



LAB39

EDITION 1 | AUGUST 2004

UKAS Guidance on the Implementation and Management of Flexible Scopes of Accreditation within Laboratories

CONTENTS

	SECTION	PAGE
1	Introduction	2
2	Overview	2
3	Applicability	3
4	Key requirements applicable to all approaches	4
5	Application for accreditation	6
6	Assessment of applicant	6
7	Monitoring	7
8	Accreditation	8
9	References	9
Annex A	Considerations for developing a flexible scope of accreditation	10
Annex B	Guidance of ISO/IEC 17025	12

CHANGES SINCE LAST EDITION

1 INTRODUCTION

- 1.1 The general requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate to a quality system, are technically competent and are able to generate technically valid results are contained within ISO/IEC 17025. This international standard forms the basis for UKAS laboratory accreditation and in cases of differences in interpretation remains the authoritative document at all times.
- 1.2 The purpose of these guidelines is to set down UKAS policy, process and guidance on assessment and accreditation of laboratories wishing to implement and maintain a management system capable of controlling a flexible scope of accreditation within the bounds of ISO/IEC 17025. It is not intended as a prescriptive document, and does not set out to introduce additional requirements to ISO/IEC 17025 but to provide amplification and guidance on the current requirements within the international standard.
- 1.3 For the purposes of this document the phrase 'flexible scope' is used throughout. However, this guidance is not restricted solely to scopes that are flexible in their entirety. It is also relevant to scopes that include a combination of fixed and flexible methods, or even for primarily fixed scopes that include one or two flexible or generic methods.

2 OVERVIEW

- 2.1 Historically, laboratory accreditation within the UK has been based on fixed scopes of accreditation, defined in terms as precise as possible, to establish accurately and unambiguously the range of tests and calibrations covered by a laboratory's accreditation. However, this can be considered as restrictive in that it does not readily enable new or modified methods to be added to a laboratory's scope, even where competence in this general area has already been demonstrated. Although applications for an extension to scope can be made at any time throughout the assessment cycle, the timescales involved may actually prevent tenders or contracts being met within a client's timeframe.
- 2.2 Flexible scopes of accreditation can allow a laboratory to undertake certain tests/calibrations, and to report the results as accredited, even though they may not be explicitly stated on their accreditation schedule. This may involve:
 - (a) the inclusion of new or amended tests in accordance with a generic method;
 - (b) the modification of existing methods to broaden their applicability (e.g. to deal with new materials tested or properties measured, etc);
 - (c) the inclusion of newly revised or technically equivalent standard methods that are already covered by accreditation.
- 2.3 Accreditation of a flexible scope places more of the responsibility onto the laboratory itself for demonstrating that valid, fit-for-purpose tests are undertaken competently and consistently. However, this does not mean that a laboratory can then undertake any test that is requested of it by a client. The bounds within which the scope is flexible must be clearly defined, with the laboratory demonstrating to UKAS that it has the knowledge, experience and competence to work within the full range of its flexible

scope, as well as possessing suitable laboratory environments and equipment. These bounds should be set with respect to the range of:

- the materials/products tested
- type of test (e.g. chemical, physical, mechanical, etc)
- properties measured
- measurement
- equipment/techniques used

- 2.4 Where a laboratory wishes to apply for a flexible scope of accreditation it must demonstrate that it has a management system in place that can control its proposed approach whilst continuing to comply with the requirements of ISO/IEC 17025. This shall include, but not be limited to, clear policy statements within its quality documentation and processes for functions such as method validation/acceptance, competence of key personnel, record keeping and reporting. Annexe A and B provide additional details of aspects to be considered.

