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DRIVING STANDARDS OF EXCELLENCE

CQI AND IRCA CERTIFIED PR328: QMS ISO 9001:2015 LEAD AUDITOR

MODULE 7

CQI | IRCA

CERTIFIED COURSE

Topics we'll cover

- Review of Previous work
- Non-conformity writing & corrective action
- Closing Meeting
- Raising nonconformities
- Case Study
- Finish.

Learning objectives

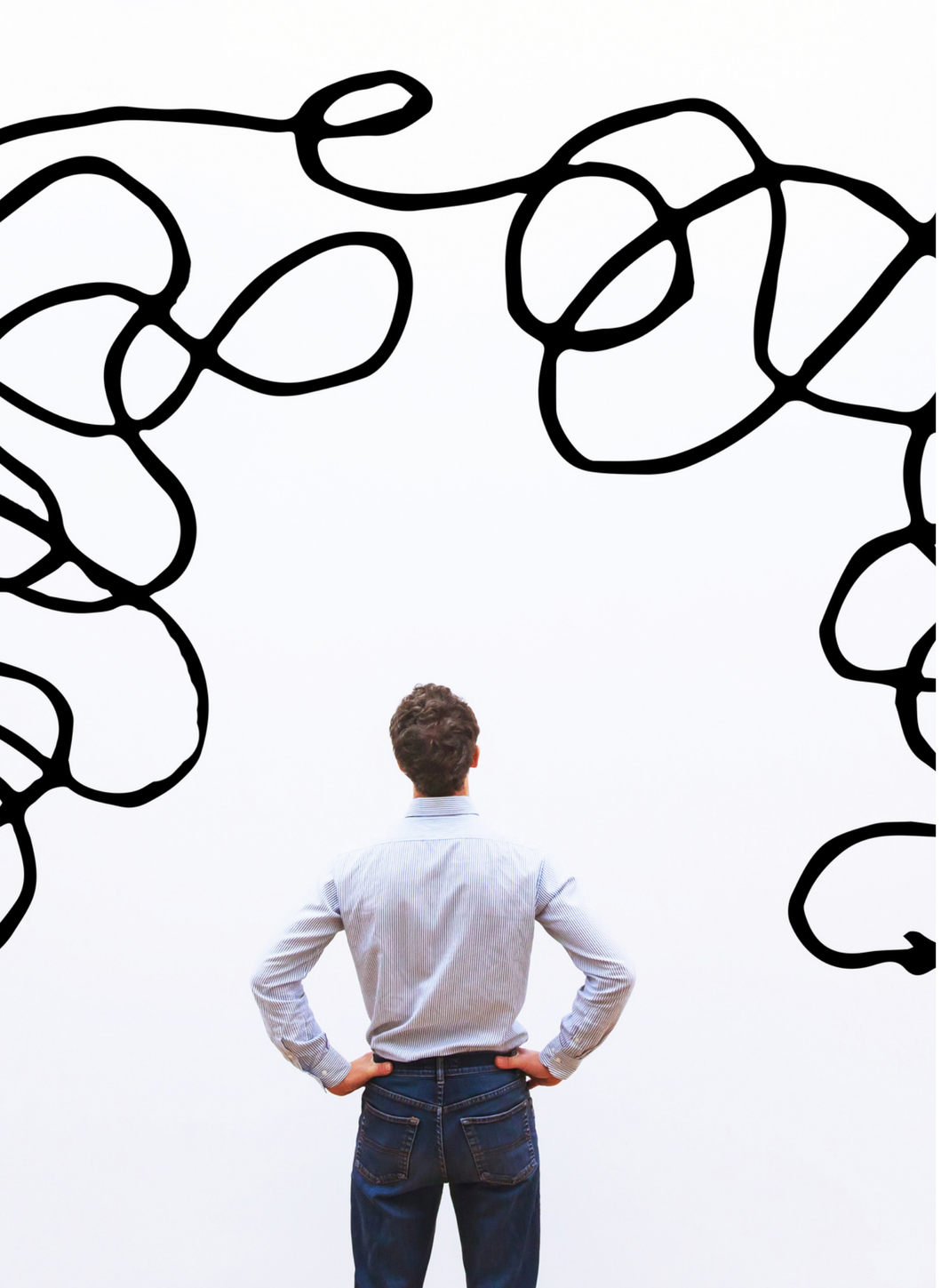
- Learn Non Conformity Identification, reporting & acknowledging positive observations
- Understand the identification of a Minor/Major non conformities and making observations
- Understand the importance of the audit report and identifying improvements
- Understand the management of corrective action
- Understand the layout of non conformities and corrective actions
- Understand the importance of closing meetings
- Understanding the scope of quality management systems
- Understanding the creation of an audit report
- Conducting an audit and identify findings in the case study.

