Certification Report and Checklist on the Evaluation of the Ambient Air Particulate Matter Test Reports Submitted for Approval and Certification within the MCERTS Scheme for UK Particulate Matter

Evaluation with Respect to:
MCERTS Performance Standards for Ambient Air Quality Monitoring Systems and its Annex:
Requirements of the UK Competent Authority for the Equivalence Testing and Certification of Automated Continuous Methods and Manual Discontinuous Methods that Monitor Particulate Matter in Ambient Air

Instrument Manufacturer:	Thermo Fisher Scientific, 27 Forge Parkway, Franklin, Massachusetts, 02038, USA
Type of Instrument Evaluated:	Partisol™ Plus 2025 Sequential Ambient Particulate Sampler with $PM_{2.5}$ pre-separator
Report prepared by:	Certification Committee for MCERTS Performance Standard for Automated Continuous Methods and Manual Discontinuous Methods that Monitor Particulate Matter in Ambient Air
Report number:	MCERTSCCPMT3TFS140514/V3
Date of certification committee Report:	March 2015

Published by SIRA

CONTENTS

This page is left blank intentionally

Executive Summary

This Report provides the MCERTS certification committee's evidence to support the recommendations for certification under the Environment Agency's MCERTS Performance Standards for Continuous Ambient Air Monitoring Systems, and its Annex regarding MCERTS for UK Particulate Matter.

The manufacturer of this manual particulate monitoring method with automatic sequential filter changer is:

Thermo Fisher Scientific
27 Forge Parkway,
Franklin, Massachusetts, 02038, USA

E1. Description of the Candidate Method

This Evaluation Report prepared by the MCERTS certification committee covers the following manual particulate $PM_{2.5}$ measurement method:

(a) Hardware

Partisol™ Plus[1] 2025 Sequential Ambient Particulate Sampler with $PM_{2.5}$ pre-separator measuring system consisting of the following parts:

- United States EPA-style PM_{10} sampling inlet operating at 16.7 l min^{-1};
- $PM_{2.5}$ Sharp Cut Cyclone operating at 16.7 l min^{-1};
- Sampling tubes;
- Partisol 2025 Sequential Ambient Particulate Sampler;
- Mass Flow Controller set to control and report flow to ambient conditions;
- Vacuum pump.
- A schematic diagram of air flow sampling of the Partisol 2025 sampler is given in Figure 1 in the main text of this Report

NOTE: It is important to recognise that any operation of this type of instrument that employs components in combinations and permutations other than the above is not covered by this Report. As such this is not recommended for approval without further consideration by the UK MCERTS certification committee. They must assess the implications of any such variations.

Three models of the Partisol 2025 $PM_{2.5}$ particulate sampler all have the same hardware as defined above. These are the models A, B, and i. The A and B models were each subjected to some of the field tests discussed in this Report, during a long series of field trials carried out with 12 different tests at nine different sites between the years 2000 and 2011. It should also be recognised that the hardware changes for A, B, and i models are associated with modifications to the sampler for parts of it that are not in contact with the airflow or are all downstream of where the particulate matter of the atmospheric sample is deposited onto a filter, and it is therefore judged that these modifications will not have a significant effect on the $PM_{2.5}$ particulate matter that is weighed on that filter. In addition, the CEN tests and the subsequent field tests, which were carried out on these different models at different times

[1] The terms "Partisol" and "Partisol Plus" have sometimes been used interchangeably. This is because the "Partisol Plus" designation was used for certain previous 2025 versions of this type of sampler, but it is not used with the current Series 2025i. As discussed in this Report all the samplers are considered to be identical as regards their performance as "equivalent", regardless of these differences in designation. Therefore, in this Evaluation Report the term "Plus" is not subsequently used.

within the time period of the tests, also support this conclusion. A discussion of the small differences between these models is given in Section 2.3 of this Report.

(b) Serial Numbers of the Candidate Method Tested

This Evaluation Report produced by the MCERTS certification committee has reviewed all the technical evidence in the two reports produced by CEN and BV that are listed in (d) below, and these are further described in more detail in Section 2.3 of the main body of this Report.

The CEN report lists a number of different types of manual PM samplers that were tested at a number of EU sites (9) as part of the validation measurements that were required to be carried out during the formulation of the CEN standard from 2000 – 2003. This CEN standard for $PM_{2.5}$ was ultimately published as EN14907:2005 [Ref.10[2]]. It will be superseded by a combined new PM_{10} and $PM_{2.5}$ standard EN12341:2014 [Ref.11[2]], which should be specified in future as the European Union reference method for $PM_{2.5}$ particulate monitoring. However, since these types of manual sampler that were described in the CEN report were all necessarily commercially available monitors (see this Report Section 2), the serial numbers of these commercial manual samplers were not recorded. Instead, these manual samplers were all anonymised by defining them as Candidate Methods (CMs) in the report and in the data obtained they were listed as CMs 1 – 6, to avoid commercial exploitation of the results.

Nevertheless, the Partisol™ 2025 Sequential Ambient Particulate Sampler with $PM_{2.5}$ pre-separator measuring system is identified in the CEN report as CM3. This was subsequently not selected as one of the reference methods for application in the CEN standard, as it had a larger repeatability as determined during these tests (probably due to a factor of a 2.3 times lower flow rate than the subsequently selected standard method). Hence this is covered in this MCERTS Evaluation Report as a Candidate Method for use as an ***equivalent*** method.

NOTE: It is important to recognise that the term “Candidate Method” as it is used in the CEN report is a candidate method potentially for definition as a CEN standard method, as no such $PM_{2.5}$ standard methods/reference methods existed at that point. The term “Candidate Method” used in this Evaluation Report by the MCERTS certification committee, and in the BV report, is a Candidate Method for becoming an equivalent method. The Partisol Candidate Method that is being evaluated is listed as CM A - CM I in the BV report. The samplers CM A through to CM D are the four Partisol 2025 samplers that were tested as part of the CEN 2000 – 2003 study.

NOTE: It is also important to recognise that there were no CEN standard methods for $PM_{2.5}$ during the validation trials for the CEN standard. These are, however, identified within the CEN standard that was subsequently prepared. The EN standard method selected is now also identified in the CEN report (Section 6) as the CM4 & CM5 low volume samplers. One of these types had sheath air cooling and automated filter changing, and the other type had no sheath air cooling with manual filter changing – see also bullet 2 below in this Section.

As noted above, these CEN field trials were carried out at nine sites in Europe during the period 2000 -2003, as indicated in Table 1 of this Report (taken from the BV report). These trials were also carried out using *two pairs* of the same type of the Partisol 2025 sampler (i.e. a total of four samplers) as specified in Section (a) above, in order to shorten the timescale of these CEN trials.

[2] References in this Executive Summary are not in numerical order. They are in numerical order in the main body of this Evaluation Report.

It should also be noted that, although results were obtained at these nine sites, the results from five of these have been excluded from consideration in this MCERTS Evaluation Report, following a careful review of their data, as summarised in Section 2.2 of this Report, and as also presented in the BV report.

Three other sets of field tests were carried out after the CEN trials had been completed, two at one site in the UK (2007 & 2010) and the other in Germany (2011). These were carried our rigorously and comprehensively following the requirements of the EU Guidance to the Demonstration of Equivalence of Ambient Air monitoring Methods (Section 1.2 of this Report), and the results of these are included in this Evaluation Report.

The serial numbers of the instruments used in these latter three field trials (model 2025B) were as follows:

(i) Teddington, UK, 2007: Serial numbers 21017 & 21215 (Known as Candidate Methods E & F in the BV report);

(ii) Teddington, UK, 2010: Serial numbers 21249 & 21912 (Known as Candidate Methods G & H in the BV report);

(iii) Cologne, Germany 2011: Serial numbers 21912 & 22067 (Known as Candidate Methods H & I in the BV report);

It should therefore be noted that the field test results were therefore obtained from a total of seven tests at six sites, including two in the UK. These are described in detail in the BV report noted below, are reviewed in this Evaluation Report by the MCERTS certification committee, and presented in Section 2.3 of this Report.
The laboratory tests were carried out on the Partisol 2025B sampler with the serial number 21912.

(c) Firmware/Software of the Method

It is not known exactly which version of firmware was used in the tests conducted from 2000 to 2003, as this was not stated in the CEN report, and no other documented evidence has been located. A TÜV test report of 2000 [Ref. 8] presents the tests carried out in 1999 and states that samplers were equipped with firmware version 1.201, and this is believed to be correct at the date of the tests. It is judged that the 2000 - 2003 tests were conducted with the same or a later firmware version. Instruments employed in the UK networks are operated with different firmware versions the earliest of which is 1.202. The changes between this version and the latest version released for A and B series instruments (version 1.5) are minor, and relate to improvements from user experience, and do not impact on any part of the operation that would affect sampling. The latest version 1.5 was released in July 2011 after Approval by the US EPA in June 2011(see below). It is therefore recommended that A and B series instruments that are operated with firmware version 1.202 onwards are accepted, but that every effort should be made to install the latest firmware version (version 1.5). The firmware for use of i series instruments (version 2.0) has been subject to audits by TÜV Rheinland since 2011, and changes to the software are recorded. It is also noted that the United States Environmental Protection Agency approves all firmware versions from 1.003 to 1.5 for the A and B series instruments and version 2.0 onwards for i series instruments [Refs.7 & 9].

E2. Reports and other Documents Reviewed for this Evaluation

Reports and associated documents concerning this Candidate Method have been reviewed by the MCERTS certification committee. These are:

1. *Field test experiments to validate the CEN standard measurement method for $PM_{2.5}$, Final Report, dated July 2006 [Ref.6].*

This CEN report produced the results of the complete validation programme defined by CEN Technical Committee 264 Working Group 15. This involved the testing in the field of six types of manual particulate $PM_{2.5}$ samplers at different sites across Europe, in order to evaluate their possible application as a CEN standard method that could then be specified by the European Union as a *reference method.* The report concluded that the validation results were suitable to allow three of these types of $PM_{2.5}$ samplers to be designated as standard methods in the CEN standard, not including the Partisol 2025 because it did not have the same sample flow rate as the other candidates, it had a flow rate that was 2.3 time lower, and hence had a slightly worse repeatability. This Partisol sampler is thus the subject of this Evaluation Report by the MCERTS certification committee. The results obtained in the CEN tests are used herein for the evaluation of the Partisol 2025 as defined above, as a *candidate for use as an equivalent method*.

2. *UK Report on the Equivalence of the $PM_{2.5}$ Partisol™ 2025, Report No: AGGX5508189/BV/DH/2900, Bureau Veritas Air Quality, dated January 2015 [Ref.7];*

This report (known in this MCERTS Evaluation Report as the BV report) carries out a series of evaluations that were taken from the results obtained from the above CEN report [Ref.6] and reviewed their completeness and correctness as regards the requirements for an equivalent method. The UK report also determined whether the results conform to the requirements of the MCERTS Performance Standards for Ambient Air Quality [Ref.3], and in particular the Annex to this [Ref.5] that includes specific requirements to be fulfilled in terms of the UK's ambient air quality for PM pollution climate. Three of the sites that were used in the CEN Report [Ref.6] were excluded from this UK review as *not being the same* as the UK's particulate pollution climate. Another of the CEN sites was excluded for *technical quality reasons,* and one other excluded for not having the requisite number of valid daily comparisons (≥40). In addition, three other equivalence testing programmes were carried out after the CEN report was completed, and the results of these are included in this BV report on equivalence, and are included in this Evaluation report of the MCERTS certification committee. All the sites that qualify with these above requirements are discussed in the UK BV report, and are also summarised in this Evaluation Report.

These reports are discussed in more detail in the main body of this Evaluation Report.

A further test report has been provided [Ref.8]. This covered the testing by TUV Germany of a Partisol sampler with a PM_{10} head. However, it was tested for conformance with the original EN12341 standard, and it was submitted for testing in 1999 by Rupprecht & Patashnik Co. Inc., USA, before they were taken over by Thermo Fisher Scientific. This MCERTS Evaluation Report has therefore not considered this test report in any detail. The TUV report is discussed in the BV report [Ref.7 Section 3] and it is stated that it provides supporting evidence for the conclusions drawn in this Evaluation Report.

E3. Significant Issues Considered in the Preparation of this Evaluation Report

The results used in this Evaluation Report are atypical of those that are generally reviewed by this MCERTS certification committee, and the requirements of the MCERTS Annex document, discussed in Section 1.3 of this Report, are not all strictly adhered to - for a number of reasons that are clarified in the main body of this Report. These may be summarised:

1. About half of the results evaluated are taken from the CEN report of the field tests carried out between 2000 and 2003, which were used for the validation of the CEN standard method during its development. The laboratories that carried out the work were not accredited to the EN ISO 17025 standard for this testing, as this requirement was not then in place. Instead there was a technical protocol defined by the CEN Working Group itself. The field trials used two pairs of Partisol $PM_{2.5}$ 2025 samplers that were deployed at different sites (for the sites that they were deployed at see [Ref.7 Section 9]. These CEN field trials were not explicitly carried out with the intention of demonstrating the equivalence of any candidate methods, including the type of Partisol 2025 $PM_{2.5}$ sampler evaluated here, but the results have provided a large and valid dataset - particularly from the four sites that have been selected for review in this Evaluation Report. These data have now been used for this purpose in the BV report listed above.
2. No EU $PM_{2.5}$ reference method had been identified, or was in existence, during these CEN validation trials, since the main purpose of these trials was to carry out validation work on different $PM_{2.5}$ samplers at different sites, and then to select the most suitable manual $PM_{2.5}$ samplers that could then be prescribed in a CEN standard - and subsequently to be specified by the EC as the $PM_{2.5}$ reference method. The final published CEN $PM_{2.5}$ standard allowed for automated sampling with sheath air cooling, and another type where there is no sheath air cooling but in this case the filter must be removed immediately after sampling is allowed as given in an Appendix of EN 12341: 2014 [Ref.11] These two types of low-volume $PM_{2.5}$ sampler were both identified as relevant to the CEN $PM_{2.5}$ standard method by the end of the CEN field trials [Ref. 6 Section 6]. The version of the standard method (defined in [ref.1] as the reference method) that was chosen for comparisons with the Partisol sampler in this Evaluation Report and in the BV report was the version with manual sample changes and without sheath air cooling. This type of standard method/reference method was also used in the subsequent three tests in the UK and Germany. The results from all these have been treated in this Evaluation Report, and in the BV report, as the reference method. There were two of these in use at all of the selected sites.
3. The exact *serial numbers* of the four Partisol 2025 samplers that were used in the CEN validation trial are not known at this time. All four were identified by the label CM3 in these CEN trials. The serial numbers of the Partisol samplers that were used in the subsequent three trials carried out in the UK and Germany (2007 – 2011) are, however, known and are listed above in the executive summary and also in Section 2.1 of this Report. All of the results from the four selected CEN trials and those of the three subsequent field tests are used together in this equivalence determination, which is presented in the BV report, and reviewed in this Evaluation Report.

