GAHAR Handbook for

CLINICAL LABORATORIES ACCREDITATION STANDARDS

2025 Edition

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Foreword

Quality healthcare has become a global priority, particularly in the context of the Sustainable Development Goals (SDGs), which emphasize the need for universal health coverage, financial protection, and access to safe and effective healthcare services. The World Health Organization (WHO) highlighted these critical needs in its 2018 reports, reinforcing the importance of strong healthcare systems worldwide.

we are deeply committed to driving excellence in healthcare reform by fostering a strong culture of safety and quality. We are proud to introduce the 2025 edition of the GAHAR Handbook for Clinical Laboratories Accreditation Standards, an updated version that reflects the latest advancements in patient safety practices and quality improvement concepts. This edition is designed to help both accredited and non-accredited laboratories identify key safety risks and continuously enhance their services.

This handbook integrates the latest best practices in quality improvement and patient safety, ensuring laboratories are equipped to meet emerging challenges in healthcare. Our mission remains clear: to uphold the highest standards of safety, quality, and patient-centered care while supporting healthcare professionals in delivering safer, more effective services.

We hope this revised edition serves as both a practical guide and a source of inspiration for laboratories across Egypt, the Middle East, and Africa, helping them advance their quality journey and improve patient outcomes. Together, we can build a healthier future .

Introduction

Welcome to the Second Edition of the GAHAR Handbook for Clinical Laboratories Accreditation Standards, 2025.

Clinical laboratories play a vital role in modern healthcare, providing essential diagnostic services that support patient care, disease prevention, and clinical decision-making. To ensure the highest standards of safety, accuracy, and efficiency, laboratories must follow structured processes that cover every stage of testing—from examination requests and patient preparation to specimen collection, analysis, reporting, and ongoing quality assurance.

This updated guide reflects our continued commitment to raising the bar in healthcare. It provides clear, practical standards to help clinical laboratories achieve excellence in quality, safety, and patient-centered care.

Building on the success and lessons from the 2021 edition, we've enhanced this handbook with valuable feedback from our users and experts across various sectors. This collaborative effort involved key stakeholders, including the Ministry of Health and Population, private sector professionals, university faculty, and professional syndicates. Their insights have helped us refine each chapter to keep pace with the ever-evolving healthcare landscape.

The 2025 edition of the GAHAR Handbook for Clinical Laboratories Accreditation Standards builds on the foundation of previous version, incorporating the latest advancements in clinical laboratories, patient safety, and quality improvement science. This edition is designed to align with international best practices while addressing Egypt's unique healthcare landscape and regulatory requirements.

The content is organized into four key sections:

1. **Accreditation Prerequisites and Conditions**
2. **Patient-Centered Standards**
3. **Testing process standards**
4. **Organization-Centered Standards**

These sections are further divided into 14 chapters, each addressing critical aspects of Laboratory's operations. This structured approach helps laboratories meet patient expectations while ensuring a safe and supportive environment for healthcare professionals.

This edition aligns with the Institute of Medicine's **STEEEP** principles, emphasizing:

Safety, Timeliness, Effectiveness, Efficiency, Equity, Patient-Centeredness.

By upholding these standards, we are dedicated to fostering a healthcare system that consistently delivers outstanding care.

At the heart of this handbook are the **9 GAHAR Safety Requirements (GSRs)**; a fundamental roadmap to creating a safer healthcare environment and ensuring compliance with accreditation standards.

We've refined and streamlined the content for better clarity and ease of use. While all essential details remain, the improved structure makes it easier to navigate and implement in real-world settings.

With this guide, we aim to empower laboratories with the tools and knowledge to achieve and maintain the highest standards of patient care and operational excellence.

Scope of this Handbook

These standards apply to the laboratories seeking to be accredited by the General Authority for Healthcare Accreditation and Regulation (GAHAR):

Inclusions

These standards are applicable to:

- Standalone laboratories.
- Specialized clinical laboratories e.g.; genetics, molecular biology, bacteriology
- Reference laboratories which receive samples from other healthcare facilities.

Exclusions

These standards are not applicable to:

- Non-clinical laboratories (Research /calibration).
- Hospital laboratories (Not fulfilling the above criteria).

Purpose

GAHAR Handbook for Clinical Laboratories Accreditation Standards 2025 Edition is designed to establish a clear framework for ensuring safe, high-quality, and patient-centered laboratory services. These standards define the competency levels required across all phases of laboratory testing, providing a benchmark for performance assessment and continuous improvement.

The primary goal of this handbook is to enhance patient safety and service reliability by guiding laboratories in implementing best practices in quality management, operational efficiency, and risk mitigation. By adhering to these standards, laboratories can improve diagnostic accuracy, streamline workflows, and ensure compliance with national and international regulatory requirements.

This edition also emphasizes strong governance and workforce development, ensuring that laboratory personnel are well-trained, competent, and supported in delivering exceptional care. It provides guidance on staffing structures, documentation processes, and new technologies, helping laboratories adopt innovative solutions while maintaining ethical and professional integrity.

Compliance with GAHAR accreditation standards reinforces accountability and promotes a culture of excellence, encouraging laboratories to continuously assess and enhance their practices. This handbook serves as a valuable tool for laboratory leaders, healthcare providers, and quality management teams, helping them drive sustained improvements in patient care and workplace safety.

By following the GAHAR 2025 Clinical Laboratories Standards, laboratories will be better equipped to meet evolving healthcare challenges, support universal health coverage goals, and contribute to a stronger, more resilient healthcare system.

Ultimately, the handbook seeks to elevate the overall standard of healthcare delivery by providing a structured approach to accreditation, ensuring patient-centered care, and promoting accountability among healthcare providers.

Reading and Interpretation of the book

- The General Authority for Healthcare Accreditation and Regulation evaluates the organization's structure, process, and/or outcome by setting standards that address these concepts.
- This book is divided into Four sections, in addition to the foreword, introduction, Scope of this handbook, Purpose, Use, Accreditation overview, Acknowledgments, Acronyms, Survey activities and readiness, Glossary and References.
- Each section is divided into chapters when applicable.
- Each chapter has:
  - An introduction that contains an overall intent.
  - purpose that details follow the introduction, and each one has a standard or more.
  - Summary of changes to the chapter.
- A standard is a level of quality or achievement, especially a level that is thought to be acceptable; it is composed of a standard statement, keywords, intent, survey process guide, evidence of compliance, and relevant standards.

Standard Components

- Standard Statement:
  - In this handbook, each standard is written as a standard statement preceded with a code.
  - Each standard is followed by a *non-black-scripted statement* that describes the essential quality dimension(s) addressed by the standard.
- Keywords

  -To help organizations understand the most important element of standard statements, as these are words or concepts of great significance. It answers the question of WHAT the standard is intended to measure.
- Intent:
  - Standard intent is meant to help organizations understand the full meaning of the standard.
  - The intent is usually divided into two parts:
    - Normative: that describes the purpose and rationale of the standard provides an explanation of how the standard fits into the overall program. It answers the question of WHY the standard is required to be met.
    - Informative: is meant to help organizations identify the strategy to interpret and execute the standard. It answers the question of HOW the standard is going to be met.
  - Some standards require the implementation of minimum components of processes to be documented, implemented, recorded, and/or monitored. These components are usually preceded with the phrase "at least the following", followed by a numbered/lettered list of requirements. Hence, these elements are considered essential, indivisible parts of compliance with the minimum acceptable standard.
- Evidence of compliance (EOCs):
  - Evidence of compliance of a standard indicates what is reviewed and assigned a score during the on-site survey process.
  - The EOCs for each standard identify the requirements for full compliance with the standard as scoring is done in relation to "Met EOCs".
- Survey process guide:
  - facilitates and assists the surveyors in the standard's rating for the required EOCs.
- Related standards:

As healthcare is a complex service, each standard measures a small part of it. To understand what each standard means in the overall context of healthcare standards, other standards need to be considered as well.

- Standards are categorized and grouped into three sets of groups:
  - Chapters, where standards are grouped as per uniform objective.
  - Quality dimensions, where each standard addresses a particular quality dimension, and strategic categorization of standards to analyze their quality characteristics.
  - Documentation requirements, where some standards require certain types of documents.

Used Language and Themes

This handbook used certain themes and vocabulary to ensure uniformity and clarity; These are the most important ones that will help laboratories to interpret the standards: Process, Policy, Procedure, Program, Plan, Guideline, Protocol

Whenever 'Process' is used in a standard, it indicates a requirement that is necessary to follow.

- 'Process':
  A series of actions or steps taken in order to achieve a particular end.
- 'Documented Process':
  A document that describes the process and can be in the form of policy, procedure, program, plan, guideline, or protocol.
- Policy:
  - A principle of action adopted by an organization.
  - It usually answers the question of what the process is.
  - It is stricter than guidelines or protocols.
  - It does not include objectives that need to be met in a certain timeframe.
- Procedure:
  - An established or official way of doing something.
  - It usually answers the question of how the process happens.
  - It is stricter than guidelines or protocols.
  - It does not include objectives that need to be met in a certain timeframe.
- Plan:
  - A detailed proposal for doing or achieving something.
  - It usually answers the question of what the goal is, why, how it is going to be achieved, and when.
  - It includes objectives that need to be met in a certain timeframe.
- Guideline:
  - A general rule, principle, or piece of advice.
  - It usually answers the question of what the process is and how it should happen.
  - Usually, it is more narrative than protocol.
- Protocol:
  - A best practice protocol for managing a particular condition, which includes a treatment plan founded on evidence-based strategies and consensus statements.
  - Usually, it has graphs, flow charts, mind maps, and thinking trees.

1) Document versus Record:
   - Document:
     Created by planning what needs to be done.
   - Record:
     Created when something is done.
2) Physician Versus Medical staff member:
   - Physician:
     A professional who practices medicine
   - Medical Staff member:
     A professional who practices medicine, dentistry, and other independent practitioners.

Accreditation Overview

This chapter aims to set the rules and requirements to obtain GAHAR accreditation for the laboratory which includes, but not limited to, the following:

1. Compliance with licensure requirements for licensing the laboratory as mandated by laws and regulations.
2. The laboratory must be operational for at least six months before it can apply for accreditation.
3. Compliance with the GAHAR Safety Requirements for laboratories(herein included), to ensure the safety of the patients/ patients' families, visitors, and staff.
4. Compliance with the requirements of the standards according to Accreditation Decision Rules in this handbook.

A) General rules:

The accredited laboratory has to inform GAHAR of any change in the field of services provided (adding a new service, cancelling an existing service, or increasing the volume of an existing service by more than 20%) in writing to the e-mail **reg@gahar.gov.eg.** at least one month prior to the actual implementation of this change.

- The laboratory shall ensure the validity of the documents and data provided at all stages of the accreditation process. If there is evidence that the submitted documents are proven to be inaccurate, the laboratory is at risk for rejection of accreditation.
- The accreditation may be withdrawn or at risk of rejection, if there is evidence that the facility has falsified or withheld or intentionally misleading the information submitted to GAHAR.
- The facility is not permitted to use GAHAR's certificate or logo in a misleading manner.
- GAHAR shall inform the facility about the accreditation decision within a period not exceeding 30 working days starting from the date of completion of the survey visit.
- GAHAR has the right to publish the end result of survey visit, accreditation suspension or rejection, according to the requirements.
- The accredited laboratory has to communicate all sentinel events to GAHAR within 48 hours of the event or becoming aware of the event via email notification using the following link: Sentinel.Event@gahar.gov.eg. The root cause analysis shall be submitted no later than 45 days starting from the date of the occurrence or its notification with the appropriate corrective plan to prevent/reduce its recurrence according to the nature of the event, (Refer to standard no. QPI.06 for more information).

B) Compliance with current relevant laws, regulations, licensures requirements, and their updates.

C) Accreditation may be suspended (for a period not exceeding 6 months**) if**:

- The laboratory fails to pass unannounced survey,
- The laboratory data in the application form does not match its status upon evaluation visit.
- Sentinel events related to the safety of patients, healthcare providers or visitors that has been reported to GAHAR while root cause analysis with the appropriate corrective plan not submitted within 45 days starting from the date of the occurrence or its notification.
- The GAHAR has not been notified of any changes in the scope of services provided (e.g. adding a new service, cancelling an existing service, or increasing the volume of an existing

service by more than 20%) within at least one month before the actual implementation of this change.

D) Accreditation may be withdrawn or at risk of rejection if:

- The facility fails to pass follow up surveys in case of conditioned accreditation.
- GAHAR team discover any falsification, withhold or intentionally misleading the information submitted during or after the survey visit, or it is proven that the attached and submitted documents are inaccurate.
- The facility prevents GAHAR regulatory team/inspectors from doing their duties, such as refusal or preventing them from reviewing documents and data related to the scope of their duties.
- The facility refuses to meet the auditors' team or GAHAR surveyors in the announced / unannounced evaluation visits.
- A legal document issued by an administrative agency or Supreme Court rules against the facility either by permanent or temporary closure.
- Moving the facility from its actual place mentioned in the application form, or when the facility is demolished, reconstructed, or rebuilt without any pre notification to GAHAR.
- Exceeding the period prescribed for suspension of accreditation without correcting the reasons for this suspension.

How to apply for a GAHAR survey?

A laboratory, seeking GAHAR accreditation begins by:

- Log in to the online platform (Portal) of the General Authority for Health Accreditation and Regulation to register the data of the laboratory, via the following link https://eportal.gahar.gov.eg.
- Create a new account.
- Choose the type of service, type of facility, and user's data.
- Complete the basic data of the application (the electronic registration application).
- Complete the contact information; the applicant's data; and the Laboratory data and upload the required documents.
- Print the application request, fill in the declaration, and get it sealed with the laborator's seal, re-upload, and click on "Issue application".
- You can browse the system anytime to follow up the status of the request and implement the required requests of GAHAR.
- GAHAR will determine the survey financial fees, and bank account details will be shared.
- The Laboratory will make the payment to the central bank of Egypt on the bank account, and it will send to receipt back via email.
- An appointment for the survey visit will be determined for the Laboratory.
- GAHAR's Surveyors team will evaluate your Lab, according to the GAHAR handbook for Laboratories accreditation standards.
- The survey report is submitted to the accreditation committee to review and decide based on decision rules.
- The Laboratory is notified of the decision of the accreditation committee. The laboratory has 15 days to submit an appeal. If no appeal is submitted, the chairman of GAHAR approves the decision, and a final certificate is issued.

Look back period

- Surveyors are required to review standards requirements and evaluate organization compliance with them over a lookback period.
- Look back period: It is the period before the survey visit during which any laboratory, is obliged to comply with the GAHAR accreditation standards. Failure to comply with this rule affects the accreditation decision.
- Look back period varies from one laboratory, to another, depending on the laboratory's accreditation status.

- A laboratory, seeking accreditation will:
    - Comply with the GAHAR Handbook for laboratory Accreditation Standards as applicable for at least **four months** before the actual accreditation survey visit.

- A laboratory, seeking re-accreditation:
    - For GAHAR-accredited laboratories, compliance with the GAHAR Handbook for laboratories Accreditation Standards from receiving the approval of the previous accreditation till the next accreditation survey visit.

Scoring Guide

During the survey visit, each standard is scored for evidence of compliance (EOC).
These are mathematical rules that depend on the summation and percentage calculation of scores of each applicable EOC as follows:

- **Met** when the laboratory, shows 80% or more compliance with requirements during the required lookback period with a total score of 2.
- **Partially met** when the laboratory, shows less than 80% but more than or equal to 50% compliance with requirements during the required look back period with a total score of 1.
- **Not met** when the laboratory, shows less than 50% compliance with requirements during the required look back period with a total score of 0.
- **Not applicable** when the surveyor determines that, the standard requirements are out of the organization's scope (the score is deleted from the numerator and denominator).
- While most EOCs are independent, stand-alone units of measurement that represent the structure, process, and/or outcome, few EOCs are dependent on each other. Dependence means that compliance with one EOC cannot be achieved (or scored) without ensuring compliance with other EOCs.

Scoring of each standard

- **Met**: when the average score of the applicable EOCs of this standard is 80% or more.
- **Partially met** when the average score of the applicable EOCs of this standard is less than 80% or not less than 50%.
- **Not met** when the average score of the applicable EOCs of this standard is less than 50%.

Scoring of each chapter
Each chapter is scored after calculating the average score of all applicable standards in this chapter.

Accreditation Decision Rules

A laboratory can achieve accreditation by demonstrating compliance with certain accreditation decision rules. These rules mandate achieving certain scores on a standard level, chapter level, and overall level as the accreditation decision is composed of four decisions.

1st Decision: Status of Accreditation for a laboratory, (3 years).
- Overall compliance of 80% and more, and
- Each chapter should score not less than 70%, and
- Only one whole standard is scored as not met, and
- No single not met GSR standard.

2nd Decision: Status of Conditioned Accreditation for a laboratory, (2 years).
- Overall compliance of 70% to less than 80%, or
- Each chapter should score not less than 60%, or
- Up to one standard not met per chapter, and
- No single not met GSR standard.

3rd Decision: Status of Conditioned Accreditation for a laboratory, (1 year).
- Overall compliance of 60% to less than 70%, or
- Each chapter should score not less than 50%, or
- Up to two standards not met per chapter, and
- No single not met GSR standard.

4th Decision: Rejection of Accreditation
- Overall compliance of less than 60%, or
- One chapter scored less than 50%, or
- More than two standards not met per chapter, or
- Not met GSR standard.

Laboratories having status of accreditation or conditioned accreditation with elements of noncompliance are requested to:
- Submit a corrective action plan for unmet or partially met EOCs and standards within 90 days for 1st decision, 60 days for 2nd decision, and 30 days for 3rd decision to the email reg@gahar.gov.eg.
- Apply and pass the accreditation survey in 2 years for 2nd Decision and 1 year for 3rd Decision.

Accreditation is valid for 3 years. Accreditation may be suspended or withdrawn if:
- The laboratory fails to pass follow-up surveys in case of conditioned accreditation.
- The laboratory fails to submit corrective action plans in case of the presence of not met EOC(s).
- The laboratory fails to pass the unannounced survey.
- The laboratory fails to comply with GAHAR circulars when applicable.

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List of Acronyms

acronym	*Explanation*
AAP	Alternative Assessment Procedure
ABHR	Alcohol-Based Hand Rub
APC	Accreditation Prerequisites and Conditions
APIC	Association for Professionals in Infection Control and Epidemiology
ASCLS	The American Society for Clinical Laboratory Science
Bsc	Biosafety Cabinet
CCTV	Closed-circuit television
CDC	Centers for Disease Control and Prevention
EFQM	The European Foundation for Quality Management
EFS	Environmental and Facility Safety
EMS	Equipment Management System
EOC	evidence of compliance
FEFO	First Expire First Out
FMEA	Failure Mode and Effects Analysis
GSRs	GAHAR Safety Requirements
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
ICRA	Infection Control Risk Assessment
IFIC	International Federation of Infection Control
IMT	Information Management and Technology
IPC	Infection prevention and control
LEP	Laboratory Examination Process
LIS	Laboratory Information System
LPO	Laboratory Post-examination
LPR	Laboratory Pre- Examination Process
LQC	Laboratory Quality Control
OGM	Organization Governance and Management
PASS	Pull, Aim, Squeeze, and Sweep
PCC	Patient-Centeredness Culture
PCRA	Pre-Construction Risk Assessment
PDCA	Plan-Do-Check-Act
PPE	Personal Protective Equipment
PT	Proficiency Testing
QC	Quality Control
QPI	Quality and Performance Improvement
RACE	Rescue, Alarm, Confine, Extinguish/Evacuate
SCM	Supply Chain Management
SD	Standard Deviation
SDGs	Sustainable Development Goals
SDS	Safety Data Sheets
SMART	Specific, Measurable, Achievable, Relevant, and Time-Bound
SOP	Standards of Procedure
STEEEP	Safety, Timeliness, Effectiveness, Efficiency, Equity, Patient-Centeredness

acronym	***Explanation***
TAT	Turnaround time
UPS	Uninterrupted Power Supply
WHO	World Health Organization

Section 1: Accreditation Prerequisites and Conditions

Section Intent

This section aims at providing a clear and ethical framework that a laboratory must follow in order to comply with the GAHAR survey process.

Scores of these standards must be *met* in order to continue the survey process. One partially met or not met evidence of compliance is to be dealt with on GAHAR accreditation committee level and may result in denial or suspension of accreditation.

Section purpose:

This section contains only one chapter, which addresses two main objectives:

1- To ensure a transparent and ethical relationships during the accreditation process.
2- To sustain compliance with accreditation standards.

APC Summary of Changes

GAHAR Clinical Labs 2025	*GAHAR Clinical Labs 2021*	*Details of changes*
APC.01 **KW:** Accurate and complete information	**APC.03** **KW:** Accurate and complete information	- **Modified Standard Statement: (**The laboratory provides GAHAR with accurate and complete information through **all steps** of the accreditation process. - **Modified** EOC: (**EOC.01**: The laboratory reports accurate and complete information to GAHAR during the accreditation process). - **Modified** EOC: (**EOC.03:** The laboratory reports within 30 days any structural changes in the laboratory scope of work of addition or deletion of services by more than 20% of its scope, building expansions, or demolitions). - **Add new** EOC: (**EOC.02**: The laboratory reports accurate and complete information to GAHAR in between accreditation visits).
APC.02 **KW:** Professional standards during surveys	**APC.05** **KW:** Professional standards during surveys	- **Modified** EOC: (**EOC.01:** The laboratory reports any conflict of interest to GAHAR with evidence before or during surveys). - **Added new** EOC**: (EOC.05:** The accredited laboratories use the GAHAR accreditation seal according to GAHAR's rules).
APC.03 **KW:** Sustaining compliance with accreditation standards	**APC.01** **KW:** Sustaining registration requirements	- **Modified Standard statement: (**The GAHAR accredited laboratory ensures continuous compliance with the standards). - **Modified** EOCs: • (**EOC.01:** The laboratory establishes a process for periodic assessment of compliance with accreditation standards.) • (**EOC.02:** The laboratory acts on all feedback and reports received from GAHAR during the **accreditation period**). • (**EOC.03:** The laboratory reacts to all GAHAR requirements and reports in a timely manner.) - **Added new** EOC**: (EOC.04:** The laboratory demonstrates (using monitoring tools) the compliance with GAHAR Safety Requirements and acts on identified gaps.)

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

Transparent and ethical relationships

APC.01 The laboratory provides GAHAR with accurate and complete information through all steps of the accreditation process.

Effectiveness

Keywords:

Accurate and complete information.

Intent:

During the accreditation processes, there are many points at which GAHAR requires data and information. When a laboratory is accredited, it lies under GAHAR's scope to be informed of any changes in the laboratory and any reports from external authorities. The laboratory provides information to GAHAR verbally, through direct observation, an interview, application or any other type of communication with a GAHAR employee. Relevant accreditation policies and procedures inform the laboratory of what data and/or information are required and the period for submission. The laboratory is expected to provide timely, accurate, and complete information to GAHAR regarding its structure, laboratory scope of work, building, governance, licenses, and evaluation reports by external evaluators. GAHAR requires each laboratory to be engaged in the accreditation process with honesty, integrity, and transparency.
Any major laboratory changes including leadership shall be submitted to the GAHAR authority within 30 days of the changes.

Survey process guide:

- GAHAR surveyor may review reports of accreditation, licensure, inspection, audits, legal affairs, reportable sentinel events, and reportable measures.

Evidence of compliance:

1. The laboratory reports accurate and complete information to GAHAR during the accreditation processes.
2. The laboratory reports accurate and complete information to GAHAR in between accreditation visits.
3. The laboratory reports within 30 days any structural changes in the laboratory, scope of work of addition or deletion of services by more than 20% of its scope, building expansions, or demolitions.
4. The laboratory provides GAHAR access to evaluation results and reports of any evaluating organization.

Related standards:

OGM.03 Governing body responsibility, OGM.02 Laboratory Director. IMT.01 Documentation management system, QPI.06 Incident Reporting System.

APC.02 The laboratory maintains professional standards during the surveys.

Equity

Keywords:

Professional standards during surveys

Intent:

surveyors' aim is to perform their duties and responsibilities and to attain the highest levels of performance by the ethical requirements generally to meet the public interest and maintain the reputation of GAHAR. To achieve these objectives, the survey process has to establish creditability, professionalism, quality of service, and confidence. The laboratory is expected to maintain professional standards in dealing with surveyors. The laboratory is expected to report to GAHAR if there is a conflict of interest between a surveyor and the laboratory that could affect any of the following:

a) Integrity
b) Objectivity
c) Professional competence
d) Confidentiality
e) Respect

The laboratory ensures that there are no immediate risks for surveyors' safety and security. The laboratory respects the confidentiality and sensitivity of the survey process. The laboratory shall display GAHAR Gold Seal prominently (e.g., at facility entrance, website, external official documents, and advertisements).

Survey process guide:

- GAHAR surveyor may observe that all aspects of safety, security, confidentiality, privacy, respect, integrity, objectivity, professional competence values, and proper ethical management implementation.

Evidence of compliance:

1. The laboratory reports any conflict of interest to GAHAR with evidence before or during surveys.
2. During surveys, the laboratory maintains professional standards on dealing with surveyors.
3. During surveys, the laboratory ensures that the environment does not pose any safety or security risks to surveyors.
4. During surveys, the laboratory avoids media or social media releases without GAHAR's approval.
5. The accredited laboratories use the GAHAR accreditation seal according to GAHAR's rules.

Related standards:

OGM.06 Ethical management.

Sustaining compliance with accreditation standards

APC.03 The GAHAR accredited laboratory ensures continuous compliance with the standards.

Effectiveness

Keywords:

Sustaining compliance with accreditation standards

Intent:

Accreditation requirements are considered the optimum quality, safety, and compliance level for any laboratory aiming to enroll in the Universal Health Insurance system. When the laboratory is accredited, it is expected that the laboratory sustains or improves the same level of quality scored during all subsequent accreditation visits. This standard is not applicable during the first accreditation visit.

Survey process guide:

- GAHAR surveyors may review the laboratory's process of periodic assessment of compliance with the safety and regulatory requirements and may review the related corrective action plans.
- GAHAR surveyor may review and observe evidences of the laboratory's corrective actions taken in response to GAHAR feedback reports during the accreditation period.

Evidence of compliance:

1. The laboratory establishes a process for periodic assessment of compliance with accreditation standards.
2. The laboratory acts on all feedback and reports received from GAHAR during the accreditation period.
3. The laboratory reacts to all GAHAR requirements and reports in a timely manner.
4. The laboratory demonstrates (using monitoring tools) the compliance with GAHAR Safety Requirements and acts on identified gaps.

Related standards:

QPI.01 Quality improvement Plan, QPI.02 Performance Measures, QPI.04 Internal assessment and nonconformity management, QPI.07 Sustained Improvement activities.

Section 2: Patient-Centered Standards

Patient-centered care represents a paradigm shift in how patients, healthcare professionals, and other participants think about the processes of treatment and healing. Patient-centered care in clinical laboratories focuses on ensuring that laboratory services are aligned with the needs, values, and expectations of patients. This concept emphasizes accurate and timely diagnostic testing, clear communication of results, respect for patient rights, and collaboration with healthcare providers to support effective treatment decisions. Applying patient-centered care in clinical laboratories involves implementing quality control measures, maintaining confidentiality, improving turnaround times, and engaging in continuous training to enhance service delivery. It also requires laboratory professionals to adopt a compassionate approach, ensuring that patients feel informed and supported throughout the diagnostic process. The effects of patient-centered care in laboratories include improved diagnostic accuracy, increased patient trust in healthcare, enhanced collaboration between medical teams, and overall better health outcomes. By prioritizing the patient experience, laboratories play a crucial role in delivering safe, efficient, and high-quality healthcare services.

GAHAR Safety Requirements

Chapter intent:

Clinical laboratories are vital to healthcare, providing accurate and timely diagnostic results that impact patient outcomes. However, the complexity of laboratory processes, human factors, and system limitations create risks that require continuous safety improvements. Despite quality controls and skilled professionals, vulnerabilities persist, emphasizing the need for a strong safety culture focused on error prevention, open communication, and learning. Accreditation bodies uphold safety by setting rigorous standards, with key areas including specimen integrity, result accuracy, infection control, and staff competency. As part of GAHAR accreditation, laboratories must comply with GAHAR Safety Requirements (GSRs) to ensure safe, reliable operations. Regular assessments verify adherence to these standards, reinforcing a commitment to patient safety and regulatory compliance.

Chapter purpose:

1) **Provide** a comprehensive overview of GAHAR Safety Requirements.
2) **Support** organizational efforts to create a culture of safety.
3) **Enhance** client outcomes by minimizing risks and adverse events.

No standards are scored under this chapter; all GAHAR Safety Requirements will be scored in their corresponding chapters.

Summary of NSR Changes

- NSR (National Safety Requirements) – Renamed to be – GSR (GAHAR Safety Requirements)

GAHAR Safety Requirements

Code	Standard keyword	Code in this handbook
General Patient Safety Standards		
GSR.01	Specimen identification and collection.	**LPR.04**
GSR.02	Critical test result.	**LPO.05**
GSR.03	Specimen reception and tracking.	**LPR.06**
Infection Prevention and Control Standards		
GSR.04	Hand Hygiene	**IPC.02**
Environmental Safety Standards		
GSR.05	Fire and smoke safety plan, fire drill	**EFS.03**
GSR.06	Hazardous materials safety and waste management.	**EFS.04**
GSR.07	Safety and security management plan	**EFS.05**
GSR.08	Equipment management plan.	**EMS.01**
GSR.09	Utilities Management plan	**EFS.06**

Patient-Centeredness Culture

In today's healthcare landscape, patient experience is paramount, and the contributions of all healthcare professionals are increasingly vital. This includes a critical examination of the role of clinical laboratories, which, while not directly involved in patient care, play a crucial role in it.

Clinical laboratories provide the essential evidence base for clinical decision-making, directly impacting patient outcomes. By delivering accurate and timely test results, and by offering guidance on appropriate diagnostic procedures, laboratories contribute to avoiding unnecessary testing, reducing costs, and ultimately enhancing patient experience.

The American Society for Clinical Laboratory Science (ASCLS) recognizes the crucial role of clinical laboratory services in achieving optimal patient outcomes and patient-centered care.
Laboratories are not simply processing tests; they are generating critical data that informs diagnosis, treatment, and monitoring. In an ideal healthcare environment, laboratory directors and staff can collaborate with physicians, providing expertise on the effectiveness and limitations of various diagnostic tests in specific clinical contexts. This collaboration directly impacts patient management, leading to more informed decisions and improved patient satisfaction. For instance, by advising on the most appropriate test for a given condition, or by interpreting complex results in a clear and concise manner, the laboratory contributes to efficient and effective patient care.

Furthermore, laboratories can play a proactive role in quality improvement by monitoring testing trends, identifying areas for optimization, and working with clinicians to ensure the best possible patient outcomes.

Chapter purpose:

1. Planning and protecting the patient-centeredness culture.
2. Outlining the fundamental rights and responsibilities of patients.
3. Empowerment and involvement of patients and their families
4. Responsiveness to patients' and families' voices

PCC Summary of Changes

GAHAR Clinical Labs 2025	*GAHAR Clinical Labs 2021*	*Details of changes*
PCC.01 Multidisciplinary client-centeredness	**PCC.02** **KW:** interdisciplinary patient-centeredness	- **Modified Standard Statement: (**Client-centered culture is developed **by Multidisciplinary** collaboration**.)** - **Modified** EOCs: • **(EOC.01:** The laboratory has an approved plan fulfilling the detailed practices for client-centered activities includes elements mentioned in intent from a) to f). • **(EOC.03:** Laboratory staff is oriented on a client-centeredness activities). - **Added new** EOCs: **(EOC.05:** Laboratory leadership takes action to encourage staff participation in client-centeredness initiatives).
PCC.02 **KW:** Client and family rights.	**PCC.02** **KW:** Patient and family rights	- **Added new** EOC: (**EOC.06:** Violations against clients' rights are reported and analyzed, and corrective action is taken).
PCC.03 **KW:** Client and family responsibilities.	**PCC.03** **KW:** Patient and family responsibilities	- **Rephrasing** EOC: • (**EOC.03:** Clients are informed of their responsibilities in a manner they can understand). • (**EOC.04:** Clients' responsibilities are posted in all public areas in the laboratory and visible to clients, families, and staff). - **Added new** EOC: (**EOC.05:** Violations against clients' responsibilities are reported and analyzed, and corrective action is taken).
PCC.04 **KW:** Client and health education materials	**PCC.05** **KW:** Patient and family education materials.	- **Rephrasing of Standard statement**: (The laboratory provides adequate client and health education materials). - **Updated** EOC (EOC.05) by merging (EOC.04 and EOC.05) in laboratories 2021 edition**.**
PCC.05 **KW:** Informed consent		- **New Standard.**

GAHAR Clinical Labs 2025	*GAHAR Clinical Labs 2021*	*Details of changes*
PCC.06 **KW:** Client and family feedback.	**PCC.06** **KW:** Patient and family feedback.	- **Rephrasing of EOCs:** • **(EOC.02:** Feedback from clients and families and other customers is received, analyzed, and interpreted in a timely manner.) • **(EOC.03:** The interpreted feedback is shared with the staff members concerned). - **Add new EOC: (EOC.04:** The laboratory monitors the reported data on clients' and families' feedback and takes actions to control or improve the process as appropriate.
PCC.07 **KW:** Complaints and suggestions.	**PCC.07** **KW:** Complaints and suggestions.	- **Add new EOC: (EOC.02:** Staff is aware of complaints and suggestion policy). - **Modified** EOC: (EOC.04: Complaints and suggestions are investigated, analyzed by the laboratory, and resolved in an approved timeframe).

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

Planning and protecting the patient-centeredness culture

PCC.01 Client-centered culture is developed by Multidisciplinary collaboration.

Client-centeredness

Keywords:

Multidisciplinary client-centeredness.

Intent:

Client centered culture development and maintenance require careful planning, agile implementation, close monitoring. it is essential to enhance the community's understanding of available laboratory services by providing clear and accessible information about the types of laboratory services offered, laboratory professionals, cost of services, and working hours of the laboratory.

Client-centeredness culture sustainability requires informing and engaging staff on how to be client-centered. An assigned personnel should be established to oversee and support the implementation and maintenance of a client-centered culture. Participation should include, at a minimum, clients and their family members to ensure their perspectives are represented, integrated and addressed all aspects of client-centered care, including client experiences, satisfaction, complaints, suggestions, and the related procedures and practices.

Developing a client-centered culture requires a collaborative teamwork from multiple disciplines. The laboratory leadership can develop client-centered initiatives, but it requires staff adoption and implementation. The team may also go for quick wins till the culture change matures up and becomes an integrated part of daily processes. The laboratory shall have a plan to guide client-centered activities practices. The plan addresses at least the following:

a) Create a vision of establishing a client-centered culture with the required approaches to achieve it.
b) Communicate this vision to multiple stakeholders and staff members.
c) Education and training of the staff to ensure that they understand and can implement client-centered care practices including empowerment of clients to make an informed choice/decision.
d) Involving the clients in the client centered activities and initiatives planning.
e) Identify potential obstacles and resistance.
f) Work to remove these obstacles and ease down resistance.

Survey process guide:

- GAHAR surveyor may review the plan describing client-centered activities practices.
- GAHAR surveyor may interview laboratory head of departments to inquire about the strategies and measures in place to plan, assist, and maintain client-centered practices.
- GAHAR surveyor may interview laboratory staff to check their awareness of client-centered activities.

Evidence of Compliance:

1. The laboratory has an approved plan fulfilling the detailed practices for client-centered activities includes elements mentioned in intent from a) to f).
2. Laboratory leadership assign an individual(s) with defined responsibilities and authorities to oversight client centeredness plan.
3. Laboratory staff is oriented on a client-centeredness activities.
4. Clients and family members are involved in client centeredness activities.

5. Laboratory leadership takes action to encourage staff participation in client-centeredness initiatives.

Related standards:

PCC.02 Client and family responsibilities, PCC.06 Client and family feedback, PCC.05 Informed consent, OGM.02 Laboratory Director.

Outlining the fundamental rights and responsibilities of clients

PCC.02 Client and family rights are protected and informed to clients and families.

Client-centeredness

Keywords:

Client and family rights.

Intent:

Seeking and receiving service at a laboratory can be overwhelming for clients, making it difficult for them to act on their rights. The laboratory provides direction to staff regarding their role in protecting the rights of clients and families. Clients should be able to understand their rights and know how to use them. If for any reason, a client does not understand his/ her right, the laboratory is committed to helping him/her to gain knowledge of his/her rights. The laboratory shall empower staff members, clients, and families to report violations of any client's or family's rights.

The laboratory shall respect the client's information as confidential and implement processes to protect such information from leakage, loss, or misuse and ensure client privacy particularly during sample collection or any other procedure. Client cultural context, emotional, religious, spiritual needs, and other preferences shall be addressed and recognized. Where appropriate, provide separate facilities and services for women and men according to their cultural needs.

The laboratory develops and implements policies and procedures to ensure that all staff members are aware of, respect, and respond to client and family rights when they interact with and care for clients throughout the laboratory. The policy addresses at least the following:

a) Client and family rights as defined by laws and regulations, and the ethical code of Healthcare Providers' Syndicates
b) Client and family rights to know the name and the title of laboratory staff members.
c) Client and family rights to respect the client's personal values, beliefs, choices and preferences including cultural and spiritual.
d) Client and family rights to security, personal safety, privacy, confidentiality and dignity.
e) Client and family right to identify, choose or refuse their options for provided care (if applicable).
f) Client and family rights to make a complaint or suggestion without fear of retribution.
g) Client and family rights to know the procedures and price of services.
h) A child or adolescent client has the right to expect that services provided by the laboratory will be appropriate to his or her age and needs.
i) Clients with special needs has the right to expect that the services provided by the laboratory will be appropriate to his or her needs.

Survey process guide:

- GAHAR surveyor may review client rights policy and procedure defining client and family right, and the corrective action taken when violation against clients' rights is reported.
- GAHAR surveyor may interview staff members to check their awareness of clients' and families' rights and their roles in protecting their rights.
- GAHAR surveyor may observe client rights statements posted in the laboratory, may also observe how clients receive information about their rights.
- GAHAR surveyor may observe conditions under which client rights are protected.

Evidence of Compliance:

1. The laboratory has an approved policy and procedure guiding the process of defining client and family rights, includes elements mentioned in intent from a) to i).
2. All staff members are aware of clients' and families' rights and their roles in protecting their rights.
3. Information about client rights is provided in written or in another manner that the client understands and is posted in all public areas in the laboratory.
4. Client and family rights are protected in all areas of the laboratory and at all times.
5. Rights for clients with special needs, children and adolescents are available.
6. Violations against clients' rights are reported and analyzed, and corrective action is taken.

Related standard:

PCC.01 Multidisciplinary client-centeredness, PCC.05 Informed consent, PCC.03 Client and family responsibilities, PCC.06 Client and family feedback, PCC.07 Complaints and suggestions.

PCC.03 Clients and families are empowered to assume their responsibilities.

Equity

Keywords:

Client and family responsibilities.

Intent:

Clients and their families shall be able to understand and assume responsibilities towards the laboratory. If for any reason a client/family member does not understand his/her responsibilities, the laboratory is committed to help him to gain relevant knowledge. The laboratory is responsible to make the clients' responsibilities visible to clients and staff at all times. The laboratory shall empower staff members, clients, and families to report violations of any client's or family's responsibilities.

The laboratory shall develop and implement a policy and procedures to ensure that clients are aware of their responsibilities.

The policy shall address at least the following:

a) Clients and their families have the responsibility to comply with the procedures of the laboratory
b) Clients and their families have the responsibility to comply with financial obligation according to laws and regulations and laboratory policy.
c) Clients and their families have the responsibility to show respect to other clients and laboratory workers.

d) Clients and their families have the responsibility to release honestly and transparently the information required by laboratory staff about medication intake, fasting hours or data which can affect the result of the clients.

Survey process guide:

- GAHAR surveyor may review client responsibilities policy and procedure, corrective action taken when violation against clients' responsibilities is reported.
- GAHAR surveyor may interview staff members to check their awareness of Client and family responsibilities.
- GAHAR surveyor may observe client responsibility statements posted in the laboratory, and may also observe how clients receive information about their responsibilities.

Evidence of Compliance:

1. The laboratory has an approved policy and procedure guiding the process of defining client and family responsibilities includes elements mentioned in intent from a) to d).
2. All staff members are aware of clients' and families' responsibilities.
3. Clients are informed of their responsibilities in a manner they can understand.
4. Clients' responsibilities are posted in all public areas in the laboratory and visible to clients, families, and staff.
5. Violations against clients' responsibilities are reported and analyzed, and corrective action is taken.

Related standard:

PCC.01 Multidisciplinary client-centeredness, PCC.05 Informed consent, OGM.05 Billing system.

Empowerment and involvement of clients and their families

PCC.04 The laboratory provides adequate client and health education materials.

Client-centeredness

Keywords:

Client and health education materials

Intent:

Client and family education helps to understand the process and empowers clients and families to make informed decisions. The laboratory shall Identify client and family needs that may vary from one client to another. The method of education is provided according to client and family values and level of learning, as well as in a language and format that they understand.

The laboratory may provide mass education of clients and families on certain health topics based on the served community needs and /or client condition.

Mass education may take the form of videos, social media posts, brochures, pamphlets, text messages or other forms. It is important for the laboratories to make sure that these materials are available when needed, especially during health campaigns and to ensure that these education materials are understandable by the target audience with different languages or pictorial illustrations if needed. Education materials should be appropriate for the laboratory's scope of services and the client's health

needs, level of education, language, and culture to support, maintain, and improve their own health and well-being. Education materials may include smoking cessation programs, stress management advice, diet and exercise guidance and substance abuse management.

Survey process guide:

- GAHAR surveyor may review a list of all potential topics, places, and/or timings of distributing client education materials.
- GAHAR surveyor may interview staff members to check their awareness of client and health education materials.
- GAHAR surveyor may observe client education materials posted for clients in laboratory reception desks, waiting areas, collection rooms, and others.

Evidence of Compliance:

1. The laboratory identifies the topics, places and/or timings for distributing client education materials
2. Laboratory staff is aware of clients' and families' education process.
3. Client education materials are readily available, in the places and for the topics identified by the laboratory.
4. Client education materials contain relevant and evidence-based information.
5. Client education materials are appropriate for readers of varying literacy levels and translated in different languages for foreigner client groups.

Related standard:

PCC.02 Client and family rights, LPR.01 Laboratory services information, PCC.05 Informed consent.

PCC.05 The laboratory has a defined process to obtain informed consent for certain processes.

Client-centeredness

Keywords:

Informed consent

Intent:

One of the main pillars to ensure client's involvement in their care decisions is by obtaining informed consent. Informed consent is a process in which a client or their legal representative agrees to disclose personal information or undergo a specific laboratory test after receiving clear, relevant, and comprehensive information about the test. After receiving this information, the client either consents to or refuses such a procedure.

To give consent, a client should be informed of many factors to make an informed decision.

