



How to prepare for an audit





You are listening to....



Dagmar Engel MacDonald



Lead QMS Auditor (IRCA)

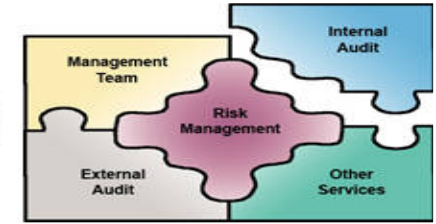
Evaluator of Packaging Technology (IOP)



Training and Consultancy

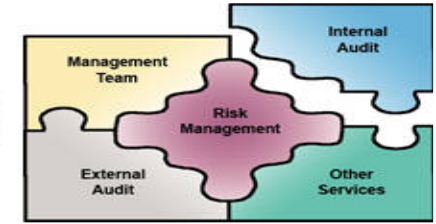
Wattenheim, Germany





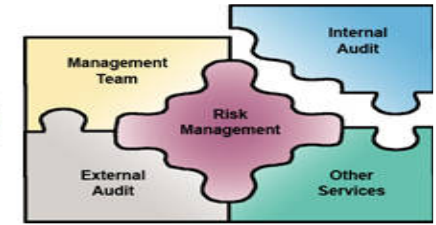
What is an audit anyway?





AUDIT

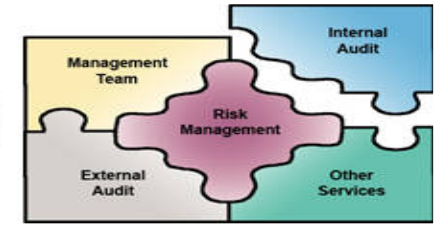
- A systematic and independent examination to determine whether activities and results comply with documented procedures
- also*
- Whether defined procedures are implemented effectively and are suitable to achieve the objectives.



AUDIT - The Important Question

Are you doing what you say
you are doing and is it
appropriate?

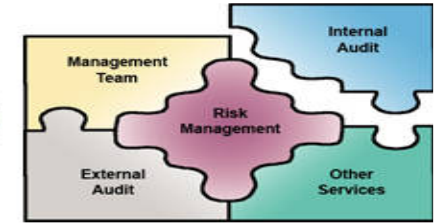
Dillon and Griffin (1997)



A definition of 'audit'

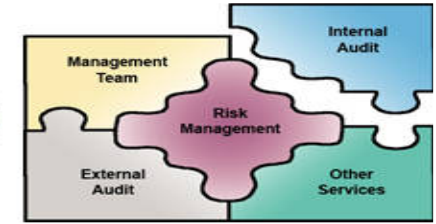
An audit is an evidence gathering process. Audit evidence is used to evaluate how well audit criteria are being met.

Audits must be **planned**, **objective**, **impartial** and **independent**, and the audit process must be both **systematic** and **documented**.



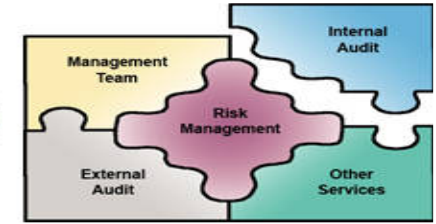
Audit v. Inspection

- audire (Latin) – to hear
- auditus compoti (Medieval Latin) – audit of an account
- Presented *orally*
- ‘Are you doing what you say you do and is it appropriate’ *Dillon & Griffith 1997*



