Illuminating the Path to ISO15189 Accreditation

SLMTA 3

Curriculum Overview

ISO15189

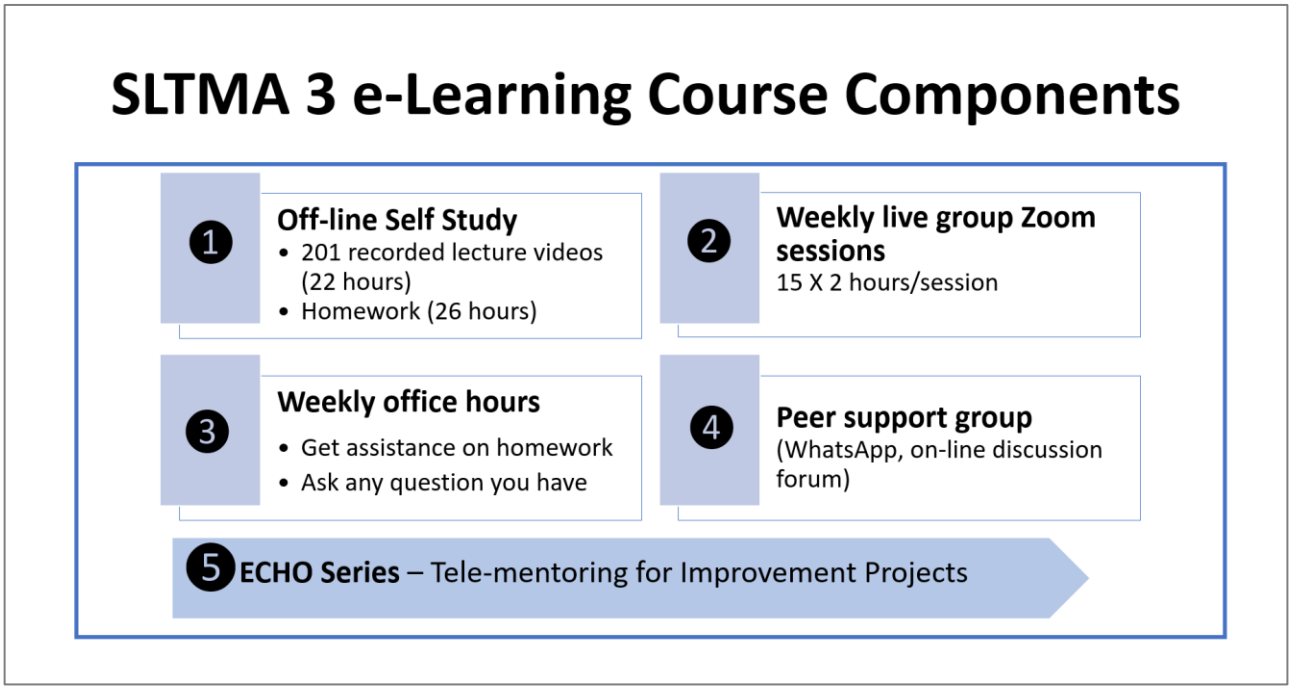
BEYOND THE STARS

SLMTA 3 CURRICULUM AT-A-GLANCE

Cohort 2

The SLMTA 3 curriculum is composed of four modules – QMS 1, QMS 2, QMS 3, and QMS4. Each module is further divided into sections and activities. When repurposing the classroom version of the curriculum for on-line delivery, the following 4 activities have been eliminated: Planning Improvement Projects – Master Class, Reporting Improvement Projects, Conducting a Site Visit, Redesigning The Floor Plan of Your Laboratory, and What's Wrong with this Storeroom. Improvement project planning and implementation will be instead covered in the new ECHO sessions.

The ***on-line version*** includes an off-line/self-study component (lecture recordings and homework assignments) and an on-line/live component, as well as optional office hours and peer support discussion forum. The total time for completing the mandatory components of the on-line curriculum is ***64*** hours, as opposed to 86 hours of delivery time in the classroom based version.



Curriculum Time Breakdown

Classroom-Based vs e-Learning Version

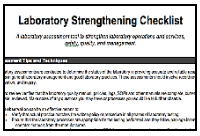
Activity	Classroom-based	e-Learning (in minutes)	
		Self-Study	Live
0.0 Workshop Introduction		6	0
QMS 1 - MANAGEMENT RESPONSIBILITY			
1.0 QMS 1 Overview	-	2	0
1.1 Introduction	0:40	27	0
1.2 Management Tools			
1.2.1 Process Mapping	2:05	55	80
1.2.2 Using the Model for Improvement	2:30	120	40
1.2.3 Managing Performance	2:30	71	90
1.2.4 Creating a Management Calendar	1:25	58	30
1.3 Quality Management System			
1.3.1 Designing a Continuously Improving QMS	2:45	50	25
1.3.2 Designing Fit-for-Purpose Processes	2:05	41	25
1.4 Document and Records			
1.4.1 Introduction to Documentation System		10	10
1.4.2 Documents Process Map	1:15	40	15
1.4.3 Why Was the Outdated Version Used?	1:40	110	15
1.4.4 Records Process Map	1:00	35	15
1.5 Planning and Conducting a Staff Meeting	1:00	30	15
QMS 2 - RESOURCE MANAGEMENT			
2.0 Introduction to QMS 2	-	5	0
2.1 Personnel			
2.1.1 Personnel Management Process Map	1:00	37	15
2.1.2 Competency Assessment Program	1:30	35	20
2.1.3 Creating a Personnel File	1:20	23	25
2.1.4 How Do You Assign Personnel to Tasks?	1:25	14	10
2.2 Infrastructure and Safety			
2.2.1 Process + Structure = Outcome	2:40	86	50
2.2.2 Improving a Problem Floor Plan	0:45	40	15
2.2.3 Mapping-out the Floor Plan of Your Lab	1:30	137	30
2.2.4 Workstation Set-Up	2:00	86	25
2.2.5 Laboratory Safety Demonstrations	0:25	20	0
2.2.6 Assessing Safety Incidents	1:00	22	20
2.2.7 Conducting a Safety Audit	1:35	0	95
2.2.8 What did we see on the Site Visits?	0:45	0	30
2.3 Purchasing and Inventory			
2.3.1 Purchasing and Inventory Process Map	1:00	40	15
2.3.2 Forecasting and Calculating Ordering Amounts	1:15	47	15
2.3.3 Did You Receive What You Ordered?	1:15	28	10

Activity	Classroom-based	e-Learning (in minutes)	
2.4 Equipment			
2.4.1 Equipment Management Process Map	1:35	80	15
2.4.2 Creating a Maintenance and QC Log	2:00	31	10
2.4.3 Making a Service Call	1:00	7	5
QMS 3 - PATH OF WORKFLOW			
3.1 Pre-Examination			
3.1.1 Specimen Management	1:10	0	45
3.1.2 Packaging Specimens for Shipment to Referral Sites	1:30	63	0
3.1.3 Tracking Referral Specimens	1:25	33	60
3.2 Examination			
3.2.1 Overview of Examination Phase		8	0
3.2.2 Using Standard Operating Procedures	1:25	12	10
3.2.3 Is QC That Important?	1:15	53	10
3.2.4 Is There More to QC Than Just Plotting the Data?	1:50	37	10
3.3 Post-Examination			
3.3.1 Validation of Test Results	1:00	29	30
3.3.2 Is the Test Report Ready to be Released?	0:45	15	25
3.3.3 Customer Service	1:00	7	30
3.3.4 Meet the Clinician	1:30	30	65
QMS 4 - EVALUATION & CONTINUAL IMPROVEMENT			
4.0 Overview of QMS 4		4	0
4.1 Occurrence Management			
4.1.1 Overview of Occurrence Management		7	0
4.1.2 Mapping Nonconformities	1:10	47	15
4.1.3 Just Culture	0:50	23	15
4.1.4 Selecting the Winning Problem(s)	2:50	68	25
4.1.5 Root Cause Analysis	7:15	143	155
4.1.6 Preventive Action	2:00	40	30
4.2 Internal Auditing			
4.2.1 Introduction to Internal Audit	2:20	15	10
4.2.2 How to Set-up an Internal Audit Programme	1:50	33	10
4.2.2 Internal Audit Planning and Preparation	4:10	83	20
4.2.4 Internal Audit Methods	1:00	46	25
4.2.5 Audit Techniques and NCE Writing	3:20	53	35
4.2.6 Audit Reporting	1:25	59	20
4.3 Management Review Process			
4.3 Management Review	2:30	52	80
Grand total (hh:mm)	**86:25**	**39:13**	**24:50**

The rest of the document provides further details of each activity contained in this curriculum.

QMS 1
Management Responsibility

Management responsibility requires a commitment to quality and making a quality management system (QMS) a strategic goal. Because a QMS is comprised of numerous interrelated or interacting processes, the standard encourages a process-based approach (i.e. the identification and interactions of these processes and their management). In QMS 1, participants will learn about the process approach and how to manage processes through the use of quality tools.

This part supports the following SLIPTA checklist items and ISO 15189 requirements	
Checklist Items 	Section 1.0: Documents and Records 6.3 Risk Management Are assessment of potential pitfalls performed for all laboratory processes including pre examination, examination and post examination? 8.7 Documentation of Examination Procedures Are examination procedures documented in a language commonly understood by all staff and available in appropriate locations? Section 11: Occurrence Management and Process Improvement
ISO 15189	4.1. Organization and Management Responsibility 4.2. Quality Management Systems 4.12 Continual Improvement 4.14. Evaluation and Audits:

QMS 1
Management Responsibility

What's in this Module?

ACTIVITY TITLE	PURPOSE	DURATION
Session 1.1: Management Introduction		
Introduction	To strengthen laboratory management towards accreditation, leaders must develop an understanding of quality and quality management principles. In addition to this discussion, an overview of the training is presented, and the workshop expectations are reviewed.	40 min
Session 1.2: Management Tools		
Process Mapping	Mapping a process (all the steps from the beginning to the end of an activity) is a tool that allows analysis and optimization of workflow and service delivery. In this activity, participants will map and create a table analyzing the Path of Workflow (PoW) process.	2 hours 5 min
Using the Model for Improvement (MFI)	This activity introduces participants to the Model for improvement – a structured approach to achieving rapid and significant improvements through small tests of change. Participants will get an opportunity to practice the model by addressing a typical management issue.	2 hours 30 min
Managing Performance – the Balanced Scorecard	The balanced scorecard, a performance management tool, provides a snapshot of laboratory functions by presenting key quality indicators in an easy-to-read format. Scenarios provide practical opportunities to analyze and investigate laboratory quality data and implement the improvement cycle.	2 hours 30 min
Creating a Management Calendar	A calendar is an essential management tool for planning and organizing lab tasks. In this activity, participants learn to create and use a calendar to schedule, coordinate, balance, and prioritize lab activities.	1 hour 25 min

QMS 1
Management Responsibility

ACTIVITY TITLE	PURPOSE	DURATION
Session 1.3: Quality Management System		
Designing a Continuously Improving QMS	To achieve a quality management system (QMS) that is repeatable, measurable, and constantly improving, ISO 15189 requires laboratories to take a process-based approach towards quality management. In this session, participants will integrate and align ISO 15189's management and technical requirements into a process-based model, thus allowing participants to design a high-level outline for an effective and efficient QMS.	2 hours 45 min
Designing Fit-for-Purpose Processes	All laboratory work is a series of connected processes. Therefore, to adequately perform root cause analysis and risk assessment, management must first identify and understand the processes involved. In this activity, document control processes are used to explore the benefits of applying processes in problem resolution efforts. Working with the document control process, participants will be better prepared to support their QMS improvements and the accompanying documentation changes at their site.	2 hours 5 min
Session 1.4: Planning and Implementing Improvement Projects		
Activity: Planning Improvement Projects – Master Class	Actual measurable laboratory improvement is the desired outcome of this program. In this small-group learning activity, each participant takes turns receiving one-on-one coaching to develop an individualized implementable plan for his/her improvement project.	3 hours 5 min
Activity: Conducting a Site Visit	Site Visits are an integral part of laboratory improvement, providing the connection between the presentation of new knowledge, skills, or tools and actual laboratory practice. This activity allows participants to explore the functions of site visits, to understand what to prepare for a site visit, and to gain insight into how to conduct an effective site visit.	1 hour

QMS 1
Management Responsibility

ACTIVITY TITLE	PURPOSE	DURATION
Activity: Reporting Improvement Projects	Reporting improvement projects promotes reflection on accomplishments made, lessons learned, and challenges faced. This activity encourages participants to synthesize, summarize, and share this information, thereby building a learning network among in-country peers.	20 min plus project reporting by labs and feedback
	Total Module Time:	**18 hours 5 min** plus project reporting and feedback

QMS 1
Management Responsibility

References

Apondi, H. (2017, January 14). Protect The Vital Few From The Trivial Many (The Pareto Principle). Retrieved from https://medium.com/@apondihazel/protect-the-vital-few-from-the-trivial-many-the-pareto-principle-7f5bb070b810

Arter, D. R., Cianfrani, C. A., & West, J. E. (2003). *How to Audit the Process-Based QMS.* Milwaukee: American Society for Quality, Quality Press.

