Qualification Pack

Junior Engineer-EMI/EMC testing for Medical Devices and IVD

QP Code: LFS/Q6302

Version: 1.0

NSQF Level: 5.5

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LFS/Q6302: Junior Engineer-EMI/EMC testing for Medical Devices and IVD

Brief Job Description

Junior Engineer - EMI/EMC testing for Medical Devices and IVD is responsible for planning, conducting, and analysing electromagnetic compatibility tests on medical devices to ensure compliance with regulatory standards. The person is responsible for preparing the documents for reporting the test results and ensures ISO/IEC 17025 testing facility . He/she also carries out the validation of testing protocols and evaluating risk assessment as per ISO 14971

Personal Attributes

The individual should have good communication skills in the regional language and able to comprehend the instructions and process documents in the English language. He/she should have good analytical skills. The job holder should be able to give attention to detail and understand the criticality of work.

Applicable National Occupational Standards (NOS)

Compulsory NOS:

1. LFS/N6301: Adherence to Environment, Health and Safety as per guidelines

2. LFS/N6306: Perform checks in the testing lab before and after the start of EMI/EMC testing for medical devices and IVD

3. LFS/N6303: Analyze and evaluate the risk assessment as per ISO 14971

4. LFS/N6307: Perform EMI/EMC testing for Medical devices and IVD in compliance with regulatory guidelines

5. LFS/N6305: Perform result analysis, reporting and documentation to meet quality and regulatory standards

6. LFS/N0134: Coordinate and communicate with reporting supervisor/engineer, teams and auditors

7. DGT/VSQ/N0102: Employability Skills (60 Hours)

Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Quality-Medical Devices and IVD

Country	India
NSQF Level	5.5
Credits	18
Aligned to NCO/ISCO/ISIC Code	NCO-2015-2143.0200, 2143.0300

Minimum Educational Qualification & Experience	Graduate (Engineering in Electronics/Electric/mechatronics, Computer Science, IT or related fields)
	     OR
	Completed 2nd year diploma after 12th (Engineering (after 12th Class) approved by AICTE or State Technical Education Body in relevant Field (Electronics/Electric/mechatronics, Computer Science, IT or related fields,)) with 1 Year of experience
	     OR
	Completed 3 year diploma after 10th (Engineering (after 10th Class) approved by AICTE or State Technical Education Body in relevant Field (Electronics/Electric/mechatronics, Computer Science, IT or related fields,)) with 2 Years of experience

Minimum Level of Education for Training in School	
Pre-Requisite License or Training	NA
Minimum Job Entry Age	19 Years
Last Reviewed On	NA
Next Review Date	01/11/2026
NSQC Approval Date	01/11/2023
Version	1.0
Reference code on NQR	QG-5.5-LS-01271-2023-V1-LSSSDC
NQR Version	1.0

LFS/N6301: Adherence to Environment, Health and Safety as per guidelines

Description

This NOS is about adherence to environment, health and safety as per guidelines

Scope

The scope covers the following :

- The scope of NOS are:
- Adhere to health and hygiene protocols
- Adhere to safety and security procedures
- Follow emergency procedures

Elements and Performance Criteria

Adhere to Health and Hygiene Protocols

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

PC1. comply with health and personal hygiene-related protocols as per regulatory guidelines

PC2. sanitize your hands before entering in Testing lab area and ensure the adherence of same by subordinates

PC3. report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person

PC4. take preventive actions on the report of any allergy, sickness or any other environment related breach by subordinates

PC5. wear lab equipments like close-toed shoes, coat, etc., all the time while working in Testing lab area and ensure adherence of the same by every person visiting/ working in the Testing facility

PC6. Ensure proper disposal of used accessories

Adhere to Safety and Security Procedures

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

PC7. comply with safety and security policies and procedures

PC8. use appropriate safety gears like gowns, shoecover, headgear, masks, gloves and other relevant safety accessories as per regulatory guidelines throughout the process

PC9. report any identified breaches in safety and security policies and procedures to the designated person

PC10. use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools

PC11. comply with material handling, segregation, storage, and MSDS guidelines as per 5S system

PC12. segregate material and follow the 5S system at the storage area

PC13. record the details of completed safety drills and training

Follow Emergency Procedures

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

PC14. raise the alarm and report any hazards which is not competent to deal with, to the relevant person in line with organizational procedures and warn other people who may get affected

PC15. inform the concerned person immediately about every unsafe act/ incident

PC16. follow emergency protocol for any alarms and ensure the safety of subordinates in the area

PC17. follow emergency protocols efficiently

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. individual's role and responsibilities in maintaining healthy, hygienic, safe and secure working environment

KU2. company's procedures and protocols for the environment, health and safety

KU3. relevant legislative requirements as per local laws

KU4. implications that any non-compliance with health, safety and security may have on individuals and the organization

KU5. workplace hazards in the manufacturing/ research facility in the life sciences sector and reporting procedures for unhealthy/ unsafe act/incidents, hazards and accident as per regulatory guidelines

KU6. limits of individual responsibility for dealing with hazards

KU7. relevant testing facility substances, their characteristics, and required precaution and safety measures

KU8. testing facility specialized wearables

KU9. the organization's emergency procedures for different emergency situations and the importance of following these

KU10. evacuation procedures for employees, contract staff and visitors

KU11. procedure to summon medical assistance and the emergency services, where necessary

KU12. different types of breaches in the environment, health, safety and security and how and when to report these

KU13. WHO guidelines for personal hygiene

KU14. types of safety gears and procedure to use them

KU15. importance of material segregation and 5s system

KU16. guidelines for handling and storing hazardous material

KU17. ISO/IEC17025 guidelines for testing facility

Generic Skills (GS)

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

GS1. use reading and comprehension skills to read instructions, guidelines, procedures, rules, and signages

GS2. use written communication skills to accurately record every information required to be reported as per SOP and regulatory guidelines in the language prescribed by the company's SOP

GS3. apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements

GS4. use critical thinking skills to ascertain the breach/ compliance of EHS protocols

GS5. apply customer centricity to remain compliant with data integrity rules and regulatory guideline to evaluate impact of wrongdoings

