



AQMLM – An Historical Perspective

**Jonathan Middle BA MA PhD ALCM
Chair AQMLM**

A Potted History of Quality Standards ...

BS 5750:1979

In the 1970's many major organizations published their own quality management standards (eg Ford's Q101, the Ministry of Defence's 05-20 series, etc.) which introduced the idea that confidence in a product could be gained from an approved quality management system and quality manuals.

By the late 70's it was decided that, for the first time, there would be a national standard on what constituted a quality system. BS5750 was developed from the earlier BS5179 guidelines but was firmly based around Ministry of Defence (MoD) requirements and terminology.

But



British Standard (BS) 5750 - quality assurance?



[View as PDF](#)

with original layout

D. J. Pratt *

Abstract

BS5750 is the British Standard on "Quality Systems". Its equivalent in European Standards is EN29000 and in the International Standards Organisation ISO9000. This paper points out that these standards lay down formalised procedures and require documentation but do not *ipso facto* lead to quality assurance.

The author points to the Japanese post-war industrial success as being an example of Total Quality Management within the framework provided by the philosophy of Dr. W. Edwards Deming (1988 and 1993). This philosophy on the management of "systems" to provide high quality products and services is briefly outlined.

The author argues that improvement in prosthetic and orthotic services will not be reached through implementation of BS5750 but rather through radical rethinking and the adoption and application of the Deming philosophy.

ISO 9000 series

Emergence of ISO 9000.

- **1987:** Building on BS 5750, the International Organization for Standardization published the first version of the ISO 9000 series. This included ISO 9000, ISO 9001, ISO 9002, and ISO 9003 standards, each focusing on different aspects of quality management systems and applicable to different types of organizations

Evolution and Revisions

- **1994:** The ISO 9000 series was revised to improve clarity and reflect more contemporary quality management practices. However, the structure of multiple documents (ISO 9001, ISO 9002, ISO 9003) remained.
- **2000:** A significant overhaul combined ISO 9001, ISO 9002, and ISO 9003 into a single standard, ISO 9001:2000. This revision introduced a process approach to quality management and emphasized continuous improvement and customer satisfaction.
- **2008:** Minor revisions were made to ISO 9001:2008 to clarify existing requirements and improve compatibility with other management standards.
- **2015:** ISO 9001:2015 was released, featuring a high-level structure (HLS) to align with other ISO management system standards, a stronger emphasis on risk-based thinking, and more focus on leadership and organizational context.

ISO 15189

From: IBMS Article, 5th March 2017 IS YOUR LAB READY?
Julie Russell, Head of Culture Collections at Public Health England

ISO 15189 took seven years to develop and was published in 2003. It was revised and republished in 2007 and 2012. By 2013, it had been adopted by accreditation bodies in over 60 countries.

The key principles of ISO 15189:2012 were that the laboratory management must have a clear remit and responsibility to manage all aspects of the work of the laboratory, they must know who the users (customers) are and what they need, and they must provide a physical environment that is appropriate for the laboratory workers and the tests they undertake.

The laboratory must be able to demonstrate a clear understanding of what the service should be achieving (specification, standards); clear evidence of how assurance is being achieved (key indicators, measurements), and there must be clear consequences if assurance is not provided (corrective actions).

We all know that ISO 15189 was revised again in 2022, with its enhanced requirements for medical laboratories to plan and implement actions to address risks, especially risks to the patients, and opportunities for improvement. It now incorporates ISO 22870 on POCT.

A Potted History of Laboratory Accreditation

Clinical Pathology Accreditation (CPA)

Clinical Pathology Accreditation (CPA) (UK) Ltd was established in 1992 as a not-for-profit organization with the goal of improving the quality of clinical pathology services in the UK through a structured accreditation process. CPA provided a framework for laboratories to assess their services against established standards, ensuring high-quality patient care and compliance with regulatory requirements.

It was co-owned by The Royal College of Pathologists (RCPth), Institute of Healthcare Management (IHM), Institute of Biomedical Science (IBMS), Association of Clinical Pathology (ACP), Association of Clinical Biochemistry (ACB)

However, in 2003, its standards were revised ...

