Annex to the MCERTS Performance Standards for Ambient Air Quality Monitoring Systems:

Requirements of the UK Competent Authority for the Equivalence Testing and Certification of Automated Continuous and Manual Discontinuous Methods that Monitor Particulate Matter in Ambient Air

Department for Environment, Food and Rural Affairs
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Foreword

The Department of Environment Food and Rural Affairs (Defra), in conjunction with the Environment Agency of England and Wales and its MCERTS scheme, has prepared this document to define the requirements for “equivalence testing” (product conformity and certification), of some specific monitoring methods for particulate matter in ambient air, in alignment with relevant guidance from the European Commission.

This document contains background information, and the requirements for equivalence testing, to achieve certification to MCERTS for UK Particulate Matter. This is a new type of certification that has been brought in to provide formal recognition that Defra and the Devolved Administrations of Scotland, Wales and Northern Ireland, as the Competent Authority for the UK, have provided approval of PM monitoring methods for use in the UK, where they are found to be “equivalent” to the relevant CEN Standard, and also meet the requirements of this document. The processes are based on those required for MCERTS certification in accordance with the MCERTS Performance Standard for Continuous Ambient Air Quality Monitoring Systems, but have additional requirements that include a specification for conformance with a UK Particulate Matter Pollution Climate.

The Competent Authority has already approved as “equivalent” a number of measurement methods for monitoring particulate matter, and this new process and requirements should not apply to these methods. A number of concessions will be made by the MCERTS certification committee for methods for which certification is sought, and which are already being tested when this document is published. Further details of this are available in Section 3.3.

Record of Amendments

Version Number	Date	Record of Amendments
Version 1	July 2012	
Version 1.1	31 July 2012	Correction to Table 3

Contents

i) Terms and Definitions

For the purposes of this document the following terms and definitions apply. The origins of these terms and definitions are indicated where appropriate by square brackets [Ref.] after the definition, taken from the list of references given in Section 7 of this document.

Ambient air

Outdoor air in the troposphere (excluding workplaces defined by Directive 89/654/EEC, where provisions concerning health and safety at work apply, and to which members of the public do not have regular access) [Ref.1].

Automated (measurement) method

A measurement method or system performing measurements or samplings of a specified pollutant in an automated way, generally directly in the field [Ref.3].

Availability (of the candidate method)

The fraction of the total and consecutive monitoring time during all the field trials involved in the equivalence testing programme for which data of acceptable quality are collected. The times required for scheduled calibrations and maintenance shall not be included. The method for calculating this fractional time is given in Section 5.2 Eq.2. Availability defined here is the same as the minimum data capture requirements given in the data quality objectives in Directive 2008/50/EC for the relevant pollutant.

Calibration (of a candidate method)

Determination of the function between the concentrations of a specific pollutant in the ambient air as determined with respect to the reference method, and the responses of the candidate method to those same concentrations. This is applicable to the candidate method with time-limited validity [Ref.3].

Candidate method

A measurement method proposed as an alternative to the relevant reference method - for which equivalence is sought to be demonstrated [Ref. 3].

CEN standard

International standard for normalization (norm) developed by the organisation the European Committee for Standardization (CEN) for the objective of removing trade barriers for European industry and consumers [Ref.2].

Combined standard uncertainty

Standard uncertainty of the result of a measurement when that result is obtained from the values of a number of other quantities, equal to the positive square root of a sum of these

terms, the terms being the variances or co-variances of these other quantities weighted according to how the measurement result varies with changes in these [Ref.10]. This may be expressed either as a relative (percentage) uncertainty, or as an absolute uncertainty, of the result.

Competent Authority

Organisation within the Member State that is designated by its national government to have overall responsibility for enacting all provisions of a set of European directives and/or other European regulations that are implemented into national regulations [Ref.9].

This is the organisation in the Member State that has national and legal responsibility for the provisions and requirements of Directive 2008/50/EC [Ref.1], and it is generally a national government ministry or an agency of national government, with political and administrative responsibilities for the relevant field of the legislation [Ref.9].

Competent body

Organisation designated by the Competent Authority in the Member State to carry out one or more technical or administrative functions at a national level, that in this document are those required by Directive 2008/50/EC [Ref.1], particularly those functional responsibilities that are specified in Article 3 of that Directive [Ref.9].

This is generally a designated scientific and technical organisation, rather than a government ministry, that enables all the functional responsibilities defined in Article 3 of the Directive to be carried out. These responsibilities are applicable to all of the ambient air pollutants that are regulated across the EU, including those covered by Directive 2004/107/EC, and one organisation is not generally capable of carrying out all of these, and there are therefore usually several competent bodies within a Member State.

Coverage factor

Numerical factor used as a multiplier of the combined standard uncertainty in order to obtain an expanded uncertainty [Ref.10].

Designated body

Particular organisation that is designated for a specific task (type approval tests, equivalence tests, and/or Quality Assurance / Quality Control activities in the field) by the Competent Authority in that Member State.

This is a competent body that has been designated to carry out a particular scope of activities. It is required that a designated body that is appointed at a national level be accredited for the specified task(s) according to the EN ISO/IEC 17025 standard.

Environmental conditions

The specified range of meteorological conditions, the range of PM mass concentrations, and the range of semi-volatile components present in the sampled PM mass, that shall be present during one or more of the comparison tests carried out to demonstrate conformance with the "equivalence" requirements specified in this document.

Equivalent method

A measurement method other than the reference method for the measurement of a specified regulated air pollutant, capable of meeting the Data Quality Objectives given in Ref. 1, for which equivalence has been demonstrated [Ref.1 Annex IV B & Ref.3 Section 4].

Expanded uncertainty

Quantity defining an interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand [Ref.10]. The fraction may be viewed as the coverage probability or level of confidence of the interval. (A specific level of confidence associated with this interval defined by the expanded uncertainty requires assumptions about the probability distribution characterised by the measurement result and its combined standard uncertainty.)

Field (equivalence) test or comparison

Experimental programme carried out by a test laboratory at a selected location in the field to compare the results obtained by the particulate matter reference method with those obtained by a particulate matter candidate method, during the course of establishing whether the candidate method conforms to the requirements for an equivalent method for monitoring particulate matter. This individual experimental field test or comparison forms part of a complete experimental test programme, together with a laboratory test programme where required, for demonstrating whether the candidate method may be deemed to be an equivalent method.

Laboratory (equivalence) test

Experimental programme carried out by a test laboratory in the environment of its laboratory to determine whether a particulate matter candidate method conforms to the requirements for an equivalent method for monitoring particulate matter. This laboratory test programme, where required, forms part of a complete experimental programme, together with the field test programme, for demonstrating whether the candidate method may be deemed to be an equivalent method. There are very limited requirements for laboratory tests in certain circumstances in the MCERTS standard (and in the Guide to Demonstration of Equivalence [Ref 3]), but German test laboratories are required to carry out a greater and more comprehensive range of tests, many of which are being incorporated into a new CEN standard. These are discussed in Section 4.2.

Limit value

A concentration level of a pollutant in the ambient air that is fixed on the basis of scientific knowledge, with the aim of avoiding, preventing or reducing harmful effects on human health and/or the environment as a whole, to be attained within a given period and not to be exceeded once attained [Ref.1].

Manual (measurement) method

A measurement method by which sampling is performed on site, generally for fixed short time intervals, with sample analysis performed subsequently in a laboratory [Ref.3].

Manufacturer (of the equipment)

The manufacturer of the hardware and associated software that makes up part of the *measurement method/candidate method* and is responsible for designing and/or manufacturing a product with a view to placing it on the market under its name. The manufacturer becomes the MCERTS certificate holder and is listed on the certificate, and has responsibility for compliance with the relevant MCERTS performance standards and regulations.

A manufacturer may also be an organisation that assembles, packs, processes, imports or labels ready-made products with a view to them being placed on the market under its name. The manufacturer may also be the manufacturer's agent or the equipment supplier of the automated or manual PM method when it has been MCERTS certified [Ref.5].

The term "manufacturer" is thus used to mean the equipment manufacturer, the manufacturer's commercial agent, or their equipment supplier, whichever is relevant as the customer in the MCERTS certification procedure.

Manufacturer's site audit

Initial and annual visits to the equipment manufacturer's plant by trained technical personnel as agreed by the MCERTS Certification Body to establish that equipment being manufactured is of the same type as that submitted as a candidate method for the equivalence tests [Ref.5].

MCERTS certification

The approval of a candidate particulate matter monitoring method that meets all the MCERTS ***technical requirements*** but it has not necessarily been demonstrated for, or assessed for, use in the UK with its specific pollution climate for ambient PM monitoring [Ref.6]. This is a decision taken within the MCERTS certification procedure, and does not by itself involve, or denote approval by, the UK Competent Authority. This definition is restricted to the scope of this document, and is not intended to define all systems covered by MCERTS certification.

MCERTS certification for UK Particulate Matter

A candidate particulate matter monitoring method that has met all the MCERTS technical requirements, and is also demonstrated as equivalent for use in the UK with its Particulate Matter Pollution Climate for ambient monitoring, by means of additional investigations. This constitutes approval from the UK Competent Authority that the method has been tested satisfactorily for equivalence, and can be used in the UK for undertaking assessment in line with the requirements of Directive 2008/50/EC. Directive 2004/107/EC covers the requirements to monitor certain heavy metals and polycyclic aromatic hydrocarbons using the sampling methods, including sample heads, that are within the scope of this document, and in certain cases these may be considered as equivalent methods (Section 2.6). This MCERTS classification may also be used for other monitoring activities, if required, including those carried out by Local Authorities – where appropriate.

This definition is restricted to and only relevant to the scope of this document, and it is not intended for other systems covered by MCERTS certification.

MCERTS Standard

Standard developed by The Environment Agency of England and Wales to prescribe the performance of monitoring instrumentation, equipment, or personnel that has to be achieved for MCERTS certification to take place [Ref.4].

Measurement method

A complete description of the total operation of all aspects of the specific equipment, its operating procedures, data collection and storage, and data analysis, initial and on-going quality control and maintenance, that together make up the method, and that produce specific measurement results of defined quality [Ref.11].

The measurement method comprises: all parts of the hardware (such as the sample head, the analytical equipment, and data processing hardware) and all the software used, all documented procedures for its use, all aspects of the associated control and analysis software, and all other procedures specified for use to enable valid measurement results to be produced.

Particulate Matter Pollution Climate

Characterisation of ambient particulate matter concentrations and certain compositional properties as representative in terms of its concentration range, its geometrical properties, its compositional range at the selected locations, together with selected meteorological conditions (wind speed, atmospheric temperature and ambient humidity) that are also representative.

PM_X

Particulate matter that is suspended in ambient air, and which passes through a size-selective sample inlet with a 50% efficiency cut-off at an aerodynamic diameter of x µm (usually PM_{10} or $PM_{2.5}$).

Pollutant

Any substance present in ambient air and likely to have harmful effects on human health and/or the environment as a whole [Ref.1].

Reference (measurement) method or reference method

European standard method developed by CEN, referred to in Directive 2008/50/EC Annex VI, and/or in Directive 2004/107/EC, and specified in that Directive as the reference method for the measurement of a specific ambient air pollutant. This measurement method produces, by convention, the accepted reference value of the measurand, with only a random uncertainty applicable to that value. (For the case of PM_{10} and $PM_{2.5}$ mass monitoring, these reference methods are specified as manual methods in [Ref.1].)

Regional, national, and local locations (for the equivalence tests)

Types of locations that have a similar PM pollution climate where the Competent Authority may choose to carry out equivalence tests and may install methods that have been deemed equivalent at these locations.

Sampled air

Ambient air that has been sampled through the sampling inlet and sampling system of the measurement method.

Semi-volatile fraction of particulate matter

The fraction of semi-volatile component within a sampled PM_{10} or $PM_{2.5}$ mass measurement result that shall be analysed from a sample obtained by a reference method or a candidate method during the equivalence test programme. (The semi-volatile channel of an automated PM mass analyser will usually indicate this fraction during the tests in the field – requirements for this fraction are given in Sections 3.2 and 4.3.)

Standard uncertainty

Uncertainty of the result of a measurement expressed as a standard deviation [Ref.10].

Test laboratory

Organisation that is capable of carrying out all or part of the laboratory tests and/or the field tests specified in this document; that is contracted by the manufacturer for these; that has

the agreement of the MCERTS certification body to perform these; and that is accredited to the EN ISO/IEC 17025 standard (latest published version) for these.

Uncertainty (of measurement)

Parameter, associated with the result of a measurement that characterises the dispersion (variability) of the values that could reasonably be attributed to the measurand [Ref.10].

ii) Abbreviations used in this Document

AQD	Air Quality Directive 2008/50/EC
CAM	Ambient Air Quality Monitoring System (generally means “Continuous” - but this is not restricted to “continuous” in this Document and thus allows certain discontinuous PM samplers to be tested for equivalence)
CEN	European Committee for Standardization [Ref.2]
CM	Candidate method
EC	European Commission
EU	European Union
GDE	EC Guide to the Demonstration of Equivalence of Ambient Air Monitoring Methods, January 2010 [Ref.3]
GM	Geometric mean (of particulate mass concentrations)
MCERTS	The Environment Agency’s Monitoring Certification Scheme [Ref.4]
PM	Particulate matter
RM	Reference method
QA	Quality assurance
QC	Quality control
UKAS	United Kingdom Accreditation Service
VDI/DIN	Verein Deutscher Ingenieure / Deutsches Institut fur Normung e.V.

