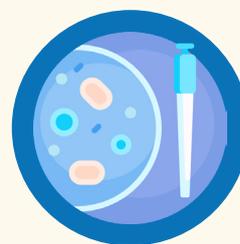
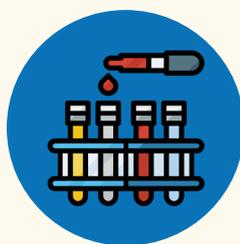
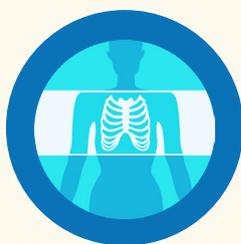




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MINISTRY OF HEALTH-ETHIOPIA

# DIAGNOSTICS QUALITY MANAGEMENT SYSTEM TRAINING

## Facilitator Guide

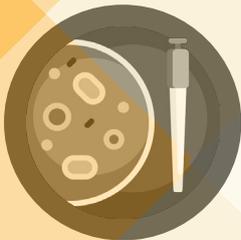


Medical Service Lead Executive Office

2024 Addis Ababa, Ethiopia



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MINISTRY OF HEALTH-ETHIOPIA



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## Facilitator Guide

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## Foreword



As a Ministry of Health, it is my privilege to introduce this Training Manual for Diagnostics Service: Enhancing Affordability, Equity, Availability, and Quality. In our commitment to ensuring accessible and high-quality healthcare for all citizens, diagnostics services play a pivotal role. This manual represents a significant step forward in our ongoing efforts to improve diagnostics services across laboratory, pathology, and radiology departments nationwide.

The provision of timely and accurate diagnoses is essential for effective patient care and treatment planning. However, we recognize that disparities in access to diagnostics services persist, particularly among underserved populations. Addressing these disparities requires a concerted effort to enhance the skills and capabilities of our healthcare workforce, strengthen infrastructure, and promote innovation and collaboration within the diagnostics ecosystem.

This manual has been meticulously crafted in alignment with the National Diagnostics Strategy, reflecting a comprehensive approach to addressing the healthcare needs of our nation. Drawing inspiration and guidance from this strategic framework, we have endeavored to create a resource that not only complements but also advances the objectives outlined within it. By synthesizing key principles, priorities, and goals outlined in the strategy, this manual serves as a practical tool for implementing and operationalizing its vision across laboratory, pathology, and radiology services.

I commend the authors and contributors of this manual for their dedication and expertise in developing a comprehensive resource that addresses the multifaceted challenges facing diagnostics services today. I urge all healthcare professionals to make full use of this manual and to continue their commitment to excellence in diagnostics care.

Together, let us strive to build a healthcare system that is accessible, affordable, and equitable for all citizens.

A handwritten signature in black ink, consisting of stylized initials and a surname.

**Dr. Elubabor Buno**

Medical Service Lead Executive Office Director  
Ministry of Health - Ethiopia

## Approval Statement of the Ministry

The Federal Ministry of health of Ethiopia has been working towards standardization and institutionalization of In-Service Trainings (IST) at a national level. As part of this initiative, the ministry developed a national in-service training directive and implementation guide for the health sector. The directive requires all in-service training materials fulfill the standards set in the implementation guide to ensure the quality of in-service training materials. Accordingly, the ministry reviews and approves existing training materials based on the IST standardization checklist annexed on the IST implementation guide.

As part of the national IST quality control process, this national training on diagnostic quality management system training manual training package has been reviewed and revised based on the standardization checklist and approved by the ministry in November,2024.



**Assegid Samuel Cheru**

Human Resource Development and Improvement  
Lead executive officer  
Ministry of Health- Ethiopia

## Acknowledgement

The Ministry of Health-Ethiopia acknowledges the dedication and technical expertise of the National Diagnostics Service Technical Working Group (TWG) members and key contributors, as well as their affiliated organizations, whose unwavering support has been essential in the development of this training manual. Special gratitude is extended to the Clinton Health Access Initiative (CHAI), UNICEF, and the Ministry of Health (MOH) for their invaluable technical and financial assistance in bringing this manual to fruition. The MOH also expresses appreciation to the individuals and organizations comprising the National Diagnostics Service TWG for their invaluable contributions to the content and structure of this training material. Their collective efforts have played a significant role in ensuring the quality and effectiveness of this manual in advancing diagnostics services in Ethiopia.

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## Acronyms

<b>MOH</b>	Ministry Of Health
<b>HDD</b>	Hospital and Diagnostics Desk
<b>DIMS</b>	Diagnostics Information Managements System
<b>MEMIS</b>	Medical Equipment's Managements Information System
<b>AP</b>	Anatomical Pathology
<b>ESP</b>	Ethiopian Society of Pathology
<b>QMS</b>	Quality Management System

## Symbols/icons

Symbol/Icon	What it Refers to	Description
	Individual Reflection	Individual Reflection: is a systematic reviewing process for all trainers which allow you to make links from one experience to the next.
	Think Pair share	Think Pair share: Think-pair-share (TPS) is a collaborative learning strategy where students work together to solve a problem or answer a question about an assigned reading.
	Small Group Discussion	Small group discussion: In this method of training two or more participants to converse or engage in meaningful deliberations about a particular topic that is facilitated by a trainer/discussion leader.
	Case Scenario	Case Scenario: is a method that provides descriptive situations which stimulate trainees to make decisions
	Case study	Case study provides a concrete example of the real-life impact of diagnostic services on patient outcomes, illustrating the critical need for accessible, affordable, and high-quality diagnostics in healthcare
	Keynote	Main point in the chapter

# Introduction to the the manual

## Background

In today's healthcare landscape, diagnostic services form the backbone of effective treatment and patient care. The accuracy and timeliness of diagnoses are critical for developing effective treatment plans, improving patient outcomes, and ensuring efficient healthcare delivery. As technological advances continue to reshape the healthcare field, the demand for reliable, accessible, and high-quality diagnostics has never been more essential.

This facilitator guide is crafted to support healthcare professionals across laboratory, pathology, and radiology departments in delivering diagnostic services that are not only available but also affordable, equitable, and of high quality. Designed to equip facilitators with the necessary resources and strategies, this guide aims to enhance the capacity of professionals to address patient needs comprehensively. By doing so, it ensures that diagnostic services align with the overarching goals of improved healthcare accessibility, quality, and efficiency.

## Rationale for the Facilitator Guide

Diagnostics services are integral to detecting, diagnosing, and managing health conditions, yet disparities in access to these services can lead to delayed diagnoses, ineffective treatments, and higher healthcare costs. Geographic, economic, and systemic barriers often restrict equitable access, particularly in underserved areas. This guide seeks to address these gaps by enhancing the quality, affordability, and availability of diagnostic services, thus promoting healthcare equity and improving patient outcomes.

The rationale behind this facilitator guide focuses on four core objectives:

1. **Enhancing Accessibility and Equity in Diagnostics:** By bridging geographic and socioeconomic disparities, the guide aims to make diagnostics accessible to all patients, ensuring timely and accurate care irrespective of a patient's location or financial situation.
2. **Promoting Affordability:** With diagnostic services often being cost-prohibitive, this guide provides insights into resource optimization and workflow improvement, making diagnostics more affordable and sustainable for healthcare facilities and patients alike.
3. **Upholding High-Quality Standards:** Quality diagnostics are essential for effective patient care. This guide emphasizes best practices, quality assurance, and standardized protocols to help professionals provide accurate and reliable diagnostic services across departments.
4. **Empowering Professionals through Knowledge and Skills Development:** This guide equips healthcare providers with updated knowledge and practical skills for laboratory analysis, pathology assessment, and radiological imaging, enabling them to deliver excellent diagnostic care and enhance the overall patient experience.

Ultimately, this facilitator guide is intended to drive impactful change in diagnostics, supporting professionals in delivering services that are consistent, equitable, and patient-centered. By fostering these improvements, the guide contributes to reducing healthcare disparities, improving patient outcomes, and strengthening the healthcare system's capacity to serve diverse patient populations effectively.