GS6. apply decision-making skills to make balanced judgments within the authority in different situations while dealing with hazards and breaches

GS7. apply problem-solving skills to find solutions for workflow-related difficulties

GS8. use verbal communication skills to communicate with supervisor/ manager/ EHS Incharge or any other concerned authority clearly for escalating any emergency situation or hazard

GS9. Identify and resolve the issues and challenges

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Adhere to Health and Hygiene Protocols	**10**	**10**	**5**	**5**
PC1. comply with health and personal hygiene-related protocols as per regulatory guidelines	-	-	-	-
PC2. sanitize your hands before entering in Testing lab area and ensure the adherence of same by subordinates	-	-	-	-
PC3. report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person	-	-	-	-
PC4. take preventive actions on the report of any allergy, sickness or any other environment related breach by subordinates	-	-	-	-
PC5. wear lab equipments like close-toed shoes, coat, etc., all the time while working in Testing lab area and ensure adherence of the same by every person visiting/ working in the Testing facility	-	-	-	-
PC6. Ensure proper disposal of used accessories	-	-	-	-
Adhere to Safety and Security Procedures	**10**	**15**	**5**	**5**
PC7. comply with safety and security policies and procedures	-	-	-	-
PC8. use appropriate safety gears like gowns, shoecover, headgear, masks, gloves and other relevant safety accessories as per regulatory guidelines throughout the process	-	-	-	-
PC9. report any identified breaches in safety and security policies and procedures to the designated person	-	-	-	-
PC10. use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools	-	-	-	-
PC11. comply with material handling, segregation, storage, and MSDS guidelines as per 5S system	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. segregate material and follow the 5S system at the storage area	-	-	-	-
PC13. record the details of completed safety drills and training	-	-	-	-
Follow Emergency Procedures	**10**	**15**	**5**	**5**
PC14. raise the alarm and report any hazards which is not competent to deal with, to the relevant person in line with organizational procedures and warn other people who may get affected	-	-	-	-
PC15. inform the concerned person immediately about every unsafe act/ incident	-	-	-	-
PC16. follow emergency protocol for any alarms and ensure the safety of subordinates in the area	-	-	-	-
PC17. follow emergency protocols efficiently	-	-	-	-
NOS Total	**30**	**40**	**15**	**15**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N6301
NOS Name	Adherence to Environment, Health and Safety as per guidelines
Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Quality-Medical Devices and IVD
NSQF Level	5
Credits	1.0
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023

LFS/N6306: Perform checks in the testing lab before and after the start of EMI/EMC testing for medical devices and IVD

Description

This NOS is about performing checks in the testing lab before and after the start of EMI/EMC testing for medical devices and IVD

Scope

The scope covers the following :

- The scope of NOS are:
- Laboratory-specific routine checks
- Environment Sustainability
- Activities after completion of work

Elements and Performance Criteria

Laboratory-specific routine checks

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

PC1. ensure the use of PPE before entering the testing facility area as per SOP

PC2. perform proper cleaning of machinery and equipments before the start work

PC3. ensure all necessary documentation, including requirement and test standards , test protocols, standard operating procedures (SOPs), and any required permits or licenses are in place

PC4. ensure adequate validation for the work being carried out as per SOP for test method and work instruction to operate the instruments

PC5. conduct regular checks for lab equipment and instrument for their calibration and validation state as per schedule

PC6. ensure out of order/ non calibrated/ non validated equipment are labelled and segregated for maintenance

PC7. segregate and store the material with an appropriate label in designated places

PC8. ensure logbook entries of all the test performed are done as per SOP

Environment Sustainability

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

PC9. ensure energy conservation by switching off the machine and equipment post operations

PC10. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes

PC11. ensure energy conservation by optimizing the machine/ equipment performance

PC12. identify recyclable and non-recyclable, and hazardous waste generated

PC13. segregate waste into different categories to achieve minimum pollution of land and water

Activities after completion of work

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

PC14. ensure proper labelling of tested sample in designated places

PC15. ensure removal of scrap material from work area

PC16. ensure cleaning of the equipment after every testing as per SOP

PC17. ensure clean and dry area after completion of work as per SOP

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. the different PPE and their use in the testing facility

KU2. the different regulatory guidelines like ISO/IEC17025, ISO 14971, IEC 60601-1 and others

KU3. the organizational coding system of different material and equipment

KU4. the quality specifications and policy of the company

KU5. the environment sustainbility guidelines

KU6. the levels of hygiene required for the workplace and the importance of maintaining the same

KU7. the escalation procedures for soils or stains that could not be removed

KU8. the requirements for EMI/EMC testing

KU9. the properties of equipments and their working principle

KU10. the procedure for reporting incidents where standard operating procedures are not followed

KU11. the units of measurement of temperature, humidity and pressure

KU12. worksheets, logbooks, date and time formats to be followed in a medical devic testing facility

Generic Skills (GS)

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

GS1. use reading and comprehension skills to gauge the relevant information manuals, SOPs, health and safety instructions, memos, reports, job cards, and notes/comments

GS2. use problem-solving skills in dealing with any deviation from SOPs and day-today problems

GS3. use critical skills in analyzing any situation which needs an immediate escalation or emergency alarm

GS4. use critical skills in analyzing impact of pollution and hazards to the environment and living beings in every activity

GS5. use written communication skills to record and communicate details of work done to appropriate stakeholders by using written/typed report or computer-based record/electronic mail

GS6. apply critical skills to analyze and identify when to report an issue/concern to the supervisor and to deal with a colleague individually, depending on the type of concern

