الهيئة العامة للاعتماد والرقابة الصحية
GAHAR

GAHAR HANDBOOK FOR

CLINICAL LABORATORIES STANDARDS

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Version 2021

IEEA | International Society
for Quality in Health Care
External Evaluation Association

**General Authority for Healthcare Accreditation
and Regulation**

**GAHAR Handbook for Clinical Laboratories
Accreditation Standards, Edition 2021**

Awarded by ISQua EEA
following an independent assessment
against the Guidelines and Principles for the
Development of Health and Social Care Standards,
5th Edition

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is from
August 2021 until **August 2025**

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Foreword

As an essential step towards implementing the comprehensive healthcare recovery in Egypt, here is the GAHAR Handbook for Laboratory standards – Edition 2021 issued by the General Authority for Healthcare Accreditation and Regulation (GAHAR). This edition is a continuation of the efforts started in the last century for improving healthcare services in the country through standardization. The development of these standards is a valuable eventual product of collaborative efforts of representatives from the different health sectors in Egypt, including the Ministry of Health and Population, the private sector, university professors, and professional syndicates.

This book of standards handles healthcare delivery from three main perspectives, the patient-centered perspective, the organization-centered perspective and the total testing process perspective. Each perspective is thoroughly handled in a separate section with focus on the minimal requirements needed for laboratories' accreditation. The first section discusses accreditation prerequisites and conditions. The second section discusses patient-centered standards and adopts Picker›s model for patient-centered care to ensure responsiveness of organizations to patients› needs. The third section discusses the organization centered care standards and the fourth section discusses the total testing process standards, highlighting many aspects required for workplace suitability to provide safe and efficient healthcare.

While these standards were carefully tailored to steer the current situation of Egyptian healthcare in the direction of Egypt's 2030 Vision, they have been finely compared to international standards and found to meet their basic intent that apply to Egyptian laws, regulations, and culture. It is expected that the standards shall be a catalyst for applying change and improvement in both the culture and practice of medical laboratories in Egypt.

Introduction

Clinical laboratory services are essential to patient care and therefore have to be available to meet the needs of all patients and the clinical personnel responsible for the care of those patients.

Such services include arrangements for examination requests, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent interpretation, reporting and advice, in addition to the considerations of safety and ethics in Clinical laboratory work. Whenever allowed by national, regional or local regulations and requirements, it is desirable that Clinical laboratory services include the examination of patients in consultation cases, and that those services actively participate in the prevention of disease in addition to diagnosis and patient management. Each laboratory should also provide suitable educational and scientific opportunities for professional staff working with it.

Patient-centered care in laboratories is concerned with being respectful of, and responsive to, the preferences, needs and values of patients and consumers. Surveys measuring patients' experience of healthcare are optimal for such purposes. Scientific based evidences have demonstrated that patient-centered care improves patient care experience and creates public value for services. When laboratory administrators and healthcare providers work in partnership with patients and their families, the quality and safety of healthcare rise, costs decrease, provider satisfaction increases and patient care experience improves. Patient centered care can also positively affect business metrics such as finances, quality, safety, satisfaction and market share.

Patients are not the only customers of laboratories. Laboratory workers are considered of no less importance. Although debate continues regarding whether worker wellbeing should be considered part of the patient safety initiatives, many laboratories have already placed them as key players and success partners in the healthcare industry worldwide. Three major aspects may affect workers› well-being: Safety, Stress and Organizational Structure.

This book defines the minimum requirements for laboratories to comply with patient safety, centeredness while maintaining a safe, structured and positive work environment

Scope of this Handbook

These standards apply to clinical 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 standards describe the competent level of service in each phase of laboratory testing process. They reflect a desired and achievable level of performance against which a laboratory's actual performance can be compared. The main purpose of these standards is to direct and maintain safe healthcare practice. These standards also promote and guide organization management. They assist staff, management team, and the laboratory as a whole to develop safe staffing practices, delegate tasks to licensed and unlicensed staff members, ensure adequate documentation, and even create policies for new technologies. Compliance with GAHAR standards guarantees laboratory accountability for its decisions and actions. Many standards are patient-centred and safety-focused to promote the best possible outcome and minimize exposure to the risk of harm. These standards encourage laboratory staff to persistently enhance their knowledge base through experience, continuing education, and the latest guidelines. These standards can be used to identify areas for improvement in laboratory practice and work areas, as well as to improve patient and workplace safety.

Use
Reading and Interpretation of the book

- The General Authority for Healthcare Accreditation and Regulations evaluates organization's structure, process, and/or outcome by setting standards that address these concepts.
- Within this context, there should be no confusion between accreditation standards and licensure standards. When applied to licensure of an individual practitioner or laboratory, the standard is usually set at a minimal level designed to protect public health and safety.
- This book is divided into four sections, in addition to the foreword, introduction, Scope of this handbook, Purpose, Use, 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.
  - implementation guiding documents that need to be checked in order to achieve good compliance with the standards.
  - purpose that details follow the introduction, and each one has a standard or more.
- 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 related standards.

Standard Component:
- **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**
  Keyword is meant 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 meet 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.
- Documents:
  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.
- Document:
  Created by planning what needs to be done.
- Record:
  Created when something is done.

Applying for a GAHAR survey

A laboratory seeking GAHAR accreditation begins by:
- Applying to join the program via www.gahar.gov.eg or by sending an email to reg@gahar.gov.eg
- GAHAR is going to respond by sending an application template attached to the email. The laboratory will complete the application and upload the required documents.
- The laboratory documents will be reviewed.
- GAHAR will determine survey financial fees, and bank account details shall be shared.
- The laboratory will make the payment to the Central Bank of Egypt on the bank account, and it will send the receipt back via email
- An appointment for the survey visit will be determined for the laboratory.
- GAHAR's surveyor team will evaluate your laboratory according to the GAHAR Handbook for laboratory standards.
- The survey report is submitted to the accreditation committee to review and decide based on the 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 to them over a look back period of time.
- Look back period: It is the period before the survey visit to which any laboratory is obliged to comply with the GAHAR accreditation standards. Failure to comply with this rule will affect the accreditation decision.
- Look back period varies from one laboratory to another, depending on registration and accreditation status.
- A registered laboratory seeking accreditation will:
  - Comply with the National Safety Requirements during the whole period between receiving the approval of registration and the actual accreditation survey visit.
  - Comply with the rest of the GAHAR Handbook for laboratory standards for at least four months before the surveyor's visit.
- A laboratory seeking re-accreditation:
  - For GAHAR accredited laboratories, compliance with the GAHAR Handbook for laboratory standards from receiving the approval of the previous accreditation till the next accreditation survey visit is required.

Scoring Guide

During the survey visit, each standard is scored for the evidence of compliance (EOC).
These are mathematical rules that depend on summation and percentage calculation of scores of each applicable EOCs 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 lookback period with a total score of 1
- **Not met** when the laboratory shows less than 50% compliance with requirements during the required lookback period with a total score of 0
- **Not applicable** when the surveyor determines that, the standard requirements are out of the organization 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% but 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
- No single whole standard is scored as not met.

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 NSR 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 NSR 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 NSR standard.

Laboratories having status of accreditation or conditioned accreditation with elements of non-compliance are requested to:
- Submit a corrective action plan for unmet 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 me 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 presence of one not met EOC or more,
- The Laboratory fails to pass unannounced survey,

The Laboratory fails to comply with GAHAR circulars when applicable.

Acknowledgments
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Acronyms

Code	Decoding (Meaning)
APC	Accreditation prerequisites and conditions
NSR	National Safety Requirements
PCC	Patient Centeredness Culture
OGM	Organization Governance and Management
EFS	Environment and Facility Safety
EMS	Equipment management system
IPC	Infection Prevention and control
SCM	Supply chain management
WFM	Workforce Management
QPI	Quality and Performance Improvement
TPR	Technical pre-examination
TEX	Technical examination
TEQ	Technical examination quality
TPO	Technical post examination
IMT	Information Management and Technology
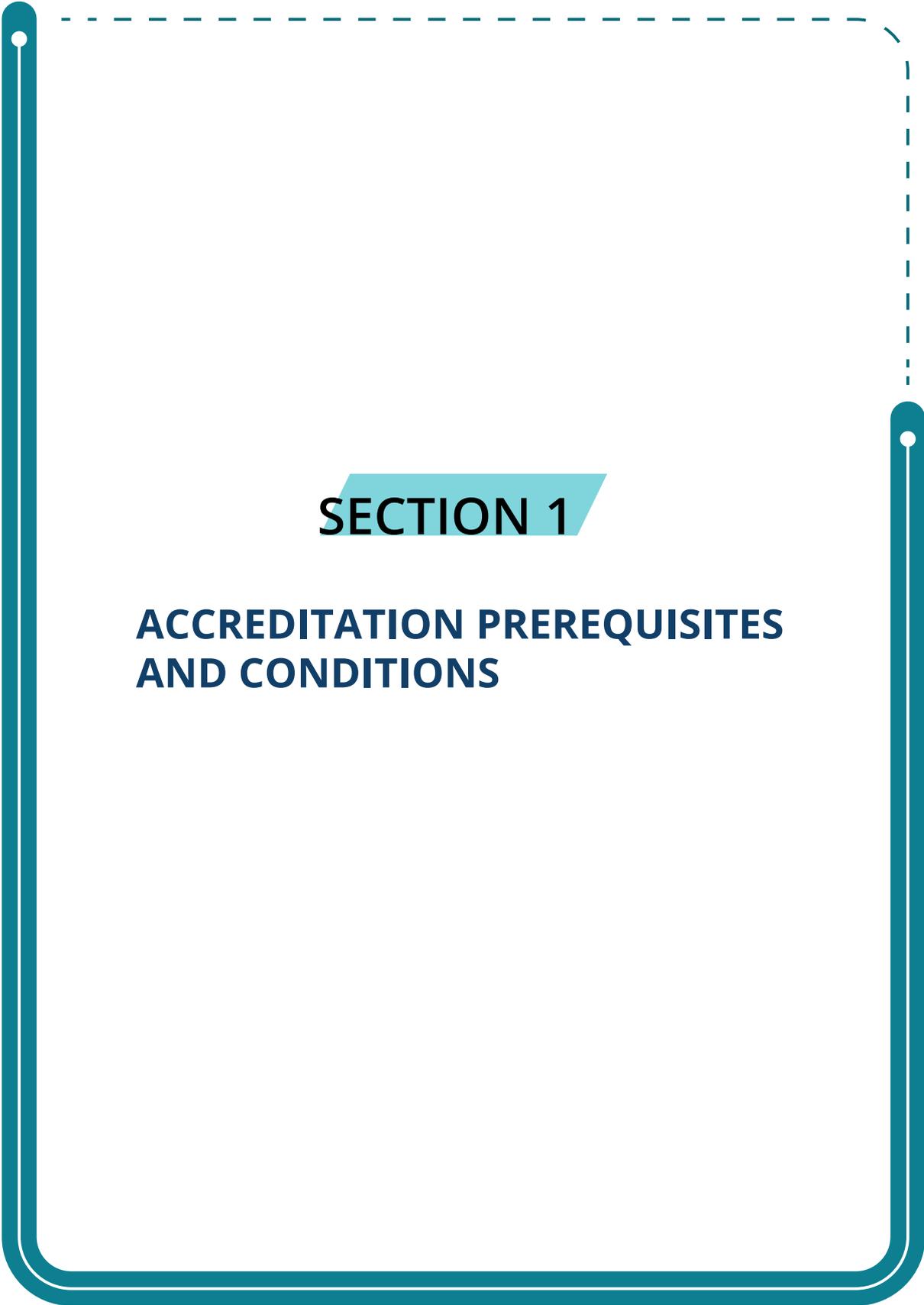
SECTION 1

ACCREDITATION PREREQUISITES AND CONDITIONS

Section 1: Accreditation Prerequisites and Conditions

Section Intent:

This section consists of specific requirements for participation in the GAHAR accreditation process and for maintaining an accreditation award. Scores of these standards are always be met in order to continue the survey process. One partially met or not met evidence of compliance is to be dealt with on the GAHAR accreditation committee level and may result in denial or suspension of accreditation.

Compliance with GAHAR accreditation prerequisites

APC.01 For GAHAR registered laboratories, the laboratory sustains, ensures and monitors compliance with registration requirements.

<div align="right">Safety</div>

<u>Keywords:</u>

Sustaining registration requirements

<u>Intent:</u>

Registration requirements are considered the minimum level of quality, safety, and compliance for any laboratory aiming at being enrolled in the Universal Health Insurance system. The laboratory is required to complete the electronic application form and submit the following documents upon registration for accreditation or re-accreditation:

a) Scope of service
b) Strategic Improvement Plan (SIP)
c) Proficiency Testing (PT) (one full cycle for accreditation).
d) Internal quality control (IQC) (one-year QC data for accreditation)
e) Method Verification records
f) Appointment decree of laboratory director and quality management responsible individual
g) Policies and procedures of the following:
   - Patient-Centered Standards
   - Organization-Centered Standards
   - Total Testing Process standards

When the laboratory is registered, it is expected that the laboratory shall sustain or improve the same level of quality scored during the registration visit.

Any major laboratory changes including leadership shall be submitted to the GAHAR authority within 30 days of the changes.

<u>Survey process guide:</u>

During the GAHAR survey, the surveyor shall assess compliance with the standard requirements.

Evidence of compliance:

1. The laboratory provides GAHAR with documents from a) to g) in the intent upon registration for accreditation or re-accreditation
2. The laboratory establishes a process of frequent assessment of compliance with registration requirements.
3. The laboratory acts on all feedback and reports received from GAHAR during the registration period in a timely manner.
4. When a gap is identified, the laboratory takes all necessary measures to improve performance and sustain compliance.
5. The laboratory reports to GAHAR any challenges that affect compliance with registration requirements.
6. The laboratory reports to GAHAR any major changes within 30 days of the changes.

Related standards:

OGM.07 Strategic and operational Plans, TEQ.01 Internal quality control plan, TEQ.05 proficiency testing samples, TEQ.06 Alternative assessment procedure, external quality assessment, TEX.01 validated examination procedure.

APC.02 The laboratory ensures safe medical provision through complying with GAHAR Healthcare Professionals Registration.

Safety

Keywords:

Registration of staff

Intent:

Laboratory staff registration process aims at ensuring the competence of laboratory staff by matching their qualifications and experience to registered or accredited laboratory scope of services. In return, this process will improve the quality of laboratory service provided to the community. The laboratory is expected to register 100% of all laboratory members who should cover the laboratory scope of service. The laboratory leaders shall create a process to register all applicable newly hired staff members within 1-3 months.

Survey process guide:

During the GAHAR survey, the surveyor may assess compliance with the standard requirement.

Evidence of compliance:

1. The laboratory develops a process for registering all members of the required laboratory staff.
2. The process covers all full-time, part-time, or other types of contracts/agreements.
3. The laboratory reports to GAHAR, healthcare authority, and professional syndicates of any finding that can affect patient safety.

Related standards:

WFM.01 Workforce manual, Laws and regulations, WFM.03 Recruitment, WFM.07 competency assessment, WFM.08 staff performance evaluation, WFM.12 Verifying credentials

Transparent and ethical relationships

APC.03 The laboratory provides GAHAR with accurate and complete information through all phases of the registration and accreditation process.

<div align="right">Effectiveness</div>

Keywords:

Accurate and complete information.

Intent:

During registration and accreditation processes, there are many points at which GAHAR requires data and information. When a laboratory is registered, it lies under GAHAR's scope to be informed of any changes in the laboratory and any reports from external evaluators. The laboratory provides information to GAHAR through electronic application. 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, whether registered, accredited, or just interested in engaging 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:

Before and during the course of the GAHAR survey, surveyors expect transparency of sharing information, reports, or concerns related to registration, 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 registration process and along the entire period between registration and accreditation processes.
2. The laboratory reports within 30 days any addition or deletion of laboratory scope of service, any expanded facilities by 15% or greater, as measured by patient volume, scope of services, or other relevant measures or any structural changes in the laboratory (merged with, consolidated with, or acquired an unaccredited site, service, or program for which there are applicable GAHAR standards).
3. The laboratory provides GAHAR access to evaluation results and reports of any evaluating organization

Related standards:
OGM.03 Governing body responsibility, IMT.01 Documentation management system.

APC.04 The laboratory uses the accreditation process to improve safety and effectiveness.

<div align="right">Safety</div>

Keywords:
Accreditation process value

Intent:
GAHAR accreditation implies that a laboratory is a place that maintains high safety standards. Public, governmental bodies, staff, third party payers, among others, will assume credibility in accredited laboratory processes.

Thus, GAHAR has the right to obtain any information to confirm standards and accreditation policy compliance and/or evaluate patient safety and quality concerns at any time during all phases of accreditation. When external bodies other than GAHAR evaluate areas related to safety and quality such as fire safety inspections, staff working conditions inspections, and evaluation of safety incidents or quality complaints, the laboratory should report to GAHAR, and these evaluations are complementing accreditation reviews.

Creating a safe culture is not an easy task; it requires everyone to be aware of safety issues and able to report them.

The laboratory safety is improved by sharing knowledge with GAHAR about any challenges identified through internal or external processes.

The laboratory's website, advertising, promotion, brochures, newspapers, and other information are made available to the public accurately reflecting the scope of programs and services that are accredited by GAHAR.

Survey process guide:
During the GAHAR survey, surveyors expect transparency of sharing information, reports, or concerns related to safety issues. GAHAR surveyors shall expect to see announcements to inform staff and patients on mechanisms to report safety issues to GAHAR.

Evidence of compliance:
1. The laboratory permits GAHAR to perform on-site evaluations of standards and policy of compliance or verification of quality and safety concerns, reports, or regulatory authority sanctions.
2. The laboratory accurately represents its registration and accreditation status and scope.
3. The laboratory informs staff and patients on mechanisms to report safety issues to GAHAR.

Related standards:
QPI.03 Performance measures, QPI.06 Nonconformity management, QPI.09 Continues improvement program.

APC.05 The laboratory maintains professional standards during the survey.

<div align="right">Equity</div>

Keywords:
Professional standards during surveys

Intent:
A 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.

Survey process guide:
During the GAHAR survey, surveyors expects that safety, security, confidentiality, privacy, respect, integrity, objectivity, and professional competence values are going to be preserved at all times.

Evidence of compliance:
1. During surveys, the laboratory reports any conflict of interest to GAHAR with evidence.
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.

Related standards:
OGM.11 Ethical management, OGM.09 Performance and Accreditation Disclosure
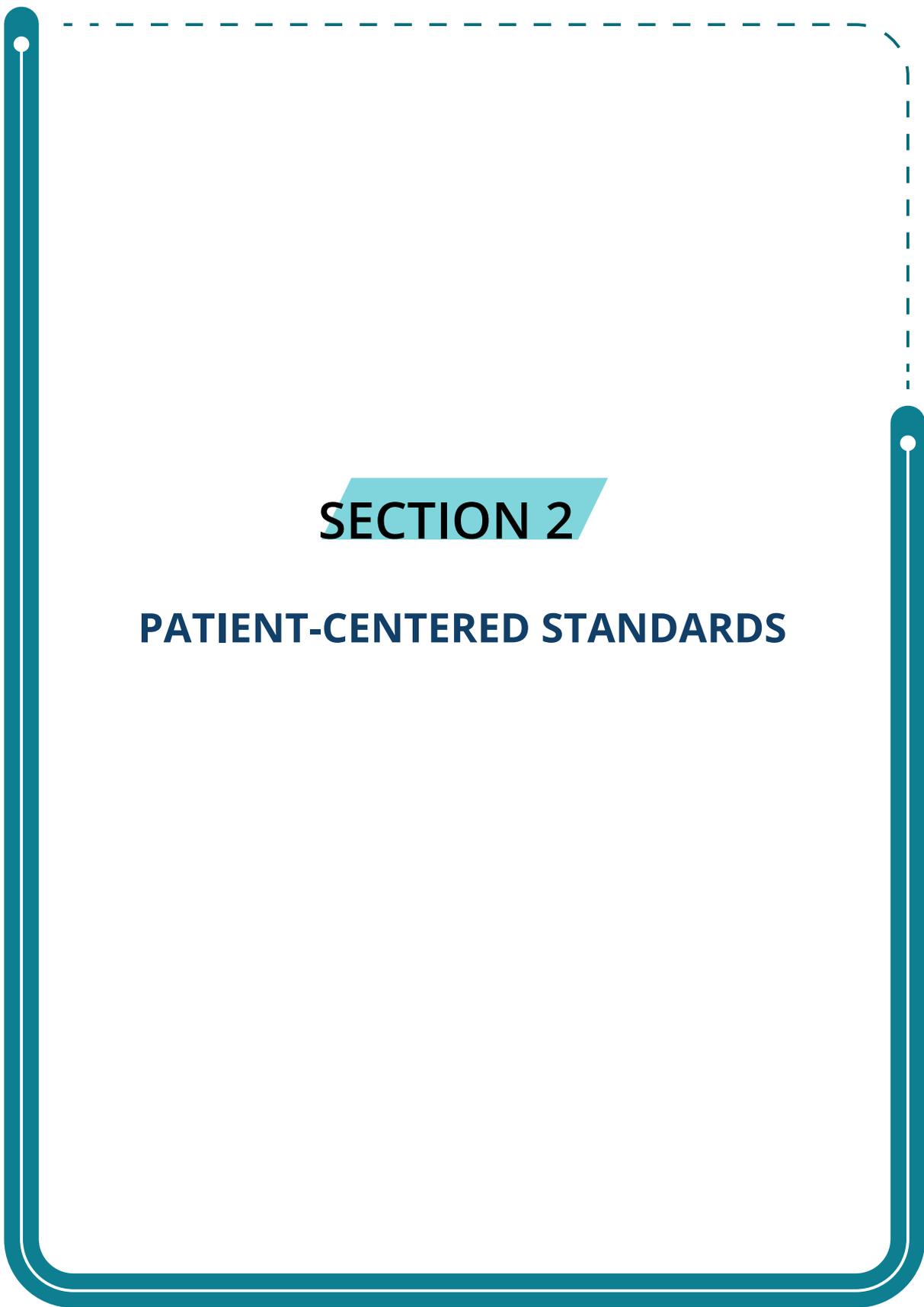
SECTION 2

PATIENT-CENTERED STANDARDS

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. It is defined by the Institute of Medicine as the act of providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions. The rise of patient-centered care makes way for a healthcare system designed to optimize the agency and comfort of the most important and vulnerable people in the equation: patients, their families, and their communities.

Over the past two decades, patient-centered care has become internationally recognized as a dimension of the broader concept of high-quality healthcare. In 2001, the semiannual US Institute of Medicine's (IOM), Crossing the Quality Chasm: A New Health System for the 21st century, defined good-quality care as safe, effective, patient-centered, timely, efficient, and equitable.

The report sets out several rules to redesign and improve patient-centered care, including ensuring that care is based in continuous, healing relationships; customizing care based on patients' needs and values; ensuring the patient is the source of control; sharing knowledge and information freely; and maintaining transparency.

The IOM report defined levels that further define quality care and the role of patient-centered care in each level:

1. The **experience level** refers to an individual patient's experience of their care. Care should be provided in a way that is respectful, informative, and supportive for the participation of patients and families

2. The **clinical micro-system level** refers to the service, department, or program level of care. Patients and families should participate in the overall design of the service, department, or program.

3. The **environment level** refers to the regulatory level of the health system. Patients and families can inform local authorities.

Internationally, healthcare services use a range of strategies to promote patient-centered care, including staff development, leadership, collecting and reporting patient feedback, redesigning and co-designing service delivery, implementing patient rights, and engaging patients and families as partners in improving care.

National Safety Requirements

Chapter intent:

The World Health Organization (WHO) defines patient safety as the reduction and mitigation of unsafe acts within the healthcare system, as well as through the use of best practices shown to lead to optimal patient outcomes. Healthcare is a complex environment where errors can injure or kill. Usually, the safeguards work. However, each layer of defenses such as alarms, standardized procedures, and trained health professionals has weak spots.

Advances and commitment to patient safety worldwide have grown since the late 1990s, which leads to a remarkable transformation in the way patient safety is viewed.

When multiple system failures occur, mistakes that would usually be caught slip through, the price we pay when such situations occur is often high, on both a human and a health-system level.

Measuring patient safety initiatives and adverse events is essential when monitoring the progress of these strategies, tracking success, and helping to flag issues or identify potential areas for improvement.

As part of GAHAR registration process, laboratories have to show commitment to patient safety, this requires compliance to each of the "National Safety Requirements – NSR".

Chapter purpose:

The main objective is to ensure that organizations provide and maintain a patient safety program effectively. To achieve this effectiveness, the chapter addresses all the National Safety Requirements. Some requirements were placed into other chapters for convenience.

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

1. Egyptian Constitution
2. Universal declaration on Human Rights year 1964
3. Cairo declaration on Human Rights in Islam, 1990
4. Egyptian code of medical ethics 238/2003
5. Code of ethics and behavior for civil service staff, 2019
6. Jeddah Declaration on Patient Safety 2019
7. WHO Patient Safety Assessment Manual
8. WHO Patient Safety Friendly Initiatives previous versions of Egyptian standards

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

Code	Standard Keyword	Standard Code
	General Patient Safety Standards	
NSR.01	Specimen collection- Patient identification	TPR.04
NSR.02	Critical test result	TPO.05
NSR.03	Specimen reception and tracking	TPR.06
NSR.04	Hand hygiene	IPC.02
	Environmental Safety Standards	
NSR.05	Fire and smoke safety	EFS.03
NSR.06	Hazardous material safety	EFS.05
NSR.07	Safety program and Security plan	EFS.06
NSR.08	Equipment management plan	EMS.01
NSR.09	Utilities management	EFS.07

Patient-Centeredness Culture

Patient experience is emerging as one of the most critical aspects of healthcare delivery, so the role of everyone becomes increasingly relevant. This necessitates critically examining the role played by those not directly involved in patient care, such as the diagnostic laboratories. By providing the evidence needed for clinical decision making, laboratories have a crucial role to play in patient care. By providing accurate test results or advising on the relevance of a diagnostic procedure, the laboratory can help avoid unnecessary tests and costs. This results in better efficiency and patient experience.

The American Society for Clinical Laboratory Science (ASCLS) highlights the importance of clinical laboratory services in ensuring optimal patient outcomes and patient centered care. By providing the evidence needed for clinical decision making, laboratories have a crucial role to play in patient care. In a fully efficient healthcare environment, laboratory heads can inform the physicians on the effectiveness of various medical tests based on specific clinical conditions. This in turn has a bearing on patient management and satisfaction. Over the past two decades, patient-centered care has become internationally recognized as a dimension of the broader concept of high-quality healthcare. In 2001, the semiannual US Institute of Medicine's (IOM), Crossing the Quality Chasm: A New Health System for the 21st century, defined good-quality care as safe, effective, patient-centered, timely, efficient, and equitable.

The goal of patient-centered healthcare is to involve and empower patients and their families to become active participants in their care not only from a clinical perspective, but also from an emotional, mental, spiritual, social, and financial perspective.

Globally, the universal declaration of human rights article 25 emphasized the human right to a standard of living adequate for the health and wellbeing of himself and of his family, which includes medical care and the right to security in the event of sickness or disability.

Locally, Egyptian legal and ethical frameworks supported patient-centered care as well. According to the Egyptian constitution, comprehensive quality-standardized healthcare is a right for Egyptians. Egyptian codes of medical, nursing, pharmaceutical, and other healthcare professionals' ethics emphasized multiple aspects of patient's rights and healthcare professional's obligations towards patients.

Practically, Organizations shall not stop their patient-centered care processes at just printing patient rights and responsibilities brochures and handing them to patients. Policies and procedures need to identify mechanisms to establish and sustain patient-centered care culture. Education and techniques to encourage patient-centeredness behaviors are needed.

During the GAHAR Survey, Surveyors shall be able to measure how organizations define their patient-centeredness culture and work to sustain it through reviewing documents pertinent to this chapter, reviewing the implementation of direct patient management, during patient

tracers, and interviewing staff. The leadership interview session may touch on this topic, as well.