Clinical Pathology Accreditation (CPA)

J Clin Pathol. 2002 Oct; 55(10): 729–733. doi: 10.1136/jcp.55.10.729

Clinical pathology accreditation: standards for the medical laboratory
D Burnett, C Blair, M R Haeney, S L Jeffcoate, K W M Scott,⁵ and D L Williams

This article describes a new set of revised standards for the medical laboratory, which have been produced by Clinical Pathology Accreditation (UK) Ltd (CPA).

The original standards have been in use since 1992 and it was recognised that extensive revision was required. A standards revision group was established by CPA and this group used several international standards as source references, so that **the resulting new standards are compatible with the most recent international reference sources.**

The aim is to make the assessment of medical laboratories as objective as possible in the future. CPA plans to **introduce these standards in the UK in 2003** following extensive consultation with professional bodies, piloting in selected laboratories, and training of assessors.

Clinical Pathology Accreditation (CPA)

J Clin Pathol. 2002 Oct; 55(10): 729–733. doi: 10.1136/jcp.55.10.729

Clinical pathology accreditation: standards for the medical laboratory

D Burnett, C Blair, M R Haeney, S L Jeffcoate, K W M Scott,⁵ and D L Williams

CONCLUSIONS

The original CPA standards have now been in use for nearly 10 years and have proved to be a major influence in laboratory medicine in the UK. However, over the years anomalies have arisen in the interpretation of the standards, leading to some inconsistency at the time of inspection.

The revision of the standards that has now been done **aims to make compliance unequivocally verifiable at assessment**, in addition to bringing them into line with the new ISO standards. In particular, the emphasis in the new standards is on the operation of a quality management system in laboratories and the authors believe that **compliance with these standards will also ensure compliance with ISO standards ISO 15189, ISO 17025:1999, and ISO 9001:2000.**

This will enable departments in the UK, and others who choose to use these standards, to have an accreditation that is recognised throughout the European Community. The detailed cross referencing of the standards to the ISO documents reinforces this point.

UKAS take-over of CPA

In 2009, the United Kingdom Accreditation Service (UKAS), the national accreditation body recognized by the UK government, took over the operations of CPA.

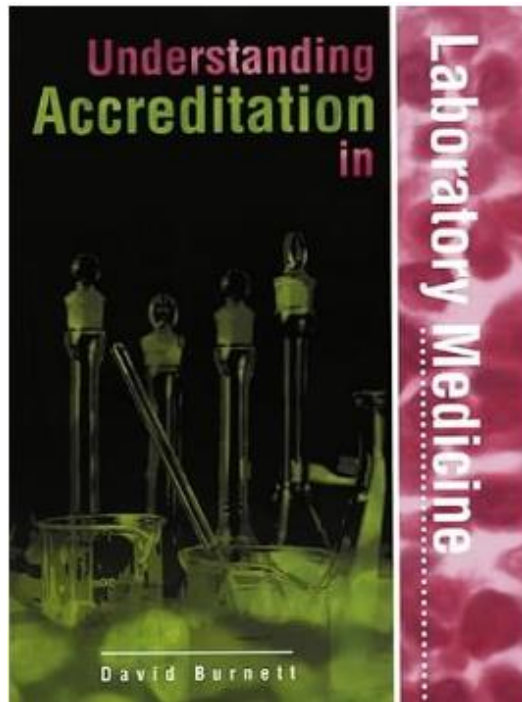
This takeover aimed to integrate CPA's specialized accreditation services into the broader accreditation framework provided by UKAS, enhancing the robustness and international recognition of the accreditation process for clinical pathology services.

The UKAS role was reinforced by the 2012's Barnes Review, commissioned following an incident in which serious negative outcomes for patient care were attributed to problems with quality assurance of laboratory results and inadequate governance processes.

