

## **NHS SCOTLAND DOCUMENT**

**Model SOP to Meet Requirements of OIG Quality Management System**



**Document Reference No: NHSSIG D76\_05\_01**

### **Policy and Procedures for Internal Quality Management System Audit**

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## 1. INTRODUCTION

### 1.1 Scope and purpose

This document, and related documents, outlines the Policy and associated Procedures for Audit of the Quality Management System for the ??? Blood Bank. This SOP is intended to meet the requirements of Clinical Pathology Accreditation (UK) Ltd (CPA), and of the Medicines and Healthcare Regulatory Authority (MHRA).

In particular, the document is intended to meet Section 6 on Self Inspection, contained in the Operational Impact Group (OIG) "Outline Specification for a Quality Management System for Hospital Blood Banks", which requires that there is an ongoing programme of self inspections (audit).

### 1.2 Responsibility

The Quality Manager, in conjunction with Departmental Managers, and Senior Staff, is responsible for ensuring the implementation and adoption of policies and procedures specified herein.

### 1.3 References

- Understanding Accreditation in Laboratory Medicine, D. Burnett, ACB Publications (1996).  
CPA (UK) Ltd – Standards for the Medical Laboratory, Version 4.02 (December 2004).  
ISO 17025 – General Requirements for the Competence of Testing and Calibration Laboratories.  
ISO 9001: 2000 – Quality Management Systems.  
ISO 15189 – Quality Management in the Medical Laboratory.  
An Approach to Audit – CPA (UK) Ltd, Version 1.0 (April 2001).  
Internal Quality Auditing in a Pathology Laboratory – Dr I. Sharp (course notes, June 2003).  
Internal Quality Control in a Routine Diagnostic Laboratory, J. Gray, PHLS Microbiology Digest 11(3), (1999).  
Development of an Internal Quality Assessment Scheme in a Bacteriology Laboratory, C.E. Constantine, et al, J. Clin. Pathol. 46 (1993).  
EAL-G3 Internal Audits and Management Reviews for Laboratories, Edition 2, 1996.
- Outline specification for a quality Management System for Hospital Blood Banks  
([www.transfusionguidelines.org](http://www.transfusionguidelines.org))
- EEC Guide to Good manufacturing Practice (contained in UK Orange Guide). Current version available on line at Eudralex (<http://pharmacos.eudra.org/F2/eudralex/vol-4/home.htm>)

