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INTRODUCTION TO PROCESS MANAGEMENT

SEMIS COURSE ON SEED QUALITY ASSURANCE, MANAGEMENT AND CONTROL PROCESSES

PRESENTED BY Munyao W. M.

wmunyao@kephis.org

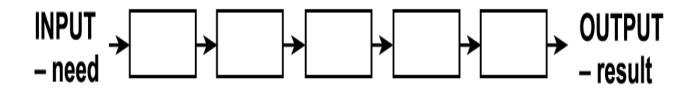
PROCESS

Definition

- A horizontal sequence of activities that transforms an input (need) to an output (result) to meet the needs of customers or stakeholders.
- Process has six components
 - a) Input and output
 - b) Interrelated activities
 - c) Horizontal: intra-functional or cross-functional
 - d) Purpose or value for customer
 - e) The use of resources
 - f) Repeatability

PROCESS

A horizontal sequence of activities...

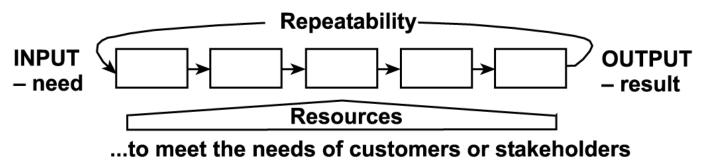


...to meet the needs of customers or stakeholders

Notes: A horizontal sequence of activities that transforms an input (need) to an output (result) to meet the needs of customers or stakeholders. Excluding the components of use of resources and repeatability, only mentioned by a few authors

PROCESS

A horizontal sequence of activities...

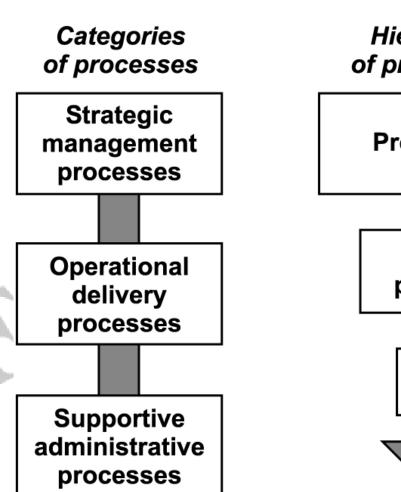


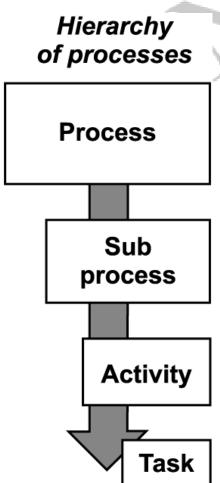
Note: The definition includes the components; input and output, interrelated activities, horizontal, purpose, use of resources and repeatability

Categories of processes

- There are three general process categories
 - Strategic management processes -Covering strategy, planning and control where management oversees and supervises the system
 - b. Operational delivery processes Producing outputs and results for external stakeholders
 - Supportive administrative processes -Required to sustain and support the delivery processes

Categories of Processes





Process roles

- The role of the process owners
 - a) accountable for all process improvement results with authority to approve process changes
 - b) responsible to optimize efficiency and effectiveness,
 - c) ensuring that external customers' requirements are met
 - d) overseeing performance control and continuous improvement

Process roles

- The roles of process team members in cross- functional process teams
 - a) to map and document the process
 - b) assess performance
 - c) analyze deficiencies
 - d) select an improvement strategy
 - e) propose design changes
 - f) implement fixes
 - g) assess results

Process characteristics

- Primary characteristics that describe and shape a process:
 - a) Defined ownership
 - b) Defined boundaries
 - c) Documented workflows
 - d) Established control points
 - e) Established measurements
 - f) Control of process deviations

Process management

Definitions

- a) A structured systematic approach to analyze and continually improve the process – Focuses on the management and improvement of single processes
- b) A holistic manner to manage all aspects of the business and a value perspective in determining organizational effectiveness

Process management

- Purpose of process management
 - a) to remove barriers between functional groups and bond the organization together
 - b) to control and improve the processes of the organization
 - c) to improve the quality of products and services
 - d) to identify opportunities for outsourcing and the use of technology to support business

