



The Conduct of CPA (UK) Ltd Medical Laboratory Assessments

Clinical Pathology Accreditation (UK) Ltd

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1 INTRODUCTION

1.1 Scope and purpose

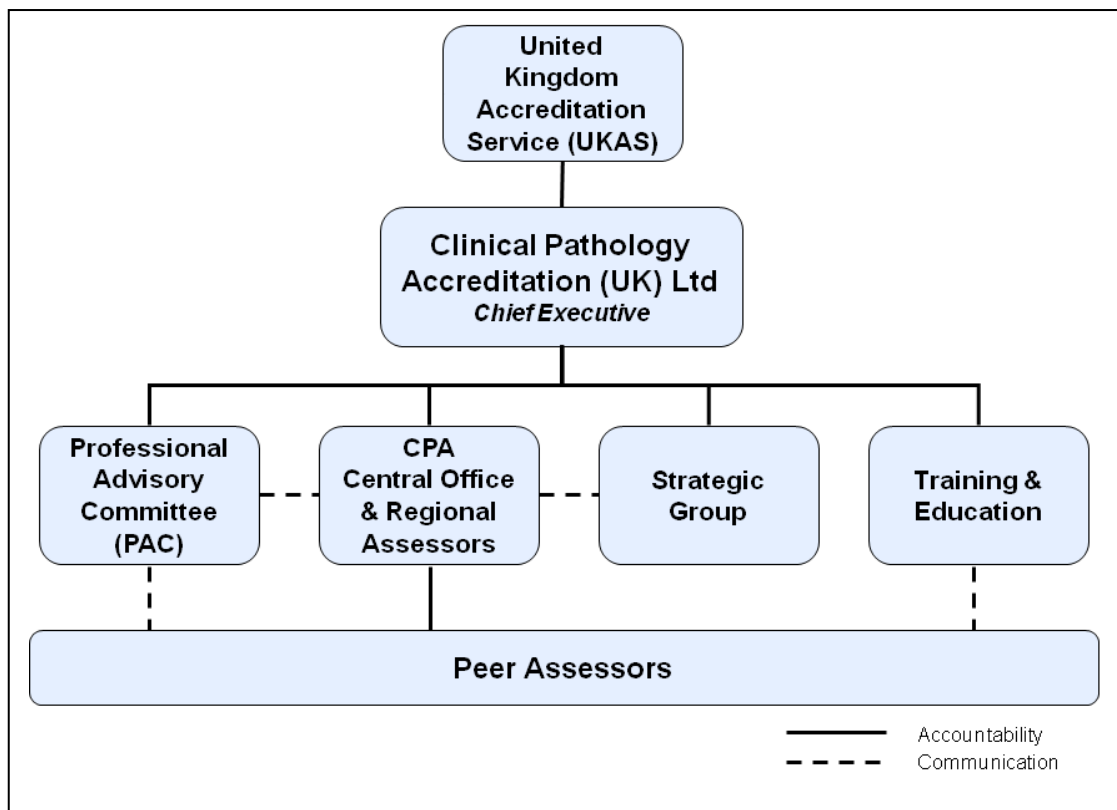
CPA has duties and responsibilities to those applying for accreditation. Applicants also have a responsibility to conform to the CPA process. Once the application is accepted by CPA there is an agreement between both parties to conform to the processes described in this handbook.

1.2 Background

The process of accreditation involves the external assessment of the medical laboratory to assess conformity with the published standards and to ensure that the medical laboratory provides a service that meets the agreed needs and requirements of its users. CPA provides a means by which this can be achieved. It is a peer-review based system for both the public and independent health care sectors. Access shall not be conditional upon the size of the laboratory or membership of any association or group nor shall accreditation be determined by the number of laboratories already accredited. The cost for the process is described in the fee structure.

1.3 Company Structure

The Company structure and its relationship with other organisations is shown below:



CPA is a wholly owned subsidiary of United Kingdom Accreditation Service.

CPA Central Office

The Company's headquarters has permanent staff that includes the Executive Manager together with administrative and secretarial support. Regional Assessors are home based. The office is responsible for all organisational and administrative aspects of the accreditation process including the publication of a newsletter twice a year providing up-to-date information on Company activities.

Within the Central Office there are regional administrative teams each headed by an Accreditation Manager. Each medical laboratory is assigned to one of these teams. The team then takes on the responsibility of dealing with all aspects of the accreditation process for that applicant. This requires close liaison with both the applicant and the Regional Assessors. The administrative teams along with the regional assessment teams form the accreditation teams described in this text.

Regional Assessors

CPA Regional Assessors are employees of the Company. If they have been employed in a medical laboratory they will not be assigned to that laboratory or their schedule, at least for a period of two years. They have continuing responsibility for the assessment of medical laboratories within one of the regions. They work with the Peer Assessors, as lead auditor, to form the assessment team. One of their objectives is to ensure that all applicants are assessed within their scheduled timescale. They are responsible for ensuring a high standard of assessments, monitoring the overall quality of assessments, and reporting any problems. They contribute to and support the development of CPA assessment and training programmes with a particular emphasis on quality systems. Each team of Regional Assessors is led by an Assessment Manager who is also involved in training, continuing education and monitoring of the team members and Peer Assessors.

Peer Assessors

CPA Peer Assessors would usually be practising Consultants/Clinical Scientists of equivalent status and Biomedical Scientists at the most senior level. CPA also uses retired assessors who have maintained statutory registration with a professional body. Retired Peer Assessors are paid a daily fee for the time they are on a site visit.

Those interested in becoming assessors are invited to apply and further details may be obtained from Central Office. The application form is available on the CPA website or via CPA Central Office. Once completed, the application form must be countersigned by the Chief Executive of the employing institution and by a representative of the relevant professional organisation. The Professional Advisory Committee (PAC) considers all applications. Successful applicants are invited to attend a training course and thereafter ongoing update sessions.