4. There are no individually prepared reports for the most recent three UK and German test programmes (2007-2011) to consider in this Evaluation Report. The results of these are all described in the BV report.
5. There are three versions of the $PM_{2.5}$ samplers under consideration by this MCERTS certification committee in this Evaluation Report, namely the Partisol 2025 models A, B, and i. These are not identical as might normally be expected. However, such changes might be expected over the 14 years that this testing and reporting covers. Nevertheless, the reasons for considering these together are summarised in point c) below, and also presented in Section 2.2 of this Report.
6. The requirements of the laboratory tests that are necessary for the Partisol 2025 are difficult to define specifically. The Partisol 2025 $PM_{2.5}$ sampler was not defined for use in the CEN standard after the CEN validation trials, and hence cannot be considered as a $PM_{2.5}$ reference method. Thus the requirements for equivalence testing for a "variation of a theme of a reference method" as given in the EU's *"Guidance to the Demonstration of Equivalence of Ambient Air Monitoring Methods (GDE)"* and as referenced in Section 1.2 of this Report cannot apply. In addition, the laboratory tests that are given in the MCERTS Performance Standard, relating to constancy of sample volumetric flow and tightness of the sampling system against leakage, do not strictly apply to PM samplers that use subsequent filter weighing. Nevertheless, it is judged that the tests for this latter case are most appropriate and relevant, and these have been carried out satisfactorily, and presented in this and the BV reports.

In view of the above atypical issues, the MCERTS certification committee has also taken account of the following important points in reaching its conclusions:

a) The field test programmes that used the CEN validation trials have been evaluated in the BV report to establish in addition whether they conform with the requirements of the UK's particulate pollution climate, and also conforming to the requirements of the GDE discussed in Section 1.2 below. There have also been additional requirements imposed in this evaluation process for the acceptable quality of the results obtained and used. This has resulted in the results from four of the nine CEN trials being considered as acceptable for use in this current evaluation.

b) The field test programme evaluated in this Report uses the results from the CEN validation trials (that used four Partisol $PM_{2.5}$ samplers and reprocesses these, and the results from the subsequent trials that followed more rigorously the requirements of the GDE. These were conducted over a large number of years, and the results of a total of seven of these were used in the current evaluation of the equivalence of this type of Partisol 2025 $PM_{2.5}$ sampler. These test sites covered different environments (traffic, urban, etc.) as indicated in Table 1 of this Evaluation Report. These all produced consistent and acceptable sets of processed results both together and separately as required. The last three field trials where the serial numbers are identified explicitly resulted in consistent results with those of the *selected* earlier CEN organised field trials [as shown in Ref.7], where the sampler serial numbers were camouflaged.

c) As noted above, up to three versions of this Partisol 2025 $PM_{2.5}$ sampler were in existence, and/or operational during the long timescale of these field trials, and it is proposed that these are considered together in this Evaluation Report. It should be

recognised that this Partisol sampler is mainly a mechanism for drawing an atmospheric sample through a filter, after the atmospheric sample has been pre-conditioned to allow samples with only $PM_{2.5}$ particles through, and this therefore comprises relatively simple hardware. It is also recognised that the hardware changes all have been made within the sampler in the air flow that is after the atmospheric particulates are deposited onto the filter for subsequent weighing at a laboratory. Hence, it is difficult to see that these version changes would affect the filter sampling.

d) There were a range of software/firmware versions in use during this extended testing time scale. These were reviewed by the US Environmental Protection Agency over a number of years, and the findings are published by the EPA [Ref.7 Section 3 & Ref. 9]. They have also been checked during audits that have taken place within the scope of EN 15267 parts 1 & 2 since 2011, by a European scientist with experience in these audits, and these modifications to the software have been deemed to be acceptable, although there is little traceable documentation currently available that explicitly covers this. The different field tests carried out during these versions all provide consistent and acceptable results when processed separately and together.

e) As noted above, the requirements for laboratory tests of this type of sampler are not completely clear in the published documents. It is not a variation of a reference method and hence the laboratory tests for this are inapplicable. It is nevertheless a sampler where the particulate is collected on a filter and subsequently weighed and thus the laboratory tests for those instruments that do not use filter weighing may not be applicable. Nevertheless, it is judged that all appropriate laboratory tests have been carried out satisfactorily.

f) The field tests were all carried before the document on “MCERTS Certification for UK Particulate Matter” [Ref.5] that is also discussed in Section 3.1 of this Evaluation Report was published. There are therefore a number of concessions that may be made in the testing programme as a consequence, some of which are summarised below:

   - The determination of the UK PM Pollution Climate is required for previous tests where data is available. In this case, the data obtained during the field trials is suitable for assessing applicability of the test sites to the UK PM Pollution Climate. The determination has therefore been carried out and presented in the BV report [ref.7] listed above. Those field test sites which did not conform with the UK PM Pollution Climate are excluded from this Evaluation Report.
   - There is a requirement for only one set of tests to be carried out in the UK for tests that were completed before the publication of the report listed in Section 1.3 below. However, two sets of UK tests were carried out and are included in this evaluation.
   - The requirements for specified variations in wind speed, and for 90% data capture, over the duration of the field trials are not necessary for tests that were completed before the publication of the report listed in Section 1.3 below. However, there were very large variations in wind speed during the selected field trials, and the data capture has been determined, and it exceeded 90%. There were also a wide range of atmospheric temperatures present during the field trials (-11^{o}C to + 31^{o}C).
   - The requirements to have two reference methods with simultaneous data over the duration of the field trials is not necessary for tests that were completed before publication of the MCERTS Annex document [Ref.5]. However, all the field trials

evaluated employed two reference methods and these were implemented in agreement with the requirements of the GDE [Ref.2].

E4. Conclusions of the MCERTS Certification Committee

The MCERTS certification committee has concluded that the evidence provided by these reports, and from the considerations discussed above, demonstrate that the minimum requirements of the MCERTS Performance Standard for Continuous Ambient Air Monitors Version 8 July 2012 [Ref.3] are fulfilled. Further it is concluded that all these requirements are fulfilled for the models A, B and i, as discussed in Section 2.2

The MCERTS certification committee also concludes that all the minimum requirements specified in the document:
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 [Ref.5], are also fulfilled for models A, B and i of the $PM_{2.5}$ Partisol sampler 2025 specified above.

Therefore it is proposed that the type of ambient air particulate monitor listed above and discussed in this Evaluation Report is accepted as conforming to the requirements of the above MCERTS Performance Standard, *and* this type of ambient PM monitor is also in conformance with the requirements of the Annex to this MCERTS Performance Standard for the requirements of MCERTS for UK Particulate Matter.
These conclusions are discussed fully in Section 5 of this Report. The restrictions that are given in the Summary and Recommendations Section of this Report (Section 5) apply.

1. Introduction to the MCERTS Evaluation Report

1.1 About this Report

This Evaluation Report has been prepared by the MCERTS certification committee that has been appointed to review the equivalence testing and certification of automated continuous methods and manual discontinuous methods to be used to monitor particulate matter concentrations in ambient air – generally for UK and EU regulatory compliance purposes.

The evaluation by the above certification committee that is presented in this Report has assessed whether all the testing that was carried out on the candidate particulate measurement method listed in this Report fulfils comprehensively and rigorously the requirements that are specified in the set of published documents described below. This MCERTS Evaluation Report must be considered together with the published MCERTS certificates for this method for monitoring ambient particulate matter, and also together with the associated technical reports listed on the certificate.

This Evaluation Report, together with its checklist, has been completed, following a review of the reports that were submitted to SIRA Certification Ltd. (see Section 2.3 of this Report for the reports that were submitted). They were submitted for consideration as to the suitability of the monitoring method in conforming to all the requirements of the documents outlined in Sections 1.2 & 1.3 below.

A completed checklist is presented in Section 4 of this Evaluation Report of the MCERTS certification committee.

Additional comments are also included in this Evaluation Report, in order to address the laboratory test requirements and other test aspects that are used for evaluation, where these *differ in some manner* from the specifications of the Environment Agency's MCERTS Performance Standards for Continuous Ambient Air Monitoring Systems and it's Annex. These are discussed in Section 3 below.

A list of specialised terms that are referred to in this Report, together with their definitions, is presented in Annex 1. A list of the abbreviations used is given in Annex 2. The references used in this Evaluation Report and its Annexes are listed in Annex 3.

1.2 Background to the Requirements for Equivalence Testing

Initial requirements for the testing of ambient air monitoring methods for their equivalence with the EU specified reference method were given in the *EU Directive 2008/50/EC* [Ref.1, Annex VI].

Methods for demonstrating this equivalence with the reference methods specified in the above Directive are given in a guidance document prepared for the European Commission,

entitled *"Guide to the Demonstration of Equivalence of Ambient Air Monitoring Methods", January 2010* [Ref.2]. It should be noted that this guidance was prepared as a document for

the competent authorities and other relevant bodies within the EU Member States - with no mandatory provisions.
Subsequently, the above EC guidance on demonstrating the equivalence of any alternative methods to that of the specified reference methods was incorporated into the Environment Agency's MCERTS Performance Standard entitled:

MCERTS Performance Standards for Ambient Air Quality Monitoring Systems, Environment Agency, Version 8, June 2012 [Ref.3].

The above document describes the MCERTS Performance Standards that must be achieved for certain categories of ambient air quality monitoring systems to allow these to be granted certification by the MCERTS scheme [Ref.4]. The ambient air pollutants that are covered by this are nitrogen monoxide (NO), nitrogen dioxide (NO_2), sulphur dioxide (SO_2) carbon monoxide (CO), benzene and benzene-like volatile organic compounds, and particulate matter (PM_{10} and $PM_{2.5}$). These CAMs are generally those that are to be applied to regulatory compliance monitoring applications. The requirements for particulate matter, both for *automated continuous and manual discontinuous methods,* are given in this MCERTS performance standards document in Sections 6.4 to 6.8 of [Ref.3], and are fully consistent with the EC Guidance document [Ref.2].

1.3 Background to MCERTS Certification for UK Particulate Matter.

Following the publication of this MCERTS Performance Standard [Ref.3], the Department of Environment Food and Rural Affairs (Defra), in conjunction with the Environment Agency and its MCERTS scheme, published a further document in order to specify comprehensively and rigorously the requirements for "equivalence testing" (product conformity and certification) in the United Kingdom, of some specific monitoring methods for particulate matter in ambient air, so as to be in alignment with the guidance from the European Commission, in a manner that is fully acceptable to the UK's Competent Authority. This document, which is prepared as a separate *Annex* to the above MCERTS Performance standards document, is entitled:

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 [Ref.5].

The above Annex document contains the background information and the requirements for equivalence testing that must be carried out ***in order to achieve certification that the Candidate Method conforms to the MCERTS Performance Standard for the pollution climate of UK Particulate Matter***. This is a new type of certification that has been brought in to provide the 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 requirements in the relevant CEN Standard, and also that they meet the requirements of the MCERTS Annex document [Ref.5]. The type of certification is known as MCERTS for UK Particulate Matter. The procedures are based on those required for MCERTS certification in

accordance with the MCERTS Performance Standard for Continuous Ambient Air Quality Monitoring Systems. There are, however, additional requirements that include a specification for full conformance with the Particulate Matter Pollution Climate in the UK.

It should be noted, however, that the Competent Authority for the UK has *already approved* as "equivalent" a number of measurement methods for monitoring particulate matter, *and this new certification process and its requirements do not need to be applied to those already approved methods.*

In addition, a number of transitional arrangements are specified by the Annex document [Ref.5] but which were tested before, or were already being tested, at the time at which the MCERTS for UK Particulate Matter was published. These are detailed in Section 3.3 of the MCERTS for UK Particulate Matter Annex [Ref.5]. These transitionsal arrangements are used identically by the MCERTS certification committee for methods for which certification is sought.

The MCERTS for UK Particulate Matter Annex also contains a checklist that has been used in this Evaluation Report for the review of the reports that were submitted for approval - within the process that is specified in that document [Ref.5].

2 Types of Monitoring Method, Scope of Equivalence Testing, and Reports Evaluated

2.1 Type of Ambient Air Particulate Matter (PM) Monitoring Method

The type of manual ambient air PM monitoring method that has been submitted to be approved for certification under the MCERTS scheme within the context of this MCERTS Evaluation Report is:

(a) Hardware

Partisol™ Plus[3] 2025 Sequential Ambient Particulate Sampler with $PM_{2.5}$ pre-separator measuring system consisting of the following parts:

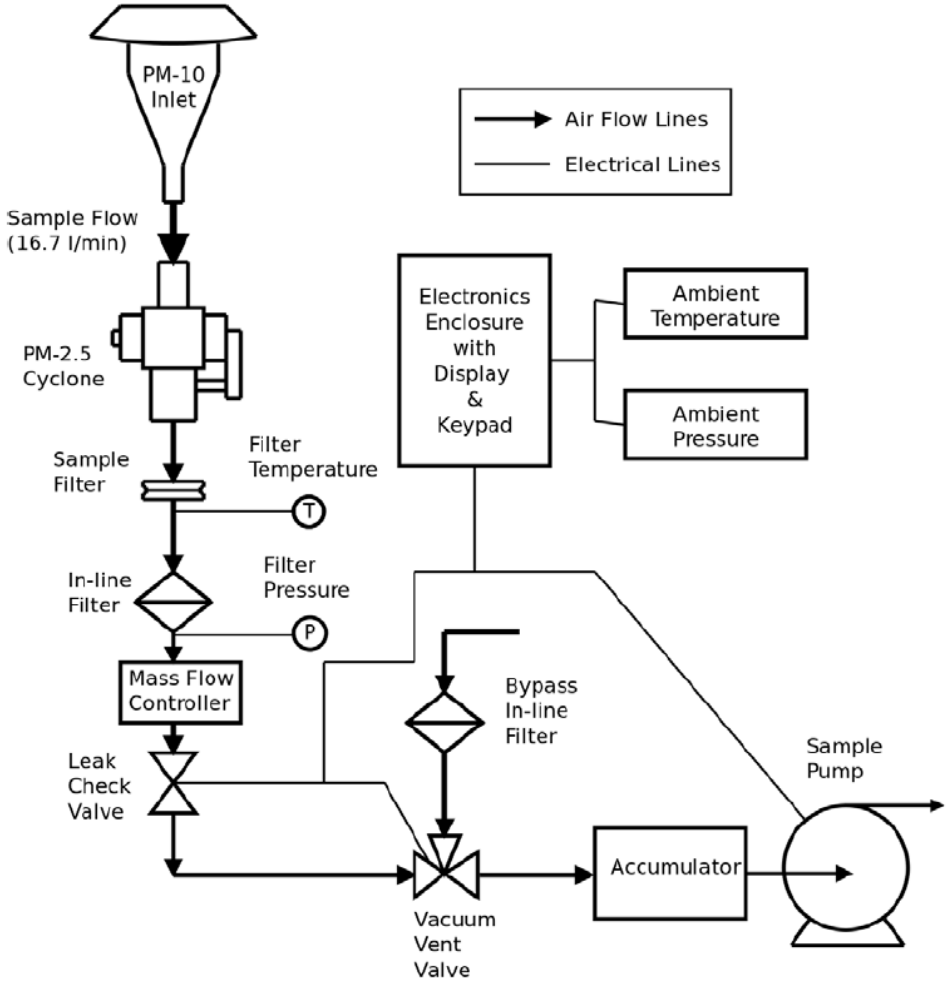
- United States EPA-style PM_{10} sampling inlet operating at 16.7 l min^{-1};
- $PM_{2.5}$ Sharp Cut Cyclone operating at 16.7 l min^{-1};
- Sampling tubes;
- Filter holder system
- Partisol 2025 Sequential Ambient Particulate Sampler;
- Mass Flow Controller set to control and report flow to ambient conditions;
- Vacuum pump.
- A schematic diagram of the airflow sampling used in the Partisol sampler is given in Figure 1 of this Report

The $PM_{2.5}$ Partisol 2025 consists of the PM_{10}-sampling inlet followed by a $PM_{2.5}$ Sharp Cut Cyclone. The airflow through the sampler is controlled to ambient conditions and maintained at 16.7 l min^{-1}. The $PM_{2.5}$ laden airflow then passes through a 47 mm filter that has been manually pre-weighed. Particulate matter is deposited on the filter. Sampling is normally undertaken for 24 hours. Subsequently, filters are removed from the instrument

[3]The terms "Partisol" and "Partisol Plus" have sometimes been used interchangeably. This is because the "Partisol Plus" designation was used for certain previous 2025 versions of this type of sampler, but it is not used with the current Series 2025i. As discussed in this report all the samplers are considered to be identical as regards their performance as "equivalent", regardless of these differences in designation. Therefore, in this Evaluation Report the term "Plus" is not used subsequently.

and manually re-weighed. The instrument incorporates a system for storing up to 16 filters and automatically changes these to a programmable schedule. The manual for the Partisol 2025 is available [Ref. 6 Appendix D], and a figure from this is shown below for convenience.

