INTERNATIONAL INSTITUTE FOR PATHOLOGY AND FORENSIC SCIENCE RESEARCH

COLLEGE of AMERICAN PATHOLOGISTS FOUNDATION

DAVID UMAHI FEDERAL UNIVERSITY OF HEALTH SCIENCES UBURU, EBONYI STATE.

Ensuring Compliance Through Laboratory Assessments & Audits

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Week 4

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Advancing Laboratory Quality Management Systems for Better Patient Outcomes

Objectives

- Conducting internal audits for quality improvement and accreditation readiness
- Key elements of ISO 15189 compliance and regulatory expectations
- Digital audit tools for enhancing accuracy and efficiency in assessments.

Introduction and Definitions

- Assessments - means for determining the effectiveness of a lab's quality management system through internal and external audits
- Definition …. An assessment can be defined as the ***systematic examination of some part (or sometimes all) of the QMS to demonstrate to all concerned that the lab is meeting regulatory, accreditation and customer requirements***.
- Accepted standards, whether international, national, local, or standards from accrediting organizations, form the basis for laboratory assessment

Questions ???

- What procedures and processes are being followed in the laboratory; what is being done?
- Do the current procedures and processes comply with written policies and procedures? And in fact, are there written policies and procedures?
- Do written policies and procedures comply with standards, regulations, and requirements?

Why perform audit/assessment?

- The ISO definition for audit is a "***systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which required criteria are fulfilled***"

- Also defined as, 'A systematic process to evaluate a laboratory's performance, procedures, and compliance with standards, policies, and regulations.

Why perform audit/assessment? - contd:

Purpose:

- For planning and implementing the quality system
- For monitoring effectiveness of the quality system
- For correcting any identified deficiencies
- For working toward continuous improvement
- Ensure adherence to good laboratory practices

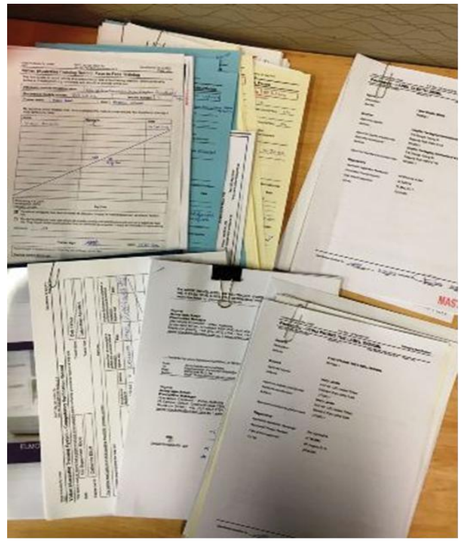
Auditing – Interval vs External:

- Internal – by lab personnel not directly working in the particular section of the laboratory being assessed
- External - by groups or agencies from outside the laboratories
- May be for accreditation, certification
- Laboratory audits should be conducted by experienced audit team proficient in the application of laboratory requirements or, at the very least, less seasoned auditors should be directed by an experienced team lead.

Aspect	Internal Audit	External Audit
Definition	Conducted by the organization's own staff to assess compliance and identify areas for improvement.	Conducted by an independent external body to verify compliance with regulations and accreditation standards.
Objective	Quality improvement, early detection of nonconformities, and preparation for external audits.	Ensuring regulatory compliance, accreditation, and certification.
Conducted By	Internal quality team or designated auditors within the organization.	Third-party auditors from regulatory agencies, accreditation bodies, or certifying organizations.
Frequency	Regular and scheduled based on organizational needs (e.g., monthly, quarterly, annually).	Periodic, often mandated by regulations
Scope	Focuses on internal processes, efficiency, and continuous improvement.	Evaluates compliance with external standards and regulations.
Reporting	Findings are reported internally to management for corrective action.	Findings are reported to regulatory bodies
Impact	Helps identify and resolve issues before external audits, improving overall compliance readiness.	Determines the laboratory's compliance status

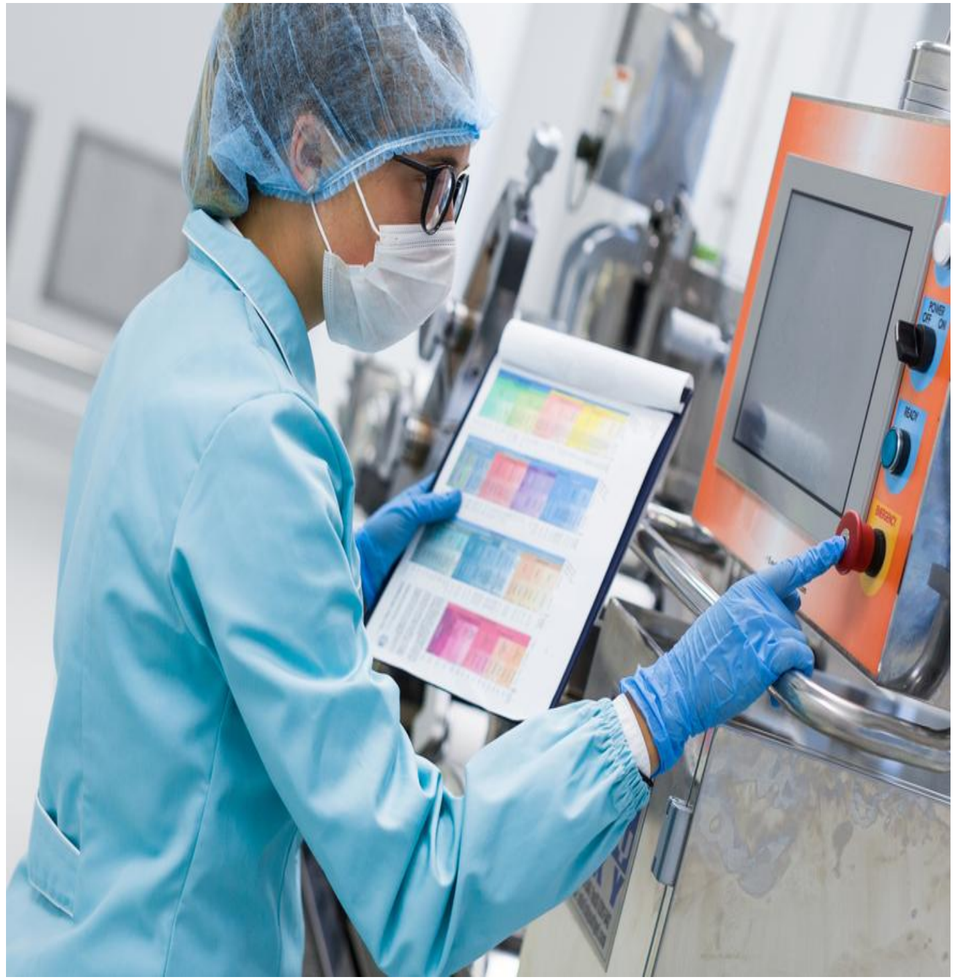
What is audited?

- Quality management, quality assurance, quality control
- Facility, Environment, Safety and Security
- Organization and Management
- Personnel, Orientations, Training
- Document control/SOPs
- Method validation
- Sample transport, receipt, processing
- Specimen collection, handling



What is audited? – contd:

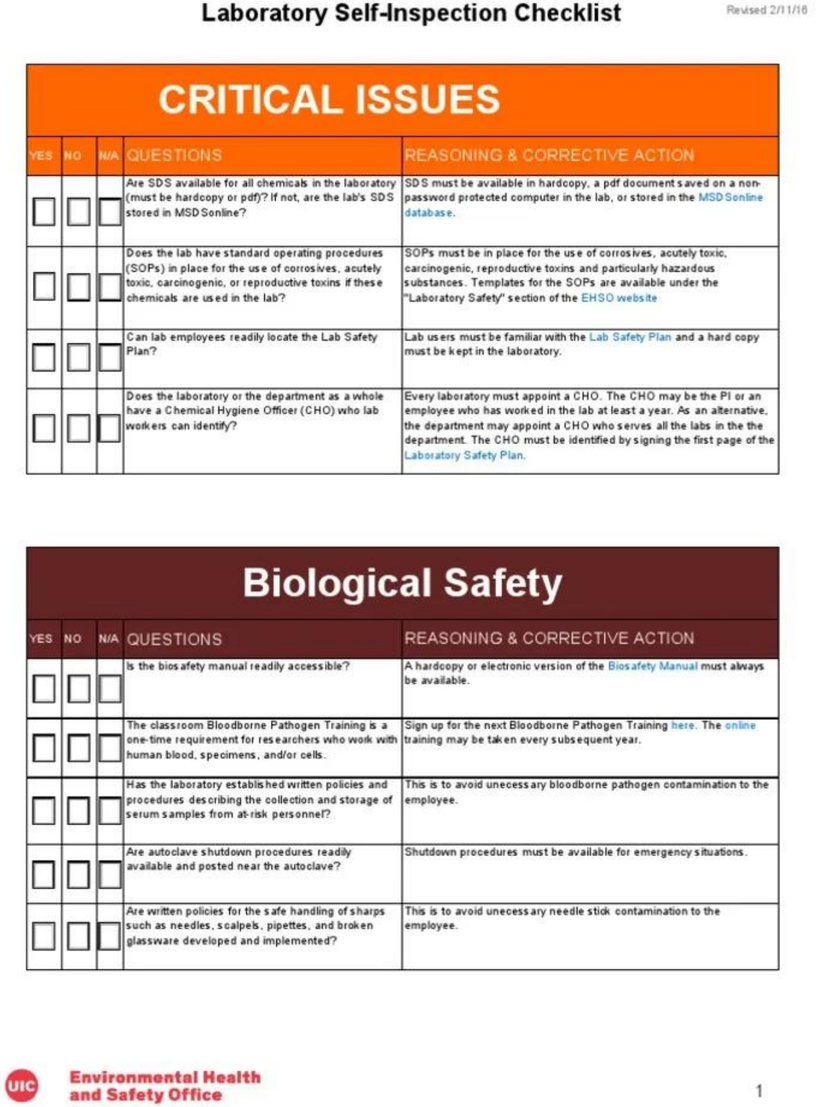
- Glassware, Quality of water, reagents
- Equipment calibration & maintenance
- Reporting of results
- Sample management
- Electronic systems
- Data management
- Steps in the whole laboratory path of workflow
- Findings are compared with the lab's internal policies and to a standard or external benchmark.



Preparing for an external audit

- Different standards can be used for the assessment processes, ranging from international standards to a locally developed checklist.

- To be ready for the external audit, it is necessary to:
  - plan thoroughly and carefully;
  - organize everything ahead of time, including documents and records, to save valuable time during the audit;
  - make all staff aware of the audit, and arrange schedules so that all staff needed for the audit will be available



Laboratory Self-Inspection Checklist Revised 2/11/16

CRITICAL ISSUES

YES	NO	N/A	QUESTIONS	REASONING & CORRECTIVE ACTION
☐	☐	☐	Are SDS available for all chemicals in the laboratory (must be hardcopy or pdf)? If not, are the lab's SDS stored in MSDSonline?	SDS must be available in hardcopy, a pdf document saved on a non-password protected computer in the lab, or stored in the MSDSonline database.
☐	☐	☐	Does the lab have standard operating procedures (SOPs) in place for the use of corrosives, acutely toxic, carcinogenic, or reproductive toxins if these chemicals are used in the lab?	SOPs must be in place for the use of corrosives, acutely toxic, carcinogenic, reproductive toxins and particularly hazardous substances. Templates for the SOPs are available under the "Laboratory Safety" section of the EHSO website
☐	☐	☐	Can lab employees readily locate the Lab Safety Plan?	Lab users must be familiar with the Lab Safety Plan and a hard copy must be kept in the laboratory.
☐	☐	☐	Does the laboratory or the department as a whole have a Chemical Hygiene Officer (CHO) who lab workers can identify?	Every laboratory must appoint a CHO. The CHO may be the PI or an employee who has worked in the lab at least a year. As an alternative, the department may appoint a CHO who serves all the labs in the the department. The CHO must be identified by signing the first page of the Laboratory Safety Plan.

Biological Safety

YES	NO	N/A	QUESTIONS	REASONING & CORRECTIVE ACTION
☐	☐	☐	Is the biosafety manual readily accessible?	A hardcopy or electronic version of the Biosafety Manual must always be available.
☐	☐	☐	The classroom Bloodborne Pathogen Training is a one-time requirement for researchers who work with human blood, specimens, and/or cells.	Sign up for the next Bloodborne Pathogen Training here. The online training may be taken every subsequent year.
☐	☐	☐	Has the laboratory established written policies and procedures describing the collection and storage of serum samples from at-risk personnel?	This is to avoid unecessary bloodborne pathogen contamination to the employee.
☐	☐	☐	Are autoclave shutdown procedures readily available and posted near the autoclave?	Shutdown procedures must be available for emergency situations.
☐	☐	☐	Are written policies for the safe handling of sharps such as needles, scalpels, pipettes, and broken glassware developed and implemented?	This is to avoid unecessary needle stick contamination to the employee.

UIC Environmental Health and Safety Office

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Impromptu External audits

- On occasion, some external audits might occur without prior notification.
- In this case, the laboratory would not be able to make special preparation, so the laboratory should always be sure its system is operating properly.

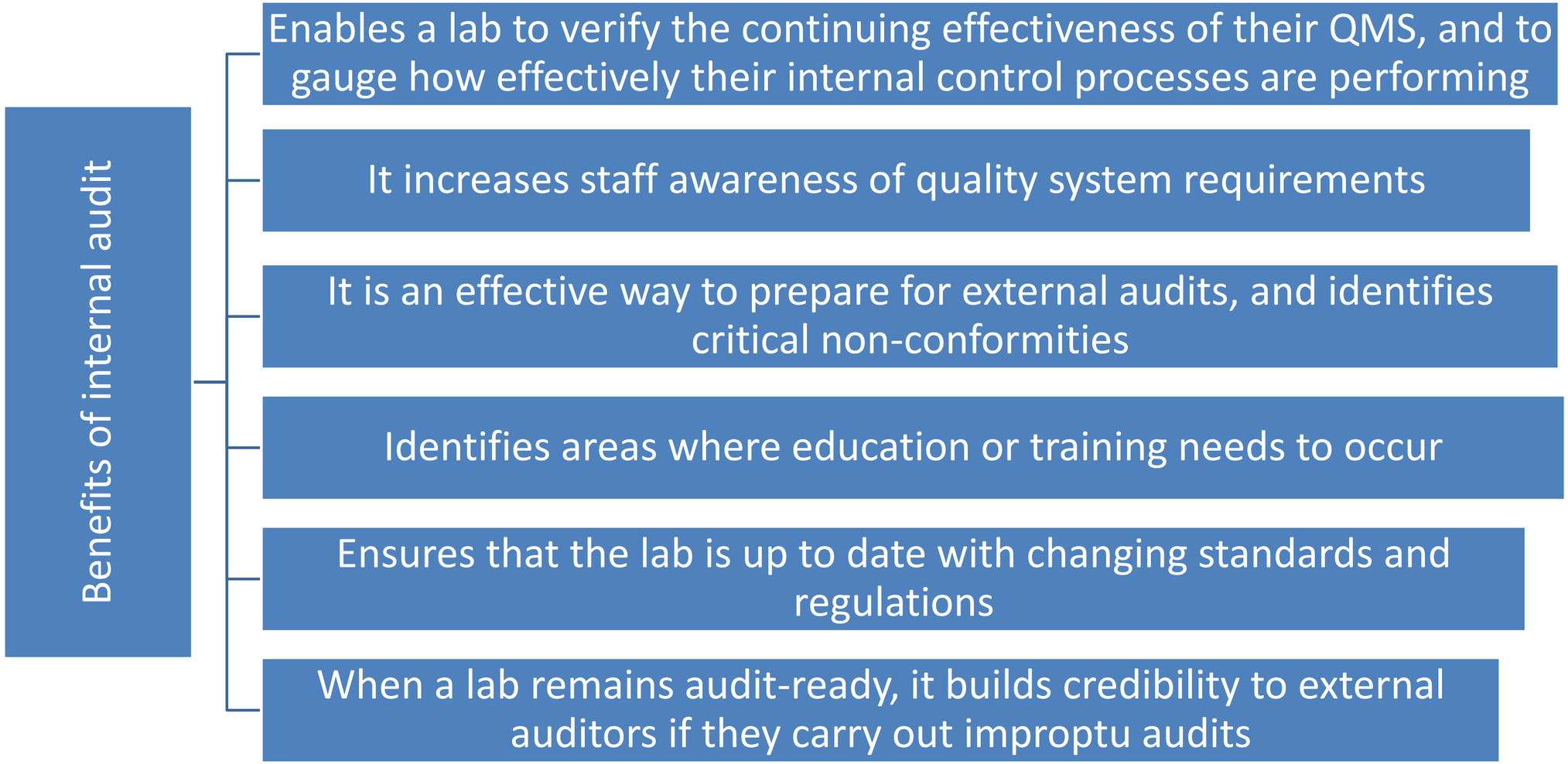
Internal audits

- Essential aspect of QMS
- Allow the laboratory to look at its own processes
- In contrast to external, can be performed as frequently as needed, and at very little or no cost.
- Internal audits should be a part of every laboratory quality system, and are a requirement of ISO standards

When to conduct internal audit

- At designated time intervals (lab policy)
- When problems that need to be studied have been identified.
- Eg, after receiving a poor performance on a proficiency testing survey
- after an increased number of unexpected abnormal results for a particular test,
- after an increase in expected TAT.

