



The Conduct of CPA (UK) Ltd Medical Laboratory Assessments

Clinical Pathology Accreditation (UK) Ltd

**45 Rutland Park
Botanical Gardens
SHEFFIELD S10 2PB**

Registered in England and Wales No. 2675095

Tel: ++44(0)114 251 5800
Fax: ++44(0)114 251 5801
e-mail: office@cpa-uk.co.uk
www.cpa-uk.co.uk

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1 INTRODUCTION

1.1 Scope and purpose

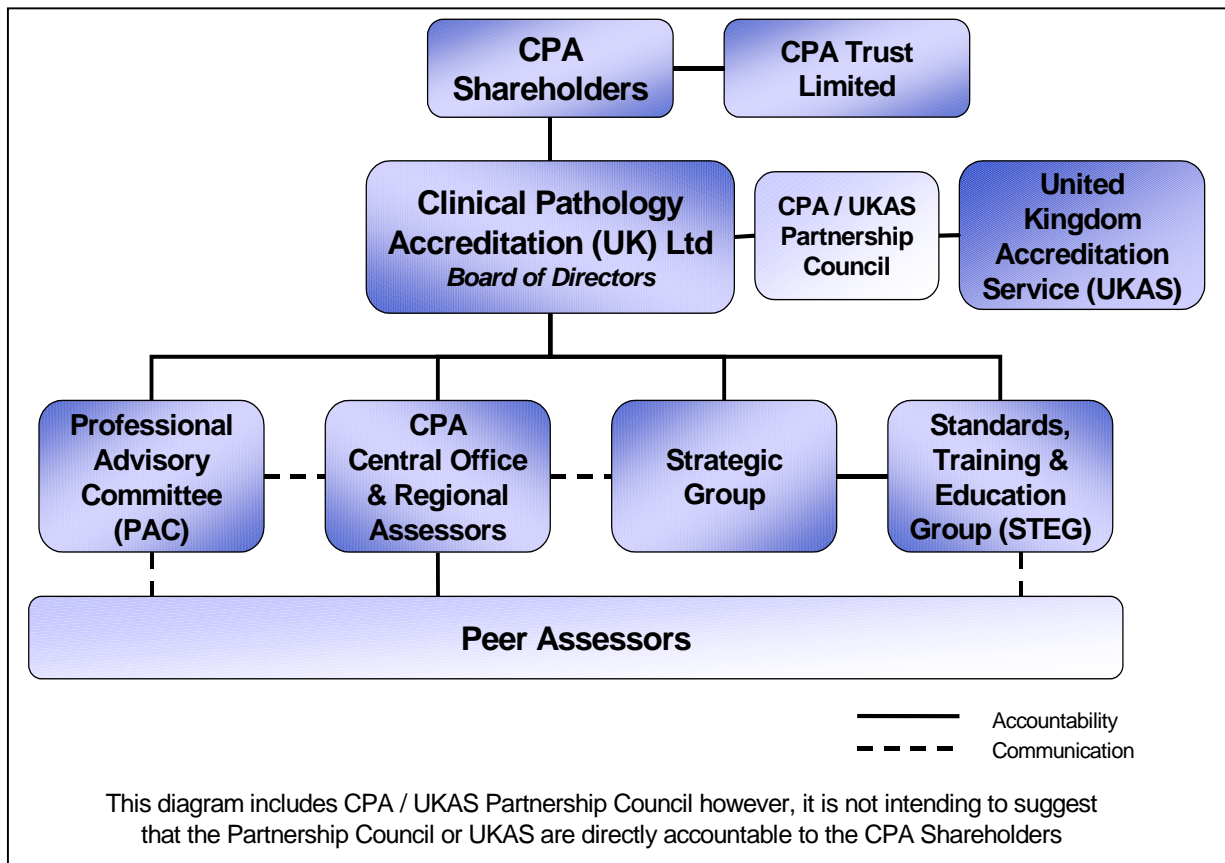
CPA has duties and responsibilities to those applying for accreditation. Applicants also have a responsibility to conform to the CPA process. Once the application is accepted by CPA there is an agreement between both parties to conform to the processes described in this handbook.