Figure 1: Flow schematic of the $PM_{2.5}$ Partisol 2025 sampler.



The above schematic diagram relates to the latest model number (i), and it is relevant to the discussion of the model numbers that are evaluated by the MCERTS certification committee, and outlined below in Section 2.2.

(b) Serial Numbers of the Candidate Method Tested

This Evaluation Report, produced by the MCERTS certification committee, has reviewed all the technical evidence in the two reports produced by CEN and BV {Refs. 6 & 7] listed the Executive Summary, and further described in more detail in Section 2.2 of the main body of this Report.

The CEN report lists a number of types (6) of manual PM samplers that were tested at nine EU sites to produce the validation measurements carried out during the formulation of the CEN standard from 2000 – 2003. This CEN standard for $PM_{2.5}$ was ultimately published as EN14907:2005 [Ref.10]. It will be superseded by a combined new PM_{10} and $PM_{2.5}$ standard

EN12341:2014 [Ref.11], which could in future be specified as the European Union reference method for $PM_{2.5}$ monitoring. However, all the types of manual sampler that were described in the CEN report [Ref.6] were necessarily commercially available monitors. Thus, the serial numbers of these commercial manual samplers were not recorded, and instead these manual samplers were all anonymised to avoid commercial utilisation of the results, by defining them as Candidate Methods (CMs) in the report and the data obtained were listed in that report as the results from CMs 1 – 6. Nonetheless the3 relevant samplers have been identified in this Report, and in [Ref.7]

The Partisol™ 2025 Sequential Ambient Particulate Sampler with $PM_{2.5}$ pre-separator measuring system is identified in the CEN report as CM3. This was not selected as one of the reference methods for application in the CEN standard, as it did not have the same flow sample rate as the other candidates for reference method, and had a slightly worse repeatability during the period of these tests (probably due to a factor of a 2.3 times lower flow rate than the subsequently selected standard method). Hence this is covered now in this MCERTS Evaluation Report as a Candidate Method for use as an ***equivalent*** method.

NOTE: It is important to recognise that the term “Candidate Method” as it is used in the CEN report is a candidate method that was intended potentially for definition as a CEN standard method, as no such $PM_{2.5}$ standard methods/reference methods existed at that time. The term “Candidate Method” used in this Evaluation Report by the MCERTS certification committee, and in the BV report, is a Candidate Method for consideration as being specified as an equivalent method. The Partisol Candidate Method that is being evaluated is listed as CM A - CM I in the BV report. The Partisol samplers CM A through to CM D are the four that were tested as part of the CEN 2000 – 2003 study.

NOTE: It is also important to recognise that although there were no CEN standard methods for $PM_{2.5}$ during the validation trials for the CEN standard. These are now identified within the CEN standard that was subsequently prepared. They are now also identified in the CEN report [Ref. 6 Section 6] as CM 4 & 5 low volume samplers.

As noted above, these CEN field trials were carried out at nine sites in Europe during the period 2000 - 2003, as indicated in Table 1 of this Report (taken from the BV report). These trials were also carried out using *two pairs* of the same type of Partisol 2025 sampler (i.e. a total of four samplers) as specified above, operated at different sites in order to shorten the timescale of the CEN trials.

It should also be noted that, although results were obtained and reported at these nine sites, the results from five have been excluded from consideration in this MCERTS Evaluation Report following a careful review of their data, as summarised in Section 2.2 of this Report, and as given in the BV report.

Three other sets of field tests were carried out after the CEN trials had been completed, two at one site in the UK (2007 & 2010) and the other in Germany (2011). These were carried out rigorously and comprehensively following the requirements of the EU Guidance to the Demonstration of Equivalence of Ambient Air Monitoring Methods (Section 1.2 of this Report), and the results of these are included in this Evaluation Report.

The serial numbers of the instruments used in these latter three field trials were as follows:

(i) Teddington, UK, 2007: Serial numbers 21017 & 21215 (Known as Candidate Methods E & F in the BV report);

(ii) Teddington, UK, 2010: Serial numbers 21249 & 21912 (Known as Candidate Methods G & H in the BV report);

(iii) Cologne, Germany 2011: Serial numbers 21912 & 22067 (Known as Candidate Methods H & I in the BV report);

These were all the Partisol 2025B. The laboratory tests were carried out on the Partisol $PM_{2.5}$ 2025B sampler with the serial number 21912.

(c) Firmware/software of the Method

It is not known which exact version of firmware was used in the CEN tests conducted from 2000 to 2003, as this was not stated in the CEN report, and no other documented evidence has been located. A TÜV test report of 2000 [Ref. 8] presents tests carried out in 1999 and states that samplers were equipped with firmware version 1.201, and this is believed to be correct given the date of the tests. It is judged that the 2000 - 2003 tests were conducted with the same firmware version. Instruments employed in the UK networks are operated with different firmware versions, the earliest of which is 1.202. The changes between this version and the latest version released for A and B series instruments (version 1.5) are minor, and relate to improvements in the user experience, and not any part of the operation that would affect the PM sampling. It is therefore recommended that A and B series instruments are operated with firmware version 1.202 onwards, but that every effort should be made to install the latest firmware version (1.5) which was released in July 2011. The firmware for use with the i series instruments (v2.0) has been subject to technical audits by TÜV Rheinland since 2011. It is also noted that the version 1.5, released in July 2011, was produced in conjunction with the United States Environmental Protection Agency and approved by them in June 2011. This organisation approved all firmware versions from 1.003 to 1.5 for the A and B series instruments and 2.0 onwards for the i series instruments in July 2011 [Ref.9,also cited in Ref.7].

2.2 Reports Reviewed by the MCERTS Certification Committee to Evaluate the Equivalence of the Thermo Fisher Scientific $PM_{2.5}$ Partisol 2025 Sampler

A CEN report was produced that was prepared by CEN Technical Committee 264 Working Group 15, as follows:

Field test experiments to validate the CEN standard measurement method for $PM_{2.5}$, Final Report, July 2006 [Ref.6].

This report presented the results of the complete validation programme defined by CEN Technical Committee 264 Working Group 15. This involved the testing in the field of six types of manual particulate $PM_{2.5}$ samplers at nine different sites across Europe, in order to evaluate their possible future application as a CEN standard method that could then be defined by the European Union as a *reference sampler method.* The report concluded that:

- The validation results were suitable to allow two similar low-volume samplers from these types of $PM_{2.5}$ samplers out of the six tested to be designated as relevant to standard methods in the CEN standard [Ref.7 Section 6 and Ref.10]. The final published CEN $PM_{2.5}$ standard allowed for automated sampling with sheath air cooling, and another type where there is no sheath air cooling but the filter must be removed immediately after sampling is allowed in an Appendix of EN 12341: 2014 [Ref.11] The version of the

standard/reference method that was chosen for comparisons with the Partisol sampler in this Evaluation Report and in the BV report was the version with manual sample changes and without sheath air cooling. This type of standard/reference method was also used in the subsequent three tests in the UK and Germany. The results from all these have been treated in this Evaluation Report, and in the BV report, as the reference method. There were two of these in use at all the selected sites.

- The types that were designated as part of the CEN standard method, and hence potentially designated as an EU reference method, did not include the Partisol 2025. This is therefore the subject of this MCERTS Evaluation Report by the certification committee for the Partisol 2025 $PM_{2.5}$ sampler to be a candidate method for equivalence. As such, the *results obtained in the above CEN tests, and those of the later three equivalence trials are used together here for the evaluation of the Partisol 2025 as defined above, as a candidate for use as an equivalent method*.

A more recent report is available, prepared by Bureau Veritas (BV). This BV report is:

UK Report on the Equivalence of the $PM_{2.5}$ Partisol™ 2025, Report No: AGGX5508189/BV/DH/2900, Bureau Veritas Air Quality, January 2015 [Ref.7];

This report contains a number of additional areas of technical information to those of the CEN Report:

- A series of calculations were carried out that were taken from the results obtained from the above CEN report [Ref.6] and their completeness and correctness were reviewed as regards the requirements for the Partisol $PM_{2.5}$ 2025 to be designated as an equivalent method.
- The report also determined whether the results conform to the requirements of the MCERTS Performance Standards for Ambient Air Quality [Ref.3], and in particular to the Annex to this [Ref.5] including specific requirements to be fulfilled in terms of the UK's ambient air quality for PM Pollution Climate.
- From the UK particulate pollution climate review, three of the test sites that were used in the CEN Report [Ref.6] were *excluded as not being the same type as the UK's particulate pollution climate (Madrid, Athens and Vredepeel – see Table 1 below)*;
- Two more of these CEN field test sites were excluded for *technical reasons as discussed in the Executive Summary of this BV report [Ref.7];*
- In addition, three other equivalence testing programmes were carried out ***after*** the CEN report was completed. These fully followed the requirements of the GDE, and these are included in this UK BV Report on Equivalence [Ref.7] and in this MCERTS Evaluation Report;
- All the field test sites that are discussed in detail in the BV report [Ref.7] are also summarised in Section 2.3 of this Evaluation Report for clarity.

The BV report also includes the results of a study of the Particulate Matter Pollution Climate in the UK, and thus the implications for the use of these instruments within the UK are discussed.

The two reports listed above have been used as the primary evidence reviewed by the UK MCERTS certification committee. Where additional information has been made available, then this information has also been considered. The individual results of the evaluation by the MCERTS certification committee are given in the checklist in Section 4 of this Evaluation

Report. This Evaluation Report (Section 3) also provides comments on the laboratory test programmes that were carried out in the UK and in Germany.

NOTE: A further test report was provided [Ref.8]. However, this covered the testing by TUV Germany of a Partisol sampler with a PM_{10} head, the tests were performed for conformance with the original EN 12341 standard (1998), and it was submitted for testing in 1999 by Rupprecht & Patashnik Co. Inc., USA, prior to their being taken over by Thermo Fisher Scientific, This MCERTS Evaluation Report therefore does not consider this in any detail, but this is discussed in [Ref.7 Section 3], and provides some supporting evidence for the conclusions in this Evaluation Report.

A summary of the MCERTS Evaluation Report and the recommendations of this MCERTS certification committee on the equivalence testing of this automated discontinuous method described here, which is to be used to monitor particulate matter ($PM_{2.5}$) in ambient air, are provided in Section 5 below.

2.3 Scope of Equivalence Testing

As discussed in Section 2.1 (a) above, the Partisol $PM_{2.5}$ 2025 sampler is based upon the measuring principle of collecting 24-hour samples onto filters that are weighed on a balance before and after sampling. In this respect the measuring principle is the same as that of the designated PM_{10} and $PM_{2.5}$ Reference Methods, and differs mainly in the flow rates and aerodynamic particle diameter cut-point characteristics of the $PM_{2.5}$ pre-separator. The UK MCERTS certification committee were consulted on the certification procedure and decided that the $PM_{2.5}$ Partisol 2025 system should undergo a full equivalence test, namely, that the requirement should be a total for at least four field tests each with at least 40 data points. Nevertheless, it is recognised that the PM_{10} Partisol 2025 is approved as an equivalent method to the PM_{10} reference method, without the need for further tests, in Appendix B2 of the recently published CEN PM_{10} and $PM_{2.5}$ standard EN 12341:2014 [Ref.11]. This PM_{10} sampler differs from the $PM_{2.5}$ Partisol 2025 in operating principle only in that the PM_{10} sampler does not have a $PM_{2.5}$ Sharp Cut Cyclone. In addition, it is recognised that the main operating principle is simply to draw atmospheric samples through aerodynamic size selective inlets onto a particulate filter, which is subsequently weighed in a laboratory. This renders the operating characteristics of the sampler relatively simple and the software and firmware used to control it also straightforward. Therefore since the Partisol 2025 PM_{10} sampler is already approved for air quality monitoring with this similar PM_{10} metric, the purpose of this Evaluation Report is to evaluate the equivalence of the monitoring of $PM_{2.5}$ by this type of sampler.

As the $PM_{2.5}$ Partisol 2025 sampling system operates in an analogous manner, with air sampling and filter weighing, to that of the European Reference method, the appropriate range is defined in the revised PM_{10} and $PM_{2.5}$ standard [EN 12341:2014 Ref.11] as:

"The range of application of this European Standard is from approximately 1 µg/m³ (i.e. the limit of detection of the standard measurement method expressed as its uncertainty) up to 150 µg/m³ for PM_{10} and 120 µg/m³ for $PM_{2.5}$.