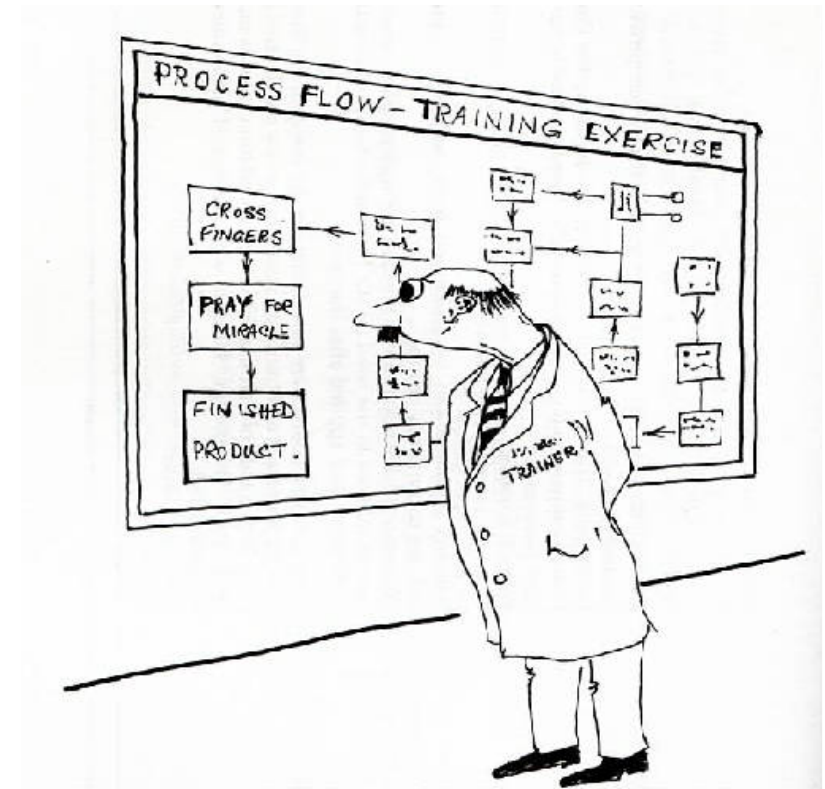
Audit v. **Inspection**

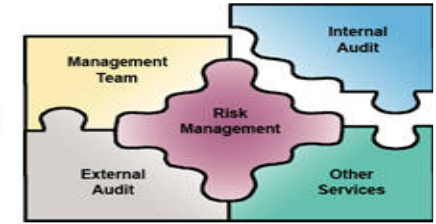
- inspicere (Latin) – to inspect
- always includes an element of sampling, measurement, examination, testing, analysis and interpretation
- Often means inspection of the product rather than the process



Types of audit?

- First party audits
- Second party audits
- Third party audits



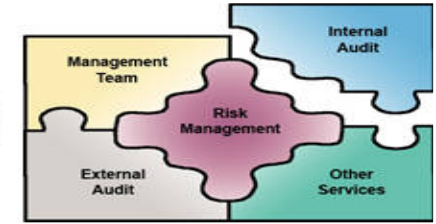


First party audit

- Also known as ‘internal audits’
- Organisations use **first party audits** to audit themselves for internal purposes. However, you don’t have to do them yourself.

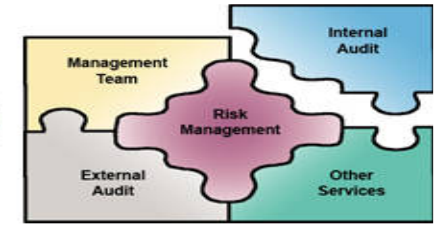
You can ask an external organisation to carry out an internal audit on behalf of your organisation. You can also use first party audits to declare that your organisation complies with, for example, the ISO 9001:2008 standard (a self-declaration).





Second party audits

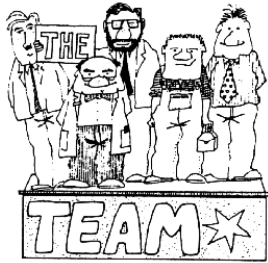
- Often called 'supplier audits'
- **Second party audits** are external audits. They're usually done by customers or by others on their behalf. However, they can also be done by any external party that has an interest in your organisation.



Third party audits

- Often called 'certification' ('registration') audits
- **Third party audits** are also external audits. However, they are performed by independent (disinterested) external organisations. Third party audits are used to determine whether or not an organisation complies with a 'recognised' standard e.g. ISO, BRC, IFS, NSF, AIB, EU Legislation, etc.

