



# LAB 3

EDITION 4 | AUGUST 2009

## The Conduct of UKAS Laboratory Assessments

### CONTENTS

	<b>SECTION</b>	<b>PAGE</b>
1	Introduction	2
2	Processing of applications	3
3	The schedule of accreditation	4
4	Pre-assessment	4
5	Preparations for the initial assessment visit	6
6	The initial assessment visit	6
7	The Introductory Meeting	6
8	The assessment	7
9	Recording assessment findings	8
10	Summary of findings	8
11	Factors affecting recommendations on accreditation	9
12	The Final Meeting	9
13	Post-assessment	10
14	Surveillance and re-assessment	11
15	Extension of schedule of accreditation	12

## CHANGES SINCE LAST EDITION

---

The document has undergone minor revision and update to reflect current practice and the revised reporting process as described in UKAS Publication Gen 3. The document also includes reference to the standard used for the assessment and accreditation of Medical Laboratories, ISO 15189 *Medical Laboratories – Particular requirements for quality and competence*.

## 1 INTRODUCTION

---

- 1.1 This publication gives general guidance on the conduct of laboratory assessments. The varied nature of assessments calls for flexibility of approach from the assessment team and the laboratory.
- 1.2 UKAS assesses and accredits the competence of laboratories to carry out specified calibrations, tests, types of test and sampling activities, and subsequently ensures, by monitoring, that the required standards are maintained. Application for laboratory accreditation initially involves a laboratory in sending UKAS a copy of its quality manual (however named) as well as providing basic information on its activities, equipment and staff in an Application Form (downloadable from the UKAS website, [www.ukas.com](http://www.ukas.com)).
- 1.3 Subsequently, the competence of the laboratory is checked by assessment at the laboratory and, where appropriate, at other sites. The laboratory may also be required to participate in proficiency testing, measurement audit or inter-laboratory comparison as appropriate to their scope. The purpose of the assessment is to determine whether the laboratory has the appropriate technical competence and complies with the requirements of ISO/IEC 17025 (the Standard). This process described in this publication is also applicable to the assessment and accreditation of Medical Laboratories to ISO 15189. In some circumstances, specialised publications provide guidance on the application of these criteria (see UKAS Website [www.ukas.com](http://www.ukas.com) for Publications).
- 1.4 All information obtained before, during or after assessment, including the fact that a particular laboratory has applied for accreditation, or that an application for accreditation has been deferred or rejected, is treated as strictly confidential by UKAS and its assessors.
- 1.5 Experts are used to assess the competence of the laboratory to perform the calibrations/tests (including sampling) for which accreditation is sought. Their assessment will be confined to investigating and reporting the findings that result from observation and discussion in the laboratory and through examination of documentation.
- 1.6 In addition to its own staff, UKAS uses assessors contracted from external sources to assess laboratories on its behalf. All UKAS assessors, including UKAS staff acting as assessors, must meet defined criteria in terms of their technical expertise and experience, must be trained in UKAS assessment procedures and are bound by confidentiality agreements.

- 1.7 UKAS laboratory assessment procedures are applicable to all sizes of laboratory. Assessors will take account of the size and complexity of the organisation when assessing the management system of a laboratory. The management system must provide assurance that the laboratory, whatever its size or complexity, or the location(s) where work is carried out, meets the requirements of the Standard.
- 1.8 The procedures described in this publication apply to pre-assessment and initial assessment visits and to visits after accreditation has been granted, for the purposes of surveillance, re-assessment, extension of scope, resolution of complaints or other purposes.
- 1.9 UKAS policy is to keep its customers informed of progress and the next steps in the accreditation process. Communications will come either from the UKAS Assessment Manager assigned to the customer or from the Commercial Support team.
- 1.10 UKAS uses some standard forms to report the findings of assessment. The forms are reviewed from time to time.