### Core competency

1. Execute principles of quality assurance and quality control to prevent and detect errors, ensuring the reliability and accuracy of diagnostic results.
2. Comply with international and national standards for quality, competence, and regulatory compliance in diagnostic services.
3. Enhance documentation practices by maintaining accurate, traceable records and updating Standard Operating Procedures (SOPs).
4. Analyze and mitigate risks in diagnostic processes, including equipment failure, sample mismanagement, and biosafety hazards.
5. Oversee the calibration, maintenance, and validation of diagnostic equipment while effectively managing the supply chain to prevent service disruptions

### Course syllabus

<b>Course description:</b>	This five-day CPD course is prepared for Medical laboratory professionals to enable them to effectively carry out detection and identification of microbial pathogens from body fluids. The course covers both the knowledge and skill aspects of the analysis of body fluid.
<b>Course goal:</b>	The goal of this course is to enhance the competency of healthcare professionals in providing accessible, affordable, and high-quality diagnostics services
<b>Learning objectives:</b>	<p>By the end of this course, the participants will be able to:</p> <ul style="list-style-type: none"> <li>• Explain the importance of diagnostics services in healthcare.</li> <li>• To discuss the laboratory analyses, pathology examination, and radiology and imaging service.</li> <li>• To develop system thinking and problem-solving skills for accurate diagnosis and treatment planning.</li> <li>• To ensure access of diagnostics services for all patients.</li> <li>• To ensure implementation of quality dimension in diagnostics service</li> </ul>
<b>Training/learning methods</b>	<ul style="list-style-type: none"> <li>• Interactive presentation</li> <li>• Case study, Demonstration</li> <li>• Group discussion</li> <li>• Think pair share</li> <li>• Individual reflection</li> </ul>



<b>Training materials/ Aids</b>	<ul style="list-style-type: none"> <li>• Participant manual</li> <li>• Facilitator guide</li> <li>• Laptop, LCD</li> <li>• FLIP chart , Marker</li> <li>• White paper</li> </ul>
<b>Participant selection criteria</b>	<ul style="list-style-type: none"> <li>• Diagnostics Professionals from clinical laboratory, anatomic pathology and imaging and radiology departments</li> <li>• Hospital Quality team diagnostics service representative</li> </ul>
<b>Method of evaluation</b>	<p>Formative</p> <p>Pretest</p> <p>Individual and group exercise</p> <p>Skill demonstration</p> <p>Summative</p> <p>Post test</p> <p>Course Evaluation:</p> <p>Daily evaluation</p> <p>End of course evaluation</p> <p>Participant reflection</p>
<b>Certification criteria</b>	<ul style="list-style-type: none"> <li>• Attendance 100% of the course sessions</li> <li>• Post test score greater than 75%</li> </ul>
<b>Trainers selection criteria</b>	<p>Professionals those who participated in document preparation (TWG)</p> <p>TOT certified Diagnostics Professionals</p>
<b>Course venue</b>	Accredited CPD training centres (providers).
<b>Course duration</b>	Five days
<b>Trainer Composition</b>	25 participants, 4 trainers (1:5 ratio).

**Continuous educational unit (CEU):** 15 CEU is allocated for this course

## Quality management system Course Schedule

Days	Time	Schedule	Responsible body	
			Lead Facilitator	Co-Facilitator
Day-1	<b>8:30-9:00AM</b>	Welcome and Registration		
	9:00 - 9:30 AM	Introduction and Opening Remark		
	9:30 – 10:30 AM	Pre-test		
	10:30 – 10:45 AM	<b>Tea Break (morning)</b>		
	10:45 – 11:30 AM	Chapter 1: Introduction to QMS		
	11:30 – 12:30 AM	Chapter 1 Continued		
	12:30 – 1:30	<b>Lunch</b>		
	1:30 – 3:45 PM	Chapter 2 Organization		
	3:45 – 4:00 PM	<b>Tea Break (afternoon)</b>		
	4:00 – 5:30 PM	Chapter 3 Personnel management		
Day-2	9:00 – 10:30 AM	Chapter 3 Equipment		
	10:30 – 10:45 AM	<b>Tea Break (morning)</b>		
	10:45 – 12:30 AM	Chapter 4 continued		
	12:30 – 1:30	<b>Lunch</b>		
	1:30 – 3:45 PM	Chapter 5 purchasing & inventory		
	3:45 – 4:00 PM	<b>Tea Break (afternoon)</b>		
	4:00 – 5:30 PM	Chapter5 Continued		
Day-3	9:00 – 10:30 AM	Chapter 6Process control		
	10:30 – 10:45 AM	<b>Tea Break (morning)</b>		
	10:45 – 12:30 AM	Chapter7 document and record		
	12:30 – 1:30 AM	<b>Lunch</b>		
	1:30 – 3:45 PM	Chapter 7 Continued		
	3:45 – 4:00 PM	<b>Tea Break (afternoon)</b>		
	4:00 – 5:30 PM	Chapter 8assessment/Audit		
Day-4	9:00 – 10:30 AM	Chapter 9 occurrence		
	10:30 – 10:45 AM	<b>Tea Break (morning)</b>		
	10:45 – 12:30 AM	Chapter 10 Quality improvement		
	12:30 – 1:30	<b>Lunch</b>		
	1:30 – 3:45 PM	Chapter 11 Customer service		
	3:45 – 4:00 PM	<b>Tea Break (afternoon)</b>		
	4:00 – 5:30 PM	Chapter 12 Facility & safety		
Day-5	9:00 – 10:30 AM	Chapter 12 Continued		
	10:30 – 10:45 AM	<b>Tea Break(morning)</b>		
	10:45 – 12:30 AM	Chapter 13 information management		
	12:30 – 1:30	<b>Lunch</b>		
	1:30 – 3:45 PM	Course evaluation, Post test		
	3:45 – 4:00 PM	<b>Tea Break(afternoon)</b>		
	4:00 – 5:30 PM	<b>Certification and closing</b>		

# 1



## CHAPTER

**Introduction to  
Diagnostic Quality  
Management System**

# Chapter 1: Introduction to Diagnostic Quality Management System



**Duration: 2hrs**



**Chapter Description**

This chapter highlights the Diagnostics Quality Management Systems essentials (DQMS), focusing on their importance in ensuring the delivery of accurate and reliable diagnostic services. It examines key components and principles of DQMS, emphasizing their role in enhancing patient safety, quality of care, and overall healthcare outcomes



**Chapter Objective:**

At the end of this chapter participants will be able to discuss diagnostic quality management system



**Learning Objectives**

By the end of this chapter learners will be able to:

- Define Diagnostics Quality Management Systems and explain their importance in healthcare
- Identify key components and principles of DQMS
- Discuss the process of implementing, challenge and maintaining an effective DQMS.

## Summary of activities

Session	Time (Min)	Instruction and guide	Method of delivery	Resource
Introduction to Diagnostics Quality Management Systems	15	Display Slide #5 and explain what quality managements in diagnostic service Display slide # 4-5, to describe the definition and importance of DQMS	Interactive presentation	Slide #5-7 PM page 3
Principles of Diagnostics Quality Management	20	Display slide #:10 to describe the Principles of Diagnostics Quality Management	Interactive presentation	Slide #9-8 PM page 3
Components of Diagnostics Quality Management System	15	Display slide #10 and describe what it means by Components of Diagnostics Quality Management System	Interactive presentation	Slide # 10-12 PM page 3-5
Implementation of Diagnostics Quality Management Systems	20	Display slide#... and explain the implementation process of Diagnostics Quality Management Systems	Interactive presentation	Slide #7 to 9 PM page: 6

Benefits and Impact in DQMS Diagnostics Service	15	Display slide # 15 and following slides describing the benefit and impact in DQMS in diagnostics service	Interactive presentation	Slide#.15 PM#7
Accreditation and Certification Need	20	Display slide # 23 and following slides describing the accreditation and certification need in DQMS in diagnostics service	Interactive presentation	Slide #.23 PM: #5
Challenge and Consideration	10	Display slide # 24 and following slides describing the challenge and consideration DQMS in diagnostics service	Interactive presentation	Slide #.24 PM: #6
Chapter Summary	15	Display side #.25 and summarize the topic by selected 12 essential diagnostics quality management system	Interactive presentation	Slide #.25 PM: #7

### Materials Required

- Flip Chart and Markers
- LCD Projector and Laptop
- Participant manual
- Trainer’s guide
- Sample session plan

### Guidance and Feedback for Activities

#### Activity 1.1

#### Guidance

### Importance of QMS for Availability, Quality, and Affordability

### Understanding Quality Management Systems in Diagnostics

A Quality Management System (QMS) is a structured approach to ensuring that every aspect of diagnostic services—whether it involves laboratory testing, pathology, or radiology—is designed, managed, and monitored to deliver reliable, timely, and high-quality results. QMS frameworks guide processes like standardization, accuracy checks, risk management, and continuous improvement, which are essential for high-quality patient care.

#### Feedback/Answers

To effectively implement QMS across diagnostic services in Ethiopia, healthcare facilities and providers can focus on key areas such as:

- **Training and capacity-building:** Equipping healthcare professionals with QMS knowledge and skills to maintain high standards.
- **Standardizing procedures:** Developing consistent procedures for diagnostics to ensure uniform quality across all facilities.
- **Continuous improvement:** Creating feedback loops for monitoring and improving processes regularly

# 2



## CHAPTER

### Organization

## Chapter 2: Organization



**Duration: 2hrs**



**Chapter Description**

This chapter describes the key elements of organizational management in the context of quality management for diagnostic services. It highlights the crucial managerial functions that coordinate employee efforts and secure necessary resources. The organization involves the division of labor among staff and the alignment of tasks to achieve the company's overarching objectives.



**Chapter Objective**

At the end of this chapter participants will be able to explain the organizational requirements of the quality management system.



