Performance Standards for Indicative Ambient Particulate Monitors

Environment Agency

August 2017

Version 4

mCERTS
THE ENVIRONMENT AGENCY'S MONITORING CERTIFICATION SCHEME

Foreword

We set up our Monitoring Certification Scheme (MCERTS) to provide a framework of standards you can use to monitor things that affect the environment. MCERTS covers:

- the standards of performance that your monitoring equipment must meet
- the level your staff must be qualified to
- accrediting laboratories and inspecting sites in line with European and International standards

This document sets out the performance standard for indicative ambient dust monitors. The standard is based on International and European standards.

Indicative dust monitors are used to make measurements of ambient dust on a qualitative or quantitative basis, as explained in section 5.9. They have a role in environmental regulation for the analysis of particulate pollution trends, source identification studies based on pollution roses, and other measurements where an indicative result is acceptable.

MCERTS is a formal product certification scheme. Sira Certification Service runs the scheme on our behalf. Sira is accredited by the United Kingdom Accreditation Service (UKAS) to ISO/IEC 17065 *'Conformity assessment - Requirements for bodies certifying products, processes and services.* Appendix 1 provides more information on MCERTS product certification.

Your equipment must be tested by laboratories and test organisations that are accredited to EN ISO/IEC 17025, which is the internationally recognised standard for testing laboratories. Sira assesses the results of the laboratory and field tests, using a group of independent experts known as the Certification Committee.

The benefits of this standard

- The standard gives you certification of your equipment that is formally recognised in the UK and is accepted internationally.
- Regulators can be confident that monitoring equipment which meets the standard provides reliable monitoring data.
- You can be confident that the equipment you use to monitor air pollution has been thoroughly tested and meets standards that are accepted by UK regulators.
- The standard gives manufacturers an independent approval of the equipment they produce, which will improve their access to international markets and increase their sales in the UK.
- The standard helps make sure the public are given accurate and reliable information about air quality.

If you have any questions about the certification process, or would like more information about how to apply, please contact:

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Record of amendments

Version number	Date	Amendment
Version 2	July 2012	Update to Reference 6: Guidance for the Demonstration of Equivalence of Ambient Air Monitoring Methods, EC Working Group 15, January 2010.
Version 2	July 2012	Update to Section 5.8 Evaluation of data from indicative particulate monitor tests
Version 2	July 2012	Removed outdated Appendix 2: CEN activities supporting this standard
Version 3	August 2015	Updated requirements for the determination of data subsets. The “greater than” subset should contain at least eight valid data pairs. The “less than” subset is not subject to evaluation. Allowing for use of a single gravimetric reference instrument which may be an automated system of well documented intra-instrument uncertainty also originating from previous studies. Allowing for the use of default uncertainty value for the reference method. Change of pass-fail uncertainty value for the reference instruments.
Version 4	August 2017	Minor update to provide for changes in standards and associated legislation for products.

Status of this document

This standard may be subject to review and amendment following publication. The most recent version is available on our website at:

www.mcerts.net

Feedback

If you have any comments on this standard please contact our National Customer Contact Centre at:

Email: enquiries@environment-agency.gov.uk

For more information on MCERTS and for copies of the performance standards and further guidance, see our website at:

www.mcerts.net

MCERTS for indicative ambient particulate monitors

1 Introduction

1.1 This document describes the MCERTS performance standards for indicative measurements of dust in ambient air.

1.2 For the purpose of this document, instruments for ambient dust monitoring are instrumental systems that continuously monitor ambient pollutant concentrations in situ and automatically produce results. Their operation can be based on non-gravimetric analysis, for example, light scattering and/or other optical or non-optical principles, or a gravimetric technique.

1.3 Indicative dust monitors are used to make measurements of ambient dust on a qualitative or quantitative basis – see section 5.9. They have a role in environmental regulation for the analysis of particulate pollution trends, source identification studies based on pollution roses and other measurements where an indicative result is acceptable. They cannot be used as a substitute for continuous ambient air quality monitoring systems (CAMs) employed in national air quality monitoring networks for the EU Air Quality Directive(1). For such applications CAMs should be certified to the MCERTS performance standard for continuous ambient air monitoring systems – see www.mcerts.net.

1.4 The main instrument performance characteristics against which an indicative dust monitoring system will be assessed are determined by field and laboratory testing including:

- field performance against a reference method
- measurement uncertainty
- constancy of sample volumetric flow
- tightness of the sampling system
- maintenance interval

1.5 The definitions of the performance characteristics (and other terms used in this document) are given in Section 4.

1.6 The general requirements and the performance standards to be met by the indicative dust monitoring instruments are presented in this document in Section 5. More information on MCERTS product certification is given in Appendix 1.

