QUALIFICATION FILE

JUNIOR ENGINEER -EMI/EMC TESTING FOR MEDICAL DEVICES AND IVD

☒ Short Term Training (STT) ☐ Long Term Training (LTT) ☒ Apprenticeship

☐ Upskilling ☒ Dual/Flexi Qualification ☒ For ToT ☒ For ToA

☒General ☐Multi-skill (MS) ☐ Cross Sectoral (CS) ☒ Future Skills ☐ OEM

NCrF/NSQF Level: 5.5

Submitted By:

Life Sciences Sector Skill Development Council

14, Palam Marg, Rear 2nd Floor, Vasant Vihar, New Delhi, PIN 110057

Phone: +91 11 41042407/ 408, E-mail: info@lsssdc.in

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Section 1: Basic Details

<table>
<tr><td>1.</td><td>Qualification Name</td><td colspan="2">Junior Engineer-EMI/EMC testing for Medical Devices and IVD</td></tr>
<tr><td>2.</td><td>Sector/s</td><td colspan="2">Life Sciences</td></tr>
<tr><td>3.</td><td>Type of Qualification: ☒ New ☐ Revised ☒ Has Electives/Options
☐OEM</td><td>NQR Code & version of existing/previous qualification: NA</td><td>Qualification Name of existing/previous version:
NA</td></tr>
<tr><td>4.</td><td>a. OEM Name
b. Qualification Name
(Wherever applicable)</td><td colspan="2">NA</td></tr>
<tr><td>5.</td><td>National Qualification Register (NQR) Code &Version</td><td>QG-5.5-LS-01271-2023-V1-LSSSDC</td><td>6. NCrF/NSQF Level: 5.5</td></tr>
<tr><td>7.</td><td>Award (Certificate/Diploma/Advance Diploma/ Any Other</td><td colspan="2">Certificate</td></tr>
<tr><td>8.</td><td>Brief Description of the Qualification</td><td colspan="2">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</td></tr>
<tr><td>9.</td><td>Eligibility Criteria for Entry for Student/Trainee/Learner/Employee</td><td colspan="2">a. Entry Qualification & Relevant Experience:
<table>
<tr><th>S. No.</th><th>Academic/Skill Qualification (with Specialization - if applicable)</th><th>Required Experience (with Specialization - if applicable)</th></tr>
<tr><td>1.</td><td>Graduate Engineering in Electronics/Electric/mechatronics, Computer Science, IT or related fields</td><td></td></tr>
<tr><td>2.</td><td>Completed 2nd year Diploma Engineering (after 12th Class) approved by AICTE or State Technical Education Body in relevant Field (Electronics/Electric/mechatronics, Computer Science, IT or related fields,)</td><td>1 Year of relevant experience</td></tr>
<tr><td>3.</td><td>Completed 3-year Diploma Engineering (after 10th Class) approved by AICTE or State Technical Education Body in relevant Field (Electronics/Electric/mechatronics, Computer Science, IT or related fields,)</td><td>2 Years of relevant experience</td></tr>
</table>
b. Age: 19 years</td></tr>
</table>

<table>
<tr><td>10.</td><td>Credits Assigned to this Qualification, Subject to Assessment</td><td>18.0</td><td colspan="4">11. Common Cost Norm Category (I/II/III) : I</td></tr>
<tr><td>12.</td><td>Any Licensing requirements for Undertaking Training on This Qualification (wherever applicable)</td><td colspan="5">NA</td></tr>
<tr><td>13.</td><td>Training Duration by Modes of Training Delivery (Specify Total Duration as per selected training delivery modes and as per requirement of the qualification)</td><td colspan="5">☒Offline ☐Online ☒Blended
<table>
<tr><th>Training Delivery Modes</th><th>Theory (Hours)</th><th>Practical (Hours)</th><th>OJT Mandatory (Hours)</th><th>OJT Recommended (Hours)</th><th>Total (Hours)</th></tr>
<tr><td>Offline Mode</td><td></td><td></td><td></td><td></td><td rowspan="5">540:00</td></tr>
<tr><td>Classroom</td><td>270:00</td><td>270:00</td><td>00:00</td><td>00:00</td></tr>
<tr><td colspan="4">OR</td></tr>
<tr><td>Blended Mode</td><td>270:00</td><td>270:00</td><td>00:00</td><td>00:00</td></tr>
<tr><td>Offline (As part of blended mode)</td><td>135:00</td><td>270:00</td><td>00:00</td><td>00:00</td></tr>
<tr><td>Online (As part of blended mode)</td><td>135:00</td><td>00:00</td><td>00:00</td><td>00:00</td><td></td></tr>
</table>
Recommended Apprenticeship : 6 Months</td></tr>
<tr><td>14.</td><td>Aligned to NCO/ISCO Code/s</td><td colspan="5">NCO-2015-2143.0200, 2143.0300</td></tr>
<tr><td>15.</td><td>Progression path after attaining the qualification</td><td colspan="5">Vertical Progression
Engineer - Medical Devices and IVD Testing
(To be developed)</td></tr>
<tr><td>16.</td><td>Other Indian languages in which the Qualification & Model Curriculum are being submitted</td><td colspan="5">English and Hindi</td></tr>
<tr><td>17.</td><td>Is similar Qualification(s) available on NQR-if yes, justification for this qualification</td><td colspan="5">☐ Yes ☒ No URLs of similar Qualifications:</td></tr>
<tr><td>18.</td><td>Is the Job Role Amenable to Persons with Disability</td><td colspan="5">☐ Yes ☒ No
If “Yes”, specify applicable type of Disability:</td></tr>
<tr><td>19.</td><td>How Participation of Women will be Encouraged</td><td colspan="5">Policy measures are needed to promote the inclusion of educated and working women, especially in science and technology fields, where only 14% of women are hired among micro, small, and medium enterprises despite comprising 43% of science and technology graduates. The conscious efforts are made</td></tr>
</table>

		by LSSSDC to sensitize organizations and hiring manager for bring Women employees on board by LSSSDC through Industry Associations and Large MNCs on governing Board and have received positive responses and assurance from most of employers in life sciences sector to bring Min. 30% share of Women employees and apprentices in the given occupation and job role. LSSSDC shall also be driving a Diversity and Inclusivity Program with Indian Pharmaceutical Alliance for catalyzing the efforts.	
20.	**Are Greening/ Environment Sustainability Aspects Covered**	**☒ Yes ☐ No**	
21.	**Is Qualification Suitable to be Offered in Schools/Colleges**	**Schools ☐ Yes ☐ No Colleges ☒ Yes ☐ No**	
22.	**Name and Contact Details of Submitting / Awarding Body SPOC**	**Name: Mrs. Shivi Chaudhary** **Email: shivi.chaudhary@lsssdc.in Contact No.: + 91 11 41042407/ 408, +91 9650433002** **Website: https://www.lsssdc.in/**	
23.	**Final Approval Date by NSQC: 1 November 2023**	**24. Validity Duration: 3 years**	**25. Next Review Date : 1 November 2026**

Section 2: Module Summary

NOS/s of Qualifications

(In exceptional cases these could be described as components)

Mandatory NOS/s:

Specify the training duration and assessment criteria at NOS/ Module level. For further details refer curriculum document.

