

# GEN 1

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## **General principles for the assessment of conformity assessment bodies by the United Kingdom Accreditation Service**

## Table of contents

<b>1. Introduction</b>	<b>4</b>
<b>2. Terms and definitions</b>	<b>5</b>
<b>3. Types and techniques of assessments</b>	<b>6</b>
<b>4. Accreditation process overview</b>	<b>8</b>
4.1 Application	8
4.2 Contract review	9
4.3 Pre-assessment / desktop assessment	11
4.4 Initial assessment	13
4.5 Surveillance activities	13
4.6 Reassessment activities	14
4.7 Extension to scope (ETS)	15
4.8 Unannounced assessments	15
<b>5. UKAS assessment process</b>	<b>16</b>
5.1 Contract review	16
5.2 Assessment plan / pre-assessment information	17
5.3 Document review	17
5.4 Assessment	18
5.5 Decision on recommendation	20
5.6 Close out of findings	21
5.7 Grant / maintenance / renewal of accreditation	22
5.8 Accreditation certificate and schedule	23
<b>6. Sanctions (withdrawal or suspension)</b>	<b>23</b>
<b>7. Complaints and appeals</b>	<b>25</b>
<b>8. Resignation</b>	<b>25</b>
<b>9. Change of organisation name, legal entity and/or ownership</b>	<b>26</b>
<b>Appendix A - Content of UKAS reports</b>	<b>27</b>
<b>Appendix B - Standard specific assessment requirements</b>	<b>30</b>
B.1 Laboratory (test, calibration, medical) requirements (ISO/IEC 17025, ISO 15189)	30
B.2 Inspection requirements (ISO/IEC 17020)	31
B.3 Certification requirements (ISO/IEC 17021-1, ISO/IEC 17024, ISO/IEC 17065)	33
B.4 Proficiency testing scheme provider requirements (ISO/IEC 17043)	37
B.5 Reference material producer requirements (ISO 17034)	37
B.6 Approved / UK notified body requirements	37
B.7 Physiological (IQIPS) and imaging service requirements	37
B.8 Validation and verification requirements (ISO/IEC 17029, ISO 14065)	38
B.9 Biobanking requirements (ISO 20387)	41
<b>Appendix C - Multi-site accreditation including fixed office locations</b>	<b>42</b>
C.1 Requirements	42
C.2 Assessment process	42

## Changes since last edition

- Reference to measurement audit removed (service no longer provided by UKAS)
- Reference added to biobanking
- UKAS Agreement updated to UKAS Customer Agreement throughout
- Reference added to the UKAS Assessment Portal and Main Portal
- §4.4.3 Expanded with respect to accreditation recommendation
- §4.5.2 Clarification given regarding circumstances to be notified to UKAS as soon as practicable
- §5.3.1 Expanded for cases where UKAS decides not to proceed with assessment on the basis of review of documented information submitted by the CAB
- §5.4.2.7 Clarified – independent review of a finding can be requested; the term appeal has been removed as this only applies to accreditation decisions as in §7
- §7.1 & §7.2 Minor editorial changes made for additional clarity
- §9.2 Amended to reflect the change to electronic signing of the UKAS Customer Agreement
- B.8 Validation and Verification (ISO/IEC 17029, ISO 14065) and B.9 Biobanking (ISO 20387) added to Appendix B
- Minor updates throughout to reflect the implementation of a digital applications process using the UKAS portal

## 1. Introduction

- 1.1 This publication gives general information and guidance on the conduct of UKAS assessments and related activities. The varied nature of assessments calls for flexibility of approach from both the assessment team and the Conformity Assessment Body (organisation seeking accreditation and hereafter referred to as 'CAB') but the general principles outlined in this document will be implemented by UKAS.
- 1.2 UKAS assesses and accredits the competence of CABs that perform a number of conformity assessment activities including testing, calibration, inspection, provision of proficiency testing, production of reference materials, biobanking, validation & verification and the certification of products, management systems and personnel.
- 1.3 CABs seeking more information on UKAS and accreditation should refer to the [UKAS website](#).
- 1.4 CABs seeking accreditation from UKAS are required to submit a formal application using the process and mechanism described on the UKAS website ('[How to apply for accreditation](#)' page).
- 1.5 Assessment of the competence of the CAB is carried out using a variety of assessment techniques that include document review, remote assessments (e.g. access to records, interviews with staff, live streaming of activities, etc), visits to the CAB's 'head office' or main location of operation and any other key location(s) included within the scope and witnessing of the conformity assessment activities including on-site witnessed assessments.
- 1.6 UKAS assessment procedures are applicable to all types and sizes of CAB. Assessments will take account of the size and complexity of the CAB when assessing its management system.
- 1.7 It is the responsibility of the CAB to demonstrate and provide evidence of competence and conformity to the relevant standard(s). This will require UKAS to have access to all relevant staff, locations, records and where appropriate witnessing activities at the CAB customer locations (as detailed in the UKAS Customer Agreement).
- 1.8 The purpose of the assessment is to determine whether the CAB has the necessary competence and conforms with the requirements of the relevant standard(s), schemes and regulations for which it holds or is seeking accreditation.
- 1.9 For some conformity assessment activities UKAS, [European co-operation for Accreditation \(EA\)](#), [International Laboratory Accreditation Cooperation \(ILAC\)](#) or [International Accreditation Forum \(IAF\)](#) and Government/Regulators may provide further mandatory requirements, guidance and sector specific interpretation on the application of accreditation criteria (see [UKAS website](#) for publications).
- 1.10 UKAS assessments are conducted by an assessment team that is normally comprised of a lead assessor, normally a permanent employee of UKAS, and one or more technical assessors, experts and/or lay assessors (where relevant). All experts and assessors must meet defined criteria for their respective roles and technical expertise. All assessors and experts sign up to a code of conduct which includes a confidentiality undertaking and requirement to identify any potential conflicts of interest.
- 1.11 As specified in the UKAS Customer Agreement, all information obtained by UKAS before, during and after assessment, including the fact that a particular CAB has applied for accreditation, is treated as strictly confidential by UKAS staff, contracted assessors and experts unless otherwise agreed in writing by the CAB or required by law.
- 1.12 The procedures described in this publication apply to pre-assessment and initial assessment, as well as to assessments after accreditation has been granted covering the four-year accreditation cycle for the purposes of surveillance, reassessment and extension to scope. It may be necessary on occasion for UKAS to conduct assessments giving little or no notice.
- 1.13 UKAS keeps its customers informed of progress and the next steps in the accreditation process. Communications will primarily come from the UKAS member of staff assigned to the CAB as the main point of contact.

## 2. Terms and definitions

- 2.1 **Accreditation** - third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.
- 2.2 **Accreditation body (AB)** - authoritative body that performs accreditation. UKAS has been appointed by Government as the UK's sole National Accreditation Body (NAB).
- 2.3 **Local accreditation body (LAB)** - the accreditation body of a foreign country where a conformity assessment body undertakes activities covered by its scope of accreditation.
- 2.4 **Conformity assessment body (CAB)** - body/organisation that performs conformity assessment services and that is the object of accreditation. This includes laboratories, inspection bodies, certification bodies, verification bodies, reference material producers and proficiency testing providers.
- 2.5 **Assessment Manager (AM)** - UKAS employee who is responsible for the overall management of the CAB's accreditation process, surveillance and reassessment cycle. Assessment Managers normally act as Lead Assessors and are responsible for identifying a suitably competent assessment team, and for the planning and conduct of assessments. Assessment Managers can also act as Technical Assessors or Experts where they hold the relevant competence.
- 2.6 **Lead Assessor (LA)** - Assessor that leads the assessment and directs the assessment team. The Lead Assessor will normally conduct the assessment of the management system of the CAB and is responsible for providing the assessment report, using input from the assessment team and for any recommendation on accreditation.
- 2.7 **Technical Assessor (TA)** - Individual who is trained in UKAS assessment processes and implementation of the relevant conformity assessment body standard (who may or may not be employed directly by UKAS) with relevant specialist knowledge to assess and evaluate the competence of the CAB to perform its activities for which accreditation is sought or held. Their activities are confined to assessing the CAB's technical competence through conformity with the requirements and reporting their findings to the CAB and to UKAS.
- 2.8 **Technical Expert (TEXP)** - Individual working under the responsibility of an authorised assessor, who provides specific knowledge or expertise with respect to the scope of accreditation to be assessed and does not assess independently.
- 2.9 **Lay Assessor** - A member of the UKAS team who provides an end-user perspective to a specific area of service delivery (e.g. patient viewpoint in healthcare).
- 2.10 **Site** - A place where an assessment will take place. This may be a key location (see 2.12) or other place where conformity assessment activities are performed e.g. a CAB's customer's premises.
- 2.11 **Multi-location organisation** - A CAB with a main location in which key activities are performed or managed with a network of one or more locations at which such activities are fully or partially managed or carried out. All locations come under the direct control of the main location and work within the same management system.
- 2.12 **Key location** - An office or facility included within the scope of application or accreditation where activities covered by the scope, or in support of the scope, take place.

- 2.13 **Improvement action (or finding)** - A finding raised by UKAS that may be a nonconformity against the assessment criteria (e.g. relevant international standard / conformity assessment body standard) including the CAB's own management system requirements or an opportunity for improvement. These can be recorded as either Mandatory or Recommended, depending upon whether or not they are a clear nonconformity against a particular assessment criterion. Improvement actions may be recorded in the UKAS Assessment Portal or on an Improvement Action Report (IAR) form.
- 2.14 **Recommendation** - A statement made by the assessment team at the end of an assessment to confirm the conclusion of the assessment team e.g. whether accreditation or an extension to scope should be granted. Recommendations are reviewed during the independent decision-making process in order for an impartial decision to be made on grant, renewal, extension, reduction or withdrawal of accreditation.
- 2.15 **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 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.
- 2.16 **Desktop review (or document review)** - the process of reviewing documentation by the assessment team in preparation for an assessment activity (e.g. contract review, site visit, witness assessment).
- 2.17 **Desktop assessment** - the process of determining the conformity of a CAB by assessing documented evidence remotely, and resulting in a formal assessment report and, where applicable, findings.

### 3. Types and techniques of assessments

- 3.1 UKAS utilises various assessment techniques to conduct its assessments. These techniques depend upon the assessment type, applicable requirements and associated risks, and shall be chosen to ensure that a CAB is assessed in the most effective way.
- 3.2 Assessment types:
- i **Pre-assessment** - performed to assess an applicant for readiness to progress to an initial assessment.
  - ii **Initial assessment** - formal assessment of a new applicant (or existing customer to a new conformity assessment body standard) to ensure that all accreditation requirements have been effectively implemented.
  - iii **Surveillance** - performed annually in years 1 to 3 of the accreditation cycle to ensure the criteria for accreditation are being maintained.
  - iv **Reassessment** - performed in the final (4<sup>th</sup>) year of each accreditation cycle to ensure that the CAB continues to comply with all accreditation requirements. The outcome of a reassessment shall lead to a recommendation on the renewal of accreditation.
  - v **Witnessed assessment** - performed to assess competence of a CAB to undertake the actual conformity assessment activities. This can be either on the site of the CAB or witnessing staff undertaking the accredited (or applicant) activity at one or more of its customers locations. The witnessed assessments may be integrated into site visits (e.g. testing) or separate activities (such as witnessing inspection activities or management system audits).

- vi **Extension to scope** - performed to change or extend a CAB's current scope of accredited activities. This can include a change of location at which the conformity assessment activities are performed, or changes to key resources e.g. equipment).
- vii **Extra assessment** - This may be performed if it was not possible to complete all aspects of an assessment during the scheduled assessment event. Alternatively, an extra assessment may be required to confirm effective implementation of corrective actions or to gain assurance in an area of weakness. Other reasons for an extra assessment include, but are not limited to, reinstatement, following a period of voluntary, compulsory or financial suspension, investigation of a complaint or assessment of a change of legal entity.
- viii **Unannounced assessment** - an assessment performed without providing the customer with any notice, or with limited notice: an unannounced assessment could be a Surveillance or an Extra assessment (see section 4.8).
- ix **Transition assessment** - performed to verify fulfilment of new/amended requirements when there is a change in a conformity assessment body standard or other key accreditation criteria to which a customer holds accreditation.

Note: If the change results in a new rather than revised standard, then this is referred to as a 'Migration' rather than 'Transition'.

3.3 Assessments may be performed using a range of techniques as listed below. These include the typical assessment techniques used, but UKAS may need to adopt other techniques to ensure a robust and effective assessment is undertaken. An assessment will consist of one, or a combination of these assessment techniques.

- i remote review of documentation (e.g. desktop)
- ii on-site assessments
- iii remote assessments (e.g. via electronic means such as online access, video links, web conferencing, telephone interviews, desktop assessment of documents, etc)
- iv technical interviews
- v witnessed assessments
- vi key location assessments
- vii post-audit review if witness activities are not possible (See [Appendix B.3](#))
- viii use of LABs to assess non-UK locations (see UKAS policy on cross-frontier accreditation for more details)



## 4. Accreditation process overview

There are a number of steps in the accreditation process. These are outlined in Figures 1 and 2. For a more detailed description of the assessment process refer to [section 5](#).