## 2 PROCESSING OF APPLICATIONS

- 2.1 All applications for laboratory accreditation are reviewed by UKAS, to ensure that UKAS:
  - (a) has fully understood the customer's requirements;
  - (b) can arrange assessment teams with all the necessary expertise and competence; and
  - (c) can make realistic estimates of the timescales and costs involved.
- 2.2 A member of UKAS staff is assigned as Assessment Manager to manage with the application. The Assessment Manager will normally have an understanding of the area of calibration, testing or sampling concerned, and will be able to discuss with the laboratory's representative any matters that may arise during the processing of the application. As far as possible, UKAS also ensures that the same Assessment Manager is responsible for processing that laboratory's application through to the accreditation stage and for liaising with the laboratory during the first few years of its accreditation.
- 2.3 The Assessment Manager will normally act as the Lead Assessor and is responsible, through contract review, for selecting and appointing the assessment team. The assessment team comprises a Lead Assessor and as many Technical Assessors or Experts as are necessary to provide the technical expertise adequately to assess the laboratory's competence. Laboratories have the right to object to the appointment of the nominated assessor(s) and, in such cases, UKAS will endeavour to offer an alternative. In the event that a suitable alternative cannot be identified, or the grounds for objection are considered to be unreasonable, UKAS reserves the right to appoint the assessor(s) originally selected.

- 2.4 The Lead Assessor reviews the Quality Manual and any supporting documentation supplied by the laboratory and advises UKAS on the laboratory's apparent compliance with the Standard. At this point, the Lead Assessor recommends whether:
- (a) a pre-assessment visit should take place; or
  - (b) exceptionally, plans for assessment of the organisation can proceed without any pre-assessment visit (this would be following discussions between the laboratory and UKAS);
  - (c) the organisation is not in a position to proceed to pre-assessment.

### 3 THE SCHEDULE OF ACCREDITATION

---

- 3.1 It is UKAS policy to define closely the scope of a laboratory's accreditation. This ensures that the laboratory's customers are provided with an accurate and unambiguous description of the range of calibration/tests covered by a laboratory's accreditation. Each laboratory is therefore asked to list, on its Application Form, the standard specifications or other methods or procedures relevant to the calibration or tests for which accreditation is sought, and the major items of laboratory equipment used to conduct those calibration/tests. Laboratories wishing to apply for a more Flexible Scope of tests/calibrations should refer to UKAS Publication Lab 39.
- 3.2 **For schedules of calibration**, the type of calibration, the range of measurements, the best measurement capability and the operators to be assessed will be provisionally agreed before the initial assessment. During initial assessment and after examination of the results of measurement audits, the content of the schedule, including best measurement capability, will be agreed with the laboratory.
- 3.3 **For schedules of testing (including sampling)**, the materials tested/sampled, type of test/sampling and method specification/equipment will be provisionally agreed before the initial assessment to enable the appropriate technical competency to be deployed at initial assessment.
- 3.4 In some cases, as the assessment proceeds, it may become clear that the laboratory is not in a position to achieve accreditation for certain areas within the proposed scope. In such cases, the Lead Assessor may be able to recommend accreditation for a suitably reduced or redefined schedule.
- 3.5 Schedules of accreditation of accredited laboratories are regarded as being in the public domain.

### 4 PRE-ASSESSMENT

---

- 4.1 The pre-assessment visit is normally carried out by the Lead Assessor (accompanied by a Technical Assessor where appropriate) and is usually completed in one day. The pre-assessment visit allows discussion with the laboratory management on the extent to which the laboratory's management system, quality manual and operating procedures appear to fulfil the requirements for accreditation to the Standard.

