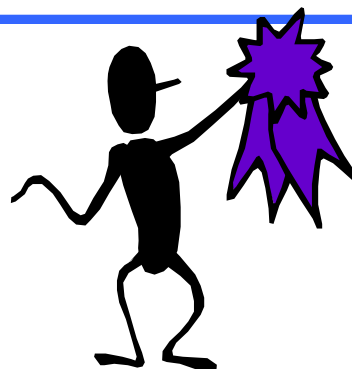
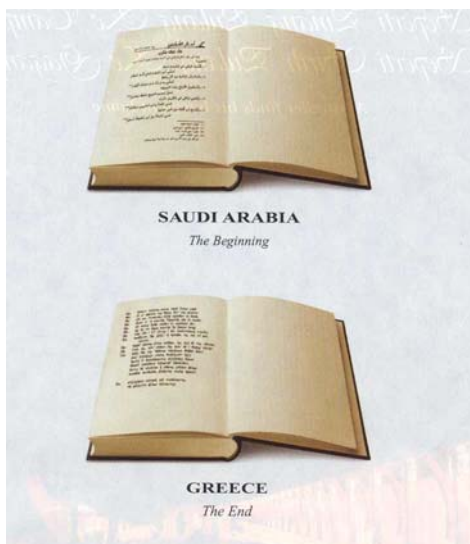


How to do effective Internal Audits

Joan Rabasseda
Head of Projects
Laboratori Agroalimentari – DARP
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 Generalitat de Catalunya
Departament d'Agricultura,
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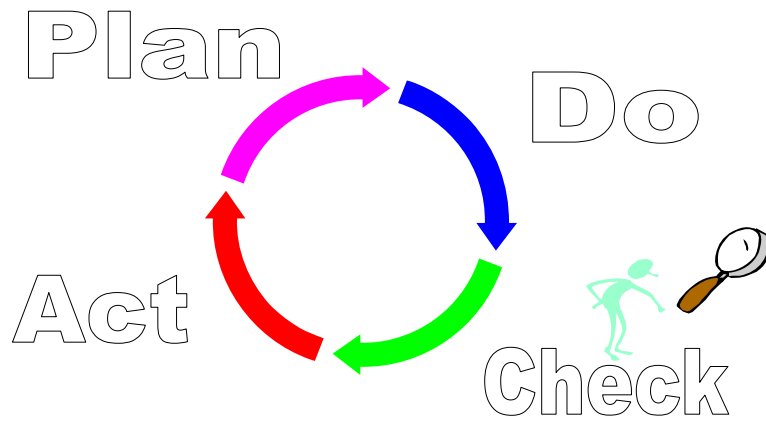



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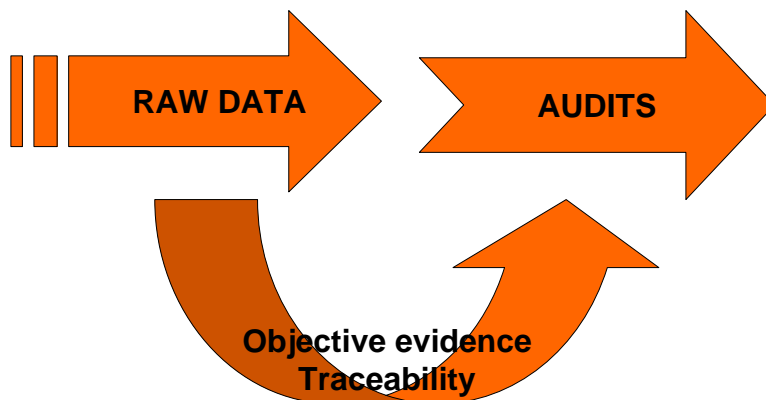
DON'T EXIST

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Quality Management System



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TRACEABILITY

- ISO 8402:1996
 - In relation to the capacity to follow the history of a product or service inside of and outside of the organization
 - In relation to the capacity to link the results with chemical standards used in the calibration
 - In relation to the documentation associated with the analytic process, "in the sense of the registration of the data, it relates to the calculations or the data generated along the "curl of quality" of a product or service."


File

TRACEABILITY

- ISO17025:2005
 - NOTE 8 the unbroken chain of calibrations or comparisons **may be achieved in several steps carried out by different laboratories** that can demonstrate traceability.
- The objective of all the tasks connected with the correct registration of primary data is to be able to have **enough information to allow the reconstruction of the whole history of the sample**, from its arrival at the laboratory to the corresponding report of the results.