Berte, L. M. (2009, May). Quality Qorner - Lingo Lession. *Lab Medicine, 40*(5), 2. Retrieved from http://www.laboratoriesmadebetter.com/pdfs/Article%20Pdfs/2009/Lab%20Med%20QQ%20May%202009.pdf

Berte, L. M. (2009, Novemeber). Quality Qorner - Who is the Customer? *Lab Medicine, 40*(11), 2. Retrieved from http://www.laboratoriesmadebetter.com/pdfs/Article%20Pdfs/2009/QQ%20Nov%2009%20Who%20is%20Customer%20Part%201.pdf

Berte, L. M. (2009, December). Quality Qorner - Who is the Cutomer? Lesson Two. *Lab Medicine, 40*(12), 708. Retrieved from http://www.laboratoriesmadebetter.com/pdfs/Article%20Pdfs/2009/QQ%20Dec%2009%20Who%20is%20Customer%20Part%202.pdf

Berte, L. M. (n.d.). How Do You Know How Well You Are Doing?: Quality Indicators for Measuring Laboratory Performance.

Berte, L. (n.d.). Understanding Why "PROCESS" is the Essential Key for Lean and Other Quality Tools to Continually Improve Your Lab's Efficiency, Cost Effectiveness, and Profitability. Retrieved January 15, 2019, from https://www.labqualityconfab.com/wp-content/uploads/Berte.TUE_.4pm_FINAL.pdf

Bio-rad Laboratories. (2013). *Looking Ahead to Patient Risk Management.* Bio-rad Laboratories, Inc.

Burnett, D. (2013). *A Practical Guide to ISO 15189 in Laboratory Medicine.* London: ACB Venture Publications.

Clinical and Laboratory and Standards Institute (CLSI). (2011). *EP23-A: Laboratory Quality Control Based on Risk Management; Approved Guideline* (Vols. 31, No. 18). Wayne: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2004). *A Quality Management System Model for Health Care; Approved Guideline (HS1-A2)* (2 ed., Vol. 24). Wayne, PA: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2004). *Application of a Quality Management System Model for Laboratory Services: Approved Guideline (GP26-A3)* (3 ed., Vol. 24). Wayne, PA: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2004). *Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline - Second Edition (GP22-A2)* (2 ed., Vol. 24). Wayne, PA: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2006). *Laboratory Documents: Development and Control; Approved Guideline GP2-A5* (5 ed., Vol. 26). Wayne, PA: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2010). *Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality: Approved Guideline (QM12-A).* Wayne, PA: Clinical and Laboratory Standards Institute .

Clinical and Laboratory Standards Institute (CLSI). (2010). *GP33-A: Accuracy in Patient and Sample Indentification; Approved Guidelines.* Wayne: Clinical and Laboratory Standards Institute .

Clinical and Laboratory Standards Institute (CLSI). (2011). *Quality Management System: Continual Improvement; Approved Guideline (QMS06-A3)* (3 ed.). Wayne, PA: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2012). *Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline (QMS14-A).* Wayne, PA: Clinical and Laboratory Standards Institute .

Clinical and Laboratory Standards Institute (CLSI). (2013). Laboratory QMS Certificate Program Module: QSE Continual Improvement.

Clinical and Laboratory Standards Institute (CLSI). (2013). Laboratory QMS Certificate Program Module: QSE Organization. CLSI U.

Clinical and Laboratory Standards Institute (CLSI). (2013). Laboratory QMS Certificate Program Module: QSE Process Management.

Clinical and Laboratory Standards Institute (CLSI). (2013). *QMS02-A6: Quality Management System: Development and Management of Laboratory Documents; Approved Guideline* (6 ed.). Wayne: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2013). *Quality Management System: Development and Management of Laboratory Documents; Approved Guideline (QMS02-A6)* (6 ed.). Wayne, PA: Clinical and Laboratory Standards Institute (CLSI).

Clinical and Laboratory Standards Institute (CLSI). (2015). *Process Management (QMS18).* Wayne, PA: Clinical and Laboratory Standards Institute (CLSI).

Cochran, C. (2003). *The Continual Improvement Process: From Strategy to the Bottom Line.* Chico, CA: Paton Press LLC.

Cochran, C. (2010). *Problem Solving in Plain English.* Chico, CA: Paton Press LLC.

Cochran, C. (2015). *ISO 9001:2015 In Plain English.* Chico, CA: Paton Professional LLC.

COLA. (2015, May 15). How to Verify Performance Specifications. *LabGuide 13*. Retrieved August 18, 2018, from http://www.cola.org/wp-content/uploads/2016/08/LG132015.pdf

Cooper, G., & Trudy , G. (2007). *Producing Reliable Test Results in the Medical Laboratory: Using a Quality Managment System Approach and ISO 15189 to Assure the Quality of Laboratory Examination Procedures.* Irvine, CA: Bio-rad Laboratories.

Cooper, W. G. (2016, July 20). *Lab Management.* Retrieved from MLO: www.mlo-online.com/resolving-qc-failures

Current Laboratory Practice Series: Laboratory Quality Management System Training Toolkit [CD-ROM]. (2009). World Health Organization.

Dark Intelligence Group, Inc. (2011). *ISO 15189 Medical Laboratories: Understanding the Four Components of a Quality Management System.*

Datema, T. A., Oskam, L., & Klatser, P. R. (2011, December 11). Review and comparison of quality standards, guidelines and regulations for laboratories. *African Journal for Laboratory Medicine, 1*(1), 7 pages. Retrieved from dx.doi.org/10.4102/ajlm.v1i1.3

Dawson, J. (2015, July-August). *Navigating ISO 15189.* Retrieved from MedicalLab Management: https://www.medlabmag.com/article/1201/?search=navigating%20ISO%2015189

Dawson, J. (2017, August 29). *Lean Six Sigma is Not Quality.* Retrieved from G2 Intelligence: https://www.g2intelligence.com/lean-six-sigma-is-not-quality/

DiMaria, J. (n.d.). ISO 9001:2015 What are the changes? Retrieved May 6, 2016, from http://bsi.learncentral.com/aicc/9kChanges2016US/index_lms.html

Draft International Standard ISO/DIS 9001 . (2014). *ISO/TC 176/SC 2*. Geneva: International Organization for Standardization.

Epstein, H. M. (2019, January 8). *Dx IQ Column #1—The most important medical issue ever: And why you need to know more about it.* Retrieved from Society to Improve Diagnosis in Medicine: https://www.improvediagnosis.org/dxiq-column/most-important-medical-issue-ever/

Health Research & Educational Trust. (2018, September). Improving Diagnosis in Medicine Change Package. Chicago, Illinois: Health Research & Educational Trust. Retrieved from http://www.hret-hiin.org/

Hill, E. (2018, August). The Role of Six Sigma in a Modern Quality Management Strategy. *Medical Laboratory Observer (MLO)*, pp. 46-47.

Institute for Quality Management in Healthcare (IQMH). (2014). Decoding ISO 15189 Interactive Online Education Series: Module 5 - The Quality Manual.

Institute for Quality Management in Healthcare (IQMH). (2014). Decoding ISO 15189 Interactive Online Education Series: Module 6 - Process Maps and Procedures.

Institute for Quality Management in Healthcare (IQMH). (2014). Decoding ISO 15189 Interactive Online Education Series: Module 9 - Quality Indicators.

International Organization for Standardization (ISO). (2012). ISO 15189: 2012 Medical laboratories -- Requirements for quality and competence.

International Organization for Standarization. (2015). Quality Management Principles. Geneva , Switzerland. Retrieved January 4, 2019, from https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/pub100080.pdf

ISO 9001:2015 Part 1: Prepare for Impending Changes. (n.d.). Retrieved March 5, 2016, from Master Control: http://www.mastercontrol.com/downloadables/customervideos/standalone.html?c=128

ISO 9001:2015 Part 2: New QMS Structure Overview. (n.d.). Retrieved March 6, 2016, from Master Control: http://www.mastercontrol.com/downloadables/customervideos/standalone.html?c=137

ISO 9001:2015 Part 3: Risk-based Thinking Goes from Implicit to Explicit. (n.d.). Retrieved March 6, 2016, from Master Control: http://www.mastercontrol.com/downloadables/customervideos/standalone.html?c=145

Juran's Trilogy. (2009, April 9). Retrieved from Quality World: http://gurujuran.blogspot.com/2009/04/jurans-trilogy.html

LabCoP ECHO Session Resource. (2018, June). LARC 2.0 Quality improvement Collaborative Workbook. Retrieved from https://bnegash-my.sharepoint.com/personal/admin_aslm_org/_layouts/15/onedrive.aspx?id=%2Fpersonal%2Fadmin%5Faslm%5Forg%2FDocuments%2FLabCoP%20From%20Dr%20Legese%2FLARC%202%2E0%20WORKBOOK%20V2%2EPDF&parent=%2Fpersonal%2Fadmin%5Faslm%5Forg%2FDocuments%2FLa

Makary, M. A., & Daniel, M. (2016). Medical error—the third leading cause of death in the US. *BMJ*, 353 :i2139 .

McKinney, B. C. (n.d.). Quality Improvement: Applications for the Viral Load Cascade.

New York State Department of Health, Wadsworth Center. (2010). *Guidance for Implementing a Laboratory Quality Management System.*

Noble, M. (2018, January 2). *Fit for Process versus Fit for Purpose.* Retrieved from Making Medical Lab Quality Relevant: http://www.medicallaboratoryquality.com/2018/01/

Noble, M. (2019, February 4). *GB/T32230: Quality Culture and the Medical Laboratory.* Retrieved from Making Medical Lab Quality Relevant: http://www.medicallaboratoryquality.com/2019/02/gbt32230-quality-culture-and-medical.html?utm_source=feedburner&utm_medium=email&utm_campaign=Feed%3A+MakingMedicalLabQualityRelevant+%28Making+Medical+Lab+Quality++Relevant%29

Pendergraph, G. E., & Gruber, E. J. (2012). Risk Management in the Clinical Laboratory. *MediaLab, Inc.*

Pereira, P. (2017, February). *ISO series Part 2 - ISO 15189:2012 "Medical laboratories - Requirements for quality and competence.* Retrieved from Westgard QC: www.westgard.com/iso-15189-2012-requirements-1.htm

Plebani, M. (2017, August). *Quality in laboratory medicine: an unfinished journey.* Retrieved from Journal of Laboratory Precision and Medicine: http://jlpm.amegroups.com/article/view/3740/4449

Quality Planning Models - The Math . (n.d.). Retrieved from Westgard QC: www.westgard.com/lesson72.htm

Quinley, E. D. (n.d.). *Quality, It's More than Compliance.* Retrieved July 10, 2016, from Ortho On Demand: https://vts.inxpo.com/scripts/Server.nxp?LASCmd=AI:1;F:SF!40000&BoothKey=239788

Return on Investment. (n.d.). Retrieved from Society to Improve Diagnosis in Medicine: https://www.improvediagnosis.org/roadmap-for-research-to-improve-diagnosis-return-on-investment/

Royal Tropical Institute. (2014). Laboratory Quality Stepwise Implementation Tool. Retrieved from https://extranet.who.int/lqsi/content/homepage

Russell, J. (2010). *The Process Auditing and Techniques Guide* (2 ed.). Milwaukee: American Socieity for Quality, Quality Press.

