GEN 4

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UKAS policy and general guidance for the implementation and management of flexible scopes of accreditation

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Changes since last edition

This is the first edition of this publication, which has combined, and further developed, the guidance previously provided in the following UKAS publications *(which have now been withdrawn)*:

LAB 39 UKAS Guidance on the Implementation and Management of Flexible Scopes of Accreditation within Laboratories

TPS 59 Implementation and Management of Flexible Scopes of Accreditation for the Commissioning of Site Laboratories

It also incorporates European Accreditation requirements published in:

EA-2/15 M: 2019 EA Requirements for the Accreditation of Flexible Scopes

1. Terms and Definitions

For general guidance on terms and definitions used within accreditation, please refer to **GEN 1** - *General Principles for the Assessment of Conformity Assessment Bodies*.

1.1 **Scope of accreditation** - Conformity assessment activities for which a body holds accreditation.

1.2 **Fixed scope** - Clearly defined description of the specific conformity assessment activities for which the body holds accreditation.

1.3 **Flexible scope** - the scope of accreditation expressed to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the competence of the conformity assessment body (see 4.2). This also includes extending the scope of accreditation to introduce new locations.

1.4 **Conformity Assessment Body (CAB**) - A body (legal entity) that performs conformity assessment activities and that can be the object of accreditation.

1.5 **Conformity assessment activity** - An activity that demonstrates that specific requirements are fulfilled. This can include testing, examination, inspection, certification and verification.

1.6 **Object of conformity assessment** - any particular material, product, installation, process, system, person, claim or body to which conformity assessment is applied.

1.7 **Conformity Assessment Body standard** - a normative standard that provides requirements for the operation of a specific type of conformity assessment body, and which is used by UKAS to assess and accredit a CAB to ensure that a product, service or system meets requirements. These include the ISO/IEC 17000 series of standards, and cover conformity assessment activities including certification, inspection, testing, calibration, proficiency testing provision, reference material production and verification.

1.8 **Schedule of accreditation** - the document that UKAS issues, accompanying the certification of accreditation, to define the scope of accreditation awarded.

2. Introduction

2.1 The general requirements that conformity assessment bodies (CABs) have to meet in order to demonstrate that they are competent, impartial and capable of consistently providing their conformity assessment activities are contained within conformity assessment body standards e.g. those produced by ISO including ISO/IEC 17020, ISO/IEC 17021-1, ISO/IEC 17025, ISO 15189, ISO/IEC 17065, etc.

2.2 The conformity assessment body standards form the basis for UKAS accreditation and in cases of differences in interpretation remain the authoritative documents at all times.

2.3 The purpose of this document is to set down UKAS policy, process and guidance on assessment and accreditation of CABs wishing to implement and maintain a management system capable of controlling a flexible scope (see 2.4) of accreditation within the bounds of a relevant conformity assessment body standard. It is not intended as a prescriptive document and does not seek to introduce additional requirements to those already contained within the conformity assessment body standard.

2.4 This document uses the phrase ‘flexible scope’. However, this guidance is not restricted solely to scopes that are flexible in their entirety. It is also relevant to schedules of accreditation that include a combination of fixed and flexible scopes, or even for fixed scopes that include some inherent flexibility in their application.

2.5 For some conformity assessment activities UKAS, the European co-operation for Accreditation (EA), the International Laboratory Accreditation Cooperation (ILAC) or International Accreditation Forum (IAF) may provide further guidance and sector specific interpretation on the application of flexible scope (see UKAS Website for Publications).

2.6 CABs seeking more information on the accreditation and application process should refer to the UKAS Website.

3. Overview

3.1 Historically, accreditation was defined in very precise terms and presented as a fixed scope in the schedule of accreditation; this provided an accurate and unambiguous range of conformity assessment activities covered by a CAB's accreditation. However, over time this became considered as restrictive in that it did not readily enable new or modified activities to be added to a CAB's scope, even where competence had already been demonstrated in associated activities. Although applications for an extension to scope could be made at any time throughout the assessment cycle, the timescales involved for the subsequent assessment and accreditation may prevent the CAB responding promptly to market needs.

3.2 Flexible scopes of accreditation provide a mechanism to allow a CAB to undertake new or modified activities within its scope of accreditation, even though the specific conformity assessment activities may not be explicitly stated on its schedule of accreditation. The degree of flexibility awarded can vary between technical disciplines and conformity assessment activities.

3.3 Within some fields of conformity assessment, CABs may be required to establish temporary facilities or new locations to serve specific customer needs. To enable the activities at these locations to be included within the scope of the CAB's accreditation without undue delay, UKAS can consider the option of awarding accreditation for adding new locations under a flexible scope, where competence in the performance of the activities has already been demonstrated at previous locations.

3.4 Accreditation of a flexible scope places more responsibility onto the CAB itself for demonstrating that valid, fit-for-purpose processes/activities are undertaken competently, impartially, and consistently and comply with the relevant conformity assessment body standard. However, this does not mean that a CAB can undertake any activity that is requested of it by a client and claim that it is accredited. The bounds within which the scope is flexible must be clearly defined, with the CAB demonstrating to UKAS that it has the competence to work within the full range of its flexible scope, as well as having suitable resources. These boundaries will be dependent on the accreditation maintained, but could include flexibility in specific component(s) of an accredited activity:

(a) area of activity, products, parameters, product/process standards, certifications, materials, schemes, sample types

(b) range of activity, tests/examinations, technical/clinical areas, clustering of scope IAF codes (or part thereof)

(c) methods, procedures, parameters, equipment, measurement, extent of technical/clinical area, specification

(d) type of activities undertaken at a location

(e) commissioning of new locations

4. UKAS Policy on Flexible Scopes

4.1 Flexible scopes of accreditation can be applicable to a wide range of different conformity assessment activities, as discussed in Annex A.