***Th.**-Theory **Pr.**-Practical **OJT**-On the Job **Man.**-Mandatory Training **Rec.**-Recommended **Proj.**-Project*

S. No	NOS/Module Name	NOS/Module Code & Version *(if applicable)*	Core/ Non-Core	NCrF/NSQF Level	Credits as per NCrF	Training Duration (Hours)					Assessment Marks					
						Th.	Pr.	OJT-Man.	OJT-Rec.	Total	Th.	Pr.	Proj.	Viva	Total	Weightage (%) *(if applicable)*
1.	Introduction to Life Sciences industry and the job role				1.0	30	30			60						
2.	Adherence to Environment, health and safety guidelines in Testing facility	LFS/N06301, v1	Non-Core	5	1.0	15	15	00	00	30	30	40	15	15	100	10%
3.	Perform checks in the testing lab before the start of EMI/EMC testing for medical devices and IVD	LFS/N06306, v1	Core	5.5	3.0	30	60	00	00	90	30	40	15	15	100	15%
4.	Analyze and Evaluate the risk assessment as per ISO 14971	LFS/N6303, v1	Core	5	3.0	30	60	00	00	90	40	40	10	10	100	15%
5.	Perform EMI/EMC testing for Medical devices and IVD in compliance with regulatory guidelines	LFS/N6307, v1	Core	5.5	5.0	60	90	00	00	150	20	40	20	20	100	20%
6.	Perform result analysis, reporting and documentation to meet the quality and regulatory standards	LFS/N6305, v1	Core	5	2.0	30	30	00	00	60	30	40	15	15	100	20%
7.	Coordinate and communicate with reporting Supervisor/ engineer, teams and auditors	LFS/N0134, v1	Non-Core	5	1.0	15	15	00	00	30	30	40	15	15	100	10%

S. No	NOS/Module Name	NOS/Module Code & Version *(if applicable)*	Core/ Non-Core	NCrF/NSQF Level	Credits as per NCrF	Training Duration (Hours)					Assessment Marks					
						Th.	Pr.	OJT-Man.	OJT-Rec.	Total	Th.	Pr.	Proj.	Viva	Total	Weightage (%) *(if applicable)*
8.	Employability Skills	DGT/VSQ/N0102	Non-Core	4	2.0	60	00	00	00	60	20	30			50	10%
Duration (in Hours) / Total Marks					18.0	270	270	00	00	540	200	270	90	90	650	100%

Optional OJT training: Apprenticeship Training

S. No	NOS/Module Name	NOS/Module Code & Version *(if applicable)*	Core/ Non-Core	NCrF/NSQF Level	Credits as per NCrF	Training Duration (Hours)					Assessment Marks					
						Th.	Pr.	OJT-Man.	OJT-Rec.	Total	Th.	Pr.	Proj.	Viva	Total	Weightage (%) *(if applicable)*
1.	**Apprenticeship Training**								990	990						
Duration (in Hours) / Total Marks									990	990						

Assessment - Minimum Qualifying Percentage

*Please specify **any one** of the following:*

Minimum Pass Percentage – Aggregate at qualification level: 70 % *(Every Trainee should score specified minimum aggregate passing percentage at qualification level to successfully clear the assessment.)*

Minimum Pass Percentage – NOS/Module-wise: 70 % *(Every Trainee should score specified minimum passing percentage in each mandatory and selected elective NOS/Module to successfully clear the assessment.)*

Section 3: Training Related

1.	**Trainer's Qualification and experience in the relevant sector (in years)** *(as per NCVET guidelines)*	Graduate (B.Tech) in Electronics/ Electric/ mechatronics, Computer Science, IT or related fields minimum with 6 years of industry relevant experience in EMI/EMC testing for Medical devices and IVD and 2 years of experience in On the job assessment/ Training experience/ Vocational assessment/ Academic assessment Or

		Postgraduate with Electronics/ Electric/ mechatronics, Computer Science, IT or related fields minimum with 4 years of industry relevant experience in EMI/EMC testing for Medical devices and IVD and 2 years of experience in On the job assessment/ Training experience/ Vocational assessment/ Academic assessment Certified for job role: "Junior Engineer -EMI/EMC testing for Medical Devices and IVD"mapped to Qualification Pack: "LFS/Q6302, V1.0" with minimum accepted 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%.
2.	**Master Trainer's Qualification and experience in the relevant sector (in years)** *(as per NCVET guidelines)*	Graduate (B.Tech) in Electronics/ Electric/ mechatronics, Computer Science, IT or related fields minimum with 8 years of industry relevant experience in EMI/EMC testing for Medical devices and IVD and 4 years of experience in On the job assessment/ Training experience/ Vocational assessment/ Academic assessment Or Postgraduate with Electronics/ Electric/ mechatronics, Computer Science, IT or related fields minimum with 6 years of industry relevant experience in EMI/EMC testing for Medical devices and IVD and 4 years of experience in On the job assessment/ Training experience/ Vocational assessment/ Academic assessment Certified for job role: "Junior Engineer -EMI/EMC testing for Medical Devices and IVD"mapped to Qualification Pack: "LFS/Q6302, V1.0" with minimum accepted score of 80%. Recommended that the Trainer is certified for the Job Role: "Master Trainer (VET and Skills)", mapped to the Qualification Pack: "MEP/Q2602, v2.0" with minimum score of 80%.
3.	**Tools and Equipment Required for Training**	☐Yes ☐No (*If "Yes", details to be provided in Annexure)*
4.	**In Case of Revised Qualification, Details of Any Upskilling Required for Trainer**	

Section 4: Assessment Related

1	**Assessor's Qualification and experience in relevant sector (in years)** *(as per NCVET guidelines)*	Graduate (B.Tech) in Electronics/ Electric/ mechatronics, Computer Science, IT or related fields minimum with 10 years of industry relevant experience in EMI/EMC testing for Medical devices and IVD and 2 years of experience in On the job assessment/ Training experience/ Vocational assessment/ Academic assessment Or Postgraduate with Electronics/ Electric/ mechatronics, Computer Science, IT or related fields with 7 years of industry relevant experience in EMI/EMC testing for Medical devices and IVD and 2 years of experience in On the job assessment/ Training experience/ Vocational assessment/ Academic assessment