The laboratory shall develop and implement a policy and procedures to describe how and where informed consent is used and documented as required by applicable laws and regulations. The policy includes at least the following:

a) The list of processes when informed consent is needed; this list includes:
    i. Complex sampling techniques (e.g. prostatic secretion, vaginal smear, needle biopsy, bone marrow aspiration).
    ii. HIV testing

iii. Research and education.

b) Discussion of benefits and risks of doing this technique and involve the use of decision aids (if any).
c) Informed consent in case of refusing provided care is documented and clients is informed of the consequences of their decision (if applicable).
d) Certain situations when consent can be given by someone other than the client, as well as Mechanisms for obtaining and recording it according to applicable laws and regulations and approved laboratory policies.
e) Required staff training on obtaining informed consent
f) Consent forms available in all applicable locations.

Survey process guide:

- GAHAR surveyor may review the laboratory policy guiding the process of obtaining informed client consent.
- GAHAR surveyor may review the list of processes when informed consent is needed.
- GAHAR surveyor may review a sample of clients' records to check informed consent completion.
- GAHAR surveyor may observe the distribution and availability of informed consent forms by visiting areas where they are most needed.

Evidence of compliance:

1. The laboratory has an approved policy guiding the process of informed consent includes elements mentioned in intent from a) to f).
2. Informed consent is obtained when required in a manner and language that the client understands and does not contain abbreviations.
3. Informed consent given by someone other than the client complies with applicable laws and regulations.
4. Informed consent records are maintained.

Related standard:

PCC.02 Client and family rights, LPR.02 Test requesting, PCC.04 Client and health education materials

Responsiveness to clients' and families' voices

PCC.06 The laboratory improves provided services based on measured clients', families' and other customer's feedback.

Client-centeredness

Keywords:

Client and family feedback.

Intent:

Client feedback could include concerns, compliments, and formal complaints or through surveys, which may help laboratory to identify ways of improving performance. Ultimately, that translates into better laboratory services and satisfied clients.
Laboratory can solicit feedback from clients in a variety of ways: phone surveys, written surveys, focus groups or personal interviews. Many laboratories use written surveys, which tend to be the most cost-

effective and reliable approach. The laboratory shall develop and implement a policy and procedures to guide the process of managing client feedback that addresses at least the following:

a) Measuring feedback for walk in clients.
b) Measuring feedback from other customers as contracted or insurance companies.
c) Measuring feedback for home visit clients.
d) Measuring feedback for referring doctors.

Laboratory defines if the process addresses measurement of client experience or client satisfaction. For client experience, the laboratory assesses whether something that should happen in a laboratory setting (such as clear communication with laboratory staff), actually happened and how often it happened. While for client satisfaction, the laboratory measures whether a client's expectations about service were met. Measuring alone is not enough; laboratory needs to analyze and interpret information obtained from measured feedback and identify potential improvement projects or plan for new services. All the findings of the analysis and the improvement shall be submitted periodically to the laboratory head of departments.

Survey process guide:

- GAHAR surveyor may review the policy of client and family feedback.
- GAHAR surveyor may review the reported data on clients' and families' feedback to assess the process of consequent performance improvement.

Evidence of Compliance:

1. The laboratory has an approved policy guiding the process of client and family feedback measurement includes elements mentioned in intent from a) to d).
2. Feedback from clients and families and other customers is received, analyzed, and interpreted in a timely manner.
3. The interpreted feedback is shared with the concerned staff members.
4. The laboratory monitors the reported data on clients' and families' feedback and takes actions to control or improve the process as appropriate.

Related standard:

PCC.01 Multidisciplinary client-centeredness, PCC.02 Client and family rights, PCC.07 Complaints and suggestions, QPI.07 Sustained improvement activities, QPI.02 Performance measures.

PCC.07 Clients, families and other parties are able to make oral or written complaints or suggestions through a defined process.

Client-centeredness

Keywords:

Complaints and suggestions.

Intent:

While laboratories shall be able to proactively measure and use client's feedbacks, clients, families and other parties may also want to give oral or anonymous complaints or suggestions about their service and to have those complaints or suggestions reviewed and acted upon. The laboratory shall develop and implement a policy and procedures to create a uniform system for dealing with different complaints and

suggestions from clients and/or their families to make it easy to follow up, monitor, and learn from practices. The laboratory policy addresses at least the following:

a) Mechanisms to inform clients and families of communication channels to voice their complaints and suggestions.
b) Tracking processes for clients' and families' complaints and suggestions.
c) Responsibility for responding to clients' complaints and suggestions.
d) Timeframe for giving feedback to clients and families about voiced complaints or suggestions.
e) Monitor the reported data on clients' complaints and take actions to control or improve the process.

Survey process guide:

- GAHAR surveyor may review the policy of managing client complaints and suggestions.
- GAHAR surveyor may interview laboratory staff to check their awareness about complaints and suggestion policy.
- GAHAR surveyor may review the reported data on clients' complaints and suggestions to assess the process of managing client suggestions and complaints.

Evidence of Compliance:

1. The laboratory has an approved policy guiding the process of managing clients' complaints and suggestions includes elements mentioned in intent from a) to e).
2. Staff is aware of complaints and suggestion policy.
3. The laboratory allows the complaining process to be publicly available.
4. Complaints and suggestions are investigated, analyzed by the laboratory, and resolved in an approved timeframe.
5. Clients and families receive feedback about their complaints or suggestions within approved timeframes and according to the level of urgency of the complaint.
6. Evaluation of the effectiveness of the corrective actions taken.

Related standard:

PCC.01 Multidisciplinary client-centeredness, PCC.02 Client and family rights, PCC.06 Client and family feedback, QPI.07 Sustained improvement activities, QPI.02 Performance measures.

Section 3: Total Testing Process Standards

Total Testing Process (TTP) standards in clinical laboratories ensure accuracy, reliability, and patient safety across three essential phases: pre-analytical, analytical, and post-analytical. The pre-analytical phase includes proper patient identification, specimen collection, handling, and transportation to prevent errors before testing. The analytical phase focuses on precise testing procedures, instrument calibration, and maintaining laboratory internal and external quality control (IQC & EQC) programs. Internal quality control (IQC) ensures daily accuracy and consistency through routine checks, while external quality control (EQC) involves proficiency testing and inter laboratory comparisons to verify performance against established standards. The post-analytical phase ensures accurate result verification, timely reporting, and effective communication with healthcare providers for appropriate clinical decisions. Adhering to TTP standards enhance laboratory efficiency, minimize errors, and foster continuous quality improvement, ultimately improving patient outcomes.

Laboratory Pre- Examination process

Chapter intent:
Laboratory testing is crucial for modern diagnosis and disease management but selecting the right tests and interpreting results correctly is essential.
Inappropriate test ordering wastes resources and burdens healthcare systems. While clinical history is key for diagnosis (with clinical examination confirming it), lab tests play a vital role in confirming findings, aiding prognosis, classifying diseases, and sometimes providing a definitive diagnosis.

The pre-examination phase, encompassing all steps from test ordering to specimen delivery, is the most vulnerable part of the testing process. Errors here significantly impact result quality and pose a major challenge for lab professionals. While labs have traditionally focused on analytical quality control, evidence shows that quality cannot be assured by focusing solely on the testing itself. Most errors occur before (pre-examination) or after (post-examination) the analytical phase.

Therefore, improving quality and reducing errors requires prioritizing the standardization of pre-examination procedures. This includes client preparation and identification, sample collection, transport, handling, storage, and preparation. Standardization can be achieved through adherence to guidelines, implementing total quality management systems (including pre-analytical requirements), and continuous education for healthcare staff responsible for blood sampling.

Chapter Purpose:
This chapter addresses the pre- examination phase including the following:

1. Safe and proper testing process.
2. Specimens requesting, collection, handling, and transportation.
3. Proper specimen reception, tracking and Pre-examination storage.

LPR Summary of Changes

GAHAR Clinical Lab 2025	*GAHAR Clinical Lab 2021*	*Details of changes*
LPR.01 **KW:** Laboratory services information	**TPR.01** **KW:** Laboratory service manual.	- **Modified Standard statement**: (The laboratory services and related information are provided for clients and users**.)** - **Rephrasing of** EOC**: (EOC.01:** Laboratory Service information describes the requirements as mentioned in intent from a) through p). - **Modified** EOCs**:** • **(EOC.03:** Laboratory service information is provided to clients (Service users) in a manner they understand.) • **(EOC.04:** Clients (Service users) are aware of the laboratory service information as per their need and according to laws and regulations.) • **(EOC.05:** Any changes in the laboratory service information are communicated to all laboratory staff members, and service users as per need.) - **Add new EOC: (EOC.02:** Staff is aware of laboratory service information.)
LPR.02 **KW:** Test requesting.	**TPR.02** **KW:**.Test requesting	- **Modified** EOCs**:** • **(EOC.01:** The laboratory has an approved procedure that describe the process of test request including elements mentioned in the intent from a) through b). • **(EOC.03:** Request form includes all items mentioned in the intent from i) to ix).

GAHAR Clinical Lab 2025	*GAHAR Clinical Lab 2021*	*Details of changes*
		- **Add new EOC:(EOC.02:** Responsible staff is aware of requesting laboratory test procedure).
LPR.03 **KW:** Client preparation assessment	**TPR.03** **KW**: Patient assessment.	- **Modified Standard statement**: (The laboratory performs preparation assessments before sampling.) - **Modified EOCs:** • **(EOC.01:** The laboratory has an approved procedure to guide client preparation assessment before sampling process following testing algorithm and guidelines.) • **(EOC.02:** The responsible staff is qualified and aware of the process of client preparation assessment. • **(EOC.03:** The client preparation assessment is recorded in the client's request form.)
LPR.04 **KW:** Specimen identification and collection	**TPR.04** **KW:** Specimen collection, Patient identification.	- **Modified Standard Statement**: (The laboratory has a process for specimen identification and collection.) - **Modified EOC: (EOC.01:** The laboratory has an approved procedure that describe specimens' collection as mentioned in intent from a) through g). - **Add new EOCs:** • **(EOC.03:** Specimens labelling is performed according to the laboratory procedure.) • **(EOC.04:** Care of client and phlebotomy adverse incidents are managed.)
LPR.05 **KW:** Specimen handling and transportation	**TPR.05** **KW:** Specimen handling and transportation.	- **Add new EOC: (EOC.03:** The procedure for specimens handling and transportation is followed within the laboratory).

GAHAR Clinical Lab 2025	*GAHAR Clinical Lab 2021*	*Details of changes*
LPR.06 **KW:** Specimen reception and tracking	**TPR.06** **KW:** Specimen reception and tracking.	- **Rephrasing** of **Standard statement: (**The laboratory has a process for specimen reception and tracking.) - **Modified** EOCs**:** - **(EOC.01:** The laboratory has approved procedures that describe process for specimen reception and tracking including elements mentioned in the intent from a) to e). - **(EOC.03:** All accepted, rejected and suboptimal specimens are recorded including all data mentioned in the intent). - **(EOC.05:** All specimens referred to other laboratories are recorded).
LPR.07 **KW:** Pre-examination specimen storage.	**TPR.07** **KW:** Pre-examination specimen storage.	- **Modified Standard Statement: (**The laboratory defines storage conditions for specimens during all pre-examination activities.). - **Add new EOC: (EOC.02:** Responsible staff is aware about the proper storage condition of the specimen.)

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

Safe and proper testing process

LPR.01 The laboratory services and related information are provided for clients and users.

Effectiveness

Keywords:

Laboratory services information

Intent:

Laboratory service information provides an overview of the laboratory service to clients (Service users) and explains everything they need to know regarding the services provided in a manner and language that clients understand. Some Information may be publicly available via the laboratory's website (if applicable).

Laboratory service information is available to clients and users and shall include the following:

a) The location and opening hours of the laboratory.
b) Available tests and services offered by the laboratory (including clinical advice on requesting of examinations and on interpretation of examination results) .
c) Registration process.
d) Correct completion of request form.
e) Client preparation assessment including special preparation requirements.
f) Proper unique client identification by at least two identifiers.
g) Type of specimen, volume, stability, container, preservative required.
h) Specimen labelling, handling and transportation including specimens of referral laboratory.
i) Turn Around Time for each laboratory test.
j) Biological reference intervals, and clinical decision values.
k) Specimen rejection process.
l) Process of handling urgent requests.
m) Client information protection policy.
n) Complaint procedure.
o) Factors that may affect the performance of the examination or the interpretation of the results.
p) Special procedures need written consent.

Survey process guide:

- GAHAR surveyor may review laboratory service information document.
- GAHAR surveyor may interview laboratory staff to assess their awareness about laboratory service information.
- GAHAR surveyor may observe laboratory service information communicated to clients (Service users) as per their need.

Evidence of compliance:

1. Laboratory Service information describes the requirements as mentioned in intent from a) through p).
2. Staff is aware of laboratory service information.
3. Laboratory service information is provided to clients (Service users) in a manner they understand.
4. Clients (Service users) are aware of the laboratory service information as per their need and according to laws and regulations.
5. Any changes in the laboratory service information are communicated to all laboratory staff members, and service users as per need.

Related standards:

LPR.02 Test requesting, LPR.03 Client preparation assessment, LPR.04 Specimen identification and collection, LPR.05 Specimen handling and transportation, LEP.04 Biological reference interval and clinical decision values, LPO.04 Turnaround time, LPO.06 STAT results, PCC.02 Client and family rights, PCC.04 Client and family education materials, PCC.07 Complaints and suggestions, PCC.05 Informed consent.

Proper Specimens requesting, collection, handling, and transportation

LPR.02 The laboratory ensures proper test requesting process.

Efficiency

Keywords:

Test requesting.

Intent:

Quality and accuracy of laboratory results can be assured when requests and specimen meet specific acceptability criteria. Proper client identification and complete, legible test request information are essential for client safety and valid laboratory results.

The laboratory shall develop a procedure to define the process of requesting laboratory test that includes:

a) Use of appropriate request form according to the test ordered.
b) Completion of request form (whether electronic or paper) shall include at least the following:
    i. Complete, accurate client information (client name, date of birth, gender, and client contact).
    ii. Name of the ordering individual/physician or referring laboratory (when available).
    iii. Tests requested.
    iv. Date and time of specimen collection.
    v. Identification of the person who collected the specimen.
    vi. Clients' preparation assessment.
    vii. Clinical information (as required)
    viii. Type of specimen (including source in special type of specimens)
    ix. Special marking for urgent tests request.

Survey process guide:

- GAHAR surveyor may review requesting laboratory test procedure.
- GAHAR surveyor may interview laboratory staff to check their awareness on completion of request form.
- GAHAR surveyor may review request forms to check their completion.
- GAHAR surveyor may review records of requests and urgent requests.

Evidence of compliance:

1. The laboratory has an approved procedure that describe the process of test request including elements mentioned in the intent from a) through b).
2. Responsible staff is aware of requesting laboratory test procedure.
3. Request form includes all items mentioned in the intent from i) to ix).
4. Test requesting records are available.

Related standard:
PCC.05 Informed consent, LPR.03 Client preparation assessment, LPR.04 Specimen identification and collection, LPR.01 Laboratory service information, IMT.01 Documentation management system.

LPR.03 The laboratory performs preparation assessments before sampling.

Client-centeredness

Keywords:

Client preparation assessment.

Intent:
Client preparation assessment is one of important points to be performed before sampling to identify the client status and needs by a qualified individual. This requires the active participation of clinical pathologist and physicians who are the most knowledgeable about the best uses and interpretations of specific laboratory tests.
Testing algorithms are known as reflex testing have been used to promote the best client outcome at lowest cost following evidence-based care guidelines and pathways.
The laboratory shall include the preparation assessments performed for the high-risk clients to mitigate and minimize harm of the client, based on the laboratory risk management plan\program.
The preparation assessment is recorded in request form and shall include all relevant data needed according to the laboratory scope of service.
The laboratory shall develop a procedure for client preparation assessment before sampling process.
The laboratory shall identify clients' clinical needs by defining the minimum content of these preparation assessments and check that the client preparation assessment is completed and recorded before sampling.

Survey process guide:

- GAHAR surveyor may review the laboratory procedure guiding client preparation assessment before sampling process.
- GAHAR surveyor may interview staff members to check their awareness of the process.
- GAHAR surveyor may review a client request form to check client preparation assessment recording.

Evidence of compliance:

1. The laboratory has an approved procedure to guide client preparation assessment before sampling process following testing algorithm and guidelines.
2. The responsible staff is qualified and aware of the process of client preparation assessment.
3. The client preparation assessment is recorded in the client's request form.

Related standard:
LPR. 01 Laboratory service information, LPR.02 Test requesting, IMT.01 Documentation management system.

LPR.04 GSR.01 The laboratory has a process for specimen identification and collection.

Effectiveness

Keywords:

Specimen identification and collection.

Intent:

Proper specimen collection is a key to client's satisfaction while poor collection practice can lead to defective results, improper treatment, duplicated specimen collections, re-testing, vessel trauma and pain.

The laboratory develops and implements a procedure describing how specimens are collected in the laboratory sampling area to ensure that all samples are managed properly. This procedure is available to those responsible for primary specimen collection at all sample collection areas, including specimens that are distant from the laboratory.

Responsible laboratory staff are familiar with the information in the procedure, and are able to answer questions about the information included. The procedure shall include the following:

a) Unique client identification.
b) Client preparations including instructions for dietary requirements (e.g., fasting and special diets); timed testing (e.g., glucose tolerance, therapeutic drug monitoring); and medication restriction.
c) Description of specimen collection techniques.
d) Care of client and phlebotomy adverse incidents (fear, phobia, hematoma formation, syncope and fainting, excessive bleeding, edema …. etc.).
e) Proper specimen labelling e.g. (Two client identifiers, Collection date, type of sample and test requested).
f) Defining criteria for safe disposal of materials used in the collection.
g) The identity of the collector shall be traceable.

Survey process guide:

- GAHAR surveyor may review the laboratory procedures of specimen collection and check availability and accessibility of procedures at all sample collection areas.
- GAHAR surveyor may observe specimens' collection from clients and specimens labelling to assess compliance with laboratory procedures.
- GAHAR surveyor may interview responsible laboratory staff to check their awareness on preparation requirements and specimen collection procedures.

Evidence of compliance:

1. The laboratory has an approved procedure that describe specimens' collection as mentioned in intent from a) through g).
2. The responsible laboratory staff is aware and trained about the primary specimen collection process.
3. Specimens labelling is performed according to the laboratory procedure.
4. Care of client and phlebotomy adverse incidents are managed.
5. The sample collection process is followed and regularly monitored.

Related standard**:**

LPR.05 Specimen handling and transportation, WFM.08 Continuous EducationProgram, QPI.06 Incident Reporting System, QPI.02 Performance measures.

LPR.05 The laboratory ensures proper and safe specimens handling and transportation.

Effectiveness

Keywords:

Specimen handling and transportation.

Intent:

Laboratory testing provides information about a client's health to assist physicians in diagnostic and therapeutic decisions. Specimen integrity is dependent on many variables in the pre-analytical processes including client preparation, specimen collection, handling, and transportation. Improper handling or transportation of specimens can give erroneous results and compromise the care of the client.

The laboratory procedures for handling and transportation of specimens include at least the following:

a) Safety precautions and instructions for proper safe specimens packing.
b) Handling and transportation whether to the laboratory, within the laboratory or to referral laboratory including instructions for handling and transportation of irretrievable specimens (specimens that are extremely difficult or impossible to recollect due to the nature of the specimen or due to unique circumstances under which the specimen was obtained).
c) Special transportation safety requirements (e.g., Specified temperature interval, within a certain time appropriate to nature of requested tests to ensure integrity of specimens during transportation, in appropriate safe containers, etc.)

For specimens received by or sent to referral laboratories, the referring laboratory properly follows all the instructions for requisition, collection and handling specifications of the referral laboratory to maintain specimen integrity, including specimen temperature, transport time and any special precautions for the type of specimen.

Competent personnel are responsible for proper specimen handling and transportation according to the approved procedures.

Survey process guide:

- GAHAR surveyor may review the laboratory procedures for handling and transportation of specimens.
- GAHAR surveyor may interview staff members to assess their awareness of laboratory procedures.
- GAHAR surveyor may observe handling and transportation procedure of client specimens, including the special transportation safety requirements, specimens of referring laboratory, and irretrievable specimens.

Evidence of compliance:

1. The laboratory has an approved procedure that describe process of specimen handling and transportation including elements mentioned in the intent from a) to c).
2. Competent personnel are responsible for specimen handling and transportation according to the approved procedures.
3. The procedure for specimens handling and transportation is followed within the laboratory.
4. The procedure for packing and transportation of specimens to referral laboratories is consistent with the referral laboratory collection and handling requirements.

Related standard:

LPR.04 Specimen identification and collection, WFM.09 Competency assessment, SCM.06 Referral laboratory.

Proper specimen reception, tracking and Pre-examination storage.

LPR.06 GSR.03 The laboratory has a process for specimen reception and tracking.

Effectiveness

Keywords:
Specimen reception and tracking.

Intent:
Specimen reception and tracking processes are starting with specimen requesting, collection and labelling to specimen reception, analysis and storage to properly allow workers to identify the specimen location, history and status.
Without precisely following the correct procedures in any stage the traceability of the sample is not guaranteed, the quality of results is not assured, and the health of both client and staff members is risked.
The specimen reception and tracking procedure include at least the following:

a) Criteria of acceptance or rejection of specimens
b) Process of recording of all specimens received in an accession book, worksheet, computer or other comparable system.
c) Process of evaluation of the received specimens by authorized personnel to ensure that they meet the acceptance criteria relevant for the requested examination(s).
    i. Acceptable specimen: recording includes the date and time of specimen's reception/ requesting and the identity of the person receiving the specimen.
    ii. Unacceptable specimen: Records of rejection are maintained, including the cause of rejection, time and date, name of rejecting person, and name of the notified individual.
    iii. Indications of acceptance of suboptimal specimens, recording that includes client notification and insertion of test comment, taken measures, the date and time of specimen's reception/ requesting and the identity of the receiving person.
d) Process of traceability of all portions of a specimen to the original primary specimen.
e) Process of recording all specimens referred to other laboratories for testing.

Survey process guide:

- GAHAR surveyor may review laboratory procedure guiding specimen reception and tracking.
- GAHAR surveyor may interview staff members to inquire about their awareness of laboratory procedure.
- GAHAR surveyor may observe how specimens are accessioned once received by the laboratory.
- GAHAR surveyor may review laboratory specimen identification and traceability process, records of received, referred and/or rejected specimen.

Evidence of compliance:

1. The laboratory has approved procedures that describe process for specimen reception and tracking including elements mentioned in the intent from a) to e).
2. Responsible staff is aware and trained about the instructions of specimen reception.
3. All accepted, rejected and suboptimal specimens are recorded including all data mentioned in the intent.
4. All portions of a specimen are traceable to the original primary specimen.
5. All specimens referred to other laboratories are recorded.

Related standard:
LPR.04 Specimen identification and collection, SCM.06 Referral laboratory, LPR.07 Pre-examination specimen storage, WFM.08 Continuous EducationProgram, IMT.01 IMT.02 Record management system.

LPR.07 The laboratory defines storage conditions for specimens during all pre-examination activities.

Effectiveness

Keywords:

Pre-examination specimen storage.

Intent:
The specimen may be stored prior to testing for certain conditions defined by the laboratory according to the stability of the specimen or as mentioned in the test procedure. Proper specimen storage is extremely important for accurate results. The laboratory shall develop procedure and ensure providing appropriate facilities for securing client specimen and avoiding deterioration, loss or damage during storage in the pre-examination phase and prior to testing. The laboratory should define the specific storage conditions of each specimen type and test. The laboratory should properly maintain and monitor the storage conditions of the specimens.

Survey process guide:

- GAHAR surveyor may review laboratory procedures for pre-examination specimen storage.
- GAHAR surveyor may observe the facilities for specimen storage, how specimens are stored and monitoring of the storage conditions.
- GAHAR surveyor may interview laboratory staff to ensure their awareness of laboratory proper storage conditions.

Evidence of compliance

1. The laboratory has approved procedures that describe process for proper specimen storage in pre-examination phase.
2. Responsible staff is aware about the proper storage condition of the specimen.
3. Conditions of specimens' storage are identified and controlled.
4. Specimens are stored in appropriate conditions during all pre-examination activities.

Related standard:

LPR.05 Specimen handling and transportation, LPR.06 specimen reception and tracking, IPC.01 IPC program, risk assessment, guidelines, IPC.09 Biosafety and biosecurity plan.

Laboratory Examination process

Chapter intent:

Examination procedures cover the activities from the time the specimen reaches the testing area till the time the tests are performed and the results are ready to reviewed and interpreted. The examination phase shows the lowest rate of errors in the Total Testing Process (TTP). Advances in examination techniques, laboratory instrumentation and automation have improved examination quality. Also, errors occur much less frequently in the examination phase of laboratory testing than in either the pre-examination or post examination phases because of

- The qualifications of technical personnel.
- The effectiveness of internal quality control programs and external assessment practices that assist in identifying examination errors and detecting possible sources.
- Establishing and verifying test method performance specifications as to test accuracy, precision, sensitivity, specificity, and linearity are a hedge against unrecognized examination errors.

Nonetheless, examination quality is still a significant issue. Errors that may be encountered during the examination activities include both human and instrumentation errors. Errors in the examination phase may be random or systematic.

Chapter Purpose:

This chapter address quality measures for the examination phase including the following:

1. Ensure accurate reagent labelling.
2. Develop criteria of laboratory method selection.
3. Highlight the importance of laboratory test validation or verification of methods used.
4. Properly implement the examination procedures.

LEP Summary of Changes

GAHAR Clinical Lab 2025	***GAHAR Clinical Lab 2021***	***Details of changes***
LEP.01 **KW:** Prepared/reconstituted reagents**.**	**TEX.05** **KW:** Prepared/reconstituted reagents.	- **Modified** EOC**:(EOC.01:** Reagents/solutions labelling satisfying all requirements as mentioned in intent from a) to g).
LEP.02 **KW:** Examination procedures selection.	**TEX.01** **KW:** Validated examination procedure.	- **Rephrasing of Standard statement**: (The laboratory selects examination procedures which are fit for their intended use).
LEP.03 **KW:** Verification / validation.	**TEX.02** **KW**: Verification / validation.	- **Modified EOC:(EOC.01:** The laboratory has an approved procedure that describe the process for verification /validation of examination methods for all laboratory tests.) - **Rephrasing of** EOC**: (EOC.03: T**he laboratory follows verification/validation methods endorsed by guidelines.)
LEP.04 **KW:** Biological reference interval and clinical decision values.	**TEX.03** **KW:** Biological reference interval and clinical decision values	- **Rephrasing of Standard Statement**: (The laboratory defines and verifies biological reference intervals and defines clinical decision values for examination methods.) - **Updated EOC (EOC.02) by merging two EOCs (EOC.02 & EOC.04) in Clinical Labs 2021.** - **Add new EOCs: (EOC.04:** Biological reference intervals and clinical decision values are reviewed at least annually.)
LEP.05 **KW:** Examination procedure.	**TEX.0**4 **KW:** Examination procedure.	**Modified EOCs:** • **(EOC.01:** The laboratory has a documented and implemented examination procedure for each analytical test method). • **(EOC.03:** Each procedure includes all the required elements mentioned in the intent from a) to k). • **(EOC.05:** The laboratory examination procedures are reviewed at least annually by the authorized personnel).

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

Ensure accurate reagent labelling

LEP.01 Prepared/reconstituted reagents and solutions are identified.

Safety

Keywords:

Prepared/reconstituted reagents.

Intent:

Unambiguous identification of chemicals and reagents in a laboratory is of utmost importance. Reagent labelling is a complement to other sources of information such as the SDS and other labelling requirements.

It aims to assist with the safer use of a substance by identifying hazards likely to be associated with the use of the substance. Proper labelling of reconstituted/ prepared reagent should be done accurately to ensure quality of the performed test procedure. Reagent data are recorded on the container itself and in a log. All containers are identified so as to be traceable. Reagent labels shall include at least the following:

a) Content.
b) Concentration/titre.
c) Preparation/reconstitution or opening date.
d) Expiration date.
e) Storage requirements.
f) Identity of the personnel preparing/reconstituting the reagents and solutions.
g) A new stability date and/or storage conditions for the opened, prepared or reconstituted reagent.

Survey process guide:

- GAHAR surveyor may check reconstituted reagents for proper labelling and review implementation.
- GAHAR surveyor may interview the laboratory staff to check their awareness.

Evidence of compliance:

1. Reagents/solutions labelling satisfying all requirements as mentioned in intent from a) to g).
2. Staff is aware of the reagents/solutions labelling and storage requirements.
3. The reagents/solutions labelling identification process is monitored and tracked.

Related standards:

SCM.03 Inventory management, QPI.02 Performance measures.

laboratory method selection

LEP.02 The laboratory selects examination procedures which are fit for their intended use

Effectiveness

Keywords:
Examination procedures selection.

Intent:
In order to ensure accurate and relevant test results, the laboratory uses accurate and reproducible analytical methods. The specified requirements for each examination procedure relate to the intended use of that examination.

Examination procedures are those specified in the instructions for use of in vitro diagnostic devices or those that have been published in established/authoritative textbooks, peer-reviewed texts, journals, international consensus standards, guidelines, national or regional regulations. The laboratory assigns qualified, competent personnel for different activities of the selected methods in approved authorization list.

Survey process guide:

- GAHAR surveyor may review the process of selection and the reference of the selected examination procedures used.
- GAHAR surveyor may review the authorization list of the personnel performing the examination procedures and their qualifications.
- GAHAR surveyor may interview staff to evaluate their awareness about examination procedure.

Evidence of compliance:

1. The laboratory has a process for the selection of the examination procedures for all subspecialties present in the laboratory.
2. Responsible laboratory staff is aware about the examination procedures.
3. Authorization list of the personnel performing the examination procedures is available in the laboratory.
4. Reference of selected examination procedures used are available.

Related standards:

LEP.03 Verification / validation, WFM.05 Verifying credentials, clinical privilege, LEP.05 Examination procedure, WFM.06 Staff Files.

Laboratory test verification / validation

LEP.03 Verification / validation of the selected examination methods are performed before being in routine use.

Effectiveness

Keywords:
Verification / validation.

Intent:
Analytical laboratory techniques and testing provide the data required to drive test improvement or meet regulatory compliance requirements. In order to ensure accurate and relevant test results, the laboratory uses accurate and reproducible analytical methods.
This can be confirmed when the specified requirements for each examination procedure relate to the intended use of that examination are met. The validated examination procedures used without modification is subjected to verification by the laboratory before being in routine use.
The manufacturer claim is confirmed, the laboratory documents the procedures used for verification and records the results obtained and the staff with the appropriate authority reviews the result and records the review. The laboratory shall develop a procedure for verification /validation of examination methods following reliable guidelines.
Verification of performance characteristics of the test procedure includes at least the following:

a) Measurement of trueness
b) Measurement of precision
c) Measurement of linearity (detection and quantification limits)

The laboratory shall validate the examination procedures when:

I) using non-standard method
II) Standard method used outside its intended scope.
III) Modification in a validated method.

The laboratory shall follow verification/validation methods endorsed by reliable and guidelines. When changes are made to a verified/ validated examination procedure, a new verification/validation shall be carried out and documented.

Survey process guide:

- GAHAR surveyor may review laboratory procedure during document review session and check the references used.
- GAHAR surveyor may interview staff members to assess their awareness of laboratory procedure, in addition to their competence and knowledge of the introduced or changed tests.
- GAHAR surveyor may review verification/validation records for each test method.

Evidence of compliance:

1. The laboratory has an approved procedure that describe the process for verification /validation of examination methods for all laboratory tests.
2. The authorized staff is aware about the verification/validation process.
3. The laboratory follows verification/validation methods endorsed by guidelines.
4. Records of verification and/or validation results fulfill acceptable criteria based on predetermined guidelines.

Related standards:
LEP.05 Examination procedure, IMT.01 Documentation management system.

LEP.04 The laboratory defines and verifies biological reference intervals and defines clinical decision values for examination methods.

Efficiency

Keywords:

Biological reference interval and clinical decision values.

Intent:

Reference intervals are the most common decision support tool used for clinical interpretation of test results. As laboratory results may be interpreted by comparison with these intervals, the quality of the reference intervals plays as large a role in result interpretation as the quality of the result itself.

The laboratory shall define the biological reference intervals or clinical decision values, determine the source of the reference intervals or decision values, and communicate this information to users. The biological reference intervals are verified according to a reliable guideline. When the laboratory changes any element in the testing process, the laboratory reviews associated reference intervals and clinical decision values.

Survey process guide:

- GAHAR surveyor may review the biological reference interval of each test in the laboratory information system (LIS) or the client final report as well as verification records of biological reference intervals and the guideline used.
- GAHAR surveyor may review the biological reference intervals and clinical decision values in clients' reports to check that they are in accordance with that in the examination procedures.

Evidence of compliance:

1. Biological reference intervals and clinical decision values are defined by the laboratory.
2. Biological reference intervals and clinical decision values have a reliable and accepted references or guidelines (in accordance with the related examination procedures when applicable).
3. Biological reference intervals and clinical decision values in examination procedures are in accordance with that in the clients' reports.
4. Biological reference intervals and clinical decision values are reviewed at least annually.

Related standards:

LPO.01 Reporting results, LEP.05 Examination procedure, LEP.03 Verification / validation.

properly Implement the examination procedures.

LEP.05 Instructions for performing test methods and procedures are documented and followed.

Effectiveness

Keywords:

Examination procedure.

Intent:

A documented examination procedure provides a foundation for the laboratory's quality assurance program, it provides essential information for both new and experienced employees on how to perform all examination procedures to ensure consistency while striving for quality.
The laboratory has technical procedures for all examination test methods. The laboratory technical procedures are written in a language commonly understood by the working staff and available in appropriate location. It could be paper based, electronic or web-based format.
The Laboratory technical procedures are consistently followed and regularly reviewed. They shall include at least the following:

a) Principle and clinical significance of the test.
b) Requirements for client preparation and specimen type, collection and storage, Criteria for acceptability and rejection of the sample.
c) Reagents and equipment used.
d) Method performance criteria.
e) Test procedure including test calculations and interpretation of results.
f) Calibration and control procedures.
g) Biological reference intervals/clinical decision values.
h) Critical test results.
i) Analytical measurement range and instructions for determining results when it is not within the measurement interval.
j) Limitations in methodologies including interfering substances.
k) References.

Survey process guide:

- GAHAR surveyor may review the documented laboratory technical procedures and check their availability to staff.
- GAHAR surveyor may observe the staff using the updated technical procedures.
- GAHAR surveyor may interview laboratory staff members to check their awareness of analytic procedures.

Evidence of compliance:

1. The laboratory has a documented and implemented examination procedure for each analytical test method.
2. Responsible laboratory staff is aware of the laboratory examination procedures.
3. Each procedure includes all the required elements mentioned in the intent from a) to k).
4. The laboratory examination procedures are readily available when needed.
5. The laboratory examination procedures are reviewed at least annually by the authorized personnel.

Related standards:

LPR.03 Client preparation assessment, LPR.07 Pre-examination specimen storage, LPR.04 Specimen identification and collection, LEP.04 Biological reference interval and clinical decision values, LQC.01 Laboratory internal quality control, LPO.05 Critical test result, EMS.03 Calibration plan.

Laboratory Quality Control of Examination Procedures

Chapter intent:

The goal of quality control (QC) is to evaluate, detect, and correct errors. These errors may be due to test system failure, adverse environmental conditions, or operator performance. QC gives the laboratory confidence that test results are accurate and reliable before client results are reported.

The laboratory ensures the quality of examinations by performing them under defined conditions.

Quality control processes vary, depending on whether the laboratory examinations use methods that produce quantitative, qualitative or semiquantitative results.

Quantitative examinations measure the quantity of an analyte present in the sample, and measurements need to be accurate and precise.

Qualitative examinations are those that measure the presence or absence of a substance, or evaluate cellular characteristics such as morphology. The results are not expressed in numerical terms, but in qualitative terms such as “positive” or “negative”; “reactive” or “nonreactive”; “normal” or “abnormal”; and “growth” or “no growth”, e.g., haematological and histo-pathological examination.

Semi-quantitative examinations are similar to qualitative examinations, in that the results are not expressed in quantitative terms. The difference is that results of these tests are expressed as an estimate of how much of the measured substance is present, which is often represented numerically in a semi quantitative manner, e.g., in immune-histo-chemical staining.

Chapter Purpose:

1. To ensure safety and effectiveness of laboratory internal quality control (QC) system.
2. To identify quality control result violations and implement appropriate corrective and preventive actions
3. To highlight the role of external quality programs and proficiency testing in ensuring quality standards.
4. To determine alternative assessment procedure(s)/methods and instruments comparison

LQC Summary of Changes

GAHAR Clinical Lab 2025	***GAHAR Clinical Lab 2021***	***Details of changes***
LQC.01 **KW:** Laboratory internal quality control.	**TEQ.01** **KW:** Internal quality control plan	- **Modified Standard statement**: (An internal quality control process is developed and implemented for all laboratory tests**)** - **Rephrasing of** EOC**: (EOC.05:** Internal QC records are retained for all laboratory tests for at least one year). - **Modified** EOCs**:** • **(EOC.01:** The laboratory has an approved procedure that describe the internal QC process of all laboratory tests fulfilling items mentioned in the intent from a) to e). • **(EOC.03:** Responsible authorized laboratory personnel are competent in performing and monitoring internal QC). - **Add new EOC: (EOC.04:** All quality control processes are performed according to the internal quality control procedure**).**
LQC.02 **KW:** Quality control data review.	**TEQ.02** **KW**: Quality control data review.	- **Modified** EOC**:(EOC.01:** The laboratory has approved procedures that describe the process for reviewing the internal quality control data). - **Rephrasing of** EOC**: (EOC.02:** Authorized personnel reviews internal quality control process and checks data at regular intervals). - **Add new EOC:(EOC.04:** Evaluation of the effectiveness of the actions taken).
LQC.03 **KW:** Quality control result violation, Corrective / preventive action.	**TEQ.03** **KW**: Quality control result violation, Corrective action.	- **Modified Standard statement**: (Corrective / preventive actions are taken upon quality control result violation(s). - **Modified EOCs:** • **(EOC.01:** The laboratory has approved procedures that describe the process for taking proper corrective /

GAHAR Clinical Lab 2025	***GAHAR Clinical Lab 2021***	***Details of changes***
		preventive actions to deficiencies identified). • **(EOC.02:** The laboratory staff is aware of the corrective / preventive action for deficiencies identified. • **(EOC.03:** The laboratory's corrective / preventive actions include elements mentioned in intent from a) through e). • **(EOC.04:** Quality control data and error/incident logs are reviewed to identify the corrective / preventive actions to be taken).
LQC.04 **KW:** External quality program, proficiency testing (PT).	**TEQ.04** **KW:** External quality program, proficiency testing. .	- **Modified EOC: (EOC.02:** The laboratory participates in a PT program following the criteria mentioned in the intent from I) to V).
LQC.05 **KW:** Proficiency testing samples.	**TEQ.05** **KW:** Proficiency testing samples.	- **Modified** EOC: (**EOC.01:** The laboratory has **approved procedures** that describe the process of proficiency testing requirements includes elements mentioned in intent from a) through e). - **Add new EOC: (EOC.04:** Records of PT results are retained either as hard or soft copy).
LQC.06 **KW:** Alternative assessment procedure (AAPs).	**TEQ.06** **KW:** Alternative assessment procedure.	- **Modified** EOCs**:** • **(EOC.01:** The laboratory has an approved procedure that identify the method and the frequency of testing of AAPs includes elements mentioned in intent from a) to c). • **(EOC.04:** Records of AAPs results and corrective / preventive actions are reviewed by authorized person and retained for at least 1 year.
LQC.07 **KW:** Method Comparison.	**TEQ.07** **KW:** Method Comparison.	**No change**

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

Laboratory internal quality control system

LQC.01 An internal quality control process is developed and implemented for all laboratory tests.

Safety

Keywords:
Laboratory internal quality control.

Intent:
Quality control (QC) testing is performed to ensure the proper functioning of materials, equipment, and methods during operations. Internal quality control testing is performed within a laboratory to monitor and ensure the reliability of test results produced by the laboratory.
Control materials are used to monitor the test procedure and verify that quality of client test results have been attained. A quality control material is a stabilized sample with a predetermined range of result values that simulates a client sample. The laboratory develops a procedure to describe the internal QC process which include at least the following:

a) The frequency for QC testing is determined by the laboratory in accordance with guidelines and manufacturer instructions whichever is more appropriate.
b) Quality control materials to be used are defined, handled and tested in the same manner and by the same laboratory personnel testing client samples.
c) QC performance expectations and acceptable ranges and rules should be defined and readily available to staff so that they will recognize unacceptable results and trends in order to respond appropriately.
d) The QC results are approved by the authorized personnel prior to specimen testing.
e) The internal QC procedure complies at least with the following items:
    i. Quantitative testing includes quality control at different levels and frequency according to the manufacturer and guidelines.
    ii. Qualitative testing includes positive and negative controls.
    iii. Semi-quantitative testing with graded or tittered results includes a control material of graded or tittered reactivity.

Survey process guide:

- GAHAR surveyor may review laboratory procedure and records of internal QC.
- GAHAR surveyor may observe laboratory internal quality control procedures.
- GAHAR surveyor may interview laboratory staff members to check their awareness about quality control performance and guidelines.

Evidence of compliance:

1. The laboratory has an approved procedure that describe the internal QC process of all laboratory tests fulfilling items mentioned in the intent from a) to e).
2. Internal QC for all laboratory tests includes at least the items mentioned in the intent from i) to iii).
3. Responsible authorized laboratory personnel are competent in performing and monitoring internal QC.
4. All quality control processes are performed according to the internal quality control procedure.
5. Internal QC records are retained for all laboratory tests for at least one year.

Related standards:

LQC.02 Quality control data review, QPI.04 Internal assessment and nonconformity management, WFM.09 Competency assessment, IMT.02 Record management system.

LQC.02 Internal quality control data are reviewed at regular interval.

Effectiveness

Keywords:

Quality control data review.

Intent:

Internal quality control is designed to detect, reduce, and correct deficiencies in a laboratory's internal analytical process prior to the release of client results.

Reviewing of the quality control data is of utmost importance as it is able to find and correct trends in the analytical processes of a laboratory before potentially incorrect client results are released. The laboratory shall have procedures for reviewing the internal quality control data. Quality control data is reviewed at regular intervals and must be documented and include follow-up for outliers or trends in examination performance that may indicate problems in the examination system. When such trends are noted, preventive actions are taken and recorded before major problems arise.

Survey process guide:

- GAHAR surveyor may review procedures that describe the process for reviewing the internal quality control data.
- GAHAR surveyor may review records as well as documented regular review of the internal quality control data.
- GAHAR surveyor may review and check the action taken for trends or outliers.

Evidence of compliance:

1. The laboratory has approved procedures that describe the process for reviewing the internal quality control data.
2. Authorized personnel reviews internal quality control process and checks data at regular intervals.
3. Preventive and corrective actions are taken whenever indicated.
4. Evaluation of the effectiveness of the actions taken.