### 4.1 Application

#### 4.1.1 New applicants

- 4.1.1.1 CABs seeking accreditation for the first time are required to submit a formal application to UKAS by following the process detailed in the UKAS website - see '[How to apply for accreditation](#)' and '[Application for Accreditation](#)' pages. After initial screening by UKAS, and on payment of the application fee (refer to the [UKAS Standard Terms of Business](#)), the applicant will receive log-in details for the UKAS Portal where they will submit their full application, detailing their accreditation scope requirements. All applicants are required to sign the standard UKAS Customer Agreement electronically (specimen Agreement accessible [here](#)). UKAS will then begin consideration of the applicant's readiness for an assessment.
- 4.1.1.2 If UKAS has not provided accreditation against a specific standard or a technical scope before it still could be accredited. However, the accreditation process may involve establishing a development project which is likely to incur increased costs and timescales. If a CAB is planning to apply for a new area of activity, they should contact UKAS prior to application.
- 4.1.1.3 Applications shall not be progressed until UKAS has received confirmation of the payment of the application fee. In addition, all new applicant CABs are subject to a credit check, and credit terms will only be extended to CABs with a good and proven credit history. If this is not the case, then UKAS shall require assessment fees to be paid in advance of any assessment work being undertaken.
- 4.1.1.4 Applications submitted without provision of all of the specified documentation requested will not normally be accepted until the missing documentation has been made available. UKAS will provide acknowledgment of receipt of an application (typically within 1 week of receipt).
- 4.1.1.5 Once a new applicant has been received and accepted it shall be allocated to the relevant team within UKAS. A member of the team will contact the applicant to clarify its needs, confirm accreditation requirements, and to discuss costs, pre-assessment options and timescales.
- 4.1.1.6 Following this initial contact, and after confirming the applicant's needs, an employee of UKAS, usually an Assessment Manager, will be appointed as the customer's main contact. This person will be the contact point for the customer to discuss the scope of the application, location of activities and ascertain readiness to progress to the next stage.
- 4.1.1.7 Prior to any work being carried out, UKAS will provide an estimate of the assessment effort required (in terms of person days) to proceed to the next stage of the assessment process. The charges for UKAS assessment activities are listed in the [UKAS Standard Terms of Business](#).
- 4.1.1.8 All UKAS customers are given a customer number, which also acts as their accreditation number, and will be quoted on all communications from UKAS.
- Note: CABs accredited prior to 2011 will have customer numbers that are different to their accreditation numbers.
- 4.1.1.9 The primary function of UKAS is to meet the needs of businesses and institutions within the United Kingdom. However, UKAS may also consider applications for accreditation from CABs based outside of the United Kingdom. For further information on [overseas \(non-UK\) applications](#) refer to the UKAS website.
- 4.1.1.10 Progress of applications is regularly reviewed and where there has been no progress for more than one year, UKAS will contact the CAB to determine whether they still intend to proceed. Applications with no progress for over two years shall be withdrawn from the application process unless there are mitigating circumstances. In some instances, withdrawal may take place sooner than this depending upon the level of response from the applicant. Applicants shall be informed of this action.



#### **4.1.2 Extension to scope (ETS)**

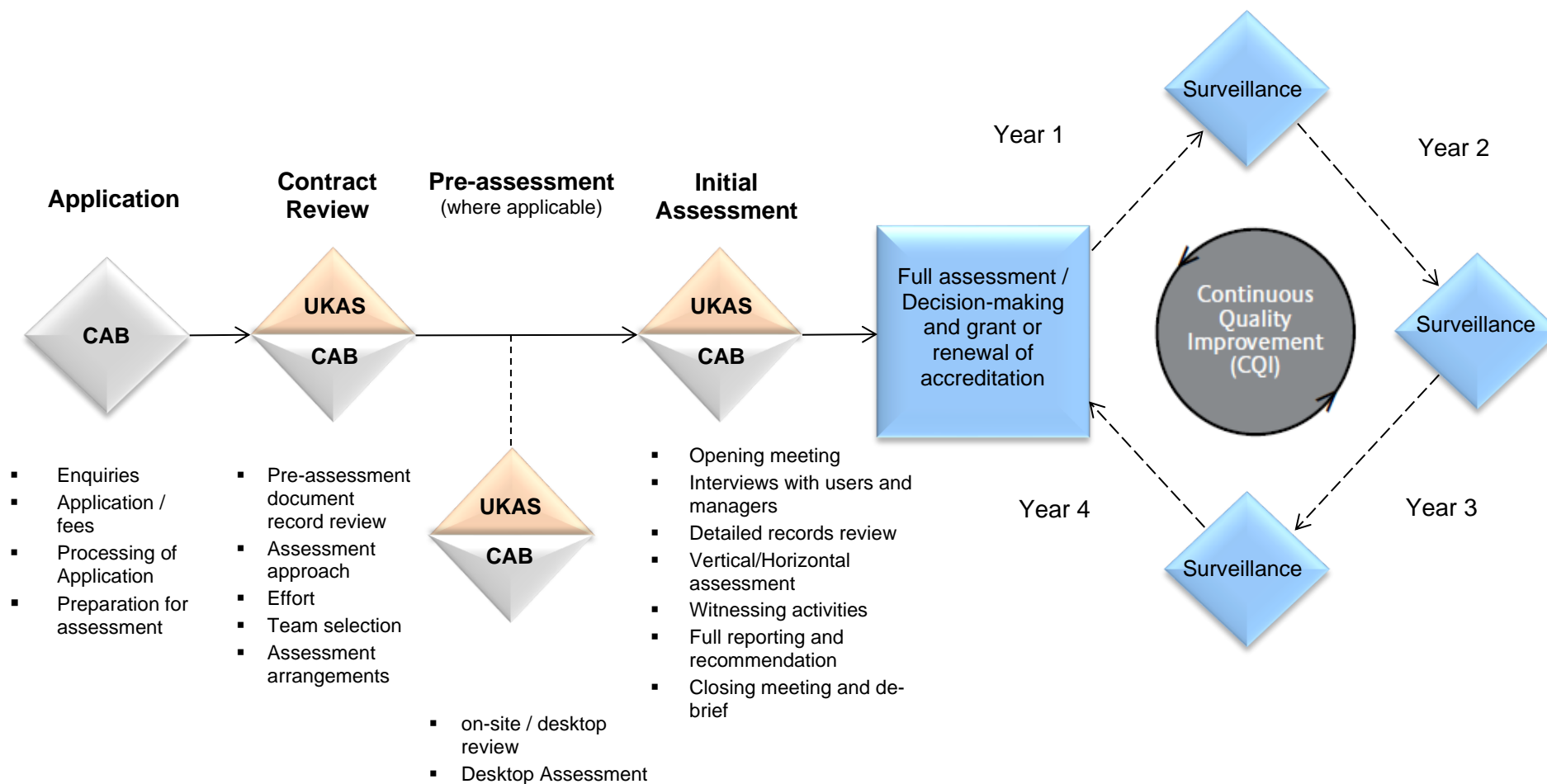
- 4.1.2.1 Where an existing accredited CAB wishes to extend its scope of accreditation under a conformity assessment standard it shall complete an extension to scope application in the UKAS Portal. In support of this, the relevant documentation indicated must also be supplied.
- 4.1.2.2 Checks will be carried out to ensure that all required information has been made available prior to its acceptance. UKAS will provide acknowledgment of receipt of an application (typically within 2 working days).
- 4.1.2.3 To help UKAS to plan the assessment within the CABs expected timeframe, the application for extension to scope should be submitted to UKAS at least 3 months before assessment is required. CABs are advised to discuss plans for extensions to scope with UKAS at the earliest opportunity.
- 4.1.2.4 If the extension is to be assessed during a scheduled assessment it must not adversely impact on the assessment of activities already planned to be covered during the assessment and therefore additional time is likely to be required. As a consequence, UKAS will not normally accept applications for extension to scope requested during the course of an assessment.

#### **4.1.3 Changes to conformity assessment body standards**

- 4.1.3.1 When a conformity assessment body standard is revised, UKAS will need to verify that any new or amended requirements have been effectively implemented in order to transfer accreditation to the new version. At the outset of the transition period all affected CABs will be informed of the transition requirements via the publication of a [Technical Bulletin](#) on the UKAS website, or through direct communication with the CABs concerned. These bulletins/communications will provide the internationally agreed timeframe for the transition, and the details of the transition process that UKAS shall employ. The process can vary depending on the number of CABs requiring transition and the timeframe involved but may require CABs to complete and submit a pre-prepared transition template in advance of any assessment.

#### **4.2 Contract review**

- 4.2.1 The documentation and information submitted in support of an application will be reviewed by UKAS to determine whether the relevant accreditation requirements have broadly been met and that the CAB is ready to proceed to the next step (e.g. pre-assessment or initial assessment). If the CAB is not in a position to proceed, then it shall be contacted to discuss what further action is required.
- 4.2.2 Before the application can be progressed, UKAS will perform a contract review to determine the most appropriate assessment approach, the composition of the assessment team, and the total effort required (covering preparation and any assessment (on-site or remote) activities) to conduct a robust assessment. The CAB will be informed of the names and affiliations of all assessment team members sufficiently in advance of the assessment, allowing time for reasonable objections to be raised about any potential conflicts of those proposed (see section 5.1.4).
- 4.2.3 UKAS will provide an estimate of the effort required for assessment activities.
- 4.2.4 If UKAS is unable to undertake an initial assessment within the timeframe requested by the CAB this shall be communicated to the CAB.



**Figure 1: Overview of Accreditation Process**



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### 4.3 Pre-assessment / desktop assessment

- 4.3.1 Pre-assessments are optional but are strongly recommended for CABs that do not have any, or only limited, previous experience of being accredited. Generally, pre-assessments are for new applicants, however an existing CAB can request a pre-assessment if it feels this will help progress an extension to scope, for example in an area of accreditation that is new to them.
- 4.3.2 A pre-assessment typically involves a desktop review of documentation submitted by the CAB followed by an on-site visit. Alternatively, a remote desktop assessment of the documentation could be undertaken with the possibility of a follow up call or web-meeting to discuss the outcome.
- 4.3.3 A pre-assessment is not a formal assessment but will provide a gap analysis between current processes and accreditation requirements. The discussions during a pre-assessment will assist the CAB in identifying potential major nonconformities so that these can be addressed before the initial assessment. As a result, this can improve the likelihood of a successful outcome and reduce the timeframe between assessment and grant of accreditation. The pre-assessment also provides an informal introduction to accreditation, the assessment process and the assessment team.
- 4.3.4 The pre-assessment is structured so that the assessment team can ascertain whether the essential components of a management system for quality, administrative, technical operation and competence of the CAB have been put in place or have been addressed. Where possible and appropriate, the assessment team will also carry out a brief assessment of the facilities and resources/equipment in place and discuss the proposed scope of accreditation as stated in the application. It is recommended that the CAB makes its own notes on the topics discussed as the pre-assessment report produced at the end of the pre-assessment will only provide details of significant gaps identified.
- 4.3.5 It is important that UKAS remains impartial and independent of any systems, processes or activities that it will assess. As a result, UKAS is unable to provide specific advice on how the CAB should address specific requirements or design its processes during a pre-assessment or any other assessment activity. The provision of consultancy services to CABs by an accreditation body is strictly prohibited.
- 4.3.6 When the pre-assessment has been completed, a pre-assessment report is compiled to outline the present situation including a summary of the CAB's level of conformity with the requirements for accreditation. The report will identify any areas that may require attention in order to fulfil the requirements of the conformity assessment body standard(s) and any other applicable requirements but does not contain any formal record of findings/nonconformities. The pre-assessment report will indicate the proposed next steps:
- i. Whether plans for initial assessment of the CAB can proceed
  - ii. Whether a further pre-assessment is recommended
  - iii. Specific reasons why assessments cannot proceed, should this be the case
  - iv. Whether any additional assessment is required
  - v. For some CABs there will be confirmation that quality assurance mechanisms are appropriate (e.g. PT/EQA as discussed in UKAS Publication TPS 47)
  - vi. Consideration of timescale for formal assessment (Initial or extension to scope)

Once the CAB and UKAS have agreed that they are ready to proceed to the next stage a formal assessment (initial assessment or extension to scope) will be arranged. When considering timescales for initial assessment the CAB needs to factor in the time to address gaps identified at the pre-assessment stage and also allow a suitable time period where the CAB is working to the new process (this is to enable effective implementation of the systems/processes to be assessed).

