ISO 9001:2015 Internal Audit Training

Incorporating ISO 19011:2018 Guidelines for auditing

Macro Vision Consultancy

Course Objectives: Notes:

- To learn and understand the process of performing internal audit.
- To understand the importance of performing audits.
- To apply the Principles of Auditing
- To be qualified as an Internal Auditor for QMS.

ISO 9001:2015 standard requires that:

- 9.2.1
  The organization shall conduct internal audits at planned intervals to provide information on whether the QMS:
- Conforms to:
  - The organization's own requirements for its QMS…
  - The requirements of this international standard
- Is effectively implemented and maintained

- 9.2.2 – Internal Audit Programme
- The Audit Programme defines the following:
  - Frequency
  - Methods
  - Responsibilities
  - Planning Requirements
  - Reporting

- B) Determine audit criteria and scope of each audit
- C) Select auditors and conduct audits to ensure objectivity and the impartiality of the audit process
- D) Ensure results are reported to relevant managers
- E) Take correction and corrective action without undue delay
- F) Retain documented information

MASTER COPY
Macro Vision Consultancy
Date: 1/08/2019

Terms & Definitions

- **Audit** – Systematic, independent and documented process for obtaining "audit evidence" and evaluating it objectively to determine the extent to which "audit criteria" are fulfilled.

- **Audit Criteria** – set of requirements used as a reference against which audit evidence is compared.
    - Note: Requirements may include policies, procedures, work instructions, legal requirements, contractual obligations, etc.

- **Combined Audit** – audit carried out together with a single auditee on two or more Management Systems.

- **Auditor** – Person who conducts an audit. An individual with the relevant skills and experience to perform audits.

- **Auditee** – Organization as a whole, or part thereof being audited.

- **Audit Team** – one or more auditors conducting an audit, supported if needed by technical experts.

- **Technical Expert** – person who provides technical knowledge or expertise to the team.

- **Audit Scope** – extent and boundaries of an audit

- **Audit Findings** – results of the evaluation of the collected audit evidence against audit criteria

- **Note1:** Audit findings indicate conformity or nonconformity
- **Note2:** Audit findings can lead to the identification of risks, opportunities for improvement or recording good practices.

- **Conformity** – Fulfillment of a requirement

- **Nonconformity** – Non-fulfillment of a requirement

Classification of Nonconformity

- _Major Nonconformity_ – is described as the absence, or complete breakdown, of a required system.
- _Minor Nonconformity_ – is described as an isolated failure to comply with a specified requirement of the QMS. However, a number of related minor nonconformities seen in different areas of the organization, can be clasified as "MAJOR".
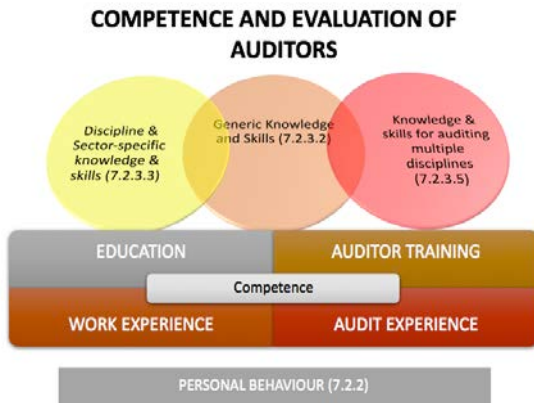
MASTER COPY
Macro Vision Consultancy
Date: 1/08/2019

ISO 9001:2015 Internal Audit Training
Incorporating ISO 19011:2018 Guidelines for auditing
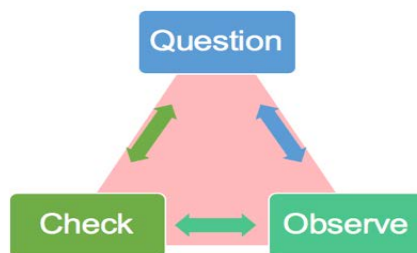## Macro Vision Consultancy

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

KINDS OF AUDIT

- ADEQUACY AUDIT – This is normally an office-based exercise determining the extent to which the documented system (the QMS Manual and associated documented information) meets the requirements of the QMS standard.
- COMPLIANCE AUDIT – This is the audit which seeks to establish the extent to which the documented system is implemented and observed by the workforce i.e., are people complying the QMS?