1.7 Throughout this document the terms “MCERTS certificate” and “certificate” refer to the MCERTS product-conformity certificate.

2 Air quality limit values and operational conditions

2.1 Air quality limit values

2.1.1 The performance standards specified in this document are generally expressed as measurement results from which the values of standard uncertainties can be derived. Table 2.1 gives the standards from the Air Quality Strategy for England, Scotland, Wales and Northern Ireland [3] and the European Union air-quality limit values [4] in absolute concentration units.

Table 2.1 National air quality objectives for particulates and European Directive limit and target values for the protection of human health

Pollutant	Applies	Objective	Concentration measured as	Date to be achieved and maintained thereafter	European obligations	Date to be achieved and maintained thereafter	New or existing
Particles PM_{10}	UK	50 µg/m^3 not to be exceeded more than 35 times per year	24 hour mean	31 December 2004	50 µg/m^3 not to be exceeded more than 35 times per year	1 January 2005	Retain existing
	UK	40 µg/m^3	annual mean	31 December 2004	40 µg/m^3	1 January 2005	
	Indicative 2010 objectives for PM_{10} (from the 2000 Strategy and 2003 Addendum) have been replaced by an exposure reduction for $PM_{2.5}$ (except in Scotland)						
	Scotland	50 µg/m^3 not to be exceeded more than 7 times per year	24 hour mean	31 December 2010			Retain existing
	Scotland	18 µg/m^3	annual mean	31 December 2010			
Particles $PM_{2.5}$ Exposure reduction	UK except Scotland	25 µg/m^3	annual mean	2020	Target value 25 µg/m^3	2010	New (European obligations still under negotiations)
	Scotland	12 µg/m^3		2020	Limit value 25 µg/m^3	2015	
	UK urban areas	Target of 15% reduction in concentrations at urban background		Between 2010 and 2020	Target of 20% reduction in concentrations at urban background	Between 2010 and 2020	

The EU limit values are, in general, very similar to the concentrations given in the UK's Air Quality Strategy. The limit values that have been used to derive the performance characteristics specified in this document are given in Table 2.2.

Table 2.2 Limit value used for MCERTS performance standards for particulates

Pollutant	Limit value
Particulate matter (PM_{10})	50.0 μg/m^3
Particulate matter ($PM_{2.5}$)	25.0 μg/m^3

2.2 Operational conditions

2.2.1 Indicative monitors should be assessed under conditions which are representative of the most challenging intended application for which certification is sought. In rural and remote sites, low concentration levels may be encountered, and monitors should have appropriate detection limits and minimal zero and span drift characteristics. In urban locations, including kerbside sites, monitors are expected to monitor rapidly varying concentrations, over a wide dynamic range.

2.2.2 Typical levels of particulate PM_{10} concentrations measured in the UK are given in Table 2.3.

Table 2.3: Typical concentrations of particulates at different locations

Pollutant	Rural		Kerbside	
	Short term	Long term	Short term	Long term
Particulates (PM_{10})	30 μg/m^3 hourly average	20 μg/m^3 annual average	45 μg/m^3 annual average	35 μg/m^3 annual average

3 References

1 Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on Ambient Air Quality and Cleaner Air for Europe.

2 European Air Quality Framework and First Daughter Directives, Framework Directive, 96/62 EC, Daughter Directive for SO_2, NO_2, PM_{10} and Lead, 1999/30/EC, 22 April 1999.

3 The Air Quality Strategy for England, Scotland, Wales and Northern Ireland, (Volume 1) DEFRA, July 2007.

4 Statutory Instruments 2010, No.1001 Environmental Protection, The Air Quality Standards Regulations 2010.

5 Guide to the Expression of Uncertainty in Measurement, ISBN 92-67-10188-9, 1st edition, Geneva, Switzerland, ISO, 1993.

6 Guidance for the Demonstration of Equivalence of Ambient Air Monitoring Methods, EC Working Group 15, January 2010.

7 Ambient Air-Standard gravimetric measurement method for the determination of the PM_{10} or $PM_{2.5}$ mass concentrations of suspended particulate matter, EN12341.

8 EN 16450. Ambient Air. Automated measuring systems for the measurement of the concentration of particulate matter (PM10; PM2.5)

4 Definitions of performance characteristics and other terms

Availability: Fraction of the total monitoring time for which data of acceptable quality have been collected (excluding servicing and calibrations).

Averaging time: Period of time over which an arithmetic or time weighted average of concentrations is calculated [T_a – is the averaging period used by the CAM; T_{ra} is the required data averaging period, e.g. prescribed by legislation].

Measurement uncertainty: Uncertainty calculated by comparing the measurement results with a standard reference method assuming linear relationship between both measurements and applying orthogonal regression calculations.