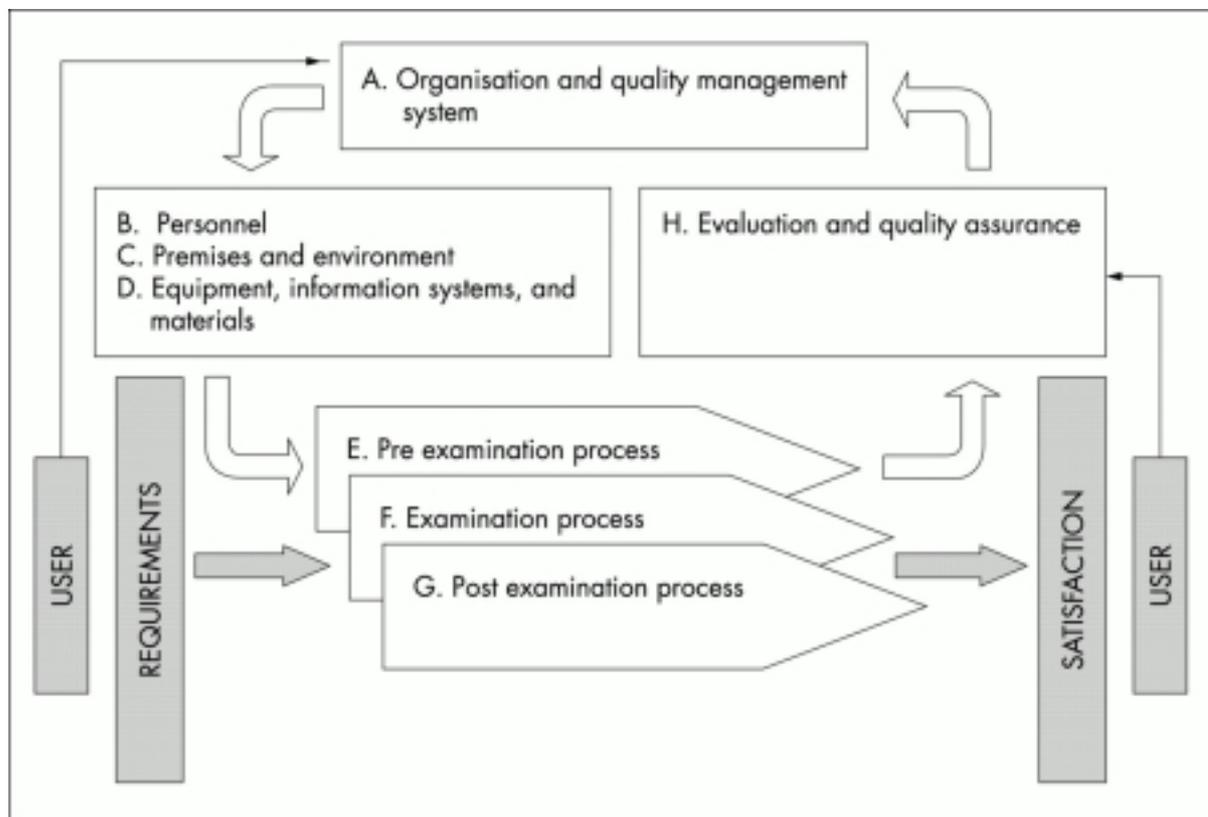
### 1.4 Definitions

Necessary definitions are provided within the text.

## 2.0 QUALITY, THE QUALITY MANAGEMENT SYSTEM AND AUDIT

The purpose of performing Internal Audit is to examine whether approved procedures have been implemented and are being adhered to – this is termed Quality Assurance. Alternatively, Internal Audit can be used to identify the capacity for, or the need for change or improvement in working practices.

In all cases adequate documentation forms the basis of the Quality Assurance system by achieving standardisation of methods and traceability of results on individual specimens. The management of blood banks should ensure a planned and systematic approach to quality assurance in order to give service users the highest degree of confidence that the laboratory's objectives are constantly met and it is this planned and systematic approach that has become known as the Quality Management System.



**Process based relation between sections of the Clinical Pathology Accreditation standards**

As can be seen from the above diagram, a Quality Management System (QMS), in compliance with MHRA and CPA (UK) Ltd Standards, shall involve a process-based approach and includes; the organisational structure, responsibilities, procedures, processes and resources for implementing quality management. There are several different components of a QMS which should be in place and operational before the end product (the laboratory report) is likely to be achieved. These include:

- Quality assurance

- Internal quality control
- Quality assessment
- Accreditation
- Internal QMS audit

This document, and related documents, serves to outline the Policy and associated Procedures for Internal Quality Management System Audit.

### 3.0 AUDIT PROGRAMME

The scope, policy, procedures, including reporting responsibilities of Departmental staff for Internal Audit, should be defined in a suitable document.

The Quality Manager is responsible for: preparing the audit calendar; planning and scheduling audits; ensuring corrective / preventive actions are carried out; and, reporting audit details to the relevant local Management process. It is suggested that all aspects of the operation of the blood bank are covered in a 2 year audit cycle.

In addition, whenever there is reason to doubt the effectiveness of the Quality Management System or the validity of test results, it may be necessary to carry out additional unscheduled audits. Similarly, service user complaint or system failure, will normally warrant un-scheduled audit.

The audit programme should include all aspects of the operation of the blood bank. This should cover the following areas of activity.

#### 3.1 Laboratory Activities

The component parts of the laboratory service, including pre-examination, examination and post examination processes, should be regularly reviewed.