3 APPLICABILITY

- 3.1 Flexible scopes of accreditation are applicable to a wide range of different laboratories, primarily in testing but also, in some instances, in calibration. The differing needs of these laboratories means that there is no single way of implementing flexible scopes. Instead it is the responsibility of each laboratory to determine exactly what its requirements are, how it can approach this within the framework of ISO/IEC 17025, and how it demonstrates to UKAS that this approach is fit for its intended use and capable of being maintained within control.
- 3.2 Some common approaches are presented below, but this does not necessarily preclude other approaches from being adopted if their suitability and effectiveness can be demonstrated to the satisfaction of UKAS.

3.3 Modification of existing methods

- 3.3.1 Accreditation to a fixed scope is generally sufficient in meeting the needs of laboratories that undertake routine analysis of specified test and/or calibration items. The methods covered by the accreditation will have been validated to cover the full range of items processed by the laboratories. However, although some laboratories have methods/techniques that they routinely use, they may not always know what the application of these will be in advance. For instance a customer might request that a method be used on a new material/product or for a new measurand that has not previously been included within the validation process. In these circumstances, as long as the request falls within the agreed bounds of a flexible scope, a laboratory can implement a process of review/development and validation of an existing accredited method. This should follow a predefined protocol in order to demonstrate that the method is fit for purpose for the new application.
- 3.3.2 Examples of this type of approach include chemistry laboratories that may have a standard method for analysing a range of pesticides in soil, but are requested to analyse for a new pesticide for which the method has not previously been validated. Alternatively, a physical testing laboratory accredited for testing the temperature and pressure resistance of pipes might be requested to carry out similar tests on the fittings that connect the sections of pipe together.

3.4 Development of new methods

- 3.4.1 In certain areas, such as research and development, laboratories are provided with samples that are not routine. In these instances the laboratory may be required to develop a new method specifically for these samples, one that may never be used again. In this instance it may not be cost effective to apply for an extension to scope on each occasion, even if the ISO/IEC 17025 requirements relating to method validation, uncertainty of measurement and quality assurance are met.
- 3.4.2 In order to be able to develop a new method under existing accreditation a laboratory must already have demonstrated to UKAS that it is competent to undertake each of the key components involved (including test item preparation as well as testing). In addition to this it needs to demonstrate that it has the technical competence required to design and validate a method that is fit-for-purpose. The laboratory can achieve this by documenting a generic process to be followed when developing and validating new methods, enabling UKAS to ensure that all relevant issues will be covered on an ongoing basis. The laboratory will also need to have experienced staff who have a thorough technical understanding of the testing procedures and technologies applied, and are competent to review the validation data prior to authorising the method for use; such personnel should be authorised to perform this role by management.

3.5 Inclusion of technically equivalent standard methods

- 3.5.1 In some sectors laboratories specialise in certain tests in accordance with standard methods specified by the client. Under a fixed scope of accreditation the laboratory would need to demonstrate competence to undertake each specific standard method. However, in some cases the client may request the test to be conducted to a national, or similar, standard that has not been specifically accredited by UKAS although, with the possible exception of one or more minor differences in parameters such as time, temperature, pressure, etc, it may be regarded as technically equivalent to one for which the laboratory has been accredited. Where such occurrences arise, as long as the laboratory has undertaken a formal review of the new standard method against their existing accredited method to determine the key differences and to ensure that these are within the bounds of its flexible scope, then these can be authorised by the laboratory for use. UKAS must have confidence in the laboratory's capability to conduct these standard methods having previously determined the competence and capability required by the laboratory to conduct similar methods.

3.6 Inclusion of revised standard methods

- 3.6.1 This approach is similar to 3.5 above, although it is more concerned with laboratories working within a sector (e.g. EMC testing) where standard methods are continually being updated. In order for laboratories operating within such environments to demonstrate ongoing competence to UKAS they need to be able to demonstrate that the revisions remain within their specified competence and capabilities. Therefore, laboratories will need to have a formal process in place to review the revised standard, determine the changes and, if they fall within the bounds of their flexible scope, authorise the revised standard for use.