Non-Conformity Identification and reporting & acknowledging positive observations

- It is vital we achieve a level of consistency in the identification of nonconformities, and in the reporting of them.
- We have two categories of non-conformity.
- Within the audit process it is important to acknowledge and identify positive findings.
- This could include for example, excellence in management of statutory and regulatory requirements, best in class standard operating procedures or where factors of risk and opportunities have really been embraced by the organisation.
- Clearly, this demonstrates that top management commitment and involvement.

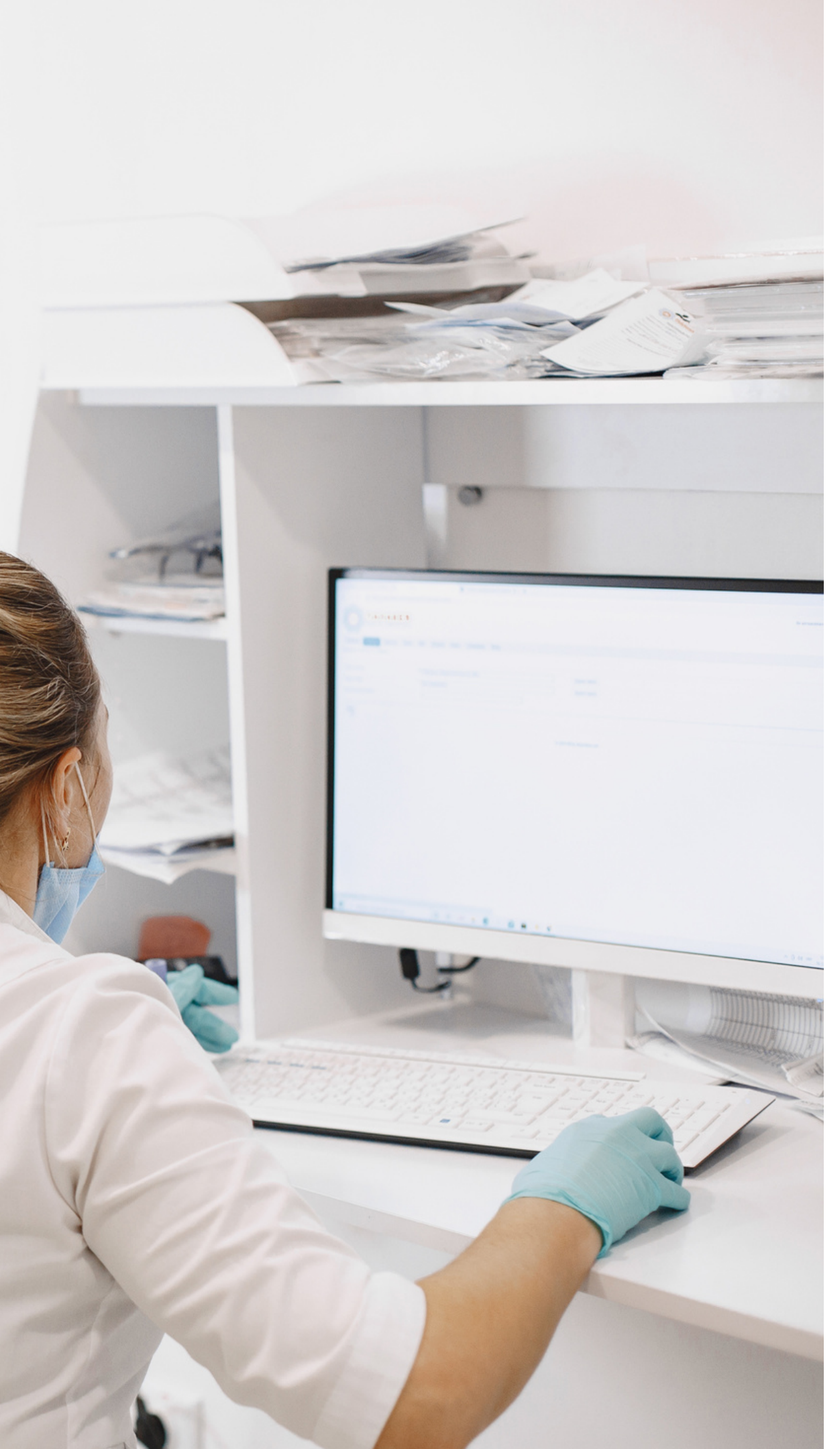
Minor Non-Conformity

A single identified lapse or minor omission, which would not in itself lead to the organisation’s management system failing to achieve its intended output.