Benefits of internal audit



ISO 15189:2022 requirements for internal audits

- 8.8.3.2 The laboratory shall plan, establish, implement and maintain an internal audit program that includes:

  a. priority given to risk to patients from laboratory activities;

  b. a schedule which takes into consideration identified risks; the outcomes of both external evaluations and previous internal audits; the occurrence of nonconformities, incidents, and complaints; and changes affecting the laboratory activities;

  c. specified audit objectives, criteria and scope for each audit;

  d. selection of auditors who are trained, qualified and authorized to assess the performance of the lab's management system, and, whenever resources permit, are independent of the activity to be audited

ISO 15189:2022 requirements for internal audits – contd:

e. ensuring objectivity and impartiality of the audit process

f. ensuring that the results of the audits are reported to relevant personnel;

g. implementation of appropriate correction and corrective actions without undue delay;

h. retention of records as evidence of the implementation of the audit program and audit results.

- ISO standards put much emphasis on internal audits, and for those seeking accreditation under ISO, internal audits are required

ISO 15189 requirements for internal audits – contd:

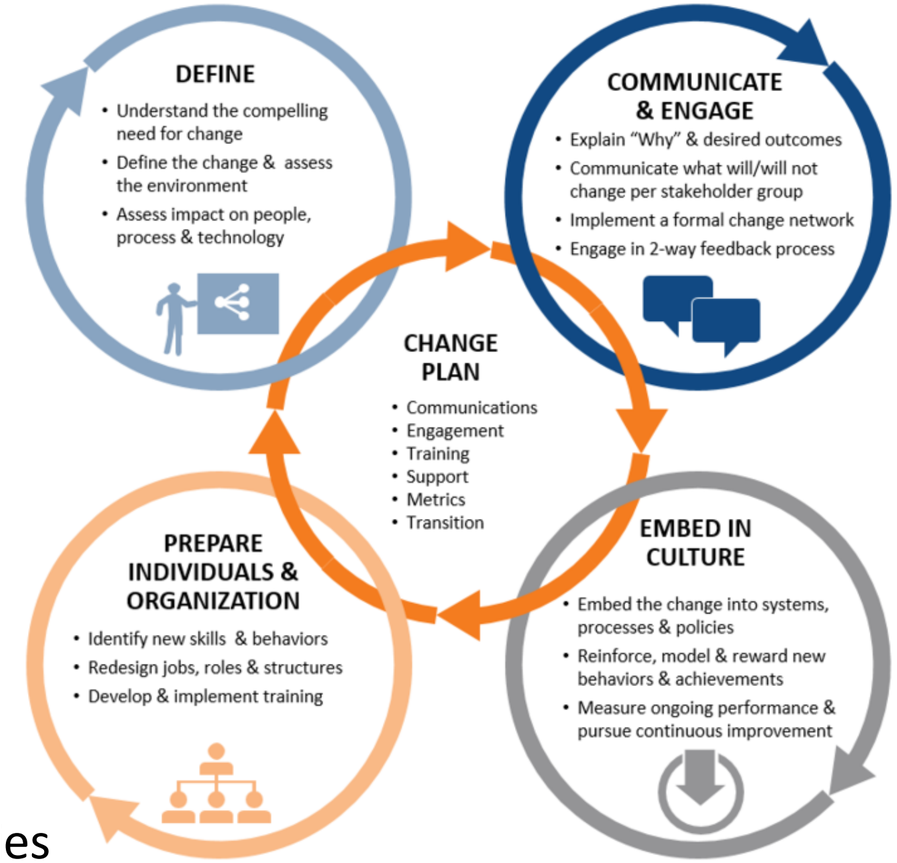
- ISO 15189:2007 [4.14.2] states: "The main elements of the QMS should normally be subject to internal audit ***once every twelve months***".
- Establish a policy that, at specified intervals, some section of the lab or a specific process will have an internal audit.
- In general, audit regularly and consider 3 - 6 months intervals between audits. If audits reveal specific problems, it may be necessary to include more frequent audits.
- Audits should lead to actions – preventive & corrective (documented)

Post audit action plan

- Review the recommendations of the assessors;
- Identify gaps or nonconformities, learning where benchmarks or standards were not fully met;
- Plan to correct the nonconformities—this will result in a plan for all needed corrective actions to be taken by the lab, should include a timeline, and personnel responsible for doing the work;
- Record all results and actions taken so that the laboratory has a permanent record of the event—often a written report is useful for preserving all information.

Common Challenges and Solutions in Audit Implementation

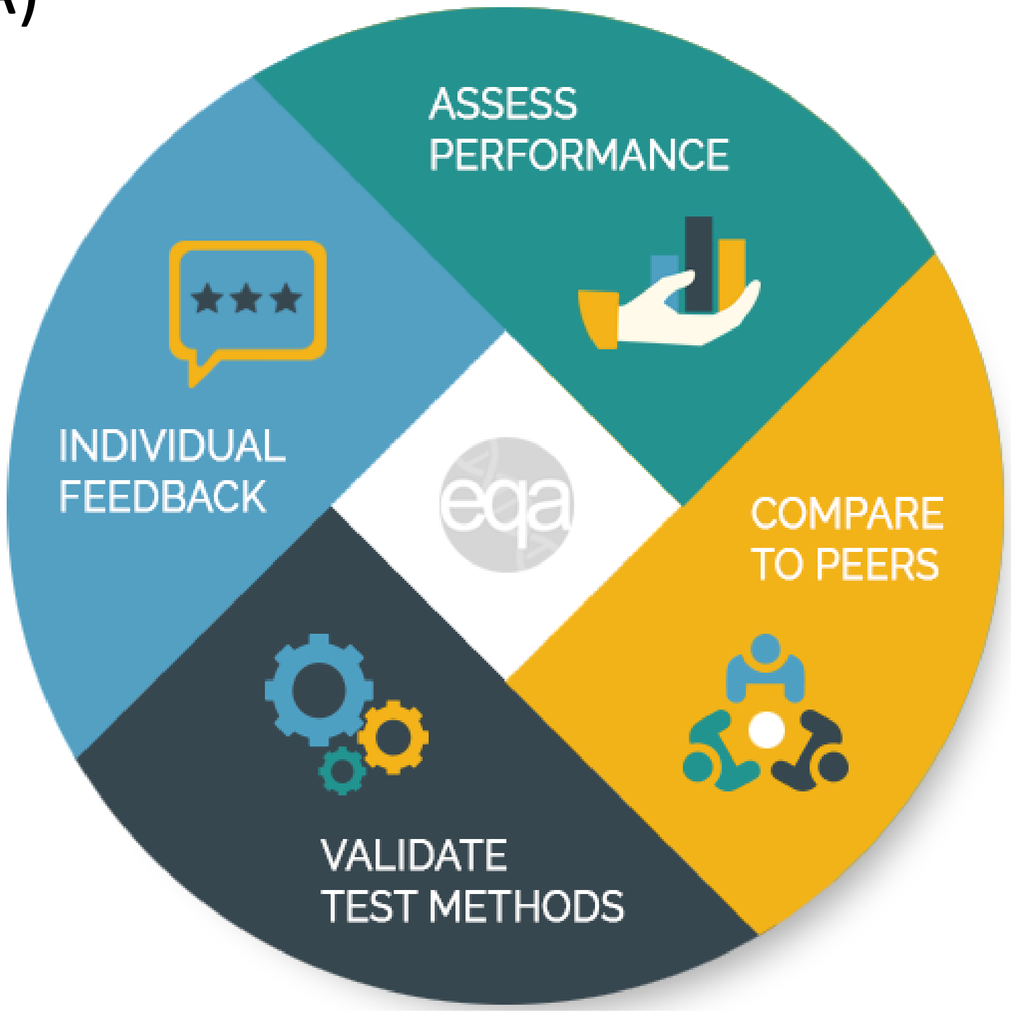
- Challenge: Resistance from staff due to fear of blame.
  - Solution: Promote a culture of learning rather than punishment.
- Challenge: Lack of trained internal auditors.
  - Solution: Provide training in audit methodologies and ISO 15189 requirements.
- Challenge: Inconsistent audit frequency or scope.
  - Solution: Establish a structured audit schedule with clear objectives.
- Challenge: Poor documentation and follow-up on audit findings.
  - Solution: Implement digital audit tools for tracking nonconformities and CAPA actions.



External Quality Assessment (EQA)

EQA – A system for objectively checking the laboratory's performance using an external agency or facility.

- WHO.

