



Regulatory Affairs Executive(Ayurveda Siddha Unani)

QP Code: HSS/Q3702

Version: 1.0

NSQF Level: 5.5

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HSS/Q3702: Regulatory Affairs Executive(Ayurveda Siddha Unani)

Brief Job Description

Regulatory Affairs Executive ensure compliance with all ASU regulations and guidelines. They prepare and submit dossiers for product approvals, renewals, and amendments according to the receiving country's requirements. They guide the product labels, packaging, and promotional materials to comply with Ayush Drugs & Cosmetics Act norms. Coordinate with AYUSH departments and Pharmacopeial Labs for certifications and testing. Assist in preparing the company for audits by regulatory bodies.

Personal Attributes

They should exhibit good coordination, self-discipline, dedication, persistence, ethical behaviour and the ability to deal empathetically with clients and their families. They should have good communication skills in Hindi, English or any other local language.

Applicable National Occupational Standards (NOS)

Compulsory NOS:

1. [HSS/N3704: Conduct Regulatory Compliance, Licensing, and Submissions](#)
2. [HSS/N3705: Conduct Regulatory Information Database](#)
3. [HSS/N3706: Regulatory Liaisoning for Product Registration and Labelling.](#)
4. [HSS/N3707: Report and documentation](#)
5. [HSS/N9624: Maintain a safe and secure working environment](#)
6. [HSS/N9618: Follow infection control policies & procedures including biomedical waste disposal protocols](#)
7. [DGT/VSQ/N0102: Employability Skills \(60 Hours\)](#)

Qualification Pack (QP) Parameters

Sector	Healthcare
Sub-Sector	AYUSH
Occupation	Ayurveda-Pharmacy
Country	India

NSQF Level	5.5
Credits	18
Aligned to NCO/ISCO/ISIC Code	NCO-2015/ 2230
Minimum Educational Qualification & Experience	UG in relevant field (5.5-year UG (BAMS, BUMS, BSMS)) with NA of experience OR Completed 3 year UG degree (in Science/ Pharmacy (Ayurveda/Siddha/ Unani/Allopathy)) with 1.5 years of experience
Minimum Level of Education for Training in School	
Pre-Requisite License or Training	NA
Minimum Job Entry Age	21 Years
Last Reviewed On	NA
Next Review Date	NA
NSQC Approval Date	25/02/2026
Version	1.0

Remarks:

NA

HSS/N3704: Conduct Regulatory Compliance, Licensing, and Submissions

Description

This Occupational Standard outlines the systematic approach to conduct regulatory compliance and licensing of the drugs according to particular guidelines.

Scope

The scope covers the following :

- It consists of Drugs and Cosmetics Act and rules along with licensing process and international regulations.

Elements and Performance Criteria

Drugs and Cosmetics Act and rules

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

- PC1.** Wear Personal Protective Equipment (PPE)
- PC2.** Overview of the Manufacturing industry in India
- PC3.** Maintain a conducive ambience, environment and cleanliness in the setup
- PC4.** Identify regulatory authorities, regulations, legislation, and good practices
- PC5.** Demonstrate osmetics Act and rules, DMR(Drug and magical remedy act),legal metrology in India.

Licensing process and challenges

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

- PC6.** Explore the regulations governing ASU products
- PC7.** Coordinate for preparing regulatory dossiers for product approval
- PC8.** Coordinate for the licensing process and related challenges.
- PC9.** Facilitates the process of submission with regulatory authorities.
- PC10.** Monitor the e-aushadhi portal, online system of license applications and product approval

International regulations

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

- PC11.** Evaluate International regulations of major destinations for ASU product export.
- PC12.** Demonstrate the international regulatory frameworks, including the US FDA, EMA etc.
- PC13.** Guide and advise marketing and promotional departments for promotional material in compliance with regulatory norms
- PC14.** Identify regulations, guidelines, and standards applicable to their products or industry nationally or internationally.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** Relevant protocols, good practices, standards, policies, and procedures related to manufacturing.
- KU2.** Basic Knowledge of proper donning, doffing, and disposal procedures for each type of PPE kit.
- KU3.** Ability to cross reference and understand traditional formulation.
- KU4.** Concept of Pharmacopeial standards.
- KU5.** Traditional Knowledge of formulations.
- KU6.** Basic knowledge of GMP Schedule T.
- KU7.** Corrective and Preventive actions in the unit.
- KU8.** Development and management of programs.