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 including the United Kingdom Accreditation Service (UKAS) is shown below:



Shareholders

CPA is co-owned by the Royal College of Pathologists (RCPATH), the Institute of Healthcare Management (IHM), the Institute of Biomedical Science (IBMS), the Association of Clinical Pathologists (ACP), the Association for Clinical Biochemistry (ACB) and the English Community Care Association (ECCA). The Company is a not for profit organisation limited by shares with each of the various groups involved being shareholders and each appointing Directors.

Board of Directors

CPA is controlled by a Board composed of Directors appointed by the shareholder organisations with numbers proportionate to the size of their shareholding. There are four from the RCPATH, three from the IHM, two from the IBMS, and one each from the ACP, the ACB and ECCA. The Board with the approval of the shareholders appoints an independent Chairman. Board meetings are held four times each year with invited observers from the four UK Government Health Departments.

The Board appoints a Chief Executive.

CPA Trust

The CPA Trust Ltd (referred to as "The Charity") is a Company limited by guarantee. The CPA shareholders who are its members founded it. The members appoint trustees. Additional Trustees are the Company Executive Officers and the CPA Chairman chairs the Trust.

The principle objectives of the Trust are to:

- promote an association for training and/or education and/or research into all areas of quality in medical laboratories
- finance or provide funding for pilot EQA schemes covering healthcare quality assessment or assurance.

In order to achieve these objectives the Trust invites applications for bursaries or pilot EQA funding annually.

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 on going 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, in good standing, of one of the professional shareholding bodies of CPA 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 CPA Board 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. The advisors in Transfusion Medicine, Cytopathology, Virology Andrology and Histocompatibility & Immunogenetics are nominated by agreement between all the relevant shareholding bodies of CPA. PAC Members normally serve for a period of four years.

All appointees from professional bodies must meet with the approval of the CPA Board. 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, Quality Manager, Regional Assessment Managers and Accreditation Managers. 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. The Chairman presents a report to each Board meeting.

Strategic Group

The Strategic Group advises the CPA Board on matters relating to policy and strategic planning for the organisation. The membership includes the CPA Chief Executive (Chair), the Executive Manager, the PAC Chairman and an EQA representative from the PAC. This group is directly responsible to the CPA Board. The group reserves the right to co-opt individuals when necessary depending on the nature of the business/project requirements.

Standards Training and Education Group (STEG)

The Standards Training and Education Group (STEG) advise the CPA Board on all matters relating to standards, training and education.

Company Officers and the Regional Assessment Managers are full time members of the group. The Board appoints an independent Chairman and other members of the group may be co-opted as required. The Chairman presents a report to the Board.

STEG is responsible for revision of documents relating to the assessment process including the standards. This is an ongoing process and document revision will be scheduled for a date one year after the documents are issued. The group is responsible for all public presentations regarding the activities of CPA and provides all education and training material. Assessor training and updates fall within its responsibility.

1.4 CPA/UKAS Partnership

Within the UK there are two national laboratory accreditation bodies, operating in complementary fields, CPA and the United Kingdom Accreditation Service (UKAS).

CPA and UKAS work in a partnership that enables the two organisations to co-operate on the development of accreditation policy and facilitates the exchange of best practice. Where appropriate the activities of the two organisations are aligned thereby benefiting laboratories that require dual accreditation.

The partnership is aimed at strengthening the authority and reputation of accreditation both in the UK and internationally by bringing together organisations with established reputations in their respective fields. It is also a means of reducing the risk of fragmenting accreditation and avoiding proliferation of accreditation standards for laboratories.

There is an increasing demand for accreditation across a wide range of services and an associated need for the accredited services to be accepted internationally. CPA and UKAS are working together to maximise the international recognition of accreditation.

UKAS is recognised by Government as the national accreditation body and is the signatory of international mutual recognition agreements on behalf of the UK. It is intended that the partnership will in due course be incorporated into these agreements.