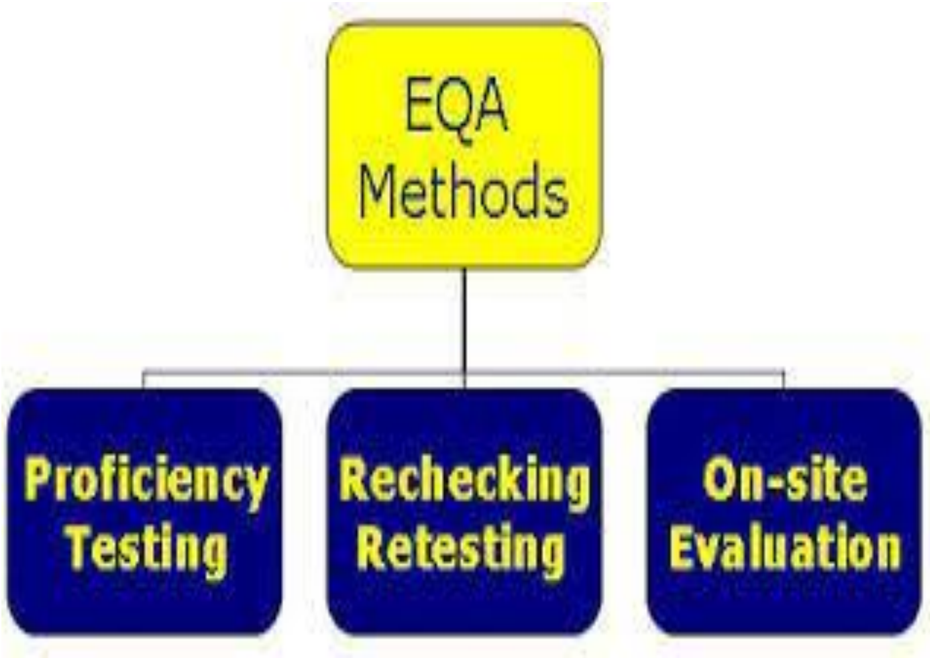


External Quality Assessment (EQA) – Types:

1. **Proficiency testing**—external provider sends unknown samples for testing to a set of laboratories, and the results of all laboratories are analyzed, compared and reported to the laboratories. Typically involves sending out unknown samples to participating labs and analyzing their results against a reference value

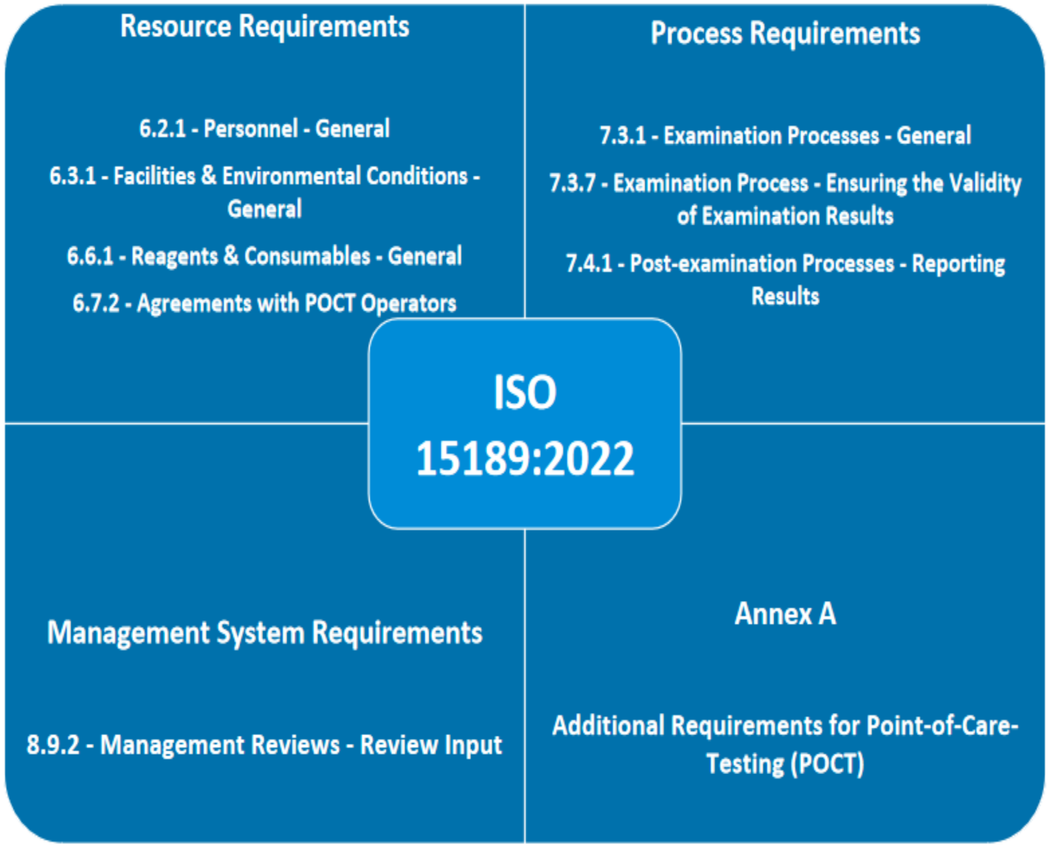
2. **Rechecking or retesting**—slides that have been read are rechecked by a reference laboratory; samples that have been analyzed are retested, allowing for interlaboratory comparison.

3. **On-site evaluation**—usually done when it is difficult to conduct traditional proficiency testing or to use the rechecking/retesting method.



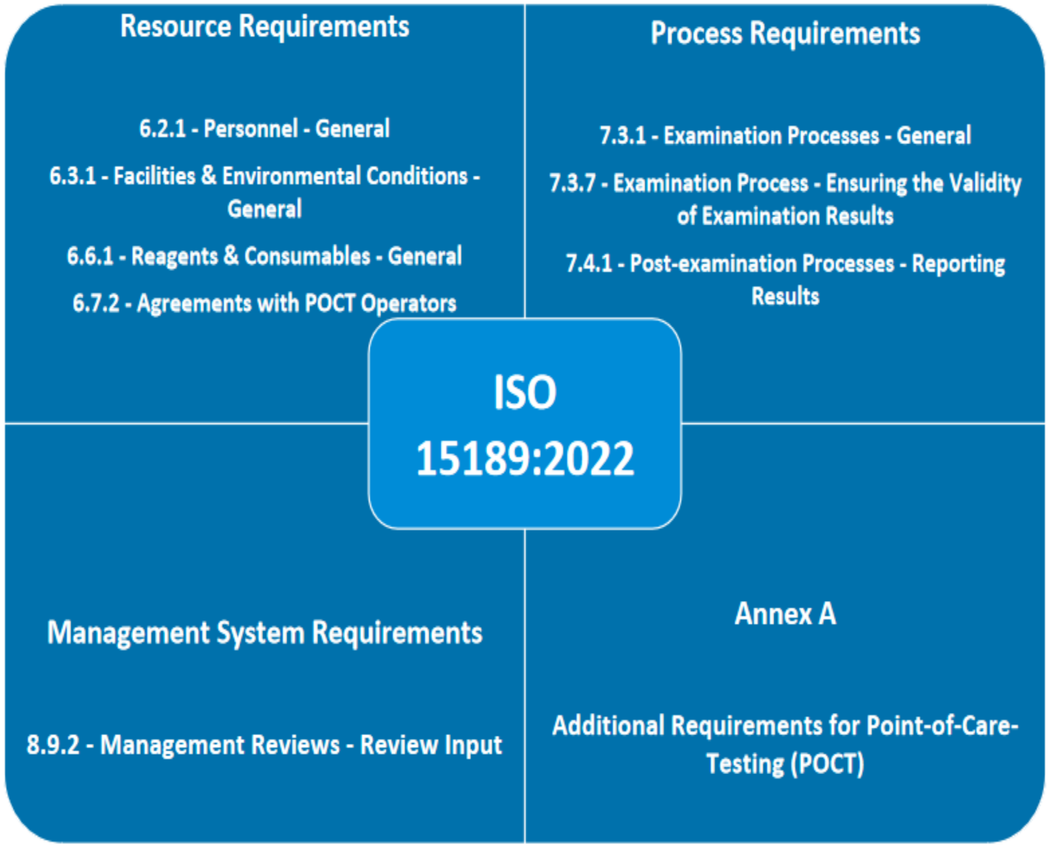
ISO 15189:2022 EQA requirements

- 7.3.7.3 - The laboratory shall monitor its performance of examination methods, by comparison with results of other laboratories. This includes participation in EQA programs
  - When an EQA program is either not available, or not considered suitable – Acceptable alternatives
    1. participation in sample exchanges with other labs
    2. inter laboratory comparisons using identical IQC materials
    3. analysis of a different lot number of the manufacturer's end-user calibrator or the manufacturer's trueness control material