4.2 UKAS will give consideration to applications from CABs to operate under a flexible scope that allows them to make changes to accredited activities (see 3.4) and/or commissioning accredited activities at a new location undertaken by contracted staff of the accredited entity.

4.3 UKAS does not consider that the flexible scope approach is appropriate for allowing CABs to introduce a new activity where it has not previously demonstrated competence for undertaking the key components involved. An example of a new activity for testing/calibration would be a new analytical technique, whereas in certification/inspection, this would be a new scheme.

4.4 Where a flexible scope is considered applicable, UKAS will consider applications on a case-by-case basis taking account of the CAB's ability to demonstrate appropriate management controls for the level of risks associated with its activities.

4.5 When considering the level of risk associated with a proposed flexible scope, and its overall applicability, UKAS will take into account a number of factors, including:

- degree of understanding by the CAB of the rules and procedures for implementing and managing a flexible scope;
- performance and stability of the CAB's management system;
- complexity of the conformity assessment activities;
- extent of flexibility requested;
- reputational risks for UKAS, CAB and market;
- impact on independence & impartiality;
- market sector maturity and associated risks;
- retention of technical personnel within CAB responsible for the activities relating to the flexible scope;
- knowledge of the CAB and its compliance to the relevant standards and activities;
- stakeholder/regulatory expectations;
- the planned/likely frequency of use of flexible scope;
- extent of controls proposed for managing a flexible scope;
- location and any geographical risks.

4.6 It should be noted that the more traditional fixed scopes can incorporate a degree of flexibility, depending on the risk associated with the conformity assessment activity. The level of inherent flexibility within the fixed scope will be agreed between UKAS and the CAB at the time the activity is first assessed (i.e. initial assessment or extension to scope) and subsequent offer/award of accreditation. For these situations the requirements within this document are applicable for managing this degree of flexibility within a fixed scope.

5. Key Requirements Applicable to All Approaches

5.1 It is the responsibility of the CAB to demonstrate and provide evidence of competence and compliance with the relevant conformity assessment body standard. This will require UKAS to have access to all relevant staff, locations, records and, where appropriate, witnessing activities at the locations of the CAB's client(s).

5.2 Where a CAB wishes to apply for a flexible scope of accreditation, it shall demonstrate that its management system is effective in managing and controlling its flexible scope activity, whilst continuing to comply with the requirements of the specific conformity assessment body standard. This shall include, but not be limited to, clear policy statements within its quality documentation and processes for functions such as method validation/acceptance, risk analysis, competence of key personnel, record keeping and reporting (see section 5.4 for more detail).

5.3 CABs may have 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 CAB, and it is therefore accepted that there can be a degree of variation within the management system of CABs operating within the same sector. Nevertheless, there are a number of key requirements that are equally applicable to any approach adopted, and these must be in place before UKAS can award a flexible scope of accreditation.

5.4 All CABs seeking a flexible scope of accreditation shall demonstrate competence, impartiality and conformity with the following key requirements:

(a) new activities, modifications/updates of existing activities shall not incorporate new principles (e.g. components - see 3.4) that are not included within the agreed bounds of the flexible scope of accreditation. For additions outside the bounds of the flexible scope the CAB will need to apply to UKAS following the normal route for an extension to scope;

(b) CABs applying for a flexible scope of accreditation to introduce new or modified activities and/or locations shall demonstrate their competence to implement these processes in accordance with the relevant part of the conformity assessment body standard;

(c) the CAB management shall authorise appropriate personnel as competent to take responsibility for specific tasks including the development/review, validation and the authorisation of modified or new activities (see 3.4) and/or new locations for inclusion within the system. Any changes to individuals undertaking these key tasks shall be notified to UKAS at the earliest opportunity, in accordance with the UKAS Agreement;

(d) the CAB shall implement suitable quality control/evaluation procedures to assure the validity of newly introduced activities;

(e) the process for development/review and accepting/authorising processes under a flexible scope shall be incorporated into the internal audit programme. Information on the application of the flexible scope process shall be fed into the management reviews;

(f) Ongoing consideration of the flexible scope activities shall be included within the CABs' risk assessment process and should include risks to its independence and impartiality;

(g) all requests, tenders and contracts shall be carefully reviewed to determine the requirements of the client and whether their request falls within the agreed bounds of the CAB's flexible scope of accreditation. The CAB's client shall be clearly informed whether or not the CAB is capable of undertaking the work within its flexible scope, and whether the results/outcome can be reported as accredited;

(h) the CAB shall maintain a record system that can demonstrate, as applicable:

i. how an activity was developed/modified and approved
ii. how risks associated with the new activity were evaluated
iii. the justification for any modifications
iv. who is responsible for each key processes (see 6.6)
v. how a new location has been commissioned

The information recorded should be sufficient to allow internal audits and external assessments to clearly follow the events leading to the introduction of each new or modified activity and/or location;

(i) all reports and certificates that bear results which are covered by the flexible scope of accreditation shall clearly state that the outcome falls within the bounds of the flexible scope of accreditation. Attention shall also be given to any reporting requirements placed on the CAB, either by the activity or by the client;

(j) the CAB shall inform UKAS about all modified or newly developed processes and/or new locations within an agreed timescale. This timescale shall be agreed between UKAS and CAB management, and will depend upon the system put in place and risks associated with the activity;

(k) the CAB shall keep an up to date list of accredited activities, including newly modified, introduced or developed activities, available for review by UKAS and other interested parties;

(l) the CAB shall inform UKAS in advance of including a new location under its flexible scope arrangements so UKAS can update the schedule of accreditation and include the new location in the forward plan for the assessment of the CAB;

(m) the CAB shall inform UKAS of the removal of a location to ensure the schedule of accreditation is updated and enable UKAS to establish whether any further assessment is required.

