Model Curriculum

NOS Name: In-Vitro Diagnostics (IVD) device services

QP Code: HSS/N0924

QP Version: 1.0

NSQF Level: 4

Model Curriculum Version: 1.0

Healthcare Sector Skill Council || Healthcare Sector Skill Council,520, DLF Tower A, 5th Floor, Jasola District Centre, New Delhi – 110025

Table of Contents

Training Parameters

Sector	Healthcare
Sub-Sector	Allied Health & Skilled Health Professionals
Occupation	Non-Direct care
Country	India
NSQF Level	4
Aligned to NCO/ISCO/ISIC Code	NCO-2015/3211.0501
Minimum Educational Qualification and Experience	• 12th grade pass or equivalent with 1.5 years of experience in biomedical instrumentation services or • Previous relevant Qualification of NSQF Level 4 with 1.5-year of experience in biomedical instrumentation services
Pre-Requisite License or Training	Not Applicable
Minimum Job Entry Age	18 Years
Last Reviewed On	18/02/2025
Next Review Date	18/02/2028
NSQC Approval Date	18/02/2025
QP Version	1.0
Model Curriculum Creation Date	18/02/2025
Model Curriculum Valid Up to Date	18/02/2028
Model Curriculum Version	1.0
Minimum Duration of the Course	90 Hrs.
Maximum Duration of the Course	90 Hrs.

Program Overview

This section summarizes the end objectives of the program along with its duration.

Training Outcomes

At the end of the program, the learner should have acquired the listed knowledge and skills.

- Familiarize with medical device industry, categories of In-Vitro Diagnostics (IVD) devices.
- Demonstrate technical skills during delivery, installation and set-up of the specified medical equipment/devices.
- Provide post-installation technical assistance and instruction to the hospital staff on the installed medicalequipment, operation and maintenance safely and correctly.
- Conduct scheduled calibration and periodic preventive maintenance
- Maintain inventory and supply chain of parts and supplies
- Diagnose, repair and provide on-call and on-site assistance for equipment malfunctions.
- Schedule and oversee third party repair and maintenance work
- Describe and follow safety procedures while working with the equipment and at the workplace
- Manage work efficiently in professional practice of bio-medical instrumentation services
- Demonstrate technical and communication skills while facilitating biomedical instrumentation services for medical equipment

Compulsory Modules

The table lists the modules and their duration corresponding to the Compulsory NOS of the QP.

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
Module 1: Fundamental knowledge of function and operation of In-Vitro Diagnostics	20:00	15:00	00:00	00:00	
Module 2: Fundamentals on Installation, set-up, repair, maintenance, calibration and biomedical instrumentation Services for In-Vitro Diagnostics	10:00	15:00	00:00	00:00	
Total	**30:00**	**30:00**	**30:00**	**00:00**	**90:00**

Module Details

Module 1: Fundamental knowledge of function and operation of In-Vitro Diagnostics devices

Mapped to: HSS/N0924

Terminal Outcomes:

- Differentiate between normal and abnormal functioning of the In-Vitro Diagnostics devices.
- Apply the principles of operation of In-Vitro Diagnostics devices during their inspection, performance evaluation, calibration, testing, etc.

Duration: *20:00*	**Duration**: *15:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**

• List the various categories of In-Vitro Diagnostics (IVD) devices (analyzers and instruments):
  ○ Clinical chemistry
  ○ Hematology
  ○ Immunology
  ○ Microbiology
  ○ Toxicology
• List the various types of In-Vitro Diagnostics devices required in the healthcare settings.
• Discuss the basic features, specifications, functioning, risk category and operation of all In-Vitro Diagnostics devices listed as per the latest guidelines.
• List all possible spare parts, tools, different types of resources, and regulatory requirements for successful installation and operation of In-Vitro Diagnostics devices.
• Identify the circuits of the In-Vitro Diagnostics devices.
• Identify the electronic components in theIn-Vitro Diagnostics devices.
• Identify different types of cables and connectors used in In-Vitro Diagnostics devices.
• Identify the types of socket outlets, plugs and wiring of sockets and plugs in the In-Vitro Diagnostics devices.
• Keep abreast of the latest technology or new medical equipment/device under category of In-Vitro Diagnostics devices as per latest guidelines.
	• Identify name and uses of all listed In-Vitro Diagnostics devices as per latest guidelines.
	• Demonstrate the basic functioning and operationof In-Vitro Diagnostics devices.
	• Prepare a chart depicting various components of the In-Vitro Diagnostics devices.