The partnership is the culmination of discussions, which started with a joint statement of intent in 1998 to co-operate in areas of mutual interest and benefit. It is the recently introduced international standards for laboratory accreditation (ISO 17025:1999 and ISO 15189:2003) however, that enables CPA and UKAS to capitalise on common criteria thereby making a partnership possible and desirable.

A Council has been set up to oversee the development of the partnership. The partnership retains the individual corporate identities of CPA and UKAS and each partner maintains control over professional [technical] decisions and standards. UKAS shall retain the Government's sole recognition status as the National Accreditation Body.

Applicants seeking accreditation to:

- the CPA standards for medical laboratories incorporating ISO 15189:2003 and EQA schemes incorporating ILAC G13:2000 will continue to be managed, assessed and accredited by CPA;
- ISO 17025 (medical laboratories) will continue to be managed, assessed and accredited by UKAS. Wherever appropriate, UKAS will seek technical input from CPA for the assessment of such laboratories.
- ISO 15189 (medical laboratories) will be registered and managed under the terms of the CPA/UKAS Partnership and Agreement.
- ISO Guide 43 (medical EQA schemes) will normally be registered and managed under the terms of our Partnership and Agreement.

When our Partnership has been successfully evaluated by the European Cooperation for Accreditation (EA), any medical laboratories or EQA schemes that are accredited by CPA and/or UKAS will, if desired, be able to apply for a certificate of accreditation to ISO 15189 or ISO Guide 43 to be issued by the CPA/UKAS Partnership, thus ensuring international recognition.

1.5 Documentation

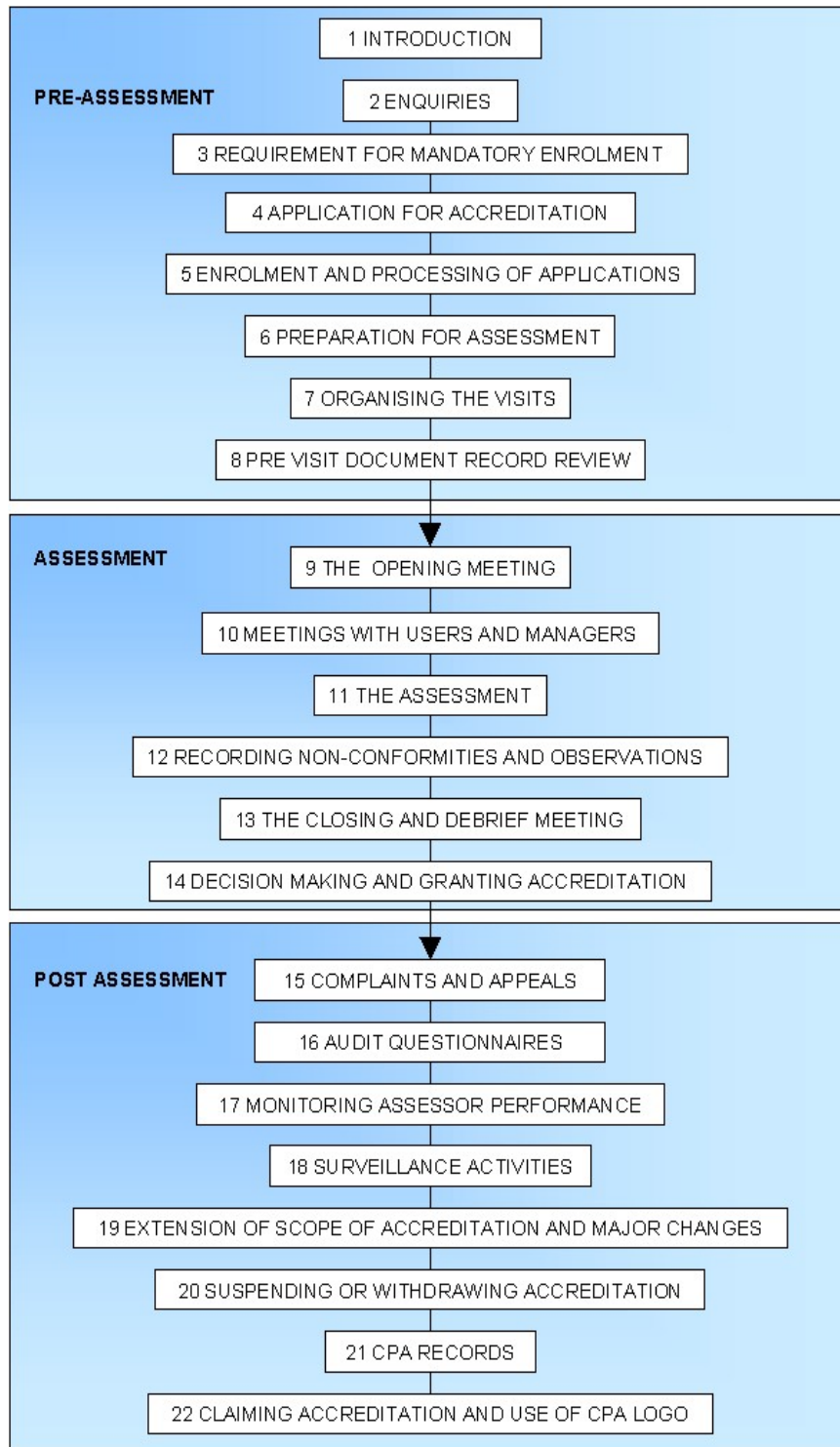
Documents referred to in this handbook are listed in Appendix A.