6. Flexible Scope Application

6.1 Applications from CABs seeking a flexible scope of accreditation will need to clearly state that they would like their management system to be assessed for the purposes of maintaining a flexible scope of accreditation. The relevant application form (i.e. AC 1 - 7) should clearly define the activities and areas that are proposed for inclusion within the bounds of the flexible approach.

6.2 The CAB's documented management system shall clearly state whether it maintains a flexible scope of accreditation and if so, that it addresses the requirements of section 5.4.

6.3 The CAB shall submit all relevant information to UKAS with its application form for review at least three months prior to the planned assessment date, or within an appropriate timescale agreed between UKAS and the CAB. This information shall include:

(a) documentation defining the policies, processes and responsibilities for controlling the inclusion of a new or modified activity (see 3.4) within the CAB's scope;

(b) criteria defining the competence of the CAB's personnel for the purposes of developing/reviewing and authorising new and/or modified activities (see 3.4) within the bounds of the flexible scope;

(c) records of competence (ability to apply knowledge and skills to achieve intended results) of the CAB's personnel authorised to develop/review and authorise new and/or modified activities within the bounds of the flexible scope;

(d) examples of supporting documentation and records associated with the CAB implementing its flexible scope process in introducing a new or modified activity or location (e.g. procedures, training/competence, criteria and evaluation, validation, quality controls, traceable calibration/reference material, audits, reports).

6.4 If UKAS has not assessed the proposed scope of flexibility before, it may seek internal/external advice to determine whether the risks and controls are at an acceptable level. This may involve development/office effort. Whether an application can be taken forward or not will be the decision of UKAS.

6.5 Where the scope of flexibility requested includes an activity that UKAS has not accredited before, it may be treated as a development activity and the usual UKAS development process will be followed.

6.6 Prior to offering accreditation for a flexible scope UKAS must have confidence that the staff are technically competent and that the management system controlling relevant key processes (e.g. development, review, validation, competence determination, authorisation, etc) is both robust and effective. For an existing accredited CAB, UKAS will have prior knowledge of its competence and ability to maintain its system and introduce new activities from the compliance of previous extension to scope applications and/or assessments. For an applicant CAB, UKAS will not have any previous knowledge and therefore will adopt an assessment approach that will allow confidence to be established. This may require UKAS to offer a fixed scope of accreditation in the first instance and then review a number of examples where the flexible scope principles have been employed prior to extending the scope to include the flexibility applied for.

7. Initial Assessment Approach

7.1 The assessment will include:

(a) the competence and capability of the CAB to perform each activity included within the bounds of the flexible scope of accreditation;

(b) the management system and controls implemented by the CAB for the purpose of maintaining a flexible scope of accreditation;

(c) the process of reviewing, validating, approving and authorising new and/or modified activities for use within the bounds of the flexible scope of accreditation, including risk evaluation;

(d) the process for commissioning a new location (if applicable).

7.2 To assess the CAB's competence to control a flexible scope of accreditation, UKAS will use the following assessment techniques, through a combination of remote and on-site visits, as appropriate:

(a) assessment of documentation submitted in support of flexible scope arrangements;

(b) assessment of the effective implementation of the procedures and practices;

(c) assessment of the adequacy of the competence criteria for all key CAB personnel;

(d) examination of the adequacy of mechanisms in place to determine and monitor the competence of CAB personnel;

(e) interview of nominated key CAB personnel to verify the suitability of the CAB's evaluation of the competency of individuals responsible for maintaining the flexible scope;

(f) assessment of CAB records that define and justify the basis upon which new/modified activity have been developed and implemented;

(g) use of other assessment tools, as appropriate.

NOTE: If a CAB does not have live examples to demonstrate the implementation of its processes for introducing or modifying activities under a flexible scope, then confidence in the CABs competence to do so can be determined through the review of changes introduced following the more traditional extension-to-scope process employed for fixed scopes. Demonstration to the assessment team that such extensions-to-scope can be introduced without the need for additional actions or information to be provided to UKAS should provide confidence that the CAB possesses the necessary level of technical competence to manage a flexible scope.

7.3 As part of the assessment UKAS will require discussions with authorised person(s) who are responsible for managing the flexible scope process to confirm the CAB's competency. Where the application includes a number of locations such assessments may be on a sampling basis, taking into account an evaluation of the risks involved and the degree to which the CAB has demonstrated its ability to effectively control their locations.

7.4 Following the award of accreditation of a flexible scope, records of the first processes/activities authorised by the CAB under its flexible scope may be requested by UKAS, outside of the normal accreditation cycle assessment activities, in order to confirm the effective implementation of the relevant management controls.

8. Ongoing Assessment Activities

8.1 The implementation and effectiveness of a CAB's management system in controlling its flexible scope of accreditation will be monitored as part of the normal accreditation assessment cycle. Sufficient time will be allowed at future surveillance and reassessment visits to assess the continuing competence of the CAB to operate a flexible scope. This will include the examination of CAB records relating to decisions on new and/or modified activities since the last assessment visit, on an appropriate sampling basis. The time required for these assessment activities will depend upon the approach taken, the activities involved, risks associated with activities, and the number and complexity of new/modified activity and/or locations included. In some circumstances this may require an additional visit, or visits, to be made to a CAB's premises; this will be agreed prior to the award of the flexible scope of accreditation and reviewed thereafter on an ongoing basis.