Assessors are bound by confidentiality agreements and sign a Code of Conduct and Letter of Engagement with CPA.

Successful applicants will be:

- Consultants/Clinical Scientists of equivalent status and Biomedical Scientists employed at a senior professional level within their own organisation
- a member of one of the professional bodies and endorsed as such
- supported by the Chief Executive and the Head of laboratory of their own organisation
- working in a CPA accredited, or conditionally approved laboratory
- able to undertake all the necessary training and attend the update sessions.

Professional Advisory Committee (PAC)

The Professional Advisory Committee (PAC) advises the Chief Executive on matters relating to accreditation of medical laboratories.

The specialties of Clinical Biochemistry, Haematology, Histopathology, Immunology and Microbiology are each represented by a consultant and a Biomedical Scientist. There is a single representative for Genetics. Two consultants and a Biomedical Scientist represent EQA activity. The consultant representatives are nominated jointly by The Royal College of Pathologists and the Association of Clinical Pathologists and also in the case of Clinical Biochemistry, the Association for Clinical Biochemistry. The Institute of Biomedical Science nominates the five Biomedical Scientists and there is a representative from the independent healthcare sector. There are additional advisors in Transfusion Medicine, Cytopathology, Virology, Andrology and Histocompatibility & Immunogenetics. PAC Members normally serve for a period of four years.

All appointees must meet with the approval of the Chief Executive of CPA and the PAC Chair. They are expected to be experienced assessors with CPA and are required to sign a code of conduct and letter of engagement with CPA.

Permanent members include the Company Chief Executive, Executive Manager, and other CPA employees attend by invitation where appropriate. The PAC meets on a regular basis and it is important that each pathology discipline is represented by at least one of the relevant members.

Strategic Group

The Strategic Group advises the Chief Executive on strategic matters relating to the professional aspects of accreditation. The membership includes the CPA Chief Executive (Chair), the Executive Manager, the PAC Chairman and an EQA representative from the PAC. The group reserves the right to co-opt individuals when necessary depending on the nature of the business/project requirements.

Training and Education Group (TEG)

The Standards, Training and Education group is evolving. During 2010 the Executive Manager will develop new structures to replace the activities of STEG, including the development of a new group to lead the development of the Standards. The new proposals will be implemented following approval by the Chief Executive. The present group is now designated for Training and Education.

1.4 Documentation

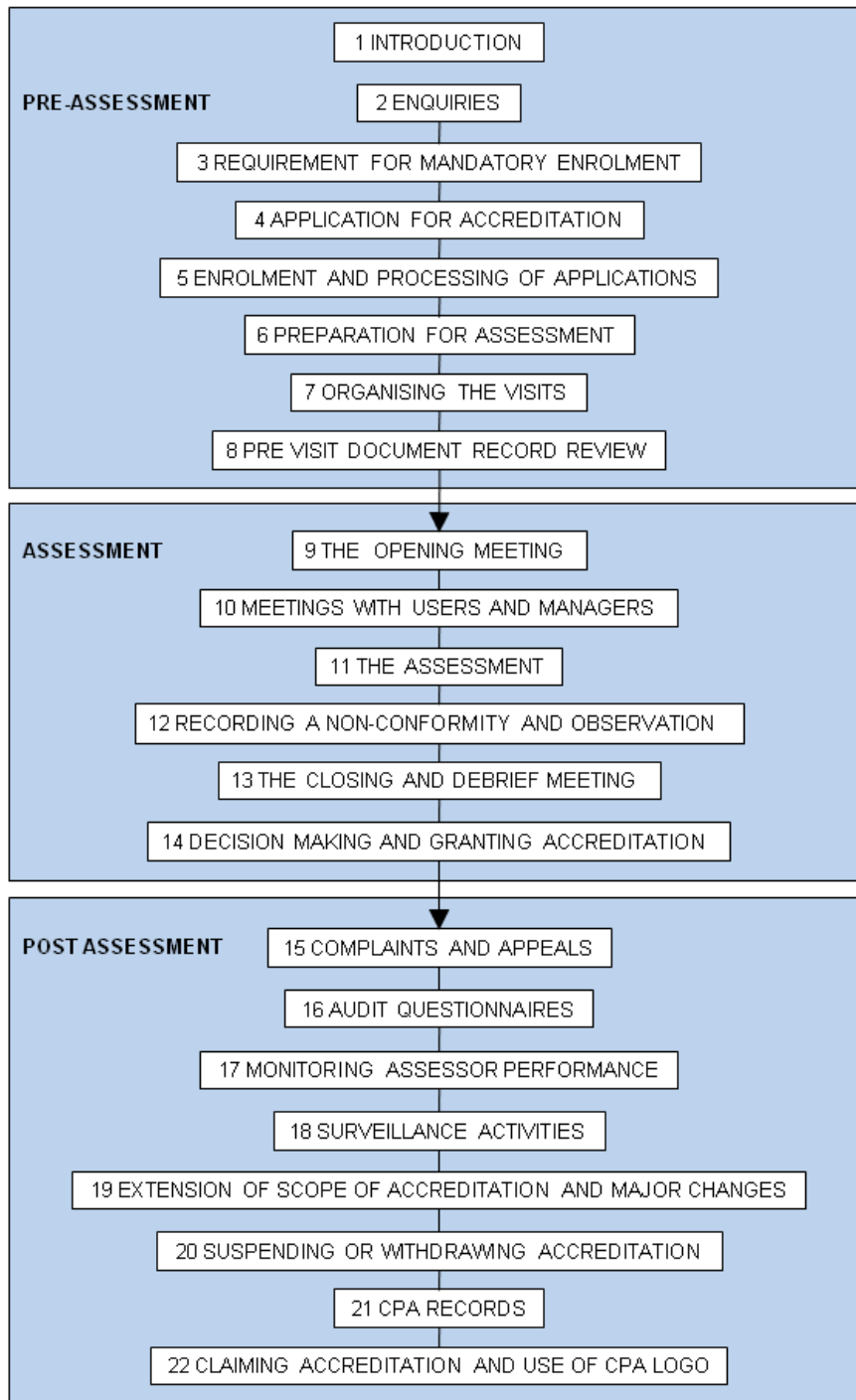
Documents referred to in this handbook are listed in Appendix A.