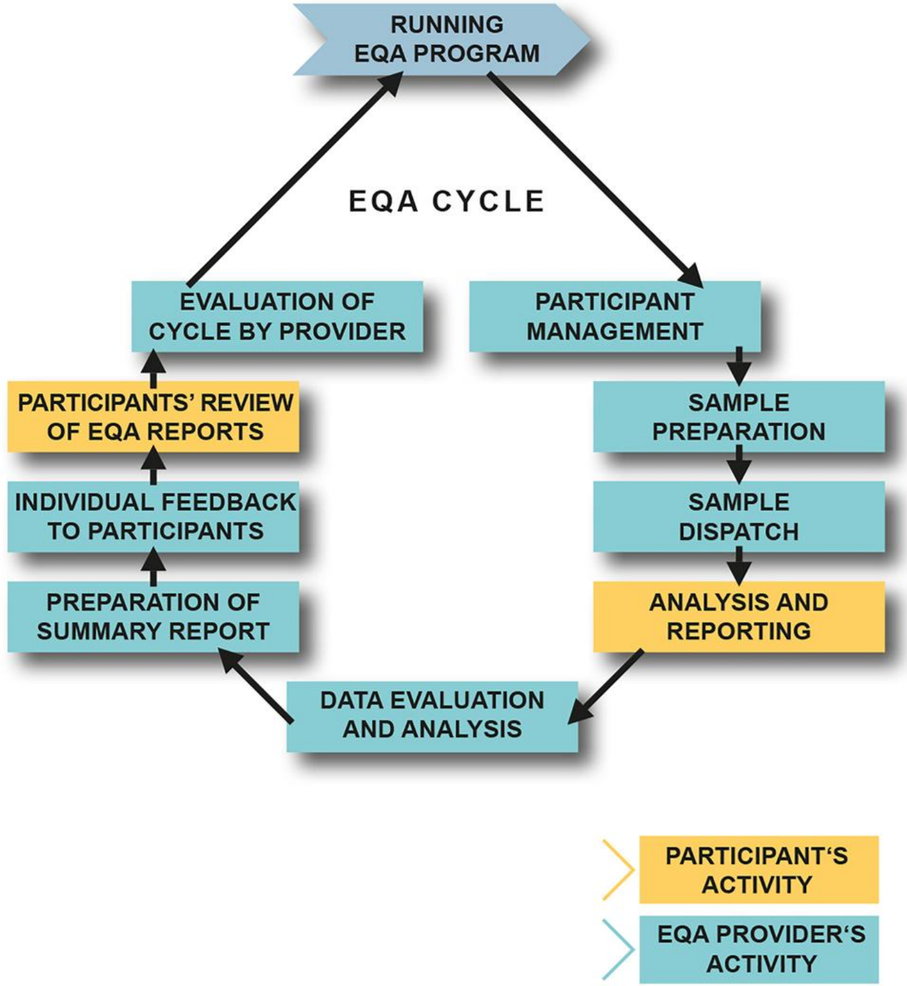
ISO 15189:2022 EQA requirements

4. analysis of microbiological organisms using split/ blind testing of the same sample by at least two persons, or on at least two analyzers, or by at least two methods
5. analysis of reference materials considered to be commutable with patient samples;
6. analysis of patient samples from clinical correlation studies
7. analysis of materials from cell and tissue repositories



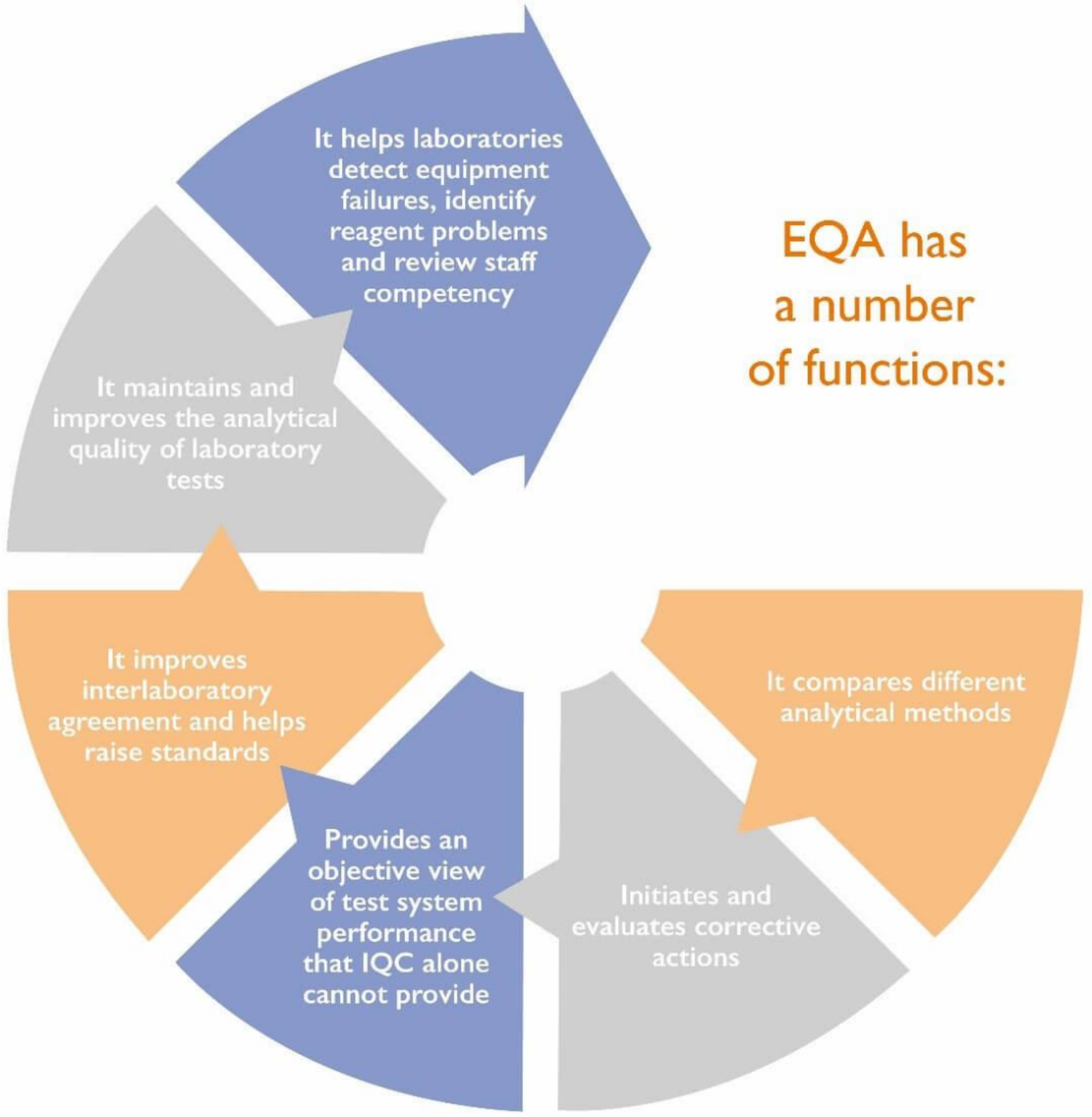
ISO 15189:2022 EQA requirements

- EQA data shall be reviewed at regular intervals with specified acceptability criteria, in a time frame which allows for a meaningful indication of current performance
- Where EQA results fall outside specified acceptability criteria, appropriate action shall be taken, including an assessment of whether the non-conformance is clinically significant as it relates to patient samples.
- Where it is determined that the impact is clinically significant, a review of patient results that could have been affected and the need for amendment shall be considered and users advised as appropriate.