		Certified for job role: "Junior Engineer -EMI/EMC testing for Medical Devices and IVD"mapped to Qualification Pack: "LFS/Q6302, V1.0" with minimum accepted score of 80%. Recommended that the Assessor is certified for the Job Role: "Assessor (VET and SKILLS)", mapped to the Micro credentials: "MEP/Q2701 Ver 2.0" with minimum score of 80%.
2	**Proctor's Qualification and experience in relevant sector (in years)** *(as per NCVET guidelines)*	Graduate (B.Tech) in Electronics/ Electric/ mechatronics, Computer Science, IT or related fields with 10 years of industry relevant experience in EMI/EMC testing for Medical devices and IVD and 2 years of experience in On the job assessment/ Training experience/ Vocational assessment/ Academic assessment Or Postgraduate with Electronics/ Electric/ mechatronics, Computer Science, IT or related fields with 7 years of industry relevant experience in EMI/EMC testing for Medical devices and IVD and 2 years of experience in On the job assessment/ Training experience/ Vocational assessment/ Academic assessment Certified for job role: "Junior Engineer -EMI/EMC testing for Medical Devices and IVD"mapped to Qualification Pack: "LFS/Q6302, V1.0" with minimum accepted score of 80%.
3	**Lead Assessor's/Proctor's Qualification and experience in relevant sector (in years)** *(as per NCVET guidelines)*	Graduate (B.Tech) in Electronics/ Electric/ mechatronics, Computer Science, IT or related fields with 12 years of industry relevant experience in EMI/EMC testing for Medical devices and IVD and 6 years of experience in On the job assessment/ Training experience/ Vocational assessment/ Academic assessment Or Postgraduate with Electronics/ Electric/ mechatronics, Computer Science, IT or related fields with 10 years of industry relevant experience in EMI/EMC testing for Medical devices and IVD and 6 years of experience in On the job assessment/ Training experience/ Vocational assessment/ Academic assessment Certified for job role: "Junior Engineer -EMI/EMC testing for Medical Devices and IVD"mapped to Qualification Pack: "LFS/Q6302, V1.0" with minimum accepted score of 80%. Recommended that the Assessor is certified for the Job Role: "Lead Assessor (VET and SKILLS)", mapped to the Micro credentials: "MEP/Q2702 Ver 2.0" with minimum score of 80%.
4	**Assessment Mode** *(Specify the assessment mode)*	Offline and online
5	**Tools and Equipment Required for Assessment**	☒ Same as for training ☐ Yes ☐ No *(details to be provided in Annexure-if it is different for Assessment)*

Section 5: Evidence of the need for the Qualification

Provide Annexure/Supporting documents name.

1.	**Latest Skill Gap Study (not older than 2 years) (Yes/No):** Yes
2.	**Latest Market Research Reports or any other source (not older than 2 years) (Yes/No):** Yes
3.	**Government /Industry initiatives/ requirement (Yes/No):** no
4.	**Number of Industry validation provided:** 12
5.	**Estimated nos. of persons to be trained and employed:** 1500
6.	**Evidence of Concurrence/Consultation with Line Ministry/State Departments:** No the mail has been to Line ministry If "No", why:

Section 6: Annexure & Supporting Documents Check List

Specify Annexure Name / Supporting document file name

1.	**Annexure:** NCrF/NSQF level justification based on NCrF level/NSQF descriptors *(Mandatory)*	Yes
2.	**Annexure:** List of tools and equipment relevant for qualification *(Mandatory, except in case of online course)*	Yes
3.	**Annexure:** Detailed Assessment Criteria *(Mandatory)*	Yes
4.	**Annexure:** Assessment Strategy *(Mandatory)*	Yes
5.	**Annexure:** Blended Learning *(Mandatory, in case selected Mode of delivery is "Blended Learning")*	Yes
6.	**Annexure:** Multiple Entry-Exit Details *(Mandatory, in case qualification has multiple Entry-Exit)*	*NA*
7.	**Annexure:** Acronym and Glossary *(Optional)*	Yes
8.	**Supporting Document:** Model Curriculum *(Mandatory – Public view)*	Yes
9.	**Supporting Document:** Career Progression *(Mandatory - Public view)*	Yes
10.	**Supporting Document:** Occupational Map *(Mandatory)*	Yes
11.	**Supporting Document:** Assessment SOP *(Mandatory)*	Yes
12.	**Any other document you wish to submit:**	

Annexure: Evidence of Level

NCrF/NSQF Level Descriptors	Key requirements of the job role/ outcome of the qualification	How the job role/ outcomes relate to the NCrF/NSQF level descriptor	NCrF/NSQF Level
Professional Theoretical Knowledge/Process	Few of the job elements, expected to be performed by Junior Engineer -EMI/EMC testing for Medical devices and IVD ● Laboratory-specific routine checks ● Environment Sustainability ● Perform analysis of risk assessment ● Risk Mitigation support for research ● Prepare for testing process ● Perform inspection of medical devices and its components ● Test medical device and its components for faults in laboratory ● Conduct testing of medical device under running condition ● Perform post-testing activities	Junior Engineer -EMI/EMC testing for Medical devices and IVD performs preparation for testing process ,Conduct testing of medical device under running condition, test medical device for fault and post testing activities to checks to ensure compliance with regulatory standards and procedures. The job holder is responsible for Inspection, identification of non-conformities. He/she is also responsible for performing continuous reporting and documentation at every step. All the above performance outcomes are routine and common in all the work assigned to by Junior Engineer -EMI/EMC testing for Medical devices and IVD, hence they are categorized as familiar and predictable processes where the Junior Engineer -EMI/EMC testing for Medical devices and IVD has a situation of clear choice	Level 5.5
Professional and Technical Skills/ Expertise/ Professional Knowledge	Few of the job elements, expected to be performed by Junior Engineer -EMI/EMC testing for Medical devices and IVD ● Laboratory-specific routine checks ● Environment Sustainability ● Perform analysis of risk assessment ● Risk Mitigation support for research ● Prepare for testing process ● Perform inspection of medical devices and its components ● Test medical device and its components for faults in laboratory	To perform the tasks given in the left-hand side box, Junior Engineer -EMI/EMC testing for Medical devices and IVD needs to have the factual knowledge of facts, principles, processes and general concepts related to medical device testing , how to perform testing of medical device in both running and stable condition and also knowledge about risk mitigation by recalling the work safety guidelines. The job holder should also be efficient to coordinate with Manager, colleagues, and auditors to meet the communication needs to fulfill work requirements of Junior Engineer -EMI/EMC testing for Medical devices and IVD	Level 5.5