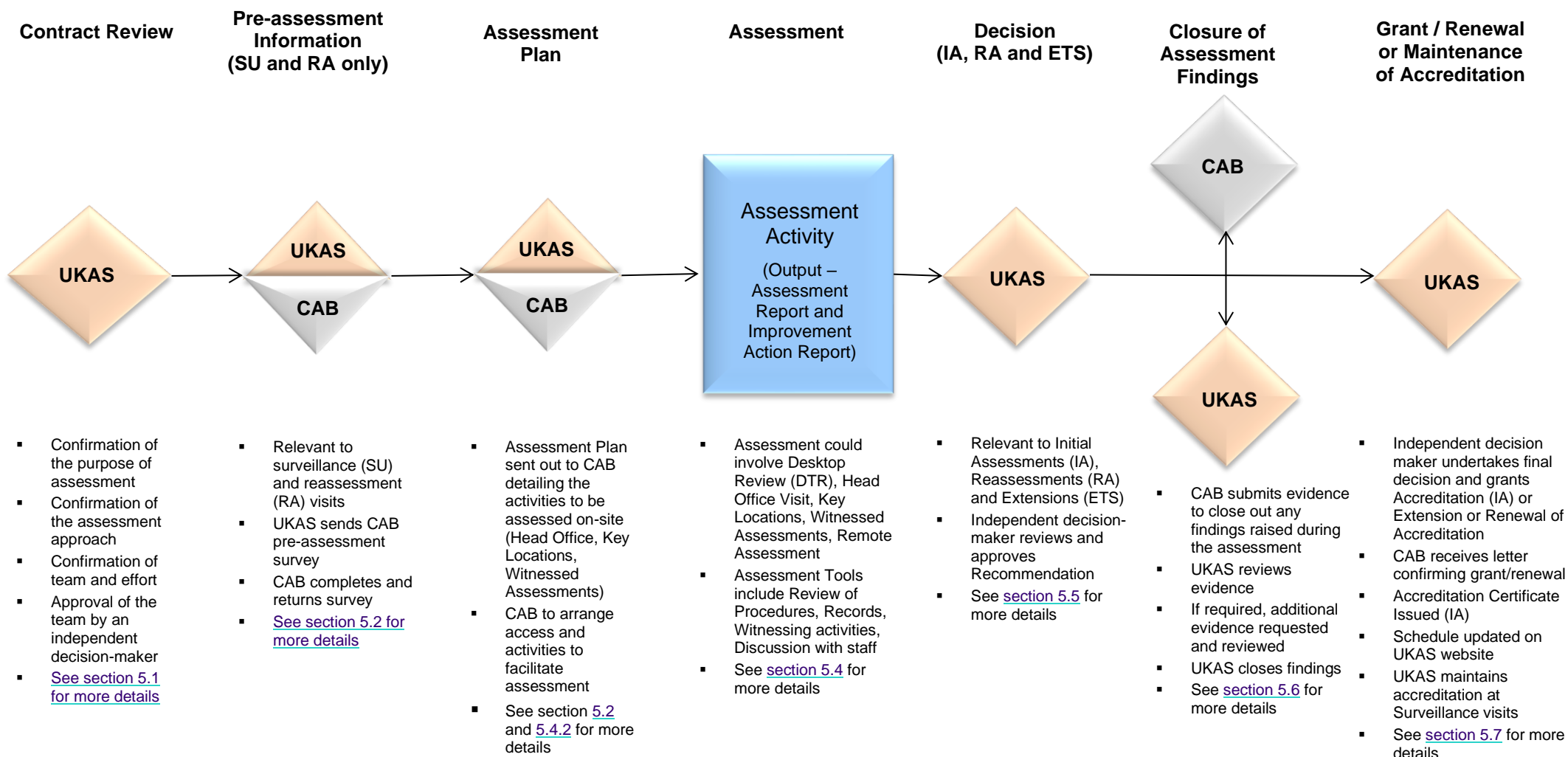


Figure 2: Overview of Typical Assessment Process



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## 4.4 Initial assessment

- 4.4.1 An initial assessment is performed to assess all aspects of the CABs activities that are covered by the application for accreditation including the applicant conformity assessment activities, supporting management system, and underpinning policies, procedures and supporting processes. In addition, if the CAB undertakes any activities which UKAS consider relevant to the application at other locations, these key locations will also be covered. This may involve a sample of locations based upon a risk analysis. Details of the assessment process can be found in section 5.4.
- 4.4.2 The assessment will normally involve witnessing the conformity assessment activities covered by the application (preferably live but possibly through demonstration work). If it is not possible for the CAB to demonstrate the technical activities due to regulatory or contractual restrictions (i.e. work can only be performed under accreditation), alternative assessment techniques can be considered. Where actual witnessing is not possible prior to grant of accreditation, it may be necessary for witnessing of the technical activities at the first opportunity once accreditation has been granted.
- 4.4.3 Upon completion of the initial assessment the assessment team will prepare a report including a recommendation on whether or not accreditation can be offered (including details of any conditions of grant) and any findings (improvement actions) recorded, along with the proposed corrective actions from the CAB. The CAB is provided with a period of up to three months to supply UKAS with details of root cause, impact and extent, and evidence that appropriate corrective action has been taken to address each finding raised. This will normally be accepted by electronic means (usually via the portal), although if the nonconformities raised are deemed to be significant then an additional assessment may be required.
- 4.4.4 Following completion of the initial assessment activities, the assessment information and recommendation on accreditation is subject to an independent review by a UKAS decision-maker. Where it is provisionally agreed that accreditation can be granted subject to successful clearance of any identified mandatory findings, a letter offering accreditation will be sent to the CAB along with a draft schedule of accreditation defining the scope being offered.
- 4.4.5 The final decision on accreditation can only be made after the CAB has submitted satisfactory evidence identifying the root cause of each finding, the extent of the nonconformities, and that effective corrective actions have been implemented. In addition, the CAB will also be required to return a signed copy of the offer of accreditation letter, which includes acceptance of the scope being offered. Any discrepancies between the scope being offered by UKAS and that expected by the CAB will need to be resolved before the final decision can be considered. Only following completion of the final decision, and upon issue of a formal grant of accreditation letter can the CAB claim accreditation for the defined scope.
- 4.4.6 Once accreditation has been granted the CAB will be issued with an accreditation certificate, and a schedule of accreditation will be published on the [UKAS website](#) defining the accredited scope. In exceptional circumstances, such as matters of security, where a CAB does not want specified information to be placed in the public domain it can make a request to UKAS for this to be considered.

## 4.5 Surveillance activities

- 4.5.1 Following grant of accreditation, a newly accredited CAB moves into a four-year accreditation cycle. This will involve three surveillance activities (including on-site and/or remote assessments as applicable), with the first typically six months after the initial grant of accreditation and then subsequent surveillances undertaken annually. A fourth assessment, scheduled to take place 6 months prior to expiry of accreditation, shall be a reassessment (see Section 4.6). A four-year plan of witnessing activities (five years for management system certification, in accordance with IAF MD 17) is established to ensure comprehensive coverage of the scope during the accreditation cycle.
- 4.5.2 The CAB must inform UKAS of any circumstances which may affect its ability to fulfil the requirements for accreditation, such as significant changes to staff, premises, working environment, resources (including key equipment), technical capability, policies or procedures, or any significant complaints, nonconforming work or incidents that may lead to enforcement

action against the CAB, as soon as practicable, as per the requirements in the UKAS Customer Agreement. Details of what constitutes a *significant* nonconformity can be found in the UKAS Customer Agreement.

- 4.5.3 Prior to the surveillance activity, UKAS may request the CAB to complete and return a pre-assessment survey to gather the latest background information on the CAB's accredited activities. This information shall be used by UKAS to consider the on-going risk factors associated with the CAB and its operations, and to review the assessment effort and team required to adequately cover the scope.
- 4.5.4 The surveillance assessment takes the same structure as the initial assessment but may only sample certain aspects of the technical scope and management system, noting that all technical activities must be covered at least once during the four-year accreditation cycle.
- 4.5.5 The outcome of a surveillance assessment is a decision on the maintenance of accreditation during the accreditation cycle. Unless a change to the scope is recommended, such decisions do not require the same degree of independent scrutiny as decisions granting or reducing/withdrawing accreditation and hence can be made by the Lead Assessor with no input from a decision maker. However, where changes are required (i.e. due to an extension to scope or an imposed sanction), then an independent decision-maker will be required.
- 4.5.6 CABs have up to one month to submit evidence to support close out of any mandatory findings raised during the assessment(s). For minor Mandatory findings the lead assessor may not require evidence to be submitted (see section A.5.3.3 in Appendix A).
- 4.5.7 Once all mandatory findings have been satisfactory closed the CAB will receive a maintenance of accreditation letter to confirm that its accreditation status has been maintained.

## **4.6 Reassessment activities**

- 4.6.1 Accreditation is granted for a period of four years. UKAS will need to assess, as a minimum, all activities within the technical scope over this period. However, some technical activities may be covered more frequently based on identified risk factors, or due to sector scheme requirements or expectation of stakeholders.
- 4.6.2 In the fourth year a reassessment is undertaken to re-evaluate the competence and conformity of the CAB against the applicable accreditation criteria and other relevant requirements (similar to the initial assessment). This shall cover all requirements relating to the management system but may only sample the technical activities (ensuring that the full scope has been adequately covered during the four-year cycle).
- 4.6.3 Prior to the reassessment, UKAS may request the CAB to complete and return a pre-assessment survey to gather the latest background information on the CAB's accredited activities. This information shall be used by UKAS to consider the on-going risk factors associated with the CAB and its operations, and to review the assessment effort and team required to adequately cover the scope.
- 4.6.4 The reassessment follows the same structure as the initial assessment.
- 4.6.5 The outcome of the reassessment will result in a recommendation on renewal of accreditation for a further four-years. The Assessment Report (AR), Improvement Action (Report or Portal) and evidence that all mandatory actions have been satisfactorily addressed and closed will be reviewed by an independent decision-maker prior to renewal of accreditation.
- 4.6.6 CABs have up to one month to submit evidence to support close out of any mandatory findings raised during the assessment(s). For minor mandatory findings the lead assessor may not require evidence to be submitted (see section A.5.3.3 in Appendix A).
- 4.6.7 Once all findings have been closed and the decision-maker is satisfied that a robust assessment has been completed, the CAB will receive a renewal letter stating a new expiry date for accreditation (a new certificate will not normally be issued).



## **4.7 Extension to scope (ETS)**

- 4.7.1 Once a CAB has gained accreditation for its initial scope, it can request an extension to scope at any time by submitting an appropriate application (e.g. for extra technical activities, additional sites/locations, changes to the existing accredited activities, including location and equipment).
- 4.7.2 As part of the extension to scope process the CAB will be required to make supporting documentation available; this will be reviewed by UKAS to confirm that the CAB is ready to proceed.
- 4.7.3 Depending on the nature of the requested extension, it may be possible for the CAB to have a pre-assessment for the extension to scope activities if it believes this would be beneficial.
- 4.7.4 UKAS will determine the assessment approach/techniques, team and effort and communicate this to the CAB.
- 4.7.5 The assessment process may involve a range of assessment techniques depending on the application (e.g. desktop review prior to on-site assessment, visits to key locations, remote assessments, witness assessment, desktop assessment).
- 4.7.6 On completion of the extension to scope activities the Assessment Report and Improvement Action Report along with the assessment team's recommendation regarding the extension the scope of accreditation will be reviewed by an independent decision-maker at UKAS.
- 4.7.7 CABs have up to three months to submit evidence to support close out of any mandatory findings raised during the assessment(s). For minor mandatory findings the lead assessor may not require evidence to be submitted (see section A.5.3.3 in Appendix A).
- 4.7.8 Once all findings are closed and the decision-maker is satisfied that a robust assessment has been completed, the CAB will receive a grant of extension to scope letter, a new certificate of accreditation (if the extension related to a new conformity assessment body standard), and the schedule of accreditation on the UKAS website will be updated accordingly.
- 4.7.9 Following an extension to scope for a new technical activity and/or site/location, the new addition or change will be included within the four-year assessment programme to ensure that all technical activities are assessed within the accreditation cycle.

## **4.8 Unannounced assessments**

- 4.8.1 UKAS may determine the need to undertake unannounced assessments to confirm the continuous conformity of a CAB during its intervening assessments. In addition, unannounced assessments may be undertaken when serious concerns (but not serious enough to warrant an immediate recommendation for suspension or withdrawal of accreditation) have been raised regarding a CAB's conformity with accreditation requirements. This may have resulted from a routine UKAS assessment or via a third-party complaint or whistle-blower. In some instances, short term notification (e.g. day before) may be provided to ensure the UKAS team can access the site and there are suitable activities to be witnessed but assessment plans shall not be provided in advance.



## 5. UKAS assessment process

### 5.1 Contract review

- 5.1.1 UKAS shall undertake a contract review for each new request by a customer (pre-assessment, initial assessment or extension to scope), for renewal of accreditation (leading to accreditation of a new four-year cycle) or where additional effort is required by UKAS (extra assessment or imposed sanction).
- 5.1.2 The contract review process is undertaken to ensure:
- i that UKAS has a clear understanding of what the CAB is seeking or requires
  - ii that the appropriate conformity assessment body standard has been identified
  - iii that other relevant assessment criteria, if applicable, have been identified
  - iv that UKAS has the resource and capacity to meet the above, or whether specific provision is required
  - v that the team leader and technical assessors/experts selected for the assessment team are technically competent and appropriate for the assessment (competence to cover the entire scope of the assessment needs to be held by the team, not necessarily be each individual)
  - vi that UKAS is clear on the CAB's expected timeframe and whether this can be met (If not feasible then this shall be discussed with the CAB at the earliest opportunity)
  - vii that sufficient time is allocated for a thorough assessment, including time for preparation and post assessment activities to be performed
  - viii that appropriate assessment techniques have been identified to ensure sufficient evidence of competence is gathered (see assessment techniques in Section 3)
  - ix whether it is necessary to assess all technical activities, or if a representative sample can be selected
  - x whether there is a need to assess all key activities
  - xi that in the case of multi-location activities, including on-site activities, all locations where key activities are performed are assessed, or that a justifiable sampling plan has been developed
  - xii whether parts of the assessment will need to take place outside of the United Kingdom and therefore whether this will need to be subcontracted to the Local Accreditation Body
  - xiii that any feedback from the CAB on the proposed assessment process is considered
- 5.1.3 The assessment team will be appointed during the contract review process. The names and affiliations of each team member shall be provided to the CAB in advance, allowing the CAB sufficient opportunity to consider whether any potential conflicts of interest exist. The CAB has the right to make an objection to the appointment of any nominated team member(s); any such objection must be made within 10 working days of team notification and must be reasonable and justifiable. In such cases UKAS will endeavour to offer an alternative. In the event that a suitable alternative cannot be identified, or the grounds for the selection are considered unreasonable, UKAS reserves the right to appoint the assessor(s) originally proposed.
- 5.1.4 The assessment team will normally be led by a lead assessor, normally supported by one or more technical assessors or experts and lay assessors as deemed necessary to cover the technical scope of the assessment. During initial assessments and reassessments, it is expected that the assessment team will consist of at least two team members. For surveillances or extensions to scope, where the technical scope of the assessment is small and within the technical competence of the lead assessor, the lead assessor may conduct the assessment on their own, fulfilling the role of both lead and technical assessor.
- 5.1.5 Prior to any work commencing, UKAS will provide an estimate of the effort required for the assessment activities, including preparation time (and travel time if the assessment is conducted outside of the United Kingdom).

