APPRENTICESHIP CURRICULUM

for

Maintenance Assistant- Life Sciences

Under

Life Sciences

for

NSQF compliance

National Apprenticeship Promotion Scheme

1	**Program Title**	Maintenance Assistant- Life Sciences
2	**Program Code, if any**	LFS/Q0215
3	**Any related NSQF approved QP/Course/NOS and code**	LFS/Q0215- Maintenance Assistant- Life Sciences 1. LFS/N0238: Support supervisors in the maintenance process 2. LFS/N0237: Comply with maintenance schedules and ensure smooth flow of work 3. LFS/N0103: Ensure cleanliness in the work area 4. LFS/N0102: Carry out reporting and documentation 5. LFS/N0101: Maintain a healthy, safe and secure working environment in the life sciences facility
4	**Hours for Basic Training (Block I)**	160 Hours/ 20 Days
5	**Hours for On the Job Training (Block II)**	4304 Hours / 23.2 Months Year 1: 2144 Hours / 11.2 Months Year 2: 2160 Hours / 12 Months Note: (48 hours per week for Year 1 & 45 hours per week for Year 2)
6	**Certifying body for Basic Training Program**	Life Sciences Sector Skill Development Council
7	**Certifying Body for On the Job training**	Industry/ Industries from Life Sciences Sector
8	**Any Licensing requirements, wherever applicable**	NA
9	**Minimum eligibility criteria (Educational and/ or technical Qualification)** **Exemptions, if any**	Preferably 10^{th}-12^{th} Class
10	**Trainer's Qualification and Experience**	ITI with 8 years relevant exp. or Polytechnic Diploma with 6 years relevant exp. or Graduate Engineer with 5 years relevant exp.
11	**NCO code and occupation**	NCO 2015-7233.1100/Manufacturing

12	**Proposed NSQF level**	3
13	**Indicative list of training tools required to deliver this qualification (may be attached)**	Attached in Annexure A

14 Formal structure of the curriculum

	Modules	Notional hours- Theory	Notional hours- Practical	Total duration
Basic Training Program	1. Describe Life Sciences Industry and its regulations for manufacturing	05:00	00:00	5 Hours
	2. Providing Support in the maintenance process in line to GMP protocols	40:00	25:00	65 Hours
	3. Complying with Maintenance schedule and ensuring smooth flow of work as per GMP protocols	15:00	10:00	25 Hours
	4. Transportation of Material and tools	02:00	04:00	6 Hours
	5. Basics Communication at Workplace for Maintenance Assistant	02:00	03:00	5 Hours
	6. Reporting, Recording and communication to comply GMP	05:00	03:00	8 Hours
	7. Use of IT Skills in Reporting and Recording	02:00	08:00	10 Hours
	8. Information Security	01:00	00:00	1 Hour
	9. Ensure Healthy, Safe and Secure Workplace	15:00	05:00	20 Hours
	10. Ensure cleanliness in the work area in compliance to GMP	10:00	05:00	15 Hours
Total		97.00	63.00	160 Hours

On the Job Training Program	1. Maintain Safety and Hygiene	16:00	64:00	80 Hours
	2. Clean and maintain shop floor area and machines	16:00	64:00	80 Hours
	3. Follow Good Manufacturing Practice	08:00	32:00	40 Hours
	4. Assist in maintenance of plant machineries	120:00	1976:00	2096 Hours
	5. Assist in maintenance of Utility System (HVAC/ Water/Gases/Electrical)	120:00	1152:00	1272 Hours
	6. Complete documentation as per SOP and GMP	32:00	64:00	96 Hours
	7. Follow maintenance schedule as per GMP	120:00	384:00	504 Hours
	8. Coordinate with cross functional teams	16:00	40:00	56 Hours
	9. Perform Waste disposal and Management as per GMP and EHS rules	16:00	64:00	80 Hours
Total		464.00	3840.00	4304 hours

15 Total Pass marks

	Pass Marks-Theory	**Pass Marks- Practical**
Basic Training Program	**70%**	**70%**
On the Job Training Program	**0**	**70%**

16	**Job description-brief**	The maintenance assistant assists maintenance supervisors in carrying out maintenance activities for various utilities like HVAC, Water, Gases, and Steam & Electricity.
17	**Progression from the qualification (Please show Professional**	**Upward progression:** Maintenance Supervisor/ Incharge – HVAC- Life Sciences (Level-5)

	and academic progression)	Maintenance Supervisor/ Incharge – Water- Life Sciences (Level-5) Maintenance Supervisor/ Incharge – Gases- Life Sciences (Level-5) Maintenance Supervisor/ Incharge – Steam- Life Sciences (Level-5) Machine Operator – Life Sciences (Level-4) Effluent Treatment Plant Operator (Level-4) **Lateral/ Horizontal progression:** Fitter Mechanical- Life Sciences (Level-3)
18	**Employment avenues/opportunities**	The candidates after their tenure as apprentice may do any of the following: a. Maintenance Assistant (immediately) b. Fitter Mechanical- Life Sciences (1-2 years exp.) c. Machine Operator – Life Sciences (with 2-3 years exp.) d. Effluent Treatment Plant Operator (with 2-3 years exp.) e. Maintenance Supervisor/ Incharge – HVAC- Life Sciences (with 5 years exp.) f. Maintenance Supervisor/ Incharge – Water- Life Sciences (with 5 years exp.) g. Maintenance Supervisor/ Incharge – Gases- Life Sciences (with 5 years exp.) h. Maintenance Supervisor/ Incharge – Steam- Life Sciences (with 5 years exp.)
19	**Assessment strategy (Basic training and On the Job)**	Attached in Annexure B
20	**Curriculum update version and date**	V1.0, 24/12/2018
21	**Curriculum revision date**	24/04/2022