Process management

- e) to improve the quality of collective learning within the organization and between the organization and its environment
- f) to align the business process with strategic objectives and customer needs
- g) to improve organizational effectiveness and improve business performance

Approaches and tools for process management

- The methodology for process management:
 - a) Process selection Based on
 - i. analysis of the value chain
 - ii. identifying customers and suppliers,
 - iii. data collection and
 - iv. process targeting
 - b) Process description and mapping
 - Understanding and defining the process key activities and the process architecture

Approaches for process management

- c) Organizing for quality
 - i. Establishing ownership of the process, defining and appointing process owners
- d) Process measurements and quantifications
 - i. Identifying performance measurements and
 - ii. targets for controlling the process
- e) Process improvements
 - i. Identifying process improvements (e.g. based on measurements and taking corrective actions)

Tools for process management

- Process mapping
- Process measurement
- Process re-engineering or re-design
- Models for continuous improvement
- Instruments for benchmarking

In summary process management

- 1. Includes the three ingredients the customer, the product, and the flow of work;
- 2. enables an organization to see how work actually gets done, which is through processes that cut across its functional boundaries; and
- 3. Shows the internal customer-supplier relationships through which products and services are delivered

THANK YOU wmunyao@kephis.org

Accreditation bodies and their mandate (NPPOs, NSAs, ISTA)

SEMIS COURSE

Presented by Munyao W. M.

National Plant Protection Organization (NPPO)

- NPPO have the sole authority by legislative or administrative means for control and issuance of phytosanitary certificates.
- In using this authority, the NPPO should:
 - bear the legal authority for its actions
 - implement safeguards against potential problems such as conflicts of interest and fraudulent use of certificates.
- The NPPO have the authority to prevent the export of consignments which do not meet an importing country's requirements.
- The NPPO must be a signatory of the IPPC and have agreed to follow IPPC guidelines for issuing phytosanitary certificates.

NPPO Responsibility

The key responsibilities of a NPPO are taking phytosanitary measures that include:

- 1. Import permit
- 2. Certification scheme
- 3. Pre-inspection
- 4. Defined entry ports
- 5. Inspection /testing on entry
- Post entry quarantine (PEQ)
- 7. Disinfestation
- 8. Others:

National Seed Authorities (NSA)

Established by National laws with specific mandates that includes:

- Regulation of production and sale of certified seed
- Regulation of seed import and export
- Quality assurance of seed Seed certification
- Variety testing and registration

OECD Seed Scheme

- The objective of the Organization for Economic Co-operation and Development (OECD) Seed Schemes for the varietal certification of seed is to encourage the use of seed of consistently high quality in participating countries
- Basic principles and the method of operation common to all Seed Schemes:
 - a) Includes only varieties which are officially recognized as distinct and having an acceptable value in at least one participating country.
 - b) The names of the variety are published in an official list

OECD Seed Scheme

- c) Restriction/control of generation seed classes. Certified seed must be related to authentic basic seed. Satisfactory conditions for production and processing of basic and certified seed must be ensured
- d) Post control To ascertain that the scheme is working satisfactory and to determine if varietal characteristics remain unchanged in the multiplication process. (Varietal identity and purity)

Participation in OECD Seed Scheme

Who can join

- OECD member countries
- Any member of the United Nations
- Specialized Agencies e.g. WTO

Who implements the Scheme?

Authorities designated by for this purpose and responsible to the governments of the state's operating the scheme

Requirements for joining the OECD Seed Schemes

Technical criteria to be satisfied includes:

- A national seed law which provides the legal framework for variety registration and seed certification.
- A national list of varieties.
- An efficient domestic certification system, with adequate equipment and qualified staff for field inspection, seed sampling and labeling that has been in operation for last fives years

Requirements for joining the OECD Seed Schemes

- An efficient laboratory for seed analysis according to ISTA Rules or equivalent.
- A system of post-controls to check the varietal purity of the certified seed.