	• Conduct testing of medical device under running condition • Perform post-testing activities		
Employment Readiness & Entrepreneurship Skills & Mind-set/Professional Skill	Few of the job elements, expected to be performed by Junior Engineer -EMI/EMC testing for Medical devices and IVD • Laboratory-specific routine checks • Environment Sustainability • Perform analysis of risk assessment • Risk Mitigation support for research • Prepare for testing process • Perform inspection of medical devices and its components • Test medical device and its components for faults in laboratory • Conduct testing of medical device under running condition Perform post-testing activities	To perform the tasks of by Junior Engineer -EMI/EMC testing for Medical devices and IVD the job holder utilizes professional skills like good communication and interpersonal skills, good analytical, reasoning skills, attention to details, critical thinking, and excellent organizational skills. For routine job activities and tasks the Junior Engineer -EMI/EMC testing for Medical devices and IVD uses planning and organizing skills. The job holder demonstrates analytical and critical thinking skills while performing medical devices testing. The scope of utilization of all above professional skills remains limited to routine and repetitive and for a narrow range of applications	Level 5.5
Broad Learning Outcomes/Core Skill	Few of the job elements, expected to be performed by Junior Engineer -EMI/EMC testing for Medical devices and IVD • Laboratory-specific routine checks • Environment Sustainability • Perform analysis of risk assessment • Risk Mitigation support for research • Prepare for testing process • Perform inspection of medical devices and its components • Test medical device and its components for faults in laboratory	To perform the tasks written on the left-hand side box, Junior Engineer -EMI/EMC testing for Medical devices and IVD uses organizing information, communication, and problem-solving skills. For reporting and documentation proposed, he/she applies the basics of arithmetic and algebraic principles and organizational skills. For coordination related tasks and ensuring compliance to organizational SOPs and regulatory requirements, the job holder is expected to have a basic understanding of the social-political and natural environment at the place of work/ organization he/she is working for.	Level 5.5

	• Conduct testing of medical device under running condition • Perform post-testing activities		
Responsibility	Few of the job elements, expected to be performed by Junior Engineer -EMI/EMC testing for Medical devices and IVD • Laboratory-specific routine checks • Environment Sustainability • Perform analysis of risk assessment • Risk Mitigation support for research • Prepare for testing process • Perform inspection of medical devices and its components • Test medical device and its components for faults in laboratory • Conduct testing of medical device under running condition Perform post-testing activities	Junior Engineer -EMI/EMC testing for Medical devices and IVD has responsibility for his/her work and learning and supports Junior Engineer while testing and cross functional Teams. And in case of a scenario/situation of no clear choice, he is expected to take guidance from the Head of Testing/Quality Department.	Level 5.5

Annexure: Tools and Equipment (Lab Set-Up)

List of Tools and Equipment

Batch Size: 30

S. No.	Tool / Equipment Name	Specification	Quantity for specified Batch size
1.	Cleanroom Gown	Unit= Pc	As Per standard Requirement
2.	Industrial Safety Gloves	Unit= Pc	As Per standard Requirement
3.	Gloves ({Heat, Acid, Chemical} Resistant) & Nitrile	Unit= Pc	As Per standard Requirement
4.	Face Mask (Half Face & Full Face)	Unit= Pc	As Per standard Requirement
5.	Safety Shoes	Unit= Pc	As Per standard Requirement
6.	Manual Bottle Eye Washer	Unit= Pc	As Per standard Requirement

7.	PVC Apron	Unit= Pc	As Per standard Requirement
8.	Hammer	Unit= Pc	As Per standard Requirement
9.	analytical balance with printer (of different capacity and sensitivity 0.001 mg, 0.01 mg,0.1 mg,1 mg sensitivity)	Unit= Pc	As Per standard Requirement
10.	Dry Heat Air Oven	Unit= Pc	As Per standard Requirement
11.	Depyrogenation oven	Unit= Pc	As Per standard Requirement
12.	Refrigerator	Unit= Pc	As Per standard Requirement
13.	Deep freezer	Unit= Pc	As Per standard Requirement
14.	Labotary incubator for different temperature range	Unit= Pc	As Per standard Requirement
15.	Co2 type Fire Extinguisher	Unit= Pc	As Per standard Requirement
16.	ABC Type Fire Extinguisher	Unit= Pc	As Per standard Requirement
17.	Material Safety Data Sheet	Unit= Pc	As Per standard Requirement
18.	Formats of Log Books	Unit= Pc	As Per standard Requirement
19.	Magnetic field coil	Unit= Pc	As Per standard Requirement
20.	Conductivity sensitivity tester	Unit= Pc	As Per standard Requirement
21.	ISN	Unit= Pc	As Per standard Requirement
22.	Harmonic testing system	Unit= Pc	As Per standard Requirement
23.	EMI TEST Receiver	Unit= Pc	As Per standard Requirement
24.	Test receiver (varies from test to test)	Unit= Pc	As Per standard Requirement
25.	CDN M2-M3	Unit= Pc	As Per standard Requirement
26.	ESD generator	Unit= Pc	As Per standard Requirement
27.	ESD gun	Unit= Pc	As Per standard Requirement
28.	LISN	Unit= Pc	As Per standard Requirement

29.	Network - LISN	Unit= Pc	As Per standard Requirement
30.	Low noise pre Amplifier	Unit= Pc	As Per standard Requirement
31.	Pre amplifier	Unit= Pc	As Per standard Requirement
32.	Pulse Limiter	Unit= Pc	As Per standard Requirement
33.	EM Clamp	Unit= Pc	As Per standard Requirement
34.	Digital Multimeter	Unit= Pc	As Per standard Requirement
35.	Current Injection Probe	Unit= Pc	As Per standard Requirement
36.	Test Receiver	Unit= Pc	As Per standard Requirement
37.	Compact immunity simulator	Unit= Pc	As Per standard Requirement
38.	Power failure and power frequency magnetic field module	Unit= Pc	As Per standard Requirement
39.	Pulse magnetic field converter	Unit= Pc	As Per standard Requirement
40.	Capacitance coupling clamp	Unit= Pc	As Per standard Requirement
41.	3 meter / 5 meter SSC Chamber	Unit= Pc	As Per standard Requirement

Classroom Aids

The aids required to conduct sessions in the classroom are:

1. Whiteboard
2. Marker Pen
3. Computer or Laptop attached to LCD projector.
4. Computer speaker
5. Pencil

Annexure: Validations Summary

Provide the summary information of all the industry validations in table. This is not required for OEM qualifications.

S. No	Organization Name	Representative Name	Designation	Contact Address	Contact Phone No	E-mail ID	LinkedIn Profile *(if available)*
1.	Translumina Therapeutics LLP	Vickysh Mevawala	G.M. Quality Assurance and Plant Regulatory Affairs	-	9898964334	vickyshmevawala@translumina.in vsmevawala@gmail.com	-
2.	Peerless Biotech Pvt Ltd	S. Mohan kumar	CEO and Director	-	9042049602	mohankumar@peerlessbio.com	-
3.	Association of Diagnostics Manufacturers of India (ADMI)	Rajat Kapoor	Assistant Director – Secretariat	-	9599358095	secretariat@admi-india.org	-
4.	Agappe Diagnostics Ltd	Thomas John	Managing Director	-	9388754200	cmdoffice@agappe.com	-
5.	Medsource Ozone Biomedicals Pvt. Ltd	Ajay Kumar Bhatt	Chief Executive Officer	-	9999311335	ajaykumar.bhatt@ozonebio.com	-
6.	Jagan's Institute of Pharmaceutical Sciences	Dr. S. Angala Parmeshawari	Principal	-	9550426490	eswarialagusundaram@gmail.com	-
7.	Ratnam Institute of Pharmacy	Dr. C. Madhavilatha	Professor and HOD , Department of Pharmacy Practices	-	9052987936	madhavilathacology@gmail.com	-
8.	Vignan Pharmacy College	Dr. P. Srinivasa Babu	Principal	-	9866399382	psbabu01004@gmail.com	-
9.	QIS College of Pharmacy	Dr. D. Dhachinamoorthi	Principal	-	9866268129	principal@qiscp.edu.in	-
10.	Raghu College of Pharmacy	Dr. Jagdeesh Panda	Principal	-	9490302033	raghucollegeofpharmacy@redifmail.com	-
11.	Bellamkonda Institute Of Technology And Science	Dr. NAIDU NARAPUSETTY	Principal	-	9866622931	ph.principal@jntuk.edu.in	-
12.	CPC Diagnostics Pvt Ltd	Govindan SV	DGM - Supply Chain	-	9841770554	govindh@cpcdiagnostic.in	-

