CQI/IRCA ISO 9001 LEAD AUDITOR COURSE

(QUALITY MANAGEMENT SYSTEMS)

Charis
The Training Company

Overview

The aim of this course is to provide delegates with the knowledge and skills required to perform first, second and third-party audits of quality management systems against ISO 9001, in accordance with ISO 19011 and ISO/IEC 17021, as applicable.

Objectives of Course

Delegates will, at the end of the course be able to:

- Explain the purpose of a quality management system, of quality management systems standards, of management system audit, of third-party certification and the business benefits of improved performance of the quality management system
- Explain the role and responsibilities of an auditor to plan, conduct, report and follow-up a quality management system audit in accordance with ISO 19011, and ISO/IEC 17021, as applicable
- Plan, conduct, report and follow-up an audit of a quality management system to establish conformity (or otherwise) with ISO 9001 and in accordance with ISO 19011, and ISO/IEC 17021

Course Duration

5 FULL DAYS

MON	TUE	WED	THU	FRI
9am- 5pm	9am- 5pm	9am- 5pm	9am- 5pm	9am- 5pm

Assessment

To be successful on the course delegates must:

- Complete/attend all elements of the course
- Pass the continuous assessment (focused on the three learning objectives)
- Pass the written examination (focused on the three learning objectives).

Prerequisite Courses

Delegates are expected to have the following prior knowledge:

1. ISO 9001:2015 Foundation (QMS)

2. Management systems

- The Plan, Do, Check, Act (PDCA) cycle
- The core elements of a management system and the interrelationship between top management responsibility, policy, objectives, planning, implementation, measurement, review and continuous improvement.

3. Quality management

- The fundamental concepts and the seven quality management principles (see ISO 9000)
- The relationship between quality management and customer satisfaction.

4. ISO 9001

- Knowledge of the requirements of ISO 9001 and the commonly used quality management terms and definitions, as given in ISO 9000, which may be gained by completing an CQI and IRCA Certified ISO 9001:2015 Foundation (QMS)Training or equivalent.

DETAILED COURSE OUTCOMES

Delegates will as a minimum, come out of the course able to do the following:

1 Explain the purpose of a quality management system, of quality management systems standards, of management system audit, of third-party certification and the business benefits of improved performance of the quality management system

- Explain the purpose of a quality management system and the business benefits of improving quality management system performance
- With reference to ISO 9001:
  - Explain the PDCA cycle and its application to quality management processes
  - Outline the processes involved in establishing, implementing, operating, monitoring, measuring, analysing, evaluating, reviewing, maintaining and improving a quality management system, including the significance of these for QMS auditors
  - Explain the terms and definitions used in ISO 9000
  - State the requirements for QMS documented information and explain the difference between maintaining and retaining documented information.
- Explain the purpose of, and differences between, a first-party, second-party and third-party certification audit of management systems, including the role of the QMS Auditor in evaluating an organisation's ability to meet the customer, statutory and regulatory requirements applicable to the products and services, and the organisation's own requirements
- Explain the benefits of third-party accredited certification of quality management systems for organisations and stakeholders

2 Explain the role of an auditor to plan, conduct, report and follow-up a quality management system audit in accordance with ISO 19011 (and ISO/IEC 17021 as applicable)

- **Audit process- Explain the audit process, making reference to similarities and differences in the process between first-party, second-party and third-party certification audit, including:**
- Determining audit objectives – the purpose and significance of the audit scope and criteria
- Identifying the appropriate personnel for the audit, the importance of auditor and team competence, and the selection of team members – particularly with regard to knowledge of the relevant management system discipline, industry sector, regulations and legislation, and auditor training. Outline different audit methods, including on-site and remote audits, and audit activities requiring human interaction and no human interaction
- The purpose of a stage 1 audit, including the documented information review, and describe a typical stage 1 audit process and outputs
- Preparing for a stage 2 audit, including preparing an audit plan
- Conducting on-site audit activities, including preparing working documents, conducting audit meetings, gathering and verifying audit evidence, determining audit findings, preparing audit conclusions, preparing, approving and distributing the audit report, and conducting the audit follow-up.
- **Auditor responsibilities**
- Explain the roles and responsibilities of the audit client, auditors, lead auditors, auditees, guides and observers
- Explain the management responsibilities of the Lead Auditor in managing the audit and the audit team
- Explain the need for effective communication with the auditee throughout the audit process
- Explain the need for auditor confidentiality.