How to join the OECD Seed Scheme

- Application letter to OECD Secretariat with the following information
 - Seed certification in the country
 - Import and export
 - Varieties registered on National list
 - Post control
- 2. Evaluation mission
 - Undertaken by OECD (all costs are met by the applicant)

How to join the OECD Seed Scheme

- 3. Evaluation report
 - Represented to annual meeting of the seed Schemes
- 4. Official admission procedures
 - Approval by consensus at the OECD Annual meeting, OECD committee for Agriculture and the OECD Council

Association of Official Seed Certifying Agencies (AOSCA)

AOSCA provide:

- Coordinated, professional and unbiased field inspections
- 2. Unbiased record system for use in meeting state, federal and international seed law requirements.
- Seed buyers with assurance that the designated seed has met purity standards related to a known description across seed lots and years of production.

International Seed Testing Association (ISTA) Rules for seed testing

- The ISTA International Rules for Seed Testing provides annually updated and worldwide uniform seed testing methods
- The ISTA Accreditation Programme guarantees worldwide harmonized seed testing results

ISTA Rules for seed testing

- The ISTA International Seed Analysis
 Certificates issued exclusively by ISTA
 Accredited Laboratories, truly reflecting
 the quality of a seed lot
- The promotion of research, training,
 publishing and information in all areas
 of seed science and technology and
 cooperation with related organizations

- ISO 9000 and ISO 9001:2008 are the standards used to CERTIFY companies in, for example, manufacturing or service industries.
- Testing laboratories are certified using another standard - ISO 25 (now known as ISO/IEC 17025)
- The ISO 17025 standard is used for the ACCREDITATION of testing laboratories

- It is based on ISO 9000 but places extra emphasis on:
 - a. Staff competence
 - b. Equipment control and calibration
 - c. Appropriate methods and method development
 - d. Mandatory referee tests (proficiency testing)

- The ISTA Standard is adapted from ISO 17025 to meet the specific needs of seed labs.
- Specific features of the ISTA Standard include:
 - a) Sampling
 - b) Independence of labs
 - c) Use of ISTA Rule
 - d) Staff competence

e) Mandatory participation in the ISTA referee test programme



Highlights of ISTA Standard

INTERNATIONAL SEED TESTING ASSOCIATION
ASSOCIATION INTERNATIONALE D'ESSAIS DE SEMENCES
INTERNATIONALE VEREINIGUNG FÜR SAATGUTPRÜFUNG

Secretariat, Zürichstrasse 50, P.O. Box 308, 8303 Bassersdorf, CH-Switzerland Phone: +41-1-838 60 00 - Fax: +41-1-838 60 01 - Email: ista.office@ista.ch - http://www.seediest.on



ISTA Seed Testing Laboratory Accreditation Standard

- 1. Management Requirements
- 2. Staff
- 3. Environment, equipment and calibration
- 4. Lot identification, sampling and handling of samples
- 5. Methods and Procedures
- 6. Test Reports and Certificates
- 7. Records
- 8. Quality Assurance System

16.10.2002

The ISTA Accreditation System:

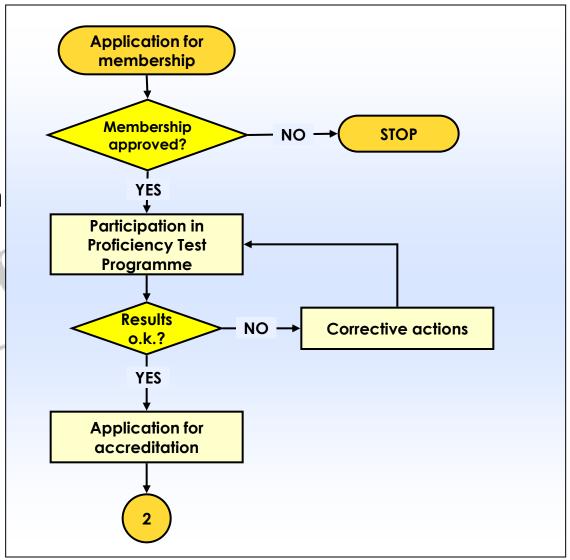
Accreditation

= formal recognition of a laboratory to competently carry out specific tests



International Seed Testing Association

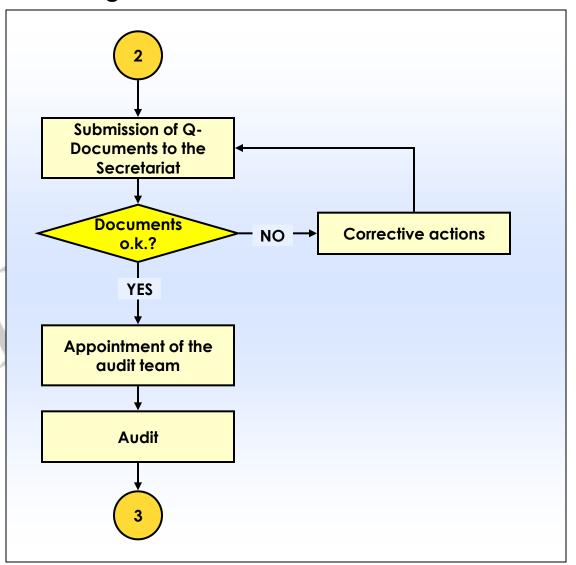
The Accreditation Procedure:





International Seed Testing Association

The Accreditation Procedure:





International Seed Testing Association

Substantial **Corrective actions** YES **Deficiencies?** NO The Accreditation NO Corrective **Procedure:** actions o.k.? Approval by the EC YES YES **Accredited and** authorisation

Association of Official Seed Certifying Agencies (AOSCA)

AOSCA provide:

- 1. Coordinated, professional and unbiased field inspections
- Unbiased record system for use in meeting state, federal and international seed law requirements.
- 3. Seed buyers with assurance that the designated seed has met purity standards related to a known description across seed lots and years of production.

Association of Official seed Analysts (AOSA)

- The AOSA seed testing protocols:
 - a. Establish the AOSA Rules for Testing Seeds.
 - b. Contribute to the refinement and modification of the rules and procedures for seed testing.
 - c. Ensure that testing procedures are standardized between analysts and between laboratories.

THANKS

Munyao W. M.

KEPHIS

wmunyao@kephis.org

PRINCIPLES OF AUTHORIZATION/ACCREDITATION

By W.M. Munyao KEPHIS

UNIVERSITY OF NAIROBI

ACCREDITATION / AUTHORIZATION FOR SEED CERTIFICATION SERVICES

WHY?

- >Saves time
- > Reduces cost
- ➤ Develops links between National Certification Agency and Seed Companies
- > Improves quality management of companies
- Promotes dynamic seed production

ACCREDITATION / AUTHORIZATION FOR SEED CERTIFICATION SERVICES Cont'd

How?

➤ Quality should be maintained, official checks

➤ Seed certified under accreditation = Seed certified without accreditation

Scope & partners = National Authority decision : work with chosen species, companies, laboratories

ACCREDITATION / AUTHORIZATION FOR SEED CERTIFICATION SERVICES Cont'd

How?

- ➤ Official Guidelines to be followed by accredited staff and companies
- ➤ Granted accreditation is always temporary, renewable/can be withdrawn
- Ability and efficiency are regularly controlled by the Certification Agency
- ➤ Governments retain overall responsibility

ACCREDITATION / AUTHORIZATION FOR SEED CERTIFICATION SERVICES

What is it?

- ➤ Official delegation to private individuals or organisations of some activities of the seed certification process
- ➤ Co-operation between private & public sectors under official responsibility
- Formal recognition of a laboratory or institution or individual to competently carry out specific tasks on behave of National Designated Authority

PRINCIPLES ACCREDITATION / AUTHORIZATION FOR SEED CERTIFICATION SERVICES

Requirements

- ☐ Independence in operations for the authorized activities
- ☐ Access to the services of the Designated Authority
- □ Scope of authorization May cover all seed certification activities or may be limited to one or a few (Field inspection, sampling, labeling and sealing, seed testing)
- Maintenance of confidentiality of the information obtained in the course of authorization activities