Classroom Aids:	
Charts, Models, Video presentation, Flip Chart, White-Board/Smart Board, Marker, Duster	
Tools, Equipment and Other Requirements	
Dummy In-Vitro Diagnostics devices as listed in CDSCO guidelines	

Module 2: Fundamentals on installation, set-up, repair, maintenance, calibration and biomedical instrumentation services for In-Vitro Diagnostics devices

Mapped to: HSS/N0924

Terminal Outcomes:

- Perform installation and setting-up of the In-Vitro Diagnostics devices.
- Maintain defined periodicity of calibration, repair and maintenance of In-Vitro Diagnostics devices.
- Carry out activities in compliance with all relevant laws, regulations, and codes for technology and technical safety laid down by regulatory bodies.

Duration: *10:00*	**Duration**: *15:00*
Theory – Key Learning Outcomes	**Practical – Key Learning Outcomes**
• Discuss steps of procurement of the In-Vitro Diagnostics devices on a qualitative, reasonable, timely and priority basis as per the consumer demand/specifications. • Discuss ways of finding the best possible manufactures, vendors, suppliers, service providers and third-party interface for procurement and set up the In-Vitro Diagnostics devices. • Discuss specific points to remember for calibration and maintenance checklist for In-Vitro Diagnostics devices. • Discuss necessary documentation required for each step, each person and each stakeholder involved in successful installation, calibration, preventive maintenance, technical assistance and repair of In-Vitro Diagnostics devices as per policies, regulations and specifications. • State the relevant laws, regulations, and codes for technology and technical safety laid down by regulatory bodies for setting up and operationalization of In-Vitro Diagnostics devices. • Identify specific safety hazards, troubleshooting techniques and the corrective measures to be taken with respect to In-Vitro Diagnostics devices. • Discuss the escalation matrix to handle safety hazards with respect to In-Vitro Diagnostics devices. • Discuss the standard biological precautions to be taken during diagnosis, repair, calibration and final testing/ verification of In-Vitro Diagnostics devices.	• Prepare a work-plan for the installation, calibration, preventive maintenance, technical assistance and repair of In-Vitro Diagnostics devices indicating the deliverables, timelines, requisites, involved personnel, supportive equipment, tools, resources, and regulatory pre-requisites. • Prepare a sample work order depicting various specifications related to In-Vitro Diagnostics devices. • Demonstrate the basic steps involved in facilitating periodic calibration, repair, maintenance and troubleshooting of In-Vitro Diagnostics devices using the sample service manuals and circuit diagrams. • Demonstrate basic steps for facilitating the delivery, installation and set-up of In-Vitro Diagnostics devices in mock set-up. • Perform a role play demonstrating post-installation instructions and user maintenance checklist for In-Vitro Diagnostics devices.
Classroom Aids:	
Charts, Models, Video presentation, Flip Chart, White-Board/Smart Board, Marker, Duster	
Tools, Equipment and Other Requirements	
Dummy In-Vitro Diagnostics devices as listed in CDSCO guidelines	

Mandatory Duration: *30:00*	**Recommended Duration:** *00:00*
Module Name: On-the-Job Training **Location: On Site**	
Terminal Outcomes • provide, or coordinate the provision of, appropriate information related to the set-up, features, routine use, trouble shooting, cleaning, and maintenance of all equipment provided • provide relevant information and/or instructions about infection control issues related to the use of all equipment provided • ensure that the hospital staff can use all equipment provided safely and effectively • make sure training and instructions provided to the hospital staff shall be commensurate with the risks, complexity, and manufacturer's instructions and/or specifications for the equipment • document all training and communication in the providers record, including the date, time, and signature of the person providing the service • demonstrate installation, set-up, operation, calibration, maintenance, internal components and functional verification testing of all equipment provided	

Annexure

Trainer Requirements

Trainer Prerequisites						
Minimum Educational Qualification	**Specialization**	**Relevant Industry Experience**		**Training Experience**		**Remarks**
		Years	***Specialization***	***Years***	***Specialization***	
B.E./B.Tech.	Bio-medical Engineer	1				
B.Sc.	Bio-medical Instrumentation	2				
B.E./B.Tech.	Electrical/ Mechanical Engineering	3	Biomedical instrumentation			

Trainer Certification	
Domain Certification	**Platform Certification**
Certified for Job Role: "In-Vitro Diagnostics (IVD) devices Services" mapped to NOS: "HSS/N0924, v1.0" with minimum score of 80%.	Recommended that the Trainer is certified for the Job Role: "Trainer (VET and Skills)", mapped to the Qualification Pack: "MEP/Q2601, v2.0" with minimum score of 80%.