Sikaris, K. A. (2017). Enhancing the Clinical Value of medical Laboratory Testing. *Clinical Biochemistry Reviews, 38*(3), 107-114.

Smith, C. A. (n.d.). *Promoting High Reliability on the Frontline.* Retrieved from American Nurse Today: https://americannursetoday.mydigitalpublication.com/publication/index.php?i=476895&pjs=1&p=&pn=&ver=html5&pid=&view=articleBrowser&article_id=3021618#{%22issue_id%22:476895,%22view%22:%22articleBrowser%22,%22article_id%22:%223021618%22}

UK Essays. (2013, November). The Eight Principles Of Quality Management Principles Management Essay. Retrieved January 4, 2019, from ukessays.com/essays/management/the-eight-principles-of-quality-management-principles-management-essay.php?vref=1

Vetter, L. P. (2006, July). A Laboratory Management Primer. *Lab Medicine, 37*(7), 397-403.

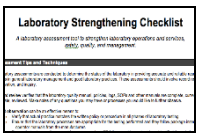
Westgard, J., & Westgard, S. (2015, June 10). *Simplifying ISO 15189: The Real-world Impact to Laboratory Quality Management.* Retrieved from Thermo Fisher Scientific: www.thermofisher.com/us/en/home/clinical/diagnostic-testing/quality-controls-assurance-program/quality-control-webinar-simplifying-iso-15189-registration.html

Westgard, S. (2016, February). *Quality Goals at the Crossroads: Growing, Going, Gone?* Retrieved from Westgard QC: www.westgard.com/gone-goals-gone.htm

World Health Organization, Regional Office for Africa. (2015). Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Cheklist (ver. 2:2015).

QMS 2
Resource Management

Laboratory management must provide the resources needed to meet the requirements of the quality management system and to continually improve its effectiveness. In QMS 2, participants will explore the necessary support processes and their management.

This part supports the following SLIPTA checklist items and ISO 15189 requirements	
Checklist Items 	Section 1.0: Documents and Records 2.1 Routine Review of Quality and Technical Records Does the laboratory routinely perform a documented review of all quality and technical records? Section 3.0: Organization and Personnel Section 5.0: Equipment Section 7.0: Purchasing and Inventory 8.7 Documentation of Examination Procedures Are examination procedures documented in a language commonly understood by all staff and available in appropriate locations? 8.8 Reagents Acceptance Testing Is each new reagent preparation, new lot number, new shipment of reagents or consumables verified before use and documented? 8.12 Are environmental conditions checked and reviewed accurately? 9.4 Analytic System/Method Tracing When more than one instrument is in use for the same test, are test results traceable to the equipment used for testing? 9.5 Archived Data Labelling and Storage Are archived results (paper or data-storage media) properly labelled and stored in a secure location accessible only to authorized personnel? Section 12.0: Facilities and Biosafety
ISO 15189 ®	4.1.Organization and Management Responsibility 4.2.Quality Management Systems 4.3 Document Control 4.6 External Services and Supplies 4.13 Control of Records 5.1 Personnel 5.2 Accommodations and Environmental Conditions 5.3 Laboratory Equipment, Reagents, and Consumables 5.5 Examination Processes

QMS 2
Resource Management

What's in this Module?

ACTIVITY TITLE	PURPOSE	DURATION
Session 2.1: Personnel		
Then and Now	Through process mapping, the activity steps and their linkages will be discussed so that participants will better understand the ISO 15189 sub-clause and how to achieve the intended quality output and minimizes the risks of unintended (e.g. defective, nonconforming) outputs. Gaining clarity, the participants will be better able to effectively lead the quality planning at their site. In this activity, participants will explore the numerous interrelated or interacting processes of ISO 15189 5.1 Personnel, a QMS sub-system.	1 hour
Competency Assessment Program	A competency assessment program should efficiently assess and document the competency of the laboratory staff. This activity includes 1) performing a desk review of a laboratory's competency assessment program for the examination phase, and 2) conducting a direct observation using a checklist in the pre-examination phase.	1 hour 30 min
Creating a Personnel File	Managing human resources requires documentation and organization of employee information, education, work history, training, and performance data. In this activity, participants review the Personnel File Management Process which is responsible for managing all this information.	1 hour 20 min
How Do You Assign Personnel to Tasks?	A duty roster helps a manager coordinate tasks among laboratory staff to better serve customers. It assigns personnel to workstations with well-defined tasks and responsibilities. In this activity, participants learn to create a duty roster based on a testing menu, workload, personnel available, and operational hours.	1 hour 25 min
Planning and Conducting a Staff Meeting	Establishing an Internal Communications Plan requires laboratory management to plan for quality and effective communications with their staff. In this activity, participants will explore elements of an Internal Communications Plan.	1 hour

QMS 2
Resource Management

ACTIVITY TITLE	PURPOSE	DURATION
Session 2.2: Infrastructure and Safety		
Process + Structure = Outcome	Optimal laboratory design involves two factors: ▪ physical layout of the allotted space ▪ workflow path designed around the steps of the process to be performed in that space. In this activity, participants design a laboratory layout regarding the workflow using the provided floor plan.	2 hours 40 min
Improving a Problem Floor Plan	Optimal laboratory design requires that the physical work environment is safe and appropriate for testing. In this activity, participants will identify hazardous elements in the work environment of the provided laboratory floor plan. Using the floor plan, participants will redesign the layout so that the problems are addressed.	45 min
Mapping-out the Floor Plan of Your Laboratory	significantly reduces waste by removing excess movement, time and effort. To effectively redesign a laboratory, the current floor plan and workflow path must be evaluated. In this activity, participants learn how to create a floor plan of their own laboratories. A follow-up activity will allow them to improve the workflow by redesigning the floor plan of their laboratories.	1 hour 30 min
Redesigning the Floor Plan of Your Laboratory	A good laboratory floor plan eliminates waste by removing excess movement, time and effort. In this activity participants redesign their laboratory layout to improve the workflow by repositioning movable items in their floor plan.	45 min
Workstation Set-Up	A workstation's design influences the productivity and efficiency of the workflow. An organized workstation places all essential items within easy reach in an orderly manner. This allows timely completion of all duties assigned to the workstation. In this activity, participants progressively construct an efficient workstation.	2 hours

QMS 2
Resource Management

ACTIVITY TITLE	PURPOSE	DURATION
Laboratory Safety Demonstrations	Safety concerns may be overlooked in the bustle of day-to-day laboratory activities. Two interactive and light-hearted demonstrations sensitize participants to the importance of safety.	25 min
Assessing Safety Incidents	Unsafe structures and practices impact the productivity and efficiency of laboratories. Through role-plays, participants learn to assess, document, correct, and follow-up safety incidents.	1 hour
Conducting a Safety Audit	Safety is a primary concern for laboratory operations. In this activity, participants are introduced to conducting an assessment of facility and personal safety using the WHO-AFRO SLIPTA Checklist and reviewing laboratory photographs.	1 hour 35 min
What did we see on the Site Visits?	Knowledge of good laboratory safety practices does not always result in the implementation of these practices. This activity uses actual site visit photos to highlight and discuss why these unsafe practices persist despite knowledge to the contrary.	45 min
Session 2.3: Purchasing and Inventory		
Then and Now	Through process mapping, the activity steps and their linkages will be discussed so that participants will better understand the ISO 15189 sub-clause and how to achieve the intended quality output and minimizes the risks of unintended (e.g. defective, nonconforming) outputs. Gaining clarity, the participants will be better able to effectively lead the quality planning at their site. In this activity, participants will explore the numerous interrelated or interacting processes of ISO 15189 5.3.2 Laboratory Reagents and Consumables, a QMS sub-system.	1 hour

QMS 2
Resource Management

ACTIVITY TITLE	PURPOSE	DURATION
Forecasting and Calculating Ordering Amounts	An effective procurement management system is one that ensures sufficient inventory is available to meet testing needs while simultaneously avoiding waste incurred from unused and expired reagents. In this activity, participants learn how to forecast and determine reorder levels for their laboratory. The concepts are reinforced with an assigned homework activity.	1 hour 15 min
Did You Receive What You Ordered?	A laboratory must have a process developed to inspect the quality and quantity of reagents and supplies before they are placed into storage or use. In this activity, participants compare the purchasing document with the shipping invoice and the items received. In addition to the receipt inspection, participants learn to place and submit orders properly, maintain proper inventory records, track orders placed, and resolve discrepancies.	1 hour 15 min
What's Wrong with this Storeroom?	An important component of inventory management is the storage oversight and handling of reagents and supplies needed for laboratory testing. In this activity, participants assess the deficiencies of a simulated storeroom.	50 min
Session 2.4: Equipment		
Then and Now	Through process mapping, the activity steps and their linkages will be discussed so that participants will better understand the ISO 15189 sub-clause and how to achieve the intended quality output and minimizes the risks of unintended (e.g. defective, nonconforming) outputs. Gaining clarity, the participants will be better able to effectively lead the quality planning at their site. In this activity, participants will explore the numerous interrelated or interacting processes of ISO 15189 5.3.1 Laboratory Equipment, a QMS sub-system.	1 hour 35 min

QMS 2
Resource Management

ACTIVITY TITLE	PURPOSE	DURATION
Creating a Maintenance and QC Log	Instrument logs must be available to record proper equipment maintenance and quality control (QC). Using excerpts from an operator's manual, participants learn to create an instrument log.	2 hours
Making a Service Call	To have a mutually beneficial relationship with a supplier, the laboratory must be able to clearly communicate their concerns and questions. In this activity, participants write an email to a supplier. A plenary discussion will explore how the laboratory should communicate its quality needs.	1 hour
Session 2.5: Document and Record Control		
Then and Now for Documents	Through process mapping, the activity steps and their linkages will be discussed so that participants will better understand the ISO 15189 sub-clause and how to achieve the intended quality output and minimizes the risks of unintended (e.g. defective, nonconforming) outputs. Gaining clarity, the participants will be better able to effectively lead the quality planning at their site. In this activity, participants will explore the numerous interrelated or interacting processes of ISO 15189 4.3 Document, a QMS sub-system.	1 hour 15 min
Why Was the Outdated Version Used?	Document control ensures staff members have the current, correct, and consistent information to perform their work. In this activity, participants utilize a master file index to control common documents used in the laboratory.	1 hour 40 min

QMS 2
Resource Management

ACTIVITY TITLE	PURPOSE	DURATION
Then and Now for Records	Through process mapping, the activity steps and their linkages will be discussed so that participants will better understand the ISO 15189 sub-clause and how to achieve the intended quality output and minimizes the risks of unintended (e.g. defective, nonconforming) outputs. Gaining clarity, the participants will be better able to effectively lead the quality planning at their site. In this activity, participants will explore the numerous interrelated or interacting processes of ISO 15189 4.3 Record, a QMS sub-system.	1 hour
	Total Module Time:	**30 hours 30 min**

References

Barasch, S. P., Adem, P. V., & Curtis, R. (2017, October). Massive Transfusion Protocol Competency Assessment. *Medical Laboratory Observer (MLO)*, pp. 14, 16.