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Laboratory-specific routine checks	**10**	**10**	**5**	**5**
PC1. ensure the use of PPE before entering the testing facility area as per SOP	-	-	-	-
PC2. perform proper cleaning of machinery and equipments before the start work	-	-	-	-
PC3. ensure all necessary documentation, including requirement and test standards , test protocols, standard operating procedures (SOPs), and any required permits or licenses are in place	-	-	-	-
PC4. ensure adequate validation for the work being carried out as per SOP for test method and work instruction to operate the instruments	-	-	-	-
PC5. conduct regular checks for lab equipment and instrument for their calibration and validation state as per schedule	-	-	-	-
PC6. ensure out of order/ non calibrated/ non validated equipment are labelled and segregated for maintenance	-	-	-	-
PC7. segregate and store the material with an appropriate label in designated places	-	-	-	-
PC8. ensure logbook entries of all the test performed are done as per SOP	-	-	-	-
Environment Sustainability	**10**	**15**	**5**	**5**
PC9. ensure energy conservation by switching off the machine and equipment post operations	-	-	-	-
PC10. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes	-	-	-	-
PC11. ensure energy conservation by optimizing the machine/ equipment performance	-	-	-	-
PC12. identify recyclable and non-recyclable, and hazardous waste generated	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC13. segregate waste into different categories to achieve minimum pollution of land and water	-	-	-	-
Activities after completion of work	**10**	**15**	**5**	**5**
PC14. ensure proper labelling of tested sample in designated places	-	-	-	-
PC15. ensure removal of scrap material from work area	-	-	-	-
PC16. ensure cleaning of the equipment after every testing as per SOP	-	-	-	-
PC17. ensure clean and dry area after completion of work as per SOP	-	-	-	-
NOS Total	**30**	**40**	**15**	**15**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N6306
NOS Name	Perform checks in the testing lab before and after the start of EMI/EMC testing for medical devices and IVD
Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Quality-Medical Devices and IVD
NSQF Level	5.5
Credits	3
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023

LFS/N6303: Analyze and evaluate the risk assessment as per ISO 14971

Description

This NOS is about analyzing and evaluating the risk assessment as per ISO 14971

Scope

The scope covers the following :

- The scope of NOS are :
- Perform analysis of risk assessment
- Risk Mitigation support for research

Elements and Performance Criteria

Perform analysis of risk assessment

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

PC1. identifying potential hazards and risks associated with medical devices, both in the design and function

PC2. perform thorough risk analysis, including risk estimation and evaluation using tools like FMEA (Failure Modes and Effects Analysis) and fault free analysis

PC3. effectively document risk level after risk assessments by creating Risk Management Files as required by ISO 14971

PC4. collect, analyze, and interpret data related to risk assessments

PC5. communicate risk assessments findings effectively within cross-functional teams and with stakeholders

PC6. prepare documents for audit and participate in regulatory audits and inspections, ensuring compliance with ISO 14971 and related standards

PC7. ensure compliance with any potential legal and liability implications associated with risk management

Risk mitigation support for research

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

PC8. develop risk mitigation strategies that can be applied practically to minimize risks in medical devices

PC9. ensure monitoring and follow control mechanisms to track the effectiveness of risk mitigation measures

PC10. evaluate ethical implications of risk assessment and mitigation in research of medical device, particularly in ensuring the safety and integrity of research participants and data

PC11. follow integration of risk assessment and mitigation into the overall research project management framework

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. internal product standards finalized within the organization

KU2. quality norms and standards prescribed in the Quality Manual by the organization

KU3. Safety norms and 5S practiced in the organization

KU4. different parameters used to evaluate the performance of the medical devices

KU5. process for setting up of test benches, test platforms and test apparatus

KU6. basic laws of physics, chemistry, metallurgy & mathematics

KU7. various defects related to running medical devices and potential impact on the working of the final medical devices

KU8. mandatory checks which need to be conducted on medical devices

Generic Skills (GS)

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

GS1. use reading and comprehending skills to read and understand manuals, SOPs, health and safety instructions

GS2. use written communication skills to draft reports or electronic mails to communicate the details of work done to appropriate people

GS3. use problem-solving skills in dealing with any deviation from SOPs and day-today problems

GS4. use critical skills in analyzing any situation which needs an immediate escalation or emergency alarm

GS5. apply problem-solving skills to find solutions for workflow-related difficulties using concepts of basic sciences Physics, mathematics, statistics

GS6. use planning and organizing skills in every activity planned and performed in production operations and to achieve resource optimization

GS7. apply analytical skill to observe and identify OOS/ OOT/ deviations in the process

GS8. apply decision making skills to take balanced judgments within the authority while dealing with daily work-life situations

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Perform analysis of risk assessment	**20**	**20**	**5**	**5**
PC1. identifying potential hazards and risks associated with medical devices, both in the design and function	-	-	-	-
PC2. perform thorough risk analysis, including risk estimation and evaluation using tools like FMEA (Failure Modes and Effects Analysis) and fault free analysis	-	-	-	-
PC3. effectively document risk level after risk assessments by creating Risk Management Files as required by ISO 14971	-	-	-	-
PC4. collect, analyze, and interpret data related to risk assessments	-	-	-	-
PC5. communicate risk assessments findings effectively within cross-functional teams and with stakeholders	-	-	-	-
PC6. prepare documents for audit and participate in regulatory audits and inspections, ensuring compliance with ISO 14971 and related standards	-	-	-	-
PC7. ensure compliance with any potential legal and liability implications associated with risk management	-	-	-	-
Risk mitigation support for research	**20**	**20**	**5**	**5**
PC8. develop risk mitigation strategies that can be applied practically to minimize risks in medical devices	-	-	-	-
PC9. ensure monitoring and follow control mechanisms to track the effectiveness of risk mitigation measures	-	-	-	-
PC10. evaluate ethical implications of risk assessment and mitigation in research of medical device, particularly in ensuring the safety and integrity of research participants and data	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC11. follow integration of risk assessment and mitigation into the overall research project management framework	-	-	-	-
NOS Total	**40**	**40**	**10**	**10**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N6303
NOS Name	Analyze and evaluate the risk assessment as per ISO 14971
Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Quality-Medical Devices and IVD
NSQF Level	5
Credits	2.0
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023

LFS/N6307: Perform EMI/EMC testing for Medical devices and IVD in compliance with regulatory guidelines

Description

This NOS is about performing EMI/EMC testing for Medical devices and IVD in compliance with regulatory guidelines

Scope

The scope covers the following :

- The scope of NOS are :
- Prepare for electrical testing
- Perform inspection of medical devices and its components cum accessories
- Test medical device and its components for faults in laboratory
- Conduct testing of medical device under running condition
- Perform post-testing activities