Generic Skills (GS)

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

- GS1.** Write instructions as per the customized plan.
- GS2.** Complete all activities accurately and on time.
- GS3.** Interact and convey information effectively to clients and others.

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Drugs and Cosmetics Act and rules</i>	33	30	20	20
PC1. Wear Personal Protective Equipment (PPE)	-	-	-	-
PC2. Overview of the Manufacturing industry in India	-	-	-	-
PC3. Maintain a conducive ambience, environment and cleanliness in the setup	-	-	-	-
PC4. Identify regulatory authorities, regulations, legislation, and good practices	-	-	-	-
PC5. Demonstrate osmetics Act and rules, DMR(Drug and magical remedy act),legal metrology in India.	-	-	-	-
<i>Licensing process and challenges</i>	35	30	10	20
PC6. Explore the regulations governing ASU products	-	-	-	-
PC7. Coordinate for preparing regulatory dossiers for product approval	-	-	-	-
PC8. Coordinate for the licensing process and related challenges.	-	-	-	-
PC9. Facilitates the process of submission with regulatory authorities.	-	-	-	-
PC10. Monitor the e-aushadhi portal, online system of license applications and product approval	-	-	-	-
<i>International regulations</i>	32	30	10	20
PC11. Evaluate International regulations of major destinations for ASU product export.	-	-	-	-
PC12. Demonstrate the international regulatory frameworks, including the US FDA, EMA etc.	-	-	-	-
PC13. Guide and advise marketing and promotional departments for promotional material in compliance with regulatory norms	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC14. Identify regulations, guidelines, and standards applicable to their products or industry nationally or internationally.	-	-	-	-
NOS Total	100	90	40	60

National Occupational Standards (NOS) Parameters

NOS Code	HSS/N3704
NOS Name	Conduct Regulatory Compliance, Licensing, and Submissions
Sector	Healthcare
Sub-Sector	
Occupation	Ayurveda-Pharmacy
NSQF Level	5.5
Credits	4
Version	1.0
Next Review Date	NA

HSS/N3705: Conduct Regulatory Information Database

Description

This unit describes the systematic and ongoing process of ensuring that all unit operations, products, and practices consistently meet every applicable law, regulation, and guidelines.

Scope

The scope covers the following :

- The scope contains regulations, guidelines, and standards with data collection and maintenance along with data retrieval and reporting method.

Elements and Performance Criteria

Classify regulations, guidelines, and standards

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

- PC1.** Check Adherence to Approved Specifications and SOPs.
- PC2.** Identify Drugs and Cosmetics Act, 1940, and Rules thereunder (specifically Chapter IVA for ASU drugs).
- PC3.** Identify Pharmacopeial and GMP standards.
- PC4.** Classify guidelines governing ASU products

Data Collection and Maintenance

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

- PC5.** Identify data of Raw Material.
- PC6.** Check data for Finished Product .
- PC7.** Identify Regulatory Submission Data
- PC8.** Check for in process control data.

Data Retrieval & Reporting method

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

- PC9.** Facilitate Documentation and Traceability of Finished Product.
- PC10.** Track Documentation and record keeping.
- PC11.** Monitor standard operating procedures (SOPs) for reporting.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** Data Collection and Maintenance in the manufacturing unit.
- KU2.** Good Manufacturing Practices (GMP) for Documentation.
- KU3.** Data Governance and Data Ownership.
- KU4.** Concept of Drugs and Cosmetics Act, 1940.
- KU5.** Regulatory Reporting Requirements.
- KU6.** Audit Trail and Traceability.

KU7. Confidentiality and Data Security.

KU8. KU8. Audit and Inspection Techniques.

KU9. Regulations, Guidelines, and Standards related to the manufacturing unit.

Generic Skills (GS)

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

GS1. Read instructions and pamphlets provided by organization.

GS2. Keep abreast of the latest knowledge by reading relevant materials

GS3. Communicate in a polite, calm, empathetic and congenial manner.

GS4. Adopt a communication style to reflect gender, cultural, and religious sensitivities.