8.2 UKAS will ensure that, depending upon their longevity, any new locations introduced via a flexible scope are assessed. UKAS will take into account the risks associated with the activities/location to determine the frequency the new location is assessed and/or visited within the accreditation cycle.

8.3 Between scheduled assessments UKAS may select an activity or location introduced via the flexible scope arrangements and request that the CAB submits for assessment the relevant records relating to its validation/competency/authorisation for review.

8.4 Prior to each scheduled assessments, UKAS will request a list of activities carried out under the flexible scope arrangements since the previous visit and may request that the CAB submits for assessment the relevant records relating to some or all of its implementation documentation for review. The CAB must provide the requested information without undue delay. The CAB can also provide details of any activities under its flexible scope, which it wishes to be included on its schedule of accreditation, (i.e. moved to a fixed scope).

8.5 UKAS may re-sample/witness flexible scope activities or revisit previous activities which had not been previously reviewed or transferred to a fixed scope (see section 9.4).

8.6 The CAB shall maintain, and be able to demonstrate, competence in implementing the flexible scope process. If this process is only infrequently used, then additional UKAS assessment criteria may be applicable as detailed in UKAS publication TPS 68 *UKAS Policy on Accreditation of Infrequently Performed Conformity Assessment Activities*.

9. Accreditation

9.1 The UKAS schedule of accreditation will define the bounds of the flexible scope within which the CAB 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 will be clearly identified, reference to the CABs in-house procedure for implementing its flexible scope process and also the reference list (as per 5.4 k)). The actual way in which the flexibility is presented will vary depending upon the type of flexible scope operated by the CAB.

9.2 The schedule of accreditation may employ footnotes, reference to documented CAB developed methods and procedures, or clarifying statements. However, in all cases the schedule should provide sufficient detail to enable the CAB, its clients and UKAS to determine whether a new activity is included within the CABs scope of accreditation.

9.3 If the implementation of a new or modified activity is to become routine within a CAB, then it may be specifically included within the schedule of accreditation once the CAB has confirmed it has introduced all the necessary routine quality controls, where relevant. Depending upon the needs of the CAB the schedule of accreditation will be updated at predetermined intervals, as agreed with UKAS. However, UKAS retains the right to refuse the inclusion of a new or modified activity if there are doubts about it falling within the bounds of the CAB's flexible scope.

9.4 Where a new activity introduced under the flexible scope arrangement is transferred to the 'fixed scope' on the schedule of accreditation, then it will also be included within the CAB's four-year accreditation cycle, and hence assessed on a regular basis taking into account risk-based factors.

9.5 When the CAB commissions or decommissions a location under the flexible scope it shall provide UKAS with the following details, to update the schedule of accreditation:

(a) the address of the location;

(b) contact details of the CAB's representative on site;

(c) the activities to be carried out at the location;

(d) the date from which the location will operate, or cease to operate, under its accreditation.

9.6 The approach for controlling a flexible scope of accreditation places the main responsibility for making and justifying decisions relating to the inclusion of modified/new activities with the CAB. If it is discovered that a CAB has not maintained its competence to manage its flexible scope, and that the controls have not been effectively implemented resulting in the inappropriate authorisation of new or modified activities or locations, then appropriate sanctions will be imposed upon that CAB by UKAS. The severity of the sanction will depend upon the nature, implications and frequency of the non-conforming system, but may consist of actions including:

(a) the suspension of a specific activity or area from the flexible approach;

(b) the revocation of the CAB's ability to operate a flexible scope of accreditation;

(c) the total suspension of all accredited CAB activities.

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

10. References

ISO/IEC 17011:2017	*Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies*
ISO/IEC 17025:2017	*General requirements for the competence of testing and calibration laboratories*
ISO/IEC 17021-1: 2015	*Conformity assessment - Requirements for bodies providing audit and certification of management systems*
ISO/IEC 17024: 2012	*Conformity assessment - General requirements for bodies operating certification of persons*
ISO/IEC 17043: 2010	*Conformity assessment - General requirements for proficiency testing*
ISO 17034 :2016	*General requirements for the competence of reference material producers*
ISO/IEC 17065:2012	*Conformity assessment - Requirements for bodies certifying products, processes and services*
ISO/IEC 17020: 2012	*Conformity assessment - Requirements for the operation of various types of bodies performing inspection (ISO/IEC 17020:2012)*
ISO 15189: 2012	*Medical laboratories - Requirements for quality and competence*
EA-2/15 M: 2019	*EA Requirements for the accreditation of flexible scopes*
EA-4/17 M: 2008	*EA position paper on the expression description of scopes of accreditation within Medical Laboratories*
ILAC G28:07/2018	*Guideline for the Formulation of Scopes of Accreditation for Inspection Bodies*
NACE - Rev 2	"*Nomenclature générale des Activités économiques dans les Communautés Européennes" (Statistical classification of economic activities in the European Communities) - Rev 2 2008*
TPS 68	*UKAS Policy on Accreditation of Infrequently Performed Conformity Assessment Activities*

ANNEX A: Examples of Flexible Scopes of Accreditation

A1 Testing and Calibration Laboratories (ISO/IEC 17025)

A1.1 Fixed scopes of accreditation

Accreditation for a fixed scope is generally sufficient to meet the needs of testing and calibration laboratories as it defines the specific activities which it has demonstrated competence to undertake. However, a laboratory may benefit from implementing a flexible scope approach in the following section.