All CPA documents are available from:

- CPA Central Office
- CPA website www.cpa-uk.co.uk

General information, including addresses and current accreditation status of enrolled medical laboratories and EQA schemes is also available on the website. An additional support website (www.cpa-uk.co.uk/support/) provides up to date information to prepare for both applicants and assessors for the assessment visit. This website includes current CPA policies and procedures and references to national and professional guidelines to provide support in interpreting the CPA Standards.

1.5 An Overview of the assessment process



The assessment process is illustrated in the diagram on the left and involves a number of steps detailed in sections 2-22 of this handbook. These steps are divided into pre-assessment, assessment and post assessment phases. Within the phases shown, the numbering of the individual steps corresponds with the paragraphs of this handbook. The fee structure for the process can be downloaded from the CPA website or obtained from the CPA office. Once enrolled, fees are collected annually.

2 ENQUIRIES

The following information is available to the enquirer:

- The Conduct of CPA (UK) Ltd Medical Laboratory Assessments
- CPA (UK) Ltd - Standards for the Medical Laboratory
- Application for Accreditation

3 REQUIREMENT FOR MANDATORY ENROLMENT

3.1 Introduction

As part of the Modernisation of Pathology Strategy, the Department of Health in England requires that all medical laboratories enrol with an accreditation programme. The Scottish Government and the Welsh Assembly Government have similar requirements.

All enrolled Medical Laboratories may be found on the CPA website.

3.2 Categories of enrolled medical laboratories

Externally on the CPA website all enrolled medical laboratories will fall into one of four main categories; these are *Accredited*, *Conditional Approval*, *Awaiting Assessment* and *Non Accredited* (see table below). Additionally within the Non-accredited category CPA recognises four sub categories that are shown in the table below.

External Record	Internal Record
<ul style="list-style-type: none"> ACCREDITED 	<ul style="list-style-type: none"> ACCREDITED
<ul style="list-style-type: none"> CONDITIONAL APPROVAL 	<ul style="list-style-type: none"> CONDITIONAL APPROVAL
<ul style="list-style-type: none"> AWAITING ASSESSMENT 	<ul style="list-style-type: none"> AWAITING ASSESSMENT
<ul style="list-style-type: none"> NON-ACCREDITED 	<ul style="list-style-type: none"> NON-ACCREDITED - Application not yet accepted NON-ACCREDITED – Declined assessment within time scale NON-ACCREDITED - Conditions not met NON-ACCREDITED - Referred

3.3 Descriptions of main categories of enrolment used externally

The four main categories used externally are described below:

ACCREDITED

Accreditation is granted, after assessment, when there is full conformity with all CPA standards. A certificate of accreditation is provided.

CONDITIONAL APPROVAL

Non-conformities have been recorded. These must be corrected for accreditation to be granted.

AWAITING ASSESSMENT

CPA have accepted the application for accreditation and Quality Manual and the medical laboratory is awaiting assessment.

NON - ACCREDITED

The medical laboratory is **not** currently accredited, conditionally approved, or awaiting assessment with CPA

3.4 Descriptions of sub categories of NON - ACCREDITED used internally

The four sub categories of Non-Accredited are used on the CPA database and are defined below:

NON - ACCREDITED - Application not yet accepted

The medical laboratory has conducted a self-assessment and submitted an Application Form and Quality Manual to CPA. Details of the medical laboratory are held on the CPA database.

At self-assessment, the medical laboratory may have recorded non-conformities with the CPA standards or may have failed to submit an up to date, or complete, Quality Manual. In this event, the medical laboratory will remain enrolled pending acceptance of revised or complete documentation. It will not be placed in the *awaiting assessment* category at this time.

NON – ACCREDITED – Declined assessment within timescale

The medical laboratory has refused an assessment within the required timescale. The medical laboratory will remain enrolled and CPA will enter into an iterative process with the laboratory.

NON - ACCREDITED - Conditions not met

Post assessment, the applicant is unable to correct the non-conformities. The medical laboratory will remain enrolled and CPA will enter into an iterative process with the applicant. This will involve re-application for assessment.

NON - ACCREDITED - Referred

If the assessors identify critical non-conformities, then accreditation may be refused. The medical laboratory will remain enrolled and CPA will enter into an iterative process with the applicant. This will involve re-application for assessment.

4 APPLICATION FOR ACCREDITATION

New Applicants

New applicants must submit to CPA Central Office a completed application form together with the applicant's Quality Manual.

Re-application for Accreditation

At the beginning of each four year period a new Application Form and Quality Manual is required. The documents are due in the first three months prior to the assigned period in accordance with the assigned schedule. It is important to have up to date information in order to plan for the correct assessment team and the number of days required on site. Failure to submit these documents on time will result in delay and could affect the CPA status.

5 ENROLMENT AND PROCESSING OF APPLICATIONS

CPA accredits the complete service of a medical laboratory and applicants must declare their full repertoire to CPA. All services managed by the applicant must be declared. This declaration is on the 'Other Sites Managed by the Laboratory' form within the application form. One form must be completed for each site e.g. Main Laboratory, Mortuary, Blood Bank, POCT. Inaccuracies identified at assessment may delay the process.

Before an application is accepted CPA assesses its ability to carry out the assessment in terms of its own policy, its competence and the availability of suitable assessors. The Application Form and Quality Manual are assigned to the appropriate accreditation team.

Once the application is accepted the applicant medical laboratory will be issued with an enrolment date and details of the future schedule for all assessments. The applicant's details are recorded on the CPA database and the applicant will be listed on the CPA website as "Awaiting Assessment". A Regional Assessor will be given responsibility for the department.