Curriculum

Module Name with duration	Key Learning outcomes
Theory/Basic Training Program- Block I	
Describe Life Sciences Industry and its regulations for manufacturing **Theory Duration** (hh:mm) 05:00 **Practical Duration** (hh:mm) 00:00 **Corresponding NOS Code** Bridge Module	• Demonstrate general discipline of the class room • Outline Life Sciences Industry working environment and practices in Indian and Global context • Recall relevant Govt. scheme, social security benefits, and manufacturing basics and requirements in the pharmaceutical & biopharmaceutical sub-sector of Life Sciences Industry • Explain the Regulatory Authorities and Government policies, rules and regulations and their impact on maintenance activities in manufacturing organisations, relevant to Life Sciences Industry. • Explain the organization Structure and Benefits in Life Sciences Industry (in context of large/ medium/ small enterprises) • Illustrate about typical maintenance activities of manufacturing processing function in a Life Sciences organization. • Summarize the Role of a maintenance assistant and required skills and identify its Career Path • Interpret the basic idea of the machinery used in production and take responsibility for assisting the maintenance supervisors in monitoring and installing infrastructure for HVAC, Water, Gases and Steam & Electricity • Apply correct process of tools handling.
Providing Support in the maintenance process in line to GMP protocols **Theory Duration** (hh:mm) 40:00 **Practical Duration** (hh:mm) 25:00 **Corresponding NOS Code** LFS/N0238	• Select the right tools for proper assembly installation and maintenance of utility infrastructure and production machines and their parts in life sciences plant and facility • Implement the requirement of maintenance of manufacturing equipment parts in compliance to GMP protocols • Use the correct maintenance equipment, materials or chemicals for maintenance activities in life sciences plant and facility • Facilitate supervisor to maintain proper levels of material/ supplies / gases as per GMP protocols and other safety instructions and SOPs • Assess different defects in the utility equipment and production machines and perform the maintenance procedure as guided by the maintenance supervisor • Perform maintenance activities by applying the knowledge of machines & utilities (HVAC, gases, water, electricity, steam), their

	operating steps and their fault tolerance and preventive maintenance requirements • Perform maintenance activities in compliance with Good Manufacturing Practices, Quality Assurance procedures, all other applicable regulations and company policies • Pull damaged or ineffective equipment off the production line • Remove utility and machine attachments • Dispose the waste material from machinery before maintenance and then install/ uninstall/ dissemble the machine and its part • Distinguish faults and perform their repair or recovery or replacement • Initiate the change request process as per GMP protocol • Report the maintenance status & take corrective action in response to typical faults and inconsistencies as per GMP protocol • Facilitate in verifying the equipment accuracy post maintenance activity, by performing trail runs and ensure that there are no leakages • Facilitate in recalibration of the machine/ part/ equipment post every corrective maintenance • Assure elimination of water leaks from pipes and faulty valves • Prove that the discharge air from cooling towers is not re-cycled into the intake • Assure that heat exchange coils are kept clean • Assess whether the AHUs are performing active de-humidification or humidification • Control fan coils using room air temperature sensors • Eliminate all sources of air leakage through damaged flexible connections, poor ductwork joints and access doors/panels • Respond to emergency calls for system and equipment failure • Carry out disposal of waste and leftover maintenance material as per the standard operating procedure • Dispose all materials used in the maintenance activities as per the health and safety management system of the company in compliance to local laws and good manufacturing practices • Assess for damaged labels, outdated chemicals, and damaged containers and update them as per the required schedule and get them ready for future use • Demonstrate Core Skills and Professional Skills at work: • Reading, writing, listening and speaking, critical thinking, problem solving, decision making, customer centricity, plan and organizing, analytical thinking and meet the desired work specifications

Complying with Maintenance schedule and ensuring smooth flow of work as per GMP protocols **Theory Duration** (hh:mm) 15:00 **Practical Duration** (hh:mm) 10:00 **Corresponding NOS Code** LFS/N0237	• Act as per maintenance work flow sequence and schedules • Perform periodic preventive maintenance and calibration as per the SOPs and GMP protocols • Show the appropriate signage for the work being conducted • Evaluate adequate ventilation before starting the maintenance activity • Clean the shop floor area or workplace after maintenance activity to avoid slippage or scrap material on floor, in compliance with cleaning procedures and protocols • Demonstrate compliance to safety instructions and GMP rules for every maintenance activity • Initiate the maintenance activity with permission of the shop floor supervisor and communicate the estimated time for maintenance activity • Estimate the material requirements for maintenance activity and report supervisor for indenting/ sourcing the required resource • Report maintenance status on time and proactively inform the supervisor about his/ her absence/ vacation plans • Identify and report Implications of delays in maintenance process • Adapt safety procedures and maintain safety data sheets as per GMP protocols • Establish time and cost estimates for the installation and maintenance of machines; and demonstrate the compliance to estimates • Demonstrate Core Skills and Professional Skills at work: • Reading, writing, listening and speaking, critical thinking, problem solving, decision making, customer centricity, plan and organizing, analytical thinking and meet the desired work specifications
Transportation of Material and tools **Theory Duration** (hh:mm) 02:00 **Practical Duration** (hh:mm) 04:00 **Corresponding NOS Code** LFS/N0237	• Adapt correct methods of handling and moving of material, tools, machine and parts • Assure the proper handling, storage, transportation and removal of all hazardous materials • Perform Basic physical activities of climbing, lifting, stooping, walking etc. • Attach slings, ropes, cables to the object • Use the fork lift or trolley as applicable • Demonstrate the compliance to the methods of driving while using the transport machineries • Perform the maintenance of transport machineries • Examine the obstructions in the path of transportation • Load & stack the stock, tools & transport it safely