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Classify regulations, guidelines, and standards</i>	27	30	12	20
PC1. Check Adherence to Approved Specifications and SOPs.	-	-	-	-
PC2. Identify Drugs and Cosmetics Act, 1940, and Rules thereunder (specifically Chapter IVA for ASU drugs).	-	-	-	-
PC3. Identify Pharmacopeial and GMP standards.	-	-	-	-
PC4. Classify guidelines governing ASU products	-	-	-	-
<i>Data Collection and Maintenance</i>	30	20	10	10
PC5. Identify data of Raw Material.	-	-	-	-
PC6. Check data for Finished Product .	-	-	-	-
PC7. Identify Regulatory Submission Data	-	-	-	-
PC8. Check for in process control data.	-	-	-	-
<i>Data Retrieval & Reporting method</i>	27	30	10	10
PC9. Facilitate Documentation and Traceability of Finished Product.	-	-	-	-
PC10. Track Documentation and record keeping.	-	-	-	-
PC11. Monitor standard operating procedures (SOPs) for reporting.	-	-	-	-
NOS Total	84	80	32	40

National Occupational Standards (NOS) Parameters

NOS Code	HSS/N3705
NOS Name	Conduct Regulatory Information Database
Sector	Healthcare
Sub-Sector	
Occupation	Ayurveda-Pharmacy
NSQF Level	5.5
Credits	4
Version	1.0
Next Review Date	NA

HSS/N3706: Regulatory Liaisoning for Product Registration and Labelling.

Description

This unit covers all critical activities performed by relevant personnel across all departments that impact product quality, safety, and regulatory compliance, ensuring that operations are conducted securely and ethically.

Scope

The scope covers the following :

- It consists of post-marketing requirements.

Elements and Performance Criteria

• *Post-marketing requirements*

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

- PC1.** Coordinate for Post-Marketing Studies.
- PC2.** Identify product quality reviews.
- PC3.** Advise marketing and promotional departments for promotional material in compliance with regulatory norms.
- PC4.** Demonstrate pharmacovigilance for drugs.
- PC5.** Describe the process of submission with regulatory authorities regarding inquiries and clarifications.
- PC6.** Conduct the packaging and labelling.
- PC7.** Demonstrate how to track changes, maintain version control, and ensure accountability for data updates.
- PC8.** Conduct safety procedures for routine and non-routine operations.
- PC9.** Identify potential hazards and risks associated with specific tasks, equipment, and the work environment.
- PC10.** Identify all applicable local, national, and industry-specific laws, regulations, and standards.
- PC11.** Facilitate detailed batch records/coding in the manufacturing and packaging of each drug batch.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** Safety policies, procedures, and best practices within an organizational context.
- KU2.** Incident reporting, investigation processes.
- KU3.** Regulatory classifications and requirements for various types of post-marketing studies.
- KU4.** The concept of batch documentation.
- KU5.** Concept of national and international standards and certifications.

KU6. Basic Knowledge of the importance of permits, licenses, and statutory registrations required for operations.

Generic Skills (GS)

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

GS1. Communicate in polite, calm, empathetic and congenial manner.

GS2. Keep abreast of the latest knowledge by reading relevant materials.

GS3. Be-sensitive to the non-verbal communication of the client and relatives.

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
• <i>Post-marketing requirements</i>	38	30	20	20
PC1. Coordinate for Post-Marketing Studies.	-	-	-	-
PC2. Identify product quality reviews.	-	-	-	-
PC3. Advise marketing and promotional departments for promotional material in compliance with regulatory norms.	-	-	-	-
PC4. Demonstrate pharmacovigilance for drugs.	-	-	-	-
PC5. Describe the process of submission with regulatory authorities regarding inquiries and clarifications.	-	-	-	-
PC6. Conduct the packaging and labelling.	-	-	-	-
PC7. Demonstrate how to track changes, maintain version control, and ensure accountability for data updates.	-	-	-	-
PC8. Conduct safety procedures for routine and non-routine operations.	-	-	-	-
PC9. Identify potential hazards and risks associated with specific tasks, equipment, and the work environment.	-	-	-	-
PC10. Identify all applicable local, national, and industry-specific laws, regulations, and standards.	-	-	-	-
PC11. Facilitate detailed batch records/coding in the manufacturing and packaging of each drug batch.	-	-	-	-
NOS Total	38	30	20	20

National Occupational Standards (NOS) Parameters

NOS Code	HSS/N3706
NOS Name	Regulatory Liaisoning for Product Registration and Labelling.
Sector	Healthcare
Sub-Sector	
Occupation	Ayurveda-Pharmacy
NSQF Level	5.5
Credits	3.5
Version	1.0
Next Review Date	NA

HSS/N3707: Report and documentation

Description

This unit describes the critical process of recording, organizing, and communicating all data, findings, and related information generated.

