

BS EN 14181 PROJECT – GUIDANCE FOR LABORATORIES CARRYING OUT SITE QAL2 AND ANNUAL SURVEILLANCE TESTS TO EN 14181.

1. Introduction

- 1.1 The purpose of this document is to give guidance on the application of various clauses of ISO/IEC 17025¹ – General requirements for the competence of testing and calibration laboratories and ISO/IEC 17020² – General criteria for the operation of various types of bodies performing inspection, in relation to the conduct of establishing and maintaining quality assurance levels (QALs) on automated measuring systems (AMS) sited on industrial stacks and flues. It will be used by UKAS assessors during the assessment of laboratories carrying out activities required by BS EN 14181³, and will form the basis of establishing conformity or otherwise with accreditation requirements.
- 1.2 The Environment Agency requires organisations performing monitoring required by BS EN 14181 to be accredited to ISO/IEC 17025 for the MCERTS manual stack emission monitoring performance standard for organisations⁴. In addition, the Agency requires the applicable clauses of BS EN 14181 specified in this document to be within the organisations' scope of accreditation, once the pilot project comes to a successful conclusion.
- 1.3 The guidance has been produced in consultation with the Environment Agency, the UKAS technical group for stack emission monitoring, professional bodies, certification bodies, laboratories, inspection bodies, contractors, training organisations and customers.
- 1.4 The application of BS EN 14181 by test laboratories involves 6 stages.
- Stage 1 – determining whether the AMS is QAL1 compliant, i.e. whether the AMS is MCERTS certified for the appropriate determinands and ranges.
 - Stage 2 – establishing that the functional tests have been performed in accordance with the requirements of Clause 6.2 and Annex A of the Standard.
 - Stage 3 – Performing the validation of the AMS against standard reference methods (SRMs) as specified by Clause 6.3 of the Standard.
 - Stage 4 – Performing the calculations as specified in Clauses 6.4 to 6.7 inclusive of the Standard, and generating the report, as detailed in Clause 6.8.
 - Stage 5 – Determining whether the process operator has a appropriate QAL3 procedure, as required by Section 7 of the Standard.
 - Stage 6 – Performing the annual surveillance tests (ASTs) as specified in Section 8 of the Standard.
- 1.5 By following the guidance given in this document, organisations will be able to demonstrate at assessment that they meet the requirements BS EN 14181 and have due regard for the requirements of Environment Agency Technical Guidance Note

(TGN) M20⁵.

- 1.6 BS EN 14181 requires test laboratories to use Standard Reference Methods (SRMs), which follow the hierarchy of CEN, ISO, national or other international standards. Test laboratories may use alternative methods to standards in the hierarchy, provided that they are specified in the TGN M2⁶, and that the test laboratories have demonstrated that these alternatives give an equivalent outcome to the primary SRM. This document does not cover all of the requirements of ISO/IEC 17025, ISO/IEC 17020, or the MCERTS performance standards for manual stack emission monitoring for organisations, which remain as the authoritative documents on accreditation matters.

Note: EA publication 5/01⁽⁷⁾ (Accreditation of inspection bodies: Guidelines on the application of ISO/IEC 17020) provides useful guidance on the application of ISO/IEC 17020.

- 1.7 It is not foreseen that organisations will seek accreditation for the activities listed in 1.4 which relate solely to inspection.
- 1.8 Following the ‘pilot assessment’ programme, this guidance will be reviewed, and subsequently published to enable accreditation for all activities required by BS EN 14181.
- 1.9 Accreditation will be granted for BS EN 14181 activities under ISO/IEC 17025. Currently, it is anticipated that the grant of accreditation to laboratories meeting the relevant accreditation requirements will take place in April 2009 (following completion of the UKAS Development Project).

2 GUIDANCE ON ACCREDITATION.

The following paragraphs contain guidance on specific requirements of ISO/IEC 17025, ISO/IEC 17020 and the MCERTS performance standards for manual stack emission monitoring for organisations, which are considered to be of relevance to manual stack emissions monitoring, and the application of BS EN 14181 site clearance certification activities.

2.1 Review of requests, tenders and contracts ISO/IEC 17025 clause 4.4 (ISO/IEC 17020 clause 10.5)

2.1.1 Whilst the specific aspects of generating a site specific protocol (SSP) are covered in Section 5.7 of the MCERTS performance standard, there will be additional requirements to demonstrate that areas requiring inspection have been identified and satisfactorily addressed. These additional requirements, which fall under the definition of inspection activities, are described in BS EN 14181 under the sections on QAL1, functional tests, assessments of the site-operator's monitoring provisions, and provisions for QAL3.