Company



Consultants



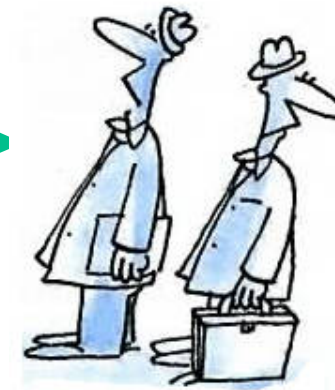
implement
Standard



Certification



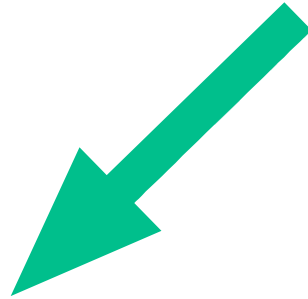
assess system
against
Standard

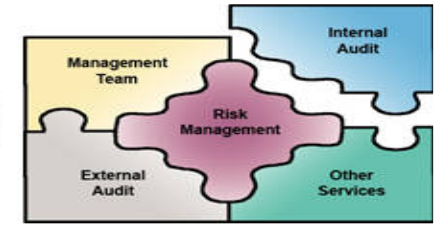


Auditors

Certification
Body

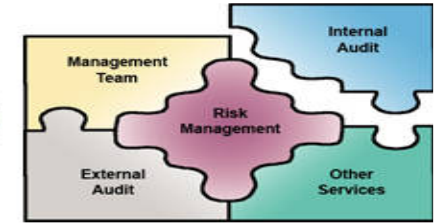
confirm standard
implementation





Reasons for third party auditing

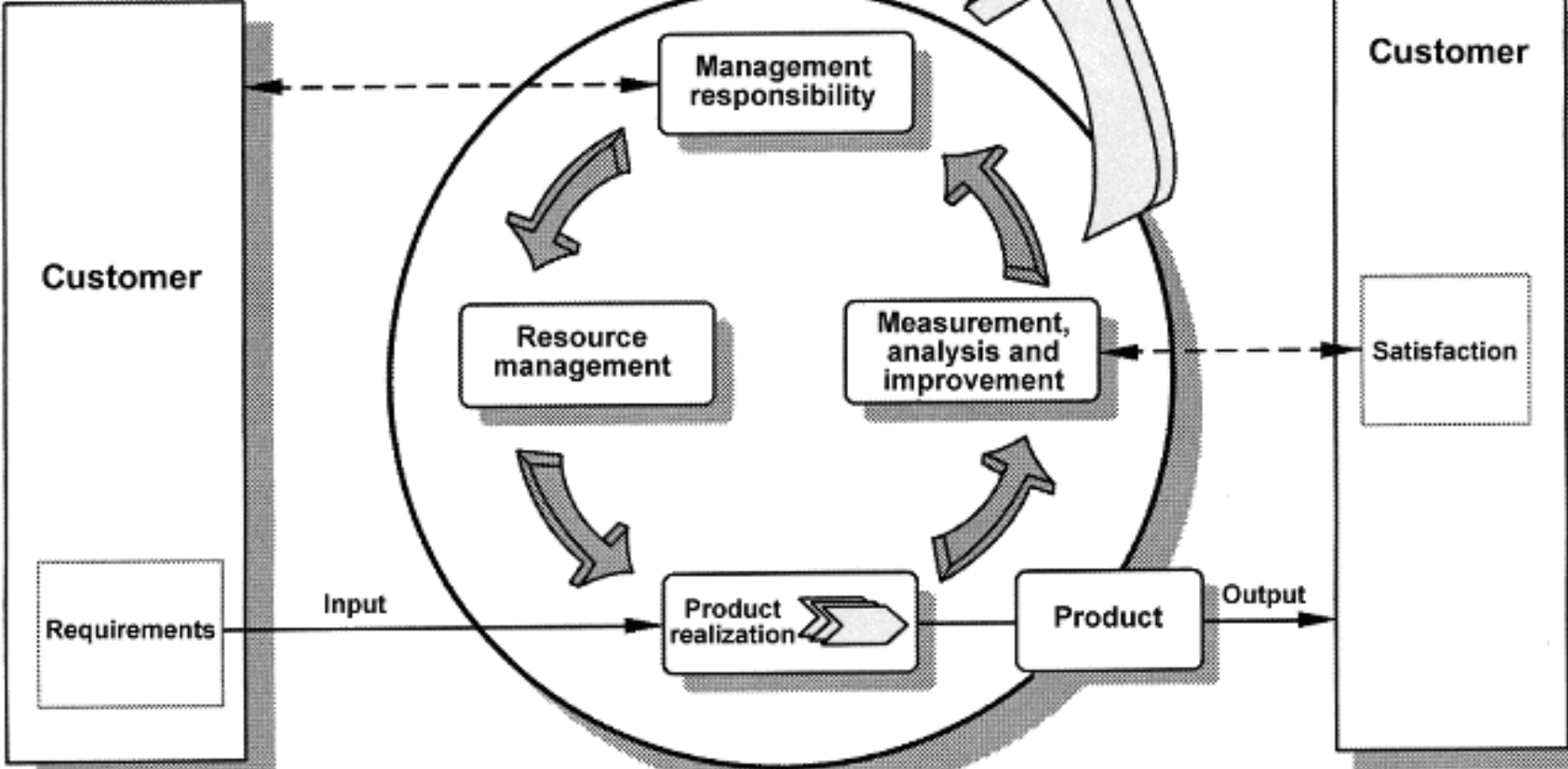
- independent assessment will ensure greater confidence
- certification demonstrates that your system is efficient
- certification may reduce the amount of second party audits and support the customer/supplier relationship