Elements and Performance Criteria

Prepare for electrical testing

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

PC1. interpret the SRF (Service request form) sheet and coordinate with the superior for confirming the testing tasks and type of tests required to be conducted on the Medical devices mapped with risk assessment file provided along with the product

PC2. identify, select and arrange the testing equipment as per SOP,WI required during the testing process

PC3. check the calibration status of testing equipment before the use

PC4. identify the testing parameters which need to be measured during the test procedure

PC5. place the medical device securely on the designated testing platforms/ benches as per the SOP

Perform inspection of medical devices and its accessories

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

PC6. follow safety instructions recommended as per SOP during the inspection and testing process

PC7. perform the visual inspection test for fault diagnosis as per the SOP

PC8. calibrate, align and adjust the settings of medical device as per the SOP and organizational standards

PC9. ensure part clearances as specified in the SOP

Test medical device and its components for faults in laboratory

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

PC10. set the test apparatus as per the selected testing process and SOPs

PC11. connect the various data capturing meters and gauges to capture the stress levels and other data points

PC12. check the working of the test apparatus post-connecting the test component/ medical device to ensure error free testing activity

PC13. diagnose faults in the various sensors, power supply lines, electrical and electronic circuits and aggregates etc. in the medical device by following senior's instructions as well as user manual and risk management file

PC14. conduct various tests such as Emission tests, Immunity test, Electrostatic Discharge Test, Harmonic Current Emission Test, Surge Immunity Test, Voltage Flicker & Fluctuations test, etc. as per SOP under the supervision as per IEC 60601-1-2

PC15. record observations/ readings as per the parameters mentioned in the testing manual/work instructions

PC16. make minor modification in test setup/medical device /component cum accessories under testing to take reading under different scenarios as per the requirement

PC17. observe any deviations, noise or vibrations during the testing process and inform the test supervisor about the same

Conduct testing of medical device under running condition

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

PC18. Check the medical device before starting the testing on medical device as per the checklist and required collateral standards requirements

PC19. check working of all the safety features and system warning indicators showing system failures, etc. of medical device as per the testing parameters

Perform post-testing activities

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

PC20. maintain and update the records test results, data log etc. as per SOP

PC21. report and document the errors in the medical devices to the supervisor

PC22. clean and store the tools, equipment and process auxiliaries as per SOP after completion of work

PC23. dispose off scrap or waste material in accordance with the company policies and environmental regulations

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. internal product standards finalized within the organization

KU2. quality norms and standards prescribed in the Quality Manual by the organization

KU3. Safety norms and 5S practiced in the organization

KU4. different parameters used to evaluate the performance of the medical devices

KU5. process for setting up of test benches, test platforms and test apparatus

KU6. basic laws of physics, chemistry, metallurgy & mathematics

KU7. various defects related to running medical devices and potential impact on the working of the final medical devices

KU8. mandatory checks which need to be conducted on medical devices

KU9. potential health and safety hazards and related safety precautions

Generic Skills (GS)

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

GS1. use reading and comprehending skills to read and understand manuals, SOPs, health and safety instructions

GS2. use written communication skills to draft reports or electronic mails to communicate the details of work done to appropriate people

GS3. use problem-solving skills in dealing with any deviation from SOPs and day-today problems

GS4. use critical skills in analyzing any situation which needs an immediate escalation or emergency alarm

GS5. apply problem-solving skills to find solutions for workflow-related difficulties using concepts of basic sciences Physics, mathematics, statistics

GS6. use planning and organizing skills in every activity planned and performed in production operations and to achieve resource optimization

GS7. apply analytical skill to observe and identify OOS/ OOT/ deviations in the process

GS8. apply decision making skills to take balanced judgments within the authority while dealing with daily work-life situations

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Prepare for electrical testing	**5**	**10**	**5**	**5**
PC1. interpret the SRF (Service request form) sheet and coordinate with the superior for confirming the testing tasks and type of tests required to be conducted on the Medical devices mapped with risk assessment file provided along with the product	-	-	-	-
PC2. identify, select and arrange the testing equipment as per SOP,WI required during the testing process	-	-	-	-
PC3. check the calibration status of testing equipment before the use	-	-	-	-
PC4. identify the testing parameters which need to be measured during the test procedure	-	-	-	-
PC5. place the medical device securely on the designated testing platforms/ benches as per the SOP	-	-	-	-
Perform inspection of medical devices and its accessories	**5**	**10**	**5**	**5**
PC6. follow safety instructions recommended as per SOP during the inspection and testing process	-	-	-	-
PC7. perform the visual inspection test for fault diagnosis as per the SOP	-	-	-	-
PC8. calibrate, align and adjust the settings of medical device as per the SOP and organizational standards	-	-	-	-
PC9. ensure part clearances as specified in the SOP	-	-	-	-
Test medical device and its components for faults in laboratory	**5**	**10**	**5**	**5**
PC10. set the test apparatus as per the selected testing process and SOPs	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC11. connect the various data capturing meters and gauges to capture the stress levels and other data points	-	-	-	-
PC12. check the working of the test apparatus post-connecting the test component/ medical device to ensure error free testing activity	-	-	-	-
PC13. diagnose faults in the various sensors, power supply lines, electrical and electronic circuits and aggregates etc. in the medical device by following senior's instructions as well as user manual and risk management file	-	-	-	-
PC14. conduct various tests such as Emission tests, Immunity test, Electrostatic Discharge Test, Harmonic Current Emission Test, Surge Immunity Test, Voltage Flicker & Fluctuations test, etc. as per SOP under the supervision as per IEC 60601-1-2	-	-	-	-
PC15. record observations/ readings as per the parameters mentioned in the testing manual/work instructions	-	-	-	-
PC16. make minor modification in test setup/medical device /component cum accessories under testing to take reading under different scenarios as per the requirement	-	-	-	-
PC17. observe any deviations, noise or vibrations during the testing process and inform the test supervisor about the same	-	-	-	-
Conduct testing of medical device under running condition	**2**	**5**	**3**	**2**
PC18. Check the medical device before starting the testing on medical device as per the checklist and required collateral standards requirements	-	-	-	-
PC19. check working of all the safety features and system warning indicators showing system failures, etc. of medical device as per the testing parameters	-	-	-	-
Perform post-testing activities	**3**	**5**	**2**	**3**

