ICTQual AB

Qualification Specification

ICTQual AB Level 3 Certificate in Quality Control Medical Equipment

ICTQual AB's

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Qualification Specification about

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About ICTQual AB's

ICTQual AB is a distinguished awarding body based in the United Kingdom, dedicated to fostering excellence in education, training, and skills development. Committed to global standards, ICTQual AB's provides internationally recognized qualifications that empower individuals and organizations to thrive in an increasingly competitive world. Their offerings span diverse industries, including technical fields, health and safety, management, and more, ensuring relevance and adaptability to modern workforce needs.

ICTQual AB's delivers high-quality educational solutions through a network of Approved Training Centres worldwide. Their robust standards and innovative teaching methodologies equip learners with practical knowledge and skills for personal and professional growth. With a mission to inspire lifelong learning and drive positive change, ICTQual AB's continuously evolves its programs to stay ahead of industry trends and technological advancements.

Course Overview

The ICTQual AB Level 3 Certificate in Quality Control Medical Equipment is a specialized qualification designed for individuals seeking to develop the factual, procedural, and theoretical knowledge required to perform quality control tasks on medical equipment. This program addresses complex, non-routine problems within the field, emphasizing the interpretation and evaluation of technical information. It aims to make participants aware of different perspectives and approaches to quality control, preparing them for a career in a dynamic and highly regulated sector.

Aims

The primary aim of this qualification is to equip learners with the necessary skills and understanding to ensure the safety, accuracy, and reliability of medical equipment. It focuses on the practical application of quality control principles and procedures. The course aims to:

- Develop a strong foundation in the principles and practices of quality control as they apply to medical devices.
- Foster an understanding of the regulatory frameworks, standards, and ethical considerations governing the medical equipment industry.
- Enhance the ability to interpret and evaluate technical data from quality control tests and reports.
- Cultivate an awareness of the nature of the work and the different methodologies used in quality control.
- Prepare learners for entry-level roles or further study within the medical equipment and healthcare technology sectors.

Objectives

Upon successful completion of this qualification, learners will be able to:

- Demonstrate knowledge of the key components and functions of various medical devices.
- Apply procedural knowledge to perform routine and non-routine quality control tests.
- Interpret and evaluate test results to identify faults or non-compliance
- Understand and apply relevant safety protocols and quality standards.
- Complete documentation related to quality control checks and maintenance.
- Address and solve complex, non-routine problems related to equipment functionality and performance.
- Communicate effectively with colleagues and supervisors regarding quality control issues.

Target Audience

This certificate is ideal for individuals who are currently working or aspiring to work in roles that involve the maintenance, testing, or quality assurance of medical equipment. It is particularly suited for:

- Medical equipment technicians or those looking to specialize in this area.
- Quality control and assurance personnel in healthcare or manufacturing settings.
- Biomedical engineers seeking to formalize their knowledge of quality control procedures.
- Students who have completed a related Level 2 qualification and wish to progress to a higher level of technical expertise.
- Individuals who are interested in a career path that combines technical skills with the critical importance of patient safety.

Certification Framework

Qualification title	ICTQual AB Level 3 Certificate in Quality Control Medical Equipment
Course ID	QC0040
Grading Type	Pass / Fail
Competency Evaluation	Coursework / Assignments / Verifiable Experience
Assessment	The assessment and verification process for ICTQual AB's qualifications involves two key stages: **Internal Assessment and Verification:** ✓ Conducted by the staff at the Approved Training Centre (ATC) to ensure learners meet the required standards through continuous assessments. ✓ Internal Quality Assurance (IQA) is carried out by the centre's IQA staff to validate the assessment process. **External Quality Assurance:** ✓ Managed by ICTQual AB's verifiers, who periodically review the centre's assessment and IQA processes. Verifies that assessments are conducted to the required standards and ensures consistency across centres

Entry Requirements

To enrol in ICTQual AB Level 3 Certificate in Quality Control Medical Equipment, learner must meet the following entry requirements:

- **Age Requirement:** Learners must be at least 18 years of age at the time of enrolment to ensure maturity and readiness for the course content and professional responsibilities.
- **Educational Background:** A minimum of a Level 2 qualification or equivalent in a relevant field such as science, engineering, or healthcare is required. Learners should possess a solid foundation in basic mathematics and science to support understanding of technical concepts.
- **Work Experience:** While prior experience in healthcare, medical equipment handling, or quality control is beneficial, it is not mandatory. The course is suitable for both new entrants and those seeking to upskill in a healthcare or biomedical setting.
- **English Proficiency:** As the course is delivered in English, learners must have a good command of the language to follow instructions, understand technical documentation, and complete written assessments effectively.
- **Technical Understanding:** Learners should possess a basic understanding of how medical devices function, including knowledge of common equipment used in diagnostic and therapeutic settings.

