**APPRENTICESHIP CURRICULUM (OPTIONAL TRADE)**

**Life Sciences**

**Specialist- Quality Assurance (Pharma, Biological Products and Medical Devices): Process Validation**

**Course Code: CO022500005**

[x] **NAPS** [ ] **Non-NAPS**

**NSQF Level: 5.5**

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# Course Details

|  |  |  |
| --- | --- | --- |
|  | **Course Name** | **Specialist- Quality Assurance (Pharma, Biological Products and Medical Devices): Process Validation**  |
|  | **Course Code** | **CO022500005** |
|  | **Apprenticeship Training Duration:***(2 to 4 weeks of BT is embedded in this duration as per the requirement of the establishment)* | **Months: 6 Months**  |
| **Remarks** |  |
|  | **Credit** | **20.00** |
|  | **NSQF Level** (*Mandatory for NAPS*) | 5.5 **NSQC Approval Date:** 29th September 2023 |
|  | **Related NSQF aligned qualification details** |

|  |  |  |  |
| --- | --- | --- | --- |
| **S. No.** | **Instantiated QP Name** | **Instantiated QP Code & Version** | **NQR Code** |
| 1. | **Specialist- Quality Assurance (Pharma, Biological Products and Medical Devices): Process Validation** | **LFS/Q0313-SI002(v1.0)** | **QG-5.5-LS-00998-2023-V1-LSSSDC** |

 |
|  | **Brief Job Role Description** | A Specialist- Quality Assurance (Pharma, Biological Products and Medical Devices): Process Validation performs physical checks, conducts document verification exercise, ensures compliance to quality management systems and procedures, undertakes risk control assessment, conducts/participates in internal/external audits and also carries out process and equipment validation and in-process sampling, finished product sampling activities. |
|  | **NCO-2015 Code & Occupation** (*Access the NCO 2015 volumes from:* [*https://labour.gov.in/organizationsofmole/directorate-general-employment-training-dget*](https://labour.gov.in/organizationsofmole/directorate-general-employment-training-dget) ) | NCO-2015/2131.1300Quality |
|  | **Minimum Eligibility Criteria** *(Educational and/ or Technical Qualification)* | M. Pharma final year studentOR M.Tech (in relevant field) final year studentORB. Tech (in relevant field)/B. Pharma with 2 Year experience (Quality Assurance/Quality Control/production)OR M.Sc (in relevant subjects) with 2 Year experience (Quality Assurance/Quality Control/production) OR Previous Relevant Qualification of NSQF Level 5 Certificate of Chemist In-process Quality Assurance (Pharma, Biologics and Medical Device) with 1.5 Years of Exp. in relevant area ORPrevious Relevant Qualification of NSQF Level 5 Certificate of Analyst/Chemist-Quality Control with 1.5 Years of Exp. in relevant area ORPrevious Relevant Qualification of NSQF Level 5 Certificate of Chemist Production with 1.5 Years of Exp. in relevant area |
|  | **Entry Age for Apprenticeship** | 21 Years |
|  | **Any Licensing Requirements** (*wherever applicable*) | NA |
|  | **Is the Job Role amenable to Persons with Disability** | [ ]  **Yes** [x]  **No****If yes, check the applicable type of Disability**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [ ]  **Locomotor Disability** | [ ]  **Leprosy Cured Person** | [ ]  **Cerebral Palsy**  | [ ]  **Dwarfism** | [ ]  **Muscular Dystrophy** |
| [ ]  **Acid Attack Victims** | [ ]  **Blindness** | [ ]  **Low Vision** | [ ]  **Deaf**  | [ ]  **Hard of Hearing** |
| [ ]  **Speech and Language Disability** | [ ]  **Intellectual Disability** | [ ]  **Specific Learning Disabilities** | [ ]  **Autism Spectrum Disorder** | [ ]  **Mental Illness** |
| [ ]  **Multiple Sclerosis** | [ ]  **Parkinson's Disease** | [ ]  **Hemophilia** | [ ]  **Thalassemia** | [ ]  **Sickle Cell Disease** |
| [ ]  **Multiple Disabilities** |  |  |  |  |
|  |