The applicant and the Chief Executive of the parent organisation will be informed by CPA if an assessment visit cannot be arranged within the scheduled timeframe.

If CPA are able to organise an assessment within the scheduled timescale but the applicant requests a delay then the medical laboratory will be categorised on the CPA database as Non-Accredited – *Declined assessment within timescale* and on the CPA website as Non-Accredited. Applicants declining a visit date will be required to re-submit an up-to-date Application Form more relevant to the new assessment date. CPA reserves the right to charge a cancellation fee to cover administrative costs.

6 PREPARATION FOR ASSESSMENT

6.1 Visits

Over a 4-year cycle there are different types of on site visits as follows:

- Main visit – full assessment visit with a full assessment team led by a Regional Assessor.
- Surveillance visit – on site one day conducted by the Regional Assessor scheduled within two years of the main visit. In exceptional circumstances a Peer Assessor may be required.
- Clearance visit – on site usually for one day may or may not require a Peer Assessor.

CPA reserves the right to enter and assess any enrolled laboratory at any time and without notice.

For each of these visits the applicant is required to nominate a member of the staff to act as the on-site co-ordinator and the Regional Assessor will contact that person to arrange a date within the CPA appointed timescale. If under exceptional circumstances the dates are unsuitable then the procedure is halted and a solution sought by the accreditation team.

Once the date is scheduled CPA will contact the Peer Assessors for their availability. Letters of confirmation of the date are issued to all parties involved in the visit.

6.2 Selection of Peer Assessors

Peer Assessors are selected on the basis of their competency to assess the repertoire. Assessors should be independent of the applicant laboratory and should not be closely acquainted with, or a competitor of, the applicant medical laboratory. PAC members may be used for assessments at the discretion of the Company. To maintain the impartiality of the process in such cases the PAC member will not be part of the decision making process.

Each assessment team normally consists of a Regional Assessor and two Peer Assessors. For large, complex or multi-disciplinary applications, and at the discretion of CPA, extra Peer Assessors may be used.

In the event that Peer Assessors are unavailable for the scheduled dates another date will be arranged for either a full team or an assessor to cover the remaining repertoire. The dates will be discussed and arranged between the Regional Assessor and applicant.

6.3 Objections to assessors

If the applicant has good reason to object to any of the Peer Assessors then that individual will be replaced. Objections to team members must be received within two weeks of receipt of the team list. In exceptional circumstances there may also be a need to replace the Regional Assessor. Such agreement will be made with the Executive Manager. The applicant may not object to the team structure.

7 ORGANISING THE VISITS

7.1 Main Visit

The procedure followed at any site visit can vary according to local situation i.e. the nature of the institution concerned, how many disciplines are to be assessed at any one time, what the geographical constraints are and if any additional Peer Assessors are required.

The usual format is for the assessment team to spend two days in one discipline, checking conformity with CPA standards and taking the opportunity to solicit the confidential views of users and institutional manager(s). Geographically scattered services will require more time for assessment. It is important that all premises from which one or more key activities are performed are visited. The Regional Assessor will be present on site throughout. Peer Assessor(s) will attend during the assessment and the amount of time needed will be decided when the timetable is considered. This is the responsibility of the Regional Assessor. The applicant will be informed once the timetable has been confirmed.

7.2 Surveillance visit

There will be a one-day surveillance visit carried out by a Regional Assessor within two years of the main assessment visit. In exceptional circumstances additional surveillance visits may be required and will be arranged on an ad hoc basis. This is not a full assessment but the assessor reserves the right to check any of the CPA standards while on site. The Regional Assessor will make contact to arrange a date. Sometimes these dates may be set at the main visit. As with main assessments there will be a timetable issued together with a list of documents/evidence that should be readily available during the visit. This visit will mainly involve those staff dealing with the laboratory quality management system. It will not normally be necessary for the assessors to meet with the users or institutional manager(s). It may be necessary to include a Peer Assessor on the team.

7.3 Clearance Visit

In order to clear the non-conformities an additional visit may be required. These will be arranged at the discretion of the Regional Assessor following discussion with the Regional Assessment Manager. The factors taken into account will be: timescale, severity nature and/or complexity of the original findings. A clearance visit will always be required if it takes longer than 12 months for submission of evidence from the date of the last visit.

7.4 Responsibilities of CPA

In advance of the visit CPA will,

- maintain close contact with the applicant
- select Peer Assessors appropriate to the repertoire of the department
- replace Peer Assessors if required
- provide a timetable
- provide a list of documents required to be available during the visit
- provide an assessment team list
- provide the Peer Assessors with forms relevant to the assessment
- book hotel accommodation for the assessment team

During the visit the Regional Assessors will

- conduct the opening and closing meetings
- chair the meeting with users and institutional manager(s)
- ensure all paperwork is completed for return to CPA Central Office

7.5 Responsibilities of Peer Assessors

In advance of the visit (if included in the team) they will

- return the signed agreement to perform the assessment visit
- make own travel arrangements
- review documentation
- prepare sufficient vertical and examination assessment forms for the visit

7.6 Responsibilities of applicant medical laboratories

In advance of the visit the applicant will be required to provide information within a timeframe.

This will include where relevant:

- Application Form and Quality Manual
- Names, positions and contact details of the users to be interviewed (no later than three weeks prior to the visit)
- name and position of the executive officer to be interviewed

NB Where a number of disciplines are being assessed over a short period it is helpful if a single laboratory coordinator can be assigned to submit this information only once.

During the visit the applicant must ensure availability of

- all key staff or nominated deputies
- staff to assist assessors in finding information during the assessment
- individual(s) with the authority to agree findings and sign off non-conformity or observation forms
- evidence to support conformity with the standards; if this is stored electronically, access and printing facilities must be provided
- remotely stored documents on-site at the time of the visit
- a private room in close proximity to the laboratory for the use of the assessment team throughout the visit
- refreshments, including a sandwich lunch
- photocopying facilities

8 PRE VISIT DOCUMENT RECORD REVIEW

The Regional Assessor will review documentation relevant to the type of visit. This will include:

- Quality Manual
- Application Form
- previous report
- evidence of clearances
- any other relevant documents

Peer Assessors will be kept informed of outcome of horizontal assessment of the quality management system.