A1.2 Development of a new method

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 order to be able to develop a new method under existing accreditation a laboratory shall already have demonstrated to UKAS that it is competent to undertake each of the key components involved (including test/sample preparation as well as testing/examination). 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.

A1.3 Modification of existing test/calibration and sampling methods

Some laboratories have methods/techniques that they routinely use, although 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/sample type or for a new measurand/characteristic 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.

- 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. For a physical testing laboratory accredited for testing the temperature and pressure resistance of pipes it might be requested to carry out similar tests on the fittings that connect the sections of pipe together.

A1.4 Inclusion of technically equivalent standard methods

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.

- For example, a laboratory is accredited to ASTM D6379:2011-06 but its customer requests testing to IP 436:2015. IP 436:2015 requires the laboratory to have the same competence and equipment however there are some differences in timings associated with the test.

A1.5 Inclusion of revised standard methods

This approach is similar to A1.4, although it is more concerned with laboratories working within a sector (e.g. electromagnetic compatibility 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.

A1.6 Temporary Site Locations / Addition of methods at another site

It is recognised that for some fields of testing/sampling, established laboratories may need to establish site laboratories to serve specific customer requirements. These site laboratories often need to be commissioned at short notice and/or operate for a short period of time. In order for the activities of each site laboratory to be included within the scope of the laboratory's accreditation UKAS is able to award accreditation for a flexible scope which includes the commissioning of site laboratories. The laboratory will need to demonstrate it has a process in place to implement the management system, competent personnel, currently accredited method from another site, appropriate equipment, validation of method in new location, environment monitoring (if applicable) and quality assurance mechanisms.

Similarly, a laboratory may require the flexibility to introduce an accredited method from one site to another site.

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A2 Medical Laboratories (ISO 15189)

A2.1 Fixed scopes of accreditation

For the routine tests undertaken within a medical laboratory a fixed scope of accreditation is appropriate as it allows its healthcare service users to confirm what is covered by the accreditation.

For fixed scope accreditation there can be some inherent flexibility within the scope, which will be defined when accreditation is awarded. This inherent flexibility includes referring to groups of organisms in microbiology and disorders in genetics in the schedules of accreditation instead of the specifics. However, there may be some situations where a flexible scope may be more beneficial for a medical laboratory to cover the following situations as described in this section.

A2.2 Modification of existing test/methods

If a user of a medical laboratory or other healthcare service requested an examination on a different sample type or patient group for a particular examination, which was outside of the scope of accreditation, the service would need to apply to UKAS for an extension to scope. However, under a flexible scope it is possible to define boundaries which would enable the service to add sample types or patient groups. In order to be able to modify a method under existing accreditation a medical laboratory shall already have demonstrated to UKAS that it is competent to undertake each of the key components involved (including test/sample preparation as well as testing/examination). In addition to this it needs to demonstrate that it has the technical competence required to design and validate a method/examination that is fit-for-purpose for the healthcare user.

- For example, a medical laboratory could be accredited for clinical chemistry where the scope associated with a particular analyser would list the analytes (or similar). A user could request an analyte which was not included in the original verification (and possibly not validated). A flexible scope, if applied to the use of this analyser, would enable the medical laboratory in this instance to validate and verify this additional analyte and to report results for this new analyte as accredited without the need for the laboratory to approach UKAS for an extension to scope.

A2.3 Inclusion of technically equivalent standard methods and revisions to standards

Medical laboratories with a microbiology department (including virology), may use examinations which are based on Public Health England SMIs (Standards for Microbiology Investigations). A new SMI may necessitate a new examination process, but this change may not impact on any required competences and a flexible scope appropriately described could enable a medical laboratory to change an examination to the revised SMI without necessitating an assessment by UKAS under an extension to scope process, (if the amendment was within the competence of the laboratory and within the boundaries of the flexible scope).

Under a suitably defined flexible scope that captures amendments to SMIs, a revision to an existing SMI, which did not indicate a different range of competences to that already accredited, could be validated and verified by the laboratory and reported as accredited without needing to be assessed as an extension to scope.

A2.4 Addition of new point of care testing locations (ISO 22870:2016).

Point of Care (Near Patient) Testing is inherently dynamic with delivery points frequently added. The provider could have the flexibility as defined in the flexible scope, to add delivery points onto the scope of the service without necessitating an application to UKAS and assessment for an extension to scope. A generic procedure would be in place to demonstrate what criteria are used by the provider to commission sites prior to use for Point of Care Testing.

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A3 Management System (MS) Certification (ISO/IEC 17021-1)

A3.1 Fixed scopes of accreditation

Accreditation to a fixed scope is generally sufficient to meet the needs of a certification body (CB) that has a stable client base and provides accredited certification in a defined scope as detailed in their schedule of accreditation. The schedule will identify the scopes dependent upon the management system type e.g. for QMS full IAF code scopes as detailed in IAF ID1 economic sectors or limited scopes relating to NACE 2 descriptors.

A flexible scope of accreditation with respect to management system certification could be considered to enable a CB the ability to include new 'scopes' within an existing management system standard. Examples of which are provided in A3.2 to A3.5

If a CB requires the addition of a new MS standard it will need to apply to UKAS following the normal route for an extension to scope.

A3.2 Modification of existing limited technical scope

For CBs whose customer base operates in a restricted technical area a fixed technical scope of accreditation is generally appropriate. The CBs will have demonstrated competence in undertaking certification activities for the limited scope (e.g. specific NACE descriptors within an IAF ID1 economic sector). However, if the CB wishes to certify a client within a scope area in which the CB does not hold full accreditation, a flexible scope approach could be considered. Under a flexible scope approach a CB can offer accredited certification as long as the request falls within the agreed bounds of a flexible scope (e.g. IAF Number and Description of economic sector/activity) and it implements a process to review/develop and validate its service within the 'new' sub-scope. This should follow a predefined protocol in order to demonstrate that required competences are appropriate to cover the scope of the certification request.