 |
|  |  | **Remarks:** |
|  | **Submitting Body Details** | **Name:** Life Sciences Sector Skill Development Council**E-mail ID:** info@lsssdc.in**Contact Number:** 011-41042407/8 |
|  | **Certifying Body**  | Life Sciences Sector Skill Development Council |
|  | **Employment Avenues/Opportunities** | **Pharmaceutical/Biotechnology/Contract Research Organizations/Medical Device/Regulatory Agencies etc.**Jobs Opportunities in private companiesThe trainees can get a job in a corporate as Specialist- Quality Assurance (Pharma, Biological Products, and Medical Devices). |
|  | **Career Progression** | **Vertical progression** 1.Manager- Quality Assurance (Pharma, Biological Products & Medical Devices) 2. Quality Assurance Lead Auditor- (Pharma, Biological Products & Medical Devices) **Lateral/Horizontal progression** 1. QC Reviewer/Section In- Charge (Pharma, Biological Products & Medical Devices) 2. Specialist- Quality Control Instrumental Analysis (Pharma, Biological Products & Medical Devices) |
|  | **Trainer’s Qualification & Experience:** | Graduate B.Tech/B.Pharma with 7 years of experience in Specialist Quality Assurance occupation and 2 years of experience on the Job assessment/Training experience/Vocational assessment/ Academic assessment with Certification for Job Role: “Specialist- Quality Assurance (Pharma, Biological products, and Medical Devices)” mapped to Qualification Pack: “LFS/Q0313, V1.0” with minimum accepted score of 80%. OrPostgraduate M.Sc with 5 years of experience in Specialist Quality Assurance occupation and 2 years of experience on the Job assessment/Training experience/Vocational assessment/ Academic assessment with Certification for Job Role: “Specialist- Quality Assurance (Pharma, Biological products, and Medical Devices)” mapped to Qualification Pack: “LFS/Q0313, V1.0” with minimum accepted score of 80%.OrPostgraduate M.tech/M.Pharma with 5 years of experience in Specialist Quality Assurance occupation and 3 years of experience on the Job assessment/Training experience/Vocational assessment/Academic assessment with Certification for Job Role: “Specialist- Quality Assurance (Pharma, Biological products, and Medical Devices)” mapped to Qualification Pack: “LFS/Q0313, V1.0” with minimum accepted score of 80%.AndRecommended that the Trainer is certified for the Job Role: “Trainer (VET and Skills)”, mapped to the Qualification Pack: “MEP/Q2601, v3.0” with minimum score of 80%. |
|  | **Curriculum Creation Date** | 04 February 2024 |
|  | **Curriculum Valid up to Date** | 29 September 2026 |

