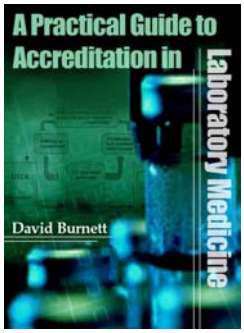
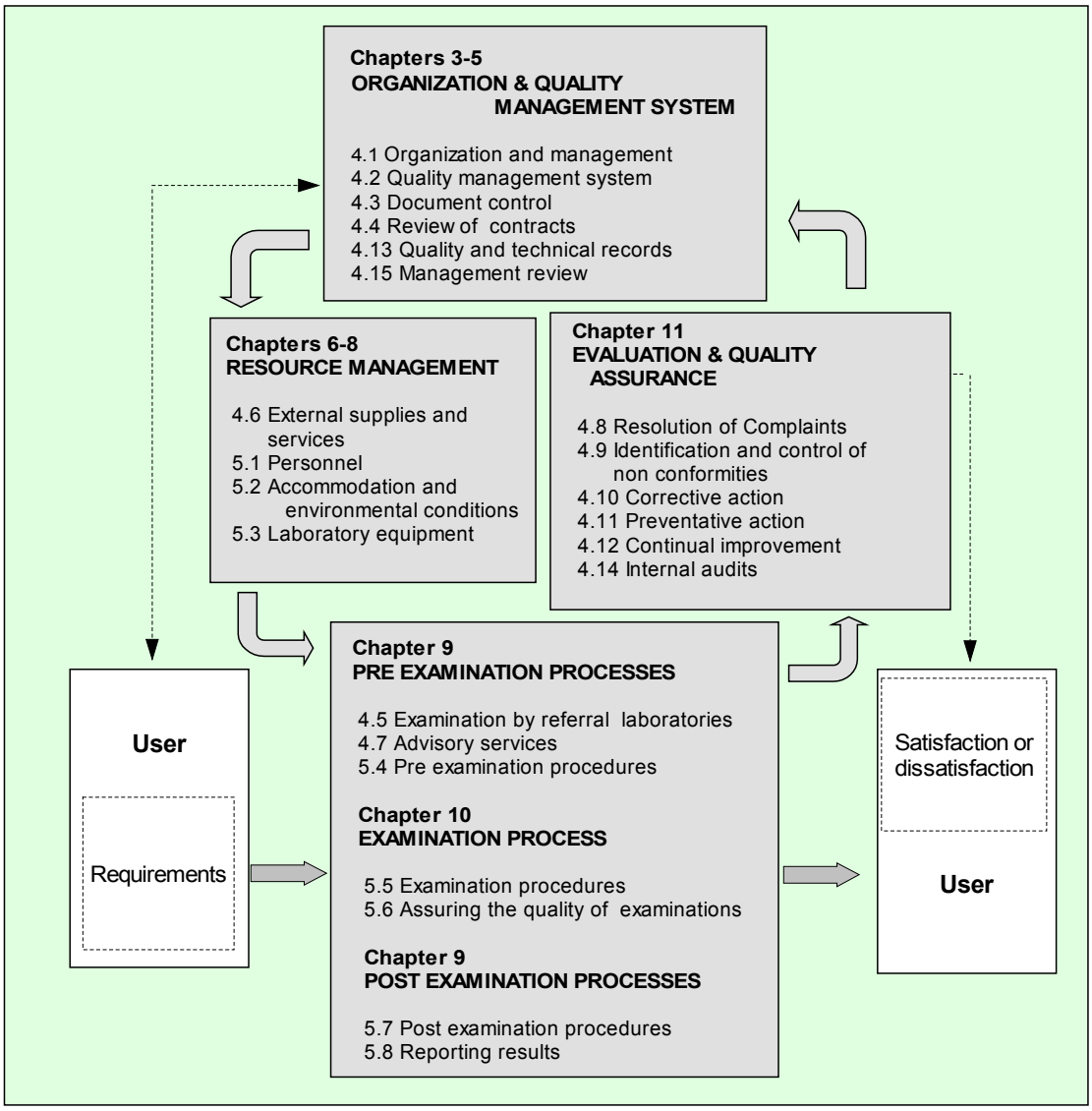
A companion to 'A Practical Guide to Accreditation in Laboratory Medicine' for use with ISO 15189:2003 Medical laboratories-Particular requirements for quality and competence'