1. Introduction

1.1 European Legislative Context

The European Union (EU) Directive 2008/50/EC of the European Parliament and of the Council on ambient air quality and cleaner air for Europe (the Air Quality Directive, or AQD) is the main EU regulation that requires the monitoring of certain ambient air pollutants [Ref.1]. This Directive specifies that *reference methods* should be used for the monitoring of the ambient air pollutants that are regulated by that Directive (Annex VI).

This Directive defines and classifies these reference methods as different ***automated continuous reference measurement methods*** for use in monitoring the gaseous pollutants in ambient air, and as defined in European Standards EN 14211, EN14212, EN 14625, EN 14626, & EN 14662-part 3 that have been prepared by the CEN organisation [Ref.2]. The Directive also defines other methods prepared by CEN for the other regulated pollutants that are classified as ***non-automated discontinuous manual reference measurement methods*** *(*currently EN12341:1998 for monitoring PM_{10}, and EN14907:2005 for monitoring $PM_{2.5}$).

Annex VI of AQD, however, *also* allows for the use of alternative methods with respect to these reference measurement methods, providing that the results obtained with these alternative methods comply with the results obtained with the reference methods, demonstrated through an acceptable "equivalence testing" programme.

The European Commission's (EC) guidance on how to perform this equivalence testing for *particulate matter (specifically mass) monitoring methods* is given in the "Guide to the Demonstration of the Equivalence of Ambient Air Monitoring Methods" (GDE), Section 9 [Ref.3].

The GDE has mainly been applied in Europe for the "equivalence testing" of different automated continuous methods that are to be used to monitor the *mass concentrations* of particulate matter (PM), particularly that of PM_{10} and $PM_{2.5}$, for the purposes of compliance assessment of each EU Member State's conformance with the AQD's requirements. However, it also covers non-automated discontinuous particulate mass monitoring methods that are not considered as reference methods. In this context of PM monitoring, the GDE mainly covers field comparison exercises between the PM reference methods and these other PM methods, although there are certain limited testing requirements in the laboratory in addition.

1.2 UK Roles and Responsibilities

The responsibility for implementing all the AQD requirements for ambient air monitoring, equivalence testing, etc., lies with the Competent Authority in the particular EU Member State. In the case of the UK, this is the Department for Environment, Food and Rural Affairs (Defra) with the Devolved Administrations of Scotland, Wales and Northern Ireland.

1.3 Environment Agency's Monitoring Certification Scheme (MCERTS)

The Environment Agency's Monitoring Certification Scheme (MCERTS) provides a framework of standards to use to monitor things that affect the environment. MCERTS covers:

- The standards of performance that the monitoring equipment must meet;
- The level that the technical and scientific staff of an organisation must be qualified to;
- Assessment of laboratories and inspection of sites in line with European and International standards.

A general overview and an introduction to the MCERTS complete certification procedure and its benefits, including its requirements for product conformity testing, is given in [Ref.5]. Section 2 below further explains the MCERTS processes and procedures, and also gives the scope and purpose of this document.

2. Background Information on the MCERTS Process

2.1 MCERTS Performance Standard for CAMs

An existing procedure is in place within the Environment Agency's MCERTS Scheme, currently operated by Sira Certification, for product conformity testing of a range of pollution monitoring equipment [Ref. 5]. This leads to MCERTS certification of the specific monitoring equipment.

The MCERTS Performance Standard for Continuous Ambient Air Quality Monitoring Systems (CAMs) [Ref.4] that has been developed by the Environment Agency of England and Wales, covers the type-approval testing and subsequent certification of the ambient air ***automated continuous reference methods for gaseous pollutants*** that are specified in the AQD.

The MCERTS Performance Standards are updated as new requirements evolve. The MCERTS Performance Standard [Ref.4] also specifies the methodology for the "equivalence testing" of automated continuous methods and manual (non-reference) methods for certain forms of particulate monitoring, so as to allow them to be used for these compliance assessment purposes. This "equivalence" testing programme, contained in the MCERTS Performance Standard, v8, Sections 6.4-6.8, is fully consistent with the GDE Section 9, January 2010. However, in addition, the MCERTS standard includes, more specifically than the GDE, the requirements for the testing and certification of other manual PM mass-monitoring methods that are not classified by the EC as reference methods.

For the purpose of evaluating the equivalence-testing programme described in this document, all the measurement methods, comprising PM sample heads with automated instrumental or with manual sampling methods, as specified in the MCERTS Performance Standard for CAMs [Ref.4], are known as Candidate Methods (CMs), in conformance with the GDE.

2.2 Scope and Context of this Document

This document sets out the specific requirements for two levels of certification (see Section 2.5).

The initial requirements are the same as those covered in the MCERTS testing and certification process in the MCERTS Performance Standard, v8, Sections 6.4-6.8 for product conformity and certification of automated continuous monitoring instruments and manual samplers that monitor ambient particulate matter. These provide alternative and potentially "equivalent" measurement methods to the reference methods for particulate matter specified in the AQD.

The second set of requirements, to be considered in addition to the initial set are not covered by the MCERTS Standard [Ref. 4] in any detail. This document contains background information to and the detailed, specific UK testing requirements process to achieve an

additional level of MCERTS certification based on the UK's Particulate Matter Pollution Climate.

These secondary requirements are those required in the GDE for the method to be deemed equivalent in (and by) any Member State. The GDE requires that all field tests undertaken shall be suitably representative of the conditions of a "Particulate Matter Pollution Climate" in which the instruments will subsequently be deployed for monitoring purposes, but provides no details on how this should be achieved. The existing MCERTS testing and certification process therefore does not consider in detail whether a different Particulate Matter Pollution Climate exists within the UK, or parts of the UK, or in another Member State, or in a region of that other Member State. This document therefore sets out these additional requirements.

2.3 Objectives of MCERTS Certification for PM Methods

In this document, in common with the overall aims and objectives of MCERTS certification, there are a number of aims and objectives with benefits to the users and manufacturers of the methods, to the Competent Authority, and to other interested parties. The aims and objectives specific to this part of the MCERTS certification process for "equivalent PM methods" may be summarised as:

- MCERTS certification is an independent, transparent, and validated process that is used to assess equivalence testing that is carried out in the UK and for use in the UK – to confirm that the testing has been carried out in conformance with a valid determination of the equivalence of a given automatic or manual method to the specified reference method – for acceptance within the UK. I.e. it is used to demonstrate rigorously, objectively and comprehensively that the requirements of the GDE are fulfilled.
- MCERTS is a validated and accepted process across Europe for other product conformity testing requirements, and thus should be acceptable in other Member States where appropriate, provided it is also used with a valid methodology for the assessment of the "Particulate Matter Pollution Climate" in those Member States (as set out in Section 3.2 and Section 4.3).
- MCERTS may also be utilised as a formal internationally acceptable process for the rigorous evaluation of equivalence tests that are carried out in other Member States, so as to provide evidence that supports the decisions of the UK's Competent Authority on the acceptance of these other test results for PM equivalence.

The requirements that shall be fulfilled to achieve MCERTS certification of automated and manual ambient air PM methods to establish whether they are "equivalent" are given in Section 4.

2.4 Role of the MCERTS Certification Committee

The issue of "equivalence testing" of any specific type of PM method ***and its acceptance as equivalent*** is specified in the AQD as the responsibility of the Competent Authority in each

Member State (in this case Defra with the Devolved Administrations). This is a complex issue involving not only the instrumentation that is tested and the exact procedures that are used, but also of the pollution climate in which it is located, and the quality assurance and quality control regime in which it is tested and subsequently operated.

This therefore requires an MCERTS certification committee with relevant and wide scientific expertise in the field, in order to provide robust defensible evidence-based decisions that will give confidence to the Competent Authority. This MCERTS certification committee shall be involved in all aspects of the definition of the test programme, a review of the final report, the evaluations of the results, and in providing recommendations to the Competent Authority for approval.

2.5 MCERTS Certification Levels, and Certification for the UK PM Pollution Climate

Measurement methods certified under MCERTS shall be deemed to be equivalent within one of two categories, depending on whether they are certified to the MCERTS Performance Standard for CAMs *alone* [Ref. 4] or whether they are certified to fulfil the complete requirements of this document. These two categories are:

- MCERTS – for candidate particulate matter monitoring methods that meet all the *technical requirements* of the MCERTS Performance Standard for CAMs, including all the laboratory tests that are required, and the field tests, but have not been demonstrated for use in the UK with its specific pollution climate for ambient PM monitoring, as set out in this document. *This is a decision taken within the MCERTS certification procedure, and does not by itself involve, or denote approval of equivalence by, the Competent Authority.*
- MCERTS for UK Particulate Matter– candidate particulate matter monitoring methods that meet all the MCERTS technical requirements, including all the laboratory tests, that are required, and the field tests, and that are also demonstrated as equivalent for use in the UK with its climate for ambient PM monitoring, by means of additional investigations. *This constitutes approval from the Competent Authority that the method that has been tested satisfactorily for equivalence, and can be used in the UK.* These methods shall meet all the requirements of this document.

Where candidate methods for PM have already been declared equivalent by the Competent Authority prior to the transposition of Directive 2008/50/EC into the UK in June 2010 the manufacturers of these will be encouraged to, but not be required to, seek MCERTS certification in order to gain full MCERTS certification for UK Particulate Matter. Where Candidate Methods have completed or have begun the field-testing programme when this document is published, certain concessions will apply. These are detailed in Section 3.3.

It is also important to be aware that:

(1) A new CEN standard is being drafted on automated PM monitoring systems used for the purposes of air quality compliance evaluation. This standard follows the framework of, and augments, the requirements of the GDE for automated PM monitoring systems. It also includes additional tests to be carried out in the laboratory that are similar to those carried out in test laboratories in Germany. When this is published it may replace the EC GDE. Where practical it may be beneficial for these extra laboratory tests to be carried out. This would be optional; this new standard may not be validated, published, and accepted by the EC for several years.

(2) Another CEN standard is being revised to cover the two CEN manual methods that are referred to in Directive 2008/50/EC as PM reference methods, and it covers the revision of the two current standards EN12341 (PM_{10}) and EN 14907 ($PM_{2.5}$) This revision will replace these two current PM reference methods, when published and accepted by the EC as a reference method. This is expected to also contain a list of other acceptable currently-used or previously-used manual particulate mass-monitoring methods that may historically be deemed to be "reference methods".

2.6 Scope of the Methods Covered by this Document

The MCERTS testing and the certification procedure presented in this document is, as noted above, an explanation of the MCERTS Performance Standard for Continuous Ambient Air Quality Monitoring Systems (v8, Sections 6.4-6.8). This is applicable to those automatic continuous instrumental methods, and certain manual discontinuous methods, that monitor the *mass concentrations* of particulate matter (PM) with appropriate sampling heads for the correct aerodynamic size sampling of the particulates. It is not restricted to PM methods that collect and measure *directly* the mass of PM deposited - it covers all methods that provide mass results by any surrogate monitoring technique (e.g. beta attenuation, optical methods, oscillating filter). However, these manual methods for speciated particulate measurements may be determined to be equivalent for the speciation measurements where certain conditions are met and provided that they gain MCERTS certification for UK PM (see Section 3.2).

The MCERTS testing and certification procedure primarily has application to automatic instruments and manual sampling methods that monitor PM_{10}, $PM_{2.5}$, and PM_{Coarse} (PM_{10} – $PM_{2.5}$) mass concentrations for purposes of compliance assessment for conformance with the Directive's requirements. It may also be applied to methods that measure other PM size fractions and that report the results gravimetrically (e.g. $PM_{1.0}$).

This MCERTS procedure does not, however, strictly cover current manual methods that determine the regulated speciated components of PM (heavy metals, elemental carbon/organic carbon, anions and cations, and polycyclic aromatic hydrocarbons). These methods for particulate measurements may be determined to be equivalent for these speciated measurements, provided that they gain full MCERTS certification for PM mass concentration measurement for the same type of manual sampler that is employed to monitor the speciated components within the PM, and in addition, *where the relevant reference method for the speciated components is used for its analysis.* It is then expected

that this speciated monitoring method will also be determined to be equivalent *provided that*:

- All of the operating conditions and the complete operating procedure for the PM sampling are the same as those used in the equivalence field tests;
- The filters that were used during the PM equivalence tests are compatible with the filter requirements of the speciated analyses;
- There is sufficient PM material available on the samples taken to enable valid speciated analyses to be made.