NOTE 1: Although the European Standard is not validated for higher concentrations, its range of application could well be extended to ambient air concentrations up to circa 200 µg/m³ by using suitable filter material"

The highest concentration monitored in the current study was 118 µg/m³, which is just within the range expected for a filter based instrument measuring $PM_{2.5}$, and as such it is **accepted that the $PM_{2.5}$ Partisol 2025 is certified for the measurement range:**

- **0 µg/m^3 to 120 µg/m^3 for a 24 hour sample.**

The particulate pollution climate calculations are presented in [Ref.7 Section 15]. These calculations show that the requirements for the *selected sites* are that they have a similar particulate $PM_{2.5}$ pollution climate to the UK, and they have a suitable range of wind speeds, ambient temperatures, ambient dew points, and volatile component concentrations. The field test sites that were utilised cover Urban Background, Rural and Road Traffic locations. It is accepted, therefore, that this $PM_{2.5}$ Partisol 2025 sampler **is suitable for use at Urban Background, Rural, and Road Traffic locations within the UK.**

No laboratory tests were performed as a function of ambient temperature by ISO 17025 accredited organisations in the present studies reviewed here, although the manufacturer states the operating range in the manual [Ref.7 Appendix D] as:
"Operating Temperature: -30 °C to +50 °C. Temperatures down to -40 °C require additional optional hardware."
The optional additional hardware was not operated in the studies that are reviewed in this Evaluation Report.
The range of average daily temperatures encountered in the field studies utilised in this evaluation was -11.3 °C to +31.6 °C. **As such, it is accepted that the $PM_{2.5}$ Partisol 2025 is certified for the temperature range:**

- **-11.3 °C to +31.6 °C averaged for a 24 hour sample.**

The site types of the twelve sets of tests and the range of dates when they were carried out are shown in Table 1 below.

Table 1: Field Test Sites Reviewed in the BV Report and in this MCERTS Evaluation Report

Site	Start Date	End Date	Characterisation
Berlin	27 Sep 2000	1 Feb 2001	Traffic
Madrid	06 Mar 2001	20 Jul 2001	Urban Background
Vienna	19 Sep 2001	01 Mar 2002	Traffic
Rome	29 Apr 2002	27 Sep 2002	Traffic
Athens	30 Mar 2003	24 Jul 2003	Suburban
Duisburg	07 Mar 2001	07 Jul 2001	Urban Background
Vredepeel	06 Nov 2001	15 Mar 2002	Rural
Aspvreten	23 May 2002	03 Oct 2002	Rural
Teddington 2003	13 Jan 2003	08 May 2003	Urban Background
Teddington 2007	11 Jun 2007	28 Aug 2007	Urban Background
Teddington 2010	27 Apr 2010	14 Jul 2010	Urban Background
Cologne	09 Mar 2011	13 May 2011	Urban Background

The first nine of these datasets were carried out during the Pan-European study organised by CEN Technical Committee 264 Working Group 15, jointly with the European Joint Research Centre (see [Ref.6]), who were tasked with formulating a European $PM_{2.5}$ standard. The CEN report that provides the results of these nine studies anonymised the types and serial numbers of the manual methods tested. However, it is practical to identify the Partisol $PM_{2.5}$ 2025 sampler from this report as CM3, and the finalised data set from all these tests is available in a dataset that clearly identifies each type of instrument. In addition, whilst the primary purpose of these nine studies was not to define equivalence of any of the candidate methods tested, the datasets are extremely suitable to be assessed using the published equivalence criteria. Further discussion of this CEN report is given in Section 2.2 above.

It may also be noted from the above list that all of the field tests were conducted *before* the publication of the MCERTS for UK Particulate Matter document [Ref.5 - July 2012]. Therefore concessions are allowed for the scope of these field tests [Ref.5 Section 3] as below:

1. It was not necessary that all the field test sites had a similar particulate pollution climate to that of the UK. Instead calculations of this are presented in Ref.7, and the *results* from those sites that do not conform with the UK's particulate pollution climate are *excluded* from the calculations in Ref.7, and from the review in this MCERTS Evaluation Report (see below);
2. There is a requirement for there to be at least one UK field test with a valid set of results in this evaluation. The $PM_{2.5}$ Partisol 2025 results are discussed in Ref.7, and in this MCERTS Evaluation Report, and the valid results of this evaluation exceed this requirement. There are two acceptable UK test sites.
3. There is no requirement that two collocated reference methods are used for each field test - although two reference methods were actually included in all twelve test sites listed above
4. The reference methods considered here are the same type that are specified in the recently piblished standard EN 12341:2014 [Ref.11];
5. There is no requirement for there to be at least 90% data availability, although the calculation of this is presented in Ref. 7, this exceeds 90%, and this is also summarised in this MCERTS Evaluation Report.

As noted previously the first nine of the field tests shown in Table 1 above were from a 2000 to 2003 Pan- European study [Ref.6], which was organised by CEN Technical Committee 264 Working Group 15 jointly with the European Joint Research Centre (JRC), in Italy. For those field tests that were conducted as part of the 2000 to 2003 Pan-European study, there was no requirement to have ISO 17025 accreditation at that time. Instead, a rigorous set of procedures were specified that each site operator adhered to.

The last three studies, organised separately, were undertaken by the National Physical Laboratory (NPL) in the UK, and by TÜV Rheinland in Germany. Both these organisations have the appropriate EN ISO 17025 accreditations, which are included in Ref.7 Appendix B.

Calculations of the between sampler uncertainties of the $PM_{2.5}$ Partisol 2025 samplers and the expanded uncertainties relative to the reference method are published in the BV Report [ref.7 Sections 9-14].

Calculations of the suitability of the data relative to the particulate pollution climate within the UK were undertaken by BV in their report [Ref. 7 Section 15]. These calculations indicated that the datasets from Vredepeel, Madrid, and Athens, were not suitable to be considered for equivalence within the UK - as they did not conform with the requirements for the UK particulate pollution climate.

In addition, the data obtained at the Teddington 2003 field trial, was not processed further, and not considered in this Evaluation, because there were fewer than 40 valid data points.

Further, at Aspvreten Sweden there were numerous problems during the beginning of that campaign [Ref.7]. As such, the data from the beginning of the campaign was deleted in Ref.7. After deleting the problematic data, there are fewer than 40 data-points remaining, and thus the Aspvreten dataset was also removed from the calculations and not considered in this evaluation.

After the removal of these above listed five CEN datasets from the evaluation, there is still at least one site in the remaining datasets with at least 40 data pairs that meets the lower threshold for each of wind speed, ambient temperature, ambient dew point and amount of semi volatile component, and at least one site in the remaining datasets with at least 40 data pairs that meets the higher threshold, as required by [Ref.5].

A series of *laboratory tests* were also undertaken by TÜV Rheinland and NPL [Ref.7 Sections 6 – 8] and these are summarised in this Evaluation Report. The Maintenance Interval is also discussed [Ref. 7 Section 11], and the data capture that has been calculated in accordance with MCERTS for UK Particulate Matter [Ref.5 Section 5.2] is presented in the checklist of this Report, and in its summary and recommendations – Section 5.

In summary, The BV report [Ref.7] sets out all the findings of the field campaigns, laboratory testing and particulate pollution climate calculations, and this report is structured to include the 17 numbered sections as specified in the MCERTS for UK Particulate Matter document [Ref. 5 Section 6]. Thus, this BV report is fully compatible with all the requirements of MCERTS for UK Particulate Matter, including its reporting structure, and it has been reviewed by the MCERTS Certification Body, and its certification committee, as the evidence that is required to assess whether all the testing carried out is compliant with all the requirements of MCERTS for UK Particulate Matter [Ref.5].

There are three variants of the Partisol 2025: A; B and i, which are being considered together by the certification committee in this MCERTS Evaluation Report:

- **A:** The original Instrument.
- **B:** In approximately 2001, changes were made that modified the hardware of the filter shuttle. This modification replaced a pneumatically-driven plunger with an electrically-driven plunger that is used to put the filter in place from a supply tube holder, and to remove it to the storage tube holder. The parts of this replacement that are in contact with the sample stream containing the $PM_{2.5}$ particulate were not changed, but the mechanism used to handle the lift and push of the plunger was. The B series were discontinued in September 2011.
- **i:** Recently, the i series has been developed from the B series. Most importantly all parts that are in contact with the sample gases before they are collected by the filter were *not changed*. The main changes were to the electronics and to the arrangement of the

parts in the enclosure downstream of the sample filter, in order to provide a more modular approach. Thermo Fisher Scientific simplified the plumbing through this change to allow for easier access to parts, and improved serviceability. The user interface has changed, but Thermo has tried to maintain as many of the features and functions of the original models as practical. Figure 1 above in this Report shows a schematic diagram of the Partisol $PM_{2.5}$ 2025 sampler, taken from the operating manual of the i series. It is recognised that the same sample path was used in the A & B series. A discussion on this is given [Ref.7 Section 3], where further data is presented on tests carried out at Thermo Fisher Scientific on the i series of the sampler.

The instruments utilised in the field tests were a mixture of A and B series samplers. The laboratory tests discussed in Ref. 7, and summarised in this MCERTS Evaluation Report, were conducted on a B series sampler. As the changes between A and B series are only to ensure an improved filter exchange, and do not interfere with the sample flow in any way, before the particulate is sampled on the filter, it is accepted in this MCERTS Evaluation Report that the certification covers A and B series instruments (at least).

The changes between the B and i series also involved updating and modifying the software, in addition to some re-arrangement of the hardware downstream of the sampled filter, and this is software/firmware modification is discussed in Section 2.1 (c) above. An additional laboratory test has been conducted by Thermo Fisher on an i series instrument, to confirm that thios gives equiva;lent results, and this is discussed in Ref.7.

3. Requirements and Options for the Laboratory Test Programme

3.1 Requirements of the MCERTS Annex Document

The Annex to the MCERTS Performance Standards Document [Ref.5 Section 4.2] provides the scope of the laboratory test programme that is specified in the GDE, and also those that are specified in the MCERTS Performance Standard [Ref.3].

The somewhat *different* test requirements of the GDE [Ref 2], of the MCERTS Performance Standard [Ref 3], of the MCERTS Annex Document [Ref 5], and of the German VDI/DIN Guidelines, are discussed below - as applied to the BV report [Ref.7] that has been submitted for MCERTS Certification.

NOTE: This Section also lists below the additional testing requirements, where relevant, that are specified in current German VDI/DIN Guidelines [Refs.12 & 13]. These are required to be carried out for suitability testing/type approvals for automated continuous methods to be accepted for use in Germany. (There are similar, but not identical to, additional requirements that are in a draft European standard being prepared by CEN, but a precursor to this is *currently published* as a CEN Technical Specification [Ref.14], although this is not mandatory.) *These German VDI/DIN tests did not form part of this test programme and hence are not evaluated here.*

The evaluations and the conclusions arising from the MCERTS certification committee's review of the part of the BV report that are concerned with the laboratory tests are given below in this Section
- In each case there is a heading "Evaluation and Findings" with the findings of that test in *italic text* below.

3.2 The Laboratory Test Programme required by the Guide to the Demonstration of Equivalence

3.2.1 Requirements

Section 9.3 of the GDE [Ref.2], covers only two laboratory testing applications that relate to certain limited modifications of the manual CEN PM standard method (PM_{10} or $PM_{2.5}$), which the AQD has specified 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 [Ref.2 Sections 9.3.2 and 9.3.3] respectively. There are no laboratory tests prescribed in the GDE for candidate methods that are different to these.

3.2.2 Evaluation and Findings for 3.2.1 above

The candidate methods discussed in the BV report [Ref.7] do not relate to the limited modifications of the manual CEN standard method that are stated in the GDE, and as listed in 1a and 1b above. Thus the BV report and this Evaluation Report do not discuss such tests. They are not required.

NOTE: While these tests are not required, information relating to the first of these can be found in TÜV report of 2000 [Ref.8], and it was shown that he effect of filter exchanges had no significant effect upon the performance of the instrument. This is discussed in the BV Report [Ref.7 Section 3], but it is recognised that the findings have limited relevance to the present Evaluation Report of the certification committee.

3.3 The Laboratory Test Programme required by the MCERTS Performance Standard

3.3.1 Requirements

The MCERTS Performance Standard [Ref.3] specifies further tests as compared to those in the GDE listed in Section 3.2 above, 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:

a. Constancy of the sample volume flow, is tested as specified in the MCERTS Standard [Ref.3 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 criterion given in the MCERTS Performance Standard [Ref.3 Table 6.2].

b. The leak tightness of the sampling system 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 – to achieve the performance criterion given [Ref.3 Table 6.2].

c. In addition, the same tests are required in The MCERTS Performance Standard [Ref.3] as in the two limited specific applications in the GDE [Ref.2] that relate to certain limited modifications of the manual CEN standard method - where the AQD [Ref.1] defines it as a reference method. These limited test procedures in the two documents are the same as those in Section 3.2.1 1a and 1b above, and are:

   - Application of automated filter changers with 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 [Ref.3] also requires a set of laboratory tests. These are as given in its Sections 6.6.2 and 6.6.3 respectively.

It is required in [Ref.5] that the laboratory tests that are specified in the MCERTS Performance Standard [Ref.3] shall be the minimum laboratory tests that are carried out to show conformance with the requirements of this Evaluation Report.

3.3.2 Evaluation and Findings for Paragraphs 3.3.1a and 3.3.1b above

The tests required by MCERTS that are listed in Section 3.3.1 a) and b) above were carried out by TÜV Rheinland and NPL respectively, within their procedures that are EN ISO 17025 accredited. The test procedures and the results obtained were presented to BV for their report, and these are presented in Sections 8.1 & 8.2 of that report [Ref.7]. They are also summarised below in this MCERTS Evaluation Report.

The laboratory test that is to be carried out to fulfil Paragraph (a) above of the MCERTS Performance Standard [Ref.3] states:

a) Constancy of sample volumetric flow: The testing shall be carried out by providing loaded filters, and a volumetric flow measuring device such as, for example, a mass flow meter and a pressure measuring device. Three pre-loaded filters with the particulate load of approximately 0%, 50%, and 80% of the maximum permissible filter loading shall be used. For each filter the constancy of the sample volumetric flow shall be recorded every 30 minutes as a 3 minute average over the time period of at least 24 hours. The criteria required in Table 6.2 of the MCERTS standard [Ref.3] are shown in Table 1 below.

Table 2: Specific performance criteria for laboratory volume flow and leakage of the PM sampling system given in the MCERTS Performance Standard [Ref.3]

Parameter	Performance requirement
Constancy of sample volumetric flow	Sample volumetric flow averaged over the sampling time to remain constant within ± 3% of the rated value. All instantaneous values to remain within ± 5% of the rated value.
Tightness of the sampling system	Leakage not to exceed 1 % of the sampled volume.

Both the above tests were carried out with the instrument with serial number 21912, which is a B series instrument manufactured in July 2006. This device was used in the field tests at Teddington 2010 and Cologne 2011.

The TÜV testing was carried out using a very similar procedure to that specified in the MCERTS standard, and was implemented as follows:

The sampler was placed in a room that varied between 27.0 °C and 28.3 °C and between 33.8 %RH and 39.0 %RH over the complete measurement period. The inlet of the instrument was connected to a calibrated mass flow rate measuring device (Type 4043 Manufacturer: TSI).