Detection limit: The concentration value of determinand substance above which there is at least a 95 % degree of confidence that the measured value is different from zero.

Maintenance interval: Time in the operating environment in the field over which the CAM's does not require maintenance operations.

Constancy of sample volumetric flow: Sample volumetric flow averaged over the ampling time at different filter dust loading.

Tightness of the sampling system: Leak rate of the sampling system measured either by volume flow differential or by the pressure drop method.

5 General instrument requirements

5.1 General requirements for indicative particulate monitors

5.1.1 Manufacturers are required to submit the following:

- two identical, complete particulate monitoring systems
- all necessary components for operation under field conditions
- all sampling components (including the sampling head, if provided)

5.1.2 The particulate concentrations measured are generally expressed in density units (mass of determinand per unit volume of the ambient atmosphere). Results reported in units of mass per unit volume shall be expressed at measured temperature and pressure.

5.1.3 Instruments that have output readings sensitive to ambient air temperature and/or pressure shall be able to make corrections for changes in these parameters. These corrections may be carried out by using in-built pressure and temperature sensors or by using external sensors. The manufacturer shall provide the test house with information as to whether any in-built temperature and pressure corrections are being applied. Where no internal corrections are applied, the manufacturer or supplier shall provide the test house with any algorithms that are required for the conversion of the instrument readings to different ambient temperatures and pressures.

5.1.4 Instruments submitted for testing shall meet the requirements of all applicable EC Directives. These include: the Electro-magnetic Compatibility Directive 2014/30/EU (formerly 2004/108/EC); the Low Voltage Directive 2014/35/EU (formerly 2006/95/EC), covering electrical equipment designed for use within certain voltage

limits, and; the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (2011/65/EU). Instrument manufacturers or suppliers shall supply declarations of conformity to all relevant Directives applicable to the equipment.

5.2 Response times

5.2.1 For the response times RT_{rise} and RT_{fall} as defined in Section 4 (not determined as part of the performance tests) relevant estimates can be provided by the manufacturer.

5.3 Averaging times

5.3.1 Most of the performance requirements given in this document apply to results produced by particulate analysers that are averaged values of the pollutant concentration over a period defined as the averaging time T_a. In cases where the monitor internally produces averaged results and where the averaging time T_a is selectable, then it shall be selected by the manufacturer or supplier, in consultation with the MCERTS Certification Committee and the test house(s). In most cases the averaging times specified for air quality monitoring given in Table 5.1 should be used. The averaging times actually used will be stated on the MCERTS certificate. Shorter averaging times may be required when the particulate monitors are used to assess individual source impact on ambient air quality in conjunction with the meteorological information. Table 5.1 lists examples of the averaging times used in the UK for collecting ambient air quality information.

Table 5.1: Examples of averaging times used for sampling

Pollutant	**Typical averaging time (T_a[a])**
Particulates (PM_{10})	24 hours(legislative)
Particulates ($PM_{2.5}$)	24 hours(legislative)
Particulates (PM_{10})	1 hour (in source impact studies)
Particulates ($PM_{2.5}$)	1 hour (in source impact studies)

[a] defined in Section 4.

5.4 Certification range

5.4.1 The instrument manufacturer or supplier shall specify and agree with the MCERTS Certification Committee a certification range of concentrations over which the instrument is to be tested.

5.4.2 Each certification range shall be generally between zero and a maximum value of the particulate concentration. These values shall be agreed by the MCERTS Certification Committee as being fit for the intended purpose.

5.4.3 Typical values of the certification range for indicative monitors are given in Table 5.2. These ranges are recommended unless the monitor manufacturer or supplier and the Certification Committee agree that there is a strong justification for selecting different ranges. If a manufacturer or supplier wishes to demonstrate performance over different ranges, additional testing will be required for each range.

Table 5.2: Typical certification ranges for indicative monitors

	Rural and remote sites (Category 1)		**Urban background/centre, suburban, kerbside, roadside and industrial sites (Category 2)**	
	Scale min.	**Scale max.**	**Scale min.**	**Scale max.**
PM_{10}	0.0 $\mu g/m^3$	75 $\mu g/m^3$	0.0 $\mu g/m^3$	150 $\mu g/m^3$
$PM_{2.5}$	0.0 $\mu g/m^3$	50 $\mu g/m^3$	0.0 $\mu g/m^3$	75 $\mu g/m^3$

5.4.4 Where the instrument has user-selectable settings, range for example, these would be chosen by the instrument manufacturer or supplier and agreed with the Certification Committee in conjunction with the test house(s), to be appropriate for the certification range. In practice, the range selected is likely to be similar to the certification range, although this is not essential. However, the instrument will be tested only over the certification range. The settings, once chosen, will not be altered during the tests. The settings used will be stated on the certificate.