9 THE OPENING MEETING

The on site assessment visit commences with an opening meeting chaired by the Regional Assessor. This meeting follows a prescribed agenda:

1. Opening, introductions and domestic arrangements
2. Health and safety - fire arrangements
3. Confidentiality
4. Purpose of the assessment
5. Review of scope of assessment
6. Disclaimer with explanation

'This assessment relies upon the sampling of laboratory activity. It follows that on completion of the assessment there may be undetected non-conformities. If laboratory management is aware of any non-conformity, it has a responsibility to declare it. Failure to do this will result in the contract with CPA (UK) Ltd being broken.'

7. Complete Opening Meeting Declaration
8. Review of the schedule and confirmation of working times etc
9. Confirm arrangements for final meeting and any interim meetings
10. Confirmation of resources and facilities needed by the assessment team and identification of at least one co-ordinator peer assessor
11. EQA Statement
12. The functions and responsibilities of the assessment team
13. Method and procedures used to conduct the assessment
14. Code of Conduct

CPA are aware that the assessors are invited guests in the department. Professional behaviour is expected from both the assessors and the laboratory personnel throughout the visit. If at any time during the visit there is cause for concern about the conduct of any CPA representative it must be brought to the attention of the regional assessor or CPA at the time.

In turn CPA as an employer, has a duty of care to it's employees. CPA cannot and will not tolerate the use or threat of aggression against its representatives. Every applicant is obliged, under its contractual agreement with CPA to offer reasonable access and co-operation as necessary to enable the assessment team to monitor conformity against the relevant standards.

15. Questions and clarification
16. Close

The Opening Meeting Declaration (agenda item 7) allows the opportunity for the applicant to declare any changes to repertoire, sites, key staff or any other major changes not previously notified to Central Office. It also gives the applicant laboratory a further opportunity to declare any non-conformity.

A register of those attending the meeting is completed and any notes taken will be submitted to CPA with the report.

10 MEETINGS WITH USERS AND MANAGERS

For a main assessment visit the applicant is asked to arrange two separate meetings one with the institutional manager(s) and the other with representatives of the clinical user group, usually to be held over lunchtime.

During the visit the Regional Assessor will meet with the institutional manager(s) of the owning organisation. On the second day the assessment team will meet with representatives of the clinical user group. Where a number of disciplines are being assessed within a short space of time it may be necessary to organise single meetings with the institutional manager(s) and users. A list of the names and positions of those attending these meetings must be forwarded to CPA no later than three weeks before the visit date. CPA reserves the right to request interviews with additional persons. It is important to note that these meetings are held in confidence and there must be no representative from the applicant medical laboratory present.

If any of the assessors are not satisfied that the meeting has covered the discipline in sufficient detail, further contact will be made with additional users in consultation with the Regional Assessor.

More detailed information regarding these meetings is provided in the leaflet, "Meetings with Users and Managers", available from CPA. Copies are automatically provided to the applicant laboratory once the visit is organised for distribution to relevant individuals. Confidential notes will be taken at these meetings and a register of those attending the meeting is completed. These will be submitted to CPA with the report.

11 THE ASSESSMENT

11.1 Introduction

The assessment process relies upon obtaining evidence that enables the assessor to judge whether the medical laboratory is operating in conformity with the Standards. Findings are recorded as a non-conformity or observation (see Section 12).

The Regional Assessors examine the laboratory's quality management system and its associated documentation with the assistance of the quality manager to verify that it meets the needs and requirements of the standards.

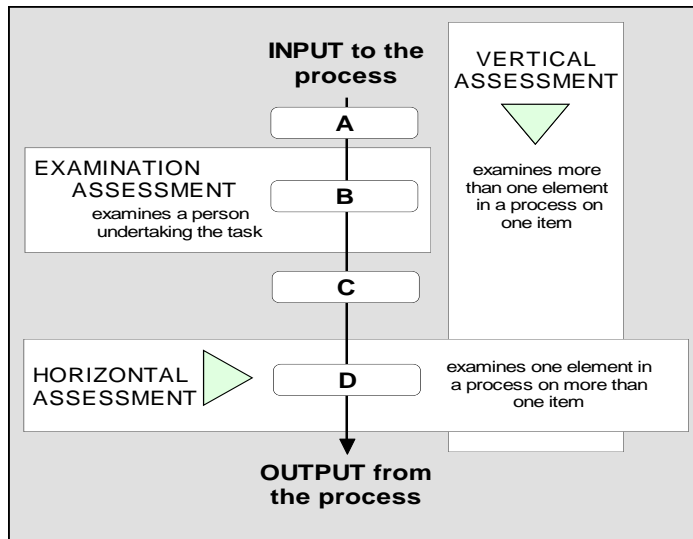
Peer Assessors audit the clinical and technical aspects of the service.

In order to ensure the competency to perform the service across the scope of activity a representative number of staff need to be interviewed.

11.2 Working with an assessment team

The assessment team work to a timetable that is planned prior to the assessment visit. It should be emphasised that there may be occasions when this timetable has to be altered at the last minute to accommodate unforeseen events. Assessors and applicants are requested to be flexible in their approach to this timetable. The assessment team will meet at intervals during the day to discuss and agree findings. This is most useful when more than one discipline is being assessed and common areas are being visited. These meetings should be in a private area set aside by the applicant for this purpose.

11.3 Tools for assessment



A diagram of the tools for assessment is shown on the left. The term 'assessment' is used to describe this external process whereas 'audit' is used to describe internal processes conducted within the laboratory for its own benefit as part of its quality management system.