- 5.1.6 Unless related to a minor change, the contract review will be reviewed by an independent UKAS decision-maker to ensure a reliable assessment of the competence and compliance of the CAB will be undertaken for the full range of activities included in its scope of accreditation, and that there is a level of harmonisation with contract reviews of a similar nature.
- 5.1.7 The contract review process may be re-visited through the lifetime of the application or accreditation cycle if there is any change in the CABs resource, supporting information or if changes to the assessment team are required.

## **5.2 Assessment plan / pre-assessment information**

- 5.2.1 Following the contract review, the plan for the assessment will be communicated to the CAB. A formal assessment plan outlining the required content of the assessment and details such as timing, team, and activities to be witnessed will be produced and sent to the CAB approximately four weeks prior to the assessment, except where desk-top review is being conducted for an extension to scope.
- 5.2.2 Key information on the CAB's organisation may be requested for review prior to any assessment. This may be in the form of a pre-assessment survey which is sent out prior to the assessment planning process. The returned information will be reviewed and will input into the assessment planning process.

## **5.3 Document review**

- 5.3.1 UKAS may require certain documents and information in advance of an assessment to review their content, conformity with the requirements of the relevant standard(s) and provide sufficient technical detail to demonstrate robustness and reliability of the technical areas. This documentation is used in preparation for an on-site assessment or may form part of a standalone remote assessment (see section 5.4.3). Note that UKAS may decide not to proceed with further assessment if the review of the documented information does not demonstrate that the CAB is suitably prepared. In such cases justification for the decision shall be provided in writing to the CAB.
- 5.3.2 Such information may include, but is not limited to, the following as specified in the relevant application forms (provision of access to required information via an online system is acceptable). Note: some of the following information relates to specific conformity assessment activities and will not be applicable to all CAB types:
- i Quality manual or equivalent set of documents which outline the CAB's policies and management system
  - ii Quality procedures
  - iii Quality records (e.g. internal audit schedule and management review minutes)
  - iv Technical records and procedures including competence criteria
  - v Technical assurance documents (validation, EQA/PT performance, in-house calibration, measurement traceability)
  - vi Training records
  - vii Scheme information
  - viii Impartiality arrangements
  - ix Independence type
  - x Management system requirement option of the conformity assessment body standard, for example Option "A" or "B" (ISO 9001), where such an option is included within the standard
  - xi Stability data and homogeneity data
  - xii Subcontractor information

## 5.4 Assessment

- 5.4.1 Prior to any on-site assessment the CAB will need to provide information in relation to any specific health and safety issues and also confirm what, if any, PPE is required and whether it is able to provide appropriate PPE for the team or not.

### 5.4.2 On-site assessments

- 5.4.2.1 An opening meeting will be held, normally conducted by the Lead Assessor in order to:

- i Introduce the assessment team and explain their role(s) in the assessment
- ii Explain the purpose and process of the assessment
- iii Clarify and confirm the accreditation criteria and scope of the assessment
- iv Confirm the details of the assessment plan, logistics, guides and facilities required by the team
- v Confirm reporting arrangements and determine who is authorised by the CAB to agree corrective actions resulting from the assessment visit
- vi Confirm confidentiality undertaking

- 5.4.2.2 Ideally, the opening meeting will be held on the first day of the assessment visit. If a witnessed assessment involves observing a CAB at a client site, the lead assessor will try to arrange an additional opening meeting or briefing privately with the CAB's representatives. When members of the assessment team are scheduled to arrive at different times during the course of the assessment, several separate opening meetings to cover the activities of that specific assessor may be performed.

- 5.4.2.3 The Lead Assessor will manage the assessment team to ensure the relevant activities are assessed and provide support and advice as necessary. A member of the CAB's staff should be nominated by the management to accompany each assessor where practicable. If there are more assessors than staff UKAS will look at the logistics/planning of the visit with the CAB to facilitate appropriate supervision.

- 5.4.2.4 The assessment will proceed in accordance with the assessment plan in order to assess the competence of the CAB and its ability to meet the requirements of the relevant conformity assessment body standard(s) and other applicable requirements. The assessment team will gather objective evidence to support any findings and conclusions drawn from the assessment. Where the team identifies significant issues with the ability to conduct the assessment in accordance with the assessment plan, the plan may be revised as necessary.

Note: the assessment plan outlines how the assessment team intends to conduct the assessment, but the assessment team are not tied to the order and timing of events as listed in the plan. Should it be appropriate for an assessor to spend more or less time on a specific subject or even to cover a subject not listed in the plan (but still within the scope of accreditation) then this is permissible.

- 5.4.2.5 Any Improvement Actions (findings) will be recorded using the UKAS Improvement Action Report Form or through the assessment portal and classified as either 'Mandatory' (nonconformity) or 'Recommended' (opportunity for improvement). All findings shall be discussed and agreed with appropriate CAB representatives during the assessment at the earliest opportunity (this could occur in a private meeting following completion of a witnessed assessment if taking place on a client's site).

- 5.4.2.6 Findings shall be objective and unambiguous and, where necessary, further explanation shall be provided to ensure understanding by the CAB. However, it is important that any proposed improvement action (corrective action) to address a finding is formulated by the CAB; this can be in discussion with the assessor although to safeguard impartiality UKAS cannot provide any consultancy or offer specific solutions to the CAB. To aid reporting it is permissible for the assessor to populate the improvement action report or assessment portal with the agreed action, but this must be following discussion with the CAB, and reflect the action proposed by the CAB. The proposed action must be agreed with the assessor.

5.4.2.7 If the CAB does not agree that a recorded finding is a nonconformity, they shall be required to acknowledge the finding but can submit a request in writing that it is independently reviewed at UKAS. If the finding is confirmed to be a nonconformity following completion of an independent review, then the CAB shall be required to provide an acceptable corrective action to UKAS.

5.4.2.8 When it is not possible to agree actions on-site (e.g. remote assessment, personnel responsible for agreeing actions is not present at a witnessed assessment) the CAB will be provided with the improvement action report and given a specified time to supply UKAS with its proposed improvement action. Following submission of the proposed corrective actions, the assessment team will need to agree that the corrective actions are appropriate. Once agreed, the CAB will be provided with the timescales for the submission of evidence to demonstrate that the nonconformities have been satisfactorily addressed.

Note: in the case of CABs holding multi-site accreditation, UKAS may agree that the CAB can consider the individual findings on completion of all the site assessments and/or agree a single date by which to submit all of the evidence to UKAS.

5.4.2.9 Towards the end of the on-site assessment, the assessment team will hold a team meeting to analyse all relevant information and evidence gathered during the document and record review and the on-site assessment activity. They will discuss the outcome of the assessment and agree the recommendation on accreditation. Possible outcomes from an assessment could be (but are not limited to):

- i unconditional grant of accreditation/extension to scope
- ii a conditional grant of accreditation/extension to scope upon satisfactory closure of all mandatory findings and/or additional assessment activity
- iii that a recommendation on grant of accreditation/extension to scope is not possible at that time (without further assessment activity taking place)
- iv that where a CAB is already accredited, accreditation is to be suspended/partially suspended or withdrawn

5.4.2.10 For surveillance activities the lead assessor will consider whether or not accreditation can be maintained upon the satisfactory close out of any mandatory findings and/or additional assessment activities.

5.4.2.11 Ideally the Assessment Report (as per [Appendix A](#)) should also be completed during this meeting, but if this is not possible then a written Executive Summary and Recommendation should be produced alongside any Improvement Action Reports.

5.4.2.12 Where circumstances prevent any written reports being produced at the time of the assessment then, as a minimum, a verbal summary shall be presented to the CAB. Where the written Assessment Report is not provided at the time of the assessment it shall normally be provided to the CAB within five working days of the assessment. If the outcome of the written report differs from the outcome delivered at the close of the assessment UKAS shall inform the CAB prior to issuing the report and provide an explanation in writing.

5.4.2.13 The procedure and requirements for reporting UKAS assessments are described in [Appendix A](#).

5.4.2.14 Before leaving site, the assessment team shall hold a closing meeting with the CAB which shall be chaired by the lead assessor. A technical assessor may do this if they are on-site alone. The audience for this closing meeting is determined by the CAB, but it is recommended that a representative of the management team and the relevant technical areas are present. The assessment team shall:

- i Provide a review of the scope of the assessment
- ii Provide a verbal summary of the outcome of the assessment from each member of team
- iii Highlight areas of good performance
- iv Highlight any areas of concern with the CAB
- v Reiterate confidentiality undertaking

- vi Clarify possibility that nonconformity may exist that was not identified during the assessment as the assessment is a sampling exercise
- vii Provide a clear recommendation on the grant, extension, renewal or reduction of accreditation, or a statement on maintenance of accreditation if the assessment was a surveillance activity
- viii Provide a verbal quotation of the additional effort required by the team to review evidence of corrective actions in order to close recorded nonconformities
- ix Provide timescale for the submission of evidence of the correct actions taken to address the recorded nonconformities
- x Agree arrangements for issuing the Assessment Report and Improvement Actions Report
- xi Outline next steps

5.4.2.15 Interim meetings may be held during the visit, particularly if a number of assessors are present over a number of days.

5.4.2.16 If the Assessment Report is sent after the visit, the CAB shall acknowledge receipt of the report and its content.

### **5.4.3 Remote assessments**

5.4.3.1 If the contract review process determines that a remote or virtual assessment is applicable, the assessment team will review all relevant documentation away from the location / activity being assessed and then discuss this with CAB representatives using technologies such as online meeting platforms. Further assurance of competence may be obtained from remote interviews with key staff, remote access to networked management systems, the use of webcams for live streaming, etc.

5.4.3.2 Remote assessments shall commence with an opening meeting at a pre-arranged time. This shall follow the same format as for an on-site assessment (See 5.4.2.1). The assessment itself may be broken down into a series of small meetings, meaning that it lasts over a number of days rather than being a single intensive event.

5.4.3.3 Upon completion of the assessment the assessment team will produce a report as detailed in Appendix A with a recommendation as applicable.

5.4.3.4 If any findings are raised, then an Improvement Action Report will be sent to the CAB, who will then need to confirm the corrective actions they plan to undertake to address the findings.

### **5.4.4 Standard specific assessment requirements**

5.4.4.1 See Appendix B for specific assessment requirements for different accreditation standards.

- [Test & calibration requirements \(ISO/IEC 17025, ISO 15189\)](#)
- [Inspection requirements \(ISO/IEC 17020\)](#)
- [Certification requirements \(ISO/IEC 17021-1, 17024, 17065\)](#)
- [Proficiency testing scheme providers requirements \(ISO/IEC 17043\)](#)
- [Reference material producer requirements \(ISO 17034\)](#)
- [Approved / UK notified body requirements](#)
- [IQIPS and Diagnostic Imaging requirements](#)
- [Validation and verification requirements \(ISO/IEC 17029, ISO 14065\)](#)
- [Biobanking requirements \(ISO 20387\)](#)

## **5.5 Decision on recommendation**

5.5.1 For all assessments where accreditation is to be granted or extended, or where the assessment concludes that sanctions should be imposed, the actual decision is required to be made by a UKAS staff member that was not involved in the assessment itself. This is a requirement on all



accreditation bodies, ensuring that the actual decision is made by an impartial person, and that the decision is based purely on the evidence gathered by the team. Therefore, at the end of the assessment, the Assessment Manager or Lead Assessor makes a recommendation on accreditation that will then be submitted to an independent UKAS decision-maker.

- 5.5.2 The UKAS decision-making process is split into two stages to minimise delays in the final outcome. Once the assessment is completed, the report and supporting documentation is submitted for a provisional decision. This decision will take place at the same time that the CAB is addressing any findings that have been raised, and therefore as evidence has yet to be provided to demonstrate that appropriate and effective corrective actions have been put in place, the decision can only be made on whether the agreed actions between the team and CAB look appropriate. If the decision-maker is satisfied, a provisional decision can be made. Following submission and review of evidence of the corrective actions, and the closure of all findings, then the case will be resubmitted to the decision-maker for final decision: The outcome of the assessment and recommendation of the team (e.g. to grant/extend/withdraw/suspend) will not become effective until the date of the final decision.
- 5.5.3 Upon submission for a provisional decision, each recommendation goes through a comprehensive, independent review that ensures that a thorough and robust assessment has taken place covering all of the required elements and that the conclusions of the assessors support the recommendation made.
- 5.5.4 The decision-maker may require further information or assurance from the assessment team as part of the decision process to ratify the recommendation. This may require the assessment team requesting further information from the CAB.
- 5.5.5 For initial assessments the decision-maker will send an offer of accreditation letter to the CAB once a successful provisional decision has been made. This letter specifies the scope to be offered and the on-going effort to maintain accreditation once granted. The CAB is responsible for checking the content of the letter for accuracy and should contact UKAS immediately should it believe that this does not reflect what was agreed in the assessment teams' recommendation or subsequent discussions.
- 5.5.6 The final decision is made after all corrective actions are completed and the assessment team has closed all mandatory findings (see section 5.7). The effective date of accreditation is the date that the final decision is made. Once the final decision has been made this will be communicated to the CAB.