4 KEY REQUIREMENTS APPLICABLE TO ALL APPROACHES

- 4.1 Section 3 established that there are a number of different approaches to developing, implementing and maintaining a flexible scope of accreditation. The applicability of a particular approach is dependent upon the specific needs of the laboratory, and it is therefore accepted that there can be a degree of variation within the management

system of laboratories operating within the same sector. Nonetheless there are a number of key requirements that are equally applicable to any approach adopted, and must be in place before a UKAS assessment team can recommend a laboratory for a flexible scope of accreditation.

- 4.2 All laboratories seeking accreditation for a flexible scope of accreditation must be able to demonstrate compliance with the following key requirements:
- (a) new methods, or modifications/updates of existing ones, shall not incorporate new measurement principles that are not included within the agreed bounds of the flexible scope of accreditation. For such an addition the laboratory will need to apply to UKAS following the normal route for an extension to scope;
 - (b) laboratories applying for a flexible scope of accreditation in order to be able to introduce new or modified methods must demonstrate their technical capability to validate these methods in accordance with Section 5.4 of ISO/IEC 17025;
 - (c) laboratory management must authorise appropriate personnel as competent to take responsibility for key tasks including the development/review, validation and the authorisation of modified or new methods for inclusion within the system. Any changes to these key posts shall be notified to UKAS at the earliest opportunity, in accordance with paragraph 2.7 of the *UKAS Agreement*;
 - (d) the laboratory must implement sufficient quality control procedures to assure the validity of newly introduced methods;
 - (e) the process for development/review and accepting/authorising methods under a flexible scope must be incorporated into the internal audit programme. Application of the flexible scope process must be fed into the predetermined management reviews;
 - (f) all requests, tenders and contracts must be carefully reviewed to determine the requirements of the client and whether the required parameters (as listed in 2.3 above) fall within the agreed bounds of the laboratory's flexible scope of accreditation. The client should be clearly informed whether or not the laboratory is capable of undertaking the work within its flexible scope, and whether the results can be reported as accredited;
 - (g) the laboratory must maintain a record system that can demonstrate how a method was developed/modified and accepted, the justification for any modifications, and who was responsible for each key activity. The information recorded should be sufficient to allow audits to clearly follow the events leading to the introduction of each new and/or modified method;
 - (h) all reports and certificates that bear results derived from a flexible scope of accreditation must clearly indicate the method used, and whether this falls within the bounds of the flexible scope of accreditation. Attention should also be given to any reporting requirements placed on the laboratory, either by the method or by the client;
 - (i) the laboratory must inform UKAS about all modified or newly developed methods within an agreed timescale. This timescale shall be agreed between UKAS and laboratory management, and will depend upon the system put in place;
 - (j) the laboratory shall keep an updated list of accredited test/calibration methods, including newly modified, introduced or developed methods, available for review by UKAS.

5 APPLICATION FOR ACCREDITATION

- 5.1 Applicant laboratories, applying for accreditation of testing/calibration for the first time, should clearly state in the application form if they would also like their management system to be assessed for the purposes of controlling a flexible scope of accreditation. The application form should clearly define the testing/calibration activities and areas that are proposed for inclusion within the bounds of the flexible approach.
- 5.2 A laboratory that is already accredited for testing/calibration can apply to UKAS to modify its accreditation from a fixed to a flexible scope at any time. The application must clearly define the accredited testing/calibration activities and areas that are proposed for inclusion within the bounds of the flexible approach. Such applications shall be processed by UKAS following the normal route for extensions of scope.
- 5.3 Prior to offering accreditation for a flexible scope UKAS must have a high degree of confidence that the staff are technically competent and that the management system controlling certain key processes (e.g. development, review, validation, authorisation, etc) is both robust and effective. For an existing accredited laboratory UKAS will have prior knowledge of its competence and ability to maintain its system. For an applicant laboratory UKAS will not have any previous knowledge and therefore will have to adopt an assessment approach that will allow confidence to be established.