A Practical Guide to Accreditation in Laboratory Medicine David Burnett
ACB Venture Publications September 2002
ISBN 0 902429 39 6 (www.acb.org.uk)



This document is intended as a companion to my book for laboratories looking for ideas on how to implement **ISO 15189:2003 Medical laboratories-Particular requirements for quality and competence**. It provides a cross reference of useful figures in my book 'A Practical Guide to Accreditation in Laboratory Medicine' to the relevant clauses of ISO 15189:2003.

My book is structured on a process based quality management system for a medical laboratory and the figure below is adapted from Figure 3.5 in the book and shows the main clauses of ISO 15189:2003 and the corresponding chapters in my book



This model can be viewed in two different ways.

1. User requirements are formulated in consultation with laboratory management *Organisation and quality management system* and are then expressed as requests to the laboratory. The laboratory responds by carrying out pre-examination, examination and post-examination processes *Pre examination process, Examination process, Post examination process)* and produces a report for the user. Depending on whether requirements have been met or not, users may be defined as 'satisfied' or 'dissatisfied'.

2. A process model in which laboratory management *(Management responsibility)* 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 process, Examination process, Post examination process)* to fulfil the requirements of the user. The pre-examination, examination and post-examination processes are continually evaluated and improvements made as appropriate *(Evaluation and quality assurance).* Evaluation and continual improvement activities would include for example, assessment of users requirements, internal audit of the examination processes and review of participation in external quality assessment schemes.

The following table provides cross references between the clauses of ISO 15189:2003 and relevant chapters and figures from 'A Practical Guide to Accreditation in Laboratory Medicine'. Some figures in my book provide the content headings for procedures that have been used in the fictional laboratory at St Elsewhere's Hospital Trust. These figures are indicated in bold script.

Clause of ISO 15189:2003	Chapter or figure in 'A Practical Guide to Accreditation in Laboratory Medicine'
4 Management requirements	
4.1 Organisation and management	Figure 6.15 Responsibilities of a laboratory director Figure 6.16 Good standards of laboratory and clinical practice --- **Figure 4.2 Contents page of the procedure for the management of pathology**
4.2 Quality management system	Figure 3.8 Building a quality management system Figure 3.10 The sequence of action in quality management Figure 4.4 Evidence of compliance with attributes or characteristics of a laboratory Figure 5.2 General requirements of a quality management system --- Figure 4.10 Purposes of a quality manual Figure 4.11 Quality manual-front page Figure 4.12 Quality manual-contents page Figure 4.13 Quality manual-general information Figure 4.14 Quality manual-quality policy Figure 4.15 Quality manual-relationship of the Pathology Laboratory to St Elsewhere's Hospital Trust Figure 4.15 Quality manual-relationships within the pathology laboratory Figure 5.4 Quality manual-the quality management system --- Figure 4.5 Content of a quality policy Figure 4.6 Quality policy of the laboratory of St Elsewhere's Hospital Trust --- Figure 4.8 CPA(UK)Ltd Standard A7 Quality manager