Related standards:

LQC.01 Laboratory internal quality control, QPI.04 Internal assessment and nonconformity management, WFM.05 Verifying credentials, clinical privilege.

Identify Quality control result violations and implement appropriate corrective / preventive actions.

LQC.03 Corrective / preventive actions are taken upon quality control result violation(s).

Safety

Keywords:
Quality control result violation, Corrective / preventive action.

Intent:
Quality control (QC) is of utmost importance in laboratory testing, it ensures both precision and accuracy of client sample results. The laboratory may follow corrective action for rejection rules and preventive action for warning rules based on laboratory procedures. The laboratory should have procedures that include instructions to follow when control results are violating acceptable criteria and define backup systems when timely correction cannot be made. The laboratory's corrective / preventive actions shall meet the following criteria:

a) Taken immediately after problem has been identified.
b) Consistent with defined quality control procedure.
c) Support timely response to inspections or off-site consultation.
d) Adequate to correct all the deficiencies implicated in the problem (for example, if one client's results are discovered to be incorrect, other clients' results from the same testing sequence are evaluated to ensure correctness).
e) Includes a process to review the adequacy of actions taken.

When the quality control rules are violated and the examination results are likely to contain clinically significant errors, the results are halted by authorized staff and relevant client samples are re-examined after the error condition has been corrected and the performance is verified. In case the checked client specimens revealed unacceptable deviation, The laboratory should evaluate the results from client specimen that were examined after the last successful quality control event.

Survey process guide:

- GAHAR surveyor may review internal quality control records to check for appropriate corrective / preventive actions taken to deficiencies identified.
- GAHAR surveyor may interview responsible laboratory staff to assess their awareness of corrective / preventive actions for deficiencies identified.
- GAHAR surveyor may check client results examined after the last successful quality control event.

Evidence of compliance:

1. The laboratory has approved procedures that describe the process for taking proper corrective / preventive actions to deficiencies identified.
2. The laboratory staff is aware of the corrective / preventive action for deficiencies identified.
3. The laboratory's corrective / preventive actions include elements mentioned in intent from a) through e).
4. Quality control data and error/incident logs are reviewed to identify the corrective / preventive actions to be taken.

Related standards:
QPI.04 Internal assessment and nonconformity management, LQC.02 Quality control data review.

External quality programs and proficiency testing in ensuring quality standards

LQC.04 The laboratory participates in an external quality assessment program.

Safety

Keywords:

External quality program, proficiency testing (PT).

Intent:

External quality assessment program (Proficiency Testing, PT) is a system designed to objectively assess the quality of results obtained by laboratories. PT programs should be accredited or certified by recognized authority. Using proficiency testing (PT) is an objective way to assess the accuracy of testing unknown samples. It can identify performance problems not identified by internal quality control systems. It obtains consensus values when true values are unknown and it acts as an educational tool and used for performance improvement. External quality testing helps the laboratory determines how its results are compared with those of other laboratories that use the same methodologies. The laboratory shall participate in acceptable PT programs according to availability for all non-waived tests to validate ongoing performance. Selection of PT Program shall fulfil the following criteria:

a) Proficiency testing programs are accredited or certified by recognized authority.
b) The analyte in the PT program is comparable to the analyte being monitored.
c) The program has adequate participants to warrant sound statistics with maximal confidence and thus minimal uncertainty, an adequate relevant peer group (including 9 or more labs) is always preferred to an all-method comparison group.
d) Suitability of the PT materials for the intended use.
e) The frequency at which the PT program is operated.
f) The availability of details about the program (procedures for establishment of assigned values, procedures for statistical treatment of data, criteria for defining peer groups, criteria for accepting results, clear schedule of cycles starting dates, clear agreement on PT materials delivery dates and finally clear PT provider manual regarding amending and late results.

The criteria for participation of a laboratory in a PT program include at least the following:

I) 50% of laboratory scope of tests in each laboratory discipline (e.g., chemistry, hematology, bacteriology, molecular etc.).
II) These 50% must include both high frequency tests in the laboratory (the laboratory shall provide evidence of the high frequency) and the high risk or critical tests (e.g. cardiac markers, blood gases etc.)
III) The participation shall cover at least 75% of the tests in each discipline by the end of the accreditation cycle.
IV) If the laboratory has more than one testing site, PT enrolment and participation is required for non-waived tests.
V) For Anatomic Pathology laboratories, PT test covering both preparation and interpretation are required for each test.

The laboratory tests proficiency specimens according to a written protocol and submits results back to the proficiency testing provider within the required time period.

The laboratory must provide PT satisfactory performance (attain a satisfactory score for an analyte) in 70% of program samples.

PT records are reviewed, approved by laboratory management and retained for at least one full cycle. Review of PT results shall include the following:

i) Corrective / preventive action and root cause analysis are documented for any single or multiple challenge(s) of each analyte that does not fall within acceptable limits.
ii) When PT results exceed acceptable performance limits or demonstrate trends, laboratories are required to investigate, determine root cause, consider impact on client results and take corrective / preventive action. The laboratory must provide evidence that an alternate assessment (AAP) was conducted to ensure accuracy during the time frame when two consecutive unacceptable results (results greater than ±3.0 SDI) for an analyte in PT programs provide 12 samples/year or one unacceptable result in an analyte in PT programs provide 4-5 samples/year or less "Unacceptable results" fall outside the evaluation criteria, as defined by the PT provider).
iii) Other problems or potential problems identified during the review are documented, along with corrective / preventive actions.
iv) The laboratory should discontinue testing of any analyte when the laboratory has one or more of the following:
    - Has confirmed a clinically significant impact on client results
    - Cannot verify the accuracy and reliability of test results
    - Cannot determine the cause of significant or ongoing PT failure.
    - The results are used for education, re-education, or training of one or more employees, when indicated.

Survey process guide:

- GAHAR surveyor may review records of participation in an external quality assessment program for at least one full cycle including the documented reviewing of laboratory director.
- GAHAR surveyor may review the analysis records that evaluate unacceptable results and the related corrective / preventive actions taken.
- GAHAR surveyor may interview responsible laboratory staff to assess their awareness about the external quality assessment.

Evidence of compliance:

1. The laboratory participates in an acceptable external quality assessment proficiency testing program according to the criteria mentioned in the intent from a) to f).
2. The laboratory participates in a PT program following the criteria mentioned in the intent from I) to V).
3. The laboratory reports the PT results within the required timeframe and according to the provider's instructions.
4. The laboratory provides PT satisfactory performance in 70% of program samples.
5. A review of PT reports includes the requirements mentioned in intent from i) to iv).
6. Records of all PT processes are retained for at least one full cycle.

Related standards:

LQC.05 proficiency testing samples, LQC.06 Alternative assessment procedure (AAPs), IMT.02 Record management system.

LQC.05 Proficiency testing specimens are integrated within the routine laboratory workflow.

Effectiveness

Keyword:

Proficiency testing samples.

Intent:

Proficiency testing specimens should be tested as same as clients' specimens to represent clients' results quality. The procedure of proficiency testing specimen should meet the following requirements:

a) Samples are tested along with the laboratory's regular client testing workload by personnel who routinely perform the laboratory test(s) using routine methods.
b) Laboratory personnel test the proficiency specimens the same number of times that they routinely test client samples.
c) Communication between participating laboratories about the results of proficiency testing samples should occur only after the date by which the laboratory is required to report them to the provider.
d) The laboratory does not send specimens to another laboratory for analysis.
e) For automated tests the laboratory must retain the print out of PT specimen result. This should be readily available for review either as hard copy or stored in the instrument.

Survey process guide:

- GAHAR surveyor may review the procedure of proficiency testing requirements.
- GAHAR surveyor may review print-out records of proficiency testing results to ensure that they are tested as same as client specimen.
- GAHAR surveyor may interview the responsible laboratory staff to assess their awareness of the proficiency specimen testing requirement.

Evidence of compliance

1. The laboratory has approved procedures that describe the process of proficiency testing requirements includes elements mentioned in intent from a) through e).
2. Laboratory staff is aware of the proficiency specimen testing requirement.
3. Records of proficiency specimen testing support implementation.
4. Records of PT results are retained either as hard or soft copy.

Related standards:

LQC.04 External quality program, proficiency testing, LQC.06 Alternative assessment procedure (AAPs), IMT.02 Record management system.

Alternative assessment procedure(s)/Methods and instruments comparison

LQC.06 Alternative assessment procedure(s) (AAPs) are performed for tests that are not included in the external quality assessment program.

Safety

Keywords:
Alternative assessment procedure (AAPs).

Intent:
The laboratory performs an alternative assessment procedure to ensure the reliability of the analytical testing process. For tests not included in the formal external quality assessment program, the laboratory shall include them in a procedure identifying the method and the frequency of testing.
The laboratory should identify and apply AAP for the following:

a) Tests for which PT is not available.
b) Tests for which PT is available but are not yet included in the laboratory PT program.
c) Tests that show unacceptable PT results.

The (AAPs) procedures shall be selected and performed according to guidelines.
The laboratory should define the limits of acceptability for each quantitative assessment procedure in advance, before performing the procedure. Laboratories may develop limits of acceptability from total allowable error, internal QC data (eg, ± 2 or 3 standard deviations [SD] from the mean), or lab uncertainty limits provided that sufficient QC data exist.
Evidence-based results of AAPs should be reviewed by the director or an appropriate supervisor (e.g. raw data from equipment etc.….), and when results are outside acceptable limits, corrective / preventive actions are taken and documented. The results of AAPs are documented and retained by the laboratory for at least one year.

Survey process guide:

- GAHAR surveyor may review procedure of the alternative assessment testing (AAPs) for each test with no available PT and check records of AAPs performed to ensure that they comply with the procedure requirement
- GAHAR surveyor may interview authorized laboratory staff to assess their knowledge about the alternative assessment procedures (AAPs).

Evidence of compliance:

1. The laboratory has an approved procedure that identify the method and the frequency of testing of AAPs includes elements mentioned in intent from a) to c).
2. The laboratory staff is aware of the alternative assessment procedure(s).
3. The laboratory develops and documents the alternative assessment procedures including the limits of acceptability for each quantitative assessment.
4. Records of AAPs results and corrective / preventive actions are reviewed by authorized person and retained for at least 1 year.

Related standards
LQC.04 External quality program, proficiency testing, LQC.05 proficiency testing samples, IMT.02 Record management system, WFM.05 Verifying credentials, clinical privilege.

LQC.07 Methods and instruments comparison are performed when more than one method and/or instrument is used to test a given analyte.

Effectiveness

Keywords:

Method Comparison.

Intent:

The results of methods / instruments comparison determine the quality of the results and validity of the conclusions to prevent misinterpretation of the results. The laboratory uses a procedure to evaluate and correlate the relationship between results for the same test performed with different methodologies, instruments or at different sites following guidelines.

The laboratory shall take actions in case of deviation from acceptable criteria. The laboratory method comparison procedure shall include:

a) The instructions for method/instrument comparison following guidelines.
b) If the laboratory performs the same test using two or more identical analyzers, verification and comparability studies shall be done between the equipment along with acceptable AAPs according to guideline.
c) If the laboratory performs the same test using two different analyzers, Comparability studies shall be done during verification or when needed.

Survey process guide:

- GAHAR surveyor may review the procedures and records of comparison of testing methodologies or instruments used to perform the same test.

Evidence of compliance:

1. The laboratory has an approved procedure that describe the process for comparison of different methods /instruments includes elements mentioned in intent from a) to c).
2. The laboratory implements procedures for comparability between instruments/methods and defines actions to be taken in case comparability is not achieved.
3. Records of correlation between testing methodologies or instruments comparability are retained.

Related standards:

LQC.06 Alternative assessment procedure (AAPs), IMT.02 Record management system.

Laboratory Post-Examination process

Chapter intent:

Post-examination key processes in the path of workflow include activities related to reporting results and archiving results and specimen material.

The overall purpose of all post examination activities is to ensure that the results of examinations are presented accurately and clearly, and that they reach the user in a timely and secure manner. In addition to the accurate reporting of laboratory results, the laboratory has an additional responsibility to ensure that, as far as possible, the examinations are correctly interpreted and applied in the client's best interest. Specialist advice regarding the selection and interpretation of examinations is part of the laboratory service.

A recent review of errors in laboratory medicine concluded that in the delivery of laboratory testing, mistakes occur more frequently after the test has been performed.

In a modern approach to total quality, that is centered on clients' needs and satisfaction, the risk of errors and mistakes in post-examination steps must be minimized in order to guarantee total quality to laboratory services.

Chapter purpose:

This chapter addresses quality measures for the activities from reporting client test results to archiving results and specimens including the following:

1. Ensuring safe, accurate client results' reporting.
2. Proper specimen's storage, retention and disposal
3. Ensuring appropriate turnaround time for each laboratory test.
4. Accurate identification of critical test results
5. Process of amended laboratory reports.

LPO Summary of Changes

GAHAR Clinical Lab 2025	***GAHAR Clinical Lab 2021***	***Details of changes***
LPO.01 **KW:** Reporting results.	**TPO.01** **KW:** Reporting patient results.	- **Modified Standard statement**: (The laboratory ensures accurate reporting). - **Modified** EOC**:(EOC.01:** The laboratory has approved procedures that describes the process of test results reporting as mentioned in intent from a) to d). - **Rephrasing of EOC: (EOC.05:** The laboratory reports including those from referral laboratories are reviewed to include elements mentioned in intent from i) through xiii). - **Add new EOCs:** • **(EOC.02:** Authorized staff is aware about the content of the report). • **(EOC.03:** List of staff authorized to review the reports is available.
LPO.02 **KW:** Reviewing, release and retention of the reported result	**TPO.02** **KW:** Reviewing, release and retention of the reported result.	- **Rephrasing of Standard statement**: (The laboratory has a process for reviewing, releasing and retaining client results.) - **Modified EOCs:** • **(EOC.01:** The laboratory has approved procedures that describe the process of reviewing, releasing, and retaining the reported results that includes elements mentioned in intent from a) to f). • **(EOC.03:** The retention process of a final laboratory report is implemented with easy retrieval). - **Rephrasing of EOC: (EOC.04:** Test results are released to the authorized recipient).
LPO.03 **KW:** Storage, Retention and Disposal of specimen.	**TPO.03** **KW**: Storage, Retention and Disposal of specimen.	- **Rephrasing of Standard statement**: (The laboratory ensures safe storage, retention and disposal of post-examination specimens). - **Modified EOCs:** • **(EOC.01:** The laboratory has an approved procedure that describe the process for proper specimen storage and retention

GAHAR Clinical Lab 2025	***GAHAR Clinical Lab 2021***	***Details of changes***
		includes elements mentioned in intent from a) to f) • **(EOC.02:** Staff is aware of specimens' storage, retention and disposal time). • **(EOC.03:** The procedure of specimen storage, retention, and disposal is implemented. - **Add new** EOC**: (EOC.04:** Required specimens are easily retrieved.)
LPO.04 **KW:** Turnaround time.	**TPO.04** **KW:** Turnaround time.	- **Rephrasing of Standard Statement**: (Laboratory results are reported within the acceptable turnaround time.) - **Modified EOCs:** • **(EOC.01:** The laboratory has an approved procedure defining each laboratory test's total turnaround time and means of measuring it). • **(EOC.02:** The laboratory monitors the reported data on reporting times for laboratory tests and takes actions to control or improve the process as appropriate). • **(EOC.03:** Delays in turnaround time are notified to requestors/end-user)
LPO.05 **KW:** Critical test result.	**TPO.05** **KW:** Critical test result.	- **Modified Standard Statement**: (Critical results are communicated in time and documented according to a defined process). - **Modified EOCs:** • **(EOC.01:** The laboratory has an approved procedure of the critical test results reporting that describe the process of "write down "and «read-back» by the recipient). • **(EOC.03:** The laboratory defines lists of critical values for specific tests). • **(EOC.04:** All critical results are recorded within a predefined timeframe, includes

GAHAR Clinical Lab 2025	***GAHAR Clinical Lab 2021***	***Details of changes***
		elements mentioned in intent from a) through h). - **Add new EOC: (EOC.05:** The laboratory monitors the reported data on critical results and takes actions to control or improve the process as appropriate).
LPO.06 **KW:** STAT results	**TPO.06** **KW: STAT results.**	- **Modified EOCs:** • **(EOC.01:** The laboratory has an approved procedure describing STAT testing process.) • **(EOC.04:** The laboratory monitors the reported data on STAT turnaround time and takes actions to control or improve the process as appropriate).
LPO.07 **KW:** Amended / discrepant laboratory reports.	**TPO.07** **KW:** Amended laboratory results.	- **Modified Standard Statement**: (Amended / discrepant laboratory reports are identified and maintained). - **Modified EOCs:** • **(EOC.01:** The laboratory has an approved process for amended / discrepant reports. • **(EOC.02:** Laboratory staff is aware and trained about process of amended / discrepant reports. • **(EOC.06:** Amended / discrepant reports are modified by authorized personnel. - **Add new EOCs:** • **(EOC.03:** Amended report is identified and includes elements mentioned in intent from a) through e). • **(EOC.04:** Discrepant report is identified and includes elements mentioned in intent from I) through V). **(EOC.05:** Amended / discrepant reports is reported to the authorized individual and proper actions are taken accordingly).

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

Ensuring Safe, accurate client results reporting

LPO.01 The laboratory ensures accurate reporting.

Safety

Keywords:

Reporting results.

Intent**:**

The physicians take medical decisions based on laboratory test reports in order to provide timely and effective client care.

Laboratory recommendation and advisory comments for further investigations may be added to the final report based on testing algorithms (reflex testing). The laboratory should develop procedures for reporting client results accurately, clearly, and unambiguously, in accordance with any specific instructions outlined in the examination procedures. To ensure clarity in reporting, if an abbreviation is not commonly used or widely recognized, the laboratory shall provide the full term beside the abbreviation. The procedures shall include at least the following:

a) Identifying the person(s) who performed the test (totally or partly), as well as the individual who reviewed and approved results.
b) The laboratory defines and implements the format and the essential data of the laboratory report which includes at least the following:
    i. The identity of the laboratory that performed the test
    ii. Client identification (by two unique identifiers of the client and the specimen), age and gender.
    iii. The tests performed.
    iv. Identification of the ordering clinician when available.
    v. Date and time of specimen collection and the source of specimen (in special types of tests).
    vi. Reporting date and time.
    vii. Test results, reference interval or clinical decision value for the tests performed.
    viii. Identification of the authorized individual who verified the report results.
    ix. Interpretation of results, where appropriate.
    x. Advisory, explanatory comment or limitation of the method when needed.
    xi. When needed, conditions of specimen that may compromise the adequacy of testing.
    xii. A comment should accompany any results noting any suboptimal specimen characteristics.
    xiii. For any special procedure (molecular biology, cytogenetics, protein and Hb electrophoresis tests… etc.), the report includes the essential or required information needed for proper interpretation of results (testing methodology used, limitations of the method, any interpretation of findings (either fixed statement or changeable according to the case, any recommendations for additional testing.)
c) Referral laboratory reports include the above-mentioned elements.
d) Referral laboratory reports are not modified in any way that would change their meaning.

Survey process guide:

- GAHAR surveyor may review sample of paper or electronic laboratory reports, and contract laboratories reports to check their content.

- GAHAR surveyor may review result report of referral laboratory to ensure that its content is not modified.
- GAHAR surveyor may interview authorized staff members to assess their awareness of laboratory procedure.

Evidence of compliance

1. The laboratory has approved procedures that describes the process of test results reporting as mentioned in intent from a) to d).
2. Authorized staff is aware about the content of the report.
3. List of staff authorized to review the reports is available.
4. There is a mean of identifying the individual(s) who performed a particular test.
5. The laboratory reports including those from referral laboratories are reviewed to include elements mentioned in intent from i) through xiii).

Related standard:

LPO.02 Reviewing, release and retention of the reported result, SCM.06 Referral laboratory, WFM.05 Verifying credentials, clinical privilege, LEP.04 Biological reference interval and clinical decision values, IMT.01 Documentation management system,, IMT.05 LIS validation, IMT.03 LIS management.

LPO.02 The laboratory has a process for reviewing, releasing and retaining client results.

Effectiveness

Keywords:

Reviewing, release and retention of the reported result.

Intent:

Health outcomes depend on the accuracy of the testing and reporting of laboratory test results. Inaccurate results lead to a significant consequences as unnecessary treatment, failure to provide the proper treatment, treatment complications, delay in correct diagnosis, additional and unnecessary diagnostic testing.

The laboratory has certainly a role and a responsibility in reviewing the test result to provide the clinicians with accurate information that will support decision on the subsequent data. The laboratory has a written, implemented procedure to ensure that client data are only accessible to those individuals who are authorized to review and release test results.

The procedure addresses at least the following:

a) Instructions for reporting results by any mean used by the laboratory (electronic transfer of data from an instrument or analyzer into a computer system, manual entry of data into a computer system or manually on paper report forms).
b) Authorized, qualified personnel review, verify and interpret the client results.
c) Confidentiality of the released test results.
d) Released test result to authorized recipients (the requesters or their agents …etc.), in particular for special tests (e.g. semen, certain genetic or infectious disease examinations).
e) Instructions for electronic and/or paper archiving of reported result in a manner that prevents loss, damage, unauthorized access and promotes easy retrieval.
f) The defined retention time of laboratory results according to laws and regulations, guidelines for best practice and organizational needs.

Survey process guide:

- GAHAR surveyor may review laboratory procedure for reviewing, release, and retention of the reported results.
- GAHAR surveyor may interview staff members to inquire about their awareness of laboratory procedure.
- GAHAR surveyor may review the archived test results to ensure the period of retention as defined by laboratory.
- GAHAR surveyor may interview the responsible laboratory staff to inquire about their experience regarding laboratory reviewing and releasing of test results.

Evidence of compliance:

1. The laboratory has approved procedures that describe the process of reviewing, releasing, and retaining the reported results that includes elements mentioned in intent from a) to f).
2. Clients' reports are reviewed, interpreted, and released by defined authorized personnel.
3. The retention process of a final laboratory report is implemented with easy retrieval.
4. Test results are released to the authorized recipient.

Related standard:

LPO.01 Reporting results, IMT.10 Data storage and retrieval, IMT.05 LIS validation, IMT.03 LIS management.

Proper specimen's storage, retention and disposal

LPO.03 The laboratory ensures safe storage, retention and disposal of post-examination specimens.

Safety

Keywords:

Storage, Retention and Disposal of specimen.

Intent**:**

Additional testing on retained specimens is often necessary and is beneficial to both the client and the clinician since it results in a reduction of turnaround times and client inconveniences resulting from recollection.

Disposal of retained specimens shall be done according to national and international guidelines to ensure safe and clean working environment.

The laboratory develops and implements procedure that includes requirements for specimen storage after testing, describe how samples should be stored or retained and the step-by-step instructions for archiving materials such as compatibility testing specimens, hematology slides, cytology and histology tissue blocks and slides.

The procedure defines at least the following:

a) The appropriate storage conditions for each type of specimen that prevent specimen deterioration or contamination.
b) The location of specimen storage.
c) The defined retention time of client samples according to laws and regulations, guidelines for best practice and organizational needs.
d) The safe disposal of clinical specimens.

e) Tracking process for all specimens received is clearly defined for easy retrieval of required specimens.
f) Time limits for requesting additional examinations or further examinations on the same primary specimen.

Survey process guide:

- GAHAR surveyor may review laboratory procedure of storage, retention, and disposal of specimen.
- GAHAR surveyor may interview staff members to assess their awareness of laboratory procedure.
- GAHAR surveyor may observe the storage conditions of the specimen and its fulfilment to laboratory procedure.
- GAHAR surveyor may observe laboratory specimen disposal and retrieval.

Evidence of compliance:

1. The laboratory has an approved procedure that describe the process for proper specimen storage and retention includes elements mentioned in intent from a) to f).
2. Staff is aware of specimens' storage, retention and disposal time.
3. The procedure of specimen storage, retention, and disposal is implemented.
4. Required specimens are easily retrieved.

Related standard:

LPR.03 Specimen identification and collection, LPR.07 Pre-examination specimen storage.

Ensuring appropriate turnaround time for each laboratory test

LPO.04 Laboratory results are reported within the acceptable turnaround time.

Effectiveness

Keywords:

Turnaround time.

Intent:

Turnaround time (TAT) is a period of time required for completing a particular process. Turnaround time is one of the most noticeable signs of the quality of the provided laboratory services and is often used to measure the overall performance of the laboratory.
The clinician requires a prompt service based on rapid turnaround of test results. The laboratory develops and implements procedure for defining and monitoring the turnaround time for each laboratory test. The laboratory has a process for measuring turnaround times and assigns some responsible laboratory personnel for measuring and monitoring TAT. The process includes means to ensure that turnaround times are acceptable. The laboratory shall have an implemented process for notifying the requester when testing is delayed.

Survey process guide:

- GAHAR surveyor may review laboratory procedure defining each laboratory test's total turnaround time.

- GAHAR surveyor may interview staff members to inquire about their awareness of laboratory procedure and their experience regarding laboratory service reporting time.
- GAHAR surveyor may review the process and records of notification of delays in turnaround time.
- GAHAR surveyor may review monitoring data reports on reporting time for laboratory tests.

Evidence of compliance:

1. The laboratory has an approved procedure defining each laboratory test's total turnaround time and means of measuring it.
2. The laboratory monitors the reported data on reporting times for laboratory tests and takes actions to control or improve the process as appropriate.
3. Delays in turnaround time are notified to requestors/end-user.

Related standard:

LEP.05 Examination procedure, QPI.07 Sustained improvement activities, LPO.06 STAT results, QPI.03 Performance measures.

Accurate identification of critical test results

LPO.05 GSR.02 Critical results are communicated in time and documented according to a defined process.

Safety

Keywords:

Critical test result.

Intent:

Critical laboratory results have been identified as a potentially dangerous or life-threatening state in which immediate medical action is necessary.
A delay in reporting to the clinicians may result in a serious adverse outcome to the client. The laboratory shall define Lists of critical values for specific tests.
The laboratory develops a procedure to guide the process of identifying and reporting critical results. The process includes instructions for immediate notification of the authorized individual responsible for the client with results that exceed the critical intervals.
The laboratory documents the notification, including the following:

a) The means of notification
b) Date and time of notification
c) Identification of the notifying responsible laboratory staff member,
d) Identification of the notified person.
e) Description of the sequence of conveying the result.
f) Examination results conveyed.
g) Any difficulties encountered in notifications.
h) The individual notified should write down and read back the result to ensure that it has been understood accurately.

Survey process guide:

- GAHAR surveyor may review laboratory procedure of reporting critical test results and lists of critical values.
- GAHAR surveyor may interview staff members to inquire about their awareness of laboratory critical test results reporting procedure.
- GAHAR surveyor may review previous critical client results and assess laboratory result reporting time.
- GAHAR surveyor may review monitoring report on laboratory results reporting time.
- GAHAR surveyor may interview laboratory staff to inquire about their experience regarding dealing with critical test results.

Evidence of compliance

1. The laboratory has an approved procedure of the critical test results reporting that describe the process of "write down "and «read-back» by the recipient.
2. Staff is aware of the critical test result process.
3. The laboratory defines lists of critical values for specific tests.
4. All critical results are recorded within a predefined timeframe, includes elements mentioned in intent from a) through h).
5. The laboratory monitors the reported data on critical results and takes actions to control or improve the process as appropriate.

Related standard:

LPO.01 Reporting results, IMT.02 Record management system, QPI.02 Performance measures.

LPO.06 STAT results are reported within a predefined timeframe.

Effectiveness

Keywords:

STAT results.

Intent:

STAT testing is defined as laboratory testing urgently needed for quicker diagnosis "and/or treatment of the client and any delay can be life threatening, this includes frozen section in anatomic pathology. The laboratory develops and implements procedure for defining and monitoring the STAT testing process. The laboratory develops processes to meet the needs of its clients for rapid test and improve turn -around time of emergency specimens with the aim of quicker diagnosis. There are four main parts to the STAT testing process: requesting, specimen collection, testing, and reporting of results.
The laboratory process for urgent samples addresses the four main parts to the STAT testing process.
The laboratory defines the tests that can be requested on a STAT basis and the interval of time between when the sample is collected (or received in the lab if not collected by the lab) and the results are reported.

Survey process guide:

- GAHAR surveyor may review laboratory procedure of STAT test results.
- GAHAR surveyor may interview staff members to assess their awareness of laboratory STAT testing procedure.
- GAHAR surveyor may review previous urgent client's results and assess laboratory result reporting time.

- GAHAR surveyor may interview responsible staff members to inquire about their experience regarding STAT laboratory service reporting time.
- GAHAR surveyor may review monitoring data on laboratory STAT turnaround time.

Evidence of compliance:

1. The laboratory has an approved procedure describing STAT testing process.
2. The laboratory has a list of STAT tests that defines its acceptable reporting time.
3. Cases of unacceptable STAT reporting time are investigated and proper actions are taken accordingly.
4. The laboratory monitors the reported data on STAT turnaround time and takes actions to control or improve the process as appropriate.

Related standard:

LPO.01 Reporting results, LPO.04 Turnaround time, IMT.02 Record management system, QPI.02 Performance measures.

Process of amended laboratory reports

LPO.07 Amended / discrepant laboratory reports are identified and maintained.

Effectiveness

Keywords:

Amended / discrepant laboratory reports.

Intent:

A variety of clinical impacts were attributed to the laboratory errors, most commonly delayed, inappropriate, or unnecessary therapy.
Amended laboratory results (modified) may be one of the laboratory-related adverse events, that can result in client care errors because clinicians are not anticipating a change in information and may have already acted on erroneous information.
In case of amended or discrepant result reporting, the laboratory notifies immediately the ordering clinician or other authorized qualified individual who can take decisions or actions to avoid the harm to the client.
An Amended report is issued when the laboratory test report has been modified after its initial issuance for error correction (e.g. mislabelling or incorrect test results), when additional information becomes available, or for further clarification. Amended report should be clearly identified as a revision and should contain the following:

a) Reasons for the revision.
b) Changes to client results and its impact on the client diagnosis or treatment.
c) Accompanying reference intervals and /or interpretations.
d) Date and time of the modification.
e) Name of the individual authorized for the change.

Discrepant report is issued when the results of laboratory tests do not align with expected outcomes, previous test results, or clinical finding. This discrepancy can raise concerns about the accuracy or reliability of the test results and may require further investigation or confirmation. It should be clearly identified and should contain the following:

I) Identification of discrepancy.

II) Comparison data with previous results or expected outcome.
III) Investigation for the cause of discrepancy, including repeat testing or additional analysis.
IV) Clinical implications for the client's diagnosis or treatment.
V) Recommendations for further testing, consultation or monitoring (if any).

The laboratory maintains both the original and corrected reports, and identifies both copies of the report.

Survey process guide:

- GAHAR surveyor may review laboratory process for Amended / discrepant reports.
- GAHAR surveyor may observe laboratory area to assess authorization of reviewing, correcting, and release of amended/discrepant laboratory results.
- GAHAR surveyor may review the archived amended/discrepant test results for comparison with the original results and ensures that they are corrected by authorized personal.
- GAHAR surveyor may interview authorized staff to inquire about their experience regarding process of amending/discrepant results.

Evidence of compliance:

1. The laboratory has an approved process for amended / discrepant reports.
2. Laboratory staff is aware and trained about process of amended / discrepant reports.
3. Amended report is identified and includes elements mentioned in intent from a) through e)
4. Discrepant report is identified and includes elements mentioned in intent from I) through V).
5. Amended / discrepant reports is reported to the authorized individual and proper actions are taken accordingly.
6. Amended / discrepant reports are modified by authorized personnel.

Related standard:

LPO.01 Reporting results, IMT.01 Documentation management system. IMT.10 Data storage and retrieval, WFM.05 Verifying credentials, clinical privilege.

Section 4: Organization-Centered Standards

Organization-Centered Standards in healthcare serve as a structured framework that ensures the efficiency, safety, and quality of services within medical institutions, including clinical laboratories. These standards focus on enhancing governance, leadership, resource management, staff competency, operational efficiency, and risk management to create a well-regulated and high-performing healthcare environment. They establish clear protocols for workforce training, infrastructure maintenance, patient safety, infection control, data security, and compliance with national and international regulations to maintain service quality and reliability.

By implementing organization-centered standards, healthcare institutions can streamline workflows, reduce variability in service delivery, minimize errors, and improve overall patient outcomes. These standards emphasize a culture of continuous improvement, encouraging institutions to assess their performance regularly through internal audits, staff feedback, and quality monitoring programs.

In clinical laboratories, organization-centered standards play a critical role in ensuring accurate diagnostic testing, laboratory safety, and regulatory compliance. They provide guidance on quality control measures, equipment calibration, and standardized reporting processes to prevent diagnostic errors and ensure reliable patient care. By aligning laboratory operations with these standards, institutions can maintain high levels of professionalism, accountability, and efficiency, ultimately leading to better healthcare delivery and patient trust

Environmental and Facility Safety

Chapter intent:

Laboratory Environmental and Facility Safety (EFS) is a comprehensive program designed to minimize risks and create a secure and compliant laboratory environment. It encompasses adherence to all applicable laws, regulations, codes (including fire and building codes), and best practices for environmental management. EFS covers a broad range of areas, from chemical and biological waste disposal and environmental protection to accident prevention and staff training in emergency preparedness.

Facility safety within a laboratory focuses on proactive hazard identification and risk reduction. This includes maintaining the structural integrity of the laboratory, ensuring code compliance, and conducting regular safety inspections. Crucially, it also involves developing and implementing robust emergency preparedness plans to address various crises, from chemical spills and biological contamination to fires and other emergencies.

Effective staff training is paramount for both environmental and facility safety in a laboratory setting. Lab personnel must receive thorough and ongoing training in accident prevention, emergency response procedures, and the proper use of safety equipment, including personal protective equipment (PPE). This training should cover critical topics such as handling hazardous chemicals and biological agents, responding to fires or chemical spills, and safely evacuating the laboratory.

This chapter focuses on planning and effectively managing laboratory EFS. It emphasizes the development, implementation, monitoring, evaluation, and regular updating of environmental safety plans. The core aim is to enable the organization to identify and address safety concerns and establish effective plans to maintain and improve environmental safety.

Specifically, this chapter addresses:

- Fire Safety: Strategies for fire prevention, detection, response, and safe evacuation specific to laboratory settings.
- Hazardous Materials (Chemical & Biological): Safe handling, storage, transport, use, and disposal of hazardous chemicals, biological agents and waste.
- General Safety: Maintaining a safe environment for all occupants by ensuring the laboratory building, work areas, and equipment are free from hazards.
- Security: Protecting the property of everyone in the laboratory from loss, theft, damage, or unauthorized access, including securing sensitive research materials and equipment.
- Utility Systems: Ensuring the reliable operation of all utilities, including specialized lab equipment, through regular inspection, maintenance, testing, and repair.
- Disaster Preparedness: Preparing for and responding to disasters and emergencies, including chemical spills, biological releases, and fires, as well as assessing the structural integrity of the laboratory.

EFS Summary of Changes

GAHAR Clinical Labs 2025	***GAHAR Clinical Labs 2021***	***Details of changes***
EFS.01 **KW:** Laboratory environment and facility safety	**EFS.01** **KW:** Laboratory environment and facility safety structure **EFS.02** **KW:** Environmental and safety structure.	- **Updated standards by merging two standards (EFS.01 & EFS.02) in Clinical Labs 2021.**
EFS.02 **KW:** Environment and facility safety monitoring	**EFS.01** **KW:** Laboratory environment and facility safety structure	- **New Standard Statement: (**The laboratory environment and facility safety are overseen and monitored by a trained staff.) - **Add new EOCs:** • **(EOC.01:** The laboratory ensures the availability of a trained staff to oversee the environmental and facility safety activities.) • **(EOC.02:** The responsibilities of the EFS staff include the items mentioned in the intent from a) to d) in the intent.) • **(EOC.03:** The EFS staff is aware and perform its responsibilities.) • **(EOC.04:** The EFS staff reports on inspecting findings to the laboratory leadership at least quarterly.
EFS.03 **KW:** Fire and smoke safety plan, fire drill	**EFS.03** **KW:** Fire and smoke safety	- **Modified** EOCs: • **(EOC.01:** The laboratory has an approved fire and smoke safety plan that includes the elements mentioned in the intent from a) to f) and it is evaluated and updated annually). • (**EOC.03:** The laboratory fire alarm systems are available, functioning,

GAHAR Clinical Labs 2025	***GAHAR Clinical Labs 2021***	***Details of changes***
		inspected, tested, and maintained on regular basis.) • (**EOC.04:** The laboratory fire-fighting systems are available, functioning, inspected, tested, and maintained on regular basis.) • (**EOC.05:** The laboratory guarantees safe evacuation through unobstructed and clearly signage for evacuation. - **Added a new** EOC:(**EOC.06:** Fire drill is performed at least annually with the required documentation as mentioned in the intent from I) to V).
EFS.04 **KW:** Hazardous materials safety and waste management.	**EFS.05** **KW:** Hazardous materials safety.	• **Modified** Standard Statement: (The laboratory ensures safe handling, storage, usage and transportation of hazardous materials and waste management.) • **Modified** EOCs: • **(EOC.01:** The laboratory has an updated hazardous material and waste management plan as mentioned in the intent from a) through k) in the intent.) • **(EOC.03:** The laboratory ensures safe usage, handling, storage, availability of SDS and labelling of hazardous materials.) • **(EOC.04:** The laboratory ensures safe, handling, storage, and labelling for waste occurs according to laws and regulations. • **(EOC.05:** The laboratory has a documented investigation of spill or other hazardous materials related incidents.) • **(EOC.06:** The plan is evaluated and updated annually with aggregation and

GAHAR Clinical Labs 2025	***GAHAR Clinical Labs 2021***	***Details of changes***
		analysis of necessary data and corrective actions acted upon.) - **Add new** EOC:**(EOC.02:** Staff is trained on hazardous material and waste management plan.)
EFS.05 **KW:** Safety and security management plan.	**EFS.06** **KW:** Safety program, Security plan.	- **Modified Standard Statement:** (The laboratory ensures a safe and secure work environment.). - **Add new EOC**: **(EOC.01:** The laboratory has an approved updated plan to ensure a safe work environment including the items mentioned in the intent from a) to f) in the intent.) - **Modified** EOCs: • **(EOC.02:** The laboratory has an approved updated security plan including the elements mentioned in the intent from I) to VII). • **(EOC.05:** Security measures are implemented.) • **(EOC.06:** Safety and security plan/plans is/are evaluated and updated annually.) - **Added a new** EOCs: • **(EOC.03:** Staff is trained on safety and security plan/s.) • **(EOC.04:** Safety measures and PPEs are available and used whenever indicated.
EFS.06 **KW:** Utilities Management plan	**EFS.07** **KW:** Utilities Management	- **Modified** EOCs: • **(EOC.01:** The laboratory has an approved and updated utility management plan include the elements mentioned in the intent from a) to k).

GAHAR Clinical Labs 2025	***GAHAR Clinical Labs 2021***	***Details of changes***
		• **(EOC.03:** Records are maintained for utility systems inventory, testing, periodic preventive maintenance, and malfunction history). • **(EOC.04:** Critical utility systems are identified, and backup availability is ensured and evaluated on regular basis). - **Added a new** EOCs: • **(EOC.02:** The laboratory has trained staff members to oversee utility management). • **(EOC.05:** The plan is evaluated and updated annually with aggregation and analysis of necessary data).
EFS.07 **KW:** Pre-Construction risk assessment		**New standard**
EFS.08 **KW:** Disaster Plan	**EFS.04** **KW:** Emergency preparedness plan	- **Rephrasing of Standard statement: (**Emergency preparedness plan addresses responding to disasters that have the potential of occurring within the geographical area of the laboratory**.)** - **Modified EOC:** (**EOC.01:** There is an approved laboratory emergency preparedness plan includes the elements mentioned in the intent from a) to e). - **Add new EOCs:** • **(EOC.04:** The laboratory demonstrates preparedness for identified emergencies based on risk assessment.) • **(EOC.05:** The plan is evaluated at least annually with aggregation and analysis of necessary data.)

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

Effective leadership and planning of environment and facility safety.

EFS.01 The laboratory facility complies with laws, regulations, and civil defense requirements.

Safety

Keywords:
Laboratory environment and facility safety

Intent:
A safe physical environment in laboratories is essential to prevent accidents, protect personnel, and ensure efficient operations. The laboratory shall comply with relevant laws, regulations, and codes like civil defense, fire and building codes to ensure the safety of clients, staff, visitors, vendors, and the environment.
While laboratories are meant to provide diagnostic services, they also include certain dangers. Laboratories contain hazardous chemicals, and infectious materials among other threatening items.
The laboratory area has to be designated to ensure safety for both clients and working staff.
Working areas should be separated if conflicting activities are performed.
Considerations for laboratory areas that have special requirements must be met. These areas shall include the following:

a) The physical accessibility of the building is designed to be user-friendly and within reasonable reach of those who need them including wheelchair accessible entrances and clear signage with respect to those with vision and hearing impairments and needs.
b) Client centered waiting area is adequate for the expected number of clients, well-lit, well-ventilated, clean and safe, suitable for basic human needs.
c) Administrative area physically separated from working areas.
d) Clean and contaminated areas in the laboratory are separated.
e) Spaces for specimen collection areas are adequately designed to allow respect and accommodation for clients' privacy, confidentiality, security, comfort, disabilities, and culturally appropriate by providing separate areas for women and men.
f) The space provided is suitable to accommodate all laboratory technical areas and ensures the following:
    i. Bench space is adequate for the activities performed by laboratory staff.
    ii. There is appropriate space for sample preparation, handling, and processing.
    iii. Each piece of equipment has enough space for easy access and adequate ventilation so it can function properly and not be affected by other equipment.
    iv. Separation or segregation of some areas due to the nature of the work performed is according to infection control and WHO guidelines (e.g. microbiology laboratory, tuberculosis laboratory and mycology work).
g) Well- ventilated, well-lit and clean staff rest areas including spaces that are used solely by employees for hygiene needs, clothes change, rest and eating when applicable (such as staff lounge)
h) Well- ventilated, well-lit and clean storage areas including spaces that are used for the following:

I. Proper storage and arrangement of reagents in a safe manner and according to Manufacturers' guidelines.
II. Special storage requirements are met for flammable liquids, compressed gases, and any other reagents with special requirements.
III. Storage for specimens and control materials is adequate and appropriate.

IV. Proper storage for supplies and equipment.
V. Adequate storage space is provided for records, files, and manuals.

If an external authority, such as civil defense, reported an observation during its inspection, the laboratory leadership is responsible for providing a corrective action plan for any non-compliance within the required timeframe.

Survey process guide:

- GAHAR surveyor may review documents demonstrating laboratory drawings, budget, work permits, and external authorities reports with action plans.
- GAHAR surveyor may observe compliance with local laws and regulations requirements and matching allocated spaces to departmental functions.