**Enabling Objective**

At the end of this chapter, participants will be able to

- Describe elements of organizational requirements for diagnostic service
- Discuss management roles and responsibilities in a diagnostic service
- Explain the process for designing, implementing, maintaining, and improving organizational requirements of diagnostic service

### Summary of activities

Session	Time (Min)	Instruction and guide	Method of delivery	Resource
Introduction to organization	20	<ul style="list-style-type: none"><li>• Display slide #..... describe how the organization begins by emphasizing the importance of defining the diagnostic's legal identity, ownership, and scope of service</li></ul>	Interactive presentation	Slide # 3 PM page:.....9
Activities to Organization	20	<ul style="list-style-type: none"><li>• Display Slide #.... Display slide #..... With the activity and instruct participant to take 5 minute and then reflect on What quality practices are already in use in diagnostics and the level of knowledge of current staff</li></ul>	Inter active presentation Activity	Slide #...4. to .... PM page10 ...

Management Role Management Functions and its implementation	20	<ul style="list-style-type: none"> <li>• Display slide #.... and describe the role and responsibilities of management for providing effective leadership in the diagnostics service.</li> <li>• Display slide#.... and explain the functions expected from the organization management and its implementation</li> </ul>	Interactive presentation	Slide #...5.. to .... PM page 10-11
Elements for successful implementation of Quality Management System (QMS	20	<ul style="list-style-type: none"> <li>• Display slide #... and following slides list and describing the Elements for successful implementation of Quality Management System (QMS</li> </ul>	Interactive presentation	Slide #... 7to ...10. PM page11-12
Quality Policy Manual and Quality objectives	20	<ul style="list-style-type: none"> <li>• Brief the activity questions and instruct participant to form a group of 3-5 individuals display slide #... and assign groups to discuss on the topics displayed</li> <li>• Display slide #... and describe the importance of quality policy manual</li> </ul>	Interactive presentation Activity	Slide#.....11 PM#.....13
Chapter Summary	20	Display side #.... and summarize the topic by selected 3 core ideas	Interactive presentation	Slide... PM:.....14

### Materials Required

- Flip Chart and Markers
- LCD Projector and Laptop
- Participant manual
- Trainer's guide
- Sample session plan

### Guidance and Feedback for Activities

#### Activity 2.1

#### Guidance

- instruct participant to take 5 minute
- then reflect on What quality practices are already in use in diagnostics and the level of knowledge of current staff

# 3



## CHAPTER

### Personnel management

## Chapter 3: Personnel management



**Duration:2hrs**



**Chapter discretion**

This chapter provides comprehensive guidance on the recruitment, orientation, training, competency assessment, ongoing professional development, performance evaluation, appraisal and end of employment of diagnostic personnel.



**Chapter Objective**

By the end of this chapter participants will be able explore how to possess the necessary standards for diagnostic service personnel management.



**Enabling Objective**

By the end of this chapter participants will be able to:

- Describe the impact of personnel competency management in healthcare diagnostics
- Develop sample strategy for recruiting, selecting, developing and retaining a qualified personnel.
- Discuss regulatory compliance and standards adherence.

### Summary of activities

Session	Time (Min)	Instruction and guide	Method of delivery	Resource
Introduction to personnel	15	<ul style="list-style-type: none"><li>• Display slide # 64. to describe the system requirement and importance of personnel management in a diagnostic service</li></ul>	Interactive presentation	Slide # 4 PM page 17.
Personnel Competency assessment	12	<ul style="list-style-type: none"><li>• Display Slide # 66 and explain what competency assessment in diagnostic service mean and mansion traceable standards to ascertain the need of competency assessment</li><li>• Display slide # 67 With the activity and instruct participant to think and reflect on what issue diagnostic personnel need to be competent and how to conduct competency assessment.</li></ul>	Interactive presentation Activity	Slide #.6 to 7 PM page 19-19

Performance Appraisal	12	<ul style="list-style-type: none"> <li>• Display slide #68 and describe what it means by performance appraisal and related issues</li> <li>• Display slide #69 Instruct participant to think about the criteria, frequency and expected outcome of performance appraisal, let them pair to share ideas</li> <li>• Display slide# 70 and further explain the process of performance appraisal</li> </ul>	Interactive presentation Activity Interactive presentation	Slide #.8 to10 PM page: 19-20
Continuous professional development	16	<ul style="list-style-type: none"> <li>• Display slide# 71 and explain the need of CPD as described in international standards</li> <li>• Display slide#72 And instruct participants to form 3 groups each to develop a strategy on the 3 challenges of CPD</li> <li>• Display slide #73 to further elaborator suggested strategy to the challenges of CPD.</li> </ul>	Interactive presentation Activity Interactive presentation	Slide #11 to 13 PM page:21
Standards of compliance and regulatory practice in professional development	15	<ul style="list-style-type: none"> <li>• Display slide #74 and following slides describing the documentation and record requirements in personnel management, what standards of compliance are expected, and priority issues in personnel management</li> <li>• Brief the activity questions and instruct participant to form a group of 3-5 individuals display slide #... and assign groups to discuss on the topics displayed</li> </ul>	Interactive presentation Activity	Slide#14-15 PM#21
Chapter Summary	5	Display side #75and summarize the topic by selected 3 core ideas	Interactive presentation	Slide#25 PM#21

## Learning activity summary

### Activity 3.1 Small group activity



**Purpose:** the purpose of this activity is to help participant understand the quality concepts in diagnostic personnel management more specifically on consideration of employment, performance measure and end-of-work management.

- Introduce the activity by displaying the slide #67 and instruct participants to form a group of 5-7 and instruct to have a discussion on 3 of the issues to come up with group ideas
- Facilitate the activity rounding to each group and controlling the timing as well. Also invite representative from each group to reflect what they have discussed so far.
- Summarize the activity by describing that quality emphasis and appropriate work force management practices synergistically enhance managerial performance by meeting and exceeding customer needs and preferences through accurate, consistent, reliable, and durable service and also implementing the Total Quality Concept in personnel management can increase the effectiveness of training departments and the company in general. End-of-employment management practices involves various processes, including exit interviews,

knowledge transfer, retrieval of organizational assets, and compliance with legal and regulatory requirements. By effectively managing the end of employment, diagnostic service providers can mitigate risks associated with data security breaches, maintain continuity of operations, and uphold professional standards. Additionally, these practices can help identify areas for improvement within the organization and enhance overall employee satisfaction and retention. Ultimately, implementing robust end-of-employment management practices demonstrates a commitment to professionalism, ethical conduct, and responsible stewardship of resources in the healthcare industry.

### Activity 3.2 Individual reflection



Purpose: The Purpose of this activity is to increase insight of participants about potential areas of competency and how to conduct the assessment

- To Introduce the activity, display slide #71 and invite participants to reflect what they feel and/or know about the potential areas of competency required and how it can be done in a diagnostic service set up.
- Facilitate the activity as much participant to respond as possible and encourage them to reflect more as the topic seems sensitive when it gets to the real situation.

Summaries the activity by describing essential to personnel endeavor is the assurance that they possess the requisite competence to execute specific diagnostic tasks with proficiency. Moreover, diagnostic management must establish clear procedures for both initial and continuous competency assessment, aligning with international, national, regulatory, and accreditation standards.

Techniques and approaches aimed at thoroughly assessing personnel proficiency.

- **Direct Observation:** Supervisors or trainers observe employees performing tasks to assess their competency firsthand.
- **Written Examinations:** Employees may be required to complete written exams to demonstrate their knowledge and understanding of relevant procedures, protocols, and regulations.
- **Performance Evaluations:** Employees' performance in carrying out specific tasks or procedures may be assessed against predetermined criteria.
- **Proficiency Testing:** Employees may participate in proficiency testing programs where their performance is evaluated against established standards or peers.
- **Case Studies:** Employees may be presented with case scenarios or patient samples to analyze and interpret, demonstrating their diagnostic skills and decision-making abilities.
- **Simulation Exercises:** Simulated scenarios or patient encounters may be used to assess employees' ability to respond effectively and appropriately in various situations.

Diagnostic management need to take and document corrective action when there is clear evidence that an employee has been determined as not competent to perform specific task. Accordingly, it is essential to address the situation promptly and effectively with the following CLSI Recommendations.

- **Additional Training and Education:** Provide targeted training and education to address identified areas of weakness and enhance competency.
- **Supervision and Mentorship:** Assign a mentor or supervisor to provide guidance, support, and oversight to help the individual improve their skills and knowledge.
- **Performance Improvement Plan (PIP):** Develop a structured performance improvement plan outlining specific goals, timelines, and expectations for improvement.
- **Reassessment:** Conduct regular reassessments to monitor progress and determine whether the individual has successfully addressed areas of incompetence.
- **Transfer or Reassignment:** Consider transferring the individual to a different role or department where their skills may be better suited, if feasible.
- **Disciplinary Action:** In cases of severe incompetence or failure to improve despite interventions, disciplinary action may be necessary, up to and including termination of employment.

### Key Note

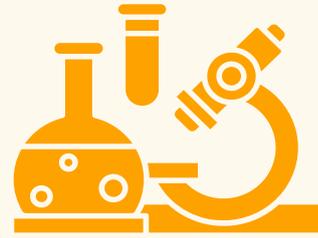


It is crucial to handle cases of incompetence with professionalism, empathy, and a focus on supporting the individual in improving their performance while maintaining the quality and integrity of diagnostic services.



According to CLSI statement; Competency assessment is also distinguished from organization's periodic performance evaluation process which is usually performed in conjunction with the organization's HR department or function. However, the competency assessment outcomes maybe included as a component of organizational performance evaluation process.