PRINCIPLES ACCREDITATION / AUTHORIZATION FOR SEED CERTIFICATION SERVICES Cont'd

- □ Regular deployment in the activities for which one or institutions are authorized
- ☐ Familiarity with the implementation of the National Seed Schemes as per their scope of authorization through training and experience
- Documentation and document change controls
- Surveillance and audit
- □ Training

SCOPE OF ACCREDITATION/AUTHORIZATION

Field inspection

- Seed sampling
- Labelling and sealing of seed lot

Seed testing

FIELD INSPECTION OF SEED CROPS BY AUTHORISED INSPECTORS UNDER OFFICIAL SUPERVISION

- NDA may under official supervision authorize private inspectors to carry out field inspections for Certified category
- Authorized inspectors shall have the necessary qualifications through training and their competence confirmed in official examination
- Authorized inspectors shall be sworn in or sign a statement of commitment to the rules governing official inspections

FIELD INSPECTION OF SEED CROPS BY AUTHORISED INSPECTORS UNDER OFFICIAL SUPERVISION cont'd

- Pre-basic and Basic crops must be inspected by official seed inspectors.
- Authorized inspectors may inspect certified generation categories of crops where seed of the generation prior to Basic seed is officially controlled.
- Where authorized inspectors inspect certified generation crops, a proportion of these crops shall be check inspected by official seed inspectors to assess performance.

FIELD INSPECTION OF SEED CROPS BY AUTHORISED INSPECTORS UNDER OFFICIAL SUPERVISION cont'd

 NDA shall determine the penalties applicable to infringements of the rules governing examination under official supervision.

SEED SAMPLING AND SEED ANALYSIS BY AUTHORISED PERSONS OR LABORATORIES UNDER OFFICIAL SUPERVISION

- NDA may authorize seed samplers who are under its direct and exclusive authority to draw, under official supervision, samples under the Schemes.
- 2. Laboratories may also be authorized to carry out seed analysis as required under the seed regulations, and shall be accredited to a normative standard as per the 1STA testing requirements
- 3. Sampling, sealing and labelling of seed containers may be entrusted to authorized persons.

Seed samplers

- Authorized private seed samplers shall have the necessary qualifications through training and their competence confirmed in official examination
- They shall carry out seed sampling in accordance with current international methods.
- Seed sampling premises and equipment must be officially recognised to be satisfactory for the purpose by NDA, within the scope of the authorisation. Such equipment used shall be calibrated to traceable national and international standards.

Seed samplers

Seed samplers shall be:

- (a) independent natural persons, or,
- (b) persons employed by natural or legal persons whose activities do not involve seed production, seed growing, seed processing or seed trade, or,
- (c) persons employed by natural or legal persons whose activities involve seed production, seed growing, seed processing or seed trade.

Seed samplers

- In the case referred to in point (c), a seed sampler may carry out seed sampling only on seed lots produced on behalf of his employer, unless it has been otherwise agreed between his employer, the applicant for certification and the NDA.
- The performance of seed samplers shall be subject to proper supervision by NDA and shall include check sampling or process monitoring as appropriate

Authorized laboratories

- Seed testing shall be carried out by seed testing laboratories which have been authorized for that purpose by NDA.
- The laboratory shall be maintained in premises and with equipment officially considered by NDA to be satisfactory for the purpose of seed testing, within the scope of the authorization.

- The laboratory shall have a seed analystin-charge responsible for the technical operations of the laboratory and with qualifications for technical management of a seed testing laboratory.
- Seed analysts should have technical qualifications obtained in training courses organized under conditions applicable to official seed analysts and confirmed by official examinations.

- The laboratory shall carry out seed testing in accordance with current international methods.
- Methods should be validated and documentary evidence of such validation provided

The laboratory shall be:

- a) an independent laboratory or
- b) a laboratory belonging to a seed company

- In the case referred to in point (b), the laboratory may carry out seed testing only on seed lots produced on behalf of the seed company to which it belongs, unless it has been otherwise agreed between the seed company, the applicant for certification and NDA.
- The laboratory's performance of seed testing shall be subject to proper supervision by NDA.
- Supervision shall include check-analysis and regular audits of expertise, implementation, processing of results and response to nonconformities.

Thank you