Evidence of compliance:

1. The laboratory maintains basic requirements for compliance with environmental safety laws, regulations, and civil defense requirements.
2. The laboratory areas have sufficient space according to laws, regulations, and IPC standards as mentioned in the intent from a) to h).
3. The laboratory responds to external inspection reports within the required timeframe.
4. The laboratory leadership ensures the availability of current and updated work permits when required.
5. The laboratory allocates budgets for maintaining and upgrading laboratory environmental safety.

Related standard:

EFS.03 Fire and smoke safety plan, fire drill, EFS.04 Hazardous materials safety and waste management, OGM.01 Governing body Structure and responsibilities.

EFS.02 The laboratory environment and facility safety are overseen and monitored by a trained staff.

Safety

Keywords:

Environment and facility safety monitoring

Intent:

Maintaining a safe and active environment within a facility requires specialized skills to assess performance, identify gaps, and implement corrective actions.

The laboratory should ensure the availability of trained staff (at least training on safety requirements and civil defense) according to the scope of the provided services, local laws, and regulations to oversee the environmental and facility safety activities.

One or more trained individuals is/are responsible for:

a) Inspecting laboratory areas to identify maintenance and safety issues, such as clogged drains, leaky ceilings, and faulty electrical switches, availability of warning signs, etc.
b) Review of aggregated essential data, incident reports, drill reports, safety plans measures, and recommended actions.
c) Following up to ensure compliance with all safety requirements.
d) Providing quarterly reports to the laboratory's leadership on inspection findings.

Different tools could be used, like inspection checklists that cover different components of environmental safety activities. Risk assessment is used to identify high-risk observations that require appropriate intervention.

Survey process guide:

- GAHAR surveyor may review responsible staff members' files to check their qualifications.
- GAHAR surveyor may interview responsible staff members to ensure their awareness of environmental safety responsibilities.
- GAHAR surveyor may review environment and facility safety reports.

Evidence of compliance:

1. The laboratory ensures the availability of a trained staff to oversee the environmental and facility safety activities.
2. The responsibilities of the EFS staff include the items mentioned in the intent from a) to d) in the intent.
3. The EFS staff is aware and perform its responsibilities.
4. The EFS staff reports on inspecting findings to the laboratory leadership at least quarterly.

Related standards:

OGM.02 Laboratory Director, OGM.04Laboratory head of departments.

Safe fire planning

EFS.03 GSR.05 Fire and smoke safety plan addresses prevention, early detection, response, and safe evacuation in case of fire.

Safety

Keywords:
Fire and smoke safety plan, fire drill

Intent:

A key factor in designing a laboratory is fire prevention, especially regarding the combustibility of construction and furnishing materials, as well as controlling the spread of fire and smoke. In the case of accidental or intentional fires, early detection and suppression equipment must be easily accessible.
Staff should be trained to use this equipment effectively, remain calm, and work cooperatively in line with prior training.
The laboratory shall perform risk assessment that include fire and smoke separation, areas under construction and other high-risk areas, (eg. stores, electrical control panels, garbage room, etc.). Risk mitigation measures are taken based on the fire and other disasters risk assessment which shall be updated annually.
The laboratory shall develop and implement a fire and smoke safety plan that addresses at least the following:

a) Fire and smoke risk assessment.
b) Preventive measures, that include at least:
   i. Assesses compliance with Civil Defense requirement, and related laws and regulations.
   ii. Safe storage and handling of highly flammable materials.
   iii. Comply with no smoking policy according to laws and regulations.

iv. Safe handling of electric panel, cords, and connections

c) Early detection of fire and smoke system, including monitoring method of the alarm system like central control panel connected to all areas in laboratory according to its functionality, and ensure continuous monitoring 24/7.
d) Regular inspection testing of early detection system & fire suppression systems.
e) Safe evacuation through availability of safe, unobstructed fire exits, with clear signage to assembly areas and emergency light, in addition to other related signage's like how to activate the fire alarm, using a fire extinguisher and hose reel.
f) The plan is evaluated and updated annually.

A drill ensures staff preparedness for fire and other disasters by equipping them with a solid understanding of the fire safety plan through regular training and simulations.

The laboratory must train all staff practically to demonstrate RACE, PASS, and other safety procedures during disasters. The laboratory shall record fire drills details including, but are not limited to, the following:

I) Dates and timings.
II) Staff who participated in the drill.
III) Involved areas.
IV) Shifts.
V) Drill evaluation and corrective action plan.

Survey process guide:

- GAHAR surveyor may review the approved fire and smoke safety plan, laboratory fire safety inspections, and fire system maintenance.
- GAHAR surveyor may interview staff to check their awareness of the fire and smoke safety plan.
- GAHAR surveyor may observe that fire alarm; firefighting and smoke containment systems are working effectively and complying with civil defense requirements.
- GAHAR surveyor may review plan of testing (drills) and staff training documents.

Evidence of compliance:

1. The laboratory has an approved fire and smoke safety plan that includes the elements mentioned in the intent from a) to f) and it is evaluated and updated annually.
2. All staff are trained on fire safety plan and can demonstrate their roles during fire.
3. The laboratory fire alarm systems are available, functioning, inspected, tested, and maintained on regular basis.
4. The laboratory fire-fighting systems are available, functioning, inspected, tested, and maintained on regular basis.
5. The laboratory guarantees safe evacuation through unobstructed and clearly signage for evacuation.
6. Fire drill is performed at least annually with the required documentation as mentioned in the intent from I) to V).

Related standard:

EFS.01 Laboratory environment and facility safety, EFS.07 Disaster Plan, WFM.07 Orientation Program, WFM.08 Continuing Education Program, QPI.05 Risk Management plan/program.

Safe hazardous materials and waste management plan

EFS.04 GSR.06 The laboratory ensures safe handling, storage, usage and transportation of hazardous materials and waste management.

Safety

Keywords:

Hazardous materials safety and waste management.

Intent:

Hazardous materials are chemical substances that, if released or misused, can threaten the environment, life or health. These chemicals are used in industry, agriculture, medicine, research, and consumer goods.

Hazardous materials come in the form of explosives, poisons, flammable and combustible substances, These substances are most often released because of transportation accidents or chemical accidents in laboratories. Because the effects of hazardous materials can be devastating and far-reaching, it is important that laboratory plans its safe use to ensure safe working environment.

A hazardous waste is a waste with properties that make it dangerous or capable of having a harmful effect on human health or the environment. Infectious waste includes cultures and stocks of pathogens, disposable culture plates and instruments used for transferring, inoculating, and mixing cultures, pathological materials (such as wet tissue, human blood and its derivatives, and other body fluids), as well as sharp objects. Biohazardous waste must be kept in a designated, secure room, following national laws and regulations.

The laboratory environment, staff, clients, relatives and vendors should be safe from hazardous material exposure and waste all the time, the laboratory should have a hazardous materials and waste management plan that include at least the following:

a) A current and updated inventory of hazardous materials used in the laboratory, the inventory should include the material name, hazard type, location, usage, consumption rate, and responsibility.
b) Safety data sheet (SDS) should be available and includes information such as physical data, hazardous material type (flammable, corrosive, carcinogenic, etc.), safe storage, handling, spill management and exposures, first aid, and disposal.
c) Appropriate labelling of hazardous materials.
d) Procedure for safe usage, handling, and storage of hazardous materials.
e) Appropriate waste segregation, labelling, and storage,
f) Safe handling, transportation, and disposal of all categories of hazardous waste.
g) Availability of required protective equipment and spill kits, safe showers and eye washes.
h) Investigation and documentation of different incidents such as spill and exposure.
i) Compliance with local laws and regulations, availability of required licenses, and/or permits
j) Staff training and orientation.
k) The plan is evaluated and updated annually and/or when required.

Survey process guide:

- GAHAR surveyor may review the hazardous material and waste management plan to make sure that it covers all safety requirements of hazardous materials, safe storage, handling, spills, required protective equipment and waste disposal according to local laws and regulations.
- GAHAR surveyor may review the hazardous material and waste disposal plan, hazardous material and waste inventories, as well as Material Safety Data Sheet (SDS).
- GAHAR surveyor may observe hazardous material labelling and storage in addition to waste collection segregation storage and final disposal.

Evidence of compliance:

1. The laboratory has an updated hazardous material and waste management plan as mentioned in the intent from a) through k) in the intent.
2. Staff is trained on hazardous material and waste management plan.
3. The laboratory ensures safe usage, handling, storage, availability of SDS and labelling of hazardous materials
4. The laboratory ensures safe, handling, storage, and labelling for waste occurs according to laws and regulations.
5. The laboratory has a documented investigation of spill or other hazardous materials related incidents.
6. The plan is evaluated and updated annually with aggregation and analysis of necessary data and corrective actions acted upon.

Related standard:

EFS.01 Laboratory environment and facility safety, LPO.03 Storage, Retention and Disposal of specimen, WFM.07 Orientation Program, WFM.08 Continuing Education Program, IPC.03 PPE, guidelines, Physical Barriers.

Safety and security planning

EFS.05 GSR.07 The laboratory ensures a safe and secure work environment.

Safety

keywords:

Safety and security management plan.

Intent:

Health services are committed to providing a safe and secure environment for clients, staff, and visitors. Laboratory safety arrangements keep clients, staff, and visitors safe from inappropriate risks.The laboratory must have a safety plan with safety mitigation measures based on the risk assessment that covers the building, property, and systems to ensure a safe physical environment for all occupants. The safety plan shall include at least the following:

a) Regular inspection with documentation of results, performing corrective actions, and appropriate follow-up.
b) Safety measures based on risk assessment for example:
    i. Availability of emergency showers, eyewash stations.
    ii. electric hazards management.
    iii. prohibiting applying cosmetics, wearing contact lenses, and perform mouth pipetting.
    iv. wearing proper PPEs like safety goggles, gloves, and appropriate footwear, use face shields or respirators if handling hazardous substances.
c) Processes for pest, insects, and rodent control.
d) Responsibilities according to laws and regulations.
e) Safety training on general safety plan.
f) The plan is evaluated and updated annually.

To address security challenges like violence, theft, and harassment, these facilities adopt a range of security measures including the use of (closed-circuit television) CCTV cameras, and electronic access

control systems for doorways. By employing and training security staff, they can protect individuals from various threats, ensuring that occupants have a secure environment, free from safety concerns.
The laboratory shall develop and implement a security plan based on Security risk assessment that includes at least the following:

I) Ensuring the identification of staff in the laboratory.
II) Ensuring the identification of visitors and vendors/contractors with restrictions on their movement within the laboratory.
III) Identification of restricted areas.
IV) Vulnerable clients such as the elderly, those with mental disorders, and handicapped should be protected from abuse.
V) Workplace aggression and violence management.
VI) Staff training and orientation.
VII) The plan is evaluated and updated annually.

Survey process guide:

- GAHAR surveyor may review the laboratory safety plan/s security plan/s.
- GAHAR surveyor may interview staff to check their awareness of the facility safety and security plan/s.
- GAHAR surveyor may observe the availability and staff compliance with wearing suitable personal protective equipment (PPE) in different areas.
- GAHAR surveyor may observe the implemented security measures, e.g., cameras, monitors, staff ID, and access-controlled areas.

Evidence of compliance:

1. The laboratory has an approved updated plan to ensure a safe work environment including the items mentioned in the intent from a) to f) in the intent.
2. The laboratory has an approved updated security plan including the elements mentioned in the intent from I) to VII).
3. Staff is trained on safety and security plan/s.
4. Safety measures and PPEs are available and used whenever indicated.
5. Security measures are implemented.
6. Safety and security plan/plans is/are evaluated and updated annually.

Related standard:

EFS.01 Laboratory environment and facility safety, EFS.03 Fire and smoke safety plan, fire drill, EFS.04 Hazardous materials safety and waste management, EFS.08 Pre-Construction risk assessment, QPI.05 Risk Management plan/program, PCC.02 Client and family rights, WFM.07 Orientation Program, WFM.08 Continuing Education Program, IPC.03 PPE, guidelines, Physical Barriers.

Safe utility plan

EFS.06 GSR.09 Essential utilities plan addresses regular inspection, maintenance, testing and repair.

Safety

Keywords:

Utilities Management plan

Intent:

As laboratories' utility systems form the operational infrastructure that enables the provision of accurate and reliable test results, it is crucial for laboratories to plan and implement effective response and recovery activities in the event of a failure in their utility systems.

Some of the essential utilities include mechanical systems (e.g., heating, ventilation, and cooling), electrical systems (e.g., normal power and emergency power); domestic hot and cold water, deionized water, or purified water systems; waste management systems; technology systems, including laboratory communication and data transfer systems; fuel systems; access control, fire alarms.

The laboratory shall have a utility management plan to ensure the efficiency and effectiveness of all utilities. The plan shall include at least the following:

a) Inventory of all essential utility systems, for example, electricity, purified water, heating, ventilation and air conditioning, communication systems, waste disposal systems, fire alarms, and backup power systems.
b) Layout of the utility systems.
c) Staff training on utility plan.
d) Regular inspection, testing, and corrective maintenance of utilities.
e) Regular testing of alarms (refrigerators, incubators, biosafety cabinet alarms, gas detectors, and others).
f) Testing of the electric generator with and without a load on a regular basis.
g) Providing fuel required to operate the generator in case of an emergency.
h) Preventive maintenance plan, according to the manufacturer's recommendations, for all laboratory utilities.
i) Identification of critical utility systems and ensuring backup availability for essential processes, such as uninterrupted power supply (UPS) for sensitive laboratory instruments.
j) The laboratory performs regular, accurate data aggregation and analysis (for example, frequency of failure, preventive maintenance, compliance with proper monitoring, updating, and improvement of the different systems).
k) The plan is updated annually based on evaluation.

This ensures laboratories maintain operational continuity, accuracy in testing, and safety for staff, equipment, and processes.

Survey process guide:

- GAHAR surveyor may review the laboratory utility management plan to ensure coverage of all required measures, e.g. regular inspection, maintenance, and backup for all essential utility systems management.
- GAHAR surveyor may interview responsible staff to assess their training and inquire about critical utility.
- GAHAR surveyor may review inspection records, preventive maintenance schedule, contracts, as well as testing results of generators, tanks, and/or other essential utility systems to make sure of facility coverage 24/7.

Evidence of compliance:

1. The laboratory has an approved and updated utility management plan include the elements mentioned in the intent from a) to k).
2. The laboratory has trained staff members to oversee utility management.
3. Records are maintained for utility systems inventory, testing, periodic preventive maintenance, and malfunction history.
4. Critical utility systems are identified, and backup availability is ensured and evaluated on regular basis.
5. The plan is evaluated and updated annually with aggregation and analysis of necessary data.

Related standards:

EFS.05 Safety and security management plan, WFM.08 Continuing Education Program, IMT.02 Record management system.

EFS.07 The laboratory performs a pre-construction risk assessment when planning for construction or renovation.

Safety

Keywords:
Pre-Construction risk assessment

Intent:
The new construction or renovation of a laboratory has detrimental effects on all occupants, including changes in air quality due to dust or odors, increased noise and vibration, and potential hazards from debris.
Upon new construction or renovation in the laboratory, a pre-construction risk assessment (PCRA) should be performed and evaluated to develop a plan that will minimize associated risks. Involvement of all departments affected by construction or renovation which may include project management, infection control, safety, security, housekeeping, information technology, engineering, laboratory departments, and external constructors, should be ensured.
The pre-construction risk assessment includes, but is not limited to, the following:

a) Noise level
b) Vibration
c) Infection control risk assessment (ICRA)
d) Air quality
e) Fire risk
f) Hazardous materials
g) Waste and wreckage
h) Any other hazards related to construction and renovation.

The laboratory shall ensure monitoring and documentation of all activities, and all risks related to construction and renovation.

Survey process guide:

- GAHAR surveyor may review the laboratory pre-construction risk assessment documents.
- GAHAR surveyor may observe the implemented risk assessment recommendations.
- GAHAR surveyor may interview staff, clients, or contractors in the construction area to check their awareness of required precautions.

Evidence of compliance:

1. The laboratory performs a pre-construction risk assessment before any construction or renovation.
2. All affected departments are involved in the risk assessment.
3. The laboratory performs preventive and corrective actions whenever risks are identified.
4. There is a mechanism, such as work permission, to empower risk assessment and recommendations.
5. If a contractor is used, contractors' compliance is monitored and evaluated by the laboratory.

Related standards:

EFS.03 Fire and smoke safety plan, fire drill, EFS.04 Hazardous materials safety and waste management, EFS.05 Safety and security management plan, QPI.05 Risk Management plan/Program, IPC.01 IPC program, risk assessment, guidelines.

Safe emergency preparedness plan

EFS.08 Emergency preparedness plan addresses responding to disasters that have the potential of occurring within the geographical area of the laboratory.

Safety

Keywords:
Disaster Plan

Intent:

With the onset of climate change, escalating pollution levels, and technological advancements, the Earth is increasingly susceptible to natural disasters. While these events may not be entirely preventable, their impact can be mitigated through effective planning.

The laboratory must conduct a risk assessment for possible emergencies and disasters, both internal and external in nature.

These may include heavy rains, earthquakes, floods, extreme heat, acts of war, bomb threats, terrorist attacks, traffic accidents, power outages, fires, gas leaks, and the potential for epidemics or pandemics.

The laboratory needs a risk assessment tool to prioritize potential emergencies by considering both their likelihood and impact. Preparedness levels will then be evaluated based on the identified risks, with various tools.

The laboratory shall develop and implement an emergency preparedness plan, and the frequency of reviewing and updating the plan is done in accordance with the results of the current risk assessment and analysis and at least annually.

The laboratory emergency preparedness plan shall include at least the following:

a) Communication strategies: Internal communication may be in the form of Clear call tree that includes staff titles and contact numbers, and External communication channels may include civil defense, ambulance centres, and police.
b) Clear duties and responsibilities for the facility head of departments and staff.
c) Identification of required resources such as utilities, medical equipment, medical, and nonmedical supplies, including alternative resources.
d) Business Continuity:
    i. Staff main task is maintained in case of emergencies.
    ii. Alternative care sites, and back-up utilities.

e) Drill schedule: the laboratory must have a drill schedule for emergencies at least annually and ensure the attendance of staff; proper evaluation and recording of the drill includes, but is not limited to:
   I. Scenario of the drill.
   II. Observations on code announcement, timing, staff attendance, response, communication, triaging, and clinical management.
   III. Clear corrective actions if needed.
   IV. Debriefing.

Survey process guide:

- GAHAR surveyor may review emergency preparedness plan and its records to confirm that it covers all the identified risks.
- GAHAR surveyor may review preparations in terms of equipment, supplies, action cards, and others.
- GAHAR surveyor may interview staff to check their awareness of the emergency preparedness plan.

Evidence of compliance:

1. There is an approved laboratory emergency preparedness plan includes the elements mentioned in the intent from a) to e).
2. Staff members are trained on the emergency preparedness plan.
3. The laboratory performs at least one drill annually that includes the item (e) in the intent.
4. The laboratory demonstrates preparedness for identified emergencies based on risk assessment.
5. The plan is evaluated at least annually with aggregation and analysis of necessary data.

Related standards:

EFS.03 Fire and smoke safety plan, fire drill, EFS.05 Safety and security management plan, WFM.07 Orientation Program, WFM.08 Continuing Education Program, QPI.05 Risk Management plan/program.

Equipment Management System

Effective laboratory equipment management is crucial for accurate, reliable, and timely testing. A robust program ensures high laboratory performance by reducing test result variability, increasing confidence in accuracy, and lowering repair costs.

This program also extends equipment lifespan and minimizes service interruptions due to breakdowns. Furthermore, it enhances worker safety and boosts customer satisfaction. A comprehensive equipment management program should encompass the entire lifecycle of each instrument, including acquisition and installation, regular maintenance, performance verification, and eventual retirement.

The retirement process should include secure data handling and proper disposal or retiting of the equipment, adhering to all relevant safety and environmental regulations.

Chapter purpose:

The main objective is ensuring the laboratory provides an effective performance improvement program. The chapter discusses the following objectives:

1. Effective equipment management plan.
2. Safe laboratory equipment utilization.
3. Effective equipment retirement process.

EMS Summary of Changes

GAHAR Clinical Lab 2025	***GAHAR Clinical Lab 2021***	***Details of changes***
EMS.01 **KW:** Equipment management plan.	**EMS.01** **KW:** Equipment management plan.	- **Modified** EOCs**:** • **(EOC.01:** The laboratory has an approved equipment management plan as mentioned in the intent from a) through h) in the intent.) • **(EOC.02:** Relevant staff is aware of the laboratory equipment plan and use. - **Add new EOCs: (EOC.03:** Laboratory requisite equipment in accordance to pre-selection criteria as mentioned form I) to X) in the intent).
EMS.02 **KW:** Equipment reception, installation, acceptance, usage instructions.	**EMS.02** **KW:** Equipment reception, installation, acceptance. **EMS.03** **KW:** Equipment instructions	**Updated Standard** by merging two Standards(**EMS.02** and **EMS.03**) in Clinical Laboratories 2021.
EMS.03 **KW:**. Calibration plan.	**EMS.04** **KW**: Calibration plan.	- **Modified EOCs:** • **(EOC.01:** The laboratory has a current, approved calibration plan for all laboratory equipment with a predefined date of recalibration, that follows the manufacturer's calibration recommendations or guidelines.) • **(EOC.04:** Action taken monitored in case of deviation from acceptable criteria. - **Add new** EOC**: (EOC.02:** Relevant staff is aware of calibration plan.)

GAHAR Clinical Lab 2025	***GAHAR Clinical Lab 2021***	***Details of changes***
EMS.04 **KW:** Equipment maintenance, monitoring and failure management.	**EMS.05** **KW:** Equipment maintenance and monitoring. **EMS.06** **KW:** Equipment failure management.	• **Updated Standard** by merging two Standards(**EMS.05** and **EMS.06**) in Clinical Laboratories 2021.
EMS.05 **KW:** Equipment records and files.	**EMS.07** **KW:** Equipment records and files.	- **Modified EOCs:** **(EOC.02:** Equipment management program maintains records as mentioned in the intent from I) to VII). - **Add new** EOC**:(EOC.04**: Equipment file and records are kept up to date.)
EMS.06 **KW:** Retiring of equipment.	**EMS.08** **KW:** Retiring of equipment.	- **Modified EOCs:** • **(EOC.01:** The laboratory has an approved procedure that describe the process for retiring laboratory equipment). • **(EOC.02:** Relevant staff is aware of equipment retiring process.)

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

Effective equipment management plan

EMS.01 GSR.08 laboratory equipment management plan ensures selection, inspection, testing, and safe use.

Safety

Keywords:
Equipment management plan.

Intent:
Appropriate selection of laboratory equipment is essential to the quality and the effectiveness of the laboratory testing process also selecting the right equipment can maximize the productivity of the laboratory.
The laboratory head of departments are responsible for providing all the equipment essential for all laboratory activities (including primary sample collection, sample preparation, sample processing, examination and storage).
The laboratory plan shall address at least the following:

a) Developing criteria for selecting new laboratory equipment.
b) Inspection and testing of new laboratory equipment upon procurement.
c) Calibration and Periodic preventive maintenance of laboratory equipment according to the manufacturer's recommendations and/or its usage.
d) Training of staff on safe usage of laboratory equipment upon hiring and upon installation of new equipment, and whenever needed by a qualified person.
e) Inventory of laboratory equipment and their identification and status (e.g. in use, out of use, under repair…).
f) Dealing with equipment adverse incidents, including actions taken, backup system, and reporting.
g) Malfunction and repair of laboratory equipment.
h) Retiring of laboratory equipment.

The laboratory head of departments are responsible for selecting needed equipment, that affects the quality of services. The process of equipment selection should consider the criteria established by the laboratory.
The laboratory replaces equipment as needed to ensure the quality of examination results. The equipment selection criteria include but not limited to the following:

I) Scope of service
II) Match the instrument specifications provided by the laboratory.
III) Performance characteristics of the instrument.
IV) Cost of the equipment.
V) Readily available reagents.
VI) Ease of operation.
VII) Consumption of electricity and water.
VIII) Supplier's support and available ongoing after sale services.
IX) Updated technology in accordance to the intended use.
X) Respecting safety measures.

Survey process guide:

- GAHAR surveyor may review the laboratory medical equipment management plan and related documents, e.g. (inventory of medical equipment, preventive maintenance schedule, calibration schedule, and staff training records).

- GAHAR surveyor may interview relevant staff to check their awareness of the laboratory equipment management plan and use.
- GAHAR surveyor may observe the laboratory equipment to confirm that they comply with the selection criteria.
- GAHAR surveyor may review the records of staff training and qualifications for equipment operation.

Evidence of Compliance

1. The laboratory has an approved equipment management plan as mentioned in the intent from a) through h) in the intent.
2. Relevant staff is aware of the laboratory equipment plan and use.
3. Laboratory requisite equipment in accordance to pre-selection criteria as mentioned form I) to X) in the intent.
4. The laboratory ensures that only trained and competent staff handles the specialized equipment.
5. The plan is evaluated and updated annually.

Related standards:

EFS.06 Utilities Management plan, SCM.01 Supply Chain Management, SCM.3 inventory management, WFM.09 Competency assessment, WFM.08 Continuing Education Program, WFM.04 Job Description, LQC.01 Laboratory internal quality control, EMS.03 Calibration plan.

EMS.02 The laboratory ensures equipment reception, installation, acceptance and authorized personnel following usage instructions.

Effectiveness

Keywords:

Equipment reception, installation, acceptance, usage instructions.

Intent:

Before equipment is installed, the laboratory shall ensure that all physical requirements (electrical, space, doors, ventilation, water supply, and elevator access) are met.

Installation is done by the vendor according to the manufacturer's specifications. The vendor's responsibilities for installation are documented.

Prior to testing client specimens, it is important to evaluate the performance of new equipment to ensure that it is performance meets the expected specifications.

The expected performance specifications are developed according to manufacturer's instructions and regulations if present. The laboratory develops procedures that clearly describe the process of equipment installation and acceptance. These procedure(s) defines the criteria for initial acceptance of the equipment provided (e.g.: meeting ordering specifications…). Instructions for use, safety and maintenance of equipment, including any relevant manuals provided by the manufacturer are important for safe operation of laboratory equipment and should be readily available. Only trained and authorized personnel are allowed to use the equipment.

Survey process guide:

- GAHAR surveyor may review the laboratory procedures for reception, installation, acceptance of new laboratory equipment and ensures that it is matched with the manufacturer's specifications.

- GAHAR surveyor may interview laboratory professionals involved in evaluation of the performance of new the equipment to check their awareness.
- GAHAR surveyor may review equipment installation and acceptance records.
- GAHAR surveyor may review each equipment manual and instructions for use and interview laboratory staff members to check their awareness about the procedure of operating and maintaining each instrument.
- GAHAR surveyor may check availability of the instructions for use in the operation site.
- GAHAR surveyor may review personnel authorization list for each equipment and records of training on equipment operation to ensure competency.

Evidence of Compliance:

1. The laboratory has approved procedures that describe the installation and acceptance of the equipment.
2. The acceptance criteria of each equipment are identified.
3. Installation is performed by the vendor and according to the manufacturer's specifications.
4. Trained and authorized personnel are allowed to operate and monitor the equipment
5. Instructions for use for all laboratory equipment are developed, available and written in a manner that equipment user can understand.
6. Instructions for use are strictly followed.

Related standards:

EMS.01 Equipment management plan, EMS.03 Calibration plan, WFM.05 Verifying credentials, clinical privilege, WFM.04 Job Description, WFM.08 Continuous Education Program.

Safe laboratory equipment use

EMS.03 Equipment calibration plan ensures the reliable and effective use of laboratory medical equipment.

Effectiveness

Keywords:

Calibration plan.

Intent:

Calibration is the process of evaluating and adjusting the equipment measurements. Proper calibration of an instrument ensures the production of valid data by elimination reducing bias.

Calibration of auxiliary equipment is performed before use, after any activity that may alter its calibration and at predefined intervals as part of a calibration plan while the main equipment (e.g. Auto analyzers) shall follow the manufacturer's calibration recommendations, guidelines, references, etc.

The frequency and the calibration method are done according to the manufacturer's instructions or through an accredited calibration provider.

The laboratory should take appropriate measures in case of deviation from acceptance criteria.

Survey process guide:

- GAHAR surveyor may review equipment calibration plan, calibration schedule, calibration certificates, and staff training records in addition to the corrective actions taken in case of deviation.

- GAHAR surveyor may interview relevant laboratory staff to check their awareness about the calibration plan.

Evidence of Compliance:

1. The laboratory has a current, approved calibration plan for all laboratory equipment with a predefined date of recalibration, that follows the manufacturer's calibration recommendations or guidelines.
2. Relevant staff is aware of calibration plan.
3. calibration certificates from accredited calibration provider are available.
4. Action taken monitored in case of deviation from acceptable criteria.

Related standard:

EMS.01 Equipment management plan, EMS.04 Equipment maintenance, monitoring and failure management, QPI.04 internal assessment and nonconformity management.

EMS.04 The laboratory develops a maintenance, monitoring, and failure management system for equipment.

Effectiveness

Keywords:

Equipment maintenance, monitoring and failure management.

Intent:

Maintenance of laboratory equipment is an integral part of quality assurance in the laboratory.
Well maintained laboratory equipment ensures integrated service with better productivity. Laboratory equipment must be operated within defined specifications to ensure the quality of test results and services. The minimum procedures performed are those recommended by the manufacturer.
Laboratory head of departments shall develop a maintenance program with a defined frequency to regularly monitor the proper function of instruments. The program also includes preventive maintenance at defined intervals for each equipment. Equipment is assessed through periodic inspections, performance testing, and a maintenance program, which includes at least the following:

a) Monitoring and maintenance procedures following the manufacturer's instructions.
b) Description of the maintenance check elements.
c) Description of the frequency of each check (e.g., daily, weekly, monthly).
d) Identification of the responsible party
e) Description of actions to be taken in the event of unsatisfactory performance (e.g.: systemic, random errors or maintenance of equipment)
f) Monitoring of equipment status (e.g.,reallocation, equipment failure...)
g) Process for decontaminating equipment prior to service or disposal.

Equipment failure management is essential for tracking deviations and recurrent failures and to determine the need for procedural changes. Defective equipment is removed from service and clearly labelled.
The laboratory shall develop a detailed procedure for equipment failure management with strict empathies on ensuring its effectiveness. The investigation and follow-up of equipment failure shall include at least the following:

I) Reporting to the vendors, the manufacturer and appropriate authorities, as required.
II) Immediate action and troubleshooting.

III) Assessment of the failure-impact on reported results.
IV) Backup plan implementation.
V) Reporting of delayed results.

Survey process guide:

- GAHAR surveyor may review equipment preventive maintenance program.
- GAHAR surveyor may interview staff to check their awareness of the equipment maintenance program.
- GAHAR surveyor may review schedule of preventive maintenance, and records of implementation.
- GAHAR surveyor may review the procedure of equipment failure management and check the process of investigation and follow up.
- GAHAR surveyor may check the equipment failure backup plan and its effectiveness.
- GAHAR surveyor may review records of equipment failure and evaluate the corrective action taken.

Evidence of Compliance:

1. The laboratory has an approved equipment preventive maintenance program as mentioned in the intent from a) to g).
2. Staff is aware of the equipment maintenance program.
3. Equipment preventive maintenance is documented according to the program.
4. The laboratory has an approved procedure that describes the process for the equipment failure management, including at least the items mentioned in the intent from I) to V).
5. Equipment failures are investigated and gaps in services are identified.
6. Authorized personnel are knowledgeable about the dealing with adverse incidents and accidents related to equipment malfunction or failure.

Related standards:

EMS.01 Equipment management plan, IMT.02 Record management system, QPI.05 Risk Management plan/Program, LEP.03 Verification / validation, QPI.06 Incident Reporting System.

EMS.05 Equipment files and records are maintained.

Effectiveness

Keywords:
Equipment records and files.

Intent:
Equipment file (records) provide not only all the information and instructions related to the function and monitoring of the equipment but also allows the tracking of the equipment history since its installation in the laboratory.
Maintaining a list of all equipment helps in the management of all equipment functions and is used to ensures that all appropriate actions are performed and recorded.
Each item of equipment is uniquely labelled, marked or otherwise identified for proper asset management. The unique identifier may be the manufacturer's serial number or a unique identification applied by the laboratory.
The equipment file and records whether paper or electronic based should include at least the following:

a) List of all laboratory equipment with unique identity of each including Manufacturer's name, model and serial number or other unique identification.
b) Contact information for the supplier or the manufacturer.
c) Date of receiving and date of entering into service.
d) Location of the equipment.
e) Condition when received (e.g. new, used or refurbished…)

Equipment management program documents / record addresses at least the following:

I) Equipment initial installation calibration records
II) Performance specification records of the equipment upon installation
III) Equipment instructions for use.
IV) Maintenance carried out and the schedule for preventive maintenance.
V) Equipment performance records entire history that confirm the equipment's ongoing acceptability for use).
VI) failure, or malfunction, modification, or repair of the equipment.
VII) List of authorized personnel for each equipment function.

Survey process guide:

- GAHAR surveyor may review equipment file and equipment management program records to assess compliance with Equipment management program recordings and ongoing update.

Evidence of Compliance:

1. Equipment files and records includes the elements mentioned in the intent from a) to e).
2. Equipment management program maintains records as mentioned in the intent from I) to VII).
3. Equipment files and records are readily available and easily retrieved.
4. Equipment file and records are kept up to date.

Related standards:

SCM.01 Supply Chain Management, EMS.01 Equipment management plan, EMS.03 Equipment reception, installation, acceptance, usage instructions, IMT.01 Documentation management system, IMT.02 Record management system.

EMS.06 The Laboratory develops an effective equipment retiring process.

Effectiveness

Keywords:

Retiring of equipment.

Intent:

This usually occur when it is clear that the instrument is not functioning no providing the required quality of service and/ or could it not be repaired, it may also happen when the equipment becomes outdated and needs replacement.

Once an equipment is fully retired and it has been determined to have no further use, it is disposed of in an appropriate manner. Any potential hazards are assessed and all safety disposal measures are followed.

Survey process guide:

- GAHAR surveyor may review equipment retiring procedure to check the safe equipment disposal measures.
- GAHAR surveyor may review any equipment retirement records if available.
- GAHAR surveyor may interview staff to check their awareness of equipment retiring process and safe disposal measures.

Evidence of Compliance:

1. The laboratory has an approved procedure that describe the process for retiring laboratory equipment.
2. Relevant staff is aware of equipment retiring process.
3. Safety disposal measures are followed when retiring and disposing of equipment.
4. Equipment retiring records are available.

Related standards:

EMS.01 Equipment management plan, IMT.01 Documentation management system, IMT.02 Record management system.

Infection Prevention and Control

Chapter Intent:

Infection prevention and control (IPC) program is an essential components of laboratory settings, particularly those that handle infectious agents and biological materials. This program is designed to minimize the risk of infections among laboratory personnel, clients, and the community at large.
Laboratory workers are often exposed to various pathogens through their daily activities.
Infections within laboratory settings can also lead to contamination of samples or reagents used in testing procedures.
Implementing robust IPC measures minimizes the likelihood of cross-contamination within the lab environment. Maintaining sample integrity is crucial for obtaining accurate test results; errors due to contamination could lead to misdiagnosis or inappropriate treatment plans for clients. Reliable results bolster confidence in laboratory findings among healthcare providers and clients alike.

Effective IPC practices in stand-alone laboratories include comprehensive strategies such as appropriate personal protective equipment (PPE) usage, sterilization policies, safe handling and disposal of biological specimens, and the implementation of rigorous environmental cleaning procedures. Additionally, laboratories must ensure that staff are properly trained in these policies and adhere to national and international standards and guidelines.

An integral component of IPC is biosafety and biosecurity measures, which focus on minimizing risks associated with handling hazardous biological materials and protecting sensitive biological data, respectively. Biosafety refers to the containment measures and practices that prevent the accidental release or exposure to harmful microorganisms. It encompasses proper laboratory design, the use of biological safety cabinets, and protocols for managing infectious agents at varying levels of containment (from BSL-1 to BSL-4).
Biosecurity, on the other hand, focuses on safeguarding laboratories from intentional misuse of biological materials. This involves securing access to laboratory spaces, monitoring for potential security breaches, and implementing policies to control the transfer of dangerous pathogens. Both biosafety and biosecurity are essential to preventing both accidental and deliberate incidents that could compromise laboratory integrity or public health.
The goal of infection prevention, biosafety, and biosecurity is to minimize risks of contamination, protect staff health, and prevent any inadvertent or malicious transmission of infectious agents. Through well-established IPC practices, stand-alone laboratories can contribute significantly to public health safety while maintaining high standards of scientific integrity, reliability, and security.

IPC Summary of Changes

GAHAR Clinical Labs 2025	***GAHAR Clinical Labs 2021***	***Details of changes***
IPC.01 **KW:** IPC program, risk assessment, guidelines	**IPC.01** **KW:** IPC program, risk assessment, guidelines. **IPC.04** **KW:** Risk assessment.	- **Updated Standard** by merging **(IPC.01 and IPC.04)** in Clinical labs 2021.
IPC.02 **KW:** Hand Hygiene	**IPC.02** **KW:** Hand Hygiene	- **Modified** EOCs: • (**EOC.01:** The laboratory has approved Hand Hygiene policies and procedures based on current evidence-based guidelines that address all the elements mentioned in the intent from a) to f). • (**EOC.02:** Laboratory professionals are trained on these policies and procedures.). - **Add new EOCs:** • **(EOC.03:** Hand hygiene is implemented according to the policy.) • **(EOC.06:** The laboratory monitors the reported data on the hand hygiene process and takes actions to control or improve the process as appropriate.)
IPC.03 **KW:** PPE, guidelines, Physical Barriers	**IPC.03** **KW:** PPE guidelines.	- **Modified** EOC: **(EOC.01:** The laboratory has approved personal protective equipment (PPE) policy and procedures, that address all the elements mentioned in the intent from a) to e). - **Added a new** EOCS: • (**EOC.02:** The choice of PPE to be purchased is based on standardized product specifications.) • (**EOC.04:** All staff is trained on the proper way and sequence of donning and doffing of various PPE.)

GAHAR Clinical Labs 2025	***GAHAR Clinical Labs 2021***	***Details of changes***
		• (**EOC.05:** Proper selection and use of PPE according to the client's suspected infection and/or procedure.)
IPC.04 **KW:** Environmental cleaning, evidence-based guidelines	**IPC.05** **KW:** Environmental cleaning & disinfection, evidence-based guidelines.	- **Modified Standard Statement: (**Environmental cleaning and disinfection activities are aligned with current national/international guidelines.) - **Modified** EOCs: • **(EOC.01:** The laboratory has approved cleaning and disinfection policy and procedures, that address all elements mentioned in the intent from I) to VII). • **(EOC.04:** The cleaning technique and disinfectant of choice match the requirements of each cleaned area according to the approved policy.) - **Rephrasing of EOCs**: • (**EOC.02:** Laboratory Staff members involved in environmental cleaning activities are trained on the policy.) • (**EOC.05:** Clear instructions are available and followed for dealing with biological spills.) - **Added a new** EOC: (**EOC.03:** The laboratory identifies high-risk areas with different schedules for each area and includes all elements mentioned in the intent from a) through c).
IPC.05 **KW:** Sterilization, laboratory autoclave, microbiology and cultures media		- **New Standard.**
IPC.06 **KW:** Safe sampling practices		- **New Standard.**

GAHAR Clinical Labs 2025	***GAHAR Clinical Labs 2021***	***Details of changes***
IPC.07 **KW:** Respiratory Hygiene Protocol, cough etiquette		- **New Standard.**
IPC.08 **KW:** Sterile technique, Aseptic technique		- **New Standard.**
IPC.09 **KW:** Biosafety and biosecurity plan		- **New Standard.**

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

Efficient structure of the infection prevention and control program

IPC.01 A comprehensive infection prevention and control program is developed, implemented, and monitored.

Safety

Keywords:
IPC program, risk assessment, guidelines

Intent:

Healthcare-associated infections and laboratory acquired infections are common risks encountered in the laboratories. Therefore, formulating a comprehensive infection prevention and control (IPC) program is of utmost importance in order to effectively reduce these risks.
The program development requires a multidisciplinary approach that is carried on by qualified staff member(s) and based on the annual laboratory risk assessment plan, national and international guidelines (CDC, WHO, APIC, IFIC, etc.), standard laboratory techniques & accepted practices, and applicable laws and regulations.
The IPC program should include all laboratory sections and cover clients, staff, visitors and environment.
The laboratory shall develop and implement an infection prevention and control program that addresses at least the following:

a) Scope and objectives.
b) Infection control policies and procedures include at least the following:
    i. Hand hygiene policy.
    ii. PPE policy.
    iii. Environmental cleaning and disinfection policy.
    iv. Processing of laboratory equipment policy and its monitoring.
    v. Safe injection (sampling) policy.
    vi. Cough etiquette respiratory hygiene policy.
    vii. Waste management.
    viii. Standard aseptic techniques policy.
    ix. Occupational health program.
    x. Biosafety and biosecurity program.
c) Risk assessment to identify laboratory services with increased potential risk of infection and risk mitigation plan.
d) Monitoring system to monitor and track infection rates and incidents within the laboratory.
e) Staff education and training on infection control principles and practices.
f) Staff immunization.
g) Continuously assess and improve infection prevention and control practices within the laboratory.

Survey process guide:

- GAHAR surveyor may review an infection prevention and control program to ensure that it is based on the risk assessment, covers all laboratory sections and includes all relevant individuals, review the training plan or an annual evaluation report and update of the IPC program.
- GAHAR surveyor may review the documentation of monitoring of data on infection prevention and control program, performance measures, data analysis reports, recommendations for improvement and observe their implementation.

Evidence of compliance:

1. The laboratory has an infection control program that addresses all the elements mentioned in the intent from a) to g).
2. The laboratory staff involved in infection prevention and control are aware of the contents of the program.
3. The program is based on an updated risk assessment, current scientific knowledge, accepted practice guidelines, and applicable laws and regulations.
4. The program is implemented in all laboratory sections and covers clients, visitors, staff and environment.
5. The laboratory monitors the reported data on the infection prevention and control program and takes actions to control or improve the processes as appropriate.

Related standards:

IPC.02 Hand Hygiene, IPC.03 PPE, guidelines, Physical Barriers, IPC.04 Environmental cleaning, evidence-based guidelines, IPC.05 Sterilization, laboratory autoclave, microbiology and cultures media, IPC.06 Safe sampling practices, IPC.07 Respiratory Hygiene Protocol, cough etiquette, IPC.08 Sterile technique, Aseptic technique, IPC.09 Biosafety and biosecurity plan, QPI.05 Risk Management plan/program, WFM.07 Orientation Program, WFM.08 Continuing Education Program.

Safe standard precautions

IPC.02 GSR.04 Evidence-based hand hygiene guidelines are adopted and implemented throughout the laboratory.

Safety

Keywords:

Hand Hygiene

Intent:

Hand hygiene is the cornerstone of reducing infection transmission in all laboratories. It is considered the most effective and efficient strategy for infection prevention and control.