Scope

The scope covers the following :

- Scope consists of report and documentation, licensing and registration, labelling and packaging documentation.

Elements and Performance Criteria

Ensures batch manufacturing and packaging records are accurately completed, reviewed, and archived as per Schedule M

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

- PC1.** Ensures batch manufacturing and packaging records are accurately completed, reviewed, and archived as per Schedule M.
- PC2.** Identify Product Quality / Annual Product Reviews as per Schedule. M
- PC3.** Monitor quality, safety, and regulatory impacts.

Licensing and Registration Documentation

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

- PC4.** Demonstrate complete and accurate new manufacturing license applications to State Licensing Authorities.
- PC5.** Maintain the timely renewal of existing manufacturing licenses and product permissions.
- PC6.** Check and submits documentation for amendments to existing licenses.
- PC7.** Maintains record of all current licenses, registrations, product permissions etc.

Labelling and Packaging Documentation

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

- PC8.** Maintain primary, secondary, and tertiary packaging labels comply strictly with the content and format requirements.
- PC9.** Maintains labelling and artwork control, ensuring use of only approved versions.
- PC10.** Undertake the regulatory approval process for any changes to labelling or packaging materials.
- PC11.** Coordinate batch coding, manufacturing date, and expiry date on all packaging components as per regulatory requirements.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** The principles for manufacturing, quality control, and regulatory documentation.
- KU2.** Concept of documenting and managing output from the system.

- KU3.** Comprehensive understanding of the various manufacturing license .
- KU4.** Drug labelling and packaging as prescribed by the Drugs and Cosmetics Rules, 1945.
- KU5.** Serialisation and barcoding requirements.
- KU6.** Documentation during pre-licensing and post-licensing inspections.
- KU7.** The concept of material identification systems, batch numbers, unique codes, and labelling standards.
- KU8.** The concept of storage layout and segregation principles to prevent cross-contamination and facilitate efficient retrieval.
- KU9.** Hygiene and sanitation protocols for equipment, tools, and processing areas specific to ASU manufacturing unit.
- KU10.** Risks associated with improper segregation.
- KU11.** Quality control checks at the packaging stage.

Generic Skills (GS)

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

- GS1.** Prepare a checklist and document findings and observations.
- GS2.** Keep abreast of the latest knowledge by reading relevant materials.
- GS3.** Communicate in polite, calm, empathetic and congenial manner.

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Ensures batch manufacturing and packaging records are accurately completed, reviewed, and archived as per Schedule M</i>	25	20	15	10
PC1. Ensures batch manufacturing and packaging records are accurately completed, reviewed, and archived as per Schedule M.	-	-	-	-
PC2. Identify Product Quality / Annual Product Reviews as per Schedule. M	-	-	-	-
PC3. Monitor quality, safety, and regulatory impacts.	-	-	-	-
<i>Licensing and Registration Documentation</i>	27	20	15	10
PC4. Demonstrate complete and accurate new manufacturing license applications to State Licensing Authorities.	-	-	-	-
PC5. Maintain the timely renewal of existing manufacturing licenses and product permissions.	-	-	-	-
PC6. Check and submits documentation for amendments to existing licenses.	-	-	-	-
PC7. Maintains record of all current licenses, registrations, product permissions etc.	-	-	-	-
<i>Labelling and Packaging Documentation</i>	25	20	15	20
PC8. Maintain primary, secondary, and tertiary packaging labels comply strictly with the content and format requirements.	-	-	-	-
PC9. Maintains labelling and artwork control, ensuring use of only approved versions.	-	-	-	-
PC10. Undertake the regulatory approval process for any changes to labelling or packaging materials.	-	-	-	-
PC11. Coordinate batch coding, manufacturing date, and expiry date on all packaging components as per regulatory requirements.	-	-	-	-
NOS Total	77	60	45	40

National Occupational Standards (NOS) Parameters

NOS Code	HSS/N3707
NOS Name	Report and documentation
Sector	Healthcare
Sub-Sector	
Occupation	Ayurveda-Pharmacy
NSQF Level	5.5
Credits	3
Version	1.0
Next Review Date	NA

HSS/N9624: Maintain a safe and secure working environment

Description

This OS unit is about the ensuring a safe and secure working environment

Scope

The scope covers the following :