## 5.6 Close out of findings

- 5.6.1 Where UKAS identifies findings, these will be left with the CAB at the end of the assessment together with an Improvement Action Summary Form (IASF). The CAB is required to complete the IASF detailing outcomes of root cause analysis and extent of nonconformity, actions taken, and evidence supplied (*where required* – see [Appendix A section A.5.3 on IARs](#)) for each finding raised. Once the CAB has completed its actions, the IASF shall be submitted to UKAS, together with supporting evidence of actions taken to address the findings where required, within the specified timeframe.

Note: As UKAS implements its assessment portal, findings raised during assessment together with agreed actions and related evidence can be recorded and submitted within the portal rather than the forms described above.

- 5.6.2 For an initial assessment or an extension to scope the CAB will be allowed up to 3 months to address the findings and submit evidence to UKAS. For surveillance assessments and reassessments this time frame is generally 1 month. Evidence may be reviewed remotely or if required this can be reviewed on site with the CAB in an extra visit.
- 5.6.3 For mandatory findings which do not require evidence to be submitted (see Appendix A, A.5.3.3), the CAB still needs to record outcomes of root cause analysis and extent of nonconformity and to confirm, either on the IASF or via the portal, that the agreed actions have been completed. UKAS reserves the right to review the effectiveness of the corrective action during the next assessment.

- 5.6.4 UKAS will review the submitted actions and supporting evidence to determine whether the CAB has demonstrated that it has addressed the nonconformities satisfactorily. Feedback will be provided to the CAB on the outcome of the review within 4 weeks of receipt. Where findings have not been addressed satisfactorily, UKAS will request further evidence to be submitted typically within 2 weeks.

Note: If the CAB fails to submit the completed IASF and supporting evidence by the agreed deadline then the timeframes for the UKAS review may be affected, and appropriate action taken against the CAB may be considered.

- 5.6.5 In situations where the findings have either not been closed within two rounds of evidence submission, not closed within a reasonable time period, where the technical method has since changed or where there are questions over the effectiveness of corrective action implementation, UKAS may undertake an extra assessment to confirm conformity before completion of the assessment process.

## **5.7 Grant / maintenance / renewal of accreditation**

- 5.7.1 For any assessment activities that require an independent decision (e.g. for initial grant, renewal of accreditation, extension to scope, re-instatement of accreditation) a final decision is undertaken to confirm that all improvement actions have been closed appropriately. The outcome of the assessment will only become effective upon completion of the final decision.
- 5.7.2 Following the final decision for an initial assessment the CAB will be informed of the grant of accreditation. A grant letter and an estimate of the accreditation cycle effort will be sent to the CAB with a link to the digital Accreditation Certificate (if relevant). A schedule of accreditation is then published or updated on the UKAS website detailing the agreed scope of activities.
- 5.7.3 Before grant of a new conformity assessment body standard (e.g. either following an initial assessment or an extension to include a new conformity assessment body standard) the CAB will be sent an offer of accreditation letter for the specific standard by the decision-maker, after the provisional decision has been approved (see section 5.5.5).
- 5.7.4 Following the successful completion of a reassessment, the renewal of accreditation is confirmed in a renewal letter that is sent after the final decision process; this specifies the new expiry date of accreditation (i.e. the end date of the new four-year cycle). Unless there has been a change in the name of the CAB or of the conformity assessment body standard used, a new certificate will not be required.
- 5.7.5 At the time of grant or renewal of accreditation, the CAB will be provided with an estimate of the on-going assessment effort required for the technical scope of accreditation. The main UKAS point of contact will provide updates to this effort at the contract review stage or the inclusion or removal of technical activities from the scope.
- 5.7.6 In some cases, as the assessment proceeds, it may become clear that the CAB is not in a position to achieve, or maintain, accreditation for certain areas within the assessed scope. In such cases, the grant or maintenance of accreditation may be confirmed for a suitably reduced or redefined scope.
- 5.7.7 It may also be possible to partially grant a reduced/redefined schedule of accreditation for the activities until the CAB demonstrates that all actions have been satisfactorily implemented. In instances of partial grant, all quality related findings associated with the CABs own management system need to be satisfactorily completed as well as findings relating to the specific technical activities covered by the partial grant.
- 5.7.8 Where partial grants are approved, the CAB will still need to address the outstanding findings for the remaining scope within an acceptable and agreed timeframe. Failure to achieve this will result in the application being closed and the CAB would therefore need to apply for an extension to scope in order for the remaining activities to be progressed.
- 5.7.9 Following the successful completion of the surveillance assessment, UKAS will confirm that the CAB's accreditation has been maintained until the next assessment activity. This confirmation will normally take the form of a maintenance letter, which includes the expiry date of the existing 4-year accreditation cycle.



## 5.8 Accreditation certificate and schedule

- 5.8.1 When the final decision has been made to grant accreditation, an electronic accreditation certificate shall be produced, and a link provided to the CAB. The accreditation certificate confirms the name of the legal entity that has been awarded accreditation, the conformity assessment body standard against which accreditation has been awarded, and the dates when accreditation was first awarded, and the certificate issued.
- 5.8.2 The technical activities covered by the accreditation are detailed in a schedule of accreditation which is published, and maintained up-to-date, on the [UKAS website](#). A separate accreditation certificate and schedule shall be issued for each standard that a CAB holds accreditation for. With respect to laboratory accreditation under ISO/IEC 17025, separate accreditation certificates and schedules will be issued for testing and calibration activities.
- 5.8.3 It is UKAS policy to closely define the scope of a CAB's accreditation. This ensures that the CAB's customers are provided with an accurate and unambiguous description of the scope covered by the accreditation.
- 5.8.4 The wording for the schedule will be determined by the information provided on the application form and the outcome of the assessment. As well as detailing the activities covered by accreditation, it shall contain details such as the name of the legal entity and any relevant trading names, locations and contact details.
- 5.8.5 The scope of accreditation for all CABs operating out of multiple locations will be detailed on the multi-site schedule format (including mobile and on-site testing activities). See Appendix C for more details on multi-site accreditation.
- 5.8.6 All sites or key locations notified to UKAS will be assessed and listed on the schedule. The schedule will indicate which sites/locations are accredited for which activities.
- 5.8.7 The scope of a CAB's accreditation is defined as precisely as possible on the schedule to avoid confusion. However, in some instances a CAB can apply for a more flexible scope of accreditation allowing it the possibility of including new or modified activities without the need to apply for an extension to scope. CABs holding a flexible scope of accreditation will have this clearly reflected on the schedule of accreditation. More details on flexible scopes of accreditation can be found in UKAS publication GEN 4. Further guidance is also available in European cooperation for Accreditation publication [EA-2/15 M EA Requirements for the Accreditation of Flexible Scopes](#).

## 6. Sanctions (withdrawal or suspension)

- 6.1 Where UKAS determines that a CAB is failing to meet accreditation requirements (e.g. during an assessment or following an investigation into a complaint) or maintain its competence in a way that affects all or part of its accredited scope, then it will consider imposing a sanction. Sanctions may also be considered when CABs do not cooperate with UKAS in arranging assessments, including those related to key location or witnessed assessments, or impedes the ability of UKAS to assess them.
- 6.2 CABs may voluntarily request that their accreditation be suspended, reduced or resigned should their circumstances change to the extent that they will not be able to meet accreditation requirements, either for a period of time or permanently. In such circumstances these are not considered as sanctions, although the same process will be followed, and the same requirements will apply for reinstatement in the case of suspensions and reductions. However, if UKAS determines that the CAB has been operating outside of accreditation requirements or there is evidence of fraudulent behaviour, false information is provided, or information is concealed then it reserves the right to reject such a request and impose an appropriate sanction (including full withdrawal) instead.
- 6.3 There are five main categories of sanction that UKAS may consider:
- i Partial suspension of accreditation; this action relates to a cessation of one or more (but not all) accredited activities in the specified schedule of accreditation for a limited

- duration. Moratoria on extensions to scope and/or the issue of further accredited certificates for new work can be considered as partial suspensions
- ii Total suspension of accreditation; this action relates to a cessation of all accredited activities in the specified Schedule of Accreditation for a limited duration
  - iii Partial withdrawal of accreditation (i.e. reduction); this action relates to the permanent removal of part of the scope of accreditation
  - iv Total withdrawal of accreditation; this action is the permanent removal by UKAS, of the complete accreditation of a CAB organisation
  - v Financial suspension for non-payment of fees (see terms and conditions for re-instatement fees)
- 6.4 Other sanctions that might be deemed appropriate and imposed by UKAS include:
- i Increased surveillance activity
  - ii Compulsory and/or repeated witnessed visit activities, including unannounced visits
- 6.5 If at any point during the application or assessment process UKAS discovers evidence of fraudulent behaviour, or of the CAB intentionally providing false information or concealing information, then UKAS shall reject the application or terminate the assessment process for applicants or initiate its process for withdrawal of accreditation of accredited bodies.
- 6.6 Suspensions should be treated as short-term measures to enable a CAB to bring its system back into compliance, and therefore they should not normally exceed a period of three months. However, in exceptional circumstances, and with justification, UKAS may allow a suspension to continue beyond this period.
- 6.7 Following completion of an assessment/investigation resulting in a recommended sanction the CAB shall be made aware of what actions it will need to take in order for the sanction to be lifted and given the opportunity to comment on the recommendation and proposed actions ahead of submission for decision and to provide any additional information or evidence it considers pertinent and which may not have been available at the time the recommendation was made. Any comments made shall be documented and form part of the decision-making process. The submission of the recommendation for an independent and impartial decision shall be made with the minimum of delay (normally within 24 hours). No imposed sanction will come into effect until a decision ratifying the recommendation has been made.
- Following the decision, UKAS will inform the CAB of the outcome in writing. If the sanction is supported then UKAS shall confirm that the CAB is aware of the actions required, particularly any added during the decision-making process and timeframes applicable in order for the sanction to be lifted. The CAB will need to satisfactorily address the actions required within the applicable timeframes before the sanction can be lifted.
- 6.8 Following the imposition of a full suspension or withdrawal of UKAS accreditation, the schedule of accreditation will be removed from the UKAS website and the 'Organisations under Sanction' page of the UKAS website will be updated accordingly.
- 6.9 In the case of a partial suspension or withdrawal of accreditation for specific activities then a revised schedule(s) will be published on the UKAS website.
- 6.10 Once a decision on suspension or withdrawal is made, UKAS shall consider whether any other organisation needs to be notified of the change of status, e.g. a Competent Authority or scheme owner. In some cases, it may be necessary to notify a Competent Authority before the sanction is imposed. Examples of where this applies include where a CAB is an Approved Body, where a CAB is/has been accredited for some sector scheme(s), and for the UK Emissions Trading Scheme.
- 6.11 Once a sanction takes effect UKAS will require that the CAB ceases to conduct or report any affected work as accredited by UKAS and inform its customers without undue delay of the full or partial suspension/withdrawal of its UKAS accreditation and the associated consequences. UKAS may require the CAB to recall accredited output from a specific client or group of clients.

- 6.12 In some circumstances it may be necessary to notify UKAS' sponsoring government department of its intention to impose a sanction. Whilst UK government cannot influence the decision to impose a sanction, and customer confidentiality must be maintained, UK government may need to be notified where the sanction could have a significant impact on UK business.
- 6.13 If an accreditation is partially or totally suspended, whether voluntarily or imposed by UKAS, CABs are still required to pay their annual accreditation fee (if applicable) falling during the period of suspension. Accreditations that expire during the period of suspension will not be renewed during this period. If an accreditation is withdrawn or resigned, UKAS will not refund the annual accreditation fee.
- 6.14 In order to reinstate accreditation UKAS will need to undertake an assessment activity which can take the form of reviewing evidence of completion of any corrective actions, an additional site visit and/or remote assessment. A final decision will be required before a sanction can be lifted and accreditation reinstated (with the possible exception of financial suspensions).
- 6.15 If the period of suspension crosses over the deadline for transition to a new/revised standard applicable to the CAB and the CAB has not yet demonstrated it meets the requirements of the new/revised standard, then any reinstatement will also be reliant on the CAB demonstrating it meets the requirements of the new/revised standard.
- 6.16 Withdrawals of accreditation cannot be reversed, except in the cases of a successful appeal.

## **7. Complaints and appeals**

- 7.1 If a CAB wishes to lodge a complaint about the conduct of its assessment or any other aspect of the service it receives from UKAS, it should first raise the issue with the lead assessor or its assigned Assessment Manager. If the issue is not resolved to the CAB's satisfaction, it may submit a formal complaint to UKAS following the complaints process, as detailed on the UKAS website.
- 7.2 An applicant or accredited body may formally request UKAS to reconsider any adverse accreditation decision related to its desired accreditation status. In order to appeal an adverse accreditation decision please refer to the appeals process as detailed on the [UKAS website](#).

## **8. Resignation**

- 8.1 A CAB can request a full or partial resignation at any time: this must be submitted to UKAS in writing. Where a CAB requests that its resignation takes effect after its profiled date, or after an arranged assessment, then the planned assessment shall take place as normal.
- 8.2 If the request for resignation occurs before a planned surveillance assessment or reassessment is scheduled, UKAS may still need to assess the conformity and competence of the CAB covering accredited activities undertaken during the period from its last assessment to the requested date of resignation. This may still require UKAS to carry out an assessment to ensure such activities continued to comply with accreditation requirements and that the outcomes can be relied upon by customers.
- 8.3 UKAS will provide confirmation of resignation to the CAB in writing. At this time UKAS shall require the CAB to cease conducting or reporting any affected work as accredited by UKAS and to inform its customers of the full or partial resignation of its UKAS accreditation. The CAB will also be required to remove any reference to its affected accreditation (including use of UKAS accreditation symbols) from all of its publicity materials including its website.
- 8.4 Where UKAS is unable to make contact with a CAB and it appears that this is because the CAB has ceased trading, UKAS reserves the right to resign the accreditation of the CAB, even if UKAS is unable to obtain responses from the CAB.
- 8.5 If there is no progress with an application for more than one year the application shall be reviewed and discussed with the CAB to determine whether it still intends to proceed. Where

applications have shown no progress for over two years, or where contact cannot be made with the CAB after one year, UKAS reserves the right to withdraw the application.