- Examples of this type of approach could be that a CB has a limited number of NACE descriptors within the scope of IAF 1 (NACE 2 Divisions 5 to7) and has a robust process to ensure competency for other technical areas (NACE 2 Divisions 8 and 9) outside the limited scope if it was required.

A3.3 Development of technical scopes within a technical cluster (as per IAF MD17 or equivalent)

Similar to A3.2, where a CB currently certifies within a specific sector, it may receive a request to certify a technical scope within a technical cluster. In this situation the CB may consider using a flexible scope to manage requests across a technical cluster which share similar competence requirements.

- Examples of this type of approach could be that a CB has demonstrated competence and holds accreditation for certifying clients to ISO 9001 for machinery and equipment (as defined in IAF 18). With an appropriate flexible scope process in place the CB would be able to offer accredited certification in the area of basic metals and fabricated metal products (as defined in IAF 18) as this is within the 'mechanical technical' cluster as defined in IAF MD17.

The CB shall document a generic process for ensuring that all relevant issues/risks will be covered on an ongoing basis. The CB shall have competent staff that have a thorough technical understanding of the scope area, and prior to authorising the scope competence such personnel shall be authorised to perform this role.

A3.4 Expansion of geographic issuance area

The schedule of accreditation will provide details of the geographical areas where a CB issues certificates within its scope of accreditation. Where a CB wishes to have flexibility and provide its services in a new area it may apply for a flexible scope. In this case the CB shall demonstrate that it has the capability to manage and deploy audit teams with knowledge and competence with respect to the geographic context (e.g. legal, social, cultural) of the individual customers.

A3.5 Addition or modification of accredited activities at a new location

A CB may wish to hold a flexible scope to enable the commissioning of activities at new locations in the following circumstances:

- Extending the scope of a current location on the schedule of accreditation to include an accredited activity already covered at another site.

- To commission a new location (where staff are directly contracted to the entity) which is under the control of the head office for activities which are currently within the scope of its accreditation.

The CB shall demonstrate that it has processes and management controls in place to ensure that when new activities are developed for deployment at any location to be included under its flexible scope.

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A4 Products, Processes and Services Certification (ISO/IEC 17065)

A4.1 Fixed scopes of accreditation

A fixed scope of accreditation is normally sufficient for the needs of a CB Providing certification of products, processes and services. UKAS will assess the applicability of the product certification scheme[+] and the competence of the CAB taking into consideration the evaluation methodology(ies) and parameters relating to the specific object of the conformity assessment applicable at the time.

All new schemes will need to be evaluated and assessed by UKAS prior to accreditation being awarded. However, there may be situations where there are changes to existing schemes which could be managed under a flexible scope, these are described in section A4.2 and A 4.3.

A4.2 Modification of the evaluation methodology and/or parameters

For continuing maintenance and development of the certification scheme, it may be necessary to periodically change the evaluation methodology / parameters therein. Therefore, a flexible scope would allow a CAB to undertake changes to the scheme without UKAS initial review, as long as the changes do not reduce the confidence in the outcome of the specific conformity assessment activity. An example of this would be the introduction of a new version or a technically equivalent version of an existing normative document containing specified requirements.

The CB shall have a generic process which it follows to ensure the changes to the scheme have been agreed by the scheme owner, appropriate review of the changes undertaken, procedures updated and assurance that it has appropriate resources including updating training/competence of staff.

A4.3 Extended range of the object of conformity assessment within an accredited conformity assessment scheme.

Depending upon the specific object of the conformity assessment scheme, some fixed scopes of accreditation may state an applicable range rather than a series of individual objects covered by that fixed scope. That applicable range may be extended under a flexible scope arrangement providing it is the same conformity assessment scheme applying the same evaluation methodology(ies) and other parameters. An example of this would be to extend the current scope for the product certification of medium density fibreboard (MDF) for range of 10mm to 20 thickness (as detailed on schedule of accreditation) to include 25mm thickness. Similarly, the range of non-electrical equipment for potentially explosive atmospheres can be extended based on the coverage of BS EN 13463 if the fixed scope only covers a defined list of equipment.

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[+] ***Certification scheme*** *as defined in ISO/IEC 17065:2012 is "certification system related to specified products, to which the same specified requirements, specific rules and procedures apply."*

A5 Certification of Persons (ISO/IEC 17024)

A5.1 Fixed scopes of accreditation

A fixed scope of accreditation is normally sufficient for the needs of a CB providing certification of persons. UKAS will assess the applicability of the person certification scheme[+] and the competence of the CAB taking into consideration the evaluation methodology(ies) and parameters relating to the specific person of the conformity assessment applicable at the time.

All new schemes will need to be evaluated and assessed by UKAS prior to accreditation being awarded.

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[+] ***Certification Scheme*** *as defined in ISO/IEC 17024:2012 is "competence and other requirements related to specific occupational or skilled categories of persons*

A6 Inspection (ISO/IEC 17020)

A6.1 Fixed scopes of accreditation

A fixed scope of accreditation is normally sufficient for the needs of an Inspection Body (IB). UKAS will assess the applicability of the inspection scheme[+] and the competence of the CAB, taking into consideration the evaluation methodology(ies) and parameters relating to the specific object of the conformity assessment applicable at the time.