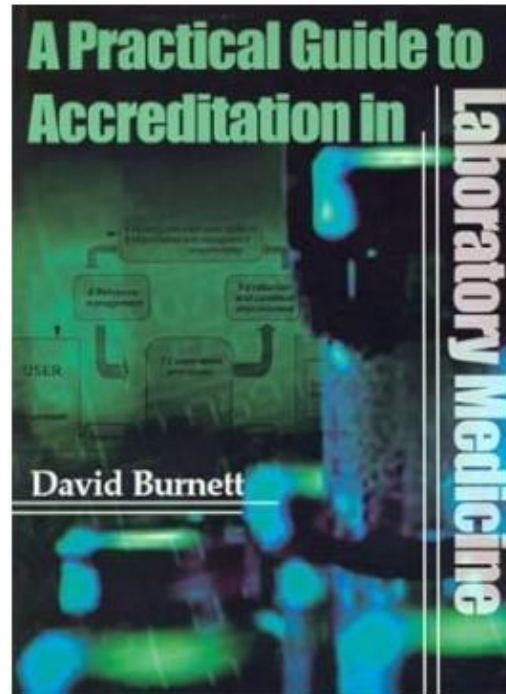
The contribution of Dr David Burnett OBE to the Accreditation of Laboratory Services

We must acknowledge David Burnett's hugely significant contribution to the writing of CPA and ISO standards and his highly influential books on accreditation.

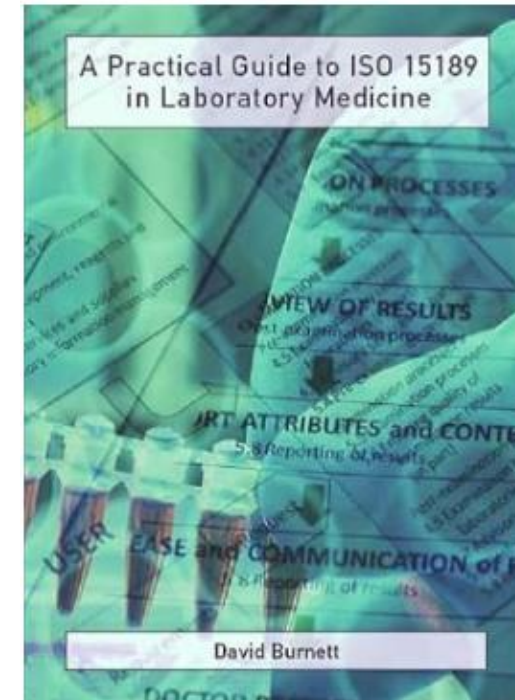
1996



2002



2013



WMCLQMA – the precursor to AQMLM

West Midlands Clinical Laboratory Quality Managers Association – WMCLQMA

- This organization, led by Dr Richard Daw assisted by Alan Dench and Jonathan Middle, started in 2003. It brought together quality managers from across the West Midlands – a very large area
- It held a number of very successful, well attended meetings
- It is still going, although, like many organisations, its activities were curtailed by COVID
- It was from this group that AQMLM emerged



Pathology Quality Managers Networking Meeting

jointly organised by the
West Midlands Clinical Laboratory Quality Managers Association
East of England Pathology Quality Managers
East Midlands Pathology Quality Managers

Thursday 5th June 2008 : 9.30 am – 3.30pm
▲ **Sunley Management Centre, Northampton University, Northampton**

- | | |
|----------------------|---|
| 09.30 – 10.00 | <i>Registration and refreshments</i> |
| 10.00 – 10.30 | Welcome Respective Chairs of the three groups |
| 10.30 – 11.30 | <u>GMP</u> : Practical implications for the clinical pathology laboratory
Barbara Morris. Watermark Quality Consultants Ltd |
| 11.30 - 11.45 | <i>Questions and comfort break</i> |
| 12.00 – 13.00 | Round Table Discussion with Phil Shread, CPA Regional
Assessment Manager, West and Wales. |
| 13.00 – 14.00 | <i>Networking Lunch</i> |
| 14.00 – 14.45 | <u>Human Tissue Act</u> : Practical advice following HTA Licence
inspection, Barbara Lloyd, Addenbrooke's NHS Foundation Trust |
| 14.45 – 15.15 | <u>Root Cause Analysis</u> : Richard Edgeworth |
| 15.15 | <i>Tea</i> |
| 15.30 – 16.00 | Business Meetings for participating groups
Re-launch of East of England Group |