Hand hygiene in stand-alone laboratories includes:

i. Hand wash with plain soap and water.
ii. Alcohol-based hand rub (ABHR).
iii. Procedural hand antisepsis / pre-procedural hand preparation: - antiseptic handwash or antiseptic hand rub performed pre-procedurally (e.g. Bone Marrow aspiration and biopsy, by the laboratory specialist)

Selection of the type of hand hygiene should be based on the type of procedure and risk assessment. Alcohol-based hand rubs may replace hand wash in the laboratory unless hands are visibly soiled to overcome the shortage in sinks. Functional Hand hygiene stations (sinks, clean single-use towels, hand hygiene posters, general waste basket and appropriate detergent) must be present in appropriate numbers and places, according to national building codes. The laboratory shall develop and implement a hand hygiene policy that includes at least the following:

a) Hand hygiene techniques
b) Indications for hand Hygiene
c) Accessibility of hand hygiene facilities,
d) Nail Care and Jewellery,
e) Hand hygiene education and training,
f) Monitoring the compliance.

Survey process guide:

- GAHAR surveyor may review the policy of hand hygiene and hand hygiene guidelines.
- GAHAR surveyor may interview laboratory staff to ask about hand hygiene techniques, and WHO's five moments of hand hygiene.
- GAHAR surveyor may review laboratory staff 's training records.
- GAHAR surveyor may observe hand washing facilities at each laboratory section and check the availability of supplies (soap, tissue paper, alcohol hand rub, etc.) and hand hygiene posters.
- GAHAR surveyor may observe to ensure compliance of laboratory professionals with hand hygiene technique and WHO five moments of hand hygiene with WHO observation audit tool.

Evidence of compliance:

1. The laboratory has approved Hand Hygiene policies and procedures based on current evidence-based guidelines that address all the elements mentioned in the intent from a) to f).
2. Laboratory professionals are trained on these policies and procedures.
3. Hand hygiene is implemented according to the policy.
4. Hand hygiene posters are displayed in required areas.
5. Hand hygiene facilities are present in the required numbers and places.
6. The laboratory monitors the reported data on the hand hygiene process and takes actions to control or improve the process as appropriate.

Related standards:
IPC.01 IPC program, risk assessment, guidelines, WFM.07 Orientation Program, WFM.08 Continuing Education Program, QPI.02 Performance measures.

IPC.03 Personal protective equipment is available and used when indicated.

Safety

Keywords:
PPE, guidelines, Physical Barriers

Intent:
Wearing personal protective equipment (PPE) is an important tool in the protection of both clients and laboratory staff in stand-alone laboratories.
PPE term refers to the availability and appropriate use of barriers that a susceptible host may wear to provide a physical barrier between him/her and an infectious agent/infected source.
PPE include gloves, gowns, masks, eye protection, facial protection (including face shields or masks with visor attachments) and respirators.
Proper selection of PPE depends on each procedure risk assessment; laboratory staff education and training are of the utmost importance.
The laboratory shall develop and implement a personal protective equipment (PPE) policy that includes at least the following:

a) Different types of personal protective equipment (PPE).
b) Standardized product specifications of Personal protective equipment (PPE).
c) Selection of Personal protective equipment (PPE) to be used, based on the risk assessment.
d) Staff education and training on the proper way and sequence of donning and doffing of various PPE.
e) Monitoring the compliance.

Survey process guide:

- GAHAR surveyor may observe to ensure the availability and accessibility of PPE.
- GAHAR surveyor may interview laboratory staff members to ask about the constant availability, accessibility, and proper use of PPE.
- GAHAR surveyor may assess staff compliance with proper selection and use of PPE according to the client's suspected infection and/or procedure.
- GAHAR surveyor may review PPE standardized product specifications and disbursement permits.

Evidence of compliance:

1. The laboratory has approved personal protective equipment (PPE) policy and procedures, that address all the elements mentioned in the intent from a) to e).
2. The choice of PPE to be purchased is based on standardized product specifications.
3. The laboratory provides PPE that is easily accessible and appropriate to the task.
4. All staff is trained on the proper way and sequence of donning and doffing of various PPE.
5. Proper selection and use of PPE according to the client's suspected infection and/or procedure.

Related standards:

IPC.01 IPC program, risk assessment, guidelines, IPC.02 Hand Hygiene, IPC.04 Environmental cleaning, evidence-based guidelines, IPC.05 Sterilization, laboratory autoclave, microbiology and cultures media, WFM.07 Orientation Program, WFM.08 Continuing Education Program, QPI.02 Performance measures, SCM.01 Supply Chain Management, SCM.02 Supplies selection, reception and inspection.

IPC.04 Environmental cleaning and disinfection activities are aligned with current national/international guidelines.

Safety

Keywords:

Environmental cleaning, evidence-based guidelines

Intent:

The laboratory environment is considered a reservoir for pathogens and may be a significant source of health care - associated infections, so cleaning and disinfection of environmental surfaces is an important tool to prevent the development of these infections. Contact with contaminated surfaces in the laboratory can easily lead to cross-contamination of microorganisms between the environment and laboratory staff.

The determination of environmental cleaning and disinfection procedures for laboratory areas, including frequency, method, and process, and should be based on the risk of pathogen transmission. This risk is a function of the probability of contamination, vulnerability of the clients and laboratory worker to infection, and potential for exposure (i.e., high-touch vs low-touch surfaces).

To provide quality care, the laboratory must have a clear method and schedule for environmental cleaning and disinfection, including bench surfaces, computers, telephones, walls, floors, ceilings, and furniture.
Medical equipment should be cleaned on a regular schedule with an approved disinfectant based on the manufacturer's recommendations for use.
Cleaning activities and times are listed for each area. The schedule must address environmental cleaning activities for each area as follows:

a) Activities to be done every day.

b) Activities to be done every shift.
c) Deep cleaning activities.

Biological spills are reported, recorded, contained and dealt with according to national and international guidelines.
Strict laboratory procedures for dealing with biological spills must be followed, and included in the laboratory standard of procedure (SOP).
The laboratory shall develop and implement an environmental cleaning and disinfection policy and procedures based on national/international guidelines for the process of environmental / all surfaces and equipment/device cleaning /disinfection that addresses at least the following:

I) Biosafety level of the laboratory
II) Identification of risk areas.
III) High-touch environmental surfaces
IV) Frequency of environmental cleaning and disinfection
V) Environmental detergents and disinfectants to be used.
VI) Method of cleaning and disinfection
VII) Procedures for dealing with biological spills in the laboratory.

Survey process guide:

- GAHAR surveyor may review the laboratory policy guiding laboratory environmental cleaning and disinfection
- GAHAR surveyor may review the laboratory list of all environmental services that require cleaning, cleaning schedules and spill kits.
- GAHAR surveyor may interview laboratory staff and environmental cleaning staff members to ask about the availability, accessibility, and laboratory IPC procedures for dealing with biological spills.

Evidence of compliance:

1. The laboratory has approved cleaning and disinfection policy and procedures, that address all elements mentioned in the intent from I) to VII).
2. Laboratory Staff members involved in environmental cleaning activities are trained on the policy.
3. The laboratory identifies high-risk areas with different schedules for each area and includes all elements mentioned in the intent from a) through c).
4. The cleaning technique and disinfectant of choice match the requirements of each cleaned area according to the approved policy.
5. Clear instructions are available and followed for dealing with biological spills.

Related standards:

IPC.01 IPC program, risk assessment, guidelines, IPC.04 Environmental cleaning, evidence-based guidelines, IPC.05 Sterilization, laboratory autoclave, microbiology and cultures media, WFM.08 Continuing Education Program, QPI.05 Risk Management plan/program.

IPC.05 Laboratory supplies and client care equipment are sterilized and used based on evidence-based guidelines, and manufacturer instructions.

Safety

Keywords:

Sterilization, laboratory autoclave, microbiology and cultures media

Intent:

The purpose of this standard is to ensure the sterilization of laboratory supplies, culture media to eliminate any microbial contamination.
All laboratory supplies, including but not limited to glassware, plasticware, metal instruments, and any reusable items that come in contact with biological or chemical materials should be sterile.
The processing of laboratory reusable supplies and equipment is a critical process.
In laboratory procedures that involve contact with procedural equipment, it is crucial that laboratory staff follow standard practices and guidelines to clean and sterilize.
The cleaning process is a mandatory step in the processing of laboratory supplies and equipment. Cleaning, and sterilization can take place in a physically separated centralized sterile processing area. The assigned processing area shall have workflow direction.

The centralized sterile processing area in stand-alone laboratories should have: -

I) Laboratory autoclave (Gravity Displacement Autoclave):
   i. This is the most basic type of autoclave, relying on gravity to displace air from the chamber and replace it with steam. The steam then sterilizes the items. Typically used for sterilizing liquids, glassware, culture media and non-porous materials.
   ii. Biological Indicator Testing: To verify effective sterilization, the use of biological indicators (e.g., bacterial spore test) should be part of the standard protocol to confirm that microorganisms have been effectively destroyed.

II) Decontamination autoclave (pre-vacuum class B) for Decontamination of biohazardous Materials.
   i. This Waste Decontamination autoclave should be capable of sterilizing biological and hazardous waste materials, including contaminated media, culture materials, and disposable laboratory items (e.g., gloves, pipette tips, and petri dishes).
   ii. Biological Indicator Testing: To verify effective decontamination, the use of biological indicators (e.g., bacterial spore test) should be part of the standard protocol to confirm that microorganisms have been effectively destroyed.

Quality control measures are performed in such laboratories to monitor and ensure the reliability of sterilization processes. Quality controls can identify performance problems not identified automatically and help to determine the safety of procedures. Management of routine quality control includes developing the QC protocols, implementation of the program, oversight of the program, and responsibility for determining the need for corrective action.

The laboratory shall develop and implement a policy and procedures to guide the process of sterilization and quality control performance that addresses at least the following:

a) Receiving and cleaning of used items.
b) Preparation and processing.
c) Storage of clean and sterile supplies: properly stored in designated storage areas that are clean, dry, and protected from dust, moisture, and temperature extremes. Ideally, sterile supplies are stored separately from clean supplies, and sterile storage areas must have limited access.

d) Logbooks are used to record the sterilization process.
e) Expiration dates for sterilized items if present.
f) Sterilization quality control elements, method and frequency.
g) Sterilization quality control performance expectations and acceptable results shall be defined and readily available to staff.

Survey process guide:

- GAHAR surveyor may review laboratory policy guiding the process of sterilization and performance quality control.
- GAHAR surveyor may assess the laboratory presence of physically separated area according to the standard with unidirectional airflow, for the central sterilization processes.
- GAHAR surveyor may assess the laboratory availability of functioning laboratory autoclave and Decontamination pre-vacuum class B sterilizers, during visiting areas where sterilization is performed.
- GAHAR surveyor may assess the ability of involved laboratory staff members to perform the sterilization process properly.
- GAHAR surveyor may assess quality control procedures during visiting areas where sterilization is performed.
- GAHAR surveyor may review logbooks for biological indicators documentation for each autoclave

Evidence of compliance:

1. The laboratory has an approved policy to guide the sterilization processes and quality control performance, that addresses all elements mentioned in the intent from a) through g).
2. Laboratory staff members involved in sterilization are trained on the laboratory policy.
3. All laboratory supplies and clients care equipment should be sterile, and sterility is maintained.
4. Biological indicator test and control is done for each autoclave weekly.
5. Log book should be present and records are kept for each autoclave

Related standards:

IPC.01 IPC program, risk assessment, guidelines, IPC.05 Sterilization, laboratory autoclave, microbiology and cultures media, WFM.08 Continuing Education Program, IMT.02 Record management system.

IPC.06 The laboratory ensures Safe injection (sampling) practices.

Safety

Keywords:
Safe sampling practices

Intent:
Laboratory staff members safety should always be a priority within such settings, where certain procedures necessitate injections such as sampling procedures.

The Term " Laboratory sampling" refer to the process of collecting biological specimens, such as blood, urine, or tissue, from clients for the purpose of diagnostic testing and analysis. This procedure is critical, and should be done under strict protocols to maintain sample integrity as the accuracy of laboratory test results heavily depends on the quality of the collected samples.

Safe laboratory sampling practices are designed to prevent the transmission of infections and ensure the safety of both laboratory staff members and clients involved in various procedures.

Adherence to strict protocols is essential for safe sampling practices including: Using sterile equipment, preventing the reuse of needles/syringes, and ensuring that proper hand hygiene is practiced with proper PPE (sterile/clean gloves) use can significantly reduce the risk of transmitting bloodborne pathogens such as HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV). This protective measure not only safeguards laboratory staff but also protects clients from potential infections associated with unsafe sampling techniques.

The laboratory shall develop and implement a policy and procedures to guide safe sampling practices. That address at least the following:

a) Definitions: ("safe sampling practices," "sharps," "contaminated items," etc)
b) Purpose, which include preventing infections, ensuring safe handling of sharps and promoting a culture of safety within the laboratory.
c) Define roles and responsibilities of laboratory staff regarding safe sampling practices, including oversight responsibilities of laboratory supervisors to monitor compliance.
d) Pre-sampling procedures including Hand Hygiene – PPE (clean or sterile gloves)- preparation area.
e) Sampling technique.
f) Post-sampling practices including safe disposal of sharps. Disposal protocols: * Immediately dispose all used needles/syringes into designated puncture-resistant sharps containers.
g) Responsible laboratory staff members training.
h) Compliance Monitoring & tracking/reporting Incident related to unsafe injection practices and taking corrective actions.

Survey process guide:

- GAHAR surveyor may review laboratory policy and procedures guiding safe sampling practices.
- GAHAR surveyor may interview responsible laboratory staff members to check their awareness of laboratory policy.
- GAHAR surveyor may review responsible laboratory staff training records.
- GAHAR surveyor may observe responsible laboratory staff compliance with safe sampling practices.

Evidence of compliance:

1. The laboratory has approved policy and procedures guiding safe sampling practices that all addresses elements mentioned in the intent from a) to h).
2. Responsible laboratory staff members are trained on safe sampling practices.
3. Safe sampling practices are implemented within the laboratory.

Related standards:
IPC.01 IPC program, risk assessment, guidelines, IPC.02 Hand Hygiene, IPC.03 PPE, guidelines, Physical Barriers, WFM.08 Continuing Education Program.

IPC.07 Respiratory hygiene is implemented.

Safety

Keywords:
Respiratory Hygiene Protocol, cough etiquette

Intent:
Respiratory hygiene and cough etiquette interventions are intended to limit the spread of infectious organisms from stand-alone laboratory clients with potentially undiagnosed respiratory infections. For respiratory hygiene interventions to be effective, early implementation of infection prevention and control measures needs to exist at the first point of entry to the laboratory and be maintained throughout the duration of the stay.

The effort of respiratory hygiene interventions shall be targeted at clients and accompanying significant others with respiratory symptoms and applies to any person entering a laboratory with signs of respiratory illness, including cough, congestion, rhinorrhoea, or increased production of respiratory secretions. Respiratory hygiene and cough etiquette interventions (alcohol rub, tissues, surgical masks, and posters) should be present in all entries of the stand- alone laboratory and all waiting areas.

Survey process guide:
- GAHAR surveyor may observe the availability of respiratory hygiene/cough etiquette posters in appropriate places.
- GAHAR surveyor may assess accessibility and use of detergents, antiseptics, and disinfectants in the relevant areas and the availability and accessibility of the relevant resources in proper places.
- GAHAR surveyor may assess compliance with respiratory hygiene/cough etiquette within the laboratory.

Evidence of compliance:
1. Respiratory hygiene/cough etiquette supplies are displayed at appropriate places.
2. Resources such as tissues and surgical masks are available in numbers matching clients' and laboratory staff members' needs.
3. Respiratory hygiene/cough etiquette is implemented in stand-alone laboratory.

Related standards:
IPC.01 IPC program, risk assessment, guidelines, IPC.02 Hand Hygiene, IPC.03 PPE, guidelines, Physical Barriers, SCM.01 Supply Chain Management, SCM.02 Supplies selection, reception and inspection.

IPC.08 Current evidence-based aseptic techniques are followed during all laboratory procedures.

Safety

Keywords:
Sterile technique, Aseptic technique

Intent:
The aseptic technique refers to practices designed to render and maintain objects and areas maximally free from microorganisms. This technique prevents contamination from person to person, from one body site to another and from the environment to the clients.

The term 'aseptic technique' encompasses several key elements: a clean environment, practicing of hand hygiene, use of appropriate personal protective equipment, and use of standardized routine cleaning, disinfection, and sterilization practices.

All laboratory professionals shall be cognizant of their movement, barrier use, and practices to prevent inadvertent breaks in aseptic techniques, alerting others when the field or objects are potentially contaminated. The choice of the level of antisepsis shall be based on a risk assessment.
Procedural sterile technique to prevent the transfer of any organisms from one person to another or from one body site to another. The goal of the sterile technique is to maintain the microbe count at an irreducible minimum.
Procedural aseptic technique refers to a practice in the laboratory setting 0that may not have the capacity to follow the same strict level of sterile technique. However, the goal of avoiding infection remains in all laboratory sections.
Clean technique, refers to practice interventions that reduce the number of microorganisms to prevent and reduce transmission risk from one person (or place) to another.

The laboratory shall develop and implement an aseptic techniques policy and procedures based on current evidence-based guidelines and address at least the following:

a) Identification of risk procedures,
b) Types of aseptic techniques,
c) Clients preparation.

Survey process guide:

- GAHAR surveyor may review the laboratory policy guiding aseptic techniques.
- GAHAR surveyor may interview laboratory professionals to ask about how they choose and perform aseptic techniques properly in relevant laboratory sections.
- GAHAR surveyor may review laboratory professional's training records.
- GAHAR surveyor may observe the places and practices of performing aseptic techniques in the relevant laboratory sections.

Evidence of compliance:

1. Laboratory has approved aseptic techniques policy(s) and procedures that address all elements mentioned in the intent from a) to c).
2. Laboratory professionals are trained and educated on aseptic techniques relevant to their jobs and according to the policy.
3. Various aseptic techniques are performed in the laboratory according to evidence-based guidelines.
4. Clients preparation is done according to the type of procedures and the laboratory policy.

Related standards:

IPC.01 IPC program, risk assessment, guidelines, IPC.02 Hand Hygiene, IPC.03 PPE, guidelines, Physical Barriers, IPC.04 Environmental cleaning, evidence-based guidelines, WFM.08 Continuing Education Program.

Biosafety-Biosecurity plan

IPC.09 Laboratory biosafety and biosecurity plan is implemented.

Safety

Keywords:

Biosafety and biosecurity plan

Intent:

The term "Biosafety" means containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release.

The term " biosecurity" means securing hazardous material to prevent unauthorized possession, loss, theft, sabotage, misuse, diversion, and accidental or intentional release.

Laboratory biosafety and biosecurity activities are fundamental to protect the laboratory workforce and the wider community against unintentional exposures or releases of pathogenic biological agents.

Laboratory biocontainment measures should include the combination of physical design parameters and procedural practices.

There are three biocontainment elements:

1) Good laboratory practices: standard, special.
2) Safety equipment (primary barriers):
   - Personal protective items
   - Biological safety cabinets
   - Safety centrifuge cups
3) Facility safeguard (secondary barriers):
   - Separation of laboratory work area from public access
   - Decontamination facilities
   - Specialized ventilation systems

Biosafety cabinet play a vital role in stand-alone laboratories by providing essential containment and protection when handling potentially hazardous biological materials. Laboratories must choose the appropriate BSC class based on the risk level of the biological agents they are working with and ensure that they meet the necessary regulatory requirements and safety standards. Each level of BSC offers specific features and safety protocols to ensure the protection of laboratory personnel, the environment, and the integrity of the work being conducted. Proper usage, maintenance, and regular certification of BSCs are essential for maintaining safety in laboratory settings.

A table (1) summarizing the different classes of biosafety cabinets (BSCs) mentioned in Annex A.

The laboratory shall develop and implement biosafety plan that include at least the following:

a) The laboratory should assess the risk categories of potential biological exposure (microorganisms) managed within the setting and determines the corresponding biosafety level that aligns with these risk groups.
b) Proper transportation, handling and disposal of infectious biological material and waste.

c) At least one decontamination autoclave is present. Proper use, maintenance and calibration of the autoclave are ensured
d) All biohazard incidents (including lab. acquired infections) are reported and documented, and relevant corrective actions and improvement plans are constructed accordingly.
e) The laboratory staff members should receive relevant biosafety training programs. Training program should be documented.
f) The laboratory assigns personnel to oversee infection control biosafety policies and practices.

The laboratory shall develop and implement biosecurity plan that include at least the following:
I) Biosecurity policy
II) Biosecurity risk assessment
III) Types of laboratory biosecurity incidents
IV) Biosecurity measures based on the risk assessment
V) biosecurity control measures
VI) Information security

Survey process guide:

- GAHAR surveyor may review the updated laboratory biosafety and biosecurity plans to ensure that is based on risk assessment, covers all laboratory sections and includes all relevant individuals, and review the annual evaluation report.
- GAHAR surveyor may interview laboratory staff members to assess their awareness of the laboratory biosafety and biosecurity plans.
- GAHAR surveyor may review laboratory biohazard and biosecurity incidents, corrective actions and recommended improvement documentation and review staff training records
- GAHAR surveyor may assess implemented laboratory biosafety and biosecurity measures and availability of biosafety and biosecurity equipment.

Evidence of compliance**:**

1. The laboratory has an approved biosafety plan that addresses all elements mentioned in the intent from a) to f).
2. The laboratory has an approved biosecurity plan that addresses all elements mentioned in the intent from I) to VI).
3. Relevant laboratory biosafety and biosecurity practices are implemented.
4. All staff members are continuously educated and trained on laboratory biosafety and biosecurity plans.
5. When accidents occur, corrective actions are taken, documented, and reviewed.

Related standards:

IPC.01 IPC program, risk assessment, guidelines, IPC.02 Hand Hygiene, IPC.03 PPE, guidelines, Physical Barriers, IPC.04 Environmental cleaning, evidence-based guidelines, EMS.03 Calibration plan, EMS.04 Equipment maintenance, monitoring and failure management, WFM.08 Continuing Education Program, IMT.04 LIS security, unauthorized access and modifications, QPI.05 Risk Management plan/program.

Organization Governance and Management

Chapter intent:

Effective clinical laboratory head of departments hinges on a clear understanding of individual roles, responsibilities, and authority, and how these elements intertwine to ensure seamless collaboration. Those who govern, manage, and lead a laboratory hold both authority and responsibility, collectively and individually, for legal and regulatory compliance, and most importantly, for meeting the laboratory's crucial responsibility to the client population it serves. Strong head of departments fosters a positive environment, overcoming communication barriers and enhancing laboratory efficiency and effectiveness. This chapter explores governance, head of departments, and management in clinical laboratories. It emphasizes the importance of clear organizational structures and defined roles for effective head of department and accountability. It covers various governance models (ownership, committees, boards) and stresses that strong head of department, strategic planning, and clear communication are crucial for smooth laboratory operations.

The chapter highlights the need to understand stakeholder needs, align services with broader healthcare initiatives, and adapt to the evolving healthcare landscape, including value-based care and financial considerations. Finally, it addresses key organizational aspects like billing system, ethical management, and staff engagement, emphasizing collaborative management for a high-performing laboratory focused on quality client care.

Chapter purpose:

The chapter focuses on checking the laboratory structure resilience by looking into the following:

1) Effectiveness of governing body.
2) Effective organization direction.
3) Effective organization head of departments.
4) Effective financial management.
5) Safe, ethical, and positive organization culture.

OGM Summary of Changes

GAHAR Clinical Lab 2025	***GAHAR Clinical Lab 2021***	***Details of changes***
OGM.01 **KW:** Governing body Structure and responsibilities.	**OGM.01** **KW:** Governance structure **OGM.02** **KW:** Mission Statement. **OGM.03** **KW:** Governing body responsibility**.** **OGM.04** **KW:** Governing body performance. **OGM.05** **KW:** Effective communication with governing body.	**Updated** Standard by merging Five Standards (**OGM.01, OGM.02, OGM.03, OGM.04, OGM.05) in Clinical Laboratories 2021 Edition.**
OGM.02 **KW:** Laboratory Director.	**OGM.06** **KW:** Laboratory Director.	- **Modified Standard statement**: (A full-time qualified director is appointed by the governing body to manage the laboratory according to applicable laws and regulations). - **Modified** EOC**:** • **(EOC.01:** There is a job description for the laboratory director covering the requirements as mentioned in the intent from a) to i). - **Add new EOCs:** • **(EOC.03:** The laboratory identifies the proper communication channels between staff and laboratory head of department) • **(EOC.04:** The governing body receives a periodic report from the laboratory head of department. about quality, client safety, and performance measures at least annually.).

GAHAR Clinical Lab 2025	***GAHAR Clinical Lab 2021***	***Details of changes***
		-Rephrasing of EOC: • (EOC.05: There is evidence of delegation of authority when needed.)
OGM.03 **KW:** Strategic and operational Plans. .	**OGM.07** **KW**: Strategic and operational Plans.	- **Rephrasing of EOCs:** • **(EOC.01:** The laboratory has an approved strategic plan with defined goals and objectives**.)** • **(EOC.03:** The strategic plan is regularly reviewed.**)** • **(EOC.05:** Operational plans are reviewed at least annually.)
OGM.04 **KW:** Laboratory head of departments	**OGM.08** **KW:** Laboratory leaders. **OGM.10** **KW:** Departmental management.	- **Updated standard by merging two standards (OGM.08 & OGM.10) in Clinical Labs 2021.**
OGM.05 **KW:** Billing system		- **New Standard.**
OGM.06 **KW:** Ethical management	**OGM.11** **KW:** Ethical management	- **Modified Standard statement: (**The laboratory has an ethical management process.) - **Rephrasing** of EOC: (**EOC.03:** Ethical issues are discussed and managed according to the approved code of ethics and resolved within defined time frame). - **Modified** EOCs**:** - **(EOC.01:** The laboratory has an approved policy for ethical management that addresses at least a) to g) in the intent). - **(EOC.02:** Laboratory staff is aware of the ethical management policy and approved code of ethics.) - **(EOC.04:** Addressed ethical issues are used for education and staff professional development.).

GAHAR Clinical Lab 2025	***GAHAR Clinical Lab 2021***	***Details of changes***
OGM.07 **KW:** Safety Culture.	**OGM.12** **KW:** Safety Culture.	- **Modified Standard Statement: (**Head of each department create a culture of safety and quality within the laboratory). - **Modified** EOCs**:** - **(EOC.01:** Head of departments participate in regular safety audits). - **(EOC.02:** Head of departments support quality and safety initiatives, monitoring, and improvement activities.) - **(EOC.03:** Head of departments creates a just culture to encourage reporting errors and near misses.).
OGM.08 **KW:** Positive Workp Culture	**OGM.13** **KW:** Positive Workplace Culture	- **Modified** EOC: (**EOC.01:** The laboratory has an approved policy for positive workplace culture, that addresses at least a) to f) from the intent.) - **Add new EOC:** (**EOC.04:** There are communication channels between staff and Laboratory head of departments.)
OGM.09 **KW:** Staff health	**WFM.10** **KW:** Staff health	- **Rephrasing of Standard Statement**: (The laboratory has a staff health program that is monitored and evaluated annually according to laws and regulations.) - **Modified** EOCs**:** • **(EOC.01:** There is a staff health program according to laws and regulations that cover items a) to k) in the intent.) • **(EOC.03:** Staff members are educated about the risks within the laboratory environment, their specific job-related hazards, positive health promotion strategies, and periodic medical examinations.) - **Add new EOC:** (**EOC.04:** All staff members are subject to the immunization program and to work restrictions according to evidence-based guidelines, laws and regulations, all test results and

GAHAR Clinical Lab 2025	***GAHAR Clinical Lab 2021***	***Details of changes***
		immunizations are recorded in the staff health record.)
OGM.10 **KW:** Community needs and Initiatives.	**OGM.15** **KW:** Community Initiatives.	- **Modified Standard Statement: (**Laboratory services <u>are designed to meet</u> community needs and comply with international, national, regional, and local community initiatives**.)** - **Modified** EOCs**:** • **(EOC.01:** The laboratory <u>services</u> reflect alignment with international, regional, and/or national community initiatives). • **(EOC.02:** <u>All staff</u> is aware of laboratory community initiatives). - **Add new EOC:** (**EOC.03:** The laboratory aligns the services provided with the assessed community health needs).

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

Effective governing body

OGM.01 The laboratory has a defined governing body structure, responsibilities, and accountabilities.

Effectiveness

Keywords:

Governing body Structure and responsibilities.

Intent

The governing body is responsible for defining the laboratory direction and ensuring the alignment of its activity with its purpose. It is also responsible for monitoring its performance and future development.

In order to ensure the proper governance and efficient management of any organization, its structure has to be well-defined, and members of the governing body are identified by title and name. The governing entity is represented or displayed in an organizational chart that clearly defines lines of authority and accountability. A governing body should be diverse, reflect the community's interests and desired competencies, and evaluate its performance annually. The governing body meets at set intervals, with meeting minutes recorded.

It should consider that in a centralized system, one governing body governs several subsidiary organizations. On the other hand, a governing body can be a board of directors, or a single owner in the case of the private sector. A clear two-way communication process between governance and management, usually between the head of the governing body and the laboratory director, enhances the laboratories well-being.

The governing body responsibilities shall be defined and directed towards the laboratories principal stakeholders and shall include:

a) Defining the laboratory mission, vision and values.
b) Support, promotion, and monitoring of performance improvement, Client safety, risk management efforts, and safety culture.
c) Setting priorities for activities to be executed by the laboratory; The process of prioritization among selected activities follows this process of selection.
d) Prioritization criteria should be known to all to ensure a fair and transparent resource allocation process.
e) Approval of:
    i. The laboratory strategic plan.
    ii. The operational plan and budget, capital investments.
    iii. The quality improvement, Client safety, and risk management programs.
    iv. Community assessment and involvement program.

By fulfilling these responsibilities, the governing body ensures the laboratory operates efficiently, provides high-quality care, and meets its commitments to Clients, staff, and the community.

To ensure effective governance, the governing body should evaluate its performance annually and provide ongoing education and development opportunities for board members to stay informed about healthcare trends and governance practices.

Survey process guide:

- GAHAR surveyor may review the laboratory organization chart.

- GAHAR surveyor may interview head of departments to check their awareness of the governing body roles and responsibilities.
- GAHAR surveyor may review the related documents and checking their details and approvals in addition to reviewing monitoring reports of the approved plans.
- GAHAR surveyor may observe the mission statement posters, brochures, or documents focusing on its last update, approval, alignment and visibility.
- GAHAR surveyor may review the strategic plan, operational plans, budget, quality improvement, and risk management programs.
- GAHAR surveyor may review evidences of open defined communication channels, frequency of communication and evidence of feedback to submitted reports on both sides.

Evidence of compliance:

1. The governing body structure is represented in the laboratory organization chart.
2. The governing body meets at predefined intervals and minutes of meetings are recorded.
3. The laboratory has vision and mission statements approved by the governing body and are visible in public areas to staff, clients, and visitors.
4. The governing body has defined its responsibilities and accountabilities as mentioned in the intent from a) to e) and has a process for resources allocation that includes clear criteria for selection and prioritization.
5. The strategic plan, operational plans, budget, quality improvement, and risk management programs are approved, monitored, and updated by the governing body.
6. The governing body members and laboratory head of departments are aware of the process of communication and approve the communication channels.

Related standards:

APC.03 Sustaining compliance with accreditation standards, OGM.02 Laboratory Director, OGM.03 Strategic and operational Plans, OGM.04 Laboratory head of departments, QPI.01 Quality improvement plan

Effective organization direction

OGM.02 A full-time qualified director is appointed by the governing body to manage the laboratory according to applicable laws and regulations.

Effectiveness

Keywords:

Laboratory Director.

Intent

Any organization needs an executive that is responsible and accountable for implementing the governing board's decisions and to act as a link between the governing board and the laboratory staff. Such a position requires a dedicated qualified director guided by relevant laws and regulations and/or as further defined by the governing board.

The laboratory shall appoint a full-time qualified director and define any head of department delegation authority for managing the laboratory in the absence of the laboratory director.

The laboratory director has appropriate training and/or experience in laboratory management, as defined in the job description.

The laboratory director responsibilities include at least the following:

a) Providing oversight of day-to-day operations
b) Ensuring clear and accurate posting of the laboratory services and hours of operation to the community
c) Ensuring that policies and procedures are developed, implemented by laboratory staff and approved by the governing body.
d) Providing oversight of human, financial, and physical resources.
e) Evaluating the laboratory's performance annually
f) Ensuring appropriate response to reports from any inspecting or regulatory agencies, including accreditation.
g) Ensuring that there is a functional, organization-wide program for performance improvement, Client safety and risk management with appropriate resources.
h) Setting a framework to support coordination within and/or between departments or units, as well as a clear process of coordination with relevant external services.
i) Regular reports to the governing body on how legal requirements are being met.

Achieving the mission of laboratory depends on collaboration and active participation. This involves sharing knowledge and engaging staff in decision-making. Communication channel serve as a means to combine the diverse knowledge and skills from various parts of the laboratory, enabling effective decision-making. Laboratories need to define the types of communication channels between the governing body, the head of department team, and the laboratory staff.

Survey process guide:

- GAHAR surveyor may review the laboratory director's job description.
- GAHAR surveyor may review the laboratory director staff file to check compliance with all required documents of training, job description, roles, and responsibilities.
- GAHAR surveyor may review an authority matrix or delegation letters for tasks that the laboratory director delegated to any other staff member or committees.
- GAHAR surveyor may interview the laboratory director to check his awareness of his responsibilities.

Evidence of Compliance:

1. There is a job description for the laboratory director covering the requirements as mentioned in the intent from a) to i).
2. The laboratory director has appropriate training and/or experience as defined in the job description.
3. The laboratory identifies the proper communication channels between staff and laboratory head of department.
4. The governing body receives a periodic report from the laboratory head of department. about quality, client safety, and performance measures at least annually.
5. There is evidence of delegation of authority when needed.

Related standards:

APC.03 Sustaining compliance with accreditation standards, OGM.01Governing body Structure and responsibilities, OGM.03 Strategic and operational Plans, OGM.04 Laboratory head of departments, OGM.07 Safety Culture, WFM.04 Job Description, QPI.01 Quality improvement plan, QPI.02 Performance measures

OGM.03 Strategic and operational plans are developed under oversight and guidance of the governing body.

Effectiveness

Keywords:
Strategic and operational Plans.

Intent:
Strategic planning is a process of establishing a long-term plan to achieve an organization's specified vision and mission through the attainment of high-level strategic goals.
A strategic plan looks out over an extended time horizon from three to five years or more. The plan establishes where the organization is currently, where head of department wants to go, how they will get there and how they will know when they have achieved their strategic goals. A strategic plan might be established on a higher level (governing body) with the involvement of laboratory head of departments.
The governing body shall approve the strategic plan, and resource allocation for implementation within the laboratory.
The strategic plan should be reviewed regularly to discuss the progress of goals and objectives and make the necessary adjustments for the upcoming years.
Operational plans are the means through which organization fulfil its mission. They are detailed, contain specific information regarding targets, related activities and needed resources within a timed framework. Head of departments establish operational plans that include at least the following:

a) Clear goals and objectives (SMART objectives).
b) Specific activities and tasks for implementation.
c) Timetable for implementation
d) Assigned responsibilities
e) Sources of required budget
f) Means for measuring achievement

The operational plans should be approved by the governing body and shall link to the other plans within the laboratory. Head of departments regularly evaluate the operational plans annually for services provided to identify facility and equipment needs for the upcoming operational cycle. Operational plan progress reports are reviewed and utilized in the next planning cycle. Every planning cycle ends with analysis phase where planners review what worked well and what didn't. These insights, often called "lessons learned," help refine future plans, leading to continuous improvements in laboratory performance.

Survey process guide:

- GAHAR surveyor may review the laboratory's strategic plan.
- GAHAR surveyor may interview the laboratory head of departments to check their involvement and participation in the development of the strategic plan.
- GAHAR surveyor may interview staff and head of departments to check their awareness of the operational plan and participation in developing related strategic and operational plans and give them the opportunity to talk about their inputs and how they are communicated.
- GAHAR surveyor may review the evidence of monitoring operational plan progress/ progress reports, and actions taken to improve performance.

Evidence of Compliance:

1. The laboratory has an approved strategic plan with defined goals and objectives.

2. Participation of staff, laboratory head of departments, community, and other identified stakeholders in the strategic plan is documented.
3. The strategic plan is regularly reviewed.
4. The laboratory has operational plans that includes items from a) to f) in the intent.
5. Operational plans are reviewed at least annually.

Related standards:
APC.03 Sustaining compliance with accreditation standards, OGM.01Governing body Structure and responsibilities, OGM.02 Laboratory Director, OGM.04 Laboratory head of departments

Effective organization head of department

OGM.04 The responsibilities and accountabilities of the head of departments are identified.

Effectiveness

Keywords:
Laboratory head of departments.

Intent:
An effective and efficient department/service heads ensures that department services are known and are aligned with other departments services and that there are adequate resources to offer them.
Each department or service (e.g.: chemistry, microbiology, haematology, sampling, inventory …) shall have a qualified staff member responsible for delivering the required services as defined by the organization mission and related plans to ensure alignment between departments/services and with the laboratory as a whole.
The responsibilities of the designated head of each department and service are defined in writing and include at least the following:

a) Sustaining a firm laboratory structure:
   i. Planning for upgrading or replacing systems, buildings, or components needed for continued, safe, and effective operation.
   ii. Collaboratively developing a plan for staffing the laboratory that identifies the numbers, types, and desired qualifications of staff according to workload and approved scope of service.
   iii. Defining a written description of the services provided by the department (scope of service).
   iv. Defining education, skills, and competencies needed by each category of staff.
   v. Ensuring that there is a department specific orientation and continuing education program for the department's staff.
   vi. Ensuring all required policies, procedures, and plans have been developed and implemented.
   vii. Providing adequate space, equipment, and other resources based on strategic and operational plans and needed services.
   viii. Selecting equipment and supplies based on defined criteria that include quality and cost-effectiveness.

b) Running smooth directed operations
   i. Creating a "Just Culture" for reporting errors, near misses, and complaints, and using the information to improve the safety of processes and systems.

ii. Designing and implementing processes that support continuity, coordination of care, and risk reduction.
iii. Ensuring that services are developed and delivered safely according to applicable laws and regulations and approved organization strategic plan with input from the users/staff.
iv. Ensuring coordination and integration of these services with other departments when relevant.

c) Continuous monitoring and evaluation
   i. Ensuring that all quality control is implemented, monitored, and action is taken when necessary.
   ii. Ensuring that the department's/service's performance is monitored and reported annually to head of department.
   iii. Ensuring the laboratory meets the conditions of facility inspection reports or citations.
   iv. Annually assessing the operational plans of the services provided to determine the required facility and equipment needs for the next operational cycle.
   v. Annually reporting to the laboratory governing body or authority on system or process failures and near misses, and actions are taken to improve safety, both proactively and in response to actual occurrences. The laboratory data are reviewed, analyzed, and used by management for decision-making.

d) Continuous Improvement
   i. Ensuring that the department is involved in the performance improvement, client safety and risk management program(s).

Survey process guide:

- GAHAR surveyor may interview laboratory head of departments to check their awareness of their roles and their responsibilities.
- GAHAR surveyor may review the laboratory head of departments' job descriptions and periodic reports.

Evidence of compliance:

1. The laboratory has a valid job description for each laboratory head of department to identify the required qualification and responsibilities.
2. There is a head for each department of the laboratory who is qualified as required by the job description.
3. The responsibilities of the departments/ services heads include at least a) to d) in the intent.
4. Departments and services heads are aware of and perform their responsibilities.
5. Departments and services heads submit periodic reports on their activities

Related standards:

OGM.02 Laboratory Director, WFM.04 Job Description, WFM. 06 Staff Files, OGM.03 Strategic and operational Plans, OGM.07 Safety Culture, QPI.01 Quality improvement plan,QPI.02 Performance measures, QPI.06 Incident Reporting System.

Effective financial management

OGM.05 The laboratory manages a client billing system.

Efficiency

Keywords:

Billing system

Intent:

The billing process is a crucial component of laboratory management. Due to its complexity, billing errors can lead to significant financial losses, these errors may arise from missing or incorrect invoices for laboratory materials, missing barcodes, or inaccurate test result reports.

The billing process includes that all of the services and items provided to the client are recorded in the client's account, then all information and charges are processed for billing. For third-party payer systems, the process for billing is based on the requirements of insurance companies/agencies, which generally have reimbursement rules.

The laboratory shall develop a policy and procedures for the billing process addresses at least the following:

a) Availability of an approved price list.
b) Clients are informed of any potential costs related to requested laboratory services.
c) A process is in place to ensure accurate billing.
d) Use of accurate and approved coding for laboratory tests (when applicable).

Survey process guide:

- GAHAR surveyor may review the approved policy for the billing process and price list(s).
- GAHAR surveyor may observe the presence of the price list for all services displayed in all related areas.
- GAHAR surveyor may interview billing staff and some clients to check their awareness of the policy and the different payment methods.

Evidence of compliance:

1. The laboratory has an approved policy for the billing process includes the items mentioned in the intent from a) to d).
2. Billing staff are oriented on various health insurance processes.
3. There is an approved price list for the provided laboratory services.
4. Clients are informed of any potential costs related to the requested laboratory tests.
5. The laboratory uses accurate and approved codes for laboratory tests (when applicable).
6. In the case of a third-party payer (or health insurance), the timeliness of approval processes is monitored.

Related standards:

PCC.02 Client and family rights, OGM.02 Laboratory Director, IMT.01Documentation management system, OGM.04 Laboratory head of departments.

Safe, ethical, and positive organization culture

OGM.06 The laboratory has an ethical management process.

Safety

Keyword
Ethical management

Intent:
Laboratory ethics involves examining a specific problem, usually a test report, and using values, facts, and logic to decide what the best course of action should be.
Laboratory staff may deal with a variety of ethical problems for example conflict of interest and inequity of clients' care. The laboratory shall ensure impartiality by avoiding conflicts of interest and ensuring all decisions are made objectively and fairly.
The policy of the laboratory ethical management addresses at least the following:

a) Developing and implementing the code of ethics
b) Developing and implementing of laboratory values
c) Handling errors that affect the client and medico-legal case.
d) Developing client confidentiality rules
e) Identifying and disclosing conflict of interest
f) Management of discrimination, and harassment.
g) Ensuring impartiality and gender equality.

When conducting research involving specimen testing, formal approval from an ethics committee must be obtained. The laboratory shall establish and maintain a framework promoting ethical decision-making, integrity, and compliance with legal and professional standards.

Survey process guide:

- GAHAR surveyor may review policy of ethical management.
- GAHAR surveyor may interview staff to inquire about code of ethics and handling of errors.

Evidence of Compliance:

1. The laboratory has an approved policy for ethical management that addresses at least a) to g) in the intent.
2. Laboratory staff is aware of the ethical management policy and approved code of ethics.
3. Ethical issues are discussed and managed according to the approved code of ethics and resolved within defined time frame.
4. Addressed ethical issues are used for education and staff professional development.