# 4



## CHAPTER

### Equipment

## Chapter 4: Equipment



**Duration: 2 hrs**



**Chapter Description**

This chapter describes the importance of establishing criteria and method for all aspects of managing general and service specific equipment, instruments and analytical systems of diagnostic service.



**Chapter Objective**

At the end of this chapter participant will be able to describe effective diagnostic equipment management practices.



**Learning Objectives**

By the end of this chapter learners will be able to:

- Analyze a comprehensive diagnostic service equipment management criterion.
- Explain diagnostic service equipment management process
- Illustrate diagnostic service equipment decommissioning process

### Summary of activities

Session	Time (Min)	Instruction and guide	Method of delivery	Resource
Overview of equipment management	15	<ul style="list-style-type: none"><li>• Display slide #76 to describe and review basics of medical equipment management.</li><li>• Display Slide# 77 and instruct participants to reflect on one of the terminologies.</li></ul>	Interactive presentation Activity	Slide #6 and 7 PM page#23-24
Planning and equipment implementation	12	<ul style="list-style-type: none"><li>• Display Slide #78 and explain what planning is and how to consider in diagnostic service</li></ul>	Interactive presentation	Slide #8 PM page# 25
Equipment selection, Identification and acquisition.	12	<ul style="list-style-type: none"><li>• Display slide #79 and describe what it means by Equipment selection, Identification and acquisition.</li><li>• Display slide #80 to let trees see examples of selection criteria.</li></ul>	Interactive presentation Interactive presentation	Slide #9 to 10 PM page# 26

Equipment qualification	16	<ul style="list-style-type: none"> <li>• Display slide#81 And instruct participants to reflect what IQ, OQ and PQ are.</li> <li>• Display slide# 82-85 and explain the concept of what IQ, OP, PQ, HA and validation report are</li> </ul>	Activity Interactive presentation	Slide #11 to 15 PM page 27 to 30
Equipment calibration and maintenance	15	<ul style="list-style-type: none"> <li>• Display slide #86 and explain the importance of performing recommended equipment maintenance and the calibration requirement principles.</li> </ul>	Interactive presentation	Slide#16 PM#30
Medical equipment information management system	15	<ul style="list-style-type: none"> <li>• Display slide # 87 and explain the importance of considering Medical device information management system.</li> <li>• Display slide#88 and explain the breakdowns of the requirement</li> </ul>	Interactive presentation	Slide#17 to 18 PM#31 to 32
Equipment decommissioning	15	<ul style="list-style-type: none"> <li>• Display slide#89 And instruct participants to think-pair and share about equipment decommissioning</li> <li>• Display slide# 90 and explain the steps required to effectively decommission an equipment.</li> </ul>	Activity Interactive presentation	Slide#9 to 20 PM page# 32 to 33
Chapter Summary	5	Display side #91 and summarize the topic	Interactive presentation	Slide# 21 PM34

## Materials Required

- Flip Chart and Markers
- LCD Projector and Laptop
- Participant manual
- Trainer's guide
- Sample session plan

## Guidance and Feedback for Activities

### Activity 4.1 Individual reflection



**Purpose:** The purpose of this reflection is to indirectly assess the participants understanding about medical equipment management and the meaning of related terminologies.

Display slide # 77 and invite participants to reflect on one of the displayed words. Invite as much participant as possible to cover all terminologies displayed. On the process please be sure that one participant should not have double chance to reflect.

Summaries the reflection activity by depicting the meaning of those important terminologies in the contact of medical device management and how they are going to be done as explained below.

**Selection and Purchasing:** Determine the criteria for selecting new equipment and decide whether purchasing or leasing is more advantageous.

- **Installation:** Identify installation requirements for new equipment and designate responsible parties for installation.
- **Calibration and Performance Evaluation:** Establish protocols for calibrating and validating equipment performance, both for new acquisitions and existing instruments.
- **Maintenance:** Define a maintenance schedule recommended by manufacturers and assess the need for additional preventive measures. Ensure current maintenance procedures are being executed effectively.
- **Troubleshooting:** Develop clear procedures for troubleshooting issues with each instrument to expedite problem resolution.
- **Service and Repair:** Evaluate the cost and accessibility of service and repair options within the diagnostic geographical area.
- **Retiring and Disposing of Equipment:** Determine the process for retiring and disposing of old equipment when replacement is necessary.

#### Activity 4.2 Individual reflection



**Purpose:** The purpose of this activity is to ascertain the meaning and importance of critical qualifications in medical equipment management.

Display slide# 81 so that participants can see words like (Installation Qualification, Operational Qualification, And performance qualification. Instruct participants what the meaning those words mean and how to assure those qualifications in the practical world. Please be receptive as different experience may arise in different diagnostic environment.

Summarize by explaining what those words mean and how to manage them in accordance to the CLSI standard which says:-

#### Installation Qualification (IQ)

The IQ is a set of formal checks and records that confirm the equipment and its components were supplied as ordered and properly installed in the workplace with any integral software and hardware according to the manufacturer's requirements. Although this activity is frequently conducted by the manufacturer's technical service engineer, diagnostic service management is responsible for ensuring records are generated that meet organizational and compliance requirements. Usually, the manufacturer's installation engineer shall provide or shall be asked to provide documentation that certifies the instrument is ready, safe, and meets installment specifications including but not limited. (read the rest of the meaning as described in participant's manual)

### Activity 4.3 Think-Pair-Share



Purpose: the purpose of this activity to facilitate a condition between participants to share their understanding and practice with regard to the most important final stage of equipment management called decommissioning.

Instruct participant to think what equipment decommissioning is, the process of decommissioning and Purpose of decommissioning. Give 2 minutes to think; and pair and share their ideas and believes in the remaining 3 minutes. Receive shared ideas equally and with out discrimination.

Summarize the activity by explaining that decommissioning equipment involves a process to ensure the equipment meets the health and safety requirements for the equipment's next use, such as reassignment to another facility or final disposition to an approved recycling/disposal center. Decommissioning requirements vary according to equipment type and the nature of substances used in operating the equipment. On many occasions, the manufacturer takes responsibility for decommissioning the equipment.

# 5



## CHAPTER

**Purchasing and  
inventory**

## Chapter 5: Purchasing and inventory



**Duration:2hrs**



### Chapter Description

This chapter describes the essential components of purchasing and inventory management in diagnostic service quality management to assure quality of purchasing selection, quantification, storage and distribution of supplies



### Chapter Objective

At the end of this chapter participants will able to explain the purchasing and inventory management, and illustrate diagnostic service standard of purchasing and inventory control program.



### Learning Objectives

By the end of this chapter learners will be able to:

- Describe the steps required to implement an inventory control program.
- Name factors to consider in procurement of supplies.
- Describe a monitoring plan for the inventory system.
- Discuss the importance of documentation related to purchasing and inventory

### Summary of activities

Session	Time (Min)	Instruction and guide	Method of delivery	Resource
Session introduction		Display slide # 1 and introduce the session by stating the benefit and usefulness of diagnostic document and record control.what relevant experience and skills they do have?		
Outline		Display slide # 2 and describe the session objective		
Session objectives		Display slide # 3 and Telling the learners what they will be able to do as a result of participating in the learning intervention or activity		
Introduction to purchasing and inventory	20	<ul style="list-style-type: none"> <li>• Display slide # 124.to provides a comprehensive guide of purchasing and inventory management in diagnostic services.</li> </ul>	Interactive presentation	Slide # 124-127 PM page:36..

Case scenario	20	<ul style="list-style-type: none"> <li>• Display slide #127 With the activity and instruct participant and reflect on task to ensure the diagnostics equipped to handle the increased volume and new types of tests.</li> <li>• What steps would you take to identify the specific supplies and equipment required for the new tests?</li> </ul>	Interactive presentation Activity	Slide #... to 127... PM 37 bpage ...
purchasing	20	<ul style="list-style-type: none"> <li>• Display slide #...130.. and describe what it means by purchasing and how to identify needs, evaluating suppliers  Negotiating Contracts Placing Orders and related issues</li> </ul>	Interactive presentation Activity Interactive presentation	Slide #...130. to ...40.. PM page 37-40
Inventory management	20	<ul style="list-style-type: none"> <li>• Display slide#...133 and explain the need of Effective inventory management and how it begins with accurately tracking stock levels to ensure that diagnostic services have the necessary supplies on hand. include:</li> </ul>	Interactive presentation Activity Interactive presentation	Slide #... to ...133. PM page:...41
Documentation and Record Keeping	20	<ul style="list-style-type: none"> <li>• Display slide #...138. and following slides describe how documentation is crucial in purchasing and inventory management, as it ensures transparency.</li> </ul>	Interactive presentation Activity	Slide#...138PM#...42
Chapter Summary	10	<ul style="list-style-type: none"> <li>• Display side #..145. and summarize the topic by selected 3 core ideas</li> </ul>	Interactive presentation	Slide3154PM:43

### Materials Required

- Flip Chart and Markers
- LCD Projector and Laptop
- Participant manual
- Trainer's guide
- Sample session plan

### Guidance and Feedback for Activities

#### Activity 5.1 Case Scenario

#### Guidance

Guide participants to understand the case scenario and proceed per manual instruction

#### Feedback/Answers

Check as the answers are related with the power points concepts.