5.4.5 The certificate will list all the ranges certified and the instrument settings used, and will state explicitly the performance characteristics tested and the application category or which each range is certified, together with any relevant limit value (where applicable).

5.5 Performance standards for indicative monitors measuring particulate matter (PM10 and PM2.5)

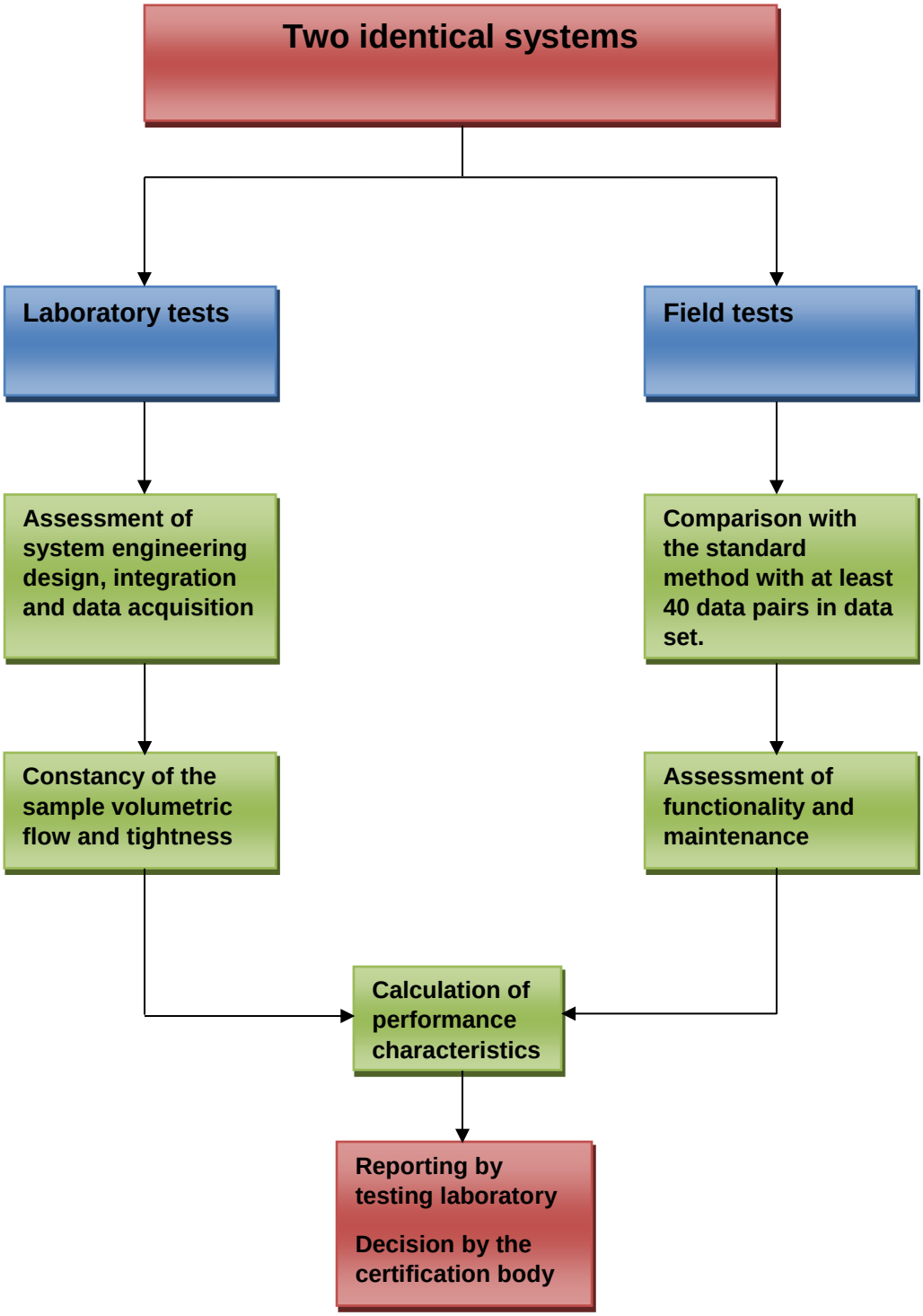
5.5.1 Indicative monitors measure particulate material over a defined averaging time (T_a) and:

- apply a non-gravimetric measurement principle such as for example light scattering or laser nephelometry
- use a gravimetric technique
- measure different particulate fractions, either using sampling heads or simulating the required cut-off characteristics through a software algorithm

5.5.2 The sampling system is an inherent component of gravimetric particulate monitors, as they require size-selective sampling heads to collect particulate material preferentially according to its aerodynamic size. Two categories of particulate material are currently monitored, PM_{10} and $PM_{2.5}$. These refer to the aerodynamic size of ambient particulates collected with sampling heads for which a 50% cut-off is achieved. In instruments not equipped with sampling heads the cut off characteristic may be simulated by the relevant software.

