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# **CBS INTERNAL AUDIT CYCLE: How to do it?**

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## What does an Internal Audit provide?

Internal audit provides Assurance, insight and objectivity.

- **Assurance** that the organization is operating as management intends.
- **Insight** for improving controls, processes, procedures, performance, and risk management; and for reducing expenses, enhancing revenues, and improving profits.
- **Objective** assessments of operations.

## WHY AUDIT



- Ensure compliance with ISO 9001:2015
- Ensure compliance with the organisation requirements
- Ensure compliance with regulatory requirements
- Ensure the QMS is effectively implemented and maintained
- Evaluations of various processes, functions, departments, and activities (NOT people)
- Look for risks and opportunities and determine whether those risks are adequately mitigated
- Look for outstanding emphasis on customer satisfaction

## WHY INTERNAL AUDITOR MAY COME KNOCKING ON YOUR DOOR?

- As part of a core process evaluation audit, a key function/activity audit, a common function/activity audit
- As part of a continuous audit (looking at specific transactions for compliance)
- As a department (organization unit) audit
- As part of an investigation
- In response to a request (consultation)



## **Pre Audit**

1. Prepare annual audit plan
2. Auditor preparation

## **During audit**

1. Hold opening meeting
2. Performing the audit
3. Document Findings
4. Prepare draft audit report
5. Hold closing meeting

## **Post Audit**

1. Prepare audit file
2. Disseminate final report
3. Follow up to ensure NC closure

## 1. Prepare Annual Audit Schedule

An annual audit Schedule is prepared based on each department/function, at the beginning of each calendar year. Each area will be audited twice a year. Adhoc audits can also be conducted upon discretion of QAD.

The Lead Auditor (QAO) will:

- Prepare and maintain the annual audit schedule
- Circulate the audit schedule to all departments/employees
- Assign auditors based on their availability
- Initiate audits by sending reminders to the auditors 30 calendar days in advance
- Book meeting rooms and send meeting request to the auditor and HODs, on confirmation by all.
- Guide/monitor the internal auditors in conducting the audit.

## 2. Auditor preparation

Internal auditors are responsible for verifying the effective implementation of the QMS. Internal auditors must complete an internal auditor training course.

(CBS internal auditors have completed a 2 day IA training provided by CSA consultants)

The Auditor will:

- Once the dates are conformed by lead auditor, the auditor will prepare the audit plan/agenda for the day using the template CBS-F-QA-12-Audit\_Plan\_1.0 and circulate to the auditees.
- Auditor to request the department to be audited to provide relevant information / documentation to the scope of the audit.
- The auditor will review the documents and be aware of the activities of the department / function to be audited.
- The auditor should be aware of the requirements of the standard. A comparison of the quality system documentation against the requirements of the standard to be done before the audit.



## 2. Auditor preparation (...continued)

For details refer to :

- ISO 9001:2015 standard
- Internal audit study materials provided by CSA consultants
- Auditors Responsibility: refer to IA procedure

### How does Internal Auditor know what to audit?

- Identify key risks of the organization
- Look at all areas of exposure, not just financial
- Focus on the issues that matter most

## 1. Opening Meeting

Auditor to explain to the auditee the following:

- Purpose/ Scope of audit
- Function, area, requirement, system or process being audited.
- Assure confidentiality of the audit findings

## 2. Performing the audit

After the opening meeting you will start your audit.

- Using your checklists ([CBS-F-QA-11-Audit\\_Checklist\\_1.0](#)) and procedures as references, go out to observe the process and talk to people in the department
- Look for evidence that the Quality Management System is working effectively
- An effective audit will depend on your ability to put people at ease and encourage open honest communication

## 2. Performing the audit (..continued)

As an auditor you will:

- Check documents and records
- Ask questions or ask for clarification if you do not understand
- Observe processes and compare them with documented procedures/work instructions
- Identify non-conformances
- Document objective evidence to support NC identified.
- Follow audit trails, be curious
- Take good notes
- Provide due credit to positive observations
- ensure employees aware of, trained on and following the QMS documentation and requirements

Notes:

- Follow the audit plan
- Have all necessary documents like ISO standard, checklist, report ready in your folder
- Ensure the audit is completed within the allocated time frame
- Preferable not to have any meetings just before or after the audit
- Ensure no disruptions/distractions can occur

### **3. Documenting the Audit findings**

You have to use the following mentioned checklist and document your findings:

[CBS-F-QA-11-Audit\\_Checklist\\_1.0](#)

### **4. Prepare Draft audit report**

Once you complete your audit, you will prepare a draft audit report and document any non-conformances. The findings has to be documented in the following template:

[CBS\\_F\\_QA\\_07\\_Internal Audit Report\\_1.0](#)

## 5. Closing Meeting

When your documentation is complete you will be ready to hold your closing meeting. The auditor will lead the meeting.

- ❑ Thank the group for their cooperation
- ❑ Remind them that this is an evaluation of the processes not the people
- ❑ Summarize the findings
- ❑ Highlight areas that are working well
- ❑ Review each of the non-conformances, allow questions and discuss the finding to make sure that the group understands the non-conformances
- ❑ Set timelines for closing the nonconformities in consultation with auditee
- ❑ Discuss any previous corrective actions that you followed up on that were not found to be effective
- ❑ Once again assure confidentiality of the audit findings
- ❑ Remind the auditee to raise the NCs as per the audit report in the NCR (CBS\_F\_QA\_08\_Non Conformity Report\_1.0)form.
- ❑ Also state that auditor and the lead auditor will follow-up for the NC closure timelines

### **5. Prepare Audit File**

Final audit file includes:

- Audit plan
- Audit checklists
- Audit report – the final audit report should be prepared in consultation with lead auditor.

These documents should be submitted to QAO for review and archiving.

### **6. Disseminate final audit report**

The final audit report should be circulated to the auditee(s), line manager, the department head of the auditee and lead auditor.

### **7. Follow-up**

The auditor and lead auditor will follow-up to ensure all NCs raised are closed.

## WRITING NON-CONFORMANCES

- NCs must be clearly written.
- Should address the **process/system** which is deficient.
- Objective evidence gathered should identify which **process** is deficient.
- What is the **process**?
  - You must understand the process to verify conformance or non-conformance.
- Is the non-conformance identified, systemic to the **process**?

### Three Distinct Parts of An NC

An audit NC should have three distinct parts:

- A clear statement of the non-conformance.
- The requirement, or specific reference to the requirement.
  - **If you cannot identify a requirement, then you cannot raise a non-conformance.**
- And finally, objective evidence that supports the statement of non-conformance; based on the requirement.

## CORRECTIVE ACTION ACCEPTANCE/CLOSURE

Does CA response address system process NC?

Is Root Cause adequate?

You must know and understand the process to accept the CA and root cause.

Does auditee's response ensure no re-occurrence?

The auditee's corrective action response should cover three areas, as a minimum:

- Containment of the current situation and identified systemic failure.
- Action to control or mitigate a problem; could includes correction, corrective action.
- Root cause analysis as to why the system failed.
- Finally, a systemic corrective action to prevent a recurrence of a failure in the system/process (could be preventive action may apply here.)



## QUALITY INTERNAL AUDIT COMMITTEE

An Audit Committee has been formed to oversee the audit process within the organization with the following objectives:

- Establish and maintain a quality assurance program to promote high service standards.
- Review of yearly audit plan
- Review of Audit reports

The committee will meet every quarter.

For details: Refer Quality Internal Audit Committee TOR

### **Responsibilities Of The Audit Committee**

The Audit Committee is responsible to exercise oversight responsibility over

- Internal Audit
- External Audit
- Reporting (financial and non financial information)
- Compliance with applicable laws and regulations
- Internal Control



## MANAGEMENT REVIEW MEETINGS

Management Review is the routine evaluation of whether the Quality Management Systems are performing as intended and producing the desired results as efficiently as possible.

Management Review Meetings (MRM) are undertaken to:

- Determine and evaluate QMS performance
- Determine the need for change and improvement
- Determine the suitability of the policies and the objectives

MRM will be conducted twice a year.

The MRM agenda will also consider the audit results, nonconformities and corrective actions taken.