2.1.2 The organisation shall have a documented plan to provide for the elements of BS EN 14181 and TGN M20, and the organisation shall have agreed the proposed activities with the customer. The organisation may have a separate documented plan which relates to the SSP, or the organisation may expand the SSP to include the additional activities.

2.2 Control of records, ISO/IEC 17025 clause 4.13, (ISO/IEC 17020 : clause 12)

2.2.1 The organisation shall retain QAL2 and AST reports, as well as the raw data used to generate the reports, for at least five years from the time of the production. The organisation shall retain a representative sample of QAL3 data, including control charts, for each QAL2 and AST report. A representative sample is at least two month's of data for the site between assessed for compliance with the QAL3 requirements of EN 14181.

2.2.2 The use of photographic records is desirable, subject to the granting of permission by the customer.

2.3 Internal audits, ISO/IEC 17025 clause 4.14 (ISO/IEC 17020 clause 7.7)

2.3.1 The organisations programme for internal audits shall include auditing of all authorised personnel carrying out or performing BS EN 14181 activities on at least a 12-monthly basis. Such auditing shall be carried out by a designated "competent person" (i.e. that possesses qualifications, training, experience and knowledge to support auditing, and an appropriate level of technical knowledge).

2.4 Personnel, ISO/IEC 17025 clause 5.2 (ISO/IEC 17020 clause 8)

- 2.4.1 Staff responsible for conducting inspections as part of the BS EN 14181 activities are required (by both ISO/IEC 17025, ISO/IEC 17020 and the MCERTS performance standards) to have appropriate qualifications, training, experience and knowledge
- 2.4.2 A member of staff qualified to MCERTS Level 2 and who participates in the proficiency scheme for EN 14181 shall have overall responsibility for the technical aspects of all reports, and calculations of all reports for QAL2 and ASTs.

2.5 Test and inspection methods, ISO/IEC 17025 clause 5.4 (ISO/IEC 17020 clause 10)

- 2.5.1 In order to assess compliance with the QAL1 requirements of BS EN 14181, the organisation shall carry out the following inspection activities as a minimum:

- Determine the make and model of AMS.
- Determine whether the AMS is MCERTS certified to the appropriate determinands and ranges, using range multipliers, as specified in BS prEN 15267-3.

The organisation shall document the findings of the above inspection in an appropriate report. This information will need to be made available not only in support of QAL2 work, but re-established for the ASTs to ensure that no change has occurred in the AMS, where such changes could adversely affect compliance with BS EN 14181. The organisation shall have a documented procedure to satisfy the above inspection and reporting activities.

- 2.5.2 In order to assess compliance with the requirements of QAL2 and the AST, the organisation shall have documented procedures to satisfy the requirements specified in 5.3, 6.2 to 6.8, and 8.1 to 8.6 of BS EN 14181.
- 2.5.3 If the organisation is performing the functional tests as specified in 6.2 and Annex A of BS EN 14181, then the organisation shall have documented procedures for the inspection and testing activities specified.
- 2.5.4 If the organisation is evaluating the performance of the functional tests by a third party, then the organisation shall have documented procedures on how this evaluation shall be performed.
- 2.5.5 In order to assess compliance with the QAL3 requirements of BS EN 14181, the organisation shall carry out the following inspection activities as a minimum:
- Determine how the AMS generates and reports data.
 - Determine whether there is zero and span data, and whether this data demonstrates if any drift remains within specifications, as required by prEN 15267-3.

- Assess whether the frequency of zero and span checks is appropriate for the AMS.
- Determine whether the process operator is using control charts to record and analyse zero and span drift, as required by 7.1 to 7.4 of BS EN 14181.

The organisation shall document the findings of the above inspection in an appropriate report. This information will need to be made available not only in support of QAL2 work, but re-established for the ASTs to ensure that no change has occurred in the AMS, where such changes could adversely affect compliance with BS EN 14181. The organisation shall have a documented procedure to provide for the above inspection and reporting activities.

- 2.5.6 The organisation shall validate its calculation procedures used to satisfy the requirements of 6.4 to 6.7, and 8.3 to 8.5 of BS EN 14181.

