

ISO 15189:2003 – A PRACTICAL TOOL FOR THE MANAGEMENT OF QUALITY IN THE MEDICAL LABORATORY

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Summary: The requirements of ISO 15189:2003 are discussed in the context of a process and outcome based quality management model in which the user's needs are the central focus. The requirements of ISO 15189:2003 are examined in terms of organisation and a quality management system and stress the importance of evidence, document control and control of records and clinical material. Examples are provided from the areas of resource management, pre examination, examination and post examination processes. In the final section the importance of evaluation and continual improvement is presented in relation to internal audit and external assessment, non-conformity, corrective and preventative action and management review.

Key words: quality management, process, procedures, audit, continual improvement, management review

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' provided a unique focus for this interest. This paper looks at the requirements of the Standard and reorganises it into a process and outcome based quality management system model. Material from the author's book, 'A Practical Guide to Accreditation in Laboratory Medicine' illustrates how it can become a practical tool for the management of quality in the medical laboratory. A fictional device of the Pathology Laboratory of St Elsewhere's Hospital Trust, is deployed to provide practical examples.

A process and outcome based approach to quality management systems

During the preparation of ISO 15189:2003 the authors were constrained to structure its requirements in accordance with the structure of ISO 17025:1999,

the generic standard for testing and calibration laboratories. This meant that the management (quality management system) and technical (competence) requirements are presented in two separate sections, as shown in *Figure 1*, making it difficult for laboratories to discover the dynamic relationships between the quality and competence requirements.

4 Management requirements	5 Technical requirements
4.1 Organisation and management	5.1 Personnel
4.2 Quality management system	5.2 Accommodation and environmental conditions
4.3 Document control	5.3 Laboratory equipment
4.4 Review of contracts	5.4 Pre-examination procedures
4.5 Examination by referral laboratories	5.5 Examination procedures
4.6 External services and supplies	5.6 Assuring the quality of examination procedures
4.7 Advisory services	5.7 Post-examination process
4.8 Resolution of complaints	5.8 Reporting results
4.9 Identification and control of nonconformities	
4.10 Corrective action	
4.11 Preventive action	
4.12 Continual improvement	
4.13 Quality and technical records	
4.14 Internal audits	
4.15 Management review	

Figure 1 Requirements of ISO 15189:2003

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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 2* represents the basics of how a quality management systems for medical laboratories work irrespective of the content of the particular standard being used.

The model shown in *Figure 2* 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,

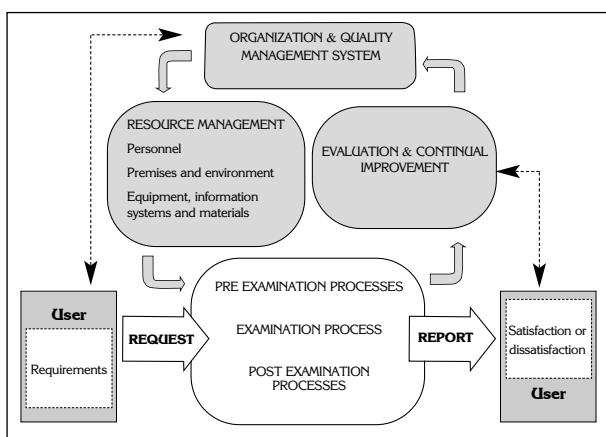


Figure 2 A process and outcome based quality management system for medical laboratories

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.

The requirements of ISO 15189:2003 can be reorganised into this process and outcome model as illustrated in *Figure 3*.

The preamble to Standard A4 in the Clinical Pathology Accreditation (UK) Ltd '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 paper 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 4*. 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.

