SEED ENTERPRISE MANAGEMENT INSTITUTE (SEMIs)
National Plant Protection Organizations (NPPOs) And
Seed Quality Regulators Short Course
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Internal quality requirements for seed companies

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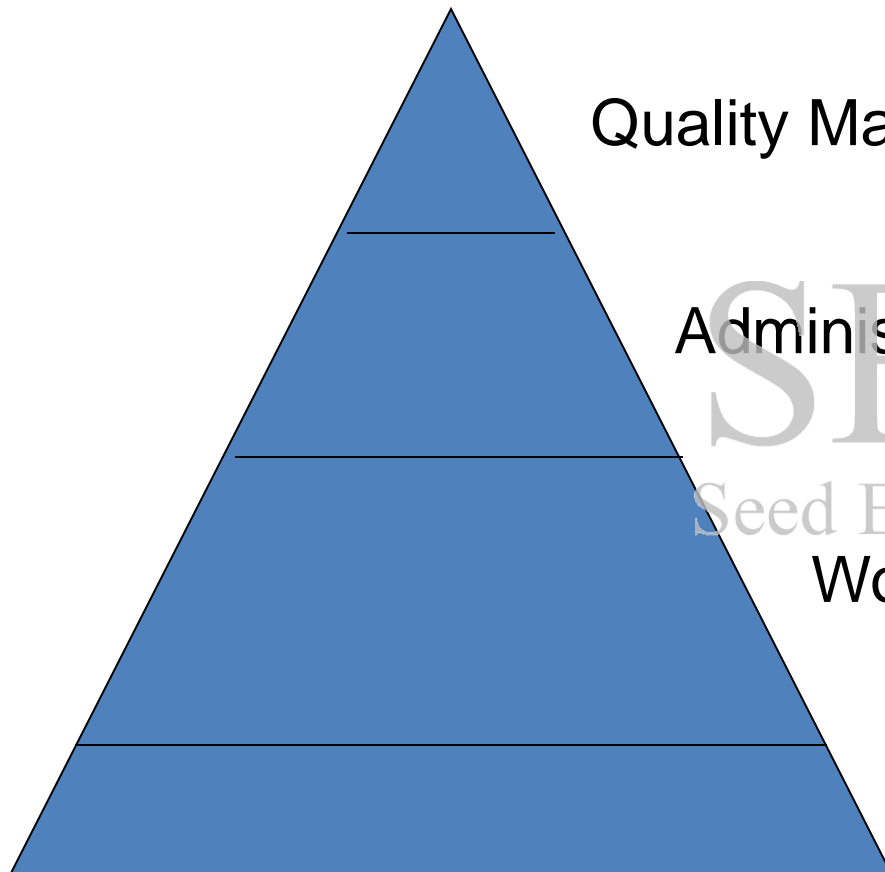University of Nairobi

OBJECTIVES OF INTERNAL QUALITY CONTROL

- Confirmation we have alignment with business objectives and customer expectations
- Audit/Measurement/Validation
- Managing cost and productivity
- Identification of process improvement opportunities
- Reduction in employee stress
- Possible leveraging opportunities related to regulatory compliance.

What Is Process Management?

- Identification of critical business areas that must be defined, controlled and maintained.
- Critical business actions must be repeatable and measurable
- System design must allow for changing business needs
- Customer requirements must be identified and incorporated into the system.

Documentation in internal quality control

Quality Manual (50 pages maximum)