# Module Details

| **S. No** | **Module/NOS Name, Code, Version** | **Outcomes** | **Assessment Marks** | **Passing Percentage**  |
| --- | --- | --- | --- | --- |
| **Th.** | **Pr.** | **Th.** | **Pr.** |
|  | **Ensure adherence to Environment, health and safety guidelines in a manufacturing facility and GMP controlled areas : LFS/N0125 v1.0** | * Adhere to health and personal hygiene- related protocols as per WHO standards and cGMP guidelines.
* Ensure to wash the hands and feet before entering the manufacturing area with soap/alcohol-based sanitizers.
* Check any communicable or contagious diseases like allergy, sickness, or any other environment related issues and inform your supervisor.
* Follow gowning procedures as per SoP while entering an environment- controlled work area and emergency procedures efficiently.
* Adhere to safety and security policies, procedures, and emergency protocols for any alarms to ensure the safety of individuals in the area under supervision.
* Use appropriate safety gears, like headgear, mask, gloves and other accessories as per SOP guidelines.
* Report the alarm and notify the designated person immediately for action in cases of spill, fall, injury, toxic inhalation, fire, explosion, or any hazards.
* Maintain discipline for material segregation and 5S system is followed at the storage area under supervision
* Assist supervisor to implement preventive and corrective actions for identified deviations in safety and security policies and for reported hazards in consultation with EHS personnel.
* Follow the safety and security policies and procedures under supervision .
 | 30 | 70 | 70% | 70% |
|  | **Coordinate with Manager, colleagues and auditors: LFS/N0302 v3.0** | * Report supervisor about the process-ﬂow improvements, production defect which is received from the previous process.
* Report about any deviations / abnormal incidents and any potential hazards or expected process disruptions to the manager.
* Assist to find the solutions to workﬂow related diﬃculties with mutual agreement under the guidance.
* Assist supervisor for coordination with QA for audit related documentation for QC analysis.
* Adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act.
* Report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee under the guidance of a supervisor.
* Respect all genders, religions, & caste and empathize with the people with disability.
 | 35 | 65 | 70% | 70% |
|  | **Ensure GxP compliance, respond to issues and non-conformance to maintain regulatory standards and procedures: LFS/N0348 v1.0** | * Assist manager in following the key GxP (GMP, GLP, GCP, GDP) regulations and their specific requirements in maintaining product quality, patient safety, and regulatory compliance under the guidance.
* Ensure proper collection of the information regarding the nature, context, and scope of the non-conformance incident under the guidance of manager.
* Assist manager in maintaining the routine monitoring and auditing requirements as specified by SOPs and in accordance to GMP under supervision.
* Assist manager in risk assessments to evaluate potential impact and likelihood of non-conformance.
* Ensure preparation of proper document related to non- conformance incidents accurately, including relevant evidence and comprehensive report which is suitable for cross- functional communication & regulatory purposes under the guidance of senior.
* Assist in Organizing and maintaining documentation for regulatory inspections related to non-conformance incidents.
* Assist manager to take the appropriate corrective and or preventive action in response to compliance issues.
* Practice how to provide the document support to regulatory departments for compilation of various regulatory documents, including verification of in-process quality check documentation under the guidance of manager.
* Support manager for collaboration with the production/packaging teams for providing line clearance regular documentation (online/offline) of all the activities to remove compliance.
* Follow the Monitoring and reporting compliance metrics to track performance under supervision.
 | 30 | 70 | 70% | 70% |
|  | **Employability Skills (90 Hours) : DGT/VSQ/N0103 V1.0** | * Comprehend the importance of employability skills in fulfilling the current demands of the job market and the future of work.
* Learn strategies for navigating learning and employability platforms effectively.
* Delve into the significance of legal values, encompassing civic rights and responsibilities, citizenship, and societal obligations.
* understand personal values and ethics like integrity, honesty, respect, and empathy.
* Apply 21st Century Skills such as self-awareness, interpersonal skills, time management, critical and adaptive thinking, problem-solving, creative thinking, cultural and social awareness, emotional intelligence, and continuous learning in both personal and professional spheres.
* Read and comprehend routine information, notes, instructions, emails, letters, etc., presented in English.
* Practice basic English communication for everyday conversations in various contexts, both in person and over the telephone.
* Write concise messages, notes, letters, and emails in English.
* Differentiate between a job and a career and grasp their distinctions.
* Demonstrate respectful and appropriate communication and behavior when interacting with individuals of all genders and persons with disabilities (PWD).
* Discuss the protocol for reporting instances of sexual harassment in the workplace according to the guidelines set out in the POSH Act.
* Identify the key components of a salary, calculate income, expenses, taxes, and potential investments.
* Explore relevant rights and laws and utilize legal resources to combat instances of exploitation.
* Recognize and enumerate various forms of entrepreneurship and enterprises, and evaluate potential business opportunities through research.
* Identify potential sources of funding, and anticipate and address potential financial or legal challenges in pursuing a business opportunity.
* Explain the process of identifying different customer types and understanding their needs.
* Identify available apprenticeship opportunities and complete the registration process following the provided guidelines and requirements.
* Prepare a sample career development plan with short- and long-term goals, based on aptitude.
* Practice following verbal and nonverbal communication etiquette and active listening techniques in various settings.
* Practice how to carry out offline and online financial transactions, safely and securely.
* Operate digital devices and carry out basic internet operations securely and safely.
* Demonstrate the use of e- mail and social media platforms and virtual collaboration tools to work effectively.
* Practice the of use basic features of word processor, spreadsheets, and presentations.
* Develop a sample business plan and a work model, considering the 4ps of marketing product, price, place, and promotion.
* follow appropriate hygiene and grooming standards.
* Create a sample professional curriculum vitae (résumé)
* Practice how to search for suitable jobs using reliable offline and online sources such as employment exchange, recruitment agencies, newspapers etc. And job portals, respectively
* Identify job openings using offline /online methods as per requirement
 | 20 | 30 | 70% | 70% |
|  | **Perform Process validation: LFS/N0305, v2** | * Assist manager in coordination and performance of QC method qualifications, validations, and transfers.
* Learn how to prepare and execute the process of validation protocols for new products and for changes to existing products.
* Assist manager in developing the testing strategies and rationale for equipment and systems.
* Learn how to manage the change control requests and Corrective and Preventive Action Systems (CAPAS) that relate to process validation.
* Support the manager in developing and executing risk assessments.
* Assist to maintain complete and accurate documentary evidence concerning Qualification and Validation exercises .
* Follow company procedures (SOPs) regarding validations under supervision.
* Learn how to create documents to ensure compliance with applicable quality objectives and regulatory requirements under the guidance of manager.
* Assist to ensure the compliance with applicable quality objectives and regulatory requirements under supervision.
* Learn how to plan and coordinate all process validation testing with QC and how to review the validation analytical data.
* Learn how to monitor the regulatory and inspection trends under supervision and report to the manager.
* Support to the manager in ensuring conformance with current process validation regulations.
* Assist to maintain the routine programs and processes to ensure high quality products and compliance with current Good Manufacturing Practices (GMPs) and Good Laboratory Practices (GLPs).
 | 30 | 70 | 70% | 70% |
|  | **Documentation for process validation: LFS/N0351, v1** | * Learn how to ensure alignment with regulatory requirements and internal procedures through conducting review of process validation documentation under supervision.
* Assist manager in ensuring that all process validation documentation complies with both internal procedures and industry guidelines.
* Maintain all required documentation is present and properly filled out under the guidance of manager.
* Assist manager in reviewing documentation to confirm that risk assessment activities are conduct appropriately.
* Learn how deviations and non- conformances encountered during process validation.
* Assist manager to collaborate with validation team members and other stakeholders to address documentation- related issues and concerns.
* Learn how to identify opportunities for improvement in documentation processes and enhancement in efficiency and effectiveness of equipment validation.
* Determine how to implement improvements to streamline documentation review procedures and promote best practices.
 | 30 | 70 | 70% | 70% |
|  | **Perform Process Validation for change control: LFS/N0352, v1** | * Learn how to analyze the scope and extent of the changes to determine the necessary validation activities.
* Follow the comprehensive validation protocols that cover all critical aspects of the process changes.
* Support the manager in ensuring validation protocols align with regulatory guidelines, industry best practices, and internal quality standard
* Assist to collaborate with relevant stakeholders, including engineering, production, and quality teams to gather input and ensure alignment on validation plans under the guidance of manager.
* Help manager to identify the areas for improving process validation processes within change control.
* Learn how to conduct equipment testing, including all relevant parameters functional, performance, and qualification testing, as per the validation protocols.
* Maintain accurate and reliable data during validation activities, assist manager in ensuring adherence to predefined data collection methods under supervision.
* Assist to verify the validation documentation meets regulatory expectations and internal change control procedures under supervision.
* Support manager to identify potential impacts on process performance, reliability, and regulatory compliance.
 | 30 | 70 | 70% | 70% |
| **Total Marks** | **205** | **445** | **70%** |