The generic process shown, as steps A-D, is equally applicable to the sequence of 'receipt of a sample, its analysis and reporting'; as it is to the processes involved in 'document control'. Descriptions of horizontal, vertical and examination assessment are given below.

Horizontal assessment

A horizontal assessment focuses on the system for managing quality and assesses individual standards. This assessment involves a detailed check of a particular aspect of documentation and its implementation and will cover all aspects of the documentation. Interviewing the Quality Manager is an important part of the process.

Vertical assessment

A vertical assessment focuses on the pre-examination, examination and post examination process (Section E, F and G of the standards) and the management of associated resources (Sections B, C, and D of the standards). This assessment involves a detailed check that all the elements associated with a chosen examination are implemented. It is expected that each assessor will be able to complete at least one vertical assessment.

A vertical assessment is a retrospective activity. A report is chosen at random either from hard copy or the database. The assessor then reconstructs the events from reception to report for this particular examination. Findings are recorded on the vertical assessment form.

Examination assessment

An examination assessment involves witnessing an examination as it is performed. The objectives are to ensure that, a) what is being done reflects what is described in the procedure and b) that the person carrying out the examination has an underpinning knowledge of all aspects of the procedure. It is expected that each assessor will complete a minimum of two examination assessments. If the laboratory provides a specialist screening service or is required to report to an external agency it is required that at least one examination assessment covers this area of work.

As this is a real time assessment assessors must ensure that they deal with the laboratory personnel in a sensitive manner.

Findings are recorded on the examination assessment form.

12 RECORDING A NON-CONFORMITY AND OBSERVATION

12.1 Definitions - Non-conformity and Observation

It is important to have clear definitions of these terms, which are given below.

A **non-conformity** is defined as *'the failure to fulfil the requirements of a standard, in whole or in part'*. Assessors are asked to distinguish between two categories of non-conformity: critical non-conformity and non-critical non-conformity and additionally to record observations.

A **critical non-conformity** is the *'failure to fulfil the requirements of a CPA Standard to such a degree that there is evidence of a system failure'*. Normally, it is evidenced by the failure to conform to the whole of a CPA Standard. A **system failure** is evidenced by the inability of an applicant to:

- meet the agreed needs and requirements of its users OR
- ensure a safe environment for staff / patients or visitors OR
- ensure the quality of all the laboratory examinations performed

A **non-critical non-conformity** is the *'failure to fulfil the requirements of a CPA Standard at a level that would not lead to a system failure'*. Normally this would be evidenced by the failure to conform to a part of a CPA Standard. Failure to correct the non-conformity within a specified period of time may result in the removal of accreditation.

Finally, some findings are recorded as **observations** that *'are records of deficiencies noted by assessors, which have the potential to affect the functioning of the applicant medical laboratory'*. They are reported to the applicant and form part of the final report. This will assist the applicant when conducting subsequent annual reviews.

12.2 Recording Findings

The findings are recorded on the Non-conformity or Observation Form provided by CPA. One form should be completed for each finding. The finding should be recorded as far as possible in the words of the standard.

For example the finding might be: *'There was no written procedure for controlling process records and quality records.'* The finding should be formally accepted by the laboratory representative and classified by the assessor as a critical or non-critical non-conformity or as an observation. A record is made of the relevant clause or sub clause of the CPA Standard, e.g. A9.1.

The most important part of the process is obtaining agreement that the findings are recorded accurately at regular intervals throughout the assessment. It is essential that ongoing dialog between the Regional Assessor, Peer Assessors and the laboratory representative is maintained. If agreement cannot be reached on the classification of the finding there are two options. The form allows for both the assessor and applicant to record their differing classifications and leave the final decision to CPA or advice may be sought immediately from CPA by telephone. CPA will audit differences of opinion and a report will be made to applicants and assessors at update sessions.

12.3 General overview report and EQA statement

In the final report the assessors will provide a balanced summary of the visit. The overview report will also contain a statement about the quality management system. There is a separate EQA statement, used to provide information relating to the EQA participation. Neither of these forms should include any non-conformity previously recorded on the non-conformity or observation forms.

13 THE CLOSING AND DEBRIEF MEETING

The assessment team close the on site assessment with a meeting in two parts that follows a prescribed agenda. The agenda is dependent on the type of visit. The Regional Assessor will chair the meeting. The first part, the closing meeting, allows the assessor(s) to present balanced feedback including positive aspects and to offer thanks to the staff for their hospitality.

The second part is to sign off any findings. It is important that the personnel representing the laboratory have the authority to agree these findings with the assessor(s). This avoids any confusion post assessment when CPA produces the final report. Copies of the findings are left with the applicant and there should be no additional findings in the final written report from CPA.

The agenda of these meetings is as follows:

CLOSING MEETING

1. Thanks
2. Repeat of disclaimer
3. Re-affirmation of confidentiality
4. A balanced summary of the assessment
5. Closing meeting declaration

DEBRIEF MEETING

6. Presentation of detailed findings
7. Reporting to CPA
8. Clearing findings for submission of corrective actions
9. Conclusion with respect to effectiveness of the laboratory
10. Questions and discussion
11. Close of meeting

A register of those attending the meeting is completed and any notes taken will be submitted to CPA with the report.

14 DECISION MAKING AND GRANTING ACCREDITATION

14.1 The reporting process

Following the site visit, the Regional Assessor will return to CPA the completed documentation relevant to the type of visit.

14.2 Decision Making

The Accreditation Managers process the reports and liaise closely with the reporting Regional Assessor. It may be necessary for findings to be reclassified or attributed to additional / alternative standards. If any changes have been made to Regional Assessor findings, the Accreditation Manager will liaise with them to clarify the changes.