Qualification Structure

This qualification comprises 3 mandatory units. Candidates must successfully complete all mandatory units to achieve the qualification.

Mandatory Units	
Unit Ref#	Unit Title
QC0040-01	Fundamentals of Medical Equipment Quality Control
QC0040-02	Inspection, Testing, and Maintenance Procedures
QC0040-03	Regulatory Compliance and Documentation in Healthcare Technology

Centre Requirements

To ensure quality training delivery, centres must adhere to the following standards:

1. Centre Approval

- ✓ Centres must be formally approved by ICTQual AB's before delivering this qualification.

- ✓ Approval involves a review of facilities, policies, and staff qualifications.

2. Qualified Staff

- ✓ **Tutors:** hold a minimum of a Level 4 qualification (or its equivalent) in a field directly relevant to the course, such as Biomedical Engineering, Medical Device Technology, or in Medical equipment.

- ✓ **Assessors:** Must hold a recognized assessor qualification (e.g., CAVA, AVRA) or equivalent)

- ✓ **Internal Quality Assurers (IQAs):** Must hold a recognized IQA qualification (e.g. Level 4 Award in the IQA and Level 4 Certificate in Leading the IQA) and experience to oversee assessment standards

3. Learning Facilities

Centre must offer:

- ✓ Private study areas and internet-enabled workspaces (for blended or physical delivery)
- ✓ Academic and pastoral support for learners
- ✓ Administrative support must be available to manage enrolment, tracking, and learner queries efficiently

4. Health and Safety Compliance

- ✓ All training facilities must comply with health and safety regulations.

- ✓ Centres must conduct regular risk assessments for practical activities.

5. Learning Resources

- ✓ **Course Materials:** Approved textbooks, study guides, and digital content must align with the qualification standards.

✓ **Assessment Tools:** Templates and guidelines must be provided to ensure standardized evaluation processes.

✓ **E-Learning Support:** Centres offering online or blended learning must implement an effective Learning Management System (LMS).

6. Assessment and Quality Assurance

✓ Centres must ensure assessments meet ICTQual AB's competency standards.

✓ Internal quality assurance (IQA) must be conducted to maintain consistency.

✓ External verifiers from ICTQual AB's will review assessment and training practices.

7. Learning Support

✓ **Qualification Guidance:** Support for coursework and assignments.

✓ **Career Pathway Assistance:** Information on progression opportunities in sustainability and energy sectors.

✓ **Accessibility Support:** Accommodations for learners with disabilities or language barriers.

8. Policies and Compliance

Centres must uphold the following policies in accordance with ICTQual AB's standards:

✓ Equality, Diversity, and Inclusion Policy.

✓ Health and Safety Policy.

✓ Safeguarding and Learner Protection Policy.

✓ Complaints and Appeals Procedure.

✓ Data Protection and Confidentiality Policy.

9. Reporting Requirements

• Centres must provide ICTQual AB's with regular reports on learner registrations, progress, and certification outcomes.

• Assessment records must be maintained for external auditing and quality assurance purposes.

Support for Candidates

Centres should ensure that materials developed to support candidates:

- ✓ Facilitate tracking of achievements as candidate's progress through the learning outcomes and assessment criteria.
- ✓ Include information on how and where ICTQual AB's policies and procedures can be accessed.
- ✓ Provide mechanisms for Internal and External Quality Assurance staff to verify and authenticate evidence effectively.

This approach ensures transparency, supports candidates' learning journeys, and upholds quality assurance standards.

Assessment

This qualification is competence-based, requiring candidates to demonstrate proficiency as defined in the qualification units. The assessment evaluates the candidate's skills, knowledge, and understanding against the set standards. Key details include:

1. **Assessment Process:**

   - ✓ Must be conducted by an experienced and qualified assessor.
   - ✓ Candidates compile a portfolio of evidence that satisfies all learning outcomes and assessment criteria for each unit.

2. **Types of Evidence:**

   - ✓ Observation reports by the assessor.
   - ✓ Assignments, projects, or reports.
   - ✓ Professional discussions.
   - ✓ Witness testimonies.
   - ✓ Candidate-produced work.
   - ✓ Worksheets.
   - ✓ Records of oral and written questioning.
   - ✓ Recognition of Prior Learning (RPL).

3. **Learning Outcomes and Assessment Criteria:**

   - ✓ **Learning Outcomes:** Define what candidates should know, understand, or accomplish upon completing the unit.
   - ✓ **Assessment Criteria:** Detail the standards candidates must meet to demonstrate that the learning outcomes have been achieved.

This framework ensures rigorous and consistent evaluation of candidates' competence in line with the qualification's objectives.