# CHAPTER

# 6



## Process Control in diagnostic service

## Chapter 6: Process Control in diagnostic service



**Duration: 2hrs**



**Chapter Description**

This chapter describes the application of process control principles and methodologies in the entire diagnostic services complex.



**Chapter Objective**

At the end of this chapter the participant will be able to explain the principles, techniques and practices related to process control in diagnostic services.



**Learning Objectives**

By the end of this chapter learners will be able to:

- Define process control in diagnostic service
- Contrast pre examination, examination and post examination process
- Explain how to Monitor and evaluate process control

### Summary of activities

Session	Time (Min)	Instruction and guide	Method of delivery	Resource
Session introduction	10min	<ul style="list-style-type: none"> <li>• Display slide # 1 and introduce the session by stating the benefit and usefulness of process control in diagnostics and what relevant experience and skills they do have?</li> </ul>	presentation	Slide #1 PM page:45
Description	10min	<ul style="list-style-type: none"> <li>• Display slide # 2 and describe the session</li> </ul>	presentation	Slide #2 PM page:45
Session objectives	10min	<ul style="list-style-type: none"> <li>• Display slide # 3 and Telling the learners what they will be able to do as a result of participating in the learning intervention or activity</li> </ul>	presentation	Slide #2 PM page:45
Introduction to process control in diagnostic service	20min	<ul style="list-style-type: none"> <li>• Display slide #...3... to Introduce to process control in diagnostic service</li> <li>• Display slide #...4 instruct trainers to be in group of three and discuss on the given activity .</li> </ul>	Interactive presentation Discussion	Slide #3 PM page:46

Pre examination steps in process control	10min	<ul style="list-style-type: none"> <li>• Display Slide #.... and explain Pre examination steps in process control</li> </ul>	Interactive presentation	Slide #... to ...PM Page 46
Examination steps in process control	20min	<ul style="list-style-type: none"> <li>• Display Slide #.... and explain examination steps in process control</li> </ul>	Interactive presentation	Slide #.... to ...PM 49 page .....
Post examination steps in process control	20min	<ul style="list-style-type: none"> <li>• Display Slide #.... and explain examination steps in process control</li> </ul>	Interactive presentation	Slide #... to ... PM page 52
Case Scenario	15	<ul style="list-style-type: none"> <li>• Display slide #....25 instruct trainers to be in group of three (laboratory, Radiology and Pathology) and discuss on the given activity .</li> </ul>	Discussion	Slide #... to ... PM page 53
Chapter Summary	5min	<ul style="list-style-type: none"> <li>• Display side #.... and summarize the topic by selected 3 core ideas</li> </ul>	Interactive presentation	Slide... PM:....54

### Materials Required

- Flip Chart and Markers
- LCD Projector and Laptop
- Participant manual
- Trainer's guide
- Sample session plan

### Guidance and Feedback for Activities

#### Activity 6.1

##### Guidance

- Create group of 3 and proceed per manual instruction

##### Feedback/Answers

Check as the answers are related with the power points concepts.

#### Activity 6.2

##### Guidance

- Create group of 3 (laboratory, Radiology and Pathology) and discuss on the given activity per manual instruction

##### Feedback/Answers

Check as the answers are related with the power points concepts.

# 7



## CHAPTER

### Document and Record Control

## Chapter 7: Diagnostic document and record



**Duration: 80min**



**Chapter description**

This chapter is designed to discuss key concepts of diagnostic document and record.



**Chapter objective**

Explain the principles, importance and benefits of document and record management in Diagnostic services.



**Enabling objective**

At the end of this chapter, participant will be able to:

- Identify the difference between documents and records;
- List the important elements of document and record management system;
- Develop sample quality management system document and record
- Discus proper management of document as per standards

### Session 7.1

Introduction to document and record

Activity	Time (Min)	Instruction and guide	Method of delivery	Resource
Session introduction	10 min	<ul style="list-style-type: none"> <li>• Display slide # 1 and introduce the session by stating the benefit and usefulness of diagnostic document and record control, what relevant experience and skills they do have?</li> </ul>		Slide # 1 PP PM –56
Outline	10 min	<ul style="list-style-type: none"> <li>• Display slide # 2 and describe the session objective</li> </ul>		PP Slide # 2 PM 56
Session objectives	20 min	<ul style="list-style-type: none"> <li>• Display slide # 3 and Telling the learners what they will be able to do as a result of participating in the learning intervention or activity</li> </ul>		Slide # 3 PM 56
Introductory activity	10min	<ul style="list-style-type: none"> <li>• Display slide # 5 and introduce the session by telling the trainers carefully read the activity and reflect what they understand and then give them feedback from slide # 6</li> </ul>		Slide # 5 & 6 PM 57

introduction to document and record	20 min	<ul style="list-style-type: none"> <li>Make an interactive lecture and discussion on introduction to document and record, types of document # 7-15</li> </ul>	Presenting	Slide # 7-15 PM :-58
discussion on document and record, management		<ul style="list-style-type: none"> <li>Make an interactive lecture and discussion on document and record, management</li> </ul>	Presenting	Slide # 16-21 PM :-58-63
discussion on document and record, management	20min	<ul style="list-style-type: none"> <li>Make an interactive lecture and discussion on document and record preparation #22-41</li> </ul>	Presenting	Slide #22-41 PM :-64-70
diagnostic document control	10min	<ul style="list-style-type: none"> <li>Make an interactive lecture and discussion on types of diagnostic document control #42-44</li> </ul>	Presenting	Slide #42-44 PM :-70-76
Session summary	10	<ul style="list-style-type: none"> <li>Display slide # 45 and 46 Summarize the session by highlighting the key points</li> </ul>	Session summary	Slide # 45-46 PM :-77
Application	5 min	<ul style="list-style-type: none"> <li>Ask /challenge learner to reflect on document and record</li> </ul>	Application	Slide #46
	5 min	<ul style="list-style-type: none"> <li>Give opportunity to reflect or raise any question on the session</li> </ul>	Activity	Slide # 46

### Resources Needed

- Flip Chart, paper and Markers
- LCD Projector and Laptop

### Advanced Preparation

- None

### Learning Activities

#### Learning Activity 1: Individual reflection on the importance of document and record management 10 min)



- The main purpose of this learning exercise is to help the learners understand clearly the importance of diagnostic document and record management term 'document and record' and their relation ship.
- Introduce the session by asking the participant the guiding questions on Slide #5, encouraging the learners to develop the answer while attending this session.
- Emphasize that the importance of document and record management. And to understand their management, it may be needed to distinctly define each word.
- Ask the learners to think of the importance, of document, And record management

#### Activity: Summary

- Summarize the activities by emphasizing the importance of document and record, it is necessary to know the meaning of these terms accurately.

## Learning Activity 2: Group work to identify document from record (15 min)

- The main purpose of this learning exercise is to help the learners understand clearly the difference between document and record
- Introduce the session by asking the participant the guiding questions on Slide #16, encouraging the learners to develop the answer while attending this session.

Draw the attention of the learners to the guiding question 'identify document from record, What is the advantage of identification of document from record?'

- Divide the participant into 3 small groups, and instruct them to discuss and reflect in groups
- Guide to discussion in the group and focus on the identification
- Emphasize that the word document and record. And to understand their differences, it may be needed to distinctly define each word.
- Ask the learners to think of the difference's among the terms, document, And record? Advise them to demonstrate. and list among these papers laid on table and compare with their peers.
- Invite them to look at the papers. Ask them 'How does this look compared to yours?'

### Activity: Summary

- Summarize the activities by emphasizing instruction must be based on a deliberate intentional arrangement of learning conditions to help learners achieve the learning goals. Although sometimes people use these terms interchangeably, for document and record, it is necessary to know the meaning of these terms accurately.

**Activity 1-** Which of the following statements best describes the purpose of a laboratory document control system?

- A. To ensure that all laboratory staff have equal access to office supplies.
- B. To provide a mechanism for tracking inventory levels of reagents.
- C. To maintain the integrity and accuracy of all laboratory documents by controlling their creation, review, and distribution.
- D. To ensure that all laboratory documents are kept indefinitely.

**Answer: C.** To maintain the integrity and accuracy of all laboratory documents by controlling their creation, review, and distribution.

**Activity 2-**What is the key element of a laboratory record control system to ensure compliance with regulatory standards?

- A. Storing records in a digital format only.
- B. Ensuring records are accurate, complete, and accessible for review during audits.
- C. Discarding old records as soon as new ones are created.
- D. Keeping duplicate copies of all records in different locations.

**Answer: B.** Ensuring records are accurate, complete, and accessible for review during audits.

# 8



## CHAPTER

### *Assessment/Audit*

## Chapter 8: Assessment/Audit



**Duration: 120 minutes**



**Chapter Description**

This chapter is designed to enhance professional practice for the quality of diagnostic service.



**Chapter Objective**

At the end of this chapter, the participants will be able to implement the standard assessment practice in diagnostic service.