TYPES OF AUDITS

- **1st Party:**
  - o Internal Audit
  - o Conducted by internal auditors
- **2nd Party:**
  - o External Audit
  - o Auditor comes from Supply Chain
  - o External Provider Audit
- **3rd Party:**
  - o External Audit
  - o Independent body
  - o Certification or Accreditation
  - o Statutory or regulatory compliance

Auditors' qualifications

- The success of the auditing program depends significantly upon the selection of the right people for the task

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

MASTER COPY
Macro Vision Consultancy
Date: 1/08/2019

COMPETENCE AND EVALUATION OF AUDITORS

COMPETENCE AND EVALUATION OF AUDITORS

Discipline & Sector-specific knowledge & skills (7.2.3.3) — Generic Knowledge and Skills (7.2.3.2) — Knowledge & skills for auditing multiple disciplines (7.2.3.5)

EDUCATION | AUDITOR TRAINING
Competence
WORK EXPERIENCE | AUDIT EXPERIENCE

PERSONAL BEHAVIOUR (7.2.2)

THE QMS AUDITOR
- **Auditing Skills**
  - Time Management
    - Be Punctual and Prepared
    - Prior Notification to area being audited
    - False Trials and "Unimportant Many"
    - Time wasting discussion or friendly conversation
    - Excessive Breaks
  - Communication Skills
    - Verbal Communication
    - Body Language
    - Style and sound of speech
    - Facial Expression
    - Range of Literacy
  - Fact Finding
    - Rough flowchart of area or processes

Audit Triangle

Question

Check ← → Observe

MASTER COPY
Macro Vision Consultancy
Date: 1/08/2019

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

TYPES OF QUESTIONS

- **Open Questions** – Should be used whenever possible. Those that cannot be answered by a simple "YES" or "NO." It allows the auditee to explain his process.
- **Probing Questions** – "Follow-up" or "Focusing Question." Answer is specific.
- **Closed Questions** – Can be answered by "YES" or "NO". This should be used for verification purposes only.

RUDYARD KIPLING

"I kept six honest serving men, they taught me all I know."

What
Who
When
How
Why
Where

In Auditing, the seventh...
SHOW ME!
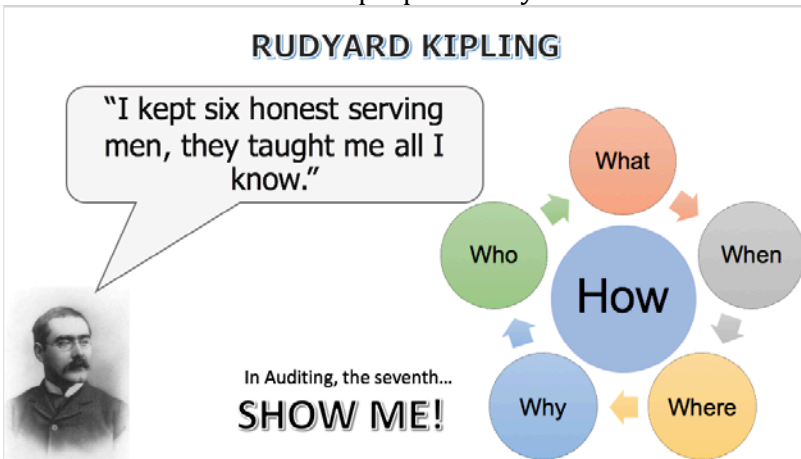
Counter Productive Questions

Questions to be avoided
Moves away to the purpose of the audit
Example includes:

* TRICKY QUESTIONS
* LEADING QUESTIONS
* AMBIGUOUS QUESTIONS
* MULTIPLE QUESTIONS

THOUGHT SPEED

- Average person speaks at 120 words per minute
- Our "thought speed" can cope 400 ~ 600 words per minute

Good listener use this to . . .

WHEN LISTENING
- Analyze what's being said.
- Summarize what's being said.
- Take brief but informative notes.
- Do not evaluate the speaker.
- Listen to message behind the words.

AUTHOR EFFECTIVENESS

- **Do not** measure an **efficient auditor** by the **number** of observations recorded / not recorded
- The ability to **identify nonconformities** and **provide recommendations** on ways to improve the process should be viewed as a positive

How to make your Audit Work?
Effective Implementation of Audit Programme

ISO 19011:2018

Reference: ISO 19011:2018

5.0 Managing an Audit Programme

Reference: ISO 19011:2018

Audit Risks and Opportunities

Communication   Implementation

Selection of Team   Control of Documented Information

Resources   Monitoring, Reviewing and Improving AP

Planning   **Risks**   Availability of Auditees

Audit Risks and Opportunities
Opportunities

• Allowing Multiple Audits in one Site
• Minimizing Time and Distance Travel to Sites
• Matching Level of Competence (Audit Team)
• Aligning Audit Date with Availability of Auditees