5.5.3 The test procedure for indicative monitors is shown in Figure 1.

Figure 1 - MCERTS certification of indicative particulate monitors



5.5.4 The laboratory tests depend on the measurement technique employed by the indicative monitor. The requirements are specified in section 5.6.

5.6 Laboratory tests for indicative particulate monitors

5.6.1 Laboratory testing of instruments measuring concentrations of particulate matter in ambient air is limited to parameters related to stability of flow through the filter or the measurement cell and the provision of a representative sample. The following parameters shall be tested:

- constancy of sample volumetric flow
- tightness of the sampling system

The performance criteria related to the above parameters are given in Table 5.3

Table 5.3 Performance requirements for indicative particulate CAMS (laboratory tests)

Parameter	Performance requirement
Constancy of sample volumetric flow	Sample volumetric flow averaged over the sampling time to remain constant within ± 3% of the rated value. All instantaneous values to remain within ± 5% of the rated value.
Tightness of the sampling system	Leakage not to exceed 2 % of the sampled volume.

5.6.2 Flow rate measurement accuracy

The reference flow meter shall have a relative expanded uncertainty (95% confidence) not exceeding 1% of the controlled flow rate.

5.6.3 Constancy of sample volumetric flow

If the instruments are equipped with an air filter system for calibration the testing shall be carried out providing loaded filters, volumetric flow measuring device and a pressure measuring device. Three pre-loaded filters with the particulate load of approximately 0%, 50%, and 80% of the maximum permissible filter loading shall be used. For each filter the constancy of the sample volumetric flow shall be recorded every 30 minutes as a 3 minute average over the time period of at least 24 hours. For instruments that do not use filters, then the flow shall be recorded under normal operating conditions.

5.6.4 Tightness of the sampling system

The testing is normally carried out with the help of a pressure measuring device and a volumetric flow measuring system. The leak rate of the entire instrument shall be determined if it is feasible. This includes the inlet as well as the whole sampling system and the measuring system. If because of the instrument design the complete system tightness cannot be measured the leak rate can be determined separately for the sampling part and the measuring part. The leak rate can be measured by the determination of volume flow at the inlet and outlet of the system or by the pressure drop method. In the latter case the system is sealed at the inlet and evacuated by a built in or separate pump and the pressure increase due to leaks is measured over the period of 5 minutes. The leak rate V_L determination shall be repeated three times. It is calculated from the following formula:

$$V = \frac{\Delta P.V_g}{P_0.\Delta t}$$

where: ΔP – pressure drop determined over the time interval Δt

P_0- pressure at time t_0

V_g- estimated total volume of the system

Δt- time interval of the pressure increment

5.7 Field testing of indicative particulate monitors

5.7.1 General principles

Field tests are performed using two instruments operated side by side with at least one standard reference method unit or an instrumental method equivalent to a standard reference method. The purpose of the measurements is to assess the uncertainty of the instruments working in parallel with the standard reference method or the instrumental method equivalent to a standard reference method.

Results of existing studies can be used provided that the requirements of the relevant sampling standards have been met.

Performance criteria for field test results are given in Table 5.4. The tests, calculations of the performance characteristics and calibration procedures shall be conducted in accordance with the Guidance for the Demonstration of Equivalence of Ambient Air Monitoring Methods [6].

5.7.2 Experimental conditions

The test sites selected for the field tests should be representative of the conditions under which the instruments are likely to operate. Occurrences of possible episodes of high concentrations are desirable. One comparison run consisting of 40 paired results should be carried out with the emphasis on the following variables:

- composition of the PM fraction, preferably including high and low fractions
- high and low air temperature and humidity
- large variations of wind speed to cover the impact on sampling inlet performance

During the tests the following information should be collected and recorded:

- setting-up procedures, equipment and intervals
- results of the quality assurance checks
- temperature and pressure of the sampled air
- humidity and other relevant conditions
- events likely to affect the measurement results

A minimum of 40 measurement results, each averaged over a period of 24 hours constitutes a comparison run. The site selected for testing should have a dust composition representative of the intended application and the range of

concentrations should be appropriate for the certification range. The Certification Committee will confirm the suitability of the selected site.

