



# **The Conduct of CPA (UK) Ltd Assessments**

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## **1 CONTRACTUAL AGREEMENT**

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.

## **2 INTRODUCTION**

Clinical Pathology Accreditation (CPA) is the leading, reputable and authoritative provider of accreditation services in the health sector. CPA is a non-profit distributing organisation that acts in the public interest. It assesses and declares the competence of Medical Laboratories in the public and independent sector, and External Quality Assessment (EQA) Schemes in the UK and overseas. Although accreditation is voluntary, the majority of UK medical laboratories are currently enrolled, demonstrating that they have been assessed against the accepted standards.

## **3 BACK GROUND**

### **3.1 About CPA**

CPA originated from an initiative of the Royal College of Pathologists, the Association of Clinical Pathologists, the Institute of Biomedical Science, and the Association for Clinical Biochemistry supported by the Department of Health. The Company was incorporated on the 6 January 1992 as a joint venture between these organisations. Initially accreditation was confined to medical laboratories, but in 1996 this was extended to the accreditation of EQA Schemes. In 1998, CPA signed an agreement with the United Kingdom Accreditation Service (UKAS), the UK's national accreditation body, as both organisations shared common interests relating to laboratory accreditation. This relationship strengthened in 2009 as CPA became a wholly-owned subsidiary of UKAS as part of a strategy by both companies to contribute to the modernisation of pathology services in the UK, and to ensure that accreditation is delivered independently of Government and the professions.

In the UK, the Department of Health requires that all medical pathology laboratories enrol with CPA. The Care Quality Commission (CQC), the UK Regulator for health and social care recognises CPA accreditation to support its regulatory responsibilities.

### **3.2 About UKAS**

UKAS is the national accreditation body in the UK, recognised by Government, to assess and declare the competence of organisations against internationally recognised standards. It is independent from Government, subject to peer review, and has a duty to act in the public interest. Following the implementation of European Regulation EC 765/2008, UKAS has been formally appointed as the National Accreditation Body providing for the first time, a legal basis for accreditation. The influence and use of UKAS accreditation continues to grow across a wide range of areas to support the delivery of informed and effective purchasing, good governance and public confidence. UKAS fully complies with the international standard ISO/IEC 17011:2004, the standard setting out requirements for accreditation bodies assessing and accrediting conformity assessment bodies.

## **4 BENEFITS OF CPA ACCREDITATION**

CPA is committed to providing a service of the highest quality and is aware and takes into consideration the needs and requirements of all interested parties. In order to ensure that the needs and requirements of all interested parties are met, CPA:

- operates a quality management system to integrate the organisation, procedures, processes and resources
- sets quality objectives and plans in order to implement this quality policy

- ensures that all personnel are familiar with this quality policy to ensure customer satisfaction
- commits to health, safety and welfare of its entire staff
- upholds professional values and is committed to good professional practice and conduct.

#### **4.1 For Commissioners:**

The need to drive up the quality of care for patients, whilst delivering efficiency and productivity, is a key principle for commissioners of healthcare services. CPA accreditation is a tool that can be used to support the commissioning of medical laboratory services that are safe, reliable and that continually improve the experience for patients by:

- providing an independent assurance of quality and safety that supports world-class commissioning decisions to deliver better care and value for patients
- providing a mechanism for measuring quality improvement
- supporting consistency in the quality of care
- encouraging innovation.

#### **4.2 For Patients**

CPA accreditation demonstrates that medical laboratories comply with a standard, confirming that:

- there is consistency in the quality of patient safety
- the service has up-to-date-technologies and its procedures and techniques reflect current best practice
- staff providing the services are competent to undertake the tasks they perform.

#### **4.3 For Medical Laboratories:**

CPA accreditation provides proof that a laboratory complies with best practice. It provides authoritative assurance of the technical competence of a laboratory to undertake specified analysis or measurements according to validated methods. CPA accreditation:

- prevents unnecessary duplication of gathering information on performance related to the Care Quality Commission (CQC) registration process
- encourages the sharing of best practice, inter-collegial friendship and contacts
- stimulates innovation
- brings together other kinds of quality assessment in a single package
- allows participation in any EQA scheme
- reduces risk, controls cost.

CPA organises three regional conferences each year, which provide an excellent platform to learn from CPA senior management and assessors and to establish new contacts. CPA assessors attend the conferences, which provide laboratory staff the opportunity to gain a greater understanding of the standards and the expectations of CPA. CPD points are available to attendees due to the educational value of the agenda and content matter.