Basics Communication at Workplace for Maintenance Assistant **Theory Duration** (hh:mm) 02:00 **Practical Duration** (hh:mm) 03:00 **Corresponding NOS Code** LFS/N0237 LFS/N0102	• Secure historical record of equipment maintenance, layout/ circuit diagram, user manual before carrying out the maintenance activity • Read and interpret maintenance requirement and machine specifications, job sheets, procedures, diagrams of basic machine control panels, material labels and safety information as provided • Read and interpret the graphs/ images of product and instructions given in tool/ equipment manual • Interpret basic understanding of machines/ engineering plants control panel, material labels & safety signage, applicable GMP protocols, various coding system of the company by regular communication with supervisors, operators and quality assurance team • Record and summarise details of work done in compliance to GMP protocols • Adapt daily report format and submission as per the instructions laid in SOPs and GMP protocols • Evaluate the impact of wrong practices and inform to supervisor • Compose maintenance assessment report with inputs from shop floor team, in compliance to GMP protocols • Distinguish un-resolved issues and report to supervisor for finding solutions
Reporting, Recording and communication to comply GMP **Theory Duration** (hh:mm) 05:00 **Practical Duration** (hh:mm) 03:00 **Corresponding NOS Code** LFS/N0102	• Recall company's standard operating procedure, GMP and EHS guidelines • Read and compose memos, job cards, reports etc. in pre-decided format both Offline and online as per SOPs • Select the correct method of documentation as per SOPs and GMP protocols • Report in time about each and every incident • Adapt validation process of document as per GMP protocols • Identify and report incidents where SOP are not followed • Adapt escalation matrix for decision making that is not defined in SOP • Record & describe the work done in local language and/ or English • Use efficient and clear communication methods for reporting the incidents and communication with team
Use of IT Skills in Reporting and Recording **Theory Duration** (hh:mm)	• Apply Information technology in online reporting as per GMP protocols • Operate computers, internet, MS Word and MS Excel • Use MS outlook for mail communication • Enter the data/information as per the SOPs

02:00 **Practical Duration** (hh:mm) 08:00 **Corresponding NOS Code** LFS/N0102	
Information Security **Theory Duration** (hh:mm) 01:00 **Practical Duration** (hh:mm) 00:00 **Corresponding NOS Code** LFS/N0102	• Recognize confidential and sensitive information while performing the maintenance activities • Adapt the data integrity rules while entering the information in various types of documents in compliance of GMP protocol • Demonstrate compliance to the information security procedures while communicating • Imitate data integrity while communicating with supervisor, auditors, clients and QA team
Ensure Healthy, Safe and Secure Workplace **Theory Duration** (hh:mm) 15:00 **Practical Duration** (hh:mm) 05:00 **Corresponding NOS Code** LFS/N0101	• Recall the concepts of Safety including Hazards, Accidents, Safety Signs and Signals and Heinrich Pyramid and practice same at shop floor • Adapt the EHS guidelines, local laws, SOPs and GMP protocols while maintaining the Water Systems, Utilities and other Engineering related tools and techniques to operate the machine safely. • Demonstrate the Clean Room Behaviour practices • Utilize Material Data Safety Sheet and follow the process of Safety Analysis. • Use the Fire Safety concepts in case of fire emergency at shop floor. • Use PPEs in different maintenance operations • Perform Job Safety Analysis for maintenance of various utility/ production machines/ equipment and provide the critical information to concerned team members. • Adapt the Emergency Procedures as and when required and perform first aid for occupational injury • Demonstrate Core Skills and Professional Skills at work: Reading, writing, listening, speaking, plan and organize, critical thinking, problem solving, decision making, customer centricity

Ensure cleanliness in the work area in compliance to GMP **Theory Duration** (hh:mm) 10:00 **Practical Duration** (hh:mm) 05:00 **Corresponding NOS Code** LFS/N0103	• Assure level of hygiene as required by storage/ working area/ manufacturing/ lab as the most important part of maintenance activity at workplace • Adapt basic instructions and tools used for housekeeping • Recall methodology for storage area inspection with best methods and materials required for cleaning variety of surfaces and equipment • Recall all types of stains and cleaning material required to remove the specific stain • Apply the cleaning procedure including various types of risks, time and efficiency assessment • Examine alternate solution in case of unavailability of remover at that particular time • Distinguish the area under maintenance with the help of signage or labelling • Assess all types of working environment conditions (ventilation, temperature) and required personal protective equipment at the time of cleaning method & material usage. • Use correct methods as per GMP and SOP for various types of soiling & surface • Describe all types of accidental damage at the time of work • Assess any out of control situation and report to supervisor • Examine the workplace for cleanliness and ready to reuse post every maintenance activity • Examine the floor post cleaning activity for oily substance and scrap material around the work area • Anticipate accidental damage and reinforce the GMP protocol and workplace SOPs • Predict the need of cleaning kit and supplies • Initiate the procurement request for replenish the stock of cleaning kit and supplies • Assure storage of stock of cleaning kit and supplies as per GMP and GDP protocols • Use personal protective equipment and after use put them at neat and clean place • Dispose waste and scrap, and clean all equipment and follow manufacturer's instructions • Demonstrate Core Skills and Professional Skills at work: • Reading, writing, listening and speaking, critical thinking, problem solving, decision making, customer centricity, plan and organizing, analytical thinking and meet the desired work specifications