- 8.6 Resignations cannot be reversed once the above process has been completed. If, at a later date, a CAB decides that it would like to hold UKAS accreditation again then it can reapply, and in such cases a new accreditation number shall be allocated.

## **9. Change of organisation name, legal entity and/or ownership**

CABs must inform UKAS at the earliest opportunity should they decide to change their name, legal entity or ownership. For more details, please refer to Change of Ownership, Name or Legal Entity page in the Customer Area of the UKAS website.

- 9.1 Where a CAB relocates its premises, the impact on maintenance of accreditation will need to be determined. UKAS will consider whether the CAB's accreditation should be suspended (in full or part) if the CAB is unable to demonstrate continued conformity with the requirements during the period of the relocation. UKAS will need to ensure that the new location/premises/facilities are assessed at the earliest opportunity to confirm continued conformity with the requirements and reinstate accreditation as necessary. Where environmental, accommodation or the operations of equipment are critical to the activities an on-site assessment may be required in addition to an off-site document review.
- 9.2 Where the name of the CAB's legal entity has changed it will be required to sign a new UKAS Customer Agreement. An electronic version of the Agreement shall be sent to the CAB by UKAS upon receipt of a formal notification of a change.

## Appendix A - Content of UKAS reports

A.1 UKAS reports, any notes made by assessors and other information collected by the assessment team to support the conclusions of the assessment are used by UKAS for accreditation decision-making purposes.

A.2 UKAS reports, including improvement action reports, shall be typed and issued electronically, normally via the UKAS assessment portal. All reports of assessments are maintained electronically by UKAS for a defined period of time in accordance with the UKAS policy for maintaining assessment records.

### A.3 Pre-assessment

A.3.1 Pre-assessment reports may be issued at any point in the pre-assessment process, as agreed with the CAB.

A.3.2 A UKAS pre-assessment report may be issued on completion of:

- i a document review
- ii a meeting between the CAB and UKAS
- iii a site/office visit(s)
- iv a witnessed activity
- v or any other agreed pre-assessment activity

A.4 The purpose of the pre-assessment is to advise the CAB of the actions that it needs to take to prepare for the UKAS assessment. If more than one pre-assessment report is issued, the latest report will cross reference any previously issued reports.

### A.5 Assessment

A.5.1 UKAS will report the outcome of any type of assessment (initial assessment, surveillance, extension to scope, reassessment) using:

- i UKAS Improvement Action Report(s)
- ii UKAS Assessment Report

A.5.2 There may also be attachments to the assessment report providing additional/supplementary information.

#### A.5.3 Improvement Action Report / Assessment Portal

A.5.3.1 Improvement Action Reports (IAR) or the assessment portal record the following types of findings:

- i Nonconformities (an issue that requires corrective action by the assessed CAB to enable it to meet accreditation requirements)
- ii Opportunities for improvement (including potential nonconformities)

A.5.3.2 Where appropriate, the main clause of the accreditation criteria and reference to relevant guidance documents relating to the reported finding will be stated in the Improvement Action Report or assessment portal

A.5.3.3 Each finding reported in Improvement Action Reports will be categorised as follows:

- **'M'** - Action is Mandatory

A finding that identifies nonconformity is indicated as 'M' (Action is Mandatory) in the Improvement Action Report. The CAB will need to identify the cause and take appropriate action to resolve the nonconformity prior to UKAS granting or confirming continuity of accreditation. All root causes and actions against findings indicated as 'M' will need to be resolved by the CAB within an agreed timescale and evidence submitted to UKAS.

Note: For each Mandatory finding the IAR or assessment portal will state whether supporting evidence is required to be submitted with the close-out response or not (*Evidence required 'Y'* / *'N'*). At initial assessments evidence will be required for all Mandatory findings along with the

root cause. For other assessment events the assessment team will make a judgement as to whether any evidence of agreed improvement actions will need to be provided to UKAS or whether a statement to confirm implementation is sufficient. When making such judgements the team will take account of the significance of the finding, the CAB's proposed improvement action and its past performance with respect to timeliness and effectiveness of improvement actions.

- **'R' - Action is Recommended**

A finding that identifies an opportunity for improvement or a potential nonconformity is indicated as 'R' (Action is Recommended) in the Improvement Action Report. The CAB is recommended to take appropriate action to resolve any finding that is indicated as 'R' but the CAB is not required to agree improvement actions with UKAS (although it may be in the interests of the CAB to do so in order to establish their understanding of the finding) or to provide evidence of such improvement actions.

#### **A.5.4 Assessment Report**

A.5.4.1 Lead Assessors will report the results and conclusions of the assessment under the key headings of Scope, Organisation, Management, Evaluation Processes, Technical Competence and Impartiality & Integrity in the assessment report.

Note: The term 'Evaluation Processes' in the assessment report covers the conformity assessment activities (e.g. testing, calibration, inspection or certification) as appropriate to the business of the organisation being assessed.

A.5.4.2 The assessment report will document the assessment that has been performed and the areas sampled. For initial assessment and reassessment all areas will be assessed and commented on in the report (as detailed on page 2 of the report). For annual surveillance assessments, not all areas need to be covered each year although certain key areas will always be assessed (e.g. complaints, internal audits, nonconformities, management review, technical competence, on-going technical assurance performance).

A.5.4.3 The assessment report will also contain an 'Executive Summary' which will provide the CAB with an overview of the assessment. The main conclusions of the assessment based on the findings will be included in the Executive Summary. Where appropriate, the recommendation for accreditation and the next step of the accreditation process will also be included in the Executive Summary. The Executive Summary, or other sections of the assessment report, will include the following:

- i The scope of assessment
- ii The key strengths and weaknesses of the CAB and where appropriate significant risks to the accredited CAB's business based on assessment evidence
- iii Comments on the extent of competence of the assessed CAB
- iv Comments on conformity with accreditation requirements
- v Effectiveness of management systems
- vi Reliability of internal audits
- vii Where applicable, how effectively the results of quality assurance / quality control techniques such as proficiency testing, inter laboratory comparisons are used to reduce the risk of providing incorrect test/ calibration/ inspection/ certification results
- viii Where applicable, useful comparisons with results of previous assessments

A.5.4.4 Where a CAB requires a more detailed report due to a business need (e.g. a CAB may wish additional information about a particular aspect of their system to determine resource/investment needs) this should be requested in advance of the assessment at the planning stage. UKAS will produce an assessment report which will include additional relevant information.

A.5.4.5 The assessment report will include comments on the extent of competence and conformity of the assessed CAB. Findings that do not require the CAB to take improvement action may also be included in the assessment report.





### **A.5.5 Notes of assessment**

A.5.5.1 The purpose of any notes taken during an assessment, which may be in the form of assessor notes, proformas or other format, is to act as a record of the assessment.

### **A.5.6 Other types of assessment reports**

A.5.6.1 There are a number of other types of report which might be used as part of the assessment process and provided to the CAB. These include:

- i Desktop Assessment Reports (Provides a summary, recommendation and details of the documentation reviewed and its conformity with the requirements)
- ii Witnessed Assessment Reports (Typically completed by a Technical Assessor detailing the conformity and competence of any witnessed activities)
- iii LAB Reports (Assessment Report produced by a Local Accreditation Body as part of the international accreditation cross border agreements)



## Appendix B - Standard specific assessment requirements

### B.1 Laboratory (test, calibration, medical) requirements (ISO/IEC 17025, ISO 15189)

- B.1.1 Witnessing of the testing/sampling/calibration activities carried out by the laboratory forms the most important part of the assessment. Although the assessment should, as far as possible, make use of normal on-going work, it may be necessary for UKAS to ask the laboratory to provide a demonstration of some activities that are not on-going, in order to cover the range of tests or calibrations for which accreditation is sought. This should normally be evident from the assessment plan. Assessors need to establish the laboratory's overall competence in all aspects required by the standard.
- B.1.2 Following the dispersal of the assessment team to various sections of the laboratory, the Lead Assessor (or other nominated assessor) will examine the laboratory's management system and quality documentation with the Quality Manager and any other appropriate staff, to verify that it meets the requirements of the standard.
- B.1.3 The technical assessors will proceed according to the agreed programme and examine the management system in operation and the competence of the laboratory staff to perform specific activities. All components of the management system involved will be assessed.
- B.1.4 Assessors will examine the calibration/testing/sampling procedures and their implementation in the laboratory. They will determine whether the treatment of measurement uncertainty is in accordance with UKAS and international criteria. It may not always be necessary to examine every procedure in operation because of the similarities between some activities, but assessors will verify the implementation of the procedures for the calibration/tests listed in the assessment programme. The assessors will ask to see the equipment involved, the manufacturer's manuals, and establish the state of calibration of the equipment.
- B.1.5 Assessors will witness measurements and examine documentation concerning calibration/testing/sampling in progress and will review associated records and reports/certificates.
- B.1.6 During assessments of calibration laboratories, the assessors will establish the laboratory's capability to make measurements that are traceable to national standards and according to the uncertainty claimed for each parameter for which accreditation is being sought. This will include the examination of calibration certificates and the results of any in-house calibrations to ensure that imported uncertainty and drift contributions can be substantiated. Assessors will also examine the performance of the laboratory in relevant proficiency testing schemes and/or interlaboratory comparisons.
- B.1.7 Likewise, during assessment of testing laboratories (including sampling), assessors will examine the laboratory's processes for establishing traceability of measurements including any in-house calibrations, reference material (as per requirements of TPS 57) and the results from participation in appropriate proficiency testing schemes (as per requirements of TPS 47) and other QC/QA procedures. Assessors will also assess procedures used to establish the validity of methods used.
- B.1.8 The object of assessment is to establish by observation whether the work of the laboratory meets the requirements of the standard and that the results issued can be relied upon. Observations made will be based on objective evidence and will be recorded and verified with the accompanying laboratory representative.

## **B.2 Inspection requirements (ISO/IEC 17020)**

- B.2.1 Prior to assessment, the inspection body may be requested to provide UKAS with a list of current inspectors, the fields and types of activity and the locations (however named) at which they are currently operating. This information will enable the assessment manager to plan the assessment and take into account all the factors necessary to enable a reliable assessment of the inspection body's competence to carry out the inspections included in the scope of application. The planning process will determine, in conjunction with the inspection body, the sampling level of locations and which inspectors will be subject to on-site assessment (see 5.5).
- B.2.2 The nature of the assessment will be dependent upon the scope of accreditation required by the inspection body and the complexity of the quality system that is being operated. However, the following elements may need to be covered:
- i central office assessment
  - ii assessment of all locations where key activities take place
  - iii on-site assessments of inspections for different fields and types of inspection and inspectors
- B.2.3 On-site assessment (where possible) of inspections is an essential part of the UKAS assessment of inspection bodies to ISO/IEC 17020. This is particularly important when the inspection body is performing inspections of such a nature where the inspector's professional judgement is crucial to the outcome of inspection.
- B.2.4 When deciding on the number of on-site assessments of inspections needed the following aspects, at least, will be considered by UKAS:
- i the fields and types of inspection on the accreditation schedule
  - ii the inspection body's procedures for selecting, training authorising and monitoring inspectors, having regard to the qualifications and experience required for different fields and types of inspection
  - iii the internal auditing arrangements of the inspection body
  - iv the locations from which inspectors operate
  - v any statutory requirements
  - vi the extent to which inspectors are required to exercise professional judgement
  - vii the number of inspectors
  - viii frequency of inspections
  - ix competence requirements of inspectors e.g. personnel certification or formal qualification
- B.2.5 As a minimum, one inspector carrying out inspections will be assessed on-site for the fields and types of inspection on the accreditation schedule.
- B.2.6 When deciding on which inspectors will be assessed account will be taken of:
- i new recruits or new authorisations
  - ii qualifications and experience
  - iii location
  - iv any statutory requirements
  - v the extent to which inspectors are required to exercise professional judgement
- B.2.7 If none of the inspectors can cover the entire scope of a specific field, then more than one inspector will be assessed for that field. Where there is any evidence which casts doubt on the competence of inspection staff, the sample size of inspectors assessed on site may be increased.
- B.2.8 It will be necessary to examine equipment and documentation, such as procedures and instructions, records, reports and planning arrangements. If an inspector operates from home,

this examination will be arranged at a mutually acceptable location. It may also be appropriate to review the participation in proficiency testing schemes (as per requirements of TPS 47), use of reference material (as per requirements of TPS 57) and validation (as per ILAC G27) for testing activities that directly affect and determine the inspection results, or where required by law or by regulators.

B.2.9 UKAS assessors will ensure that their role during on-site assessment of inspections is one of observer and they will not influence the inspection being performed.

B.2.10 The team will be looking to see that as a minimum:

- i the inspector has the competence for the inspection performed
- ii the inspector's competence is consistent with the competence criteria
- iii the inspector has been supplied with all necessary documented inspection methods, procedures and equipment
- iv the procedures are up-to-date
- v the inspector implements the procedure in full and correctly i.e. no shortcuts, no personalised application where it is not permissible to do so
- vi records of all observations are made while on site as required by the procedure
- vii records clearly identify what has been inspected, using what method/procedure and when
- viii all records are authorised and controlled as applicable
- ix all findings that indicate immediate or urgent action are reported as required to the client whilst on site

B.2.11 On-site (or remote) assessment of inspections will normally be carried out at each surveillance assessment. The same criteria used for assessment will be considered when determining the number and type of inspections, and the inspectors to be witnessed. At least one aspect of the technical scope of the Inspection Body must be witnessed every year.