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

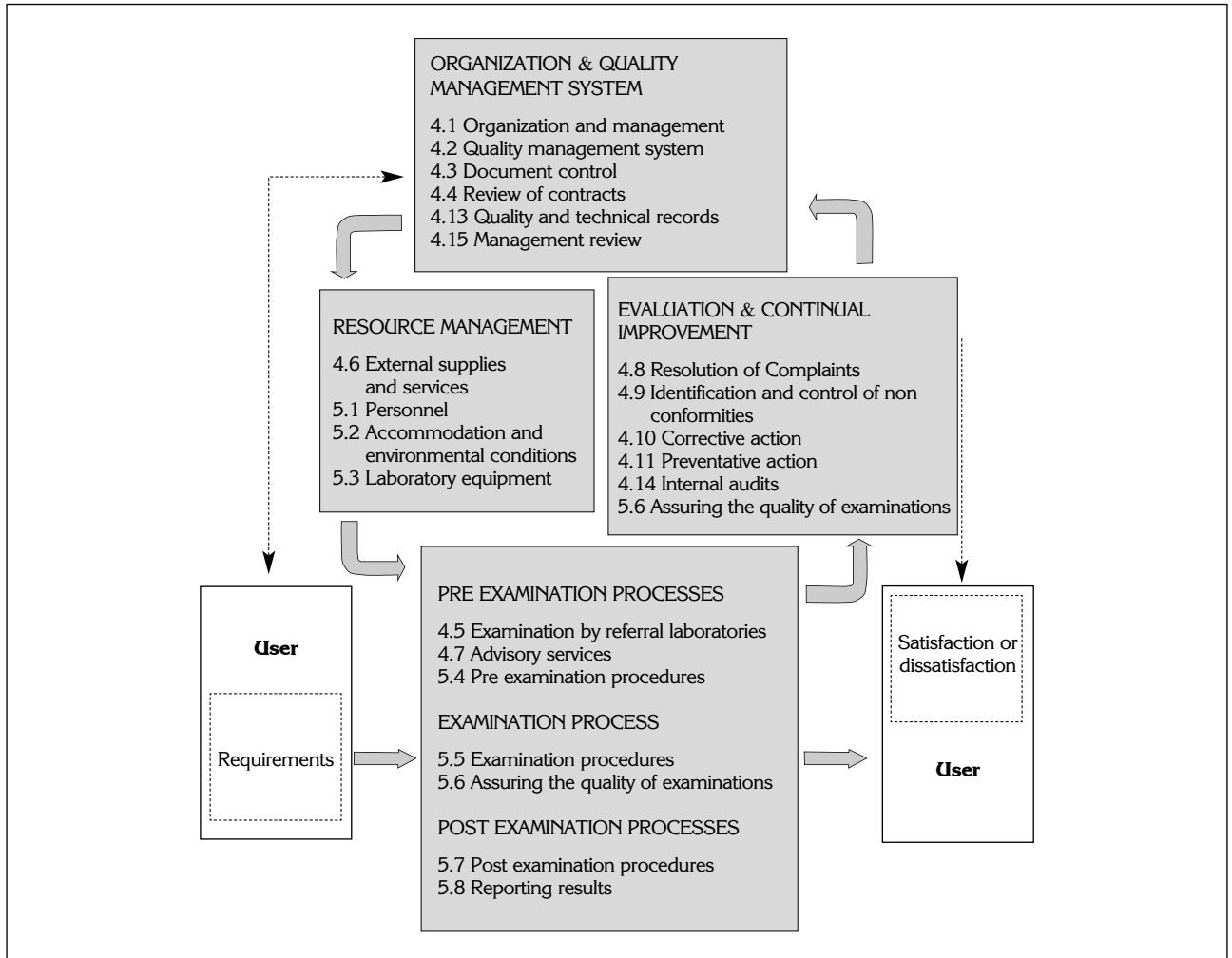


Figure 3 Requirements of ISO 15189:2003 in a process and outcome based quality management system model

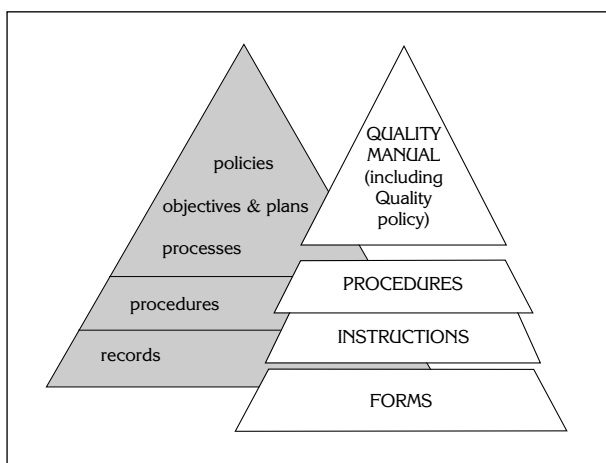


Figure 4 Action in quality management and a hierarchy of documentation

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 4*. 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 5* is a page

St Elsewhere's Hospital Trust

Edition: 1.0

Filename: QM-GEN-QualMan

PATHOLOGY LABORATORY

Author: J. Qualiman

Authorised by: W. Jaggard

Date of issue: 03/01/2001

Page: 7/24

3.2 ORGANIZATION AND RESPONSIBILITIES WITHIN THE PATHOLOGY LABORATORY



The Pathology Laboratory has four main departments, each with a Head of Department and Chief Technologist. In departments with more than one Consultant Pathologist or Clinical Scientist, the headship is held on a rotating basis.