• On the Job Training Program- Block II	
Maintain Safety and Hygiene **Theory Duration** (hh:mm) 16:00 **OJT Duration** (hh:mm) 64:00 **Corresponding NOS Code** LFS/N0101	• Practice safety while performing maintenance activity by following gowning procedures as per SOP • Practise the Clean Room behaviour as per SOP while performing • Use personal protective equipment while maintenance work in plant • Follow EHS guidelines, local laws, SOPs and GMP protocols while maintaining the Water Systems, Utilities and other Engineering related tools and techniques to operate the machine safely • Follow organization guidelines for spillage and waste management • Adapt the Emergency Procedures as and when required and perform first aid for occupational injury • Follow the permit systems as per SOP • Perform Job Safety Analysis for maintenance of various utility/ production machines/ equipment and provide the critical information to concerned team members • Distinguish the area under maintenance with the help of signage or labelling as per SOP • Assess any out of control situation and report to supervisor
Clean and maintain shop floor area and machines **Theory Duration** (hh:mm) 16:00 **OJT Duration** (hh:mm) 64:00 **Corresponding NOS Code** LFS/N0101 LFS/N0103	• Explain existing shop floor infrastructure, equipment and relevant usage • Perform cleaning by using different methods as per SOP and GMP for various types of soiling and surface • Clean and maintain manufacturing machines and utility system as per SOP • Recall all types of stains and cleaning material required to remove the specific stain • Perform the cleaning procedure as per SOP including various types of risks, time and efficiency assessment • Use basic instructions and tools for maintenance activity • Maintain level of hygiene required by storage/ working area/ manufacturing/ lab after performing maintenance activity at workplace • Use personal protective equipment and after use put them at neat and clean place • Inspect the workplace for cleanliness and ready to reuse post every maintenance activity • Regularly checks/amends checklists, operation steps, spare parts consumption • Initiate the procurement request for replenish the stock of cleaning kit and supplies

	• Perform disposal of waste and scrap as per SOP and GMP • Perform cleaning validation under supervision
Follow Good Manufacturing Practice **Theory Duration** (hh:mm) 08:00 **OJT Duration** (hh:mm) 32:00 **Corresponding NOS Code** LFS/N0101 LFS/N0102 LFS/N0103 LFS/N0237 LFS/N0238	• Perform the role of a Maintenance Assistant following the good manufacturing practices • Explain the importance of GMP in life sciences manufacturing • Practice deviation management • Follow CAPA and change control procedure as per SOP and cGMP • Follow the principals of total productivity maintenance, 6-Sigma and lean sigma • Use the knowledge of process validation and equipment qualification for maintenance activities • Follow Ten Principles of GMP • Follow steps of quality risk management as per SOP • Practice data Integrity
Assist in maintenance of plant machineries **Theory Duration** (hh:mm) 120:00 **OJT Duration** (hh:mm) 1976:00 **Corresponding NOS Code** LFS/N0101 LFS/N0238	• Perform assembly, installation and maintenance of all machines and equipment using appropriate tools • Perform periodic calibration as per the SOPs and GMP protocols • Pull damaged or ineffective equipment off the production line • Remove utility and machine attachments • Attach slings, ropes, or cables to objects such as pipes, hoses, or bundles • Maintain all the accessories like cleaning brush, levers and release agent ready • Set and adjust controls for various machines and equipment • Verify that all electrical and mechanical equipment are always in proper working condition • Implement safety measures while carrying out maintenance activity • Perform daily checks of machines and equipment, UPS and electrical equipment as per SOP and maintain their logbooks • Ensure 100% supply of power to shop floors • Coordinate with building technicians (Mechanical & Electrical) • Run simulated testing of emergency lights powered through invertors • Carry out electrical planned preventive maintenance (PPM) and coordinate with (Annual Maintenance Contract) AMC vendor • Carry out Preventive Maintenance as per Schedule for all machines and equipment

	• Supervise maintenance works of AMC vendors • Record log entries of all incidents that happen with any equipment • Inform supervisor about any deviations in operating parameters that may result in an untoward incident
Assist in maintenance of Utility System (HVAC/ Water/Gases/ Electrical) **Theory Duration** (hh:mm) 120:00 **OJT Duration** (hh:mm) 1152:00 **Corresponding NOS Code** LFS/N0237 LFS/N0238 LFS/N0101	• Perform assembly, installation and maintenance of utility system (HVAC/Water/Gases/Electrical) using appropriate tools • Operate machines or equipment for HVAC, gases, water, steam and electricity • Remove utility and machine attachments • Switch on all utilities as required and ensure all systems are up and running. • Check utility parameters and record the same in logbooks for each equipment • Control the clean room operations using HVAC and electrical systems • Maintain the heat exchangers in a clean state • Replace or clean air filters regularly as per maintenance schedules • Check whether the AHUs are performing active de-humidification or humidification • Control fan coils using room air temperature sensors • Maintain proper levels of materials/supplies/gases to ensure timely and efficient completion of necessary tasks • Carry out Preventive Maintenance as per Schedule for Utility System • Use gases for machine operation wherever applicable • Use electricity for machine operation and identify the backup system available • Practice lean sigma, six sigma and GMP for smooth operations
Complete documentation as per SOP and GMP **Theory Duration** (hh:mm) 32:00 **OJT Duration** (hh:mm) 64:00 **Corresponding NOS Code** LFS/N0102	• Follow standard operating procedure, guidelines and various coding system of the company • Interpret the machines control panel signs, material labels & safety signage • Read and interpret the graphs/ images and instructions given in tool/ equipment manual, preventive maintenance plan and schedules, production work flow sequence and material safety sheet • Use the right format of documentation for recording and communicating details of work done as per SOP, GMP and GDP guidelines • Follow daily report format and submission as per the SOPs • Report and record every incident / deviation in time and as per SOP

