Unit 43: Inspection, Assembly, Packaging of Medical Devices in a Controlled Environment

Level:	**4**
Unit type:	**Optional (Decontamination Science)**
Credit value:	**10**
Guided learning hours:	**76**

Unit summary

This unit will give you the knowledge and skills you need to prepare medical devices for the sterilisation process. You will be required to inspect, assemble, and pack medical devices in a safe manner. You will be required to take appropriate reporting action when non-conformances are identified and undertake remedial action. This knowledge will be extended and applied to specific processing methods as you build your professional practice and practice safely in the workplace.

Unit assessment requirements

There are no specific assessment requirements for this unit. Please refer to the assessment strategy in *Annexe B*.

Additional information

All procedures must be undertaken in accordance with Standard Operating Procedures (SOPs) and the requirements of own area of work.

AC4.2 includes:

- power tools
- laparoscopic medical devices
- rigid endoscopes
- general medical device checks
- robotic medical devices
- purpose: ensuring device is fit for use.

AC5.1 includes:

- power tools
- laparoscopic medical devices
- rigid endoscopes
- general medical device checks

- robotic medical devices.

AC5.3 includes:

- preparation of device to be sent for repair
- decontamination certificate
- return process for device once repair has been completed.

AC6.2 includes:

- the consequences of not following the manufacturer's instructions for use.

AC8.2 includes:

- tray wrap
- crepe paper
- pouches
- containers
- non-cellulose wrap.

AC8.3 includes:

- envelope method
- parcel method.

Learning outcomes and assessment criteria

To pass this unit, learners need to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements that the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** and **Quality Management Systems** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of wearing Personal Protective Equipment (PPE) in the IAP room	1.1	Describe the personal protective equipment to be worn whilst working in the IAP room			
		1.2	Explain the reason the PPE is worn and what it protects			
		1.3	Evaluate the standard operating procedures for PPE for both entering and exiting the IAP room			
2	Understand the principles and practice of product release from the washer/disinfector process	2.1	Evaluate the standard operating procedure for product release of medical devices from washer/disinfectors			
		2.2	Define the purpose and process of product release of medical devices			
		2.3	Explain the criteria required to complete the product release of medical devices			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to perform the product release from the washer/disinfection process	3.1	Demonstrate the product release process from the washer/disinfector			
		3.2	Demonstrate the criteria required and how it is checked			
		3.3	Describe the process to be completed should the product release process indicate a fail status			
		3.4	Explain the process to be taken after a fail status has been identified for medical devices post processing and the washer/disinfector			
4	Understand the principles and practice of the inspection process of medical devices	4.1	Evaluate the standard operating procedure for the inspection of medical devices			
		4.2	Explain the purpose of the inspection process and the checks that need to be carried out on a range of devices			
		4.3	Explain the consequences to the clinical colleagues and patients if a device that is unfit for use is released to them			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Be able to perform an inspection process on a range of medical devices	5.1	Demonstrate checks that need to be carried out on each type of device			
		5.2	Demonstrate the process required for a device that fails the checking process			
		5.3	Explain the process that is required to ensure that the remedial work is completed to enable the device to be returned to a fit for use condition			
6	Understand the principles and practice of assembly of medical devices	6.1	Evaluate the standard operating procedure for the assembly of medical devices into packs/sets			
		6.2	Describe the reasons for assembly or non-assembly of medical devices prior to sterilisation			
		6.3	Explain the reasons for the checklist and the responsibilities for completion of each section by all decontamination science departments			
		6.4	Explain the construction of the checklist and the importance of following the information contained within it			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
7	Be able to perform the assembly process on appropriate medical devices	7.1	Perform the assembly of medical devices as defined in the manufacturer's instructions for use			
		7.2	Perform the assembly of a pack/set following the information contained on the checklist			
		7.3	Demonstrate the process to be followed when non-conformance is identified and take remedial action to resolve the issue			
8	Understand the principles and practice of wrapping or containerising medical devices	8.1	Evaluate the standard operating procedure for selecting the correct wrapping process			
		8.2	Explain the reason why different wrapping processes and material would be selected			
		8.3	Explain the reason that the wrapping material is folded in a prescribed manner and the purpose of this process			
		8.4	Describe the different criteria for each type of wrap and when it would be used			
		8.5	Explain the advantages and disadvantages of each type of wrap			
		8.6	Describe the checks that would need to be made for each type of wrap to ensure it is fit for purpose			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
9	Be able to perform the wrapping or containerisation of medical devices	9.1	Perform the envelope and parcel wrap as appropriate to medical devices			
		9.2	Perform the actions required to pack medical devices into a pouch			
		9.3	Perform the actions required to pack medical devices into a container			
10	Be able to record all tasks carried out in the IAP room in the departmental information system	10.1	Record all tasks in the departmental information systems			
		10.2	Retrieve information on individual medical devices from the departmental information system			
		10.3	Produce departmental information system reports			
		10.4	Describe how the departmental information system assists with meeting contractual arrangements			
11	Be able to perform the required housekkeping duties in the inspection, assembly, and packaging of medical devices	11.1	Explain the housekeeping schedule carried out by others in your area of work			
		11.2	Perform the housekeeping duties within your area of responsibility			
		11.3	Describe the requirements of finishes within this area (fabric and furniture) to ensure compliance with infection control standards			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
12	Be able to produce and prioritise reports from activities completed in the IAP room for validation	12.1	Review all housekeeping documentation and highlight areas of concern or gaps to an appropriate senior colleague			
		12.2	Review prepared reports for the environmental monitoring testing for referral to an appropriate senior colleague			
		12.3	Observe an environmental monitoring test being performed			
		12.4	Describe the actions required should the environmental conditions move to fail status			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)