Annexure: Training & Employment Details

Training and Employment Projections:

Year	Total Candidates		Women		People with Disability	
	Estimated Training #	Estimated Employment Opportunities	Estimated Training #	Estimated Employment Opportunities	Estimated Training #	Estimated Employment Opportunities
Year 1	500	-	50	-	-	-
Year 2	500	-	50	-	-	-
Year 3	500	-	50	-	-	-

Data to be provided year-wise for next 3 years

Training, Assessment, Certification, and Placement Data for previous versions of qualifications:

Qualification Version	Year	Total Candidates				Women				People with Disability			
		Trained	Assessed	Certified	Placed	Trained	Assessed	Certified	Placed	Trained	Assessed	Certified	Placed

Applicable for revised qualifications only, data to be provided year-wise for past 3 years.

List Schemes in which the previous version of Qualification was implemented:

1.
2.

Content availability for previous versions of qualifications:

☐ Participant Handbook ☐ Facilitator Guide ☐ Digital Content ☐ Qualification Handbook ☐ Any Other:

Languages in which Content is available:

Annexure: Blended Learning

Blended Learning Estimated Ratio & Recommended Tools:

Refer NCVET "Guidelines for Blended Learning for Vocational Education, Training & Skilling" available on:
https://ncvet.gov.in/sites/default/files/Guidelines%20for%20Blended%20Learning%20for%20Vocational%20Education,%20Training%20&%20Skilling.pdf

S. No.	Select the Components of the Qualification	List Recommended Tools – for all Selected Components	Offline : Online Ratio
1	☐Theory/ Lectures - Imparting theoretical and conceptual knowledge	LMS Portal- LSSSDC Daksh Portal will be utilized with online content/virtual lectures	50:50
2	☐Imparting Soft Skills, Life Skills, and Employability Skills /Mentorship to Learners	LMS Portal- LSSSDC Daksh Portal will be utilized with online content/virtual lectures	50:50
3	☐Showing Practical Demonstrations to the learners	LMS Portal- LSSSDC Daksh Portal will be utilized with online content/virtual lectures / Skill labs	100:00
4	☐Imparting Practical Hands-on Skills/ Lab Work/ workshop/ shop floor training	Skill Labs	100:00
5	☐Tutorials/ Assignments/ Drill/ Practice	LMS Portal- LSSSDC Daksh Portal will be utilized with online content/virtual lectures / Field Visits	50:50
6	☐Proctored Monitoring/ Assessment/ Evaluation/ Examinations	Parakh	00:100
7	☐On the Job Training (OJT)/ Project Work Internship/ Apprenticeship Training	Offline	00:100

Annexure: Detailed Assessment Criteria

Detailed assessment criteria for each NOS/Module are as follows:

NOS/Module Name	Assessment Criteria for Performance Criteria/Learning Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
1. LFS/N6301 Ver 1.0 **Adhere to Environment, health, and safety as per guidelines Testing facility**	*Adhere to health and hygiene protocols*	**10**	**10**	**5**	**5**
	PC 1 comply with health and personal hygiene-related protocols as per regulatory guidelines	-	-	-	-
	PC 2 sanitize your hands before entering in Testing lab area and ensure the adherence of same by subordinates	-	-	-	-
	PC 3 report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person	-	-	-	-
	PC 4 take preventive actions on the report of any allergy, sickness or any other environment related breach by subordinates	-	-	-	-
	PC 5 wear lab equipment 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	-	-	-	-
	PC 6 Ensure proper disposal of used accessories	-	-	-	-
	Adhere to safety and security procedures	**10**	**15**	**5**	**5**
	PC 7 comply with safety and security policies and procedures	-	-	-	-
	PC 8 use appropriate safety gears like gowns, shoecover, headgear, masks, gloves and other relevant safety accessories as per regulatory guidelines throughout the process	-	-	-	-
	PC 9 report any identified breaches in safety and security policies and procedures to the designated person	-	-	-	-
	PC 10 use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools	-	-	-	-
	PC 11 comply with material handling, segregation, storage, and MSDS guidelines as per 5S system	-	-	-	-
	PC 12 segregate material and follow the 5S system at the storage area	-	-	-	-

	PC 13 record the details of completed safety drills and training	-	-	-	-
	Follow emergency procedures	**10**	**15**	**5**	**5**
	PC 14 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	-	-	-	-
	PC 15 inform the concerned person immediately about every unsafe act/ incident	-	-	-	-
	PC 16 follow emergency protocol for any alarms and ensure the safety of subordinates in the area	-	-	-	-
	PC 17 follow emergency protocols efficiently	-	-	-	-
	Total Marks	**30**	**40**	**15**	**15**
2. LFS/N6306, Ver1.0 Perform checks in the testing lab before and after the start of EMI/EMC testing for medical devices and IVD	*Laboratory-specific routine checks*	**10**	**10**	**5**	**5**
	PC 1 ensure the use of PPE before entering the testing facility area as per SOP	-	-	-	-
	PC 2 perform proper cleaning of machinery and equipments before the start work	-	-	-	-
	PC 3 Ensure all necessary documentation, including requirement and test standards , test protocols, standard operating procedures (SOPs), and any required permits or licenses are in place	-	-	-	-
	PC 4 ensure adequate validation for the work being carried out as per SOP for test method and work instruction to operate the instruments	-	-	-	-
	PC 5 conduct regular checks for lab equipment and instrument for their calibration and validation state as per schedule	-	-	-	-
	PC 6 ensure out of order/ non calibrated/ non validated equipment are labelled and segregated for maintenance	-	-	-	-
	PC 7 segregate and store the material with an appropriate label in designated places	-	-	-	-
	PC 8 ensure logbook entries of all the test performed are done as per SOP	-	-	-	-
	Environment Sustainability	**10**	**15**	**5**	**5**