Table 5.4 Performance standards for indicative CAMs measuring PM_{10} and $PM_{2.5}$ field tests)

Performance characteristic	Performance standard
Intra-instrument uncertainty for the reference method	$\leq$ 2.5 $\mu g/m^3$. If only a single reference method instrument is available, then values from previous tests performed by the same laboratory/network using identical pattern of samplers can be used. If those are not available a default value of 0.67 $\mu g/m^3$ can be assumed.
Intra-instrument uncertainty for the candidate method	$\leq$5 $\mu g/m^3$ for all data as well as for the subsets: less than and greater than or equal to 30 $\mu g/m^3$ or 18 $\mu g/m^3$ for PM_{10} or $PM_{2.5}$, respectively. The "greater than" data subset shall contain at least 8 data pairs. If 80 data pairs are produced still without generating the required 8 data pairs in the "greater than" subset then this is considered sufficient and the testing may be terminated.
Highest resulting uncertainty estimate comparison against data quality objective (measurement uncertainty).	$W_{CM} \leq W_{dqo}$ Measurement uncertainty defined as W_{dqo}= 50% for indicative instruments. The resultant expanded uncertainty is assessed for the full dataset, and the dataset split to be greater than 30 $\mu g/m^3$ or 18 $\mu g/m^3$ for PM_{10} or $PM_{2.5}$ respectively. The less than or equal to subset of the data need not be evaluated.
Maintenance interval	Greater or equal to two weeks. This performance characteristic shall be stated by the manufacturer and verified during the field tests.

Note: Calculation algorithm of W_{CM} criterion is defined in Guidance for the Demonstration of Equivalence of Ambient Air Monitoring Methods [6].

5.7.3 Calculation of performance characteristics

The intra instrument uncertainty should be determined:

- For the complete candidate method data set.
- For the "greater than" candidate method data set obtained by splitting the whole data set according to PM concentrations; as defined in Table 5.4. Note that, due to the low number of data pairs of significant concentration expected, then this criterion may not be fulfilled. Failure to attain this criterion shall not be considered sufficient for the instrument to fail type approval, though the reason should be clearly stated on the certificate.
- For the "less than or equal" candidate method subset split according to PM concentrations as defined in Table 5.4.
- For the standard reference method or the instrumental method previously shown to be equivalent to the standard reference method instrument. If only one

reference or equivalent instrument was deployed then it is not possible to calculate this intra instrument uncertainty.

5.7.4 Comparison with the standard reference method

For the evaluation of uncertainty due to the lack of comparability between the instrument under test and the standard reference method it is assumed that the relationship between both measurements can be described by a linear function described in Guidance for the Demonstration of Equivalence of Ambient Air Monitoring Methods[6].

The equation coefficients are calculated using a regression technique involving symmetrical treatment of both variables. A commonly applied computational technique is that of orthogonal regression. The regression equation is calculated for:

- each of the instruments individually
- data sets for each individual site if data from different sites are used

5.8 Evaluation of data from indicative particulate monitor tests

5.8.1 Data evaluation procedures

Evaluation of the collected data involves the following stages:

- Evaluation of suitability of data sets
- Calculation/evaluation of performance characteristics including between sampler/instrument uncertainty and comparison with the standard method
- Calculation of the expanded uncertainty of the sampler/instrument under test
- Application of the calibration functions (if required)
- Application of the pass-fail criteria based on the comparison of the highest expanded uncertainty of the test results with the data quality objective

The highest resulting uncertainty estimate W_{CM} is compared with the expanded relative uncertainty based on the data quality objectives W_{dqo}. The criteria for acceptance or rejection are as follows:

$W_{CM} \leq W_{dqo}$ the instrument is accepted as indicative

$W_{CM} > W_{dqo}$ the instrument is not accepted as indicative

Data may be removed from the data set when there are sound technical reasons for doing so. This data ratification process applies in particular to spikes that can be considered unrealistic for a particular data set. The data ratification process cannot deplete the data set below the data capture level of 90%. The calculation procedures and formulae for evaluation of the data sets are given in the Guidance [6, 8]. The flow chart illustrating the data evaluation process is given in Figure 2.

5.8.2 Summary of the requirements for the indicative instruments

To achieve compliance with the requirements for the indicative instruments the following conditions have to be fulfilled:

a) The reference method used throughout the testing programme must be either a manual method as specified in EN 12341[7] or an automated instrumental method demonstrated to be equivalent to the manual reference method [6, 8]. If an

automated instrumental method is employed the certification committee shall be presented with the results of the expanded uncertainty calculations obtained during the field testing programme and an estimate of its inherent measurement uncertainty relative to the standard reference method obtained during the equivalence testing. The uncertainties calculated from the testing programme and the instrumental method inherent uncertainty shall be combined. The certification committee shall be presented with the details and results of the statistical approach employed.