All new schemes will need to be evaluated and assessed by UKAS prior to accreditation being awarded. However, there may be situations where there are changes to existing schemes which could be managed under a flexible scope, these could be:

A6.2 Modification of the evaluation methodology and/or parameters

For continuing maintenance and development of the inspection scheme, it may be necessary to periodically change the evaluation methodology / parameters therein. Therefore, a flexible scope would allow a CAB to undertake changes to the scheme without UKAS initial review as long as the changes do not reduce the confidence in the outcome of the specific conformity assessment activity.

- An example of this would be the introduction of new versions or technically equivalent versions of existing normative documents containing specified requirements.

- Another example would allow ab inspection body to adapt and apply an inspection scheme to specific patient care pathways within the healthcare sector.

The IB shall have a generic process which it follows to ensure the changes to the scheme have been agreed by the scheme owner, appropriate review of the changes undertaken, procedures updated and assurance that it has appropriate resources including updating training/competence of staff.

A6.3 Extended range of the object of inspection within the scope of accreditation.

Depending upon the specific object of the inspection scheme, some fixed scopes of accreditation may state an applicable range rather than a series of individual objects covered by that fixed scope. That applicable range may be extended under a flexible scope arrangement providing it is the same conformity assessment scheme applying the same evaluation methodology(ies) and other parameters. An example of this would be to extend a current fixed scope for the inspection of pressure vessels to vessels of a different size where the vessels are of the same construction and to which the same specified requirements apply.

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[+] *Inspection **scheme** as defined in ISO/IEC 17020:2012 is "inspection system to which the same specified requirements, specific rules and procedure apply.*

A7 Reference Material Producers (ISO 17034)

A7.1 Fixed scopes of accreditation

Accreditation to a fixed scope is generally sufficient to meet the needs of reference material producers (RMPs) that undertake routine production of the reference materials detailed in their schedule of accreditation.

In most cases it is recognised that there is inherent flexibility in the scope which will be defined when accreditation is awarded; the constraints of that flexibility will generally be in the selection of matrix/artefact and/or in the property value(s) / identity / characterisation range as specified in the schedule of accreditation.

For example, without the need to apply for an extension to scope, a RMP may:

- choose a variety of components from the defined list to produce a multi-component reference material (e.g. specific chemical elements) or
- select a variety of property values for components within the defined range to produce a multi-property value reference material (e.g. particular concentrations of chemical elements) or combine both of the above options to produce multi-component, multi-property value reference material (e.g. a multi-element, multi-concentration material)

A.7.2 Production of new materials within a flexible scope of accreditation

When accrediting RMPs, it is important to recognise that it is the competence of the RMP itself that is being assessed (i.e. that it is competent to produce defined reference materials) rather than the quality of individual reference materials (although this will be ensured as a consequence of the RMPs demonstrable competence). It is important to remember that ISO 17034 is not product certification. Therefore, it is possible for an RMP to demonstrate competence across a defined range of different reference materials, even if it hasn't previously produced every material that could fall within that range. Such competence cannot necessarily be reflected in a fixed scope and, if this model best reflects the business needs of an RMP, then this can only be effectively achieved through the adoption of a flexible scope.

There are many benefits of reference material production operating within a flexible scope. For instance, it can be applied to RMPs that frequently receive customer requests for non-routine materials that may often fall outside of the pre-defined parameters specified within a fixed schedule. Alternatively, it could benefit RMPs that make materials that last for such extended periods that demonstrating competence on a routine basis is considered unnecessary and would entail unnecessary costs.

Specific examples where a flexible scope may be beneficial include:

- cases where a fixed scope includes the assay of a list of specific stoichiometric reference materials. A flexible scope would allow for the assay of other stoichiometric reference materials, not currently listed in the schedule of accreditation.
- cases where a fixed scope includes gravimetric production of standard solutions containing a range of chemicals which are listed in the schedule of accreditation. A flexible scope would allow production of customer specified reference materials containing other chemicals that are not named in the schedule. In such an example, the RMP will need to have demonstrated to UKAS its competence to:
  - identify when such mixtures are incompatible, and that the reference material cannot therefore be produced
  - establish traceability for the new chemical(s)
  - determine stability for the mixture(s)
  - identify and report to the customer any specific instructions on storage, handling, or intended use, due to the nature of the custom mix they have requested

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A8 Proficiency Testing Providers (ISO/IEC 17043)

A8.1 Introduction of a new proficiency testing Scheme

A scope of accreditation to provide proficiency testing (PT) or external quality assessment (EQA) is inherently flexible to a degree. The UKAS schedule of accreditation will make reference to the proficiency testing scheme name(s) and provide a reference to where the details of the scheme(s), can be found; this will usually be a controlled document and/or a website page. The PT provider shall inform UKAS of any change to this web page or document.

A8.2 Modification of existing proficiency testing scheme

UKAS will discuss with PT/EQA providers any potential application for a flexible scope which increases the degree of inherent flexibility already applied. This could include, for example, the type of PT items, statistics applied in data analysis and homogeneity/stability techniques. The boundaries of this proposed flexibility shall be clearly defined, for example if flexibility in the PT items submitted to participants in already accredited schemes is required, clear boundaries such as but not limited to, the techniques used for homogeneity/stability testing, any preparation steps prior to submission to participants and any specific environmental requirements would need to be considered.

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ANNEX B: Guidance on General Standard Requirements

The information contained below are general aspects of conformity assessment body standards to be considered when implementing a system to manage a flexible scope of accreditation.

Impartiality

B.1 The emphasis of this requirement is on the CAB being able to demonstrate that it maintains impartiality and avoids conflicts of interest through management control. CABs need to consider the risk to its impartiality that any activity/location included within the bounds of its flexible scope could introduce.