Barker, T., & Noguez, J. (2015, January). The High Cost of Low Morale in the Clinical Laboratory: How Workplace Environment Impacts Patient Safety. *Clinical Laboratory News*, 24-25.

Barrowman, N. (2018). Why Data Is Never Raw . *The New Atlantis*(Summer/Fall). Retrieved January 18, 2019, from https://www.thenewatlantis.com/publications/why-data-is-never-raw

Bazanele-Sabatka, C., & Montoya, E. (2018, July). Conquer Your QC Fears: Quality Control in the Modern Lab. *Critical Values*, pp. 20-23.

Berte, L. (n.d.). Understanding Why "PROCESS" is the Essential Key for Lean and Other Quality Tools to Continually Improve Your Lab's Efficiency, Cost Effectiveness, and Profitability. Retrieved January 15, 2019, from https://www.labqualityconfab.com/wp-content/uploads/Berte.TUE_.4pm_FINAL.pdf

Boysen, P. G. (2013). Just Culture: A Foundation for Balance Accountability and Patient Safety. *The Ochsner Journal*, *13*, 400-406.

Brooks, Z. C. (2003). *Basic Concepts.* Worthington, Ontario, Canada: Zoe Brooks Quality Consulting.

Burnett, D. (2013). *A Practical Guide to ISO 15189 in Laboratory Medicine.* London: ACB Venture Publications.

Clinical and Laboratory Standards Institute (CLSI). (2004). *Application of a Quality Management System Model for Laboratory Services: Approved Guideline (GP26-A3)* (3 ed., Vol. 24). Wayne, PA: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2006). *Laboratory Documents: Development and Control; Approved Guideline GP2-A5* (5 ed., Vol. 26). Wayne, PA: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2007). *GP18-A2: Laboratory Design; Approved Guideline* (2 ed., Vol. 27). Wayne: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2009). *GP21-A3: Training and Competence Assessment; Approved Guideline - Third Edition* (Vol. 29). Wayne: Clinical and Laboratory Standards Institute .

Clinical and Laboratory Standards Institute (CLSI). (2009). *GP31-A: Laboratory Intrument Implementation, Verification, and Maintenance; Approved Guideline.* Wayne: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2010). *Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality: Approved Guideline (QM12-A).* Wayne, PA: Clinical and Laboratory Standards Institute .

Clinical and Laboratory Standards Institute (CLSI). (2010). *GP33-A: Accuracy in Patient and Sample Indentification; Approved Guidelines.* Wayne: Clinical and Laboratory Standards Institute .

Clinical and Laboratory Standards Institute (CLSI). (2011). *GP05-A3: Clinical Laboratory Waste Management: Approved Guideline* (3 ed.). Wayne: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2011). *QMS13-A: Quality Management System: Equipment; Approved Guideline* (Vol. 31). Wayne: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2011). *Quality Management System: A Model for Laboratory Services: Approved Guideline (GP26-A4)* (4 ed.). Wayne, PA: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2012). *Clinical Laboratory Safety; Approved Guideline* (3 ed.). Wayne: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2013). Laboratory QMS Certificate Program Module: QSE Documents and Records.

Clinical and Laboratory Standards Institute (CLSI). (2013). *Quality Management System: Development and Management of Laboratory Documents; Approved Guideline (QMS02-A6)* (6 ed.). Wayne, PA: Clinical and Laboratory Standards Institute (CLSI).

Clinical and Laboratory Standards Institute (CLSI). (2015). *QMS16: Laboratory Personnel Management* (1 ed.). Wayne: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2016). *QMS03: Training and Competence Assessment* (4 ed.). Wayne: Clinical and Laboratory Standards Institute .

Clinical and Laboratory Standards Institute (CLSI). (2016). *QMS21: Purchasing and Inventory Management.* Wayne: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2017). *GP41: Collection of Diagnostic Venous Blood Specimens* (7 ed.). Wayne: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2017). *GP48: Essential Elements of a Phlebotomy Training Program* (1 ed.). Wayne: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2018). *Management of Paper-based and Electronic Laboratory Information.* Wayne: Clinical and Laboratory Standards Institute.

QMS 2
Resource Management

Connor , M., Duncombe, D., Barclay, E., Bartel, S., Borden, C., Gross, E., . . . Reid Ponte, P. (2007, October). Creating a Fair and Just Culture: One Institution's Path Toward Organziational Change. *The Journal of Quality anf Patient Safety, 33*, 617-624.

Cooper, G. (2008). *Basic Lessons in Laboratory Quality Control.* Bio-Rad Laboratories, Inc.

Cooper, G. (2018, March). Continuing Education-QA/QC: Commutability, Traceability, and Uncertainty of Measurement. *Medical Laboratory Observors (MLO)*, pp. 8, 10, 12, 14.

Current Laboratory Practice Series: Laboratory Quality Management System Training Toolkit [CD-ROM]. (2009). World Health Organization.

Dark Intelligence Group, Inc. (2011). *ISO 15189 Medical Laboratories: Understanding the Four Components of a Quality Management System.*

Dawson, J. (2015, March-April). *Robust Document and Record Management.* Retrieved from MedicalLab Management: https://www.medlabmag.com/article/1181/MarchApril_2015/Robust_Document_and_Record_Management/

Dawson, J. (2015, July-August). *Navigating ISO 15189.* Retrieved from MedicalLab Management: https://www.medlabmag.com/article/1201/?search=navigating%20ISO%2015189

Dawson, J. (2016). Cultivating a Culture of Quality. Retrieved May 1, 2016, from https://www.aacc.org/store/thought-leadership/10600/cultivating--a-culture-of-quality-in-the-laboratory

Dawson, J. (2017, February 9). Do No Harm: Diagnostic Errors and the Lab. Retrieved from http://www.labtestingmatters.org/do-no-harm-diagnostic-errors-and-the-lab/

Dawson, J. (2017, August 29). *Lean Six Sigma is Not Quality.* Retrieved from G2 Intelligence: https://www.g2intelligence.com/lean-six-sigma-is-not-quality/

DiMaria, J. (n.d.). ISO 9001:2015 What are the changes? Retrieved May 6, 2016, from http://bsi.learncentral.com/aicc/9kChanges2016US/index_lms.html

Ehrmeyer, S. S. (2012). *The New Poor Lab's Guide to the Regulations.* Madison: Westgrd QC, Inc.

Ellinger, P. J. (2006, March). Competency Assessment: Strategies to Meet the Ongoing Challenge. *Laboratory Medicine, 37*(3), pp. 176-178.

Goudarzi, S. (2018, June 4). Making the Most Out of Lab Meetings. *Lab Manager*. Retrieved January 16, 2019, from https://www.labmanager.com/leadership-and-staffing/2018/06/making-the-most-out-of-lab-meetings#.XD8Nvc17nIU

Grech, J. (2017, October 11). *There is Always Someone Cheaper.* Retrieved from LinkedIn: https://www.linkedin.com/pulse/always-someone-cheaper-jason-grech/

International Organization for Standardization (ISO). (2012). ISO 15189: 2012 Medical laboratories -- Requirements for quality and competence.

International Organization for Standarization. (2015). Quality Management Principles. Geneva , Switzerland. Retrieved January 4, 2019, from https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/pub100080.pdf

Kilner, P. (2018, October 4). Simple Ways to Improve Efficiency and Accuracy Using Lean Principles. Retrieved February 6, 2019, from http://www.fishersci.com/us/en/healthcare-products/webinars/simple-ways-improve-efficiency-accuracy-using-lean-principles.html

Kridelbaugh, D. (2018, March 5). Creating a Successful Laboratory Training Program. *Lab Manager*. Retrieved January 16, 2019, from https://www.labmanager.com/leadership-and-staffing/2018/03/creating-a-successful-laboratory-training-program#.XD8FDM17nIW

Lab Manager. (2017, December 7). Lab Safety Rules and Guidelines. *Lab Manager*. Retrieved January 16, 2019, from https://www.labmanager.com/lab-health-and-safety/2017/12/science-laboratory-safety-rules-guidelines#.XD8XXs17nIW

McKinney, B. C. (n.d.). Quality Improvement: Applications for the Viral Load Cascade.

McLeod, V. (2018, July 9). Guidance and Consistency Ensure Effective PPE. *Lab Manager*. Retrieved January 16, 2019, from https://www.labmanager.com/lab-health-and-safety/2018/07/guidance-and-consistency-ensure-effective-ppe#.XD8Uvs17nIV

McLeod, V. (2018, May 7). Working with Biohazards. *Lab Manager*. Retrieved January 16, 2019, from https://www.labmanager.com/lab-health-and-safety/2018/05/working-with-biohazards#.XD8Vps17nIU

Newitt, V. N. (2019, March). *Labs add safety net to critical values procedure.* Retrieved from CAP TODAY: https://captodayonline.com/labs-add-safety-net-to-critical-values-procedure/

Plebani, M. (2017). Quality in laboratory medicine: an unfinished journey. *Journal of laboratory and Precison Medicine, 2*(63).

Reeve, J. (2019, February 12). *Culture and Strategy are Related.* Retrieved from LinkedIn: https://www.linkedin.com/pulse/culture-strategy-related-john-reeve/

Return on Investment. (n.d.). Retrieved from Society to Improve Diagnosis in Medicine: https://www.improvediagnosis.org/roadmap-for-research-to-improve-diagnosis-return-on-investment/

Reynolds, T., & Scharton-Kersten, T. (2013, December 6). Designing Labs for Lean Operation. *Lab Manager*. Retrieved January 16, 2019, from https://www.labmanager.com/lab-design-and-furnishings/2013/12/designing-labs-for-lean-operation#.XD8L6817nIV

Rivenburgh, D. (n.d.). *How to Create a Virbrant, Thriving Culture.* Retrieved March 2, 2016, from American Society for Quality Knowledge Center Webcast: http://asq.org/knowledge-center/webcasts.html

Roche Molecular Systems, Inc. (2013, May). Cobas AmpliPrep/COBAS TaqMan HIV-1 Test, version 2.0. *Cobas*. Roche Daignostics.

Rosenstein, A. H., & O'Daniel, M. (2008). *A Survey of the Impact of Disruptive Behaviors and Communication Defects on Patient Safety.* The Joint Commision Journal on Quality and Patient Safety.

Royal Tropical Institute. (2014). Laboratory Quality Stepwise Implementation Tool. Retrieved from https://extranet.who.int/lqsi/content/homepage

Saah, A., & Hoover , D. (1997, January 1). "Sensitivity" and "specificity" reconsidered: the meaning of these terms in analytical and diagnostic settings. *Annals of Internal Medicine, 126*(1), 91-94. Retrieved March 6, 2019, from https://www.ncbi.nlm.nih.gov/pubmed/8992938

Scott, T. A. (2013, May 27). *Competency Assessment.* Retrieved from Advance Healthcare Network for Laboratory: http://laboratory-manager.advanceweb.com/competency-assessment/

Scungio, D. (2018, Various). Retrieved from Dan's Blog: Dan the Lab Safety Man: http://danthelabsafetyman.com/blog/

Scungio, D. (2019, February 23). *Accidents Happen – Now What?* Retrieved from Dan the Lab Safety Man: http://danthelabsafetyman.com/accidents-happen-now-what/

Scungio, D. (2019, January 9). *Over the River and Through the Woods….* Retrieved from Lablogatory: A Blog for Medical Laboratory Professionals: https://labmedicineblog.com/2019/01/09/over-the-river-and-through-the-woods/

Smith, C. A. (n.d.). *Promoting High Reliability on the Frontline.* Retrieved from American Nurse Today: https://americannursetoday.mydigitalpublication.com/publication/index.php?i=476895&pjs=1&p=&pn=&ver=html5&pid=&view=articleBrowser&article_id=3021618#{%22issue_id%22:476895,%22view%22:%22articleBrowser%22,%22article_id%22:%223021618%22}

Tools, Technologies and Training for Healthcare Laboratories. (n.d.). Retrieved from Westgard QC: www.westgard.com

UK Essays. (2013, November). The Eight Principles Of Quality Management Principles Management Essay. Retrieved January 4, 2019, from ukessays.com/essays/management/the-eight-principles-of-quality-management-principles-management-essay.php?vref=1

University of Medicine & Dentistry of New Jersey: School of Health Related Professions. (2007). Clinical Laboratory Data Analysis. *CLSC 5213*.