There was discussion on which maximum value should be chosen for the PM loading of the filter. Following consultation with the UK MCERTS certification committee, a decision was made to perform the test on the filters that would correspond to 50% and 80 % of the filter loading of the maximum of the PM_{10} range (150 µg/m³) - as opposed to the maximum of the $PM_{2.5}$ range (120 µg/m³). The rationale for this was that the PM_{10} test will produce a greater pressure drop and so is more challenging, and that by performing the test at the PM_{10} filter loadings, the laboratory test data would be suitable for Partisol 2025 samplers operating at both PM_{10} and $PM_{2.5}$. 50% and 80 % of 150 µg/m³ are 75 µg/m³ and 120 µg/m³ respectively. These concentrations are usually beyond the range of concentrations observed with the Partisol 2025 sample filter, but this covers the certification range listed in this Report (Section 2.2), and provides an additional justification for this. As the reference method has a higher flow rate than the Partisol, the filters of this method are generally more heavily loaded. Thus the reference method filters were sourced with the appropriate mass to area ratio. The mathematics used for these calculations is summarised in [Ref.7 Section 8.1]. The three filters were operated for 24 hours each.

The results are shown in [Ref.7 Section 8.1 Table 5], which are reproduced below:

Table 3: Results of the Laboratory Flow Test.

Filter	Mean Flow / LPM	% Deviation from Nominal Flow	Max Flow / LPM	% Deviation from Nominal Flow	Min Flow / LPM	% Deviation from Nominal Flow
Blank	16.34	-1.95	16.54	-0.78	16.26	-2.46
50%	16.44	-1.40	16.68	0.06	16.32	-2.10
80%	16.62	-0.29	16.82	0.90	16.52	-0.90

It can be that the highest deviation from the nominal flow was 2.46% (rounded to 2.5%) at the minimum flow, and the 50% and 80% loaded filters did not show significant differences.

The requirements for constancy of the sample volume flow to be within ± 3% are therefore fulfilled.

The laboratory test carried out fulfil paragraph (b) above of the MCERTS Performance Standard [Ref.3] states:

b) Tightness of the sampling system: The testing is normally carried out with the aid of a pressure measuring device and a volumetric flow measuring system. The leak rate of the entire instrument shall be determined if it is feasible. This includes the inlet as well as the whole sampling system and the measuring system. If because of the instrument design the complete system tightness cannot be measured the leak rate can be determined separately for the sampling part and the measuring part. The leak rate can be measured by the

determination of volume flow at the inlet and outlet of the system or by the pressure drop method. In the latter case the system is sealed at the inlet and evacuated by a built in or separate pump and the pressure increase due to leaks is measured over the period of 5 minutes. The leak rate V_L determination shall be repeated three times.

The performance criterion to meet the requirements of Table 6.2 of the MCERTS standard [Ref.3] is given in Table 2 above.

The testing was carried out by NPL to meet the above requirements of MCERTS on the tightness of the sampling system as given in [Ref.7 Section 8.2]. The results are shown in [Ref.7 Section 8.2 Table 6], which is reproduced below:

Table 4: Results of the leak tightness test.

Time	Pressure drop (mbar) – with respect to ambient;			
	Run 1	Run 2	Run 3	Run 4
0:00 (P0 mbar)	713	717	716	520
0:30	619	632	633	448
1:00	536	556	557	381
1:30	460	486	485	
2:00	394	422	421	274
2:30	334	366	366	231
3:00	282	316	315	194
3:30	238	272	271	162
4:00	200	233	232	135
4:30	167	198	198	113
5:00	139	170	168	94
ΔP	574	547	548	426
ΔT, min	5	5	5	5
Leak rate / LPM	0.0713	0.0676	0.0678	0.0725
Flow rate / LPM	16.67	16.67	16.67	16.67
Leak as % of flow rate	0.43	0.41	0.41	0.44

The MCERTS performance criterion is that the leakage shall not to exceed 1 % of the sampled volume.

(NOTE: The performance criterion in Germany [Refs.12&13] is the same as that for the MCERTS Performance Standard [Ref.3] - leakage shall not exceed 1 % of the sampled volume.)

The maximum leakage as a percentage of flow rate is 0.44%, and the requirements for this test are therefore fulfilled.

3.3.4 Evaluation and Findings for Paragraph 3.3.1c above

The laboratory test that should be carried out to fulfil paragraph (c) in Section 5.3 of the MCERTS Performance Standard [Ref.3] is not relevant to the BV report [Ref.7] since these tested CMs do not relate to limited modifications of the manual CEN standard method specified in the GDE [Ref.2]. Thus the BV report does not describe such tests. They are not required.

3.4 Tests Carried Out as an Option - Additionally to the Requirements of the MCERTS Performance Standard and the MCERTS Annex Document

3.4.1 Requirements

In Germany there are minimum requirements and test procedures for automated methods [Refs.12&13] that are additional to those of the GDE [Ref 2], the MCERTS Performance Standard [Ref 3], and the MCERTS Annex Document [Ref 5]. These requirements and procedures would need to be met and followed in addition for automated continuous or manual discontinuous PM methods that are to be used in Germany for regulatory purposes. These standards include references to EN 12341 (in terms of equivalence testing for PM_{10}) and to the GDE [Ref 2] (in terms of equivalence testing for PM_{10} and $PM_{2.5}$). The additional laboratory tests include:

- Measured value display;
- Easy maintenance;
- Functional test;
- Set-up and warm-up times;
- Instrument design;
- Unintended adjustment;
- Certification and measuring ranges;
- Negative signals;
- Failure in mains voltage;
- Operating states;
- Repeatability STD at zero;
- Dependence of zero and span on surrounding temp (5°C to 40°C);
- Dependence of span on electric voltage;
- Assessment of the measuring range(s);
- Ensuring negative signals are not suppressed;
- Zero level and detection limit;
- Measurement of effects of mains voltage and frequency fluctuations, and of mains voltage failure;

In this case none of the above tests according to the revised VDI/DIN Guidelines (2010) {Refs.12 & 13] were carried out.

3.4.2 Evaluation and Findings

*In the case of this sampler, **none** of the additional optional tests were carried out. These laboratory tests are also outside of the scope of the requirements of the MCERTS*

Performance Standard for Continuous Ambient Air Monitoring Systems [Ref.3], and its Annex [Ref.5]. Therefore, as such, none of the test results need to be evaluated within the MCERTS procedure.

4. Checklist for Assessing the Acceptability of the Equivalence-Testing Programme

This section covers the MCERTS certification committee's checklist for the assessment of conformance with the requirements of the MCERTS Standard for the UK Particulate Matter.

(i) Manufacturer and Monitoring Method

Manufacturer of the automated or manual particulate monitoring method (including name and address)	Thermo Fisher Scientific 27 Forge Parkway, Franklin, Massachusetts, 02038, USA
Is the above manufacturer requiring the equivalence testing, or does the manufacturer have an agent?	Manufacturer above required equivalence testing; Manufacturer's UK agent: AIR MONITORS Ltd. 2 Bredon Court, Brockeridge Park, Twyning, Tewkesbury, Gloucestershire, GL20 6FF, United Kingdom
Contact name at the manufacturer and/or the manufacturer's agent	Dr. Henk Oele, Thermo Fisher Scientific, Takkesbijsters, 4817 BL Breda, The Netherlands
Telephone numbers of contact names	+ 31 76 5795643 Email: henk.oele@thermofisher.com
Description of automated or manual PM method (model, serial numbers, software details etc.)	Partisol™ 2025 Sequential Ambient Particulate Sampler with $PM_{2.5}$ pre-separator measuring system consisting of the following parts: ○ United States EPA-style PM_{10} sampling inlet operating at 16.7 l min^{-1}; ○ $PM_{2.5}$ Sharp Cut Cyclone operating at 16.7 l min^{-1}; ○ Sampling tubes; ○ Partisol 2025 Sequential Ambient Particulate Sampler; ○ Mass Flow Controller set to control and report flow at ambient conditions; ○ Vacuum pump. Model numbers A, B, and i; Serial numbers for 2007 to 2011 tests: 21017, 21215, 21249, 21912, & 22067;
All the initial stages of the MCERTS Certification process shall be completed (Ref.5].	Yes – It is being processed through the MCERTS Certification Body

(ii) Details of the Test Laboratories and Other Laboratories Involved

Name of Companies	1. TÜV Rheinland Energie und Umwelt GmbH, Germany (current name) carried out the tests in Cologne Germany, and one laboratory test. 2. National Physical Laboratory, United Kingdom – carried out the tests in the UK within the CEN test programme and thereafter, and one laboratory test; 3. Bureau Veritas UK Ltd. – production of UK [Ref.7] report – see Section 2.2 of this MCERTS certification committeee Evaluation Report 4. A group of European research laboratories as given in Ref.6
Addresses	1. Am Grauen Stein, Koln, D-51105, Germany 2. Hampton Rd., Teddington, Middlesex. TW110LW,UK 3. Brandon House, 180 Borough High St., London SE11LB, UK
Contact Names	1. Dipl.-Ing. Karsten Pletscher 2. Mr David Butterfield 3. Dr Richard Maggs
Telephone numbers of Contacts	1. +49-221-806-2592 2. +44-208-943-6391 3. +44-845-600-1828
Email address of Contacts	1. karsten.pletscher@de.tuv.com 2. David.butterfield@npl.co.uk 3. Richard.maggs@uk.bureauveritas.co.uk
Dates tests were carried out	7 sets of tests, September 2000 – May 2011
Test Laboratory Report number and date	For details - see Section 2 of this Evaluation Report of the MCERTS certification committee, and also Ref.7
Laboratory tests shall be carried out - where the tests have been made: ○ According to MCERTS Standard [Ref.3] Sections 6.5–6.6 ○ And to VDI/DIN Germany Standards VDI 4201-1 and VDI 4203 [Refs.12 & 13] requirements.	Yes - MCERTS Performance Standard. No tests were carried out according to VDI/DIN Guidelines in this test programme – see Sections 3.3 and 3.4 of this Evaluation Report;

(iii) General Requirements of the Equivalence Testing

Relevant clause of the MCERTS Annex document [Ref.5] (& GDE Ref.2)	Requirement	Comments: including location of the relevant information in the Equivalence test report, or the FINAL test report, and its acceptability
Ref.5 Section 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 any concessions as set out in Ref 5.	*Not applicable:* All the test results for this type of CM were obtained prior to publication of the MCERTS Annex requirements document [Ref.5];
Ref.5 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.	*Not applicable*
Ref.5 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.	*Not applicable*
Ref.5 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).	*Accepted:* see Ref.6 and Sections 10 & 17 of the BV report [Ref.7]
Ref.5 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.	*Accepted:* Section 2 Ref.6 and Sections 10 & 17 of the BV report [Ref.7]
Ref.5 4.3(vi)	Two complete CMs of the same type shall be used, and they shall be clearly and uniquely identified as such;	*Accepted*: the CMs are identified in in Ref.6. Section 2.1, and in the BV report [Ref.7] Section 10. *Although Section 2.1 Paragraph b) of this MCERTS Evaluation Report should be noted and considered - regarding the identification of each candidate method as being required to be anonymous - at the time of CEN testing and the publication of Ref.6*
Ref.5 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's sample head shall be documented as specified in Ref.5 Section 4.2 and GDE	The sample head of the CM was not operated with the specifications of the CEN reference method, which operates at 2.3 m^3 hr^{-1}. Instead, the CM was operated with a US-EPA style PM_{10} sampling inlet operating

	[Ref.2 Section 9]	at 16.7 l min^{-1}, followed by a $PM_{2..5}$ Sharp Cut Cyclone operating at 16.7 l min^{-1}. The CM must be operated with both the specified PM_{10} inlet and $PM_{2.5}$ cyclone in order to be deemed equivalent *The requirement is considered to be fulfilled*
Ref.5 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	*Accepted:* The CMs are located adjacent to one of the same type, and to the RMs, and the sites were selected to have no significant local emission sources. [Ref.6 Section 4 and Ref.7 Section 9]
Ref.5 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.	*Not applicable:* In this test programme the results of regional instruments are not used. Moreover, there were no requirements for > 6 months of measurements at the sites during this test programme. *The requirement is fulfilled*
Ref.5 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[Ref. 2], and in EN 12341 or EN 14907 for RMs.	*Accepted:* Within the CEN report, there is acceptable information on the operation of all the methods used during the trials, and the results obtained. The data from some of the trials were not used in this Evaluation Report where there were concerns about QA/QC. There is a description of the QA/QC performed by the test laboratories according to the GDE [Ref 2] and other draft documents of the time. Additional information has also been made available in the UK BV report [Ref.7] There is sufficient information to make the judgement that the quality assurance and quality control carried out is satisfactory and fit for purpose. *The requirement is fulfilled*
Ref.5 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 by Grubbs test or other means- or otherwise discarded.	*Accepted:* The outlier rejections of the RM are shown explicitly (Ref.7 Section 10 & Annex 4).
Ref.5 4.3(xi) & 5.2	Both CMs shall have a minimum data capture and availability of greater or equal to 90%, as determined in Ref.5 Section 5.2, where tests have begun after Ref.5 entered into force.	*Accepted:* There is limited information available in Ref.6. However, Ref.7 gives the data capture for the three most recent field trials. The averaged data capture of the types of CMs in all the three latest test programmes were all >90%, with no failures of the CMs, -a site power failure was the only interruption (see Ref.7 Section 11). The effective data capture and availability is determined to be 100%.