Other types of audit

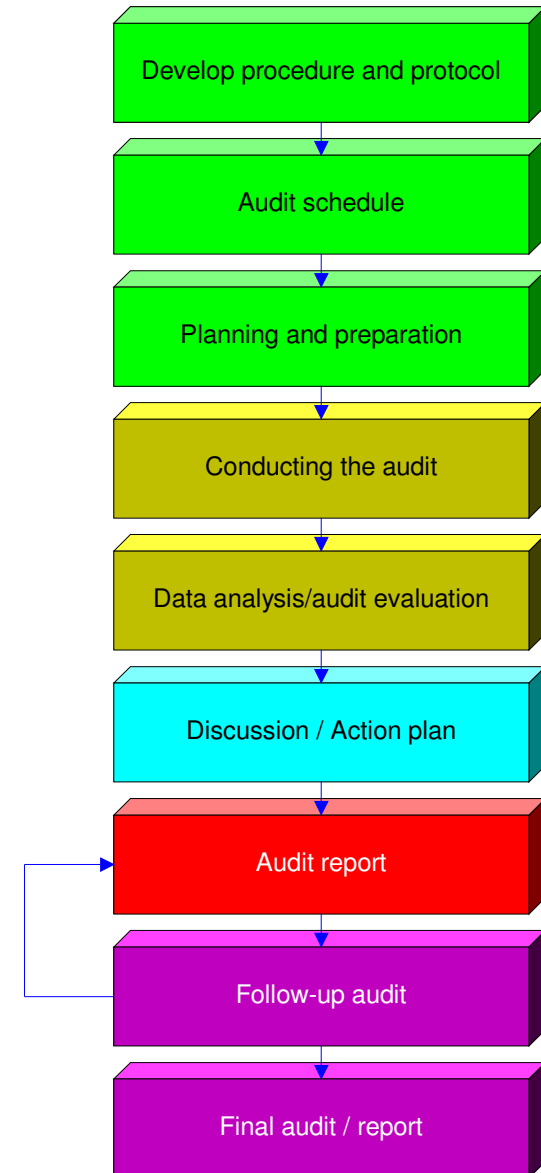
- Gap Analysis
- Desk Review
- Compliance Audit
- System Audit
- Process Audit
- Product Audit
- Surveillance Audit
- Stage I and Stage II Audits

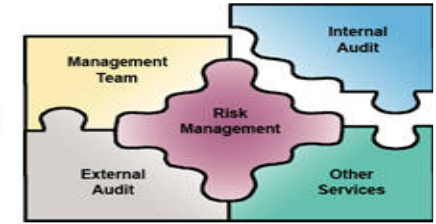
**Continual improvement of
the quality management system**



Auditing is preventive system maintenance

- pre-assessment
- assessment
- re-assessment
- random audit



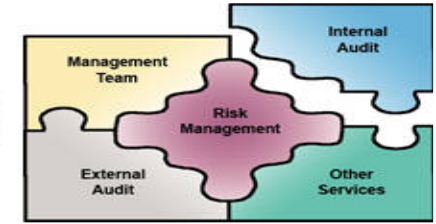


AUDIT STAGES

- Preparation
- Opening Meeting
- On-site Audit
 - Interviews
 - Site Tour
 - Document review
- Closing Meeting
- Records and Reporting