Major Non-Conformity

A breakdown or failure to fulfil one or more requirements of the management system standard to effectively control the processes for which it was intended, or a situation where nonconforming product or service would be delivered, or a situation that raises significant doubt about the ability of the organization’s management system to achieve its intended outputs.



Observations may be raised:

- Where insufficient objective evidence is available to justify a nonconformity
- To identify to the client a potential nonconforming situation
- To comment on the client's management system or good practice seen
- To identify an opportunity for improvement
- During pre-certification assessments.

Report

- At the end of an assessment and prior to the assessment team leaving site, it is best practice to leave a report
- The assessor will verbally inform the client/auditee of any conclusions, non conformities and observations
- The report may be in either paper or electronic but must contain all the key aspects as required in an audit report and left with the auditee
- Note, The audit report will be part of the case study.

The audit report is applicable to various interested parties and their needs, which could include:

- The Audit Client
- Top management and Board of Directors
- Management Representatives
- Internal Auditors
- Accreditation Body
- Accreditation decision Maker
- Certification Body
- Certification Decision Maker
- Audit Team performing future certification audits
- Regulatory Body

Creating an Audit Report: What should go in a typical Audit Report **(external)**

A) identification of the certification body;
b) the name and address of the client and the client's representative;
c) the type of audit (e.g. initial, surveillance or recertification audit or special audits);
d) the audit criteria;
e) the audit objectives;
f) the audit scope, particularly identification of the organizational or functional units or processes audited and the time of the audit;
g) any deviation from the audit plan and their reasons;
h) any significant issues impacting on the audit programme;
i) identification of the audit team leader, audit team members and any accompanying persons;
j) the dates and places where the audit activities (on site or offsite, permanent or temporary sites) were conducted.

Creating an Audit Report: What should go in a typical Audit Report **(external)**

k) audit findings (see 6.5.1), reference to evidence and conclusions, consistent with the requirements of the type of audit;
l) significant changes, if any, that affect the management system of the client since the last audit took place;
m) any unresolved issues, if identified;
n) where applicable, whether the audit is combined, joint or integrated;
o) a disclaimer statement indicating that auditing is based on a sampling process of the available information;
p) recommendation from the audit team
q) the audited client is effectively controlling the use of the certification documents and marks, if applicable;
r) verification of effectiveness of taken corrective actions regarding previously identified nonconformities, if applicable.

Improvement

Actions required to meet customer requirements and satisfaction:

Audits should be aimed at identifying risks and opportunities as well as non-conformance categories and should also be aimed at improving the effectiveness and efficiency in operational management within the organisation and ensuring that they consider the strategic direction and relevant stakeholder needs and expectations.

Conducting the Audit

- It is important that we plan the audit effectively in terms of time management for both auditor and auditee to be effective. An audit plan ensures that the allocated time to conduct the assessment is effectively managed.
- The auditor has the skills and through a professional approach with integrity should build the rapport with the auditee to ensure an effective approach is undertaken so that both parties can manage the risk and opportunity as part of the audit.
- Auditor has the ability to use different audit methods that will include effective interview process and giving the auditee time to explain, at this point the auditor communication skills are essential and this includes the ability to listen.
- Explanations can then be validated in terms of “show me via objective evidence” the explanations just given.

Non-Conformity and Corrective action

When a non-conformity occurs, including any rising from complaints, the organisation shall:

1. Take action to contain and correct it.
2. Deal with the consequences.
3. Evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does nor recur or occur elsewhere by:
4. Reviewing and analysing the nonconformity.
5. Determining the root cause of the nonconformity and see if similar issues exist or occur.
6. Update risks and opportunities determined during planning if necessary.
7. Make changes to the QM system if necessary.

Management of Corrective action

- There should be an agreement of the period that corrective action will be sent to the auditor for closure.

- In the event of a third party audit, if a proposed corrective action plan has been dispatched then it should be cross checked with the actual corrective action plan.