Uncertainty and the Future

9:30	Coffee & Registration	
10:30	Introduction	Richard Daw (Chairman)
10:40	SESSION 1 <i>Implementing Uncertainty – A practical approach!</i>	Dietmar Stöckl SST Consulting Belgium
11:20	<i>The Electronic Health Record - Implications for Quality Management?</i>	Rick Jones Associate Clinical Director NPFIT
12:00	Discussion	
12:20	Lunch & networking	
13:20	SESSION 2 <i>Corrective & Preventive Action – A practical guide</i>	Andrew Dowall IRCA Certified QMS2000 Lead Auditor
14:00	KEYNOTE Lecture <i>Laboratory Quality Management after Darzi & Carter</i>	Ian Barnes National Clinical Director for Pathology
14:40	Discussion	
15:00	Analytical & Process Quality <i>A National Initiative - Introduction</i> <i>Presentation</i>	Jonathan Middle UK NEQAS (Birmingham) David Burnett Consultant in Quality & Accreditation Systems
15:30	Drinks Reception & Finish	

The Beginning of AQMLM

15:00	Analytical & Process Quality <i>A National Initiative - Introduction</i> <i>Presentation</i>	Jonathan Middle UK NEQAS (Birmingham) David Burnett Consultant in Quality & Accreditation Systems
-------	---	---

Article for ACB News 17th April 2009 - 1

Since the advent of CPA(UK)Ltd and ISO 15189, process quality management has become a burgeoning activity throughout laboratory medicine. Quality Managers have been appointed and quality management systems initiated, in order to fulfil CPA and ISO requirements for document control, internal audit, corrective and preventive action and continuous quality improvement.

Alongside this increase in **process** quality management activity, there appears to have been less emphasis on **analytical** quality management, for example, understanding the concepts of measurement traceability and uncertainty in the numeric disciplines. Analytical accuracy may be assumed despite the wide differences in results observed between methods, and the limitations of assays are not appreciated by consumers of laboratory services.

In order to bring practitioners together for mutual support and sharing of experience, a number of informal regional groups have emerged. One of these – the **West Midlands Clinical laboratory Quality Managers Association (WMCLQMA)** has been in existence since 2003, and during that time has held a number of successful Workshops and Symposia. The feedback from these has demonstrated that many staff involved in quality need support and encouragement from colleagues in the wider community.

Article for ACB News 17th April 2009 - 2

At the **WMCLQMA Spring Symposium** on **27th March 2009**, a new national organisation – the **Association for Quality Management in Laboratory Medicine – AQMLM** – was launched.

- AQMLM has the principal objectives of enhancing the role of all those engaged in process and analytical quality throughout all disciplines of laboratory medicine
- AQMLM will be led by a team of four individuals with extensive experience in analytical and process quality: Jonathan Middle (Chair), Richard Daw, Alan Dench and Jane French
- David Burnett OBE has agreed to be Honorary President of AQMLM
- The principal activities of AQMLM will be regular workshops and symposia and the development of educational materials in analytical and process quality
- Members of AQMLM may be individuals or local/regional groups who have any kind of quality role in laboratory medicine, whether this is formal - quality manager, quality officer, EQA Organiser/manager – or informal, for example those developing and/or evaluating methods in a laboratory or the diagnostic industry
- Registration is by submission of a simple form on the AQMLM website and payment of a modest fee, which will secure special rates and pre-registration for AQMLM's activities
- AQMLM is non-profit and will evolve in accordance with the wishes of its members and the role of the emerging speciality of quality management in laboratory medicine