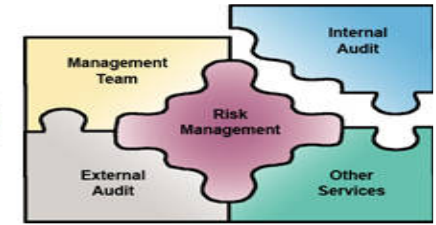
Audit Programme





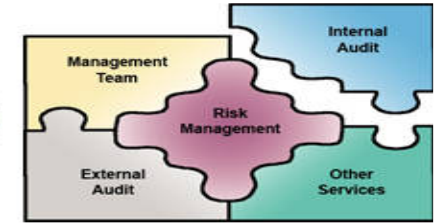
First: PREPARATION

- Who's coming?
- Make yourself familiar with the audit team !
- Check audit programme
- Sort out your agenda and interview partners



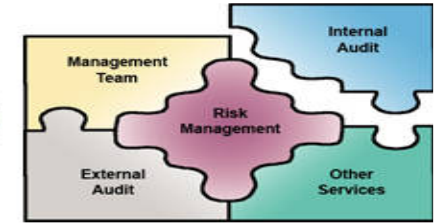
Selecting your team

- Team leader
- Appropriate members for all topics
- Technical experts
- Check resources (i. e. meeting room; PPE)



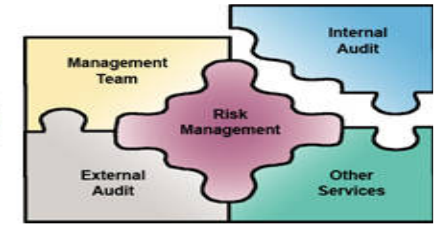
Check your documentation

- Quality manual
- Operational procedures / working instructions
- Test instructions
- Production protocols
- Product specifications
- If applicable: certificates of analysis
- Check your last audit report:
 - Nonconformity reports
 - Corrective and preventative actions
 - Verification of corrective actions



RECORDS FOR EXAMINATION

- HACCP Log Sheets
- Hold / Trace / Recall
- Training Records
- Cleaning Schedules
- Internal / External Audit Records
- Calibration Records
- Delivery Notes
- Customer Complaints
- Process Deviations
- Risk Assessments
- Recipes
- Despatch Notes
- Process Flows
- Heat Process Records
- Pest Control
- Maintenance Records



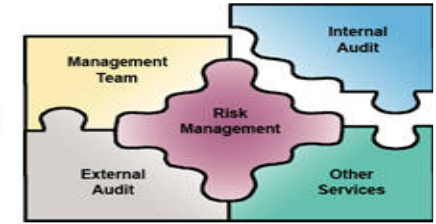
Audit Practicalities

- Stick to the schedule.
- Make sure all interview partners are lined up.
- Be courteous at all times.
- Show an interest – help the auditor!
- Offer explanations and technical assistance.

Opening Meetings – Purpose?

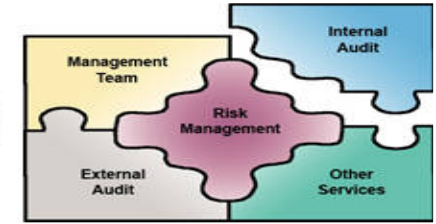
- ‘Setting the Scene’
- Confirm audit schedule and escort
- Discuss timetable
- Present your team – make sure that the senior management is present
- Enquire about the final report
- Emphasise confidentiality
- Discuss provisional time for closing meeting





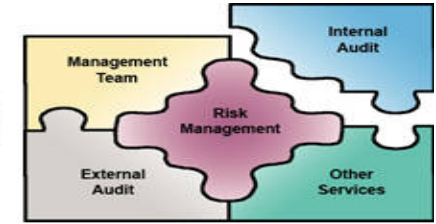
Audit „etiquette“

- You are the host – the auditor is your guest.
- You are also the client – the auditor is a service contractor.
- The auditor conducts the programme, but you define your company rules (protective equipment, visitor registration, personal hygiene rules are all applicable to the audit team).



