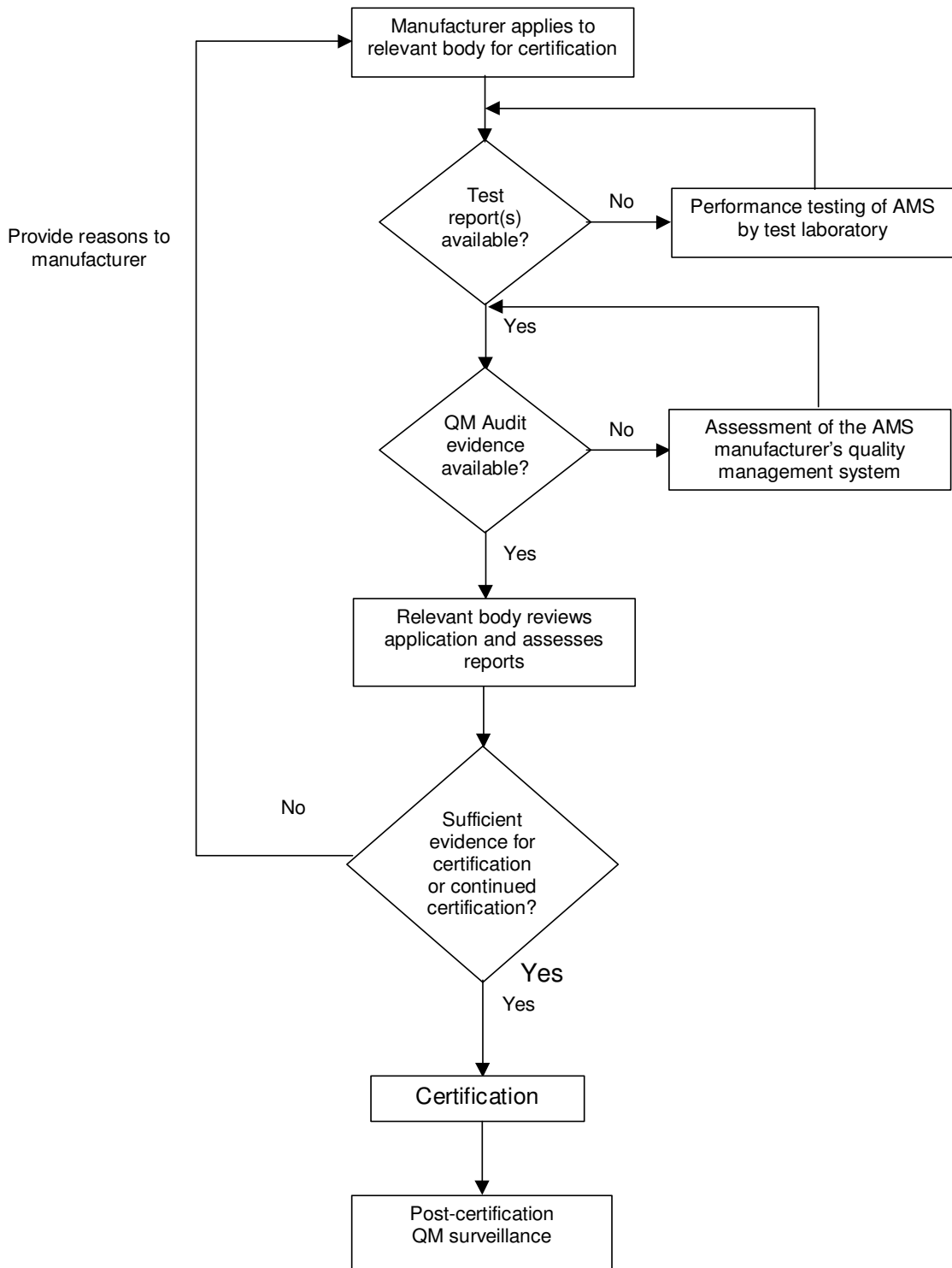
Note 1: The post certification surveillance is normally carried out, for example, by the certification body which made the initial assessment of the manufacturer's quality management system.

Note 2: Where the relevant body is a certification body accredited to EN 45012 for quality management systems and to EN 45011 for product certification of AMS it may carry out the initial assessment, post-certification surveillance and the product certification activities described above.

A7.6 Review of certifications

The relevant body shall keep the validity of the certification of the AMS under continuous review taking into account the reports from technical changes to the AMS, post-certification surveillance, any changes in the technical requirements notified by competent authorities, and complaints from users.