EQA benefits

- **Allows comparison of performance and results among different test sites;**
- **Provides early warning for systematic problems associated with kits or operations;**
- **Provides objective evidence of testing quality;**
- **Indicates areas that need improvement;**
- **Identifies training needs.**
- **Required by accreditation bodies**
- **Ensures comparable results during surveillance activities.**

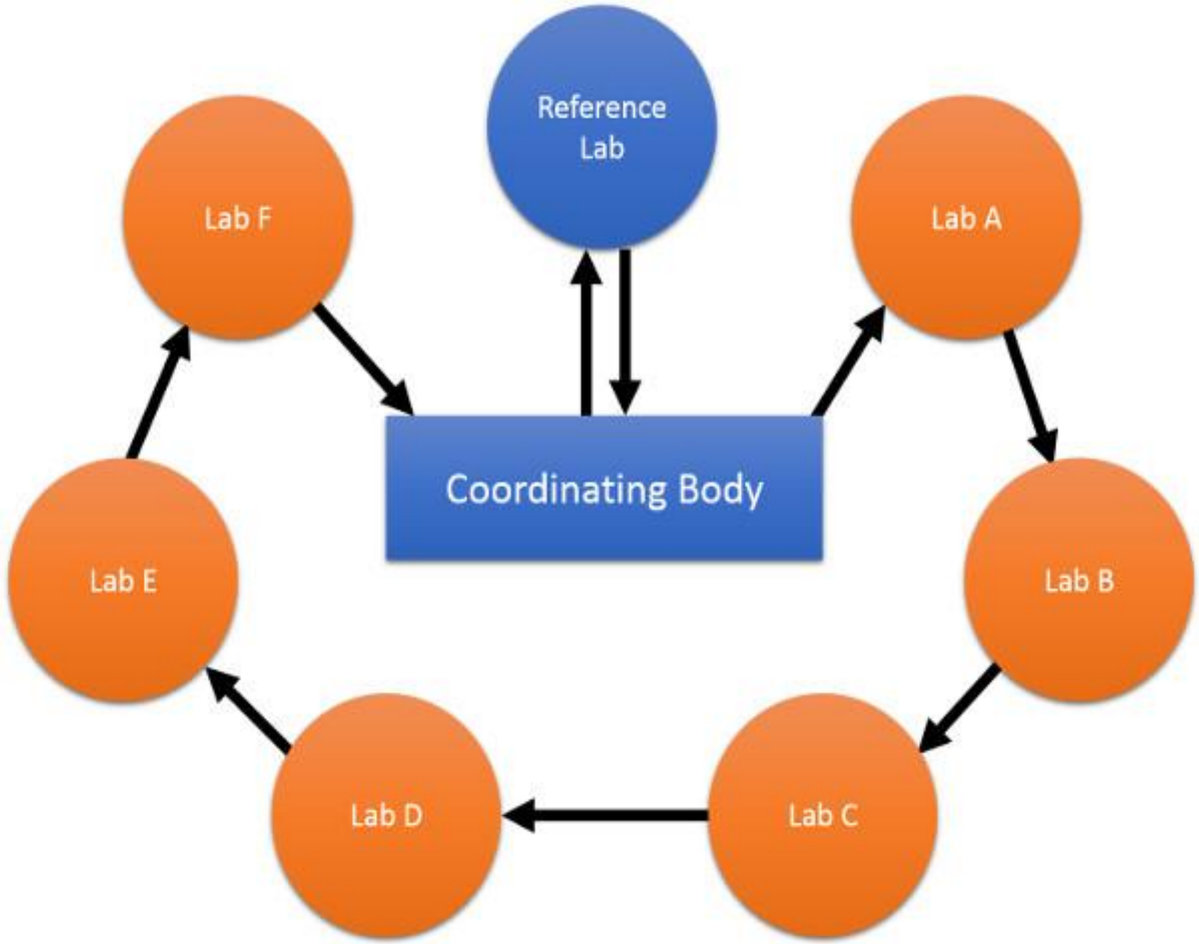


Proficiency Testing

Process used to evaluate a laboratory's performance. It validates the entire testing process, including the testing personnel competency.

Proficiency Testing – **How does it work?**

- A PT program sends samples to your laboratory on a regular basis (usually 3 – 6 times each year)
- After testing, your lab reports its results to the PT program,
- The program compares your laboratory's test results against CLIA grading criteria.
- Sends the laboratory scores reflecting how accurately it performed the testing

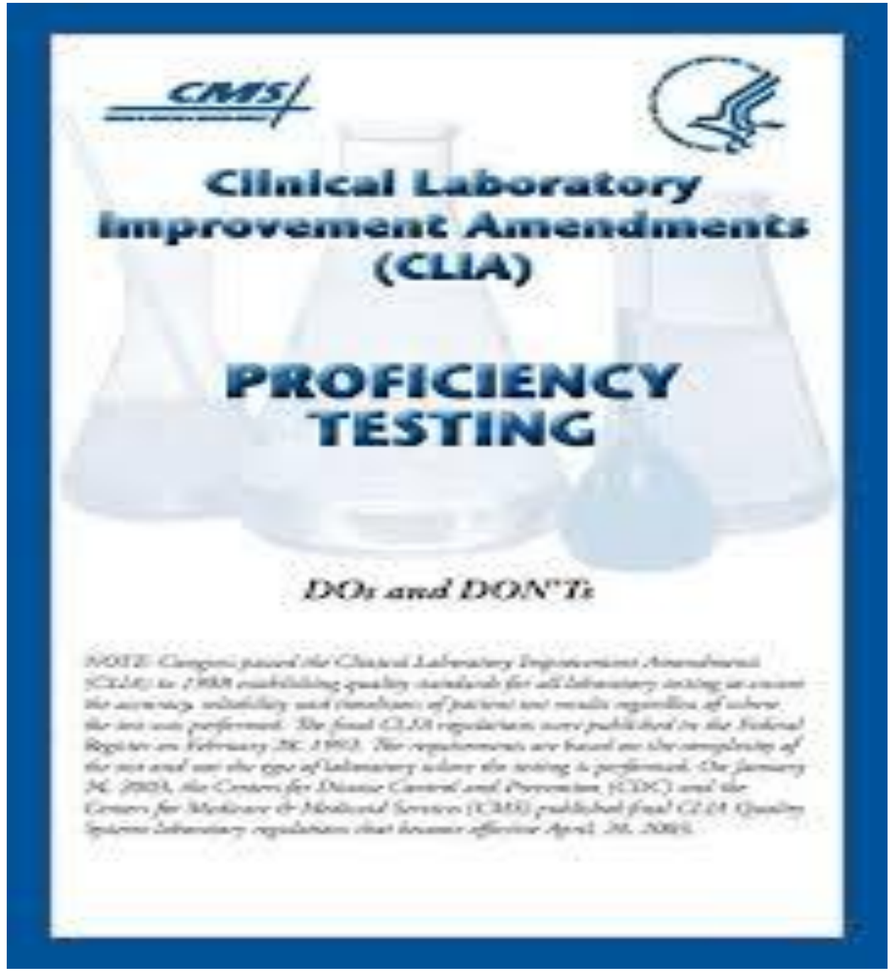


Proficiency Testing..

- Clinical Laboratory Improvement Amendments (CLIA) are US *federal regulatory standards* that apply to any facility which performs lab testing on human specimens for the purpose of providing information for health assessment, diagnosis, prevention or treatment of disease.
- 1988, In 2019 CLIA proposed a new set of quality requirements for proficiency testing. They were updated July 11, 2022.
- They became official law on July 11,2024. They get implemented by proficiency testing organizations on January 1st, 2025.

Proficiency testing

- The target value and acceptance limit constitute the *criterion for acceptable performance*
- CLIA regulations specify the acceptance limit (+/-) around the target value that must be used by all approved PT programs – Subpart 1 of CLIA for each analyte
- In some disciplines PT/EQA, eg in clinical chemistry, is provided almost exclusively in a quantitative format, whereas in others, in particular Microbiology and Anatomic Pathology have many elements of a more qualitative and semi-quantitative nature.



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Escalation Process for Proficiency Testing (PT) Failures of CLIA-Regulated Analytes/ Subspecialties/ Specialties

1 DEFINITIONS

Event: An occurrence of PT. Regulations require participation in 3 events per year for each analyte/ subspecialty/ specialty (Mycobacteriology requires 2 events per year).

Unsatisfactory PT performance: Failure to attain at least 80% for a regulated analyte/ subspecialty/ specialty (ABO, Rh, and Compatibility Testing requires 100%). Clerical errors or data omissions are considered unsatisfactory PT performance.

Unsuccessful PT performance: Failure to attain at least 80% for a regulated analyte/ subspecialty/ specialty for 2 consecutive or 2 out of 3 testing events (ABO, Rh, and Compatibility testing requires 100%). Unsuccessful PT performance and unsuccessful PT participation are interchangeable.

Repeat unsuccessful PT performance (Cease Testing): Unsatisfactory PT performance in 3 consecutive, 3 out of 4, or 2 sets of 2 out of 3 PT events identified for the same regulated analyte/subspecialty/ specialty within 6 PT events.

2 CAP PT PERFORMANCE MONITORING

As mandated by the Clinical Laboratory Improvement Amendments (CLIA), PT monitoring is a process that continually looks for trends of unsatisfactory PT performance.

Unsatisfactory PT performance must be investigated and documentation of corrective action must be maintained by the laboratory for inspection purposes.

Unsuccessful PT performance requires the laboratory to complete and return a Proficiency Testing Compliance Notice (PTCN) response form to the CAP, documenting corrective action taken to prevent further PT failures.

Repeat unsuccessful PT performance requires that the laboratory cease patient/client testing for the regulated analyte/ subspecialty/ specialty for a period of 6 months.

