



**Australian Government**

**Department of Education, Employment and Workplace Relations**

# **FDFPH2005A Operate an aseptic fill and seal process**

**Release 2**

## FDFPH2005A Operate an aseptic fill and seal process

### Modification History

September 2012: clarified pre-requisite information.

### Unit Descriptor

<b>Unit descriptor</b>	This unit of competency covers the skills and knowledge required to set up, operate, adjust and shut down an aseptic fill and seal process. This is a primary packaging process to fill product into packaging. This unit is based on and equivalent to FDFOP2021A Operate a fill and seal process.
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### Application of the Unit

<b>Application of the unit</b>	This unit has application in an aseptic packaging process within a graded clean room environment. When batch or product changeover procedures are part of this work process, the procedures should be used to customise the application of this unit. Where more detailed changeovers are carried out, FDFOP2011A Conduct routine maintenance, should be considered.
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### Licensing/Regulatory Information

Not applicable.

### Pre-Requisites

<b>Prerequisite units</b>		
	FDFOP2032 A	Work in a clean room environment* <i>FDFFS2001A Implement the food safety program and procedures</i> <i>FDFPH2001A Apply Good Manufacturing Practice procedures</i>

## Employability Skills Information

<b>Employability skills</b>	This unit contains employability skills.
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## 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.
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## Elements and Performance Criteria

ELEMENT	PERFORMANCE CRITERIA
1. Prepare the filling and sealing equipment and process for operation	1.1. Materials and packaging components/consumables are confirmed and available to meet operating requirements 1.2. Cleaning and maintenance requirements and status are identified and confirmed 1.3. Machine components and related attachments are fitted and adjusted to meet operating requirements 1.4. Operating parameters are entered as required to meet safety and production requirements 1.5. Equipment performance is checked and adjusted as required 1.6. Pre-start checks are carried out as required by workplace requirements
2. Operate and monitor the filling and sealing process	2.1. The process is started and operated according to workplace procedures 2.2. Equipment is monitored to identify variation in operating conditions 2.3. Variation in equipment operation is identified and maintenance requirements are reported according to workplace reporting requirements 2.4. Packaging quality and seal integrity are monitored to confirm that specifications are met 2.5. Out-of-specification process outcomes are identified, rectified and/or reported to maintain the process within specification 2.6. The work area is maintained according to housekeeping standards 2.7. Work is conducted in accordance with workplace environmental guidelines 2.8. Spillages are reported and removed according to standard operating procedures 2.9. Workplace records are maintained according to workplace recording requirements
3. Shut down the filling and sealing process	3.1. End-of-batch procedures are completed in accordance with batch instructions and standard operating procedures (SOPs) 3.2. The process is shut down according to workplace procedures 3.3. Maintenance requirements are identified and reported according to workplace reporting requirements

## 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 identify processing requirements
- select, fit and use personal protective clothing and/or equipment, including gowning up, following required work area entry and exit procedures and moving around the work area to minimise risk of contamination
- confirm supply of necessary packaging components/consumables and product
- conduct pre-start checks, such as inspecting equipment condition to identify any signs of wear, disinfecting and sterilising equipment and surfaces, selecting appropriate settings and/or related parameters, cancelling isolation or lock outs as required, confirming that equipment is clean and correctly configured for packaging requirements, ensuring packaging components/consumables are loaded, positioning sensors and controls correctly, ensuring any scheduled maintenance has been carried out, and confirming that all safety guards are in place and operational
- start, operate, monitor and adjust the filling and sealing process equipment to achieve required outcomes, including monitoring control points and conducting inspections as required to confirm process remains within specification, such as:
  - flow rates
  - weights and volumes
  - fill levels
  - temperature, including materials and sealing temperatures
  - supply of packaging components/consumables
  - packaging quality and seal integrity, and where required, testing packaging integrity
- take corrective action in response to out-of-specification results
- monitor supply and flow of materials to and from the process
- respond to and/or report equipment failure within level of responsibility
- locate emergency stop functions on equipment
- follow isolation and lock out/tag out procedures as required to take filling and sealing process and related equipment off-line in preparation for cleaning and/or maintenance within level of responsibility
- demonstrate product/process changeovers
- follow end of batch procedures including line clearance and cleaning, yield calculation, materials reconciliation and product labelling
- complete workplace records as required
- maintain work area to meet housekeeping standards
- use process control systems according to enterprise procedures

## REQUIRED SKILLS AND KNOWLEDGE

- collect samples and conduct tests according to enterprise procedures
- 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 basic principles of filling and sealing, including properties of packaging materials used, the principles of heat sterilisation and its effect on microbiological characteristics of the product and packaging materials, and the filling process (methods may require exclusion of air using inert gas, such as nitrogen and filling under vacuum)
- aseptic container preparation, handling and loading
- basic operating principles of aseptic filling and sealing equipment, such as main equipment components, status and purpose of guards, equipment operating capacities and applications, the purpose and location of sensors and related feedback instrumentation, and services required for operation of filling equipment used in the workplace
- quality characteristics and legal requirements to be achieved by the filling and sealing process, such as quality requirements of packaging components/consumables, sterilisation requirements and procedures, filling (fill levels and weights), requirements of seal formation and integrity, and where relevant, understanding integrity testing procedures
- the flow of processes supplying the filling and sealing process and the effect of outputs on downstream processes
- operating requirements and parameters and corrective action required where operation is outside specified operating parameters
- typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems
- methods used to monitor the process, such as inspecting, measuring and testing as required by the process
- inspection or test points (control points) in the process and the related procedures and recording requirements
- Good Manufacturing Practice (GMP) requirements associated with the liquid manufacturing process and related control measures
- common causes of variation and corrective action required, including the effect of variation in both product and packaging components/consumables on filling and sealing performance, e.g. it may include an understanding of the effect of temperature variation on the filling process
- product/packaging changeover procedures
- occupational health and safety (OHS) hazards and controls, including the limitations of protective clothing and equipment relevant to the work process