6 ASSESSMENT OF APPLICANT

- 6.1 The assessment of an applicant laboratory shall include:
- (a) the competence and capability to perform each technique included within the bounds of the flexible scope of accreditation;
 - (b) the management system and controls implemented by the laboratory for the purpose of maintaining a flexible scope of accreditation;
 - (c) the process of reviewing, validating, approving and authorising new and/or modified methods for use within the bounds of the flexible scope of accreditation.
- 6.2 The laboratory's documented quality system must clearly state whether it maintains a flexible scope of accreditation and if so, specify the areas of activity and the limits within which it operates. The process of modifying, adding, reviewing and authorising methods must be documented.
- 6.3 The laboratory must submit all relevant documentation to UKAS for review three months prior to the planned assessment date, or within an appropriate timescale agreed between UKAS and the laboratory. This should include:
- (a) documentation defining the responsibilities and processes (procedures & practices) controlling the inclusion of a new or modified method within the laboratory's scope;

- (b) criteria for defining the competence of laboratory personnel for the purposes of developing/reviewing and authorising new and/or modified methods within the bounds of the flexible scope;
 - (c) records of qualifications, experience and training of laboratory personnel authorised to develop/review and authorise new and/or modified methods within the bounds of the flexible scope;
 - (d) records of a recent assessment undertaken by the laboratory in order to authorise a new or modified method for inclusion within the proposed flexible scope of accreditation.
- 6.4 To assess the laboratory's competence to control a flexible scope of accreditation UKAS shall use the following assessment techniques as appropriate:
- (a) examination of the effective implementation of the procedures and practices;
 - (b) examination of the adequacy of the competence criteria for all key laboratory personnel;
 - (c) examination of the adequacy of mechanisms in place to determine and monitor the competence of laboratory personnel;
 - (d) interview of nominated key laboratory personnel to verify qualifications, experience, technical knowledge and training;
 - (e) examination of laboratory records that define and justify the basis upon which new/modified methods have been developed and implemented;
 - (f) use of other assessment techniques, as appropriate.
- 6.5 Following grant of accreditation of a flexible scope, records of the first methods authorised by the laboratory under its flexible scope may be requested by UKAS in order to confirm the satisfactory functioning of the relevant management controls.

7 MONITORING

- 7.1 The implementation and effectiveness of a laboratory's management system in controlling its flexible scope of accreditation shall be monitored as part of the normal assessment cycle. Sufficient time shall be allowed at future surveillance and re-assessment visits to assess the continuing effectiveness of the management system. This shall include the examination of laboratory records relating to decisions on new and/or modified methods since the last assessment visit, on a sampling basis as appropriate. The time required for these surveillance activities will depend upon the approach taken, the technical area(s) involved, and the number and complexity of new/modified methods included. In some circumstances this may require an additional visit, or visits, to be made to a laboratory's premises; this shall be agreed during the initial assessment stage.
- 7.2 Between scheduled visits UKAS may randomly select a method introduced via the flexible scope process and request that the laboratory submits for assessment the relevant records relating to its validation/authorisation for review.

8 ACCREDITATION

- 8.1 The UKAS Schedule of Accreditation shall define the bounds of the flexible scope within which specified testing/calibration areas or activities can operate. The general format of the schedule will be the same as that used for fixed scopes of accreditation, with the exception that the areas of flexibility shall be clearly identified. The actual way in which the flexibility is presented will vary depending upon the type of flexible scope operated by the laboratory, but this should be agreed between UKAS and the laboratory management taking into account the guidance provided in EA-2/05 "*The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing*"
- 8.2 The schedule of accreditation may employ footnotes, reference to documented laboratory-developed methods and procedures, or clarifying statements, etc as appropriate. However, in all cases the schedule should provide sufficient detail to enable the laboratory, customer and UKAS to determine whether a new activity can be included within the laboratory's scope of accreditation.
- 8.3 If the conduct of a new or revised method is to become routine within a laboratory then it may be specifically included within the schedule of accreditation. Depending upon the needs of the laboratory the schedule shall be updated at predetermined intervals, as agreed with UKAS. However, UKAS retains the right to refuse the inclusion of a new or modified standard if there are doubts about it falling within the bounds of the laboratory's flexible scope.
- 8.4 The approaches for controlling a flexible scope of accreditation place the main responsibility for making and justifying decisions relating to the inclusion of modified/new methods with the laboratory. If it is discovered that a laboratory has not maintained its management system, and that the controls have not been effectively implemented resulting in the inappropriate authorisation of modified or new methods, then appropriate sanctions shall be imposed upon that laboratory by UKAS. The severity of the sanction will depend upon the nature, implications and frequency of the non-conformant system, but may consist of actions including:
- (a) the suspension of a specific testing/calibration activity or area from the flexible approach;
 - (b) the revocation of the laboratory's ability to operate a flexible scope of accreditation;
 - (c) the total suspension of all accredited testing/calibration activities.