		However, this is for information for the customer, as this is not an applicable requirement for tests carried out before the MCERTS Annex document [Ref 5] was published.
Ref.5 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 are 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 particulate pollution climate evaluation, and at different seasons - The test laboratories shall be accredited to the ISO/IEC 17025 standard for all the MCERTS tests;	*Accepted:* The tests provided valid results at seven selected test sites in total - each with > 40 valid results - with two sets of tests in the UK during different seasons. The tests were all completed before publication of Ref.5 so this is not a requirement. The laboratories were not accredited for the CEN tests [Ref.6] that were completed in 2003. The accreditation was then not a requirement, and would have been difficult to implement because these were a newly specified set of tests. The test laboratories for these last three MCERTS tests (2007-2011) were accredited to EN ISO 17025 - two sets of field tests in the UK and one in Germany. *The requirements are fulfilled.*

(iv) Laboratory Tests to fulfil the Requirements of the MCERTS Performance Standard and/or VDI/DIN Guidelines

Section 4.2 of Ref.5 & this Evaluation report Section 3.3	The laboratory test to be carried out to fulfil Paragraph 6.5.2 of the MCERTS Performance Standard [Ref.3] states: *Constancy of sample volumetric flow:* The testing shall be carried out providing loaded filters, volumetric flow measuring device such as, for example, a mass flow meter and a pressure measuring device. Three pre-loaded filters with the particulate load of approximately 0%, 50%, and 80% of the maximum permissible filter loading shall be used. For each filter the constancy of the sample volumetric flow shall be recorded every 30 minutes as a 3 minute average over the time period of at least 24 hours.	This laboratory test was carried out by TÜV Rheinland , as discussed in [Ref. 7 Section 8.1], and in this Evaluation Report Section 3.3.2. The maximum deviation from the normal flow determined in the test was –2.5%, with the performance criterion is +- 3%. *The requirement for constancy of the sample volume flow is therefore fulfilled.*
Section 4.2 of Ref.5 & this Report Section 3.3	The laboratory test to be carried out to fulfil paragraph 6.5.3 of the MCERTS Performance Standard [Ref.3] states: *Tightness of the sampling system:* The testing is normally carried out with the aid of a pressure measuring device and a volumetric flow measuring system. The leak rate of the entire instrument shall be determined if it is feasible. This includes the inlet as well as the whole sampling system and the measuring system. If because of the instrument design the complete system tightness cannot be measured the leak rate can be determined separately for the sampling part and the measuring part. The leak rate can be measured by the determination of volume flow at the inlet and outlet of the system or by the pressure drop method. In the latter case the system is sealed at the inlet and evacuated by a built in or separate pump and the pressure increase due to leaks is measured over the period of 5 minutes. The leak rate V_L determination shall be repeated three times. The criterion of both the UK and the German requirements are ±1% of the sample volume	This laboratory test was carried out by NPL as described in [Ref.7 Section 8.2], and in this Evaluation Report Section3.3.2. The maximum leakage measured as a function of normal flow rate was 0.44%, and the performance criterion is that the leakage shall not exceed 1% of the sample volume *The requirement for the leakage test is therefore fulfilled.*

Section 4.2 of Ref.5 & this Evaluation Report Sections 3.2.2 & 3.3.4	Laboratory tests are required where relevant, on two applications that relate to certain limited modifications of the manual CEN standard method (PM_{10} or $PM_{2.5}$) specified in the GDE tests, where the AQD defines it as a reference method. These are: o Application of automated filter changers leading to filter storage conditions deviating from those prescribed in the CEN standards; o 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 [Ref.3] requires a set of laboratory tests that are as given in its Sections 6.6.2 and 6.6.3 respectively.	*Not applicable:* This laboratory test is not relevant It needs to be carried out only to fulfil paragraph (c) in Section 5.3 of the MCERTS Performance Standard [Ref.3] and section 4.2 2c of the MCERTS Annex document [Ref.5]. The tested CMs do not relate to limited modifications of the manual CEN standard method. Thus the test report does not give such tests, as they are unnecessary.
Section 4.2 of Ref.5 & this Evaluation Report Section 3.4	There are minimum requirements and test procedures in Germany for automated continuous methods defined in VDI 4202-Part 1 and VDI 4203-Part 3 (re-published 2010) [Refs. 12 & 13] that are additional to those of the GDE [Ref 2], the MCERTS Performance Standard [Ref 3], and the MCERTS Annex Document [Ref 5]. These requirements and procedures would need to be achieved and followed in addition for automated continuous or manual discontinuous PM methods that are used in Germany for regulatory purposes. These 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 $PM_{2.5}$).	*Not applicable:* The additional tests referred to in Section 3.4 of this MCERTS Evaluation Report, are outside the scope of the requirements of the MCERTS Performance Standard for Continuous Ambient Air Monitoring Systems [Ref.3], and its Annex [Ref.5], and as such do not need to be evaluated within the MCERTS procedures. In this test programme there were no such additional tests.

(iv) Requirements of the Field Test Conditions

Ref.5 Section 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) and in the close proximity to the field test site may be used as the basis for the assessment ([Ref.5 section 3.2]. The individual atmospheric components that make up the successful demonstration of the PM pollution climate are *listed below*:	*Accepted:* The determination of the UK PM pollution climate has been carried out in the BV UK report [Ref.7] and is appropriate; Only those test sites that were carried out within the CEN test programme [Ref.6] that conform to the requirement to be representative of the UK's PM pollution climate, are included in the evaluation in Ref.7, and in the review in this MCERTS Evaluation Report (see Section 2.2 & 2.3). Three of the CEN test sites were excluded from the evaluation. *The requirements are fulfilled*
Ref.5 Section 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 4.4(ii) of Ref.5	*Accepted: ref.7 Section 15;*
Ref.5 Section 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.	*Accepted: Ref. 7 Section 9;*
Ref.5 Section 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.	*Accepted:* There are two valid UK test sets for Teddington UK in summer and spring (excluding the Teddington 2003 results). There are two test sites in Germany, and a further three test sites elsewhere in Europe. These were all completed before the MCERTS Annex document was published. *This is thus not a requirement for these tests, but the requirements are nevertheless fulfilled*
Ref.5 Section 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	*Accepted:* see Ref. 7 Section 15, in comparison with the MCERTS Annex document [Ref 5]Table 3;
Ref.5 Section 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.	*Accepted:* see Ref.7 Section 15, in comparison with the MCERTS Annex document [Ref 5] Table 3;
Ref.5 Section	There shall be evidence that the measurements were taken at both high and low wind-speed	*Accepted*: see Ref.7 Section 15, in comparison with the MCERTS

4.4(iv)	conditions during specified times of the complete test programme.	Annex document [Ref 5] Table 3
Ref.5 Section 4.4(iv)	The comparisons should be carried out during different UK climatic conditions;	*Accepted :* see Ref.7 Section 15, in comparison with the MCERTS Annex document [Ref 5] Table 3
Ref.5 Section 4.4(iv)	The individual comparative results from both the RMs and CMs shall be taken at regular intervals during all the comparisons;	*Accepted:* see Ref.7;
Ref.5 Section 4.4(v)	There shall be a comprehensive and valid evaluation of the UK "PM pollution climate" carried out as summarised in Ref.5 Section 3.2 and given in Ref.5 section 4.4(v), utilising all the variable atmospheric components given in that Section of Ref.5.	*Accepted:* see Ref.7 Section 15 and MCERTS Annex document [Ref 5] Table 3, and [Ref.16];
Ref.5 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"	*Accepted:* see Ref.7 Section 15, and MCERTS Annex document [Ref 5] Table 3, and [Ref.16].
Ref.5 Section 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.)	*Accepted*: see Ref.7 Section 15, MCERTS Annex document [Ref 5] Section 3, and [Ref.16].

(vi) Requirements of the Candidate Method in the Field Tests

Ref.5 Section 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.	*Accepted:* The original CEN test programme did not identify the serial numbers of the CMs used during 2000-2003. The serial numbers of the CMs used subsequently in 2007 – 2011 have suitable serial numbers. The software used in these tests is not explicitly identified in detail. However, there are justifiable circumstances to accept that the CMs are all acceptable - see BV report [Ref.7] Sections 1.2 & 3, [Ref.10] and this Evaluation Report Section 2.
Ref.5 Section 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 (vii)below)	*Accepted:* The QA/QC programme is documented in different parts of the CEN report [Ref.6], and it was specified as best practice at the time of the CEN tests. The subsequent tests carried out in the UK and Germany have applied QA/QC as given in [Ref.5]. Within the BV report [Ref.7], the information has been collated into Appendix D.
Ref.5 Section 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 Ref.5 Section 4.7. 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%.	*Accepted:* All the results are documented on an average daily basis. Within the CEN report [Ref.6] it is not explicit whether there are any partial day's results that have been removed – but there is a statement that no CM data has been discarded so that this appears to be satisfactory. Further information is provided in the BV UK report [Ref.7];
Ref.5 Section 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.)	*Accepted: T*he times of the filter changes that occurred every 24 hours were logged permanently by the CMs. The Partisol 2025 sampler performs a filter change in less than one minute in every 24 hours. *The requirements are fulfilled*
5. Ref.5 Section 2	The availability (data capture) of the two CMs shall be separately evaluated as given by Ref.5 Section 5.2, equation 2, for all tests that are carried out in or after 2012. This shall be included in the test report and in the	*Accepted:* The data capture is not reported in the CEN report [Ref.6]. The data capture of the last three field trials has been reported and is above requirements. The data capture over these

	MCERTS test certificate, with the acceptance criterion of 90%.	field tests is determined to be 100% – see the BV report [Ref.7 Section 11] - *This is not a requirement for this test programme [Ref.5 Section 3] but is useful for a customer*
Ref.5 Section 5.3	The between-candidate method standard uncertainty defined in Ref 5 Section 5.3 shall be determined (after all the results have been evaluated and any removed or discarded as specified in Ref 5 Section 5.5.1), in order to define the complete set of *valid* results. These shall be ≥ 40 valid results per comparison trial or the 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;	There are > 40 results for each of the seven selected final field test datasets. The BV report [Ref.7] Sections 12.4 & 12.5, gives a maximum of 1.62 µg m^{-3} for results > 18 µg m^{-3}, 1.29 µg m^{-3} for results < 18 µ m^{-3} and 1.45 µg m^{-3}, for all the combined results, before and after correction for the significant intercept, which are all less than the performance criterion; *The requirement is fulfilled*
Ref.5 Section 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.	The BV report [Ref.7 sections 12.4 & 12.5], when using the seven selected final field data sets, gives 1.08ug/m3 for results ≥ 18 ug/m3, 0.63 ug/m3 for results , 18 ug/m3, and 0.88 ug/m3 for all results. These are all less than the performance criterion of 2.5 µg m^{-3}; *The requirement is fulfilled*

(vii) Requirements of the Reference Method in the Field Tests

Ref.5 Section 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;	The CEN report [Ref.6] Section 2,lists all the instruments that were candidates for the standard CEN method including the two that were subsequently selected, and Ref.7 Section 10 lists one of these reference methods for the last three field trials, and the BV report [Ref.7] also uses this reference method to perform the equivalence determination of the selected CEN test sites *The requirement is fulfilled*
Ref.5 Section 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 Ref.5 Section 5.5.3.1	*Accepted:* The CEN report [Ref.6] Section 2 lists the candidates for the standard CEN method including the two that were subsequently selected as standard methods, and Ref. 7 uses one of those selected as the subsequent reference method for the last three trials.(Specifically the low volume sampler 3 with manual filter changes and without sheath air

		cooling.) Two reference methods were used for all the field trials in this Evaluation. *The requirement is fulfilled*
Ref.5 Section 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.	*Not applicable: T*he RM used had manual filter changing
Ref.5 Section 5.4	The between RM standard uncertainty defined in Ref.5 Section 5.4 equation 3 shall be determined: - After all the results have been evaluated and removed or discarded as specified in Ref.5 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:	CEN report [Ref.6] Section 5 presents this. BV report [Ref.7] presents this for the complete set (Sections 12.4 &12.5) *The requirement is fulfilled*
Ref.5 Section 5.4	The between RM uncertainty of ≤ 2.0 $\mu g.m^{-3}$ shall be satisfied for both RMs, across the complete data set [Ref.5].	CEN report [Ref.6] Section 5 presents this. BV report [Ref.7] presents this for the complete set. Sections 12.4 &12.5; *The requirement is fulfilled*

(viii) Requirements of the QA/QC Programme in the Field Tests

Ref.5 Section 4.6	The requirements of the GDE [Ref 2] Annex D for calibrations and quality control checks shall be met during the complete field test programme	*Accepted:* Requirements met;
Ref.5 Section 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.	*Accepted:* Requirements met;
Ref.5 Section 4.6	All the information listed in Reference 5 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 Reference 5 Section 6.	*Accepted:* Most of the information is in different sections of the CEN report. Within the BV Report [Ref.7], in the required Defra format, the information is collated into Appendix C.

(ix) Assessment of the Suitability of the Results Obtained in the Field Tests

Ref.5 Section 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;	There are greater than the minimum required valid results, at all seven selected sites. *The requirement is fulfilled*
Ref.5 Section 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.	The BV report [Ref.7] describes an acceptable outlier rejection method, which is presented in Section 10. The removals have been justified. *The requirement is fulfilled*
Ref.5 Section 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;	Grubbs tests has been applied correctly to the RM results and no more than 2.5% of outliers have been removed; *The requirement is fulfilled*
Ref.5 Section 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.	*The requirement is fulfilled*
Ref.5 Section 5.5.1	≥20% of the remaining paired results of the full dataset shall have greater than the prescribed PM concentrations of 17µg m^{-3}, as determined by the collocated RM.	Results have been tabulated correctly and greater than 20% criterion achieved in nearly all measurement sites; *The requirement is fulfilled*

(x) Assessment of the Procedure used to Evaluate the Resultant Final Data Sets of the Field Tests

Ref.5 Section 5.5.1	The results of all the paired data obtained, after carrying out the procedure in Ref.5 Section 5.5.1, shall be processed assuming a linear relationship between CM and RM of the form given in Ref.5 equation.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	The BV UK report [Ref.7] presents all the results processed utilising orthogonal regression in the form as specified in the GDE [Ref.2] and in CEN/TS16450:2013. In addition, as part of this MCERTS certification committee's evaluation, re-calculations for the seven sites were carried out, and the formulae were validated. This included using the EU accepted and verified RIVM_PM_ spreadsheet_v2.9 (25 October 2011 [Ref.15].) *The requirement is fulfilled*
Ref.5 Section 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;	Correctly processed; *The requirement is fulfilled*
Ref.5 Section 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.	Correctly processed; *The requirement is fulfilled*
Ref.5 Section 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 Ref.5 equations 5 and 6. If these criteria are met the calculations in Ref.5 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 in Ref.5 Section 5.5.3, and as indicated below in this checklist.	*Partially accepted:* When the calibration function is NOT applied, the expanded uncertainties of some of the individual dataset results are greater than the allowed 25%. Therefore, the BV report [Ref.7 Section 12] has applied corrections for both slope and intercept separately, and also for slope and intercept together. The BV report [Ref.7] states that: when slope correction alone was applied, not all of the expanded uncertainties dropped to below 25 %, and that therefore slope correction alone is not recommended. Similarly, the BV report [Ref.7] states that there was no significant benefit to correcting for both slope and intercept relative compared to that correcting for intercept alone. The BV report [Ref.7] also states that intercept correction was shown to be compulsory in order for the critical expanded uncertainties to all drop below 25 %.