Resource Requirements - Personnel

B.2 These requirements are to ensure all staff act impartially, are trained, competent and authorised. Specifically, for a flexible scope defined personnel need to be authorised to take responsibility for relevant associated tasks. Depending upon the level of responsibility held consideration should be given to the knowledge and understanding of the technologies/practices/activities applied and to general and specific requirements expressed in standards, etc where relevant. Records of the relevant authorisation and competences, etc shall be maintained.

B.3 CABs need to have procedures in place for ensuring that key personnel authorised to make decisions on the acceptance of modified/new activities or new locations maintain their knowledge and technical understanding of the relevant procedures and technologies/practices/activities up to date.

Resource Requirements - Facilities (if applicable)

B.4 The CAB should ensure that it has the ability to maintain an environment suitable to facilitate correct performance of all activities capable of inclusion within the bounds of its flexible scope

Resource Requirements - Equipment (if applicable)

B.5 Where a CAB has the ability to introduce new and/or modified activities within its scope of accreditation, it shall be furnished with all items of sampling, measurement, test and inspection equipment required for the correct performance of any activity 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.

Resource Requirements - Metrological Traceability (If applicable)

B.6 This clause relates 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.

Process Requirements - Review of applications, requests, tenders and contracts

B.7 This requirement relates to the activities that, together, are referred to below as ‘contract review’. A robust contract review process is an essential element in a CAB’s demonstration of its ability to manage a flexible scope of accreditation.

B.8 The process of contract review will need to confirm that the client's requirements have been understood, and that the CAB has determined the most appropriate activity for meeting these requirements. The review should also determine whether the appropriate activity can be introduced within the bounds of the flexible scope, and whether the CAB has the necessary technical resources to achieve this within the timescales of the client. The client should be informed that the activity falls within the bounds of the flexible scope and process required to deliver an accredited output, especially if the activity has not been undertaken before.

Process Requirements - Selection, verification and validation of methods

B.9 The emphasis of this requirement is on the CAB being able to demonstrate that it uses appropriate and valid procedures for all activities within its accredited scope. CABs operating under flexible scopes of accreditation will need to demonstrate that all activities undertaken within the accredited system fall within the pre-determined bounds of the flexible scope.

B.10 Key technical areas with respect to operating under a flexible scope of accreditation, include:

- that any activity used shall meet the needs of the client and that these needs shall be clearly understood before the activity can be selected;
- that CAB-developed activities can only be introduced if they are appropriate for the intended use and have been verified/validated: The techniques and parameters of these activities shall be within the bounds of the flexible scope to avoid the need to apply for an extension of scope;
- that development of new activities shall be a planned activity undertaken by qualified personnel, i.e. competent staff authorised by management;
- that the CAB demonstrates that it can operate the activities methods before introducing them into the accredited system, and that this demonstration shall be repeated if changes are made to and of the component of the activity (4.4).

Process Requirements - Validation of methods (If applicable)

B.11 Appropriate method validation and verification procedures are one of the primary management controls in the maintenance of an effective flexible scope of accreditation. The CAB shall take full responsibility for ensuring that all activities conducted under accreditation have been validated to the extent necessary to confirm that the methods are fit for their intended use.

B.12 If the CAB operates under a flexible scope that allows methods to be modified for use outside of their intended scope, then additional validation shall be required to demonstrate that the modified activity is fit for its specified use.

Process Requirements - Handling of items (if applicable)

B.13 Where a CAB's flexible scope of accreditation allows for the inclusion of different types of items then the CAB shall need to have procedures available to protect the integrity of these items.

Process Requirements - Evaluation of measurement uncertainty (if applicable)

B.14 The CAB's procedures on the estimation of uncertainty of measurement shall be applied to all new and/or modified activities. 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.

Process Requirements - Assuring the Quality of Output / Results

B.15 A CAB's policies and procedures for the development, review, validation (If applicable) and authorisation of new and/or modified activities or new locations shall consider appropriate activities for assuring the quality of output/results.

Process Requirements - Report/Certificates

B.16 Although there are no additional considerations required relating to reports/certificates derived from an activity that has been introduced via a flexible scope of accreditation, the report/certificate shall identify the activity used and include deviations from, additions to, or exclusions from the activity where this is necessary for the interpretation of results. It shall also be clear that the activity was undertaken within the bounds of the CAB's flexible scope of accreditation.

Management Requirements - Management system documentation

B.17 The CAB's policies and procedures for introducing new and/or modified activities or locations need to be documented within the quality system, or as part of a certified ISO 9001 system (recognised via Option B).

Management Requirements - Control of records

B.18 This requirement addresses the CAB's system for recording evidence of its accredited activities and systems. Records relating to the development and authorisation of new and/or modified activity or new locations are important in the management of a flexible scope of accreditation as they provide the information required to justify the inclusion of these activities or location as accredited.

B.19 The CAB shall maintain comprehensive records of the development/review and authorisation of new or modified activities, 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.

Management Requirements - Management of nonconforming work

B.20 This clause applies when there is doubt about the validity of a new or modified activity introduced by the activity or location under its flexible scope of accreditation. Impact on all work under the flexible scope should be considered.

Management Requirements - Internal audits

B.21 The management controls put in place to manage the flexible scope of accreditation shall be included within the internal auditing system of the CAB. In addition, the process of introducing new activities and locations (including development, review, approval and authorisation) shall be included within the audit programme, as should new and modified activities that become routine practice within the CAB or at new locations.

Management Requirements - Management review

B.22 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 activities and locations 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 CAB.

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