Clause of ISO 15189:2003	Chapter or figure in 'A Practical Guide to Accreditation in Laboratory Medicine'
4.3 Document control	Figure 5.3 Hierarchy of documentation Figure 5.5 Organisation of procedures Figure 5.6 Requirement for document control **Figure 5.7 Contents of a procedure for preparation and control of documents** Figure 5.8 Steps in the document preparation and control process Figure 5.9 Document identification-informative filenames Figure 5.10 Document identification required on each page Figure 5.11 Procedure content-introduction Figure 5.12 Content of a document amendment form Figure 5.13 Label for a document from an external source Figure 5.14 Functions of a document register
4.4 Review of contracts	Figure 4.3 Attributes or characteristics of a laboratory Figure 4.4 Evidence of compliance with attributes or characteristics of a laboratory Figure 4.5 Content of a quality policy
4.5 Examination by referral laboratories	**Figure 9.14 Contents of a procedure for specimen reception** Figure 9.15 Requirements for referral laboratories
4.6 External supplies and services	**Figure 8.14 Management and use of consumable IVDs** Figure 8.15 Data items for stock control system of consumable IVDs
4.7 Advisory services	Figure 9.20 NPAAC Standard 2 – Staffing, supervision and consultation --- Figure 9.6 Contents of a pathology user's handbook Figure 9.8 Examining the body after death-information for relatives about post-mortems Figure 9.22 Consent for phlebotomy-alternative uses
4.8 Resolution of complaints	Figure 11.9 Completed form for registering complaints
4.9 Identification and control of nonconformities	See Examination procedures
4.10 Corrective action	Figure 11.2 Definitions in relation to evaluation and quality improvement
4.11 Preventative action	Figure 11.2 Definitions in relation to evaluation and quality improvement
4.12 Continual improvement	Figure 11.2 Definitions in relation to evaluation and quality improvement **Figure 11.3 Contents of the procedure for the management of evaluation and quality improvement** --- Figure 11.17 Cycles of continual improvement Figure 11.19 Partially completed form for recording nonconformities
4.13 Quality and technical records	**Figure 5.15 Contents of a procedure for control of records** Figure 5.17 Retention of management and quality records Figure 5.18 Retention of examination records Figure 5.19 Forms into records Figure 5.20 Partially completed minutes for St Elsewhere's Pathology Management Board --- **Figure 9.21 Contents of a procedure for control of clinical material** Figure 9.23 Retention of clinical material form
4.14 Internal audits	Figure 11.5 Methods of audit Figure 11.6 An audit schedule Figure 11.7 The steps to be taken in conducting an audit (Q-pulse) ---

Clause of ISO 15189:2003	Chapter or figure in 'A Practical Guide to Accreditation in Laboratory Medicine'
	Figure 11.4 Content of EA-4/04, 'Internal audits and management review for laboratories' Figure 11.10 Vertical audit of examination processes Figure 11.11 The vertical audit form (examination processes) Figure 11.12 Witness audit form
4.15 Management review	Figure 11.4 Content of EA-4/04, 'Internal audits and management review for laboratories' Figure 11.20 Inputs to the management review Figure 11.21 Conduct of the annual management review
5 Resources and technical requirements	
5.1 Personnel	Figure 6.2 The involvement of people in the work of an organisation **Figure 6.3 Content of a procedure for personnel management** Figure 6.4 Completed person specification form Figure 6.5 Terms and conditions of employment Figure 6.8 Categories of information for new employees Figure 6.6 Functions of a job description Figure 6.7 Job description for a Medical Laboratory Assistant in Haematology Figure 6.7 continued. Job description for a Medical Laboratory Assistant in Haematology Figure 6.14 The staff record --- Figure 6.10 Benefits of an annual joint review Figure 6.11 Annual joint review-a cycle of continual improvement Figure 6.12 Annual joint review form Figure 6.12 continued. Annual joint review form Figure 6.13 Annual joint review-agreed action points --- Figure 6.17 Partially completed training record
5.2 Accommodation and environmental conditions	Figure 7.2 ISO 15189:2002 clause 5.2 Accommodation and environmental conditions Figure 7.3 Physical aspects of premises in relation to health and safety Figure 7.4 Separation of incompatible activities Figure 7.5 CPA(UK)Ltd Standard C2-Facilities for staff Figure 7.6 Staff accommodation requirements Figure 7.7 Patient facilities-guidance for premises and equipment Figure 7.8 Information for visiting the laboratory Figure 7.9 NPAAC Blood Bank and Transfusion Services-Cold Storage --- Figure 7.11 The provisions of ISO/DIS 15190 Medical laboratories-requirements for safety management Figure 7.12 Main principles of the Directive 89/391/EEC on health and safety **Figure 7.14 Content of a procedure for the organisation and management of health and safety** Figure 7.15 The health and safety policy of St Elsewhere's Hospital Trust Figure 7.16 The role of a laboratory safety officer Figure 7.17 Contents of the Health and Safety handbook at St elsewhere's laboratory Figure 7.18 Model rules for laboratory office staff Figure 7.19 Five steps to risk assessment Figure 7.20 Categories of reportable incidents