3 CEASE TESTING REINSTATEMENT REQUIREMENTS

Laboratories with repeat unsuccessful PT performance for a regulated analyte/ subspecialty/ specialty will be required to cease patient/client testing for that test. Per CLIA, cease testing will be enforced for 6 months.

Before the laboratory can resume testing, it must:

- Determine the reason for the PT failures.
- Determine whether patient results were impacted by the PT failures, and take appropriate action if patient results were affected.
- Develop and implement a corrective action plan to prevent future PT failures.
- Perform 2 events of successful reinstatement PT.
- Submit to the CAP appropriate documentation such as:
  - Investigation report
  - Corrective action plan
  - Patient impact analysis
  - Retraining documentation
  - Evidence on how the laboratory will ensure patient/client results are not reported during the cease testing period
  - Observe the CLIA-mandated 6 month cease testing period

Performing patient/client testing during a cease testing period will result in an adverse action against the laboratory's accreditation status.

Note: If the regulated test is performed in more than one area or by more than one method in a single CLIA/ CAP number, the cease testing directive applies to all areas and methods performing the regulated test.

4 FOR MORE INFORMATION

Need assistance? Call 800-323-4040 ext. 6052 or 847-832-7000, or email PTCN@cap.org.

Visit cap.org/eLAB Solutions Suite/ CAP Accreditation Resources/ Proficiency Testing Toolbox (Analyte Specific Troubleshooting Guides are available in the Toolbox)

Go to www.cms.gov/ Regulations and Guidance/ Clinical Laboratory Improvement Amendments (CLIA)

August 2015

Proficiency testing – process.

- CLIA regulations require five specimens in three (3) PT events each year. (Mycobacteriology requires two events per year):
- **“unsatisfactory” PT performance means**
  - Failure to attain at least 80% correct results for a regulated analyte, subspecialty, or specialty
  - NB: (ABO, Rh, and compatibility testing require 100%)
- **“unsuccessful performance” means**
  - Failure to attain at least 80% correct results for a regulated analyte, subspecialty, or specialty for 2 out of 3 testing events
  - NB: (ABO, Rh, and compatibility testing require 100%)

What Constitutes PT failures?..

- What happens in "**unsuccessful performance**" situations?
- If your lab has not had previous unsuccessful performance for any PT analyte, subspecialty, or specialty, CLIA regulations may permit technical assistance and training, versus a more serious sanction in certain situations.
- A subsequent unsuccessful PT performance within six or fewer PT events is called ***repeat unsuccessful PT performance*** and requires the laboratory to cease testing for that analyte, subspecialty, or specialty for six months
- Repeat unsuccessful performance can be 3 consecutive failures, 3 out of 4 failures, or two sets of 2 out of 3 failures within the six events.

PT failures/Reinstatement

- Eg 1 (3 out of 4 failures): **2015/1 20%** | **2015/2 60%** |
- 2015/3 100% | **2016/1 20%** |
- Eg 2 (two sets of 2 out of 3): **2015/1 20%** | **2015/2 60%** |
- 2015/3 100% | 2016/1 100% | **2016/2 20%** | **2016/3 0%**

- **CEASE TESTING REINSTATEMENT REQUIREMENTS**
- To be reinstated, the laboratory must
  - complete a root-cause analysis detailing the cause of the repeat unsuccessful PT performance.
  - detail the corrective actions that have been put in place to prevent recurrence.

REINSTATEMENT REQUIREMENTS

- provide an analysis of the impact of the PT failure on patient testing
- provide documentation of any required personnel training/retraining.
- successfully complete two events of reinstatement PT for the analyte.
- ensure that the laboratory is in compliance with the cease-testing directive.

Poor performance on EQA? – Review all aspects!

Pre-examination:

- Compromised sample integrity during preparation, shipping, or after receipt in the laboratory by improper storage or handling.
- Improper sample labelling or processing

Examination:

- Possible sources of analytical problems include reagents, instruments, test methods, calibrations and calculations. Investigate to determine whether error is random or systemic.
- The EQA materials may exhibit a matrix effect in the examination system used by the participating laboratory.
- Competence of staff will need to be considered and evaluated

Poor performance on EQA?..

Post-examination:

- The report format can be confusing.
- Interpretation of results can be incorrect.
- Clerical or transcription errors can be sources of error.

THE COMPLETE BLOOD COUNT SAMPLE REPORT

Different laboratories generate reports that can vary greatly in appearance and in the order and kind of information included. This is one example of what a lab report for a Complete Blood Count may look like. Names and places used have been made up for illustrative purposes only. The numbered key to the right explains a few of the report elements.

1	**University Medical Center, Dept. of Pathology**			**Report Date/Time:**		
	123 University Way, City, ST 12345			02/10/2014	16:40	2
3	**Name:**	Doe, John Q.	**Age/Sex:** 73/M	**DOB:**	01/01/1941	
4	**Patient ID:**	987654321		**Status:** 6	Routine	
5	**Ordering Dr:**	Smith, Peter MD		**Physician Copy for:**	Smith, Jane MD	
7	**SPEC #:**	223456	**Collection Date/Time:**	02/10/14	14:30	10
			Received Date/Time:	02/10/14	15:00	11
8	**SPECIMEN:**	Whole blood				
9	**ORDERED:**	Complete Blood Count and White Blood Cell Differential				
	QUERIES:	*[Comments and testing instructions]*				

12 Test	13 Normal	14 Abnormal	15 Flag	16 Units	17 Reference Range
COMPLETE BLOOD COUNT					
White Blood Cell (WBC)	6.9			K/mcL	4.8-10.8
Red Blood Cell (RBC)		1.8	*L*	M/mcL	4.7-6.1
Hemoglobin (HB/Hgb))		6.5	*L***	g/dL	14.0-18.0
Hematocrit (HCT)		19.5	*L***	%	42-52
Mean Cell Volume (MCV)		109.6	*H*	fL	80-100
Mean Cell Hemoglobin (MCH)		36.5	*H*	pg	27.0-32.0
Mean Cell Hb Conc (MCHC)	33.3			g/dL	32.0-36.0
Red Cell Dist Width (RDW)		16.0	*H*	%	11.5-14.5
Platelet count	180			K/mcL	150-450
Mean Platelet Volume	7.9			fL	7.5-11.0
WBC Differential					
Neutrophil (Neut)	50			%	33-73
Lymphocyte (Lymph)	36			%	13-52
Monocyte (Mono)	8			%	0-10
Eosinophil (Eos)	5			%	0-5
Basophil (Baso)	1			%	0-2
Neutrophil, Absolute	3.5			K/mcL	1.8-7.8
Lymphocyte, Absolute	2.5			K/mcL	1.0-4.8
Monocyte, Absolute	0.6			K/mcL	0-0.8
Eosinophil, Absolute	0.4			K/mcL	0-0.45
Basophil, Absolute	0.1			K/mcL	0-0.2

Flag Key: L= Abnormal Low, H= Abnormal High, **= critical value

Comment: **Hgb of 6.5 and Hct of 19.5 reported to Dr. J Smith at 15:20 on 2/10/14 by M. Peters 18

** END OF REPORT **

1. Name and address of the lab where the test was performed. Tests may be run in a physician office lab, a lab located in a clinic or hospital, and/or samples may be sent to a reference laboratory for analysis.
2. Date this copy of the report was printed. This date may be different than the date the results were generated, especially on cumulative reports (those that include results of several different tests run on different days).
3. Patient name or identifier. Links results to the correct person.
4. Patient identifier and identification number. Links results to the correct person.
5. Name of doctor. The lab will send the results to the doctor(s) or other healthcare practitioners listed.
6. Status of the test request, such as Routine or STAT (perform test as rapidly as possible).
7. Unique identification number(s). Number(s) assigned to the sample(s) when it arrives at the laboratory.
8. Test requested is a CBC and WBC differential.
9. Information about the person and blood sample. Any pertinent information regarding the patient's test preparation or the condition of specimen may be noted here.
10. The date and time of sample collection
11. The date and time that the laboratory received the sample.
12. A listing of the individual items that are being evaluated. Test names may be abbreviated on lab reports. You can look for these test names or abbreviations in the pull-down menu on the home page of this site or type the name into the search box to find information on specific tests.
13. A listing of the CBC and differential results that are normal.
14. A listing of the CBC and differential results that are abnormal.
15. An 'H' in this column may mean that the result is higher than the reference range. 'L' may mean 'low.' Either represents a result outside the reference range/value.
16. Units of measurement (for quantitative results). The units of measurement that labs use to report your results can vary from lab to lab. Regardless of the units that the lab uses, your results will be interpreted in relation to the reference ranges supplied by the laboratory.
17. Reference intervals (or reference ranges). These are the ranges in which "normal" values are expected to fall. The ranges that appear on your report are validated and supplied by the laboratory that performed your test.
18. Critical results are dangerously abnormal results that must be reported immediately to the responsible person, such as the ordering physician. The laboratory will often draw attention to such results with an asterisk (*) or something similar and will usually note on the report the date and time the responsible person was notified.