#

# Glossary

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

# Acronyms

|  |  |
| --- | --- |
| **Acronym**  | **Description** |
| AA | Assessment Agency |
| AB | Awarding Body |
| ISCO | International Standard Classification of Occupations  |
| QP | Qualification Pack  |
| NCO | National Classification of Occupations |
| NCrF | National Credit Framework |
| NSQF | National Skills Qualification Framework |
| NSQC | National Skills Qualification Committee |
| NOS | National Occupational Standards |
| AYUSH  | Ayurveda, Yoga, Naturopathy, Unani |
| PPE | Personal Protective Equipment |
| hrs | Hours |

#

# Annexure 1: Tools and Equipment

## List of Tools and Equipment

The tools and equipment required are:

|  |  |  |
| --- | --- | --- |
| **S. No.** | **Tool / Equipment Name** | **Specification** |
|  | Co2 type and ABC type fire extinguisher | As per Industry Requirements |
|  | Face Mask (Half and Full Face) | As per Industry Requirements |
|  | Gloves | As per Industry Requirements |
|  | GMP Guideline Book | As per Industry Requirements |
|  | Sample Job Card | As per Industry Requirements |
|  | Sample Log Books | As per Industry Requirements |
|  | Flip Charts | As per Industry Requirements |
|  | Sample Production Planning Schedule | As per Industry Requirements |
|  | Sample Shift Schedule | As per Industry Requirements |
|  | Sample Method Validation Reports | As per Industry Requirements |
|  | Sample Audit Reports and Sample Audit Responses | As per Industry Requirements |
|  | Sample Calibration Records | As per Industry Requirements |
|  | Sample Change Control Records | As per Industry Requirements |
|  | Sample SOP (Standard Operating Procedure) | As per Industry Requirements |
|  | Sample Qualification Reports (DQ, IQ, OQ, PQ) | As per Industry Requirements |

##

## Classroom Aids

The aids required to conduct sessions in the classroom are:

1. Projector
2. Computer/laptops
3. Internet connectivity
4. Whiteboard
5. Scanner
6. Computer speaker
7. Marker pens
8. Pencil

# Annexure 2: 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.

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. **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. **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. ***Digital Written test for knowledge assessment:***

**Scope –** Is used to test the knowledge component of the QP.

**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. ***Digital Written test for skill assessment:***

**Scope –** Is used to test primarily the Skill component of the QP. 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. **Steps for assessment tool development:**
		+ The selection of assessment tool(s) is done as per the assessment criteria prescribed in Qualification Pack
		+ Specialist- Quality Assurance (Pharma, Biological Products, and Medical Devices): Process Validation 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 QP 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 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.
	2. **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. Tab based assessment using physical proctoring
		2. Smartphone-based assessment using e-proctoring
		3. **Tab-based assessment using physical proctoring**
			+ A representative from the Assessment agency is present on the day of assessment to executing 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.
		4. **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.
1. **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
1. **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
1. **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
1. **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
1. **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):**

* 1. Each module/ NOS will be assessed separately.
	2. The candidate must score minimum percentage as per assessment criteria laid out in qualification in each module to successfully complete the OJT exam.
	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
	1. 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 3: Not Applicable