USAID | DELIVER PROJECT, Task Order 1. (2018, July). Guidelines for Managing the Laboratory Supply Chain: Version 2. Arlingtion, VA. Retrieved from http://iaphl.org/wp-content/uploads/2016/05/Guidlines-for-Managing-the-Lab-Supply-Chain.pdf

Vetter, L. P. (2006, July). A Laboratory Management Primer. *Laboratory Medicine, 37*(7), 397-403.

Wachter, R. M., & Pronovost, P. J. (2009+, October 1). Balancing "No Blame" with Accountability in Patient Safety. *The New England Journal of Medicine, 361*(14), 1401-1406.

Westgard, J. (n.d.). *Mapping the Road to Analytical Quality.* Retrieved from Westgard QC: www.westgard.com/essayant.htm

Westgard, J. O. (2000). *Basic Planning for Quality.* Madison: Westgard QC, Inc. .

Westgard, J. O. (2003). *Basic Method Validation* (2nd ed.). Madison: Westgard QC, Inc.

Westgard, J. O. (2007). *Basic QC Practices* (2nd ed.). Madison: Westgard QC, Inc.

Westgard, J. O. (2008). *Basic Method Validation* (3rd ed.). Madison: Westgard QC, Inc.

Westgard, J. O. (2010). *Basic QC Practices* (3rd ed.). Madison: Westgard QC, Inc.

Westgard, J. O. (2016). *Basic QC Practices* (Vol. 4th). Madison: Westgard QC, Inc.

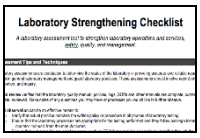
Westgard, J. O., & Westgard, S. A. (2014). *Basic Quality Management Systems.* Madison: Westgard QC, Inc.

Westgard, J. O., & Westgard, S. A. (2014). *Basic Quality Management Systems.* Madison: Westgard QC, Inc.

World Health Organization, Regional Office for Africa. (2015). Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Cheklist (ver. 2:2015).

QMS 3
Path of Workflow

The Path of Workflow (PoW) is comprised of interrelated or interacting activities that transforms biological patient sample material into laboratory results and information to ultimately assure the most appropriate clinical outcome. QMS 3 focuses on this key process and how to manage the activities involved in service realization.

This part supports the following SLIPTA checklist items and ISO 15189 requirements	
Checklist Items 	Section 4.0: Client Management and Customer Service Section 8.0 Process Control Section 9 Information Management 10.1 Are all identified nonconforming activities/ work identified and documented adequately?
ISO 15189 ®	4.1.Organization and Management Responsibility 4.2.Quality Management Systems 4.5 Examination by Referral Laboratories 4.7 Advisory Services 4.9 Identification and Control of Nonconformities 5.4 Pre-examination Processes 5.5 Examination Processes 5.6 Ensuring the Quality of Examination Results 5.7 Post-examination Processes 5.8 Reporting of Results 5.9 Release of Results

QMS 3
Path of Workflow

What's in this Module?

ACTIVITY TITLE	PURPOSE	DURATION
Session 3.1: Pre-Examination		
Specimen Management	The quality of the inputs to the laboratory directly determines the quality of the outputs. Assuring that specimens are acceptable is an important function of laboratory management and is highlighted by this role-play.	1 hour 10 min
Packaging Specimens for Shipment to Referral Sites	Referral testing requires proper packaging and shipping of patient specimens to preserve their integrity and suitability and to protect all persons involved in their transportation. In this activity, participants learn the importance of safe and effective specimen packing and practice appropriately packing samples with available materials of varying levels of sophistication.	1 hour 30 min
Tracking Referral Specimens	Referral specimen status is essential for specimen management to ensure the timely return of test results. In this case study, participants learn to use a log to track referral specimens, follow up on an issue, and document the occurrence.	1 hour 25 min
Session 3.2: Examination		
Using Standard Operating Procedures	The simple process of hand washing is used to demonstrate the utility and importance of Standard Operating Procedures (SOPs). In this activity, writing and following a simple SOP is a preface to a discussion about how SOPs will be used in the participants' own laboratories.	1 hour 25 min
Is QC That Important?	For an effective Quality Control (QC) management system, QC must be consistently performed, monitored, reviewed, and deemed essential. In this activity, participants have an opportunity to voice and examine underlying perceptions or issues which can undermine a QC program.	1 hour 15 min

QMS 3
Path of Workflow

ACTIVITY TITLE	PURPOSE	DURATION
Is There More to QC Than Just Plotting the Data?	The right quality control (QC) approach can detect and prevent errors. In this activity, participants learn the importance of establishing acceptable ranges for control material and the importance of control rule selection in interpreting changes in the analytical system.	1 hour 50 min
Session 3.3: Post-Examination		
Validation of Test Results	The total testing process can be divided into three phases, the pre-analytical phase, the analytical phase, and the post analytical phase. A problem or error in any of the three phases can invalidate the results of the entire testing process. In this activity, participants identify the potential sources of errors or problems and create a checklist to verify patient results before their release.	1 hour
Is the Test Report Ready to be Released?	Test result reports should be complete, accurate, legible, and clinically valid. In this activity, participants cross-check a test report to identify errors and omissions that must be resolved before the report is released.	45 min
Customer Service	The laboratory is a service organization and its primary reason for existence is to care for patients. In this activity, following sensitization to the patient's perspective, participants are provided tools for developing a customer friendly laboratory.	1 hour
Meet the Clinician	Clinicians and laboratorians must work as a team to provide quality patient care. In this activity clinicians and laboratory personnel meet and share viewpoints with the goal of improving delivery of quality service to the patients.	1 hour 30 min
	Total Module Time:	**12 hours 50 min**

References

Astion, M. (2018, January 1). *Patient Satisfaction Is Not the Same as Patient Safety. Q&A with Michael Astion, MD, PhD.* Retrieved from Clinical Laboratory News: https://2019aacc.org/sitecore/content/sites/aacc/home/publications/cln/articles/2018/janfeb/patient-satisfaction-is-not-the-same-as-patient-safety

Berte, L. (n.d.). Understanding Why "PROCESS" is the Essential Key for Lean and Other Quality Tools to Continually Improve Your Lab's Efficiency, Cost Effectiveness, and Profitability. Retrieved January 15, 2019, from https://www.labqualityconfab.com/wp-content/uploads/Berte.TUE_.4pm_FINAL.pdf

Brooks, Z. (n.d.). *Awesome Numbers*. Retrieved from www.awesome numbers.org

Brooks, Z. C. (2001). *Performance-driven Quality Control.* Washington DC: AACC Press.

Brooks, Z. C. (2003). *Basic Concepts.* Worthington, Ontario, Canada: Zoe Brooks Quality Consulting.

Burnett, D. (2013). *A Practical Guide to ISO 15189 in Laboratory Medicine.* London: ACB Venture Publications.

Clinical and Laboratory Standards Institute (CLSI). (2010). *GP33-A: Accuracy in Patient and Sample Indentification; Approved Guidelines.* Wayne: Clinical and Laboratory Standards Institute .

Clinical and Laboratory Standards Institute (CLSI). (2017). *GP41: Collection of Diagnostic Venous Blood Specimens* (7 ed.). Wayne: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2017). *GP48: Essential Elements of a Phlebotomy Training Program* (1 ed.). Wayne: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2018). *Management of Paper-based and Electronic Laboratory Information.* Wayne: Clinical and Laboratory Standards Institute.

Datema, T. A., Oskam, L., & Klatser, P. R. (2011, December 11). Review and comparison of quality standards, guidelines and regulations for laboratories. *African Journal for Laboratory Medicine, 1*(1), 7 pages. Retrieved from dx.doi.org/10.4102/ajlm.v1i1.3

Dawson, J. (2015, July-August). *Navigating ISO 15189.* Retrieved from MedicalLab Management: https://www.medlabmag.com/article/1201/?search=navigating%20ISO%2015189

Dawson, J. (2017, February 9). Do No Harm: Diagnostic Errors and the Lab. Retrieved from http://www.labtestingmatters.org/do-no-harm-diagnostic-errors-and-the-lab/

Dawson, J. (2017, August 29). *Lean Six Sigma is Not Quality.* Retrieved from G2 Intelligence: https://www.g2intelligence.com/lean-six-sigma-is-not-quality/

Epstein, H. M. (2019, January 8). *Dx IQ Column #1—The most important medical issue ever: And why you need to know more about it.* Retrieved from Society to Improve Diagnosis in Medicine: https://www.improvediagnosis.org/dxiq-column/most-important-medical-issue-ever/

Han, Y., Makarova, E., Ringel, M., & Telpis, V. (2019, January). *Digitization, automation, and online testing: The future of pharma quality control.* Retrieved from McKinsey and Company: https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/digitization-automation-and-online-testing-the-future-of-pharma-quality-control?cid=soc-web

Health Research & Educational Trust. (2018, September). Improving Diagnosis in Medicine Change Package. Chicago, Illinois: Health Research & Educational Trust. Retrieved from http://www.hret-hiin.org/

Homer, M. (2019, February 26). *After death of St. Luke's patient, review uncovers 122 issues with blood labels over four-month period.* Retrieved from KHOU 11: https://www.khou.com/article/news/health/after-death-of-st-lukes-patient-review-uncovers-122-issues-with-blood-labels-over-four-month-period/285-07798e96-d21b-489b-b54e-43601557d760

International Organization for Standarization. (2015). Quality Management Principles. Geneva , Switzerland. Retrieved January 4, 2019, from https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/pub100080.pdf

Laposata, M., & Rohde, R. E. (2019, April 18). *Preventing diagnostic errors by uniting the clinical laboratory with direct patient care.* Retrieved from Elsevier Connect:

https://www.elsevier.com/connect/preventing-diagnostic-errors-by-uniting-the-clinical-laboratory-with-direct-patient-care

Lundberg, G. D. (2018, December 19). *A Doctor's Rules for Other Doctors - Part 2.* Retrieved from Medscape Internal Medicine: https://www.medscape.com/viewarticle/906529?nlid=126774_1025&src=WNL_mdplsfeat_181226_mscpedit_path&uac=29841HJ&spon=43&impID=1844171&faf=1

Medical Lab Management. (2017, October). Specimen Labeling & Tracking in the Ambulatory Setting. *Medical Lab Management, 6*(8), pp. 2, 4-5.

Newitt, V. N. (2019, March). *Labs add safety net to critical values procedure.* Retrieved from CAP TODAY: https://captodayonline.com/labs-add-safety-net-to-critical-values-procedure/

Noble, M. (2018, January 2). *Fit for Process versus Fit for Purpose.* Retrieved from Making Medical Lab Quality Relevant: http://www.medicallaboratoryquality.com/2018/01/

Plebani, M. (2017). Quality in laboratory medicine: an unfinished journey. *Journal of laboratory and Precison Medicine, 2*(63).

Rhoads, D. G. (2012). *Lab Statistics Fun and Easy* (5th ed.). South Burlington, VT: Data Innovations, LLC.

Return on Investment. (n.d.). Retrieved from Society to Improve Diagnosis in Medicine: https://www.improvediagnosis.org/roadmap-for-research-to-improve-diagnosis-return-on-investment/

Saah, A., & Hoover , D. (1997, January 1). "Sensitivity" and "specificity" reconsidered: the meaning of these terms in analytical and diagnostic settings. *Annals of Internal Medicine, 126*(1), 91-94. Retrieved March 6, 2019, from https://www.ncbi.nlm.nih.gov/pubmed/8992938

Sikaris, K. A. (2017). Enhancing the Clinical Value of medical Laboratory Testing. *Clinical Biochemistry Reviews, 38*(3), 107-114.