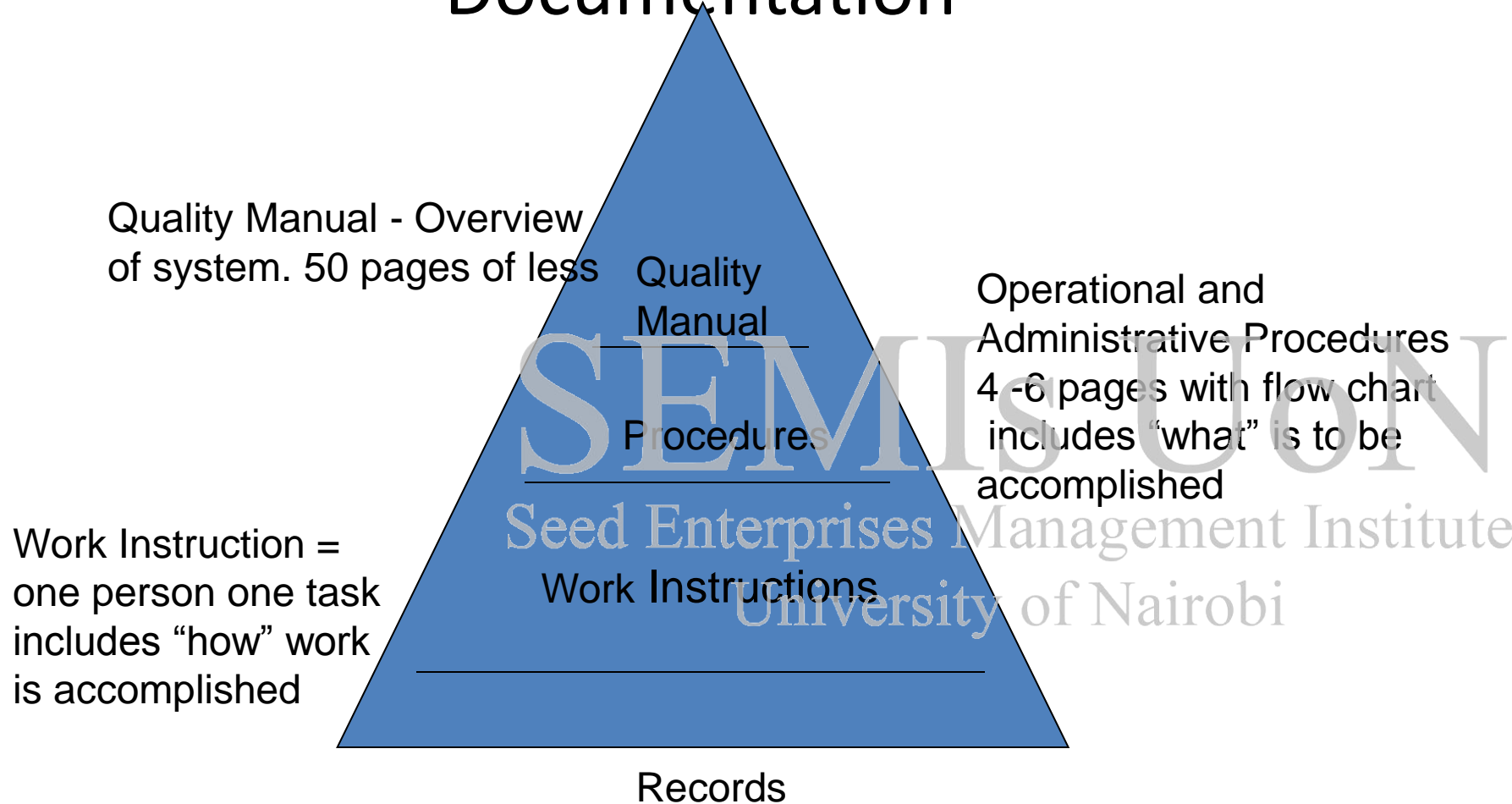Administrative and Operational Procedures