	PC 9 ensure energy conservation by switching off the machine and equipment post operations	-	-	-	-
	PC 10 identify ways to optimize the usage of electricity/energy in various tasks/activities/processes	-	-	-	-
	PC 11 ensure energy conservation by optimizing the machine/ equipment performance	-	-	-	-
	PC 12 identify recyclable and non-recyclable, and hazardous waste generated	-	-	-	-
	PC 13 segregate waste into different categories to achieve minimum pollution of land and water	-	-	-	-
	Activities after completion of work	**10**	**10**	**5**	**5**
	PC 14 ensure proper labelling of tested sample in designated places	-	-	-	-
	PC 15 ensure removal of scrap material from work area	-	-	-	-
	PC 16 Ensure cleaning of the equipment after every testing as per SOP	-	-	-	-
	PC 17 ensure clean and dry area after completion of work as per SOP	-	-	-	-
	Total Marks	**30**	**40**	**15**	**15**
3. LFS/N6303 Ver 1.0 Analyze and Evaluate the risk assessment as per ISO 14971	*Perform analysis of risk assessment*	**20**	**20**	**5**	**5**
	PC 1 identifying potential hazards and risks associated with medical devices, both in the design and function	-	-	-	-
	PC 2 perform thorough risk analysis, including risk estimation and evaluation using tools like FMEA (Failure Modes and Effects Analysis) and fault free analysis.	-	-	-	-
	PC 3 effectively document risk level after risk assessments by creating Risk Management Files as required by ISO 14971	-	-	-	-
	PC 4 collect, analyze, and interpret data related to risk assessments	-	-	-	-
	PC 5 communicate risk assessments findings effectively within cross-functional teams and with stakeholders	-	-	-	-
	PC 6 prepare documents for audit and participate in regulatory audits and inspections, ensuring compliance with ISO 14971 and related standards.	-	-	-	-

	PC 7 ensure compliance with any potential legal and liability implications associated with risk management	-	-	-	-
	Risk Mitigation support for research	**20**	**20**	**5**	**5**
	PC 8 develop risk mitigation strategies that can be applied practically to minimize risks in medical devices	-	-	-	-
	PC 9 ensure monitoring and follow control mechanisms to track the effectiveness of risk mitigation measures.	-	-	-	-
	PC 10 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.	-	-	-	-
	PC 11 follow integration of risk assessment and mitigation into the overall research project management framework	-	-	-	-
	Total Marks	**40**	**40**	**10**	**10**
4. LFS/N6307 Ver 1.0 Perform EMI/EMC testing for Medical devices and IVD in compliance with regulatory guidelines	*Prepare for testing process*	**5**	**10**	**5**	**5**
	PC 1 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	-	-	-	-
	PC 2 identify, select and arrange the testing equipment as per SOP,WI required during the testing process	-	-	-	-
	PC 3 Check the calibration status of testing equipment before the use	-	-	-	-
	PC 4 identify the testing parameters which need to be measured during the test procedure	-	-	-	-
	PC 5 place the medical device securely on the designated testing platforms/ benches as per the SOP	-	-	-	-
	Perform inspection of medical devices and its components cum accessories	**5**	**10**	**5**	**5**
	PC 6 follow safety instructions recommended as per SOP during the inspection and testing process	-	-	-	-
	PC 7 Perform the visual inspection test for fault diagnosis as per the SOP	-	-	-	-

	PC 8 calibrate, align and adjust the settings of medical device as per the SOP and organizational standards	-	-	-	-
	PC 9 ensure part clearances as specified in the SOP	-	-	-	-
	Test medical device and its components for faults in laboratory	**5**	**10**	**5**	**5**
	PC 10 Set the test apparatus as per the selected testing process and SOPs	-	-	-	-
	PC 11 connect the various data capturing meters and gauges to capture the stress levels and other data points	-	-	-	-
	PC 12 check the working of the test apparatus post-connecting the test component/ medical device to ensure error free testing activity	-	-	-	-
	PC 13 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	-	-	-	-
	PC 14 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	-	-	-	-
	PC 15 record observations/ readings as per the parameters mentioned in the testing manual/Work Instructions	-	-	-	-
	PC 16 make minor modification in test setup/medical device /component cum accessories under testing to take reading under different scenarios as per the requirement	-	-	-	-
	PC 17 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**
	PC 18 Check the medical device before starting the on testing of the medical device as per the checklist and required collateral standards requirements	-	-	-	-
	PC 19 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**
	PC 20 maintain and update the records test results, data log etc. as per SOP	-	-	-	-
	PC 21 Report and Document the errors in the medical devices to the supervisor	-	-	-	-
	PC 22 clean and store the tools, equipment and process auxiliaries as per SOP after completion of work	-	-	-	-
	PC 23 dispose of scrap or waste material in accordance with the company policies and environmental regulations	-	-	-	-
	Total Marks	**20**	**40**	**20**	20
5. LFS/N6305, Ver 1.0 To carry out result analysis, reporting and documentation to meet quality and regulatory standards	*Reporting*	**10**	**10**	**5**	**5**
	PC 1 report defects/problem/incidents/quality issues/test results as applicable in a timely manner	-	-	-	-
	PC 2 report to the appropriate authority as laid down by the company	-	-	-	-
	PC 3 follow reporting procedures as prescribed by the test report format(TRF)	-	-	-	-
	PC 4 work with quality team to provide feedback regarding quality standards and issues	-	-	-	-
	PC 5 help other lab staff with any other testing required during the Quality test	-	-	-	-
	Recording and documentation	**10**	**15**	**5**	**5**
	PC 6 identify documentation to be completed relating to ones role	-	-	-	-
	PC 7 record details accurately in an appropriate format	-	-	-	-
	PC 8 accurately document the results of the inspections and testing	-	-	-	-
	PC 9 maintain all controlled document files and test records in a timely and accurate manner	-	-	-	-
	PC 10 ensure that the final document meets regulatory and compliance requirements	-	-	-	-
	PC 11 make sure documents are available to all appropriate authorities to inspect	-	-	-	-

	PC 12 evaluate problems and make initial recommendations for possible corrective action to supervise	-	-	-	-
	PC 13 perform a review of records and other documentation for compliance to established procedures and good documentation practices	-	-	-	-
	PC 14 write and update the inspection procedures, protocols, and checklists	-	-	-	-
	PC 15 prepare inspection reports as per the inspection activity performed	-	-	-	-
	Information Security	**10**	**15**	**5**	**5**
	PC 16 document the results of the testing and analysis accurately	-	-	-	-
	PC 17 maintain all original and controlled document files and quality records in a timely and accurate manner following ALCOA PLUS principles	-	-	-	-
	PC 18 respond to requests for information in an appropriate manner whilst following organizational procedures	-	-	-	-
	PC 19 make sure documents are available to all appropriate authorities to inspect/ audit	-	-	-	-
	Total Marks	**30**	**40**	**15**	**15**
6. LFS/N0134 Ver 1 .0 Coordinate with Manager, Supervisor/engineer, teams and auditors	*Coordination with Supervisor*	**10**	**10**	**5**	**5**
	PC 1 receive work instructions from reporting supervisor	-	-	-	-
	PC 2 communicate to reporting supervisor about the progress on job allocated and device performance to the superiors	-	-	-	-
	PC 3 escalate problems to superiors that cannot be handled	-	-	-	-
	PC 4 communicate deviations / abnormal incidents to the reporting manager	-	-	-	-
	PC 5 communicate any potential hazards or expected process disruptions to the manager	-	-	-	-
	Coordination with colleagues and auditors	**10**	**15**	**5**	**5**
	PC 6 support team members and colleagues of other departments in work	-	-	-	-
	PC 7 resolve inter-personnel conflicts and achieve smooth workflow	-	-	-	-
	PC 8 deposit faulty modules and tools to stores	-	-	-	-