Smith, C. A. (n.d.). *Promoting High Reliability on the Frontline.* Retrieved from American Nurse Today: https://americannursetoday.mydigitalpublication.com/publication/index.php?i=476895&pjs=1&p=&pn=&ver=html5&pid=&view=articleBrowser&article_id=3021618#{%22issue_id%22:476895,%22view%22:%22articleBrowser%22,%22article_id%22:%223021618%22}

Tony Badrick Gay, S., McCaughey, E. J., & Georgiou, A. (2017, February 15). External Quality Assessment beyond the analytical phase: an Australian perspective. *Croatian Society of Medical Biochemistry, 27*(1), 73-80.

Westgard, J. O. (2007). *Basic QC Practices* (2nd ed.). Madison: Westgard QC, Inc.

Westgard, J. O. (2010). *Basic QC Practices* (3rd ed.). Madison: Westgard QC, Inc.

Westgard, J. O. (2016). *Basic QC Practices* (4th ed.). Madison: Westgard QC, Inc.

World Health Organziation, Regional Office for Africa. (2015). Stepwise Labarotry Quality Improvement Process Towards Accreditation (SLIPTA) Cheklist (ver. 2:2015).

QMS 4
Evaluation and Continual Improvement

In QMS 4, The STUDY and ACT phases of the QMS will be explored. Four continual improvement tools will be discussed.

The Evaluation and Continual Improvement module is composed of the following three sections:

4.1 Occurrence Management System

4.2 Internal Audit Program

4.3 Management Review Process

Please note: each of the above sessions has its own overview file that includes:

- Connections with the requirements
- Activities and their corresponding times
- List of references used

ISO 15189 Continual Improvement Tools

- Using Quality Indicator information
- Managing non-conformities (Occurrence Management System)
- Performing internal and external audits
- Conducting regular management reviews

STUDY – Gather and analyze information to make a decision

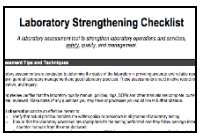
ACT – Take appropriate action based on the decision made

Measurement, Analysis, and Improvement component of a QMS

QMS 4
Evaluation and Continual Improvement

QMS 4.1: Occurrence Management Systems (OMS)

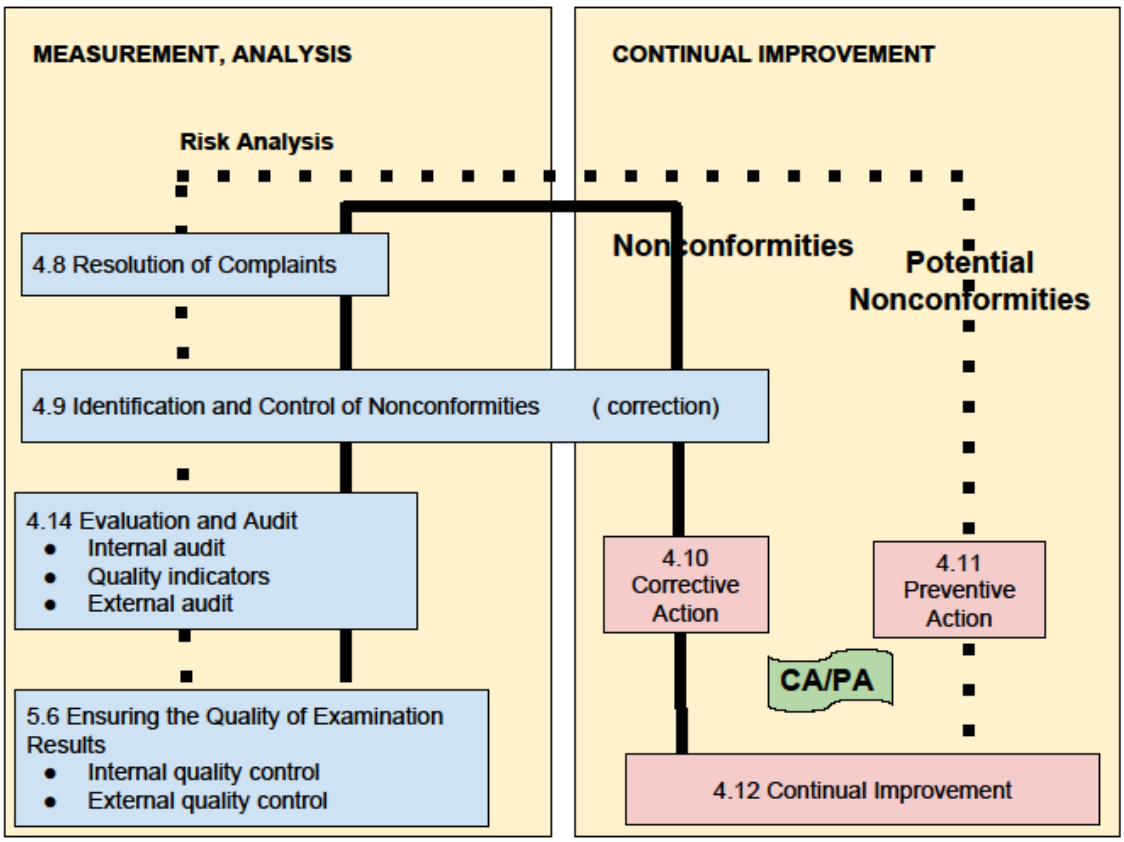
An effective Occurrence Management System (OMS) facilitates the continuous improvement effort by identifying process problems or potential problems that can affect patient safety, consume resources, and adversely impact the ability to provide quality services. Understanding the process interactions within an OMS can play a pivotal role in designing an OMS that is able to utilize a risk-based approach towards prioritizing, designing, and implementing improvement projects.

This part supports the following SLIPTA checklist items and ISO 15189 requirements	
Checklist Items 	1.5 Laboratory Policies and Standard Operating Procedures Are policies and/or standard operating procedures (SOPs) for laboratory functions, technical and managerial procedures current, available and approved by authorized personnel? (Communication, Service Agreements, Resolution of Complaints and Feedback, Identification and Control of Nonconformities, Corrective Action, Preventive Action, Continual Improvement, Risk Management, Reporting and Release of Results) 2.1 Routine Review of Quality and Technical Records Does the laboratory routinely perform a documented review of all quality and technical records? 3.4 Quality Management System Oversight Is there a quality officer/manager with delegated responsibility to oversee compliance with the quality management system? 3.7 Laboratory Staff Training 4.2 Resolution of Complaints Does the laboratory investigate (review) and resolves of customer complaints? 4.4 Communication Policy on Delays in Service Is timely, documented notification provided to customers when the laboratory experiences delay or interruptions in testing (due to equipment failure, stock outs, staff levels, etc.) or finds it necessary to change examination procedures and when testing resumes? 4.5 Evaluation Tool and Follow up Is there a tool for regularly evaluating client satisfaction, staff suggestions and is the feedback received effectively utilized to improve services? 6.3 Risk Management Is assessment of potential pitfalls performed for all laboratory processes including pre examination, examination and post examination? 8.2 Does the laboratory adequately collect information needed for examination performance? 9.1 Test Result Reporting System Are test results legible, technically verified by an authorized person, and confirmed against patient identity? 10.0 Corrective Action 11.0 Occurrence/Incident Management and Process Improvement

QMS 4
Evaluation and Continual Improvement

ISO 15189	4.1 Organization and Management Responsibility 4.2. Quality Management Systems 4.4 Service Agreements 4.8 Resolution of Complaints 4.9 Identification and Control of Nonconformities 4.10 Corrective Action 4.11 Preventative Action 4.12 Continual Improvement 5.6 Ensuring Quality of Examination Results 5.8 Reporting of Results 5.9 Release of Results

Occurrence Management System



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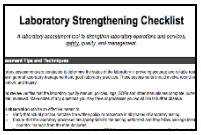
ge adapted from Burnett, 2013, p.302

QMS 4
Evaluation and Continual Improvement

QMS 4.2: Internal Auditing

Internal audits (IA) provide a measure of current performance and benchmarks the level of quality currently being achieved.

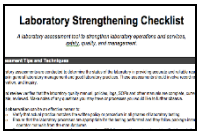
In Part II, participants learn how to implement a practical internal audit program that meets ISO15189 requirements while adding significant, measurable value to the laboratory's continual improvement activities.

This part supports the following SLIPTA checklist items and ISO 15189 requirements	
Checklist Items 	1.5 Laboratory Policies and Standard Operating Procedures Are policies and/or standard operating procedures (SOPs) for laboratory functions, technical and managerial procedures current, available and approved by authorized personnel? (Internal Audits, Risk Management, Personnel Training) 2.1 Routine Review of Quality and Technical Records Does the laboratory routinely perform a documented review of all quality and technical records? 3.4 Quality Management System Oversight Is there a quality officer/manager with delegated responsibility to oversee compliance with the quality management system? 3.7 Laboratory Staff Training 6.0 Evaluation and Audits 10.0 Identification of Nonconformities, Corrective and Preventive Action 11.0 Occurrence Management and Process Improvement
ISO 15189	4.1 Organization and Management Responsibility 4.2. Quality Management Systems 4.10 Corrective Action 4.11 Preventative Action 4.12 Continual Improvement 4.14 Evaluation and Audits

QMS 4
Evaluation and Continual Improvement

QMS 4.3: Management Review Process

The purpose of the review is for management to assess its level of commitment to the quality system at regular intervals, evaluate the effectiveness of the system, and recommend changes as necessary. Findings and actions taken by laboratory management as a result of the review are documented and become a quality record.

This part supports the following SLIPTA checklist items and ISO 15189 requirements	
Checklist Items 	1.5 Laboratory Policies and Standard Operating Procedures Are policies and/or standard operating procedures (SOPs) for laboratory functions, technical and managerial procedures current, available and approved by authorized personnel? (Risk Management, Management Review) 2.1 Routine Review of Quality and Technical Records Does the laboratory routinely perform a documented review of all quality and technical records? 2.2 Management Review Does the laboratory management perform a review of the quality system at a management review meeting at least annually? 2.3 Are findings and actions from MR communicated to the relevant staff? 2.4 Does lab management ensure actions from MR are completed within defined timeframes?
ISO 15189	4.1 Organization and Management Responsibility 4.2. Quality Management Systems 4.12Continual Improvement 4.15Management Review

QMS 4
Evaluation and Continual Improvement

What's in this Module?