The Inaugural Symposium

AQMLM Symposium 2009 30th November 2009 Austin Court, Birmingham

Programme

<i>09:30</i>	<i>Coffee & Registration</i>	
10:00	Quality in Laboratory Medicine - its definition and management	David Burnett
10:40	Measuring and improving quality across the request-report cycle	Jonathan Kay
11:20	User verification of performance	Zahra Khatami
12:00	Free discussion	
<i>12:20</i>	<i>Lunch, sponsors & networking</i>	
13:20	LEAN applied to specimen reception	David Ricketts
14:00	A non-numeric discipline's approach to traceability	Jo Sheldon
14:40	Assessing the quality of interpretation	Jane French
15:20	Free discussion	
<i>15:50</i>	<i>Tea, sponsors & networking</i>	
16:20	AQMLM members' Forum – planning the future	Jonathan Middle
<i>17:00</i>	<i>Close & departure</i>	

The Inaugural Symposium 03/11/2009



The Inaugural Symposium



Richard Daw, Alan Dench, Jane French, Jonathan Middle
the original Directors



Jonathan Kay, Zara Khatami, David Burnett



David Ricketts, Jane French

Subsequent Annual Symposia

Symposium 2010

AQMLM Symposium 2010

22nd November 2010

Austin Court, Birmingham

Good Practice in the Clinical Laboratory

Programme

09:50 - Arrival, registration & coffee

10:30 - Honorary President's Introduction: **David Burnett** - "Good x Practice *et al*"

Session 1 - "Good Practice at the clinical interface"

10:50 **Stuart Smellie** - "Moving quality onward through demand control and best practice"

11:30 **Danielle Freedman** - "Enhancing clinical best practice and adding value through interpretative reporting"

12:10 First Discussion period

12:30 Lunch

Session 2 - "Good Practice where a product is involved"

13:10 **Joan Jones** - "GMP - the Nuts & Bolts"

13:50 **Tony Coates** - "GMP in the Hospital Transfusion Laboratory"

14:30 Second Discussion period

14:50 Tea

Session 3 - "Good Practice in clinical laboratory analysis"

15:10 **Robert Hill** - "Laboratory Medicine Good Practice – You know it when you see it, but how can we embed it in the UK?"

15:50 **Permitt Wilson** - "Applying Laboratory Medicine Good Practice: Barriers and Benefits"

16:30 Third Discussion period

16:50 **AQMLM Members' Forum**

17:30 Close & departure

Symposium 2011

AQMLM Symposium 2011

7th November 2011

Austin Court, Birmingham

“Quality and Patient Safety”

Programme

10:00 *Arrival, registration & coffee*

10:20 **Professor Mario Plebani** "Quality and Patient Safety"

11:00 **David Burnett OBE** "Quality Indicators in the Medical Laboratory – pros & cons"

11:40 **Derek Truman** "Results of the AQMLM Quality Indicators Survey"

12:15 **Neil Formstone** "The Patient's Perspective"

12:45 *Lunch*

13:30 **AQMLM Member's Forum**

14:10 **Lance Sandle** "Assessment of Clinical Competency"

14:50 **Osama Ammar** "Assessment of Scientific Competency"

15:30 *Tea*

16:00 **Panel Discussion** "How do we assess Managerial Competency?"

16:45 *Close*

Symposium 2011



Lance Sandle, Derek Truman

Osama Ammar, David Burnett, Mario Plebani

Symposium 2013

AQMLM Symposium 2013

19th March 2013

Austin Court, Birmingham

“Diagnostic Conundrums – Where Laboratory Medicine Really Matters”

Programme

10:30 Arrival, registration & coffee

11:00 'Allergy diagnosis - no longer an art but a science.'

Dr Alex Richter (Birmingham)

11:40 'Finding the "bugs" using EQA!'

Mrs Shân Lloyd (Colindale)

12:20 Discussion / Q&A

12:30 Lunch & networking

13:30 'Haemoglobinopathy diagnosis: still a challenge after all these years.'

Barbara de La Salle (Watford)

14:10 'Insulin assays and their clinical use.'