Annex A-A: (Informative) - Application and Assessment Processes



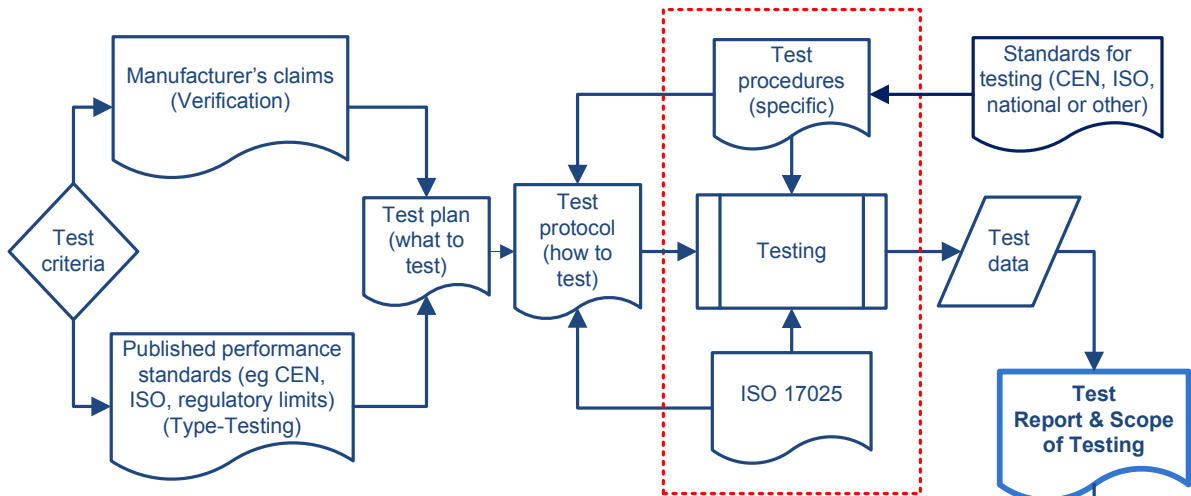
A-Bibliography

1. EN 45011:1998 General requirements for bodies operating product certification systems.
2. ISO/IEC Guide 65: 1996 General requirements for bodies operating product certification systems
3. EA-6/01: 1999 EA Guidelines on the application of EN 45011
4. ISO/IEC CD2 Guide 67: 2000 Fundamentals of product certification
5. EN ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories
6. EN ISO 9000: 2005 Quality management systems. Fundamentals and vocabulary
7. EN 45012: 1998 General criteria for certification bodies operating Quality System certification

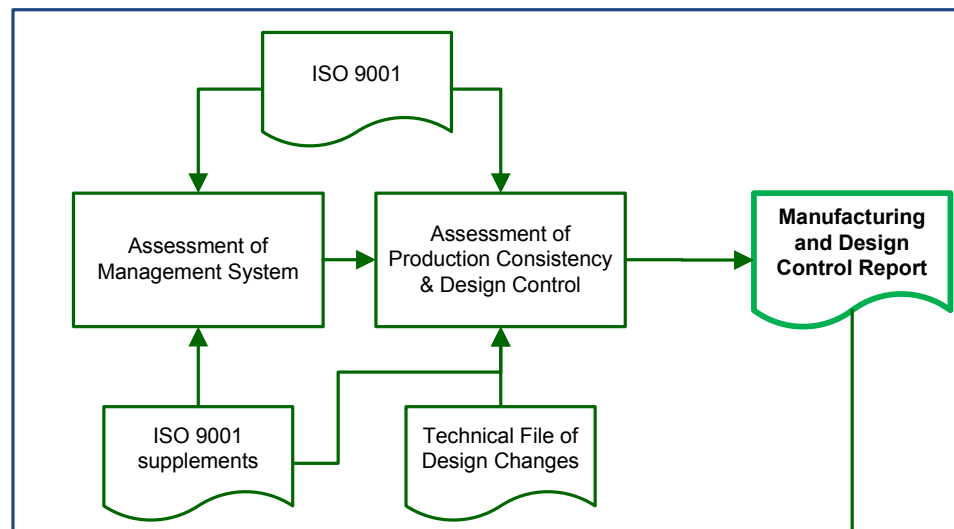
Annex 2
Possible model-framework for a flexible verification and type-approval scheme
(diagram overleaf)

Verification Programme Flowchart

Stage 1 – Testing
(Verification or Type-Testing)



Stage 2 – Assessment of Design and Manufacturing Control



Review and Issue of a Certificate