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.

1.6 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. The Department of Health, Social Services & Public Safety in Northern Ireland are considering this for their medical laboratories.

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

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 satellite services managed by the applicant must also be declared including satellite blood fridges, hot labs, clinics etc. 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.
- Preparation visit – This is a new concept for CPA. There is an intention to introduce a one-day visit by the Regional Assessor prior to the full assessment. It is not intended at this visit to raise non-conformities. However, there will be occasions when this may be unavoidable. This type of visit has proved successful with larger more complex laboratories. Further information will become available.

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. Board Directors and PAC members may be used for assessments at the discretion of the Company. It is important to consider impartiality 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. Only in exceptional circumstances there may 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 service users and institutional managers. 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. 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 be necessary for the assessors to meet with the users or Chief Executive In exceptional circumstances 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 Preparation visit

Once in place, these visits will be arranged by the Regional Assessor.

7.5 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 user group and Chief Executive meetings
- ensure all paperwork is completed for return to CPA Central Office

7.6 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

7.7 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. purpose of the assessment
3. review of scope of assessment
4. the functions and responsibilities of the assessment team
5. explanation of disclaimer
6. EQA statement
7. opening meeting declaration
8. method and procedures used to conduct the assessment
9. review of the schedule and confirmation of working times etc
10. confirmation of resources and facilities needed by the assessment team and identification of at least one co-ordinator per assessor
11. identification of individual(s) authorised to sign off findings
12. confirm arrangements for final meeting and any interim meetings
13. confidentiality
14. code of conduct
15. health and safety - fire arrangements
16. questions and clarification
17. close

The disclaimer form (agenda item 5) states that:

'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.'

Code of Conduct (agenda item 14) states that:

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 its 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.

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. It also gives the applicant laboratory a further opportunity to declare any non-conformity and to state whether or not a new Quality Manual has been issued.

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 usually to be held over lunchtime. On the first day of the visit the Regional Assessor meets with the Chief Executive, or equivalent, 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 will normally be necessary to organise single meetings with the Chief Executive 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 the assessors are not satisfied with the meetings (e.g. inappropriate representation or insufficient attendance), CPA will make further independent contact with the users/manager to obtain the relevant information.

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 submitted to CPA with the report.

A register of those attending the meeting is completed and any notes taken 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. For main visits these findings are recorded as non-conformities or observations (see Section 12). For a surveillance visit these are recorded as mandatory or recommendation (see Section 18)

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.