## **5 SERVICES PROVIDED BY CPA**

CPA carries out the assessment and accreditation of Clinical Pathology Services, External Quality Assessment Schemes (EQA) and Point of Care testing services within the hospital. CPA services are delivered using independent peer assessors.

## **6 CPA OPERATION**

The Company's headquarters are based in Feltham. The permanent staff includes the Executive Manager together with administrative support from the Customer Liaison Officer (CLO) Team. The office is responsible for all organisational and administrative aspects of the accreditation process.

### **6.1 Regional Assessors**

CPA employs a permanent staff of Regional Assessors who are high calibre professionals. In the main they are recruited with a background in laboratory medicine. They work with the Peer Assessors and are the Team Lead Assessors within the assessment team.

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.

One of the main objectives for Regional Assessors is to ensure that all applicants are assessed within their scheduled timescale.

### **6.2 Peer Assessors**

CPA services are delivered using independent peer assessors. They are active practitioners and therefore understand current practices and techniques. They are well placed to establish an ongoing dialogue with a laboratory that enables it to carry out a holistic approach to assessment that delivers value and reflects the following quality characteristics:

- open, transparent and fair
- technically and administratively proficient
- reliable, repeatable and responsive
- simple to use.

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.

#### **Applying to be a Peer Assessor**

Those interested in becoming assessors are invited to apply and further details may be obtained from the office. The application form is also available on the CPA website. 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.

### **6.3 Professional Advisory Committee (PAC)**

The Company takes advice on policy matters relating to accreditation of medical laboratories from a Professional Advisory Committee (PAC). This Committee consists of the key stakeholders, professional bodies, and patient representative groups, to ensure that the provision of accreditation remains relevant, up to date and of high value to the healthcare sector. The Committee maintains strong links with the professional bodies; Association of Clinical Pathologists, the Royal College of Pathologists, the Association for Clinical Biochemistry, and the Institute of Biomedical Science. 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

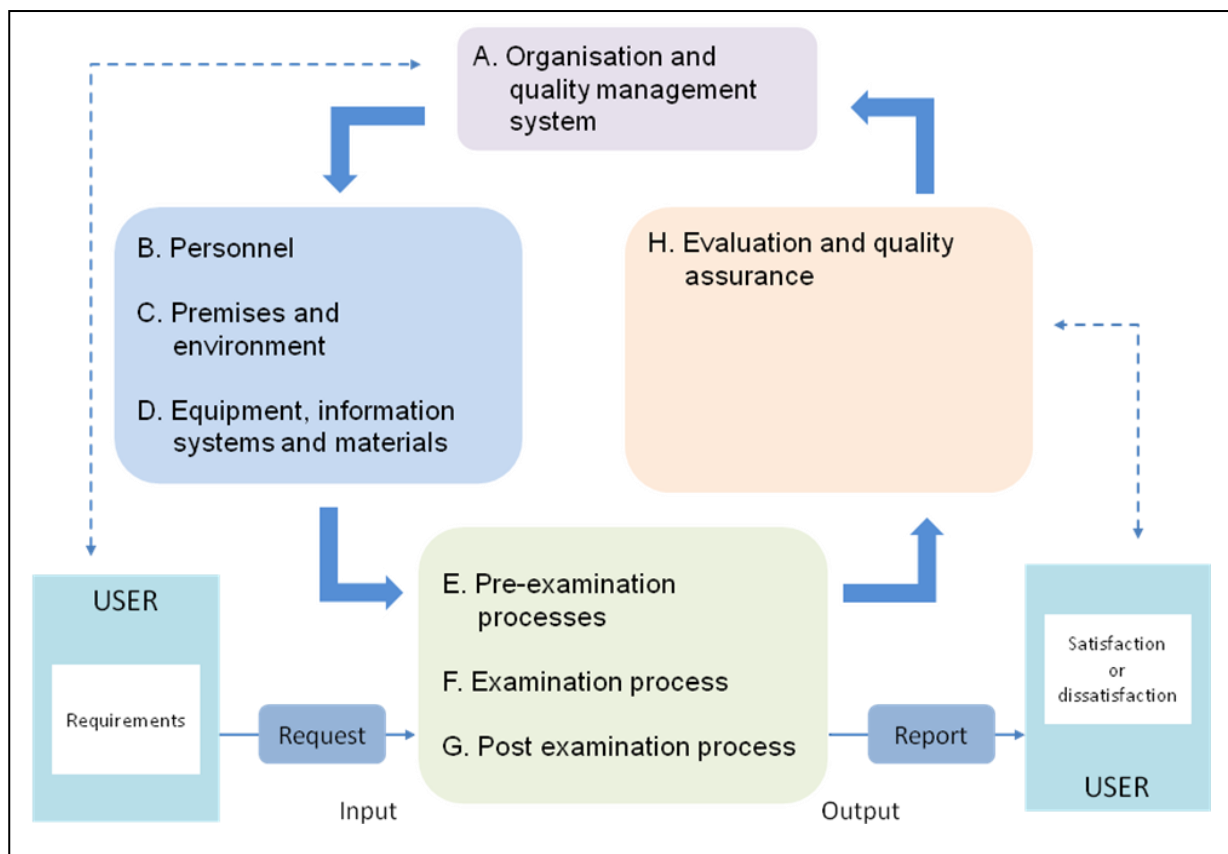
consultants and a Biomedical Scientist represent EQA activity. There are additional advisors in Transfusion Medicine, Cytopathology, Virology, Andrology and Histocompatibility & Immunogenetics. The PAC meets on a regular basis to advise CPA and to ensure that stakeholder views are captured and that peer review remains at the heart of the assessment.