- **Pre - Analytical Phase**

Audit includes review of sample transportation, specimen reception and the ensurance that service requests are appropriately logged to the Laboratory Information System (Laboratory Computer).

- **Analytical Phase**

Audit of the analytical phase, importantly, includes the ensurance that Examination Procedures (SOP's), and where appropriate, Laboratory Work Instructions are controlled with respect to Quality Control.

Examination Audit of SOP's ensures:

1. Appropriate procedures for quality control and performance monitoring are legislated.
2. Means of control, the timing of control and the criteria for result validation, are legislated.
3. Results are validated only following acceptable quality control.

4. New test methods are qualified as per written protocols prior to routine use.

▪ **Post - Analytical Phase**

Audit of the post – analytical phase includes the review of reporting mechanisms, document storage and archiving, and clinical and consultative advice.

### 3.2 Blood Storage and Issue Activities

All aspects of the control of blood components should be audited. This will include procedures for receipt, storage and distribution. In particular, documentation, cold storage, issue and traceability must all be examined.

### 3.3 Premises and Environment

Audit includes the following:

- Premises – fabric of buildings, maintenance works, laboratory security, cleanliness, etc.
- Health and Safety, including Safety Equipment, and Fire Procedures.
- Waste disposal.

### 3.4 Laboratory Equipment

Audit of laboratory equipment serves to ensure that it is in a satisfactory state. The areas to be covered will include validation, maintenance, decontamination, service records, fault logs, calibration data and records, are maintained in accordance with written protocols. All cold chain storage equipment must be audited for temperature control.

In addition, assessment of “fitness of purpose” of all laboratory equipment forms a key component of the Annual Management Review.

### 3.5 Assessment of Service User Satisfaction

CPA (UK) Ltd. directs participant laboratories to demonstrate commitment to fulfilling the needs and requirements of service users. The needs of Service Users are kept under constant review through regular informal and professional discussion and communication. In addition, the Department, audits user opinion through periodic user satisfaction surveys / questionnaires. Outputs from such surveys, including service user needs being translated into requirements, form specific discussion points for the Departmental Audit and Clinical Governance Committee.

## 4.0 Types of Audit

Three types of audit, designed to provide a comprehensive cover of the Quality Management System, are employed:

#### 4.1 Horizontal Audit

This is a detailed check of a particular component part of the Quality Management System. The items for audit can be written as questions; for example, does the Quality Manual contain a Quality Policy?

Horizontal audits can be conducted on aspects of resources, for example, for staff training and education, the question might be - Is there access to library and information services for all staff? Such questions are readily constructed from the CPA Standards. In addition, Audit Checklists serve to allow for the standardisation of audits performed on a regular basis, examples include: Equipment, Staff Training, Document Control, and so on.

#### 4.2 Vertical Audit

This is a detailed check that all elements associated with a chosen Examination Procedure (SOP) are implemented. In any single audit, a number of examinations that have recently passed through the laboratory are randomly selected. Alternatively, laboratory sample number(s) can be randomly selected such that the start of the audit trail can be varied: from a specimen container, from a computer record, from a worksheet or from a printed laboratory test report. The principle is that all activities contributing to the final report would be audited for conformance with the laboratory's pre-examination, examination, and post-examination processes.

#### 4.3 Examination Audit

This is when an Examination Procedure (SOP) or Laboratory Work Instruction is witnessed as it is performed. There are two objectives in such an audit. Firstly, to ensure that what is being done reflects what is described in the procedure, and secondly, that the person carrying out the Examination Procedure or Laboratory Work Instruction has a good understanding of all aspects of the procedure, and is performing the procedure correctly.

### 5. Audit Processes

#### 5.1 Who Performs Audits

Staff trained in audit technique shall perform Internal QMS Audits. The Quality Manager is responsible for ensuring the training of a team of auditor staff.

