



Australian Government

Department of Education, Employment and Workplace Relations

FDFOP2032A Work in a clean room environment

Revision Number: 1

FDFOP2032A Work in a clean room environment

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	This unit of competency covers the skills and knowledge required to gown-up, enter and work in a clean room environment and de-gown to minimise contamination risks.
------------------------	--

Application of the Unit

Application of the unit	This unit has application in a food processing production environment. It typically targets the production worker responsible for conducting work according to clean room standards.
--------------------------------	--

Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Prerequisite units		
	FDFFS2001A	Implement the food safety program and procedures OR
	FDFPH2001A	Apply Good Manufacturing Practice procedures

Employability Skills Information

Employability skills	This unit contains employability skills.
-----------------------------	--

Elements and Performance Criteria Pre-Content

Elements describe the essential outcomes of a unit of competency.	Performance criteria describe the performance needed to demonstrate achievement of the element. Where bold italicised text is used, further information is detailed in the required skills and knowledge section and the range statement. Assessment of performance is to be consistent with the evidence guide.
---	--

Elements and Performance Criteria

ELEMENT	PERFORMANCE CRITERIA
1. Prepare to enter a clean room environment	1.1. Appropriate clothing and footwear are identified and available 1.2. Clothing and footwear are correctly fitted and inspected prior to entering a clean room 1.3. Hand washing and disinfecting procedures are followed according to workplace procedure
2. Work in a clean room environment	2.1. Workplace procedures are followed to enter a clean room environment 2.2. Work activities are conducted so as to minimise risk of contamination
3. Exit a clean room environment and de-gown	3.1. Workplace procedures are followed to exit a clean room environment 3.2. Protective clothing and footwear is removed according to workplace procedure 3.3. Work is conducted in accordance with workplace environmental guidelines

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

This section describes the skills and knowledge required for this unit.

Required skills

Ability to:

- access workplace information to determine clean room work requirements
- confirm that protective clothing and footwear are appropriate for use
- follow procedures to fit and inspect protective clothing and footwear
- follow procedures to enter a clean room environment, including following appropriate hand washing, disinfecting procedures and fitting gloves as required
- conduct work in a manner appropriate to minimising risk of contamination, including following procedures for sterilising and disinfecting equipment and surfaces as required
- exit the clean room environment according to workplace procedures
- remove protective clothing and footwear in correct sequence and deposit for laundering according to workplace procedures
- complete records as required
- maintain work area to meet housekeeping standards
- use oral communication skills/language competence to fulfil the job role as specified by the organisation, including questioning, active listening, asking for clarification and seeking advice from supervisor
- work cooperatively within a culturally diverse workforce

Required knowledge

Knowledge of:

- purpose and conditions required in a clean room environment, including how the clean room maintains a clean environment and related airflow systems
- preparation and handling requirements for garments and footwear worn in a clean room environment, including garment features appropriate to a clean room environment and inspection procedure to confirm clothing and footwear are fit for use prior to fitting
- inspection points to confirm that clothing and footwear are correctly fitted according to workplace procedures
- procedures to follow if garments are not fit for use
- clean room control measures and related monitoring requirements, such as pressure differences between the clean room and change room and knowledge of location of pressure gauges, and checking operating conditions of ventilation systems where required
- entry procedures
- requirements for conducting work in a clean room and consequences of not complying with these requirements (typically work is conducted slowly to

REQUIRED SKILLS AND KNOWLEDGE

- minimise disturbance of particulates)
- procedures to follow to minimise risk of contamination including cleaning, sanitation, sterilisation and disinfecting of equipment and surfaces
- conditions which can cause contamination, and control measures to avoid this occurring
- occupational health and safety (OHS) hazards and controls, including the limitations of protective clothing and equipment relevant to the work process
- procedures for exiting and de-gowning
- laundering requirements and procedures
- housekeeping requirements for work area
- recording requirements and procedures

Evidence Guide

EVIDENCE GUIDE

The Evidence Guide provides advice on assessment and must be read in conjunction with the performance criteria, required skills and knowledge, range statement and the Assessment Guidelines for the Training Package.

Overview of assessment

Assessment must be carried out in a manner that recognises the cultural and literacy requirements of the assessee and is appropriate to the work performed. Competence in this unit must be achieved in accordance with food safety standards and regulations.

Critical aspects for assessment and evidence required to demonstrate competency in this unit

Evidence of ability to:

- prepare to work in a clean room environment through the correct application of required clothing and footwear
- conduct work according to clean room work standards
- follow hand washing procedures
- exit room according to clean room standards
- apply safe work practices and identify OHS hazards and controls.

Context of and specific resources for assessment

Assessment must occur in a real or simulated workplace where the assessee has access to:

- protective clothing, footwear and equipment appropriate to a clean room
- work procedures relevant to working in a clean room environment, including those specific to entering and exiting the clean room and to carrying out the relevant work function
- a clean room environment
- documentation and recording requirements and procedures.

Method of assessment

This unit should be assessed together with core units and other units of competency relevant to the function or work role.

Guidance information for assessment

To ensure consistency in one's performance, competency should be demonstrated on more than one occasion over a period of time in order to cover a variety of circumstances, cases and responsibilities, and where possible, over a number of assessment activities.

Range Statement

RANGE STATEMENT	
The range statement relates to the unit of competency as a whole. It allows for different work environments and situations that may affect performance. Bold italicised wording, if used in the performance criteria, is detailed below. Essential operating conditions that may be present with training and assessment (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) may also be included.	
Policies and procedures	Work is carried out according to company policies and procedures, licensing requirements, legislative requirements, and industrial awards and agreements. When applied to the pharmaceutical industry, relevant Good Manufacturing Practice (GMP) codes apply and reference to food safety is replaced by GMP
Workplace information	Workplace information may include: • standard operating procedures (SOPs) • specifications • production schedules and instructions • manufacturers' advice • standard forms and reports
Clean room	A clean room refers to any environmentally graded work area
Multiple gowning processes	Multiple gowning processes may be required
Protective clothing and footwear	Protective clothing and footwear are fit for purpose and appropriate to a clean room environment

Unit Sector(s)

Unit sector	Operational
--------------------	-------------

Competency field

Competency field	
------------------	--

Co-requisite units

Co-requisite units		