

## ISO 15189:2003 – FROM THEORY INTO PRACTICE

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### Introduction

Throughout the world there is an increasing interest among medical laboratory professionals in attaining accreditation status for their services. Although some may see this as a commercial advantage, equivalent to a 'designer label', the main advantage of working towards accreditation is the potential for more effective management of the laboratory. The long awaited publication, in February 2003, of the International Standard, ISO 15189:2003 'Medical laboratories-Particular requirements for quality and competence'\* provides a unique focus for this interest.

In the author's book, 'A Practical Guide to Accreditation in Laboratory Medicine' key aspects of ISO 15189:2003 as well as ISO 9001:2000, the standard for quality management systems and ISO/IEC 17025:1999, the generic standard for testing and calibration laboratories are discussed and through the fictional device of the Pathology Laboratory of St Elsewhere's Hospital Trust, a practical approach to establishing a quality management system is discussed. This article presents a summary of this approach - from theory into practice.

### A process based approach to quality management systems

In ISO 15189:2003 the management (quality management system) and technical competence requirements are presented in two separate sections making it difficult for laboratories to discover the dynamic relationships between the quality and competence requirements.

The starting point for developing a framework for process-based quality management of a medical laboratory lies in the introduction to ISO 9001:2000. It promotes the adoption of 'a process approach when developing, implementing and improving the effectiveness of a quality management system' in order 'to enhance customer satisfaction by meeting customer requirements'. Process is described as 'an activity using resources, managed in order to enable the transformation of inputs into outputs'.

In the context of a medical laboratory this translates into, **consultation with users**, receiving a **request for an examination**, carrying out **the work** and **reporting the results**, with **interpretation** where appropriate.

Within any organization (e.g. a medical laboratory) there are numerous interrelated or interacting processes, and it is 'the identification and interactions of these processes and their management', that is referred to as a 'process approach'. It is the adoption of this approach that creates a process-based quality management system.

The process-based model shown in Figure 1 represents the basics of how a quality management system for medical laboratories work irrespective of the content of the particular standard being used. The references in brackets in each section are to the chapters of PGALM.

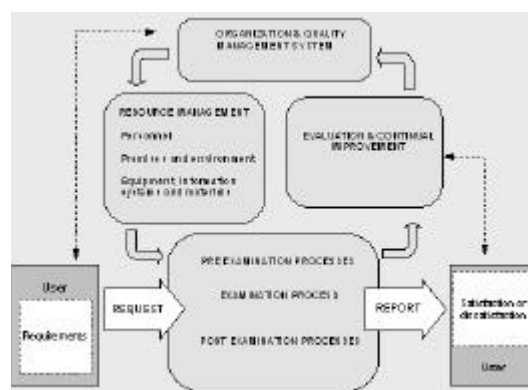


Figure 1 A process-based quality management system for medical laboratories.

The model shown in Figure 1 can be described in two different ways. Firstly, the user has requirements that are formulated in consultation with laboratory management (the request) and the laboratory responds by carrying out pre-examination, examination and post-examination processes to produce a report for the user. Depending on whether their requirements have been met or not, users may be defined as 'satisfied' or 'dissatisfied'.

The second view is that the laboratory management creates a quality system (Organisation and quality management system) and uses resources, staff, equipment etc. (Resource management) to carry out pre-examination, examination and post-examination processes (pre-examination, examination and post-examination processes) to fulfil the requirements of the user. All aspects of the quality system including the pre-examination, examination and post-examination processes are continually evaluated and improvements made as appropriate (Evaluation and continual improvement). Evaluation and continual improvement activities include for example, assessment of user needs and requirements, internal audit of the

examination processes and review of participation in external quality assessment schemes.

Free publications prepared by the author ([www.acb.co.uk](http://www.acb.co.uk)) show the clauses of ISO 15189:2003 and the CPA (Clinical Pathology Accreditation (UK) Ltd) standards transferred into the process based model illustrated in Figure 1.

The preamble to CPA Standard A4 in the 'Standards for the Medical Laboratory' describes a quality management system as providing '...the integration of organisational structure, processes, procedures and resources needed to fulfil a quality policy and thus meet the needs and requirements of users'. It is this 'all embracing' concept of a quality management system that this article seeks to emphasise.