ESSENTIALS OF AUDITING

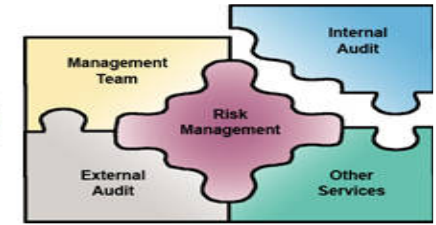
- Do not leave yourself open to criticism.
- Be supportive.
- Listen to the questions. Ask the auditor to repeat a question which has not been clear. Don't hesitate to ask twice!
- Have confidence in your ability as dialogue partner.
- Watch and observe.



During the interview

- ✚ Stay fair ! Don't get caught on the back foot.
- ✚ Involve everybody. Pass on questions. This is not a one-man-show.
- ✚ Remain calm, polite, patient and „cool“.





The audit interview – answering the questions

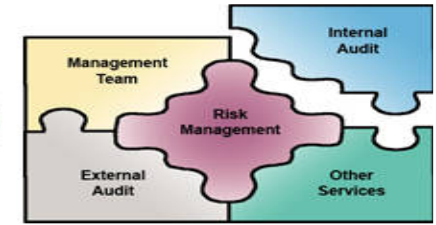


Why is it important to listen to the questions?

We need to be sure that the auditor obtains correct information which is....

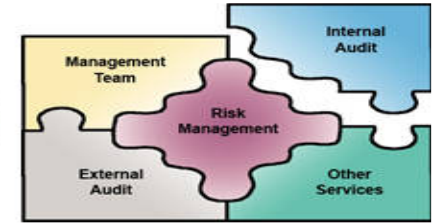
- relevant
- honest
- comprehensive
- transparent
- to the point





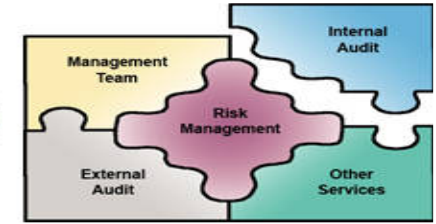
Do not hesitate to

- assure yourself that you have understood the question.
- keep your answers short and simple. Then offer to explain in more detail.
- point out that this is your system, and stress your – hopefully good – historical experiences.
- Don't jump ahead – even if you anticipate the next question !



The secret behind the auditor's questions....

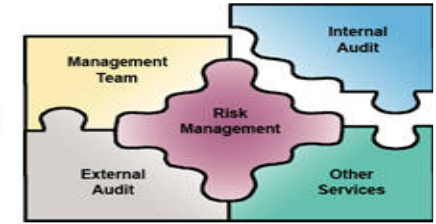
- The purpose of an audit is NOT to find out what an auditor does or knows.
- The purpose of an audit is to find out what the auditee does or knows.
- Therefore, even if the auditor appears to be the world's leading expert in HACCP – he may still ask you what it is!!!



Closing Meeting – Purpose?

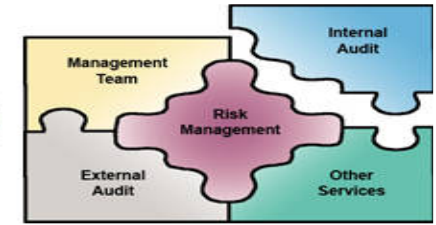
- Discuss audit findings
- Discuss potential discrepancies and opportunities for improvement
- Allow the auditee to suggest correctives actions
- Agree timetable for corrective actions
- Agree report distribution
- Sketch the way forward
- Ensure confidentiality
- Q & A session



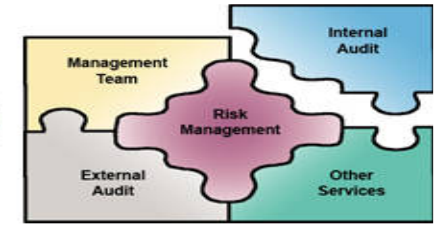


CLOSING MEETING – what matters

- Senior management to be present
- preliminary report of audit findings
- Time for discussion
 - * *to summarise*
 - * *to clarify*
 - * *to listen*
 - * *to indicate priorities*
- Agree future action

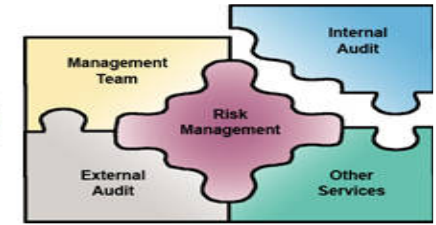


- **Corrective action** means action to eliminate the cause of a detected non-conformity or other undesirable situation.
- **Preventive action** means action to eliminate the cause of a potential non-conformity or other undesirable situation.