Unit Descriptors

QC0040-01- Fundamentals of Medical Equipment Quality Control

This unit introduces the foundational principles of ensuring medical equipment safety, reliability, and performance. Learners will explore the theoretical concepts behind quality management systems in healthcare, including risk management, quality assurance, and quality control. The focus is on understanding the importance of accurate measurements, calibration, and the impact of equipment performance on patient outcomes. Students will develop an awareness of different perspectives on quality, from manufacturer standards to clinical requirements. They will learn to interpret and evaluate information related to equipment specifications and quality metrics.

Learning Outcome:	Assessment Criteria:
1. **Understand the objectives and significance of quality control in medical equipment.**	1.1 State the main goals of quality control in a healthcare setting. 1.2 Explain why quality control is essential for ensuring patient safety. 1.3 Describe at least two potential negative effects of failing to perform proper quality control.
2. **Identify key components and functions of various types of medical devices.**	2.1 Name the key components of at least two different medical devices. 2.2 Describe the function of each identified component. 2.3 Explain how the main components work together to make the device function. 2.4 Give examples of different types of medical devices, such as diagnostic and therapeutic.
3. **Explain the role of quality assurance in maintaining healthcare equipment standards.**	3.1 Define what quality assurance means in the context of medical equipment. 3.2 Explain how quality assurance helps to maintain high standards for equipment. 3.3 Provide examples of activities involved in quality assurance.
4. **Describe essential quality control processes in relation to patient safety.**	4.1 List the standard steps of a quality control process for a medical device. 4.2 Describe how these specific steps help to protect patients. 4.3 Identify common checks and tests performed during a quality control process. 4.4 Explain the importance of performing quality control checks consistently.

QC0040-02- Inspection, Testing, and Maintenance Procedures

This unit provides the procedural knowledge and practical skills required for the inspection, testing, and maintenance of a variety of medical devices. Students will learn to apply established protocols for preventive and corrective maintenance. They will address complex, non-routine problems by interpreting technical manuals and diagnostic data. The curriculum covers a range of approaches to maintenance, including scheduled servicing and troubleshooting based on observed failures. Learners will develop the ability to document maintenance activities accurately and evaluate the effectiveness of repairs and adjustments.

Learning Outcome:	Assessment Criteria:
1. Apply standard procedures for inspecting medical equipment functionality.	1.1 Follow a provided checklist to inspect a piece of medical equipment. 1.2 Identify any visible signs of damage, wear, or incorrect assembly. 1.3 Check that the equipment powers on and off correctly.
2. Perform basic testing to evaluate equipment accuracy and reliability.	2.1 Carry out a simple test to check if a device gives an accurate reading. 2.2 Compare the test results to the expected values to evaluate accuracy. 2.3 Record the results of the test in a clear and organized way. 2.4 State whether the equipment is accurate and reliable based on the test data.
3. Carry out scheduled maintenance tasks to ensure consistent equipment performance.	3.1 Follow a maintenance schedule for a piece of medical equipment. 3.2 Perform basic maintenance tasks, such as cleaning or battery replacement. 3.3 Explain why regular maintenance is needed for consistent equipment performance.
4. Accurately document and report inspection and maintenance outcomes.	4.1 Complete an inspection report with all necessary information. 4.2 Write a clear summary of the inspection findings. 4.3 Use a maintenance log to record completed tasks and the date of completion. 4.4 Report any issues or problems found during the inspection to a supervisor.

QC0040-03- Regulatory Compliance and Documentation in Healthcare Technology

This unit focuses on the legal, ethical, and procedural aspects of regulatory compliance in healthcare technology. It covers the relevant national and international regulations governing medical devices, such as those from the FDA or EU MDR. Learners will gain factual and theoretical knowledge of documentation requirements, including incident reporting, maintenance logs, and asset management records. They will analyse the nature of the regulatory landscape and evaluate different approaches to ensuring compliance. The unit emphasizes the critical role of accurate and thorough documentation in maintaining patient safety and institutional integrity.

Learning Outcome:	Assessment Criteria:
1. **Recognise relevant regulatory bodies and their compliance requirements.**	1.1 Name at least two regulatory bodies that oversee medical equipment. 1.2 Describe the main purpose of these bodies. 1.3 Explain why regulations for medical equipment are necessary.
2. **Understand the role of documentation in ensuring traceability and accountability.**	2.1 Explain what traceability means for a medical device. 2.2 Describe how good documentation makes people accountable for their work. 2.3 List different types of documents used to ensure traceability. 2.4 Explain the risks that can arise from having poor documentation.
3. **Prepare standard compliance records and quality control reports.**	3.1 Fill out a compliance record form correctly and completely. 3.2 Gather the necessary information for a quality control report. 3.3 Write a quality control report using a standard report format.
4. **Demonstrate appropriate reporting practices for equipment faults or non-conformities.**	4.1 Identify a fault or non-conformity in a piece of equipment. 4.2 Describe the correct steps to follow when reporting a fault. 4.3 Complete a fault report form with all of the correct details. 4.4 Explain the importance of reporting faults quickly to ensure safety.

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