Related standards:
APC.02 Professional standards during surveys, PCC.02 Client and family rights, PCC.04 Client and health education materials, OGM.01Governing body Structure and responsibilities, OGM.02 Laboratory Director, OGM.04 Laboratory head of departments, WFM.08 Continuing Education Program

OGM.07 Head of each department create a culture of safety and quality within the laboratory.

Effectiveness

Keywords:
Safety Culture.

Intent:
Creating a culture of safety and quality within a laboratory requires strong head of department commitment, effective communication, and a sustained effort to ensure Client safety and continuous improvement. There are several strategies to improve such a culture. The laboratory can adopt some of the following measures:

a) Lead by example
b) Open communication
c) Provide resources to support high-quality care delivery.
d) Training and education
e) Establish a blame-free environment where errors and near misses are treated as learning opportunities.
f) Recognize and reward individuals and teams for their contributions to safety and quality.
g) Head of department safety audits
h) Use data to drive decisions and identify trends.
i) Sustain focus on the importance of safety and quality and share success stories, and celebrate milestones.

A no-blame culture emphasizes the importance of learning from mistakes and preventing future errors without assigning blame or punishment, while a just culture is a culture where individuals are accountable for their willful misconduct or gross negligence. A just culture helps create an environment where individuals feel free to report errors and help the organization learn from mistakes. The focus is on identifying system failures, improving processes, and promoting open communication.

Survey process guide:

- GAHAR surveyor may review records of head of departments' safety rounds to assess the process.
- GAHAR surveyor may interview staff to check support of quality initiatives and safety culture.
- GAHAR surveyors may interview head of departments to check their awareness of the measures to promote client safety and quality culture.

Evidence of Compliance

1. Head of departments participate in regular safety audits.
2. Head of departments support quality and safety initiatives, monitoring, and improvement activities.
3. Head of departments creates a just culture to encourage reporting errors and near misses.

Related standard:
OGM.02 Laboratory Director, OGM.04 Laboratory head of departments, OGM.08 Positive Workplace culture, QPI.06 Incident Reporting System, QPI.05 Risk Management plan/Program

OGM.08 The laboratory ensures positive workplace culture.

Effectiveness

Keywords:
Positive Workplace Culture

Intent:
Studies highlighted the importance of attention to healthcare professional needs for a safe and comfortable work environment.
The laboratory develops a policy and procedures of positive workplace culture.
The policy shall address at least the following:

a) Workplace cleanliness, safety and security measures
b) Management of workplace violence, discrimination, and harassment.
c) Communication channels between laboratory head of departments and staff.
d) Staff feedback measurement, including suggestions for provided services improvement or planning new services.
e) Planning for staff development.
f) Turnover preventive measures e.g. (fair salaries, health benefits, and incentives).

Survey process guide:

- GAHAR surveyor may review approved policy for positive workplace culture.
- GAHAR surveyor may observe cleanliness, safety, and security measures in workplaces.
- GAHAR surveyor may interview staff to inquire about workplace incidents related to this standard.

Evidence of compliance:

1. The laboratory has an approved policy for positive workplace culture, that addresses at least a) to f) from the intent.
2. The workplace is clean, safe, and security measures are implemented.
3. Management of workplace violence, discrimination, and harassment measures are implemented.
4. There are communication channels between staff and Laboratory head of departments.
5. Staff feedback and satisfaction are measured on regular basis.

Related standards:
EFS.01Laboratory environment and facility safety, EFS.05 Safety and security management plan, OGM.04 Laboratory head of departments, OGM.07 Safety Culture, WFM.11 Working Hours, WFM.10 staff performance evaluation, OGM.09 staff health, QPI.02 Performance measures,

OGM.09 The laboratory has a staff health program that is monitored and evaluated annually according to laws and regulations.

Safety

Keywords:
Staff health

Intent:
The laboratory shall implement a staff health program to ensure the safety of the staff according to workplace exposures.
A cornerstone of the staff occupational health program is the hazard/risk assessment, which identifies the hazards and risks related to each occupation. This is done in order to take the necessary steps to control these hazards, minimize possible harm arising and, if not possible, lessen its negative sequelae. This is achieved through a laboratory -wide risk assessment program that identifies high-risk areas and processes. The program scope covers all staff and addresses at least the following:

a) Pre-employment medical evaluation of new staff.
b) Periodic medical evaluation of staff members.
c) Screening for exposure and/or immunity to infectious diseases.
d) Exposure control and management to work-related hazards, such as:
    i. Ergonomic hazards that arise from the lifting and transfer of heavy objects or equipment, strain, repetitive movements, and poor posture.
    ii. Physical hazards such as lighting, noise, ventilation, electrical, and others.
    iii. Biological hazards such as body fluids, fresh tissues, pathogens and others.
    iv. Chemical hazards such as fumes of chemicals.
e) Staff education on the risks within the laboratory environment as well as on their specific job-related hazards.
f) Positive health promotion strategies, such as smoking cessation or encouraging physical activity (if applicable).
g) Scheduling of regular staff vaccination (as indicated).
h) Recording and management of staff incidents (e.g., injuries or illnesses, taking corrective actions, and setting measures in place to prevent recurrences).
i) When indicated, specific medical evaluation (tests and examinations) is required for staff members to evaluate their appropriateness for safe performance. The situational examination is recorded in staff health records, and action is taken when there are positive results, including employee awareness of these results and provision of counseling and interventions as might be needed.
j) Infection control staff shall be involved in the development and implementation of the staff health program as the transmission of infection is a common and serious risk for both staff and Clients in healthcare facilities.
k) All staff occupational health program-related results (medical evaluation, immunization, work injuries) shall be recorded and kept according to laws and regulations.

Survey process guide:

- GAHAR surveyor may interview staff members who are involved in developing and executing staff health program to check program structure, risks, education and orientation records.
- GAHAR surveyor may interview staff members to check their awareness of the risks within the laboratory environment, their specific job-related hazards, positive health promotion strategies, and periodic medical examinations.

- GAHAR surveyor may review a sample of staff health records to ensure documentation of all test results and immunizations.

Evidence of compliance:

1. There is a staff health program according to laws and regulations that cover items a) to k) in the intent.
2. There is an occupational health risk assessment that defines occupational risks within the laboratory.
3. Staff members are educated about the risks within the laboratory environment, their specific job-related hazards, positive health promotion strategies, and periodic medical examinations.
4. All staff members are subject to the immunization program and to work restrictions according to evidence-based guidelines, laws and regulations, all test results and immunizations are recorded in the staff health record.
5. Post-exposure prophylaxis and interventions are implemented and recorded.
6. There is evidence that actions are taken, and employees are informed in case of positive results.

Related standards:

EFS.05 Safety and security management plan, IPC.01 IPC program, risk assessment, guidelines, IPC.03 PPE, guidelines, Physical Barriers, IPC.09 Biosafety and biosecurity plan, QPI.05 Risk Management plan/program.

Community initiatives

OGM.10 Laboratory services are designed to meet community needs and comply with international, national, regional, and local community initiatives.

Effectiveness

Keywords:

Community needs and Initiatives.

Intent:

A community consists of individuals, families, facilities, or organizations that interact, cooperate in common activities, and address mutual concerns, typically within the geographic area served by a laboratory. Laboratories should align their services with community health needs while adhering to national, international, regional, and local healthcare initiatives.

The laboratory shall develop and implement a plan for community assessment and involvement initiatives such as Implementation of international women health, oncology, and diabetes health initiatives, or the national initiatives of Universal Health Insurance, 100 Million Healthy Lives or others.

Laboratory service planning shall be aligned with community health needs and may include evaluating prevalent health conditions, identifying gaps in diagnostic services, and adapting capabilities to support public health priorities. The laboratory utilizes information gathered from primary and/or secondary sources to assess the health needs of targeted populations, and decide which services to provide or update existing service packages accordingly. Primary data is data directly collected through surveys of citizens and providers, interviews, focus groups, etc. Secondary data is data obtained from other entities such as vital statistics, registries, censuses, etc.

Survey process guide:

- GAHAR surveyor may review community involvement plan to check that is it aligned with other initiatives and with laws and regulations.
- GAHAR surveyor may interview laboratory head of departments to inquire about the community health needs assessment during the head of department interview session.
- GAHAR surveyor may interview staff to check their awareness of community initiatives.

Evidence of compliance:

1. The laboratory services reflect alignment with international, regional, and/or national community initiatives.
2. All staff is aware of laboratory community initiatives.
3. The laboratory aligns the provided services with the assessed community health needs.
4. The community involvement plan is updated periodically to meet the needs of the community.

Related standards:

PCC.01 Multidisciplinary client-centeredness, PCC.06 Client and family feedback, PCC.07 Complaints and suggestions, OGM.01 Governing body Structure and responsibilities

Supply Chain Management

Effective supply chain management is critical for clinical laboratories to ensure the timely availability of high-quality diagnostic services. This chapter explores the essential components of a robust laboratory supply chain, encompassing the entire process from order placement to reagent utilization. A well-functioning supply chain directly impacts the laboratory's ability to deliver accurate and reliable results, thereby influencing client care and overall healthcare outcomes. The supply chain management chapter addresses key aspects including the selection and management of laboratory supplies and suppliers, adherence to stringent quality control measures for reagents, and the meticulous tracking of reagent usage. Furthermore, it addresses the critical role of contracted services, outlining best practices for service agreements, scope definition, and performance monitoring.

The chapter concludes by recognizing the significant impact of referral laboratories on overall service quality. It details the laboratory's responsibility in selecting, monitoring, and ensuring the quality of externally performed services which is crucial to ensure quality of results directly affect client safety, satisfaction, and retention.

Chapter purpose:

1. To ensure efficient supply chain management.
2. To ensure effective Inventory management system.
3. To highlight the laboratory responsibility in managing service agreement and referral laboratory services.

SCM Summary of Changes

GAHAR Clinical Lab 2025	***GAHAR Clinical Lab 2021***	***Details of changes***
SCM.01 **KW:** Supply Chain Management	**SCM.01** **KW:** Laboratory Suppliers.	- **Modified Standard statement**: (The laboratory defines supply chain management processes). - **Modified** EOCs**:** • **(EOC.01:** The laboratory has an approved procedure for supply chain management that addresses all elements mentioned in intent from a) through e). • **(EOC.02:** Responsible staff is aware of the supply chain management procedure.) • **(EOC.04:** Suppliers are monitored and evaluated at least annually.) - **Add new EOCs: (EOC.03:** The supply chain processes are recorded, monitored, and evaluated)
SCM.02 **KW:** Supplies selection, reception and inspection	**SCM.02** **KW:** Supplies reception and inspection. .	- **Modified Standard statement**: (Laboratory develops a process for selecting, receiving, and inspecting reagents and supplies before being placed in service.) - **Modified EOCs:** • **(EOC.01:** The laboratory has approved procedures that describe the process of reagents, materials and services selection, reception, and inspection). • **(EOC.02:** Staff is aware of reagents / supplies selection, reception and inspection process and corrective actions when needed.). • **(EOC.04:** Records for reception and inspection process includes items mentioned in intent from a) to d).
SCM.03 **KW:** Inventory management.	**SCM.03** **KW**: Inventory management.	- **Modified EOC:(EOC.01:** The laboratory has an approved procedure that describes the inventory management system.)

GAHAR Clinical Lab 2025	***GAHAR Clinical Lab 2021***	***Details of changes***
		- **Add new** EOC**: (EOC.02:** Staff is aware of the inventory management procedure.)
SCM.04 **KW:** Supplies requesting and dispatching.	**SCM.04** **KW:** Supplies requesting and dispatching	- **Modified EOCs:** • **(EOC.01:** The laboratory has approved procedures that describe the process of requesting and dispatching reagents and supplies includes elements mentioned in intent from a) to e). • **(EOC.02:** Responsible staff is aware of reagent requesting and dispatching process). - **Add new** EOCs**:** • **(EOC.03**: Records are updated after each dispatching process). • **(EOC.04:** Laboratory rules for dispatching material are followed.)
SCM.05 **KW:** Contracted services.	**SCM.05** **KW:** Contracted services.	- **Modified EOCs:** • **(EOC.01:** There is a list of all contracted providers). • **(EOC.04:** There are evaluation criteria for monitoring the contracted services includes elements mentioned in intent from a) to e). • **(EOC.05:** Each contract is evaluated at least annually to determine if it should be renewed, amended or terminated).
SCM.06 **KW:** Referral laboratory	**SCM.06** **KW:** Referral laboratory.	- **Modified EOCs:** • **(EOC.01:** The laboratory has an approved procedure that describe process for selection and evaluation of referral laboratories). • **(EOC.03:** The selected laboratory meets the selection criteria includes elements mentioned in intent from a) to f). - **Add new** EOC**:(EOC.06**: The referral laboratory is evaluated before, during, and upon renewal of the contract or at least annually, and actions are taken).

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

Efficient Supply chain management

SCM.01 The laboratory defines supply chain management processes.

Efficiency

Keywords:
Supply Chain Management

Intent:
The supply chain generally refers to the resources required to deliver goods or services to a consumer. An effective supply chain allows the laboratory to deal with emergency situation and find solution in short time.
In laboratories, the supply chain involves multiple stakeholders, including Suppliers and service providers (e.g.: suppliers for equipment, supplies, reagents and services), manufacturers, procurement teams, and regulatory bodies. Both physical materials, such as reagents and equipment, and critical information regarding product specifications, compliance, and inventory management should flow seamlessly across these entities to ensure uninterrupted laboratory operations.
Selecting the best supplier is a cornerstone step for the laboratory to ensure Quality of supplies and other services. It is also essential for maintaining commitment and ensuring an uninterrupted supply chain process.
The laboratory shall develop procedure for Supply Chain Management that addresses at least the following:

a) Supplier's identification and selection process.
b) Suppliers are monitored and evaluated to ensure that the purchased supplies are provided from reliable sources that refrain from dealing with counterfeit, smuggled, or damaged supplies.
c) Suppliers are also evaluated based on their response upon request, quality of received materials, check for matching predefined acceptance criteria.
d) Laboratory supplies are monitored and evaluated to ensure that no recalled reagents, supplies, equipment, or devices are used.
e) Transportation of supplies is monitored to ensure that it occurs according to applicable laws and regulations, approved organization procedures, and manufacturer's recommendations.

Survey process guide:

- GAHAR surveyor may review the supply chain management procedure.
- GAHAR surveyor may interview the responsible staff to check their awareness of the supply chain management procedure.
- GAHAR surveyor may review a sample of supply chain records to check, assess, and evaluate the process.

Evidence of compliance:

1. The laboratory has an approved procedure for supply chain management that addresses all elements mentioned in intent from a) through e).
2. Responsible staff is aware of the supply chain management procedure.
3. The supply chain processes are recorded, monitored, and evaluated.
4. Suppliers are monitored and evaluated at least annually.

Related standards:
OGM.02 Laboratory Director, OGM.04 Laboratory head of departments, EMS.01Equipment management plan

SCM.02 The Laboratory develops a process for selecting, receiving, and inspecting reagents and supplies before being placed in service.

Efficiency

Keywords:
Supplies selection, reception and inspection.

Intent:
Materials, supplies, and services are essential inputs that affect the quality of results and services being produced. Selecting reagents and supplies for the laboratory requires a comprehensive approach that considers quality, compatibility, supplier reputation, cost, safety, and regulatory compliance.
Before acceptance and use of materials, reagents, supplies or services, it should be inspected and tested to ensure that it meets specifications for their intended use.
It is essential that supplies used in the collection, processing, preservation, testing, storage, distribution and transport of specimens meet predefined acceptance criteria.
Laboratories shall develop procedures to control and prevent inadvertent acceptance and use of materials, reagents and services that do not meet specifications.
Corrective action may include returning the material to the vendor or destroying it. Reception and inspection records provide the facility with means to trace materials that have been used in a particular process and also provide information for ongoing supplier evaluation.
Records of the reception and inspection process include at least the following:

a) Date and time of reception.
b) Quantities, lot numbers and expiration dates.
c) Check for meeting predefined acceptance criteria.
d) Actions taken in the event of unsatisfactory shipment or service and unacceptable reagent and supplies.

Survey process guide:

- GAHAR surveyor may review the procedure and records of inspection and reception of supplies and reagents before being introduced in to the service to ensure implementation of the procedures.
- GAHAR surveyor may review list of reagents, supplies, and services.
- GAHAR surveyor may interview relevant staff members to assess compliance with supplies reception and inspection process requirements.

Evidence of Compliance:

1. The laboratory has approved procedures that describe the process of reagents, materials and services selection, reception, and inspection.
2. Staff is aware of reagents / supplies selection, reception and inspection process and corrective actions when needed.
3. There is a current list of reagents, supplies, and services including the name of supplier and the equipment used.
4. Records for reception and inspection process includes items mentioned in intent from a) to d).

Related standards:
SCM.01 Supply Chain Management, SCM.03Inventory management, OGM.02 Laboratory Director, OGM.04 Laboratory head of departments.

Effective Inventory management system

SCM.03 An effective inventory management system is developed and implemented.

Effectiveness

Keywords:
Inventory management.

Intent:
Inventory management system is an essential part of maintaining laboratory function and Minimize emergency requesting of reagent and supplies.
It is also important to ensure the quality of reagent and keep it from destruction and deterioration with monitoring the use and the safety limit to be implemented. The laboratory develops a procedure for an inventory management system to ensure that the storage is under monitored conditions. proper storage condition criteria for laboratory reagents are crucial for maintaining their stability, efficacy, and safety by considering factors such as temperature, light exposure, humidity, and safety regulations as specified by the manufacturer and in compliance with laws and regulations. The laboratory maintains records fulfilling at least the following:

a) Stock quantity
b) Reception date
c) Expiration date
d) Lot number of the reagents/supplies
e) Status of the reagents/supplies (accepted or under testing)
f) Date placed in service or disposition, if not used.

Supplies and reagents storage conditions are continuously monitored using an appropriate temperature and humidity, monitoring/recording system and in a manner that prevents damage, deterioration or contamination. The laboratory defines a safety limit for reordering each reagent/supply to ensure uninterrupted service.

Survey process guide:

- GAHAR surveyor may review the procedure describing inventory management system.
- GAHAR surveyor may review the records of the inventory for reagent tracking and monitoring.
- GAHAR surveyor may observe supplies and reagents storage conditions in compliance with the good storage practice.
- GAHAR surveyor may interview staff members who are involved in inventory management to check their awareness.

Evidence of Compliance:

1. The laboratory has an approved procedure that describes the inventory management system.
2. Staff is aware of the inventory management procedure.
3. Records of monitoring storage conditions includes elements mentioned in intent from a) to f).
4. Reordering supplies/reagents are according to the defined safety limit.

Related standards:
SCM.01 Supply Chain Management, SCM.04 supplies requesting and dispatching, EFS.05 Safety and security management plan

SCM.04 Reagents and supplies are requested and dispatched through a controlled process.

Efficiency

Keywords:

Supplies requesting and dispatching.

Intent:

Requesting and dispatching of reagents is important to avoid unnecessary use of reagent. It is also important for the laboratory to avoid emergency requesting and presence of expired kits. Evaluation of work load and time of peak during the year is important for adjusting the safety limit. The laboratory develops a procedure to maintain best inventory management process. The procedure for requesting and dispatching reagents or other supplies shall fulfil at least the following:

a) Identifies the personnel who is responsible for requesting and dispatching the laboratory materials.
b) Developing rules for dispatching material depend on the date of receiving and the date of expiry (e.g.: FEFO: first expire first out).
c) Implement plan for dispatching and updating the stored material on certain interval (e.g.: weekly).
d) Updating the store records after each dispatching to ensure that the list is correct and revised.
e) Implement a periodic check by the designee to evaluate the storage management process.

Survey process guide:

- GAHAR surveyor may review the procedure including the requesting and dispatching of reagents and supplies.
- GAHAR surveyor may review the records of the inventory to ensure that the reagents and other supplies are requested and dispatched properly.
- GAHAR surveyor may observe reagent dispatching process in the inventory and review the relevant requesting process.
- GAHAR surveyor may interview staff members responsible for inventory management to assess compliance to inventory management procedure.

Evidence of Compliance:

1. The laboratory has approved procedures that describe the process of requesting and dispatching reagents and supplies includes elements mentioned in intent from a) to e).
2. Responsible staff is aware of reagent requesting and dispatching process.
3. Records are updated after each dispatching process.
4. Laboratory rules for dispatching material are followed.

Related standards:

SCM.01 Supply Chain Management, SCM.03 Inventory management,OGM.04 Laboratory head of departments.

Service agreement and Referral laboratory service

SCM.05 The laboratory has a process for selection, evaluation, and continuously monitoring contracted services.

Effectiveness

Keywords:
Contracted services.

Intent:
Contracted services have indirect effects the overall quality of laboratory operations by expanding the scope of referral laboratory services and influencing customer satisfaction through housekeeping and security measures. Laboratory leadership shall define the nature and scope of services provided by contracted services, which may include housekeeping, security, consultancy and suppliers. Head of departments/services participates in selection, evaluation and continuous monitoring of contracted services to ensure service providers comply with required environmental safety, client safety and quality requirements, policies and procedures, and all relevant accreditation standards requirements. Laboratory has to ensure current licensure, education, continuous improvement, and competency for contracted consultancy services.
The contracted services are monitored and evaluated at least annually to determine if a contract could be renewed, amended or terminated. The evaluation criteria include at least the following:

a) Quality of the service provided.
b) Continuous uninterrupted service.
c) Prompt response.
d) performance evaluation.
e) Cost-Effective

Survey process guide:

- GAHAR surveyor may interview laboratory head of departments to receive information about contracted services, contractors monitoring, evaluation, and renewal process.
- GAHAR surveyor may review list of all contracted providers and the documents of each provider.

Evidence of compliance:

1. There is a list of all contracted providers.
2. There are selection criteria for each contracted service.
3. Head of departments/services participates in selection, evaluation, and continuous monitoring of the contracted services.
4. There are evaluation criteria for monitoring the contracted services includes elements mentioned in intent from a) to e).
5. Each contract is evaluated at least annually to determine if it should be renewed, amended or terminated.

Related standards:
SCM.01 Supply Chain Management, SCM.06 Referral laboratory, OGM.02 Laboratory Director, OGM.04 Laboratory head of departments.

SCM.06 Referral laboratory is selected, evaluated and continuously monitored.

Effectiveness

Keywords:

Referral laboratory.

Intent:

Referral laboratory service is a crucial function in each laboratory therefore its selection and performance monitoring are crucial to ensure quality of results directly affect client safety, satisfaction and retention.

Proper control of referral laboratory services is done through proper selection as well as regular evaluation. The laboratory develops a procedure for selection and evaluation criteria for referral laboratory. Selection of referral laboratories is done according to the following:

a) Accreditation when available.
b) The quality of performance of referral laboratory (e.g.: PT results, certification, reputation…)
c) Scope of service.
d) Sample type, stability and storage conditions.
e) Turnaround time
f) Price of service.

The laboratory implements an evaluation process either before starting contracting, during the contract or upon renewal of contract for the referral laboratory to determine if the contract should be renewed, amended or terminated through at least the following:

I) Quality of performance monitoring
II) Turnaround time
III) Prompt response
IV) Compliance with transportation procedure
V) Result reporting.

For each laboratory, the process for referral laboratory contracting is identified, and the laboratory director ensures that referral laboratories provide a proper Agreement/Service Contract. A signed document outlining the expectations of both parties is readily accessible for quick reference. Elements of such a document should include the following:

i) Scope of Service
ii) Agreement conditions
iii) Accreditation status
iv) Sample Requirements
v) Turnaround Time (TAT)
vi) Result Reporting
vii) Release of information to third party
viii) Mean of solving disputes
ix) Validity of the agreement and review schedule.

Survey process guide:

- GAHAR surveyor may interview laboratory head of departments to receive information about referred services, in addition to monitoring, evaluation, and renewal of the referral laboratory.
- GAHAR surveyor may review the procedure including the selection and evaluation criteria of the referral laboratory.
- GAHAR surveyor may review referral laboratory list, contracts, and evaluations.

Evidence of compliance:

1. The laboratory has an approved procedure that describe process for selection and evaluation of referral laboratories.
2. List of referral laboratories is available.
3. The selected laboratory meets the selection criteria includes elements mentioned in intent from a) to f).
4. Records of evaluation of referral laboratories includes elements mentioned in intent from I) to V).
5. Referral laboratory contract includes elements mentioned in intent from i) to ix).
6. The referral laboratory is evaluated before, during, and upon renewal of the contract or at least annually, and actions are taken.

Related standards:

OGM.02 Laboratory Director, OGM.04 Laboratory head of departments, SCM.05 Contracted services.

Workforce Management

Chapter Intent:

A clinical laboratory's success relies on its personnel. Meeting client needs and fulfilling its mission requires a diverse team of skilled and qualified professionals.

This chapter focuses on the critical role of laboratory leadership in cultivating a high-performing workforce. Effective workforce planning, encompassing appropriate staffing levels and skill mix, is paramount. Clear job descriptions, comprehensive orientation programs, and robust training initiatives are essential for equipping staff to deliver quality diagnostic services. A well-defined organizational structure, including departments, divisions, and medical committees, ensures clear lines of responsibility and efficient operations.

This chapter details the responsibilities of laboratory department heads in developing staff competencies, fostering professional growth, and driving performance improvement. The laboratory must invest in its staff by providing opportunities for continuous learning and professional advancement.

Employee motivation and commitment are key drivers of success, directly impacting the quality of testing and client care, prioritize credentialing and privileging for their medical staff, as well ensuring the ongoing competency and professional development of their personnel. This includes supporting continuing education, certifications, and other mechanisms for maintaining expertise. Clinical laboratories face potential staffing shortages and must adopt strategies for recruitment and retention. Furthermore, aligning with global trends, laboratories should embrace performance evaluation and recognize the value of a well-trained, motivated workforce as a crucial investment in quality and client safety.

Chapter purpose:

1. To ensure efficient workforce planning.
2. To ensure efficient staff filing process.
3. To develop effective orientation, continuing medical education, and training program.
4. To ensure equitable staff performance evaluation.
5. To ensure efficient medical workforce structure.

WFM Summary of Changes

GAHAR Clinical Labs 2025	***GAHAR Clinical Labs 2021***	***Details of changes***
WFM.01 **KW:** Workforce Laws and regulations.	**WFM.01** **KW:** Workforce manual, Laws and regulations.	- **Added a new** EOCs**:** • **(EOC.01:** The laboratory identifies all applicable laws, regulations, and norms that guide workforce management.) • **(EOC.04:** The workforce is managed and developed according to applicable laws, regulations, and norms that guide workforce management. - **Modified** EOCs: • **(EOC.02:** Responsible staff members are aware of laws, regulations, and norms that guide workforce management.)
WFM.02 **KW:** Staffing plan.	**WFM.02** **KW:** Staffing plan.	- **Modified** Standard Statement: (The laboratory staffing plan matches the laboratory's mission and professional practice recommendations.) - **Modified** EOC: **(EOC.03:** The staffing plan identifies the estimated needed staff numbers including independent practitioner, skills and to meet the laboratory needs.)
WFM.03 **KW:** Recruitment process	**WFM.03** **KW:** Recruitment	- **Modified** Standard Statement: (The laboratory implements a uniform recruitment process according to laws and regulations**.)** - **Added a new** EOC**: (EOC.04:** The recruitment process is uniform across the laboratory for similar types of jobs.)
WFM.04 **KW:** Job Description.	**WFM.04** **KW:** Job Description.	- **Rephrasing** of Standard Statement: (Job descriptions address each position's requirements and responsibilities.) - **Updated (EOC.01) by merging two EOCs(EOC.01 & EOC.02) in Clinical Labs 2021 edition.**

GAHAR Clinical Labs 2025	***GAHAR Clinical Labs 2021***	***Details of changes***
		- **Added a new** EOCs**:** • **(EOC.02: Job descriptions address each position's responsibilities, required qualifications, and reporting structure.** • **(EOC.04: The job description is signed by the staff and kept in the staff's file.** - **Modified** EOC: **(EOC.03: <u>On assignment</u>, the job description is discussed with staff members, including <u>independent practitioners.)</u>**
WFM.05 **KW:** Verifying credentials, clinical privilege	**WFM.12** **KW:** Verifying credentials	- **Modified** Standard statement: (Staff credentials are verified and <u>clinical privilege are granted to qualified staff</u>.). - **Modified** EOC: **(EOC.01:** Required credentials for each position are collected and kept in staff files including independent practitioners' files.) - **Added a new** EOCs**:** • **(EOC.05**: Clinical privileges are accessible and granted to qualified staff when needed.) • **(EOC.06: Clinical privileges are documented in the staff file including renewal when applicable.)**
WFM.06 **KW:** Staff Files.	**WFM.11** **KW:** Staff Files.	- **Modified** EOC: • **(EOC.01:** The laboratory has <u>an approved</u> policy to maintain and standardize staff files as mentioned in intent from a) through f). • **(EOC.05:** Staff files are <u>retained</u> and disposed as per laboratory policy, laws, and regulations

GAHAR Clinical Labs 2025	***GAHAR Clinical Labs 2021***	***Details of changes***
WFM.07 **KW:** Orientation Program.	**WFM.05** **KW:** Orientation Program.	- **Modified** EOCs: • **(EOC.01:** A general orientation program is performed, and it includes at least the elements from a) through d). • **(EOC.04:** All new staff members, including contracted and outsourced staff, attend the orientation program.) • **(EOC.05:** There is evidence that each staff member has completed the orientation program, which is recorded in their file.) - **Added a new** EOCs**:** • **(EOC.02:** A department orientation program is performed, and it includes at least the elements from e) through h). • **(EOC.03:** A job-specific orientation program is performed and it includes at least the elements from i) through k).
WFM.08 **KW:** Continuing Education Program	**WFM.06** **KW:** Continuous Education Program.	- **Modified** EOC: **(EOC.01:** The laboratory has a training and continuing education program for all staff categories that include elements mentioned in intent from a) through k). - **Added a new** EOC**: (EOC.04:** The educational program is based on the training needs assessment of the staff.)
WFM.09 **KW: Competency assessment.**	**WFM.07** **KW:** Competency assessment.	- **Modified** Standard statement: (The laboratory develops a process for staff competency assessment.) - **Added a new** EOCs**:** • **(EOC.02:** Competency assessment aligns with the assigned job and

GAHAR Clinical Labs 2025	***GAHAR Clinical Labs 2021***	***Details of changes***
		includes elements mentioned in the intent from a) through f). • **(EOC.04: T**here is evidence of employee feedback on competency evaluation.)
WFM.10 **KW: Staff performance evaluation.**	**WFM.08** **KW:** Staff performance evaluation.	- **Modified** Standard statement: (Staff performance is regularly evaluated.) - **Added a new** EOCs**:** • **(EOC.01:** Performance evaluation is performed at least annually for each staff member.) • **(EOC.02:** Head of departments carries out performance evaluations.) • **(EOC.03:** Performance evaluation is based on the job description.) • **(EOC.04:** There is evidence of employee feedback on performance evaluation.)
WFM.11 **KW: Working Hours**	**WFM.09** **KW:** Staff burnout and turnover.	- **Modified** Standard statement: (The laboratory ensures safe and efficient working hours.) - **Modified** EOC: **(EOC.03**: The staff schedules ensure suitable working hours, planned rest times, maternity protection, and arrangements for breastfeeding according to laws and regulations.) - **Added a new** EOC**: (EOC.04**: When working hours exceed the approved limits, measures are taken to ensure staff safety and satisfaction.)

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

Efficient workforce planning

WFM.01 Workforce recruitment, education, training, and appraisal processes comply with laws and regulations.

Efficiency

Keywords:
Workforce Laws and regulations.

Intent:
Labor laws and regulations mediate the relationship between workers, laboratories, syndicates, and the government. The laboratory should outline the essential aspects of workforce recruitment, education, training, and appraisal processes within the organization and ensure that these processes are aligned with relevant laws and regulations. Ensuring compliance not only safeguards the organization from legal risks but also promotes fairness, equity, and professionalism in our workforce practices.
The Laboratory head of departments develop workforce manual that include policies and procedures that define staffing requirements to meet the laboratory work needs, required education, skills, knowledge, training, staff appraisal and any other requirements for laboratory staff, all these requirements comply with laws and regulations.
The laboratory shall identify all applicable laws, regulations, and norms, including syndicates' codes and requirements, and defines the legal framework for its workforce management.

Survey process guide:

- GAHAR surveyor may review the legal framework documents, staff files to check compliance with laws and regulations.
- GAHAR surveyor may review workforce manual to check compliance with laws and regulations.
- GAHAR surveyor may interview responsible staff members to check their awareness of laws, regulations, and norms that guide workforce management.

Evidence of Compliance:

1. The laboratory identifies all applicable laws, regulations, and norms that guide workforce management.
2. Responsible staff members are aware of laws, regulations, and norms that guide workforce management.
3. An approved updated workforce manual is available.
4. The workforce is managed and developed according to applicable laws, regulations, and norms that guide workforce management.

Related standards
OGM.01Governing body Structure and responsibilities, OGM.02 Laboratory Director, OGM.04 Laboratory head of departments, WFM.07 Orientation Program.

WFM.02 The laboratory staffing plan matches the laboratory's mission and professional practice recommendations.

Efficiency

Keywords:

Staffing plan.

Intent:

Staff planning is the process of making sure that a laboratory has the right people to carry out the work needed for business successfully through matching up detailed staff data including number of staff, skills, potential, aspirations and location with business plans.

The staffing plan sets the number of staff and defines the desired skill mix, education, knowledge, and other requirements of staff members.

The shortage of competent healthcare professionals in multiple areas is an alarming sign. The laboratory shall comply with laws, regulations and recommendations of professional practices that define desired education levels, skills, or other requirements of individual staff members or that define staffing numbers or mix of staff for the laboratory. The plan is reviewed annually and updated as necessary.

The head of department of each clinical or managerial area define the individual requirements of each staff position. The laboratory should maintain a safe level of staff members' numbers and skill levels. Head of departments consider the following factors to project staffing needs:

a) The laboratory mission, strategic and operational plans.
b) Services provided by the laboratory.
c) Technology and equipment used in client care.
d) Workload during working hours and different shifts.

Survey process guide:

- GAHAR surveyor may review the staff planning documents, staff files to check compliance of staffing plan with mission, laws, regulations, and professional practices recommendations.
- GAHAR surveyor may interview the laboratory head of departments to evaluate the plan preparation process.
- GAHAR surveyor may observe workforce allocation and skills.

Evidence of Compliance:

1. Staffing plan matches the mission, and strategic and operational plans of the laboratory.
2. Staffing plan complies with laws, regulations, and recommendations of professional practices.
3. The staffing plan identifies the estimated needed staff numbers including independent practitioner, skills and to meet the laboratory needs.
4. Staffing plan is monitored and reviewed at least annually.

Related standards

OGM.04 Laboratory head of departments, OGM.03 Strategic and operational Plans, WFM.01 Workforce Laws and regulations, WFM.03 Recruitment process, WFM.11 Working Hours.

WFM.03 The laboratory implements a uniform recruitment process according to laws and regulations.

Equity

Keywords:

Recruitment process

Intent:

Recruitment and selection are the process of advertising a vacant position and choosing the most appropriate person for the job.

The laboratory provides an efficient, coordinated and centralized process for recruiting and hiring staff members, including independent practitioners, for available positions. If the process is not centralized, similar criteria and processes must result in a uniform process across the laboratory for similar types of staff. The recruitment process ensures the appropriate education, training, experience and demonstrated skills needed to the tasks performed.

The laboratory shall develop a policy and procedure guiding the recruitment process that addresses at least the following:

a) Collaboration with service/department heads to identify the needs for each department.
b) Communicating available vacancies to potential candidates
c) Announcing criteria of selection
d) Application process
e) Recruitment procedures

Survey process guide:

- GAHAR surveyor may review the policy describing the recruitment process.
- GAHAR surveyor may review a sample of staff files, including independent practitioners' files, to assess compliance with the laboratory policy.
- GAHAR surveyor may interview staff members who are involved in recruitment process to assess their awareness.

Evidence of compliance:

1. The laboratory has an approved policy and procedures that describe the recruitment process as mentioned in intent from a) to e).
2. Responsible staff is aware of the laboratory policy.
3. Records of the recruitment process include evaluation of the qualification of newly hired staff.
4. The recruitment process is uniform across the laboratory for similar types of jobs.

Related standards

WFM.01 Workforce Laws and regulations, WFM.02 Staffing plan, WFM 06 Staff Files, OGM.02 Laboratory Director, OGM.04 Laboratory head of departments.

WFM.04 Job descriptions address each position's requirements and responsibilities.

Effectiveness

Keywords:

Job Description.

Intent:

The job description is a broad, general, and written statement of a specific job, based on the findings of a job analysis and complies with laws and regulations.

It generally includes duties, purpose, responsibilities, scope, and working conditions of a job. It allows head of departments to make informed staff assignment, recruitment, and evaluation. It also enables staff members to understand their responsibilities and accountabilities.

Job descriptions include at least the following:

a) The required license and certification
b) The education, skills, knowledge, and experience.
c) The responsibilities and authorities of each position.
d) Job specification.

The laboratory should ensure that results of staff planning process, such as skill mix, are aligned with job requirements mentioned in the job description

Job descriptions are required for all laboratory staff, full- time, part-time, temporary staff, or those who are under training. However, the duties and responsibilities for the clinical performance of physician may be available in the physician clinical privileges.

Survey process guide:

- GAHAR surveyor may review a sample of staff files of different positions to check for the signed full job description.
- GAHAR surveyor may interview laboratory staff to assess their knowledge about their job description

Evidence of Compliance:

1. There is a job description for every position in the laboratory as mentioned in intent from a) to d).
2. Job descriptions address each position's responsibilities, required qualifications, and reporting structure.
3. On assignment, the job description is discussed with staff members, including independent practitioners.
4. The job description is signed by the staff and kept in the staff's file.

Related standards

OGM.02 Laboratory Director, OGM.04 Laboratory head of departments, WFM.01 Workforce Laws and regulations, WFM.07 Orientation Program, WFM.06 Staff Files QPI.01 Quality improvement plan QPI.03 Data aggregation, analysis, and validation.

WFM.05 Staff credentials are verified and clinical privilege are granted to qualified staff.

Effectiveness

Keywords:

Verifying credentials, clinical privilege

Intent:

Credentials are documents that are issued by a recognized entity to indicate completion of requirements or the meeting of eligibility requirements, such as a diploma from a medical school, specialty training (residency) completion letter or certificate, completion of the requirements of the related syndicates, authorities and/or others, a license to practice. These documents, some of which are required by law and regulation, and need to be verified from the original source that issued the document.

When staff members including independent practitioners are hired by the laboratory, the process of verifying credentials and evaluating the qualifications that match the requirements of the position with the qualifications of the prospective staff member must be done.

Clinical privileges are specific to the laboratory where they are granted and may vary from one laboratory to another based on their needs, the provider's qualifications, and the scope of services offered. Clinical privilege also defines the scope of practice for the healthcare providers. The Providers are required to adhere to the scope of their granted clinical privileges and must undergo periodic re-evaluation to maintain or update these privileges as their skills and qualifications evolve.

Clinical privileges may include performing examinations and making diagnoses in specific areas and may be granted in the following cases:

a) Anatomic Pathology
b) Hematology (e.g. bone marrow aspiration)
c) Genetic Testing

Survey process guide:

- GAHAR surveyor may review credential verification process and actions taken when credentials cannot be verified.
- GAHAR surveyor may review a sample of staff member including laboratory physicians and technician files to check the availability of required credentials for each position.
- GAHAR surveyor may interview staff members who are involved in credentialing process to check their awareness of the process.
- GAHAR surveyor may review medical staff files to check for the documentation of clinical privilege.

Evidence of compliance:

1. Required credentials for each position are collected and kept in staff files including independent practitioners' files.
2. There is a process for verifying credentials and evaluating the qualification in the laboratory.
3. The process is uniformly applied to assess staff members' credentials.
4. Actions are taken when credentials cannot be verified.
5. Clinical privileges are accessible and granted to qualified staff when needed.
6. Clinical privileges are documented in the staff file including renewal when applicable.

Related standards:

OGM.04 Laboratory head of departments, WFM.01 Workforce Laws and regulations, WFM.04

Job Description, WFM.06 Staff Files, WFM.08 Continuing Education Program, WFM.10 Staff performance evaluation, IMT.01 Documentation management system.

Efficient staff filing process

WFM.06 A staff file is established for each workforce member.

Efficiency

Keywords:
Staff Files.

Intent:
It is important for the laboratory to maintain a staff file for each staff member including independent practitioners.
An accurate staff file provides recording of the relevant educational and professional qualifications, training and experience, and competency assessment. The records shall be standardized and kept updated.
The laboratory shall develop and implement a policy and procedures that guide management of staff files including independent practitioners that addresses at least the following:

a) Staff file initiation
b) File contents, include at least the following:
   i. Qualifications, including education, training, certification\ credentials or license
   ii. Previous work experience.
   iii. Signed Job descriptions.
   iv. Staff Privilege
   v. Recorded evidence of newly hired general, departmental, and job-specific orientation.
   vi. Training in current job tasks.
   vii. Competency assessments.
   viii. Records of continuing education and achievements.
   ix. Reviews of staff performance.
   x. Reports of accidents and exposure to occupational hazards.
   xi. Staff health records including immunization status, when relevant to assigned duties.
   xii. Confidentiality agreement.
c) Update of file contents
d) Storage
e) Retention time
f) Disposal

Survey process guide:

- GAHAR surveyor may review the laboratory policy that guide management of staff files.
- GAHAR surveyor may interview staff involved in establishing, usage, and storage of staff files to assess their awareness.
- GAHAR surveyor may review a sample of staff files to assess the standardized contents.
- GAHAR surveyor may observe the area where staff files are kept to assess storage conditions, retention, confidentiality, and disposal mechanism.

Evidence of compliance:

1. The laboratory has an approved policy to maintain and standardize staff files as mentioned in intent from a) through f).

2. Staff members who are involved in creating, storing, and using staff files are aware of the policy requirements.
3. Staff files are confidential and protected.
4. Staff files include all the required records from i) through xii) as mentioned in the intent.
5. Staff files are retained and disposed as per laboratory policy, laws, and regulations.

Related standards

OGM.04 Laboratory head of departments, WFM.01 Workforce Laws and regulations, WFM.04 Job Description, WFM.10 Staff performance evaluation, WFM.07 Orientation Program, WFM.05 Verifying credentials, clinical privilege, WFM.08 Continuing Education Program, OGM.09 Staff health.

Effective orientation program

WFM.07 Appointed, contracted, and outsourced staff undergo a formal orientation program.

Effectiveness

Keywords:

Orientation Program.

Intent:

A new staff member needs to understand the entire laboratory structure and how their specific technical or nontechnical responsibilities contribute to the laboratory mission.

This is accomplished through a general orientation to the laboratory and their role and a specific orientation to the job responsibilities.

Staff orientation, especially for a new staff on the laboratory policies ensures alignment between laboratory mission and staff activities.

The laboratory shall build a comprehensive orientation program that is provided to all staff members regardless of their terms of employment. Orientation program for a new staff member to the new work environment includes at least the following:

General orientation program addresses at least the following:

a) The laboratory mission, vision, values, and laboratory structure.
b) Ethical framework and code of conduct.
c) laboratory policies for Environmental and Facility Safety, infection control, performance improvement, client safety, and risk management.
d) First aid training.