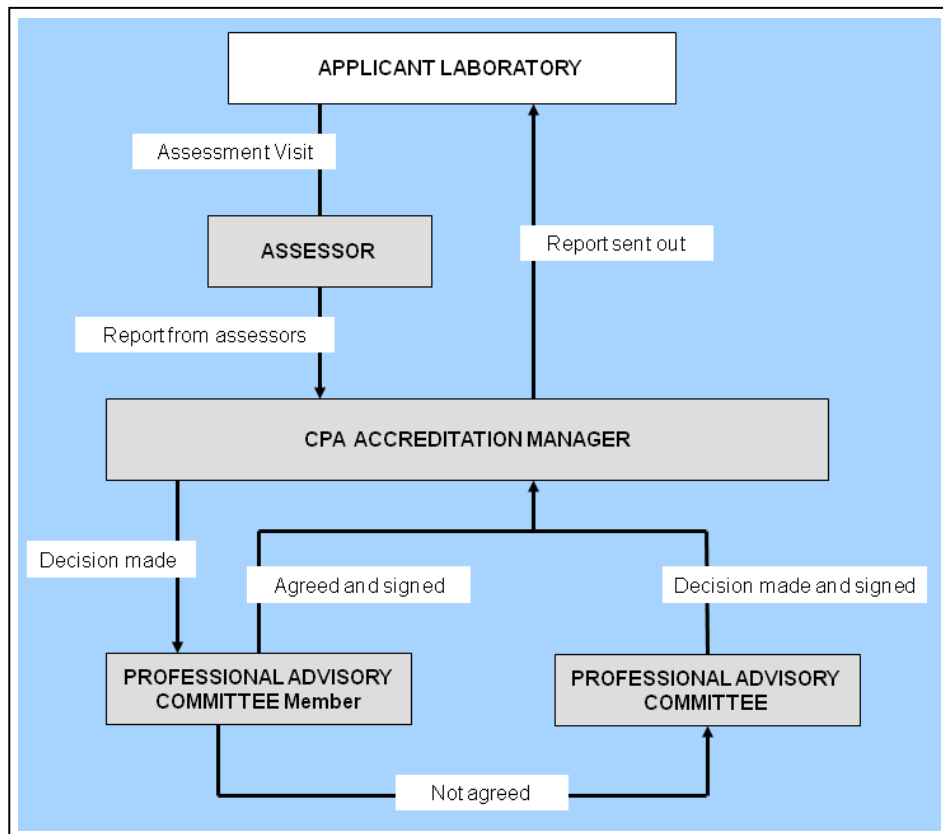
The Accreditation Manager makes an initial decision regarding the status of the applicant laboratory. In cases of uncertainty the Executive Manager is consulted.

The processed reports are then passed to the relevant member of the Professional Advisory Committee for agreement with the decision and their signature on the report. If any changes have been made to Peer Assessor findings, the PAC Member will liaise with them to clarify the changes. Any changes will be fed back to the Peer Assessor once the report is issued. The PAC member may require discussion with the Accreditation Manager before an agreement is reached. If there is still uncertainty of the decision then referral to the full PAC is possible. The final decision is signed by the Accreditation Manager on behalf of CPA based on all advice received. All decisions regarding referral are discussed at the PAC meeting.

The applicant and the Chief Executive of the parent organisation concerned are sent a copy of the report and notification of the final decision, usually within twelve weeks of the date of the visit.

14.3 Granting accreditation

An overview of the process of decision making and granting accreditation is given in the diagram below.



14.4 No adverse findings

If there are no adverse findings accreditation is granted.

14.5 Raising an observation

On occasion, the assessors may raise an observation that might only affect the future functioning of the laboratory. If this is the only type of finding this will not immediately affect the status of the applicant medical laboratory. Accreditation is granted.

14.6 Raising a non-conformity

If the non-conformity is non-critical and can be cleared with CPA within twelve weeks of the report date, applicants already holding accreditation may be able to maintain their status and an interim report will be issued. If the non-conformity is not corrected within the period identified conditional approval will be granted. A non-critical non-conformity reported in departments not holding accreditation will result in conditional approval being granted and may or may not have an expiry date depending on the severity of the finding. It is the responsibility of the applicant to ensure that the clearance form and evidence are submitted either by the expiry date or when all corrective actions have been completed.

If the non-conformity is critical and cannot be rectified within a short time frame then accreditation is withheld. The applicant medical laboratory is granted conditional approval and in some cases the applicant may be referred. This decision will be based on the severity of the non-conformity.

14.7 Correction and clearance

Once the report has been received the applicants should inform CPA as soon as findings have been corrected. The procedure is for the applicant to complete a clearance form for each finding. The completed forms must be submitted along with a copy of the original finding form and supported by appropriate evidence. This evidence must be submitted to provide sufficient time for the clearance to be processed in advance of the expiry date. Failure to provide such evidence may result in delay in achieving or maintaining accreditation. CPA will endeavour to review and process the clearance information within two weeks of receipt of the evidence. Applicants not correcting any non-conformity may have their status removed.

If initially the applicant is referred or subsequently the status is removed re-application will be required and a re-assessment will be necessary. Applicants will remain enrolled with CPA.

14.8 Clearance visits

See section 7.3.

14.9 Accreditation certificate

Once accredited, the applicant medical laboratories are informed by letter. Accreditation can be declared from the date of the letter and the Executive Manager issues a certificate of accreditation. This certificate carries a date of issue but no date for expiry. The reason being that accreditation can be removed at the discretion of CPA and thus an expiry date on the certificate could be misleading. Therefore on the face of the certificate is an explanatory note that a current letter of accreditation is required to support the certificate. When the certificate is first issued a supporting letter is included.

In order to maintain the validity of the certificate, CPA requires evidence that the laboratory continues to conform to the CPA standards. It is the applicant's responsibility to ensure that the annual registration form is submitted to CPA to allow sufficient time for it to be processed and the letter issued.

15 COMPLAINTS AND APPEALS

15.1 Complaints

Complaints made against CPA as an organisation would include for example, the conduct of CPA personnel (administrative staff, advisors, assessors), charges levied by the Company or the service provided.