Chapter purpose:

This chapter is written and arranged in a logical order that first describes the infrastructure and culture needed to comply with the chapter requirements.

It describes basic patient rights and responsibilities.

It touches on those techniques and cultural changes that organizations need to address while building a patient-centred culture.

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates and annexes)

1. Egyptian Constitution
2. Universal declaration on Human Rights year 1964
3. Cairo declaration on Human Rights in Islam, 1990
4. Law 126/2008 on Egyptian Child
5. Law 10/2018 on the rights of handicapped
6. Drafted Egyptian law for Elderly care
7. Law 181/2018 on Egyptian "Consumer Protection"
8. Egyptian standards for accounting, 609/2016
9. Presidential decree 151/2019 for Egyptian Drug Authority
10. Law 2/2018 on Universal Health Insurance
11. Law 206/2017 on advertisement for healthcare services
12. Prime Minister decree, 1063/2014 Management of Emergency cases
13. Egyptian code of medical ethics 238/2003
14. Code of ethics and behavior for civil service staff,2019, if applicable
15. Egyptian Criminal code 58/1937
16. Egyptian consent laws
17. MOH Ministerial decree number 216 / 1982 Healthcare facilities organization
18. MOH Ministerial 186/2001 Patient right to know expected cost of care

Planning and protecting the patient-centeredness culture

PCC.01 Patient-centered culture is developed by interdisciplinary collaboration.

<div align="right">Patient-centeredness</div>

Keywords:
Interdisciplinary patient-centeredness.

Intent:
Good planning of the patient centeredness culture aims to help community has a better understanding of the available laboratory services, information shall be clearly communicated about types of laboratory services, laboratory professionals, cost of services, and working hours of the laboratory.

Patient centeredness culture development requires proper implementation and monitoring of the plan.

These actions require a collaborative work from multiple disciplines.

An assigned personnel or committee shall be established to oversee and assist in the implementation and maintenance of patient centered culture.

Active involvement includes at least patients and family members.

Patient centeredness culture sustainability requires teaching staff how to be patient centered.

The laboratory leadership develop patient centered initiatives, but it requires staff adoption to ensure implementation.

Laboratory staff-patient relationship and communication courses and discussion among staff members emphasizes this culture.

Education can be in the form of lectures, demonstrations, courses, workshops, role-plays and other mechanisms.

When staff understand the required initiatives, laboratory leadership should be able to measure the compliance and evaluate staff performance accordingly.

Survey process guide:
• The GAHAR surveyor may receive information about the patient-centered initiatives and culture support during the opening presentation.
• GAHAR surveyor may review terms of references and meeting minutes during the document review session or during the leadership interview session.
• GAHAR surveyor may ask questions to explore the mechanisms taken to plan, assist, and maintain patient-centered practices.
• During GAHAR survey, GAHAR surveyor may interview staff to check their awareness about patient-centered initiatives.

Evidence of Compliance:
1. The laboratory has an approved plan fulfilling the detailed practices for patient-centered activities.
2. Laboratory leaders assign an individual(s) with defined responsibilities and authorities to

oversight patient centeredness plan.
3. Laboratory staff is oriented, educated and trained on patient centered initiatives
4. Patient-centered activities are implemented, maintained, monitored and outcome is measured
5. Patients and family members are involved in patient centeredness activities.
6. Patient centeredness plan is communicated to all laboratory staff

Related standards:
PCC.03 Patient and family responsibilities, PCC.06 Patient and family feedback, OGM.05 Effective communication with governing body, OGM.15 Community Initiatives

PCC.02 Patient and family rights are protected and informed to patients and families.
<div align="right">Patient-centeredness</div>

Keywords:
Patient and family rights.

Intent:
Seeking and receiving service at a laboratory can be overwhelming for patients, making it difficult for them to act on their rights. The laboratory provides direction to staff regarding their role in protecting the rights of patients and families. Patients should be able to understand their rights and know how to use them. If for any reason, a patient does not understand his/her right, the laboratory is committed to helping him/her to gain knowledge of his/her rights. The laboratory shall respect the patient's information as confidential and implement processes to protect such information from leakage, loss, or misuse and ensure patient privacy particularly during sample collection or any other procedure. patient 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 and respond to patient and family rights when they interact with and care for patients throughout the laboratory. The policy addresses at least the following:
a) Patient and family rights as defined by laws and regulations, and the ethical code of Healthcare Providers' Syndicates
b) Patient and family rights to know the name and the title of laboratory staff members.
c) Patient and family rights to respect the patient›s personal values and beliefs
d) Patient and family rights to security, personal privacy, confidentiality and dignity
e) Patient and family right to identify, choose or refuse their options for provided care.
f) Patient and family rights to make a complaint or suggestion without fear of retribution
g) Patient and family rights to know the price of services and procedures
h) A child or adolescent patient has the right to expect that services provided by the laboratory will be appropriate to his or her age, size or need.

i) Patients 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 patient rights policy and interview staff members to check their awareness.
- GAHAR surveyor may observe patient rights statements posted in the laboratory, may also observe how patients receive information and may check conditions under which patient rights are protected.

Evidence of Compliance:
1. The laboratory has an approved policy and procedure that clearly guiding the process of defining patient and family rights, as mentioned in the intent from a) through i).
2. All staff members are aware of patients' and families' rights and their roles in protecting their rights.
3. Information about patient rights is provided in written or in another manner that the patient understands and is posted in all public areas in the laboratory.
4. Patient and family rights are protected in all areas of the laboratory and at all times.
5. Rights for patients with special needs, children and adolescents are available.
6. Confidentiality of patient information is maintained according to laws and regulations.

Related standard:
PCC.03 Patient and family responsibilities, PCC.04 Reporting violations, PCC.06 Patient and family feedback

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

Equity

Keywords:
Patient and family responsibilities.

Intent:
Patients and their families shall be able to assume responsibilities towards the laboratory. The laboratory shall develop and implement a policy and procedures to ensure that patients are aware of their responsibilities.

Policies should be put in place to ensure that patients are aware of their responsibilities. The laboratory is responsible for making the patients' responsibilities visible to patients and staff members at all times. The policy shall address at least the following:
   a) Patients and their families have the responsibility to comply with the policies and procedures of the laboratory
   b) Patients and their families have the responsibility to comply with financial obligation according to laws and regulations and laboratory policy
   c) Patients and their families have the responsibility to show respect to other

patients and laboratory workers.

d) Patients 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 patients

Patients shall be able to understand their responsibilities and mechanisms to assume them. If for any reason a patient/family does not understand his/her responsibilities, the laboratory is committed to help him to gain relevant knowledge.

The laboratory is responsible to make the patients' responsibilities visible to patients and staff at all times.

Survey process guide:

- GAHAR surveyor may review patient responsibilities policy and interview staff members to check their awareness.
- During the GAHAR survey, the surveyor may observe patient responsibility statements posted in the laboratory. The surveyor may also observe how patients receive information about their responsibilities.

Evidence of Compliance:

1. The laboratory has an approved policy and procedure that guiding the process of defining patient and family responsibilities included items in the intent from a) to d).
2. Information about patient responsibilities is provided in writing or in another manner that the patient understands.
3. All staff members are aware of patients' and families' responsibilities.
4. An approved statement on patient and family responsibilities is posted in all public areas in the laboratory in a way that makes it visible to staff members, patients, and families.

Related standard:

PCC.01 Interdisciplinary patient-centeredness, PCC.03 Patient and family responsibilities, PCC.04 Reporting violations

PCC.04 Violations against patients' and families' rights and responsibilities are managed.

<div align="right" style="color:teal">Patient-centeredness</div>

Keywords:

Reporting violations.

Intent:

Sustaining a patient centeredness culture requires continuous monitoring of compliance and identifying opportunities of improvement.

Empowered staff, patients and families shall be able to report violations for any patient's or family's rights and responsibilities.

The violation reports are collected, analyzed, and interpreted through assigned person(s)

Survey process guide:
- GAHAR surveyor may interview staff members to inquire about mechanisms to report Violations.
- GAHAR surveyor may interview quality, risk management, or leadership staff to inquire about the process of reporting violations, its results, and improvement actions taken based on these results.

Evidence of Compliance:
1. The laboratory is responsible for collecting, analyzing, interpreting, and evaluating violations for any patient's or family's rights and responsibilities by assigned person(s).
2. Information about reporting violations to patient and family rights and responsibilities is provided to staff, patients, and families in writing or in another understandable manner.
3. Periodical report on violations to patient and family rights and responsibilities is created and sent to the laboratory director.
4. Actions are taken to improve patient centeredness practices based on those reports in a timely manner and are communicated to laboratory staff, patients and their families.

Related standard:
PCC.02 Patient and family rights, PCC.03 Patient and family responsibilities, PCC.07 Complaints and suggestions, OGM.11 Ethical management

Empowerment and involvement of patients and their families
PCC.05 Appropriate, clear patient education materials are available.

Patient-centeredness

Keywords:
Patient and family education materials.

Intent:
The laboratory may provide mass education of patients and families on certain health topics based on the served community needs and /or patient 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.

Survey process guide:
- GAHAR surveyor may be reviewing a list of all potential topics, places, and/or timings of distributing patient education materials.
- During the GAHAR survey, the surveyor may observe patient education materials posted for patients 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 patient education materials
2. Patient education materials are readily available, in the places and for the topics identified by the laboratory
3. Patient education materials contain relevant and evidence-based information
4. Patient education materials are appropriate for readers of varying literacy levels
5. Patient education materials are translated in different languages for foreigner patient groups.
6. Laboratory staff is aware of the education material and how to enable the patient to use it.

Related standard:

OGM.15 Community Initiatives

Responsiveness to patients' and families' voices

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

<div align="right">Patient-centeredness</div>

Keywords:

Patient and family feedback.

Intent:

Patient feedback surveys may help laboratory to identify ways of improving performance. Ultimately, that translates into better laboratory services   and satisfied patients.

Laboratory can solicit feedback from patients in a variety of ways: phone surveys, written surveys, focus groups or personal interviews. The policy addresses at least the following:

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

Laboratory defines if the process addresses measurement of patient experience or patient satisfaction. For patient 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 patient satisfaction, the laboratory measures whether a patient's expectations about service were met. Two people who receive the same service, but who have different expectations for how that service is supposed to be delivered, can give different satisfaction ratings because of their different expectations measuring alone is not enough, laboratory needs to analyze and interpret information obtained from measured feedback and identify potential improvement projects. All the findings of the analysis and the improvement shall be submitted periodically to the laboratory leaders.

Survey process guide:
- GAHAR surveyor may review the policy of patient and family feedback.
- GAHAR surveyor may assess the process of use of patient and family feedback for performance improvement during leadership interview sessions or during quality management review sessions.

Evidence of Compliance:
1. The laboratory has an approved policy, guiding the process of measuring patient feedback.
2. There is evidence that the laboratory has received, analyzed and interpreted feedbacks from patients and families and other customers in a timely manner.
3. There is evidence that interpreted feedbacks have been shared with concerned staff members and planned for improvement.
4. Reports are analyzed and submitted to the laboratory leaders.

Related standard:
PCC.01 Interdisciplinary patient-centeredness, PCC.02 Patient and family rights, PCC.07 Complaints and suggestions, QPI.09 Continues improvement program

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

<div align="right">

Patient-centeredness
</div>

Keywords:
Complaints and suggestions.

Intent:
While laboratories are able to proactively measure and use patient's feedbacks, Patients, 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. Laboratories need to create a uniform system for dealing with different complaints and suggestions from patients and/or their families to make it easy for follow up, monitor, and learn from practices. Laboratory policy addresses at least the following:
a) Mechanisms to inform patients and families of communication channels to voice their complaints and suggestions.
b) Tracking processes for patients' and families' complaints and suggestions.
c) Responsibility for responding to patients' complaints and suggestions.
d) Timeframe for giving feedback to patients and families about voiced complaints or suggestions.
e) Remedial and corrective actions taken.

Survey process guide:
- GAHAR surveyor may review the policy of managing patient complaints and suggestions.

- GAHAR surveyor may assess the process of managing patient suggestions and complaints during tracer activities, leadership interview session, or during quality management review session.

Evidence of Compliance:
1. The laboratory has an approved policy guiding the process of managing patients› complaints and suggestions as mentioned in the intent from a) through e).
2. The laboratory allows the complaining process to be publicly available.
3. Patients and families are allowed to provide suggestions and complaints.
4. Complaints and suggestions are investigated and analyzed by the laboratory.
5. Patients 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.02 Patient and family rights, PCC.04 Reporting violations, PCC.06 Patient and family feedback, QPI.09 Continues improvement program, QPI.06 Nonconformity management.
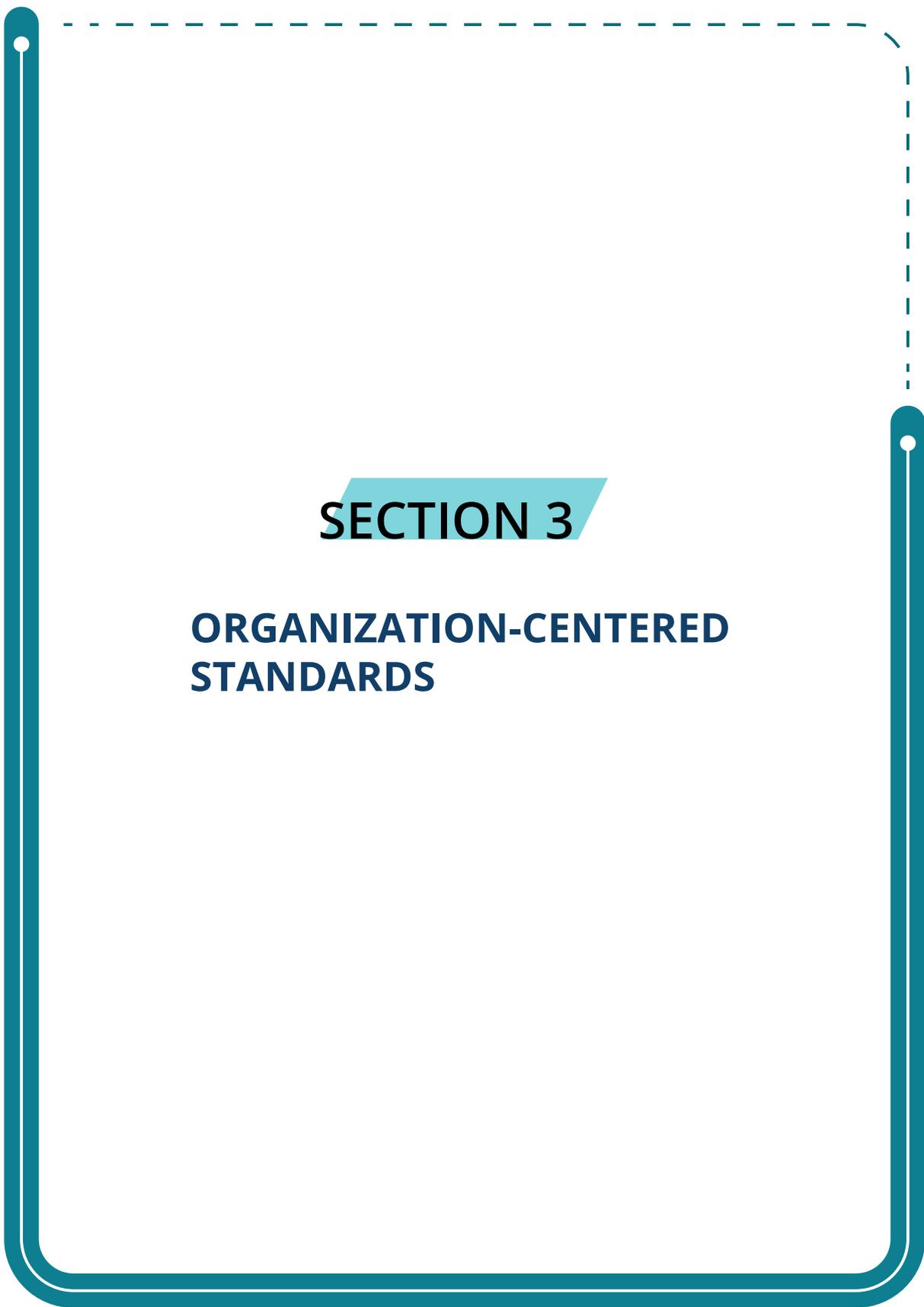
SECTION 3

ORGANIZATION-CENTERED STANDARDS

Section 3: Organization-Centered Standards

While in the previous section, Patient safety and centered care was the focus. Yet, Patients are not the only customers of healthcare systems. Healthcare professionals face risks, as well. Although debate continues regarding whether worker wellbeing should be considered part of the patient safety initiatives, many organizations think about it that way, including major players in the healthcare industry worldwide. Three major aspects may affect worker›s wellbeing: Safety, Stress, and Laboratory Structure.

Regarding Safety, according to the United States Department of Labor, Occupational Safety and Health Administration (OSHA), a laboratory is one of the most hazardous places to work. Healthcare professionals experience some of the highest rates of non-fatal illness and injury surpassing both the construction and manufacturing industries. In 2011, U.S. laboratories recorded 253,700 work-related injuries and illnesses, a rate of 6.8 work-related injuries for every 100 full-time staff. From 2002 to 2013, the rate of serious workplace violence incidents (those requiring days off for an injured worker to recuperate) was more than four times greater in healthcare than in private industry on average. In fact, healthcare accounts for nearly as many serious violent injuries as all other industries combined. Many more assaults or threats go unreported. Workplace violence comes at a high cost; however, it can be prevented.

On the other hand, being exposed to stress for too long may lower a person›s efficiency and could trigger negative consequences on one›s health or family and social life. Nevertheless, not every manifestation of stress is always workplace stress. Workplace stress may be caused by various factors. Some professions are inherently more stressful than others are. Some studies showed that healthcare professions are among the first six most stressful ones. Not all health professionals develop the same level of stress, and not all of them develop signs of professional burnout.

Laboratory structure provides guidance to all staff by laying out the official reporting relationships that govern the workflow of the company. A formal outline of a laboratory structure makes it easier to add new positions in the laboratory, as well, providing a flexible and ready means for growth. Organization management needs to be according to a clear ethical framework that is responsive to community needs. Organizations have an obligation to act for the benefit of the community at large. Workers, as community members, need to be engaged in assessing community needs and responding to them, in addition, to being protected from safety and stress hazards while working in the laboratory.

Nevertheless, both the laboratory and the staff have the responsibility to keep the workforce safe. For example, while management provides personal protective equipment (PPE), such as safety glasses to keep debris and chemical splashes away from the eyes, it is the staff›s responsibility to wear the PPE when performing work that management has identified as

requiring it. More generally, it is the responsibility of management to prepare detailed work instructions that clearly describe how work should be performed in order to prevent quality and safety failures; the staff is responsible for following these procedures.

Thus, this section shall focus on some of the newer ideas about healthcare workplace suitability to provide a safe, efficient, and improving environment for healthcare service. One of the tools used to design this section is called HealthWISE, which is an action tool developed by the International Labor Organization (ILO) in collaboration with the WHO. This tool emerged from traditional thinking about patient safety and improvement more generally. It describes a process and structure that may lead to improved safety in a variety of healthcare settings.

Elements For Safe Healthcare

The aim of HealthWISE is to provide healthcare institutions with a practical, participatory and cost-effective tool to improve work conditions, performance, occupational health and safety for health workers, and the quality of health services provided. Improvements are introduced and sustained by the combined efforts of management and staff, brought together in a dedicated team. HealthWISE puts the health workforce in focus and addresses topics that are key to delivering quality care. It encourages everyone to participate in making their workplace not only a good place to work but a quality healthcare environment appreciated by patients and the community.

As organization management is responsible for providing an efficient laboratory structure, where a governing body is well defined and responsive to the laboratory needs, Leaders work collaboratively to run the laboratory towards preset approved strategic directions. An established structure includes defining capacity and roles of the laboratory workforce, providing sufficient orientation and education, and continuous monitoring and evaluation. Hence, strong information management and technology are needed to record data and information, in addition to a strong quality management program that can capture and interpret data and information.

Environmental and Facility Safety

Environment and Facility Safety is a specialty that sets requirements and implements practical aspects necessary to protect environment and control risks associated with the handling or storage and disposal of hazardous agents in clinical laboratories.

From a safety standpoint, it involves creating organized efforts and procedures for identifying workplace hazards and reducing accidents and exposure to harmful situations and substances. Specialized laboratories might need to develop additional safety requirements to meet specific risk factors. It also includes training of personnel in accident prevention, accident response, emergency preparedness, and use of personal protective equipment

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. These activities are implemented using a risk assessment framework and through the development of a safety culture which is needed to ensure a safe workplace where adequate measures are applied to minimize risk of any potential exposure to biological agents, it involves creating a systematic approach to complying with environmental regulations, such as managing waste and maintaining a safe environmental condition.

Laws, regulations, and inspections by local authorities determine in large part how a facility is designed, used, and maintained. All organizations, regardless of size and resources, must comply with these requirements as part of their responsibilities to their patients, families, staff, and visitors.

Chapter purpose:

This chapter started by planning and effective management of the organization environmental facility safety. Followed by requiring the development, implementation, monitoring, improvement, evaluation and annual update of the safety plans.

The main objective is to ensure that the laboratory is able to identify the safety and security issues and provide safe and effective program to handle and maintain environment safety, also safe and secure laboratory operations are essential components of compliance with the International Health Regulations and prevention of acute public health threats so, the chapter discusses the following:

- **Proper Laboratory design:**
  The laboratory has adequate and functional space to ensure that quality of work, patient as well as personnel safety are not compromised. The laboratory space meets the local and international regulations and has:
    a) Proper design and location.
    b) Adequate patient waiting areas and lavatories.

    c) Adequate space for each laboratory activity/section.

    d) Adequate storage space for reagents, supplies, consumables, samples, waste holding and records.

    e) Adequate space for administrative and clerical staff.

- **Risk management system**

  Develop and maintain a risk management system to control or minimize risk to acceptable levels in relation to employees, the community and others as well as the environment which could be directly or indirectly exposed to hazardous agents.

- **Safety and security**

  Safety—The degree to which the organization's buildings, construction areas, grounds, and equipment do not pose a hazard or risk to samples, patients, staff, or visitors.

  Security—Protection from loss, destruction, tampering, or unauthorized access or use.

- **Hazardous materials**

  Handling, storage, and use of radioactive and other materials are controlled, and hazardous waste is safely disposed including Infectious waste, Pathological waste, Sharps, Genotoxic waste, Chemical waste, Wastes with high content of heavy metals, Pressurized containers, and Radioactive waste.

- **Fire safety**

  Performing of ongoing assessment of risks to enhance protection of property and occupants from fire and smoke.

- **Utility systems**

  Electrical, water, compressed gases and other utility systems are maintained to minimize the risks of operating failures.

- **Disaster preparedness:**

  Responding to the disasters and emergencies that have the potential of occurring within the geographical area of the laboratory with an evaluation of the structural integrity of the patient care environment.

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates and annexes)

1. Egyptian Constitution
2. Universal declaration on Human Rights year 1964
3. Cairo declaration on Human Rights in Islam, 1990
4. Egyptian code of medical ethics 238/2003
5. Code of ethics and behavior for civil service staff, 2019
6. Employment and labor law 12/2003

7. Law 2/2018 on Universal Health Insurance
8. Law 4/1994 on Egyptian environment
9. MOH Ministerial decree 216 / 1982 Healthcare facilities organization National law for laboratories, 367/ 1954
10. The Egyptian code for health care facilities design
11. Environmental Safety: National strategy in disasters management
12. Environmental Safety: Atomic Energy Commission rules
13. Environmental Safety: The Egyptian Guideline for Medical Device Vigilance System
14. U.S. Department of Labor: Occupational Safety and Health Administration. (2016) Worker Safety in Laboratories: Caring for Our Caregivers. Retrieved from: https://www.osha.gov/dsg/laboratorys/index.html
15. The Joint Commission: Improving Patient and Worker Safety. Retrieved from: http://www.jointcommission.org/assets/1/18/tjcimprovingpatientandworkersafety-monograph.pdf
16. U.S. Department of Labor: Occupational Safety and Health Administration. (2016) About OSHA. Retrieved from: https://www.osha.gov/about.html

Effective leadership and planning of environment and facility safety

EFS.01 The laboratory facility complies with laws, regulations, fire, and national building codes.

<div align="right">Safety</div>

<u>Keywords:</u>
Laboratory environment and facility safety structure

<u>Intent:</u>
While laboratories are meant to provide diagnostic services, they also include certain dangers. Laboratories contain hazardous chemicals, radioactive and infectious materials among other threatening items. For this reason, governmental authorities enforce laws and regulations to ensure protection against these exposures. In addition, there are also dangers from fire and smoke that can be particularly perilous for laboratory patients and staff. Building codes were established to provide guidance on safety measures while designing laboratory settings.

The laboratory should comply with relevant laws, regulations, and codes like civil defense, fire and building codes to ensure the safety of patients, staff, visitors, vendors, and the environment.

The laboratory develops and maintains basic infrastructure for environmental and facility safety program:

a) 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.

b) Laboratory services and activities having adequate space according to applicable laws, regulations, and approved laboratory scope of service.

c) Permits, licenses and laboratory design drawings are available, valid, and current.

d) Budget is planned for upgrading and/or replacement of instruments or systems to keep environmental safety and/or to expand services provided within the laboratory.

e) Qualified environmental safety staff are available and match requirements of laboratory scope of services, laws and regulations.

The laboratory builds an environmental safety oversight structure that includes at least the following:

f) The laboratory should have an authorized, qualified staff member overseeing the environmental safety activities and trainings regularly or urgent if needed.

g) An authorized, qualified staff member role should include review of aggregated essential data, incident reports, drill reports, and safety plans measures, recommended actions, and following up to ensure compliance with all safety requirements.

h) An authorized, qualified staff member should report to the laboratory's leadership quarterly and a feedback from laboratory leadership should be received.

Survey process guide:

- GAHAR surveyor may review documents demonstrating laboratory drawings, budget, safety staff qualifications, external authorities report with action plans and recorded meeting notes and agenda.
- During laboratory tours and tracers, GAHAR surveyor may observe compliance to laws and regulations and matching of allocated spaces to departmental functions.

Evidence of compliance:

1. The laboratory leadership complies with environmental safety laws, regulations, and national building codes.
2. The laboratory maintains basic requirement for development of environment and facility safety program as required in elements a) to g) in the intent.
3. The laboratory has a committee/authorized, qualified staff member overseeing the environmental safety with approved terms of references.
4. Environment and facility safety meetings are regularly   recorded.

Related standards:

EFS.02 Environmental and safety structure, EFS.05 Safety program, Security plan.
, IPC.01 IPC program, risk assessment, guidelines, OGM.13 Positive Workplace Culture

EFS.02 The laboratory has a designated area accommodates all laboratory activities safely.

Environmental

Keywords:
Environmental and safety structure.

Intent:

Separate laboratory spaces are often necessary for certain functions due to the nature of operation, equipment requirements, security concerns, other spaces with varying degrees of chemical hazards as well as administrative area. Meeting the safety and comfort needs of laboratory personnel and maintaining a positive safety culture at the same time are challenging to fulfil the above requirements.

The laboratory area has to be designated in a way that accommodates efficiently and safely different procedures performed in the laboratory and shall include adequate staff facilities separated from any laboratory work area.   All laboratory spaces are designed to ensure for both patients 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 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) Patient centered waiting area: adequate for the expected number of patients, 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 and the workflow is unidirectional according to guidelines.

e) Spaces for specimen collection areas are adequately designed to allow respect and accommodation for patients' privacy, confidentiality, security, comfort and disabilities.

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.

Survey process guide:

GAHAR surveyor may visit the laboratory area(s) as part of a laboratory tour. During this visit, the surveyor may check the laboratory space and design to ensure that its safe, meets the needs of patients and laboratory personnel and suitable to the scope of service.

Evidence of compliance:

1. Laboratory leaders plan for adequate space according to laws, regulation and infection prevention and control standards.
2. Laboratory areas have sufficient space as required in element a) to h) from the intent.
3. There is provision of adequate cleaning services for all laboratory areas.