- Workplace safety and security

Elements and Performance Criteria

Workplace safety and security

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

- PC1.** identify potential hazards of safe work practices
- PC2.** use various hospital codes for emergency situations
- PC3.** comply with safety, and security procedures within the defined scope of competence and authority
- PC4.** provide Basic Life Support (BLS) and first aid whenever applicable under defined scope of work
- PC5.** follow organizations' procedures related to any emergency efficiently
- PC6.** report any identified breaches in health, safety, and security procedures to the designated person
- PC7.** complete any health and safety records accurately

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** the importance of health, safety, and security in the workplace
- KU2.** how to identify safety and security hazards
- KU3.** the importance of identifying individual responsibilities in relation to maintaining workplace safety and security requirements
- KU4.** the relevant up-to-date information on safety, and security that applies to the workplace
- KU5.** how to report any emergency
- KU6.** various hospital codes for emergency situations
- KU7.** how to create safety records and maintain them
- KU8.** concept of first aid and BLS
- KU9.** the importance of raising alarm about hazards for safety of others

Generic Skills (GS)

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

- GS1.** read and understand organization policies and procedures
- GS2.** prepare status and progress reports
- GS3.** • communicate information (for example, facts, ideas, or messages) in a brief, clear, and
• organized manner
- GS4.** make decisions pertaining to the area of work
- GS5.** plan for safety of the work environment
- GS6.** identify hazards, evaluate possible solutions and suggest effective solutions
- GS7.** analyze the seriousness of hazards

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Workplace safety and security</i>	10	10	-	10
PC1. identify potential hazards of safe work practices	-	-	-	-
PC2. use various hospital codes for emergency situations	-	-	-	-
PC3. comply with safety, and security procedures within the defined scope of competence and authority	-	-	-	-
PC4. provide Basic Life Support (BLS) and first aid whenever applicable under defined scope of work	-	-	-	-
PC5. follow organizations’ procedures related to any emergency efficiently	-	-	-	-
PC6. report any identified breaches in health, safety, and security procedures to the designated person	-	-	-	-
PC7. complete any health and safety records accurately	-	-	-	-
NOS Total	10	10	-	10

National Occupational Standards (NOS) Parameters

NOS Code	HSS/N9624
NOS Name	Maintain a safe and secure working environment
Sector	Healthcare
Sub-Sector	Generic
Occupation	Generic
NSQF Level	4
Credits	1
Version	2.0
Last Reviewed Date	12/03/2026
Next Review Date	12/03/2029
NSQC Clearance Date	12/03/2026

HSS/N9618: Follow infection control policies & procedures including biomedical waste disposal protocols

Description

This OS unit is about the safe handling and management of health care waste and following infection control policies

Scope

The scope covers the following :

- Classification of the Waste Generated, Segregation of Biomedical Waste, Proper collection and storage of Waste

Elements and Performance Criteria

Classification of the Waste Generated, Segregation of Biomedical Waste, Proper collection and storage of Waste

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

- PC1.** handle, package, label, store, transport and dispose of waste appropriately to minimize potential for contact with the waste and to reduce the risk to the environment from accidental release
- PC2.** store clinical or related waste in an area that is accessible only to authorized persons
- PC3.** minimize contamination of materials, equipment and instruments by aerosols and splatter

Complying with an effective infection control protocols

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

- PC4.** apply appropriate health and safety measures following appropriate personal clothing & protective equipment for infection prevention and control
- PC5.** identify infection risks and implement an appropriate response within own role and responsibility in accordance with the policies and procedures of the organization
- PC6.** follow procedures for risk control and risk containment for specific risks. Use signs when and where appropriate
- PC7.** follow protocols for care following exposure to blood or other body fluids as required
- PC8.** remove spills in accordance with the policies and procedures of the organization
- PC9.** clean and dry all work surfaces with a neutral detergent and warm water solution before and after each session or when visibly soiled
- PC10.** demarcate and maintain clean and contaminated zones in all aspects of health care work
- PC11.** confine records, materials and medicaments to a well designated clean zone
- PC12.** confine contaminated instruments and equipment to a well designated contaminated zone
- PC13.** decontaminate equipment requiring special processing in accordance with quality management systems to ensure full compliance with cleaning, disinfection and sterilization protocols
- PC14.** replace surface covers where applicable
- PC15.** maintain and store cleaning equipment

