



“Further strengthening of capacities of phytosanitary sector in the fields of plant protection products, plant health and seeds and seedlings, including phytosanitary laboratories and phytosanitary inspections”

(TWINNING BA/12/IB/AG 01)

Component 3: Seeds and propagation materials

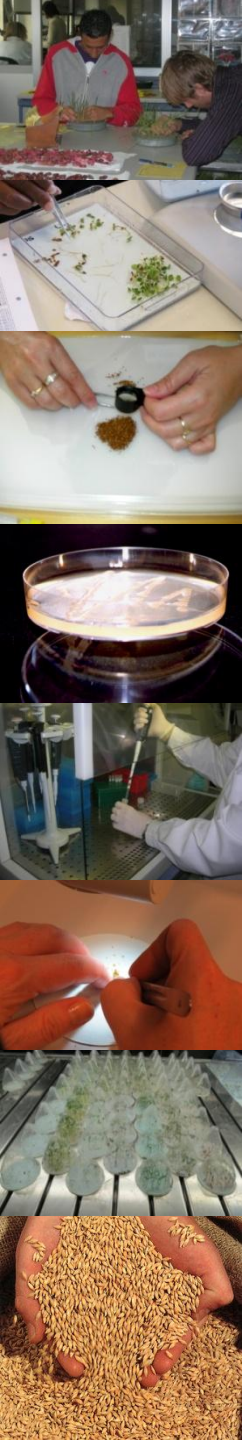
Internal audits




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Internal audits

- Definitions
- Audit types
- Requirements for ISTA Accreditation
- Audit team
- Audit process



Internal audits: definitions



An **audit** is a systematic **evidence** gathering process. Audits must be independent and evidence must be evaluated objectively to determine how well **audit criteria** are being met.

Audit evidence: records, statements of facts of other information which are relevant to the audit criteria and verifiable.

Audit criteria: set of policies, procedures or requirements (e.g. ISTA Accreditation Standard, ISTA Rules, SOPs, Work Instructions...).

Internal audits: types (intention)




1st part audit: the audit is performed by the laboratory itself (or on its behalf)

2nd part audit: the audit is performed by another organization which has interest; the goal is to provide confidence in the quality to a customer (e.g. The laboratory performs an audit of a supplier)

3rd part audit: the audit is performed by an independent organization; the goal is to provide confidence in the quality to regulators and a wider public (e.g. ISTA, other accreditation bodies)

Internal audits: types (scope)



System audit: the aim is to check if the laboratory management system, procedures and methods are capable to meet the requirements (e.g. Accreditation Standard, Rules, Norms..).

Process audit: the aim is to check process capability to meet process key figures.

Product audit: the aim is to check if a product complies with defined specifications.

Internal audits: Requirements

(ISTA Accreditation Standard)

Internal audits: at least performed yearly

Predetermined schedule and procedure

Performed in a way to verify compliance with the ISTA Accreditation Standard

Must address all the elements of quality system activities, including seed sampling and testing

Carried out by trained, qualified and independent staff

Identified non-conformities: timely corrective actions (client informed if relevant)

Area/activity audited, findings, non-conformities; recorded

Follow-up audits: verify implementation and effectiveness of corrective actions



Internal audits: Requirements

(ISTA Accreditation Standard)

The laboratory needs to establish a written procedure for internal audits. Audits are carried out basing on a audit programme. All elements of the system must be covered.

- 1) System part:** internal/external audits, staff training, check testing/check sampling, complaints, corrective/preventive actions, document control, evaluation of suppliers (...)
- 2) Technical part:** sampling, all tests in the scope of accreditation, completing certificates (...)
- 3) Equipment part:** control, calibration, certification of reference materials (...)