Related standard

EFS.01 Laboratory environment and facility safety structure, OGM.13 Positive Workplace Culture

Safe fire planning

EFS.03 NSR.05 Fire and smoke safety plan addresses prevention, early detection, response, and safe evacuation in case of fire and/or other internal emergencies.

<div align="right">Safety</div>

Keywords:

Fire and smoke safety.

Intent:

Fire safety is the set of practices intended to reduce the destruction caused by fire.

Fire safety measures include those that are intended to prevent ignition of an uncontrolled fire, and those that are used to limit the development and effects of a fire after it starts.

Fire safety measures include those that are planned during the construction of a laboratory or implemented in structures that are already standing, and those that are taught to laboratory staff.

The laboratory must be vigilant about fire safety as fire is an ever-present risk in a facility.

The laboratory shall develop a fire and smoke safety plan that addresses at least the following:

a) Compliance with Civil defense requirements.
b) Documented Inspection of fire detection and suppression systems.
c) Maintenance and testing of fire protection and abatement systems in all areas.
d) Staff training on fire response and evacuation.

The laboratory staff should be well trained on firefighting and safe evacuation through practical simulations and regular drills to ensure staff readiness in case of fire and/or other internal emergencies.

The laboratory shall record fire drills details including, but are not limited to, the following: Dates and timings.

a) Staff who participated in the drill.
b) Involved areas.
c) Shifts.
d) Drill evaluation and corrective action plan.

Survey process guide:

- GAHAR surveyor may review the fire safety plan, laboratory fire safety inspections, and fire system maintenance.
- GAHAR surveyor may check 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 (all staff should be trained on fire safety).

- GAHAR surveyor may review the records of fire and evacuation drills with dates, timings, staff who participated, the involved areas in the laboratory and corrective action plan based on the drill evaluation.
- GAHAR surveyor may interview staff to check the awareness of fire safety plan and basic procedures in such cases like (Rescue, Alarm, Confine, Extinguish/Evacuate and Pull, Aim, Squeeze, Sweep).

Evidence of compliance:

1. The laboratory has an approved fire and smoke safety plan that includes all elements from a) through d) in the intent.
2. The laboratory fire alarm, firefighting and smoke containment system are available, functioning and comply with civil defence requirements.
3. Inspection, testing and maintenance of fire alarm, firefighting and smoke containment systems are performed and recorded.
4. The laboratory provides training for fire response and evacuation to all staff at least once annually.
5. The laboratory guarantees safe evacuation processes for all occupants in case of fire and/ or other internal emergencies.
6. The fire and smoke safety plan is evaluated annually and, whenever indicated, with aggregation and analysis of necessary data.

Related standard

EFS.01 Laboratory environment and facility safety structure, EFS.05 Safety program, Security plan, QPI.07 Risk Management plan/Program, QPI.05 Internal assessment program

EFS.04 Emergency preparedness plan addresses the responding to potential external disasters.

Safety

Keywords:
Emergency preparedness plan.

Intent:
Last few decades have witnessed an increased frequency in disasters causing tremendous human casualties, in terms of loss of life and disability in addition to huge economic losses. Although these may not be totally-preventable but their impact can be minimized by effective planning. Equally important are the peripheral emergencies, like road, rail and air accidents, industrial accidents, explosions and terrorist attacks that have an inherent potential to convert into a mass casualty incident. Preparedness measures are taken before a disaster can greatly increase the ability to control it. The laboratory shall have a risk assessment tool to prioritize potential emergencies based on probability and impact.

The emergency preparedness plan shall be evaluated regularly with aggregation and analysis of necessary data and include at least the following:

a) Risk assessment of potential external disasters, which may affect the laboratory›s building and/or activities.

b) Degree of preparedness according to the level of risk.

c) Communication strategies: internal communication may be in the form of a clear call tree that includes staff titles and contact numbers, and external communication channels may include civil defence, ambulance centre, police.

d) Clear duties and responsibilities for laboratory leaders and staff.

e) Identification of required resources such as utilities, medical equipment.

f) Drill schedule for external disaster. The laboratory shall have a drill schedule for external 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.

    iii) Clear corrective actions if needed.

    iv) Debriefing.

Survey process guide:

The GAHAR surveyor may review external disaster preparedness plan and its records to confirm that it covered all the identified risks.

The GAHAR surveyor may review preparations in terms of equipment, supplies, staff and others during the laboratory survey tours and tracers.

Evidence of compliance:

1. The laboratory has an emergency preparedness plan that includes items a) through f) in the intent.

2. Staff training is performed and evaluated.

3. The laboratory performs at least one drill for external disaster annually that includes items in point f) from the intent.

4. There is a list for the needed supplies and equipment, as identified in external disasters plan.

Related standard:

EFS.01 Laboratory environment and facility safety structure, EFS.05 Safety program, Security plan, QPI.07 Risk Management plan/Program, QPI.05 Internal assessment program.

Safe hazardous materials and waste management plan

EFS.05 NSR.06 The laboratory ensures safe handling, storage, usage and transportation of hazardous materials and waste disposal.

Safety

Keywords:
Hazardous materials safety.

Intent:

Hazardous materials are chemical substances, which, if released or misused, can pose a threat to the environment, life or health. Industry, agriculture, medicine, research, and consumer goods use these chemicals.

Hazardous materials come in the form of explosives, flammable and combustible substances, poisons, and radioactive materials. 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 plan 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. The laboratory environment, staff, patients, relatives and vendors should be safe from hazardous material exposure and waste all the time, the laboratory should have a hazmat and waste management plan that include at least the following:

a) List of all HAZMAT present in the laboratory
b) Safety requirements for handling and storage of HAZMAT
c) Availability and proper use of personal protective equipment
d) Appropriate labeling of hazardous materials and waste
e) Disposal in accordance with laws and regulation
f) Investigation and documentation of different incidents such as spills
g) Monitoring incidents' data and proper corrective action taken.
h) Staff training and orientation.
i) 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 management plan, hazardous material, and waste inventories, as well as Material Safety Data Sheet (MSDS) during document review session or during laboratory visit and tracers.

• GAHAR surveyor may inspect hazardous material labeling and storage in addition to waste collection segregation storage and final disposal.

Evidence of Compliance:

1. The laboratory has an approved plan for the hazardous material and waste management that addresses all elements from a) through i) in the intent.
2. The laboratory ensures staff safety when handling hazardous materials/or waste.
3. Waste disposal process is managed according to laws and regulations.
4. The laboratory ensures safe usage, handling, storage, and labeling of hazardous materials.
5. The laboratory has an approved document for spill management, Investigation, and recording of different incidents related to hazardous materials.
6. The plan is evaluated and updated annually with aggregation and analysis of necessary data.

Related standards:

IPC.03 PPE guidelines, IPC.06 Biological waste management, IPC.04 Risk assessment

Safety and security planning

EFS.06 NSR.07 There is a well-structured and implemented safety program and security plan.

<div align="right">Safety</div>

Keywords:

Safety program, Security plan.

Intent:

The laboratories face a variety of risks, that can affect and severely disrupts the laboratory operations and working environment. Presence of safety and security systems can mitigate these risks. The laboratory should ensure a safe and secure physical environment in all laboratory disciplines. Maintaining an active environment and facility safety program requires special skills to measure performance, identify gaps and do corrective actions. Environment and Facility safety supervisor (s) are responsible for inspecting buildings to identify maintenance and safety issues, such as clogged drains, leaky ceilings, and faulty electrical switches. The laboratory ensures availability of qualified staff according to the scope of provided services, local laws, and regulations.

Environment and facility safety program includes, but not limited to, the following:

a) Availability of working safety equipment in the laboratory facility
b) Continuous monitoring mechanisms for environment and facility safety.
c) Assigned, qualified safety supervisor is appointed to oversight the environment and facility safety program implementation
d) Surveillance rounds across all laboratory areas and services are performed at least twice annually.
e) Reporting of environment and facility surveillance rounds results to the concerned stakeholders and laboratory leadership.
f) Prohibiting laboratory staff in technical areas from eating, drinking, smoking, applying

cosmetics, manipulating contact lenses, and mouth pipetting.

g) Staff training and orientation.

A good laboratory security system can lessen a number of risks, such as: Theft, and or damage, of critical equipment, chemicals and intellectual property and accidental or intentional release of or exposure to hazardous materials.

The laboratory security plan includes, but is not limited to, the following:

a) Security risk assessment.
b) Ensuring the identification of patients, visitors, and staff in the laboratory.
c) Identification of vendors/contractors with the restriction of their movement within the laboratory.
d) Control access – restricted laboratories to authorized personnel only
e) Vulnerable patients such as the elderly, infants, those with mental disorders, and handicapped should be protected from harms.
f) Monitoring of remote areas.
g) Staff training and orientation.
h) The plan is evaluated annually and, if needed, according to related performance measures results or major incidents.

Survey process guide:

- GAHAR surveyor may review security plan/s to make sure that they include suitable risk assessment surveillance, security high-risk areas and security requirements, as well as access control areas
- GAHAR surveyor may review surveillance rounds plan, checklist, different observations, and proper corrective actions.
- GAHAR surveyor may check staff ID, cameras and access-controlled areas
- GAHAR surveyor may review safety program to make sure that they include all the required elements
- GAHAR surveyor may inspect workers in different areas like work areas and waste collection areas to check usage of suitable personal protective equipment (PPE)
- During the GAHAR survey, the surveyor may interview staff to assess staff awareness of environment safety requirements.
- During the GAHAR survey, the surveyor may interview staff or review staff files to assess environment safety staff numbers and qualifications and to assess staff awareness of environment safety requirements.
- GAHAR surveyor may ensure that the technical areas are smoking-free, followed by interviewing staff and/or patients to check their awareness of laboratory smoking policy.

Evidence of compliance:

1. The laboratory has an approved security plan that includes items a) through h) in the intent.
2. Security plan education is provided at least annually to all staff.

3. Security measures are implemented, evaluated and updated annually with aggregation and analysis of necessary data.
4. The laboratory has an approved safety program   that include items a) through g) in the intent
5. The laboratory ensures availability of qualified staff that matches the needs of laboratory scope of services, laws, and regulations.
6. The laboratory ensures that interdisciplinary environment and facility surveillance rounds are performed across all laboratory areas and services at least twice annually and reports are submitted

Related standard:

EFS.01 Laboratory environment and facility safety structure, EFS.02 Environmental and safety structure, EFS.03 Fire and smoke safety, IPC.03 PPE guidelines, WFM.06 Continuous Education Program

Safe utility plan

EFS.07 NSR.09 Essential utilities plan addresses regular inspection, maintenance, testing and repair.

Safety

Keywords:
Utilities Management

Intent:

Laboratory is expected to provide safe and reliable service to their patients. Planning appropriate response and recovery activities for a failure of the laboratory's utility systems is essential to satisfy this expectation. The laboratory should keep safe and effective key utility system to ensure efficiency and effectiveness of all utilities. The plan shall cover at least the following:
   a) Electricity; including back up system according to the size of the organization and the workload.
   b) Potable water availability.
   c) Heating, ventilation, and air conditioning including appropriate temperature, humidity, and odors' elimination.
   d) Communications systems.
   e) Staff training on utility plan.
The proper utility management process minimizes potential risk and include the following:
   1) Regular inspections.
   2) Regular testing.
   3) Regularly scheduled maintenance.
   4) Correction of identified risks and deficiencies.

Survey process guide:

- Surveyor may review utility management plan to confirm availability of all required systems, regular inspection, maintenance, and backup utilities.
- GAHAR surveyor may review inspection documents, preventive maintenance schedule, contracts, and equipment, as well as testing results.
- Surveyor may interview plan implementation responsible to evaluate the plan implementation status

Evidence of compliance:

1. The laboratory has an approved utility management plan including items in the intent from a) to e).
2. The laboratory has a clear process for utility management that covers items in intent from 1 to 4.
3. Regular Inspection, testing, maintenance is performed and recorded.
4. Backup utilities are evaluated on regular basis

Related standards

EFS.01 Laboratory environment and facility safety structure, IPC.01 IPC program, risk assessment, guidelines, QPI.05 Internal assessment program, IPC.07 Infection prevention, renovation, construction, SCM.05 Contracted services.

Infection Prevention and Control

Chapter intent:

Infection prevention and control (IPC) is a scientific approach designed to prevent harm caused by infection to patients and healthcare workers. It is grounded in infectious diseases, epidemiology, social science and health system strengthening. IPC occupies a unique position in the field of patient safety and quality universal health coverage since it is relevant to health workers and patients at every single health-care encounter.

Infection prevention and control (IPC) program in laboratory aims to identifying and reducing or eliminating the risks of acquisition and transmission of infections among patients, laboratory workers, volunteers, students, visitors, and the community, also intended to prevent morbidity due to infections in laboratory workers, laboratory-associated infections (LAIs) may furthermore impact public health.

An adequate laboratory infrastructure and an implemented bio-risk management system form the basis of prevention and control in the laboratory setting, IPC program is risk based this means that a risk assessment is needed to promptly identify and proactively address possible infection risks among individuals and in the environment.

The goal of an organization's infection prevention and control program is to identify and to reduce or eliminate the risks of acquiring and transmitting infections among patients, staff, contract workers, and the community.

The infection risks and program activities will differ from laboratory to laboratory, depending on the laboratory's activities and services, patient population(s) served, geographic location, patient volume, and number of staff. The program's priorities should reflect the identified risks in the laboratory global and community developments, and the complexity of services provided.

Effective infection prevention and control programs have in common identified leaders, well-trained staff, methods to identify and to proactively address infection risks in persons and the environment, appropriate policies and procedures, staff education, and coordination throughout the laboratory.

Chapter purpose:

Important processes and activities addressed in this chapter include the following:
- Assigned responsibilities for infection prevention and control program development
- Standard precautions through addressing policies and procedures, implementation, and monitoring.
- Setting the different biosafety levels according to the lab activities and services provided.
- Selecting and implementing quality control measures.
- Preventive measures during construction and renovation.

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates and annexes)

1. Egyptian Constitution
2. Universal declaration on Human Rights year 1964
3. Cairo declaration on Human Rights in Islam, 1990
4. Egyptian code of medical ethics 238/2003
5. Code of ethics and behavior for civil service staff, 2019
6. Employment and labor law 12/2003
7. Law 2/2018 on Universal Health Insurance
8. MOH Ministerial decree number 753 / 2015 for medical waste management
9. MOH Ministerial decree number 153 / 2004 for prevention of viral hepatitis
10. MOH Ministerial decree number 187 / 2004 for infection control personnel
11. MOH Ministerial decree 62/2004 on promotion of health care providers
12. MOH Ministerial decree number 99 / 2002 for developing infection prevention and control department
13. MOH Ministerial decree number 100 / 2002 for developing infection prevention and control departments
14. Infection Control: National guidelines for infection control (2016)
15. WHO Lab quality management system, 2011
16. WHO Laboratory biosafety manual, 2007
17. Guidelines Library | Infection Control | CDC https://www.cdc.gov/infectioncontrol/guidelines/index.html
18. Laboratory Infection Prevention and Control Resources, The Joint Commission. https://www.jointcommission.org/resources/patient-safety-topics/infection-prevention-and-control/laboratory-infection-prevention-and-control/
19. AS/NZS 2243.3.2010, Safety in laboratories, Part 3: Microbiological safety and containment
20. Laboratory biorisk management standard. https://absa.org/wp-content/uploads/2017/01/CWA15793_Feb2008.pdf
21. Interim Clinical Laboratory Guideline for Biological Safety, The American Society for Microbiology, January 2019
22. Guidelines for biosafety laboratory competency, Record number 4b289
23. Guidelines for Biosafety Laboratory Competency, CDC and the Association of Public Health Laboratories,Centers for Disease Control and Prevention MMWR, Supplement / Vol. 60
24. Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition, June 2020, Centers for Disease Control and Prevention, National Institutes of Health
25. Canadian Biosafety Standards and Guidelines. https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines.html

Efficient structure of the infection prevention and control program

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

<div style="text-align:right">Safety</div>

Keywords:
IPC program, risk assessment, guidelines.

Intent:
Healthcare associated infections are common risks encountered in any laboratory. Therefore, constructing a comprehensive IPC program is of utmost importance in order to effectively reduce these risks.

The IPC program is an integrated part of quality improvement and patient safety programs, using measures that are epidemiologically important to the laboratory.

Measurement information is essential to improve infection prevention and control activities and reduce healthcare-associated infection rates.

An effective IPC program shall be comprehensive and include all aspects of patient care, staff health, and the entire services provided by the laboratory.

The program development requires a multidisciplinary approach that is carried on by qualified staff members and is reinforced by sound up-to-date knowledge and resources in order to fulfil its mission and objectives.

Each laboratory shall design its own key performance indicators to monitor, assess, and improve the IPC program. Examples of KPI include the percentage of hand hygiene compliance and the results of sterilization monitoring.

The program shall also assure the education and training of all working staff members and Provide necessary patients, visitors, and families' education.

The National laws and regulations shall define elements of the basic program, the response to infectious disease outbreaks, and reporting requirements within the laboratory and the public health agencies.

Survey process guide:
- GAHAR surveyor may perform an infection control program review to evaluate the presence of a risk assessment, an IPC program that is based on the risk assessment and covers all laboratory areas and includes all relevant individuals, a training plan or an annual evaluation report and update of the IPC program.
- GAHAR surveyor may check the documentation of monitoring of data, performance measures data analysis reports, recommendations for improvement and observe their implementation.

Evidence of compliance:
1. The laboratory has IPC. program that clearly describe the scope, objectives, expectations, and   reporting methods.

2. IPC program includes all areas of the laboratory and covers patients, staff, visitors, and the external community.
3. IPC. program is based on IPC risk assessment, current scientific knowledge, laws and regulations and evidence based guidelines.
4. All laboratory staff is trained on the IPC program.
5. The laboratory tracks, collects, analyzes, and reports data on its IPC. program.
6. The laboratory acts on improvement opportunities identified in its IPC. program.

Related standards:

EFS.06 Utilities Management, QPI.01 Quality management program ,QPI.03 Performance measures, QPI.05 Internal assessment program, QPI.06 Nonconformity management, QPI.07 Risk Management plan/Program, IPC.02 Hand Hygiene, IPC.03 PPE guidelines, IPC.04 Risk assessment , IPC.05 Environmental cleaning & disinfection, evidence-based guidelines.

Safe standard precautions

IPC.02 NSR.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 healthcare settings. It is considered the most effective and efficient strategy for infection prevention and control. Hand hygiene facilities should be present in appropriate numbers. Hand hygiene supplies (hand soap, hand antiseptics, and single-use towels) shall be present in the appropriate places. Alcohol-based hand rubs are now the preferred products for routine hand hygiene in healthcare facilities unless hands are visibly soiled to overcome the shortage in sinks. The laboratory shall develop policy and procedures for hand hygiene in accordance with the international guidelines. All staff members shall be educated and trained on hand hygiene technique and WHO five moments of hand hygiene.

Survey process guide:

• GAHAR surveyor may review policy of hand hygiene and hand hygiene guidelines.
• GAHAR surveyor may review hand hygiene education posters and records.
• GAHAR surveyor may interview laboratory staff, enquiring about hand hygiene technique and WHO five moments of hand hygiene.
• GAHAR surveyor may observe hand washing facilities and check availability of supplies (soap, tissue paper, alcohol hand rub, etc.).
• GAHAR surveyor may observe compliance of healthcare professionals with hand hygiene technique and WHO five moments of hand hygiene.

Evidence of compliance:
1. Laboratory has approved Hand Hygiene policies and procedures based on current, evidence-based guidelines.
2. All staff members are continuously educated and trained on hand hygiene policy and procedures.
3. Laboratory staff members are performing proper hand hygiene procedures.
4. Hand hygiene posters are displayed in appropriate areas.
5. Hand hygiene facilities are present in appropriate numbers and places.

Related standards
IPC.01 IPC program, risk assessment, guidelines, QPI.03 Performance measures., WFM.08 staff performance evaluation, WFM.06 Continuous Education Program

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

Safety

Keywords:
PPE guidelines.

Intent:
Personal protective equipment (PPE) is an important tool in protection of laboratory staff. The PPE 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. It includes gloves, gowns, masks, facial protection, eye protection and respirators according to the predetermined biosafety levels.

The effective and appropriate use of PPE depend mainly on the user's adherence and competence. Proper selection of PPE depends on risk assessments.

The staff shall also be trained on the proper way and sequence of donning and doffing of various PPE to maintain maximum protection throughout the process.

Survey process guide:
• During GAHAR Survey, the surveyor may check the availability and accessibility of PPE and may interview staff members to inquire about the constant availability, accessibility, and proper use of PPE
• GAHAR surveyor may review PPE standardized products specifications.
• GAHAR surveyor may review disbursement permits of PPE
• GAHAR Surveyor will check the ability of the staff to use PPE properly.

Evidence of Compliance:
1. The laboratory has an approved policy, procedures that clearly describe the process for selection and use of required PPE according to exposure risk and guidelines.
2. All staff members are continuously educated and trained on proper selection and usage of PPE

3. Laboratory staff members adopt PPE policy.
4. The laboratory provides PPE that is readily available, easily accessible wherever needed and appropriate to the task performed.

Related standards:
EFS.04 Hazardous materials safety, EFS.05 Safety program, Security plan, IPC.01 IPC program, risk assessment, guidelines, IPC.04 Risk assessment, OGM.13 Positive Workplace Culture, WFM.10 A staff health program

Biosafety plan

IPC.04 Biosafety plan is implemented based on the laboratory risk assessment.

Safety

Keywords:
Risk assessment.

Intent:
The clinical laboratories have policies, procedures to reduce the hazards of exposure to biohazardous materials. Infections acquired in the laboratory are reported internally and, when appropriate, according to laws and regulations. The adequate containment resources and equipment are present and properly used whenever indicated. When problems with practice are identified or accidents occur, corrective actions are taken, documented, and reviewed.

The biosafety hazards and practices include at least the following:

a) The laboratory identifies risk groups of potential microorganisms handled within its facility and identifies the appropriate biosafety level that matches the type of risk groups
b) Exposures to aerosols and droplets are controlled (for example, when mixing, sonicating, centrifuging, and flaming inoculating loops).
c) Exposure to needle stick and puncture by other sharps is controlled.
d) Laboratory coats, gowns, or uniforms are worn to prevent contamination.
e) Biosafety cabinets are used, when required.
f) All biohazard incidents are reported and documented, and relevant corrective actions and improvement plans are constructed accordingly.
g) Proper transportation, handling and disposal of infectious material and waste
h) The laboratory personnel receive relevant and documented biosafety training programs
i) At least one decontamination autoclave is present. Proper use, maintenance and monitoring of the autoclave are ensured.
j) Several pipetting aids are readily available and are regularly disinfected
k) Designated personnel to oversee infection control and biosafety policies and practices.
l) Infections acquired in the laboratory are reported internally and, when appropriate, according to laws and regulations.

Survey process guide:

• GAHAR surveyor may review the updated biosafety plan to evaluate the presence of a risk assessment that covers all laboratory areas and includes all relevant individuals,

• GAHAR surveyor may evaluate the training of the staff on the plan and the annual evaluation report.

• GAHAR surveyor may check the documentation of biohazard incidents, corrective actions, biosafety training, recommendations for improvement and observe their implementation.

• During GAHAR Survey, the surveyor may check measures performed by laboratory staff to reduce risk of infection

• During GAHAR Survey, the surveyor may check availability of biosafety equipment and biosafety practices.

Evidence of compliance:

1. The laboratory has an approved policy, procedures that clearly describe the process for biosafety hazard management describing elements in the intent from a) to l).
2. All staff members are continuously educated and trained on biosafety plan.
3. Implementation of biosafety rules for relevant practices addressed in the procedure.
4. When accidents occur, corrective actions are taken, documented, and reviewed.

Related standards:

EFS.04 Hazardous materials safety, IPC.01 IPC program, risk assessment, guidelines, WFM.06 Continuous Education Program, IPC.03 PPE guidelines

Safe cleaning and disinfection

IPC.05 Environmental cleaning and disinfection activities are aligned with current evidence-based guidelines.

<div align="right">Safety</div>

Keywords:

Environmental cleaning & disinfection, evidence-based guidelines.

Intent:

Laboratory environment is considered a reservoir for pathogens and may be a significant source of laboratory acquired infections so, cleaning and disinfection of environmental surfaces is an important tool to prevent development of these infections.

Contact with contaminated surfaces in the organization can easily lead to cross contamination of microorganisms between the environment and laboratory workers.

To provide quality of care, the laboratory must have a clear, documented, communicated method and schedule for environmental cleaning and disinfection including walls, floors, ceilings, and furniture. Biological spills are reported, recorded, contained, and dealt with according to national and international guidelines.

Survey process guide:

- During GAHAR Survey, the surveyor may review the list of all environmental services that require cleaning, cleaning schedules and spill kits.
- During GAHAR Survey, the surveyor may interview laboratory staff and environmental cleaning staff members to inquire about the availability and accessibility and disinfectant use and the proper use of spill kits.

Evidence of Compliance:

1. The laboratory has an approved policy, procedures that clearly describe process for environmental cleaning and disinfection activities.
2. Staff members involved in environmental cleaning activities are trained on approved policies.
3. Cleaning technique and disinfectant of choice matches the requirements of each cleaned area and used correctly when indicated
4. Clear instructions are available for dealing with biological materials spills.
5. Schedule for cleaning and disinfection is implemented.

Related standards

IPC.01, IPC.04 Risk assessment, WFM.06 Continuous Education Program

Biological waste management plan

IPC.06   Biological waste management plan is developed, implemented, and evaluated.

<div align="right">Safety</div>

Keyword:

Biological waste management

Intent:

The laboratory produces a considerable amount of waste including the infectious waste that poses a threat to the patients, staff and environment within the laboratory and to the external environment surrounding the laboratory. Thus, the proper disposal of infectious waste contributes to the reduction of infection risk. Infectious waste includes cultures and stocks of infectious agents, disposable culture dishes and devices used to transfer, inoculate, and mix cultures, pathological wastes (wet tissue, organs, body parts, blood and body fluids removed during surgery, autopsy, and biopsies), human blood and blood products, and sharps.

The discarded cultures and stocks are put into durable, leak-proof containers that are secured when they are moved. Biohazardous waste must be stored in a specialized secured separate room in accordance with national laws and regulations.

Survey process guide:

- GAHAR surveyor may review biohazardous waste management plan
- GAHAR surveyor may assess the developed policies and procedures, training records of

Staff members and presence of a list of biohazardous waste associated with increased risk of infection.

- GAHAR surveyor may interview staff members involved in waste disposal and other laboratory staff to check their awareness on biohazardous waste disposal.
- During GAHAR Survey, the surveyor may check measures performed for biohazardous waste disposal.
- GAHAR surveyor may visit storage room that should meet the national laws and regulations.

Evidence of Compliance:

1. The laboratory has an approved   waste management plan for biohazardous waste and the safe disposal.
2. The laboratory ensures staff safety when handling biohazardous waste and proper segregation of waste at the point of generation.
3. There is a clearly labelled or colour coded bins should be in place to separate sharps waste, infectious waste and non-infectious general waste, according to national guidelines, laws and regulations.
4. Staff members involved in waste disposal activities are trained on approved policies.
5. The plan is regularly evaluated and updated with aggregation and analysis of necessary data.
6. Waste disposal occurs according to laws and regulations.

Related standard:

EFS.4Hazardous materials safety, IPC.01 IPC program, risk assessment, guidelines

construction and renovation

IPC.07 Infection risks during demolition, renovation, or construction projects are reduced.

Safety

Keywords:

Infection prevention, renovation, construction

Intent:

Demolition, construction, or renovation anywhere within the laboratory, can be a major risk to infection prevention and control.

Exposure to construction dust and debris and other biohazards can be potentially dangerous to lung function and to the safety of staff and visitors.

The laboratory shall assess the magnitude of the risks resulting from the impact of the renovation or new construction on the predetermined air-quality, IPC and utility requirements and initiate a plan to minimize such risks.