Audit Programme must take into consideration:

• Complexity of processes
• Results of Previous audits
• Internal & External Audits
• Changes affecting the Organization
• Risks
• Environmental Importance of Process
• New or revised statutory & regulatory requirements
• Critical areas

MASTER COPY
Macro Vision Consultancy
Date: 1/08/2019

6.0 Conducting an Audit

Reference: ISO 19011:2018

Conducting an Audit

Initiating an Audit

Establishing Contact with the auditee

Determining Feasibility of Audit

PERFORMING REVIEW OF DOCUMENTED INFORMATION
- Gather information to better understand auditee's operation:
    - Management System Documents & Re
    - Previous Audit Reports
    - Pending CARs, etc.

    AUDIT PLANNING
    - ***Develop an Audit Plan***
        - Annual Audit Plan
        - Detailed Audit Plan
            - Dates, places and time duration of the audit to be conducted
            - Audit objectives and scope
            - Methodology for auditing the QMS appropriate for the organization;
            - Auditees;

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

MASTER COPY
Macro Vision Consultancy
Date: 1/08/2019

Risk Based Approach to Planning

1 Composition of Team
- Competency issues. Risk of auditing unfamiliar requirements.

2 Sampling Techniques
- Unable to cover enough samples.

3 Opportunities
- Opportunities to improve effectiveness and efficiency of audit activities

4 Risks to the Auditee
- Risks created by performing the audit (e.g. Cleanroom Contamination, Health and Safety, Impact to Environment or Quality etc.)

Audit Planning Details

When planning, take into account…
- Identification of Auditee's Representative(s)
- Working and reporting language.
- Logistics and communication arrangements (e.g. site inspections, the need for interpreters)
- Matters related to confidentiality and information security
- Any follow-up actions from previous audits (e.g. pending CARs, lessons learned)

ASSIGNING WORK TO AUDIT TEAM

The audit team leader, in consultation with the audit team, should assign to each team member responsibility for auditing specific processes, activities, functions or locations and, as appropriate, authority for decision-making.

Take into Account

Impartiality

Competence

Objectivity

PREPARING DOCUMENTED INFORMATION FOR AUDIT

- Physical or Digital Checklist
- Audit Sampling Details
- Audio Visual Presentation*
  *Note: If determined to be necessary

AUDIT CHECKLIST
- Purpose of Checklist
  - To ensure all aspects are addressed
  - To act as a prompt to the auditor
  - Aid time management
  - Can be used as auditor's notes
- Sources for Creating a Checklist
  - Compliance to the ISO standard.

MASTER COPY
Macro Vision Consultancy
Date: 1/08/2019

- Compliance to documented Quality Management System
- Ideas from other auditors
- Known or Classic Problems
- Previous Checklists
- Risk Assessment
- Key Elements of Procedures

Conducting an Audit

Opening Meeting
- The opening meeting is an introductory meeting that the lead auditor politely and diplomatically chairs.
- Purpose:
    - Introduction of the participants, including observers and guides, and an outline of their roles;
    - Confirmation of the audit objectives, scope and criteria;
    - Presentation of the methodology to be used to conduct the audit, including advising the auditee that the audit evidence will be based on a sample of the information available;
    - Confirmation of matters relating to confidentiality and information security;
    - Information on the methodology of reporting audit findings including grading, if any;
    - Confirmation that the resources and facilities needed by the audit team are available;

- Communicating During Audit
    - The audit team should confer periodically to exchange information, assess audit progress and reassign work between the audit team members, as needed.
    - During the audit, the audit team leader should periodically communicate the progress, any significant findings and any concerns to the auditee and audit client, as appropriate, including changes in the Audit Plan.

MASTER COPY
Macro Vision Consultancy
Date: 1/08/2019

- Collecting Audit Evidence
    - Information gathered through interviews should be verified by acquiring supporting information from independent sources such as:
        - Observations
        - Records/Documented Information
        - Results of existing measurements

Types of Evidence
- Physical Evidence
    - Evidence that can be observed or touched, such as missing man-hole covers for oil interceptors.
    - However, this information alone is insufficient to verify compliance, it will just guide the auditor to further trail evidence that the QMS has been implemented.

- Documentary Evidence
    - Evidence that is traceable through a paper trail, although it cannot accurately confirm that an activity occurred (but as an auditor, trust the integrity of the records presented).
    - Example: Inspection report, training attendance

- Circumstantial Evidence
    - Observed situation caused by circumstance
    - Evidence, such as a poorly maintained record system, is limited to indicating an impression and cannot be used as audit evidence.
    - Auditor will still further trail record and look for documentary evidence.