		However, it is believed that intercept correction *via* a systematic correction factor of adding 1.425 µg/m³ is not appropriate, particularly given that this correction factor was calculated using data from filters some of which had been stamped with ink, and some that were produced from filter media that are known to change mass over time. (Note: it would be possible to delete the results of the data sets in this evaluation that exceeded the 25% criterion and still retain most of the requirements of Ref.5 but this would not result in any UK field tests) However, in order to improve the accuracy of data collected by both Partisol 2025s (and reference method instruments) at both PM_{10} and $PM_{2.5}$ size fractions, the UK have adopted a policy of: ○ using filters that have been shown to be relatively stable over long periods (Emfab); ○ not stamping filters in a manner that could cause a loss of mass over time; ○ correcting all measurements for field blanks. It is judged that this policy removes the requirement for intercept correction to enable these Partisol 2025 samplers to conform to the required measurement uncertainty of 25%. It is recommended that this approach is followed by users of the $PM_{2.5}$ and PM_{10} Partisol 2025s. *The MCERTS certification committee for PM agrees with the approach taken in the BV report [Ref. 7], although it has stipulated that data from uncorrected, slope corrected, intercept corrected, and both slope and intercept corrected datasets, should be included on the certificate for clarity and completeness.* Further this policy emphasises strongly the requirement of the GDE [Ref.2] (and of CEN TS/16450 –Ref.14) that all PM instruments that are NOT reference methods should be checked for calibration in the field at intervals, against the EU specified reference method in order to demonstrate their on-going equivalence*. It should also be noted that the UK are following the above approach in the on-going equivalence testing that is required [Ref.2 Section 9.9.2]* *It is judged that with the above approach the requirements are fulfilled.*

(xi) Evaluation of the Method Used to Determine the Uncertainty of the Results of the CM in the Field Tests

Ref.5 Section 5.5.3.1	No correction for the slope or intercept has been applied to determine the Uncertainty of the Results of the CM in the field Tests 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.	*Accepted:* This determination has been carried out correctly in the BV report [Ref.7]. However, when the calibration function is not applied, the expanded uncertainties of some of the individual dataset results are greater than the allowed 25%. See Section 5 below for the measurement uncertainty results.
Ref.5 Section 5.5.3.2	A valid correction for the intercept has been applied as given in Table ix above, and Ref.5 Eq.12 shall be applied for the evaluation of the uncertainty of the results of both the CMs.	*Accepted:* This determination has been carried out correctly in the BV report [Ref.7]. See Section 5 below for the measurement uncertainty results *The requirement is fulfilled when an intercept correction is applied (but see comments on Section 5.5.2 above) ;*
Ref.5 Section 5.5.3.3	A valid correction for the slope has been applied as given in Table ix above, and Ref.5 Eq.16 shall be applied for the evaluation of the uncertainty of the results of both the CMs.	*Accepted:* This determination has been carried out correctly in the BV report [Ref.7]. This states, however, that when slope correction alone was applied, not all of the expanded uncertainties were below 25 %, and that therefore slope correction alone is not accepted for this data. See Section 5 below for the measurement uncertainty results.
Ref.5 Section.5. 3.4	Corrections for both the slope or intercept has been applied as given in Table ix above, and Ref.5 equation 21 shall be applied for the evaluation of the uncertainty of the results of both the CMs.	*Accepted:* This determination has been carried out correctly in the BV report [Ref.7]. See Section 5 below for the measurement uncertainty results. *The requirement is fulfilled when slope and intercept correction is applied (see Section 5 below for the measurement uncertainty results but see comments on Section 5.5.2 above) ;*
Ref.5 Section 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 Ref.5 Section 5.5.3.1 as $\mathbf{u_{bs,RM}/\sqrt{2}}$ (Eq.3)	*Accepted:* Within the CEN report, it is not explicitly stated that this has been done, and the calculations were made before this requirement was published. However, this is not used in the Evaluation Report, and within the BV UK report, the situation is clarified as "In all cases the uncertainty of the reference method was calculated for each individual dataset in accordance with the GDE [Ref 2]. As in all cases there were two reference methods available, it was not necessary to use the recommended default uncertainty of 0.67 for any of the calculations." The uncertainty of the RM has been correctly applied in the BV Report for all cases of uncorrected; intercept corrected; slope corrected; and both slope and intercept corrected [Ref. 7] *The requirement is fulfilled;*

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

Ref.5 Section 5.5.3.5	The relative standard measurement uncertainty of both the CMs shall be calculated using Ref.5 equation.22	*Accepted:* *The requirement is fulfilled;*
Ref.5 Section 5.5.3.5	The calculation of Ref.5 equation.22 shall be carried out using the full dataset.	*Accepted:* *The requirement is fulfilled;*
Ref.5 Section 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 $PM_{2.5}$).	These "limit" values have been applied correctly; *The requirement is fulfilled;*
Ref.5 Section 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 Ref.5 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.	These have been applied correctly; *The requirement is fulfilled;*
Ref.5 Section 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 [Ref 2] Section 9.5.4)	No additional term has been applied or need be applied, as there is evidence that the QA/QC procedures used were satisfactory; *The requirement is fulfilled;*
Ref.5 Section 5.5.3.5	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;	Accepted; *The requirement is fulfilled;*

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

Ref.5 Section 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 [Ref 1];	This comparison has been done correctly both before the intercept correction, and simultaneous slope and intercept factors have been carried out, and also afterwards. *The requirement is fulfilled;*
Ref.5 Section 5.6	One of two cases shall be determined: (i) $\mathbf{W_{CM}} \leq \mathbf{W_{dqo}}$ then the CM is accepted as equivalent to the RM; (ii) $\mathbf{W_{CM}} > \mathbf{W_{dqo}}$ then the CM is not accepted as equivalent to the RM;	In the case of the corrections for intercept alone and for both slope and intercept together, $\mathbf{W_{CM}} \leq \mathbf{W_{dqo}}$ and thus the CM is accepted as equivalent to the RM; However, in order to improve the accuracy of data collected by Partisol 2025s (and reference method instruments) at both PM_{10} and $PM_{2.5}$ size fractions. The UK have adopted a policy of: o using filters that have been shown to be relatively stable over long periods (Emfab); o not stamping filters in a manner that could cause loss of mass over time; o to correct all measurements for field blanks. ***It is judged that this policy removes the requirement for intercept correction to enable these Partisol 2025 samplers to conform to the required measurement uncertainty of 25%.*** *The MCERTS certification committee agrees with the approach taken by the BV report [Ref. 7], although the committee has stipulated that data from uncorrected, slope corrected, intercept corrected, and both slope and intercept corrected datasets should be included on the certificate.* Further this policy emphasises strongly the requirement of the GDE [Ref.2] (and of CEN TS16450) that all PM instruments that are NOT reference methods should be checked for calibration in the field at intervals, against the EU specified reference method in order to demonstrate their on-going equivalence.

5. Summary and Recommendations

This Evaluation Report produced by the MCERTS certification committee reviews and provides evidence to support the recommendations for certification under the Environment Agency's MCERTS Performance Standards for Continuous Ambient Air Monitoring Systems [Ref.4}, and its Annex regarding MCERTS for UK Particulate Matter [Ref.5].
The manufacturer of this manual particulate monitoring method and automatic sequential filter changer is:

Thermo Fisher Scientific
27 Forge Parkway,
Franklin, Massachusetts, 02038,
USA

5.1 Type of Particulate $PM_{2.5}$ Method Evaluated

The type of manual ambient air particulate monitoring method that has been submitted to be approved for certification under the MCERTS scheme within the context of this Report is:

(a) Hardware

Partisol^{TM} 2025 Sequential Ambient Particulate Sampler with $PM_{2.5}$ pre-separator measuring system consisting of the following parts:

- United States EPA-style PM_{10} sampling inlet operating at 16.7 l min^{-1};
- $PM_{2.5}$ Sharp Cut Cyclone operating at 16.7 l min^{-1};
- Sampling tubes;
- Partisol 2025 Sequential Ambient Particulate Sampler;
- Mass Flow Controller set to control and report flow to ambient conditions;
- Vacuum pump.
- A schematic diagram of the airflow sampling used in the Partisol $PM_{2.5}$ sampler is given in Figure 1 of the main body of this Report

The $PM_{2.5}$ Partisol 2025 consists of PM_{10}-sampling inlet followed by a $PM_{2.5}$ Sharp Cut Cyclone. The airflow through the sampler is controlled to ambient conditions and maintained at 16.7 l min^{-1}. The $PM_{2.5}$ laden airflow then passes through a 47 mm filter that has been manually pre-weighed, and particulate matter is deposited on the filter. Sampling is undertaken for 24 hours. The instrument incorporates a system for storing up to 16 filters and automatically changes these to a programmable schedule.

(b) Serial numbers

This Report reviewed all the technical evidence in the two reports produced by CEN and by BV listed in Section 2.3 of the main body of this Evaluation Report.

The CEN report lists a number of types of manual PM samplers that were tested at nine EU sites to produce the validation measurements carried out during the formulation of the CEN standard from 2000 – 2003. The CEN standard for $PM_{2.5}$ was ultimately published as EN14907:2005 [Ref.10]. However, since these types of manual sampler that were described in the CEN report were all commercially available monitors, the serial numbers of these commercial manual samplers were not recorded. Instead, these samplers were all anonymised by defining them as Candidate Methods and the data obtained were listed as the results from the CMs 1 – 6, to avoid commercial utilisation of the results.

Three later sets of field tests were carried out after the CEN trials, two at one site in the UK (2007 & 2010) and the other in Germany (2011). These were carried out following the requirements of the EU Guidance to the Demonstration of Equivalence of Ambient Air Monitoring Methods (Section 1.2 of this Report), and the results of these are included in this Evaluation. The serial numbers of the instruments used in these latter field trials were:

(j) Teddington, UK, 2007: Serial numbers 21017 & 21215 (Model 2025B - known as Candidate Methods E & F in the BV report);

(ii) Teddington, UK, 2010: Serial numbers 21249 & 21912 (Model 2025B - known as Candidate Methods G & H in the BV report);

(v) Cologne, Germany 2011: Serial numbers 21912 & 22067 (Model 2025B - known as Candidate Methods H & I in the BV report);

The laboratory tests were carried out on the Partisol $PM_{2.5}$ Model 2025B sampler with the serial number 21912.

(c) Firmware/software of the Method

It is not known which exact version of firmware was used in the CEN tests conducted from 2000 to 2003, as this was not stated in the CEN report, and no other documented evidence has been located. A TÜV test report of 2000 [Ref. 8] presents the tests carried out in 1999 and states that samplers were equipped with firmware version 1.201, and this is believed to be correct given the date of the tests. It is judged that the 2000 - 2003 tests were conducted with the same or a slightly later firmware version. Instruments employed in the UK networks are operated with different firmware versions, the earliest of which is 1.202. The changes between this version and the latest version released for A and B series instruments (version 1.5) are minor, and relate to improvements in the user experience, and not any part of the operation that would affect the PM sampling. It is therefore recommended that A and B series instruments are operated with firmware version 1.202 onwards, but that every effort should be made to install the latest firmware version (1.5). The firmware for use with the i series instruments (v2.0) has been subject to audits by TÜV Rheinland since 2011. It is also noted that the United States Environmental Protection Agency has approved all firmware versions from 1.003 to 1.5 for the A and B series instruments and 2.0 onwards for the i series instruments [Ref.9 also cited in Ref.7].

(d) Models Covered

Three versions of the $PM_{2.5}$ samplers were under consideration by this MCERTS certification committee in this Evaluation Report, namely the Partisol 2025 models A, B, and i. These are not identical as might normally be expected. However, these changes might be expected over the 14 years that this testing and reporting covers. Nevertheless, the reasons for considering these together are given in Section 2.2 of this Report, and may be summarised:
This Partisol 2025 sampler is mainly a mechanism for drawing an atmospheric sample through a filter, after the atmospheric sample has been pre-conditioned to allow samples with only $PM_{2.5}$ particulates through, and this therefore comprises relatively simple hardware. It is also recognised that the hardware changes all were made within the sampler in the air flow that is after the atmospheric particulates are deposited onto the filter for subsequent weighing at a laboratory. Hence, it is difficult to see that these version changes would affect the filter sampling.

5.2 Scope of the Equivalence Testing Evaluated

The $PM_{2.5}$ Partisol 2025 Candidate Method (CM) was tested against the European Reference Method (RM) over a series of twelve field campaigns listed in Table 1 of this current Evaluation Report:

The first nine of these studies were from a 2000 to 2003 from the Pan European study [Ref.6] organised by CEN Technical Committee 264. For those field tests conducted as part of the 2000 to 2003 Pan European study, there was no requirement to have ISO17025 accreditation at that time. Instead, a rigorous set of procedures were instigated by WG15 and the JRC that each site operator adhered to.

The later three studies were organised separately, and were undertaken by the National Physical Laboratory (NPL) in the UK and by TÜV in Germany. Both organisations have appropriate EN ISO 17025 accreditations.

Calculations of the suitability of the data relative to the particulate pollution climate within the UK were undertaken [Ref.7]. These calculations indicated that the datasets from three of the twelve sites (Vredepeel, Madrid, and Athens) were not suitable to be considered for the PM particulate pollution climate within the UK. One further site (Teddington 2003) was excluded because there were fewer than 40 valid data points. At another site (Aspvreten) there were problems during the campaign, including the quality of the results near the beginning of the field tests, and after deleting this data there are fewer than 40 data-points, so this last dataset was also removed from the calculations.

Nevertheless, after the deletion of these five datasets, there were still seven valid datasets that were assessed in [Ref.7], and evaluated in this Report, and at least one of these sites containing at least 40 data pairs, meets the lower threshold for each of Wind Speed, Ambient Temperature, Ambient Dew Point and Semi Volatile component, and at least one of these sites with at least 40 data pairs meets the higher threshold.
Laboratory tests were undertaken by TÜV and NPL [Ref.7 Section 8.1 & 8.2] The Maintenance Interval is also discussed [Ref.7 Section.3] with data capture calculated according to MCERTS for UK Particulate Matter [Ref.5].

5.3 Findings of the Equivalence Testing Carried Out

The following tables and their associated notes summarise the results and conclusions in relation to MCERTS for UK Particulate Matter.

Certification Range: $PM_{2.5}$	**0 to 120 µg/m^3 for a 24 hour sample**
Ambient temperature range:	**-11.3 °C to +31.6 °C averaged over a 24 hour sample**.

Table 5a: Summary of the field test results: The results in this table relate to the sampler both *without correction and with correction for intercept.*

These results were all calculated from the data of the 7 field test sites outlined above.