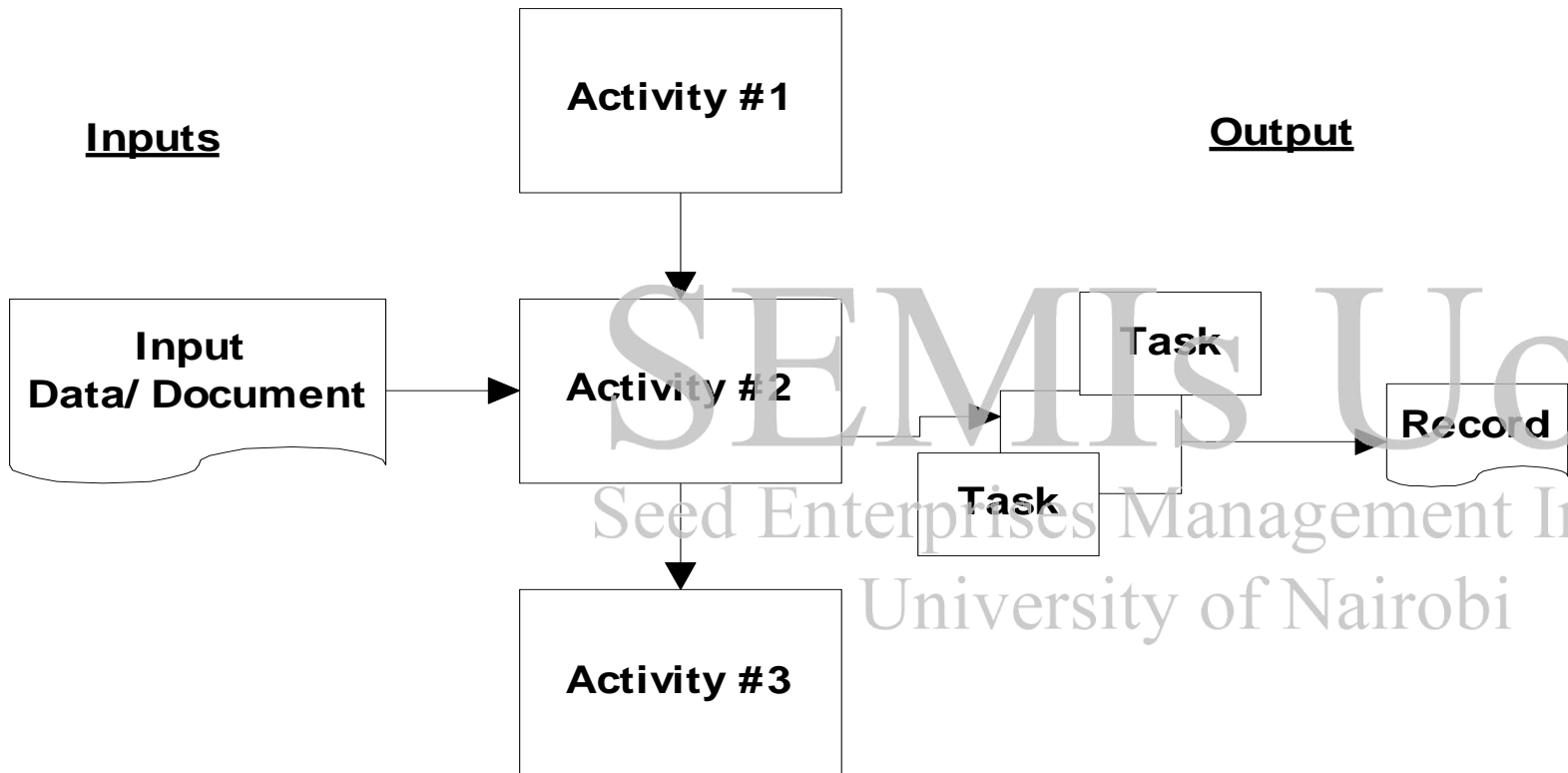
Work Instructions (task level detail)