**Learning Objectives**

By the end of this chapter learners will be able to:

- Describe the assessment process of diagnostic service.
- Explain the structure of audit process in diagnostic service
- Implement standardized audit tool in diagnostic service.

### Summary of activities

Session	Time (Min)	Instruction and guide	Method of delivery	Resource
Chapter description	10	<ul style="list-style-type: none"> <li>• Display slide ----and describe session objective to participants</li> </ul>	Interactive presentation	Plide # PM page: 79
Session objectives	20	<ul style="list-style-type: none"> <li>• Display slide #--- and Telling the learners what they will be able to do as a result of participating in the learning intervention or activity</li> </ul>	Interactive presentation	Plide # PM page: 79
Introduction to assessment and audit	20	<ul style="list-style-type: none"> <li>• Display slide #..... Display slide # 5 and introduce the session by telling the trainers carefully read the activity and reflect what they understand</li> <li>• describe the system requirement and importance of assessment in a diagnostic service</li> </ul>	Interactive presentation	Slide # PM page:...80..

Structure of internal audit Process	20	<ul style="list-style-type: none"> <li>• Display Slide #.... and explain the importance of preparation that both the auditor and auditee are prepared for the audit.</li> <li>• Display Slide #.... Give them interactive lecture on the outline of audit and audit processes</li> </ul>	Interactive presentation Activity	Slide#.... to .... PM 81-83
Small Group Activity	20	<ul style="list-style-type: none"> <li>• Display slide #.... and describe what it means by performance appraisal and related issues</li> <li>• Display slide #.... Instruct participant to be in group of 3 and discuss on the given activity</li> <li>• Display slide#....and further explain the process and audit tools</li> </ul>	Interactive presentation Activity Interactive presentation	Slide #.... to ..... PM page .....83
Conducting audit on diagnostics	20	<ul style="list-style-type: none"> <li>• Display slide#.... and explain the audit process and how to use audit findings</li> </ul>	Interactive presentation	Slide #... to .... PM page:8 5-87
Chapter Summary	10	<ul style="list-style-type: none"> <li>• Display side #.... and summarize the topic by selected 3 core ideas</li> </ul>	Interactive presentation	Slide-... PM:....87

### Materials Required

- Flip Chart and Markers
- LCD Projector and Laptop
- Participant manual
- Trainer's guide
- Sample session plan

### Guidance and Feedback for Activities

#### Activity 8.1

##### Guidance

- Telling the trainers carefully read the activity and reflect what they understand

##### Feedback/Answers

- .....
- .....

#### Activity 8.2

##### Guidance

- Telling the trainers to be in group of three and discuss on the given discussion

# 9



## CHAPTER

**Diagnostic Service  
Occurrence Management**

## Chapter 9: Diagnostic Service Occurrence Management



**Duration: 60min**



**Chapter description:**

This chapter highlights an occurrence management and its theoretical foundations in diagnostic services that are related to effectively managing occurrences and incidents.



**Chapter objective:**

At the end of this chapter participants will be able to describe an occurrence management in diagnostic services



**Enabling Objective**

At the end of this chapter participants will be able to

- Explain how the Quality Management process plays a crucial role in managing occurrences in diagnostic services.
- Discuss best practices for identifying, analyzing, and addressing occurrences and incidents in the context of the QMS in diagnostic services.
- Describe the delivery of high-quality diagnostic services and facilitate continuous improvement within the QMS through effective occurrence management.

### Session 9.1

Introduction to Occurrence Management

Time	Activity	Sample instruction and guide	Resource
10min	Session introduction	<ul style="list-style-type: none"> <li>• Display slide # 1 and introduce the session stating the benefit and usefulness of diagnostic Occurrence Management, what relevant experience and skills they do have?</li> </ul>	Slide # 2 PM -;-89
10min	Outline	<ul style="list-style-type: none"> <li>• Display slide # 2 and describe the session objective</li> </ul>	Slide # 3 PM 89
10 min	Session objectives	<ul style="list-style-type: none"> <li>• Display slide # 3 and Informing learners what they will be able to do as a result of participating in the learning intervention or activity</li> </ul>	Slide # 4-5 PM -89
20 min	Introduction	<ul style="list-style-type: none"> <li>• Display slide # 4 and introduce the session by presenting the introduction part</li> </ul>	Slide # 7 & 9 PM -90

10 min	Activity	<ul style="list-style-type: none"> <li>Display slide # 5 introduce the session by telling the trainers to be in group of 4 and to study the case and finally share their finding to the whole class # 6</li> </ul>	Slide # 10-11 PM :-90
10min	Presenting	<ul style="list-style-type: none"> <li>Give the trainers interactive lecture on occurrence identification.</li> </ul>	Slide #12-14 PM :-90
			Slide #15-17 PM :-90
10min	Presenting	<ul style="list-style-type: none"> <li>Then describe how to analysis, investigate and develop corrective and preventive actions and about continuous improvements</li> </ul>	Slide #18-23
10min	Activity	<ul style="list-style-type: none"> <li>Give the trainers guidance for individual reflection</li> </ul>	Slide # 24 PM :-91
10min	Session summary	<ul style="list-style-type: none"> <li>Display slide # 16 and 17 Summarize the session by highlighting the key points</li> </ul>	Slide # 27-29 PM :-93
10 min	Application	<ul style="list-style-type: none"> <li>Ask /challenge learner to reflect on Occurrence Management</li> </ul>	Slide # 30
10min		<ul style="list-style-type: none"> <li>Give opportunity to reflect or raise any question on the session</li> </ul>	

### Resources Needed

- Flip Chart, paper and Markers
- LCD Projector and Laptop

### Advanced Preparation

- None

### Learning Activities

#### Learning Activity 1: Individual reflection on the importance of Occurrence Management 10 min)



- The main purpose of this learning is to exercise and help learners understand clearly the importance of diagnostic Occurrence Management
- Introduce the session by asking the participant by asking guiding questions on slide #4, encouraging the learners to develop the answer while attending this session.
- Emphasize that the importance of Occurrence Management and to understand their attitude towards it it may be needed to define and understand the term.
- Ask the learners to think of the importance, of Occurrence Management.

### Learning Activity 9.1: Think pair share



- Summarize the activities by emphasizing the importance of Occurrence Management, it is necessary to know the meaning of “Occurrence” accurately.

### Learning Activity 9.2: Individual reflection on Occurrence Management (20 min)



- The main purpose of this learning exercise is to help the learners understand clearly about occurrence and systematic investigation and managing Occurrence Management

Introduce the session by asking the participant the guiding questions based on activity on Slide #8, encouraging the learners on how to analyze Occurrence and participating while attending this session.

Draw the attention of the learners to the guiding question to discuss and think in depth on occurrence and how to analyze.

- Select randomly the participant to answer the questions and reflect their ideas
- Guide to discussion in the group and focus on the Management
- Emphasize that the occurrence Management is crucial in QMS and better understanding of it is very important.
- Ask the learners to think of if the occurrence may not be detected

### Activity: Summary

- Summarize the activities by emphasizing instruction must be based on a deliberate intentional arrangement of learning conditions to help learners achieve the learning goals. Occurrence Management helps to achieve the goals towards QMS in diagnostic services.

# 10



## CHAPTER

**Diagnostic Services  
Quality Improvement**

## Chapter 10: Diagnostic Services Quality Improvement



**Duration: 60 minutes**



### Chapter Description

This chapter provide highlights appropriate quality improvement principles and interventions at Diagnostic service.



### Chapter Objective

At the end of this chapter, Participants will be able to discuss the principles, Models and indicators of quality improvement in diagnostic service.



### Learning Objectives

By the end of this chapter learners will be able to:

- Identify process improvement models in diagnostic service.
- Describe continues process improvement of diagnostic service.
- Explain the tools to monitor diagnostic service's quality indicators

### Summary of activities

Session	Time (Min)	Instruction and guide	Method of delivery	Resource
Session introduction	10 min	<ul style="list-style-type: none"> <li>• Display slide # 1 and introduce the session by stating the benefit and usefulness of diagnostic quality improvement program, what relevant experience and skills they do have?</li> </ul>		Slide # 1 PP PM –95
Outline	10 min	<ul style="list-style-type: none"> <li>• Display slide # 2 and describe the session objective</li> </ul>		PP Slide # 2 PM 95
Session objectives	20 min	<ul style="list-style-type: none"> <li>• Display slide # 3 and Telling the learners what they will be able to do as a result of participating in the learning intervention or activity</li> </ul>		Slide # 3 PM 95
Activity:10.1	15	<ul style="list-style-type: none"> <li>• Display slide #.... With the activity and instruct participant to think and pair share the activity</li> </ul>	Interactive presentation	Slide # 3 PM page:96

Introduction to quality improvement program	15	<ul style="list-style-type: none"> <li>• Display slide #..... to describe the system requirement and importance of quality improvement program in a diagnostic service</li> </ul>	Activity	Slide # 5 PM page:96
Process improvement models	12	<ul style="list-style-type: none"> <li>• Display Slide #.... and give brief description on Process improvement models</li> </ul>	Interactive presentation	Slide #...7. to .... PM page 97
quality improvement models in Ethiopia	12	<ul style="list-style-type: none"> <li>• Briefly describe the common improvement models in Ethiopia</li> </ul>	Interactive presentation	Slide #...9.. to .... PM page 97
Activity:10.2	16	<ul style="list-style-type: none"> <li>• Display slide#..10.. With the activity and instruct participant to individually reflect their ideas</li> </ul>	Activity	Slide #... to 11 PM page:98
Change Idea Generation	15	<ul style="list-style-type: none"> <li>• Display slide #.... and following slides describing the process of creating, developing and communicating abstract, concrete or visual ideas</li> </ul>	Interactive presentation Activity	Slide#..13 PM#....99
Monitoring quality in diagnostic service area		<ul style="list-style-type: none"> <li>• Display slide #.... and following slides describe how to monitor quality in diagnostics</li> </ul>	Interactive presentation	Slide#..18 PM#....102
Chapter Summary	5	<ul style="list-style-type: none"> <li>• Display side #..... and summarize the topic by selected 3 core ideas</li> </ul>	Interactive presentation	Slide 25.. PM:103

### Materials Required

- Flip Chart and Markers
- LCD Projector and Laptop
- Participant manual
- Trainer's guide
- Sample session plan

### Guidance and Feedback for Activities

#### Activity 10.1

#### Guidance

- .....
- .....
- .....