Survey process guide:

- GAHAR surveyor may perform an infection control program review to assess developed policies and procedures, training records of healthcare professionals
- GAHAR surveyor may visit areas under demolition/renovation/construction and review infection risk assessment for these areas. A documented work permission from the IPC team, if required by the laboratory policy, may be reviewed as well.

Evidence of compliance:

1. The laboratory has an approved policy for infection risk assessment for areas under demolition, renovation, or construction.
2. Infection risk assessment of renovations, or new constructions has defined criteria
3. Staff members involved in demolition/construction/renovation are trained on approved policy.
4. There is a mechanism, such as work permission, to empower infection risk assessment and recommendations.
5. Infection prevention measures, considerations and recommendations are considered during any demolition, renovation, or construction projects.

Related standards:

IPC.01 IPC program, risk assessment, guidelines, QPI.07 Risk Management plan/Program.

Organization Governance and Management

Chapter intent:

Effective leadership begins with understanding the various responsibilities and authority of individuals in the laboratory and how these individuals work together. Those who govern, manage, and lead a laboratory have both authority and responsibility. Collectively and individually, they are responsible for complying with laws and regulations and for meeting the laboratory's responsibility to the patient population served. Over time, effective leadership helps overcome barriers and communication problems in the laboratory, and the laboratory becomes more efficient and effective.

This chapter is concerned with structures for governance and accountability that may differ according to the laboratory and its size, mandate, and whether it is publicly or privately owned. Possible structures include an individual or group owner, government committee or ministry, or Board of Directors. Having a defined governance structure provides clarity for everyone in the laboratory, including managers, technical leadership, and staff regarding who is accountable for making final decisions and oversight of the laboratory›s overall direction. While governance provides oversight and support, it is the commitment and planning efforts of the laboratory leadership as well as the departments and services leaders that ensures the smooth and efficient management of the laboratory.

Effective planning is initiated by identifying the stakeholders' needs and designing the service accordingly, the laboratory vision provides a direction and common goal to the laboratory to ensure effective safe and patient centred care is provided equally for patients the chapter guides the laboratory to assign duties to the different levels of management and to ensure effective communication to achieve planned goals and objectives.

Chapter purpose:
- To ensure the effectiveness of governing body
- To assure the effectiveness of direction
- To ensure the effectiveness of leadership
- To assure the effectiveness of financial management
- To enhance and improve the ethical management
- To enhance effective staff engagement, health and safety

Implementation guiding documents:
(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates and annexes)
1. Egyptian Constitution
2. Egypt 2030 vision, Ministry of planning
3. Law 51/1981 organization healthcare facilities
4. MOH Ministerial 186/2001 Patient right to know expected cost of care.

5. MOH Ministerial decree 25/2002 for medical responsibility and suspension of medical practice
6. Research: MOH- Research ethics committee guidelines,2013
7. Law 181/2018 on Egyptian "Consumer Protection"
8. Egyptian standards for accounting, 609/2016
9. Women council publications on gender equality
10. Professional code of ethics- prime minister decree 238, year 2003
11. Law 206/2017 on advertisement for healthcare services
12. National Labour Law.
13. WHO International Health Regulation IHR
14. WHO-ILO Health WISE action manual
15. Staff Health and Safety regulations

Effective governing body

OGM.01 The laboratory has a defined governing body structure.

<div align="right">*Effectiveness*</div>

Keywords:
Governing body Structure.

Intent
The governing body is responsible for defining the laboratory direction and ensuring the alignment of its activity with its purpose. Such a body is also responsible for planning, leading and monitoring its performance and future development. Therefore, defining the governing structure of a laboratory ensures that it operate effectively and efficiently.

A laboratory governing body can be a group of individuals (such as board of directors), one or more individual owners and in a centralized system several subsidiary laboratories are governed by one governing body, in order to ensure the proper governance and efficient management of any laboratory resources thus its structure has to be well defined.

The definition of the governance structure should indicate the nature of the working relations between its various components. Such relations, which are sometimes complex, can be illustrated through an organization chart with arrows denoting lines of authority and accountability. Ideally structure should be simple and follow function with minimum unnecessary layers and tailored to the laboratory purpose and management structure.

Governing bodies: collectively responsible for overseeing the institution's activities. Governing bodies determine the institution's future direction and should foster an environment in which the institutional objectives are to be achieved. In more concrete terms: approving the mission and strategic vision, long-term business plans, annual budgets, appointing the head of the institution as laboratory director/chief executive, ensure and monitor systems of control and accountability, and monitoring institutional performance.

Good governance dictates that individuals responsible for governance are not also responsible for management (as much as possible) as separation of function minimizes conflict of interest. Therefore, it is NOT advisable that the head of the governing body is also the executive director of the laboratory in order to protect the governing function of the governing body. Furthermore, governing bodies should have a minority of members who hold executive positions in the laboratory.

Survey process guide:
GAHAR surveyor may observe the required information about the governance structure through the whole process of survey with special attention given to opening presentation, document review session and leadership interview session.

Evidence of compliance:
1. The governance structure is represented in the laboratory organization chart.
2. Members of the governing body are identified by title and name.
3. The governing body meets regularly, and minutes of meetings are recorded.

Related standards:
WFM.04 Job Description, WFM.01 Workforce manual, Laws and regulations, OGM.05 Effective communications with governing body

OGM.02 The governing body works with the laboratory leaders to set the laboratory mission statements.

Effectiveness

Keywords:
Mission Statement.

Intent
Mission statement is a description of the laboratory core purpose, and answer the question why the laboratory exists. It is the ground element for establishing the strategic direction of a facility leading to the formulation of its objectives and related strategies.
Defining the main purpose of the facility in the form of a mission is one of the fundamental roles of the governing body.
The laboratory mission shall be aligned with the national healthcare mission.
Mission statement shall be communicated to the stakeholders including staff, patients and visitors.

Survey process guide:
• GAHAR surveyor may observe the mission statement posters, brochures or documents focusing on its last update, approval, alignment and visibility.
• GAHAR surveyor may evaluate staff knowledge during surveying round.

Evidence of Compliance:
1. The laboratory has a mission statement approved by the governing body.
2. Mission statement is well communicated to all laboratory staff.
3. Mission statement is evaluated annually.
4. The mission statement is visible in public areas to staff, patients and visitors.

Related standard:
OGM.03 Governing body responsibility, OGM.07Strategic and operational Plans, WFM.05 Orientation Program, QPI.01 Quality management program

OGM.03 Governing body responsibilities and accountabilities are identified.

Effectiveness

Keywords:
Governing body responsibility.

Intent:
Governing bodies are responsible for the health and wealth of their laboratory and are thus accountable primarily for its sustainability. Governing bodies do that by monitoring the effectiveness of the management strategies set to achieve these goals. Resources include financial, human resources, technology, information systems.

The governing body supports, promotes and monitors performance improvement, patient safety, risk management efforts and safety culture. The governing body approves, monitors and improves the contracting services.

The governing body responsibilities includes approval, receiving reports and regularly evaluating and updating at least the following:

a) The laboratory strategic plan
b) The operational plan and budget
c) The quality improvement, patient safety and risk management programs.
d) Allocating resources and effective financial planning
e) Responsiveness to internal and regulatory inspection reports

Survey process guide:
GAHAR surveyor may observe governing body role and responsibilities through the whole process of survey with special attention given to opening presentation, document review session and leadership interview session, questions shall include reviewing the required documents and checking their details and approvals in addition to reviewing monitoring reports of the approved plans.

Evidence of Compliance:
1. Governing body responsibilities and accountabilities are defined in a written document.
2. Governing body oversight the implementation of the laboratory policies and procedures.
3. Strategic plan, operational plan and laboratory budget are approved, monitored and updated by the governing body.
4. Quality improvement, patient safety and risk management programs are approved, monitored and updated by the governing body.
5. The governing body has a well communicated process for resources allocation with laboratory leaders that includes clear criteria for selection and prioritization.
6. Governing body responsiveness to internal and regulatory inspection reports.

Related standards

APC.03 Accurate and complete information, WFM.01 Workforce manual, Laws and regulations, OGM.07 Strategic and operational Plans, QPI.01 Quality management program, QPI.09 Continues improvement program, OGM.14 Supply Chain Management

OGM.04   The governing body performance is evaluated annually.

Effectiveness

Keywords:

Governing body performance.

Intent:

The purpose of a governing body performance evaluation is to identify opportunities for the governing body as a whole and individual governing body member to improve their governance performance over time as well as the evaluation of its capability to achieve the laboratory strategic goals.

Ideally, evaluation should be against objective(s), pre-agreed criteria and with a defined process

The governing body performance is evaluated by itself annually versus the strategic plan to identify whether or not the governing body is fulfilling their responsibilities.

Survey process guide:

GAHAR surveyor may observe the required information through document review session for the evaluation reports and leadership interview session to evaluate the performance evaluation process implementation

Evidence of Compliance:

1. The laboratory has a clear process and predefined criteria for governing body performance evaluation.
2. The results of annual evaluation for the governing body performance are documented.
3. The laboratory leaders ensures that actions are taken based on the governing body performance evaluation

Related standard:

OGM.01 Governing body Structure, OGM.03 Governing body responsibility, OGM.05 Effective communications with governing body, OGM.07 Strategic and operational Plans

OGM.05 The laboratory leaders ensure effective communication with the governing body.

<div align="right">Effectiveness</div>

Keywords:
Effective communication with governing body.

Intent:
A clear two-way communication process between governing body, leaders and laboratory staff, enhances the laboratory well-being.

It ensures the governing body's understanding of the laboratory›s performance and associated risks that can hinder the achievement of its goals.

In addition, it gives the laboratory leaders the opportunity to report and receive feedback on the organization performance especially those that are problematic. Furthermore, defining the nature of the relation between governing body and leaders to ensure sustained cooperation and organization wellbeing.

Accomplishing the facility mission requires engagement and teamwork. Such requirements are established through knowledge sharing and staff involvement in decision making. Pathways for communication and opportunities for staff involvement should be developed and made available to all staff.

The laboratory needs to define the communication channel between the governing body, laboratory leaders and staff. communication channel may be in the form of official reports, meetings and conferences or any other types depending on the type and size of the laboratory.

Survey process guide:
GAHAR surveyor may observe evidences of defined communication channels, frequency of communication and evidence of feedback to submitted reports on both sides.

Evidence of Compliance:
1. There is defined process of communication throughout the laboratory.
2. Governing body members, laboratory leaders and staff are aware of the defined process of communication
3. The governing body submits feedback reports to the laboratory director.

Related standards:
PCC.01Interdisciplinary patient-centeredness, OGM.01 Governing body Structure,OGM.04 Governing body performance, OGM.06 Laboratory Director, OGM.07Strategic and operational Plans, OGM.13 Positive Workplace Culture

Effective organization direction

OGM.06 A qualified director is appointed by the governing body to manage the laboratory according to applicable laws and regulations.

<div align="right">*Effectiveness*</div>

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 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) Ensuring the documentation and implementation of the laboratory quality management system

b) Providing oversight of day-to-day operations

c) Ensuring clear and accurate posting of the laboratory›s services and hours of operation to the community

d) Ensuring that policies and procedures are developed, implemented by laboratory staff and approved by the governing body and /or laboratory director

e) Providing oversight of human, financial, and physical resources

f) Evaluating the laboratory's performance annually

g) Ensuring appropriate response to reports from any inspecting or regulatory agencies, including accreditation.

h) Ensuring that there is a functional, organization-wide program for performance improvement, patient safety and risk management with appropriate resources.

Survey process guide:

• GAHAR surveyor may expect to meet the laboratory director at least once during the course of laboratory survey.

• GAHAR surveyor may review laboratory director staff file to check compliance with all required documents of training, job description, role and responsibilities

• GAHAR surveyor may review formal delegation for the director responsibilities to another competent employee when needed.

Evidence of Compliance:

1. There is a job description for the laboratory director covering the standard requirements from a) through h) as in the intent.

2. The laboratory director has appropriate training and/or experience as defined in the job description.
3. There is a formal delegation for the director responsibilities to another competent employee when needed

<u>Related standards:</u>

WFM 04 Job Description, OGM.05 Effective communication with governing body, OGM.08 Laboratory leaders, WFM.01 Workforce manual, Laws and regulations, WFM.03 Recruitment, WFM.06 Continuous Education Program

OGM.07 Strategic and operational plans are developed under oversight and guidance of the governing body.

<p align="right">Effectiveness</p>

<u>Keywords:</u>
Strategic and operational Plans.

<u>Intent:</u>
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 leadership wants to go, how they will get there and how they will know when they have achieved their strategic goals.

The strategic plan provides an overall framework within which all stakeholders can find their appropriate roles and make their appropriate contribution.

The laboratory develops a strategic plan containing defined achievable goals/desired outcomes with predefined timelines

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.

The operational plans include at least the following:
   a) Clear goals and objectives
   b) Specific activities and tasks for implementation
   c) Timetable for implementation
   d) Assigned responsibilities
   e) Sources of required budget
   f) Means for achievement measuring

Leaders regularly assess the annual operational plans of the services provided to determine required facility and equipment needs for the next operational cycle. Any planning cycle ends with an analysis or an assessment phase through which planners understand what went well and what went wrong with the plan. This analysis or better called lessons learnt should feed into the new cycle of planning for better facility performance.

Survey process guide:
- GAHAR surveyor may receive information about strategic plan during the opening presentation then more questions about involvement and monitoring of strategic plan shall be posed during the leadership interview session.
- GAHAR surveyor may inquire about operational plans during laboratory tours and tracers to give an opportunity to staff and department leaders to talk about their plans and how they are communicated.
- GAHAR surveyor may be looking for evidence of monitoring plan progress, identification of opportunities of improvement and actions taken to improve performance.

Evidence of Compliance:
1. The laboratory has an approved strategic plan with participation of laboratory leaders and communicated throughout the organization.
2. The laboratory has operational plans includes items a) to f) in the intent with participation of laboratory leaders communicated throughout the organization.
3. There are progress review reports to evaluate the strategic plan at least annually.
4. Operational plan progress reports are available and evaluated at least annually.
5. Participation of staff, laboratory leaders, community, and other identified stakeholders in the strategic plan is documented.

Related standards:
APC.01 Sustaining registration requirements, OGM 03 Governing body responsibility, OGM.02 Mission Statement, OGM.04 Governing body performance, OGM.08 Laboratory leaders, OGM.10 Departmental management

OGM.08 The responsibilities and accountabilities of the laboratory leaders are identified.

<div align="right">Effectiveness</div>

Keywords:
Laboratory leaders.

Intent:
Usually, governing body leaves it to their executives to see that their decisions are carried out and that the day-to-day operations of the laboratory are performed successfully. While another standard addresses laboratory director's responsibilities, the laboratory leadership may have other important responsibilities e.g., technical manager, quality manager, information officer, and sometimes administrative director (according to the size and resources of each lab). The laboratory shall establish authorities and responsibilities for each leader.
The laboratory leadership is responsible for:
a) Sustaining firm laboratory structure
b) Running smooth directed operations

c) Continuous monitoring and evaluation

d) Continuous Improvement

Survey process guide:

GAHAR surveyor may interview laboratory leaders during the course of GAHAR survey and during leadership interview session, questions about their responsibilities and their evaluations shall be raised. Answers shall be matched with job description review during staff file review session.

Evidence of compliance:

1. The laboratory has a valid job description for each laboratory leader (depending on the laboratory organization   chart) to identify the required qualification and responsibilities.
2. The responsibilities of the laboratory leaders include at least a) through d) in the intent.
3. Laboratory leaders are aware and understand their responsibilities.
4. Laboratory leaders perform their responsibilities and document their activities.

Related standards:

WFM.04 Job Description, WFM.11 Staff Files, OGM.07 Strategic and operational Plans, OGM.11 Ethical managements, OGM.12 Safety Culture, QPI.01 Quality management program, QPI.09 Continues improvement program, QPI.07 Risk Management plan/Program

OGM.09 The customers are informed of the results of performance improvement activities and current accreditation status.

<div align="right">Patient centeredness</div>

Keywords:

Performance and Accreditation Disclosure.

Intent:

Patients have the right to know the performance of the organization they are going to be managed in. The same applies to communities as they hold future patients. Disclosure of performance is one way of organizations realizing their accountability towards their customers.

Survey process guide:

GAHAR surveyor may interview laboratory customers during the course of GAHAR survey inquiring about their knowledge, about the performance improvement or accreditation status. Answers shall be matched with the actual projects and accreditation status

Evidence of Compliance:

1. The laboratory has a process that guide performance and accreditation disclosure for customer.
2. Reports and certificates of past attempts and current accreditation status are available to the services users.

3. Customers are knowledgeable about accreditation status and performance improvement activities.

Related standard:
APC.05 Professional standards during surveys , PCC.01 Interdisciplinary patient-centeredness, QPI.03 Performance measures.

Effective departmental leadership

OGM.10 A designated qualified staff member is assigned to supervise each department and / or service with defined responsibilities.

<div align="right">Effectiveness</div>

Keywords:
Departmental management.

Intent:
Each department or service (e.g.: chemistry, microbiology, hematology, sampling, inventory …) has to have a designated individual responsible for delivering the required services as defined by the organization mission and related plans to ensure alignment between departments/services and with the organization as a whole.

An effective and efficient department/service supervisor ensures that department services are known and are aligned with other departments services and that there are adequate resources to offer them. He/she should also ensure that all human resources within his responsibility are well qualified and receive continuous training according to their needs. He/she should ensure that his department and staff are engaged in performance improvement, patient safety, and risk management activities and that there is an annual report of the services provided and improvement programs running within the department/service.

The responsibilities of the designated supervisor of each department and service are defined in writing and include at least the following:

a) Defining a written description of the services provided by the department (scope of service).

b) Recommending space, staffing, and other resources needed to fulfil the department›s approved scope of service.

c) Recommending staff minimum number and qualifications required according to workload and approved scope of service.

d) Defining education, skills, and competencies needed by each category of staff

e) Ensuring that there is a department specific orientation and continuing education program for the department›s staff.

f) Ensuring coordination and integration of these services with other departments when relevant.

g) Ensuring that the department›s/service›s performance is monitored and reported annually to leadership.

h) Ensuring that the department is involved in the performance improvement, patient safety and risk management program(s).

Survey process guide:

- GAHAR surveyor may interview department leaders during the course of GAHAR survey,
- GAHAR surveyor may pose questions about their responsibilities and their evaluations. Answers may be matched with job description review during staff file review session.

Evidence of Compliance

1. There is a supervisor/head for each department/ service provided by the laboratory who is qualified and competent as required by the job description.
2. The responsibilities of Departments/ services supervisors/ heads defined in the job description and include at least a) to h) in the intent.
3. Departments and services heads/ supervisors perform their responsibilities according to their job descriptions

Related standards:

WFM.02 Staffing plan, WFM.04 Job Description, WFM.08 staff performance evaluation, WFM.09 Staff burnout and turnover, OGM.07 Strategic and operational Plans, QPI.01 Quality management program , QPI.07 Risk Management plan/Program, QPI.09 Continues improvement program

Safe, ethical, and positive organization culture

OGM.11 The laboratory ensures ethical management.

<div align="right">Safety</div>

Keywords:

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 patients' care.

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 patient and medico-legal case.
    d) Developing patient confidentiality rules
    e) Identifying conflict of interest
    f) Gender and religion equality

In case where research analysis is conducted and specimens are tested, formal ethical committee approval shall be submitted.

Survey process guide:
- GAHAR surveyor may review laboratory policy.
- GAHAR surveyor may interview staff to inquire about code of ethics, handling patient results and error reporting.
- GAHAR surveyor may interview laboratory leaders during leadership session to inquire about all elements including mechanisms put in place to ensure gender equality as per the Egyptian law requirements.

Evidence of Compliance:
1. The laboratory has an approved policy and procedures that clearly describe the process for laboratory ethical management that addresses at least a) to f) in the intent.
2. Approved code of ethics is disseminated to the whole laboratory staff.
3. Laboratory staff is aware of the approved code of ethics.
4. Solved ethical issues are used for education and staff professional development.
5. Ethical issues are discussed and managed in a defined time frame and according to the approved code of ethics.

Related standards:
APC.05 Professional standards during surveys, PCC.04 Reporting violations, PCC.05 Patient and family education materials, OGM.08 Laboratory leaders, OGM.03 Governing body responsibility, OGM.06 Laboratory Director, WFM.06 Continuous Education Program

OGM.12 Leaders create a culture of safety and quality within the laboratory.

<div align="right">Effectiveness</div>

Keywords:
Safety Culture.

Intent:
Laboratory services are complex, and sometimes, due to unintentional errors, it can harm patients and even staff. To minimize such risk, causes of errors and near misses should be explored and efforts made to prevent their occurrence in the future.

For this to happen, a safety culture within the facility is essential where staff feel confident when reporting on a safety incident that they will be treated fairly, in a confidential manner, and that the information they provide will be used to improve the care process and environment.

Survey process guide:
- GAHAR surveyor may review records of leaders' safety rounds during the leadership interview session.
- GAHAR surveyor may interview staff to check support for quality initiatives and safety culture.

Evidence of Compliance

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

Related standard:

OGM.08 Laboratory leaders, OGM.06 Laboratory Director, OGM.13 Positive Workplace Culture, QPI.08 Incident Reporting System, QPI.07 Risk Management plan/Program

OGM.13 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) What are the measures taken by the management to prevent workplace violence, discrimination, and harassment
c) Communication channels between laboratory leaders and staff.
d) Staff feedback measurement
e) Planning for staff development

Survey process guide:

- GAHAR surveyor may review approved policy for positive workplace culture
- GAHAR surveyor may observe workplaces and shall 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 clearly addresses at least a) to e) 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. Staff feedback and satisfaction are measured on regular basis.

Related standards:

EFS.02 Environmental and safety structure, OGM.12 Safety Culture, OGM.05 Effective communications with governing body, WFM.08 staff performance evaluation, WFM.10 A staff health program, WFM.09 Staff burnout and turnover, IPC.03 PPE guidelines

Efficient utilization management

OGM.14 The laboratory defines utilization management processes.

Efficiency

Keywords:
Utilization Management.

Intent:
Organizational utilization management is crucial for any laboratory for proper utilization of resources for efficient operation

The laboratory leaders evaluate periodically different resources of the laboratory in order to ensure proper and efficient utilization of resources to achieve its goal and strategic plan. The different resources of the laboratory include:

  a) Human
  b) Assets
  c) Financial
  d) Reagents
  e) Space

These resources must be evaluated at least annually, and laboratory leaders should prepare report to governing body for resource utilization and area of improvement which lead to proper utilization of each resource, for example: proper utilization of equipment by continuous monitoring of the volume of send out tests to be added to the scope of the laboratory after cost measurement.

The proper utilization of resources is one of the most important measures to evaluate and monitors the performance of laboratory leaders and indicate proper engagement for management laboratory resources.

Survey process guide:
GAHAR surveyor may review laboratory policy during document review session and discussions with laboratory leaders shall take place to ensure the utilization of resources.

Evidence of Compliance:
1. The laboratory has an approved policy and procedures that clearly describe the process of utilization management of different resources.
2. Evidence of implementation for efficient resources utilization management is recorded and evaluated.
3. Regular review and monitoring for utilization management measures and actions taken accordingly.

Related standard:
OGM.07 Strategic and operational Plans, QPI.01 Quality management program, QPI.03 Performance measures, EMS.01 Equipment management plan, SCM.01 Laboratory Suppliers, SCM.05 Contracted services, TEQ.01Internal quality control plan

Community initiatives

OGM .15 Laboratory services are planned in line with international, national, regional, or local community initiatives.

<div align="right">*Effectiveness*</div>

Keywords:
Community Initiatives.

Intent:
Community is 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. The laboratory develops and implements a plan for community assessment and involvement initiatives that may include:

Implementation of international women health, oncology health and diabetes health initiatives

National initiatives of Universal Health Insurance, 100 Million Healthy Lives or others.

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 inquire about community involvement plan during leadership interview session
- GAHAR surveyor may interview staff to check their awareness of community initiatives

Evidence of compliance:
1. The laboratory plans reflect alignment with international, regional, and/or national community initiatives
2. Relevant staff is aware of laboratory community initiatives.
3. Community initiatives are in compliance with laws and regulations.

Related standards:
PCC.01 Interdisciplinary patient-centeredness, PCC.05 Patient and family education materials, PCC.06 Patient and family feedback, OGM.03 Governing body responsibility

Workforce Management

Chapter Intent:

Clinical laboratory is an integral part of quality health care. The clinical laboratory workforce includes multiple categories of laboratory science practitioners, who have various levels of education bachelor, and graduate or professional degrees. Clinical laboratory practitioners include pathologists, doctoral-level clinical scientists, technologists/scientists, and technicians, and each has a vital role in the health care system, managing and applying evidence-based, scientific testing that supports patient care and protects against public health threats.

The Laboratory needs an appropriate variety of skilled, qualified people to fulfil its mission and to meet customer needs. The laboratory's workforce refers to the staff within the laboratory. Recruiting and retaining qualified staff is essential to laboratory quality. Planning the appropriate number and skill mix of workforce is essential. Developing clear job descriptions, strong orientation and training programs help staff in delivering proper healthcare services. A good laboratory should always have a clear structure of its medical staff, including departments, divisions, and medical committees. This chapter defines the laboratory leaders' roles and responsibilities in developing staff competencies and professional career path as well as their performance improvement. The laboratory should provide leaders and staff with opportunities to learn and to advance personally and professionally, Success or failure depends on the knowledge and skills of the people in the laboratory, and their commitment and motivation to do the job to perform tasks as described in the job description. Motivated employees are more likely committed to their work.

GAHAR surveyors shall review the implementation of laws and regulations, workforce manual, Policies, procedures and plans reflecting processes of human resources department through interviews with leadership and staff and reviewing different healthcare provider's personnel files.

Chapter purpose:
1. To ensure that the laboratory maintain effective Workforce Management
2. To develop Effective workforce planning.
3. To develop Effective orientation, continuous medical education and training program
4. To ensure Periodic evaluation of the staff performance.

Implementation guiding documents:
(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates and annexes)
1. Egyptian code of medical ethics 238/2003
2. Code of ethics and behavior for civil service staff,2019.
3. National law for laboratories, 367/ 1954

4. MOH Ministerial decree 25/2002 for medical responsibility and suspension of medical practice
5. MOH Ministerial decree 293/2000 on promotion of doctors
6. MOH Ministerial decree 62/2004 on promotion of healthcare providers.

Efficient workforce planning

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

<div align="right">Efficiency</div>

Keywords:
Workforce manual, Laws and regulations.

Intent:
Personnel are the most important laboratory resource, so success or failure depends on the knowledge and skills of the people in the laboratory, and their commitment and motivation to perform tasks as described in the job description. With the projected need for more clinical laboratory personnel in the coming years coupled with an aging workforce, effective management of the clinical laboratory workforce is essential to meet the demand for staffing in the near future and beyond.

Innovative techniques for recruiting and retention; training and competency assessment; staffing and scheduling; communication, motivation, and recognition; and technology solutions to increase efficiency are critical to ensure the future viability of laboratories.

The Laboratory leaders 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 laws, regulations and norms including syndicates codes and requirements and define the legal framework for its workforce management.

Survey process guide:
- GAHAR surveyor may review the legal framework documents, observe workforce management practices and review the workforce manual to check compliance with laws and regulations.
- GAHAR surveyor may evaluate the knowledge of the staff about workforce manual.

Evidence of Compliance:
1. An approved, updated workforce manual is available.
2. The workforce manual includes policies and procedures that complies with laws and regulations.
3. Laboratory staff is educated and aware of the workforce manual.
4. Workforce manual is periodically reviewed.

Related standards
APC.02 Registration of staff, OGM.03 Governing body responsibility, OGM.06 Laboratory Director, OGM.10 Departmental managements, WFM.05 Orientation Program

WFM.02 Staffing plan requirements are identified.

Efficiency

Keywords:
Staffing plan.

Intent:
Laboratory leaders, clinicians and patients rely on laboratory staff to provide timely and accurate results. The goal of every clinical laboratory is to strike a balance between overstaffing situations that lead to financial waste and under staffing situations that can compromise patient care.