## **B.3 Certification requirements (ISO/IEC 17021-1, ISO/IEC 17024, ISO/IEC 17065)**

### **B.3.1 Initial assessment planning**

B.3.1.1 UKAS will determine the overall programme for the assessment including the assessment team members and technical activities that will be subject to witnessed assessment. At initial assessment all technical areas and fixed office locations performing key activities will be subject to assessment using a variety of assessment techniques ([see section 3](#)).

- i Where the applicant is a management system certification body, at least one stage one and one stage two audit must be witnessed as part of the initial assessment programme
- ii For persons certification bodies using external examination providers UKAS may elect to witness the certification body's evaluation of at least one of these providers
- iii The witnessing of the evaluation activities of a product certification body will depend upon the nature of the certification scheme(s) concerned

B.3.1.1 Prior to initial assessment, the certification body shall provide UKAS with a list of all forthcoming audit activities, the fields and types of activity, the assigned auditor and client details, from which the assessment manager selects the witnessed assessments.

### **B.3.2 Surveillance / reassessment planning**

B.3.2.1 UKAS will determine the overall programme for the accreditation cycle including team members and technical activities that will be subject to assessment including witnessed assessment. A Head Office assessment along with a number of witness audits will be undertaken annually, along with assessments of some or all fixed office locations.

B.3.2.2 Witnessed assessments associated with annual surveillance assessments and reassessments will be conducted within a 12-month calendar period. During the last quarter of each year, UKAS will communicate to the certification body any witnessed assessments to be conducted in the following calendar year based on the 4-year accreditation cycle and the review of the pre-visit survey (annual questionnaire) details. The witnessed assessment programme will, as a minimum, cover the scope of accreditation over the 4-year cycle unless stipulated otherwise in IAF MD 17.

B.3.2.3 The frequency and volume of witnessed assessments is dependent on several factors, including:

- i the nature of risks and complexity associated with the certification activities, scopes of certification of management system, product or persons, and countries involved
- ii the certification body's procedures for selecting, training, authorising and monitoring personnel, having regard to the competences required for different technical areas, scopes and schemes of certification
- iii The internal auditing arrangements of the certification body
- iv The locations from which evaluators operate
- v Any sector scheme or statutory requirements
- vi the CB's overall performance
- vii factors such as process complexity or legislation etc. which influence the ability of the certified organisation to demonstrate its ability to meet the intended outcomes of the MS
- viii feedback from interested parties including complaints about certified organizations
- ix changes in CB work patterns - growth of work within a specific region or technical area
- x number of clients within the CB's scope of accreditation
- xi confidence in the CB's auditor evaluation and approval process
- xii previous or other office or witnessing assessment results, etc.
- xiii International (e.g. International Accreditation Forum) and UKAS policy (e.g. TPS 66) on witnessing activities within a cluster of technical activities (relating to ISO/IEC 17021-1)

B.3.2.4 The following additional factors may be taken into account to select witnessed activities:

- i number of certificates issued
- ii number of auditors/evaluators
- iii different auditors/evaluators
- iv whether auditors are internal staff or external resource
- v different audits/evaluations, initial audit (stage 1/stage 2), surveillance and recertification
- vi complex clients, combined and/or integrated audits, multi-site audits
- vii countries where audits in the certification process are performed
- viii result of previous witnessing activities
- ix complaints, customer surveys
- x interested parties and regulators requests
- xi the technical clusters already assessed
- xii experience from other types of accreditation of the CB
- xiii previous history of the CB's ability to manage its operations
- xiv level of controls exercised by a CB over its critical activities
- xv specific scheme requirements
- xvi national agreements with clients

B.3.2.5 When requested, the CAB shall promptly provide UKAS with a complete and updated schedule of confirmed and planned audits (dates, location, audit team composition, audit type and scope, etc.), in order to allow UKAS to plan its assessment activities.

### **B.3.3 Initial assessment requirements**

B.3.3.1 The following elements will need to be covered at initial assessment:

- i Full review of the implementation of the management system
- ii Head office assessment
- iii Assessment of all fixed office locations where key activities take place
- iv Witnessed assessments for different standards, scopes and types of certification

B.3.3.2 UKAS will collect objective evidence to assist in the determination of competence which will specifically include:

- i conformity with the certification body's own documented system and procedures
- ii conformity to the requirements of the applicable standards and any other requirement of UKAS, EA, and IAF or the sector scheme as appropriate

B.3.3.3 The assessment of the competence of the certification body's auditors or audit team shall include the following:

- i preparedness for the evaluation
- ii audit technique and conformity with the procedures and guidance on auditing
- iii knowledge of the certification requirements
- iv knowledge of and adherence to the certification body's own documented system and procedures
- v knowledge of the industry being audited

B.3.3.4 After grant of accreditation UKAS will produce a 4-year assessment programme detailing the intended assessment activities (head office, fixed office location(s) and witnessed assessments) to be covered during each year of the accreditation cycle (note: the witness

assessment coverage may be a 5-year cycle for management system certification as detailed in IAF MD 17). The programme is subject to review and potential revision following the completion of each annual assessment and any extension to scope. The programme will be communicated to the certification body upon creation and subsequent revision.

### **B.3.4 Witness assessment requirements**

B.3.4.1 The witnessed assessment requirements for an initial assessment will be comprised of:

- i at least 25% of the scopes applied for, although this may be higher where the scopes applied for are deemed 'high risk' scopes, or where a sector scheme or statutory requirements demand a higher level of witnessing (remaining scope of application will be assessed by other assessment tools as detailed in Section 6.4.3)
- ii at least two witnessed assessments for initial assessment, (for management system certification bodies this shall include at least one stage one and one stage two audit)
- iii assessment of a suitable sample of the auditors employed or contracted by the certification body
- iv The requirements detailed in TPS 66 with regards to witnessing of activities within technical clusters of IAF codes for QMS and EMS management systems

B.3.4.2 The objective of the witnessed assessment for any type of visit (IA/SU/RA/ETS) is to support assessment in determining whether the certification body can demonstrate competence and conformity with the required standard. It is the responsibility of the certification body to ensure that its clients give full access to UKAS assessment teams for this purpose. If the CAB cannot provide access for a given witnessed activity, sanction may be imposed by UKAS. In particular the witnessed assessment is essential in confirming that the certification body's personnel can:

- i apply the procedures and instructions of the certification body
- ii exhibit the necessary characteristics of an auditor
- iii demonstrate the required competence for which the assessment activity is being undertaken
- iv Identify the required competence and assign appropriate personnel
- v undertake the conformity assessment activity effectively

B.3.4.3 The witnessed assessment will also assist in determining the effectiveness of the certification body's processes, typically its contract review and planning processes and its internal assessment and approval process of personnel competence.

B.3.4.4 The UKAS assessor shall not involve themselves directly in the audit in which the certification body auditor(s) is/are being witnessed. However, the assessor can ask the certification body auditor for clarification and additional information if necessary, to ensure a clear understanding of the audit process taking place. This should be done at a suitable time so as not to interrupt the audit or inconvenience the certification body's client in any way. It is expected that the UKAS assessor will be provided with access to the client's documentation that the certification body reviews as part of its audit. Any documentation reviewed by the certification body during the conduct of the audit should be made available to the UKAS assessor to review.

B.3.4.5 If the situation arises where the UKAS assessor observes a nonconformity in the certification body's client's operations which is not reported by the certification body's team, the UKAS assessor shall inform the certification body's team about such findings during the post-witness closing meeting rather than in front of the certification body's client. The only exception is when the UKAS assessor observes a practice or nonconformity that presents an immediate risk to health and safety. In these cases, the UKAS assessor has a duty of care to report the issue without delay.

B.3.4.6 All activities of the certification body's evaluation should be witnessed, including the opening and closing meetings. Where the certification body utilises a team to conduct the evaluation UKAS may require additional assessors to ensure it can observe the entire evaluation process.



### **B.3.5 Post-audit review**

B.3.5.1 In exceptional cases and at the discretion of UKAS, a post-audit review may be utilised as an alternative to a witnessed assessment. The general principle for the format of a post-audit review is to complete an in-depth interview with an audit team using the output from the selected audit which will provide the equivalent confidence to a witnessed assessment. In the process of arranging a post-audit review the UKAS assessment manager will determine the plan taking into consideration the following points:

- i Location of post-audit review to be conducted to ensure all relevant documentation can be accessed
- ii Attendees in addition to audit team

B.3.5.2 The UKAS assessor shall, in light of findings during the post-audit review activity, using a range of assessment tools, consider whether the certification body's methods for determining audit requirements, duration and audit team competence are sufficient to address accreditation requirements for an effective audit.

### **B.3.6 Mechanism for impartiality requirements**

B.3.6.1 Where a certification body uses a committee for safeguarding impartiality, UKAS will observe at least one of its meetings during the cycle as part of the assessment programme. If the certification body uses an alternative mechanism to safeguard impartiality, then this will be reviewed accordingly, including interviews with personnel involved in the mechanism. Where possible this will be conducted alongside annual surveillance or reassessment visits.

### **B.3.7 Extension to scope requirements**

B.3.7.1 Following receipt of an application for an extension to scope, UKAS will determine whether or not there is a need for a head office and/or fixed office location assessment and/or witnessed assessments to take place. Factors that will be taken into consideration will include:

- i the range of existing scope of accreditation
- ii the volume of business in the new scope area
- iii the locations at which the extension to scope is sought
- iv the risk (high/low) of the extension to scope

B.3.7.2 Normally extensions to scope will require a head office (or fixed office location) assessment and witnessed assessments. The volume of witnessed assessments required is determined as per B.3.4 although a minimum of one (not two) witnessed assessments are required.

B.3.7.3 Where a certification body already holds accreditation for management system certification for one or more certification standards (e.g. ISO 9001 or ISO 14001) and wishes to seek accreditation for additional certification standards (e.g. ISO/IEC 27001) then this is deemed to be an extension to scope.

B.3.7.4 Where a certification body applies for a new fixed office location to perform critical activities to be added to its schedule of accreditation, UKAS will review the application to determine the appropriate assessment approach. A new fixed office location must be visited by UKAS or an appropriate Local Accreditation Body.

## **B.4 Proficiency testing scheme provider requirements (ISO/IEC 17043)**

B.4.1 There are no additional assessment requirements in relation to ISO/IEC 17043.

## **B.5 Reference material producer requirements (ISO 17034)**

B.5.1 There are no additional assessment requirements in relation to ISO 17034.

## **B.6 Approved / UK notified body requirements**

B.6.1 Please refer to UKAS publication GEN 5 for further details on the application process; the requirement on CABs to notify the relevant Competent Authority of an application to UKAS; the UKAS assessment process; and the requirement on UKAS to notify the relevant Competent Authority of the outcome of an assessment for the purposes of notification.

## **B.7 Physiological (IQIPS) and imaging service requirements**

B.7.1 Witnessing of the activities carried out by the service forms the most important part of the assessment. Although the assessment should, as far as possible, make use of normal on-going work, it may be necessary for UKAS to ask the service to provide a demonstration of some activities that are not on-going, in order to cover the range of activities for which accreditation is sought. This should normally be evident from the assessment plan. Assessors need to establish the service's overall competence in all aspects required by the standard.

B.7.2 Following the dispersal of the assessment team to various sections of the service, the Lead Assessor (or other nominated assessor) will examine the service's management system and quality documentation with the Service Representative and any other appropriate staff, to verify that it meets the requirements of the standard

B.7.3 The technical assessors will proceed according to the agreed programme and examine the management system in operation and the competence of the staff to perform specific activities. All components of the management system involved will be assessed.

B.7.4 To comply with Care Quality Commission (CQC) requirements there will be a Lay Assessor as part of the assessment team. Lay Assessors will proceed according to the agreed programme and review activities and documentation from the patient experience perspective.

B.7.5 Assessors will examine the procedures and their implementation in the service. It may not always be necessary to examine every procedure in operation because of the similarities between some activities, but assessors will verify the implementation of the procedures for the activities listed in the assessment plan. The assessors will ask to see the equipment involved, the manufacturer's manuals, and establish the state of calibration of the equipment.

B.7.6 Assessors will witness/review activities and examine documentation relating to designated activities in the assessment plan and will review associated records and reports/certificates.

B.7.7 The object of assessment is to establish whether the work of the service meets the requirements of the standard and that the results issued can be relied upon. This will be based on objective evidence and will be recorded and verified with the accompanying service representative.

## **B.8 Validation and verification requirements (ISO/IEC 17029, ISO 14065)**

### **B.8.1 Initial assessment planning**

B.8.1.1 UKAS will determine the overall programme for the assessment including the assessment team members and technical activities that will be subject to witnessed assessment. At initial assessment all technical areas and fixed office locations performing key activities will be subject to assessment using a variety of assessment techniques ([see section 3](#)).

- i The witnessing of the evaluation activities of a validation and or verification body (VVB) will depend upon the nature of the validation and/or verification (VV) programmes concerned.

B.8.1.2 Prior to initial assessment, the VVB shall provide UKAS with a list of all forthcoming VV activities, the fields and types of activity, the assigned auditor and client details, from which the assessment manager selects the witnessed assessments supported by the relevant Technical Focus Person (TFP).