Auditors shall usually work in teams of two. In this setting, a trained auditor (lead auditor) shall take responsibility for overseeing the audit procedure and the subsequent reporting to the Quality Manager.

#### 5.2 Requirements for Audit

Internal QMS Audits shall be:

- Scheduled – As directed by the Quality Manager, audits shall be scheduled to allow for auditors to plan in advance, and for laboratory staff to know when their section / work processes are to be audited.
- Structured according to a defined protocol. This shall benefit both the auditor and the staff of the audited laboratory section. At the end of the audit, the auditor shall discuss, with the

section leader, possibly with the intervention of the Quality Manager, the requirements for remedial action, and where appropriate, non-conformance(s) and the requirements for corrective action.

- Pre-planned using, where possible, a prepared checklist.
- Independent – auditors shall not inspect an area that they work in. This approach serves to facilitate an “outside-in” objective assessment based principally on written Departmental protocols, policies, procedures, etc, and to allow for quality improvement, in that experienced auditors shall not be hindered by “accepted limitations” of working in a particular laboratory section, or performing a particular job. Furthermore, auditors shall have the opportunity to return to their own section / place of work with experience of good practice, and be able to implement better ways of doing things for their section / place of work. This “peer review system” shall also serve to ensure that auditors are professional, non judgemental of fellow colleagues, and hence, shall aid the further development of a staff culture that forms quality and quality improvement as a routine, day-to-day essential function, and not, an unwanted add-on or hindrance to work.
- Objective – recording only substantiated objective evidence. Auditors that raise non-conformances that prove to be unfounded, or, are not based on written protocols or procedures, will lose credibility with colleagues. For this reason, it is important that auditors discuss non-conformance(s), the requirements for remedial and corrective action(s) with section leaders, and where appropriate, with the Quality Manager.
- Competent – conducted by trained auditors. Experienced auditors, acting professionally, shall ensure: tact, thoroughness, persistence, technical competence, interview / communication skills, objectivity, fairness, not having “hobby horses”, and confidentiality.
- Restricted to agreed scope. When conducting an audit, it is important that the auditor sticks to the appropriate audit trail as befits the audit format employed. Problems out with the audit in question should be recorded as observations, for communication to the Quality Manager.
- Completed on time, with clear conclusions, including remedial action(s), identification of non-conformance(s) and recommendations to the Quality Manager for the need for corrective action(s).

### 5.3 Preparing For Audit

Audit Checklists, prepared by the Quality Manager, serve to allow for the standardisation of audits that are performed on a regular basis. The CPA (UK) Ltd Standards and the OIG Quality Management System will provide the starting point for the preparation of most audit checklists.

In addition to standard checklists, the auditor should review a range of documentation relating to the area to be audited. This might include the following

- Previous internal audits
- Previous external audits (including CPA, MHRA)
- Quality incidents
- Adverse reactions/ adverse events

- Results from external proficiency testing schemes

## 5.4 Conducting the Audit

### 5.4.1 The Opening Meeting

This is a brief meeting between the auditor(s) and the section leader and should:

- State the scope of the audit.
- Ask if there will be any problems carrying out the audit.
- Ask if there are areas of concern such as problems likely to be encountered.
- State an approximate time, and arrange a convenient time for a closing meeting.

### 5.4.2 Performing the Audit

- Each audit should include:
  - Checks to ensure personnel are suitably trained to perform the procedures they are performing,
  - A review of relevant documents to ensure they are correct and complete,
  - Checks to ensure that relevant procedures are being followed.
- Use, where available, a pre-prepared audit checklist as a guide when performing the audit.
- Record details of observations made as the audit is being performed. Information may be gathered by watching staff at work, inspecting the workplace, and by examining and directly relating to associated QMS documentation.
- Interview staff. It is important that staff are interviewed with regards to specific problems encountered, and their views regarding service and or process quality improvement.

### 5.4.3 Following the Audit

Following the audit, it is important that the auditor(s) meet with the section leader to mutually discuss all observations, the need for remedial actions, and non-conformance(s) for inclusion in the audit report.