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC20. maintain and update the records test results, data log etc. as per SOP	-	-	-	-
PC21. report and document the errors in the medical devices to the supervisor	-	-	-	-
PC22. clean and store the tools, equipment and process auxiliaries as per SOP after completion of work	-	-	-	-
PC23. dispose off scrap or waste material in accordance with the company policies and environmental regulations	-	-	-	-
NOS Total	**20**	**40**	**20**	**20**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N6307
NOS Name	Perform EMI/EMC testing for Medical devices and IVD in compliance with regulatory guidelines
Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Quality-Medical Devices and IVD
NSQF Level	5.5
Credits	5.0
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023

LFS/N6305: Perform result analysis, reporting and documentation to meet quality and regulatory standards

Description

This NOS is about performing result analysis, reporting and documentation to meet quality and regulatory standards

Scope

The scope covers the following :

- The scope of NOS are :
- Reporting
- Recording and documentation
- Information Security

Elements and Performance Criteria

Reporting

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

PC1.   report defects/problem/incidents/quality issues/test results as applicable in a timely manner

PC2.   report to the appropriate authority as laid down by the company

PC3.   follow reporting procedures as prescribed by the test report format(TRF)

PC4.   work with quality team to provide feedback regarding quality standards and issues

PC5.   help other lab staff with any other testing required during the Quality test

Recording and documentation

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

PC6.   identify documentation to be completed relating to ones role

PC7.   record details accurately in an appropriate format

PC8.   accurately document the results of the inspections and testing

PC9.   maintain all controlled document files and test records in a timely and accurate manner

PC10.   ensure that the final document meets regulatory and compliance requirements

PC11.   make sure documents are available to all appropriate authorities to inspect

PC12.   evaluate problems and make initial recommendations for possible corrective action to supervise

PC13.   perform a review of records and other documentation for compliance to established procedures and good documentation practices

PC14.   write and update the inspection procedures, protocols, and checklists

PC15.   prepare inspection reports as per the inspection activity performed

Information Security

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

PC16.   document the results of the testing and analysis accurately

PC17. maintain all original and controlled document files and quality records in a timely and accurate manner following ALCOA PLUS principles

PC18. respond to requests for information in an appropriate manner whilst following organizational procedures

PC19. make sure documents are available to all appropriate authorities to inspect/ audit

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. the types of documentation in an organization and the importance of maintaining the same and different methods of recording information

KU2. the different methods of recording information

KU3. the reporting and recording formats

KU4. the importance of reporting incidents where standard operating procedures are not followed

KU5. the importance of complete and accurate documentation

KU6. the escalation matrix for reporting identified issues, hazards and breakage

KU7. the ALCOA PLUS Principles

KU8. the Good Documentation Practices

KU9. how to use lab information management system and software applications like MS Office

Generic Skills (GS)

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

GS1. use written communication skills to record accurately, legibly and clearly every information required to be reported as per SOP and GMP guidelines in English language

GS2. use written communication skills to maintain proper and concise records as per given format and compliant with ALCOA principle

GS3. use reading and comprehension skills to understand the various coding systems and to read instructions, guidelines, procedures, rules, and signage to understand the procedure to be followed

GS4. use listening skills to understand the instructions and procedures to be followed

GS5. use verbal communication skills to interact with supervisor, teammates, cross-functional teams for coordination and to communicate confidential and sensitive information discretely to the authorized person

GS6. apply problem-solving skills to find solutions for workflow-related difficulties

GS7. apply planning and organizing skills to plan and organize tools and material required to fulfil documentation related requirements

GS8. apply customer-centricity while interacting with different stakeholders

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Reporting	**10**	**10**	**5**	**5**
PC1. report defects/problem/incidents/quality issues/test results as applicable in a timely manner	-	-	-	-
PC2. report to the appropriate authority as laid down by the company	-	-	-	-
PC3. follow reporting procedures as prescribed by the test report format(TRF)	-	-	-	-
PC4. work with quality team to provide feedback regarding quality standards and issues	-	-	-	-
PC5. help other lab staff with any other testing required during the Quality test	-	-	-	-
Recording and documentation	**10**	**15**	**5**	**5**
PC6. identify documentation to be completed relating to ones role	-	-	-	-
PC7. record details accurately in an appropriate format	-	-	-	-
PC8. accurately document the results of the inspections and testing	-	-	-	-
PC9. maintain all controlled document files and test records in a timely and accurate manner	-	-	-	-
PC10. ensure that the final document meets regulatory and compliance requirements	-	-	-	-
PC11. make sure documents are available to all appropriate authorities to inspect	-	-	-	-
PC12. evaluate problems and make initial recommendations for possible corrective action to supervise	-	-	-	-
PC13. perform a review of records and other documentation for compliance to established procedures and good documentation practices	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC14. write and update the inspection procedures, protocols, and checklists	-	-	-	-
PC15. prepare inspection reports as per the inspection activity performed	-	-	-	-
Information Security	**10**	**15**	**5**	**5**
PC16. document the results of the testing and analysis accurately	-	-	-	-
PC17. maintain all original and controlled document files and quality records in a timely and accurate manner following ALCOA PLUS principles	-	-	-	-
PC18. respond to requests for information in an appropriate manner whilst following organizational procedures	-	-	-	-
PC19. make sure documents are available to all appropriate authorities to inspect/ audit	-	-	-	-
NOS Total	**30**	**40**	**15**	**15**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N6305
NOS Name	Perform result analysis, reporting and documentation to meet quality and regulatory standards
Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Quality-Medical Devices and IVD
NSQF Level	5
Credits	2.0
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023

LFS/N0134: Coordinate and communicate with reporting supervisor/engineer, teams and auditors

Description

This NOS is about coordinating and communicating with reporting supervisor/engineer, teams and auditors

Scope

The scope covers the following :

- The scope of NOS are:
- Coordination with reporting supervisor
- Coordination with colleagues and auditors
- Sensitivity towards all genders and people with disability

Elements and Performance Criteria

Coordination with Supervisor

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

PC1. receive work instructions from reporting supervisor

PC2. communicate to reporting supervisor about the progress on job allocated and device performance to the superiors