	PC 9 explain what information means and how it can be used by team members	-	-	-	-
	PC 10 maintain their own as well as team members sense of calm/equilibrium	-	-	-	-
	PC 11 interact with the auditor in English language	-	-	-	-
	PC 12 provide clear answers to the auditor's queries	-	-	-	-
	PC 13 produce the documented records of performed activities and operations to auditors	-	-	-	-
	Sensitivity towards all genders and people with disability	**10**	**15**	**5**	**5**
	PC 14 respect all the genders, religions, and caste	-	-	-	-
	PC 15 empathize with the people with disability	-	-	-	-
	PC 16 offer support or help to a person with disability only when asked	-	-	-	-
	PC 17 ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act	-	-	-	-
	PC 18 report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
	Total Marks	**30**	**40**	**15**	15
7. DGT/VSQ/N0102: v1 Employability Skills	*Introduction to Employability Skills*	**1**	**1**	-	-
	PC 1 identify employability skills required for jobs in various industries	-	-	-	-
	PC 2 identify and explore learning and employability portals	-	-	-	-
	Constitutional values – Citizenship	**1**	**1**	-	-
	PC 3 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.	-	-	-	-
	PC 4 follow environmentally sustainable practices	-	-	-	-
	Becoming a Professional in the 21st Century	**2**	**4**	-	-
	PC 5 recognize the significance of 21st Century Skills for employment	-	-	-	-

	PC 6 Practice 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**	-	-
	PC 7 use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-
	PC 8 read and understand routine information, notes, instructions, mails, letters etc. written in English	-	-	-	-
	PC 9 write short messages, notes, letters, e-mails etc. in english	-	-	-	-
	Career Development & Goal Setting	**1**	**2**	-	-
	PC 10 understand the difference between job and career	-	-	-	-
	PC 11 prepare a career development plan with short- and long-term goals, based on aptitude	-	-	-	-
	Communication Skills	**2**	**2**	-	-
	PC 12 follow verbal and non-verbal communication etiquette and active listening techniques in various settings	-	-	-	-
	PC 13 work collaboratively with others in a team				
	Diversity & Inclusion	**1**	**2**	-	-
	PC 14 communicate and behave appropriately with all genders and PwD	-	-	-	-
	PC 15 escalate any issues related to sexual harassment at workplace according to POSH Act	-	-	-	-
	Financial and Legal Literacy	**2**	**3**	-	-
	PC 16 select financial institutions, products and services as per requirement	-	-	-	-
	PC 17 carry out offline and online financial transactions, safely and securely	-	-	-	-
	PC 18 identify common components of salary and compute income, expenses, taxes, investments etc	-	-	-	-

	PC 19 identify relevant rights and laws and use legal aids to fight against legal exploitation	-	-	-	-
	Essential Digital Skills	**3**	**4**	-	-
	PC 20 operate digital devices and carry out basic internet operations securely and safely	-	-	-	-
	PC 21 use e- mail and social media platforms and virtual collaboration tools to work effectively	-	-	-	-
	PC 22 use basic features of word processor, spreadsheets, and presentations	-	-	-	-
	Entrepreneurship	**2**	**3**	-	-
	PC 23 identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research	-	-	-	-
	PC 24 develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion	-	-	-	-
	PC 25 identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity	-	-	-	-
	Customer Service	**1**	**2**	-	-
	PC 26 identify different types of customers	-	-	-	-
	PC 27 identify and respond to customer requests and needs in a professional manner	-	-	-	-
	PC 28 follow appropriate hygiene and grooming standards	-	-	-	-
	Getting ready for apprenticeship & Jobs	**2**	**3**	-	-
	PC 29 create a professional Curriculum vitae (Resume)	-	-	-	-
	PC 30 search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively	-	-	-	-
	PC 31 apply to identified job openings using offline /online methods as per requirement	-	-	-	-

	PC 32 answer questions politely, with clarity and confidence, during recruitment and selection	-	-	-	-
	PC 33 identify apprenticeship opportunities and register for it as per guidelines and requirements	-	-	-	-
	Total Marks	**20**	**30**	**-**	-
Grand Total		**200**	**270**	**90**	90

Annexure: Assessment Strategy

This section includes the processes involved in identifying, gathering, and interpreting information to evaluate the Candidate on the required competencies of the program.

Mention the detailed assessment strategy in the provided template.

1. Assessment System Overview:

The assessment for the Training will be conducted toward the end of the training duration. The assessment of the qualification shall be carried out by NCVET approved assessment agencies empaneled by LSSSDC after a defined evaluation process. For Execution of the assessment for training for the qualification, LSSSDC will be engaging more than one NCVET approved assessment agency/ body.

1.1 Criteria of selection of assessment body/agency:

The assessment body/agency is selected based on:

- Prior experience and understanding of Life Sciences or similar sector.
- Experience in conducting assessments for similar job roles.
- Manpower and Technical capabilities.
- Geographical reach
- Existing Network in the Life Sciences Sector
- Agencies internal policies to maintain standards, quality & professional Integrity
- Agencies policy and practices in assessor management
- NCVET approval

1.2 Assessment tool development for assessment of Training:

For the Training assessment, the assessment instrument development is done by the selected assessment body with close monitoring and support of LSSSDC at every stage.

1.2.1 Digital Written test for knowledge assessment:

Scope – Is used to test the knowledge component of the Qualification/ Micro Credential/ NOS.
Tools –computer or tab based online or offline.
Method – objective type questions, match the columns, fill in the blanks, tick the odd man out, choose the correct option, choose the best answer, True or false, Identify the object, tool or machinery, arrange in proper sequence, case study, scenario-based responses.
Analysis – Question paper is divided into sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section-wise calculation of marks gives a clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

1.2.2 Digital Written test for skill assessment:
Scope – Is used to test primarily the Skill component of the Qualification/ Micro Credential/ NOS. Trainee's expertise in handling and managing the situation is tested.
Tools – computer or tab based online or offline questions
Method – A situation is narrated or created in the question posed to the trainee and he is asked objective type questions to select the correct reaction to the situation. The selected situations are based on real situations.
Analysis – Question paper is divided into sections. Each Section intends to assess a particular skill field of the trainee. Thus, section-wise calculation of marks gives a clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

1.3 Steps for assessment tool development:

- The selection of assessment tool(s) is done as per the assessment criteria prescribed in Qualification Pack.
- For Junior Engineer -EMI/EMC testing for medical devices and IVD assessment a blueprint of the question paper is part of the assessment tool for training.
- Development of layout of Question paper is such that the entire PCs (Performance Criteria) of that Qualification/ Micro Credential/ NOS are covered.
- Score per question maps with the weightage given to that PC, in the assessment criteria, and the level of difficulty of the question.
- An expert from industry is selected who is called "Subject Matter Expert" (SME). This SME must have over 13-15 years of experience in the industry in Quality – Medical Devices and IVD occupation.
- SME is screened and approved by LSSSDC. He/she is oriented by both LSSSDC and Assessment agency on – creating question Bank, level of questions, end the desired outcome of the assessment.