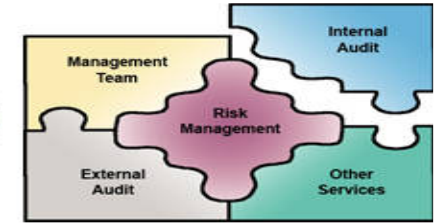


Action Plans

- Where appropriate, an **action plan** should be drawn up and delivered by the auditee. It should propose time-bound corrective and preventive action to address any weakness identified by the audit or audit programme.
- The external audit team will assess the suitability of the action plan and may be involved in verifying its subsequent implementation.



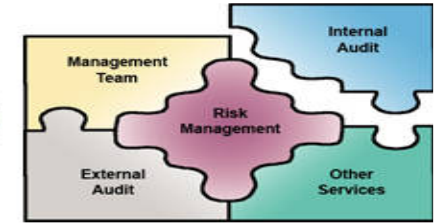
- **Corrective and preventive action** must not be confined to addressing specific technical requirements but should, where appropriate, include system-wide measures (for example communication, cooperation, coordination, reviewing and streamlining of procedures, and so forth).
- A **root cause analysis** of any non-compliance should be conducted by the auditee in order to determine the most appropriate corrective and preventive action.
- Any differences of opinion between the auditee and audit team should be resolved before the audit is finished!



AUDITING TIPS

(Before the Visit)

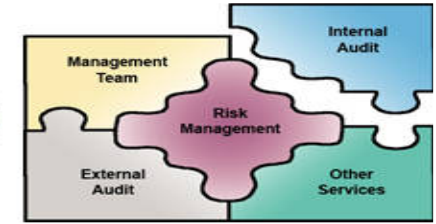
- Do your homework - plan the visit.
- Check if you can support the auditor (travel logistics, hotel accommodation etc.)
- Prepare a company presentation.
- Brief the management.
- What are your strong points – company history, client feed-back, results of product analysis....?



AUDITING TIPS

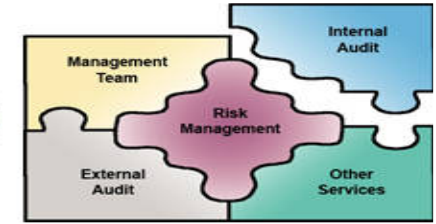
(Before Visit)

- Review your documentation and correspondence.
- Check last management review report – in most cases the auditor will want to see it.
- Make sure your HACCP study is up-to-date and verified.



PREPARATION

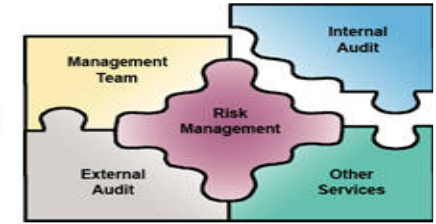
- “Keep in mind what you have to do when you are afraid. If you are prepared you will not be afraid” - Dale Carnegie
- “ An intelligent plan is the first step to success. If one does not know where he is going, how can he expect to get there?” - J.M. Braude



AUDITING TIPS

(On Site)

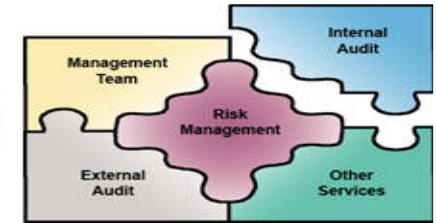
- Allow sufficient time for interviews.
- Take careful notes – don't rely on the auditor!
- Do not allow yourself to be rushed.
- Prepare for a traceability challenge.
- If applicable: make sure your test systems work !
 - Metal detectors, camera systems, temperature loggers



AUDITING TIPS

(Audit Completion)

- Ask the audit team if they need further information before the closing meeting.
- Support root cause analysis.
- Stand your ground – it is not unusual that some scenarios during the site tour have been misunderstood by the auditor.



Confidentiality

- Discuss circulation of the audit report.
- What an auditor sees and hears in an audit must be treated in confidence.
- Don't be afraid to ask the auditor to confirm confidentiality.