Clause of ISO 15189:2003	Chapter or figure in 'A Practical Guide to Accreditation in Laboratory Medicine'
	Figure 7.21 An exercise in 'good housekeeping'audit Figure 7.22 Use of display screen equipment-'What can I do to help myself?'
5.3 Laboratory equipment	Figure 8.3 IVD Directive-some key requirements for the manufacture Figure 8.4 Purpose of equipment procurement and management **Figure 8.5 Contents of a procedure for the procurement and management of IVDs** Figure 8.6 Procurement of IVDs form Figure 8.6 continued. Procurement of IVDs form Figure 8.7 Requirements for the contents of a User Manual Figure 8.8 Management of IVDs-Training Figure 8.10 Form for declaration of contamination status and authorisation to work Figure 8.11 Adverse incident reporting form Figure 8.11 continued. Adverse incident reporting form Figure 8.12 Purpose of an equipment inventory Figure 8.13 Contents of an equipment IVD inventory
5.4 Pre-examination procedures	Figure 9.6 Contents of a pathology user's handbook Figure 9.8 Examining the body after death-information for relatives about post-mortems Figure 9.22 Consent for phlebotomy-alternative uses --- Figure 9.20 NPAAC Standard 2 – Staffing, supervision and consultation --- Figure 9.9 Rationale for information required on a completed request form Figure 9.10 The general request form for biochemistry, haematology and microbiology --- Figure 9.11 WHO 'Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens'-contents **Figure 9.14 Contents of a procedure for specimen reception** Figure 9.22 Consent for phlebotomy-alternative uses
5.5 Examination procedures	Figure 10.2 Evidence and diagnostics-where do we go from here? Figure 10.3 The need for analytical goals of performance Figure 10.4 Hierarchy of models to be applied to set analytical quality specifications Figure 10.5 Techniques to be used to determine performance of a method --- Figure 10.6 ISO:15189 Content of examination documentation Figure 10.7 requirements for 'information supplied by manufacturers with in vitro diagnostic reagents' Figure 10.8 Determination and assessment of risk of hazardous chemical reagents Figure 10.9 Partially completed COSHH assessment form Figure 10.9 continued, Partially completed COSHH assessment form Figure 10.10 Hazards and precautions panel from a laboratory procedure Figure 10.11 General rules for the preparation of procedures, instructions and forms Figure 10.12 SCENARIO 1 – Documentation for the BHM Analyser Figure 10.13 Process diagram for a routine H & E stained section Figure 10.14 SCENARIO 2 – Documentation for a routine H&E stained section Figure 10.15 Headings for the Feulgen-Scheff reaction Figure 10.16 Action to be taken to adopt procedures/documents from an outside source Figure 10.17 SCENARIO 3 – Documentation for a routine urine investigation

Clause of ISO 15189:2003	Chapter or figure in 'A Practical Guide to Accreditation in Laboratory Medicine'
	Figure 10.18 Definition of internal quality control Figure 10.19 Procedure for the management of POCT
5.6 Assuring the quality of examination procedures	Figure 11.13 Definition of external quality assessment Figure 11.14 External quality assessment schemes-process **Figure 11.15 Contents for a procedure for the management of participation in external quality assessment schemes** Figure 11.16 Form for recording participation in external quality assessment schemes
5.7 Post-examination process	As clause 5.8 below
5.8 Reporting results	Figure 9.18 The Caldicott principles Figure 9.19 Release of pathology results to patients Figure 9.16 The report content Figure 9.17 CPA(UK)Ltd , standard G3 The telephoned report
Annex B (informative) Recommendations for protection of laboratory information systems (LIS)	Figure 8.16 Use of computers in the pathology laboratory **Figure 8.18 Contents of a procedure for the management of data and information** Figure 8.20 Good practices in software management Figure 8.21 Nine principles of data security