#### Feedback/Answers

- .....
- .....
- .....

# 11

## CHAPTER

**Customer Service of the  
Diagnostic Services**

## Chapter 11: Customer Service of the Diagnostic Services



**Duration:** 60min



**Chapter Description:**

This chapter describes how the quality management process helps to meet diagnostic's customer group needs, requirements and customer satisfaction.



**Chapter objective:**

At the end of this chapter participants will be able to describe the quality of customer service within the diagnostic provision system and ensure customer satisfaction.



**Enabling Objective**

At the end of this chapter you will be able to

- Describe the concept of customer service in diagnostic services
- Discuss methods to measure customer satisfaction.
- Identify the client, public health and community requirements

### Session 11.1

Introduction to Customer Service

Time	Activity	Sample instruction and guide	Resource
5 min	Session introduction	Display slide # 1 and introduce the session stating the importance of Customer Service in diagnostic QMS, and what relevant experience and skills they do have?	Slide # 1 PM -105
5min	Outline	Display slide # 2 and describe the session objective	Slide # 2 PM -105
5 min	Session objectives	Display slide # 3 and Telling the learners what they will be able to do as a result of participating in the learning intervention or activity	Slide # 3 PM -105
5min	Introductory activity	Display slide # 4 and introduce the session by telling the trainers carefully read the activity and reflect what they understand and then give them feedback from slide	Slide # 4 PM -106
10 min	Presenting	Make an interactive lecture and discussion on introduction to Customer Service	Slide # 7-15 PM :-106

10min	Presenting	Make an interactive lecture and discussion on Principles and Approaches in Customer Service	Slide #16-20 PM :-106-107
5min	Presenting	Make an interactive lecture and discussion on Make an interactive lecture and discussion on types of customer services , customer requirements requirements in diagnostic service .	Slide #21-23 PM :-107-109
5 min	Session summary	Display slide # 24 and Summarize the session by highlighting the key points	Slide # 24 PM :-110
5 min	Application	Ask /challenge learner to reflect on Customer Service in diagnostic service	Slide #25
5 min		Give opportunity to reflect or raise any question on the session	Slide # 30

### Resources Needed

- Flip Chart, and Markers
- LCD Projector and Laptop

### Advanced Preparation

- None

### Learning Activities

#### Learning Activity 11:1: Individual reflection on the difference between Good and Bad Customer 5min)



- The main purpose of this learning exercise is to help the learners understand

clearly the subject matter of good and bad practice of customer service

- Introduce the session by asking the participant the guiding questions on Slide #4, encouraging the learners to develop the answer while attending this session.
- Emphasize that the understanding of customer service and differentiate the good Vs bad customer handling technique and how to approach for both scenarios.
- Ask the learners to think of the Bad and Good customer handling and justify as an evaluator or managing professional

#### Activity: Summary

- Summarize the activities by emphasizing the distinctive difference of Bad and Good Customer and importance of customer satisfaction.

# 12

## CHAPTER

**Facility and safety in  
diagnostic service**

## Chapter 12: Facility and safety in diagnostic service



**Duration: 90 minutes**



### Chapter Description

This chapter describes the general safety requirements and consequences of negligence in diagnostic service.



### Chapter Objective

At the end of this chapter participant will be able to explain impacts of facility design in safety and general safety requirements in diagnostic services.



### Learning Objectives

By the end of this chapter learners will be able to:

- Describe how facility design impacts the efficiency and safety of diagnostic service workers
- Describe practices to prevent risks associated with diagnostic services
- Explain general safety requirements for diagnostic service
- Explain possible consequences of negligence in diagnostic service

### Summary of activities

Session	Time (Min)	Instruction and guide	Method of delivery	Resource
Session introduction	5	Display slide # 1 and introduce the session stating the importance of Facility and safety management diagnostic QMS, and what relevant experience and skills they do have?	Presenting	Slide # 1 PM page:112
Outline	5	Display slide # 2 and describe the session objective	Presenting	PP Slide #4 PM page:112
Session objectives	5	Display slide # 3 and Telling the learners what they will be able to do as a result of participating in the learning intervention or activity	Presenting	PP Slide #8 PM page:112

Introduction to Facility and safety in diagnostic service	10	<ul style="list-style-type: none"> <li>• Display slide number-and brief the reflection questions and instruct participants to read and answer the questions</li> <li>• Display slide #..... to describe Facility and safety in diagnostic service</li> </ul>	Interactive discussion for reflection question and presentation	PP Slide # 12 Slide #113 PP Slide # PM page:113
Methods to prevent and reduce risks in diagnostic service	20	<ul style="list-style-type: none"> <li>• Display Slide #.... and explain Methods to prevent and reduce risks in diagnostic service.</li> </ul>	Interactive presentation	Slide #.15to 20 PM page 113-
Facility controls	20	<ul style="list-style-type: none"> <li>• Display slide #..... and describe Facility controls</li> </ul>	Interactive presentation	Slide #23 to 25 PM page 114
General safety requirements for diagnostic service	20	<ul style="list-style-type: none"> <li>• Display slide #..... and describe General safety requirements for diagnostic service</li> </ul>	Interactive presentation	Slide #26 to 28 PM page115
Consequences of negligence in the diagnostic service	15	<ul style="list-style-type: none"> <li>• Display slide #.... and present the Consequences of negligence in the diagnostic service</li> </ul>	Interactive presentation	Slide#29 PM#.....116
Chapter Summary	10	<ul style="list-style-type: none"> <li>• Display side #..... and summarize the topic by selected 2 core ideas</li> </ul>	Interactive presentation	Slide..30 PM:.....117

### Materials Required

- Flip Chart and Markers
- LCD Projector and Laptop
- Participant manual
- Trainer's guide

### Guidance and Feedback for Activities

#### Activity 12.1

#### Guidance

Help the participants to understand reflection questions

#### Feedback/Answers

- Check whether the answers are related to the power points ideas

# 13



## CHAPTER

**Key concepts of diagnostic  
information management  
system**

## Chapter 13. Key concepts of diagnostic information management system



**Duration: 60min**



**Chapter description:**

This chapter describes how s information management involves efficiently handling data throughout examination processes.



**Chapter objective:**

At the end of this chapter participant will be able to explain how information management system operates and its relation to s quality management.



**Enabling objective**

At the end of this module, participant will be able to:

- Describe important elements of an information management system;
- Explain things to consider when developing a manual and paper-based information system;
- Describe the advantages and disadvantages of a computerized information management system.

### Session 13.1

Introduction to diagnostic information management

Session	Time (Min)	Instruction and guide	Method of delivery	Resource
Session introduction	5	<ul style="list-style-type: none"> <li>• Display slide # 1 and introduce the session by stating the importance of diagnostic information management, what relevant experience and skills they do have?</li> </ul>	Presenting	Slide # 1 PM –119;-
Outline	5	<ul style="list-style-type: none"> <li>• Display slide # 2 and describe the session objective</li> </ul>	Presenting	Slide # 2 PM 119
Session objectives	5	<ul style="list-style-type: none"> <li>• Display slide # 3 and Telling the learners what they will be able to do as a result of participating in the learning intervention or activity</li> </ul>	Presenting	Slide # 3 PM 119

Introductory activity	15	<ul style="list-style-type: none"> <li>Display slide # 4 and introduce the session by telling the trainers carefully read the activity and reflect what they understand and then give them feedback from slide # 5</li> </ul>	Activity	Slide # 4 & 5 PM -120
Presenting	20	<ul style="list-style-type: none"> <li>Make an interactive lecture and discussion on introduction to information management # 5-18</li> </ul>	Interactive presentation	Slide # 7-15 PM :-120
Presenting	20	<ul style="list-style-type: none"> <li>Make an interactive lecture and discussion on elements and types of diagnostic information management #18-25</li> </ul>	Interactive presentation	Slide #18-25 PM -121-123
Individual reflection	20	<ul style="list-style-type: none"> <li>Display slide # 26 and telling the trainers carefully read the activity and reflect what they understand and then give them feedback from slide # 27</li> </ul>	Interactive presentation	Slide #26-27 PM 127
Session summary	20	<ul style="list-style-type: none"> <li>Display slide # 29 and Summarize the session by highlighting the key points</li> </ul>	Interactive presentation	Slide # 29 PM 119
Application	10	<ul style="list-style-type: none"> <li>Ask /challenge learner to reflect on information management</li> </ul>	Interactive presentation	
		<ul style="list-style-type: none"> <li>Give opportunity to reflect or raise any question on the session</li> </ul>		Slide # 30

### Resources Needed

- Flip Chart, and Markers
- LCD Projector and Laptop

### Advanced Preparation

- None

### Learning Activities

#### Learning Activity 13:1: Individual reflection on the importance of information management (5min)



- The main purpose of this learning exercise is to help the learners understand clearly the importance of diagnostic information management.
- Introduce the session by asking the participant the guiding questions on Slide #4, encouraging the learners to develop the answer while attending this session.
- Emphasize that the importance of information management. And to understand their management, it may be needed to distinctly define each word.
- Ask the learners to think of the importance, of information management

### Activity: Summary

- Summarize the activities by emphasizing the importance of information management, it is necessary to know the management way.