Proper staffing allows a lab to meet the requirements of the right test at the right time, and all three components influence utilization.

The laboratory leaders develop a staffing plan according to the strategic and operational plans that ensures having the right number of staff with the right competencies compatible with the scope of service of the laboratory.

Staffing plans are dynamic taking into consideration staff mobility and need for new skills.

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 defines staffing numbers or mix of staff for the laboratory.

The plan is reviewed on a regular basis and updated as necessary.

The leaders of each clinical or managerial area define the individual requirements of each staff position.

Survey process guide:
• During the GAHAR survey, the surveyor may review the staff planning documents, observe workforce allocation and skills, or review staff files to check compliance of staffing plan to laws, regulations, and professional practices recommendations.
• GAHAR surveyor may interview the laboratory leaders to evaluate the plan preparation process.

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

Related standards
OGM.07 Strategic and operational Plans, OGM.10 Departmental managements, WFM.01 Workforce manual, Laws and regulations.

WFM.03 A uniform recruitment process is applied with the participation of department leaders.

<div align="right">Equity</div>

Keywords:

Recruitment

Intent:

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

The laboratory leaders provide an efficient, coordinated process for recruiting and hiring individuals for available positions. Laboratory leaders participate in the recruitment process. The recruitment process ensures the appropriate education, training, experience and demonstrated skills needed to the tasks performed. The process shall address at least the following:

a) Collaboration with service/department leaders 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 a policy describing the recruitment process.
- GAHAR surveyor may check a sample of staff files to assess compliance to standard requirements.
- GAHAR surveyor may interview staff members who are involved in recruitment process to assess the process.

Evidence of compliance:

1. The laboratory has an approved policy and procedures that clearly describe the recruitment process including items in the intent from a) to e).

2. Records of implementation of the recruitment process include evaluation of the qualification of newly hired staff.

3. Responsible staff who are involved in recruitment, are aware of the laboratory policy.

4. The laboratory leaders participate in the recruitment process.

Related standards

WFM.01 Workforce manual, Laws and regulations, WFM.02 Staffing plan, WFM11 Staff Files, OGM.06 Laboratory Director

WFM.04 The Laboratory has a uniform process to identify job responsibilities and addresses each position requirements.

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.
It generally includes duties, purpose, responsibilities, scope, and working conditions of a job. It allows leaders 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, certification or registration
   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.

Survey process guide:
•   GAHAR surveyor may check a sample of job description to assess compliance to standard requirements
•   GAHAR surveyor may interview some of the 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.
2. Job descriptions include the items from a) to d) in intent.
3. Job descriptions are discussed with staff and the discussion is recorded in the staff's file.
4. Performance evaluation is based on job descriptions.

Related standards
OGM.06 Laboratory Director, OGM.08 Laboratory leaders, WFM.01 Workforce manual, Laws and regulations, WFM.11 Staff Files, QPI.02 Quality management qualified individual, QPI.04 Data management, aggregation and analysis.

Effective orientation program

WFM.05 Appointed, contracted, and outsourced staff undergo a formal orientation program.

<div align="right">Effectiveness</div>

Keywords:
Orientation Program.

Intent:
The decision to appoint an individual to a laboratory sets several processes in motion.
To perform well, a new staff member, no matter what his or her employment experience, needs to understand the entire laboratory structure and how his/ her specific technical or nontechnical responsibilities contribute to the laboratory mission.
This is accomplished through a general orientation to the laboratory and his/ her role and a specific orientation to the job responsibilities.
All new employees (appointed, contracted, and outsourced staff), should complete a new employee orientation program that is designed to assist them in adjusting to their jobs and work environment and to instill a positive work attitude and motivation at the onset.
Staff orientation facilitates the integration of new staff with working staff to rapidly form effective teams that offer safe and quality care.
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:
   a) Review of the laboratory mission and ethical conduct.
   b) A tour of the workplace to introduce laboratory structure.
   c) Review of policies of safe working environment, infection control, performance improvement, laboratory safety program and laboratory quality management program.
   d) Cardiopulmonary resuscitation training.

Department orientation program addresses at least:
   e) Review of relevant policies and procedures.
   f) Operational processes,
   g) Key personnel and lines of authority.

 Job Specific orientation addresses at least:
   h) Technology and equipment use.
   i) Staff safety and health.
   j) Operating procedures that cover the operational issues specific to the work area.

The ultimate result of the orientation program is to deem new employees competent to work independently in performing the duties and responsibilities defined in their job descriptions. Time frames should be established to accomplish this goal.

Survey process guide:

- GAHAR surveyor may interview some of the newly hired staff members and inquire about the process of orientation
- 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. The orientation program includes at least items in the intent from a) to j)
2. The orientation completion is recorded and approved by the laboratory director or an appropriate supervisor.
3. Effectiveness for orientation program is evaluated
4. Orientation completion is recorded in the staff file
5. All staff member aware and attends orientation program regardless of employment terms.

Related Standard:

OGM.02 Mission Statement, OGM.07 Strategic and operational Plans, OGM.13 Positive Workplace Culture, WFM.11 Staff Files

Effective training and education

WFM.06 A continuing education and training program is developed and implemented.

<div align="right">Effectiveness</div>

Keywords:

Continuous 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.

To ensure that skills are maintained, the laboratory leaders shall develop a training and continuing education program relevant to the assigned duties, meet personnel needs and satisfy licensing requirements. The training program shall include at least the following areas:

  a) The quality management system.
  b) Assigned work processes, procedures and updated guidelines.
  c) The available information system.
  d) Laboratory safety program, including the infection and prevention program
  e) Dealing with the adverse incidents.
  f) Code of conducts.
  g) Confidentiality of patient information.

Personnel undergoing training are supervised at all times and the effectiveness of the training programs is reviewed.

Survey process guide:

- GAHAR surveyor may interview some staff members and inquire about the process of continuous education and training.
- GAHAR surveyor may check a sample of staff files to check evidence of attendance of education and training program.

Evidence of Compliance:

1. The laboratory has a training and continuing education program for all staff categories.
2. The laboratory training and continuing education program includes at least items from a) to g) in the intent.
3. The effectiveness of the training and continuing education program is monitored and evaluated.
4. Staff members are aware of the training and continuing education program.

Related standards:

OGM.06 Laboratory Director, OGM.11 Ethical management, IPC.02 Hand Hygiene, EFS.03 Fire and smoke safety, WFM.11 Staff Files, QPI.01 Quality management program, QPI.09 Continues improvement program, IMT.01 Documentation management system, PCC.02 Patient and family rights

Equitable staff performance evaluation

WFM.07 Competency assessment is reviewed and recorded at least biannually.

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 competence 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 leaders develop and implement policy and procedures describing the process of personnel competency assessment.

Competence of laboratory staff (technical and managerial) can be assessed biannually using any combinations, all of the following approaches or following the guidelines according to the assigned job:

a) Direct observation of routine work processes and procedures, including all safety practices. Direct observation of equipment maintenance and function checks.
b) Monitoring the recording and reporting of examination results.
c) Review of work records.

d) Assessment of problem-solving skills.

e) Examination of specially provided specimens, such as previously examined specimens, inter-laboratory comparison materials, or split specimens.

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 interview laboratory leaders and inquire about used methods, frequency and followed guidelines for staff competency assessment

- GAHAR surveyor may check a sample of staff files to assess completion of competency assessment records.

Evidence of Compliance:

1. The laboratory has an approved policies and procedures that clearly describe the process for competency assessment.

2. Records of staff competency assessment including managerial and technical levels are retained in employees' files.

3. Competency assessment is performed at least biannually for each staff member.

4. Actions taken in case of unsatisfactory competency assessment results are documented.

Related standards:

APC.02 Registration of staff, WFM.08 staff performance evaluation, WFM.11 Staff Files, OGM.10 Departmental management

WFM.08 Staff performance evaluation is reviewed and recorded at least annually.

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. Staff performance review is a continues improvement process that provides opportunities for managers to set goals for future performance. Such evaluations are used at the time of re- privileging. It also helps healthcare professionals further develop their knowledge, skills, and attitudes (competencies) in a manner that fulfills their needs and ensures the sustainability of services provided by the laboratory. Documented process of employee's performance review includes performance review methods, tools, evaluation dimensions, criteria, time interval, and responsible personal for each staff category.

Survey process guide:
- During the GAHAR survey, the surveyor may interview laboratory staff members and inquire about performance review.
- GAHAR surveyor may check a sample of staff files to assess compliance to standard requirements.

Evidence of Compliance:
1. There are policies, procedures and a clearly described process for staff performance review.
2. Reviews are performed at least annually for each staff member.
3. Managerial review and approval of staff performance review.
4. Employee feedback on their performance is evaluated.
5. Actions taken based on performance review.
6. Staff regular performance review is documented in employees' files.

Related standards
APC.02 Registration of staff, OGM.10 Departmental management, OGM.13 Positive Workplace Culture, IPC.02 Hand Hygiene, WFM.04 Job Description, WFM.07 competency assessment, WFM.11 Staff Files, QPI.01 Quality management program, QPI.09 Continues improvement program

Efficient medical workforce structure

WFM.09 The laboratory has a staff burnout and turnover preventive measures and strategies in accordance with laws and regulations.

<div align="right">Safety</div>

Keywords:
Staff burnout and turnover.

Intent:
Attention to health and well-being of laboratory professionals become more important when we consider the fact that employees are the greatest asset in an organization. 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 patient care. The laboratory shall ensure management of staff working hours and application of the Egyptian laws and regulations efficiently to avoid burnout.

The policy of efficient working hours shall address at least the following:
a) Measures to avoid staff burnout.
b) Planned rest times.
c) Maternity protection and arrangements for breast-feeding.
d) setting staff working hours according to the Egyptian laws and regulations

Survey process guide:
- GAHAR surveyors will assess the laboratory policy for working hours and application of the Egyptian laws and regulations.
- GAHAR surveyor may pose questions about measures taken to ensure appropriate working hours during leadership interview session.
- GAHAR surveyors will observe the staff rest areas and rest times.

Evidence of Compliance:
1. The laboratory has an approved policy and procedures that clearly describe the process to ensure safe and efficient working hours, the policies address a) to d) in the intent.
2. The staff schedules ensure suitable working hours planned rest times.
3. Staff is aware of laboratory policy.

Related standards
OGM.10 Departmental managements, OGM.13 Positive Workplace Culture, OGM.12 Safety Culture, WFM.10 A staff health program

Effective staff health program

WFM.10 A staff health program is developed, implemented, monitored and evaluated annually in conformance to laws and regulations.

<div align="right">Safety</div>

Keywords:
Staff health program.

Intent:
Laboratory facility shall implement staff health program to ensure safety of the staff according to workplace exposures.

A corner stone of 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 to minimize possible harm arising and, if not possible, to lessen its negative sequel. This is achieved through an organization wide staff health program that identifies high-risk areas and processes. The program scope covers all staff, the program address at least the following:
- a) Pre-employment medical evaluation of new staff.
- b) Screening for exposure and/or immunity to infectious diseases.
- c) Exposure control and management to work-related hazards: ergonomic hazards that arise from the lifting and transfer of equipment, strain, repetitive movements, and poor posture or physical hazards such as lighting, noise, ventilation, electrical and others and biological hazards from blood borne and air borne pathogens and others.
- d) Staff education on the risks within the organization environment as well as on their specific job-related hazards.

e) Staff preventive immunizations.

f) Recording and management of staff incidents (e.g., injuries or illnesses, taking corrective actions, and setting measures in place to prevent recurrences).

Pre-employment medical examination is required for all employees' categories to evaluate their appropriateness for safe performance, and staff that are exposed to certain hazards as radiation should have periodic specific medical evaluation (tests and examinations).

Situational examination may be required in case of exposure to specific substances. Results of medical evaluation are documented in staff health records and action is taken when there are positive results including employee awareness of these results and provision of counselling and interventions as might be needed.

Infection control staff shall be involved in development and implementation of the staff health program as transmission of infection is a common and serious risk for both staff and patients in healthcare facilities.

All staff occupational health program related results (e.g. Medical evaluation, immunization, work injuries) shall be documented and kept according to laws and regulations.

Survey process guide:

- GAHAR surveyors may evaluate the health safety program for the employees during the document review process.
- GAHAR surveyors shall interview the laboratory leaders to evaluate the priority areas and program development policy.

Evidence of Compliance:

1. The laboratory has an approved staff health program according to local laws and regulations that covers the items a) through f) in the intent.
2. There is an occupational health risk assessment that defines occupational risks within the facility.
3. Staff is educated about the risks within the organization environment, their specific job-related hazards and periodic medical examination.
4. There is evidence of the actions taken in case of positive results in the periodic medical evaluation including employee awareness and counselling.
5. Post exposure prophylaxis and interventions are implemented and documented.
6. All results related to health care program are documented in the staff health records (e.g.: pre-employment and periodic medical evaluation, history of exposures to any hazards and actions taken accordingly).

Related standards

OGM.13 Positive Workplace Culture, IPC.03, WFM.01 Workforce manual, Laws and regulations, WFM.04 Job Description, WFM.09 Staff burnout and turnover, WFM.11 Staff Files

Efficient staff filing process

WFM.11 A staff file is developed for each workforce member.

<p align="right">Effectiveness</p>

Keywords:
Staff Files.

Intent:
It is important for the laboratory to maintain a staff file for each staff member.

An accurate staff file provides recording of the relevant educational and professional qualifications, training and experience, and assessments of competence

Records of all personnel are maintained in either electronic or paper form and must be readily available for review at the time of survey.

The laboratory should develop a policy and procedures that guide management of staff files according to laws and regulations.

The records shall be standardized and kept updated according to the laboratory policy.

The policy shall address at least the following:

a) Staff file initiation

b) File contents, include at least the following:

    i) Educational and professional qualifications.

    ii) Copy of certification\ credentials or license.

    iii) Previous work experience.

    iv) Signed Job descriptions.

    v) Evidence of Introduction of new staff to the laboratory environment.

    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 surveyors will evaluate during the document review session the staff file and assess their completion as requested by the standard.

Evidence of compliance:
1. There are policies, procedures and a clearly describe the process for staff files that addresses at least elements from a) through f) in the intent.
2. Staff members who are involved in creation, storage and use of staff files, are aware of the policy requirements.
3. Staff files are confidential and protected.
4. Staff files include all the required records listed in item b) from the intent.
5. Staff files are disposed as per laboratory policy, laws and regulations.

Related standards

WFM.01 Workforce manual, Laws and regulations, WFM.04 Job Description, WFM.05 Orientation Program, WFM.06 Continuous Education Program, WFM.07 competency assessment, WFM.08 staff performance evaluation, WFM.10 A staff health program, WFM.12 Verifying credentials

WFM.12 New and current staff credentials are verified.

<div align="right">Effectiveness</div>

Keywords:

Verifying credentials

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.

Survey process guide:
- GAHAR surveyor may review an approved document describing the credential verification process
- GAHAR surveyor may check a sample of staff member including laboratory doctors and technician files to assess compliance to standard requirements
- GAHAR surveyor may interview staff members who are involved in credentialing process to assess compliance to standard requirements.

Evidence of compliance:
1. Required credentials for each position are kept in staff 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.

Related standards:

APC.02 Registration of staff, WFM.01 Workforce manual, Laws and regulations, WFM.11 Staff Files, IMT.01 Documentation management system

Supply Chain Management

Chapter intent:

Supply chain management is considered as an important cornerstone process as It is directly related to availability of the services covered by that laboratory and also quality of contracted services or goods which directly reflect to the quality of the service offered by that organization.

Supply chain management includes steps from ordering to delivery of supplies to the laboratory. The laboratory selects the supplies and suppliers based on selection criteria as well as maintaining, checking of the reagents and the whole process of issuing, receiving and utilization of the reagent.

Referral laboratory is one of the important factors affecting the laboratory at different steps from the service agreement, scope of service and quality of released results so it›s an important item to be highlighted in supply chain to put a clear role of laboratory management in selecting, monitoring and assurance of the quality of services performed outside the laboratory.

Chapter purpose:

1. To develop a control process for service agreement.
2. To develop polices controlling reagents selection, checking, issuing process
3. To Ensure a controlled system for inventory management and preservation standards of reagents.
4. To Ensure the role of the laboratory in selecting and monitoring the performance of referral laboratory.

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, Conditions, substitutes, amendments, updates and annexes)

1. Egyptian Constitution
2. Egypt 2030 vision, Ministry of planning
3. Law 51/1981 organization healthcare facilities
4. MOH Ministerial 186/2001 Patient right to know expected cost of care
5. Law 181/2018 on Egyptian "Consumer Protection"
6. Law of trade unions and protection 213/2017
7. Egyptian standards for accounting, 609/2016
8. Professional code of ethics- prime minister decree 238, year 2003
9. WHO Lab quality management system, 2011
10. ISO 15189:2013 Medical laboratories — Requirements for Safety

Laboratory Supplies and Materials

SCM.01 Suppliers of reagent, supplies and services are, identified, selected, and evaluated properly.

Effectiveness

Keywords:
Laboratory Suppliers.

Intent:
Selecting the best supplier is a cornerstone step for the laboratory to ensure Quality of supplies and other services. It is also essential for commitment and keeping supply chain process uninterrupted.
It allows the laboratory to deal with emergency situation and find solution in short time.
Suppliers and service providers are selected upon pre-specified criteria (eg: suppliers for equipment, supplies, reagents and services). The Supply chain management system defines a process to select and evaluate the suppliers' abilities to meet qualification requirements.
The laboratory develops and implements a process that defines the selection criteria and evaluation of suppliers. Suppliers and service providers' selection criteria, include at least the following:
a) Certification
b) Fulfilling legislation requirements
c) Previous work experience

Suppliers evaluation criteria, include at least the following:
d) Quality of received materials
e) Prompt response
f) Uninterrupted supply chain process.

Survey process guide:
- GAHAR surveyors may review the laboratory policy and procedures including the selection and evaluation criteria and check updated selected suppliers' documents.
- GAHAR surveyors may observe the implementation of selection criteria of laboratory reagents, supplies and services.
- GAHAR surveyor may interview laboratory leadership who are involved in supplier selection and evaluation process to access compliance to standard requirements

Evidence of Compliance:
1. The laboratory has a defined process for selection and evaluation of suppliers and service providers including items in the intent from a) to f).
2. Records of updated evaluation of suppliers' selection criteria of the current suppliers.
3. The staff is aware of Suppliers and service providers' selection and evaluation criteria.

Related standards:

OGM.14 Supply Chain Management, SCM.03 Inventory management, SCM.04 supplies requesting and dispatching.

SCM.02 Reagents and supplies are received and inspected properly before being placed in service.

<div align="right">Safety</div>

Keywords:

Supplies reception and inspection.

Intent:

Materials, supplies, and services are essential inputs that affect the quality of results and services being produced.

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 policy and 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 acceptance 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 Surveyors 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 interview staff members who are involved in supplies reception and inspection process to access compliance to standard requirements

Evidence of Compliance:

1. The laboratory has an approved policy and procedures that clearly describe the process of reagents, materials and services reception and inspection.

2. There is a current list of reagents, supplies and services including the name of supplier and the equipment used.

3. Records for reception and acceptance process including items a) to d) in the intent.
4. The staff is aware of reagents / supplies reception and inspection process and corrective actions when needed

Related standards:
OGM.14 Supply Chain Management, SCM.01 Laboratory Suppliers

Effective Inventory management system

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

<div align="right">Effectiveness</div>

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 an inventory management system to ensure that the storage is under monitored conditions 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) Clerical status of the reagents/supplies (e.g.: accepted, 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 Surveyors may review the records of the inventory for reagent tracking and monitoring.
- GAHAR surveyors may observe supplies and reagents storage conditions in compliance with the standard requirements.

Evidence of Compliance:
1. The laboratory has an approved policy, procedures that clearly describe the process describing the inventory management system.

2. Records of monitoring storage condition including items in the intent from a) to f).
3. Reordering supplies/reagents are according to the defined safety limit.

Related standards:
OGM.14 Supply Chain Management, SCM.04 supplies requesting and dispatching

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

<div align="right">Efficiency</div>

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. To maintain best inventory management process, the inventory process for requesting and dispatching reagents or other supplies shall fulfill 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 Surveyors may review the records of the inventory to ensure that the reagents and other supplies are requested and dispatched properly.
• GAHAR Surveyors may observe reagent dispatching process in the inventory and review the relevant requesting process.
• GAHAR surveyor may interview staff members who are responsible for inventory management to access compliance to standard requirements

Evidence of Compliance:
1. The laboratory has an approved policy and procedures clearly described process describing the requesting and dispatching of reagents and supplies and fulfilling the items in the intent from a) to e).
2. Records for updated evaluation of reagent requesting and dispatching process.
3. The staff is aware of reagent requesting and dispatching process.

Related standards:
OGM.14 Supply Chain Management, SCM.03 Inventory management.

Service agreement and Referral laboratory service

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

<div align="right">

Effectiveness

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Keywords:
Contracted services.

Intent:
Laboratory leadership defines the nature and scope of services provided by contracted services as: referral laboratory, housekeeping, security and consultancy. Contracted services have indirect effects on the quality of the whole laboratory services by adding referral laboratory scope of service and affecting the customer satisfaction through their housekeeping and security. Head of departments/services participates in selection, evaluation and continuous monitoring contracted services to ensure service providers comply with required environmental safety, patient 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 or terminated. The evaluation criteria include at least the following:
a) Quality of the service provided.
b) Continuous uninterrupted service.
c) Prompt response.
d) Competence evaluation.

Survey process guide:
- GAHAR surveyor may receive information about contracted services during the opening presentation, then questions about contracts, contractors monitoring, evaluation, and renewal shall be posed during the leadership session.
- GAHAR Surveyors may review the documents and contracts of contracted services.

Evidence of compliance:
1. There is a list of all contracted services
2. There is selection criteria for each contracted services
3. Head of departments/services participates in selection, evaluation and continuous monitoring of the contracted services.
4. There is evaluation criteria for monitoring the contracted services including items in the intent from a) to d).

5. Each contract is evaluated at least annually to determine if it should be renewed or terminated.

Related standards:
OGM.14 Supply Chain Management, SCM.06 Referral laboratory, OGM.06 Laboratory Director, OGM.10 Departmental management.

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 is crucial to ensure:
  a) Quality of results directly affect customer satisfaction and retention.
  b) Commitment of referral laboratory TAT contracting document.
  c) Referral laboratory services are properly controlled.

The referral laboratory's services may be internal (e.g., within the same organization) or external (outside the organization). Proper control of referral laboratory services is done through proper selection as well as regular evaluation. Selection of referral laboratories is done according to the following:
  d) GAHAR accreditation when available.
  e) The quality of performance of referral laboratory (e.g.: PT results, accreditation...)
  f) Turnaround time
  g) Scope of service.

The laboratory implements an evaluation process either before starting contracting, during the contract or upon renewal of contract for the referral laboratory through at least the following:
  h) Quality of performance monitoring,
  i) Turnaround time
  j) Prompt response
  k) Compliance with transportation policy
  l) Result reporting.

For each laboratory, it identifies the process for referral laboratory contracting and the laboratory director ensures that the referral laboratories provide proper Agreement/Service Contract; a signed document specifying the expectations of the two parties involved is readily available for quick referral. Elements of such a document include at least the following:
  m) Scope of Service
  n) Agreement conditions
  o) GAHAR accreditation status

p) Sample Requirements

q) Turnaround Time (TAT)

r) Result Reporting

s) Release of information to third party

t) Mean of solving disputes

u) Validity of the agreement and review schedule.

Survey process guide:

- GAHAR surveyor may receive information about contracted services during the opening presentation, then questions about contracts, contractors monitoring, evaluation, and renewal of the referral laboratory, this should be done during the leadership session.
- GAHAR Surveyors may review the policy including the selection and evaluation criteria
- GAHAR Surveyors may check selected referral laboratory contracts to ensure implementation.

Evidence of compliance:

1. The laboratory has an approved policy, procedures that clearly described process for selection and evaluation of referral laboratories.
2. List of referral laboratories is available.
3. The selected laboratory meets the selection criteria including items in the intent from d) to g).
4. Records of evaluation of referral laboratories including items in the intent from h) to l).
5. Referral laboratory contract include items in the intent from m) to u).

Related standards:

OGM.06 Laboratory Director, OGM.10 Departmental managements, SCM.05 Contracted services.

Equipment Management System

Chapter intent:

Proper management of the equipment in the laboratory is necessary to ensure accurate, reliable and timely testing. Good equipment management program helps maintaining a high level of laboratory performance; reduction in variation in test results, more confidence in the accuracy of testing results and lower costs of repair. It also leads to lengthening of the instrument's life; as well as less interruption of services due to breakdowns and failures. It increases safety for workers and produces greater customer satisfaction.

Chapter purpose:

1. To ensure equipment safety to the laboratory environment and personnel.
2. To understand the selection and provision of laboratory equipment suitable for the scope and load of services provided
3. To develop criteria for the reception, installation and acceptance of equipment
4. To define the instructions for use of the equipment.
5. To understand the process of equipment calibration.
6. To develop a process for the monitoring, maintenance and repair of equipment.
7. To develop a process for dealing with adverse incidents and accidents related to laboratory equipment.
8. To define the process for equipment records development and retention.
9. To define the process of equipment retirement.

Effective equipment management plan

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

<div align="right">Effectiveness</div>

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 leaders 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 and on a predefined interval basis.
  c) Calibration 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 on a predefined regular basis by a qualified person.
  e) Inventory of laboratory equipment including availability, criticality, and functionality.
  f) Periodic preventive maintenance according to the manufacturer›s recommendations.
  g) Dealing with equipment adverse incidents, including actions taken, backup system, and reporting.
  h) Malfunction and repair of laboratory equipment.
  i) Retiring of laboratory equipment.

The laboratory leaders are responsible for selecting needed equipment, that affect 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:
  a) Match of the instrument specifications provided by the laboratory.
  b) Performance characteristics of the instrument
  c) Cost of the equipment
  d) Readily available reagents
  e) Ease of operation
  f) Supplier's support and available ongoing services
  g) Availability of maintenance services
  h) Updated technology
  i) Respecting safety measures.

Survey process guide:
- GAHAR surveyor may review the laboratory plan for selection, Inspection, testing of new laboratory equipment and list of equipment inventory.
- GAHAR surveyor may check 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 that addresses all elementsfrom a) through i) in the intent.
2. Staff is aware of the laboratory equipment plan.
3. The plan is evaluated and updated annually.
4. Laboratory equipment are selected adequately for the type and load of service provided.
5. The laboratory ensures that only trained and competent people handles the specialized equipment(s).

Related standards:
EFS.06 Utilities Management, OGM.14 Supply Chain Management, WFM.04 Job Description

EMS.02 The laboratory ensures proper equipment reception, installation and acceptance.

<div align="right">Effectiveness</div>

Keywords:
Equipment reception, installation, acceptance.

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

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

Prior to testing patient specimens, it is important to evaluate the performance of new equipment to ensure that it is performance meets the expected specification. The expected performance specifications are developed according to manufacturer's instructions and regulations if present. The laboratory develops policies and procedures that clearly describe the process of installation and acceptance of the equipment. The laboratory policy defines the criteria for initial acceptance of the equipment provided (e.g.: meeting ordering specifications...).

Training for all operators is provided for proper operation of the instrument as well as for all necessary routine maintenance and monitoring procedures.

Survey process guide:
- GAHAR surveyor may review the laboratory policies and procedures for reception, installation, acceptance of new laboratory equipment and ensures that it is matched with the manufacturer's specifications followed by interviewing laboratory professional involved in evaluation of the performance of new the equipment.
- GAHAR surveyor may check equipment installation and acceptance records.

Evidence of Compliance:
1. The laboratory has an approved policy and procedures that clearly describe installation and acceptance of the equipment.
2. Initial acceptance criteria of each equipment are identified.
3. Installation is done by the vendor and according to the manufacturer's specifications.
4. Training of the laboratory personnel on operation and monitoring of the equipment.
5. Performance specification records of the equipment upon installation are maintained.

Related standards:
WFM.04 Job Description, OGM.14 Utilization management

EMS.03 Instructions for use of equipment are available and followed by authorized qualified competent personnel.