PC16. report and deal with spillages and contamination in accordance with current legislation and procedures

Maintaining personal protection and preventing the transmission of infections from person to person

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

PC17. maintain hand hygiene following hand washing procedures before and after patient contact /or after any activity likely to cause contamination

PC18. cover cuts and abrasions with waterproof dressings and change as necessary

PC19. change protective clothing and gowns/aprons daily, more frequently if soiled and where appropriate, after each patient contact

PC20. perform additional precautions when standard precautions alone may not be sufficient to prevent transmission of infection

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. relevant up-to-date information on health, safety, and security that applies to the organization

KU2. organizations emergency procedures and responsibilities for handling hazardous situations

KU3. person(s) responsible for health, safety, and security in the organization

KU4. good personal hygiene practice including hand care

KU5. importance of and how to handle, package, label, store, transport and dispose of waste appropriately to minimize potential for contact with the waste and to reduce the risk to the environment from accidental release

KU6. the importance to adhere to the organizational and national waste management principles and procedures

KU7. the hazards and risks associated with the disposal and the importance of risk assessments and how to provide these

KU8. the required actions and reporting procedures for any accidents, spillages and contamination involving waste

KU9. the requirements of the relevant external agencies involved in the transport and receipt of your waste

KU10. the importance of organizing, monitoring and obtaining an assessment of the impact the waste may have on the environment

KU11. The current national legislation, guidelines, local policies and protocols which affect work practice

KU12. the policies and guidance that clarify scope of practice, accountabilities and the working relationship between yourself and others

KU13. identification and management of infectious risks in the workplace

KU14. aspects of infectious diseases including opportunistic organisms & pathogens

KU15. basic microbiology including bacteria and bacterial spores, fungi, viruses

KU16. the path of disease transmission including direct contact and penetrating injuries, risk of acquisition

KU17. how to clean and sterile techniques

- KU18.** susceptible hosts including persons who are immune suppressed, have chronic diseases such as diabetes and the very young or very old
- KU19.** routine surface cleaning procedures at the start and end of the day, managing a blood or body fluid spill
- KU20.** sharps handling and disposal techniques
- KU21.** effective hand hygiene including hand wash, surgical hand wash, when hands must be washed
- KU22.** good personal hygiene practice including hand care
- KU23.** how to use personal protective equipment such as: The personal clothing and protective equipment required to manage the different types of waste generated by different work activities

Generic Skills (GS)

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

- GS1.** report and record incidents
- GS2.** read and understand company policies and procedures to managing biomedical waste and infection control and prevention
- GS3.** listen patiently
- GS4.** report hazards and incidents clearly with the appropriate level of urgency
- GS5.** take in to account opportunities to address waste minimization, environmental responsibility and sustainable practice issues
- GS6.** apply additional precautions when standard precautions are not sufficient
- GS7.** consistently ensure instruments used for invasive procedures are sterile at time of use (where appropriate)
- GS8.** consistently follow the procedure for washing and drying hands
- GS9.** consistently maintain clean surfaces and limit contamination
- GS10.** how to make exceptional effort to keep the environment and work place clean
- GS11.** identify hazards and suggest effective solutions to identified problems pertaining to hospital waste and related infections
- GS12.** analyze the seriousness of hazards pertaining to hospital waste and related infections
- GS13.** apply, analyze, and evaluate the information gathered from observation, experience, reasoning, or communication, as a guide to act
- GS14.** take into account opportunities to address waste minimization, prevent infection, environmental responsibility and sustainable practice issues