In addition, the laboratory shall be required to write to all clients that have been directly affected by any tests/calibrations in question to notify them that the previous reports were outside the laboratory's scope of accreditation. This notification must also clearly state the reason why this has occurred, and include any further actions that may be necessary as a result.

9 REFERENCES

ISO/IEC 17025 General requirements for the competence of testing and calibration
(1999) laboratories

EA-2/05 The scope of accreditation and consideration of methods and criteria for the
(2001) assessment of the scope in testing

Annex A: Considerations for developing a flexible scope of accreditation

The following questions, whilst not exhaustive, are designed to assist laboratories in identifying the key aspects that will need to be addressed to enable a flexible scope of accreditation.

A.1 What do you want to achieve by having a flexible scope?

For example, the ability under your existing accreditation to modify or adapt methods without having to seek an extension to scope from UKAS on each occasion.

Or to add newly published “standards” where the actual tests, calibrations or samplings are already covered by accreditation.

Or to apply existing accredited activities to new products or materials.

Or some other valid reason for requiring flexibility of scope.

NB It is not possible to introduce new measurement techniques under a flexible scope without prior assessment by UKAS.

A.2 How do you propose to control the flexible scope?

In other words, what processes will you be using to ensure that the work of the laboratory is adequately controlled and that decisions are being made by authorised individuals?

What are the limits of flexibility within which the laboratory will be operating?

Are staff aware of their roles and responsibilities, including limitations, in operating a flexible approach?

What training will be provided to staff to ensure that they understand, and are competent to operate within, the framework for flexibility?

Have the minimum training, experience and qualifications been specified?

Are there procedures in place for managing changes?

A.3 How will you document and record your flexible approach?

Are procedures supporting the overall framework clearly documented?

What records will be needed?

What level of detail will be recorded?

A.4 How will you validate extensions to your scope?

Are minimum validation requirements for extensions to scope specified?

Are the responsibilities for authorising validation data clearly stated?

A.5 How will UKAS be made aware of any changes?

Have you specified the types of changes that must be communicated to UKAS without delay?

In what format will you keep a register of all changes?

How frequently would you expect to keep UKAS updated?

Annex B: Guidance on ISO/IEC 17025

The material contained below is directed specifically at aspects of the standard to be considered when implementing a system to manage a flexible scope of accreditation. It is applicable equally to both testing and calibration laboratories.

ISO/IEC 17025 Clause 4.1.4

- B.1 The emphasis of this clause is very much on the laboratory being able to demonstrate that it maintains impartiality and avoids conflicts of interest through management control. In particular, for organisations that offer activities in addition to testing and/or calibration it is important that the responsibilities of key staff, including those with the authority to accept new or modified methods, are clearly defined in order to identify and manage potential conflicts of interest.

ISO/IEC 17025 Clause 4.1.5

- B.2 This clause highlights the need for the laboratory to protect the integrity of its services by ensuring that internal or external pressures do not adversely influence any stage of the process for introducing new or modified methods. In addition, if the introduction or modification of a method could compromise or reduce confidence in the testing and/or calibration provided then the laboratory must take appropriate measures to eliminate such a risk.