- 4.2 The visit should be structured so that the Lead Assessor can ascertain that the essential components of a management system for quality, administrative and technical operation of the laboratory have been put in place or have been addressed. In particular, the Lead Assessor needs to establish whether the laboratory has a stated policy for defined responsibilities and means of meeting each of the requirements of the Standard.
- 4.3 In addition to examining the documented management system prepared by the laboratory, the Lead/Technical Assessor will usually take the opportunity to discuss the proposed scope of accreditation and to carry out a brief examination of the laboratory's facilities.
- 4.4 Normally, the Lead/Technical Assessor will discuss with the laboratory any documented in-house methods used for activities that form part of the scope of accreditation and any in-house calibrations used in support of accredited measurement activities. This will allow the Lead Assessor to be satisfied that such methods have been validated and to permit any necessary changes to be made before the initial assessment. The discussion will cover the laboratory's policy and procedures for estimating uncertainty of measurement.
- 4.5 During the pre-assessment visit, the Lead Assessor will identify to the laboratory any areas that appear to require attention in order to fulfil the requirements for accreditation. The Lead Assessor will also remind the laboratory that the pre-assessment visit is not a full assessment, and will describe the nature of the full assessment visit.
- 4.6 The Lead Assessor will report his/her findings to UKAS. The report will indicate:
- (a) if a further pre-assessment visit is recommended;
  - (b) whether plans for initial assessment of the laboratory can proceed;
  - (c) specific reasons why plans cannot proceed;
  - (d) whether an interlaboratory comparison (e.g., measurement audit) is needed.
- A copy of the report of the pre-assessment visit will be passed on to the laboratory.
- 4.7 During or immediately after the pre-assessment visit, the UKAS Assessment Manager will determine the composition of the assessment team, and the effort (in mandays) required for the initial assessment visit including time for preparation and standard post visit activities. This will take into account all factors necessary to enable a reliable assessment of the competence of the laboratory to perform the full range of measurements/tests/techniques proposed for inclusion in its scope of accreditation, including,
- whether it is necessary to assess all calibration/test/sampling activities, or if a representative sample can be selected
  - the need to assess all key activities
  - and, in the case of multi-location activities including on-site calibrations/testing/sampling, the need to ensure that all locations where key activities are performed are assessed.

This forms part of UKAS' Contract Review procedure and is agreed by an independent decision maker.

*Note: Key activities include: policy formulation, process and/or procedure development and, as appropriate, contract review, approval and decision on the results of calibrations/tests.*

## **5 PREPARATIONS FOR THE INITIAL ASSESSMENT VISIT**

- 5.1 A detailed visit plan will be prepared indicating the section/activities/location(s) to be assessed by each assessor, and specify the calibrations/testing/sampling that each assessor must witness during the visit, including any on-site activities and in-house calibrations, as necessary.
- 5.2 UKAS will distribute copies of the visit plan to the laboratory and to all the assessment team; all parties are given the opportunity to raise any queries with the visit plan.

## **6 THE INITIAL ASSESSMENT VISIT**

- 6.1 The visit begins with an Introductory Meeting between the assessment team and representatives of the laboratory. The Assessment Team then depart to their respective areas to begin the assessment. The assessors will examine procedures and records and witness the relevant calibration, testing and sampling activities included in the scope. The Lead Assessor normally assesses the Management system documentation. The Lead Assessor will also manage the assessment team to ensure that the relevant activities are assessed and provide support and advice as necessary. A member of the laboratory staff nominated by the management should accompany each assessor.
- 6.2 The visits ends with a Final Meeting involving the assessment team and laboratory representatives, at which each assessor presents a summary of the areas examined and the findings (this may include more detailed reporting of the individual observations as appropriate). The Lead Assessor will report the overall findings of the team in the Assessment Report form. Interim meetings may be held during a visit, particularly if a number of assessors are present over a number of days.