## Organisation and quality management system

### Organisation and Responsibility

For there to be an effective QMS, roles and responsibilities must be clearly defined and laboratory management provide the lead in establishing the sequence of action to be taken. This sequence is illustrated in a pyramidal form on the left hand side of Figure 2. The first step in the sequence is the creation of policies that can be defined as the 'overall intentions and direction of an organization'. The second step objectives and plans, involves 'making plans and setting objectives to enable the fulfilment of the intentions expressed in the policies'. The third step processes, involves the 'definition of the activities needed to carry out the intentions' and the fourth step procedures, are the 'practical way in which intentions are translated into action'. The fifth and final step, records (made on forms) provide evidence, on a day-to-day basis, that procedures have been carried out correctly and that intentions have been fulfilled.

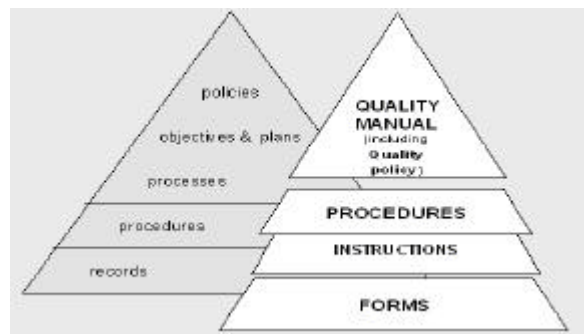


Figure 2 Figure 2 Action in quality management and a hierarchy of documentation

An example at St Elsewhere's would be that the **quality policy** of the laboratory includes a commitment to the reporting of results of examinations in a timely manner. The supplier of the laboratory computer system announces the release of a module for ward reporting of results. Laboratory management establishes the installation of this module as an **objective** for the next financial year and **planning** for this development requires the inclusion of the resource implications in the business plan. Its impact on post-examination processes is defined and **procedures and forms** reviewed and revised.

### Evidence of action in quality management

Evidence of action in quality management is adduced from the documentation that is used and illustrated on the right hand side of Figure 2. The primary requirement for evidence is to enable the laboratory to reconstruct its examination and other processes, when this is required as a result of questions asked by users of the laboratory concerning its performance. The other side of the 'evidence' coin is the need of assessors from accreditation bodies to obtain evidence to enable them to assess a laboratory's compliance with standards.

The quality manual in the Pathology Laboratory at St Elsewhere's provides a road map to the whole documentation of the laboratory. Figure 3 is a page from that manual showing the organisation and responsibilities within the laboratory. In practical terms, the manual should be no more than 25 pages in length. It contains a quality policy and describes the processes that take place in the laboratory in order to fulfil the requirements of particular standards. Examples of such processes are the procurement of equipment, the examination of specimens and the reporting of results. A pathology laboratory can have a single policy statement that is inclusive of all aspects of its work or there can be a number of separate policies relating to different aspects of the way in which a laboratory works.

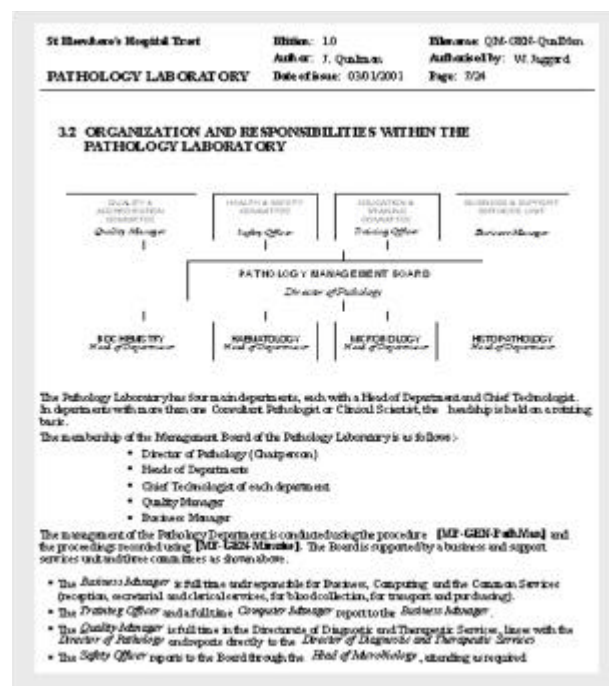


Figure 3 St Elsewhere's Pathology Laboratory - Quality Manual

Throughout the quality manual there are references to procedures that form the second level in the hierarchy of documentation. Procedures are the practical way in which policies are translated into action and describe how processes should be carried out. They are often called SOP's or standard operating procedures. The quality policy should refer to management, quality evaluation, health and safety, and laboratory methods etc. and procedures are needed which relate to the same areas.