This document also does not cover the AQD's reference methods that are currently defined in standards EN12341 – the reference method for PM_{10}, and EN14907 the reference method for $PM_{2.5}$ – since these are deemed by the EC to give the correct results within the stated random measurement uncertainties, when operated using the procedure that is specified in the relevant standard (but see Section 2.5 point (2)).

3. UK Particulate Matter Pollution Climate

This Section provides background information to the concept of the PM Pollution Climate, and the required equivalence-testing programme and subsequent analyses of the results that must be undertaken and shown to be valid and acceptable, so that the PM method can be accepted for MCERTS certification for the Pollution Climate for UK particulate matter. A Checklist in Section 8 also summarises all the requirements.

3.1 Definition of PM Pollution Climate

For a candidate method to be certified as equivalent for use in a particular Member State, the field testing shall be undertaken in locations that are representative of the area(s) of the Member State's territory for which installation of the equivalent PM monitor is intended. This representativeness applies in terms of the PM Pollution Climate of the selected sites, the type of site, (e.g. a regional site, or a national site etc.), and is an essential requirement of the GDE. It is this concept that the existing MCERTS Performance Standard does not cover.

The term PM Pollution Climate is used to describe the geometrical, chemical and other properties of the particulate matter in the UK that are "representative" of the locations in the UK where the automated and/or manual PM measurement methods are to be sited once they are certified under MCERTS as equivalent.

Section 4.3 specifies in detail all the key requirements of the candidate method that shall be fulfilled, specifies the PM characteristics of the ambient air that shall be covered, and specifies certain meteorological parameters, that shall be covered as a consequence of this procedure, in order to allow the CM to gain MCERTS Certification for UK particulate matter.

The term "climate" is generally characterised by a long time scale. (The Intergovernmental Panel on Climate Change defines this as thirty years to account for seasonal and inter-annual variability in meteorology etc.) The consideration of the length of the PM record to be evaluated, however, has to be balanced, in the case of PM in the UK, against changes in time to the PM's concentration range, to its geometrical properties, and to its composition – all over that timescale – as a result of the range of emission abatement policies and other interventions that are introduced, as well as broader background particulate compositional changes and climate change effects. In addition, the availability of the required range of measurement metrics that allow detailed characterisation of these PM properties is somewhat limited in time with, for example, semi-volatile measurements available only for the last seven years in the UK.

The analysis of the UK PM Pollution Climate has therefore been chosen to be shorter than the timescale of thirty years, but long enough so that it allows the PM Pollution Climate to be characterised at the present time, and it also allows changes in emissions (and therefore changes in PM concentrations, chemical composition etc) to be taken into account that may take place over the next ten to fifteen years - with the currently available measurements and the projected regulatory control technologies and regulatory changes in emission processes.

3.2 Assessment of the UK Particulate Matter Pollution Climate

A statistical assessment procedure has been developed to evaluate and to demonstrate what constitutes a representative Particulate Matter Pollution Climate in the UK and/or in regions of the UK [Ref.6]. This assessment is summarised below to clarify how this representativeness has been evaluated, and also specifies which and how supplementary measurements shall be made as part of the equivalence testing procedure so as to allow for an assessment of the Particulate Matter Pollution Climate, and thereby gain MCERTS certification for UK PM within this UK Particulate Matter Pollution Climate.

The assessment methodology requires the manufacturer of the PM analyser to demonstrate that the proposed equivalence field test site is representative of the UK's PM Pollution Climate, using at least six months of measurements of the relevant PM fraction with the reference method or an equivalent PM method. Ideally the assessment should be done in a period of time that encompasses the field test period, and be co-located with the field test. If either of these are not available then data from another time period, generally within the previous two years, and/or data from an alternative monitoring location similar in type to the proposed field test site (e.g. urban background, traffic, rural), and in close proximity to the field test site may be used instead, as the basis for this assessment.

The use of such alternative data obtained from a different time period and/or from another monitoring station as listed above, should be first discussed with the MCERTS certification committee who will review the proposals and provide advice on its suitability. The PM measurements need not be carried out continuously over a six monthly period, but can be determined by a number of shorter periods that make up at least six months. The assessment may involve the use of PM_{10} data instead of $PM_{2.5}$ data at the site if no suitable $PM_{2.5}$ data is available, or vice versa.

The assessment methodology also requires measurements of wind speed, temperature and ambient dew point to be made at the field test site, or close by, during the field tests.

The above procedure leads to a number of requirements for the monitoring conditions:

(i) The sites where equivalence field tests are undertaken shall be representative of the field conditions under which the instruments are likely to operate when deployed for monitoring purposes. This is implemented by using the chosen parameters of the PM and of the meteorology at the sites in the manner that is specified below:

  (a) A range of particulate mass concentrations were determined that are representative of UK conditions for all existing UK sites, and for each site type (background, traffic, rural and industrial). These have been calculated from the measurements made in the UK between 2007 and 2010 for PM_{10} mass concentrations, and for the volatile fraction data of PM_{10}. These concentration ranges will be updated annually in the future to reflect the temporally extended dataset. This will provide an accurate assessment of $PM_{2.5}$ measurements, and try to account for inter-annual variations in both PM_{10} and $PM_{2.5}$. The range of concentrations may therefore increase. Manufacturers

should therefore consult the MCERTS certification committee for the most up-to-date concentration ranges.

(b) These ranges are calculated as a geometric mean concentration to form an average value, as this is the most appropriate way of representing the log normal distribution of air pollution concentrations. The geometric mean (GM) is defined as:

$$\left(\prod_{i=1}^{n} x_i\right)^{1/n} = \sqrt[n]{x_1 \cdot x_2 \cdot \ldots \cdot x_n} = \exp\left[\frac{1}{n}\sum_{i=1}^{n} \ln x_i\right] \quad (1)$$

The GM concentration derived for the equivalence field test site should be calculated at the equivalence field test site using either the reference method, or another method that has been shown to be equivalent to the reference method. At least six months of data shall be used from any given site for inclusion in the reference data set that is used for the evaluations. The geometric mean calculated shall encompass the period of the comparison. The calculations on Particulate Matter Pollution Climate specified in this Section should generally be carried out before field tests for equivalence are begun. Where it is not possible to do this the calculations may be carried out concurrently or retrospectively, with the risk that the results will not fulfil the requirements given here.

(c) The geometric means of the PM data from all the equivalence field test sites used, obtained from at least six months of monitoring data at each site, using either the reference method, or an equivalent method, should lie in the ranges in Table 1 for the relevant site type for the PM_{10} and $PM_{2.5}$ monitoring results. Up-to-date versions of these ranges will be made available through Defra's UK-AIR monitoring webpages.

Site Type	**Geometric Mean PM_{10} Range (µg m^{-3})**	**Geometric Mean $PM_{2.5}$ Range (µg m^{-3})**
Background (urban or suburban)	11.9 – 25.7	8.4 - 18.1
Traffic	10.9 – 42.3	7.7 - 29.8
Rural	4.3 – 18.1	3.0 - 12.8
Industrial	13.8 – 24.6	9.7 - 17.4

Table 1: Range of geometric mean concentrations for each site type in the UK calculated using 2007-2010 PM_{10} data, with this *data factored to estimate the $PM_{2.5}$* geometric mean ranges.

(d) The geometric mean data in Table 1 for PM_{10} concentration ranges is taken from currently available UK data over the time period as calculated in [Ref.6.] The $PM_{2.5}$ data is however, an estimate using a suitable applied factor taken from the ratio of $PM_{2.5}$ to PM_{10}. Both these datasets will be updated by the Competent Authority when new results become available. Manufacturers should therefore consult the MCERTS certification committee for the most up-to-date concentration ranges.

(ii) A minimum of four comparisons at a minimum of two different sites must be available over the complete comparison programme, with an emphasis on the following variables and their required ranges given below:

(a) The PM fraction measured must include both high and low fractions of semi-volatile PM as defined in Table 2 where the thresholds for the high and low daily mean concentrations, and the percentage of measurements above the high threshold or below the low threshold are shown. At least one set of comparisons of the complete test programme, comprising a minimum of 40 valid results, shall have the requisite number of daily mean measurements below the low thresholds given in Table 2. At least one set of the comparisons of the complete test programme, comprising a minimum of 40 valid results, shall have the requisite percentage of daily mean measurements above the high thresholds given in Table 2, of the total number of valid measurements made in the individual comparison. Semi-volatile PM concentrations are generally measured using the reference channel of an FDMS (either for PM_{10} or $PM_{2.5}$) or by measuring the nitrate concentration in $PM_{2.5}$ as these have been shown to be closely correlated [Ref.16]. If neither of these measurements is co-located at the field test site, measurements made within 130 km can be used as a surrogate. This has been demonstrated as a working range for the Volatile Correction Model in the UK [Ref.7].

(b) The ambient temperature and dew point measured at the comparison sites must include periods of high and low ambient temperatures (to assess losses of semi-volatile PM) and with high and low humidity. The daily mean ambient temperature and daily mean ambient dew point temperature thresholds, and the percentage of measurements above the high threshold and below the low threshold are shown in Table 2. At least one set of comparisons in the complete test programme, comprising a minimum of 40 valid results, shall generally have the requisite number of daily mean measurements below the low thresholds given in Table 2. Where this is not possible the MCERTS certification committee shall review all the results and form an opinion on their validity.

At least one set of the comparisons of the complete test programme, comprising a minimum of 40 valid results, shall have the requisite percentage of daily mean measurements above the high thresholds given in Table 2, of the total number of valid measurements made in the individual comparison. These measurements of ambient temperature and dew point should ideally be made at the same sites as the equivalence tests, but may instead be made at another location (preferably nearby) where it can be demonstrated that these

measurements are sufficiently representative of the conditions that occur at the equivalence test site.

(c) The wind speed measured at the comparison sites must include both high and low wind speeds to cover any dependency of inlet performance arising from deviations from ideal behaviour as determined by the mechanical design, or deviations from the designated sampling flow rate. The wind speed threshold and the percentage of measurements above the high threshold or below the low threshold are shown in Table 2.

At least one set of comparisons of the complete test programme, comprising a minimum of 40 valid results, shall have the requisite percentage of daily mean measurements below the relevant *low threshold* given in Table 2. In addition, At least one set of the comparisons of the complete test programme, comprising a minimum of 40 valid results, shall have the requisite percentage of daily mean measurements above the relevant *high threshold* given in Table 2.

This requisite number of daily mean measurements is expressed as a percentage (in Table 2 e.g. column 10) of the total number of valid measurements made in an individual comparison. Wind speed measurements in this methodology were taken at 10 metres, and mathematically adjusted to be representative of 5 metres and 2.5 metres. These meteorological measurements should ideally be made at the same sites as the equivalence tests, but they may instead be made at another location (preferably nearby) where it can be demonstrated that these measurements are sufficiently representative of the conditions at the equivalence test site.

Threshold	**Semi-volatile / nitrate ($\mu g\ m^{-3}$)**		**Wind speed (m/s)**							**Ambient Temperature (ºC)**		**Ambient Dew Point (ºC)**	
	Threshold	%	Threshold						%	Threshold	%	Threshold	%
			10 metres		5 metres		2.5 metres						
			Urban	Rural	Urban	Rural	Urban	Rural					
Low	3.2	5	2.9	6.0	0.7	5.1	0.3	4.2	10	7.6	10	3.9	10
High	6.3	5	5.2	12.4	1.2	10.6	0.6	8.8	10	16.1	10	10.8	10

Table 2: Low and high thresholds and the requisite number of daily means for PM_{10} and $PM_{2.5}$ equivalence tests to be carried out outside these thresholds, whichever is appropriate *(as a percentage of the number of measurements within one comparison*) for semi-volatile PM mass concentrations and for selected meteorological conditions.

(iii) All the thresholds given above are expressed as percentages, rather than as absolute fractions or numbers of occurrences, so that if there are more than 40 valid data

points in a given comparison, then the absolute number of the individual daily comparisons outside of these thresholds is required to be proportionally greater - in order to ensure their comparable statistical significance.

(iv) Where all the four field comparison tests are carried out in the UK, and where all the above measurement parameters are monitored and all their criteria are satisfied as far as is practically possible, and as agreed by the MCERTS certification committee, this shall be considered as the validation for the "PM Pollution Climate" of all of the sites. The criteria take account of the variations in the semi-volatile PM fractions, and variations in meteorological parameters (wind speed, ambient temperature, relative humidity etc.) for all the selected parts of the UK, as determined during the equivalence tests, and as stated in the MCERTS Performance Standard for CAMs [Ref.4 Section 6.7.2]. The exact numerical criteria that shall be achieved during the equivalence field tests for these parameters are also as specified in Section 4.3.

(v) Where the results of equivalence tests carried out at test locations other than in the UK are evaluated, an equivalent statistical assessment shall be employed by the manufacturer in preparing the test report(s), and its applicability to the UK shall thereby be determined by the MCERTS certification committee. For test programmes which begin after this document enters into force, or for test programmes where two or fewer comparisons have been undertaken or are in progress when this document enters into force, the complete equivalence testing programme shall involve two or more comparisons each containing at least 40 valid comparisons between the CMs and the RMs, that are carried out other than in the UK, and two further sets of 40 valid comparisons at a UK site (see also Sections 3.3 and 4.2).