Dr Gwen Wark (Guildford)

14:50 'The Impact of Quality on Genetic Testing'

Dr Andrew Purvis (Edinburgh)

15:30 Discussion / Q&A

15:50 Tea & networking

16:20 AQMLM Members' Forum

17:00 Close & Departure

Symposium 2014

AQMLM Symposium

"Impact of the Barnes Review on Quality Management"

Wednesday 12th November 2014, Birmingham Research Park, B15 2SQ

This Symposium focuses on how implementation of the Review's recommendations will affect the training, development and everyday lives of Quality Managers and Leads in all disciplines of Laboratory Medicine.

Programme

09:00		<i>Arrival, registration & coffee</i>
09:50	Dr Jonathan Middle	Introduction to the day
10:00	Dr Ian Barnes	Quality Review: implementation & expectations
10:30	Mr John Ringrow (UKAS)	Impact on the Quality Management Team preparing for ISO 15189 assessment
11:10	Dr Peter Cowling (RCPath)	CQI: changing the culture in Pathology
11:50	Ms Debra Padgett (IBMS)	Delivering the Pathology Quality Review - the Quality Manager's perspective
12:30		<i>Buffet lunch & networking</i>
13:30	Professor Eric Kilpatrick	Engaging patients by directly providing advice on laboratory test results
14:10	Professor Tim Reynolds	The enhanced Joint Working Group
14:50	Mr Finlay MacKenzie	EQA results in the public domain
15:30		<i>Tea & networking</i>
16:00	Dr Jonathan Berg	Key strategies for using social media in the clinical laboratory
16:40		<i>Close & departure</i>

During 2015-2019, we changed from Annual Symposia to holding around four Networking Events, which comprised a whole day of presentations from experts on quality management issues.

Networking Events 2015 - 2019

"Audit Theory & Practice"	10-Mar-15
"Psychology of Laboratory Medicine"	12-May-15
"Quality Management for the Non-numeric Disciplines"	14-Jul-15
"Information Management"	10-Nov-15
"Effective EQA Management"	08-Mar-16
"Quality Management of POCT"	08-Jun-16
"UKAS Assessments - Lessons learnt So Far"	06-Sep-16
"Pre- and Post-Analytical KPIs"	06-Dec-16
"Training & Competency"	14-Mar-17
"Audit of Errors & Incidents"	13-Jun-17
"Quality Management of New Technologies"	19-Oct-17
"Quality Management of Screening Assays"	12-Dec-17
"The Challenge of Multi-site Quality Management"	13-Jun-18
"Audit Theory Seminar"	11-Sep-18
"Audit Practice Workshop"	12-Oct-18
"Change & Risk Management Workshop"	12-Dec-18
"There's More to Quality Management than Accreditation"	12-Sep-19

We regularly promoted AQMLM by having a small stand at the IBMS Congress Exhibitions

AQMLM at IBMS 2011, 2013, 2015, 2017, 2019 & 2023



The COVID Pandemic stopped us from holding face-to-face Networking events, so we converted to regular Zoom meetings, which have been a major feature of our activities for over four years

Zoom meetings 2020 – 2021

25th Jun 2020	UKAS Accreditation During the COVID-19 Crisis
16th Jul 2020	Creating a COVID-19 Secure Work Environment
10th Aug 2020	Maintaining a Competent Workforce
09th Sep 2020	EQA Q&A
21st Sep 2020	EQA Q&A Follow-up
09th Oct 2020	Validation & Verification
11th Nov 2020	Adding Value for the Patient
08th Dec 2020	Setting Quality Specifications Based on Biological Variation
14th Jan 2021	De-mystifying Measurement Uncertainty
05th Feb 2021	Evaluating Assay Performance Characteristics
08th Mar 2021	Pathology Quality Assurance Dashboard Update
07th Apr 2021	Diagnostic Sensitivity & Specificity, Prevalence and Predictive Value
10th May 2021	Quality Challenges in Genomics, Cell Path Technique & Blood Products
22nd Jun 2021	Preanalytical Quality Challenges
15th Jul 2021	Implications of Pathology GIRFT on Total Quality Management in Pathology
07th Sep 2021	Future of COVID-19 testing
20th Oct 2021	The Quality Management of Serum Indices (HIL)
25th Nov 2021	Harmonisation of Reference Ranges and Minimum Testing Intervals