### 5.4.4 The Closing Meeting

Ideally, the closing meeting involving the auditor and the section leader should take place immediately after the audit has been performed. If this is impracticable, a meeting should be arranged as soon as is possible. At this meeting, the lead auditor shall:

- Thank the section leader and section staff as appropriate.
- Present an overall summary of observations made, including good points, and highlighting requirements for remedial actions and, where identified, non-conformances.
- Discuss, where necessary, suggestions for corrective actions for report to the Quality Manager.

#### **5.4.5 The Audit Report Summary**

A standardised report form should be used to report all audit summary conclusions.

- This report need only be a brief statement to allow for summary of observations.
- The report shall record all negative observations.

#### **5.4.6 Lead Auditor Reporting Procedure**

The final step for the Lead Auditor is the ensurance that all appropriate documentation is prepared and dispatched to the manager(s) in the area audited and to the unit's Quality Manager. This shall include:

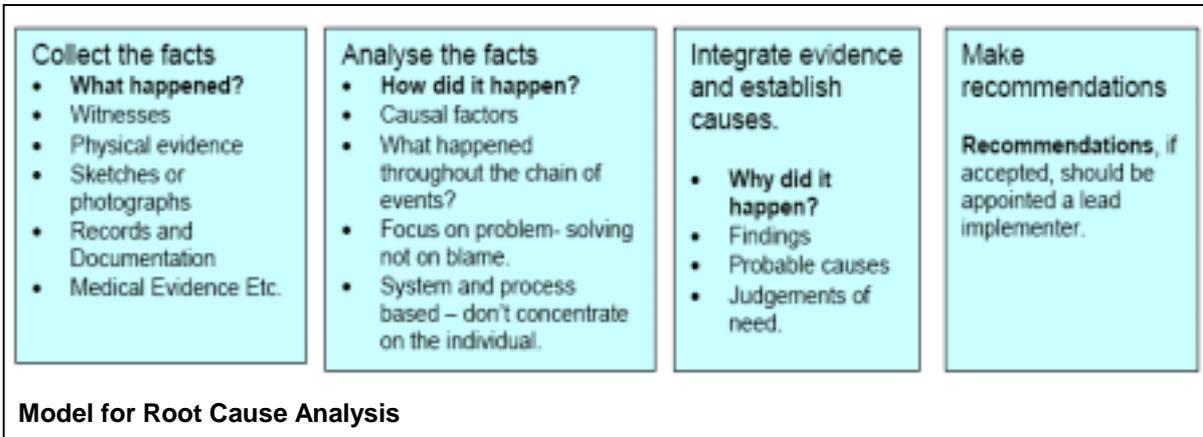
- Completed Audit Form (e.g. Vertical, Horizontal, Examination Form, or other) including details of remedial action, and identified non-conformances. The Quality Manager is responsible for ensuring the completion of Non-Conformance Forms, for each non-conformance identified and recorded on the Audit Form.
- Completed Quality Improvement Note. The report should contain suggestions for Quality Improvement, including ideas of the auditor, or possibly, suggestions that staff have made at interview during the audit process.
- Completed Audit Report Summary Form including suggestions, through discussion with the section leader, for corrective actions.

### **6.0 Dealing with Non-conformance and Corrective Actions**

Corrective action is taken to eliminate the cause of a detected non-conformance or other undesirable situation. There are two levels of corrective actions:

The first, which can be termed remedial action, deals with the immediate problem, i.e. if an instrument has not been calibrated, then get it calibrated, or if a member of staff's training record is not up to date, then update it. The need for remedial action is likely, through the audit process, to be obvious, and should be implemented, where possible, immediately by the section leader. The Quality Manager shall directly monitor the implementation of all remedial actions.