In the same way that the Quality Manual refers to procedures, so procedures can contain references to (working) instructions. This third level of documentation involves the practical day-to-day work instructions that are needed near the work situation for easy

reference. For example, they might describe, starting up or closing down a haematology analyser. Instructions can be part of a procedure or can be referred to in a procedure and published either separately or both in the document and published separately. The advantage of having them separate is that any changes to instructions do not require a change to the procedure.

The final level in the hierarchy of documentation is the form(s). These forms (and the records created using them) are a crucial part of quality management. They are the evidence that a procedure and/or related instructions have been carried out. If the procedure or instructions require something to be recorded on a form, the form should be referred to in the procedure. The forms or records do not necessarily have to be created as 'hard copy' (a paper record). A record (an electronic record) can be created by completing a form on a computer screen in the laboratory or a consultant's office, by anybody who has the correct authorization identity. In a medical laboratory, request forms and test reports are an example of such documentation. Records of any information or data such as patients' results, minutes of meetings, quality control data or the result of an audit must be made on forms of an approved format and not on the backs of envelopes or the cuffs of laboratory coats!

An example at St Elsewhere's would be a statement in the **quality policy** requiring 'the use of examination procedures that will ensure the highest achievable quality of all tests performed'. The **procedure** produced as a result of such a policy statement would be a procedure for measuring HbA1c. The procedure refers to working **instructions** for starting the HbA1c analyser and for closing it down and these are published separately and displayed near the analyser for easy reference. The analyser is interfaced to a laboratory computer and an example of a **form** is the computer-generated work sheet to assist with checking-in samples. Additionally, the computer file that holds the patient details and results is regarded as a **record**. Such computer-held data needs to be as easily accessible on demand as any paper record.

All the documents referred to in the hierarchy above must be subject to control as described below. The preparation of required documentation might appear to be a daunting task for a medical laboratory but when approached in a practical manner it provides the basis of effective quality management the laboratory.

#### Document control

Control of documents requires that they are, approved for adequacy prior to issue, reviewed and updated as required, available at point of use, remain legible and uniquely identifiable and that unintended use of obsolete documents is prevented. The purpose of regularly reviewing documents is to ensure that they remain fit for their intended purpose.

An inherent part of document control is a document register or master index of documentation. It is important to decide at an early stage whether the document register should be a manual paper record, a homemade spread sheet or database or an off the shelf (albeit customisable) commercial product. This is perhaps the most important decision that any laboratory can make in building a QMS.

#### Control of records and clinical material

A major feature of all quality management systems is the need to control process and quality records and, in the case of medical laboratories, clinical material. Whether the requirement is for control of clinical material or records, there are three distinct i

issues to be considered. Firstly, are the records being retained going to serve a useful purpose, for example to reconstruct an examination, or to audit corrective action? Secondly, what are the relevant retention times, and thirdly how should the material be kept?

### Resource management

The management of resources is a key part of any QMS and at St Elsewhere's the management of staff has a very high priority and in particular the role of joint staff review. The agreed action points (Figure 4) are seen as an essential part in the matching the changing needs of the laboratory to the needs of an individual member of staff. This is one example of the concept of 'circles of continual improvement' discussed later in the article.