2.6 Assuring the quality of test results, (ISO/IEC 17025 clause 5.9)

- 2.6.1 The organisation shall have procedures in place for evaluating and reporting the data for the QAL2 assessments (6.4 to 6.7 of BS EN 14181) and the AST (8.3 to 8.5 of BS EN 14181). The organisation shall also have procedures in place to validate the calculations required by BS EN 14181, in the clauses cited above.

- 2.6.2 As a means of demonstrating the effectiveness and correctness of these procedures, the organisation shall participate in a Proficiency Testing (PT) scheme, which assesses that organisations have an effective and correct means of performing and validating the calculations required by clauses 6.4 to 6.7 and 8.3 to 8.5 of BS EN 14181.

NOTE: The PT scheme is operated by the Source Testing Association (STA). Under the scheme, organisations receive sets of sample data every four months, and perform the necessary calculations and return a report to the STA no later than one month after receiving the data.

2.7 Reporting the results of tests and inspections, ISO/IEC 17025 clause 5.10 (ISO/IEC 17020 clause 13)

- 2.7.1 The organisation shall ensure that the requirements of DTI publication URN 98/887⁸ are complied with, and that UKAS accreditation is not claimed for BS EN 14181 activities prior to the formal grant of accreditation.
- 2.7.2 The organisation shall comply with the MCERTS performance standards for organisations when writing QAL2 and AST reports.

The following paragraphs contain guidance on specific requirements of ISO/IEC 17020 (inspection activities).

2.8 Liability insurance cover, ISO/IEC 17020 clause 3.4

- 2.8.1 The organisation shall hold appropriate liability insurance cover that relates to the carrying out BS EN 14181 activities.
- 2.8.2 Additional guidance on requirements for insurance liability cover is given in EA publication EA- 5/01, to which reference should be made.

2.9 Audited accounts, ISO/IEC 17020 clause 3.6

- 2.9.1 The organisation shall have independently audited/compiled accounts, and make these readily available for inspection.

2.10 Independence, impartiality and integrity, ISO/IEC 17020 clause 4, (See also ISO/IEC 17025 clause 4.1)

- 2.10.1 If an organisation employed for BS EN 14181 activities has links to the manufacturer or supplier of the AMS being inspected, then the organisation shall demonstrate how impartiality has been maintained.

Therefore if an organisation has any links with an AMS supplier or manufacturer by, for example: common ownership, common management, contractual arrangements, informal understanding, or other means that may have an ability to influence the outcome of BS EN 14181 activities. Then the organisation should not perform such activities, unless the organisation can demonstrate impartiality.

2.11 Guidance on staff conduct, ISO/IEC 17020 clause 8.5

- 2.11.1 The organisation shall provide guidance for the conduct of its staff whilst carrying out BS EN 14181 activities. Such guidance may cover issues relating to work ethics, impartiality, personal safety, relationship with clients/contractors, adherence to Company rules, protection of clients' proprietary rights, and any other issues needed to assure the proper conduct of laboratory staff.

2.12 Quality system, ISO/IEC 17020 clause 7.3

- 2.12.1 The organisation's quality manual shall comply with at least the requirements of Annex D of ISO/IEC 17020.

3 Literature references

- 1 *BS EN ISO/IEC 17025 International Standard General requirements for the competence of testing and calibration laboratories*. Published as ISO/IEC 17025:2005.
- 2 *BS EN ISO/IEC 17020 International Standard General criteria for the operation of various types of bodies performing inspection*. Published as ISO/IEC 17020:1998.
- 3 *BS EN 14181, Stationary source emissions – Quality assurance of automated measuring systems, 2004*.
- 4 *MCERTS - Manual stack emission monitoring performance standard for organisations*. Environment Agency, May 2007, Version 5.
- 5 Environment Agency Technical Guidance Note *TGN M20, Quality assurance of continuous emission monitoring systems*. Version 1, 2005.
- 6 Environment Agency Technical Guidance Note *TGN M2, Monitoring of stack emissions to air*. Version 4.2, 2007.
- 7 *EA – 5/01 EA Guidance on the application of EN 45004 (ISO/IEC 17020). European Co-operation for Accreditation*. Revision 3, December 2003
- 8 *Conditions for the use of national accreditation marks by UKAS and UKAS accredited organisations*. URN 98/887 - Department of Trade and Industry, published 2003