PC3. escalate problems to superiors that cannot be handled

PC4. communicate deviations / abnormal incidents to the reporting manager

PC5. communicate any potential hazards or expected process disruptions to the manager

Coordination with colleagues and auditors

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

PC6. support team members and colleagues of other departments in work

PC7. resolve inter-personnel conflicts and achieve smooth workflow

PC8. deposit faulty modules and tools to stores

PC9. explain what information means and how it can be used by team members

PC10. maintain their own as well as team members sense of calm/equilibrium

PC11. interact with the auditor in English language

PC12. provide clear answers to the auditor's queries

PC13. produce the documented records of performed activities and operations to auditors

Sensitivity towards all genders and people with disability

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

PC14. respect all the genders, religions, and caste

PC15. empathize with the people with disability

PC16. offer support or help to a person with disability only when asked

PC17. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

PC18. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. company's policies on preferred language of communication, reporting and escalation policy, quality delivery standards, and personnel management

KU2. reporting structure

KU3. communicate effectively along with strategies to give effective feedback to team members and subordinates

KU4. Importance of team management in team building

KU5. brief knowledge of emotion and stress management strategies

KU6. understanding of system thinking to situate the problem in a system

KU7. the types of possible disabilities among people with disability (PwD)

KU8. the challenges faced by PwD

KU9. the importance of displaying empathy towards PwD

KU10. the right way to use the laws acts, and provisions defined for PwD by the statutory bodies

KU11. the importance of awareness for gender sensitization and prevention of sexual harassment (POSH) act

KU12. the importance to respect for gender identities, all religion, caste, and culture

KU13. knowledge of how to develop a collaborative culture for cross-culture and gender-inclusive team

KU14. the guidelines laid on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

Generic Skills (GS)

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

GS1. use reading and comprehension skills to extract the relevant information from manuals, SOPs, health and safety instructions, memos, reports, job cards, and notes/comments

GS2. use written communication skills to maintain proper and concise records as per given format and compliant with ALCOA principle

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Coordination with Supervisor	**10**	**10**	**5**	**5**
PC1. receive work instructions from reporting supervisor	-	-	-	-
PC2. communicate to reporting supervisor about the progress on job allocated and device performance to the superiors	-	-	-	-
PC3. escalate problems to superiors that cannot be handled	-	-	-	-
PC4. communicate deviations / abnormal incidents to the reporting manager	-	-	-	-
PC5. communicate any potential hazards or expected process disruptions to the manager	-	-	-	-
Coordination with colleagues and auditors	**10**	**15**	**5**	**5**
PC6. support team members and colleagues of other departments in work	-	-	-	-
PC7. resolve inter-personnel conflicts and achieve smooth workflow	-	-	-	-
PC8. deposit faulty modules and tools to stores	-	-	-	-
PC9. explain what information means and how it can be used by team members	-	-	-	-
PC10. maintain their own as well as team members sense of calm/equilibrium	-	-	-	-
PC11. interact with the auditor in English language	-	-	-	-
PC12. provide clear answers to the auditor's queries	-	-	-	-
PC13. produce the documented records of performed activities and operations to auditors	-	-	-	-
Sensitivity towards all genders and people with disability	**10**	**15**	**5**	**5**

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC14. respect all the genders, religions, and caste	-	-	-	-
PC15. empathize with the people with disability	-	-	-	-
PC16. offer support or help to a person with disability only when asked	-	-	-	-
PC17. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act	-	-	-	-
PC18. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
NOS Total	**30**	**40**	**15**	**15**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0134
NOS Name	Coordinate and communicate with reporting supervisor/engineer, teams and auditors
Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Generic
NSQF Level	5
Credits	1
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023

Qualification Pack

DGT/VSQ/N0102: Employability Skills (60 Hours)

Description

This unit is about employability skills, Constitutional values, becoming a professional in the 21st Century, digital, financial, and legal literacy, diversity and Inclusion, English and communication skills, customer service, entrepreneurship, and apprenticeship, getting ready for jobs and career development.

Scope

The scope covers the following :

- Introduction to Employability Skills
- Constitutional values - Citizenship
- Becoming a Professional in the 21st Century
- Basic English Skills
- Career Development & Goal Setting
- Communication Skills
- Diversity & Inclusion
- Financial and Legal Literacy
- Essential Digital Skills
- Entrepreneurship
- Customer Service
- Getting ready for Apprenticeship & Jobs

Elements and Performance Criteria

Introduction to Employability Skills

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

PC1. identify employability skills required for jobs in various industries

PC2. identify and explore learning and employability portals

Constitutional values – Citizenship

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

PC3. recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc.

PC4. follow environmentally sustainable practices

Becoming a Professional in the 21st Century

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

PC5. recognize the significance of 21st Century Skills for employment

PC6. practice the 21st Century Skills such as Self-Awareness, Behaviour Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn for continuous learning etc. in personal and professional life

Basic English Skills

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

PC7. use basic English for everyday conversation in different contexts, in person and over the telephone

PC8. read and understand routine information, notes, instructions, mails, letters etc. written in English

PC9. write short messages, notes, letters, e-mails etc. in English

Career Development & Goal Setting

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

PC10. understand the difference between job and career

PC11. prepare a career development plan with short- and long-term goals, based on aptitude

Communication Skills

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

PC12. follow verbal and non-verbal communication etiquette and active listening techniques in various settings

PC13. work collaboratively with others in a team

Diversity & Inclusion

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

PC14. communicate and behave appropriately with all genders and PwD

PC15. escalate any issues related to sexual harassment at workplace according to POSH Act

Financial and Legal Literacy

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

PC16. select financial institutions, products and services as per requirement

PC17. carry out offline and online financial transactions, safely and securely

PC18. identify common components of salary and compute income, expenses, taxes, investments etc

PC19. identify relevant rights and laws and use legal aids to fight against legal exploitation

Essential Digital Skills

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

PC20. operate digital devices and carry out basic internet operations securely and safely

PC21. use e- mail and social media platforms and virtual collaboration tools to work effectively

PC22. use basic features of word processor, spreadsheets, and presentations

Entrepreneurship

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

PC23. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research

PC24. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion

PC25. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity

Customer Service

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

PC26. identify different types of customers

PC27. identify and respond to customer requests and needs in a professional manner.