<div align="right">safety</div>

Keywords:
Equipment instructions.

Intent:
Instructions for use, safety and maintenance of equipment, including any relevant manuals provided by the manufacturer of the equipment is important for safe operation of laboratory equipment and should be readily available. Only trained personnel are authorized as users.

Survey process guide:
- 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 instruction.
- GAHAR surveyor may review personnel authorization list for operating each equipment and records of training on equipment operation to ensure competency.

Evidence of Compliance:
1. Instructions for use for all laboratory equipment are developed and written in a manner understood by equipment user.
2. Instructions for use are readily available for equipment user.
3. Instructions for use are strictly followed
4. All personnel authorized to operate equipment are qualified and competent.

Related standard:

EMS.01 Equipment management plan, WFM.04 Job Description, WFM.06 Continuous Education Program

Safe laboratory equipment use

EMS.04 Equipment calibration plan ensures reliable, effective use of laboratory medical equipment.

<div align="right">Effectiveness</div>

Keywords:

Calibration plan.

Intent:

Calibration is the process of evaluating and adjusting the equipment measurement. Proper calibration of an instrument allows the production of valid data by elimination or reduction of bias.

Calibration of auxiliary equipment is performed before use, after activities that may alter the calibration and at predefined intervals through a calibration plan while the main equipment (auto analyzers) shall follow the manufacturer calibration recommendations.

The frequency and the calibration method are done according to the manufacturer's instruction or through a certified calibration provider.

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

Survey process guide:

- GAHAR surveyor may review equipment calibration plan, calibration schedule and staff training records and the corrective action taken in case of deviation.
- During the survey, GAHAR surveyor may interview 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 dates of recalibration, that follow the manufacturer calibration recommendations.
2. There are calibration certificates from accredited calibration provider.
3. Action taken in case of deviation from acceptable criteria.

Related standard:

EMS.01 Equipment management plan, EMS.06 Equipment failure management, QPI.06 Nonconformity management., QPI.08 Incident Reporting System.

EMS.05 The Laboratory develops equipment maintenance and monitoring program.

Effectiveness

Keywords:
Equipment maintenance and monitoring.

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 leaders shall develop a program with defined frequency to regularly monitor proper function of instruments. The program also includes preventive maintenance at defined intervals for each piece of equipment. Equipment is assessed through periodic inspections, performance testing, and maintenance program which includes at least the following:

Monitoring and maintenance procedures following the manufacturer instructions

a) Description of the maintenance check elements
b) Description of the frequency of each check whether daily, weekly, monthly...
c) Identification of the responsible party
d) Description of the actions to be taken in the event of unsatisfactory results.
e) Requalification of the equipment (e.g: reallocation, equipment failure...)
f) Process for decontaminating equipment prior to service or disposal.

If equipment is repaired onsite, appropriate space and personal protective equipment are provided for this work.

Survey process guide:
- GAHAR surveyor may review equipment maintenance program, and interview staff to check their awareness.
- GAHAR surveyor may review schedule of preventive maintenance, and records of implementation.

Evidence of Compliance:
1. The laboratory has an approved equipment preventive maintenance program that addresses all elements from a) to f) from the intent.
2. Records for periodic equipment preventive maintenance and monitoring are available.
3. Staff is aware of the equipment maintenance program.

Related standards:
EMS.01 Equipment management plan, QPI.07 Risk Management plan/Program

EMS.06 The laboratory has an effective equipment failure management system.

Effectiveness

Keywords:

Equipment failure management.

Intent:

Equipment failure management system is important for tracking of any deviations, recurrent failures and determine if changes to protocols and instructions are necessary.

Problems with equipment may present in many ways. The operator may notice subtle changes such as drift in quality control or calibrator values, or obvious defects in equipment function. Sometimes, the equipment fails to operate.

Whenever equipment is found to be defective, it is taken out of service and clearly labelled. The laboratory shall develop a detailed procedure for the process of failure management with strict empathies on how to ensure its effectiveness. Investigation and follow-up of equipment failure shall include at least the following:

a) Reporting to the manufacturer and appropriate authorities, as required

b) Immediate action and troubleshooting.

c) Assessment of the failure effect on reported results.

d) Backup plan implementation.

e) Report of delayed results.

Survey process guide:

• 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 check records of equipment failure and evaluate the corrective action taken.

Evidence of Compliance:

1. The laboratory has an approved policy and procedures that clearly described process for the equipment failure management including at least items from a) to e) from the intent.

2. Equipment failures are investigated and gaps in services are identified

3. Responsible authorized personnel are knowledgeable about the dealing with adverse incidents and accidents of equipment malfunction or failure.

4. Records are maintained for equipment malfunction history and related corrective action taken.

Related standards:

EMS.01 Equipment management plan, QPI.08 Incident Reporting System, QPI.06 Nonconformity management., QPI.02 Quality management qualified individual, WFM.04 Job Description

EMS.07 Equipment Records and files 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 it's installation in the laboratory.

Maintaining a list of all equipment helps in the management of all equipment functions and is used to ensure that all appropriate actions have been 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 (records) whether paper or electronic based should include at least the following:

a) List of all laboratory equipment with unique identity of each;

b) Manufacturer's name, model and serial number or other unique identification;

c) Contact information for the supplier or the manufacturer;

d) Date of receiving and date of entering into service;

e) Location of the equipment;

f) Condition when received (e.g. new, used or refurbished...)

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

1) Equipment initial installation calibration records

2) Equipment instructions for use.

3) Maintenance carried out and the schedule for preventive maintenance;

4) Equipment performance records (entire history that confirm the equipment's ongoing acceptability for use).

5) Failure, or malfunction, modification, or repair of the equipment.

Survey process guide:

GAHAR surveyor may review equipment file and equipment management program record to assess compliance to standard requirements.

Evidence of Compliance:

1. Equipment file (records) should include item in the intent from a) to f).

2. Equipment management program including item in the intent from 1) to 5).

3. Equipment file (records) are readily available and easily retrieved.

Related standards:

OGM.14 Supply Chain Management, EMS.01 Equipment management plan, EMS.03 Equipment instructions, IMT.01 Documentation management system.

EMS.08 The Laboratory develops an effective equipment retiring process.

Effectiveness

Keywords:

Retiring of equipment.

Intent:

This will usually occur when it is clear that the instrument is not functioning and is not repairable, or when it is outmoded and should be replaced with new equipment. Once a piece of equipment is fully retired and it has been determined that it has no further use, it is disposed of in an appropriate manner. Then any potential biohazards are considered and all safety disposal measures are followed.

Survey process guide:

- GAHAR surveyor may review equipment retiring policy and check the safe equipment retiring process.
- GAHAR surveyor may review any equipment retirement records (if available).
- During the survey, GAHAR surveyor may interview staff for safety disposal measures awareness.

Evidence of Compliance:

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

Related standards:

EFS.05 Safety program, Security plan, EMS.01 Equipment management plan, IMT.01 Documentation management system.

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 patients. Florence Nightingale, a nurse, was one of the pioneers in improving health care quality. Dr. Avedis Donabedian was a founder of the study of quality of healthcare and medical outcome research. 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 patient 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.

During GAHAR survey, Surveyors are going to meet the leadership, heads of departments and staff to discuss the QPI aspects, initiatives and projects. Surveyors may perform tracers to check data selection, collection, analysis of data and methods that used to follow the improvement projects and impact of projects on improving the quality dimensions.

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

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates and annexes)

1. MOH Quality and Safety Guide, 2019
2. Laboratory Performance Indicators Guide by HIO, 2013
3. National EFQM based excellence award www.Egea.gov.eg
4. Law 35/1960 National census and statistics
5. Law 2915/1964 Establishment of CAPMAS
6. CLSI/ QMS01 | A Quality Management System Model for Laboratory Services, 5th Edition
7. Competency Guidelines for Public Health Laboratory Professionals CDC and the Association of Public Health Laboratories 2015
8. WHO Lab quality management system, 2011
9. ISO 15190:2013 Medical laboratories — Requirements for Safety.

Effective leadership support

QPI.01 Laboratory leaders plan, document, implement, and monitor an organizational-wide quality management program.

<div align="right">Effectiveness</div>

<u>Keywords:</u>
Quality management program.

<u>Intent:</u>
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 heads of departments and staff. Performance improvement and risk management are parts of both strategic and departmental operational plans. To initiate and maintain a laboratory quality management and improvement process, leadership planning is essential. The laboratory director with assigned quality manager/coordinator and supervisory staff are included in the planning process whenever possible.

The laboratory's program for quality management shall be integrated, comprehensive and adequate to the size, complexity and the scope of laboratory services addresses at least the following:
a) The commitment to regulatory requirements and accreditation standards.
b) The goals of the quality management program
c) The quality measures (technical and managerial)
d) The quality management activities
e) The quality tools
f) Periodic review and update (at least annually).

Laboratory leaders communicate the quality management program to laboratory staff; this facilitates all laboratory staff involvement and enhances implementation of the program. All the following should be communicated:
1) All elements of the quality management program
2) Results of performance measure and improved services;
3) The quality measures and data collection tools;
4) Results of quality measurement and assessment activities;
5) Actions taken and changes made to improve the quality of laboratory services.

<u>Survey process guide:</u>
GAHAR surveyor may perform an interactive session with laboratory leaders to identify leadership's approach for developing the quality management system and continuous improvement, the discussion may cover the role of leaders and department heads in measures selection, reporting and review the minutes of meeting and recommendations of action plans for the selected improvement projects and its effect on the level of quality and safety in the laboratory.

<u>Evidence of compliance:</u>
1. The laboratory leaders participate in planning a program for quality management.
2. The laboratory has a documented, updated and approved quality management program containing the items in intent from a) to f).
3. The laboratory leaders participate in implementing and monitoring a program for quality management.
4. Quality management program elements is communicated to all staff including at least the items from 1) to 5).

<u>Related standards:</u>
OGM.03 Governing body responsibility, OGM.08 Laboratory leaders, OGM.07 Strategic and operational Plans, QPI.02 Quality management qualified individual, QPI.03 Performance measures, QPI.04 Data management, aggregation and analysis, QPI.06 Nonconformity management.

QPI.02 A qualified staff member(s) is assigned to oversight the laboratory quality management program.

<div align="right">Effectiveness</div>

<u>Keywords:</u>
Quality management qualified individual.

<u>Intent:</u>
Errors are caused by system or process failures, that's why it is important to adopt various quality management techniques to identify inefficiencies, ineffective service , and preventable errors to influence changes associated with systems and that require a qualified individual with a clear job description to follow up the implementation and improvement of the quality management program and put it into operation by utilizing the 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 organization wide.

<u>Survey process guide:</u>
GAHAR surveyor may review staff qualification records during document session including the qualification and job description of the assigned staff member.

<u>Evidence of compliance:</u>
1. An individual with knowledge, skills and experienced in quality management and related activities is assigned to oversight the quality management system.
2. There is a clear job description that support the work of performance improvement team to train, facilitate and coordinate the program activities.
3. Quality management individual(s) receives required support in terms of space, equipment, resources, and staffing.

Related standards:

WFM.04 Job Description, WFM.06 Continuous Education Program, OGM.08 Laboratory leaders., QPI.01 Quality management program

Efficient Data Management

QPI.03 The laboratory leaders define the quality performance measures to monitor technical and managerial structures, processes, and outcomes.

<div align="right">Efficiency</div>

Keywords:

Performance measures.

Intent:

Quality measures (indicators) are specific performance measurements designed to monitor one or more processes during a defined time and are useful for evaluating the laboratory technical and managerial processes. Each performance indicator is Specific, Measurable, Achievable, Relevant, Time-bounded, evaluated at regular interval and Recognized/ Rewarded when achieved (SMARTER).

Each laboratory selects which technical and managerial processes and outcomes are most important to monitor, based on its mission, patient needs, and services. Monitoring often focuses on those processes that are high risk to patients, are provided in high volume, or are problem prone.

The measurement of indicators used may be changed when the data for a particular process are no longer useful or the process being measured is no longer a problem. In addition, new indicators are selected to monitor new processes or processes that have become problematic.

To define an indicator properly, a description of at least the following is needed:

a) Definition
b) Specified frequency
c) Sampling techniques
d) Formula
e) Methodology of data collection and analysis
f) Bench mark the results

Quality indicators cover laboratory activities as selected by leaders covering at least the following areas:

1) The laboratory's safety and infection control programs
2) Pre examination processes
3) Examination processes
4) Post examination processes,
5) Managerial indicators
6) Utilization management indicators

Survey guide process:

- GAHAR surveyor may review document of performance measures to evaluate the process of selection of the performance measures and the fulfilment of the data needed for defining each measure
- GAHAR surveyors may interview the staff to evaluate the process of data collection and monitoring in order to assess aspects of the structure, process, or outcome of laboratory processes, benchmark used for each measure, reports and actions taken for improvement

Evidence of compliance:

1. A standardized data analysis report with specific definition criteria for each selected performance measure are available and include all elements mentioned in the intent from a) through f).
2. Staff responsible for the collection, interpretation and/or use of performance measurement are aware of data analysis report contents.
3. The results of laboratory performance measures are used in benchmark internally, externally and with best practice.
4. Results of measures analysis are regularly reported to the governing body.
5. The laboratory makes its performance results/data publicly available at least quarterly

Related standards:

APC.04 Accreditation process value, OGM.09 Performance and Accreditation Disclosure, OGM.14 Supply Chain Management, IPC.01 IPC program, risk assessment, guidelines, IPC.02 Hand Hygiene, QPI.01 Quality management program, QPI.04 Data management, aggregation and analysis

QPI.04 The laboratory assigns a staff member(s) with appropriate experience knowledge, and skills for data management and validation within approved time frame.

<div align="right">

Effectiveness

</div>

Keywords:

Data management, aggregation and analysis.

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 leaders. 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 leaders 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) when data is going to be published,
ii) sent to external bodies
iii) change in the tool ,person or process used for measurement

Survey process guide:

- GAHAR surveyor may perform an interactive quality management program review session to review data management tools that were used in the selected technical and managerial measures, or in the improvement projects.
- GAHAR surveyor may interview responsible staff to evaluate their awareness.

Evidence of Compliance:

1. The laboratory has a written process for data management and validation includes the aggregation and analysis.
2. Responsible staff members for data management and validation are aware and trained about their roles.
3. Data is aggregated and analysed on regular basis.
4. Data review techniques are implemented to ensure all the elements from a) to f) in the intent are considered.
5. Data validation is done in conditions from i) to iii).

Related standards:

WFM.04 Job Description, WFM.06 Continuous Education Program, QPI.03 Performance measures.

QPI.05 The laboratory develops internal (self) assessment program to ensure compliance to its quality management system.

Effectiveness

Keywords:

Internal assessment program.

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.

Survey process guide:

• GAHAR surveyor may review the documents of internal assessment program.

• GAHAR surveyor may interview responsible staff to evaluate their awareness.

Evidence of compliance:

1. The internal assessment program covers all the laboratory activities with predetermined frequency (at least annually), including items in the intent from a) to g).

2. Laboratory leaders review and approve the internal assessment reports and evaluate the effectiveness of the corrective actions taken

3. Competent and trained personnel performing the assessment.

Related standards:

EFS.03 Fire and smoke safety, IPC.01 IPC program, risk assessment, guidelines, QPI.01 Quality management program, QPI.06 Nonconformity management, WFM.04 Job Description.

QPI.06 The laboratory develops a process for nonconformity management.

Effectiveness

Keywords:
Nonconformity management.

Intent:
The nonconformity is defined as the failure to meet the requirements and/or organizational policies.

The non-conformity management system shall be covering all laboratory areas including pre-examination, examination or post-examination processes.

Non conformity sources may include: patient complaints, internal assessments, internal quality control, quality measures results. etc.

When the non-conformity is identified, the laboratory takes action to identify, document and eliminate the root cause(s).

The laboratory shall take corrective action to eliminate the cause(s) of nonconformities. Corrective actions shall be appropriate to the effects of the nonconformities encountered. Actions taken may include halting of the examination procedure and reports if nonconformity may affect directly the patient results and safety.

The laboratory shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

The laboratory has a procedure for identification and management of non-conformity includes at least the following:

a) The responsibilities and authorities for handling nonconformities are designated;

b) The immediate actions to be taken are defined;

c) The extent of the nonconformity is determined;

d) 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 surveyors will review the records of the non-conformities, taken corrective and preventive action taken and their appropriateness to eliminate the root cause.
- GAHAR surveys will interview the quality manager/coordinator to evaluate the appropriateness of the corrective actions taken and identify the potential preventive actions.

Evidence of compliance:
1. The laboratory has an approved policy and procedures that clearly describe the process for non-conformity management including items in the intent from a) to d).
2. Records of non-conformity in different laboratory disciplines are available.
3. Records of corrective and preventive actions taken are maintained.

4. Competent and trained personnel performing the non-conformity management.
5. Laboratory staff is aware about the non-conformity management.

Related standards:
APC.04 Accreditation process value, PCC.07 Complaints and suggestions, QPI.03 Performance measures, QPI.05 Internal assessment program

Efficient Risk Management Program

QPI.07 A laboratory risk management plan/program is developed.

<div align="right">Safety</div>

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.
An important step of risk management is risk analysis where you can assess the high-risk processes. Organization needs to adopt a proactive approach to risk management that includes developing risk mitigation strategies. 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 and risk register.
  e) Clinical risk assessment to Identify the high risk patients, such as:
  i) Patients with a communicable disease
  ii) Patients with bleeding tendency
  iii) Immunosuppressed patients
  iv) Patients with emotional or psychiatric disorders,
  v) Vulnerable patient populations, including frail elderly, dependent children, and patients at risk for abuse and/or neglect.
  vi) Patients at high risk of fall.
  f) Risk prioritization and categorization (i.e. strategic, operational, reputational, financial, other)
  g) Risk reporting to governing body and communication with stakeholder
  h) Risk Reduction plans and tools with priority given to high risks

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 perform a document review for the laboratory risk management plan, then followed by an interactive session with laboratory leaders to identify leadership's approach for improving the quality of care and continuous improvement, the discussion may cover plan\program contents, monitoring the priority focus areas, staff training related to quality concept and data management, in addition to the plans' implementation in different leadership technical and administrative.

Evidence of Compliance:

1. The laboratory has a risk management plan/program that includes all the elements from a) to h) in the intent.
2. High risk processes are re- designed based on the result of the analysis.
3. The laboratory develops and implements a proactive risk reduction plan.

Related standards:

OGM.08 Laboratory leaders, OGM.10 Departmental managements, OGM.11 Ethical managements, IPC.01 IPC program, risk assessment, guidelines, IPC.07 Infection prevention, renovation, construction, QPI.01 Quality management program

QPI.08 An incident-reporting system is developed.

<div align="right">Safety</div>

Keywords:

Incident Reporting System.

Intent:

Strong risk management is supported by efficient incident reporting systems that can identify any event which may affect the patient or employee safety.

In most laboratory injuries, patient complaints, examination errors, equipment failure,

or errors in reporting shall be included and reported.

The incidents reporting has an important influence on improving patient safety.

Incident reports help to detect, monitor, assess, mitigate, and prevent risks that includes at least the following:

a) List of reportable incidents or accidents.
b) Incident management process include how, when, and by whom incidents are reported and investigated.
c) Incidents requiring immediate notification to the management.
d) Incident classification, analysis, and results reporting.
e) Indication for performing intensive analysis and its process.

Survey process guide:

GAHAR surveyor may review the interactive quality management program to check the laboratory incident reporting, management system and review system activities in the

laboratory including identification, analysis, and correction of gaps to prevent future reoccurrence, then followed by an interactive discussion with staff during laboratory tours and tracers to assess staff members' awareness.

Evidence of compliance:
1. The laboratory has an approved policy that defines an incident-type and reporting system that include a) through e).
2. All staff is aware of the incident-reporting system, including all types of contracted and outsourced Services.
3. The laboratory communicates with patient's/services users about adverse events they are affected by.
4. Corrective actions are taken with clear time frame.

Related standards:
OGM.11 Ethical managements, OGM.12 Safety Culture, EMS.06 Equipment failure management, WFM.05 Orientation Program, QPI.07 Risk Management plan/Program

Sustaining Improvement

QPI.09 There is a laboratory- wide performance improvement plan.

<div align="right">Effectiveness</div>

Keywords:
Performance improvement plan.

Intent:
The laboratory uses the information from data analysis to identify potential improvements or reduce (or prevent) adverse events. 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 leaders.

Documentation of improvement activities is an essential element of the process to ensure that improvement was done, to provide a data base for communication with other laboratory professional to support the quality of service, to demonstrate the accountability of the staff and the evidence of impact of processes.

The plan shall at least address 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 leaders
   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

Participation of laboratory staff in performance improvement activities is highly important for increasing service quality, boosting productivity, and improving communication, reducing stress and building a stronger working community. The plan shall be communicated to the relevant stakeholders.

Survey process guide:

- GAHAR surveyor may review the improvement plan, 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 achieved improvements.

Evidence of Compliance:

1. The laboratory has a performance improvement plan including items in the intent from a) to k).
2. The priority areas are identified by the laboratory's leaders based on available data and included in improvement activities.
3. Quality improvement activities are monitored and results are reported to the governing body.
4. Laboratory staff is trained and actively participate in performance improvement activities.
5. The plan is reviewed, evaluated and updated annually
6. The plan is communicated to the relevant stakeholders

Related standards:

APC.04 Accreditation process value, PCC.06 Patient and family feedback, OGM.03 Governing body responsibility, OGM.08 Laboratory leaders., OGM.10 Departmental management, QPI.01 Quality management program, QPI.03 Performance measures
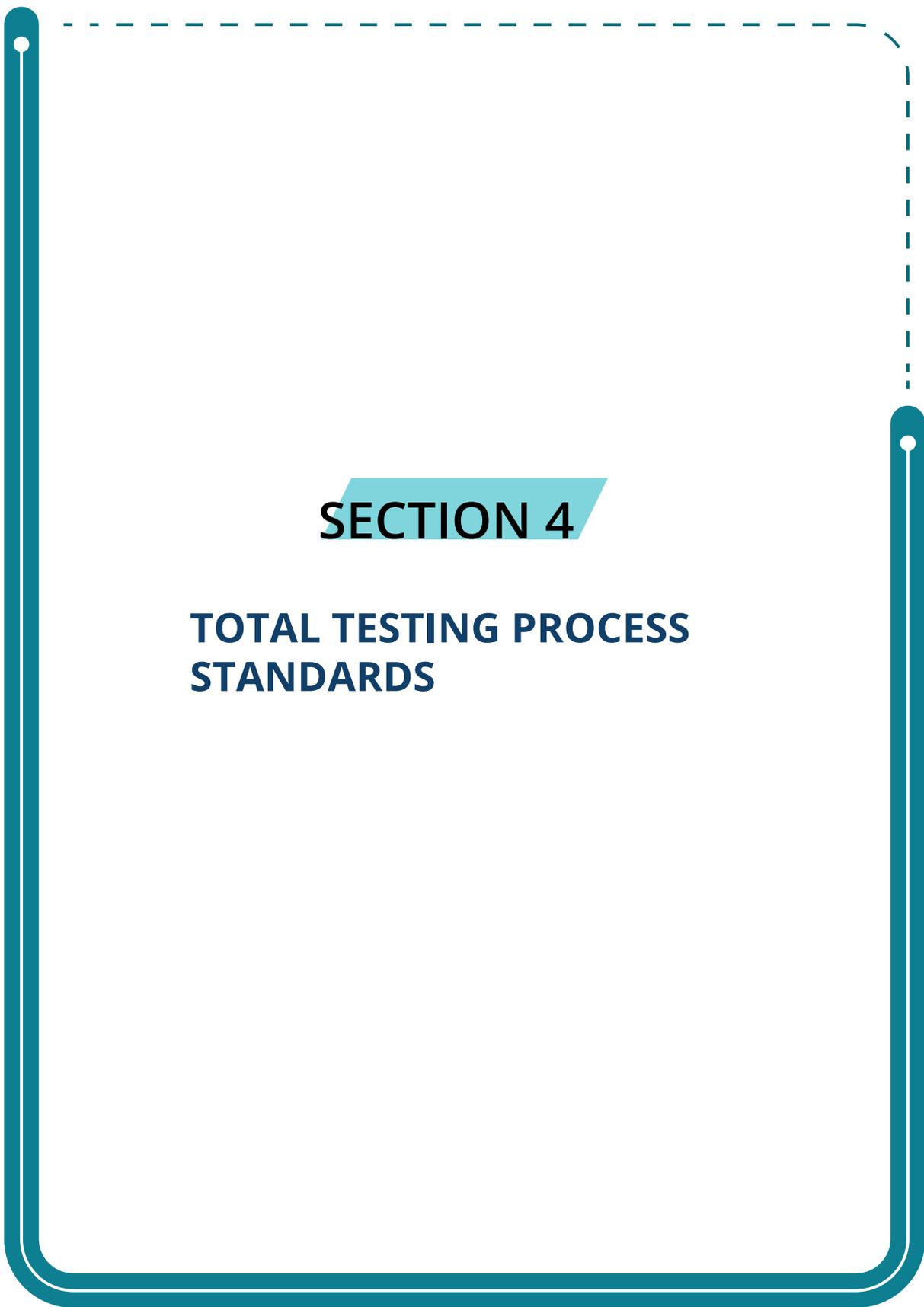
SECTION 4

TOTAL TESTING PROCESS STANDARDS

Section 4: Total Testing Process Standards
Pre-Pre Examination and Pre- Examination

Chapter intent:

Laboratory testing is important and inevitable part of modern diagnostic and disease management. An appropriate selection of a test repertoire, guided by scientific evidence with an appropriate interpretation of results, is a key target for both physicians and laboratory professionals. Inappropriate ordering of tests generates unnecessary excess of labor, expenses and waste affecting laboratory budgets and healthcare systems worldwide. Therefore, a laboratory must be proactive in effectively managing its workload in order to provide the best service for patients within defined constrains. There is a desire to re-focus on the diagnostic process, emphasizing the clinical history, since 75% of diagnoses come from a good history. Clinical examination confirms the history and laboratory tests are used to confirm findings, aid prognosis, assist disease classification or, in some cases, make a diagnosis which cannot be determined other than by laboratory testing.

Pre examination processes are the path of workflow for clinical laboratory include all activities from the time the laboratory tests are ordered through the time that the specimens are processed and delivered to the laboratory testing location or transported to referral laboratories. Pre examination phase is the most vulnerable part of the total testing process due to their impact on the quality of results of laboratory testing, Pre examination errors have been included within the greatest challenges to the laboratory professionals, during the last 20 years.

Traditionally, laboratories have focused their attention on quality control methods and quality assessment programs dealing with examination aspects. However, a growing body of evidence accumulated in recent decades demonstrates that quality in clinical laboratories cannot be assured by simply focusing on purely analytical aspects. A recent review of errors in laboratory medicine concluded that in the delivery of laboratory testing, mistakes occur more frequently before (pre- examination), and after, the test has been performed.

After a long-standing tradition of analytical quality and examination quality control programs, most medical laboratories that are aware of the need for total quality management, are experiencing new systems designed to assure quality throughout the entire total testing process, from the pre- examination to the post- examination l steps.

Therefore, to achieve appropriate quality improvement and to reduce the burden of preventable errors, standardization of the pre examination procedures including patient preparation and identification, sample collection, transport, handling, storage and preparation for testing should become our major focus. Standardization of several pre examination activities can be indeed achieved by major adherence to available guidelines, implementation of total quality management system that include pre-analytical requirements, as well as continuous education of the health staff with blood sampling responsibilities.

Chapter Purpose:

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

1. The effectiveness of the implementation of MRI.
2. The proper laboratory test ordering.
3. The appropriate   specimen collection.
4. The appropriate   specimens   handling and transportation.
5. The proper specimen   reception and tracking.