## **7 THE INTRODUCTORY MEETING**

- 7.1 This Meeting is held on arrival to enable the assessment team and the laboratory's representatives to become acquainted, to confirm the purpose of the assessment and to remind the laboratory of what is expected during the assessment. It sets the scene, and is chaired by the Lead Assessor and will cover, but not necessarily in this order:
  - (a) an explanation of the purpose of the assessment, the functions of the assessors and confirmation that the laboratory staff understand the procedure;
  - (b) discussion of the significance and status of the Quality Manual;
  - (c) confirmation of the range of calibration/testing/sampling covered by the laboratory's application and how this should be defined in the laboratory's Schedule of Accreditation;
  - (d) confirmation of the visit plan and of the programme for witnessing calibrations/tests;
  - (e) outline the use and purpose of the UKAS Report forms;

- (f) confirmation that a representative of the laboratory has been assigned to accompany each assessor, and an explanation of the role of this representative in the assessment.

*Note*

*It is often appropriate for the accompanying laboratory representative (or relevant section manager, for example) to propose actions that could address observations recorded on the Improvement Action Report forms. This can save considerable time at the closing meeting. It is however, subject to the agreement of the laboratory management and may not apply to all observations, depending (for example) on the financial or resource implications, and some actions may need to be proposed at the Final Meeting.*

- (g) an explanation of what will happen at the Final Meeting and confirmation of the attendees, time and venue;
- (h) an assurance that all findings will be treated in confidence;
- (i) arrangements for providing an office and any services needed by the assessors e.g. printing facilities, internet access;
- (j) confirmation of work hours, luncheon breaks etc, within which UKAS will endeavour to work;
- (k) an opportunity for the laboratory management and staff to ask relevant questions.

## 8 THE ASSESSMENT

- 8.1 Witnessing of the testing/sampling/calibration activities carried out by the laboratory form 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 visit plan. Assessors need to establish the laboratory's overall competence in all aspects required by the Standard.
- 8.2 Following the dispersal of the assessment team to various sections of the laboratory, normally the Lead 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.
- 8.3 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.
- 8.4 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 visit programme. The assessors will ask to see the equipment involved, the manufacturer's manuals, and establish the state of calibration of the equipment.

- 8.5 Assessors will witness measurements and examine documentation concerning calibration/testing/sampling in progress, and will review associated records and reports/certificates.
- 8.6 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 results obtained by the laboratory in measurement audits. If calibration personnel are to be confirmed as approved operators, it will be necessary for assessors to observe the performance of operators on specific calibrations at locations chosen by UKAS.
- 8.7 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 and the results from participation in appropriate proficiency testing schemes and other QC/QA procedures. Assessors will also assess procedures used to establish the validity of methods used.
- 8.8 The object of assessment is to establish by observation whether the work of the laboratory meets the requirements of the Standard. Observations made will be based on objective evidence and will be recorded and verified with the accompanying laboratory representative.

## **9 RECORDING ASSESSMENT FINDINGS**

---

- 9.1 Assessment findings, including possible nonconformities with the requirements of the Standard and opportunities for improvement are recorded in accordance with UKAS Publication Gen 3 *Reporting of UKAS Assessments*., Assessors will also record which activities they have observed. These records provide the objective evidence on which the Lead Assessor's recommendations on accreditation to UKAS will be based.

## **10 SUMMARY OF FINDINGS**

---

- 10.1 After the assessors have completed their individual assignments, they meet by themselves to produce a co-ordinated view of the laboratory's work.
- 10.2 The Lead Assessor then normally compiles the Assessment Report form based on the findings recorded on the Improvement Action Report forms.
- 10.3 The Assessment Report will summarise the assessors' findings, indicate key areas needing improvement action, and give the Lead Assessor's recommendations to UKAS. The recommendation may be for an unconditional offer of accreditation, a conditional offer (e.g. subject to the satisfactory clearance of nonconformities), or for refusal. In some cases it may be appropriate to recommend that an offer of accreditation be made for a reduced Schedule.