PC28. follow appropriate hygiene and grooming standards

Getting ready for apprenticeship & Jobs

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

PC29. create a professional Curriculum vitae (Résumé)

PC30. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively

PC31. apply to identified job openings using offline /online methods as per requirement

PC32. answer questions politely, with clarity and confidence, during recruitment and selection

PC33. identify apprenticeship opportunities and register for it as per guidelines and requirements

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. need for employability skills and different learning and employability related portals

KU2. various constitutional and personal values

KU3. different environmentally sustainable practices and their importance

KU4. Twenty first (21st) century skills and their importance

KU5. how to use English language for effective verbal (face to face and telephonic) and written communication in formal and informal set up

KU6. importance of career development and setting long- and short-term goals

KU7. about effective communication

KU8. POSH Act

KU9. Gender sensitivity and inclusivity

KU10. different types of financial institutes, products, and services

KU11. how to compute income and expenditure

KU12. importance of maintaining safety and security in offline and online financial transactions

KU13. different legal rights and laws

KU14. different types of digital devices and the procedure to operate them safely and securely

KU15. how to create and operate an e- mail account and use applications such as word processors, spreadsheets etc.

KU16. how to identify business opportunities

KU17. types and needs of customers

KU18. how to apply for a job and prepare for an interview

KU19. apprenticeship scheme and the process of registering on apprenticeship portal

Generic Skills (GS)

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

GS1. read and write different types of documents/instructions/correspondence

GS2. communicate effectively using appropriate language in formal and informal settings

GS3. behave politely and appropriately with all

GS4. how to work in a virtual mode

GS5. perform calculations efficiently

GS6. solve problems effectively

GS7. pay attention to details

GS8. manage time efficiently

GS9. maintain hygiene and sanitization to avoid infection

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Introduction to Employability Skills	**1**	**1**	**-**	**-**
PC1. identify employability skills required for jobs in various industries	-	-	-	-
PC2. identify and explore learning and employability portals	-	-	-	-
Constitutional values – Citizenship	**1**	**1**	**-**	**-**
PC3. recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc.	-	-	-	-
PC4. follow environmentally sustainable practices	-	-	-	-
Becoming a Professional in the 21st Century	**2**	**4**	**-**	**-**
PC5. recognize the significance of 21st Century Skills for employment	-	-	-	-
PC6. practice the 21st Century Skills such as Self-Awareness, Behaviour Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn for continuous learning etc. in personal and professional life	-	-	-	-
Basic English Skills	**2**	**3**	**-**	**-**
PC7. use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-
PC8. read and understand routine information, notes, instructions, mails, letters etc. written in English	-	-	-	-
PC9. write short messages, notes, letters, e-mails etc. in English	-	-	-	-
Career Development & Goal Setting	**1**	**2**	**-**	**-**

Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. understand the difference between job and career	-	-	-	-
PC11. prepare a career development plan with short- and long-term goals, based on aptitude	-	-	-	-
Communication Skills	**2**	**2**	**-**	**-**
PC12. follow verbal and non-verbal communication etiquette and active listening techniques in various settings	-	-	-	-
PC13. work collaboratively with others in a team	-	-	-	-
Diversity & Inclusion	**1**	**2**	**-**	**-**
PC14. communicate and behave appropriately with all genders and PwD	-	-	-	-
PC15. escalate any issues related to sexual harassment at workplace according to POSH Act	-	-	-	-
Financial and Legal Literacy	**2**	**3**	**-**	**-**
PC16. select financial institutions, products and services as per requirement	-	-	-	-
PC17. carry out offline and online financial transactions, safely and securely	-	-	-	-
PC18. identify common components of salary and compute income, expenses, taxes, investments etc	-	-	-	-
PC19. identify relevant rights and laws and use legal aids to fight against legal exploitation	-	-	-	-
Essential Digital Skills	**3**	**4**	**-**	**-**
PC20. operate digital devices and carry out basic internet operations securely and safely	-	-	-	-
PC21. use e- mail and social media platforms and virtual collaboration tools to work effectively	-	-	-	-
PC22. use basic features of word processor, spreadsheets, and presentations	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Entrepreneurship	**2**	**3**	**-**	**-**
PC23. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research	-	-	-	-
PC24. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion	-	-	-	-
PC25. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity	-	-	-	-
Customer Service	**1**	**2**	**-**	**-**
PC26. identify different types of customers	-	-	-	-
PC27. identify and respond to customer requests and needs in a professional manner.	-	-	-	-
PC28. follow appropriate hygiene and grooming standards	-	-	-	-
Getting ready for apprenticeship & Jobs	**2**	**3**	**-**	**-**
PC29. create a professional Curriculum vitae (Résumé)	-	-	-	-
PC30. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively	-	-	-	-
PC31. apply to identified job openings using offline /online methods as per requirement	-	-	-	-
PC32. answer questions politely, with clarity and confidence, during recruitment and selection	-	-	-	-
PC33. identify apprenticeship opportunities and register for it as per guidelines and requirements	-	-	-	-
NOS Total	**20**	**30**	**-**	**-**

National Occupational Standards (NOS) Parameters

NOS Code	DGT/VSQ/N0102
NOS Name	Employability Skills (60 Hours)
Sector	Cross Sectoral
Sub-Sector	Professional Skills
Occupation	Employability
NSQF Level	4
Credits	2
Version	1.0
Last Reviewed Date	31/01/2024
Next Review Date	31/01/2027
NSQC Clearance Date	31/01/2024

Assessment Guidelines and Assessment Weightage

Assessment Guidelines

1. Criteria for assessment for each Qualification Pack will be created by Life Sciences Sector Skill Development Council (LSSSDC)

2. Each Element will be assigned marks proportional to its importance in NOS. LSSSDC will also lay down the proportion of marks for Theory, Practical, Project, and Viva for each Element.

3. The assessment for the theory part will be based on the knowledge bank of questions created by the LSSSDC.

4. Assessment will be conducted for all compulsory NOS, and where applicable, on the selected elective/option NOS/set of NOS.