ACTIVITY TITLE	PURPOSE	DURATION
Session 4.1: Occurrence Management		
Mapping Nonconformities	In this session, participants determine the sequence and interaction of processes needed to identify and effectively control problems.	1 hour 10 min
Selecting the Winning Problem(s)	In this session, participants learn how to categorize individual NCEs to determine the appropriate action to be taken based on risk analysis. Participants also learn how to index and sort the event information in an occurrence log so that systematic trend and pattern recognition can be performed periodically to identify underlying process problems.	2 hours 50 min
Just Culture	In this session, participants explore why a Just Culture is essential for continuous improvement and how their organization can strike a balance between no blame and individual accountability.	50 min
Root Cause Analysis	Beneath every problem lies a cause for that problem. If the cause is reduced or eliminated, the risk is also reduced. In this session, participants solve a complex problem, which entered the corrective action process, using the Root Cause Analysis (RCA) methodology, a structured problem-solving approach.	7 hours 15 min
Preventive Action	Preventive action (PA) is a planned process whereby data is reviewed for change. By anticipating when potential problems may arise, the process prevents the problems from occurring or minimizes their consequences. In this session, participants will learn to recognize their PA activities they currently perform and how to make PA a viable element in their QMS.	2 hours

QMS 4
Evaluation and Continual Improvement

ACTIVITY TITLE	PURPOSE	DURATION
Session 4.2: Internal Auditing		
Introduction to Internal Auditing	Auditing is a management tool used to verify that processes are conformant, suitable to achieve objectives, and effective. To use this tool effectively, management must partner with the auditee, the expert of the process being audited. For the auditee to willingly bring forth problems, the environment first must be safe and just. In this activity, participants learn how to incorporate an internal audit program into the check/act element of a QMS, as well as, how to create an organizational environment that optimizes program effectiveness.	2 hours 20 min
Audit Process – Creating an Audit Plan	The most important phase of the internal audit is the preparation phase. The audit begins when the audit coordinator initiates the audit by defining the purpose, scope, and method approach to be used. In this activity, participants learn how to prepare for an audit by creating an audit plan.	1 hour 50 min
Audit Process – Review, Study, and Understand	When internal auditors know exactly what records and how many to review as a result of their preparation efforts, the quality of the audit increases. In this activity, participants learn how to prepare for an audit by constructing an effective checklist to use as a guide during the audit field work.	4 hours 10 min
Audit Process – Conducting an Audit	The purpose of the performance phase is to collect objective evidence, which determines conformance or nonconformance. In this activity, participants learn how to conduct an audit from the opening to the closing meetings and everything else in-between.	1 hour
Audit Process – Reporting the Audit	After the audit field work is completed, it is time to analyze and sort the information gathered and determine conformance to the documented system and the effectiveness of that system. The results of the audit are primarily reported in the form of a nonconformity statement. In this activity, participants learn how to write effective nonconformity statements and prepare an audit report.	3 hours 20 min

QMS 4
Evaluation and Continual Improvement

ACTIVITY TITLE	PURPOSE	DURATION
Internal Audit Program	Conducting planned audits throughout the laboratory's QMS requires oversight and coordination of activities. In this activity, participants learn the tasks and responsibilities required to manage an effective internal audit program.	1 hour 25 min
Session 4.3: Management Review Process		
Management Review	Management Review (MR) of the QMS is a process by which top management conducts regular, systematic evaluations of the suitability, adequacy, effectiveness, and efficiency of the QMS with respect to the quality policy and objectives. MR provides the cornerstone for the laboratory's strategic planning. In this activity, participants perform an evaluation of a laboratory's QMS for planning and improvement purposes, and then make decisions based on their evaluation.	2 hours 30 min
	Total Module Time:	**30 hours 40 min**

QMS 4
Evaluation and Continual Improvement

QMS 4.1 References

Ames, M. (n.d.). *Quality Snapshot - Corrective Action.* Retrieved March 1, 2015, from American Society for Quality Knowledge Center Webcast: http://asq.org/knowledge-center/webcasts.html

Ammerman, M. (1998). *The Root Cause Analysis Handbook.* Portland: Productivity, Inc.

Andersen, B., & Fagerhaug, T. (2006). *Root Cause Analysis: Simplified Tools and Techniques.* Milwaukee: American Socieity for Quality, Quality Press.

Andrew, W. (2007, December). A Role for Root Cause Analysis in Laboratory Medicine. *Lab Medicine, 38*(12), 709-712.

Astion, M. L., Shojania, K. G., Hamill, T. R., Kim , S., & Ng, V. L. (2003). Classifying Laboratory Incident Reports to Identify Problems that Jeopardize Patient Safety. *American Journal of Clinical Pathology*, 18-26.

Barker, T., & Noguez, J. (2015, January). The High Cost of Low Morale in the Clinical Laboratory: How Workplace Environment Impacts Patient Safety. *Clinical Laboratory News*, 24-25.

Berman, S. (2003, August). Using Aggregate Root Cause Analysis to Improve Patient Safety. *Joint Commision Journal on Quality and Safety, 29*(8), 434-439.

Boysen, P. G. (2013). Just Culture: A Foundation for Balance Accountability and Patient Safety. *The Ochsner Journal, 13*, 400-406.

Burnett, D. (2013). *A Practical Guide to ISO 15189 in Laboratory Medicine.* London: ACB Venture Publications.

CAPA Part 1: Improving CAPA Systems with a Closed-loop Methodology. (n.d.). Retrieved March 10, 2016, from Master Control: http://www.mastercontrol.com/downloadables/customervideos/standalone.html?c=115

CAPA Part 2: Taking Effective Action. (n.d.). Retrieved March 10, 2016, from Master Control: http://www.mastercontrol.com/downloadables/customervideos/standalone.html?c=116

CAPA Part 3: Effectiveness Checking and Management Review. (n.d.). Retrieved March 10, 2016, from Master Control: http://www.mastercontrol.com/downloadables/customervideos/standalone.html?c=120

Clinical and Laboratory Standards Institute (CLSI). (2004). *Application of a Quality Management System Model for Laboratory Services: Approved Guideline (GP26-A3)* (3 ed., Vol. 24). Wayne, PA: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2006). *Laboratory Documents: Development and Control; Approved Guideline GP2-A5* (5 ed., Vol. 26). Wayne, PA: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2007). *Management of Nonconforming Laboratory Events: Approved Guideline* (Vol. 27). Wayne, PA: Clincial and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2009). *Risk Management Techniques to Identify and Control Laboratory Error Sources: Approved Guideline - Second Edition (EP18-A2).* Wayne, PA: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2011). *Quality Management System: Continual Improvement; Approved Guideline (QMS06-A3)* (3 ed.). Wayne, PA: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2013). Laboratory QMS Certificate Program Module: QSE Continual Improvement.

Clinical and Laboratory Standards Institute (CLSI). (2013). Laboratory QMS Certificate Program Module: QSE Documents and Records.

Clinical and Laboratory Standards Institute (CLSI). (2013). Laboratory QMS Certificate Program Module: QSE Introduction.

Clinical and Laboratory Standards Institute (CLSI). (2013). Laboratory QMS Certificate Program Module: QSE Process Management.

Clinical and Laboratory Standards Institute (CLSI). (2013). *Quality Management System: Development and Management of Laboratory Documents; Approved Guideline (QMS02-A6)* (6 ed.). Wayne, PA: Clinical and Laboratory Standards Institute (CLSI).

Clinical and Laboratory Standards Institute (CLSI). (2014). *Undertanding the Cost of Quality in the Laboratory; A Report QMS20-R.* Wayne, PA: Clinical and Laboratory Standards Institute (CLSI).

Clinical and Laboratory Standards Institute (CLSI). (2015). *Nonconforming Event Management (QMS11)* (2 ed.). Wayne, PA: Clinical and Laboratory Standards Institute.

QMS 4
Evaluation and Continual Improvement

Clinical and Laboratory Standards Institute (CLSI). (2015). *Process Management (QMS18).* Wayne, PA: Clinical and Laboratory Standards Institute (CLSI).

Clinical and Laboratory Standards Institute. (2013). Laboratory QMS Certificate Program Module: QSE Nonconforming Event Management.

Cochran, C. (2003). *The Continual Improvement Process: From Strategy to the Bottom Line.* Chico, CA: Paton Press LLC.

Cochran, C. (2010). *Problem Solving in Plain English.* Chico, CA: Paton Press LLC.

Cochran, C. (2015). *ISO 9001:2015 In Plain English.* Chico, CA: Paton Professional LLC.

Connor , M., Duncombe, D., Barclay, E., Bartel, S., Borden, C., Gross, E., . . . Reid Ponte, P. (2007, October). Creating a Fair and Just Culture: One Institution's Path Toward Organziational Change. *The Journal of Quality anf Patient Safety, 33*, 617-624.

Dawson, J. (2016). Cultivating a Culture of Quality. Retrieved May 1, 2016, from https://www.aacc.org/store/thought-leadership/10600/cultivating--a-culture-of-quality-in-the-laboratory

Dawson, J. (2017, February 9). Do No Harm: Diagnostic Errors and the Lab. Retrieved from http://www.labtestingmatters.org/do-no-harm-diagnostic-errors-and-the-lab/

Dawson, J. (2015, July-August). *Navigating ISO 15189.* Retrieved from MedicalLab Management: https://www.medlabmag.com/article/1201/?search=navigating%20ISO%2015189

Dawson, J. (n.d.). *What's the Cost of Poor Quality? Measure the Value of Your Lab's Quality Program With the CoPQ Calculator.* Retrieved from LabLeaders: https://resourcecenter.lableaders.com/financial/whats-the-cost-of-poor-quality-measure-the-value-of-your-labs-quality-program-with-the-copq calculator?mkt_tok=eyJpIjoiT0dFd05UVXhNelk1TXpnMyIsInQiOiJtd2NkWmU1MHdZSFlvQ3h5SHplZkk0UU83K3lxTmRNMWJnSXRUaFwvRkpF

DiMaria, J. (n.d.). ISO 9001:2015 What are the changes? Retrieved May 6, 2016, from http://bsi.learncentral.com/aicc/9kChanges2016US/index_lms.html

German, R. (2014, April 24). *"Use of a Nonconforming Events (NCE) Information System in the Laboratory to Select Key Indicators of Quality, and Meet AABB and CAP Requirements for Quality Management.".* Retrieved February 18, 2016, from Otis: http://www.youtube.com/watch?v=ONmUIvpxZz8&feature=youtu.be

Homer, M. (2019, February 26). *After death of St. Luke's patient, review uncovers 122 issues with blood labels over four-month period.* Retrieved from KHOU 11: https://www.khou.com/article/news/health/after-death-of-st-lukes-patient-review-uncovers-122-issues-with-blood-labels-over-four-month-period/285-07798e96-d21b-489b-b54e-43601557d760

Institute for Quality Management in Healthcare (IQMH). (2014). Decoding ISO 15189 Interactive Online Education Series: Module 7 - Occurrence Management.

International Organization for Standardization (ISO). (2012). ISO 15189: 2012 Medical laboratories -- Requirements for quality and competence.

ISO 9001:2015 Part 1: Prepare for Impending Changes. (n.d.). Retrieved March 5, 2016, from Master Control: http://www.mastercontrol.com/downloadables/customervideos/standalone.html?c=128

ISO 9001:2015 Part 2: New QMS Structure Overview. (n.d.). Retrieved March 6, 2016, from Master Control: http://www.mastercontrol.com/downloadables/customervideos/standalone.html?c=137

ISO 9001:2015 Part 3: Risk-based Thinking Goes from Implicit to Explicit. (n.d.). Retrieved March 6, 2016, from Master Control: http://www.mastercontrol.com/downloadables/customervideos/standalone.html?c=145

Kopec, D., Levy, K., Kabir, M., Reinharth , D., & Shagas, G. (2005). Develpment of an Expert System for Classification of Medical Errors. *Student Health Technology Information Journal, 114*, 110-116.

Master Control White Paper. (n.d.). Simplifiying CAPA: Seven Steps to a Comprehensive CAPA Plan.

Master Control White Paper. (n.d.). *How to Kick-Start Your CAPA Process.*

Murphy, J., Dropp, K., Allstetter, P., Taylor, L., & Heath, C. (2009, My/June). The Root Cause Analysis (RCA) Process, One Step at a time. *Topics in Patient Safety (TIPS), 9*(3), pp. 1-3.

New York State Department of Health, Wadsworth Center. (2010). *Guidance for Implementing a Laboratory Quality Management System.*

Newitt, V. N. (2019, March). *Labs add safety net to critical values procedure.* Retrieved from CAP TODAY: https://captodayonline.com/labs-add-safety-net-to-critical-values-procedure/

Njoroge, S. W., & Nichols, J. H. (2014). Risk Managment in the Clinical Laboratory. *Annals of Laboratory Medicine, 34*, 274-278.