	• Follow escalation matrix for decision making that is not defined in SOP • Read and write memos, job cards, reports in pre-decided format both Offline and online as per SOP • Help Facility Manager in making the monthly MIS reports • Use local language or English for recording and reporting as defined in SOP • Perform the documentation required for taking over and handing over in the shift • Review and verify the handover documents while taking over from previous shift
Follow maintenance schedule as per GMP **Theory Duration** (hh:mm) 120:00 **OJT Duration** (hh:mm) 384:00 **Corresponding NOS Code** LFS/N0237 LFS/N0102	• Follow up on pending jobs and take corrective actions under supervision • Check / record events in the daily log sheets as per SOP • Check AC temperature in Data Centre, UPS Room as per schedule • Check floor occupancy level and switch on/off lights • Check all electrical installation viz. panel rooms, LT Room for any abnormality and hot spots due to loose connections or hanging wires as per schedule • Check the UPS system and ensure that critical parameters like input voltage and frequency are within limits • Take rounds of all floors and areas and ensure that AC & Lighting is adequate • Inform the supervisor of any outage/ incident • Update FM with daily report parameters and PPM activities • Co-ordinate with Building managers operations team on scheduled operations of AHU's. • Check areas surrounding electrical installations for cleanliness • Attend requests/complaints received by maintenance department • Carry out cleaning of AHU filters and coordinate with housekeeping team for cleaning of AC diffusers (Grills) by Housekeeping team • Check Main MCB panels in co-ordination with RYC Maintenance electrician. • Provide material requisition for repairs / stock as per schedule • Get the written confirmation from building manager on PPM carried out on common utilities such as Lift, Earth pits, Transformers, LT& HT panels, Common area lighting, Public address system, FPS and Fire Alarm systems • Check maintenance service reports of AMC service providers and report any deviation from standards • Check healthiness and expiry dates of fire extinguishers as per schedule • Deviations if any should be corrected and escalated as required

Coordinate with Supervisor and cross functional teams **Theory Duration** (hh:mm) 16:00 **OJT Duration** (hh:mm) 40:00 **Corresponding NOS Code** LFS/ N0238 LFS/ N0102	• Manage supervisor- reportee relationship and identify partnering opportunities at work • Submit inventory report of the previous month to the Facility/Maintenance Manager as per SOP • Coordinate with ware house for availability of maintenance related parts and material • Coordinate with cross functional team for preventive and corrective maintenance in case of break down • Coordinate with QA for material authorization, process validation, equipment validation, equipment qualification, deviation/ incident reporting, change controls and audits • Use IT tools in communication and coordination • Use English or local language in communication, documentation and reports • Follow general reporting process, protocol and escalation matrix • Practice core and professional skills at work
Perform Waste disposal and Management as per GMP and EHS rules **Theory Duration** (hh:mm) 16:00 **OJT Duration** (hh:mm) 64:00 **Corresponding NOS Code** LFS/N0238	• Explain categories for pharmaceutical and bio-pharmaceutical industrial waste • Follow the material segregation rules as per SOP • Follow 5S principles for material handling • Perform decontamination of toxic waste before disposal • Perform disposal of waste and left over material as per SOP, GMP and EHS guidelines • Summarize and implement waste management technologies used in life sciences manufacturing facilities • carry out regular checks for water leaks from chillers and the chilled water distribution system • Remove damaged labels, expired chemicals and damaged containers as per SOP

List of Assessable outcomes/assessment criteria

Assessment Criteria	
Job Role	**Maintenance Assistant – Life Sciences**
Qualification Pack	**LFS/Q0215, V1.0**
Sector Skill Council	**Life Sciences Sector Skill Development Council**

Sr. No.	Guidelines for Assessment
1	Criteria for assessment for each Qualification Pack will be created by the Sector Skill Council. Each Performance Criteria (PC) will be assigned marks proportional to its importance in NOS. SSC will also lay down proportion of marks for Theory and Skills Practical for each PC
2	The assessment for the theory part will be based on knowledge bank of questions created by the SSC
3	Individual assessment agencies will create unique question papers for theory part for each candidate at each examination/training center (as per assessment criteria laid out in Qualification Pack)
4	Individual assessment agencies will create unique evaluations for skill practical for every student at each examination/training center based on the assessment criteria laid out in qualification pack
5	To pass the Qualification Pack, every trainee should score a minimum of 70% aggregate in all NOS and a minimum of 50% in every NOS
6	In case of successfully passing only certain number of NOS's, the trainee is eligible to take subsequent assessment on the balance NOS's to pass the Qualification Pack

				Marks Allocation	
Assessment Outcome	**Assessment Criteria of outcome**	**Total Marks (500)**	**Out of**	**Theory**	**Skills Practical**
1. LFS/N0238: Support supervisors in the maintenance process	PC1. support supervisor in assembling the infrastructure properly		4	2	2
	PC2. coordinate with supervisor to get the parts ordered for installation or as spare parts		4	2	2

PC3.	assist in maintaining proper levels of materials/supplies/gases to ensure timely and efficient completion of necessary tasks		4	2	2
PC4.	support the supervisor in prevention of defects and quality as per requirement		4	2	2
PC5.	start machines or equipment for HVAC, gases, water, steam and electricity		2	2	0
PC6.	scrape waste material from the machine		2	2	0
PC7.	clean and lubricate equipment to make it fit for use as per the SOP		4	2	2
PC8.	clean the approach path of obstructions for ease in transportation from the storage area for input to the storage area for output		3	1	2
PC9.	use hands and arms in handling, installing, positioning, moving materials, and manipulating things		4	2	2
PC10.	observe equipment operations so that malfunctions can be detected, and notify operators of any malfunctions		3	1	2
PC11.	attach slings, ropes, or cables to objects such as pipes, hoses, or bundles		4	2	2
PC12.	keep all the accessories like cleaning brush, levers, and release agent ready		4	2	2
PC13.	set and adjust controls		4	2	2
PC14.	take up the results of the findings with the appropriate authority		4	2	2