The membership of the Management Board of the Pathology Laboratory is as follows:

- Director of Pathology (Chairperson)
- Heads of Department
- Chief Technologist of each department
- Quality Manager
- Business Manager

The management of the Pathology Department is conducted using the procedure [MP-GEN-PathMan] and the proceedings recorded using [MF-GEN-Minutes]. The Board is supported by a business and support services unit and three committees as shown above.

- The *Business Manager* is full time and responsible for Business, Computing and the Common Services (reception, secretarial and clerical services, for blood collection, for transport and purchasing).
- The *Training Officer* and a full time *Computer Manager* report to the *Business Manager*.
- The *Quality Manager* is full time in the Directorate of Diagnostic and Therapeutic Services, liaises with the *Director of Pathology* and reports directly to the *Director of Diagnostic and Therapeutic Services*.
- The *Safety Officer* reports to the Board through the *Head of Microbiology*, attending as required.

Figure 5 St Elsewhere's Pathology Laboratory – Quality Manual

from that manual showing the organisation and responsibilities within the laboratory. In practical terms, the manual should be less 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.

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 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 approached in 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 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 6*) 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 paper.

Pre examination, examination and post examination processes

At St Elsewhere's the provision of information for the user is 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 7*).

10 Agreed action							
Signature of staff member		<i>Elizabeth Rate</i>		Signature of reviewer		<i>Margaret Jones</i>	
Item	Agreed objective	Agreed action	Timescale	Resources required	Criteria for success		
1.	More experience of automated ESR's [LP-HAE-AutoESR]	M Jones to arrange practical training with B Rubin	3 months	Time-one day B Rubin	Examination audit of [LP-HAE-AutoESR]		
2.	Use of Microsoft Word procedure templates	Practical instruction from M Jones	3 months	3 hours with M Jones	Evidence of completion		
3.	Practical experience of writing procedures	M Jones to set 3 practical tasks	6 months	As required with M Jones	Completion of practical tasks		
4.	Improve participation in Departmental projects	M Jones to arrange place on course	1 year	Trust course, PR 07/5 days plus debrief with M Jones	Certificate of successful participation		