## 7 STANDARDS

CPA assesses to standards that have been developed over a number of years by the organisation, taking into account the requirements of international standards, the professions, healthcare regulators, and other relevant stakeholders.

### 7.1 The CPA Standards

The CPA standards for Medical Laboratories ensure a thorough assessment of all aspects of an organisation's operations, from the management, to staff and services, to patients and commissioners. It covers the organisation and quality management, the resources, and the evaluation and quality assurance activities required to ensure that pre-examination, examination and post-examination activities of the laboratory are conducted in such a manner that they meet the needs and requirement of the users.



## 8 OVERVIEW OF THE ACCREDITATION PROCESS

Accreditation is an on-going business process rather than a one-off achievement. Laboratories are assessed every two years and have to renew their registration every year, confirming that they are continuing to operate according to strict guidelines.

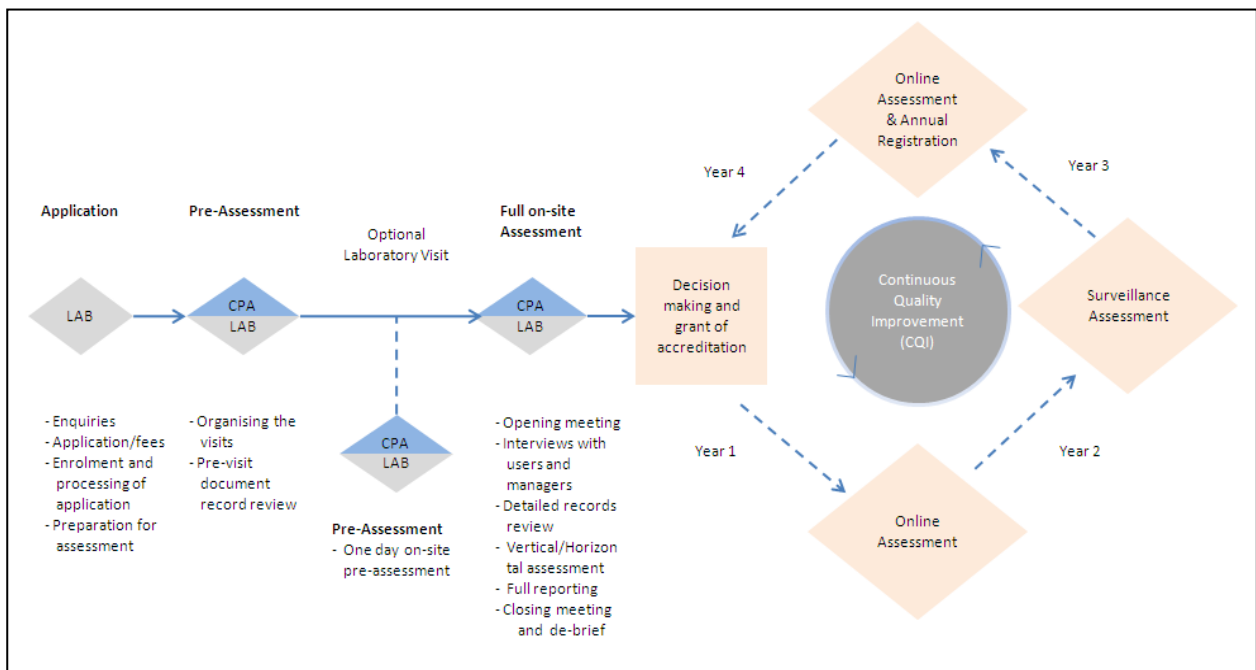
For any laboratory seeking accreditation, CPA will carry out an assessment to establish that:

- the laboratory is impartial;
- the laboratory is technically competent to do the work in question;
- the resources and facilities are appropriate and sufficient for the work;
- the laboratory's actual performance is to the required standard;
- the laboratory is capable of sustaining the required level of performance.

The first step in seeking accreditation is for an applicant to assess themselves against the relevant CPA Standards (Medical Laboratory or EQA) and then submit a completed application form to CPA accompanied by a copy of the organisation's Quality Manual.

On receipt of the documentation the applicant is enrolled and CPA assesses the application. If the application is not acceptable the department remains enrolled and CPA assists the medical laboratory with progressing its application. If the application is acceptable arrangements are made for an assessment visit. This is carried out on site by a team of Regional and Peer assessors appointed by CPA.

Following the on site assessment, a report is submitted to CPA by the assessors. The report may recommend accreditation, identify conditions that must be met before accreditation is granted, or recommend that accreditation be refused and the applicant advised to reapply at a later date. The Assessment Manager will consider the recommendations and issue a decision. The final decision about accreditation status rests with CPA.



## **9 ENQUIRIES**

The following information is available to the enquirer:

- The Conduct of CPA (UK) Ltd Assessments
- A copy of the relevant Standards for Accreditation
- Application for Accreditation

## **10 APPLICATION**

The first step in seeking accreditation is for an applicant to assess themselves against the relevant CPA Standards and then submit a completed application form to CPA accompanied by a copy of the organisation's Quality Manual.

### **10.1 Re-application for Accreditation**

At the beginning of each four year period a new Application Form, Quality Manual and Annual Management Review Summary are required. The documents are due prior to the assigned period in accordance with the schedule provided by CPA. 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.

## **11 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 on the 'Other Sites Managed by the Laboratory' page within the application form. Full details must be completed for each site e.g. Main Laboratory, Satellite Laboratory, Mortuary & Blood Bank. Inaccuracies identified at assessment may delay the process.

Before an application is accepted CPA will assess its ability to carry out the assessment in terms of its own policy, its competence and the availability of suitable assessors.

Once the application is accepted the applicant medical laboratory will be issued with an enrolment date and details of the future schedule for assessments and timetable for submission of paperwork to CPA. Initial assessment is likely to be 3 to 12 months from the acceptance of the application. 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 is able to organise an assessment within the scheduled timescale but the applicant requests a delay, then the medical laboratory will be categorised as Non-Accredited on the CPA website. 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.

## 12 PREPARATION FOR ASSESSMENT

### 12.1 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 – conducted by the Regional Assessor scheduled within two years of the main visit; on-site time is usually less than the main visit. In exceptional circumstances a Peer Assessor may be required.
- Clearance visit – where required are on site usually for one day and may or may not require a Peer Assessor.
- Limited reassessment visits – these may be necessary when a major change has occurred.

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 this individual 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.

### 12.2 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.

For single site, single discipline laboratories, the assessment team normally consists of a Regional Assessor and two Peer Assessors and is carried out over two days. For large, complex or multi-disciplinary applications, and at the discretion of CPA, extra Peer Assessors may be used and assessment time extended.

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.

### 12.3 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.

## **13 THE VISITS**

### **13.1 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. A timetable will be issued prior to the visit together with a list of documents / evidence that should be readily available. The team will assess for conformity with CPA standards and meet with users of the service and organisational management to solicit their confidential views. 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 with the amount of time needed decided when the application is reviewed. This is the responsibility of the Assessment Manager and Regional Assessor. The applicant will be informed once the timetable has been confirmed.

### **13.2 Surveillance visit**

There will be a 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 and 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.

### **13.3 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. If more than one clearance visit is necessary an extra charge may be made. If non-conformities still remain after 12 months a clearance visit will not be appropriate and a re-application for a further full assessment will be required.