	PC15. performs sanitation of machines, totes, and other areas		3	1	2
	PC16. ensure that there are no leakages		4	2	2
	PC17. ensure compliance with all regulations, 5S, TPM guidelines and company policies		4	2	2
	PC18. report & take corrective action in response to typical faults and inconsistencies		3	1	2
	PC19. support in calibrating the testing equipment periodically as per the SOP		4	2	2
	PC20. verify the equipment accuracy by performing dry runs		4	2	2
	PC21. respond to emergency calls for system and equipment failure		3	1	2
	PC22. carry out disposal of waste and left-over tested material safely as per the SOP		4	2	2
	PC23. dispose all materials used in the experiment safely as per health and safety management system of the company		4	2	2
	PC24. ensure the proper handling, storage, transportation and removal of all hazardous materials		4	2	2
	PC25. check for damaged labels, outdated chemicals, and damaged containers		4	2	2
	PC26. carry out regular checks for water leaks from chillers and the chilled water distribution system		2	1	1
	PC27. maintain log books to record the amount of refrigerant added to systems		4	2	2
	Total		**100**	**49**	**51**

2. LFS/N0103: Ensure cleanliness in the work area	PC1. survey the area while taking into account various surfaces & equipment	100	4	2	2
	PC2. take into account the material requirements for cleaning the areas inspected, by considering risk, time, efficiency and type of stain		5	2	3
	PC3. maintain the cleaning equipment & keep it in proper working condition		5	2	3
	PC4. select the suitable alternatives for cleaning the areas in case the appropriate equipment and materials are not available and inform the appropriate person		4	2	2
	PC5. know the sequence for cleaning the area to avoid re-soiling clean areas and surface		4	2	2
	PC6. inform the affected people about the cleaning activity		4	2	2
	PC7. arrange & display the appropriate signage for the work being conducted		4	2	2
	PC8. maintain adequate ventilation while the cleaning process is carried out.		5	2	3
	PC9. wear the personal protective equipment required for the cleaning method and materials being used		4	2	2
	PC10. use disposable gloves during the cleaning process		4	2	2

PC11. use the correct cleaning method for the work area, type of soiling and surface		4	2	2
PC12. carry out cleaning activity without disturbing others		4	2	2
PC13. deal with accidental damage, if any, caused while carrying out the work		4	2	2
PC14. report to supervisors in case of difficulties in carrying out your work		4	2	2
PC15. coordinate with other manufacturing helpers to carry out comprehensive cleaning		4	2	2
PC16. avoid oily substances		4	2	2
PC17. ensure that no scrap material is lying around		4	2	2
PC18. maintain and store housekeeping equipment and supplies		4	2	2
PC19. follow workplace procedures to deal with any accidental damage caused during the cleaning process		5	2	3
PC20. on completion of the work, the area is left clean and dry and meets requirements		5	2	3
PC21. dispose the waste garnered from the activity in an appropriate manner		5	2	3
PC22. maintain schedules and records for housekeeping		5	2	3

	duty (sign off & sign in according to work shifts)				
	PC23. replenish any necessary supplies or consumables		5	2	3
	Total		**100**	**46**	**54**
3. LFS/N0101: Maintain a healthy, safe and secure working environment in the life sciences facility	PC1. observe and comply with the company's current health, safety and security policies and procedures	100	10	5	5
	PC2. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines		10	5	5
	PC3. report any identified breaches in health, safety, and security policies and procedures to the designated person		10	5	5
	PC4. responsible for maintaining discipline at the shop-floor/ production area		10	5	5
	PC5. identify and correct any hazards that the individual can deal with safely, competently and within the limits of their authority		10	5	5
	PC6. adhere and comply to storage and handling guidelines for hazardous material		10	5	5
	PC7. identify and recommend opportunities for improving health, safety, and security to the designated person		10	5	5
	PC8. complete any health, safety and security activities like safety drills and prepare		10	4	6

	records legibly and accurately				
	PC9. report any hazards that the individual is not competent to deal with to the relevant person in line with organizational procedures and warn other people who may be affected		10	4	6
	PC10. follow the company's emergency procedures promptly, calmly, and efficiently		10	5	5
	Total		**100**	**48**	**52**
4. LFS/N0237: Comply with maintenance schedules and ensure smooth flow of work	PC1. judge the material requirements for carrying maintenance	100	5	2	3
	PC2. follow the defined schedule for routine maintenance in coordination with the relevant stakeholders (including preventive maintenance) activities such that work is not hindered		5	2	3
	PC3. display the appropriate signage for the work being conducted		5	2	3
	PC4. report on time and proactively inform the supervisor about absence/ vacation plans		5	2	3
	PC5. maintain the heat exchangers in a clean state		5	2	3
	PC6. ensure that there is no oily substance on the floor to avoid slippage		5	2	3

	PC7. ensure that, on completion of the work, the area is left clean and dry and meets requirements		5	2	3
	PC8. ensure that no scrap material is lying around		5	2	3
	PC9. ensure that the equipment, materials and personal protective equipment that were used are returned to the right places making sure they are clean, safe and securely stored		5	2	3
	PC10. ensure that there is adequate ventilation for the work being carried out		5	2	3
	PC11. follow safety procedures and maintain safety data sheets for crews		5	2	3
	PC12. keep time and cost estimates in mind for the installation and maintenance		5	2	3
	PC13. replenish any necessary supplies or consumables		5	2	3
	PC14. ensure elimination of water leaks from pipes and faulty valves		5	2	3
	PC15. ensure that the discharge air from cooling towers is not re-cycled into the intake		5	2	3
	PC16. ensure heat exchange coils are kept clean		5	2	3
	PC17. replace or clean air filters regularly, in accordance with maintenance schedules		5	2	3