b) Of the full dataset at least 8 points of the results obtained by employing the standard method must be greater than 30 µg/m^3 for PM_{10} and 18 µg/m^3 for $PM_{2.5}$). If 80 data pairs are produced still without generating the required 8 data pairs in the "greater than" subset then this is considered sufficient and the testing may be terminated.

c) The expanded uncertainty is to be calculated at 50 µg/m^3 for PM_{10} and 30 µg/m^3 for $PM_{2.5}$ for each candidate instrument against the average of the reference method.

d) The resultant expanded uncertainty (inclusive of the instrumental method inherent uncertainty, if such is used as a reference) must be less than 50% for the full dataset, and the greater than subset defined above. Note that, due to the low number of data pairs of the greater than subset expected, then this criterion may not be fulfilled. Failure to attain this criterion shall not be considered sufficient for the instrument to fail type approval, though the reason should be clearly stated on the certificate. The less than subset of the data need not be evaluated.

e) The final results can be corrected for slope and/or intercept to meet the acceptance criteria.

5.9 Operational conditions for the validity of MCERTS results

When certified the indicative dust monitoring analysers can be operated in one of two ways:

<u>For qualitative measurements</u>

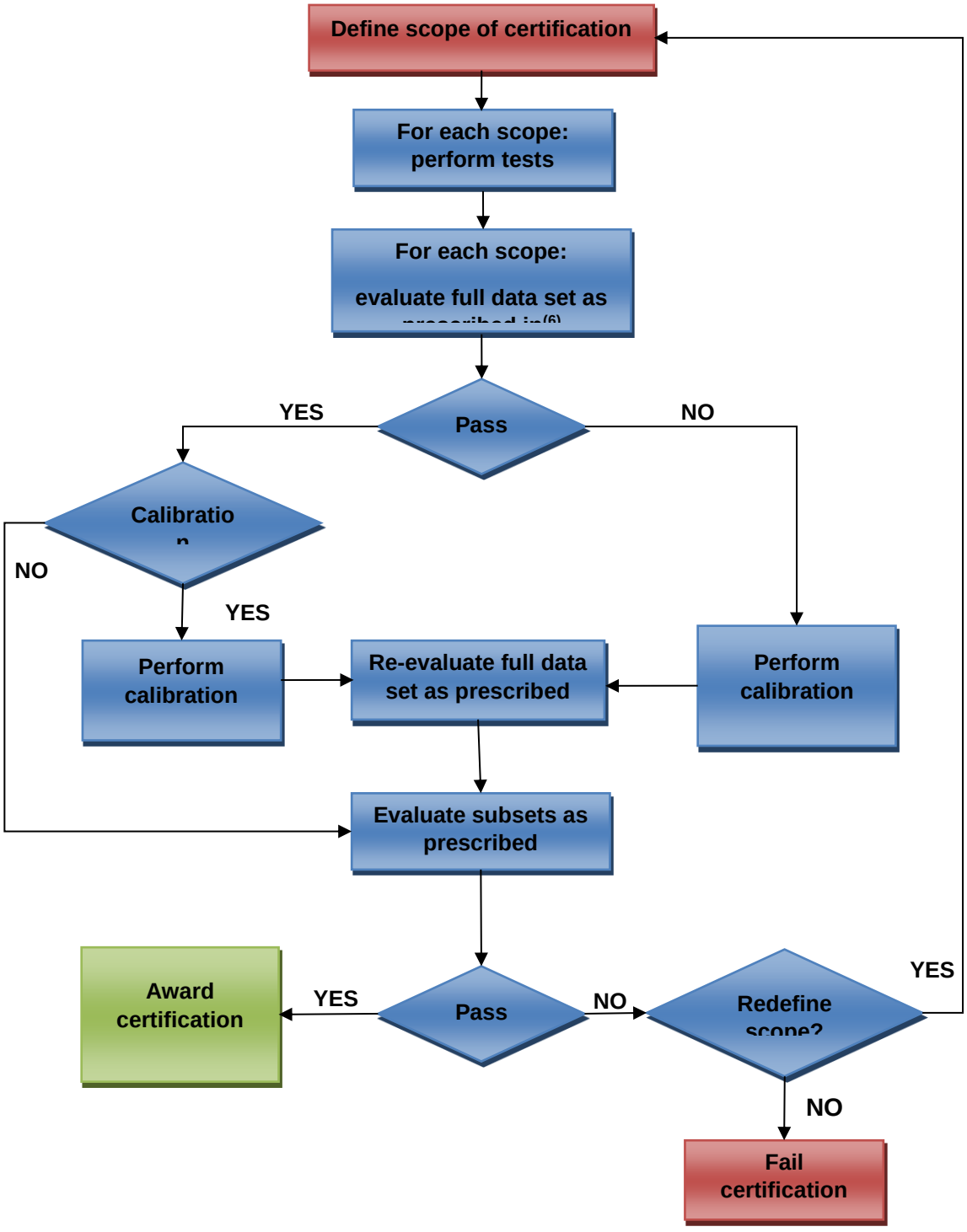
Providing qualitative measurement data for the analysis of particulate pollution trends, and source identification studies based for example on pollution roses etc. Such application can rely on instrument factory calibration only.