Records

Management System Structure - Documentation

Quality Manual - Overview of system. 50 pages of less

Quality Manual

Operational and Administrative Procedures 4 -6 pages with flow chart includes "what" is to be accomplished

Procedures

Work Instruction = one person one task includes "how" work is accomplished

Work Instructions

Records

Business Process

Procedure/ Activity

Inputs

Output

| Activity #1 |

| Input Data/ Document |

| Activity #2 |

Task

Task

Record

| Activity #3 |

Inputs

- Specifications
- Data and/or documents
- Manuals
- Regulations/laws
- Policies and guidelines
- Output from a companion process

Activity

- An action or activity or doing something
- A component of a larger process
- If activity is not initiated, the process will fail
- Typically, made up of several task involving several people

Work Instruction

- An action or activity

- Doing something

- A subcomponent of a procedure

- Typically, one task that involves one person

Work Instruction

- An action or activity

- Doing something

- A subcomponent of a procedure

- Typically, one task that involves one person

Outputs

- Confirmation that an activity has achieved a defined state of completeness
- Includes:
  - Records
  - Documents
  - Forms
  - Data

Key Points of Process Analysis

- Defined purpose and scope
- What is happening?
- Who is responsible for what?
- Who interfaces with whom?
- Timing and measurements
- Viewed from a customer and supplier relationship

Documentation Structure
System Documentation

Quality Manual (50 pages maximum)

Administrative and Operational Procedures
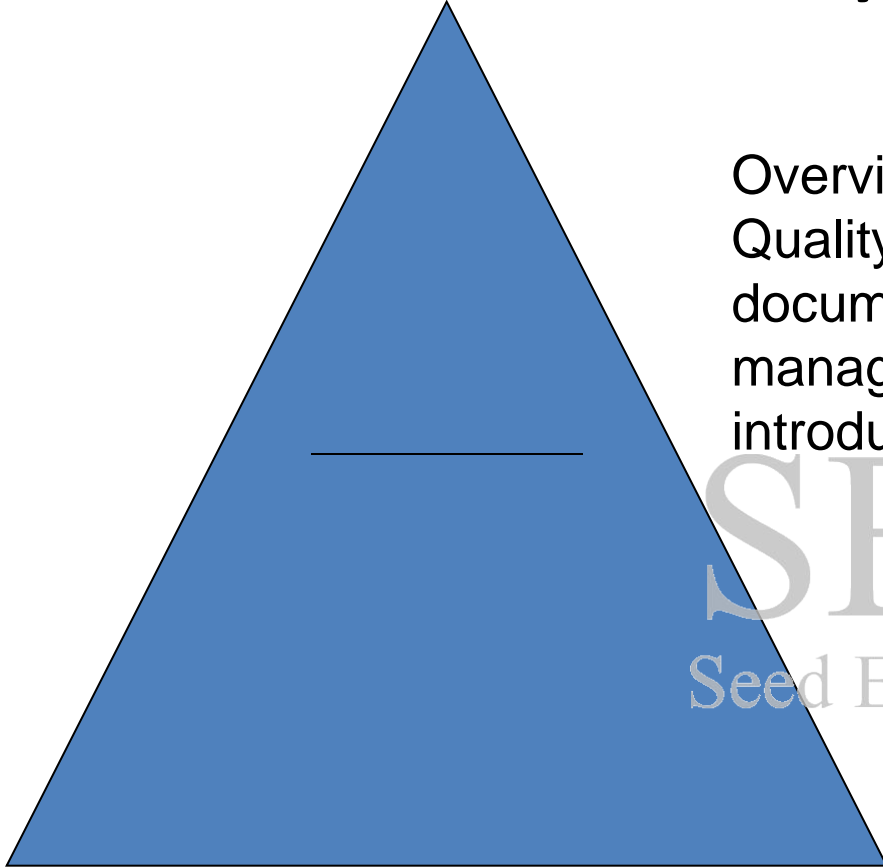
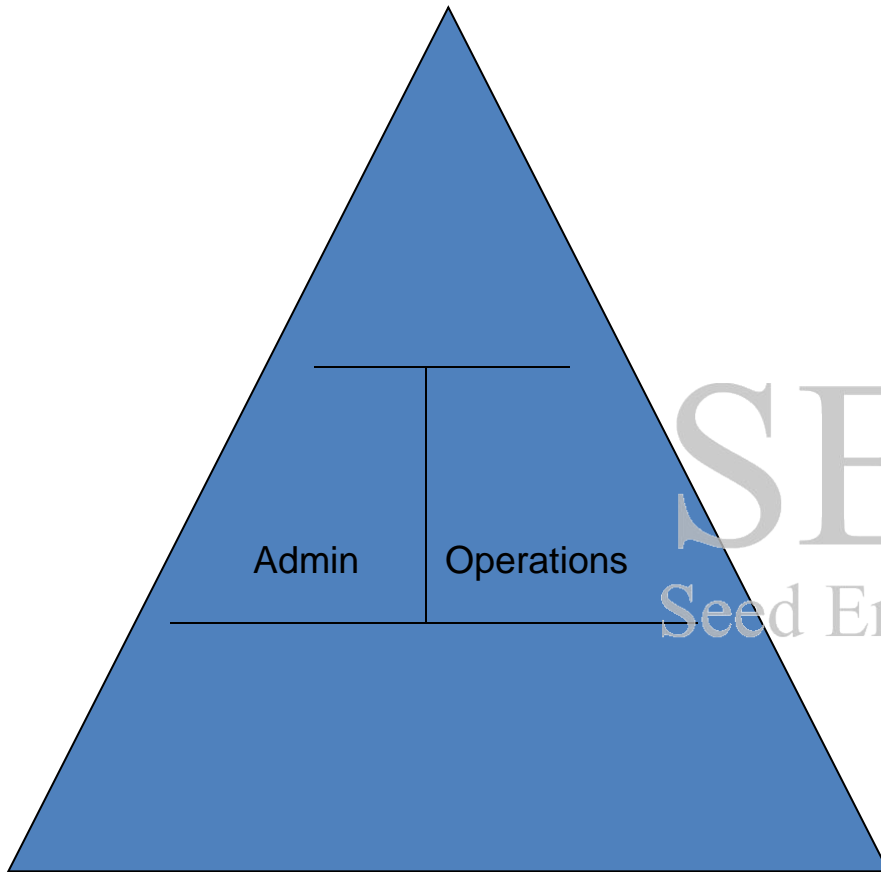Work Instructions (task level detail)