### **13.4 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

- manage the assessment
- conduct the opening and closing meetings

- chair the meeting with users and institutional manager(s)
- collate the assessment report and make available to the CPA decision makers in a timely manner

### **13.5 Responsibilities of Peer Assessors**

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

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

### **13.6 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, Quality Manual and Annual Management Review Summary
- 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
- any changes following the submission of either the Application Form or Quality Manual

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 and sign off findings
- 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 with access to a printer
- refreshments, including a sandwich lunch for the assessor each day

## **14 PRE VISIT DOCUMENT RECORD REVIEW**

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

- Quality Manual
- Application Form
- Annual Management Review Summary
- previous report(s)
- evidence of clearances
- any other relevant documents

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

## 15 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 per assessor
11. EQA Statement
12. The functions and responsibilities of the assessment team
13. Method and procedures used to conduct the assessment including electronic reporting
14. Recommendation of status by Regional Assessor
15. Reminder to Laboratories - users who are involved in the provision of the laboratory service are not allowed to attend the User Group Meeting
16. Code of Conduct

**CPA is 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.**

17. Questions and clarification
18. 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 CPA. The applicant laboratory is also obliged to declare any known non-conformity(ies).

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

## **16 MEETINGS WITH USERS AND MANAGERS**

For a main assessment visit the applicant is asked to arrange two separate meetings:

- Meeting with the institutional manager(s) usually conducted by the Regional Assessor alone
- User meeting with representatives of the clinical user group. This is to be held on a day when the Peer Assessors will be in attendance. It is preferable for this to be arranged over lunch time.

Where a number of disciplines are being assessed within a short space of time it may be necessary to arrange single meetings with the institutional manager(s). The Regional Assessor must be informed of the confirmed date / times of the meetings, and a list of the names and positions of those attending 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 user meeting has covered the discipline in sufficient detail, further contact will be made with additional users in consultation with the Regional Assessor. If issues arise during the assessment that need further discussion with either the managers or users additional meeting will be arranged.

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.

## **17 THE ASSESSMENT**

### **17.1 Introduction**

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

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

Peer Assessors assess the clinical, scientific and technical aspects of the service.

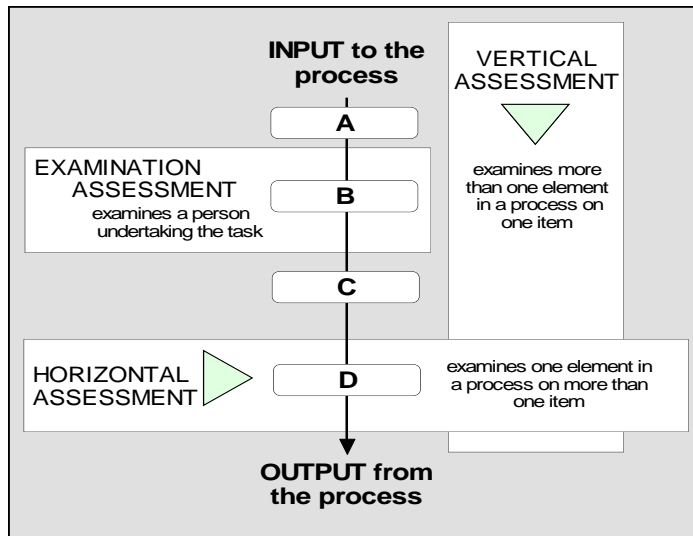
In order to ensure the competency to perform the service across the scope of activity a representative number of staff need to be interviewed.

### **17.2 Working with an assessment team**

The assessment team work to the timetable provided by the Regional Assessor 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.

The assessment team will meet at intervals during the day to discuss and agree findings. This is particularly 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.

### 17.3 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 (A and H plus B, C and D). 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 and other key staff is an important part of the process. Findings are recorded on the Horizontal Assessment form.

#### 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 pre-examination 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 per day. 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.

## 18 RECORDING A NON-CONFORMITY AND OBSERVATION

### 18.1 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, and will be reviewed at the next assessment.

### 18.2 Recording Findings

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

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.

### 18.3 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 and the competency of the organisation.

The EQA statement must be completed with information relating to EQA participation during the assessment. It will be agreed between the applicant laboratory representative and the Regional Assessors.

## 19 THE CLOSING AND DEBRIEF MEETING

The assessment team close the on site assessment with a meeting that follows a prescribed agenda. The Regional Assessor will chair the meeting; the assessor(s) will present balanced feedback including positive aspects. Any findings recorded are then read out, discussed where necessary and agreement sought from laboratory representatives with appropriate authority.