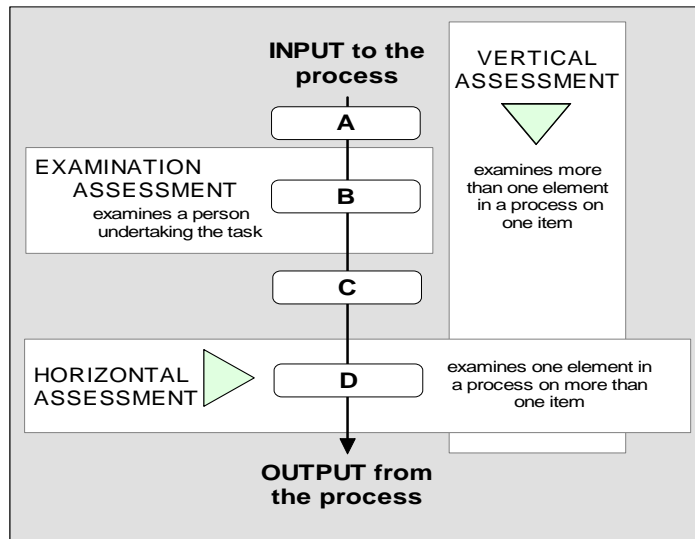
Peer Assessors audit the clinical and technical aspects of the service.

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 NON-CONFORMITIES AND OBSERVATIONS

12.1 Definitions - Non-conformities and Observations

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

Main Assessment Visit

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 Control of process and quality records*

The most important part of the process is obtaining agreement that the findings are recorded accurately at regular intervals throughout the assessment. 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.

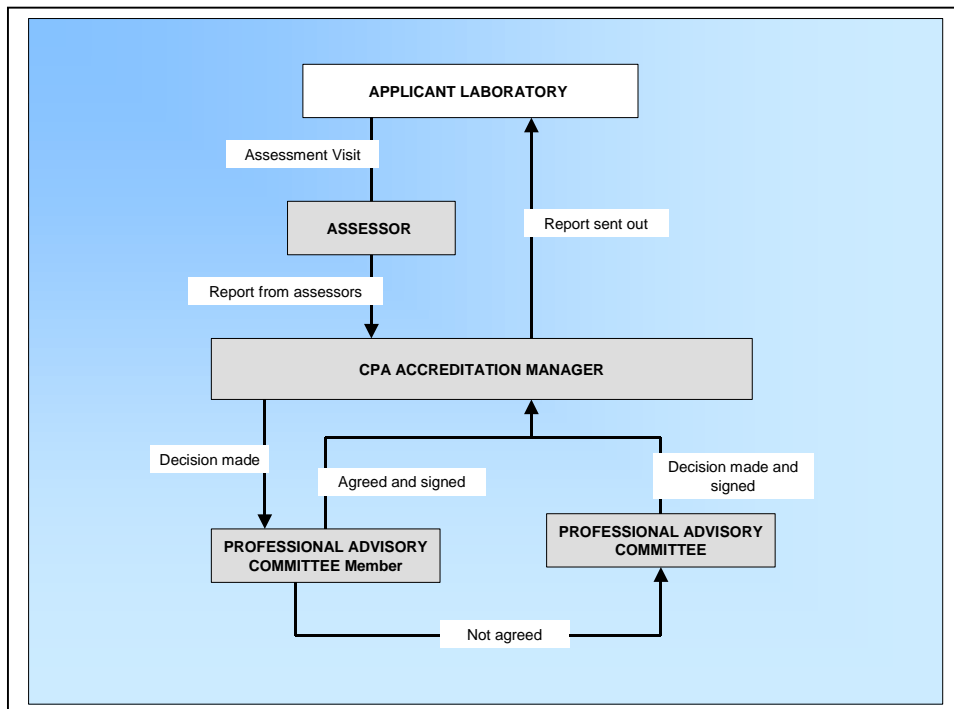
The processed reports are then passed to the relevant member of the Professional Advisory Committee for agreement with the decision and their signature on the report. If any changes have been made that affect the level of the finding, the Peer Assessor will be contacted by the PAC member to clarify the change. If changes have been made to a clause this 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 recommendation, 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 of observations

On occasion, the assessors may raise observations that might only affect the future functioning of the laboratory. If these are the only findings this will not immediately affect the status of the applicant medical laboratory. Applicants are asked to keep CPA informed of progress made to rectify these observations, at annual review. Accreditation is granted.