Complaints may also be raised about the medical laboratories accredited by CPA. If these are quality concerns see Section 20.

Any complaint may be received either in writing or verbally but in order to conduct an audit of the complaint it is necessary to receive written confirmation.

A copy of the procedure is available from CPA Central Office or can be downloaded from the website.

15.2 Appeals

A copy of the procedure is available from CPA Central Office or can be downloaded from the website.

16 AUDIT QUESTIONNAIRES

In order to audit its own activities CPA solicits the views of both applicants and assessors by means of questionnaires post assessment.

17 MONITORING ASSESSOR PERFORMANCE

CPA monitors Peer Assessors by means of a questionnaire completed by the Regional Assessor at the time of the assessment. Feedback will be provided to Peer Assessors where there are issues requiring immediate action.

CPA monitors the Regional Assessors (including the Regional Assessment Managers) by means of a questionnaire sent to the applicant with the report. In addition, the Regional Assessment Manager will monitor the Regional Assessors on-site biennially. In turn the Regional Assessment Managers will be monitored on-site by UKAS biennially. The outcome of this monitoring is used during annual staff appraisal.

It is helpful to CPA for laboratories to volunteer to allow observers to attend on site for this activity. CPA will seek permission from the laboratory when appropriate. It must be stressed that the individual observing does not take part in the assessment process.

18 SURVEILLANCE ACTIVITIES

18.1 Surveillance Visits

Surveillance visit activities are described in an earlier section.

It must be noted that CPA reserves the right to enter and assess any laboratory at any time if accreditation is held.

18.2 Recording Findings

A finding from surveillance activities is recorded in the same way as a finding from a main assessment.

18.3 Annual registration

As part of continuing surveillance of enrolled laboratories CPA requires a completed annual declaration that the laboratory continues to conform to the standards. Standard A11 requires the medical laboratory to carry out an annual management review. As part of the annual declaration information from this review is helpful to CPA. The Executive Summary of the review shall be submitted to CPA. The laboratory shall retain the supporting evidence used to compile the management review, as this may be required for subsequent assessment visits. As described in section 14.9 this re-registration is also necessary in order that a letter of support may be issued to accredited laboratories.

19 EXTENSION OF SCOPE OF ACCREDITATION AND MAJOR CHANGES

It is incumbent upon the applicant to notify CPA immediately of any substantial or important changes in staffing, repertoire, workload, organisation including mergers, resources or EQA performance as failure to do so may jeopardise the CPA status. An on site visit may be required. Guidance on what is considered "important" in this context is available from CPA and should be sought where there is any doubt. It is the responsibility of the Professional Advisory Committee to consider the significance of such changes on the accreditation status. CPA policy on merging departments is available on the CPA support website (<http://www.cpa-uk.co.uk/support>)

It is important to submit to CPA Central office an updated Quality Manual when major changes have been made that affect the quality management system.

20 SUSPENDING OR WITHDRAWING ACCREDITATION

20.1 Suspending accreditation

There are occasions when CPA might be concerned regarding the ongoing competence with the standards in an accredited laboratory.

In addition, the management of an accredited laboratory may wish to temporarily suspend accreditation during periods of potential non-conformity.

A copy of the policy is available from CPA Central Office or can be downloaded from the website.

20.2 Withdrawing accreditation

Accreditation (or conditional approval) will be withdrawn if

- major changes are declared that constitute critical non-conformity with CPA standards
- the applicant declines to proceed with any visit
- the applicant medical laboratory breaks its contract with CPA

21 CPA RECORDS

CPA maintains an up to date database of all medical laboratories enrolled with the scheme and details of Peer Assessors.

22 CLAIMING ACCREDITATION AND USE OF CPA LOGO

Only accredited laboratories are allowed to claim accreditation and use the CPA logo. The full policy can be found on the CPA website (www.cpa-uk.co.uk).

APPENDIX A

FORMS USED DURING THE ASSESSMENT PROCESS

CPA Standards For The Medical Laboratory	PD-LAB-Standards v2.01 Mar 09
Application for Accreditation	AF-LAB-Application Form
Timetable for Assessment Visit	AF-LAB-Timetable MV
Timetable for Surveillance Visit	AF-LAB-Timetable SV
List of documents required for Main Visit	AF-LAB-Documents Requested-MV
List of documents required for Surveillance Visit	AF-LAB-Documents Requested-SV
Agenda-Opening Meeting	AF-LAB-OpenMtg
Open Meeting Declaration	AF-LAB-Open Mtg Declaration
Attendance Register	AF-LAB-Register
Meeting with Users & Managers	PD-CPA-User Leaflet
User Group Comments	AF-LAB-UserComments
Chief Executive / Manager Comments	AF-LAB-CExecutive
User Group Meeting Attendance Register	AF-LAB-Register User Group
Vertical Assessment Form	AF-LAB-VertAssm
Examination Assessment Form	AF-LAB-ExamAssm
Non-conformity or Observation Form Main Visit	AF-LAB-NCorObsMV
Non-conformity or Observation Form Surveillance Visit	AF-LAB-NCorObsSV
General Overview Report	AF-LAB-Overview Report
EQA Statement	AF-LAB-EQASstatement
Agenda-Closing Meeting	AF-LAB-CloseMtg
Closing Meeting Declaration Form	AF-LAB-Close Mtg Declaration
Signature Pages	AF-LAB-Report Sign
Overall Standards Checklist	AF-LAB-Standards Checklist
Assessment Report – Cover Sheet	AF-LAB-RprtCover
Non-conformity Clearance Form	AF-LAB-Clearance
Peer Assessor Questionnaire	MF-CPA-PA Questionnaire
Applicant's Questionnaire – Assessment Process	MF-CPA-Applicant Questionnaire
Surveillance Report – Cover Sheet	AF-LAB-RprtCoverSurveillance
Annual Re-registration Form	AF-LAB-AnnReReg
Annual Management Review Form	AF-LAB-AMR