ISO/IEC 17025 Clauses 4.2.1 – 4.2.2

- B.3 The laboratory's policies and procedures for introducing new and/or modified methods need to be documented within the quality system. The quality policy statement should clearly define the bounds within which flexibility in the laboratory's scope of accreditation can be exercised.

ISO/IEC 17025 Clause 4.4.1 – 4.4.5

- B.4 These clauses relate to the activities that, together, are referred to below as 'contract review'. A robust contract review process is an essential element in a laboratory's demonstration of its ability to manage a flexible scope of accreditation.
- B.5 The process of contract review will need to confirm that the client's requirements have been understood, and that in determining the most appropriate method for meeting these requirements consideration has been given to clause 5.4.2 of ISO/IEC 17025: 'selection of methods'. The review should also determine whether the appropriate method can be introduced within the bounds of the flexible scope, and whether the laboratory has the necessary technical resources to achieve this within the timescales of the client

ISO/IEC 17025 Clause 4.9.1 – 4.9.2

- B.6 These clauses also apply when there is doubt about the validity of a new or modified method introduced by the laboratory under its flexible scope of accreditation.

ISO/IEC 17025 Clause 4.12.1 – 4.12.2

- B.7 These clauses address the laboratory's system for recording evidence of its accredited activities and systems. Records relating to the development and authorisation of new and/or modified methods are important in the management of a flexible scope of accreditation as they provide the information required to justify the inclusion of these methods as accredited tests and/or calibrations.

- B.8 The laboratory shall maintain comprehensive records of the development/review and authorisation of a new or modified method, detailing the basis upon which additions to the scope have been assessed and justified, including records of the staff involved. The records shall be sufficiently comprehensive to allow an audit to determine the appropriateness of the process followed and of the decision made.

ISO/IEC 17025 Clause 4.13.1 – 4.13.4

- B.9 The management controls put in place to manage the flexible scope of accreditation shall be included within the internal auditing system of the laboratory. In addition, the process of introducing new methods (including development, review, approval, authorisation) shall be included within the audit programme, as should new and modified methods that become routine practice within the laboratory.

ISO/IEC 17025 Clause 4.14.1 – 4.14.2

- B.10 The suitability and effectiveness of the management system controlling the flexible scope of accreditation, including an appraisal of the basis on which modified and/or new methods have been approved and of the competency requirements of the authorised personnel responsible for key tasks, shall form part of the management review of the laboratory.

ISO/IEC 17025 Clause 5.2.1 – 5.2.5

- B.11 The laboratory management shall ensure the competence of all personnel that it authorises to take responsibility for specific tasks relevant to the maintenance of a flexible scope. Competence criteria should be established specifying the qualifications, experience and knowledge required. Depending upon the level of responsibility held consideration should be given to the knowledge and understanding of the technologies applied and to general and product requirements expressed in standards, etc where relevant. Records of the relevant authorisation and competences, etc shall be maintained.

- B.12 Job descriptions of staff involved in the control of the flexible scope, as well as the staff undertaking the related testing activities, should define the limits of their responsibility and authority for undertaking key tasks.

- B.13 Laboratories need to have procedures in place for ensuring that key personnel authorised to make decisions on the acceptance of modified/new methods maintain their knowledge and technical understanding of the relevant testing procedures and technologies up to date.

ISO/IEC 17025 Clause 5.3.1 – 5.3.5

- B.14 The laboratory should ensure that it has the ability to maintain an environment suitable to facilitate correct performance of all tests and/or calibrations capable of inclusion within the bounds of its flexible scope.

ISO/IEC 17025 Clause 5.4.1 – 5.4.4

- B.15 The emphasis of these clauses is very much on the laboratory being able to demonstrate that it uses appropriate and valid methods and procedures for all tests and calibrations within its accredited scope. Laboratories operating under flexible scopes of accreditation will need to demonstrate that all tests and calibrations undertaken within the accredited system fall within the pre-determined bounds of the flexible scope.