The second action is cause analysis. This requires the asking of "Why did it go wrong?" instead of just "What has gone wrong?" (this is the audit process). Often the existence of non-conformance is indicative, or the symptom, of an underlying problem. Hence, the management of corrective actions involves a thorough inspection of the QMS, or the area of work in question, in order to identify the root cause of a problem, and by implementing corrective action, reduce the likelihood of a similar non-conformance reoccurring.



### 6.1 Non-Conformance Report Form

Non-Conformance Report Forms serve to allow for the identification, monitoring and review of all QMS non-conformance(s) identified through audit or day-to-day working. The Quality Manager, through audit reports prepared by Departmental audit staff, derives the content of these Non-Conformance Reporting Forms. The assessment of the effectiveness of corrective action forms a key element of the audit process. In most instances, repeat audit shall be undertaken, with the specific purpose of assessing, and hence ensuring, the effectiveness of the corrective action.

A non-conformance (or non-compliance) is defined as “*the failure to fulfil the requirements of a standard, in whole or in part*”. Auditors are required to distinguish between two categories of non-conformance, critical, and, non-critical non-conformance, and additionally, to record observations. For example, in accordance with the audit and reporting principles of CPA (UK) Ltd, the following definitions and categorisations for non-conformance (non-compliance) reporting could be utilised:

Definition	Categorisation & Requirements
<b>SYSTEM FAILURE</b>	A systems failure is evidenced by the inability to: <ul style="list-style-type: none"> <li>▪ Meet the agreed needs and requirements of service users, or,</li> <li>▪ Ensure a safe environment for staff, patients, or visitors to the Department, or,</li> </ul> Ensure the quality of a laboratory examination procedure
<p><b>CRITICAL Non-conformance</b></p> <p>This is defined by CPA as the “<i>failure to fulfil the requirements of a CPA standard to such a degree that in the opinion of the auditor, there is evidence of a system failure</i>”</p>	Normally, this is evidenced by the failure to comply with the whole (or significant part) of a CPA, or other legislated, standard.

<p><b>NON-CRITICAL Non-conformance</b></p> <p>This is defined by CPA as the “<i>failure to fulfil the requirements of a CPA standard that would not lead to system failure</i>”.</p>	<p>Normally, this is evidenced by the failure to comply with part of a CPA, or other legislated, standard.</p>
<p><b>Observation</b></p> <p>This is defined by CPA as “<i>records of deficiencies noted by auditors, that have the potential to affect the functioning of the Department</i>”</p>	<p>For the purposes of Quality Improvement, in addition to the reporting of observations that have the potential to affect the functioning of the Department, Departmental auditor staff are required to:</p> <ul style="list-style-type: none"> <li>▪ Note areas where service is sub-optimal, and hence, areas where service could be improved,</li> <li>▪ Note areas where, in the opinion of the auditor, service, and service delivery could be improved,</li> <li>▪ Note areas where, in the opinion of the staff, service and service delivery could be improved,</li> <li>▪ Note areas of good practice that can be communicated throughout the Department for the purposes of service improvement.</li> </ul>

## 6.2 Preventative Action

Appropriate preventative action must be taken to eliminate the cause of all non-conformances or other potentially undesirable situation found during quality audits.

**Note – Preventative action is different from corrective action in that corrective action is taken to prevent reoccurrence whereas preventative action is taken to prevent occurrence.**

There are two aspects to preventative action. The first is similar to “risk assessment”, the second, is continuous quality improvement. Hence, procedures to allow for identification and implementation of preventative action are necessary in order to identify and address improvements to the QMS, and also, potential sources of non-conformance.

All non conformances should be responded to in writing within defined time scales. These are as follows:

- Critical 7 days
- Others 28 days

The audit responses should give details of the planned remedial actions and the intended time scales for completing the intended activity.

## 6.3 Audit Closure

The auditor will review the response provided and decide whether the intended action is satisfactory. If the action is not satisfactory, further clarification will be requested

within a defined time period. Once all points have been responded to satisfactorily, the audit can be closed.

All documentation relating to the audit should be assembled in a file and archived for future consultation when required.

### Flowchart of the Internal Audit Process