14.6 Raising of non-conformities

If the non-conformity(s) are 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 these are not corrected within the period identified conditional approval will be granted. Non-critical non-conformities 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 findings. It is the responsibility of the applicant to ensure that clearances and evidence are submitted either by the expiry date or when all corrective actions have been completed.

If the non-conformities are 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(s).

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 evidence will result in delay in achieving accreditation. CPA will endeavour to review and process the clearance information within four weeks of receipt of the evidence. Applicants not correcting conditions 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 Company procedure is available from CPA.

Regular audits are undertaken to assess the effectiveness of remedial and corrective actions taken in response to complaints. A summary of these audits is reported half yearly at the PAC meeting and annually at the CPA AGM.

15.2 Appeals

Appeals must be submitted in writing within one month of the applicant medical laboratory concerned receiving its report following an on-site assessment. Beyond that time limit appeals are only considered in exceptional circumstances.

A copy of the procedure is available from CPA 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 monitor 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 monitor 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 Introduction

Surveillance activities fall into two categories:

- A maintenance visit to an accredited laboratory to check that the laboratory continues to operate in conformity with the CPA standards. Any findings indicating non conformity will be recorded and a time limit for clearing the non conformity will be agreed. It is the responsibility of an accredited laboratory to maintain its accredited status by meeting this commitment. It is the responsibility of CPA to ensure that accreditation is correctly maintained.
- A surveillance visit to a conditionally approved or non accredited laboratory. The purpose of the visit is to establish whether the laboratory is ready for accreditation.

18.2 Recording Findings

The findings are recorded on the Mandatory or Recommendation Form - Surveillance Visit 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.

The finding should be formally accepted by the laboratory representative and classified by the assessor as mandatory or recommendation.

As with the main assessment visit the most important part of the process is obtaining agreement that the findings are recorded accurately at regular intervals throughout the assessment. 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.

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 should be submitted to CPA using the Annual Re-registration Form. The laboratory should 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 is informed of concerns regarding the quality of a medical laboratory service. This information can come from a variety of sources; from the applicant themselves, users of the service or from assessors. CPA requires this information in writing before taking any action.

In the first instance, the Executive Manager contacts the Head of Laboratory concerned to request further information on the matter(s) raised. Documentary information may be requested. Information must be provided to CPA within three weeks and this will be reviewed at the first available meeting of the PAC.

If the information does not substantiate the concerns reported, the PAC Chairman will close the matter and inform Head of Laboratory in writing. If the information does substantiate the concerns reported, the PAC may suspend the accreditation status of the medical laboratory pending further investigation. The date of suspension is the date this letter is written. This will be conveyed, in writing, to the Head of Laboratory and the Trust Chief Executive (or equivalent). A copy of this suspension policy is sent with the letter and an on-site assessment is organised at the earliest opportunity.

A written report of the assessment visit is submitted to the PAC and the recommendations submitted to the Board for consideration again at the earliest opportunity.

Suspension is clearly distinguished from referral. Suspension can be imposed and lifted only at PAC or Board level. All instances of suspension by the PAC are reported to the Board. The outcome of suspension is normally resolved within a maximum interval of 6 months from the date of suspension. In exceptional circumstances this may take longer to resolve and the department remains suspended during the whole process. The Head of the Laboratory concerned and the Chief Executive are kept fully informed at all stages.

A copy of this policy can be downloaded from the CPA 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-AppForm
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 April 08
Examination Assessment Form	AF-LAB-ExamAssm
Non-conformity or Observation Form	AF-LAB-NCorObsMV
General Overview Report	AF-LAB-Overview Report
EQA Statement	AF-LAB-EQASTatement
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-StdChklst
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
Mandatory or Recommendation Form - Surveillance Visit	AF-LAB-MandorRecSV
Overall Standards Checklist – Surveillance Visit	AF-LAB-StdChklstSurv
Surveillance Report – Cover Sheet	AF-LAB-RprtCoverSurveillance
Annual Re-registration Form	AF-LAB-AnnReReg