## 11 FACTORS AFFECTING RECOMMENDATIONS ON ACCREDITATION

---

- 11.1 In deciding on the recommendation to be made, the Lead Assessor takes into account the extent of competence and conformity to the standard found during the assessment.
- 11.2 Where there are no findings requiring improvement action, the Lead Assessor normally recommends that accreditation be offered immediately.
- 11.3 Where there are findings that require improvement action, the recommendation will usually be that accreditation is offered subject to satisfactory action being taken by the laboratory
- 11.4 Where there are one or more areas of calibration, testing or sampling where the extent of competence or conformity is not acceptable, but there are no overall major systems failures, the Lead Assessor may recommend accreditation for an appropriately reduced schedule.
- 11.5 Where the number and seriousness of the findings are such that the laboratory's management system and organisation fails to demonstrate competence or conformity with the requirements of the Standard, the Lead Assessor's recommendation will be that accreditation is refused and that the laboratory is advised to discuss future actions with UKAS.
- 11.6 For laboratories in some areas of activity, accreditation may also require satisfactory completion of a proficiency test or a UKAS measurement audit.

## 12 THE FINAL MEETING

---

- 12.1 The final meeting is where all assessors present their findings to the laboratory management/staff. The Lead Assessor presents a summary of the results of the assessment and informs the management of the recommendation that will be made to UKAS.
- 12.2 The Lead Assessor chairs the Final Meeting. The following items will be addressed :
- (a) reminder of the purpose of the visit and reiteration of confidentiality;
  - (b) the possibility that nonconformity with the Standard may exist that has not been found;
  - (c) each assessor will provide an overview of his or her findings, and similarly, the Lead Assessor will present his or her own findings as an individual assessor;
  - (d) the Executive Summary, conclusions and recommendation will be presented;
  - (e) completion of the Improvement Action Report forms to record the proposed improvement actions (ideally these will have been completed before the Final Meeting);

- (f) a date by which any required improvement actions will be implemented will be agreed in consultation with the laboratory. A period of up to three months is normally acceptable for initial assessments and extension to scope visits. For surveillance and reassessment visits it is expected that improvement actions be normally implemented within one month of the visit. If improvement actions are not implemented within three months then it will normally be necessary to suspend part or all of the scope of accreditation. The implications of any recommended sanctions will also be discussed;
- (g) acknowledgement by a management representative as nominated by the laboratory, of receipt of the Assessment Report;
- (h) the laboratory will have an opportunity to discuss the assessment and to ask any questions, including questions about the findings;
- (i) copies of each Improvement Action Report, and the Assessment Report will be provided to the laboratory either on the day or shortly afterwards as circumstances allow;
- (j) the Lead Assessor will supply the laboratory with blank copies of the Improvement Action Summary Forms and explain how improvement action evidence should be presented.

## 13 POST-ASSESSMENT

---

- 13.1 Immediately after the assessment, the Lead Assessor will report his/her recommendation to UKAS. This is considered by UKAS, and if there is any change to the recommendation stated on the Assessment Report already provided to the laboratory, this is then notified to the laboratory along with the justification for the revision. Further information may need to be provided to UKAS in order to confirm the recommendation.
- 13.2 The laboratory supplies UKAS with evidence of the improvement action to be taken to address any findings. UKAS will acknowledge receipt of the evidence. The assessors involved in the assessment assess this evidence. Laboratories need to complete the improvement action summary forms and cross-reference the evidence of individual actions taken to the Improvement Action Report form and finding. Evidence shall be presented to UKAS grouped by assessor.
- 13.3 It may be necessary for a follow-up visit to be made to assess the improvement actions taken. Such an assessment will be directed specifically to the confirmation of clearance of the findings. If an assessor observes a new finding(s) he/she will bring the matter to the attention of management and will also report it, in writing, to UKAS.
- 13.4 Where the recommendation to accredit (in full or for a reduced scope – see para 11.4) has been agreed by UKAS, the decision will be confirmed in writing with the Proposed Accreditation Details. A copy of the draft schedule and summary of the proposed 4 year effort will also be provided to the laboratory. The laboratory has to agree these details, before accreditation can be granted.
- 13.5 Once the assessment team is satisfied that all findings have been satisfactorily actioned, accreditation is granted. The grant letter is sent to the laboratory with an Accreditation Certificate. A schedule of accreditation is then published on the UKAS website detailing the agreed calibration/testing/sampling activities.