Non-Conformity - Corrective Action Layout

Corrective action should be written in 3 stages

1.Statement of nonconformity

2.Requirement from ISO9001:2015 & Clause No.

3.Objective Evidence

Example of Non-Conformity - Corrective Action Layout

Statement of non-conformity

Quality policy does not capture all requirements from the international standard

Requirement - 5.2.1 Establishing the quality policy

Top management shall establish, implement and maintain a quality policy that:

a) is appropriate to the purpose and context of the organisation and supports its strategic direction;

b) provides a framework for setting quality objectives;

c) includes a commitment to satisfy applicable requirements;

d) includes a commitment to continual improvement of the quality management system.

Objective Evidence

The quality policy issue level 2 dated July 12th 2015 does not make any reference to providing a framework for setting the quality objectives

Closing Meeting

- A formal closing meeting must always be held as part of best practice in the conclusion of the audit.

- A closing meeting, facilitated by the audit team leader, should be held to present the audit findings and conclusions. Participants in the closing meeting should include the management of the auditee and, where appropriate, those responsible for the functions or processes which have been audited, and may also include the audit client and other parties.

- If applicable, the audit team leader should advise the auditee of situations encountered during the audit that may decrease the confidence that can be placed in the audit conclusions. If defined in the management system or by agreement with the audit client, the participants should agree on the time frame for an action plan to address audit findings.

ACTIVITY 27

Closing Meeting

Explain what should be included in a closing meeting

See 6.4.10

A Role play activity will be conducted during workshop.

ACTIVITY 28

Non-Conformities & Corrective Action - Part 1

Sample 1 – During an audit of a manufacturing process to control identification and traceability you identified documentation stating a material batch number was being used. However, on review you observed a different batch number on the material to what was actually on the in process documentation.

Sample 2 – During an audit of an organisations contract review, you identified that not all requirements stated had been fulfilled. Although this did not cause any customer disruption, the contract review requirements had not been met.

Raise a non-conformity/corrective action, using the 3 phased approach for each of the samples and implement proposed root cause and corrective action.

ACTIVITY 28

Non-Conformities & Corrective Action - Part 2

Use ISO 9001:2015 as a guide

Sample 3 - During an audit of the management review process, the records were not capturing all product realization processes and the support processes, e.g. Process Design

Sample 4 - Quality Control Inspection Check Sheets for hourly product checks for dimensional analysis Customer Frederick Part Number J07793337 were not on controlled documents.

Raise a non-conformity/corrective action, using the 3 phased approach for each of the samples and implement proposed root cause and corrective action.

ACTIVITY 28

Non-Conformities & Corrective Action - Part 3

Use ISO 9001:2015 as a guide

Sample 5 – On review of Power Press Maintenance Systems Limited – providing the service of machine calibration and general maintenance – it was observed that there was no definitive supplier selection criteria, furthermore – no qualification of Service Engineers had been considered or obtained and the potential impact of the externally provided processes, products and services for the organisation's ability to consistently meet customer and applicable statutory and regulatory requirements was in place. In addition to PPMS Limited, there was at least three other externally provided resource that fell into this category.

Raise a nonconformity/corrective action, using the 3 phased approach for this sample and implement proposed root cause and corrective action.

Non-Conformity Writing

Follow up of audits must be conducted in line with planned arrangements and time period agreed by the auditor and auditee.

The follow up would include an effective root cause has been established with details of the non conformity and corrective action evident to ensure that the appropriate level of risks and opportunities have been identified and managed.

Establish understanding & scope

- As required by ISO9001:2015 it is important to understand the context of the organisation and the internal and external factors that are therefore appropriate.

- Stakeholder analysis is a requirement of ISO 9001:2015 in terms of all interested parties need to be fully considered. This will later be captured in the case study.

- The boundaries of the audit/scope need to be established, for example it could be specific to a manufacturing area, service sector requirement, product, system, or adequacy as part of the quality management system documentation.

Case Study Audit: Parts 1 and 2

ISO9001:2015 Quality Management System

Please view the Case Study in the Elearning Portal. We will return to this case study when we return to tutor workshops.

Our objective is to audit the organisation’s quality management system Stage 1 and Stage 2 assessment and identify any opportunities for improvement or non-conformity that could be major or minor.

It may be applicable to comment on any aspects of positive observations.

Make notes during your audit on the audit report template. Commence completion of the audit report and complete the non-conformity template.

End of Module 7