

National Occupational Standards

In-Vitro Diagnostics (IVD) devices services

Unit Code: HSS/N0924

Version: 1.0

NSQF Level: 4

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

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Description

This is an upskilling course to prepare individuals with skills to install, set-up, repair, maintain, calibrate and provide biomedical instrumentation Services for the defined medical equipment and devices. They would also be able to provide post-installation instructions to hospital/facility staff along with management of inventory, documentation and supply chain.

Scope

The scope covers the following :

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

Elements and Performance Criteria

Perform installation and setting-up of the defined medical equipment and devices.

To be competent, the user/individual on the job must be able to:

- PC1.** Plan the bio-medical instrumentation set-up of defined medical equipment and devices as per the consumer demand/specifications in terms of the inclusions, exclusions and mandatory medical equipment, support equipment/tools, different types of resources and regulatory requirements
- PC2.** Plan the procurement of the planned equipment/others on a qualitative, reasonable, timely and priority basis as per the consumer demand/specifications.
- PC3.** Able to find the best possible manufactures, vendors, suppliers, service providers and third-party interface for procurement and set up the bio-medical instrumentation in radiology department in accordance of planning.
- PC4.** Prepare and collect necessary documentation for each step, each person and each stake holders involved in successful installation and operation of defined medical equipment and devices as per policies, regulations and specifications.
- PC5.** Prepare a work-plan for the bio-medical instrumentation set-up, preventive maintenance, technical assistance and repair indicating the deliverables, timelines, requisites & involved personnel.
- PC6.** Co-ordinate delivery, Installation and set-up of the defined medical equipment and devices

Maintain defined periodicity of calibration, repair and maintenance of the defined medical equipment and devices.

To be competent, the user/individual on the job must be able to:

- PC7.** Apply the principles of operation of the defined medical equipment and devices during their inspection, performance evaluation, calibration, testing, etc.
- PC8.** Provide post-installation technical assistance and instruction to the hospital staff on the installed medical equipment, operation and maintenance safely and correctly.
- PC9.** Conduct scheduled calibration and periodic preventive maintenance
- PC10.** Maintain inventory and supply chain of parts and supplies

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- PC11.** Diagnose, repair and provide on-call and on-site assistance for equipment malfunctions.
- PC12.** Schedule and oversee third party repair and maintenance work
- PC13.** Describe and follow safety procedures while working with the equipment and at the workplace
- PC14.** Identify safety hazards in the workplace and apply knowledge of responsibilities for notification
- PC15.** Use appropriate personal protective clothing, equipment and personnel monitoring devices required while handling electricity, fire, radiations, radio-active materials and other possible exposures
- PC16.** Ensure maintenance documentation starts with Incoming Inspection, all corrective action and preventive maintenance notations, manufacturer and/or service support documents, and equipment final disposition
- PC17.** Ensure management reports reflect all appropriate equipment histories

Carry out activities in compliance with all relevant laws, regulations, and codes for technology and technical safety laid down by regulatory bodies

To be competent, the user/individual on the job must be able to:

- PC18.** Comply the regulations laid down by regulatory bodies for setting up and operationalization of defined medical equipment and devices.
- PC19.** Ensure provision of all types of PPE (personal protective equipment) required while handling electricity, fire, radiation, radio-active materials and other possible exposures
- PC20.** Ensure proper risk assessment and control of PPE program in context of defined medical equipment and devices.
- PC21.** Ensure proper documentation in accordance of special regulations of defined medical equipment and devices.
- PC22.** Ensure action is annotated within Maintenance Management System according to departmental policy
- PC23.** Keep abreast of the latest technology or new medical equipment/device under category of the defined medical equipment and devices as per latest guidelines

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** List the various types of defined medical equipment and devices required in the healthcare settings
- KU2.** Discuss the basic features, specifications, functioning, risk category and operation of the defined medical equipment and devices listed as per the latest guidelines.
- KU3.** List all possible spare parts, tools, different types of resources, and regulatory requirements for successful installation and operation of the defined medical equipment and devices.
- KU4.** Identify the circuits of the defined medical equipment and devices.
- KU5.** Identify the electronic components in the defined medical equipment and devices.
- KU6.** Identify different types of cables and connectors used in the defined medical equipment and devices.
- KU7.** Identify the types of socket outlets, plugs and wiring of sockets and plugs in the defined medical equipment and devices.

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- KU8.** Discuss steps of procurement of the defined medical equipment and devices on a qualitative, reasonable, timely and priority basis as per the consumer demand/specifications.
- KU9.** Discuss ways of finding the best possible manufactures, vendors, suppliers, service providers and third-party interface for procurement and set up the defined medical equipment and devices.
- KU10.** Discuss specific points to remember for calibration and maintenance checklist for the defined medical equipment and devices.
- KU11.** Discuss necessary documentation required for each step, each person and each stakeholder involved in successful installation, calibration, preventive maintenance, technical assistance and repair of the defined medical equipment and devices as per policies, regulations and specifications.
- KU12.** State the relevant laws, regulations, and codes for technology and technical safety laid down by regulatory bodies for setting up and operationalization of the defined medical equipment and devices.
- KU13.** Identify specific safety hazards, troubleshooting techniques and the corrective measures to be taken with respect to the defined medical equipment and devices.
- KU14.** Discuss the escalation matrix to handle safety hazards with respect to the defined medical equipment and devices.
- KU15.** Discuss the standard biological precautions to be taken during diagnosis, repair, calibration and final testing/ verification of the defined medical equipment and devices.

Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** Manage work efficiently in the professional practice of bio-medical instrumentation services
- GS2.** Demonstrate communication skills while facilitating biomedical instrumentation services for medical equipment

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Perform installation and setting-up of the defined medical equipment and devices.</i>	30	40	30	40
PC1. Plan the bio-medical instrumentation set-up of defined medical equipment and devices as per the consumer demand/specifications in terms of the inclusions, exclusions and mandatory medical equipment, support equipment/tools, different types of resources and regulatory requirements	-	-	-	-
PC2. Plan the procurement of the planned equipment/others on a qualitative, reasonable, timely and priority basis as per the consumer demand/specifications.	-	-	-	-
PC3. Able to find the best possible manufactures, vendors, suppliers, service providers and third-party interface for procurement and set up the bio-medical instrumentation in radiology department in accordance of planning.	-	-	-	-
PC4. Prepare and collect necessary documentation for each step, each person and each stake holders involved in successful installation and operation of defined medical equipment and devices as per policies, regulations and specifications.	-	-	-	-
PC5. Prepare a work-plan for the bio-medical instrumentation set-up, preventive maintenance, technical assistance and repair indicating the deliverables, timelines, requisites & involved personnel.	-	-	-	-
PC6. Co-ordinate delivery, Installation and set-up of the defined medical equipment and devices	-	-	-	-
<i>Maintain defined periodicity of calibration, repair and maintenance of the defined medical equipment and devices.</i>	30	40	30	40
PC7. Apply the principles of operation of the defined medical equipment and devices during their inspection, performance evaluation, calibration, testing, etc.	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC8. Provide post-installation technical assistance and instruction to the hospital staff on the installed medical equipment, operation and maintenance safely and correctly.	-	-	-	-
PC9. Conduct scheduled calibration and periodic preventive maintenance	-	-	-	-
PC10. Maintain inventory and supply chain of parts and supplies	-	-	-	-
PC11. Diagnose, repair and provide on-call and on-site assistance for equipment malfunctions.	-	-	-	-
PC12. Schedule and oversee third party repair and maintenance work	-	-	-	-
PC13. Describe and follow safety procedures while working with the equipment and at the workplace	-	-	-	-
PC14. Identify safety hazards in the workplace and apply knowledge of responsibilities for notification	-	-	-	-
PC15. Use appropriate personal protective clothing, equipment and personnel monitoring devices required while handling electricity, fire, radiations, radio-active materials and other possible exposures	-	-	-	-
PC16. Ensure maintenance documentation starts with Incoming Inspection, all corrective action and preventive maintenance notations, manufacturer and/or service support documents, and equipment final disposition	-	-	-	-
PC17. Ensure management reports reflect all appropriate equipment histories	-	-	-	-
<i>Carry out activities in compliance with all relevant laws, regulations, and codes for technology and technical safety laid down by regulatory bodies</i>	10	20	15	20
PC18. Comply the regulations laid down by regulatory bodies for setting up and operationalization of defined medical equipment and devices.	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC19. Ensure provision of all types of PPE (personal protective equipment) required while handling electricity, fire, radiation, radio-active materials and other possible exposures	-	-	-	-
PC20. Ensure proper risk assessment and control of PPE program in context of defined medical equipment and devices.	-	-	-	-
PC21. Ensure proper documentation in accordance of special regulations of defined medical equipment and devices.	-	-	-	-
PC22. Ensure action is annotated within Maintenance Management System according to departmental policy	-	-	-	-
PC23. Keep abreast of the latest technology or new medical equipment/device under category of the defined medical equipment and devices as per latest guidelines	-	-	-	-
NOS Total	70	100	75	100

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National Occupational Standards (NOS) Parameters

NOS Code	HSS/N0924
NOS Name	In-Vitro Diagnostics (IVD) devices services
Sector	Healthcare
Sub-Sector	
Occupation	Medical Device and Equipment Occupations & Services
NSQF Level	4
Credits	3
Minimum Job Entry Age	18
Minimum Educational Qualification & Experience	12th grade Pass with 1.5 years of experience biomedical instrumentation services OR Certificate-NSQF (Medical Equipment Assistant, Biomedical Equipment technician) with 1.5 years of experience biomedical instrumentation services
Version	1.0
Last Reviewed Date	18/02/2025
Next Review Date	18/02/2028
NSQF Clearance Date	18/02/2025
Reference code on NQR	NG-04-HE-03777-2025-V1-HSSC
NQR Version	1
CCN Category	1