Unit 108: The Medical Equipment Lifecycle

Level:	**4**
Unit type:	**Optional (Equipment Management and Clinical Engineering)**
Credit value:	**6**
Guided learning hours:	**48**

Unit summary

In this unit, you will acquire the knowledge and skills associated with the medical equipment lifecycle and medical equipment management system in own area of practice, together with practical application of appropriate engineering workshop skills. You will be expected to develop your professional practice as you build your competence 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 legislation.

AC1.3 could include:

- ISO 9001 – Quality management
- ISO 13485 – Medical devices – Quality management systems – Requirements for regulatory purposes
- BS 70000:2017 Medical physics, clinical engineering and associated scientific services in healthcare.

AC1.5 should include an explanation for **two** items of medical equipment.

AC2.1 includes:

- purpose
- use
- data security
- governance.

AC2.6 includes:

- internal quality control and internal quality management
- external quality control and external quality management.

LO3 should refer to the relevant service's medical device management system (MDMS) and its taxonomy.

AC3.2 includes:

- raise a service request for a range of lifecycle management activities
- extract information on job progress
- produce information reports for users from medical device management systems.

AC3.5 – GS1 DataBar (formerly known as RSS or Reduced Space Symbology) is a bar code symbology that was formally adopted by the global supply chain in January 2011.

AC3.6 includes:

- planned preventive maintenance
- repair
- calibration
- decontamination
- decommissioning etc.

AC4.1 includes:

- the need to develop and evaluate basic specifications to meet user and service requirements.

AC4.2 includes:

- pre-purchase
- assessment of need
- defining or evaluation of specification
- relevant standards
- compliance with legislation
- identification of suitable equipment
- application of risk management to selection
- purchase
- purchasing processes
- purchasing authority.

AC6.1 includes:

- the need to ensure that all legislation is up to date.

AC7.3 includes:

- handling of non-conforming products
- quality improvement suggestions.

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)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the medical equipment lifecycle and its use	1.1	Explain each stage of the equipment management lifecycle and how it integrates with the wider medical device management policy and patient safety measures			
		1.2	Discuss how the medical equipment lifecycle is implemented in healthcare settings			
		1.3	Explain how quality assurance and quality management systems support the provision of high-quality, safe services in healthcare			
		1.4	Explain the importance of control of infection and decontamination within the equipment management lifecycle			
		1.5	Explain how items of medical equipment within own area of practice contribute to the care and treatment of the patient			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
		1.6	Explain how the medical equipment lifecycle underpins safe and effective patient care			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Understand the process of medical equipment management	2.1	Explain how the medical equipment management policy applies in own area of work			
		2.2	Describe the purpose of the medical device information system			
		2.3	Know the current national recommendations and best practice relating to medical equipment management within the UK			
		2.4	Explain the policies for the handling of loan devices introduced into own area of practice			
		2.5	Explain how patient safety is ensured during the use of loan equipment, including the purpose of indemnity insurance for loan equipment			
		2.6	Discuss local quality management systems			
		2.7	Explain the role of internal audit			
		2.8	Explain the approach to the handling of safety alerts in own area of work			
		2.9	Know the processes and regulations relating to the safe decommissioning and disposal of medical equipment			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
		2.10	Explain the process for responding to Medicines and Healthcare Products Regulatory Agency (MHRA) medical equipment alerts			
3	Be able to operate medical device management systems (MDMS) and quality management systems (QMS) to support all aspects of equipment management activities	3.1	Discuss how MDMS and inventories, including asset registers, are used in practice			
		3.2	Explain key activities using the MDMS			
		3.3	Explain the role of Medical Device Tracking (Radio Frequency Identification/Real Time Locating System systems)			
		3.4	Explain the Medical Device Nomenclatures			
		3.5	Explain the purpose of bar coding and GS1 Data Bar			
		3.6	Add information to the MDMS			
		3.7	Maintain data integrity and security on the MDMS			
		3.8	Produce routine reports in line with local procedures			
4	Understand the process for the procurement of medical equipment	4.1	Discuss the procurement process for medical equipment that helps to ensure the equipment is fit for purpose			
		4.2	Explain the stages in the pre-purchase and purchase process			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
5	Be able to assist in the procurement of medical equipment	5.1	Assist in the delivery and checking of equipment, accessories, or consumables following the procurement procedures			
		5.2	Complete the required documentation in line with local procedures			
		5.3	Explain the order authorisation and submission processes			
6	Be able to assist in the management of rental and loan equipment	6.1	Evaluate the standard operating procedures for the management of rental and loan equipment, including an awareness of the Department of Health national Master Indemnity Agreement (MIA) scheme and the Health Research Authority role with medical devices involved in research			
		6.2	Select the appropriate indemnity form and NHS delivery form to be completed for given circumstances			
		6.3	Use information from the MIA register of suppliers appropriately			
		6.4	Use record systems to determine equipment on rental or loan and rental/loan period that applies			
		6.5	Use record systems to determine the responsibilities of the organisation with regard to rental/loan equipment			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
7	Be able to perform quality-assurance tasks	7.1	Explain the procedures that underpin the safe and quality assured use of equipment			
		7.2	Perform quality-assurance tasks, following specified procedures			
		7.3	Explain issues that could affect the clinical performance of equipment			
		7.4	Explain how to resolve and escalate issues that can affect the clinical performance of equipment			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

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