- 13.6 Where the assessment team is unable to recommend accreditation for the full scope of the application (see paras 11.4 & 11.5), UKAS will confirm the decision in writing within one month of the assessment visit.
- 13.7 If the laboratory disagrees with the accreditation decision taken by UKAS, it may appeal. The appeal must be in writing and must be received by UKAS within one month of the decision letter. The UKAS Appeals Process is published on the UKAS website, [www.ukas.com](http://www.ukas.com).

## 14 SURVEILLANCE AND RE-ASSESSMENT

- 14.1 Following grant of accreditation, laboratories are subject to periodic surveillance and re-assessment visits. The first surveillance visit is normally carried out six months after the date of accreditation. Subsequent visits are carried out at yearly intervals from that date. However, UKAS reserves the right to make unannounced visits at any time. The first re-assessment visit will take place three and a half years after the date of accreditation, and thereafter at four-yearly intervals.
- 14.2 The purpose of surveillance/re-assessment visits is to determine whether or not a laboratory is continuing to fulfil the requirements for accreditation. The general approach described in this publication will apply to all these visits. However, at the Introductory Meeting, the Lead Assessor will establish whether all significant changes in the laboratory status or operation have been notified to UKAS and will confirm that there are no outstanding improvement actions from the previous visit.
- 14.3 If a surveillance or re-assessment visit reveals that there have been significant changes, e.g., to staff, equipment or the range of services available, these matters shall be recorded by the Lead Assessor. Assessors shall check that the changes are not such as to diminish the laboratory's capabilities as described in the schedule of accreditation, and that they have already been fully notified to UKAS.
- 14.4 Normally, during a single surveillance visit, assessors will not be expected to check the whole of the calibration/testing/sampling work for which a laboratory is accredited. The range of calibrations, tests or sampling for which the laboratory is accredited will be assessed at least once between full assessment/re-assessment. Equally, not all areas of the management system need to be covered at each surveillance visit. The assessment team will take into account the outcome of previous assessments to plan the activities to be covered. The Lead Assessor will normally include an assessment of Management Review, Audits and Complaint Records at each surveillance visit.
- 14.5 A reassessment visit will involve a comprehensive re-examination of the laboratory's management system and calibration/testing/sampling activities and will be similar in format and detail to the initial assessment.
- 14.6 At the conclusion of a surveillance or re-assessment visit, the Lead Assessor will (as with an initial assessment) make a recommendation to UKAS on the continuing accreditation of the laboratory. Suspension or withdrawal of accreditation will be recommended where the number and seriousness of the findings identify major failures in the laboratory's management system, and the laboratory is not able to demonstrate that the requirements of the Standard continue to be met.

## 15 EXTENSION OF SCHEDULE OF ACCREDITATION

- 15.1 When a laboratory applies for an extension to its Schedule of Accreditation, including the addition of new specified staff, UKAS will seek advice from the Lead Assessor and, if relevant, the technical assessor(s) on whether, after examination of documentation provided by the laboratory, accreditation can be granted without further action by the laboratory, or whether further documentation or an assessment visit is required. The Assessment Manager may arrange an assessment visit in the normal way or may suggest combining this visit with an imminent scheduled visit. It is helpful in visit planning if the application for extension of scope is submitted to UKAS at least 3 months before assessment of the extension to scope is required. Application forms available from the UKAS website [www.ukas.com](http://www.ukas.com) detail the documentation that needs to be submitted in support of extension to scope applications.
- 15.2 If the extension is to be assessed during a scheduled visit it will not be allowed to reduce the effectiveness of the normal surveillance/re-assessment visits so additional time will normally be required.