(vi) Where test programmes pre-date the publication of this document, and where three or more comparisons have already been undertaken or are in progress by this date, at least one set of valid (40) comparisons shall be carried out in the UK. This shall be an essential component of the assessment of the validity of the equivalence-testing programme that is carried out in another Member State as being acceptable, or not, to the UK Competent Authority, for use in the environmental conditions that constitute the UK PM Pollution Climate.

In summary, the above requires that each of the sites selected for the equivalence tests should have environmental conditions (defined in Table 2 and specified numerically in Section 4.4 (iv)) that are as widely variable as practically achievable in the field at the selected site(s) during these tests - in conformance with the summaries of these conditions given in GDE Section 9.4.2 and MCERTS Performance Standard, Sections 6.4 – 6.8, and as detailed in this document. This range of conditions shall be evaluated by the MCERTS certification committee to confirm that they conform to these requirements of the MCERTS Performance Standard for CAMs. The procedure for assessing this is derived from the statistical assessment procedure summarised above, and described in more detail in Section 4.3 (iv) of this document.

3.3 Requirements for Candidate Methods based on when the Equivalence Field-test Programme has been Completed or is Begun

Table 3 clarifies the Competent Authority's requirements for equipment manufacturers concerning field test programmes, based on the progress they have made with field comparisons at the date of publication of this document. The following aspects of the requirements are addressed:

- PM Pollution Climate – concentrations, semi-volatiles and meteorology (Sections 3.1, 3.2 and 4.3)
- Data Availability (Section 5.1)
- Number of UK field tests (Section 4.3)
- Number of reference methods present in the field tests (Section 4.3)

Where equivalence field testing pre-dates June 2010, the manufacturer must seek as far as possible to demonstrate conformance with the requirements of this document using the existing data, and in particular demonstrate the requirements related to the UK PM Pollution Climate. The decision on the applicability of such previous testing will remain the responsibility of the Competent Authority, and further advice should be sought by the manufacturer where needed.

	Elements of UK MCERTS Required for PM Pollution Climate Certification Procedure						
Testing scenario	**PM Concentrations Geometric Mean**	**Semi volatiles**	**Temperature & ambient dew point**	**Wind speed**	**90% data capture (see Section 5.1)**	**2 UK tests**	**2 RMs used for field comparisons**
Methods declared equivalent before June 2010.	None of the above required for instruments in this category. All initial decisions by the Competent Authority predating this document will be upheld on the basis of existing test data with respect the requirements of the 2008 AQD. This is subject to agreement of the European Commission who have final judgement on equivalence for compliance assessment and in addition potential forthcoming changes to the AQD.						
Test programme completed prior to publication of this document. Methods not declared equivalent.	Required to calculate and demonstrate these UK Pollution Climate requirements where data are available. All reasonable efforts must be made to obtain data. Recommendations will be made by the MCERTS certification committee to the Competent Authority.				Not required.	Only 1 set required.	Not required.
Test programme partially completed when this document is published: 3 or more field comparisons undertaken to date.	Required to demonstrate the above where possible for completed field comparisons and required to demonstrate the above for comparison(s) not yet begun when the document is published.				Required for comparison(s) not begun when the document is published. This is a deviation from the methodology in this Annex to calculate availability over all field programme time.	Only 1 set required.	Required for comparison(s) that have not begun when the document is published.
Test programme partially complete when this document is published: 2 or fewer field comparisons completed to date.	Required to demonstrate this where possible for completed comparisons and required to demonstrate for comparisons not yet begun when the document is published.				Required for comparison(s) not begun when the document is published. This is a deviation from the methodology in this Annex to calculate availability over all field programme time.	Required.	Required for comparison(s) not begun when the document is published.
Test programmes not begun when this document is published.	Required.						

Table 3: Requirements for CMs based on when the field test programme has been completed or is begun

4. Requirements for the Equivalence Testing Process and Certification

4.1 Initial Stages of the Process

The initial stages of MCERTS certification are given on the Sira Certification website [Ref.5], and may be summarised as follows:

(i) The manufacturer of the automated or manual PM method contacts Sira, to be provided with an information pack, application form etc., which are completed and submitted to Sira.

(ii) The manufacturer contracts the organisation (Sira) for the certification process, which entails:

- Establishing an expert MCERTS certification committee, if one is not already constituted;
- Agreeing the scope of certification, including the extent of the laboratory and field testing programme required;

This shall include a decision by the MCERTS certification committee as to whether the complete MCERTS test programme needs to be carried out, or whether the tests shall be considered as covering a modification of the relevant EN reference method (see MCERTS Standard v8, Section 6.6 and GDE Section 9.3). The requirements of the GDE and MCERTS in this case cover only situations where there are certain modifications to an existing CEN reference method – for example, an application of automated filter changers leading to filter storage conditions deviating from those prescribed in the EN standards, or the use of different weighing conditions - deviations from the requirements given in the CEN PM standards. In these cases a more limited set of tests may be allowed.

It should also be recognised that the GDE gives no specific requirements for a test programme when the CM for which equivalence testing is being sought is a variation of an already accepted equivalent method. However, the MCERTS Standard covers these, and in these cases the MCERTS certification committee shall provide guidance on the testing requirements to the Competent Authority, who shall decide on the level of testing required, taking further advice if required.

In all cases the following actions shall then be implemented:

- A test plan for the field tests shall be developed and agreed and (if required) for the laboratory tests (generally in collaboration with one or more selected and approved laboratory and field test organisations that are accredited to the ISO 17025 standard for these tests);
- A detailed test programme and schedule shall be prepared and agreed using the test plan;

It is important to recognise that, in the above production of the detailed test programme, it is the responsibility of *all the parties involved* – the MCERTS certification committee, the accredited laboratories that perform the tests, and the equipment manufacturer, to ensure that the test programme fulfils all the requirements of the MCERTS Performance Standard, and of the EC GDE, as listed specifically and in detail in this document.

Following the agreement of the detailed test programme, there shall be:

(i) Agreement on audit(s) of the manufacturer's production activities with Sira, to support an on-going demonstration of equivalence of the manufacture of the equipment. (In the case of instrumentation manufactured in Germany, and that is to be considered for MCERTS approval, these audits of the manufacturer's production activities may be carried out by a recognised German organisation.)

(ii) Commissioning by the manufacturer of the required tests directly with the selected test laboratory, or laboratories, that are to carry out all or parts of the test programme in the field, and where required, in the laboratory;

(iii) Commissioning by Sira of an audit of the manufacturer's production (or see (i) above).

4.2 Requirements and Additional Options for Laboratory Tests

This Section provides the scope of the laboratory test programme that is specified in the GDE, and as specified in the MCERTS Performance Standard [Ref. 4 Sections 6.5 &6.6]. Parts 1 and 2 listed below shall be the minimum laboratory tests that are carried out to show conformance with the requirements of this document.

This section also gives additional testing requirements that are specified in current German Guidelines that are required to be carried out for type approvals for automated continuous methods to be accepted for use in Germany, and similar additional requirements that are given in a draft European standard being prepared by CEN (see Section 2.5 above). These are suggested for the consideration of manufacturers as further options for laboratory testing.

1. The laboratory test programme required by the GDE [Ref.3 Section 9.3] covers only two applications that relate to certain (limited) modifications of the manual CEN standard method (PM_{10} or $PM_{2.5}$) which the AQD defines as a reference method. These are:

1a. Application of automated filter changers leading to filter storage conditions deviating from those prescribed in the EN standards;

1b. Use of different weighing conditions, e.g., conditions deviating from the requirements set in the EN standards.

In either of the above circumstances the GDE requires a set of laboratory tests that are given in GDE Sections 9.3.2 and 9.3.3 respectively. There are no further laboratory tests prescribed.

2. The laboratory test programme required by the MCERTS Performance Standard specifies more tests, two of which are related to the stability of the flow through the filter or measurement cell, and the provision of a representative sample. These are:

2a. Constancy of the sample volume flow, is tested as specified in the MCERTS Standard [Ref. 4 paragraph 6.5.2], using selective filters loaded with particulates to 80%, 50% and 0% of the maximum permissible filter loading specified, and the constancy of the sample volumetric flow is recorded as a 3 minute average every 30 minutes for at least 24 hours – to achieve the performance criteria given in Table 6.2 of [Ref. 4].

2b. The leak tightness of the sampling system [Ref. 4 paragraph 6.5.3] is carried out using flow and pressure monitoring equipment to determine the leak rate of the entire instrument where feasible, or by evaluating the leaks of different parts separately. The tests can be made by measuring the volume flow at the inlet and outlet of the system, or by determining the pressure drop as defined in paragraph 6.5.3 of [Ref.4] – to achieve the performance criterion given in Ref. 4 Table 6.2.

2c. In addition, tests are required on two applications that relate to certain (limited) modifications of the manual CEN standard method (PM_{10} or $PM_{2.5}$) as stated above for the GDE tests, where the AQD defines it as a reference method. These are:

- Application of automated filter changers leading to filter storage conditions deviating from those prescribed in the CEN standards;
- Use of different weighing conditions, e.g., conditions deviating from the requirements set in the CEN standards.

In either of the above circumstances the MCERTS Performance Standard requires a set of laboratory tests that are as given in its Sections 6.6.2 and 6.6.3 respectively.

These laboratory tests that are specified in the MCERTS Standard shall be the minimum laboratory tests that are carried out to show conformance with the requirements of this document.

3. In Germany there are minimum requirements and test procedures for automated continuous methods defined in VDI 4202-1 [Ref.12] and VDI 4203-3 [Ref.13]. These requirements and procedures would need to be met and followed in addition for automated continuous methods to be used in Germany. These standards include references to EN 12341 (in terms of equivalence testing for PM_{10}) and to the GDE (in terms of equivalence testing for PM_{10} and $PM_{2.5}$). The lab test includes:

- Measured value display;
- Easy maintenance;
- Functional test;
- Set-up and warm-up times;
- Instrument design;
- Unintended adjustment;
- Certification and measuring ranges;
- Negative out signals;
- Failure in mains voltage;

- Operating states;
- Instrument software;
- Repeatability STD at zero;
- Dependence of zero and span on surrounding temp (5°C to 40°C);
- Dependence of span on electric voltage;
- Constancy of sample volumetric flow;
- Tightness of measuring system;
- Assessment of the measuring range(s);
- Ensuring negative signals are not suppressed;
- Zero level and detection limit;
- Constancy of flow volume;
- Measurement of effects of mains voltage and frequency fluctuations, and of mains voltage failure;
- Dependence of the results on surrounding temperature ($5^{o}C – 40^{o}C$);
- Determination of the overall measurement uncertainty.

It is worth noting that since 2010 there has been a change in the common practice of the determination of the expanded uncertainty measurement, such that test reports from different years may not have completely comparable data. (The previously adopted practice of including a measurement uncertainty calculation based on laboratory test results has been dropped.) These test procedures are also being included where appropriate into the new and definitive CEN standard currently being drafted (see below). In the meantime, *it is proposed that the set of laboratory tests specified in the current VDI guidelines [Ref.13], be offered as an option to manufacturers seeking equivalence testing in the UK* – these also cover the more limited set of tests required by the MCERTS Performance Standard.

4. A European standard on automatic PM_{10} and $PM_{2.5}$ monitoring systems is being drafted by CEN. This contains type-approval procedures that are of the same scope and format as those of the CEN standards for gaseous ambient air pollutants. This type-approval is divided into a set of laboratory tests, and the field tests that are almost identical to those in the GDE (with some supplementary diagnostic and related tests in the field). The full type-approval test programme involves 11 laboratory and 9 field tests. The laboratory tests are drawn from those in the VDI/DIN Guidelines [Ref.13]. These also cover the two tests covered in 2a and 2b above. It is recognised that this CEN standard is still in draft form and will not be published for a number of years. However, *it is proposed that the set of laboratory tests in the standard could be offered as an option to manufacturers seeking equivalence testing in the UK* - these also cover the more limited set of tests required by the MCERTS Performance Standard.

4.3 General Requirements for Equivalence Testing in the Field

There are a number of general requirements that shall be satisfied as follows:

(i) Any declaration of equivalence by the Competent Authority that is carried out after June 2010, the date when the Directive 2008/50/EC entered into force, shall be carried out in conformance with the requirements of this document where MCERTS certification for UK PM Pollution Climate is sought. Testing carried out prior June 2010 may be submitted as part of the MCERTS certification process should the instrument manufacturer apply for this but should meet the requirements in terms of the UK PM Pollution Climate. Clarification is given in Section 3.3. Further clarification may be sought from the MCERTS certification committee and the Competent Authority as necessary.

(ii) Where the test programme is for a limited modification to an existing CEN reference method no field tests are required, and a subset of the test programme shall be carried out, in conformance with the requirements of MCERTS Performance Standard for CAMs, version 8, Section 6.6 and the GDE Section 9.3.

