



1

---

---

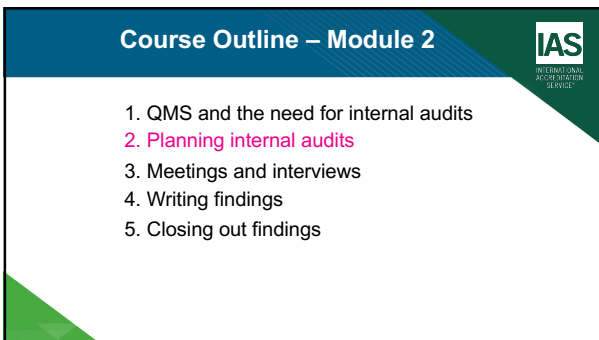
---

---

---

---

---



2

---

---

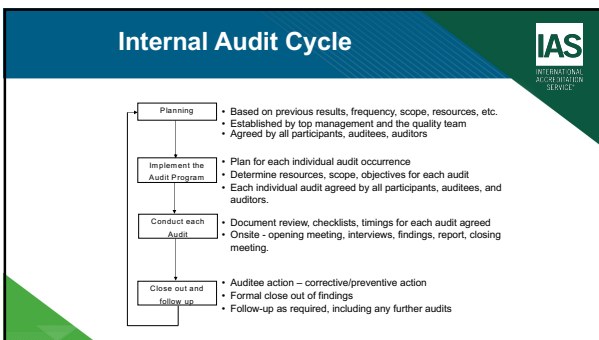
---

---

---

---

---



3

---

---

---


---

---

---

---

System Readiness for Audit



1. Documented system

2. Structured system

3. Implemented system

4

---

---

---

---

---

---

---

Documented System



• Quality policy document

• Processes / procedures

• SOPs / instructions

• Specifications

• Standards

• Codes of practice

• Regulations

• Records

5

---

---

---


---

---

---

---

Structured System



Policy

Procedures

Work Instructions

Proof

WHY

WHO  
WHAT  
WHEN  
WHERE

HOW

RECORDS

Level 1

Level 2

Level 3

Level 4

6

---

---

---


---

---

---

---

## Implemented System



Do people have access to the policies and procedures that govern their work?

Do people maintain records that demonstrate their use of the policies and procedures that govern their work?

- Records indicate the level of implementation of Documents, Processes and Procedures
- Records provide evidence that a system is being used
- 17025/17020/17065 etc have comprehensive recording requirements throughout

"If you did not write it down - it did not happen!!"

7

---

---

---

---


---

---

---

---

## Standard audit requirements



**Internal Audit Secret #3**

People do not like surprises in auditing.

In order to obtain and retain support for the process throughout the organisation, it is important to appreciate that surprises in audits are a bad thing. Prevent them.

Get agreement at every stage. In fact, each step in the audit cycle, audit program and each audit, should be confirmation of agreements made to that point of the process.

8

---

---

---

---


---

---

---

---

## Internal Audit Programme



Approved by top management and contains:

- Resource allocations
- Scope and objectives of audit activities
- Timelines

Audit Area / Period	Q1-2007	Q2-2007	Q3-2007	Q4-2007
Admin		Sally	George	
Engines	Karen			
Polymers				Bruce
Sample Reception / dispatch			Jill	

9

---

---

---

---


---

---

---

---

### Developing the Audit Plan



1. See the example on page 15 of Chapter 2.
2. Note the list of requirements on page 16 of Chapter 2 when formally presenting the plan during an opening meeting.

---

---

---

---

---


---

---

---

10

### Audit Schedule / Plan



1. Agreement on the planned approach
2. Respond to necessary adjustments to the plan
3. Confirm arrangements for logistics and resources
4. Confirm arrangements and timings for subsequent meetings
5. Confirm arrangements for the end of the audit

---

---

---

---

---


---

---

---

11

### Exercise 1 – Audit Planning



Here are the audit documents you are to review (**Each Team pick one only**):

- SP001 – Continual Improvement procedure (Ref = QM, Audit Doc = SP001)
- SP002 – Feedback procedure (Ref = QM, Audit Doc = SP002)
- SP003 – Internal Audit and Management Review procedure (Ref = QM, Audit Doc = SP003)
- SP004 – Document control and control of records procedure (Ref = QM, Audit Doc = SP004)
- SP006 – Job Hazard Assessment procedure (Ref = QM, Audit Doc = SP006)

---

---

---

---

---

---

---

---

12

Exercise 1 – Audit Planning

- The team to conduct a document review of the relevant SP.
- The team leader is to reach agreement with the auditee on the following:
  - Scope and objectives
  - Audit resources
  - Dates and timings, and
  - Participation
- The team leader is to complete sufficient Audit Plan Forms on the following pages to involve all team members in the audit such that one person from the team is auditing each of the following aspects of your selected procedure:
  - Training and qualification processes of personnel involved in the procedure
  - Processes for document control and control of records used and created by the procedure
  - Processes for continual improvement of the procedure
  - Processes for documenting and responding to feedback as regards the procedure
  - Processes for the assessment of job hazards associated with the procedure.

---

---

---

---

---

---

---

---

13

Exercise 1 – Audit Planning

- Each team member is to prepare two open-ended questions that will allow him or her to conduct the minimum line of inquiry to establish conformance of the process they are to audit within the audit team's selected procedure. The questions are to be related to the following processes.
  - Training and qualification processes of personnel involved in the procedure
  - Processes for document control and control of records used and created by the procedure
  - Processes for continual improvement of the procedure
  - Processes for documenting and responding to feedback as regards the procedure
  - Processes for the assessment of job hazards associated with the procedure.

---

---

---

---

---

---

---

---

14

Exercise 2 – Opening Meeting

Each team has already selected one of the following processes to audit:

- SP001 – Continual Improvement procedure (Ref = QM, Audit Doc = SP001)
- SP002 – Feedback procedure (Ref = QM, Audit Doc = SP002)
- SP003 – Internal Audit and Management Review procedure (Ref = QM, Audit Doc = SP003)
- SP004 – Document control and control of records procedure (Ref = QM, Audit Doc = SP004)
- SP006 – Job Hazard Assessment procedure (Ref = QM, Audit Doc = SP006)

---

---

---

---

---

---

---

---

15

## Exercise 2 – Opening Meeting



Your group is an audit team and it is to accomplish the following based on the selected process being audited:

1. The team is to plan the delivery of an opening meeting, using the agenda shown in Section 2.4 of the course handbook.
2. The team leader is to deliver the opening meeting using the agenda shown in Section 2.4 of the course handbook.
3. Each group is to deliver their opening meeting to the local QMS representative (your facilitator). Once all presentations are complete, the class will discuss the issues arising, and the salient points to retain.

---

---

---

---

---

---

---

---