3 Plan, conduct, report and follow-up an audit of a quality management system to establish conformity (or otherwise) with ISO 9001 and in accordance with ISO 19011 (and ISO/IEC 17021 as applicable)

- **Planning the audit**
- Establish that the scope, objectives, criteria, duration and resources for an audit are appropriate
- Prepare an on-site audit plan that is appropriate, above, and the organisation's context and processes
- Perform documented information review in preparation for the audit and prepare the necessary work documents, such as an audit checklist, sampling plan and forms.
- **Conducting the audit**
- Demonstrate the ability to manage meetings effectively
- Demonstrate the ability to implement the audit plan, use work documents and to follow audit trails
- Demonstrate the ability to build rapport with the auditee during the audit, including sensitivity to the needs and expectations of the auditee
- Demonstrate the ability to manage audit interviews effectively, including the ability to formulate effective audit questions
- Demonstrate the ability to collect and verify appropriate audit evidence, including appropriate sampling.
- **Auditing quality management system requirements**
- Evaluate the auditee's understanding and implementation of the relationship between external and internal issues, the relevant requirements of relevant interested parties, the actions to address risks and opportunities, and the quality management system processes needed to implement them
- Evaluate the boundaries, applicability and scope of the quality management system, including the types of products and services covered and justification for any requirement not applicable
- Evaluate the auditee's determination of customer, and applicable statutory and regulatory requirements

- Verify that the quality policy, as established by top management:
  - reflects the purpose and context of the organisation and supports its strategic direction
  - commits to compliance with requirements, including customer and applicable statutory and regulatory requirements
  - commits to continual improvement
  - is communicated by top management and understood within the organisation
  - is available to interested parties.
- Evaluate the auditee's arrangements for planning including:
  - Quality objectives consistent with the quality policy have been established at relevant functions and levels within the organisation, and are measurable, monitored, communicated and updated
  - Roles, responsibilities and authorities have been assigned, communicated and understood within the organisation
  - Determining support requirements, including human resources; their competence and awareness; the infrastructure and work environment; and the monitoring and measuring resources
  - Operational processes including the determination and review of requirements, design and development, production and service provision and release, external provision and nonconforming outputs
  - Considered the external and internal issues, the relevant requirements of relevant interested parties, and determined the risks and opportunities that need to be addressed to give assurance that the quality management system can achieve its intended result(s), prevent or reduce undesired effects, enhance desirable effects and achieve continuous improvement
  - Change to the quality management system considering the purpose of the change and any potential consequences, the integrity of the quality management system, and any impacts on resources, responsibilities and authorities
- Evaluate the auditee's arrangements for the planning, implementation and control of operational processes, and evaluate the effectiveness of the arrangements in meeting customer and applicable statutory and regulatory requirements
  - these processes include the determination and review of requirements, design and development, production, service provision and release, external provision and nonconforming outputs

- Evaluate the auditee's arrangements for monitoring, measuring, analysis and evaluation of the quality management system performance against policy and planned objectives, including requirements for internal audit
- Evaluate management review of the suitability, adequacy and effectiveness of the quality management system
- Evaluate the auditee's arrangements for continuous improvement, including the effectiveness of dealing with nonconformity and corrective action
- Evaluate top management's commitment to the quality management system.
- **Generating audit findings**
- Demonstrate the ability to evaluate audit evidence to correctly identify conformity and nonconformity with requirements
- Demonstrate the ability to prepare audit conclusions, including the extent of conformity of the management system, identification of positive audit findings in addition to nonconformity, and identification of potential risks and opportunities for improvement.
- **Reporting the audit**
- Write and grade nonconformity reports correctly
- Present audit conclusions and recommendations clearly to the auditee at a closing meeting.
- **Following up the audit- Evaluate proposals for corrective action, and differentiate between correction and corrective action.**

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