	PC18. investigate whether the AHUs are performing active de-humidification or humidification		5	2	3
	PC19. Control fan coils using room air temperature sensors		5	2	3
	PC20. Eliminate all sources of air leakage through damaged flexible connections, poor ductwork joints and access doors/panels		5	2	3
	Total		**100**	**40**	**60**
5. LFS/N0102: Carry out reporting and documentation	PC1. report data/problems/incidents as applicable in a timely manner	100	10	5	5
	PC2. report to the appropriate authority as laid down by the company		10	5	5
	PC3. follow reporting procedures as prescribed by the company		10	5	5
	PC4. identify documentation to be completed relating to one's role		10	5	5
	PC5. record details accurately in an appropriate format		10	5	5
	PC6. complete all documentation within stipulated time according to company procedure		10	5	5
	PC7. ensure that the final document meets regulatory and compliance requirements		10	5	5
	PC8. make sure documents are available to all appropriate authorities to inspect		10	5	5

	PC9. respond to requests for information in an appropriate manner whilst following organizational procedures		10	5	5
	PC10. inform the appropriate authority of requests for information received		10	4	6
	Total		**100**	**49**	**51**

Annexure A: List of Tools and Equipment for Maintenance Assistant

S. No.	Equipment Name	Minimum number of Equipment required (per batch of 30 trainees)	Unit Type	Is this a mandatory Equipment to be available at the Training Center (Yes/No)	Dimension/Specification /Description of the Equipment/ ANY OTHER REMARK
1	File 200 mm	5	Nos	Yes	
2	Hammer 200 gm	5	Nos	Yes	
3	screw driver 200 mm	5	Nos	Yes	
4	Combination pliers 200 mm	5	Nos	Yes	
5	Line tester 240 v	5	Nos	Yes	
6	Soldering Iron 100 w	5	Nos	Yes	
7	Bench vice 150 mm	5	Nos	Yes	
8	Hack saw 300 mm	5	Nos	Yes	
9	Pipe wrench 250 mm	5	Nos	Yes	
10	Snip 200 mm	5	Nos	Yes	
11	Tube cutter 4 - 12 m m	5	Nos	Yes	
12	Tube Bender	1	Set	Yes	
13	Swaging tool	2	Set	Yes	
14	Pinching tool	5	Nos	Yes	
15	Flaring tool	5	Nos	Yes	
16	Gauge manifold set	2	Nos	Yes	
17	Compound gauge	2	Nos	Yes	
18	Pressure Gauge	2	Nos	Yes	
19	Volt meter	2	Nos	Yes	
20	Ammeter	2	Nos	Yes	

21	Multi meter	2	Nos	Yes	
22	Halide torch	1	Nos	Yes	
23	Thermometer	2	Nos	Yes	
24	Double end spanner set	2	Nos	Yes	
25	Ring spanner set	2	Nos	Yes	
26	Box spanner set	1	Nos	Yes	
27	Adjustable spanner	5	Nos	Yes	
28	Crimping Tool	2	Nos	Yes	
29	Megger	1	Nos	Yes	
30	Long Nose Plier	5	Nos	Yes	
31	Line Tester	5	Nos	Yes	
32	Brazing Kit	2	Nos	Yes	
33	Grinding machine	1	Nos	Yes	
34	drilling machine	1	Nos	Yes	
35	Window AC 1 Ton	1	Nos	Yes	
36	Split AC 1.5 Ton	1	Nos	Yes	
37	Electrical Controls of Package AC	1	Set	Yes	
38	Electrical Controls Systems of Central AC	1	Set	Yes	
39	Safety Helmet	5	Nos	Yes	
40	Safety Jacket	5	Nos	Yes	
41	Safety Belt	5	Nos	Yes	
42	Safety Shoe	5	Nos	Yes	
43	Gloves	10	Nos	Yes	
44	Industrial Chiller Prototype Model	1	Nos	Yes	
45	Sling Psychrometer	2	NOS	Yes	
46	Psychrometric chart	1	Nos	Yes	
47	Vacuum Pump	2	Nos	Yes	
48	Nitrogen Cylinder with necessary	1	Nos	Yes	

	safety accessory				
49	Soap solution	5	Nos	Yes	
50	Noncontact thermometer	1	Nos	Yes	
51	Loose wire (3 C x 2.5 mm Cupper cable)	100	Meter	Yes	
52	Series Test lamp	2	Nos	Yes	
53	Earth tester	1	Nos	Yes	
54	Screw driver set 2 mm toe size to 12 mm toe	2	Set	Yes	
55	Fixed spanner or goti set	1	Set	Yes	
56	Teflon Tape	20	Nos	Yes	
57	PVC Insulation Tape	20	Nos	Yes	
58	RustLick	2	Ltr	Yes	
59	Rutoline	2	Ltr	Yes	
60	Round, flat, triangular type file (Rough/ smooth)	1 nos each type	Nos	Yes	
61	Silicon sealant	20	Nos	Yes	
62	Puff seal	5	Bottel	Yes	
63	Nitrile rubber Insulation 9mm	30	Mtr	Yes	
64	Griding, buffing and cutting wheels	5 nos each	Nos	Yes	
65	Hish speed drill bit set	2	Set	Yes	
66	L key set Inch and mm	1 each	Set	Yes	
67	Ball valve ½” half inch	5	Nos	Yes	
68	Ball valve 1”	5	Nos	Yes	
69	Switch and sockets board 15 amp	5	Nos	Yes	
70	Level gauge	2	Nos	Yes	
71	Right angle 200 mm x200 mm	1	Nos	Yes	

72	Clamp meter true RMS 100 A	1	Nos	Yes	
73	Co2 Type & ABC Type Fire Extinguisher	2	Nos	Yes	
74	Gum Boots	2	Nos	Yes	
75	Anemometer	1	Nos	Yes	
76	Inclined type /U-type manometer	1	Nos	Yes	
77	Digital manometer	1	Nos	Yes	
78	Thermal hygrometer to measure RH/Temp	1	Nos	Yes	
79	Water hardness testing kit	1	Nos	Yes	

Annexure B:

Assessment Maintenance Assistant

The assessment for the Basic Training and On the Job Training will be conducted toward the end of the OJT duration.