(iii) Where the application is for a limited modification of a method that has already been determined as equivalent, the Competent Authority shall decide on the level of testing required, taking advice from the MCERTS certification committee on a case-by-case basis, and taking account of all results of previous equivalence testing, if available.

(iv) Two RMs shall be co-located alongside two CMs for all the equivalence tests carried out after the publication of this document. (The GDE permits one RM to be used under certain circumstances. Clarification should be sought from the MCERTS certification committee where this applies.) Where equivalence testing comparisons are begun after this document is published, and the use of two RMs is not possible, then the approval of the MCERTS certification committee shall be obtained beforehand, and a complete explanation shall be documented of why this decision is taken. In addition, comprehensive information shall be supplied before the field tests commence, as to how the measurement uncertainty criterion of the one RM is accounted for and justified, and how in detail all the calculations of the results are to be carried out. Section 3.3 provides details on the use of existing test data.

(v) The two RMs used shall be identifiably of the same type throughout the test programme, and shall be as specified in the relevant EN standard. The analyses of the gravimetric results shall also conform to the requirements of that same EN standard.

(vi) Two CMs shall be of the same type throughout the test programme, normally shall be the same CMs throughout the test programme, and shall be clearly identifiable as such through reference to, for example, serial numbers and any additional necessary marks. The sample heads of the CMs should also be of the type(s) specified in the appropriate EN standard, and this shall be stated in the test report and in the MCERTS certificate. Where these are not the same type as those specified in the EN Standard, the specifications of the sample heads used, their flow rates, instrument settings, the complete set-up of the method, and of the technical procedures that

are used in the equivalence testing programme, shall be documented comprehensively in the test report, and in the MCERTS certificate. (In cases where the CM sample heads differ from those described in the CEN standards for RMs, additional measurements and analyses should be used [see Ref.4 Section 9.2]. This is specified without a detailed procedure. It will not be carried out in practice, except in exceptional circumstances that should be decided beforehand, since these analyses would give rise to significant extra costs.)

(vii) Where two *local* CMs are tested for equivalence, they shall be co-located with the two RMs, and their performance tested as described in subsequent Sections of this document, including requirements given in Section 5 relating to between-CM uncertainty and availability.

(viii) In other cases, where a *regional instrument* is used to correct for the semi-volatile fraction or provide semi-volatile data for the two local CMs in the test programme, this correction shall be applied in a valid manner. [Ref.4 Sections 9.1 & 9.4, and Ref.6]. For candidate methods consisting of one regional instrument and two local CMs, the two CMs at the test site shall be used to assess the between-instrument uncertainty, both using the same regional instrument. The assessment of the uncertainty in the calibrations performed by using the input of the regional instrument will generally be done separately as a part of the evaluation of the between-instrument uncertainty of the regional measurements. Then both the between local/regional and the local/local uncertainty terms shall be combined in quadrature to give an estimate of the local between-instrument uncertainty for comparison with the criterion given in Section 5.3, and with the GDE Section 9.4.1 [Ref.3].

(ix) Suitable quality assurance and quality control checks, and calibrations shall be used throughout the tests. [Ref.3 section 9.4.3 and its Annex D for CMs, and EN 12341 or EN 14907 for RMs] –see also Section 4.5 below.

(x) All the measurement results and all the Quality Control (QC) checks and calibrations shall be documented comprehensively. The scope and format of the required report(s) are given in Section 6.

(xi) The two CMs shall have a minimum data capture and availability of greater than or equal to 90% during the entire programme of the field tests, for new equivalence tests – see Section 3.3. This is compatible with the AQD – see Section 5.2.

(xii) Two sets of (each a minimum of 40) valid comparison tests shall be carried out in the UK. Any field test programmes that have less than two sets of tests carried out in the UK shall be approved by the MCERTS certification committee beforehand (see point (iv)). Exceptions will be made for any field test programmes which began before this document entered into force, or where three or more of the four comparisons had already begun or been completed by the date of entry into force. (Section 3.3 for more details.) These field equivalence tests should be carried out at one (or more) selected locations and/or seasons. The location(s) shall be selected to be compatible with respect to the UK PM Pollution Climate evaluation. These tests shall be carried out to produce the required results as outlined in Section 3.2, and as specified in Sections 4.3 – 5.4.

(xiii) In exceptional circumstances after this document is published, and where less than two equivalence field tests are carried out in the UK, an explanation shall be provided as to why this decision is taken, and the approval of the MCERTS certification committee shall be obtained beforehand. Information shall also be supplied before the field tests commence, as to how the between-CMs measurement uncertainty criterion shall be accounted for, and how in detail the calculations of all the results are to be carried out from all the tests carried out in the UK and elsewhere.

(xiv) The laboratory that carries out these tests shall be accredited by UKAS to the ISO IEC EN 17025 standard with the required scope, or be accredited by a recognised European Accreditation Body that is a signatory to the International Mutual Recognition Agreement to carry out these tests within the requirements of the ISO/IEC EN 17025 standard. Satisfactory evidence of this shall be made available – by means of a detailed and current description on an accreditation certificate, and on the scope of the accreditation. The test laboratory shall achieve and maintain its accreditation according to this ISO/IEC EN 17025 standard with MCERTS testing included in their scope of accreditation.

4.4 Requirements for the Field Test Conditions

A number of requirements shall be satisfied for the field test conditions as outlined in Sections 3.1 and 3.2:

(i) Suitable equivalence field test sites shall be determined using at least six months of valid measurement data obtained from the reference method or from an equivalent PM monitoring where possible the appropriate PM fraction at those selected field test site(s), and shall provide PM data for a period of six months that ideally encompasses the time of the field test period.

(ii) The geometric mean(s) of the PM data obtained from a minimum of six months monitoring at the selected monitoring site(s) shall conform to the requirements of Section 3.2 (i)c and associated Table 1.

(iii) The co-location of the RMs and CMs shall be acceptable for the complete test programme. This means that RM samplers, and the CM automated instruments or manual samplers, shall be positioned in such a way in all the field tests that the spatial homogeneity of the PM concentrations in the sampled air are demonstrably good in comparison with the other uncertainty contributions present.

(iv) A minimum of four comparisons at a minimum of two different sites shall be required with emphasis on the following variables:

(a) The PM fraction should include both high and low fractions of semi-volatiles - (3.2 – 6.3) µg m^{-3} – to be recorded during the test programme either at the site, or if applicable at another relevant "regional" measurement site [Ref.6] - e.g. within 130 km.

(b) High and low atmospheric temperatures and high and low ambient dew points in atmosphere shall be present for a significant fraction of the whole

test period - ambient temperature (7.6 – 16.1) °C, and ambient dew point (3.9 – 10.8) °C - these need to be monitored during the tests at locations that are representative of the test sites.

(c) There shall be large variability in the wind speed present during a significant fraction of the whole test period (see Table 2) dependent on the height of the sampling heads and the local topography – this needs to be monitored during the tests at locations that are representative of the test sites.

(d) There should preferably be comparisons during different climatic seasons;

(e) Comparison measurements of the RMs and the CMs shall be performed at regular intervals during all the comparisons (e.g. every second day or every working week) as specified in the GDE section 9.4.2, with minimum data capture requirements for both the CMs during the test programme as specified in Section 5.2.

(v) A valid evaluation of the "PM Pollution Climate" shall be available and presented as summarised in Section 3 above [described in Ref.6]. The MCERTS certification committee shall decide whether the requirements are met for certification of the CM for the classification "MCERTS UK Particulate Matter".

(vi) The selected test sites shall be "representative of the field conditions under which the instruments are likely to operate" (Covered primarily through the PM Pollution Climate evaluation, but additional information may be available).

(vii) The scope of the equivalence claim shall be agreed and defined satisfactorily with respect to the evaluation of the PM Pollution Climate, and with respect to the selected test site locations. (In different Member States these are often selected to be a regional, national, or different site type etc.).

4.5 Requirements of the Candidate Method

The MCERTS procedure covers both automated instrumental and manual sampling PM mass monitoring methods. A range of automated measurement instruments and manual samplers employing different principles may be used to measure the mass concentration of particulate matter in ambient air. In the context of MCERTS certification for PM equivalence methods these may all be considered CMs. In general, but not necessarily, the complete measurement method consists of:

- Size-selective inlet for PM_{10} or $PM_{2.5}$. (When using an optical system with size classification of PM, a size-selective inlet may not be required.)
- Sample tube of a length needed to meet the specific sampling height requirements given in the relevant EN standard for PM;
- Analytical unit that forms the central part of the complete measurement method, or sample filter that collects the particulate matter for subsequent weighing;
- Flow meter(s);
- Temperature and pressure sensors;

- Hardware and software for data collection, storage and calculation of measurement results;
    - Auxiliary equipment that may include:
    - sample tube heaters
    - systems for (partial) drying of the sampled air
    - humidity sensors
    - hardware/software for performing compensation measurements, (i.e., measurements to compensate for unwanted effects of interferents or random variations in the PM mass determination.)

The complete type and model of the CM, and its software version, and all the auxiliary equipment, shall be documented comprehensively. The exact hardware and software setup of the CMs must be fully documented prior to testing. This must include, for example, where applicable, temperature envelopes for sample heating and cooling, slope and offset correction, sampling time, adaptive filtering of the sample signal. Any other parameters that materially affect the instrument's operation must also be comprehensively reported.

In addition, as noted above, both the CMs shall have a *minimum data capture and availability* (as specified in Section 5.2) of greater than or equal to 90% calculated for the entire set of the field tests.

4.6 Requirements for Quality Assurance and Quality Control during the Field Tests

There are a number of requirements for quality assurance (QA) and quality control (QC) that shall be satisfied, as follows:

- Requirements for QA/QC checks and calibrations shall be complete, and as given in Annex D of GDE;
- Frequency of the QA/QC checks etc. shall be the same as those intended for the operational field conditions, to the extent that it is demonstrated that no additional uncertainty terms would arise during subsequent field operation (e.g. greater drift occurs between calibrations due to longer periods between checks). Otherwise an extra uncertainty term shall be added to provide the overall uncertainty during operational field conditions, *and this then shall conform to the Directive's data quality objectives* [Ref. 1 Annex I, and Ref.3 Annex D].
- The comprehensive QA/QC procedures that are employed in all sites of the UK national network are given in [Ref. 8].
- Candidate PM manual samplers and automated instruments shall be located in such a way that any effects of spatial inhomogeneity of the PM concentrations in the sampled air are negligible in comparison with other uncertainty contributions.
- During the tests, the following information shall be collected and recorded:

- Calibration procedures, equipment and intervals;
- Results of quality checks;
- Temperature and pressure of the sampled air;
- Other conditions relevant for the measurements performed (e.g. air humidity);
- Particular events/situations that may influence measurement results.

- All calibration procedures, calibration apparatus, and results, shall be available for assessment within the MCERTS certification process, in a report with a suitable format (Section 6).

4.7 Averaging the Results of the Field Tests

The results shall be reported in units of mass of particulate matter per unit volume of air sampled at ambient conditions. This process shall be clearly and unambiguously identified by the manufacturer of the CM. All the results obtained with the CMs should be averaged over a period of 24 hours. In each comparison test (Section 4.3) a minimum of 40 valid daily data pairs shall be obtained – with a data pair representing valid results from *at least* one RM and from *both* CMs in the same 24 hour period. The data set obtained shall be processed as given in Section 5.3.

The GDE allows the use of data from one RM and one CM during the daily comparisons in exceptional circumstances on a (limited) number of days during the trials. This is not generally acceptable, and may invalidate the results, but if this occurs during a small number of days, the complete data set shall be reviewed to establish the number of occurrences of this, and to establish whether this would make any significant impact on the calculation of the between-CM uncertainty and its availability as described in Sections 5.2 and 5.3.

5. Assessment of the Results of the Field Testing Programme

5.1 Validity of the Results Obtained with the Candidate Method

The CM shall allow for the formation of daily averages. Where a 24-hour average value is based on aggregated results with a smaller averaging time, the percentage of these values available for the CM for calculating the 24-hour average result shall be at least 75%. (This 75% specification is compatible with the required percentage for aggregating available data given in Directive 2008/50/EC Annex VII.)

In case of filter changes made by a manual CM during the sampling period, this CM shall log the time and duration of these changes and ensure this data are stored permanently. The time needed for a filter change shall be determined three times in the field. This time shall not exceed 1% of each day that this occurs. (This 1% criterion is specified currently in the CEN automatic standard that is now in draft. If the final published CEN document specifies a different percentage to this then this criterion should be changed.)

This criterion of 1% is for manual PM sampling methods only. It is recognised, however, that automatic monitoring methods do not sample continuously over each hour or day, since many current types of CMs require part of the time to take, for example, blank correction or volatile fraction measurements.