Test	Uncorrected	Intercept Corrected	MCERTS Specification
Expanded uncertainty calculated at 30 µg/m^3 for **Candidate A**			
Full data set	21.0%	17.2%	≤25%
<18 µg/m^3	65.8%	74.8%	Not specified
≥18 µg/m^3	21.2%	16.8%	≤25% (Only required when ≥ 40 data pairs)
Individual sites			
Berlin	18.5%	15.1%	≤25%
Vienna	28.4%	21.1%	≤25%
Rome	11.3%	13.2%	≤25%
Expanded uncertainty calculated at 30 µg/m^3 for **Candidate B**			
Full data set	22.8%	17.1%	≤25%
<18 µg/m^3	51.4%	60.3%	Not specified
≥18 µg/m^3	23.0%	16.9%	≤25% (Only required when ≥ 40 data pairs)
Individual sites			
Berlin	22.5%	14.6%	≤25%
Vienna	30.0%	22.4%	≤25%
Rome	11.8%	10.4%	≤25%
Expanded uncertainty calculated at 30 µg/m^3 for **Candidate C**			
Full data set (Duisburg)	18.7%	13.9%	≤25%
<18 µg/m^3	66.0%	75.2%	Not specified
≥18 µg/m^3	18.8%	11.9%	≤25% (Only required when ≥ 40 data pairs)
Expanded uncertainty calculated at 30 µg/m^3 for **Candidate D**			
Full data set (Duisburg)	12.4%	6.3%	≤25%
<18 µg/m^3	12.4%	18.4%	Not specified
≥18 µg/m^3	11.4%	1.9%	≤25% (Only required when ≥ 40 data pairs)
Expanded uncertainty calculated at 30 µg/m^3 for **Candidate E (21017)**			
Full data set (Teddington 2007)	28.7%	19.7%	≤25%
<18 µg/m^3	28.7%	19.8%	Not specified
≥18 µg/m^3	No Data Pairs	No Data Pairs	≤25% (Only required when ≥ 40 data pairs)
Expanded uncertainty calculated at 30 µg/m^3 for **Candidate F (21215)**			
Full data set (Teddington 2007)	17.2%	10.2%	≤25%
<18 µg/m^3	17.2%	10.3%	Not specified
≥18 µg/m^3	No Data Pairs	No Data Pairs	≤25% (Only required when ≥ 40 data pairs)
Expanded uncertainty calculated at 30 µg/m^3 for **Candidate G (21249)**			
Full data set (Teddington 2010)	16.6%	8.6%	≤25%
<18 µg/m^3	17.4%	9.3%	Not specified
≥18 µg/m^3	Only 1 Data Pair	Only 1 Data Pair	≤25% (Only required when ≥ 40 data pairs)
Expanded uncertainty calculated at 30 µg/m^3 for **Candidate H (21912)**			
Full data set	16.3%	12.1%	≤25%
<18 µg/m^3	13.3%	20.2%	Not specified
≥18 µg/m^3	20.3%	15.6%	≤25% (Only required when ≥ 40 data pairs)
Individual sites			
Teddington 2010	26.1%	17.3%	≤25%
Cologne	17.3%	13.8%	≤25%
Expanded uncertainty calculated at 30 µg/m^3 for **Candidate I (22067)**			
Full data set (Cologne)	16.1%	15.2%	≤25%
<18 µg/m^3	38.0%	47.0%	Not specified
≥18 µg/m^3	18.7%	16.3%	≤25% (Only required when ≥ 40 data pairs)

Table 5b: Other test results

Test	Results	MCERTS Specification
Constancy of the sample volumetric flow	-2.5%	To remain constant within ± 3% of the rated value
Tightness of the sampling system	0.44%	Leakage not to exceed 1% of the sampled volume
Other Requirements		
Maintenance Interval	Two Weeks	≥Two weeks
Data Availability Number of UK Tests	100.0% 2	≥90% ≥1
Number of Reference Methods	2	≥1
Between sampler/instrument uncertainty for the standard method **$PM_{2.5}$**		
Full data set <18 µg/m^3 ≥18 µg/m^3	0.88 µg/m^3 0.63 µg/m^3 1.08 µg/m^3	≤2 µg/m^3 Not specified Not specified
Between sampler/instrument uncertainty for the candidate method **$PM_{2.5}$**		
Full data set <18 µg/m^3 ≥18 µg/m^3	1.42 µg/m^3 1.26 µg/m^3 1.52 µg/m^3	≤2.5 µg/m^3 ≤2.5 µg/m^3 ≤2.5 µg/m^3

It can be seen in the Tables above, that *not all of the expanded uncertainties* are below 25%. In addition, some of the critical slopes and intercepts are not statistically significantly close to 1 and 0 respectively [Ref.7 Section 12]. It was therefore necessary to determine the effects of slope correction, intercept correction, and both slope and intercept correction, as shown in Table 6 below.

Table 6: The results for slope, intercept and the expanded uncertainties determined without and with slope and/or intercept correction.

$PM_{2.5}$ Partisol 2025 (7 sites)	Calculated slope of all the paired data	Calculated intercept of all the paired data	Expanded uncertainty of all the paired data	Range of individual expanded uncertainties
Uncorrected data	0.977	-1.425	18.8%	11.3% to 30.0%
Data corrected for slope by dividing by 0.977	1.000	-1.462	16.2%	9.3% to 26.9% (for datasets with at least 40 data pairs)
Data corrected for intercept by adding 1.425	0.977	0.000	13.4%	6.3% to 22.4% (for datasets with at least 40 data pairs)
Data corrected for slope and intercept by adding 1.425 and then dividing by 0.977	1.000	-0.004	13.0%	7.6% to 19.9% (for datasets with at least 40 data pairs)

In summary:

- The uncorrected data has some individual site's expanded uncertainties that are greater than 25%;
- Slope correction is shown to have limited benefit, and there are still some expanded uncertainties that are still >25% [Ref.7 Section 12.5.1], and it is recommended that it is not necessary to correct for slope.
- Intercept correction is shown to be essential in order for the specified expanded uncertainties to all decrease below 25 %. However; it is believed that intercept correction *via* a systematic correction factor of adding 1.43 µg/m³ is not appropriate, particularly given that this correction factor was calculated using data from filters some of which had been stamped with ink, and some that were produced from media that are known to change mass over time.
- Intercept correction together with slope correction also gives all the expanded uncertainty results that are below 25%, but there is the same concern as related to the intercept correction alone as given above.

In view of the issues summarised above with intercept correction alone and correction for intercept and slope correction together, it is recommended for use in the UK and to be applied as best practice in the UK:

- ***For all the versions of this monitor covered in this Evaluation that:*** **instead** ***of applying any intercept correction and/or slope correction factors, that thorough and sufficiently-frequent quality assurance and quality control procedures are employed*** as prescribed in [Refs. 10 & 11].
- *Rigorous and regular on-going procedures should be employed intermittently to calibrate or check the calibration of these Partisol 2025 $PM_{2.5}$ monitors against the CEN $PM_{2.5}$ standard method [Ref.10]. at a test site in the field (as prescribed in THE GDE [Ref.2], EN 12341:2014 [Ref.11] and CEN/TS16450:2013 [Ref.14]). One set of results obtained using this procedure are summarised in Section 5.4 below*
- *Filters are chosen and used that are stable in mass over periods of time, that the filters are not stamped with ink or other substance that may evaporate slowly over time, and that a correction is applied that is based upon the use of field blanks.*
- *The MCERTS certificate should show the range of the specified expanded uncertainties obtained both before and after correction for intercept.*

5.4 Additional Supporting Evidence

As noted above, the GDE [Ref.2] and subsequent related documents, require on-going tests to be carried out intermittently on equivalent instruments using side-by side comparisons with the relevant reference methods in the field. One such set of comparisons had been carried out in the UK on the Partisol 2025 monitor discussed in this Evaluation Report, and the results have been processed using the equivalence procedure discussed here.

These tests form part of an on-going equivalence programme for UK government in the UK at Teddington. The results of the equivalence calculations of the $PM_{2.5}$ Partisol 2025 with Emfab filters as of January 2015 indicate that the expanded uncertainty is below 25% [Ref.7 P86 Figures 56 & 57]. These results give an expanded measurement uncertainty without any

corrections of 6.03% (Ref.7 Figure 56), and an expanded measurement uncertainty when a correction is applied for the results of fortnightly field blanks of 3.96% (Ref.7 Figure 57).

These recent results support the conclusions and recommendations made in this Report, and also serve to demonstrate the continued equivalence of this type of monitor in the field.

5.5 Conclusions of this Evaluation Report of the MCERTS Certification Committee

The MCERTS certification committee has concluded that the evidence provided by the CEN BV and the TUV reports, and from the considerations discussed above in this evaluation Report, demonstrate that the minimum requirements of *the MCERTS Performance Standard for Continuous Ambient Air Monitors Version 8 July 2012 [Ref.3]* are fulfilled. Further it is concluded that all these requirements are fulfilled for the models A, B and i, as discussed in Section 2.2 of this Report

The MCERTS certification committee also concludes that all the minimum requirements specified in the document:
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 [Ref.5], including the requirements for conformance with the UK Particulate Pollution Climate, are also fulfilled for the models A, B and i of the $PM_{2.5}$ Partisol sampler 2025 specified above.

Therefore it is proposed that the type of ambient air $PM_{2.5}$ particulate monitor listed above is accepted as conforming to the requirements of the above MCERTS Performance Standard, and that this type of ambient PM monitor is in conformance with the requirements of the Annex to this MCERTS Performance Standard for the requirements of MCERTS for UK Particulate Matter.

The restrictions that are given below this Report also apply.

Restrictions:

1. The approved certification range is listed in Sections 2.3 and 5.3 of this Report;
2. The accepted ambient atmospheric temperature range is listed in Sections 2.3 and 5.3 of this Report;
3. Attention is drawn to the evolving nature of the firmware/software over time (and this should not be discouraged), but the requirement should be noted for all in-place firmware/software to be suitably approved.
4. The operation of instruments in permutations other than with the above components is not covered by this Report, and is not recommended for approval without further review by the UK MCERTS certification committee. They will assess the implications of any variations.

Notes:

1. The data availability was determined from the results obtained at the last three test sites (2007 to 2011) and was found to be 100% [Ref.7 Section 11]. This is to be compared with the EU directive 2008/50/EC [Ref.1] requirement of 90%.
2. The requirements of the EC Guidance on "Demonstration of Equivalence of Ambient Air Monitoring Methods" (GDE. [Ref 2]) are also fulfilled for the type of $PM_{2.5}$ monitor described in this Report.
3. The requirements of the laboratory tests given in the MCERTS Performance Standard [Ref.3] are fulfilled;
4. For the purposes of quality assurance and quality control of these monitors in the field, this type of $PM_{2.5}$ monitor should be calibrated, or have its calibration validated, on a field test site at intervals, by use of the CEN standard method EN 12341;2014 [Ref.11], as given in the recommendations of the GDE [Ref.2].

Annex 1 Terms and Definitions

For the purposes of this Report, its associated checklist, and for the purposes of the MCERTS Annex document [Ref.5], the following terms and definitions apply. The origins of these terms and definitions are shown as the reference where appropriate by square brackets [Ref.] after the definition, taken from the list of references given in Section (i) Page 7 of this MCERTS Annex document. These references are also specified below in Annex 3 of this Evaluation Report for convenience.

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.2].

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 reference 5, Section 5.2 Equation 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.

The MCERTS Performance Standard [Ref.3] also has a requirement that both of the candidate methods shall have an availability of greater than or equal to 90% during the entire set of field tests, and this shall be reported on the MCERTS certificate.

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.2].

Candidate method

A measurement method proposed as an alternative to the relevant reference method - for which equivalence is sought to be demonstrated [Ref.2].

CEN standard

International standard for normalization (norm) developed by the organisation the European Committee for Standardisation (CEN) for the objective of removing trade barriers for European industry and consumers [Ref.17].

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.18]. 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.19].

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.19].

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.19].

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 2008/50/EC[Ref.1] 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. One organisation in a given Member State is not generally capable of carrying out all of these, and there are therefore usually several competent bodies within a Member State [Ref.19]

Coverage factor

Numerical factor used as a multiplier of the combined standard uncertainty in order to obtain an expanded uncertainty [Ref.18].

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.2 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.18]. 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 the MCERTS standard (and in the Guide to Demonstration of Equivalence [Ref 2]), 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 MCERTS Annex document (Reference 5 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.2].

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.4].

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.4].

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.5]. 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 achieved 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 sample heads that are within the scope of this document, and in certain cases these may be considered as equivalent methods (reference 5 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 the MCERTS Annex document [Ref.5], and to related reports of the MCERTS certification committee, and the definition is not intended for other systems covered by MCERTS certification.

MCERTS (Performance) 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.3].

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.20].

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 [Ref.16].

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 Reference 5 Section 3.)

Standard uncertainty

Uncertainty of the result of a measurement expressed as a standard deviation [Ref.18].

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.18].

.

Annex 2 Abbreviations used

AQD	Air Quality Directive 2008/50/EC
BV	Bureau Veritas – the organisation that prepared the UK versions of reports provided by TÜV in order that they conform to all the requirements of Ref.5
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 Standardisation [Ref.17]
CM	Candidate method
EC	European Commission
EPA	Environmental Protection Agency (of the United States of America)
EU	European Union
GDE	EC Guide to the Demonstration of Equivalence of Ambient Air Monitoring Methods, January 2010 [Ref.2]
GM	Geometric mean (of particulate mass concentrations)
MCERTS	The Environment Agency's Monitoring Certification Scheme [Refs.3 & 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 [see Refs.12 & 13]

Annex 3 References

Reference 1: Directive 2008/50/EC of the European Council and Parliament of 21 May 2008 on ambient air quality and cleaner air for Europe, Official Journal of the European Union L152/1, 11.6.2008

Reference 2: 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 3: MCERTS Performance Standards for Ambient Air Quality Monitoring Systems, Environment Agency, Version 8, June 2012

Reference 4: 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/Form1177.pdf

Reference 5: 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 Methods and Manual Discontinuous Methods that Monitor Particulate Matter in Ambient Air, Department of the Environment, Food and Rural Affairs, Version 1, July 2012.

Reference 6: Air Quality - CEN/TC 264/WG 15 $PM_{2.5}$ - Field test experiments to validate the CEN standard measurement method for $PM_{2.5}$, document N 290, Final Report, July 2006

Reference 7: Thermo Fisher Scientific, UK Report on the Equivalence of the $PM_{2.5}$ Partisol 2025, Bureau Veritas Air Quality Report AGGX5508189/BV/DH/2900, dated March 2015

Reference 8: Test Report on the examinations regarding proof of the equivalence of the Partisol-Plus Model 2025 Air Sampler for the collection of airborne particulate matter from Rupprecht & Patashnick Co., Inc. using the reference method for airborne particulate matter, RWTÜV Order No.: 20 341 207/01, TUV Essen, 2000.

Reference 9: United States Environmental Protection Agency, List of Designated Reference and Equivalent Methods. Issue Date: June 27, 2013 http://www.epa.gov/ttnamti1/files/ambient/criteria/reference-equivalent-methods-list.pdf

Reference 10: CEN Standard EN 14907:2005: Standard Gravimetric Measurement Method for the Determination of the $PM_{2.5}$ mass fraction of suspended particulate matter in ambient air.

Reference 11: CEN recently published and revised Standard EN 12341:2014 Ambient air - Standard gravimetric measurement method for the determination of the PM_{10} or $PM_{2,5}$ mass concentration of suspended particulate matter.

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-Part 1, September 2010

Reference 13: Testing of automated measuring systems: Test procedures for point-related ambient air quality measuring systems of gaseous and particulate pollutants, Verein Deutscher Ingenieure, VDI RichtLinien VDI 4203 Part 3, 2008

Reference 14: Ambient air quality –Automated continuous measuring systems for the measurement of the concentration of particulate matter (PM_{10} , $PM_{2,5}$), CEN Technical Committee 264 Technical Specification, CEN/TS 16450:2013.

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

Reference 16: Characterising the PM climate in the UK for Equivalence Testing, D Green & G Fuller, King's College London Environmental Research Group, June 2012; ukair.defra.gov.uk/reports/cat13/1207190952_DefraCharacterisingThePMClimateInTheUKForEquivalenceTestingV3.pdf

Reference 17: European Committee for Standardisation http://www.cen.eu/cen/products/en/pages/default.aspx

Reference 18: Guide to the Expression of Uncertainty of Measurement (GUM): International Standardisation Organisation 1993

Reference 19: 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 20: 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)