10 Agreed action					
Signature of staff member		Signature of reviewer		Maryseal Jones	
Item	Agreed objective	Agreed action	Timescale	Resources required	Criteria for success
1.	More evidence of automated EPRs (LPHAS-AuBER)	M Jones to arrange practical training with B Rubin	3 months	Time-one day	Evidence audit of (LPHAS-AuBER)
2.	Use of Microsoft Word procedure bundles	Practical instruction from M Jones	3 months	3 hours with M Jones	Evidence of completion
3.	Practical evidence of writing procedures	M Jones to set 3 practical tests	4 months	As required with M Jones	Completion of practical tests
4.	In place participation in Departmental projects	M Jones to arrange place on course	1 year	Trust course PR 07/3 days plus detrief with M Jones	Certificate of successful participation

Figure 4 Joint staff review - agreed action points

## Pre examination, Examination and post examination processes

At St Elsewhere's the provision of information for the user is of top priority. This is in the form of a User Handbook (on a hospital website) and by proper signposting of the laboratory. There is little point in having a laboratory if the user or patient cannot find it. Explanatory booklets include one explaining the post mortem to relatives of a deceased patient.

Laboratory management has been devising ways in which to save time and energy by increasingly using manufacturers material to document procedures. An example is the documentation concept for the BHM Analyser used by Biochemistry, Haematology and Microbiology (Figure 5).

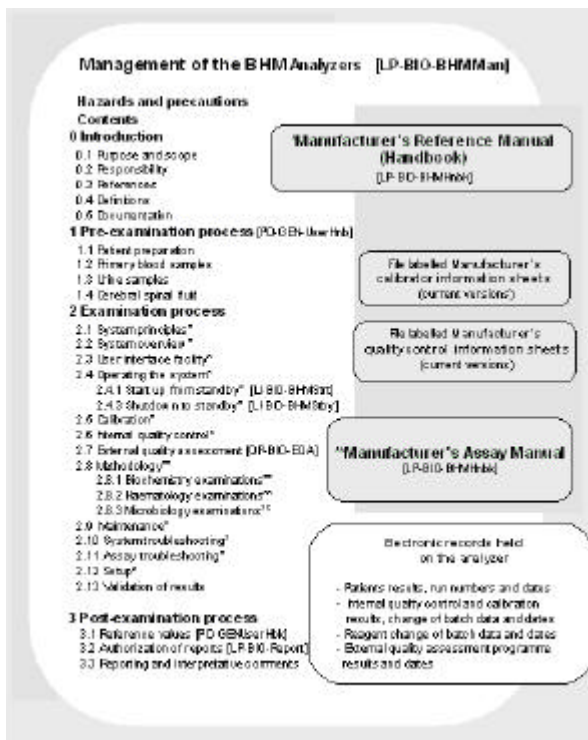


Figure 5 Documentation for the BHM analyser

The provision of a consultative and interpretation service is seen as an integral part of the service to the user

## Evaluation and continual improvement

### Evaluation and continual improvement

St Elsewhere's Pathology Laboratory has a commitment constantly to evaluate its activities and seeking to continually maintain and improve quality. Evaluation and continual improvement could be regarded as synonymous with quality assurance, but it seems increasingly uncertain what is meant by the term 'quality assurance'. The difficulty seems to arise from the meanings of the words 'assure' and 'ensure'. To try to ensure the quality of something is 'to make sure or certain' of its quality, whereas to assure 'to give confidence to oneself or others' seems a relatively impotent activity if you view it from the point of view of the user clinician.

### Internal audit and external assessment

Three different types of audit are distinguished at St Elsewhere's. The first, is an internal audit conducted by the laboratory itself on some aspect of laboratory activity such as the accuracy of transcription of data from a request form into the laboratory information system, or whether all members of staff have up-to-date job descriptions. External audit (sometimes termed assessments) conducted by some person or bodies interested in the organization such as a purchasing authority or by external independent organizations such as a national accreditation body. A third type of audit, not shown in orthodox classifications is cooperative audit. That is audit conducted between the laboratory and another party for mutual benefit. Examples of cooperative audit are clinical audit or customer satisfaction surveys and bench marking activities. Schemes for external quality assessment that are run on a primarily educational basis can in a sense be regarded as cooperative audit or equally well classified as external audit. Audits provide an important mechanism for the detection and investigation of nonconformity.

### Non-conformities / corrective and preventative action

A non-conformity can arise in two distinct ways. Firstly, from a reactive audit resulting from a problem in the conduct of a process, leading to the need for corrective and/or preventive action and thus contributing to the maintenance of quality or to continual improvement. Or secondly, a proactive audit produces a non-conformity that again requires corrective and/or preventive action, thus contributing to the maintenance of quality or to continual improvement.