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Classification of the Waste Generated, Segregation of Biomedical Waste, Proper collection and storage of Waste</i>	5	-	3	10
PC1. handle, package, label, store, transport and dispose of waste appropriately to minimize potential for contact with the waste and to reduce the risk to the environment from accidental release	-	-	-	-
PC2. store clinical or related waste in an area that is accessible only to authorized persons	-	-	-	-
PC3. minimize contamination of materials, equipment and instruments by aerosols and splatter	-	-	-	-
<i>Complying with an effective infection control protocols</i>	8	-	5	10
PC4. apply appropriate health and safety measures following appropriate personal clothing & protective equipment for infection prevention and control	-	-	-	-
PC5. identify infection risks and implement an appropriate response within own role and responsibility in accordance with the policies and procedures of the organization	-	-	-	-
PC6. follow procedures for risk control and risk containment for specific risks. Use signs when and where appropriate	-	-	-	-
PC7. follow protocols for care following exposure to blood or other body fluids as required	-	-	-	-
PC8. remove spills in accordance with the policies and procedures of the organization	-	-	-	-
PC9. clean and dry all work surfaces with a neutral detergent and warm water solution before and after each session or when visibly soiled	-	-	-	-
PC10. demarcate and maintain clean and contaminated zones in all aspects of health care work	-	-	-	-
PC11. confine records, materials and medicaments to a well designated clean zone	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. confine contaminated instruments and equipment to a well designated contaminated zone	-	-	-	-
PC13. decontaminate equipment requiring special processing in accordance with quality management systems to ensure full compliance with cleaning, disinfection and sterilization protocols	-	-	-	-
PC14. replace surface covers where applicable	-	-	-	-
PC15. maintain and store cleaning equipment	-	-	-	-
PC16. report and deal with spillages and contamination in accordance with current legislation and procedures	-	-	-	-
<i>Maintaining personal protection and preventing the transmission of infections from person to person</i>	8	-	5	10
PC17. maintain hand hygiene following hand washing procedures before and after patient contact /or after any activity likely to cause contamination	-	-	-	-
PC18. cover cuts and abrasions with waterproof dressings and change as necessary	-	-	-	-
PC19. change protective clothing and gowns/aprons daily, more frequently if soiled and where appropriate, after each patient contact	-	-	-	-
PC20. perform additional precautions when standard precautions alone may not be sufficient to prevent transmission of infection	-	-	-	-
NOS Total	21	-	13	30

National Occupational Standards (NOS) Parameters

NOS Code	HSS/N9618
NOS Name	Follow infection control policies & procedures including biomedical waste disposal protocols
Sector	Healthcare
Sub-Sector	Social Work & Community Health, Healthcare Management, Allied Health & Paramedics
Occupation	Generic
NSQF Level	4
Credits	0.5
Version	2.0
Last Reviewed Date	12/03/2026
Next Review Date	12/03/2029
NSQF Clearance Date	12/03/2026

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

Description

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

Scope

The scope covers the following :

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

Elements and Performance Criteria

Introduction to Employability Skills

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

- PC1.** identify employability skills required for jobs in various industries
- PC2.** identify and explore learning and employability portals

Constitutional values - Citizenship

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

- PC3.** recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc.
- PC4.** follow environmentally sustainable practices

Becoming a Professional in the 21st Century

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

- PC5.** recognize the significance of 21st Century Skills for employment
- PC6.** practice the 21st Century Skills such as Self-Awareness, Behaviour Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn for continuous learning etc. in personal and professional life

Basic English Skills

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

- PC7.** use basic English for everyday conversation in different contexts, in person and over the telephone
- PC8.** read and understand routine information, notes, instructions, mails, letters etc. written in English
- PC9.** write short messages, notes, letters, e-mails etc. in English

Career Development & Goal Setting

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

- PC10.** understand the difference between job and career
- PC11.** prepare a career development plan with short- and long-term goals, based on aptitude

Communication Skills

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

- PC12.** follow verbal and non-verbal communication etiquette and active listening techniques in various settings
- PC13.** work collaboratively with others in a team

Diversity & Inclusion

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

- PC14.** communicate and behave appropriately with all genders and PwD
- PC15.** escalate any issues related to sexual harassment at workplace according to POSH Act

Financial and Legal Literacy

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

- PC16.** select financial institutions, products and services as per requirement
- PC17.** carry out offline and online financial transactions, safely and securely
- PC18.** identify common components of salary and compute income, expenses, taxes, investments etc
- PC19.** identify relevant rights and laws and use legal aids to fight against legal exploitation

Essential Digital Skills

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

- PC20.** operate digital devices and carry out basic internet operations securely and safely
- PC21.** use e- mail and social media platforms and virtual collaboration tools to work effectively
- PC22.** use basic features of word processor, spreadsheets, and presentations

Entrepreneurship

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

- PC23.** identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research
- PC24.** develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion
- PC25.** identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity

Customer Service

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

- PC26.** identify different types of customers
- PC27.** identify and respond to customer requests and needs in a professional manner.
- PC28.** follow appropriate hygiene and grooming standards