### Learning Activity 13:2: Group work to identify selection method of diagnostic information management (10 min)

- The main purpose of this learning exercise is to help the learners understand clearly how to select diagnostic information management system
- Introduce the session by asking the participant the guiding questions on Slide #26, encouraging the learners to develop the answer while attending this session.
- Draw the attention of the learners to the guiding question 'how to select information management system
- Divide the participant into 3 small groups, and instruct them to discuss and reflect in groups
- Guide to discussion in the group and focus on the selection criteria
- Emphasize that types of information management system. And to understand their differences, it may be needed to distinctly define the methods
- Ask the learners to think of the difference's among the information management methods, manual, and electronic?
- Advise them to set selection criteria and compare with their peers.
- Invite them to present how did they select and . Ask them to list out their selection criteria

### Activity: Summary

- Summarize the activities by emphasizing the selection criteria and asking them the advantage and disadvantage of manual and electronic method.

**Q-1** Which of the following is a significant challenge associated with manual laboratory information management systems?

- A. High costs of electronic hardware.
- B. Limited scalability and increased risk of human error.
- C. Difficulty in training staff to use the system.
- D. High software licensing fees.

**Answer: B.** Limited scalability and increased risk of human error.

**2:** In an electronic Laboratory Information Management System (LIMS), what is a key feature that enhances data security compared to manual methods?

- A. Physical lock and key storage for documents.
- B. Regular staff training on document handling.
- C. User access controls and audit trails.
- D. Handwritten signatures for document approval.

**Answer: C.** User access controls and audit trails

## Pre and post test

### Multiple Choice Questions

1. What is the purpose of defining the diagnostic's legal identity, ownership, and scope of services?
  - A) To ensure consistent quality and accuracy in diagnostic operations.
  - B) To establish clarity and accountability within the organization.
  - C) To drive implementation of quality management activities.
  - D) To articulate the diagnostic's mission and objectives.
2. Which factor is essential for implementing an effective Diagnostics Quality Management System (DQMS)?
  - A) Strong leadership
  - B) Regulatory requirements
  - C) Patient care excellence
  - D) Risk management practices
3. Personnel are the most valuable assets of any organization that needs to function effectively to support established process flow in an organization and/or the entity with in it. Effective personnel management is crucial for: (Select all that applies)
  - A) Maintaining service quality
  - B) Enhancing patient care experiences
  - C) Organizational success in the healthcare sector
  - D) ALL
4. Diagnostic management need to take and document corrective action when there is clear evidence that an employee has been determined as **not competent to perform specific task**. Accordingly which of the following is not a recommended action.
  - A) Additional training and education
  - B) Reassignment or transfer
  - C) Disciplinary action
  - D) Immediately discontinue the employment
5. What is the main goal of effective equipment management in diagnostic services?
  - A) To minimize equipment costs
  - B) To ensure accurate and reliable testing
  - C) To comply with regulatory requirements
  - D) All of the above

6. What is the purpose of equipment identification?
  - A) To facilitate inventory management and maintenance tracking
  - B) To ensure regulatory compliance
  - C) Both A and B
  - D) None of the above
  
7. Which of the following is NOT a primary objective of process control in diagnostic services?
  - A) Ensuring consistent and reliable experimental results
  - B) Minimizing the occurrence of errors and deviations
  - C) Maximizing the production output of the diagnostic services
  - D) Optimizing resource utilization and efficiency
  
8. What is the main purpose of performing routine equipment calibration in diagnostic services?
  - A) To ensure accurate and reliable measurements
  - B) To reduce the cost of laboratory operations
  - C) To increase the speed of experimental procedures
  - D) To eliminate the need for quality control checks
  
9. Which of the following statements best describes the purpose of a laboratory document control system?
  - A) To ensure that all laboratory staff have equal access to office supplies.
  - B) To provide a mechanism for tracking inventory levels of reagents.
  - C) To maintain the integrity and accuracy of all laboratory documents by controlling their creation, review, and distribution.
  - D) To ensure that all laboratory documents are kept indefinitely.
  
10. What is the key element of a laboratory record control system to ensure compliance with regulatory standards?
  - A) Storing records in a digital format only.
  - B) Ensuring records are accurate, complete, and accessible for review during audits.
  - C) Discarding old records as soon as new ones are created.
  - D) Keeping duplicate copies of all records in different locations.

11. Which of the following best describes the primary purpose of an assessment/audit in a business context?
- A) Identifying strengths and weaknesses within the organization
  - B) Generating immediate revenue for the company
  - C) Conducting market research for product development
  - D) Improving employee morale through feedback
12. Which of the following is an essential step in maintaining the quality of diagnostic services?
- A) Ignoring patient feedback
  - B) Regularly calibrating testing equipment
  - C) Increasing the number of tests performed
  - D) Reducing staff training programs
13. Which one of the following occurrence should be reported as quickly as possible
- A) The test report of CBC is late due to pre-examination error
  - B) The CRP test from emergency is very late
  - C) The spillage of xylene in anatomic pathology laboratory
  - D) The defecting of ultrasound device
14. What is the importance of recording occurrence?
- A) For recording purpose only
  - B) For documentation and take an action by analyzing RCA
  - C) For documentation
  - D) Only very important occurrences are recorded
  - E) None of the above
15. Traditional Quality assurance is described as
- A) Proactive
  - B) Defensive
  - C) Reactive
  - D) A & B
  - E) B & C

## Explanation

**The correct answer is B and C** because traditional quality assurance involves both defensive and reactive measures. Defensive measures are taken to prevent defects and errors from occurring in the first place, while reactive measures are taken to identify and correct defects and errors after they have occurred. By combining both approaches, traditional quality assurance aims to ensure that products or services meet the desired quality standards.

16. Improving performance is dependent on improving

- A. Expectation
- B. The process
- C. The customer
- D. Attitude
- E. Correct Answer B. The process

17. Which one of the following factors contributes negatively for customer satisfaction

- A. Lengthy of TAT
- B. Malfunction of the MRI in between a procedure
- C. False positive or false negative of an examination
- D. All of the above
- E. None of the above

18. The followings should be considered when prepare a survey questionnaire

- A. Understanding the Purpose
- B. Identify the key objectives
- C. Understand the target audience
- D. Determine the critical aspects of the diagnostic service
- E. All of the above

19. Which of the following is an essential safety measure in a diagnostic facility?

- A) Regular equipment maintenance
- B) Colorful lab coats
- C) Unlabeled chemical containers
- D) Improper ventilation

20. What is the correct way to handle hazardous materials in a diagnostic services ?

- A) Dispose of them in regular trash bins
- B) Store them in open containers
- C) Wear appropriate personal protective equipment (PPE)
- D) Ignore safety guidelines

21. Which of the following is a significant challenge associated with manual laboratory information management systems?

- A. High costs of electronic hardware.
- B. Limited scalability and increased risk of human error.
- C. Difficulty in training staff to use the system.
- D. High software licensing fees.

22. In an electronic Laboratory Information Management System (LIMS), what is a key feature that enhances data security compared to manual methods?

- A. Physical lock and key storage for documents.
- B. Regular staff training on document handling.
- C. User access controls and audit trails.
- D. Handwritten signatures for document approval.

**The Answer to pre and post-test:**

- |        |        |
|--------|--------|
| 1. -B  | 13. -C |
| 2. -A  | 14. -B |
| 3. -D  | 15. -E |
| 4. -D  | 16. -E |
| 5. -D  | 17. -D |
| 6. -C  | 18. -E |
| 7. -C  | 19. -A |
| 8. -A  | 20. -C |
| 9. -C  | 21. -B |
| 10. -B | 22. -C |
| 11. -A |        |
| 12. -B |        |



**DIAGNOSTICS QUALITY MANAGEMENT SYSTEM TRAINING**

# **FACILITATOR GUIDE**