- B.16 Clauses 5.4.2 – 5.4.4 highlight key technical areas with respect to operating under a flexible scope of accreditation, namely:

- B.16.1 that any method used must meet the needs of the client and that these needs must be clearly understood before the method can be selected (see ISO/IEC 17025 clause 4.4.1);
- B.16.2 that laboratory-developed methods can only be introduced if they are appropriate for the intended use and have been validated: The techniques and parameters of these methods must be within the bounds of the flexible scope to avoid the need to apply for an extension of scope;
- B.16.3 that development of new methods must be a planned activity undertaken by qualified personnel, i.e. competent staff authorised by management;
- B.16.4 that the laboratory demonstrates that it can operate standard methods before introducing them into the accredited system, and that this demonstration shall be repeated if changes are made to the standard method.

ISO/IEC 17025 Clause 5.4.5 and 5.4.6

- B.17 Appropriate method validation procedures are one of the primary management controls in the maintenance of an effective flexible scope of accreditation. The laboratory must take full responsibility for ensuring that all tests and calibrations conducted under accreditation have been validated to the extent necessary to confirm that the methods are fit for their intended use. Additional guidance on validation is available in the Eurachem publication '*The Fitness for Purpose of Analytical Methods: A Laboratory Guide to Method Validation and Related Topics*'.
- B.18 If the laboratory operates under a flexible scope that allows methods to be modified for use outside of their intended scope, then additional validation shall be required in order to demonstrate that the modified method is fit for its specified use.
- B.19 The laboratory's procedures on the estimation of uncertainty of measurement shall be applied to all new and/or modified methods. Estimated uncertainty budgets should be taken into account when determining whether a method is fit for its intended purpose prior to its authorisation for use.

ISO/IEC 17025 Clause 5.5.1 and 5.5.2

- B.20 Where a laboratory has the ability to introduce new and/or modified methods within its scope of accreditation, it shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of any tests and/or calibrations that can be included within the bounds of its flexible scope. This equipment shall be capable of achieving the accuracy required and shall comply with relevant specifications, as defined within the parameters of the flexible scope

ISO/IEC 17025 Clause 5.6.1 – 5.6.3

- B.21 These clauses relate to the calibration of all equipment and reference standards that may have a significant effect on the accuracy or validity of results. The equipment shall be calibrated across the full range for which it is to be used. This may require calibration across the full range specified within the bounds of the flexible scope, or it may require additional calibration if a new or modified method requires calibration outside the current calibration range.

ISO/IEC 17025 Clause 5.8.4

- B.22 Where a laboratory's flexible scope of accreditation allows for the inclusion of different types of samples and sample matrices then the laboratory shall need to have procedures available to protect the integrity of these samples.

ISO/IEC 17025 Clause 5.9

- B.23 A laboratory's policies and procedures for the development, review, validation and authorisation of new and/or modified methods shall consider appropriate techniques for assuring the quality of test and calibration results.

ISO/IEC 17025 Clause 5.10

- B.24 Although there are no additional considerations required relating to reports derived from a method that has been introduced via a flexible scope of accreditation, the report should identify the method used and include deviations from, additions to, or exclusions from the method where this is necessary for the interpretation of results. It should also be clear that the method was undertaken within the bounds of the laboratory's flexible scope of accreditation.

ISO/IEC 17025 Clause 5.10.5

- B.25 Laboratories that hold a flexible scope of accreditation may also be accredited for expressing opinions and interpretations as long as they meet the requirements as specified in UKAS Publication LAB 13 '*UKAS Guidance on the Application of ISO/IEC 17025 Dealing with Expressions of Opinions and Interpretations*'. Laboratories will have to clearly indicate those areas of their flexible scope where opinions and interpretations are included within their accreditation: opinions and interpretations may not necessarily apply across the entire scope.