<u>For quantitative measurements</u>

Providing measurement data with the uncertainty defined for indicative instruments (+/- 50%). This can be achieved on condition that each instrument used for measurement has been calibrated on the specific site where monitoring is taking place against a standard reference method for a period of two weeks and the resulting slope and intercept have been used for instrument calibration. Using non-standard filters and procedures for this purpose is not acceptable.

To maintain the validity of data this calibration has to be repeated at least every twelve months or when the instrument is moved to a different site. Consistent results of the calibration may lead to less frequent repetition of the calibration process, in agreement with the Certification Committee.

Figure 2 - Evaluation of data during MCERTS certification of indicative particulate monitors



Appendix 1 – MCERTS product certification

A1.1 Certification process

MCERTS product certification comprises two phases. These are:

1) Laboratory and field testing: used to determine performance characteristics, where such testing requires a highly controlled environment;

2) Surveillance: initial and continuing – which comprises an audit of the manufacturing process to confirm that the manufacturer has provisions to ensure reproducibility and to control any design changes in such a way that they do not degrade performance below the MCERTS standards.

Manufacturers seeking certification should contact the Certification Body who will advise on any specific requirements for the automatic monitor under consideration.

Only a complete monitor shall be certified. A monitor can be supplied with a number of options, for example mains or battery powered, or different enclosure options may be available. Two complete monitors shall undergo the full conformity tests.

In selecting the options to be tested, consideration should be given to the options likely to be used in the identified applications. For additional monitor configurations, it may be possible to extend certification by carrying out a subset of the full test programme.

A1.2 Certification Committee

The role of the Certification Body is to assess and certify compliance with the MCERTS standard for defined applications and conditions.

In performing this role the MCERTS scheme requires the Certification Body to consider the relevance of the procedures defined in the MCERTS standard to the specific product to be certified. The technology or defined application of a specific product may make certain of the documented tests inappropriate. The Certification Body is required by the MCERTS scheme to exercise its technical judgement when considering these matters.

Any certification decision based on technical judgement of the standard shall be taken by an appropriately independent, competent person or group of persons, who in this MCERTS standard are referred to as the “Certification Committee”.

When the Certification Body exercises its technical judgement the rationale supporting any such decision shall be appropriately documented.

Any certificate issued by the Certification Body shall identify any variations from the normative MCERTS standard.

On request the Certification Body shall provide the MCERTS scheme owner with the rationale for any decision based on technical judgement, within the relevant confidentiality constraints.

A1.3 Certification range

An automatic monitor will be certified over the range for which it is tested.

A1.4 Testing

Manufacturers may commission testing from any organisation, provided that the requirements for testing organisations can be met. Manufacturers' own test data may also be acceptable.

A1.5 Auditing and surveillance

An audit of the manufacturing process shall be conducted by the Certification Body to confirm that the manufacturer has provisions to ensure manufacturing reproducibility and to control any design changes that may affect product performance.

Subsequent surveillance audits are normally conducted annually until sufficient evidence of a well-proven, robust system has been collected. Once this has been established the Certification Body may extend the interval between audits or require submission of specific audit data for review off site.

A1.6 Modifications to certified automatic monitors

Modifications to certified monitors are allowable so long as manufacturers can demonstrate that these design changes do not degrade the performance of the monitor below the MCERTS performance standards.

Manufacturers must keep detailed records and drawings of all design changes to monitors, and have provisions for design verification, inspection and testing to ensure that the monitors still meet the required performance standards.

The Certification Body will conduct audits of the design changes to monitors to meet the requirements of product certification. Manufacturers must notify the Certification Body of any modifications to equipment that may have a significant effect on monitor performance.

Design modifications or extensions to the range of application of a monitor may require renewed testing. The extent of this renewed testing will depend upon the nature of the modifications to the monitor.

If there is evidence that a modification has only limited effects on the performance of the monitor, then it would not be necessary to retest a monitor completely. In such cases, only a supplementary test would be required to the applicable MCERTS performance standards. In the case of modifications to software, detailed documentation (for example, source code) must be presented to the Certification Body indicating the nature of the modification as well as resultant effects on operation and functionality. The Certification Body will then decide if further testing is required.