**REQUIRED SKILLS AND KNOWLEDGE**

- end-of-batch procedures, including procedures for calculating yield, materials reconciliation and action required if yield/reconciliation is not within prescribed limits, and product labelling responsibilities and procedures
- requirements of different shutdowns as appropriate to the process and workplace production requirements, including emergency and routine shutdowns and procedures to follow in the event of a power outage
- line clearance, cleaning and sanitation procedures
- isolation, lock out and tag out procedures and responsibilities
- procedures and responsibility for reporting production and performance information
- environmental issues and controls relevant to the filling and sealing process, including waste/rework collection and handling procedures related to the process
- basic operating principles of process control, where relevant, including the relationship between control panels and systems and the physical equipment
- sampling and testing procedures where relevant
- routine maintenance procedures where relevant

## Evidence Guide

<b>EVIDENCE GUIDE</b>	
<p>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.</p>	
<p><b>Overview of assessment</b></p>	<p>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.</p>
<p><b>Critical aspects for assessment and evidence required to demonstrate competency in this unit</b></p>	<p>Evidence of ability to:</p> <ul style="list-style-type: none"> <li>• conduct pre-start checks on equipment used for filling and sealing</li> <li>• start, operate, monitor and adjust process equipment to achieve required quality outcomes</li> <li>• take corrective action in response to typical faults and inconsistencies</li> <li>• complete workplace records as required</li> <li>• apply safe work practices and identify OHS hazards and controls</li> <li>• safely shut down equipment</li> <li>• apply GMP principles and procedures to work practices</li> <li>• maintain standards of a clean room work environment.</li> </ul>
<p><b>Context of and specific resources for assessment</b></p>	<p>Assessment must occur in a real or simulated workplace where the assessee has access to:</p> <ul style="list-style-type: none"> <li>• personal protective clothing and equipment</li> <li>• work procedures, including advice on safe work practices, GMP, quality and environmental requirements, stock flow systems and production/packaging schedules</li> <li>• information on equipment capacity and operating parameters</li> <li>• specifications, control points and operating parameters</li> <li>• aseptic filling and sealing process and related equipment and services</li> <li>• materials and packaging components and consumables</li> <li>• product</li> </ul>



<b>EVIDENCE GUIDE</b>	
	<ul style="list-style-type: none"> <li>• sampling schedules and test procedures and equipment as required</li> <li>• documentation and recording requirements and procedures</li> <li>• cleaning procedures, materials and equipment as required</li> </ul>
<b>Method of assessment</b>	<p>This unit should be assessed together with core units and other units of competency relevant to the function or work role. Examples could be:</p> <ul style="list-style-type: none"> <li>• FDFOP2003A Clean equipment in place</li> <li>• FDFOP2004A Clean and sanitise equipment</li> <li>• FDFOP2011A Conduct routine maintenance</li> <li>• FDFOP2013A Apply sampling procedures</li> <li>• FDFOP2030A Operate a process control interface</li> <li>• MSL973001A Perform basic tests.</li> </ul>
<b>Guidance information for assessment</b>	<p>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.</p>

## Range Statement

<b>RANGE STATEMENT</b>	
<p>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.</p>	
<b>Policies and procedures</b>	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements
<b>Legislative requirements</b>	<p>Legislative requirements are typically reflected in procedures and specifications. Legislation relevant to this industry includes:</p> <ul style="list-style-type: none"> <li>• relevant Good Manufacturing Practice (GMP) codes</li> <li>• the Therapeutic Goods Act and/or other relevant legislation</li> <li>• legislation covering environmental management, OHS, anti-discrimination and equal opportunity</li> </ul>
<b>Workplace information</b>	<p>Workplace information may include:</p> <ul style="list-style-type: none"> <li>• SOPs</li> <li>• specifications</li> <li>• production schedules and instructions</li> <li>• manufacturers' advice</li> <li>• standard forms and reports</li> </ul>
<b>Filling and sealing equipment</b>	<p>Filling and sealing equipment may include:</p> <ul style="list-style-type: none"> <li>• pumps</li> <li>• aseptic fillers</li> <li>• hermetic sealers</li> <li>• aseptic packaging</li> </ul>
<b>Sterilisation methods</b>	<p>Sterilisation methods used may include:</p> <ul style="list-style-type: none"> <li>• use of heat (dry and steam)</li> <li>• chemicals (gases and liquids)</li> <li>• gamma irradiation</li> <li>• filtration</li> </ul>

<b>RANGE STATEMENT</b>	
<b>Operation of equipment and processes</b>	Operation of equipment and processes may require: <ul style="list-style-type: none"> <li>the use of process control panels and systems</li> </ul>
<b>Shutdown procedures</b>	Shutdown procedures may include: <ul style="list-style-type: none"> <li>cleaning (in some cases cleaning may be carried out by a dedicated cleaning crew)</li> </ul>
<b>Services</b>	Services are appropriate to the process to be operated. Typical examples include: <ul style="list-style-type: none"> <li>power</li> <li>steam</li> <li>water</li> <li>vacuum</li> <li>compressed and instrumentation air</li> </ul>

### Unit Sector(s)

<b>Unit sector</b>	Pharmaceutical manufacturing
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### Competency field

<b>Competency field</b>	
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### Co-requisite units

<b>Co-requisite units</b>	