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates and annexes)

1. Egyptian Constitution
2. Universal declaration on Human Rights year 1964
3. Cairo declaration on Human Rights in Islam, 1990
4. Egyptian code of medical ethics 238/2003
5. Code of ethics and behavior for civil service staff, 2019
6. Law 10/2018 on the rights of handicapped
7. Law 2/2018 on Universal Health Insurance
8. MOH Ministerial decree 216 / 1982 Healthcare facilities organization National law for laboratories, 367/ 1954
9. Practicing the Human medicine profession law 415/1954
10. Anatomic pathology and Microbiology checklists, CAP accreditation program, 2014
11. WHO List of essential in-vitro diagnostic tests, 2018
12. WHO Lab quality management system, 2011
13. Joint Commission International Accreditation Standards for laboratories, 6th Edition
14. CLSI/ QMS01 | A Quality Management System Model for Laboratory Services, 5th Edition
15. The National Standards for Medical Laboratories and Blood Banks CBAHI FIRST EDITION 2015.
16. CLSI, EP 23-A .Laboratory quality control based on risk management; Approved guideline (2011)
17. CLSI, GP29-A2.Assessment of laboratory tests when proficiency testing is not available; Approved guideline.2nd Edition (2008)
18. BELAC2-106 Rev1-2011. Proficiency testing :guidelines on the level of participation and evaluation of performance in proficiency testing activities in the context of accreditation assessments.
19. College of physicians and surgeons of British Columbia. Guide to fulfillment of laboratory results comparability requirement.November9,2018(version 2.0)
20. ISO-15189 (2012) Medical laboratories – Requirements for quality and competence.

Safe and proper testing process

TPR.01 The Laboratory develops and communicates a service manual that provides all needed information for patients and users.

<div align="right">Effectiveness</div>

Keywords:

Laboratory service manual.

Intent:

Laboratory service manual (LSM) provides an overview for the laboratory service to customers and contains information about laboratory and explains to customers (Service users) all what they need to know regarding the services provided. Laboratory service manual is available to patients and users and shall include:

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) Patient preparation and assessment including special preparation requirements.
f) Proper unique patient 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) Patient information protection policy
n) Complaint procedure.
o) Factors that may affect the performance of the examination or the interpretation of the results
p) Invasive or special procedures need written consent

Survey process guide:

• GAHAR surveyor may review the Laboratory service manual during document review session followed by interviewing staff members to inquire about their awareness of the Laboratory service manual.
• GAHAR surveyor may interview laboratory staff to assess their awareness about Laboratory service manual.

Evidence of compliance:

1. Laboratory Service Manual describes the requirements of elements a) through p) in the intent.
2. Laboratory service manual is distributed to customers (Service users).
3. All customers (Service users) are aware about the contents of the laboratory service manual.
4. Any changes in the LSM are formally communicated to all laboratory staff members and service users.

Related standards:

TPR.02 Test requesting, TPO.04 Turnaround time, TEX.03 Biological reference interval and clinical decision values, PCC.02 Patient and family rights, PCC.03 Patient and family responsibilities, PCC.05 Patient and family education materials, PCC.06 Patient and family feedback, PCC.07 Complaints and suggestions, OGM.12 Safety Culture

Specimens requesting, collection, handling and transportation

TPR.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 patient identification and complete, legible test request information are essential for patient safety and valid laboratory results. The policy defines the process of requesting laboratory test that includes:

a) Use of appropriate request form according to the test ordered.
b) Proper completion of request form (whether electronic or paper) shall include at least the following:
   i) Complete, accurate patient identification process.
   ii) Name of the ordering individual/physician or referring laboratory.
   iii) Tests requested.
   iv) Name and contact of individual/physician to be notified in case of critical or panic results
   v) Date and time of specimen collection.
   vi) Identification of the person who collected the specimen.
   vii) Clinical information (as required)
   viii) Type of specimen (including source in special type of specimens)
   ix) Special marking for urgent tests request.

c) Written consent is required to each special and invasive procedures or any procedure that carries risk to the patient (e.g. histocompatibility for transplantation and bone marrow biopsy).

Survey process guide:
- GAHAR surveyor may review test requesting policy during document review session.
- GAHAR surveyor may interview laboratory staff to check their awareness on completion of request form.
- GAHAR surveyor may check completion of request form, patient identification process, communication with requestors and patients during patient\sample tracing session.
- GAHAR surveyor may check previous patient request form, records of verbal or telephone orders, previous urgent request and actions are taken accordingly to ensure proper implementation.

Evidence of compliance:
1. The laboratory has an approved policy and procedures that clearly describe the process of test ordering including elements a) through c) in the intent.
2. Request form includes all items mentioned in the intent from i) to ix).
3. Test requesting records are available.
4. A written consent is available whenever needed.

Related standard:
TPR.04 Specimen collection, Patient identification, TPR.01 Laboratory service manual

TPR.03 Qualified individual performs patient assessment before sampling

<div align="right">Patient-centeredness</div>

Keywords:
Patient assessment.

Intent:
Assessment is the gathering of information about a patient's physiological and non-physiological status by a qualified individual. Patient preparation is one of important points to be assessed before sampling to identify the patient status and needs. The laboratory is involved in deciding the appropriate laboratory tests based on patient history, diagnosis, clinical data. This require 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 patient outcome at lowest cost following evidence based care guidelines and pathways.

The laboratory shall include the assessments performed for the high risk patients to mitigate and minimize harm of the patient, based on the laboratory risk management plan\program.

The assessment record shall include all relevant data needed according to the laboratory

scope of service. The laboratory shall identify patients' clinical needs by defining the minimum content of these assessments and preparation and check the completeness of patient preparation and assessment records before sampling.

Survey process guide:

- GAHAR surveyor may review patient assessment records during document review session, followed by interviewing staff members to check their awareness of the process.
- GAHAR surveyor may review testing algorithms, evidence based care guidelines and pathways
- GAHAR surveyor may trace the proper implementation.
- GAHAR surveyor may review a patient request form to evaluate compliance with standard requirements.

Evidence of compliance:

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

Related standard:

TPR. 01 Laboratory service manual, PCC.01 Interdisciplinary patient-centeredness.

TPR.04 NSR.01 The laboratory specimen collection process is followed properly

Effectiveness

Keywords:

Specimen collection, Patient identification.

Intent:

Proper specimen collection is a key to patient'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 policy and procedures 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 defines:

a) Proper unique specimen identification.

b) Patient 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 patient and phlebotomy adverse incidents (fear, phobia, hematoma formation, syncope and fainting, excessive bleeding, edema …..etc.).

e) Proper specimen labelling e.g. (Two patient identifiers, Collection date, Collector identification, 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 policy and procedures of specimen collection during document review session.

• GAHAR surveyor may observe specimens' collection of patients and check availability and accessibility of specimen collection procedures.

• GAHAR surveyor may interview responsible laboratory staff to check their awareness on preparation requirements and specimen collection policy and procedures.

Evidence of compliance:

1. The laboratory has an approved policy and procedures, fulfilling at least requirements in the intent from a) through g).

2. The sample collection process is followed and regularly monitored.

3. The responsible laboratory staff is aware and trained about the primary specimen collection process.

Related standard:

TPR.05 Specimen handling and transportation, WFM.06 Continuous Education Program

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

<div align="right">Effectiveness</div>

Keywords:

Specimen handling and transportation.

Intent:

Laboratory testing provides information about a patient's health to assist physicians in diagnostic and therapeutic decisions. Specimen integrity is dependent on many variables in the pre-analytical processes including patient preparation, specimen collection, handling, and transportation. Improper handling or transportation of specimens can give erroneous results and compromise the care of the patient. The laboratory policy and 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 policy and procedures for handling and transportation of specimens during document review session followed by interviewing staff members to inquire about their awareness of laboratory policy.
- GAHAR surveyor may observe handling and transportation procedure of patient specimens, including the special transportation safety requirements, specimens of referring laboratory and irretrievable specimens.

Evidence of compliance:

1. The laboratory has an approved policy and procedures that clearly describe process of specimen handling and transportation, fulfilling at least items from a) to c) in the intent.
2. Competent personnel are responsible for proper specimen handling and transportation according to the approved procedures.
3. The procedure for packing and transportation of specimens to referral laboratories is consistent with the referral laboratory collection and handling requirements.

Related standard:

TPR.04 Specimen collection, Patient identification, WFM.06 Continuous Education Program, SCM.06 Referral laboratory

TPR.06 NSR.03 Specimen reception and tracking process are followed effectively.

<div align="right">Effectiveness</div>

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 significantly 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 patient and staff members is risked. The specimen

reception and tracking policy and 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).

d) Recording of the date and time of specimen's reception/ requesting and the identity of the person receiving the specimen.

e) Process of traceability of all portions of a specimen to the original primary specimen.

f) The process followed when unacceptable specimens are identified (i.e., reporting problems to the client). Records of rejection are maintained   including cause of rejection, time and date, name of rejecting person, and name of notified individual.

g) Indications of acceptance of suboptimal specimens (specimens that do not meet the ideal requirements of collection e.g. a sample with one patient identifier, improperly collected and/or preserved samples (i.e. clotted, hemolyzed, contaminated), volume not sufficient for testing, container contaminated by specimen (leaking specimen), patient not properly prepared for testing …. ect) and measures taken accordingly

h) Process of recording all specimens referred to other laboratories for testing.

Survey process guide:

• GAHAR surveyor may review laboratory policy and procedure during document review session followed by interviewing staff members to inquire about their awareness of laboratory policy.

• GAHAR surveyor may observe how are specimens accessioned once received by the laboratory.

• GAHAR surveyor may check laboratory specimen identification and traceability process, records of received, referred and/or rejected specimen.

Evidence of compliance:

1. The laboratory has an approved policy and procedures that clearly describe process for specimen reception and tracking including items in the intent from a) to h).

2. The specimen reception and tracking records include the date, time and the identity of the person receiving the specimen.

3. All portions of a specimen are traceable to the original primary specimen.

4. Records of suboptimal specimens or specimen rejection are maintained and fulfilling the data in the intent.

5. Responsible staff is aware and trained about the instructions of specimen reception.

6. Records of specimens referred to other laboratories are maintained.

Related standard:

TPR.04 Specimen collection, Patient identification, TPR.07 Pre-examination specimen storage

TPR.07 Specimens are stored in appropriate conditions 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 policy and procedure and ensure providing appropriate facilities for securing patient 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 policy and procedures during document review session.
- GAHAR surveyor may observe the facilities for specimen storage, how are specimens 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 an approved policy and procedures that clearly describe process for proper specimen storage in pre-examination phase.
2. Specimens are stored in appropriate conditions during all pre-examination activities.
3. Conditions of proper specimens' storage are identified and controlled.

Related standard:
TPR.06 specimen reception and tracking, IPC.01 IPC program, risk assessment, guidelines.

Examination

Chapter intent:

Examination procedures cover the activities from the time the specimen reaches the testing area till the time results are reviewed and preliminary interpretations are made.

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. While random errors (those that occur independently of the operator) may be encountered during the examination phase.

Systematic errors that bias the measurement resulting from either instrument malfunctions or human mistakes include:

- Errors in quality control and verification of performance specifications.
- Instrument malfunctions.
- Calibration errors causing a direction of bias in results.
- Manual pipetting errors.
- Reagent errors.
- Test interference caused by unsuspected antibodies.
- Specimen interference i.e. failing to visually see sample was lipemic.
- Math errors.
- Staff errors in testing preparation and processing.
- Inadequate staffing which may precipitate errors caused by fatigue.

Chapter Purpose:

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

1. To develop criteria of selection of examination procedure.
2. To highlight the importance of validation or verification of methods used.
3. To properly implement the examination procedures.
4. To ensure quality of examination results.

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates and annexes)

1. Egyptian Constitution
2. Universal declaration on Human Rights year 1964
3. Cairo declaration on Human Rights in Islam, 1990
4. Egyptian code of medical ethics 238/2003
5. Code of ethics and behavior for civil service staff, 2019
6. Law 10/2018 on the rights of handicapped
7. Law 2/2018 on Universal Health Insurance
8. MOH Ministerial decree 216 / 1982 Healthcare facilities organization National law for laboratories, 367/ 1954
9. Practicing the Human medicine profession law 415/1954
10. Anatomic pathology and Microbiology checklists, CAP accreditation program, 2014
11. WHO List of essential in-vitro diagnostic tests, 2018
12. WHO Lab quality management system, 2011
13. Joint Commission International Accreditation Standards for laboratories, 6th Edition
14. CLSI/ QMS01 | A Quality Management System Model for Laboratory Services, 5th Edition
15. The National Standards for Medical Laboratories and Blood Banks CBAHI FIRST EDITION 2015.
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19. ISO/IEC. General requirements for the competence of testing and calibration laboratories. ISO/IEC 17025. Geneva, Switzerland: International Organization for Standardization; 2005.
20. ISO. Quality management systems—Requirements. ISO 9001. Geneva, Switzerland: International Organization for Standardization; 2008.
21. How to Write a Laboratory Quality Manual, Association of Public Health Laboratories, May 2017
22. CLSI guidelines GP26-A4: Quality Management System: A Model for Laboratory Services
23. CLSI guidelines GP38: Quality Management System: Leadership and Management Roles and Responsibilities
24. CLSI guidelines GP32: Management of Nonconforming Laboratory Events
25. CLSI document QMS25: Handbook for Developing a Laboratory Quality Manual
26. Ontario Laboratory Accreditation Program; Quality Management Program – Laboratory Services (QMP-LS), Version 3, August 2006. Guidance for Laboratory Quality Manuals

27. World Health Organization (WHO)/CLSI; Supplement to the Laboratory Quality Management System Training Toolkit, Quality Manual, Version 2013
28. Basic Quality Management Systems. Essentials for Quality Management in the Medical Laboratory. James O. Westgard, PhD Sten A. Westgard, MS. Westgard QC, Inc. Copyright © 2014
29. Good Laboratory Practice. European Commission. Internal Market, Industry, Entrepreneurship and SMEs. https://ec.europa.eu/growth/sectors/chemicals/good-laboratory-practice_en
30. OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring. https://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm#GLP_consensus_documents
31. Good Laboratory Practice (GLP). OECD, better Quaty for better Lives. https://www.oecd.org/chemicalsafety/testing/good-laboratory-practiceglp.htm
32. UK Standards for Microbiology Investigations
33. Good practice when performing molecular amplification assays. PHE. NHS.Feb2018
34. Good laboratory practice (GLP) facilities: risk-based quality assurance
35. Guidance for GLP facilities on implementing and maintaining a risk-based quality assurance programme. MHRA
36. In vitro diagnostic point-of-care test devices
37. Advice and guidance on the management and use of point-of-care testing (POCT) in vitro diagnostic (IVD) devices. MHRA.

Laboratory test validation and verification

TEX.01 The laboratory selects examination procedures which have been validated for their intended use.

<div align="right">Effectiveness</div>

Keywords:

Validated examination procedure.

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 during the document review session the procedure 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. Reference of selected examination procedures used are available.
3. Authorization list of the personnel performing the examination procedures is available in the laboratory.
4. Responsible laboratory staff is aware about the examination procedures.

Related standards:

TEX.02 Verification / validation, TEX.04 Examination procedure

TEX.02 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 make critical decisions during clinical care, 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. 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. Verification of performance characteristics of the test procedure includes at least the following:

e) Measurement of trueness
f) Measurement of precision
g) Measurement of linearity (detection and quantification limits)

The laboratory validates the examination procedures when:

1) using non-standard method
2) Standard method used outside its intended scope.
3) Modification in a validated method.

The laboratory follows verification/validation methods endorsed by reliable and updated 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, followed by interviewing staff members to inquire about their awareness of laboratory procedure, their competence and knowledge of the introduced or changed tests.
- GAHAR surveyor may review verification / validation and re-verification records for each test method.

Evidence of compliance:
1. The laboratory has an approved policy and procedures that clearly describe the process for verification /validation of examination methods for all laboratory tests.
2. Reliable and updated guidelines are used for verification/validation procedure.

3. Records of verification and /or validation results are fulfilling acceptable criteria based on predetermined guidelines.
4. An authorized staff is aware about the verification/validation process.
5. Records of reverification/revalidation is present whenever indicated.

Related standards:
TEX.01 validated examination procedure.

TEX.03 The biological reference intervals or clinical decision values for the examination methods are defined and verified.

<div align="right">Efficiency</div>

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 should 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 references interval of each test in the laboratory information system LIS or the patient final report, verification records of biological reference intervals and clinical decision values and the guideline used.
- GAHAR surveyor may check that the biological reference intervals and clinical decision values in patients' reports 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.
3. Biological reference intervals and clinical decision values in examination procedures are performed in accordance with that in the patients' reports.
4. Modified biological reference intervals are in accordance with the related examination procedures.

Related standards:
TPO.01 Reporting patient results, TEX.01 validated examination procedure, TEX.02 Verification / validation, IMT.08 Calculated values

TEX.04 Instructions for performing test methods and procedures are documented and effectively followed.

<div align="right">Effectiveness</div>

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 include at least the following:

a) Principle and clinical significance of the test.

b) Requirements for patient preparation and specimen type, collection and storage. Criteria for acceptability and rejection of the sample.

c) Reagents and equipment used.

d) Test procedure including test calculations and interpretation of results.

e) Calibration and control procedures and corrective actions to take when calibration or control results fail to meet the laboratory's criteria for acceptability.

f) Biological reference intervals/clinical decision values.

g) Critical test results.

h) Analytical measurement range and instructions for determining results when it is not within the measurement interval.

i) Limitations in methodologies including interfering substances.

j) References.

Survey process guide:

• GAHAR surveyor may review the documented laboratory technical procedures.

• 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 examination procedure for each analytical test method.

2. The laboratory examination procedures are readily available when needed.

3. Each procedure includes all the required elements from a) to j).

4. The responsible laboratory staff is aware of the laboratory examination procedures.

5. The laboratory examination procedures are regularly reviewed by the authorized personnel.

Related standards:
TEX.01 validated examination procedure, TEX.02 Verification / validation, TEX.03 Biological reference interval and clinical decision values.

TEX.05 Prepared/reconstituted reagents and solutions are properly 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 MSDS 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 labeling 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 must include at least the following:
   a) Content.
   b) Concentration/titre.
   c) Preparation/reconstitution date.
   d) Expiration date.
   e) Storage requirements.
   f) Identity of the personnel preparing/reconstituting the reagents and solutions.
Note: A new expiration date and/or storage conditions for the prepared or reconstituted reagent must be recorded if opening the container changes the expiration date or storage requirements.

Survey process guide:
GAHAR surveyor may check reconstituted reagents for proper labeling and review procedure implementation.

Evidence of compliance:
1. The laboratory has an approved policy and procedures that clearly describe the process for reagents/solutions labeling satisfying all requirements in the intent from a) to f).
2. The reagents/solutions labeling identification process is continuously monitored and tracked.
3. Staff is aware of the reagents/solutions labelling and storage requirements

Related standards:
SCM.03 Inventory management.

Quality Control of Examination Procedures

Chapter intent:

The goal of quality control (QC) is to detect, evaluate, 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 patient 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 semi-quantitative results. These examinations differ in the following ways.

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".

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.

Chapter Purpose:

1. To ensure that the quality control (QC) testing is performed to ensure the proper functioning of materials, equipment, and methods during operations.
2. To verify that the quality control (QC) performance expectations and acceptable ranges should be defined and readily available to staff so that they will recognize unacceptable results and trends in order to response appropriately.
3. To determine the frequency for QC testing as it is determined by the facility in accordance with regulatory requirements, accreditation standards and manufacturer instructions.
4. To evaluate that when unacceptable QC results are present, they must be investigated and corrective action must be taken.
5. To ensure that the quality control data is documented and include follow- up for outliers, or trends.

Laboratory internal quality control system

TEQ.01 An internal quality control plan is developed and implemented for all laboratory tests.

<div align="right">Safety</div>

Keywords:
Internal quality control plan.

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 patient test results have been attained. A quality control material is a stabilized sample with a predetermined range of result values that simulates a patient 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 facility in accordance with guidelines and manufacturer instructions whichever is more stringent

b) Quality control materials to be used are defined, handled and tested in the same manner and by the same laboratory personnel testing patient 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 acceptance/ rejection rules for internal quality control results.

e) The QC results are approved by the authorized personnel prior to specimen testing.

f) The internal QC procedures complies at least with the following items:

   i) Quantitative testing includes quality control at different levels and frequency according to the guidelines.

   ii) Qualitative testing includes positive and negative controls.

   iii) Semi-quantitative testing with graded or tittered results include a control material of graded or tittered reactivity.

Survey process guide:
• GAHAR surveyor may review laboratory policy and procedure of internal QC during document review session to ensure fulfillment of requirement.

• GAHAR surveyor may visit laboratory to check internal quality control procedures and records

• GAHAR surveyor may interview laboratory staff members to check their awareness about quality control performance and west guard rules.

Evidence of compliance:

1. There are policies, procedures and a clearly described process describing the internal QC of all laboratory tests fulfilling items in the intent from a) to f).
2. Internal QC for all laboratory tests includes at least the items in the intent 6 from i) to iii)
3. Responsible authorized laboratory personnel are knowledgeable and competent in the performance of the internal QC.
4. Records for performed quality control are retained for all laboratory tests for at least one year.

Related standards:

APC.01 Sustaining registration requirements, OGM.14 Supply Chain Management, TEQ.02 Quality control data review, QPI.06 Nonconformity management

TEQ.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 patient 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 patient results are released. 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 check records and 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 an approved policy and procedures that clearly describe the process for reviewing the internal quality control data.
2. Review of internal quality control data is done at regular intervals by responsible authorized personnel.
3. Corrective /preventive actions are taken whenever indicated.

Related standards:

TEQ.01 Internal quality control plan, QPI.04 Data management, aggregation and analysis, QPI.06 Nonconformity management.

TEQ.03: Proper corrective actions are taken upon quality control result violation(s).

Safety

<u>Keywords:</u>
Quality control result violation, Corrective action.

<u>Intent:</u>
Quality control (QC) is one of the most important impacts on laboratory testing, it ensures both precision and accuracy of patient sample results. The laboratory should have policies and procedures include instructions to follow when control results are violating acceptable criteria and the backup systems when timely correction cannot be made.

The laboratory's remedial actions shall meet the following criteria:
a) Taken immediately after problem has been identified.
b) Consistent with defined quality control policies.
c) Support timely response to inspections or off-site consultation.
d) It is adequate to correct all the deficiencies implied in the problem (for example, if one patient's results are discovered to be incorrect, other patients' results from the same testing sequence are evaluated to ensure correctness).
e) It 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 competent staff and relevant patient samples are re-examined after the error condition has been corrected and the performance is verified. The laboratory should also evaluate the results from patient specimen that were examined after the last successful quality control event.

<u>Survey process guide:</u>
•   GAHAR surveyor may review internal quality control records to check for appropriate corrective actions taken to deficiencies identified.
•   GAHAR surveyor may interview responsible laboratory staff to assess their awareness of remedial actions for deficiencies identified.
•   GAHAR surveyor may check patient results examined after the last successful quality control event.

<u>Evidence of compliance:</u>
1. The laboratory has an approved policy and procedures that clearly describe the process for taking proper corrective actions to deficiencies identified.
2. The laboratory's remedial actions meet the criteria defined in elements a) through e) in the intent.
3. The laboratory staff is aware of the remedial action for deficiencies identified.
4. Reviewing the quality control data and error/incident logs to identify the corrective actions taken.

Related standards:
QPI.06 Nonconformity management, TEQ.02 Quality control data review

Proficiency testing

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

Safety

Keywords:
External quality program, proficiency testing.

Intent:
External quality assessment program (Proficiency Testing) is a system designed to objectively assess the quality of results obtained by laboratories, by an accredited PT provider. Using proficiency testing (PT) is a formal 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 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 fulfill the following criteria:
a) Accredited according to (ISO/IEC 17043:2010) or CLIA approved Proficiency testing programs.
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 max 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 (e.g., homogeneity; stability; and where appropriate, metrological traceability).
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 policies regarding amending results, late results and failure of PT materials delivery on time).

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 disciplines (e.g., chemistry, hematology, bacteriology, molecular etc.).
ii) These 50% must include both high frequency tests in the laboratory in each discipline (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 4-year accreditation cycle.

iv) If the laboratory has more than one testing site, PT enrollment and participation is required for each testing site for non-waived tests and alternative assessment procedure(s) (AAPs) for waived tests.

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) Remedial 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 patient results and take corrective action to prevent recurrence. The laboratory must provide evidence that an AAP alternate assessment was conducted to ensure accuracy during the time frame when Two consecutive unacceptable results (results greater than ±2.0 SDI) for an analyte in PT programs provide12 samples/year or One unacceptable results 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 actions.

IV) The laboratory should discontinue testing of any analyte when the laboratory has one or more of the following:

V) Has confirmed a clinically significant impact on patient results

VI) Cannot verify the accuracy and reliability of test results

VII) Cannot determine the cause of significant or ongoing PT failure.

VIII) The results are used for education, reeducation, 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 actions taken.

• GAHAR surveyor may interview responsible laboratory staff to assess their awareness about the external quality assessment policy and procedure.

Evidence of compliance:

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

Related standards:

TEQ.05 proficiency testing samples, TEQ.06 Alternative assessment procedure, external quality assessment.

TEQ.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 patients' specimen to represent patients results quality. The policy and procedure of proficiency testing specimen should meet the following requirements:

a) Samples are tested along with the laboratory's regular patient 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 patient samples.
c) Communication between participating laboratories about the results of proficiency testing samples occurs only after the date the laboratory must report results for the testing event 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 print out records of proficiency testing results to ensure that they are tested as same as patient specimen.
- GAHAR surveyor may interview the responsible laboratory staff to assess compliance with external quality assessment policy and procedure.

Evidence of compliance

1. The laboratory has an approved policy and procedures that clearly describe the process addressing proficiency testing requirements, as described in elements a) through e) in the intent.
2. Records of proficiency specimen testing support implementation.
3. Laboratory staff is aware of the proficiency specimen testing requirement.

Related standards:

TEQ.04 External quality program, proficiency testing, TEQ.06 Alternative assessment procedure, external quality assessment.

TEQ.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.

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 plan 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 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), 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, remedial 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 plan that identify the method and the frequency of testing of AAPs.
2. The laboratory develops and documents the alternative assessment procedures including the limits of acceptability for each quantitative assessment.
3. Records of AAPs results and corrective actions are retained for at least 1 year.
4. The laboratory staff is aware of the alternative assessment procedure(s)

Related standards

TEQ.04 External quality program, proficiency testing, TEQ.05 proficiency testing samples.

TEQ.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 prevents 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, the laboratory shall follow the following criteria:
    i) If<20% of workload is done using other test method (considered as backup analyzer), verification and comparability studies are done along with acceptable AAPs at least 4times /year are required for accreditation.
    ii) If >20% of test load are done using the other test method, verification and PT are mandatory. PT reports must be provided to GAHAR for all analyzers.

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 clearly describe the process for comparison of different methods /instruments including items in the 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:

EMS.04 Calibration plan, TEQ.06 Alternative assessment procedure, external quality assessment.

Post examination and Post-post examination

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 patient's best interest. Specialist advice with regard to 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 (post- examination), the test has been performed. In a modern approach to total quality, that is centered on patients' 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 address quality measures for the activities from reporting patient test results to archiving results and specimens including the following:

1. Reviewing, release and retention of the final report.
2. Proper specimen's storage, retention and disposal
3. Ensuring appropriate turnaround time for each laboratory test.
4. Critical results reporting
5. Process of amended report

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates and annexes)

1. Egyptian Constitution
2. Universal declaration on Human Rights year 1964
3. Cairo declaration on Human Rights in Islam, 1990
4. Egyptian code of medical ethics 238/2003
5. Code of ethics and behavior for civil service staff, 2019
6. Law 10/2018 on the rights of handicapped
7. Law 2/2018 on Universal Health Insurance
8. MOH Ministerial decree 216 / 1982 Healthcare facilities organization National law for laboratories, 367/ 1954
9. Practicing the Human medicine profession law 415/1954
10. Anatomic pathology and Microbiology checklists, CAP accreditation program, 2014

11. WHO List of essential in-vitro diagnostic tests, 2018
12. WHO Lab quality management system, 2011
13. Joint Commission International Accreditation Standards for laboratories, 6th Edition
14. CLSI/ QMS01 | A Quality Management System Model for Laboratory Services, 5th Edition
15. The National Standards for Medical Laboratories and Blood Banks CBAHI FIRST EDITION 2015

Safe, accurate patient results reporting

TPO.01: Patient results are reported accurately and effectively.