1.4 Execution of Training Assessment/ RPL Assessment:

- Once the assessment date for training is decided with common agreement of Industry/ Vocational Training Centre and LSSSDC, LSSSDC allocates the batch to an NCVET approved and LSSSDC empaneled assessment body/agency.
- Assessment agency ensures.
    - the availability of required infrastructure
    - the availability of validated assessment tools for the assessment of training for the assigned qualification
    - the availability of assessor as per assessor eligibility criteria of the qualification
- Assessment agencies send the assessment confirmation to VTP/TC looping SSC.
- Assessment agency deploys LSSSDC certified assessor for executing the assessment.
- LSSSDC monitors the assessment process & records.
- The assessment is executed in two possible ways depending on the choice of the industry:

1.4.1 Tab based assessment using physical proctoring.
1.4.2 Smartphone-based assessment using e-proctoring.

1.4.1 Tab-based assessment using physical proctoring.

- A representative from the Assessment agency is present on the day of assessment to execute the assessment at the venue in case of physical proctoring.
- The assessment agency representative carries an identity card and letter from the council authorizing to conduct the assessment.
- Assessment agency representative ensures the authenticity of Trainee's identity by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving License, Passport, Election card, etc)
- The assessment agency representative maintains the records of attendance, verified documents, and tablet instruments used in the assessment.
- Assessment agency representative collects evidence of the assessment in the best possible way (videos, pictures, voice recordings, etc)
- Assessment agency representative transfers the assessment scores from tab to assessment agency server, using a secure, encrypted web-based program.
- The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days of assessment.

1.4.2 Smartphone-based assessment using e-proctoring

- All trainees enrolled in the batch due for assessment, are registered on an assessment tool application using their unique mobile number and e-mail ID along with a Govt. ID issued proof.
- An assessment link is sent to the mail ID of each trainee with a defined expiry date of the link.
- Trainee at any location can click on the link using his/her smartphone or a web camera-enabled computer system
- Using the unique credentials and Govt ID number, the trainee logs in for the start of assessment and completes the assessment.
- The authenticity of Trainee's identity is done by assessment application by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving Licence, Passport, election card, etc.) and a live photo capture
- A live video of the candidate during the assessment is captured to collect the evidence of the assessment

- Once the assessment is complete, the assessment application automatically assessment scores to the assessment agency server, using a secure, encrypted web-based program.
- The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days of assessment.

2. Testing Environment:

- The Centre/ location of the assessment is pre decided and geo tagged in case of physical assessment
- The assessment of LSSSDC qualifications are 99% done in digital environment while 1% pen and paper is used ONLY in business exigencies
- Based on the size of batch the assessment duration/ no. of required assessors are decided to ensure detailed assessment without any negative impact on quality of assessment
- The system driven automated assessment management system ensures uniform time allocation to each student, unique logins for each students and automated randomization of questions for developing multiple sets of question paper for single batch.
- Identity check of the student is mandated

3. Assessment Quality Assurance levels/Framework:

- Question bank is created by the Subject Matter Experts (SME) of Assessment Agency are verified by the other SME of LSSSDC
- All Questions are mapped to the specified assessment criteria
- Assessor eligibility criteria are structured to ensure quality and knowledge credentials of an assessor like-wise the trainer's quality and knowledge credentials.
- Eligible Assessor must be certified by LSSSDC for the respective and relevant qualification
- The tools used for assessment are validated for relevance and feasibility for skill assessment of the qualification in consideration

4. Types of evidence or evidence-gathering protocol:

- Time-stamped & geotagged reporting of the assessor from assessment location
- ID Proof of the students
- Educational qualification of students
- Certificate of Trainer
- In case of Physical assessment, geotagged photographs of the students undergoing assessment
- While students are undergoing assessment on the digital assessment platform the system captures random photos of the student which is audited by LSSSDC

5. Method of verification or validation:

- Surprise visit to the assessment location
- ID Proof of the students for identity verification
- Educational qualification verification of students for validation of entry level criteria
- Certificate of Trainer to verify the credential of vocational educator
- Random photos taken by the digital system are verified during audit by the assessment team

6. Method for assessment documentation, archiving, and access

- Hard copies and digital copies (whichever is applicable) of the assessment evidences are stored with assessment agency team for 5 years
- Assessment transcripts are stored in the server space of assessment agency for 5 years.
- Assessment question banks and validation records are stored with assessment agency and LSSSDC digitally.
- Assessment records are archived with assessment agency archive server after 5 years for another 5 years.
- Access of assessment records are controlled with restricted access to concerned department and stakeholders and is shared on demand after due approval of Head of Assessment and Certification-LSSSDC

7. On the Job Training Assessment (applicable for OJT/ Apprenticeship):

7.1 Each module/ NOS will be assessed separately.

7.2 The candidate must score a minimum percentage as per assessment criteria laid out in qualification in each module to successfully complete the OJT exam.

7.3 Tools of OJT Assessment that will be used for assessing whether the candidate is having desired skills and competence, including Soft Skills effectively:

- Videos of Trainees during OJT (wherever possible)
- Observation based mark sheet from Supervisor or OJT examiner
- Simulated question paper
- XR practice module analytics wherever possible

7.4 Assessment of each Module will ensure that the candidate is able to:

- Meet minimum performance criteria of the expected outcome/ skill set for each module/ NOS
- Understand and know the required concepts and its application at workplace
- Has gained the required employability skills

Annexure: Acronym and Glossary

Acronym

Acronym	Description
AA	Assessment Agency
AB	Awarding Body
ISCO	International Standard Classification of Occupations
NCO	National Classification of Occupations
NCrF	National Credit Framework
NOS	National Occupational Standard(s)
NQR	National Qualification Register
NSQF	National Skills Qualifications Framework
OJT	On the Job Training

Glossary

Term	Description
National Occupational Standards (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.
Qualification	A formal outcome of an assessment and validation process which is obtained when a competent body determines that an individual has achieved learning outcomes to given standards
Qualification File	A Qualification File is a template designed to capture necessary information of a Qualification from the perspective of NSQF compliance. The Qualification File will be normally submitted by the awarding body for the qualification.
Sector	A grouping of professional activities on the basis of their main economic function, product, service or technology.
Long Term Training	Long-term skilling means any vocational training program undertaken for a year and above. https://ncvet.gov.in/sites/default/files/NCVET.pdf