An example of a reactive audit, illustrated by an example from St Elsewhere's, was when the results from a new batch of quality control material being introduced on an analyser showed all three levels for each analyte were approximately 20% lower than expected (**a non-conformity**). Investigation (**an audit**) revealed that although the freeze-dried material had been reconstituted with 5 ml of reconstituting fluid as per the documented procedure, the manufacturer had changed the reconstitution volume from 5 ml to 4 ml without sending out a notice to this effect. All vials wrongly reconstituted were immediately removed (**corrective action**). Following this incident all personnel involved had the matter drawn to their attention and the procedure was altered and an adverse incident report might be dispatched to an appropriate government agency, with a copy to the manufacturer (**preventive action**).

These actions contribute to ensuring the quality of examinations, (continual improvement). An example of a proactive audit would be a 'good housekeeping audit' and such audits are at the core of maintaining a programme of continual improvement.

### Continual improvement

Examples of approaches to continual improvement are shown in Figure 6 as what has been termed 'cycles of continual improvement'. The intention of the diagram is to represent at the centre, the management review as the core focus of all continual improvement activity. The circles around the central circle represent individual circles of continual improvement focused on specific topics, for example, with Personnel, the activity is the annual joint review of staff, with Internal audit of examination processes, the vertical audit of examinations and with Equipment and diagnostic systems, the procurement of In Vitro Diagnostic Devices (IVD's).



An important question to answer at this point is when and how often should these activities take place. These circles of continual improvement should carry on throughout the year and most of the nonconformities discovered have to be resolved in a reasonably short time span for the process to be effective.

The non-conformities that are thrown up during the day-to-day activities of quality management are the 'grist to the mill' (defined in common English usage as 'anything that can be turned to profit or advantage') of continual improvement, or the cogs in the cycles of continual improvement.

However, during the course of a year, issues that require the formal setting of new objectives and detailed planning will be identified and these properly go forward as items for consideration at the (annual) management review. If the results from an EQAS indicate a problem with an examination, it is no good waiting until the management review for its resolution, whereas the requirement for new service provision may have to wait for the capital purchase of the appropriate IVD or the recruitment of new staff.

2. A further valuable resource is 'Guidelines for quality systems in medical laboratories', National Pathology Accreditation Advisory Council, Canberra, Australia 2001 ([www.health.gov.au/npaac](http://www.health.gov.au/npaac))

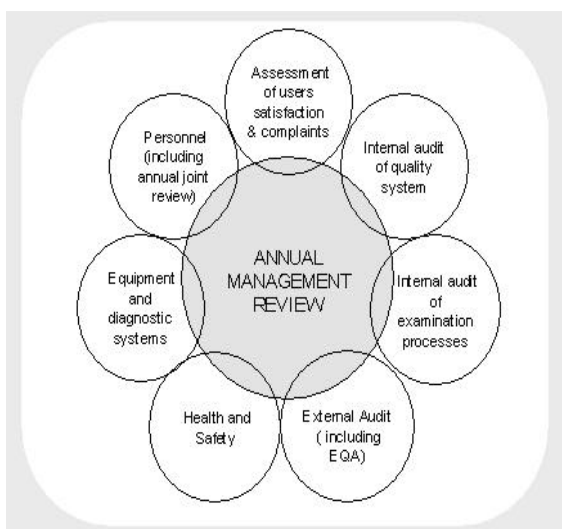


Figure 6 Cycles of continual improvement

### Management review

At St Elsewhere's the annual management review is a crucial part of the quality management system of the laboratory. It sets overall objectives for the following year and within the laboratory these are translated into objectives for the staff and thus into the staff joint reviews that identify the training needs of those staff. Continual improvement underpins the continuing provision of a quality service that aims to meet the needs and requirements of the user.

### Acknowledgements and sources

1. Most of the figures and text in this article are based on the author's book with permission from the publishers, ACB Venture Publications. Burnett D, A Practical Guide to Accreditation in Laboratory Medicine, (2002) ACB Venture Publications London ([www.acb.org.uk](http://www.acb.org.uk)). The free companions to the book mentioned in the article can be downloaded from the same website.