Department orientation program addresses at least the following:

e) The quality management system.
f) Review of relevant policies and procedures.
g) Operational processes.
h) Key personnel and lines of authority.

Job-specific orientation addresses at least the following:

i) Job-specific duties and responsibilities as per the job description.
j) Technology and equipment use.
k) Staff safety and health.

Survey process guide:

- GAHAR surveyor may interview some staff members to inquire about the orientation process.

- GAHAR surveyor may check a sample of staff files to check evidence of attendance of general, departmental, and job-specific orientation programs.

Evidence of compliance:

1. A general orientation program is performed and it includes at least the elements from a) through d).
2. A department orientation program is performed and it includes at least the elements from e) through h).
3. A job-specific orientation program is performed and it includes at least the elements from i) through k).
4. All new staff members, including contracted and outsourced staff, attend the orientation program.
5. There is evidence that each staff member has completed the orientation program, which is recorded in their file.
6. Effectiveness of orientation program is evaluated.

Related Standard:

OGM.01Governing body Structure and responsibilities, OGM.03 Strategic and operational Plans, OGM.08 Positive Workplace Culture, WFM.06 Staff Files

Effective training and education

WFM.08 A continuing education and training program is developed and implemented.

Effectiveness

Keywords:

Continuing Education Program.

Intent:

For any laboratory to fulfill its mission, it has to ensure that its human resources have the capability to deliver its services over time.

Continuing education and training programs guarantee greater productivity, satisfy staff needs and improve laboratory-employee relationship.

The program is designed in a flexible manner that satisfies all staff categories based on services provided, needs assessment, new information, and tailored training plans and delivery.

The laboratory ensures that education and training are provided and recorded according to the staff member's relevant job responsibilities and based on training needs assessment, which may include the following:

a) Quality concept, performance improvement, client safety, and risk management.
b) Assigned work processes, procedures and updated guidelines.
c) The available information system.
d) Laboratory safety program, including the infection and prevention program
e) Laboratory equipment and utility systems operations and maintenance.
f) Dealing with the adverse incidents.
g) Code of conducts.
h) Environment safety plans.
i) Client rights, client satisfaction, and the complaint/ suggestion process.

j) Provision of integrated care, shared decision-making, informed consent, interpersonal communication between clients and staff, and cultural beliefs, needs, and activities of different groups served.
k) Confidentiality of client information.

Personnel undergoing training are supervised at all times and the effectiveness of the training programs is evaluated.

Survey process guide:

- GAHAR surveyor may review the laboratory continuing education and training program.
- GAHAR surveyor may interview some staff members and inquire about the process of continuing education and training.
- GAHAR surveyor may review a sample of staff files to check evidence of attendance of continuing education and training program.

Evidence of Compliance:

1. The laboratory has a training and continuing education program for all staff categories that include elements mentioned in intent from a) through k).
2. Staff members are aware of the training and continuing education program.
3. The effectiveness of the training and continuing education program is monitored and evaluated.
4. The educational program is based on the training needs assessment of the staff.

Related standards:

PCC.02 Client and family rights, OGM.02 Laboratory Director, OGM.06 Ethical management, WFM.06 Staff Files, QPI.01 Quality improvement plan, QPI.07 Sustained improvement activities IPC.02 Hand Hygiene, EFS.03 Fire and smoke safety plan, fire drill, fire drill, , IMT.01 Documentation management system.

Equitable staff performance evaluation

WFM.09 The laboratory develops a process for staff competency assessment.

Equity

Keywords:

Competency assessment.

Intent:

Competency is the ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly. Competency assessment ensure that the laboratory personnel are fulfilling their duties and responsibilities.

Staff competency assessment is an ongoing process for managers to evaluate an employee's work performance, identify strengths and weaknesses, offer feedback and set goals for future performance. The laboratory should provide objective measurements of competency, define who will conduct the assessments, ensure that individuals with relevant expertise perform specialized evaluations, and address age-related competencies, particularly for staff providing direct client care, as practices may vary based on client demographics (e.g., pediatric vs. adult care). The laboratory shall develop and implement policy and procedures describing the process of staff competency assessment.

Competence of laboratory staff (technical and managerial) can be assessed after the probationary period (initial competency assessment), then on an ongoing basis at least biannually using any combinations, all of the following approaches or following the guidelines according to the assigned job which may include:

a) Observation of Routine Client Test Performance
b) Recording and Reporting of Test Results
c) Review of Intermediate Test Results and Records
d) Direct Observation of Instrument Function and Maintenance
e) Assessment of Test Performance
f) Assessment of Problem-Solving Skills

Retraining is provided after unsatisfactory competency assessment results.
Authorization for performing each laboratory responsibility is determined based on documented evidence of competency (experience- qualifications – certifications-skills) that are reviewed and renewed as needed.

Survey process guide:

- GAHAR surveyor may review the policy describing the competency assessment.
- GAHAR surveyor may interview laboratory head of departments and inquire about used methods, frequency, and guidelines for staff competency assessment.
- GAHAR surveyor may review a sample of staff files to assess completion of competency assessment records and employee feedback.

Evidence of Compliance:

1. The laboratory has an approved policy and procedures that describe the process for competency assessment.
2. Competency assessment aligns with the assigned job and includes elements mentioned in the intent from a) through f).
3. Records of staff competency assessment, including managerial and technical levels, are retained in employees' files.
4. There is evidence of employee feedback on competency evaluation.
5. Competency assessment is performed at least biannually for each staff member.
6. Actions taken in case of unsatisfactory competency assessment results are documented.

Related standards:
WFM.03 Recruitment process, WFM.06 Staff Files, WFM.10 staff performance evaluation, OGM.04 Laboratory head of departments.

WFM.10 Staff performance is regularly evaluated.

Equity

Keywords:

Staff performance evaluation.

Intent:

Staff performance evaluation is an ongoing process that is also called performance appraisal or performance review which is a formal assessment for managers to evaluate an employee's work performance, identify strengths and weaknesses, offer feedback, and set goals for future performance.

The laboratory uses a performance evaluation tool to ensure staff have the required criteria for doing jobs and achieving objectives. Performance evaluation also promotes communication between employees and head of departments, enabling them to make informed decisions about staff planning, selection, incentives, training and education, and career planning.

The laboratory should have a documented process for employees' performance evaluation, including performance review methods, tools, evaluation dimensions, criteria, time interval, and responsible person for each staff category, and the effective management of underperformance.

Survey process guide:

- GAHAR surveyor may interview laboratory head of departments and inquire about frequency and tools used for staff performance evaluation.
- GAHAR surveyor may review a sample of staff files to assess completion of performance evaluations and employee feedback.

Evidence of Compliance:

1. Performance evaluation is performed at least annually for each staff member.
2. Head of departments carries out performance evaluations.
3. Performance evaluation is based on the job description.
4. There is evidence of employee feedback on performance evaluation.
5. Actions are taken based on a performance review.
6. Staff regular performance review is documented in employees' files.

Related standards

OGM.04 Laboratory head of departments, OGM.08 Positive Workplace Culture, IPC.02 Hand Hygiene, WFM.04 Job Description, WFM.09 competency assessment, WFM.06 Staff Files, QPI.01 Quality improvement plan.

Efficient medical workforce structure

WFM.11 The laboratory ensures safe and efficient working hours.

Safety

Keywords:

Working Hours

Intent:

Attention to health and well-being of laboratory professionals becomes even more crucial when considering that employees represent a laboratory's most significant expense.

Burnout is a combination of exhaustion, cynicism, and perceived inefficacy resulting from long-term job stress. The consequences of burnout are not limited to the personal well-being of healthcare workers; many studies have demonstrated that provider burnout is detrimental to client care.

The laboratory shall develop a policy and procedures to ensure management of staff working hours efficiently that addresses at least the following:

a) Measures to avoid staff burnout like fair distribution of tasks, workload monitoring, and provide adequate staffing.
b) Planned rest times and minimize excessive overtime.
c) Maternity protection and arrangements for breast-feeding.
d) Proper shift scheduling and setting staff working hours according to the laws and regulations.

Survey process guide:

- GAHAR surveyors may review laboratory policy for working hours.
- GAHAR surveyor may interview staff to inquire about the measures taken to ensure appropriate working hours.

Evidence of Compliance:

1. The laboratory has an approved policy and procedures to ensure safe and efficient working hours Including elements mentioned in the intent from a) to d).
2. Staff is aware of laboratory's policy.
3. The staff schedules ensure suitable working hours, planned rest times, maternity protection, and arrangements for breastfeeding according to laws and regulations.
4. When working hours exceed the approved limits, measures are taken to ensure staff safety and satisfaction.

Related standards

OGM.04 Laboratory head of departments, OGM.08 Positive Workplace Culture, OGM.07 Safety Culture, WFM.09 staff health.

Information Management and Technology

Information Management and Technology (IMT) has become essential in modern clinical laboratory operations. Its ability to provide timely and relevant data to laboratory professionals is crucial for accurate diagnoses, effective test interpretation, and optimized laboratory workflows. At the core of laboratory IMT is the management of clinical data (test results, client demographics), administrative data (quality control records, inventory), and regulatory data (compliance documents, accreditation information).
While IMT offers significant potential to improve laboratory efficiency and the quality of testing, it also presents challenges, particularly regarding client data confidentiality and the risk of errors due to misinterpretations or system failures.

The increasing use of technology in laboratories has heightened client data confidentiality concern due to the potential vulnerability of sensitive data within electronic systems. Robust cybersecurity measures, access controls, and data encryption protocols are essential to safeguard client information and comply with privacy regulations.

Laboratory IMT faces the risk of errors from manual data entry, instrument interfaces, and software issues. Standardized procedures for data validation, quality control, system maintenance, and readily available technical support are crucial to mitigate these risks.
The clinical laboratory landscape is rapidly evolving with the adoption of technologies like laboratory information systems (LIS), middleware, automated testing platforms, and data analytics tools. These advancements offer the potential for enhanced efficiency, improved accuracy, and better data management. However, their successful implementation requires careful planning, adequate resource allocation, and ongoing training to ensure data integrity, system reliability, and compliance with regulatory requirements.

Chapter purpose:

1. To address effective document and record management.
2. To ensure effective Laboratory Information management system.
3. To maintain information confidentiality and security.
4. To describe effective data transfer and interfaces

Standards included in this chapter applies to paper and electronic data and information.

IMT Summary of Changes

GAHAR Clinical Labs 2025	***GAHAR Clinical Labs 2021***	***Details of changes***
IMT.01 **KW:** Documentation management system.	**IMT.01** **KW:** Documentation management system.	- **Modified** EOCs: • **(EOC.01:** The laboratory has approved procedures that describe the process for creating, formatting, and reviewing of documents includes elements mentioned in intent from a) to h). • **(EOC.03:** Reviewing of selected documents that comply with the mentioned procedure are conducted within defined timeframes).
IMT.02 **KW:** Record management system.	**IMT.02** **KW:** Record management system.	- **No Change.**
IMT.03 **KW:** LIS management.	**IMT.03** **KW:** LIS management.	- **Add new EOC: (EOC.05:** Confidentiality of client information is maintained according to laws and regulations).
IMT.04 **KW:** LIS security, unauthorized access and modifications.	**IMT.04** **KW**: LIS security, unauthorized modifications.	- **Modified** Standard statement**:** (Information management security is defined, tested periodically and data are protected from unauthorized access, modification and update**.**). - **Modified** EOCs: - **(EOC.01:** The laboratory has an approved policy and procedure that describe the process for information management security including accessibility, modification and updates to client data includes elements mentioned in intent from a) to h). - **(EOC.04: Authorization list** is present for staff based on their responsibilities. - **Add new EOC:**

GAHAR Clinical Labs 2025	***GAHAR Clinical Labs 2021***	***Details of changes***
		• **(EOC.03:** The laboratory that has computer-based information management system (LIS), fulfilling all elements mentioned in the intent from I) to III). • **(EOC.05:** There is a signed confidentiality agreement in each staff member's personal file.) • **(EOC.06:** Procedures are followed if confidentiality or security of information has been breached.)
IMT.05 **KW:** LIS validation.	**IMT.05** **KW:** LIS validation. **IMT.08** **KW:** Calculated values.	• **Updated standard by merging two standards (IMT.05 & IMT.08) in clinical labs 2021.**
IMT.06 **KW:** Maintenance program, Contingency plan.	**IMT.06** **KW:** Maintenance program, Contingency plan.	- **No change.**
IMT.07 **KW:** LIS User manual	**IMT.07** **KW**: LIS User manual	- **Modified** EOC: **(EOC.02:** Laboratory staff is trained on the LIS proper use according to their responsibilities).
IMT.08 **KW:** Data transfer and Interface.	**IMT.09** **KW:** Data transfer and Interface.	**No change.**
IMT.09 **KW:** Auto verification.	**IMT.10** **KW:** Auto verification.	- **No change.**
IMT.10 **KW:** Data storage and retrieval.	**IMT.11** **KW:** Data storage and retrieval.	- **Add new EOC: (EOC.04:** The laboratory backup system is implemented.)

GAHAR Clinical Labs 2025	***GAHAR Clinical Labs 2021***	***Details of changes***
Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition		

Document and Record Management

IMT.01 Documentation management system is developed for all laboratory documents.

Effectiveness

Keywords:

Documentation management system.

Intent:

Documentation management system is important for the standardization of the document formatting as well as developing a controlled process for creation, distribution, amendment and disposal of all laboratory documents. The laboratory shall control documents required by the quality management system and shall ensure that unintended use of any obsolete document is prevented. Documents that should be considered for document control are those represent laboratory key functions and used for implementation of Quality management system, including those maintained in paper-based, computer-based, or both. These documents include (e.g. policy statements, procedures, plans, forms, agreements, documents of external origin, etc).

Periodic review of the whole documents ensures that obsolete document is not used.

The laboratory has a written procedure to create, format and review documents, the procedure shall contain at least the following:

a) Standardized formatting.
b) Document control system for tracking of issues and tracking of changes;
c) The system allows each document to be identified by title, date of issue, edition and/ or current revision date, the number of pages, the person authorized of issuing and/or reviewing the document and identification of changes.
d) Obsolete controlled documents are dated and marked as obsolete
e) Required documents are available and disseminated to relevant staff
f) Staff understand how to access those documents relevant to their responsibilities.
g) Retirement of documents
h) Documents revisions

Survey process guide:

- GAHAR surveyor may review laboratory procedures followed by checking the implementation of these documents to ensure that they had standardized format, tracking system, identified approver, issuing, and revision date.
- GAHAR surveyor may interview staff to check their awareness about the process of developing, approving, tracking, and revising of policies.
- GAHAR surveyor may interview staff to check their awareness about access to relevant procedure, tracking changes in the policies, and process for management of documents retirement.
- GAHAR surveyor may observe proper distribution of all documents following the distribution matrix

Evidence of compliance:

1. The laboratory has approved procedures that describe the process for creating, formatting, and reviewing of documents includes elements mentioned in intent from a) to h).
2. Staff is aware and trained for the documentation management system.

3. Reviewing of selected documents that comply with the mentioned procedure are conducted within defined timeframes.
4. There is a list of updated authorized versions of all documents.
5. Proper distribution of all documents following the distribution matrix.

Related standard

APC.01 Accurate and complete information, IMT.02 Record management system, IMT.03 LIS management, IMT.04 LIS security, unauthorized, access and modifications, IMT.10 Data storage and retrieval.

IMT.02 Record management system is developed for all records that is used for the implementation of the quality management system

Effectiveness

Keywords:

Record management system.

Intent:

Record management system is important for management of all laboratory records through-out the record life cycle as well as archiving and indexing process. Records are created concurrently with the performance of each significant step and clearly indicate the identity of the individuals who performed each step and when it occurred. Retention of the records is important for the retrieval for any needed information within its retention period. Amendment of records without authorization can affect the client results.

The process for managing records shall ensure full compliance with laws and regulations. The laboratory shall develop a policy and a procedure(s) for creation, control, change and retention of records. It shall include at least the following:

a) Records are legible and indelible.
b) Proper completion, identification, indexing, access, storage and retrieval.
c) Records are created concurrently with performance of each critical activity.
d) Records are protected from unauthorized access.
e) If records are maintained electronically, adequate backups should exist in case of system failure. Electronic records should be readable for the entire length of their retention period as well as ensuring that copies or scans are verified as complete, legible, containing the original content and accessible before the destruction of the original records.
f) The date of changes and the identity of the individual who changed the record are documented and maintained for the retention period of the original record.
g) Record changes do not obscure previously recorded information (previously recorded information not obliterated).
h) Changes to records are verified for accuracy and completeness.

The laboratory records retained upon the laboratory regulation but not less than the time present in the table (1) attached in Annex(A).

Survey process guide:

- GAHAR surveyor may review the policy.

- GAHAR surveyor may review the related records to check the implementation.
- GAHAR surveyor may interview staff to check their awareness of the process of records indexing, retention and destruction, and/or removal of records, data, and information.
- GAHAR surveyor may review list of records with identified retention time.
- GAHAR surveyor may review record/logbook of disposed records.

Evidence of compliance:

1. The laboratory has an approved policy and procedures that describe the process of creation, control, change and retention of records includes elements mentioned in intent from a) to h).
2. Staff is aware of the record management system.
3. There is a list of retention time for different types of records.
4. There is a record/logbook of documents destruction and/or removal.

Related standard

IMT.01 Documentation management system, IMT.03 LIS management, IMT.06 Maintenance program, Contingency plan, IMT.10 Data storage and retrieval.

Effective Laboratory Information management system

IMT.03 Laboratory information management system is planned and implemented for effective management of data.

Effectiveness

Keywords:

LIS management.

Intent:

Information management is a system that incorporates all the processes needed for effective data management. The information management system may be entirely paper-based, computer-based, or both.

The laboratory develops a policy and a procedure(s) for laboratory information management. The implemented information management system, whether it is a manual, paper-based system, or an electronic system, shall include the following elements:

a) Unique identifiers for clients and samples
b) Standardized test request forms (requisitions)
c) Logs and worksheets
d) Checking processes to assure accuracy of data recording and transmission
e) Protection against loss of data
f) Protection of client confidentiality and privacy
g) Effective reporting systems
h) Effective and timely communication.

Financial constraints may require that a laboratory use a manual, paper-based system for all its information management. Careful planning, attention to detail and awareness of problems can allow the development of a good paper-based system that will provide satisfactory service.

When using a paper system or computerized system, it is important to emphasize to staff that all data entry must be complete, performed and reviewed by authorized individual.
Paper based records should be kept in a safe place where they can be easily retrieved, keeping in mind that the goals are to be able to find a result, trace a sample throughout its pathway in the entire process, evaluate a problem or an occurrence to find its source and ensure easy access to information by those who need it.
Amendments of data should be traceable by date and time and performed by authorized individual(s).

Survey process guide:

- GAHAR surveyor may review the policy and procedure of information management system.
- GAHAR surveyor may review records for implementation of the information management system procedure and check the traceability and the integrity of client data.
- GAHAR surveyor may interview staff to assess their awareness about information management system.
- GAHAR surveyor may observe retrieval and traceability of lab records by date and time.

Evidence of compliance:

1. The laboratory has approved policy and procedures that describe the process for information management system includes elements mentioned in intent from a) to h).
2. laboratory staff is aware and trained on the information management system.
3. Laboratory records (either manually or electronically) are traceable and easily retrieved.
4. Amended data is traceable by date and time and performed by authorized individual(s).
5. Confidentiality of client information is maintained according to laws and regulations.

Related standard

IMT.01 Documentation management system, IMT.02 Record management system, IMT.06 Maintenance program, Contingency plan, IMT.10 Data storage and retrieval.

Maintain Information Confidentiality and Security

IMT.04 Information management security is defined, tested periodically and data are protected from unauthorized access, modification and update.

Effectiveness

Keywords:

LIS security, unauthorized access and modifications.

Intent:

Information security is the protection of information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction. Information security is achieved by ensuring the confidentiality, integrity, and availability of information. Confidentiality means the property that health information is not made available or disclosed to unauthorized persons or processes.
Integrity means the property that health information has not been altered or destroyed in an unauthorized manner. Availability means the property that health information is accessible and useable upon demand by an authorized person. Modifications or update of information must be done through authorized personnel to avoid any changes.

The laboratory shall define who is authorized to view and administer health information or clarify and improve how and when health information is provided to clients, relatives, or other healthcare entities.
The laboratory shall develop and implement policy and procedure for the information management confidentiality, security, modification and update. It shall ensure at least the following:

a) Security and timely installation of system updates.
b) Measures for access control for authorized staff.
c) Documentation of changes approval.
d) Identification of personnel who changed or modified the data.
e) Validation of affected functions after update/modification when needed.
f) Verification of the integrity and accuracy of the data when needed.
g) Confidentiality agreements signed by all those who have access to laboratory data.
h) Procedures to follow if confidentiality or security of information has been breached.

If the laboratory uses computer-based information management system (LIS) The following shall be fulfilled:

I) The laboratory establishes security (user) codes to permit only authorized individuals to access client data and change results, alter computer tables or programs.
II) Client information sent over a public domain such as the internet or stored in «The Cloud» is considered «potentially public» Thus, it may be accessible to some unauthorized parties on that network. Systems must be in place to protect network traffic, such as «fire walls» and data encryption schemes.
III) Access control policy should include authorized entry to data center(s) housing the LIS and logging into server(s) operating system hosting the LIS.

Survey process guide:

- GAHAR surveyor may review the authorization access to ensure security of data.
- GAHAR surveyor may review information management confidentiality, security, modification and update policy, and list of the authorized individuals to have access to the client record and signed confidentiality agreement in each staff member personal file.
- GAHAR surveyor may observe implementation of confidentiality measures including storage of client's records in limited access place, each staff use of passwords and staff has no access to the information not related to their job.
- GAHAR surveyor may interview staff to assess staff awareness of confidentiality measures.

Evidence of compliance:

1. The laboratory has an approved policy and procedure that describe the process for information management security including accessibility, modification and updates to client data includes elements mentioned in intent from a) to h).
2. Laboratory staff is aware about information management security.
3. The laboratory that has computer-based information management system (LIS), fulfilling all elements mentioned in the intent from I) to III).
4. Authorization list is present for staff based on their responsibilities.
5. There is a signed confidentiality agreement in each staff member's personal file.
6. Procedures are followed if confidentiality or security of information has been breached.

Related Standards:

IMT.01Documentation management system, IMT.05 LIS validation.

Laboratory Information System (LIS)

IMT.05 Licensed laboratory information system (LIS) is validated and tested by the user prior to introduction in to the service.

Safety

Keywords:
LIS validation.

Intent:
Validation of LIS means that it meets predefined acceptance criteria, license and the manufacturer's operational specifications immediately after installation and before being introduced in to the service. Using the LIS without validation may leads to discovering defects in its functionality which will lead to major defect in its function
If any function of the LIS is not validated, errors in the client results may occur and affect client safety and satisfaction. The laboratory develops and implements policy–and procedures for Laboratory Information System (LIS) validation including calculated values that are deduced from certain equations following reference guidelines, The functionality of each component that meets predefined acceptance criteria is verified.

Survey process guide:

- GAHAR surveyor may review the policy and procedure of LIS validation.
- GAHAR surveyor may review LIS validation records.
- GAHAR surveyor may interview staff members who are using the LIS to check their awareness.
- GAHAR surveyor may check selected LIS functions to ensure validation.

Evidence of compliance:

1. The laboratory has implemented policy and procedures that describe process for LIS validation.
2. Staff members who are using LIS are aware of the policy requirements.
3. The LIS functionality is regularly evaluated.
4. Valid LIS license is available.
5. LIS user testing record is maintained.
6. Laboratory test calculated values are validated and reviewed according to evidence-based guidelines.

Related standard:

IMT.01 Documentation management system, QPI.04 Data management, aggregation and analysis, IMT.05 LIS validation, IMT.07 LIS User manual.

IMT.06 Maintenance program and Contingency plan are designed to ensure uninterrupted service.

Effectiveness

Keywords:

Maintenance program, Contingency plan.

Intent:

Maintenance of laboratory information system is crucial for effective and uninterrupted function of the LIS. The malfunction of the LIS can affect the client results and satisfaction, so rapid response of that malfunctions is important for the operation system and commitment to TAT.

The contingency plan is a course of action designed to help a laboratory respond effectively to future partial or complete downtime of LIS. Partial or complete downtime of LIS could be happened any time, which will affect the client results and satisfaction

Presence of trained competent staff to deal with these situations will directly affect the continuity of service. Ease of access to the technical support must be ensured in case of LIS malfunction.

The laboratory shall develop maintenance program that covers all types of maintenance needed for effective equipment working conditions (e.g.: preventive, curative maintenance ……). Records of technical support communications ensure effectiveness.

The maintenance program shall cover at least the following:

a) Errors and exception reports review.
b) Database maintenance.
c) Mainframe system(s).
d) Server(s).
e) Personal computer(s).
f) Printer(s).
g) Bar-code equipment (readers and printers).
h) Communication and networking equipment.
i) Uninterruptible Power Supply (UPS) system.

Each laboratory must have a controlled process to deal with downtime. Results should be reported on LIS properly after recovery of the system to ensure data integrity.

The laboratory develops and implement policy and procedures to ensure operation and computer assisted functionalities during scheduled or unexpected Laboratory Information System (LIS) downtime.

The LIS downtime policy includes at least the following:

I) Written procedures and forms to be used during downtime.
II) Documentation and reporting of client results during LIS downtime.
III) Verification of the integrity of the system and data entry after the downtime.
IV) Review of downtime assessment report.
V) The alternative system regularly tested for effectiveness.

Survey process guide:

- GAHAR surveyor may review program of LIS maintenance and check selected maintenance records to ensure implementation.
- GAHAR surveyor may review the contingency plan and the related documents, as work instructions for planned and unplanned downtime, process followed during downtime and result of annual program testing.
- GAHAR surveyor may interview staff to assess their awareness about the response to planned and unplanned downtime.

- GAHAR surveyor may check TAT of client results during planned and unplanned downtime.

Evidence of compliance:

1. The laboratory has a maintenance program for the LIS that includes elements mentioned in intent from a) to i).
2. Responsible staff is trained about the maintenance program and contingency plan.
3. The laboratory has an approved policy and procedures that describe the process for operation during LIS downtime includes elements mentioned in intent from I) to V).
4. Downtime records are regularly reviewed and maintained.

Related standard:

IMT.01 Documentation management system, IMT.07 LIS User manual, IMT.09 Auto verification.

IMT.07 LIS user manual is developed and accessible to all system users.

Effectiveness

Keywords:

LIS User manual

Intent:

LIS user manual is an important guide that gives direction to the staff using the LIS on how to operate the LIS and most common troubleshooting that may face them during operation and how to overcome it to avoid any misuse of the system. The laboratory staff is trained about using LIS according to their responsibilities. Availability and accessibility to the LIS user manual make it easy to all employees to detect errors on LIS rapidly and it can be used as a training tool for the newly hired staff and those using the LIS.
The LIS user manual should be clear, easily to follow and readily available to system users (electronically or paper form).

Survey process guide:

- GAHAR surveyor may review the LIS user manual and ensure that it is regularly updated.
- GAHAR surveyor may interview staff to ensure their awareness and ensure the accessibility of LIS user manual.
- GAHAR surveyor may review training records to ensure that responsible staff are trained on the LIS.

Evidence of compliance:

1. The laboratory has a comprehensive and accessible LIS user manual.
2. Laboratory staff is trained on the LIS proper use according to their responsibilities.
3. The LIS user manual is reviewed, updated on regular basis and when indicated.

Related standard:

WFM.07 Orientation Program, WFM.08 Continuous Education Program, IMT.01 Documentation management system

Data transfer and interfaces

IMT.08 Data transfer from equipment to the LIS is performed effectively

Effectiveness **Keywords:**

Data transfer and Interface.

Intent:

Transferring results, controls and reference ranges electronically through the interface between the equipment and the LIS decrease errors which could happened if occurred manually.
Interface makes reporting of results easier and faster than manual and directly decrease TAT.
The laboratory shall develop policy and procedures to ensure proper and effective transfer of data from equipment to LIS and control any changes that might occur consequently
The reference interval, including units of measure, may be specific for a given client result and should be attached to that result such that it will be displayed along with the client result.

Survey process guide:

- GAHAR surveyor may review the policy and procedure of LIS interface.
- GAHAR surveyor may review selected results to ensure right data transfer.
- GAHAR surveyor may interview staff to assess their awareness of right data transfer process.

Evidence of compliance:

1. The laboratory has an approved policy and procedures that describe the process for data transfer verification and control.
2. Laboratory staff is aware of right data transfer process.
3. Data transferred from the equipment to the LIS is monitored and tracked for any changes that might occur during transfer.

Related standard:

WFM.07 Orientation Program, IMT.01 Documentation management system, IMT.03 LIS management, IMT.04 LIS security, unauthorized access and modifications.

Auto- verification

IMT.09 Auto verification process is validated prior to implementation, periodically tested and easily suspended when needed.

Effectiveness

Keywords:

Auto verification.

Intent:

Auto verification is an alternative to manual review of laboratory test result and is an improvement tool that fasten the release of client results.
Auto verification process shall be properly controlled to prevent release of results that need to be verified and reviewed.
Auto verification must be carefully developed, validated and monitored regularly.

Release of results by auto verification process shall comply with predetermined criteria. The range of results for which auto verification is acceptable must be defined for all client tests subject to auto verification.
Results that fall within these defined parameters are automatically released to client reporting formats without any additional laboratory staff intervention.
Any data that fall outside the defined parameters are reviewed by laboratory staff prior to reporting.
Auto verification should be distinguished from auto filing, where results are released by laboratory staff or instrument operators and automatically filed without any rules-based evaluation.
The laboratory develops and implements policy and procedure for LIS auto verification process including the ability of laboratory personnel to suspend auto verification in the event of a problem with a test method, analytic instrument or the auto verification program.

Survey process guide:

- GAHAR surveyor may review the policy and procedure of LIS auto verification.
- GAHAR surveyor may review selected results to ensure implementation of the policy and procedure.
- GAHAR surveyor may review records for the suspension of auto verification.
- GAHAR surveyor may interview staff to assess their awareness of LIS auto verification and auto verification suspension process.

Evidence of compliance:

1. The laboratory has an approved policy and procedures that describe the process for auto verification including rapid suspension when needed.
2. Staff is ware of auto verification policy.
3. Auto verification/ validation and periodic reviewing records are available.
4. Resealed auto verified client results comply with the predetermined criteria.
5. Record for the suspension of auto verification describing the reason of suspension and the date of suspension are available.

Related standard:

IMT.01Documentation management system, IMT.03 LIS management, IMT.10 Data storage and retrieval.

Data retrieval and preservation

IMT.10 LIS data is stored for easy retrieval when needed.

Efficiency

Keywords:

Data storage and retrieval.

Intent:

Stored client results and archival information must be retrievable to enable laboratory staff to recheck any data needed at any time.
Easy retrieval of client data and results enable the client to take copy of their results at any time when needed.

The laboratory develops and implements policy and procedures for retrieving those data especially in an unexpected destructive event as fire.
Stored client result data and archival information must be easily and readily retrievable within a time frame consistent with client care needs.
Laboratories may implement a backup system (schedule and methods) to keep the data preserved for longer periods, this backup system could be servers or hardware to keep all data preserved for much more time.
Laboratories shall retrieve the client data as long as the LIS is working and then the data can be retrieved on other methods as removable desk or on cloud when the LIS was stop working.

Survey process guide:

- GAHAR surveyor may review policy and procedures for data storage and retrieval.
- GAHAR surveyor may interview stakeholders to ask about data storage and retrieval.
- GAHAR surveyor may check implementation of data backup process.
- GAHAR surveyor may interview staff to assess their awareness of storage and retrieval policy.

Evidence of compliance:

1. The laboratory has an approved policy and procedures for data storage and retrieval.
2. Laboratory staff is trained about data retrieval policy and how to recall old client results when needed.
3. Stored client result data and archival information are retrievable within a time frame consistent with client care needs.
4. The laboratory backup system is implemented.

Related standard:

IMT.01 Documentation management system, IMT.03 LIS management, IMT.04 LIS security, unauthorized access and modifications.

Quality and Performance Improvement

Chapter intent:

It is essential for organizations to have a framework to support the continuous improvement and risk management activities. This requires leadership support, well established processes, active participation from all head of departments and staff. Performance improvement and risk management are parts of both strategic and departmental operational plan.

Globally, Healthcare organizations have adopted, adapted and even created improvement tools to help enhancing the services provided to clients. Multiple quality improvement methodologies were used in healthcare organizations such as PDCA, FOCUSPDCA, Six Sigma, Lean Methodology and others. Locally, The Egyptian ministry of planning adopted the EFQM award for excellence to promote quality practices among governmental entities. Some Egyptian laboratories have participated in international conferences with Six Sigma and FOCUS PDCA projects. In 2013, Health Insurance Organization issued what was known as “Laboratory Performance Indicators Guide”. Practically, Healthcare organizations need to cherish the culture of continuous improvement. GAHAR standards don’t mandate a specific improvement tool or specific monitoring performance measures, yet, a minimum number of monitoring indicators are required. Among many improvement opportunities, GAHAR standards highlighted the importance of improving client journey and supply chain. It is important that each one in the laboratory understand his/her role in improving the healthcare quality and safety, by focusing on the leadership support, department level input and participation, measures and data collection and sustaining Improvement. Implementation of the standards should be in accordance to Egyptian laws and regulations.

Chapter Purpose:

1. To ensure that organization provides effective performance improvement program
2. To ensure effective leadership support
3. To increase effective Departmental participation
4. To improve effective Performance Measurement and Data management
5. To ensure effective Improvement Sustain

QPI Summary of Changes

GAHAR Clinical labs 2025	***GAHAR Clinical labs 2021***	***Details of changes***
QPI.01 **KW:** Quality improvement plan	**QPI.01** **KW:** Quality management program. **QPI.02** **KW:** Quality management qualified individual. **QPI.09** **KW:** performance improvement plan.	- **Updated** Standard (QPI.01) by merging Three standards (QPI.01, QPI.02, and QPI.09) in Labs edition 2021.
QPI.02 **KW:** Performance measures	**QPI.03** **KW:** Performance measures	- **Modified** Standard statement: (**Performance measures are <u>identified, defined and monitored</u> for all significant processes.)** - **Modified** EOCs: • **(EOC.01:** <u>There is a list of</u> the laboratory measures includes the items mentioned in the <u>intent from a) to e).</u> • **(EOC.03:** Staff responsible for the collection, interpretation, and/or use of performance measurement is aware of its definition and <u>identity card contents</u>). • **(EOC.04:** The relevant performance measures <u>are monitored frequently</u>.) • **(EOC.05:** Results of measures analysis are regularly reported to the governing body and to those accountable for <u>improvement and action taking</u>.) - **Add new EOC**: (**EOC.02:** There is an <u>approved identity card</u> for each selected performance measure.)

GAHAR Clinical labs 2025	***GAHAR Clinical labs 2021***	***Details of changes***
QPI.03 **KW:** Data aggregation, analysis, and validation	**QPI.04** **KW:** Data management, aggregation and analysis.	- **Modified Standard statement:** (The laboratory has a process in place for data aggregation, analysis, and validation.) - **Modified** EOC: **(EOC.01:** There is a written process for data review and validation as mentioned in the intent from I) through VII).
QPI.04 **KW:** Internal assessment and nonconformity management.	**QPI.05** **KW:** Internal assessment program. **QPI.06** **KW: N**onconformity management.	- **Updated Standard by merging** (QPI.05 and QPI.06) in Clinical Laboratories 2021 Edition.
QPI.05 **KW:** Risk Management plan/program.	**QPI.07** **KW:** Risk Management plan/program.	- **Modified** EOCs: • **(EOC.01**: The laboratory has a management plan/ program that includes elements mentioned in the intent a) to j). • **(EOC.02:** Actions are taken according to results of risk assessment.) • **(EOC.05:** The laboratory has a proactive reduction tool for at least one high-risk pro annually.) - **Added a new** EOCs: • **(EOC.03:** Results of risk management activities are communicated to the governing body at least quarterly). • **(EOC.04:** The risk management plan and the risk register are evaluated and updated at least annually or when indicated.)
QPI.06 **KW:** Incident Reporting System.	**QPI.08** **KW:** Incident reporting system	- **Rephrasing of Standard statement: (The laboratory develops an incident-reporting system.)** - **Modified** EOCs: • **(EOC.01:** The laboratory has an approved incident-reporting system that

GAHAR Clinical labs 2025	***GAHAR Clinical labs 2021***	***Details of changes***
		includes items from a) through f) in the intent). • **(EOC.03:** Reported incidents are investigated, and corrective / preventive actions are taken to close gaps in services in a timely manner. - **Rephrasing of** EOC: **(EOC.04**: The laboratory provides immediate and ongoing support to clients and staff who are affected by adverse events.) - **Added a new** EOCs: • (**EOC.05**: All sentinel events are investigated, and corrective/preventive actions are taken based on identified root cause analysis.) • (**EOC.06**: All sentinel events are communicated to GAHAR within two working days of the event or becoming aware of the event.).
QPI.07 **KW:** Sustained improvement activities		- **New Standard.**

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

Effective Leadership Support for Sustaining Improvement

QPI.01 Laboratory head of departments plan, document, implement, and monitor an organizational- wide quality improvement plan.

Effectiveness

Keywords:
Quality improvement plan

Intent
It is essential for organizations to have a framework for its quality management system to support continuous improvement. This requires leadership support, well-established processes, active participation from all staff.
Routine monitoring data, as well as data from intensive assessments, contribute to the understanding of where improvement will be planned and what priority is to be given to the improvement. In particular, improvements are planned for the priority data collection areas identified by head of departments. Quality improvement activities are continuously monitored, and the results are reported to the laboratory governing body.

They shall develop a quality improvement, client safety, and risk management plan(s) that should be comprehensive and adequate to the size, complexity, and scope of services provided.
The plan(s) shall address at least the following:

a) The goal(s) (managerial and technical goals) that fulfil the laboratory mission.
b) Organization structure and improvement reporting channels.
c) Roles and responsibilities of head of departments.
d) Define Organizational Priorities.
e) Performance measures road map selection.
f) Data collection, data analysis tools and validation process.
g) Defined criteria for prioritization and selection of performance improvement projects.
h) Defined improvement activities.
i) Quality Improvement model(s) used.
j) Information flow and reporting frequency.
k) Annual evaluation of the plan.

The participation of laboratory staff in performance improvement activities is highly important for improving service quality, productivity, communication, as well as reducing stress and building a stronger working community. The plan shall be communicated to the relevant stakeholders.

The laboratory shall assign a qualified individual with a clear job description to follow up the implementation and improvement of the quality management activities This individual shall apply their knowledge, skills and experience in different quality management tools.

The assigned staff member should be qualified by certification, experience and training to facilitate the program across the organization

Survey process guide:

- GAHAR surveyor may review the laboratory quality improvement plan.
- GAHAR surveyor may interview laboratory head of departments to check their awareness of the plan contents, staff training related to quality concepts, data management, and plan(s) implementation in different laboratory areas.

Evidence of Compliance:

1. The laboratory has an approved quality improvement, and client safety, plan including items mentioned in the intent from a) to k).
2. Laboratory staff is trained and actively participate in performance improvement activities.
3. Quality improvement activities are monitored and results are reported to the governing body.
4. The plan is communicated to the relevant stakeholders
5. A qualified individual(s) is assigned with a clear job description to oversight the quality improvement activities.
6. The plan is reviewed, evaluated and updated annually

Related standards:

APC.03 Sustaining compliance with accreditation standards, OGM.02 Laboratory Director, OGM.04 Laboratory head of departments, QPI.02 Performance measures, QPI.04 Internal assessment and nonconformity management, QPI.05 Risk Management plan/program.

Efficient Data Management

QPI.02 Performance measures are identified, defined and monitored for all significant processes.

Effectiveness

Keywords:

Performance measures.

Intent:

Performance measurement seeks to monitor, evaluate, and communicate the extent to which various aspects of the health system meet their key objectives.

A performance measure is a quantitative variable that either directly measures or may indirectly reflect the quality of care provided. It should be aligned with accountability by enabling stakeholders to make informed decisions by collecting the data and being able to interpret it. Performance measures must be Specific, Measurable, Achievable, Relevant, and Time-bounded (SMART).

To define a measure properly, the description should include, Type of sample, frequency of data collection, Rationale, Numerator, denominator, Inclusion, exclusion, Data aggregation and Communication.

The laboratories shall select a mixture of performance measures based on its mission, client needs, and services, focusing on activities that might be risky in nature to clients or staff, occurring in high volume, associated with problems or high cost.

This includes at least one indicator for each of the following:

a) The laboratory's safety and infection control programs
b) Pre-examination processes
c) Examination processes
d) Post examination processes,
e) Managerial indicators which may include:
    i. Utilization management indicators
    ii. Average waiting times in the relevant service areas
    iii. Client and family satisfaction rates.
    iv. Client complaints.
    v. Staff satisfaction.

vi. Staff complaints.
vii. Procurement of routinely required supplies.
viii. Staff performance.
ix. GAHAR safety requirements
x. Facility management

The amount of data that needs to be evaluated for a performance measure will obviously vary based on how often the data is reported and the frequency with which the subject of the measure occurs.

Once data has been collected for a meaningful amount of time, process improvements can begin to be evaluated. The laboratory uses different charts to track the improvement progress and decides the next step in the improvement plan. The relevant performance measures are monitored frequently. Relevant performance measures are monitored regularly, with results consistently reported to the governing body and those responsible for improvement. The laboratory makes its performance results publicly available at least annually.

Survey guide process:

- GAHAR surveyor may review the list of the facility quality measures.
- GAHAR surveyor may interview responsible staff to check their awareness of the data collection and interpretation process.
- GAHAR surveyor may review performance measures analysis results.

Evidence of compliance:

1. There is a list of the laboratory measures includes the items mentioned in the intent from a. to e).
2. There is an approved identity card for each selected performance measure.
3. Staff responsible for the collection, interpretation, and/or use of performance measurement is aware of its definition and identity card contents.
4. The relevant performance measures are monitored frequently.
5. Results of measures analysis are regularly reported to the governing body and to those accountable for improvement and action taking.

Related standards:

APC.03 Sustaining compliance with accreditation standards, LPO.01Reporting results, SCM.01 Supply Chain Management, OGM.02 Laboratory Director, OGM.04 Laboratory head of departments, QPI.01 Quality improvement plan, QPI.03 Data aggregation, analysis, and validation

QPI.03 The laboratory has a process in place for data aggregation, analysis, and validation.

Effectiveness

Keywords:

Data aggregation, analysis, and validation

Intent:

To reach conclusions and make decisions, data must be aggregated, analysed, and transformed into useful Information.

Data is reviewed, aggregated, analysed, trended, properly displayed and transformed into useful information in order to reach conclusions and to make decisions by laboratory head of departments. So, a qualified staff having the appropriate experiences and skills is assigned to do these tasks as data analysis provides continuous feedback of quality management information to help those individuals make decisions and continuously improve technical and managerial processes

Laboratory head of departments determine how often data are aggregated and analysed.