TRACEABILITY - FILE



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AUDITS

QUALITY CONTROL ↔ INSPECTION

QUALITY ASSURANCE ↔ AUDIT

- ISO 8402:
systematic and independent exam to determine if the activities and the related and derived results of the quality are developed according to the preset programs and if these programs are implemented and they are adapted to reach the fixed objectives.

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AUDITS

- **UNE-EN 30011-1:1993:**
methodical and independent exam that is carried out to determine if the activities and the relative results to the quality (the personnel's training, measuring equipment and testing equipments, testing methods, calibration and maintenance, etc.) they satisfy the previously established arrangements, and to check that these arrangements are really carried out and that they are the appropriate ones to reach the foreseen objectives.

AUDIT

MANAGEMENT
REVIEW

TRACEABILITY

- **ISO17025:2005**
- 4.12.1.2 All records shall be legible and shall be stored and retained in such a way that they are **readily retrievable** in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. **Retention times** of records shall be established.

INTERNAL AUDITS

- **ISO17025:2005:**
- 4.13.1 The laboratory shall periodically, and in accordance with a **predetermined schedule** and **procedure**, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this International Standard. The internal audit programme shall address all elements of the quality system, including the testing and/or calibration activities. It is the **responsibility of the quality manager** to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by **trained and qualified personnel** who are, wherever resources permit, **independent** of the activity to be audited
- NOTE: The cycle for internal auditing should normally be completed in one year.

INTERNAL AUDITS

- **ISO17025:2005:**
- 4.13.2 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratories test or calibration results, the laboratory shall **take timely corrective action**, and shall **notify clients** in writing if investigations show that the laboratory results may have been affected.
- 4.13.3 The area of activity audited, the audit findings and **corrective actions** that arise from them shall be recorded.
- 4.13.4 Follow-up audit activities shall **verify and record the implementation and effectiveness** of the corrective action taken.

INTERNAL AUDITS

- **ISO17025:2005:**
- 4.10.5 Additional audits
- Where the identification of nonconformances or departures casts **doubts on the laboratory's compliance** with its own policies and procedures, or on its compliance with this International Standard, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.13 as soon as possible.
- NOTE: Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit **should be necessary only when a serious issue or risk** to the business is identified.

INTERNAL AUDITS

- **ISO17020:1998:**
- 7.7 The inspection body shall carry out a system of **planned and documented** internal quality audits to verify compliance with the criteria of this standard and the effectiveness of the quality system. The personnel performing the audits shall be suitably **qualified and independent** from the functions being audited.

INTERNAL AUDITS

- **EN45011:1998:**
- 4.5.3 The quality system shall be documented in a quality manual and associated quality procedures, and the manual shall contain or refer to at least the following:
- n) its procedures for **conducting internal audits**, based on the provisions of ISO 10011-1.

CERTIFICATION
SERVICE

INTERNAL AUDITS

- **EN45011:1998:**
- 4.7.1 The certification body shall conduct **periodic internal audits covering all procedures** in a planned and systematic manner, to verify that the quality system is implemented and is effective.
- The certification body shall ensure that
 - a) personnel responsible for the area audited **are informed of the outcome of the audit**;
 - b) **corrective action** is taken in a timely and appropriate manner; and
 - c) the results of the audit are **documented**.

CERTIFICATION
SERVICE

AUDITS

- **Internal audit.** It is the audit where the client (person or organization that requests the audit) and the audited (person or organization object of the audit) belong to the same organization. In the internal audits the main receiver of the audit report is the audited.
- **External audit.** It is the audit in which the client and the audited don't belong to the same organization. In this case, the main receiver of the audit report is not the audited.

AUDITS

- **Horizontal audit.** It consists of a detailed examination of one or several elements of the quality system (training personnel, measuring equipment, evaluation of the quality of the test, analysis procedures, etc.)
- **Vertical audit.** It consists of a detailed examination of the group of elements of quality system related to a test or a series of tests carried out in the laboratory. A vertical audit can include the repetition of a test

AUDITS

- **Programmed audit.** It is the audit included in the annual plan of internal audits of the laboratory.
- **Specific audit.** It is not the audit included in the annual plan of internal audits of the laboratory and it can be programmed as a consequence of complaints, claims, of the detection of anomalous results, or as a measure to check the effectiveness of corrective actions.