<div align="right">Safety</div>

Keywords:
Reporting patient results.

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

Laboratory recommendation and advisory comments for further investigations may be added to the final report based on testing algorithms (reflex testing) to help physicians to monitor the care plan and determine the need for patient re-assessment when applicable.

The laboratory should develop policies and procedures for reporting patient results accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures including at least the following:

a) There is a mean of 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) Patient identification by two unique identifiers of the patient and the specimen
    iii) The tests performed.
    iv) Identification of the ordering clinician.
    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) When needed, conditions of specimen that may compromise the adequacy of testing
    ix) Identification of the authorized individual who verify the report results
    x) Interpretation of results, where appropriate
    xi) Advisory, explanatory comment or limitation of the method when needed.
    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) The above elements are also included in reports from referral laboratory.

d) Reports from referral laboratory are not modified in any way that would change their meaning.

<u>**Survey process guide:**</u>
- GAHAR surveyor may review laboratory policy and procedures for reporting patient results during document review session.
- GAHAR surveyor may check sample of paper or electronic laboratory reports and their content.
- GAHAR surveyor may review laboratory result report of referral laboratory and ensures that its content is not modified.
- GAHAR surveyor may interview staff members to inquire about their awareness of laboratory policy.

<u>**Evidence of compliance**</u>
1. The laboratory has an approved policy and procedures that clearly describe the process of reporting of test results fulfilling items from a) to d).
2. There is a mean of identifying the individual(s)who performed a particular test.
3. The patients' reports reviewed including those from referral or contract laboratories include all the requirements as specified in the intent from i) through xiii).

<u>**Related standard:**</u>
IMT.03 LIS management, IMT.05 LIS validation, IMT.10 Auto verification, TPR.03 Specimen collection, Patient identification, TPO.02 Reviewing, release and retention of the reported result.

TPO.02: Effective process for reviewing, release and retention of patient results is developed.

<div align="right">Effectiveness</div>

<u>**Keywords:**</u>
Reviewing, release and retention of the reported result.

<u>**Intent:**</u>
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   policy and procedure to ensure that patient data are only accessible to those individuals who are authorized to review and release test results.

The policy address 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 patient 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) Duration for reported results retention as defined by organizational needs or accreditation requirements.

Survey process guide:

- GAHAR surveyor may review laboratory policy and procedure for reviewing, release and retention of the reported result during document review session followed by interviewing staff members to inquire about their awareness of laboratory policy.
- GAHAR surveyor may assess authorization of reviewing and release of laboratory results.
- GAHAR surveyor may check the archived test results to ensures 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 an approved policy and procedures that clearly describe the process of reviewing, release and retention of the reported results including items in the intent from a) to f).
2. Patients' reports are reviewed, interpreted and released by defined authorized qualified personnel.
3. Retention process of laboratory final report is identified by organizational needs or accreditation requirements with easy retrieval.
4. Release of test result is done to the authorized recipient.

Related standard:

TPO.01 Reporting patient results, IMT.11 Data storage and retrieval, IMT.05 LIS validation

Post-examination specimens handling and storage

TPO.03 Post-examination specimens are stored, retained and disposed safely.

<div align="right">Safety</div>

<u>Keywords:</u>
Storage, Retention and Disposal of specimen.

<u>Intent:</u>
Additional testing on retained specimens is often necessary and is beneficial to both the patient and the clinician since it results in a reduction of turnaround times and patient inconveniences involved with recollection.

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

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

The policy 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 duration of retention as defined by regulatory or accreditation requirements, and organizational needs.
d) The safe disposal of clinical specimens.
e) Tracking process for all specimens received   is clearly defined for easily retrieval of required specimens.
f) Time limits for requesting additional examinations or further examinations on the same primary specimen.

<u>Survey process guide:</u>
• GAHAR surveyor may review laboratory policy and   procedure of storage, retention and disposal of specimen during document review session followed by interviewing staff members to inquire about their awareness of laboratory policy.
• GAHAR surveyor may review the storage conditions of the specimen and its fulfilment to standard requirement.
• GAHAR surveyor may observe laboratory specimen disposal.

<u>Evidence of compliance:</u>
1. The laboratory has an approved policy and procedures that clearly describe the process for proper specimen storage and retention including items from a) to f).
2. The procedure of specimen storage, retention and disposal is defined and followed.
3. Staff is aware of specimens' storage and retention

Related standard:
TPR.03 Specimen collection, Patient identification, TPR.06 Pre-examination specimen storage.

TPO.04 Laboratory results are reported within the acceptable turnaround time for each laboratory test.

<div style="text-align: right; color: #1ba0c4;">Effectiveness</div>

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 policy and/or 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 has an implemented process for notifying the requester when test reporting will be delayed.

Survey process guide:
- GAHAR surveyor may review laboratory policy and procedure of turnaround time during document review session followed by interviewing staff members to inquire about their awareness of laboratory policy.
- GAHAR surveyor may trace a patient receiving a laboratory service and review service request, sample time, test time and reporting time.
- GAHAR surveyor may interview laboratory staff to inquire about their experience regarding laboratory service reporting time.
- GAHAR surveyor may check the process and records of notification of delays in turnaround time.

Evidence of compliance:
1. The laboratory has an approved policy and procedures that clearly describe the process that defines the total acceptable turnaround time for all laboratory tests and how they are measured.
2. Periodic monitoring and review of turn-around-times for all laboratory tests.
3. Cases of unacceptable TAT are investigated and proper actions are taken accordingly.
4. There is a defined process for notification of delays in turnaround time.

Related standard:
TPO.05 Critical test result, TPO.06 STAT results, QPI.03 Performance measures

Accurate identification of critical test results

TPO.05 NSR.02 Critical test results are identified and notified accurately and timely.

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 patient.

The laboratory defines the critical values for specific tests.

The process includes instructions for immediate notification of the authorized individual responsible for the patient with results that exceed the critical intervals.

The laboratory documents the notification with inclusion of:

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 policy and procedure of critical test results during document review session followed by interviewing staff members to inquire about their awareness of laboratory policy.

• GAHAR surveyor may trace a critical test result and observe sample time, test time and notification process and documentation

• GAHAR surveyor may review previous critical patient results and assess laboratory result 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 a policy and procedures of the critical test results reporting that describing the process of "write down "and «read-back» by the recipient.

2. A list of critical values is available.

3. Critical test results records include items in the intent from a) to h).

4. Staff is ware of the critical test result process

Related standard:

TPO.01 Reporting patient results

TPO.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 patient and any delay can be life threatening.

The laboratory develops processes to meet the needs of its customers 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 address 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 policy and procedure of STAT test results during document review session followed by interviewing staff members to inquire about their awareness of laboratory policy.
- GAHAR surveyor may trace an urgent request and observe sample time, test time and reporting time to ensure complying with the policy.
- GAHAR surveyor may check previous urgent patient'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.

Evidence of compliance:

1. The laboratory has a documented policy and procedure describing STAT testing process.
2. The laboratory has a list of STAT tests defines its acceptable reporting time
3. The laboratory periodically monitors and review STAT reporting time for laboratory tests.
4. Cases of unacceptable STAT reporting time are investigated and proper actions are taken accordingly.

Related standard:

TPO.04 Turnaround time, TPO.01 Reporting patient results.

TPO.07 Amended laboratory results are clearly identified and maintained.

Effectiveness

Keywords:

Amended laboratory results.

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 patient care errors because clinicians are not anticipating a change in information and may have already acted on erroneous information.

In case of incorrect 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 patient.

Amended report contains changes to patient results, accompanying reference intervals and /or interpretations, as well as the date and time of the modification, and the name of the individual authorized for the change. Amended report should be clearly identified as a revision.

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

Survey process guide:

- GAHAR surveyor may visit laboratory area to assess authorization of reviewing, correcting and release of amended laboratory results
- GAHAR surveyor may check the archived amended 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 results.

Evidence of compliance:

1. The laboratory has an approved process for amending reports.
2. Records of amended results ensure that they are modified by authorized personnel.
3. Laboratory staff is aware and trained about process of amending reports.

Related standard:

TPO.01 Reporting patient results, IMT.11 Data storage and retrieval

Information Management and Technology

Chapter Intent:

Documentation provides a framework for understanding and communication throughout the organization. Documents describe how processes are intended to work, how they interact, where they must be controlled, what their requirements are, and how to implement them.

Records contain information from a particular point in time, stating results achieved or providing evidence of activities performed. When forms are used for capturing or recording data, steps, or test results, the forms become records. Data is recorded in a format that is clear and consistent. Records provide evidence that critical steps in a procedure have been performed appropriately and that products and services conform to specified requirements.

Multiple solutions for laboratory information systems (LIS) exist. Traditional systems have a local "host" database (i.e., the computer hardware and software) serving the information needs of the laboratory; the laboratory is the only "user." In the current environment, the host is often physically remote from the laboratory and in fact the host may have multiple user laboratories.

Many of the Computer Services requirements may apply to host, user, or both, depending on how information services are organized in the laboratory.

The laboratory is responsible for ensuring that the provider of host functions meets GAHAR requirements.

The requirements in this section do NOT apply to the following:

1. Desktop calculators.
2. Small programmable technical computers.
3. Purchased services such as the Quality Assurance Service.
4. Micro computers used solely for word processing, spreadsheets, or similar single user functions.
5. Dedicated microprocessors or workstations that are an integral part of an analytic instrument.

Chapter purpose:

This chapter addresses the main concepts of information management in the organization, including the following:

1. Effective Information Management Processes
2. Maintaining Information Confidentiality and Security
3. Availability of patient's data and results
4. Effective information Technology in laboratory.
5. Authority of employees to access the patient data

Standards included in this chapter shall apply on paper and electronic data and information.

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates and annexes).

1. Egyptian code of medical ethics 238/2003
2. MOH - General Directorate of Technical Inspection. The administrative tool
3. Ministry of finance decree 270/2009: Governmental Archives list
4. Ministry of finance decree 18/2019: Non-Monetary Payment
5. Ministry of communication and information technology decree 109/2005: Electronic signature.
6. Law 35/1960 National census and statistics
7. Law 2915/1964 Establishment of CAPMAS
8. Jeddah Declaration on Patient Safety 2019
9. HIPAA— Health Insurance Portability and Accountability Act Regulations1996.
10. Egyptian consent laws
11. MOH Quality and Safety Guide, 2019

Document and Record Management

IMT.01 Documentation management system is developed for all laboratory documents

<div align="right">*Effectiveness*</div>

<u>Keywords:</u>

Documentation management system.

<u>Intent:</u>

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 used for implementation of Quality management system , including those maintained in a computerized system.These documents include policy statements, instructions for use, flow charts, procedures, specifications, forms, calibration tables, biological reference intervals and their origins, posters, notices, software documentation, drawings, plans, agreements, and documents of external origin such as regulations, standards and text books from which examination procedures are taken.

Uncontrolled documents contain wrong information which can affect the patient results. Unified documents formatting will allow easier tracking and searching for any information. Periodic review of the whole documents ensures that obsolete document is not used.

The laboratory has a documented procedure to create, format and review it, 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 policies are available and disseminated to relevant staff

f) Staff understand how to access those policies relevant to their responsibilities.

g) Retirement of documents

h) Policies revisions

<u>Survey process guide:</u>

• GAHAR surveyor may review laboratory policies and 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 staff awareness about the process of developing, approving, tracking, and revising of policies

- GAHAR surveyor may check staff awareness about access to relevant policies, tracking changes in the policies and process for management of retirement of documents.

Evidence of compliance:
1. The laboratory has an approved policy and procedures that clearly describe the process for creating, formatting and reviewing of documents including elements in the intent from a) to h).
2. Reviewing of selected documents that comply with the mentioned procedure.
3. List of updated authorized versions of all documents.
4. Proper distribution for all documents following the distribution matrix.
5. Staff is aware and trained for the documentation management system.

Related standard
APC.03 Accurate and complete information, IMT.02 Record management system, IMT.04 LIS security, Unauthorized modifications, IMT.11 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

<div align="right">Effectiveness</div>

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 patient results.

The process for managing records shall ensure full compliance with laws and regulations and 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 following table:

Type of Record	Retention Period
Specimen requisitions (including the patient chart or medical record if used as the requisition)	According to the facility policy
Temperature charts	According to the facility policy
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 semiannual or annual calibration checks and preventive maintenance are retained for the life of an instrument.	As long as the equipment is working
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
Patient test results and reports, including original and corrected reports, and referral laboratory reports.	1 year
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 process guide:
- GAHAR surveyor may review the policy, followed by checking the implementation through reviewing of related records.
- GAHAR surveyor may interview staff asking to demonstrate 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 clearly describe the process of creation, control, change and retention of records including items in the intent from a) to h).
2. There is a list of retention time for different types of records.
3. There is a record/logbook of documents destruction and/or removal.
4. Staff is aware of the record management system.

Related standard
IMT.01 Documentation management system, IMT.03 LIS management, IMT.06 Maintenance program, Contingency plan, IMT.11 Data storage and retrieval

Effective Laboratory Information management system

IMT.03 laboratory information management system is planned and implemented for effective management of data.

<div align="right">Effectiveness</div>

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 patients 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 patient 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 check records for implementation of the information management system procedure and check the traceability and the integrity of patient data.

• GAHAR surveyor may interview staff to assess their awareness about information management system.

Evidence of compliance:

1. The laboratory has an approved policy and procedures that clearly describe the process for information management system including items in the intent from a) to h).
2. Laboratory records (either manually or electronically) are traceable and easily retrieved.
3. Amended data is traceable by date and time and performed by authorized individual(s).
4. laboratory staff is aware and trained on the information management system.

Related standard

IMT.01 Documentation management system, IMT.02 Record management system, IMT.06 Maintenance program, Contingency plan, IMT.11 Data storage and retrieval.

Effective security system

IMT.04 Information management security is defined, tested periodically and data are protected from unauthorized modification and update.

<div align="right">Effectiveness</div>

Keywords:
LIS security, unauthorized modifications.

Intent:
Security of the data whether manual, paper-based system, or an electronic system is important to prevent the data from being tampered with, destroyed or disclosed to others The integrity and privacy of the data are at risk from unauthorized users. Modifications or update of information must be done through authorized personnel to avoid function changing that could affect patient data.

The laboratory develops and implements policy and procedures for the information management modification and update.

The implemented process shall ensure at least the following:
  a) Security and timely installation of system updates.
  b) Documentation of changes approval.
  c) Identification of personnel who have changed or modified data.
  d) Validation of affected functions after update/modification.
  e) Verification of the integrity and accuracy of the data.

If the laboratory uses computer based information management system (LIS) The following should be fulfilled:
  i) The laboratory establishes security (user) codes to permit only authorized individuals to access patient data change results, alter computer tables or programs.
  ii) Patient 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 physical 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 policy and procedure of information management security, modification, update and privilege plan during document review session.
•   GAHAR surveyor may interview staff to check their awareness on information management security manual, paper-based system, or an electronic system.
•   GAHAR surveyor may check the authorization access to ensure security of data

Evidence of compliance:

1. The laboratory has an approved policy and procedures that clearly describe the process for information management security including accessibility, modification and updates to patient data fulfilling items in intent from a) to e) and from i) to iii) when using LIS.
2. Privilege plan or delegation letter is present for staff based on their responsibilities.
3. Laboratory staff is aware and trained about information management security.

Related standard:

PCC.02 Patient and family rights, IMT.01 Documentation management system, IMT.06 Maintenance program, Contingency plan, IMT.11 Data storage and retrieval

Laboratory Information System (LIS)

IMT.05 Laboratory information system (LIS) is validated by the provider and tested prior to introduction in to the service.

<div align="right">Safety</div>

Keywords:

LIS validation.

Intent:

Validation of LIS means that it meets predefined acceptance criteria 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 patient results may occur and affect patient safety and satisfaction. The laboratory develops and implements policy, processes, and procedures for Laboratory Information System (LIS) validation. 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 check LIS validation records.
- GAHAR surveyor may check selected LIS functions to ensure validation.

Evidence of compliance:

1. The laboratory has policy, procedures that clearly described process for LIS validation.
2. The LIS functionality are regularly evaluated and validated.
3. LIS validation record are maintained.
4. All staff who are using LIS are aware of the policy requirements

Related standard:

IMT.01 Documentation management system, QPI.04 Data management, aggregation and analysis

IMT.06 Maintenance program and Contingency plan are designed to ensure uninterrupted service.

<div align="right">Effectiveness</div>

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 patient 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 patient 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 patient 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 the policy and procedure 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 patient results during planned and unplanned downtime.

Evidence of compliance:

1. The laboratory has a maintenance program for the LIS that covers the items in the 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 clearly describe the process for operation during LIS downtime including items in the intent from i) to v).
4. Downtime records are regularly reviewed and maintained.

Related standard:
IMT.01 Documentation management system, IMT.09 Interface

IMT.07 LIS user manual is developed and accessible to all system users.

<div align="right">Effectiveness</div>

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. 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.
- GAHAR surveyor may interview staff to ensure their awareness and ensure the accessibility of LIS user manual.

Evidence of compliance:

1. The laboratory has a comprehensive and accessible LIS user manual.
2. Laboratory staff is aware of the LIS user manual and its proper use.
3. The LIS user manual is reviewed, updated on regular basis and when indicated.

Related standard:

WFM.05 Orientation Program, WFM.06 Continuous Education Program, IMT.01 Documentation management system

Patient data

IMT.08 Laboratory test calculated values are validated and periodically reviewed

<div align="right">Effectiveness</div>

Keywords:

Calculated values.

Intent:

Calculated values are the values that are deduced from certain equations following reference guidelines, such values can affect patient results and in turn the treatment plan. Errors can be inadvertently introduced into established computer programs.

Calculations involving reportable patient results must be rechecked to ensure accuracy and records should be retained. To avoid such calculated result errors which can be applied to LIS, middleware, and analyzers, more frequent checks may be required for certain specific calculations. (e.g., INR).

The laboratory develops and implements policy and procedures for periodic validation and review of calculated results.

Survey process guide:

- GAHAR surveyor may review policy, procedures and guidelines of calculated value validation and observe selected calculated results to ensure implementation.
- Surveyors may interview with selected staff to ensure implementation.

Evidence of compliance:

1. The laboratory has an approved policy and procedures that clearly describe the process for validation and review of calculated results.
2. Validation and reviewing of calculated test results by authorized competent staff are implemented
3. Laboratory test calculated values are validated and reviewed according to evidence based guidelines.

Related standard:

IMT.01 Documentation management system, IMT.05 LIS validation

Data transfer and interfaces

IMT.09 Data transfer from equipment to the LIS is performed effectively

<div style="text-align:right">Effectiveness</div>

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 develops 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 patient result and should be attached to that result such that it will be displayed along with the patient result.

Survey process guide:
- GAHAR surveyor may review the policy and procedure of LIS interface.
- GAHAR surveyor may review selected results to ensure right transfer.
- GAHAR surveyor   may interview with selected staff to ensure implementation.

Evidence of compliance:
1. The laboratory has an approved policy and procedures that clearly describe the process for data transfer verification and control.
2. Data transferred from the equipment to the LIS is effectively monitored and tracked for any changes that might occur during transfer.
3. Laboratory staff is aware of right data transfer process.

Related standard:
IMT.01 Documentation management system, IMT.03 LIS management

Auto- verification

IMT.10 Auto verification process is validated prior to implementation, periodically tested and easily suspended when needed.

<div align="right">Effectiveness</div>

<u>Keywords:</u>

Auto verification.

<u>Intent:</u>

Auto verification is an alternative to manual review of laboratory test result and is an improvement tool that fasten the release of patient 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 patient tests subject to auto verification.

Results that fall within these defined parameters are automatically released to patient 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.

<u>Survey process guide:</u>

• GAHAR surveyor may review the policy and procedure of LIS auto verification.
• GAHAR surveyor may review selected results to ensure implementation.
• GAHAR surveyor may interview with selected staff to ensure knowledge of LIS auto verification and auto verification suspension process.

<u>Evidence of compliance:</u>

1. The laboratory has an approved policy and procedures that clearly describe the process for auto verification including rapid suspension when needed.
2. Auto verification/ validation and periodic reviewing records are available.
3. Resealed auto verified patient results comply with the predetermined criteria.
4. Record for the suspension of auto verification describing the reason of suspension and the date of suspension are available.
5. Staff is ware of auto verification policy

Related standard:
IMT.03 LIS management.

Data retrival and preservation
IMT.11 LIS data is stored properly for easy retrieval when needed.

<div align="right">Efficiency</div>

Keywords:
Data storage and retrieval.

Intent:
Stored patient results and archival information must be retrievable to enable laboratory staff to recheck any data needed at any time.

Easy retrieval of patient data and results enable the patient 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 patient result data and archival information must be easily and readily retrievable within a time frame consistent with patient care needs.

Laboratories may implement a backup solution to keep the data preserved for longer periods, these backup solutions could be servers or hardware to keep all data preserved for much more time.

Laboratories shall retrieve the patient data as long as the LIS is working and then the data can be retrieved on other solutions as removable desk or on cloud when the LIS was stop working.

Survey process guide:
- GAHAR surveyor may review policy and procedures, ask stakeholders about data storage and retrieval, and shall check implementation of data backup process.
- GAHAR surveyor may interview staff to assess their knowledge about storage and retrieval policy

Evidence of compliance:
1. The laboratory has an approved policy and procedures for data storage and retrieval.
2. Stored patient result data and archival information are easily and readily retrievable within a time frame consistent with patient care needs.
3. Laboratory staff is trained about data retrieval policy and how to recall old patient results when needed.

Related standard:
IMT.01 Documentation management system, IMT.03 LIS management

Survey Activities and Readiness

Introduction:

- GAHAR survey process involves performing building tours, observations of patient's medical records, staff member files, credential files, and interviews with staff and patients.
- 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
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

<u>Why will it happen?</u>

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

<u>What will happen?</u>

GAHAR surveyors shall arrive to the laboratory and present themselves to the Laboratory staff, survey coordinator shall be available to welcome GAHAR surveyors

<u>How to prepare?</u>

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

<u>Who should collaborate?</u>

Suggested participants include laboratory staff and leaders

Opening conference

<u>Why will it happen?</u>

This is an opportunity to share uniform understanding of the survey structure, answer questions about survey activities and create common expectations

<u>What will happen?</u>

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.

<u>How to prepare?</u>

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 patients\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
5. Infection Control surveillance data from the past 12 months

Who should collaborate?

Survey coordinator and policy stakeholders.

Patient\sample tracer

Why will it happen?

Patient\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 (Greenfield et al., 2012a: 495).

GAHAR surveyors shall follow course of care and services provided to the patient 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 patients, combined with review of patient's medical records and the observations of surveyors.
- This shall help guide surveyors as they trace a patient's provided care or services.
- The individual tracer begins in the location where the patient is registered for service. The surveyor starts the tracer by reviewing a file of care with the staff person responsible for the individual's care or services. The surveyor then begins the tracer by following the course of care, or services provided to the patient from registration through post discharge, assessing the interrelationships between disciplines, departments, programs, services (where applicable), and the important functions in the care or services provided which may lead to identifying issues related to care processes.
- Most of GAHAR standards can be triggered during a patient\sample tracer activity which may also include interviewing staff, patients or family members.

How to prepare?

- Assure confidentiality and privacy of patients 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
- The minimum number of case file records required to be selected by the surveyor for review is no more than 5 (five) records total.
- 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
- The total number of records within the six-month case period Should be recorded on the review form.
- 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

<u>Why will it happen?</u>

The surveyor will learn about laboratory governance and management structure.

<u>What will happen?</u>

- 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

<u>How to prepare?</u>

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
- Patient centeredness initiatives

<u>Who should collaborate?</u>

Required participants include at least the following: laboratory director, governing body representative, laboratory leaders, quality coordinator\director.

Patient centered care activities review

<u>Why will it happen?</u>

The surveyor will assess patient centeredness initiatives and related activities.

<u>What will happen?</u>

GAHAR surveyor addresses the following issues:

- The GAHAR surveyor may receive information about the patient-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 patient-centered practices.GAHAR surveyor may interview staff to check their awareness about patient-centered initiatives.
- GAHAR surveyor may review patient assessment records and samples from the patient request form.

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:

- Patient family rights and responsibilities policy
- Patient family rights and responsibilities posters, brochures, flyers.
- Patient and family educational materials.
- Patient preparation and assessment records.
- Samples and patients' identification process.
- Patients suggestions and complaints.
- Patient 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, Current and past surveillance activity
- 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 and Actions taken as a result of surveillance and outcomes of those actions.

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

Assay: A quantitative determination or measurement of the amount, activity, or potency of a constituent or characteristic (CLSI).

Assay range: The upper and lower limits of the amount, activity, or potency of a specific analytic between which measurement is possible (ISO 3534-1-2.30).

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 patient population served by the laboratory, or participation is not required by the accrediting organization (CLSI).

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 (CLSI).

Bias: The difference between the expectation of a test result or measurement result and a true value (ISO 5725-1).

Biological reference interval: Specified interval of the distribution of values taken from a biological reference population (ISO 15189, ISO 18113-1).

Biological variation: Consists of within subject (CVI, intra-individual) and between-subject (CVG, inter-individual, group) variation (CLSI).

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 (CLSI).

Calibrator: Reference material whose value is used for the independent variable in a calibration function (ISO 17511).

Control material: A device, solution, lyophilized preparation, or cellular element intended for use in the quality control process (CLSI).

Critical interval: Interval of examination results for an alert (critical) test that indicates an immediate risk to the patient of injury or death iso15198

Examination process: (analytic) processes that include all activities for performing the examinations, verifying the reliability of the results, and interpreting the findings (ISO 15189).

Examination procedure: Set of operations, described specifically, used in the performance of

examinations according to a given method (CLSI).

External quality assessment: External quality control and assurance or proficiency testing is the evaluation of analytical performance that includes a sample for which the analyst does not know the expected measurement result (CLSI).

Guidelines: are a series of suggestions, issued by official bodies, or by independent experts, for the conduct of medical practice.

Internal quality control plan: is a 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.

Laboratory director: Person(s) with responsibility for, and authority over, a laboratory (ISO 15189).

Proficiency testing: A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification, in which each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratory and other(ISO15198).

Point of care testing: Testing performed near or at the site of a patient, with the result leading to possible change in the care of the patient (ISO22870:2006).

Precision: (of measurement) closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions (JCGM 200:2012).

Pre-examination processes: Processes starting, in chronological order, from the request for examination and including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to or within the laboratory, and ending when the analytical examination procedure begins (modified from (ISO 15189).

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 (ISO 15189).

Quality control data: Daily recorded internal quality control results and related registers such as quality control failure analysis.

Referral laboratory: External laboratory to which a sample is submitted for an examination procedure (CLSI).

Refrence laboratory: A large laboratory that performs miscellaneous testing not routinely performed such as tests that require specialized equipment.

Referring laboratory: Referring laboratory" is defined as the laboratory that refers a specimen to another laboratory for testing. "Reference laboratory" is defined as the laboratory that receives a specimen from another laboratory and that performs one or more tests on such specimen.

Sensitivity: The ability of an analytical method to detect small quantities of the component (IFCC-1978-QC Terminology).

Specificity: The ability of a test to detect only the disease or condition it is intended to find (CLSI).

Suboptimum specimen: specimens that do not meet the ideal requirements of collection-Irretrievable Specimen – specimens that are not reproducible due to clinical state and are critical to the diagnosis or treatment of the patient or specimens that are difficult or traumatic to obtain. These specimens are the only exceptions to this policy.

Traceability: (metrological) property of a measurement result whereby the result can be related to a reference through a documented.

Turnaround time: Elapsed time between two specified points through pre-examination, examination and post-examination processes (ISO 15198).

Utilization management: Effective medical lab/physician collaborations to improve how lab tests are ordered and used can deliver big improvements in patient outcomes while reducing healthcare costs.

Verification: Those activities performed before a testing system is put into use to ensure that the testing system gives the correct results (CLSI).

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