Zoom meetings 2022 – 2024

25th Jan 2022	SOP Writing Masterclass	
23rd Mar 2022	Internal Audit Masterclass	
26th Apr 2022	Quality Management of Testing Outside the Laboratory	
23rd May 2022	Artificial Intelligence in the Laboratory	
21st Jun 2022	Validation & Verification Re-visited	
23rd Aug 2022	Training & Competency re-visited	
28th Sep 2022	Internal Audit Masterclass - follow up	
26th Oct 2022	Getting the most out of your EQA reports	16th Jan 2024 "Risk-Based Thinking"
25th Nov 2022	Quality Management of Risk Assessment	14th Feb 2024 "Ensuring Customer Satisfaction"
10th Jan 2023	Harmonisation of results & units – benefits & risks	14th Mar 2024 "Staff Quality Engagement from Day 1"
15th Feb 2023	Result interpretation - is the quality good enough?	14th May 2024 "Quality Management & Precision Medicine"
16th Mar 2023	Change control - are we getting it right?	13th Jun 2024 "Getting Maximum Value from your EQAS"
18th Apr 2023	Testing outside the laboratory re-visited	17th Sep 2024 "Using Audit to drive performance enhancement"
17th May 2023	Does Genomics need better quality management?	14th Nov 2024 "ISO 15189:2022 Two Years On+
31st May 2023	Special meeting on ISO15189:2022	
15th Jun 2023	Managing the quality of non-numerical tests	
11th Jul 2023	Implementing a Holistic QMS	
13th Sep 2023	Ensuring Data Quality Throughout the Management System	
12th Oct 2023	Are You Still Uncertain about Uncertainty?	
14th Nov 2023	Focus on Post-Analytical Quality	

In July 2024, we celebrated 15 years of AQMLM activities with a two-day online Conference

15 Year Celebratory Conference

Day 1 - 3rd July 2024	
10:00	Dr Jonathan Middle - AQMLM, An historical perspective
10:40	Mr Nigel Coles - Quality Management in Genomic Services
11:20	Mrs Katy Heaney - Quality monitoring in POCT services
12:00	Dr Rachel Marrington - EQA in laboratory medicine and the laboratory's role in ensuring quality
12:40	Discussion
13:00	Close

15 Year Celebratory Conference

Day 2 - 4th July 2024	
10:00	Professor Jonathan Kay - Informatics and Artificial Intelligence
10:40	Dr Bill Bartlett - Biological Variation. Delivering reference data for quality applications
11:20	Professor Brian Keevil - Mass Spectrometry in laboratory medicine
12:00	Ms Doris-Ann Williams - IVD Manufacturers' support for Quality Management
12:40	Discussion
13:00	Close

AQMLM enabled Jonathan Middle to engage in writing and revising BSI and ISO standards

As Chair of AQMLM and as a Fellow of the Association for Clinical Biochemistry (now the Association for Laboratory Medicine), Jonathan Middle became a British Standards Institute CH/212 Committee member and was actively involved in the UK's contribution to the revision of ISO 15189.

BSI recommended him to join ISO TC 212 Working Groups 1 and 2 as the UK Principal Expert in Metrological Traceability, writing and/or revising:

- ISO 15189 (Quality & competence in the medical lab)
- ISO 17511 (Metrological traceability)
- ISO 15193 (Reference method procedures)
- ISO 15194 (Reference materials)
- ISO 15195 (Competence of reference laboratories)
- ISO/TS 20914 (Guide to measurement uncertainty)

**We acknowledge previous Directors who have
contributed so much to AQMLM!**

Mr Gary Collins
Dr Richard Daw
Mr Alan Dench
Mrs Julie Evans
Ms Jayne Fowler
Ms Katy New
Ms Dipa Parekh
Mr Mark Smith
Mr Derek Truman