5.2 Availability of the Candidate Method in the Field

The total time during the field tests in which valid measurement data of ambient air particulate concentrations are obtained is used for calculating the ***availability*** of the CM (***also known as the minimum (valid) data capture requirement –see discussion below).*** The time needed for the scheduled calibrations and maintenance (e.g. cleaning, change of consumables) shall not be included. The availability, A, shall be calculated as:

$$A = \left(t_{valid} + t_{cal,maint}\right)/t_{field} \quad (2)$$

Where:

t_{valid} = total time during which valid data have been collected during the complete field test programme – comprising four CM/RM daily comparison tests each with a minimum of forty comparisons;

$t_{cal,maint}$ = total time taken for scheduled calibrations and maintenance;

t_{field} = total duration of the field tests;

The MCERTS Performance Standard [Ref.4] has the requirements that *both* of the CMs shall have a *minimum data capture* of greater than or equal to 90% as determined using the field tests for all ***CAMs that monitor gaseous species***.

This requirement for availability/minimum data capture shall ***also apply to all equivalence field tests*** that take place after the date that this document is published – as described in Table 3. This availability/minimum data capture shall be evaluated during the MCERTS certification process, and reported on the MCERTS certificate.

It should be recognised that this numerical value of 90% is also specified in Directive 2008/50/EC Annex 1, as a ***minimum data capture requirement*** and is one of the Directive's data quality objectives for *each year's operational data* when monitoring both PM and gaseous species. Therefore the 90% minimum data capture requirement specified in this document for PM, over the complete equivalence field test programme, serves as a surrogate for the (annual) requirement in the Directive.

5.3 Uncertainty between the Candidate Methods in the Field

The between-CM uncertainty, u_{bs}, shall be calculated from the differences of all the 24-hour results of the two candidate instruments operated in parallel as:

$$u_{bs}^2 = \frac{\sum_{i=1}^{n} (y_{i,1} - y_{i,2})^2}{2n} \qquad (3)$$

Where:

$y_{i,1}$ and $y_{i,2}$ are the results of the parallel measurements of the two CMs for the single i^{th} 24-hour period;

n = number of 24-hour measurement results.

The between-CM uncertainty shall then be determined for:

- All the results together;
- Separately for the two datasets obtained by splitting the full dataset for each of the complete sets of PM_{10} or $PM_{2.5}$ results according to PM concentrations into two ranges: of greater than or equal to 30 $\mu g.m^{-3}$ for PM_{10} and of less than this, and concentrations greater than or equal to 18 $\mu g.m^{-3}$ for $PM_{2.5}$ and less than this.
- Taking account of the uncertainty of any regional instrument when this is being used (Section 4.2)

A between-CM uncertainty of >2.5 $\mu g.m^{-3}$ for *any* of these datasets is a demonstration of the unsuitable performance of one or both of the CM instruments. Approval for equivalence shall not be granted for the CM when the criterion of $\leq$ 2.5 $\mu g.m^{-3}$ is not satisfied for both the CMs tested.

The type of sample head and the flow rates used in the CMs during the testing programme shall be reported and included on the MCERTS certificate.

5.4 Performance of the Reference Method in the Field

Two RMs shall in general be operated alongside the two CMs during the entire equivalence-testing programme (as specified in Sections 4.2 & 4.6).

Where there is an automatic filter changer that forms part of the operation of the RM, the times of this shall be logged for review after the field tests for quality control purposes.

The between-RM uncertainty $u_{bs,RM}$ shall be calculated from the differences of all 24-hour results of the RMs operated in parallel using:

$$u_{bs,RM}^2 = \frac{\sum_{i=1}^{n}\left(y_{i,1} - y_{i,2}\right)^2}{2n} \quad (4)$$

Where:

$y_{i,1}$ and $y_{i,2}$ are the results of parallel measurements for the i^{th} single 24-hour period;

n = number of 24-hour measurement results.

The between-RM uncertainties shall be determined for all the results together.

A between-RM uncertainty of >2.0 $\mu g.m^{-3}$ for the dataset is an indication of unsuitable performance of one or both of the RMs during the testing. In this case, the data may be evaluated so as to remove outliers (Section 5.5.1), providing that this does not reduce the data sets to fewer than 40 per comparison.

5.5 Assessment of Equivalence Testing Datasets

5.5.1 Suitability of the complete dataset

- During each equivalence field testing comparison of 40 days or more, between the two RMs and the two collocated CMs, valid comparative measurement results shall be collected, and each averaged over 24 hours.
- At least 20% of the full dataset of results obtained using the standard method shall be greater than the upper assessment threshold for the annual limit values [as specified in Ref.1 Annex II].
- There shall be a minimum of four sets of comparisons at a minimum of two sites, each containing a minimum of 40 paired results, for both of the candidate methods.
- Paired RM and CM results may be removed/discarded from the complete dataset – *all results shall be presented to show those that have been discarded, and these removals shall be justified with sound technical reasons.*

- Results for the RM may be removed as statistical outliers – where they shall be removed using one Grubb's test on the individual single-period variances, with the outlier test at the 99% confidence level for a large set of data points [Ref.3 Section 9.5.1]. This often identifies more than 2.5% of the results as outliers, depending on the repeatability of the dataset. In this case the outliers removed shall not exceed 2.5%. When this process removes more than 2.5% of the data pairs, *then the results shall not be valid.*
- 40 (valid) measurement-paired results shall ***remain*** in each comparison for both CMs, after the removal of paired data by Grubb's tests etc. – *where less than 40 measurement pairs remain, the data shall not be valid.*
- Greater than or equal to 20% of the ***remaining paired results*** of the full dataset shall be greater than the upper assessment thresholds for the annual limit values [as specified in Ref.1 Annex II], and as measured by the collocated reference method, for the data to be valid.

5.5.2 Procedures for evaluating the resultant datasets

Where the RM and the CM are fully equivalent, the relationship between the results of both methods is described by a linear relation $y_i = x_i$. However, since the measurands of both methods are usually different, it is assumed that the relationship between measurement results of the CM and the RM can be described by a linear relation of the form:

$$y_i = a + bx_i \tag{5}$$

Where:

y_i = the result of a CM for an individual 24-hour period *i* (in µg/m^3 at ambient air conditions)

x_i = the (average) result of the two RMs for the same individual 24-hour period *i* (expressed in µg/m^3 at ambient air conditions)

a, b = calculated constants for the intercept and slope of the linear relationship.

The relationship between the results of the two CMs *and the average results of the two RMs* shall be established ***for each of the CMs individually*** *using a regression technique that leads to a symmetrical treatment of both variables.* A commonly applied technique is orthogonal regression.

Validated software algorithms that use orthogonal (or nonlinear least squares) regression are publicly available, and are produced by a number of different organisations:

(i) An algorithm (known as "BLeast"), has been developed for use in certain scientific calculations for the International Standardization Organisation. This is made available by the VDI /DIN organisation in Germany.

(ii) An algorithm known as XGENLINE has been developed and validated by the National Physical Laboratory (NPL) in the UK, and has been applied to a range of scientific calculations in the physical and chemical sciences. This is available from the NPL website.

(iii) Algorithms for the calculation of the regression coefficients and their variances are also given in Annex B of the GDE.

(iv) An algorithm has been developed *specifically for the determinations required for equation 5 of this document, and it is available from the EC website given in Ref.15.*

It is advisable that the last algorithm be used for these calculations since this has been developed and validated for this particular application. This will be used by a number of Member States and thus should provide comparable results. If any of the other algorithms are used care should be taken to check if these provide identical results to that of the spreadsheet given in Ref.15, although all these algorithms have been validated for a range of applications

The relationship of equation (5) shall be established using orthogonal regression separately for:

- All the results together
- Datasets representing PM concentrations greater than or equal to 30 µg.m^{-3} for PM_{10}, or concentrations greater than or equal to 18 µg.m^{-3} for $PM_{2.5}$, provided that the subset contains 40 or more valid data pairs;
- The data sets at each individual site.
- The procedure shall be applied separately for each specific situation for which a specific equivalence claim is made (e.g. for specific site types)

For each dataset for each CM, the following ***two criteria for acceptance of the calibration function of the CM shall apply:***

- The slope b is insignificantly different from 1: $|b - 1| \leq 2 \cdot u_b$ (6)
- The intercept a is insignificantly different from 0: $|a| \leq 2 \cdot u_a$ (7)

Where:

u_b = the standard uncertainty of the slope *b*, calculated as the square root of its variance;

u_a = the standard uncertainty of the intercept *a*, calculated as the square root of its variance.

Where these preconditions have not been met, the CMs may be calibrated using the values for the slope and/or intercept obtained as above (see Clause 9.7 of the GDE for the specific procedure and also the GDE Annex B). The values used for this calibration shall be the slope and/or the intercept of the *complete paired dataset.*

5.5.3 Methods for determining uncertainty of the candidate method

As specified above, the results from comparisons of the CMs with the average results from the RMs may be satisfactory without recalibration. In this case the measurement uncertainty of the results u_{CR} as a function of x_i obtained for the each CM shall be calculated separately as given in Section 5.5.3.1.

In the other cases, where a correction for the intercept, slope, or for both of these, is required as stated in Equations 6 & 7 above, the procedures for calculating the measurement uncertainty, u_{CR} as a function of x_i, shall be carried out as given in Sections 5.5.3.2, 5.5.3.3 ***or*** 5.5.3.4 respectively.

Then, in each case, the combined relative uncertainty of the candidate method, $\mathbf{w_{CM}}$ shall be calculated from the relevant u_{CR} according to Section 5.5.3.5 below.

5.5.3.1 No correction for slope and/or intercept

For the evaluation of the uncertainty of the results of the CM, $\boldsymbol{u_{CR}}$ as a function of x_i, the following relationship shall be used where no correction for the intercept (a) OR slope (b) is applied.

$$u_{CR}^2(y_i) = \frac{RSS}{(n-2)} - u^2(x_i) + [a + (b-1)x_i]^2 \qquad (8)$$

Where:

$u_{CR}(y_i)$ = the uncertainty of the CM measurement result y_i

RSS = the sum of the relative residuals resulting from the orthogonal regression

n = the number of data pairs used for the regression

$u(x_i)$ = random uncertainty of the reference method - the between-instrument uncertainty for the application of the reference method in these tests shall be used.

$u(x_i)$ shall be taken as $u_{bs,RM}/\sqrt{2}$ (Eq.4) wherever two co-located reference samplers have been used.

In other (exceptional) cases where two collocated RMs are not used, e.g. when information is used from experiments performed by other networks or laboratories, a value for $u^2(x_i)$ of 0.67 $(\mu g.m^{-3})^2$ shall be used by default - *but see Section 4.3.*

The sum of the (relative) residuals, *RSS,* required for Eq. 7 above shall be calculated as:

$$RSS = \sum_{i=1}^{n} (y_i - a - bx_i)^2 \quad (9)$$

5.5.3.2 Correction for intercept

In this case, the value of intercept a may be used as a term to recalculate all input values y_i derived from the complete data set obtained by combining all the results of the CM, as follows:

$$y_{i,cal} = y_i - a \quad (10)$$

The resulting values of $y_{i,cal}$ shall then be used to calculate (Eq.5 above) a new relationship by linear regression to form:

$$y_{i,cal} = c + dx_i \quad (11)$$

Once the calibration function has been corrected for the intercept (a) being significantly different from 0, then the following relationship shall be used for the evaluation of the uncertainty of the results of the CM:

$$u_{CR}^2(y_{i,cal}) = \frac{RSS}{(n-2)} - u^2(x_i) + [c + (d-1)x_i]^2 + u^2(a) \quad (12)$$

Where:

$u_{CR}^2(y_{i,cal})$ = the uncertainty of the CM measurement result y_i obtained after correction (GDE Annex B)

c, d = new regression coefficients obtained after correction is applied (GDE Annex B).

$u(x_i)$ = random uncertainty of the reference method: the between-instrument uncertainty for the application of the reference method in these tests shall be used.

$u(x_i)$ shall be taken as $u_{bs,RM}/\sqrt{2}$ (Eq.4) wherever two co-located reference samplers have been used.

In other (exceptional) cases where two collocated RMs are not used, e.g. when information is used from experiments performed by other networks or laboratories, a value for $u^2(x_i)$ of 0.67 $(\mu g.m^{-3})^2$ shall be used by default - *but see Section 4.3.*

The RSS used for Eq. 12 shall be calculated as:

$$RSS = \sum_{i=1}^{n} (y_i - c - dx_i)^2 \quad (13)$$

5.5.3.3 Correction for slope

When the calibration function needs to be corrected for a slope (b) significantly different from 1, the value of slope (b) shall be used as a term to recalculate all input values y_i as follows:

$$y_{i,cal} = \frac{y_i}{b} \tag{14}$$

The resulting values of $y_{i,cal}$ shall then be used to re-calculate by linear regression (Eq. 5) a new relationship to form:

$$y_{i,cal} = c + dx_i \tag{15}$$

The resulting values of $y_{i,cal}$ may then be used to perform a new linear regression to calculate $u_{CR}^2(y_{i,cal})$ as:

$$u_{CR}^2(y_{i,cal}) = \frac{RSS}{(n-2)} - u^2(x_i) + [c + (d-1)x_i]^2 + x_i^2 \cdot u^2(b) \tag{16}$$

where u(b) is the uncertainty of the original slope b, the value of which has been used to obtain $y_{i,cal}$ (see GDE Annex B for calculation of u(b)).