Assessment Process:

The assessment will be in two parts as below:

Part 1: OJT Assessment

For OJT assessment the Industry nominated assessor will be assessing the candidates based on the OJT monitoring report submitted by Industry supervisor and Viva by the Industry nominated assessor

1.1 Industry nominated assessor:

The Assessors are engaged to conduct the assessments by Industry. The selection takes place as follows

- Industry defines the criteria for profile of an assessor.
- Assessor is a person who is currently working in the same industry on same or higher job role and has minimum 5-7 years of experience.
- Once selected, the assessor is oriented by Industry using LSSSDC guidelines on various aspects of the assessment and management of assessment, such as
- QP and its background.
- Training on Assessment methodology and how to use Assessment tools. Scoring system. (as per the attached assessment guide)
- Maintain integrity at the assessment site.
- Crisis handling and support system available for the same.
- Scope of his authorities
- Administrative responsibilities.
- Required documentation of Trainee credentials, mark sheet management.
- Confidentiality management.

1.2 Assessment Tool for OJT:

1.2.1 OJT Monitoring Report:

- As in Life Sciences Sector reproducing the evidence for assessment is not feasible due to constraints like cost, confidentiality and controlled environment, every apprentice is required to record the evidences performed during the OJT and the same gets authorized by his/her supervisor.
- The evidence recording is done in a structured monitoring report, termed as OJT monitoring report.
- During the OJT, every trainee is required to fill the OJT monitoring report which is required to be signed by his/her supervisor.
- Towards the end of OJT period these reports are submitted with the HR department of company
- These duly submitted reports are then verified by an Industry nominated assessor for verification of evidence.

1.2.2 Viva:

Scope – Is used to test the knowledge and understanding and skills acquired during the OJT as well as to conform the OJT monitoring report.
Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth of knowledge, comprehension, presentation, patience etc) can also be tested required for the QP.

Tools – Direct dialogue between assessor and Trainee.

Method – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision making based questions. Different questions are included to test relevant PCs from the QP

Analysis – Assessor draws a spectrum of ready answers to be expected from trainee. This reduces effect of subjectivity of the assessor. Comparative quality of trainees with in a batch or different institutes can be gauged.

1.3 Execution of OJT Assessment:

- HR department then hands over the individual OJT monitoring report with Industry nominated assessor and schedules an assessment meeting for each trainee
- Industry nominated assessor assesses each trainee based on OJT monitoring report, viva on each PC and attendance with each trainee towards the end of the OJT period.

- The OJT marks are compiled for each NOS by the Industry nominated assessor and submitted with HR department of company.
- The OJT assessment results are then sent to LSSSDC by HR department of company in a sealed envelope for compiling the assessment results.

Part 2: Basic Training Assessment

For Execution of the assessment for basic training, LSSSDC will be engaging more than one assessment agencies/ body.

2.1 Criteria of selection of assessment body/agency:

The assessment body/agency is selected on the basis of

- 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 in assessor management

2.2 Assessment tool for Basic Training:

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

2.2.1 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 in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

2.2.2 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 in sections. Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

2.3 Steps for assessment development:

- Selection of assessment tool(s) is done as per the assessment criteria prescribed in Qualification Pack.
- For Medical Sales Representative assessment a blue print of the question paper, is part of assessment tool for basic training.
- Development of lay-out 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 sales & marketing occupation.
- SME is screened and approved by LSSSDC. He is the oriented by both LSSSDC and Assessment agency on – creating question Bank, level of questions, end desired outcome of the assessment.

2.4 Execution of Basic Training Assessment:

- Once LSSSDC receives the OJT assessment results, the assessment date for basic training is decided with common agreement of Industry and LSSSDC and turn is directed to an assessment body/agency.
- Assessment agency ensures the availability of required infrastructure, tools for the assessment.
- The assessment is executed in two possible ways depending on the choice of industry:

2.4.1 Tab based assessment using physical proctoring
2.4.2 Smart phone-based assessment using e-proctoring

2.4.1 Tab-based assessment using physical proctoring

- A representative from Assessment agency are present on the day of assessment to execute the assessment at venue in case of physical proctoring.
- Assessment agency representative carries an identity card and letter from the council authorising to conduct the assessment.
- Assessment agency representative ensures authenticity of Trainee's identity by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving Licence, Passport, election card etc)
- Assessment agency representative maintains the records of attendance, verified documents and tablet instruments used in assessment.
- Assessment agency representative collects evidences of the assessment in best possible way (videos, pictures, voice recordings etc)
- Assessment agency representative transfer 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.

2.4.2 Smart phone-based assessment using e-proctoring

- All trainees due for assessments are registered on a 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 smart phone or a web camera enabled computer system
- Using the unique credentials and govt ID number, trainee logs in for start of assessment and completes the assessment.
- 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 candidate during the assessment is captured to collect the evidences of the assessment
- Once the assessment is complete, the assessment application automatically assessment scores 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.

Assessment Result compilation:

- LSSSDC compiles the score submitted by assessment agency and OJT score submitted by Industry HR department.
- LSSSDC cross checks and validates the data and declares the result to Industry and trainee.
- Passed trainees are provided with certificate