Records

Quality Manual

Overview of business operations including Quality Policy and reference to support documentation. Quality Manual views management system structure from an introductory point of view.

Procedures

Administrative Procedures
- Document management
- Internal audit
- Corrective action
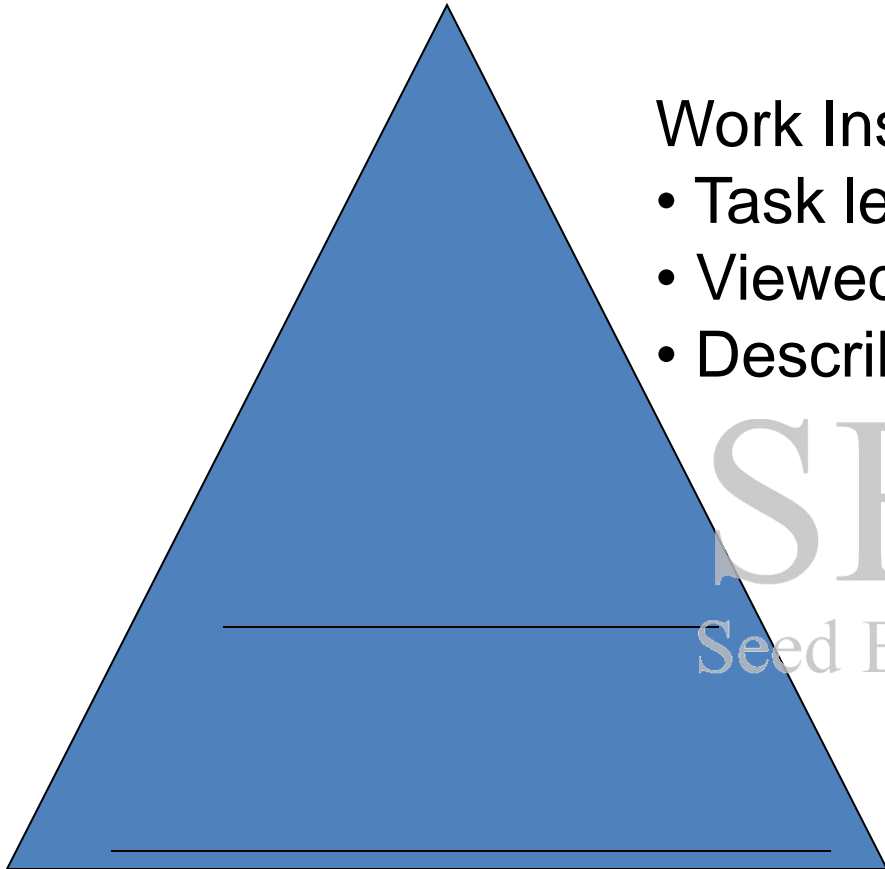- Other