### **B.8.2 Surveillance / reassessment planning**

B.8.2.1 UKAS will determine the overall programme for the accreditation cycle including team members and technical activities that will be subject to assessment including witnessed assessment. A Head Office assessment along with a number of witness audits will be undertaken annually, along with assessments of some or all fixed office locations.

B.8.2.2 Witnessed assessments associated with annual surveillance assessments and reassessments will be conducted within a 12-month calendar period. During the last quarter of each year if not earlier (dependant on the VV programme accredited), UKAS will communicate to the VV body any witnessed assessments to be conducted in the following calendar year based on the 4-year accreditation cycle and the review of the pre-visit survey (annual questionnaire) details. The witnessed assessment programme will, as a minimum, cover the scope of accreditation over the 4-year cycle.

B.8.2.3 The frequency and volume of witnessed assessments is dependent on several factors, including:

- i the nature of risks and complexity associated with the VV activities, scopes and sectors of VV programmes, and countries involved
- ii the VV body's procedures for selecting, training, authorising and monitoring personnel, having regard to the competences required for different technical areas, scopes and programmes of VV
- iii The internal auditing arrangements of the VV body
- iv The locations from which evaluators operate
- v Any sector programme or statutory requirements
- vi the VVB's overall performance
- vii factors such as process/sector complexity or legislation etc. which influence the ability of the client organisation to demonstrate its ability to meet the programme requirements
- viii feedback from interested parties including complaints about completed validation or verification activities
- ix changes in VVB work patterns - growth of work within a specific region/sector or technical area
- x number of clients within the VVB's scope of accreditation
- xi confidence in the VVB's auditor evaluation and approval process
- xii previous or other office or witnessing assessment results, feedback from Competent Authorities etc.

- xiii International (e.g. International Accreditation Forum), sector programme or UKAS policy on witnessing activities within a cluster of technical activities

B.8.2.4 The following additional factors may be taken into account to select witnessed activities:

- i number of opinion statements issued
- ii number of validators/verifiers
- iii different validators/verifiers
- iv whether auditors are internal staff or external resource
- v different validations/verifications and programmes
- vi complex clients, combined and/or integrated VVs, multi-site VVs
- vii countries where validations/verifications are performed
- viii result of previous witnessing activities
- ix complaints, customer surveys
- x interested parties and regulators/competent authority requests
- xi the scopes/sectors already assessed
- xii experience from other types of accreditation of the VVB
- xiii previous history of the VVB's ability to manage its operations
- xiv level of controls exercised by a VVB over its critical activities
- xv specific programme requirements
- xvi national agreements with clients

B.8.2.5 When requested, the CAB shall promptly provide UKAS with a complete and updated schedule of confirmed and planned VVs (dates, location, audit team composition, VV type and scope, etc.), in order to allow UKAS to plan its assessment activities.

### **B.8.3 Initial assessment requirements**

B.8.3.1 The following elements will need to be covered at initial assessment:

- i Full review of the implementation of the VV system
- ii Head office assessment
- iii Assessment of all fixed office locations where key activities take place
- iv Witnessed assessments for different standards, scopes, programmes and types of VV

B.8.3.2 UKAS will collect objective evidence to assist in the determination of competence which will specifically include:

- i conformity with the VV body's own documented system and procedures
- ii conformity to the requirements of the applicable standards and any other requirement of UKAS, EA, and IAF or the sector programme as appropriate

B.8.3.3 The assessment of the competence of the VV body's auditors or VV team shall include the following:

- i preparedness for the evaluation
- ii VV technique and conformity with the procedures and guidance on VV
- iii knowledge of the VV requirements
- iv knowledge of and adherence to the VV body's own documented system and procedures
- v knowledge of the industry/sector related to the VV activities being audited

B.8.3.4 After grant of accreditation UKAS will produce a 4-year assessment programme detailing the intended assessment activities (head office, fixed office location(s) and witnessed assessments) to be covered during each year of the accreditation cycle. The programme is subject to review and potential revision following the completion of each annual assessment and any extension to scope. The programme will be communicated to the VV body upon creation and subsequent revision.

#### **B.8.4 Witness assessment requirements**

B.8.4.1 The witnessed assessment requirements for an initial assessment will be comprised of:

- i at least two witnessed assessments for each scope/programme applied for, although this may be higher where the scope/programme applied for are deemed 'high risk' scopes, or where a sector scheme or statutory requirements demand a higher level of witnessing (remaining scope of application will be assessed by other assessment tools as detailed in Section 6.4.3);
- ii assessment of a suitable sample of the VVs employed or contracted by the VV body.

B.8.4.2 The objective of the witnessed assessment for any type of visit (IA/SU/RA/ETS) is to support assessment in determining whether the VV body can demonstrate competence and conformity with the required standard. It is the responsibility of the VV body to ensure that its clients give full access to UKAS assessment teams for this purpose. If the CAB cannot provide access for a given witnessed activity, sanctions may be imposed by UKAS. In particular the witnessed assessment is essential in confirming that the VV body's personnel can:

- i apply the procedures and instructions of the VV body
- ii exhibit the necessary characteristics of a validator/verifier
- iii demonstrate the required competence for which the assessment activity is being undertaken
- iv Identify the required competence and assign appropriate personnel
- v undertake the conformity assessment activity effectively

B.8.4.3 The witnessed assessment will also assist in determining the effectiveness of the VV body's processes, typically its contract review and planning processes and its internal assessment and approval process of personnel competence.

B.8.4.4 The UKAS assessor shall not involve themselves directly in the VV in which the certification body auditor(s) is/are being witnessed. However, the assessor can ask the VV body auditor for clarification and additional information if necessary, to ensure a clear understanding of the VV process taking place. This should be done at a suitable time so as not to interrupt the VV or inconvenience the VV body's client in any way. It is expected that the UKAS assessor will be provided with access to the client's documentation that the VV body reviews as part of its audit. Any documentation reviewed by the VV body during the conduct of the VV should be made available to the UKAS assessor to review.

B.8.4.5 If the situation arises where the UKAS assessor observes a nonconformity in the VV body's client's operations which is not reported by the VV body's team, the UKAS assessor shall inform the VV body's team about such findings during the post-witness closing meeting rather than in front of the VV body's client. The only exception is when the UKAS assessor observes a practice or nonconformity that presents an immediate risk to health and safety. In these cases, the UKAS assessor has a duty of care to report the issue without delay.

B.8.4.6 All activities of the VV body's evaluation should be witnessed, including the opening and closing meetings. Where the VV body utilises a team to conduct the evaluation UKAS may require additional assessors to ensure it can observe the entire evaluation process.

### **B.8.5 Post-audit review**

B.8.5.1 In exceptional cases and at the discretion of UKAS, a post-audit review may be utilised as an alternative to a witnessed assessment. The general principle for the format of a post-audit review is to complete an in-depth interview with a VV team using the output from the selected VV which will provide the equivalent confidence to a witnessed assessment. In the process of arranging a post-audit review the UKAS assessment manager will determine the plan taking into consideration the following points:

- i location of post-audit review to be conducted to ensure all relevant documentation can be accessed
- ii attendees in addition to audit team

B.8.5.2 The UKAS assessor shall, in light of findings during the post-audit review activity, using a range of assessment tools, consider whether the VV body's methods for determining audit requirements, duration and VV team competence are sufficient to address accreditation requirements for an effective audit.

### **B.8.6 Mechanism for impartiality requirements**

B.8.6.1 Where a VV body uses a committee for safeguarding impartiality, UKAS will observe at least one of its meetings during the cycle as part of the assessment programme. If the VV body uses an alternative mechanism to safeguard impartiality, then this will be reviewed accordingly, including interviews with personnel involved in the mechanism. Where possible this will be conducted alongside annual surveillance or reassessment visits.

### **B.8.7 Extension to scope requirements**

B.8.7.1 Following receipt of an application for an extension to scope, UKAS will determine whether or not there is a need for a head office and/or fixed office location assessment and/or witnessed assessments to take place. Factors that will be taken into consideration will include:

- i the range of existing scope of accreditation
- ii the volume of business in the new scope area
- iii the locations at which the extension to scope is sought
- iv the risk (high/low) of the extension to scope

B.8.7.2 Normally extensions to scope will require a head office (or fixed office location) assessment and witnessed assessments. The volume of witnessed assessments required is determined as per B.3.4 although a minimum of one (not two) witnessed assessments are required.

B.8.7.3 Where a VV body already holds accreditation for VV management system certification for one or more VV standards (e.g. ISO 14064-1) and wishes to seek accreditation for additional VV standards (e.g. ISO 14064-2) then this is deemed to be an extension to scope.

B.8.7.4 Where a VV body applies for a new fixed office location to perform critical activities to be added to its schedule of accreditation, UKAS will review the application to determine the appropriate assessment approach. A new fixed office location must be visited by UKAS or an appropriate Local Accreditation Body.

## **B.9 Biobanking requirements (ISO 20387)**

B.9.1 No specific additional requirements for assessment, but all collection facilities will need to be included in the assessment programme.



## Appendix C - Multi-site accreditation including fixed office locations

### C.1 Requirements

- C.1.1 In order for more than one location to be covered under a single accreditation, all parts of the entity seeking accreditation must operate under a single management system that meets the requirements of the relevant conformity assessment body standard(s).
- C.1.2 CABs with permanent offices/facilities in foreign countries must have a legally enforceable agreement or contractual link with the accredited legal entity in order for those locations to be included within the multi-site accreditation.
- C.1.3 In particular, CABs based at multiple locations must:
- a) Fully document the relationships between the locations and the extent of the interaction (*e.g. allocation of testing/calibration work, transfer of samples between locations, movement of technical staff and/or equipment and centralised or otherwise rationalised reporting arrangements*).
- Note: The extent of interaction possible will depend, among other factors, on the degree of commonality of procedures and their performance characteristics.
- b) Have mechanisms in place to ensure that enquiries about work in progress are handled efficiently, regardless of any transfer between locations.
  - c) Ensure that reviews of requests, tenders and contracts include appropriate consideration of clients' awareness of the way the CAB operates across the various locations.

### C.2 Assessment process

- C.2.1 In general, each location included in the scope of application/accreditation will be assessed at the initial assessment unless the associated risk determines that a sample will be appropriate.
- C.2.2 UKAS will look to use Local Accreditation Bodies (LABs) where a CAB has operations that require assessment in countries outside of the UK. These LABs will need to be signatories to relevant international (i.e. EA, ILAC or IAF) multilateral recognition arrangements.
- C.2.3 Subsequent surveillance assessments will cover a sample of the activities across the different locations to the extent necessary to form a reliable judgement about conformity with the necessary standard. It can be expected that each location will be assessed at least once in each four-year assessment cycle.
- C.2.4 Other fixed office locations, which do not perform critical activities, will be assessed as required according to a sampling plan over the four-year accreditation cycle.
- C.2.5 UKAS may increase the frequency of assessment of sites/fixed office locations, including to more than once per year, where it (or the LAB) has identified concerns regarding the management and control of the fixed office location. Issues identified at one site/location may impact upon the frequency or assessment of any other locations, depending on whether the issues identified are isolated or systemic.
- C.2.6 If UKAS raises findings that require improvement actions at the head office or at any one of the locations, the improvement action shall apply to all relevant locations.
- C.2.7 Suspensions or reductions in scope at one location, whether voluntary or imposed, will automatically involve a full consideration of the implications for the CAB as a whole. This may result in other locations being affected by this suspension/reduction.
- C.2.8 Where a CAB wishes to remove a site/fixed office location from its UKAS schedule of accreditation, the CAB will be required to demonstrate how the specific activities have been maintained to the relevant accreditation activities (it may require a UKAS assessment). In addition, the CAB will need to demonstrate that responsibilities for that location have been reassigned to ensure continued service to clients and continued conformity with the conformity assessment body standards.

- C.2.9 Locations in territories which UKAS or other MLA signatory Accreditation Bodies cannot attend due to safety, security or political reasons (e.g. where the territory is under a trade embargo) cannot be added to the schedule of accreditation unless appropriate remote assessment techniques can be effectively deployed, and UKAS considers it appropriate to do so.
- C.2.10 Where a CAB has a location already present on its schedule of accreditation and subsequently UKAS or other MLA signatory Accreditation Bodies are unable to visit that location due to safety, security or political reasons then remote assessment tools will be utilised to assess that location according to the sampling plan.
- C.2.11 If significant concerns are raised about the operations of a location which subsequently cannot be visited to confirm or otherwise these concerns, then this location may be removed from the schedule of accreditation before completion of the accreditation cycle. Reinstatement of such location will require the CAB to submit an application for extension to scope and cannot be granted until an on-site assessment has demonstrated that the concerns have been addressed.
- C.2.12 Where locations operate in a language other than English, UKAS will utilise independent translation or interpretation services to conduct the assessment. Any associated costs to provide these services shall be met by the CAB.
- C.2.13 Where subcontracted assessment reports from LABs are provided to UKAS in a language other than English, UKAS will utilise independent translation services to translate the reports. Any associated costs to provide these will be charged to the CAB. Note: UKAS retains responsibility for information security risk management in this instance.
- C.2.14 The relevant accreditation symbol can be used by any location listed on the schedule of accreditation, subject to the requirements in the Department for Business and Trade's publication entitled "*The National Accreditation Logo and Symbols: Conditions for use by UKAS and UKAS accredited organisations*", which is accessible via the Publications page in the Resources section of the UKAS website.
- C.2.15 Where a CAB makes reference to accreditation without the use of the symbol, "*The National Accreditation Logo and Symbols: Conditions for Use by UKAS and UKAS-accredited organisations*" specifies the wording to be used. It is acceptable, although not a requirement, to indicate that the accreditation covers multiple locations alongside the use of this statement.