Internal audits: Requirements

(ISTA Accreditation Standard)

Example of an audit programme

Check testing	Q1/2016
Document control	Q1/2016
Check sampling	Q2/2016
Management review	Q3/2016
Other system activities	Q4/2016
Sampling	Q1/2016
Purity	Q2/2016
Germination	Q3/2016
Other technical activities	Q4/2016



Internal audits: Purpose

An audit is aimed to check:

- If the laboratory follows its own procedures
- If the laboratory fulfils the accreditation requirements (e.g. ISTA Accreditation Standard)
- If the laboratory fulfils technical requirements (e.g. use of ISTA methods)
- If the documents are updated, reviewed, suitable for the laboratory needs
- If the equipment is regularly calibrated
- If records are kept

The internal auditor should be trained in audit and have some experience in the audited activity

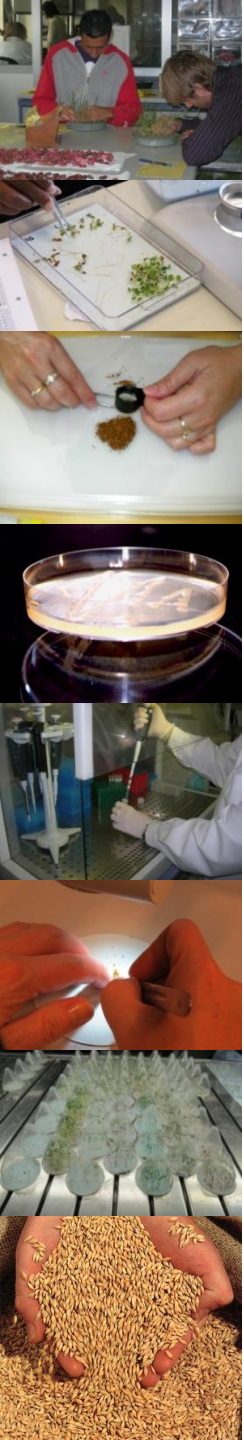


Internal audits: Audit Team

Audits should be carried out by trained and qualified auditors (preferred independent):

- Auditor must have the necessary qualification
- They must be independent from the audited activity (stringent for 2nd and 3rd party audits)

Seed Testing Laboratories: usually 2-3 auditors (lab staff, colleagues form other department, other labs)



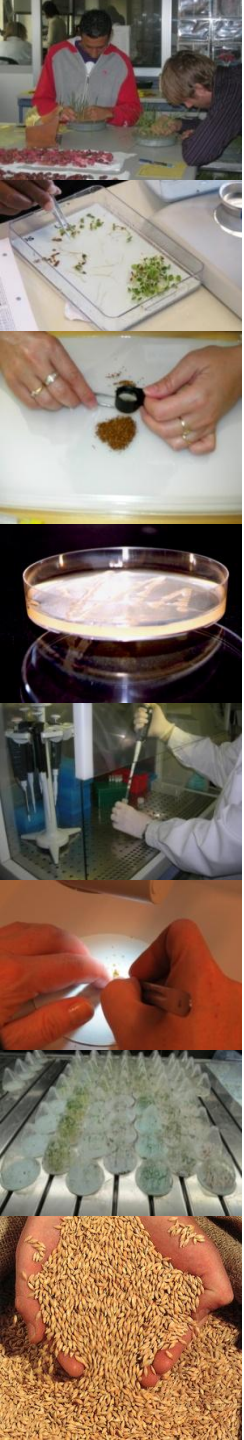
Internal audits: Audit process

- 1) Documents
- 2) Opening meeting
- 3) Audit of the selected activity/ies
- 4) Closing meeting
- 5) Corrective Actions
- 6) Evaluation of Cas



Internal audits: Audit process

- 1) Documents (Q-Manual, SOPs, Wis, external reference documents..). Review of documents:
 - to evaluate compliance with reference standards/rules
 - to compare written procedures with daily practice
 - to evaluate if all procedures are documented (all needed written procedures are available)



Internal audits: Audit process

2) Opening meeting

- Explain purpose of the audit, scope
- Explain how it will work (time schedule, breaks..)
- Explain why you take note
- Explain the roles of auditors and auditee (*an audit is not a personal exam!*)
- Ask questions
-



Internal audits: Audit process

3) Audit of the selected activity/ies

- See, listen, observe ..
- ... and compare with the requirements and the written descriptions
- Communicate findings soon (and if required: discuss with the staff)

Tips:

- Go where the work is done
- Interview those who do the daily work
- Witness the work (not just explanations!)
- Look around... the environmental conditions, the equipment...
- Ask for records
- Use a checklist!