PT result sample

Table 2 – The ochratoxin A results[1] (ng/g) for the arabica green coffee reference materials – Samples A (1.34 ng/g) and C (4.28 ng/g).

Laboratory number	Sample A (1.34ng/g)						Sample C (4.28 ng/g).					
	Fourth round			Fifth round			Fourth round			Fifth round		
	Replicate 1	Replicate 2	Mean	Replicate 1	Replicate 2	Mean	Replicate 1	Replicate 2	Mean	Replicate 1	Replicate 2	Mean
1	2.05	1.64	1.85	4.62	1.60	3.11	3.90	3.98	3.94	4.53	18.13	11.33
2	1.84	**	NI	-	-	-	1.95	**	NI	-	-	-
3	2.46	**	NI	1.56	1.20	1.38	2.04	2.10	2.07	4.91	3.11	4.01
4	5.12	5.40	5.26	1.43	1.41	1.42	2.86	2.97	2.92	3.80	3.99	3.90
5	1.246	1.263	1.25	1.24	1.31	1.28	1.794	1.481	1.64	1.38	1.40	1.39
6	1.26	1.15	1.21	2.07	1.38	1.73	3.27	3.25	3.26	4.85	6.15	5.50
7	*	*	*	1.61	1.57	1.59	4.24	4.33	4.29	4.51	4.75	4.63
8	-	-	-	-	-	-	-	-	-	-	-	-
9	1.61	1.67	1.64	1.89	1.88	1.89	3.79	3.68	3.74	3.50	3.02	3.26
10	1	2	1.5	-	-	-	6	5	5.5	-	-	-

[1]Data not corrected for recovery, *Laboratory reported analytical problem – No results were sent by the laboratory **Single analysis; NI: no information

Note 1: Results are shown as reported by the laboratories

Digital audit tools

- An eg is **SLIPTA e-Tool**
- The Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) checklist was established by the WHO's Regional Office for Africa (WHO AFRO) to assess lab compliance to ISO 15189
- The **WHO Laboratory Assessment Tool**
- Describes a general process for assessing laboratories, providing assessment questionnaires for national laboratory systems and individual laboratory assessments.
- Based on internationally recognized standards
- PDF format and as Excel files, which enable automatic calculations of module indicators.

TABLE 1: The WHO AFRO SLIPTA checklist covering the 12 quality system essentials, the points allocated to each section and the overall star rating system.

WHO AFRO SLIPTA Checklist Audit Score Sheet (Section)	Total Points
Section 1: Documents & Records	25
Section 2: Management Reviews	17
Section 3: Organization & Personnel	20
Section 4: Client Management & Customer Service	8
Section 5: Equipment	30
Section 6: Internal Audit	10
Section 7: Purchasing and Inventory	30
Section 8: Process Control and Internal & External Quality Audit	33
Section 9: Information Management	18
Section 10: Corrective Action	12
Section 11: Occurrence/Incident Management & Process Improvement	12
Section 12: Facilities and Safety	43
Total Score	**258**

Source: World Health Organization[15]

0 stars, (0–142 pts), < 55%; 1 star, (143–165 pts), 55% - 64%; 2 stars, (166–191 pts), 65% - 74%; 3 stars, (192–217 pts), 75% - 84%; 4 stars, (218–243 pts), 85% - 94% 5 stars, (244–258 pts), ≥ 95%.

WHO AFRO, World Health Organization Regional Office for Africa; SLIPTA, Stepwise Laboratory (Quality) Improvement Process Towards Accreditation.

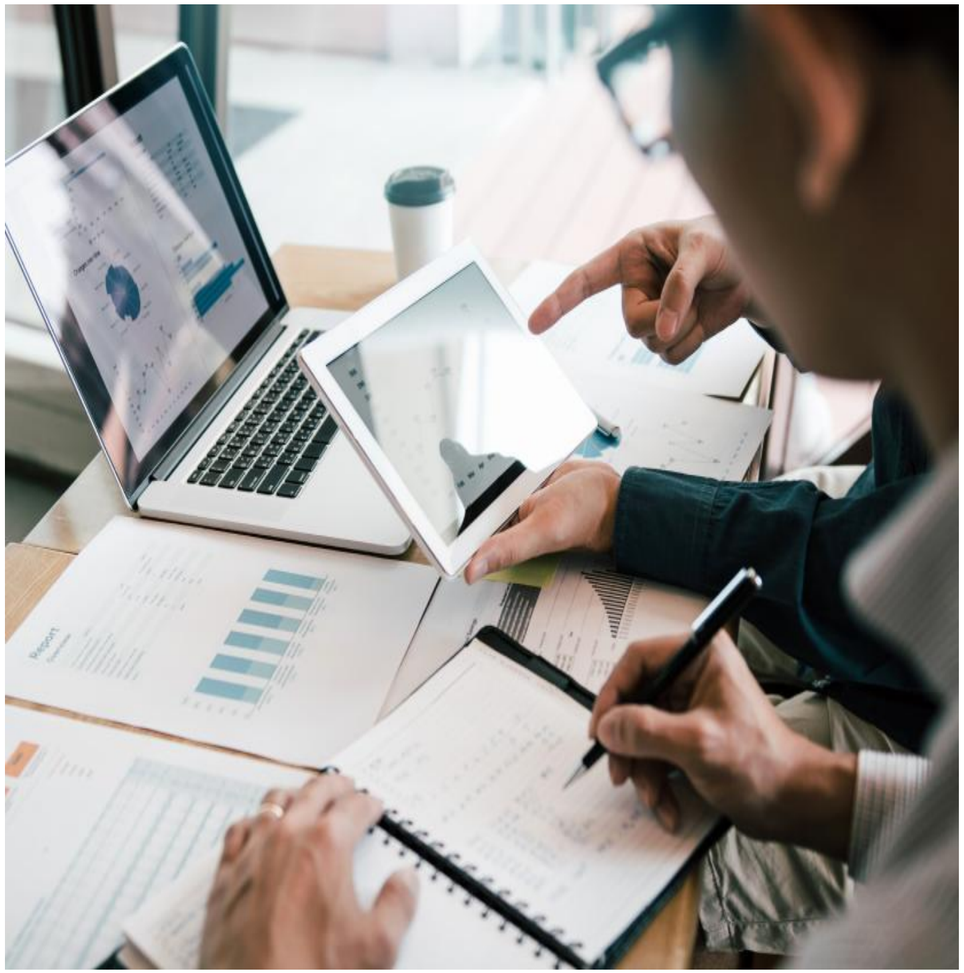
Digital audit tools…

The SPI-RRT e-Tool

- (Stepwise Process for Improving the Quality of HIV Rapid and Recency Testing) audit checklist
- Developed by the US Centers for Disease Control and Prevention (CDC), establishing minimum standards against which HIV testing sites measure their performance.
- **Audit management software (e.g., Q-Pulse, Qualtrax)** – Enables planning, scheduling, and tracking audits.
- **Cloud-based audit platforms (e.g., MasterControl, iAuditor)** – Support remote and real-time audit processes.

Future Trends in Digital Auditing for Laboratory Compliance

- **Artificial Intelligence (AI) and Machine Learning (ML):** AI-powered tools can analyze audit data, detect patterns, and predict compliance risks.
- **Blockchain for Data Integrity:** Secure audit trails using blockchain technology to prevent data tampering.
- **Integration with Laboratory Information Systems (LIS):** Seamless data exchange between audit tools and laboratory management systems for comprehensive compliance tracking.
- **Automated Compliance Monitoring:** Real-time alerts and predictive analytics to address potential nonconformities before audits.



Conclusion

Audit is an essential laboratory process aimed at continuous quality improvement.

When used in conjunction with External Quality Assessments, it attests to the effectiveness of the implemented QMS….

…and gives confidence to both the lab clients and staff as regards the quality of their services.

INTERNATIONAL INSTITUTE FOR PATHOLOGY AND FORENSIC SCIENCE RESEARCH

COLLEGE of AMERICAN PATHOLOGISTS FOUNDATION

DAVID UMAHI FEDERAL UNIVERSITY OF HEALTH SCIENCES UBURU, EBONYI STATE.

Thank You

NEXT WEEK:

Process Improvement & Risk Management in Laboratory QMS:

- Implementing Lean and Six Sigma for process optimization
- Root Cause Analysis (RCA) and Corrective and Preventive Actions (CAPA)
- Proactive risk management strategies for laboratory quality enhancement

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