The frequency depends on the activity or area being measured, the frequency of measurement, and the laboratory's priorities.

The analysis process includes comparisons internally, with other laboratories when available, and with published scientific standards and desirable practices. Data are analysed when undesirable trends and variation are evident from the data.

Data validation is vital to ensure the data is clean, correct, and useful. The laboratory shall use these elements to ensure the quality of data:

a) Validity: data measure what it is supposed to measure.
b) Reliability: everyone defines, measures, and collects data uniformly.
c) Completeness: data include all the values needed to calculate performance measure
d) Precision: data have sufficient detail.
e) Timeliness: data are up to date. Information is available on time.
f) Integrity: data are true.

Conditions at which data should be validated include at least the following:

I) Starting a new measure in general and a clinical measure in specific
II) Publishing the data to the community
III) Any change in the data collection methodology
IV) Unexplained results without justification
V) Change in the source of data
VI) Change in the scope of data collected
VII) Sent to external bodies

Survey process guide:

- GAHAR surveyor may review the laboratory data review and validation process and assess the implemented data review techniques.
- GAHAR surveyor may interview the responsible staff for data analysis to check their awareness.

Evidence of Compliance:

1. There is a written process for data review and validation as mentioned in the intent from I) through VII).
2. Responsible staff members for data aggregation, analysis, and validation are aware and trained about their roles.
3. Data is aggregated and analyzed on regular basis.

4. Data review techniques are implemented to ensure all the elements from a) to f) in the intent are considered.

Related standards:
QPI.01 Quality improvement plan, QPI.02 Performance measures, QPI.07 Sustained improvement activities, OGM.04 Laboratory head of departments.

QPI.04 The laboratory develops a process for internal (self) assessment and nonconformity management.

Effectiveness

Keywords:

Internal assessment and nonconformity management.

Intent:

Internal assessment of the organization is important to ensure the integrity of the quality management system as well as highlighting the opportunities for improvement.

The internal assessment program should ensure that all elements of the quality management system should be assessed at least once annually.

The internal assessment program covers at least the following:

a) Identification of the activities and quality systems to be assessed.
b) Planning/ schedule for the assessment (at least annually).
c) Assessment methodology and data collection tools.
d) Analysis and reporting of assessment results.
e) Development of corrective actions (when needed).
f) Implementation and monitoring of corrective action plan.
g) Management review and approval.

When the non-conformity is identified, the laboratory takes action to identify, document and eliminate the root cause(s). The laboratory shall take appropriate corrective/preventive actions to eliminate the cause(s) of nonconformities. The laboratory shall develop a procedure for identification and management of non-conformity includes at least the following:

I) The responsibilities and authorities for handling nonconformities are designated.
II) The immediate actions to be taken are defined.
III) The extent of the nonconformity is determined.
IV) Each nonconformity is documented and recorded, with these records being reviewed at regular specified intervals to detect trends and initiate corrective action.

Survey process guide:

- GAHAR surveyor may review the documents of internal assessment program.
- GAHAR surveyor may interview responsible staff to evaluate their awareness.
- GAHAR surveyors will review the records of the non-conformities, taken corrective and preventive action taken and their appropriateness to eliminate the root cause.

Evidence of compliance:

1. The internal assessment program covers all the laboratory activities at predetermined frequency (at least annually), as mentioned in the intent from a) to g).
2. Laboratory head of departments review and approve the internal assessment reports and evaluate the effectiveness of the corrective actions taken.
3. Competent and trained personnel performing the assessment.
4. The laboratory has an approved procedure that describe the process for non-conformity management including items in the intent from I) to IV).
5. Records of non-conformity and actions taken is available and maintained.

Related standards:

APC.03 Sustaining compliance with accreditation standards, LPO.01Reporting results, OGM.04 Laboratory head of departments, QPI.03 Data aggregation, analysis, and validation, QPI.01 Quality improvement plan, QPI.07 Sustained improvement activities.

Efficient Risk Management Program

QPI.05 A laboratory risk management plan/program is developed.

Safety

Keywords:
Risk Management plan/program.

Intent:
Risk management is designed to identify potential events that may affect the laboratory and to protect and minimize risks to the laboratory property, services, and employees.
Effective risk management ensures the continuity of laboratory operations.
The laboratory shall adopt a proactive approach to risk management, such as risk analysis where it can assess the high-risk processes, including developing risk mitigation strategies, plans, policies, procedures, a risk register, and processes that support the risk management framework.
The laboratory should take reactive and proactive measures to address identified risks. Risk management plan/program contains essential components that includes at least the following:

a) Scope, objective, and criteria for assessing risks
b) Risk management assigned responsibilities and functions.
c) Staff training on risk management concepts and tools
d) Risk identification, monitoring and reviewing with a define timeframe and updated risk register.
e) Risk management policies and procedures.
f) Clinical risk assessment to Identify the high-risk clients, such as:
    i. Clients with a communicable disease
    ii. Clients with bleeding tendency
    iii. Immunosuppressed clients
    iv. Clients with emotional or psychiatric disorders,
    v. Vulnerable client populations, including frail elderly, dependent children, and clients at risk for abuse and/or neglect.
    vi. Clients at high risk of fall.
g) Risk prioritization and categorization (i.e. strategic, operational, reputational, financial, other)
h) Risk reporting and communication with stakeholder and governing body with a defined timeframe.
i) Risk Reduction plans and tools with priority given to high risks
j) The risk management program/plan is updated annually.

Failure Mode Effect Analysis (FMEA) is one of analysis tool that can be used in the laboratory as a proactive approach.

Survey process guide:

- GAHAR surveyor may review the laboratory risk management program/plan, the risk register, and the risk assessment process.
- GAHAR surveyor may review the reported risk management activities and assess the risk mitigation processes.

Evidence of Compliance:

1. The laboratory has a risk management plan/ program that includes the elements mentioned in the intent a) to j).
2. Actions are taken according to the results of risk assessment.
3. Results of risk management activities are communicated to the governing body at least quarterly.
4. The risk management plan and the risk register are evaluated and updated at least annually or when indicated.
5. The laboratory has a proactive risk reduction tool for at least one high-risk process annually.

Related standards:

EFS.05 Safety and security management plan,EFS.07 Disaster Plan, EFS.08 Pre-Construction risk assessment, IPC.01 IPC program, risk assessment, guidelines QPI.01 Quality improvement plan, QPI.06 Incident Reporting System.

QPI.06 The laboratory develops an incident-reporting system.

Safety

Keywords:

Incident Reporting System.

Intent:

Strong risk management is supported by efficient incident reporting systems that can identify any event which may affect the client or employee safety.

In most laboratory injuries, client complaints, examination errors, equipment failure, or errors in reporting shall be included and reported.

The incidents reporting has an important influence on improving client safety.

Incident reports system helps to detect, monitor, assess, mitigate, and prevent risks that includes at least the following:

a) List of reportable incidents including near misses, adverse events, and sentinel events.
b) Incident management process includes how, when, and by whom incidents are reported and investigated.
c) Staff training on incident management process.
d) Incidents requiring immediate notification to the management.
e) Incident classification, analysis, and results reporting.
f) Indication for performing intensive analysis and its process.

A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury. Sentinel event may include unexpected mortality, wrong client, or wrong procedure events, fire, or Infant abduction.

While both adverse events and sentinel events involve harm to clients, sentinel events are a subset of adverse events that are particularly severe and demand immediate attention and investigation (root cause analysis) and response (corrective/preventive actions)

The findings from these investigations are essential for improving client safety and preventing recurrence. Root cause analysis is also indicated in potential sentinel event (near-miss).

Adverse events can have significant negative consequences for both clients and staff.

The laboratory should understand the emotional and psychological impact of such incidents and should be dedicated to providing comprehensive support to both first and second victims, including immediate

and ongoing assistance. Transparent communication and thorough follow-up are ensured to address any concerns, providing a culture of safety and trust.

Survey process guide:

- GAHAR surveyor may review evidence of incident/sentinel event reporting, analysis and corrective actions taken when gaps are detected.
- GAHAR surveyor may interview staff to check their awareness of the incident-reporting system and the proper implementation.

Evidence of compliance:

1. The laboratory has an approved incident-reporting system that includes items from a) through f) in the intent.
2. All staff is aware of the incident-reporting system, including all types of contracted and outsourced Services.
3. Reported incidents are investigated and corrective / preventive actions are taken to close gaps in services in a timely manner.
4. The laboratory provides immediate and ongoing support to clients and staff who are affected by adverse events.
5. All sentinel events are investigated, and corrective/preventive actions are taken based on identified root cause analysis.
6. All sentinel events are communicated to GAHAR within two working days of the event or becoming aware of the event.

Related standards:

EMS.04 Equipment maintenance, monitoring and failure management, OGM.07 Safety Culture, OGM.06 Ethical management, EMS.06 Equipment failure management, QPI.05 Risk Management plan/program.

Sustaining improvement

QPI.07 Sustained improvement activities are performed within an approved time frame.

Efficiency

Keywords:

Sustained improvement activities

Intent:

Sustaining improvement requires empowering the laboratory staff members for improvement. Although employees play a vital part in the continuous improvement process, it is management's role to train, empower, and encourage them to participate with ideas.

An effective continuous improvement program needs continuous measurement and feedback.

Before starting, laboratory baseline performance needs to be measured. New ideas for improving performance can then follow. Plan-Do-Check-Act (PDCA) cycle, Focus PDCA or other improvement tools allow for scientific testing improvement progress. The cycle ensures continuous improvement by measuring the performance difference between the baseline and target conditions. This information gives immediate feedback on the effectiveness of the change that can help in measuring the impacts of a continuous improvement program and that is the most effective way of sustaining it.

Survey process guide:

- GAHAR surveyor may review an improvement project, to learn how the laboratory utilize data to identify potential improvements and to evaluate actions' impact.
- GAHAR surveyor may review the laboratory monitoring and control mechanisms to sustain the achieved improvements.

Evidence of compliance:

1. There is a written process or methodology for improvement.
2. Actions to correct problems are taken within the approved timeframe.
3. Improvement activities are tested, and the results are recorded and implemented.
4. Improvements projects are monitored and sustained.
5. The laboratory conducts at least one utilization improvement project annually.

Related standards:

QPI.01 Quality improvement Plan, QPI.02 Performance Measures, OGM.02 laboratory director, APC.03 Sustaining compliance with accreditation standards.

Annex (A)

Table (1) summarizing the different classes of biosafety cabinets (BSCs)

BSC Class	*Personnel Protection*	*Product Protection*	*Airflow Design*	*Common Applications*	*Risk Level (CDC/WHO)*
Class I	Yes	No	Inward airflow, exhaust to environment	Low-risk biological work, microbiology, sample prep	**BSL-1, BSL-2**
Class II	Yes	Yes	Inward airflow + HEPA-filtered downward airflow	Diagnostic work, cell culture, viral research	**BSL-2, BSL-3**
Class III	Yes (complete containment)	Yes	Negative pressure + gloves, HEPA-filtered air exhaust	High-risk pathogens (BSL-4), viral research	**BSL-4**

Table (2) summarize the required retention time for laboratories records.

Type of Record	*Retention Period*
Specimen requisitions (including the client chart or medical record if used as the requisition)	(as per regulations)
Temperature charts	(At least 3 months)
Accession records	According to the facility policy
Quality management records	1 year
Validation/verification of method Performance specifications.	1 year after discontinuation of the test
Proficiency testing records	Current cycle and previous complete or at least one 1 year.
Quality control records	1 year
Records of major repairs, parts replacement, and semi-annual or annual calibration checks and preventive maintenance are retained for the life of an instrument.	As long as the equipment is working

Type of Record	***Retention Period***
Detailed records identifying daily, weekly, or monthly performance tests and function checks	1 year
Personnel Records	1 year after discontinuation
Testing Records:	
Instrument printouts and worksheets.	1 year
Client test results and reports, including original and corrected reports, and referral laboratory reports.	(as per regulations)
Laboratory Computer Services:	
Computer system validation records.	1 year beyond the life of the system
Records of changes to software, the test library, and major functions of laboratory Information systems.	1 year
Ongoing computer system checks (e.g. Calculation verification)	1 year

Survey Activities and Readiness

Introduction:

- GAHAR survey process involves performing building tours, observations of staff member files, credential files, and interviews with staff and clients.
- The survey is an information gathering activity to determine organization's compliance with the GAHAR standards.

Readiness Tips:

- To facilitate the completion of the survey within the allotted time, all information and documents should be readily available for the surveyors to review during survey
- If certain staff members are missing, the team will continue to perform the survey; the appropriate missing staff members may join when they are available.
- Files may be in paper or in electronic format; however, the information should, at all times, be safe and secure from unauthorized access, up-to-date, accessible, and readily retrievable by authorized staff members.

	Activity	Timeframe	Location in survey agenda
1	Arrival and Coordination	40-30 minutes	upon arrival
2	Opening Conference	15 minutes	as early as possible
3	Survey Planning	30 minutes	as early as possible
4	Document Review Session	90-60 minutes	
5	Patient\sample Tracer	90-60 minutes	Individual Tracer activity occurs throughout the survey; the number of individuals who surveyors trace varies by organization
6	Break	30 minutes	At a time negotiated with the organization Team Meeting/Surveyor Planning
7	Staff members file review	60-30 minutes	After some individual tracer activity has occurred; at a time negotiated with the laboratory
8	Environment and facility safety plans review	90-45 minutes	After some individual tracer activity has occurred; at a time negotiated with the laboratory

	Activity	Timeframe	Location in survey agenda
9	Environment and facility safety tour	120-60 minutes	After document review
10	Leadership interview	90 minutes	During early or middle of survey
11	Patient centred care activities review	60 minutes	Towards the end of survey
12	Infection Prevention and Control Review	120-60 minutes	In the middle of survey
13	Quality Program\ plan Review	40 minutes	Towards the end of survey
14	Report Preparation	120-60 minutes	At the end of survey
15	Executive Report	15 minutes	At the end of survey
16	Exit Conference	30 minutes	Final activity of survey

Arrival and coordination

To start survey process on time, GAHAR surveyors shall use the time to review the focus of the survey in the light of submitted application

What will happen?
GAHAR surveyors shall arrive to the laboratory and present themselves to the Laboratory staff, survey coordinator shall be available to welcome GAHAR surveyors

How to prepare?
Identify a location where surveyors can wait for organization staff to greet them and a location where surveyors can consider as their base throughout the survey.
The suggested duration of this step is approximately 30 to 60 minutes. Surveyors need a workspace they can use as their base for the duration of the survey. This area should have a desk or table, internet and phone coverage, and access to an electrical outlet, if possible. Provide the surveyors with the name and phone number of the survey coordinator

Who should collaborate?
Suggested participants include laboratory staff and leaders

Opening conference

Why will it happen?
This is an opportunity to share uniform understanding of the survey structure, answer questions about survey activities and create common expectations

What will happen?
GAHAR surveyors shall introduce themselves and describe each component of the survey agenda. Questions about the survey visit, schedule of activities, availability of documents or people and any other related topics should be raised at this time.

How to prepare?
Designate a room or space that will hold all participants and will allow for an interactive discussion.

Who should collaborate?
Suggested participants include members of the governing body and senior leadership. Attendees should be able to address leadership's responsibilities for planning, resource allocation, management, oversight, performance improvement, and support in carrying out your organization's mission and strategic objectives.

Survey planning

Why will it happen?
To ensure efficiency of survey time

What will happen?
Surveyors shall begin selecting clients\samples for tracers based on the care and services the laboratory provides

How to prepare?
Survey coordinator need to ensure that the following information are available for surveyors List of departments/programs/services within the laboratory.

Who should collaborate?
GAHAR surveyors only.

Document review session

Why will it happen?
To help GAHAR surveyors understand laboratory operations

What will happen?
GAHAR surveyors shall review required policies (or other quality management system documents) and policy components based on GAHAR standards

How to prepare?
Survey coordinator shall ensure that all valid current and approved quality management system documents are available for review either in paper or electronic format (approval should be visible, clear and authentic)
Use of bookmarks or notes is advisable to help surveyors find the elements being looked for

1. Performance improvement data from the past 12 months

2. Documentation of performance improvement projects being performed, including the reasons for performing the projects and the measurable progress achieved (this can be documentation in governing body minutes or other minutes)
3. Analysis from a high-risk process
4. Annual risk assessment and Annual Review of the Program

Who should collaborate?
Survey coordinator and policy stakeholders.

Client / sample tracer

Why will it happen?
client\sample tracer is defined as an assessment, made by surveyors shadowing the sequential steps of the processes in an organization that guide the quality and safety of care delivered.
GAHAR surveyors shall follow course of care and services provided to the client to assess relationships among disciplines and important functions and evaluate performance of processes relevant to the individual

What will happen?
- The tracer process takes surveyors across a wide variety of services.
- The tracer methodology's use of face-to-face discussions with staff members and clients, combined with review of records and the observations of surveyors.
- Most of GAHAR standards can be triggered during a client\sample tracer activity which may also include interviewing staff, clients or family members.

How to prepare?
- Assure confidentiality and privacy of clients during tracers including no video or audio recording and no crowdedness
- All efforts will be done to avoid having multiple tracers or tours in the same place at the same time.

Who should collaborate?
Survey Coordinator and any staff member (when relevant)

Break

Why will it happen?
To allow time for surveyor and for laboratory staff to have a break and use the information learned.

What will happen?
GAHAR surveyor shall meet in their base alone.

How to prepare?
Use separate place.

Who should collaborate?
GAHAR surveyors only.

Staff members file review

Why will it happen?
The surveyor shall verify process-related information that recorded in staff member's files. The surveyor shall identify specific staff whose files they would like to review.

What will happen?
- GAHAR surveyor may ensure that a random sample of staff files is reviewed.
- The minimum number of records selected for review is 5 staff member files
- If findings are observed during the file review, the survey team may request additional file samples to substantiate the findings recorded from the initial sample.
- Throughout the review process, if a big number of findings are observed, the survey team may document whether the findings constitute a level of non-compliance
- Surveyor may focus on orientation of staff, job responsibilities, and/or clinical responsibilities, Experience, education, and abilities assessment, Ongoing education and training, performance evaluation, credentialing and competency assessment.

How to prepare?
The laboratory shall produce a complete list of all staff members including outsourced, contracted, full-timers, fixed-timers, part-timers, visitors, volunteers, and others.

Who should collaborate?
Laboratory leaders.

Environment and facility safety plans review

Why will it happen?
GAHAR surveyor may assess the laboratory degree of compliance with relevant standards and identify vulnerabilities and strengths in the environment and facility safety plans.

What will happen?
The surveyor shall review the Environment of Care risk categories as indicated in the laboratory risk assessment and safety data analysis and actions taken by the laboratory leaders.

How to prepare?
Make sure that those responsible for environment and facility safety plans are available for discussion. Also, the following documents have to be available:
- Laboratory licenses, or equivalent
- An organization chart
- A map of the organization, if available
- Environment and facility safety data
- Environment and facility safety Plans and annual evaluations
- Environment and facility safety multidisciplinary team meeting minutes prior to survey
- Emergency\disaster preparedness Plan and documented annual review and update, including communications plans
- Annual training

Who should collaborate?

Environment and facility safety responsible staff members such as safety management coordinator, security management coordinator, facility manager, building utility systems manager, information technology (IT) representative, and the person responsible for emergency management.

Environment and facility safety tour

Why will it happen?
GAHAR surveyor observes and evaluate the laboratory actual performance in managing environment and facility risks.

What will happen?
GAHAR surveyor may Begin where the risk is encountered, first occurs or take a top-down/ bottom-up approach.
GAHAR surveyor may interview staff to describe or demonstrate their roles and responsibilities for minimizing the risk, what they are to do if a problem or incident occurs, and how to report the problem or incident.
GAHAR surveyor may assess any physical controls for minimizing the risk (i.e., equipment, alarms, building features), Assess the emergency plan for responding to utility system disruptions or failures(e.g., alternative source of utilities, notifying staff, how and when to perform emergency clinical interventions when utility systems fail, and obtaining repair services), assess If equipment, alarms, or building features are present for controlling the particular risk, reviewing implementation of relevant inspection, testing, or maintenance procedures
GAHAR surveyor may also assess hazardous materials management, waste management, safety or security measures.

How to prepare?
Ensure that keys, communication tools and contacts are available, so GAHAR surveyor able to access all laboratory facilities smoothly.

Who should collaborate?
Environment and facility safety responsible staff members such as safety management coordinator, security management coordinator, facility manager, building utility systems manager, information technology (IT) representative, and the person responsible for emergency management.

Leadership interview

Why will it happen?
The surveyor will learn about laboratory governance and management structure.

What will happen?
GAHAR surveyor addresses the following issues:

- The structure and composition of the governing body
- The functioning, participation, and involvement of the governing body in the oversight and operation
- The governing body's perception and implementation of its role in the laboratory
- Governing body members understanding of performance improvement approaches and methods
- Pertinent GAHAR Leadership standards relevant to the governing body, direction and leadership in the laboratory including organization culture

- Leadership commitment to improvement of quality and safety, creating a culture of safety, Robust process improvement and Observations that may be indicative of system level concerns

How to prepare?

GAHAR surveyor may need a quiet area for brief interactive discussion with laboratory leaders
The following documents may be reviewed during this session

- Laboratory structure
- Laboratory strategic plan
- Laboratory ethical framework
- Governing Body minutes for the last 12 months
- Leadership safety rounds
- Safety culture assessment
- Clients-centeredness initiatives

Who should collaborate?

Required participants include at least the following: laboratory director, governing body representative, laboratory head of departments, quality coordinator\director.

patient-centered care activities review

Why will it happen?

The surveyor will assess client centeredness initiatives and related activities.

What will happen?

GAHAR surveyor addresses the following issues:

- The GAHAR surveyor may receive information about the client-centered initiatives and culture support.
- GAHAR surveyor may review the related terms of references and meeting minutes with responsible staff members.
- GAHAR surveyor may ask questions to explore the mechanisms taken to plan, assist, and maintain client-centered practices. GAHAR surveyor may interview staff to check their awareness about client centered initiatives.

How to prepare?

Assure confidentiality of documents during the review including no video or audio recording of any documents.
The following documents may be reviewed during this session:

- client family rights and responsibilities policy
- client family rights and responsibilities posters, brochures, flyers.
- client and family educational materials.
- client preparation and assessment records.
- Samples and client identification process.
- clients' suggestions and complaints.
- clients' centeredness initiatives

Who should collaborate?

Required participants include at least the following: laboratory director, laboratory leaders and quality coordinator\director.

Infection prevention and control program review

Why will it happen?
GAHAR surveyor will Learn about the planning, implementation, and evaluation of infection prevention and control program, identify who is responsible for its day-to-day implementation, evaluate its outcome and Understand the processes used by the laboratory to reduce infection

What will happen?
GAHAR surveyor will evaluate laboratory IPC systems by performing system tracers.
Discussions in this interactive session with staff include:

- The flow of the processes, including identification and management of risk points, integration of key activities and communication among staff/units involved in the process; How individuals with infections are identified, Laboratory testing and confirmation process, if applicable, Staff orientation and training activities.
- Strengths in the processes and possible actions to be taken in areas needing improvement; Analysis of infection control data, Reporting of infection control data, Prevention and control activities (for example, staff training, staff vaccinations and other health-related requirements, housekeeping procedures, organization-wide hand hygiene and the storage, cleaning, disinfection, sterilization and/or disposal of supplies and equipment), staff exposure, Physical facility changes that can impact infection control.

How to prepare?
GAHAR surveyor may need a quiet area for brief interactive discussion with staff who oversee the infection prevention and control process. Then time is spent where the care is provided
The following documents may be reviewed during this session

- Infection prevention and control policies
- Infection control education and training records.
- Infection control measures data.

Who should collaborate?
Suggested participants include the infection control coordinator; physician member of the infection control personnel, Safety management staff; organization leadership; and staff involved in the direct provision of care or services.

Activity quality program\plan review

Why will it happen?
GAHAR surveyor will Learn about the planning, implementation, and evaluation of quality management program, identify who is responsible for its day-to-day implementation, evaluate its outcome and Understand the processes used by the laboratory to reduce risks

What will happen?
Discussions in this interactive session with staff include:

- The flow of the processes, including identification and management of risk points, integration of key activities and communication among staff/units involved in the process;
- Strengths in the processes and possible actions to be taken in areas needing improvement; Use of data

- Issues requiring further exploration in other survey activities;
- A baseline assessment of standards compliance.

How to prepare?
GAHAR surveyor may need a quiet area for brief interactive discussion with staff who oversee the quality management program.
The following documents may be reviewed during this session:

- Quality management program
- Performance Improvement projects
- Performance management measures
- Risk Management registers, records and logs

Who should collaborate?
Suggested staff members include quality coordinator\director, staff involved in data collection, aggregation and interpretation.

Report preparation

Why will it happen?
To provide an opportunity of clarification and consolidation of any findings.

What will happen?
Surveyors use this session to compile, analyze, and organize the data collected during the survey into a report reflecting the laboratory compliance with the standards.
Surveyors may also ask organization representatives for additional information during this session.

How to prepare?
GAHAR surveyors may need a room that includes a conference table, power outlets, telephone, and internet coverage.
Who should collaborate? GAHAR surveyors only.

Executive report

Why will it happen?
To give an opportunity to brief the most relevant outcomes of the survey and help prioritization of post-accreditation activities

What will happen?
GAHAR surveyors will review the survey findings with the most senior leader and discuss any concerns about the report

How to prepare?
GAHAR surveyor may need a quiet private area for brief interactive discussion with the most senior leader

Who should collaborate?
Laboratory available most senior leader and others at his/her discretion.

Exit conference

Why will it happen?

To thank the laboratory team for participation and share the important findings in the accreditation journey.

What will happen?

Surveyors will verbally review the survey findings summary, if desired by the most senior leader and review identified standards compliance issues.

How to prepare?

Laboratory available most senior leader may invite staff to attend, an area that can accommodate attending staff is required.

Who should collaborate?

Suggested participants include the laboratory available most senior leader (or designee), senior leaders and staff as identified by the most senior leader or designee.

Glossary

1 **Accreditation:** The objective evaluation process of officially recognizing or certifying that an institution, organization, or individual meets specific standards of quality and competence and can help health care organizations measure, assess, and improve performance in order to provide safe, high quality care for their clients.

2 **Antiseptics**: They are substances that reduce or stop the growth of potentially harmful microorganisms on the skin and mucous membranes. Or Antimicrobial substances that are applied to the skin to reduce the number of microbial floras.

3 **Appointment**: The process of reviewing an initial applicant's credentials to decide if the applicant is qualified to provide client care services that the laboratory's client need and that the laboratory can support with qualified staff and technical capabilities.

4 **Aseptic technique:** It is a method designed to reduce the risk of microbial contamination in a vulnerable body site. This may include laboratory procedures like performing an invasive procedure such as sampling procedures.

5 **Assay**: A quantitative determination or measurement of the amount, activity, or potency of a constituent or characteristic.

6 **Assay range:** The upper and lower limits of the amount, activity, or potency of a specific analytic between which measurement is possible.

7 **Alternative assessment:** A system for determining the reliability of laboratory examinations for which no Commercial proficiency testing products are available, are not appropriate for the method or client population served by the laboratory, or participation is not required by the accrediting organization.

8 **Amended report:** Report issued when the laboratory test report has been modified after its initial issuance for error correction (e.g. mislabelling or incorrect test results), when additional information becomes available, or for further clarification.

9 **Analytical validation:** The process used to confirm with objective evidence that a laboratory developed or Modified FDA-cleared/approved test method or instrument system delivers reliable results for the intended Application.

10 **Awareness**: Knowledge based on training.

11 **Bias**: The difference between the expectation of a test result or measurement result and a true value.

12 **Biological hazards:** A biological substance that poses a threat (or is a hazard) to the health of living organisms, primarily humans. This could include a sample of a microorganism, virus, or toxin that can adversely affect human health.

13 **Biological reference interval:** Specified interval of the distribution of values taken from a biological reference population.

14 **Biological variation:** Consists of within subject (CVI, intra-individual) and between-subject (CVG, inter-individual, group) variation.

15 **Biosafety**: Containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release.

16 **Biosafety cabinet (BSC): -** also known as a biological safety cabinet or microbiological safety cabinet, is an enclosed, ventilated laboratory workspace designed to protect laboratory personnel, the environment, and the materials being handled from exposure to infectious agents and other biohazards. BSCs achieve this by filtering both the inflow and exhaust air through high-efficiency particulate air (HEPA) filters, thereby maintaining a contaminant-free environment inside the cabinet.

17 **Biosecurity**: Securing hazardous material to prevent unauthorized possession, loss, theft, sabotage, misuse, diversion, and accidental or intentional release.

18 **Calibration:** The process of testing and adjustment of an instrument, kit, or test system to provide a known relationship between the measurement response and the value of the substance measured by the test procedure.

19 **Calibrator**: Reference material whose value is used for the independent variable in a calibration function.

20 **Certification**: The procedure and action by which an authorized organization evaluates and certifies that a person, institution, or program meets requirements.

21 **Certified person:** Someone who has passed exams from an accredited organization related to the work that they shall perform.

22 **Cleaning**: It is the process of removing foreign material (e.g. soil, organic material, micro-organisms) from an object.

23 **Community: -** a group of individuals, families, groups, facilities, or organizations that interact with one another cooperate in common activities, solve mutual concerns, usually within the geographic area served by a laboratory.

24 **Community initiative: -** a network of individuals and partner organizations dedicated to improving the health and welfare of a community. These initiatives aim to address and reduce the impact of social problems, thereby enhancing the quality of life for community members. The specific focus of a community initiative can vary depending on the community's unique needs, but common areas include homelessness, drug abuse, domestic violence, and other social issues.

25 **Competence or competency:** A determination of the staff’s job knowledge, skills, and behaviours to meet defined expectations. Knowledge is the understanding of facts and procedures. Skill is the

ability to perform specific actions, behaviours, such as the ability to work in teams, are frequently considered as a part of competence.

26 **Contamination**: The presence of unwanted material or organism, such as an infectious agent, bacteria, parasite, or another contaminant, that is introduced to an environment, surface, object, or substance, such as water, food, or sterile medical supplies.

27 **Control material:** A device, solution, lyophilized preparation, or cellular element intended for use in the quality control process.

28 **Credentialing**: a formal process of verifying the professional's education, training, experience, and other relevant credentials to confirm their ability to practice medicine safely and effectively and to ensure that healthcare professionals possess the necessary qualifications, training, licensure, and competence to provide high-quality care.

29 **Credentials**: Documents that are issued by a recognized entity to indicate completion of requirements or the meeting of eligibility requirements, including education (such as a diploma from a medical school, specialty training completion letter or certificate, completion of the requirements of a medical professional organization, licensure, recognition of registration with a medical or dental council, training, and experience, which indicate the individual's sustainability to fulfil a role.

30 **Critical interval:** Interval of examination results for an alert (critical) test that indicates an immediate risk to the client of injury or death.

31 **Discrepant report** is issued when the results of laboratory tests do not align with expected outcomes, previous test results, or clinical finding. This discrepancy can raise concerns about the accuracy or reliability of the test results and may require further investigation or confirmation.

32 **Disinfectants:** Substances that are applied to the surface of non-living objects in order to destroy microorganisms but not necessarily bacterial spores.

33 **Disinfection:** The process of reducing the number of pathogenic microorganisms, but not necessarily bacterial spores to a level which is no longer harmful to health. It may be high level, intermediate level or low-level disinfection depending on the level of probable risk.

34 **Evidence-Based Practice:** A way of providing health care that is guided by a thoughtful integration of the best available scientific knowledge with clinical expertise. This approach allows the practitioner to critically assess research data, clinical guidelines, and other information resources in order to correctly identify the clinical problem, apply the most high-quality intervention, and re-evaluate the outcome for future improvement.

35 **Examination process:** (analytic) processes that include all activities for performing the examinations, verifying the reliability of the results, and interpreting the findings.

36 **Examination procedure:** Set of operations, described specifically, used in the performance of examinations according to a given method.

37 **External quality assessment:** The evaluation of analytical performance that includes a sample for which the analyst does not know the expected measurement result, e.g.: External quality control and assurance or proficiency testing.

38 **Guideline**s: Series of suggestions, issued by official bodies, or by independent experts, for the conduct of medical practice.

39 **Hand hygiene:** A general term that applies to handwashing, antiseptic hand wash, antiseptic hand rub, or pre-procedural hand antisepsis.

40 **Hazardous materials and waste management plan:** The laboratory written document that describes the process it would implement for managing the hazardous materials and waste from source to disposal. The plan describes activities selected and implemented by the laboratory to assess and control occupational and environmental hazards of materials and waste (anything that can cause harm, injury, ill-health, or damage) that require special handling. Hazardous materials include chemical materials. Hazardous wastes include the biologic waste that can transmit disease (for example, blood, and tissues), toxic chemicals, and infectious waste, such as used needles and used bandages.

41 **Head of department:** The staff member who manages and directs the subgroups of the organization, commonly referred to as departments, services, units, or wards.

42 **Healthcare accreditation**: - a process in which an independent, external body evaluates and certifies that a health care organization meets established standards of quality and performance. This assessment includes various aspects of client care, safety, and organizational management, aiming to enhance the quality of health services provided.

43 **Healthcare-Acquired Infection (HAI):** Any infection(s) acquired by a client while receiving care or services in a healthcare organization.

44 **Hygiene**: The practice that serves to keep people and environments clean and prevent infection.

45 **Immunization:** is the process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine (active immunisation) or serum containing desired antibodies (passive immunisation). Vaccines stimulate the body's own immune system to protect the person against subsequent infection or disease, Infection control practitioner.

46 **Infection**: The transmission of a pathogenic microorganism.

47 **Infection control program:** An organized system of services designed to meet the needs of the laboratory in relation to the surveillance, prevention, and control of infection, which impacts clients, staff, physicians, and/or visitors.

48 **Internal quality control plan:** Set of procedures. undertaken by laboratory staff for the continuous monitoring of operations and the results of measurements in order to decide whether results are reliable enough to be released or not.

49 **Inventory**: A written list of all the objects, abilities, assets, or resources in a particular place.

50 **IPC committee:** The Infection Control Committee is generally comprised of members from a variety of disciplines within the healthcare facility; bringing together individuals with expertise in different areas of healthcare.

51 **Job description:** Statements or directions specifying required decisions and actions. Penalties, legal or otherwise, are normally assessed when laws and regulations are not followed.

52 **Laboratory acquired infections:** Infections resulting from exposure to infectious agents in laboratories due to accidents or breaches in safety protocols.

53 **Laboratory director:** Person(s) with responsibility for, and authority over, a laboratory.

54 **Laboratory Supplies:** All commodities not identified elsewhere in these definitions, normally consumed or expended during laboratory activity. Examples are clamps, filters, stopcocks, measures, stoppers, thermometers, plasticware and metal ware.

55 **Laws and regulations**: Statements or directions specifying required decisions and actions. Penalties, legal or otherwise, are normally assessed when laws and regulations are not followed.

56 **Linearity**: the ability of a laboratory method to produce test results that are directly proportional to the concentration of the analyte across a given range. It is evaluated by testing samples of varying concentrations and plotting a calibration curve to determine if the response remains consistent. A high correlation coefficient (r^2, typically >0.99) indicates good linearity. This parameter is essential in ensuring the accuracy, consistency, and reliability of laboratory test methods during verification and validation processes.

57 **Medical staff:** an organized group of licensed healthcare professionals, including physicians, dentists, and other practitioners, who are authorized by healthcare facility to provide medical care to clients.

58 **Near miss:** is an unplanned event that did not result in injury, illness, or damage – but had the potential to do so.

59 **Personal protective equipment (PPE):** it is equipment worn to minimize exposure to hazards that cause serious workplace injuries and/or illnesses.

60 **Point of care testing:** Testing performed near or at the site of a client, with the result leading to possible change in the care of the client.

61 **Post-examination:** Processes following the examination, including review of results, retention and storage of clinical material, sample (and waste) disposal, and formatting, releasing, reporting, and retention of examination results.

62 **Precision**: A key element of method verification and validation that assesses the reproducibility and repeatability of a test method. It is determined by analysing samples of varying analyte concentrations, both within a single run and across multiple runs over time. Precise methods yield results that are very close to each other, demonstrating minimal variation among repeated measurements of the same sample. This parameter is crucial for ensuring the accuracy, consistency, and reliability of laboratory test methods.

63 **Pre-examination processes:** Processes starting, in chronological order, from the request for examination and including the examination requisition, preparation of the client, collection of the primary sample, and transportation to or within the laboratory, and ending when the analytical examination procedure begins.

64 **Privileging**: the process by which a healthcare facility grants a provider the authority to perform specific procedures and offer particular services within that facility. This process involves assessing and confirming that the provider possesses the necessary skills, training, and competence to carry out those procedures safely and effectively. Unlike credentialing, which verifies a provider's general qualifications and background, privileging focuses on authorizing specific clinical activities tailored to the provider's demonstrated competencies. This distinction is crucial for maintaining high standards of client care and ensuring that providers operate within their areas of expertise.

65 **Procedure**: a series of steps to be followed as a uniform and repetitive approach to accomplish an end result. Procedures provide a platform for uniform implementation to decrease process variation, which increases procedure control. Decreasing process variation is how we eliminate waste and increase performance.

66 **Procurement**: The process of acquiring supplies, including those obtained by purchase, donation, and manufacture. It involves efforts to quantify requirements, select appropriate procurement methods, and prequalify suppliers and products. It also involves managing tenders, establishing contract terms, assuring medications quality, obtaining the best prices, and ensuring adherence to contract terms.

67 **Proficiency testing**: - an external method / system to evaluate a laboratory's proficiency and verify the accuracy of results and measurements in performing a specific test method, by analysing specimens with unknown values provided by an external source. This practice involves comparing a laboratory's results with those of peer institutions to ensure accuracy and reliability in testing procedures.

68 **Quality control data**: - various quality control procedures designed to monitor and evaluate the accuracy and precision of laboratory tests. This data is essential for detecting, reducing, and correcting deficiencies in a laboratory's analytical processes before releasing client results.

69 **Reagent:** a compound or mixture added to a system to start or test a chemical reaction. reagent can be used to determine the presence or absence of a specific chemical substance as certain reactions are triggered by the binding of reagents to the substance or other related substances.

70 **Referral laboratory:** External laboratory to which a sample is submitted for an examination procedure.

71 **Reference laboratory:** A large laboratory that performs miscellaneous testing not routinely performed such as tests that require specialized equipment.

72 **Reference laboratory:** the laboratory that receives a specimen from another laboratory and that performs one or more tests on such specimen.

73 **Referring laboratory:** The laboratory that refers a specimen to another laboratory for testing.

74 **Safe injection:** A practice intended to prevent needle stick injuries and other possible contamination during syringe introduction in a client; ultimately preventing transmission of blood borne infectious diseases between one client and another, or between a client and a healthcare professional.

75 **Safety Data Sheet (SDS**): - a standardized document that provides detailed information about a chemical substance or mixture, focusing on its hazards and guidelines for safe handling, use, storage, and disposal. The primary purpose of an SDS is to ensure that workers and emergency responders have access to essential safety information to protect health and the environment. The content and format of an SDS are internationally standardized, typically comprising 16 sections that cover various aspects of the chemical, including: Identification, hazard(s) identification, composition/information on ingredients, first-aid measures, fire-fighting measures, accidental release measures, handling and storage, exposure controls/personal protection, physical and chemical properties, stability and reactivity.

76 **Sampling**: - the process of collecting biological specimens, such as blood, urine, or tissue, from clients for the purpose of diagnostic testing and analysis. This procedure is critical, and should be done under strict protocols to maintain sample integrity as the accuracy of laboratory test results heavily depends on the quality of the collected samples. Errors in the pre-analytical phase, which includes sample collection, can significantly impact client outcomes.

77 **Sensitivity:** The ability of an analytical method to detect small quantities of the component.

78 **Sentinel Event:** A client safety event (not primarily related to the natural course of a client's illness or underlying condition) that reaches a client and results in death, severe harm (regardless of duration of harm), or permanent harm (regardless of severity of harm).

79 **service users:** - include a wide range of individuals and organizations, such as clients seeking medical tests, healthcare providers referring clients for diagnostics, and businesses conducting routine health screenings. These users benefit from the laboratory's independence, which often results in faster turnaround times and tailored services. Standalone laboratories primarily conduct standardized tests using simple technology, enabling them to function with moderate capital investment and efficiently serve local communities.

80 **Single-use device** A disposable device: it is intended for use on one client during a single procedure. It is not intended to be reprocessed (cleaned and disinfected or sterilized) and used on another client. Using disposable items improves client safety by eliminating the risk of client-to-client contamination because the item is discarded and not used on another client.

81 **Specificity:** The ability of a test to detect only the disease or condition it is intended to find.

82 **Standalone laboratory**: - an independent facility that operates separately from hospitals or physician offices, offering diagnostic testing services directly to clients or healthcare providers. This laboratory is self-contained units, providing a range of tests without relying on external medical establishments. They are characterized by autonomy, flexibility, and cost-effectiveness, making them accessible options for various communities.

83 **Sterilization**: a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods.

84 **Suboptimal specimens:** Specimens that do not meet the ideal requirements of collection e.g., samples with only one client identifier, improperly collected or preserved specimens such as clotted, haemolyzed, or contaminated samples, insufficient sample volume, leaking containers, improper client preparation, or biopsies' /smears received in inappropriate preservatives.

85 **Supplies:** the basic tools laboratory staff use to help them do their jobs in the lab, and it is vital that they be reliable, easy and safe to use, and cost effective.

86 **Traceability:** the ability to link a measurement result to a recognized reference standard through an unbroken chain of comparisons, each with a stated measurement uncertainty. It ensures the reliability, accuracy, and consistency of laboratory results. It is essential for ensuring the reliability and comparability of laboratory test results across different institutions and over time.

87 **Trueness**: - The closeness of the mean value of a set of test results to the actual or reference value. It indicates how accurately a measurement method can determine the true concentration of an analyte. It is typically assessed by comparing measured values against certified reference materials or known standards. It is considered as a key element of method verification in a laboratory setting and essential in ensuring the accuracy, consistency, and reliability of laboratory test methods during verification and validation processes.

88 **Turnaround time:** Elapsed time between two specified points through pre-examination, examination and post-examination processes.

89 **Utilization management:** the systematic evaluation of laboratory test orders to ensure they are appropriate, necessary, and cost-effective. This process aims to optimize clients care by promoting the use of necessary tests while minimizing unnecessary or redundant testing. Effective UM requires collaboration among clinicians, laboratory professionals, and administrators to establish guidelines and protocols that support evidence-based decision-making. By implementing UM strategies, healthcare facilities can enhance the quality of care, reduce healthcare costs, and improve client outcomes.

90 **Verification:** the process by which a laboratory confirms that it can competently perform a test method as documented and intended by the method's developer or standardizing body. Verification applies to methods that have been standardized, validated elsewhere (e.g., by the method developer, a collaborative study, or another laboratory), or published in reputable sources

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