Internal audits: Audit process

4) Closing meeting

- Give your overall evaluation (including positive outcome and impressions!)
- Explain the findings (there should be no surprises..)
- Be open to questions and ready to answer (and discuss, if needed)
- Agree on follow up (procedure, time schedule)

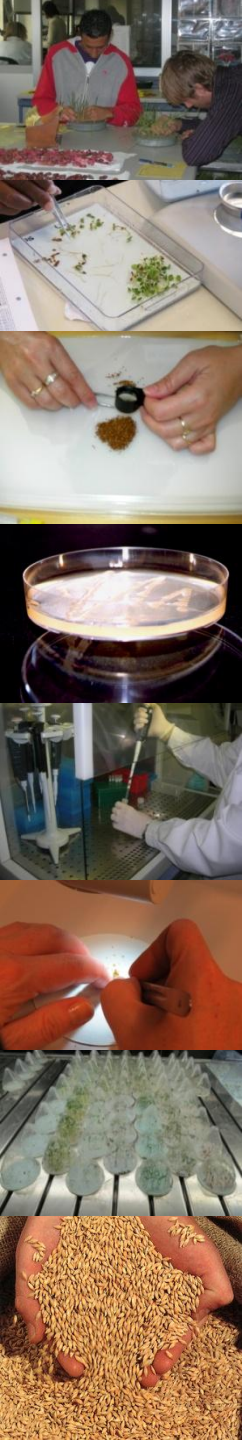


Internal audits: Audit process

5) Corrective actions: not for the auditors

6) Evaluation of corrective actions. E.g.

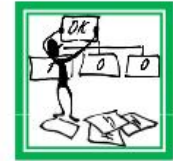
- Are they appropriate?
- Are they effective?
- Was the deadline met?
- ...



Internal audits: An auditor should be..

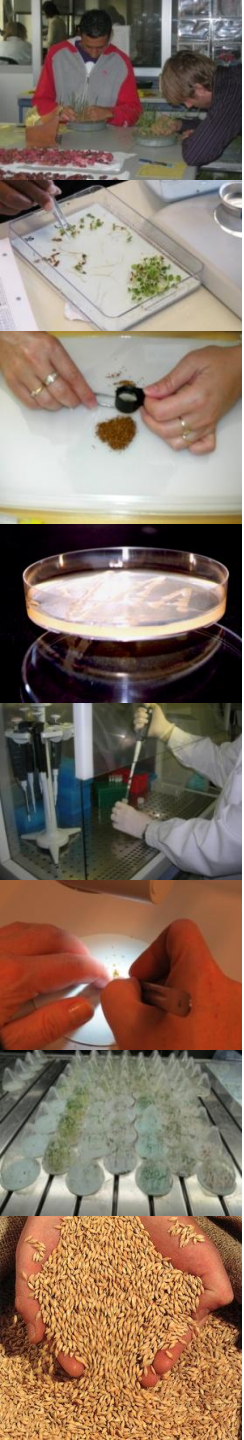


3. Perform the audit



ISO 19011:2002 (chapter 7: personal attributes) auditors should be:

- Ethical, i.e. fair, truthful, sincere, honest, discreet;
 - Open-minded, i.e. willing to consider alternative ideas;
 - Diplomatic, i.e. tactful in dealing with people;
 - Perceptive, i.e. instinctively aware and able to understand situations;
 - Versatile, i.e. adjusts readily to different situations;
 - Decisive, i.e. reaches timely conclusions based on logical reasoning and analysis;
 - Self-reliant, i.e. acts and functions independently while interacting effectively with others;
 - Etc.
- From: a presentation by Rasha El-Khadem –
Head of ISTA Accreditation Department**



**THANK TO:
RASHA EL-KHADEM
ISTA SECRETARIAT**

THANK TO YOU FOR YOUR ATTENTION