Getting ready for apprenticeship & Jobs

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

- PC29.** create a professional Curriculum vitae (Résumé)
- PC30.** search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively
- PC31.** apply to identified job openings using offline /online methods as per requirement
- PC32.** answer questions politely, with clarity and confidence, during recruitment and selection
- PC33.** identify apprenticeship opportunities and register for it as per guidelines and requirements

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** need for employability skills and different learning and employability related portals
- KU2.** various constitutional and personal values
- KU3.** different environmentally sustainable practices and their importance
- KU4.** Twenty first (21st) century skills and their importance
- KU5.** how to use English language for effective verbal (face to face and telephonic) and written communication in formal and informal set up
- KU6.** importance of career development and setting long- and short-term goals
- KU7.** about effective communication
- KU8.** POSH Act
- KU9.** Gender sensitivity and inclusivity
- KU10.** different types of financial institutes, products, and services
- KU11.** how to compute income and expenditure
- KU12.** importance of maintaining safety and security in offline and online financial transactions
- KU13.** different legal rights and laws
- KU14.** different types of digital devices and the procedure to operate them safely and securely
- KU15.** how to create and operate an e- mail account and use applications such as word processors, spreadsheets etc.
- KU16.** how to identify business opportunities
- KU17.** types and needs of customers
- KU18.** how to apply for a job and prepare for an interview
- KU19.** apprenticeship scheme and the process of registering on apprenticeship portal

Generic Skills (GS)

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

- GS1.** read and write different types of documents/instructions/correspondence
- GS2.** communicate effectively using appropriate language in formal and informal settings
- GS3.** behave politely and appropriately with all
- GS4.** how to work in a virtual mode

- GS5.** perform calculations efficiently
- GS6.** solve problems effectively
- GS7.** pay attention to details
- GS8.** manage time efficiently
- GS9.** maintain hygiene and sanitization to avoid infection

Assessment Criteria

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

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

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

National Occupational Standards (NOS) Parameters

NOS Code	DGT/VSQ/N0102
NOS Name	Employability Skills (60 Hours)
Sector	Cross Sectoral
Sub-Sector	Professional Skills
Occupation	Employability
NSQF Level	4
Credits	2
Version	1.0
Last Reviewed Date	06/02/2026
Next Review Date	06/02/2029
NSQC Clearance Date	06/02/2026

Assessment Guidelines and Assessment Weightage

Assessment Guidelines

1. Assessment System Overview:

- Batches assigned to the assessment agencies for conducting the assessment on SIP or email
- Assessment agencies send the assessment confirmation to VTP/TC looping SSC
- Assessment agency deploys the Assessor as per the minimum entry criteria for executing the assessment
- SSC monitors the assessment process & records

2. Testing Environment:

- Check the Assessment location, date and time
- Check that the allotted time to the candidates to complete Theory & Practical Assessment is correct.

3. Assessment Quality Assurance levels/Framework:

- Question bank is created by the Subject Matter Experts (SME) are verified by the other SME

- Questions are mapped to the specified assessment criteria
 - Assessors need to be ToA certified/minimum entry criteria
4. Types of evidence or evidence-gathering protocol:
- Time-stamped & geotagged reporting of the assessor from assessment location
 - Centre photographs with signboards and scheme specific branding
5. Method of verification or validation:
- Surprise visit to the assessment location
6. Method for assessment documentation, archiving, and access
- Hard/Soft copies of the documents are stored

Minimum Aggregate Passing % at QP Level : 70

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

Assessment Weightage

Compulsory NOS

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
HSS/N3704. Conduct Regulatory Compliance, Licensing, and Submissions	100	90	40	60	290	20
HSS/N3705. Conduct Regulatory Information Database	84	80	32	40	236	20
HSS/N3706. Regulatory Liaisoning for Product Registration and Labelling.	38	30	20	20	108	20
HSS/N3707. Report and documentation	77	60	45	40	222	20
HSS/N9624. Maintain a safe and secure working environment	10	10	-	10	30	10

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
HSS/N9618.Follow infection control policies & procedures including biomedical waste disposal protocols	21	-	13	30	64	5
DGT/VSQ/N0102.Employability Skills (60 Hours)	20	30	-	-	50	5
Total	350	300	150	200	1000	100

Acronyms

NOS	National Occupational Standard(s)
NSQF	National Skills Qualifications Framework
QP	Qualifications Pack
TVET	Technical and Vocational Education and Training

Glossary

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

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