Noble, M. (2019, February 4). *GB/T32230: Quality Culture and the Medical Laboratory.* Retrieved from Making Medical Lab Quality Relevant: http://www.medicallaboratoryquality.com/2019/02/gbt32230-quality-culture-and-medical.html?utm_source=feedburner&utm_medium=email&utm_campaign=Feed%3A+MakingMedicalLabQualityRelevant+%28Making+Medical+Lab+Quality++Relevant%29

Okes, D. (2009). *Root Cause Analysis: The Core of Problem Solving and Corrective Action.* Milwaukee: American Society for Quality, Quality Press.

Okes, D. (n.d.). *Getting the Defects Out of Root Cause Analysis Webcast.* Retrieved March 10, 2016, from American Society for Quality Knowledge Center Webcast: http://asq.org/2013/12/quality-tools/getting-the-defects-out-of-root-cause-analysis.html?WT.ac=CAR-36388

Osegbe, I. D., Zemlin, A. E., Kimengech, K. K., & Erasmus, R. T. (2013, June). The Impact of Non-Conformances on Patient Care at a Pathology Tertiary Care Laboratory In South Africa. *Medical Technology SA, 27*(1), 29-32.

Pendergraph, G. E., & Gruber, E. J. (2012). Risk Management in the Clinical Laboratory. *MediaLab, Inc.*

Rivenburgh, D. (n.d.). *How to Create a Virbrant, Thriving Culture.* Retrieved March 2, 2016, from American Society for Quality Knowledge Center Webcast: http://asq.org/knowledge-center/webcasts.html

Robitaille, D. (2003). *The Preventive Action Handbook.* Chico, CA: Patton Press.

Robitaille, D. (2004). *Root Cause Analysis: Basic Tools and Techniques.* Chico, CA: Paton Press LLC.

Robitaille, D. (2009). *The Corrective Action Handbook* (2 ed.). Chico, CA: Paton Press LLC.

Rooney, J. (2011, April). *RCA for Beginners: Part 2 - Practical Application.* Retrieved March 3, 2016, from American Society for Quality Knowledge Center Webcast: http://asq.org/2011/04/root-cause-analysis-for-beginners-part-2-webcast.html

Rooney, J. (n.d.). *RCA for Beginners: Part 1 - A Conceptual Overview.* Retrieved March 2, 2016, from American Society for Quality Knowledge Center Webcast: http://asq.org/knowledge-center/webcasts.html

Rosenstein, A. H., & O'Daniel, M. (2008). *A Survey of the Impact of Disruptive Behaviors and Communication Defects on Patient Safety.* The Joint Commision Journal on Quality and Patient Safety.

Smith, C. A. (n.d.). *Promoting High Reliability on the Frontline.* Retrieved from American Nurse Today:https://americannursetoday.mydigitalpublication.com/publication/index.php?i=476895&pjs=1&p=&pn=&ver=html5&pid=&view=articleBrowser&article_id=3021618#{%22issue_id%22:476895,%22view%22:%22articleBrowser%22,%22article_id%22:%223021618%22}

VA National Center for Patient Safety. (2015). *Root Cause Analysis Tools: Root Cause Analysis (RCA) Step-By-Step Guide.* U.S. Department of Veteran's Affairs.

Vinton, E., & George, C. (2014, May/June). Staff leadership Key to Enhancing the Root Cause Analysis Process. *Topic in Patient Safety, 14*(3), pp. 1,4.

Wachter, R. M., & Pronovost, P. J. (2009+, October 1). Balancing "No Blame" with Accountability in Patient Safety. *The New England Journal of Medicine, 361*(14), 1401-1406.

Westgard, J. O., & Westgard, S. A. (2014). *Basic Qaulity Management Systems.* Madison: Westgard QC, Inc.

World Health Organziation, Regional Office for Africa. (2015). Stepwise Labarotry Quality Improvement Process Towards Accreditation (SLIPTA) Cheklist (ver. 2:2015).

QMS 4
Evaluation and Continual Improvement

QMS 4.2 References

American Association for Laboratory Accreditation (A2LA). (2012). Internal Auditor Course Handbook.

Arter, D. R., Cianfrani, C. A., & West, J. E. (2003). *How to Audit the Process-Based QMS.* Milwaukee: American Society for Quality, Quality Press.

Arter, D. (n.d.). The How and Why of Auditing. *American Society of Quality TV Library*. Retrieved June 29, 2016, from http://videos.asq.org/product/the-how-and-why-of-auditing

Burnett, D. (2013). *A Practical Guide to ISO 15189 in Laboratory Medicine.* London: ACB Venture Publications.

Clinical and Laboratory Standards Institute (CLSI). (2006). *Laboratory Documents: Development and Control; Approved Guideline GP2-A5* (5 ed., Vol. 26). Wayne, PA: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2010). *Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality: Approved Guideline (QM12-A).* Wayne, PA: Clinical and Laboratory Standards Institute .

Clinical and Laboratory Standards Institute (CLSI). (2011). *Quality Management System: A Model for Laboratory Services: Approved Guideline (GP26-A4)* (4 ed.). Wayne, PA: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2013). *Assssments: Laboratory Internal Audit Program; Approved Guideline (QMS15-A).* Wayne, PA: Clinical and Laboratory Standards Institute .

Clinical and Laboratory Standards Institute (CLSI). (2013). Laboratory QMS Certificate Program Module: QSE Organization: QSE Assessments.

Cochran, C. (2003). *The Continual Improvement Process: From Strategy to the Bottom Line.* Chico, CA: Paton Press LLC.

Dawson, J. (2016). Cultivating a Culture of Quality. Retrieved May 1, 2016, from https://www.aacc.org/store/thought-leadership/10600/cultivating--a-culture-of-quality-in-the-laboratory

Dhatt, G. S., Sahni, S., & Damir, H. A. (2008). Aspects of Auditing in Clinical Laboratories. *Accreditation and Quality Assurance Journal, 13*, 505-509.

European Cooperation for Accreditation of Laboratories. (n.d.). *Internal Audits and Management Review for Laboratories (EAL-G3).*

Fulks, G. (2018, May 14). *The Art of Active Listening.* Retrieved January 20, 2019, from LinkedIn: https://www.linkedin.com/pulse/art-active-listening-glenna-fulks/

Institute for Quality Management in Healthcare (IQMH). (2014). Decoding ISO 15189 Interactive Online Education Series: Module 8 - Internal Audit and Management Review.

Institute for Quality Management in Healthcare (IQMH). (2014). Decoding ISO 15189 Interactive Online Education Series: Module 9 - Quality Indicators.

International Organization for Standardization (ISO). (2012). ISO 15189: 2012 Medical laboratories -- Requirements for quality and competence.

National Accreditation Board for Testing and Calibration Laboratories (NABL). (2012). *Guide for Internal Audit and Management Review for Laboratories.*

New York State Department of Health, Wadsworth Center. (2010). *Guidance for Implementing a Laboratory Quality Management System.*

Olea, S. (2016, April 5). *Tracer Methodology and Performing Mock Tracers.* Retrieved from Point of Care Group Webinars : https://www.whitehatcom.com/POC_Group_Webinars_2016.htm

Phillips, A. W. (2009). *ISO 9001:2008 Internal Audits Made Easy.* Milwaukee: American Society for Quality, Quality Press .

Quinley, E. D. (n.d.). *Quality, It's More than Compliance.* Retrieved July 10, 2016, from Ortho On Demand: https://vts.inxpo.com/scripts/Server.nxp?LASCmd=AI:1;F:SF!40000&BoothKey=239788

Robitaille, D. (2009). *The Corrective Action Handbook* (2 ed.). Chico, CA: Paton Press LLC.

Russell, J. (2007). *The Internal Auditing Pocket Guide* (2 ed.). Milwaukee: American Socieity for Quality, Quality Press.

Russell, J. (2010). *The Process Auditing and Techniques Guide* (2 ed.). Milwaukee: American Socieity for Quality, Quality Press.

Schiffgens, J. (2014, January 30). *Laboratory Internal Audit Program: Tips for Developing and Implementing an Internal Audit Process.* Retrieved from Clinical and Laboratory Institute.

Venner, M. (2019, April 4). AS9100 for Smart People-Internal Audit Planning. Retrieved from https://www.linkedin.com/pulse/as9100-smart-people-internal-auditplanning-michael-venner-beng/

Venner, M. (2019, March 26). ISO Auditor Questioning Techniques. Retrieved from https://www.linkedin.com/pulse/iso-auditor-questioning-techniques-michael-venner-beng/

Westgard, J. O., & Westgard, S. A. (2014). *Basic Quality Management Systems.* Madison: Westgard QC, Inc.

World Health Organization, Regional Office for Africa. (2015). Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Cheklist (ver. 2:2015).

QMS 4
Evaluation and Continual Improvement

QMS 4.3 References

Burnett, D. (2013). *A Practical Guide to ISO 15189 in Laboratory Medicine.* London: ACB Venture Publications.

Clinical and Laboratory Standards Institute (CLSI). (2004). *Application of a Quality Management System Model for Laboratory Services: Approved Guideline (GP26-A3)* (3 ed., Vol. 24). Wayne, PA: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2004). *Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline - Second Edition (GP22-A2)* (2 ed., Vol. 24). Wayne, PA: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2011). *Quality Management System: A Model for Laboratory Services: Approved Guideline (GP26-A4)* (4 ed.). Wayne, PA: Clinical and Laboratory Standards Institute.

Clinical and Laboratory Standards Institute (CLSI). (2012). *Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline (QMS14-A).* Wayne, PA: Clinical and Laboratory Standards Institute .

Clinical and Laboratory Standards Institute (CLSI). (2013). Laboratory QMS Certificate Program Module: QSE Organization. CLSI U.

Cochran, C. (2003). *The Continual Improvement Process: From Strategy to the Bottom Line.* Chico, CA: Paton Press LLC.

Dawson, J. (2015, July-August). *Navigating ISO 15189.* Retrieved from MedicalLab Management:https://www.medlabmag.com/article/1201/?search=navigating%20ISO%2015189

Dawson, J. (2017, February 9). Do No Harm: Diagnostic Errors and the Lab. Retrieved from http://www.labtestingmatters.org/do-no-harm-diagnostic-errors-and-the-lab/

Dawson, J. (2017, August 29). *Lean Six Sigma is Not Quality.* Retrieved from G2 Intelligence: https://www.g2intelligence.com/lean-six-sigma-is-not-quality/

Institute for Quality Management in Healthcare (IQMH). (2014). Decoding ISO 15189 Interactive Online Education Series: Module 8 - Internal Audit and Management Review.

International Organization for Standardization (ISO). (2012). ISO 15189: 2012 Medical laboratories -- Requirements for quality and competence.

LabCoP ECHO Session Resource. (2018, June). LARC 2.0 Quality improvement Collaborative Workbook. Retrieved from https://bnegash-my.sharepoint.com/personal/admin_aslm_org/_layouts/15/onedrive.aspx?id=%2Fpersonal%2Fadmin%5Faslm%5Forg%2FDocuments%2FLabCoP%20From%20Dr%20Legese%2FLARC%202%2E0%20WORKBOOK%20V2%2EPDF&parent=%2Fpersonal%2Fadmin%5Faslm%5Forg%2FDocuments%2FLa

McKinney, B. C. (n.d.). Quality Improvement: Applications for the Viral Load Cascade.

New York State Department of Health, Wadsworth Center. (2010). *Guidance for Implementing a Laboratory Quality Management System.*

Plebani, M. (2017). Quality in laboratory medicine: an unfinished journey. *Journal of laboratory and Precison Medicine, 2*(63).

Robitaille, D. (2002). *The Management Review Handbook.* Chico, CA: Paton Press.

Theodorou, D. G., & Anastasakis, P. C. (2009). Management Review Checklist for ISO/IEC 17025 and ISO 15189 Quality-management Systems. *Accreditation and Quality Assurance, 14*, 107-110.

Westgard, J. O., & Westgard, S. A. (2014). *Basic Quality Management Systems.* Madison: Westgard QC, Inc.

World Health Organization, Regional Office for Africa. (2015). Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Cheklist (ver. 2:2015).