Assessor Requirements

Assessor Prerequisites						
Minimum Educational Qualification	**Specialization**	**Relevant Industry Experience**		**Training/Assessment Experience**		**Remarks**
		Years	***Specialization***	***Years***	***Specialization***	
B.E./B.Tech.	Bio-medical Engineer	1				
B.Sc.	Bio-medical Instrumentation	2				
B.E./B.Tech.	Electrical/ Mechanical Engineering	3	Biomedical instrumentation			

Assessor Certification	
Domain Certification	**Platform Certification**
Certified for Job Role: "In-Vitro Diagnostics (IVD) devices Services" mapped to NOS: "HSS/N0924, v1.0" with minimum score of 80%.	Recommended that the Assessor is certified for the Job Role: "Assessor (VET and Skills)", mapped to the Qualification Pack: "MEP/Q2701, v2.0" with minimum score of 80%.

Assessment Strategy

The emphasis is on 'learning-by-doing' and practical demonstration of skills and knowledge based on the performance criteria. Accordingly, assessment criteria for each job role is set and made available in qualification pack.

The assessment papers for both theory and practical would be developed by Subject Matter Experts (SME) hired by Healthcare Sector Skill Council or with the HSSC accredited Assessment Agency as per the assessment criteria mentioned in the Qualification Pack. The assessments papers would also be checked for the various outcome-based parameters such as quality, time taken, precision, tools and equipment requirement etc.

Each NOS in the Qualification Pack (QP) is assigned a relative weightage for assessment based on the criticality of the NOS. Therein each Element/Performance Criteria in the NOS is assigned marks on relative importance, criticality of function and training infrastructure.

The following tools would be used for final assessment:

1. Practical Assessment: This comprises of a creation of mock environment in the skill lab which is equipped with all equipment required for the qualification pack.

Candidate's soft skills, communication, aptitude, safety consciousness, quality consciousness etc. is ascertained by observation and marked in observation checklist. The outcome is measured against the specified dimensions and standards to gauge the level of their skill achievements.

2. Viva/Structured Interview: This tool is used to assess the conceptual understanding and the behavioral aspects with regard to the job role and the specific task at hand. It also includes questions on safety, quality, environment and equipment etc.

3. On-Job Training: OJT would be evaluated based on standard log book capturing departments worked on, key observations of learner, feedback and remarks of supervisor or mentor.

4. Written Test: Question paper consisting of 100 MCQs (Hard:40, Medium:30 and Easy: 30) with questions from each element of each NOS. The written assessment paper is comprised of following types of questions:

i. True / False Statements
ii. Multiple Choice Questions
iii. Matching Type Questions.
iv. Fill in the blanks
v. Scenario based Questions
vi. Identification Questions

QA Regarding Assessors:

Assessors are selected as per the "eligibility criteria" laid down by HSSC for assessing each job role. The assessors selected by Assessment Agencies are scrutinized and made to undergo training and introduction to HSSC Assessment Framework, competency-based assessments, assessors guide etc. HSSC conducts "Training of Assessors" program from time to time for each job role and sensitize

assessors regarding assessment process and strategy which is outlined on following mandatory parameters:

1) Guidance regarding NSQF
2) Qualification Pack Structure
3) Guidance for the assessor to conduct theory, practical and viva assessments
4) Guidance for trainees to be given by assessor before the start of the assessments.
5) Guidance on assessments process, practical brief with steps of operations practical observation checklist and mark sheet
6) Viva guidance for uniformity and consistency across the batch.
7) Mock assessments
8) Sample question paper and practical demonstration

References

Glossary

Term	Description
Declarative Knowledge	Declarative knowledge refers to facts, concepts and principles that need to be known and/or understood in order to accomplish a task or to solve a problem.
Key Learning Outcome	Key learning outcome is the statement of what a learner needs to know, understand and be able to do in order to achieve the terminal outcomes. A set of key learning outcomes will make up the training outcomes. Training outcome is specified in terms of knowledge, understanding (theory) and skills (practical application).
OJT (M)	On-the-job training (Mandatory); trainees are mandated to complete specified hours of training on site
OJT (R)	On-the-job training (Recommended); trainees are recommended the specified hours of training on site
Procedural Knowledge	Procedural knowledge addresses how to do something, or how to perform a task. It is the ability to work, or produce a tangible work output by applying cognitive, affective or psychomotor skills.
Training Outcome	Training outcome is a statement of what a learner will know, understand and be able to do **upon the completion of the training**.
Terminal Outcome	Terminal outcome is a statement of what a learner will know, understand and be able to do **upon the completion of a module.** A set of terminal outcomes help to achieve the training outcome.

Acronyms and Abbreviations

Term	Description
QP	Qualification Pack
NSQF	National Skills Qualification Framework
NSQC	National Skills Qualification Committee
NOS	National Occupational Standards
CPR	Cardio-pulmonary Resuscitation
PPE	Personal Protective Equipment