$u(x_i)$ shall be taken as $u_{bs,RM}/\sqrt{2}$ (Eq.4) wherever two co-located reference samplers have been used.

In other (exceptional) cases where two collocated RMs are not used, e.g. when information is used from experiments performed by other networks or laboratories, a value for $u^2(x_i)$ of 0.67 $(\mu g.m^{-3})^2$ shall be used by default - *but see Section 4.3.*

The RSS shall be calculated using Eq. 13.

Alternatively, *in this case*, the calibration may be performed by applying orthogonal regression forced through the origin (0,0) to the original data, the resulting equation being $y_i = bx_i$.

Algorithms for the performance of orthogonal regression forced through the origin (0,0) are given in GDE Annex B. Equations 14, 15, and 16 then reduce to

$$y_{i,cal} = dx_i \tag{17}$$

$$RSS = \sum_{i=1}^{n} (y_i - dx_i)^2 \tag{18}$$

$$u_{CR}^2(y_{i,cal}) = \frac{RSS}{(n-2)} - u^2(x_i) + [(d-1)x_i]^2 + x_i^2 \cdot u^2(b) \tag{19}$$

5.5.3.4 Correction for slope and intercept

In this case, the values of the slope b and the intercept a may be used to recalculate all input values y_i as follows:

$$y_{i,cal} = \frac{y_i - a}{b} \tag{20}$$

The resulting values of $y_{i,cal}$ may then be used to perform a new linear regression to calculate $u_{CR}^2(y_{i,cal})$ as:

$$u_{CR}^2(y_{i,cal}) = \frac{RSS}{(n-2)} - u^2(x_i) + [c + (d-1)x_i]^2 + x_i^2 \cdot u^2(b) + u^2(a) \tag{21}$$

Where:

$u(b)$is the uncertainty of the original slope b, the value of which has been used to obtain $y_{i,cal}$ (see GDE Annex B for calculation of $u(b)$);

$u(a)$ is the uncertainty of the original intercept a, the value of which has been used to obtain $y_{i,cal}$ [see Annex C of Ref.3 for calculation of $u(a)$].

$u(x_i)$ shall be taken as $u_{bs,RM}/\sqrt{2}$ (Eq.4) wherever two co-located reference samplers have been used.

In other (exceptional) cases where two collocated RMs are not used, e.g. when information is used from experiments performed by other networks or laboratories, a value for $u^2(x_i)$ of 0.67 $(\mu g.m^{-3})^2$ shall be used by default - *but see Section 4.3.*

RSS used for Eq.21 shall be calculated using Eq. (13).

Equation 21 is in fact a simplification, since it does not include any covariance between slope and intercept. The resulting uncertainty from this equation may be higher than when a covariance term is included, but the above equation shall be used for the purpose of determining equivalence.

5.5.3.5 Relative standard uncertainty determined for the candidate method

For the full dataset calibrated for slope and/or intercept as carried out by the test laboratory, the combined relative uncertainty of the CM at the relevant limit value shall be calculated by:

$$w_{c,CM,cal}^2 = \frac{u_{CR}^2(y_{i,cal})}{y_i^2} \tag{22}$$

Where $u_{CR}^2(y_{i,cal})$ is that which shall be determined at the relevant limit value.

For PM_{10} the value of the daily limit value (50 µg m^{-3}) shall be used. For $PM_{2.5}$ a (surrogate) value of 30 µg m^{-3} shall be used. The national Competent Authority is permitted to require the use of a lower value of this surrogate daily limit value for $PM_{2.5}$.

The appropriate value that shall be used for $u_{CR}(y)$ depends on which of the corrections for slope and/or intercept values being significantly different from 1, or 0 respectively have been applied by the test laboratory, and Sections 5.5.3.1 to 5.5.3.4 (Eqs. 8, 12, 16, 19, or 21, respectively give the appropriate equations for each case).

5.5.3.6 Expanded uncertainty of the candidate method

For each of the datasets the expanded relative uncertainty of the results of the candidate method is calculated by multiplying $\mathbf{w}_{CM}$ by a coverage factor [Ref.10 - generally k=2] reflecting the appropriate number of degrees of freedom resulting from the determination of $w_{c,CM}$ at the appropriate limit value as:

$$W_{CM} = k \cdot w_{CM} \tag{23}$$

5.6 Evaluating the Results of the Complete Field Testing Programme

The highest resulting uncertainty estimate $\mathbf{W_{CM}}$ arising from both candidate instruments is compared with the expanded relative uncertainty based on the data quality objective for the reference method, $\mathbf{W_{dqo}}$.

One of two cases is possible:

(i) $\mathbf{W_{CM} \leq W_{dqo}}$: the candidate method is accepted as equivalent to the reference method;

(ii) $\mathbf{W_{CM} > W_{dqo}}$: the candidate method is not accepted as equivalent method.

6. Reporting Requirements

Reports on the Demonstration of Equivalence submitted to the national Competent Authority and to the European Commission should contain – at a minimum – the following information.

Title of the method

Executive summary

General information

1. A summary of the principles of the candidate method; the full Standard Operating Procedure of the method, including a description of ongoing QA/QC, shall be annexed.
2. The scope of equivalence testing, i.e., the differences between the candidate method and the reference method that require specific tests to be performed.
3. A description of the conditions for which equivalence with the reference method is claimed, e.g., concentration range, environmental conditions, type of location with reference to UK PM Pollution Climate.
4. Sources of uncertainty data for unchanged parts of the EN standards enacting the reference method, where relevant.
5. Names of the laboratories involved in the test programme(s) and the scope of their relevant competences, e.g., EN IEC/ISO 17025 accreditation.

Laboratory test programme *(as applicable)*

6. All the parameters tested in the laboratory programme with any options selected, as specified in Section 4.2.
7. A description of the test procedures used, including procedures for the establishment and maintenance of measurement traceability where relevant, and procedures for quality control and quality assurance.
8. The test results, the results of the uncertainty assessment, and the results of their comparison with the relevant data quality objectives including uncertainty or, in the absence of data quality objectives, the results of the comparison between candidate method and reference method.

Field equivalence test programme

9. Full description of the test locations, test periods and conditions (e.g. temperature, humidity, wind velocity, concentration level)
10. A description of the equipment and test procedures used, including procedures for the establishment and maintenance of measurement traceability where relevant, and procedures for quality control and quality assurance.
11. The determination of the availability and data capture percentage of both the CMs (to be reported on the MCERTS certificate)
12. The test results, the results of the uncertainty assessment, and the results of their comparison with the relevant data quality objectives including uncertainty, or, in the

absence of data quality objectives, the results of the comparison between candidate method and reference method.

13. Where relevant, explanation regarding the decision (and approval by the MCERTS certification committee) to use only one RM. Further reporting requirements on this matter are set out in point (iv) in section 4.3.
14. Where relevant, reasons for any decision to undertake less than two equivalence field tests in the UK after this document is published. Further reporting requirements on this matter are set out in point (xiii) in section 4.3.

Particulate Matter Pollution Climate evaluation

15. A report of any PM Pollution Climate assessment study that has been carried out, where available and applicable to the UK PM climate.

Conclusions

16. Results of the overall testing of the performance of the candidate method as compared to the data quality objectives specified in the relevant EU Directive.
17. The overall conclusion about the equivalence including restrictions, if any, in the conditions under which the claim to equivalence is valid or generalizations of the equivalence claim to other relevant conditions. Relevant conditions include concentration ranges, meteorological conditions, geographical locations and/or type(s) of monitoring sites.

7. References

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Reference 2: European Committee for Standardization http://www.cen.eu/cen/products/en/pages/default.aspx

Reference 3: Guide to the Demonstration of Equivalence of Ambient Air Monitoring Methods, Report by an EC Working Group on Guidance for the Demonstration of Equivalence, January 2010 http://ec.europa.eu/environment/air/quality/legislation/assessment.htm

Reference 4: MCERTS Performance Standards for Ambient Air Quality Monitoring Systems, Environment Agency, Version 8, June 2012

Reference 5: A Guide to the Certification of Products under the Environment Agency's MCERTS Scheme, Form 1177, July 2006 http://www.siraenvironmental.com/UserDocs/mcerts%20prod%20cert/Form 1177.pdf

Reference 6: Characterising the PM climate in the UK for Equivalence Testing, D Green & G Fuller, King's College London Environmental Research Group, June 2012

Reference 7: Development and validation of the volatile correction model for PM_{10} - An empirical method for adjusting TEOM measurements for their loss of volatile particulate matter, D. C Green, G. W. Fuller et al, Atmospheric Environment, 43, 2132 – 2141, 2009

Reference 8: QA/QC Procedures for the UK automatic Urban and Rural Air Quality Monitoring Network, Report AEAT/ENV/R/2837, September 2009 http://uk-air.defra.gov.uk/reports/cat13/0910081142_AURN_QA_QC_Manual_Sep_09_FINAL.pdf

Reference 9: National Air Quality Reference Laboratories and the European Network – AQUILA: Roles and Requirements for Traceability, Accreditation, Quality Assurance/Quality Control, and Measurement Comparisons, at National and European Levels, December 2009 http://ec.europa.eu/environment/air/quality/legislation/pdf/aquila.pdf

Reference 10: Guide to the Expression of Uncertainty of Measurement (GUM): International Standardisation Organisation 1993

Reference 11: International vocabulary of metrology – basic and general concept and associated terms (international vocabulary of basic and general terms VIM) - Joint Committee for Guides in Metrology, JCGM 200:2008 (E/F)

Reference 12: Performance criteria for performance tests of automated ambient air measuring systems - Point-related measurement methods for gaseous and particulate air pollutants, Verein Deutscher Ingenieure, VDI RichtLinien VDI 4202-1, September 2010

Reference 13: Testing of automated measuring systems - Test procedures for point-related ambient air measuring systems for gaseous and particulate air pollutants, Verein Deutscher Ingenieure, VDI RichtLinien VDI 4203-3, September 2010

Reference 14: Ambient air quality –Automated continuous systems for the measurement of the concentration of particulate matter (PM_{10} , $PM_{2.5}$) , WD AMS PM, CEN TC 264 WG15 N524, December 2011.

Reference 15: EC DG Environment website covering "equivalence" - spreadsheet "test the equivalence (xls)"- developed by RIVM the Netherlands http://ec.europa.eu/environment/air/quality/legislation/assessment.htm

Reference 16: Field assessment of the dynamics of particulate nitrate vaporization using differential TEOM and automated nitrate monitors, S. Hering et al., Atmospheric Environment, 38, 5183–5192, 2004;

8. Checklist for Assessing the Acceptability of an Equivalence-testing Programme for Automated and Manual Ambient Air Particulate Methods for Conformance with the Requirements of MCERTS for the UK PM Pollution Climate

(i) Applicant's Details

Manufacturer of the automated particulate method (including name and address)	
Is the above manufacturer requiring the equivalence testing or does the manufacturer have an agent? If agent give the name and address.	
Contact name at manufacturer or manufacturer's agent	
Telephone number of contact name	
Description of automated PM method (model, serial numbers, software details etc)	
All the initial stages of the MCERTS Certification process shall have been completed satisfactorily – summarised in Section 4.1;	

(ii) Details of the Test Laboratory or Test Laboratories Employed

Name of Company	
Address	
Contact Name	
Telephone number of Contact	
Email address of Contact	
Dates tests were carried out	
Test Laboratory Report number and date	
Laboratory tests shall be carried out - According to MCERTS Standard Sections 6.5–6.6? Or to VDI/DIN Germany requirements?	

(iii) General Requirements of the Equivalence Testing

Relevant clause of this document (& GDE)	Requirement	Comments: including location of the relevant information in the Equivalence Test Report, and its acceptability
4.3(i)	All decisions by the Competent Authority with regards to the declaration of equivalence after June 2010 shall meet all the requirements of this document, with concessions in Section 3.3.	
4.3(ii) (& GDE 9.4.1)	Where the CM is a limited modification of an existing CEN reference method the appropriate sub-set of tests shall be carried out completely and satisfactorily.	
4.3(iii)	Where the CM is a modification of an existing equivalent method, the test requirements shall have been specified and agreed with the UK Competent Authority. The tests shall been carried out satisfactorily in conformance with all the specifications, by a laboratory accredited to ISO/IEC EN 17025.	
4.3(iv) (& GDE 9.3)	Two RMs shall be used at all test sites – see 4.2 (iv),, 4.2 (v), & 4.3(iii).	
4.3(v)	The RMs shall be of the specified type given in the relevant CEN standard. The gravimetric analyses of the samples in the laboratory shall be applied completely as specified in that standard.	
4.3(vi)	Two complete CMs of the same type shall be used, and they shall be clearly and uniquely identified as such;	
4.3(vi) (& GDE 9.2)	The sample head of the CM shall be as specified in the relevant CEN standard. If not the complete details of the CM sample head shall be documented as specified in Section 4.2.	
4.3(vii)	The two (local) CMs shall be co-located satisfactorily with respect to each other and with respect to the adjacent RMs to sample the ambient air homogeneously	
4.3(viii) (& GDE 9.1, & 9.4)	Where a "regional" instrument is used with two local CMs in the test programme, their results shall be applied correctly, and their measurement uncertainties calculated correctly.	
4.3(ix) & 4.6 (GDE 9.4.3)	Acceptable QA/QC checks shall be carried out during the test programme as specified in GDE Annex D for CMs, and in EN12341 or EN14907 for RMs.	