If agreement cannot be reached on the classification of any finding(s) then this will be recorded by the Regional Assessor and the final decision will be made by the CPA decision maker.

The assessment team will also inform the applicant of the status that will be recommended to 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. Recommendation of CPA status
11. Questions and discussion
12. Close of meeting

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

## **20 DECISION MAKING AND GRANTING ACCREDITATION**

### **20.1 The reporting process**

Following the site visit, the Regional Assessor will return to CPA, in electronic format the completed documentation and records relevant to the type of visit.

### **20.2 Decision Making**

The Regional Assessment Manager reviews all documentation relevant to the visit liaising closely with the reporting Regional Assessor. It may be necessary for findings to be reclassified or attributed to additional / alternative standards and if any changes have been made to Regional Assessor findings, the Regional Assessment Manager will liaise with them to clarify the changes.

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

If appropriate, the processed reports are passed to the relevant member of the Professional Advisory Committee (PAC) 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 Regional Assessment Manager before an agreement is reached. If there is still uncertainty regarding the classification of findings or the final status, the report will be referred to the full Professional Advisory Committee. Based on all the evidence, the final decision is signed by the Regional Assessment Manager on behalf of CPA. All decisions regarding referral are discussed at the PAC meeting.

In cases where major discrepancies have arisen between the expectation left on site through the Regional Assessor's recommendation, and the final outcome, the applicant (normally the Head of Department) will be telephoned by the Regional Assessment Manager.

### **20.3 The Report**

The applicant and the Chief Executive of the parent organisation concerned are sent an electronic copy of the report and notification of the final decision, as soon as possible after the visit. This will usually be within two weeks.

The report includes:

- the status of the laboratory and any expiry date assigned
- findings raised
- the overview report containing statements about the competency of the organisation, the adequacy of the quality management system, and a balanced summary of the visit

Following issue of the report, the Regional Assessor then issues the Clearance Review Form to the applicant along with instructions for submission of clearance evidence.

## **20.4 No adverse findings**

If there are no adverse findings accreditation is granted.

## **20.5 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.

## **20.6 Raising a non-conformity**

If the non-conformity is non-critical and can be cleared by CPA within twelve weeks of the visit 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.

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.

# **21 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 the Clearance Review Form sent to them by their Regional Assessor, together with evidence of clearance. It is preferred that this is sent to CPA in electronic format. The evidence must be submitted sufficient time to allow 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.

## **21.1 Clearance visits**

See section 13.3.

## **22 ACCREDITATION CERTIFICATE**

Once accredited, the applicant medical laboratories are informed by letter. Accreditation can be declared from the date of the letter and a Certificate of Accreditation is issued. This certificate carries a date of issue but no date for expiry. The reason for this is that accreditation can be removed at the discretion of CPA and in this case an expiry date on the certificate could be misleading. On the certificate there is a note explaining 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 on time. If this happens the laboratory can then request an up to date letter of accreditation as and when required by third parties.

## **23 SURVEILLANCE ACTIVITIES**

### **23.1 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.

### **23.2 Recording Findings**

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

### **23.3 Annual registration**

As part of continuing surveillance of enrolled laboratories, CPA requires a completed annual declaration (Annual Registration Form) that the laboratory continues to conform to the standards, and a summary of the Annual Management Review. These documents should be submitted according to the schedule provided by CPA.

## **24 COMPLAINTS AND APPEALS**

### **24.1 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.

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 the office or can be downloaded from the website.

### **24.2 Appeals**

A copy of the procedure is available from office or can be downloaded from the website.

## **25 AUDIT QUESTIONNAIRES**

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

## 26 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. 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.

## 27 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. 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.

## 28 SUSPENDING OR WITHDRAWING ACCREDITATION

### 28.1 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.

### 28.2 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

## 29 CPA RECORDS

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

## 30 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](http://www.cpa-uk.co.uk)).



## **31 DOCUMENTATION**

All CPA documents are available from:

- CPA Office
- CPA website [www.cpa-uk.co.uk](http://www.cpa-uk.co.uk)

## **32 WEBSITE**

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/](http://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.



## **DEFINITIONS**

All enrolled Medical Laboratories may be found on the CPA website. All enrolled medical laboratories will fall into one of four main categories; Accredited, Conditional Approval, Awaiting Assessment and Non Accredited.

**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.