AUDITS

- **Non conforming work.** This concept is used a lot in the framework of the audits. It refers to the lack of execution of the specified requirements.
- **Objective evidence.** This concept is usually applied to the group of information, verification of facts, of a qualitative or quantitative nature and are based on observations, measures or test, and they can be verified. The audit activities should always be based on objective evidences.

AUDITS

- **EFFECTIVENESS:**
 - Genuineness
 - Real existence of quality policy
 - To have audit procedure
 - Existence of a Plan of Audits
 - Knowledge and collaboration of the audited
- **PROCEDURE:**
 - The client's, auditor and audited responsibilities
 - Systematic programming, preparation, communication and execution
 - Final report
 - Follow up
 - Auditors' qualification
 - Formats to use

PREPARATION

CHECKLIST

IDEAL AUDITOR

- He/she knows the idiosyncrasies of the Company
- He/she knows the quality management system of the company
- He/she knows the procedures that will be audited
- He/she knows the people target of the audit
- He/she collaborates with the audited
- He/she always maintains a positive and open attitude
- He/she asks without causing offence
- He/she always looks for objective evidences
- He/she has a work methodology
- He/she is an observer of the details in the different areas and activities

IDEAL AUDITOR

- He/she has a lot common sense and tenacity
- He/she has a lot of analysis and synthesis capacity
- He/she doesn't practice the occultism in the annotations
- He/she always avoids the confrontation with the audited
- He/she evaluates the information evenly, being based on objective evidence
- He/she treats confidential information with discretion
- He/she always has the support of the Director/Head.

AUDIT REPORT

- It has been checked the systematic used by the LAB Laboratory for the control, approval, emission and modification of the documentation of the quality system, as well as their implementation. It was observed that some procedures are not updated: the PC-101 contains a chart/table that is not the current one. The systematic of modification of documents is not complete: it doesn't indicate the maximum time that a document modified manually can stay, neither what kind of modifications imply an immediate version change.

- UNE-EN ISO/IEC 17025 4.3



AUDIT REPORT

- Some registrations don't contain all the necessary information to allow the repetition of the test or the calibration: in the registrations of verification of the stove n°014 the probe of temperature used is not identified, and in the registrations corresponding to the application of the analysis procedure PA-111 the scale used for the initial weight is not identified.
 - UNE-EN ISO/IEC 17025 4.12.



AUDIT REPORT

- In the department DEP1, the registration of the personnel's qualifications is incomplete (they lack curricula and formal qualifications for specific types of test and internal calibrations).
- In the department DEP2, just a single person is qualified for the test defined in the PA-404, that means that supervision doesn't exist or a possible substitution in the event of absence.
 - CGA-ENAC-LE 5.2



AUDIT REPORT

- Standards without expiry date have been detected for the determinations described in the PA-700. Other standards did not have enough traceability (A and B analytes) and some other ones (C analyte in the PA-705) had an excessive expiry date. It is considered that the LAB Laboratory doesn't take enough measures to ensure that the standards are adapted to the execution of the test.
 - CGA-ENAC-LE 5.3.1



AUDIT REPORT

- The LAB Laboratory has not communicated to the Accreditation Body, with enough time and in the correct form, the changes or upgrades there have been in the accredited test procedures.
- In the A analyte test according to the Regulation R, the method described in the norm is not used in the full extent.
- Objective evidence of the technical competence of the LAB Laboratory doesn't exist for the test of determination of B, because recent registrations don't exist for this analysis.
 - CGA-ENAC-LE 5.4.1



AUDIT REPORT

- During the audit, annexes of the chapters of the Quality Manual were detected that were not controlled, obsolete documents in circulation, listings of non up-to-date documents, not verified calculation sheets, and calibration and verification of equipment registrations with errors in the formats.
 - CGA-ENAC-LE 5.4.2



AUDIT REPORT

- The deviations found in some of the internal audits carried out by the LAB Laboratory have also been detected in the actual audit, because LAB had not taken measures in this respect. Therefore, the internal audits are carried out in an effective way, but not following up and closing of the found deviations.
- In the verification of the registrations of Non Conformities it has been proven that some Non Conformities remain without correction, with implementation terms expired and without justification by the responsible.
 - CGA-ENAC-LE 5.4.2