4.3(x) & 5.5.1	All the test results for the 2 RMs and the 2 CMs shall be documented completely - including all results that are rejected as outliers or otherwise discarded.	
4.3(xi) & 5.2	Both CMs shall have a minimum data capture and availability of greater or equal to 90%, as determined in Section 5.2, where tests begin after this Document enters into force (see also Section 3.3).	
4.3(xiii), &(xiv)	Where a test laboratory within a European Member State other than the UK produces the test report, at least two sets of valid 40 tests shall be carried out in that Member State at suitable sites. Where only one set of valid (40) equivalence field tests is to be carried out in the UK, there shall be at least three equivalence tests carried out in the other Member State. Where tests are begun before the date of publication of this document there shall be one or more tests carried out in the UK. Where tests are carried out that begin after the date of publication of this document, there shall be at least two tests carried out in the UK. The UK tests shall be carried out at one or more locations in the UK - selected with respect to the UK pollution climate evaluation, and at different seasons - The test laboratories shall be accredited to the ISO/IEC 17025 standard for all the MCERTS tests;	

(iv) Requirements of the Test Conditions

4.4(i)	The equivalence test sites shall be demonstrated to be representative of the UK's PM pollution climate. This shall be done using at least six months, and preferably twelve months of reference method, or equivalent method, PM measurement data. This should ideally be done in a period of time that encompasses the field test period and be co-located with the field test. If either of these is not available, then data from another time period, preferably within the two years previous to the field trial and/or data from an alternative monitoring location, similar in type to the field test site (e.g. urban background, traffic, rural) and in the close proximity to the field test site may be used as the basis for the assessment (see Section 3.2). The individual components that make up the successful demonstration of the pollution climate are listed below:	

4.4(ii)	The geometric mean(s) of the PM data (PM_{10} and/or $PM_{2.5}$) obtained from a minimum of six months of monitoring, shall conform to the requirements of Section 3.2	
4.4(iii)	The collocations of the RMs and the CMs shall be acceptable in terms of minimising the spatial inhomogeneity and differences in the PM content of the air sampled by all the methods.	
4.4(iv)	There shall be a minimum of four valid comparisons at a minimum of two sites if all the tests are all carried out in the UK.	
4.4(iv)	There shall be evidence that the sampled PM fractions have both high and low fractions of semi-volatiles during specified periods of the test programme	
4.4(iv)	There shall be evidence that the measurements were taken at both high and low ambient atmospheric temperatures and high and low relative humidity during specified times of the complete test programme.	
4.4(iv)	There shall be evidence that the measurements were taken at both high and low wind-speed conditions during specified times of the complete test programme.	
4.4(iv)	The comparisons should be carried out during different UK climatic conditions;	
4.4(iv)	The individual comparative results from both the RMs and CMs shall be taken at regular intervals during all the comparisons;	
4.4(v)	There shall be a comprehensive and valid evaluation of the UK "PM pollution climate" carried out as summarised in Section 3.2, utilising all the components listed above in this Section	
4.4(vi)	From the above and other indicators the selected equivalence test sites shall be "representative of the field conditions under which the CMs are likely to operate"	
4.4(vii)	The scope of the equivalence claim shall be defined satisfactorily with respect to the evaluation of the PM climate and with respect to the type of the selected test sites (national, regional, station type, etc)	

(v) Requirements of the Candidate Method

4.5	The complete type and model number of the CM and type of sampling head, including all its functional parts, its sensors, its software version etc, shall be documented comprehensively so that the two CMs are uniquely identified. The type and all the characteristics of the CM shall be listed on the MCERTS certificate.	

4.6	There shall be a complete and comprehensive QA/QC programme for the CMs and the RMs throughout the field test programme (see also Checklist 7 below)	
4.7 & 5.1	All the results of the field test programme shall be documented and reported in units of mass of particulate per unit volume of air sampled at ambient conditions. The results of the CMs shall be averaged correctly over each 24 hour period, to provide at least 40 data set pairs of RM and concurrent CM data for the two RMs and the two CMs, as specified in Section 4.6. Where the CM results are based on aggregated results of smaller averaging times the percentage of these values available for calculating the 24-hour average shall be at least 75%.	
5.1	In the case of filter changes that form part of the operations of a *manual* CM, The times of these changes shall be logged permanently by the CM. The time during which the filter is changed shall be limited to less than 1% of each 24 hour period (This 1% criterion is specified currently in the CEN automatic standard that is now a draft. If the final published CEN document specifies a different percentage to this then this criterion should be changed.)	
5.2	The availability (data capture) of the two CMs shall be separately evaluated as given by Eq.2, Section 5.2, for all tests that are carried out in or after 2012. This shall be included in the test report and in the MCERTS test certificate, with the acceptance criterion of 90%.	
5.3	The between-candidate method standard uncertainty defined in equation 3 of Section 5.3 shall be determined (after all the results have been evaluated and any removed or discarded as specified in Section 5.5.1 to define the complete set of *valid* results. These shall be ≥ 40 valid results per comparison trial or data is unsuitable.) : - For all the *valid* results of the (minimum) four comparisons in the total dataset together; - Separately for the two datasets obtained by splitting the full dataset according to their concentrations as given in section 5.3.3;	
5.3	The between-CM uncertainty of ≤ 2.5 µg m^{-3} shall be satisfied for both instruments and for the two datasets listed above.	

(vi) Requirements of the Reference Method

4.3(iv) & 5.4	The complete type and model number of the RM and the type of sampling head, including all its functional parts, its sensors, its software version etc (where relevant), shall be documented comprehensively so that the two RMs are uniquely identified. The type of subsequent laboratory analyses of the gravimetric filters shall be documented and shall comply with all the requirements of the relevant CEN standard - to be quoted;	
5.4 & 4.3(iv)	Two RMs shall generally be used throughout the complete test programme. If not the reason for this shall be justified comprehensively. Where only one RM is used this shall be accounted for in the evaluation of the uncertainty of the CM – see Section 5.5.3.1	
5.1	In the case of filter changes that form part of the operations of the RM, the times of these changes shall be logged by the RM.	
5.4	The between RM standard uncertainty defined in Eq. 3 of Section 5.4 shall be determined: - After all the results have been evaluated and removed or discarded as specified in Section 5.5.1 to define the complete set of remaining *valid* results – This shall be ≥ 40 valid results per comparison trial or the data is unsuitable. - For all the *valid* results of the (minimum 4 comparisons) in the total dataset together, then:	
5.4	The between RM uncertainty of ≤ 2.0 $\mu g.m^{-3}$ shall be satisfied for both RMs, across the complete data set.	

(vii) Requirements of the QA/QC Programme

4.6	The requirements of the GDE Annex D for calibrations and quality control checks shall be met during the complete filed test programme	
4.6	The requirements for, and the frequency of, QA/QC checks shall in addition be the same as those intended for operational field conditions to the extent that it is demonstrated that no additional significant uncertainty terms would arise during those subsequent field operations. Otherwise an additional uncertainty term shall be added.	
4.6	All the information listed in Section 4.6 shall be recorded during the entire field test programme and shall be made available for assessment within the MCERTS certification process, in a report in a format given in Section 6.	

(viii) Assessment of the Suitability of the Results Obtained

5.5.1	There shall be a minimum of four sets of data from comparisons between the RMs and both the CMs at a minimum of two sites, each containing a minimum of 40 paired results – If not the datasets are unacceptable;	
5.5.1	Paired results may be removed from the complete data set. If so, the removed results shall be tabulated and the removals shall be justified on sound technical grounds.	
5.5.1	Further results may be removed as statistical outliers. – if so, they shall be removed using only one Grubb's test with an outlier test at the 99% level; This shall not remove more than 2.5% of the data pairs – If more, the results are invalid;	
5.5.1	There shall be 40 (valid) measurement paired results *remaining* in each comparison for both CMs - after removal of the paired data by Grubb's tests etc.	
5.5.1	≥20% of the remaining paired results of the full dataset shall have greater than the prescribed PM concentrations as determined by the collocated RM.	

(ix) Assessment of the Procedure used to Evaluate the Resultant Final Data Sets

5.5.2	The results of all the paired data obtained, after carrying out the procedure in Section 5.5.1, shall be processed assuming a linear relationship between CM and RM of the form given in eq.4, using a regression technique that leads to a symmetrical treatment of both the variables (e.g. generalised least squares or orthogonal regression), which shall be derived from a recognised and validated source of the regression technique	
5.5.2	The results above shall be processed using the average results of the two RMs, and regressions shall be established for each of the CMs individually;	
5.5.2	The above results shall be processed (i) all together and (ii) in datasets with concentrations greater than or equal to 30 µg m^{-3} for PM_{10} or equal to or greater than 18 µg m^{-3} for $PM_{2.5}$, and (iii) datasets at each individual site where testing was performed to produce valid datasets and (iv) separately for each individual site type if applicable.	
5.5.2	For each of the datasets, for each CM, the criteria for the acceptance of the calibration function between the average of the RM results and the CM results shall conform to the requirements of Eqs. 5 and 6. If these criteria are met the calculations in Sections 5.5.3.1 and 5.5.3.5 shall be applied. If these criteria are not met, the CM may be calibrated as below, and in Section 5.5.3.	

(x) Evaluation of the Method Used to Determine the Uncertainty of the Results of the CM

5.5.3.1	No correction for the slope or intercept has been applied as specified in Table ix above, and Eq. 8 shall be applied for the evaluation of the uncertainty of the results of both the CMs.	
5.5.3.2	A valid correction for the intercept has been applied as given in Table ix above, and Eq.12 shall be applied for the evaluation of the uncertainty of the results of both the CMs.	
5.5.3.3	A valid correction for the slope has been applied as given in Table ix above, and Eq.16 shall be applied for the evaluation of the uncertainty of the results of both the CMs.	
5.5.3.4	Corrections for both the slope or intercept has been applied as given in Table ix above, and Eq.21 shall be applied for the evaluation of the uncertainty of the results of both the CMs.	
5.5.3.5	In all the above cases the correct values for the uncertainty of the RM, $u(x_i)$ shall be used as specified in Section 5.5.3.1 as $\mathbf{u_{bs,RM}/\sqrt{2}}$ (Eq.3)	

(xi) The Overall Relative Measurement Uncertainty Assignment of the CM

5.5.3.5	The relative standard measurement uncertainty of both the CMs shall be calculated using Eq.22	
5.5.3.5	The calculation of Eq.22 shall be carried out using the full dataset.	
5.5.3.5	The $u_{CR}(y_i)$ or $u_{CR}(y_{i,cal})$ values as appropriate used in the equation shall be those at the limit value – where this limit value is 50 µg m^{-3} for PM_{10}, and 30 µg m^{-3} for $PM_{2.5}$ (unless the Competent Authority has specified a different value for $PM_{2.5}$).	
5.5.3.5	The $u_{CR}(y_i)$ or $u_{CR}(y_{i,cal})$ values as appropriate used in the equation shall be those that are derived using the calculation procedure in *one* of the Sections 5.5.3.1 – 5.5.3.4, where either no corrections, correction to slope or intercept, or corrections to slope and intercept corrections, have been applied to this full dataset	
5.5.3.5	One or more additional terms for measurement uncertainty shall be applied if the QA/QC activities carried out during the equivalence field tests are more stringent than those than will be applied when the method is operated in a network (GDE Section 9.5.4)	
5.5.3.6	All the values obtained for $u_{CR}(y_i)$ or $u_{CR}(y_{i,cal})$ **whichever is applicable,** shall be multiplied by and appropriate coverage factor (k) to provide values for the expanded uncertainty, $\mathbf{W_{CM}}$, of the CM results, expressed at a 95% confidence level;	

(xii) The Overall Measurement Uncertainty Calculated for the CM with Respect to the Requirements of the Directive

5.6	The highest of the expanded uncertainty estimates $\mathbf{W_{CM}}$ arising from both CMs shall be compared with the expanded relative uncertainty stated as the data quality objective, $\mathbf{W_{dqo}}$, in Directive 2008/50/EC;	
5.6	One of two cases shall be determined: (i) $\mathbf{W_{CM} \leq W_{dqo}}$ then the CM is accepted as equivalent to the RM; (ii) $\mathbf{W_{CM} > W_{dqo}}$ then the CM is not accepted as equivalent to the RM;	