Figure 6 Joint staff review – agreed action points

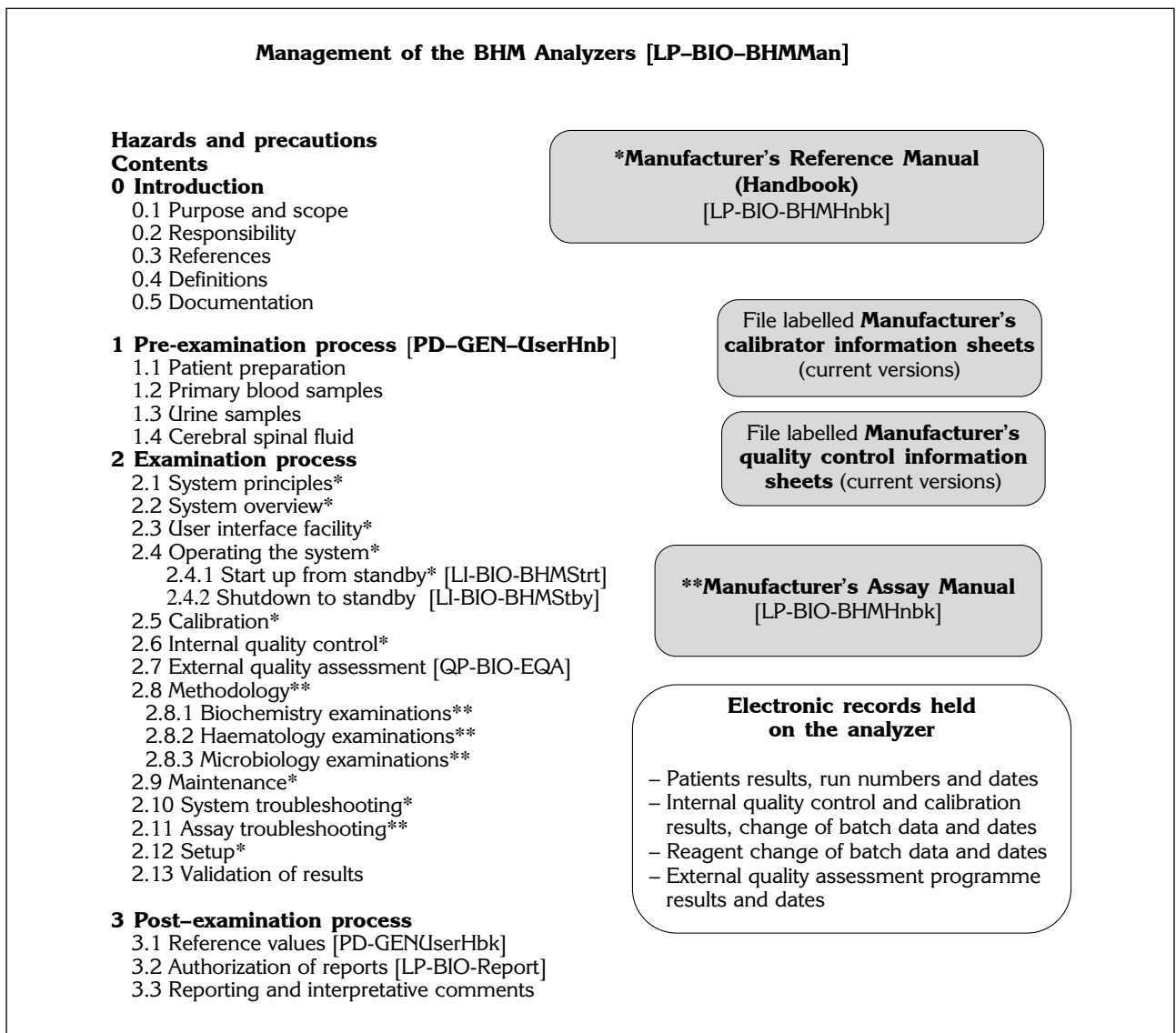


Figure 7 Documentation for the BHM analyser

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 commitment constantly evaluating 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 benchmarking 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 nonconformity can arise in two distinct ways. Firstly, from an (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 *nonconformity* 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 is 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 nonconformity**). 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 8 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).

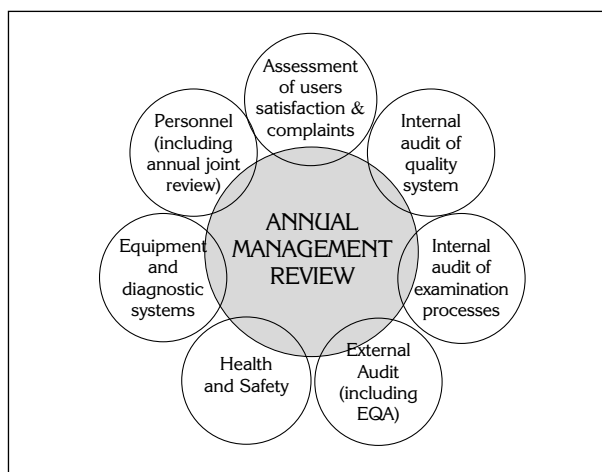


Figure 8 Cycles of continual improvement

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 nonconformities 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.

Management review

At St Elsewhere's the annual management review is crucial part of a quality management system of the laboratory. It sets overall objectives for the following year and within the laboratory they 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.

ISO 15189:2003 – PRAKTIČNO SREDSTVO ZA UPRAVLJANJE KVALITETOM U MEDICINSKIM LABORATORIJAMA

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Kratak sadržaj: Diskutovani su zahtevi ISO 15189:2003 u vezi procesa i ishoda modela upravljanja kvalitetom, a u odnosu na potrebe korisnika. Zahtevi standarda ISO 15189:2003 preispitivani su u odnosu na organizaciju i sistem menadžmenta kvalitetom a težište je stavljeno na značaj dokaza, kontrolu dokumenta i zapisa i klinički materijal. Izneti su primeri iz oblasti menadžmenta, kao i procesa pre-ispitivanja, ispitivanja i post-ispitivanja. U poslednjem delu ukazano je na značaj evaluacije i stalnog poboljšanja u odnosu na unutrašnju i spoljašnju kontrolu kvaliteta, neusaglašenosti, korektivne i preventivne mere i preispitivanje menadžmenta.

Ključne reči: menadžment kvalitetom, proces, procedure, provera, stalno poboljšanje, preispitivanje menadžmenta

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