- Admissible Evidence
    - Evidence emanates from discussion and interviews,
    - A verbal statement given by management or the auditee responsible for the area.
    - The auditor will still further trail a documentary evidence.

Verify Information Using the 4C's

Complete

Current — 4C — Correct

Consistent

MASTER COPY
Macro Vision Consultancy
Date: 1/08/2019

Generating Audit Findings
- Audit evidence should be evaluated against the audit criteria in order to determine audit findings.
- Audit findings can indicate
    - Conformity; or
    - Nonconformity
- Nonconformities can be graded depending on the context of the organization and its risks. This grading can be quantitative (e.g. 1 to 5) and qualitative (e.g. minor, major)

Determining Audit Conclusions
- **Conclusion**
    - Effectively Implemented
    - Maintained
    - Intended Outcomes are Achieved

- **Closing Meeting**
    - During the Closing Meeting:
        - Acknowledging the auditees for their help and cooperation.
        - Stating confidentiality will be maintained
        - A brief summary of the audit
        - Stating audit results and conclusions
        - During the Closing Meeting:
            - Invite questions from the auditees
            - Setting Deadlines:
                - CAR
                - Release of Audit Report
                - Closing of NCs and Follow-up Activities

6.0 Conducting an Audit

Reference: ISO 19011:2018

MASTER COPY
Macro Vision Consultancy
Date: 1/08/2019

Preparing & Distributing the Audit Report

- Summary of Audit Findings
- Prepared by the Lead Auditor
- Contains the following details:
    - The areas audited;
    - The agreed objectives, scope and plan of the audit;
    - The agreed criteria and the documents against which the audit was conducted;
    - A summary of the audit findings and obstacles encountered

A nonconformity

- a non-fulfillment of a requirement. It is a failure to deliver what is required of you or your activity or process or system.

Completing the Audit
- The audit is completed when all planned audit activities have been carried out, or as otherwise agreed with the audit client/auditee (e.g. there might be an unexpected situation that prevents the audit being completed according to the audit plan).

Conduct Audit Follow-up

- The outcome of the audit can, depending on the audit objectives, indicate the need for:
    - Corrections;
    - Corrective actions; or
    - Opportunities for improvement
- Auditees shall determine and implement the corrective action.
- Auditors shall verify the effectiveness of actions taken.
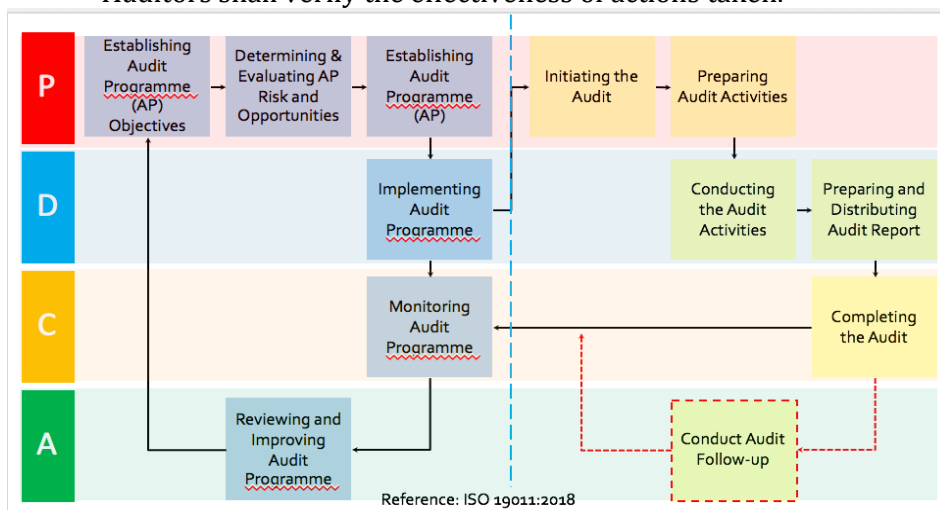
Reference: ISO 19011:2018

Questions?

MACRO VISION CONSULTANCY
Telephone No.:(02)868-4152
Email Add: admin@mvconsultancy.info
macroviz.consultancy@gmail.com
Mobile Num: Globe: 0977-8233295/Smart: 0999-9931163
Website : http://www.mvconsultancy.info

MASTER COPY
Macro Vision Consultancy
Date: 1/08/2019