5. LSSSDC as assessment and awarding body will create unique evaluations for each assessment component i.e. theory, practical, project and via for every student at each examination/training center based on this criterion.

6. Wherever any assessment component is not applicable/ feasible, the balance assessment components will be used to assess the candidate and accordingly the total marks will be calculated only for the applied

assessment component.

7. To pass the Qualification Pack, every trainee should score a minimum of 50%-70% of marks in each NOS (depending on NSQF Level) to successfully clear the assessment. In the case of a Govt funded program, the program guidelines will be overarching on the pass percentage rules.

8. In case of unsuccessful completion, the trainee may seek re-assessment on the Qualification Pack.

Minimum Aggregate Passing % at QP Level : 70

(**Please note**: Every Trainee should score a minimum aggregate passing percentage as specified above, to successfully clear the Qualification Pack assessment.)

Minimum Passing % at NOS Level: 70

(**Please note**: A Trainee must score the minimum percentage for each NOS separately as well as on the QP as a whole.)

Assessment Weightage

Compulsory NOS

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N6301.Adherence to Environment, Health and Safety as per guidelines	30	40	15	15	100	10
LFS/N6306.Perform checks in the testing lab before and after the start of EMI/EMC testing for medical devices and IVD	30	40	15	15	100	15
LFS/N6303.Analyze and evaluate the risk assessment as per ISO 14971	40	40	10	10	100	15
LFS/N6307.Perform EMI/EMC testing for Medical devices and IVD in compliance with regulatory guidelines	20	40	20	20	100	20
LFS/N6305.Perform result analysis, reporting and documentation to meet quality and regulatory standards	30	40	15	15	100	20

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0134.Coordinate and communicate with reporting supervisor/engineer, teams and auditors	30	40	15	15	100	10
DGT/VSQ/N0102.Employability Skills (60 Hours)	20	30	-	-	50	10
Total	**200**	**270**	**90**	**90**	**650**	**100**

Acronyms

NOS	National Occupational Standard(s)
NSQF	National Skills Qualifications Framework
QP	Qualifications Pack
TVET	Technical and Vocational Education and Training
SOP	Standard Operating Procedure
ISO	International Organization for Standardization
EHS	Environment, Health and Safety
ISO	International Organization for Standardization
SOP	Standard Operating Procedure
PPE	Personal Protective Equipment
ISO	International Organization for Standardization
SOP	Standard Operating Procedure
OOS	Out of Specification
OOT	Out of Trend
SOP	Standard Operating Procedure
SRF	Service Request Form
WI	Work Instruction
OOS	Out of Specification
OOT	Out of Trend
SOP	Standard Operating Procedure
GMP	Good Manufacturing Practices
ALCOA	Attributable, Legible, Contemporaneous, Original, and Accurate
POSH	Prevention of Sexual Harassment
ALCOA	Attributable, Legible, Contemporaneous, Original, and Accurate
PWD	Persons with Disability

SOP	Standard Operating Procedure
ISO	International Organization for Standardization
ISO	International Organization for Standardization
SOP	Standard Operating Procedure
OOS	Out of Specification
OOT	Out of Trend
SOP	Standard Operating Procedure
SRF	Service Request Form
WI	Work Instruction
OOS	Out of Specification
OOT	Out of Trend
SOP	Standard Operating Procedure
GMP	Good Manufacturing Practices
ALCOA	Attributable, Legible, Contemporaneous, Original, and Accurate
POSH	Prevention of Sexual Harassment
ALCOA	Attributable, Legible, Contemporaneous, Original, and Accurate
PWD	Persons with Disability

Glossary

Sector	Sector is a conglomeration of different business operations having similar business and interests. It may also be defined as a distinct subset of the economy whose components share similar characteristics and interests.
Sub-sector	Sub-sector is derived from a further breakdown based on the characteristics and interests of its components.
Occupation	Occupation is a set of job roles, which perform similar/ related set of functions in an industry.
Job role	Job role defines a unique set of functions that together form a unique employment opportunity in an organisation.
Occupational Standards (OS)	OS specify the standards of performance an individual must achieve when carrying out a function in the workplace, together with the Knowledge and Understanding (KU) they need to meet that standard consistently. Occupational Standards are applicable both in the Indian and global contexts.
Performance Criteria (PC)	Performance Criteria (PC) are statements that together specify the standard of performance required when carrying out a task.
National Occupational Standards (NOS)	NOS are occupational standards which apply uniquely in the Indian context.
Qualifications Pack (QP)	QP comprises the set of OS, together with the educational, training and other criteria required to perform a job role. A QP is assigned a unique qualifications pack code.
Unit Code	Unit code is a unique identifier for an Occupational Standard, which is denoted by an 'N'
Unit Title	Unit title gives a clear overall statement about what the incumbent should be able to do.
Description	Description gives a short summary of the unit content. This would be helpful to anyone searching on a database to verify that this is the appropriate OS they are looking for.
Scope	Scope is a set of statements specifying the range of variables that an individual may have to deal with in carrying out the function which have a critical impact on quality of performance required.
Knowledge and Understanding (KU)	Knowledge and Understanding (KU) are statements which together specify the technical, generic, professional and organisational specific knowledge that an individual needs in order to perform to the required standard.

Organisational Context	Organisational context includes the way the organisation is structured and how it operates, including the extent of operative knowledge managers have of their relevant areas of responsibility.
Technical Knowledge	Technical knowledge is the specific knowledge needed to accomplish specific designated responsibilities.
Core Skills/ Generic Skills (GS)	Core skills or Generic Skills (GS) are a group of skills that are the key to learning and working in today's world. These skills are typically needed in any work environment in today's world. These skills are typically needed in any work environment. In the context of the OS, these include communication related skills that are applicable to most job roles.
Electives	Electives are NOS/set of NOS that are identified by the sector as contributive to specialization in a job role. There may be multiple electives within a QP for each specialized job role. Trainees must select at least one elective for the successful completion of a QP with Electives.
Options	Options are NOS/set of NOS that are identified by the sector as additional skills. There may be multiple options within a QP. It is not mandatory to select any of the options to complete a QP with Options.
NOS	NOS define the measurable performance outcomes required from an individual engaged in a particular task. They list down what an individual performing that task should know and also do
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