Operational Procedures
- What
- When
- Where
- Who

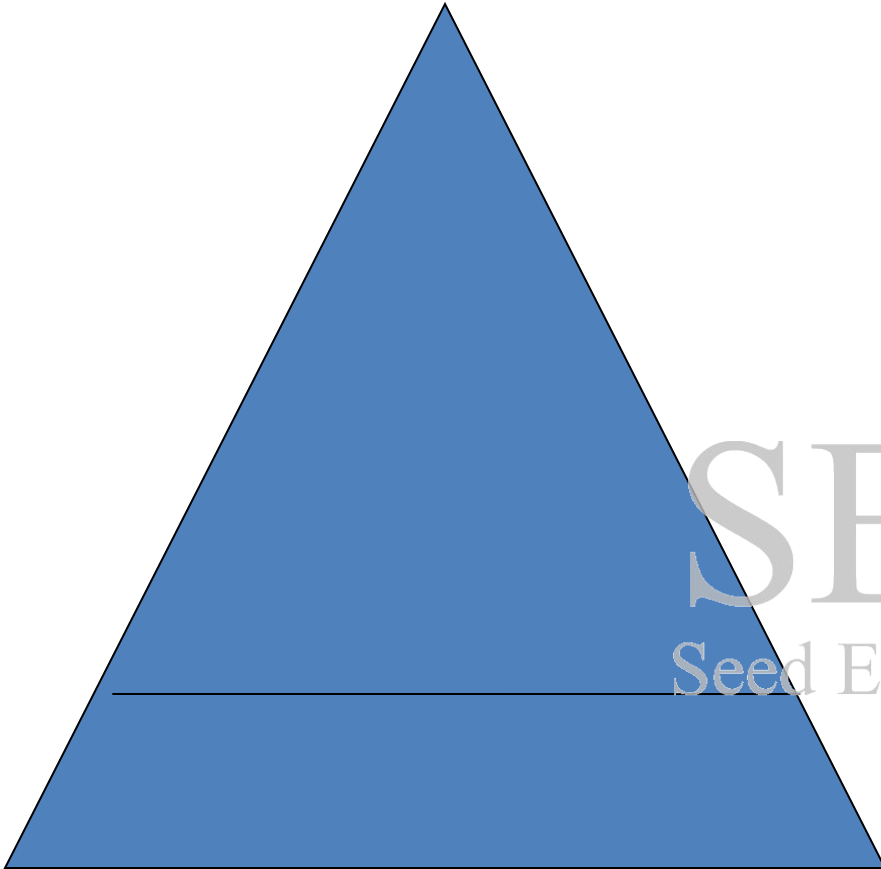Admin | Operations

Work Instruction

Work Instruction
- Task level detail
- Viewed as one person one task
- Describes "how" work is accomplished

Records

Records
- Provides objective evidence
- Demonstrates compliance

Development Quality Assurance System Documentation

- Obtain data on the actual state of the quality assurance system

- Plan the documentation system

- Collect and compile existing documentation and require additional documentation where necessary

- Review the documentation to ensure clarity, suitability and proper structure

- Develop a distribution policy

- Incorporate pertinent changes

- Communicating the company's quality policy, procedures and requirements
- Describing the quality system
- Providing documented bases for auditing quality systems
- Providing continuity of the quality system and its requirements during changing circumstances
- Training personnel in the quality system requirements and methods of compliance
- Presenting the quality system for external purposes, such as demonstrating compliance with respective accreditation standards

WHAT TO INCLUDE IN A QUALITY MANUAL

- Scope and field of application
- Table of contents
- Definitions and explanation of abbreviations
- Policy and quality objectives
- Description of the quality system and document control procedures
- Organization and management structure
- Staff and training
- Company premises
- Equipment and calibration
- Process management (work flows)
- Recording and archiving
- Quality control procedures

STANDARD OPERATING PROCEDURES (SOPS) & WORK INSTRUCTIONS

- SOPs serve the staff members as a practical working aid for daily use.
- They should be compiled in such a way that they can be used like a "cooking recipe".
- SOPs should be kept concise, exact, to the point and represent the reality by using simple wording.
- Where necessary, SOPs may be supplemented by work instructions, describing single aspects even more detailed or giving examples

Why SOPs instead of referring to general regulations/ standards

- General regulations do not always describe the activities to be conducted sequentially.

- General regulations provide different options for a specific activity; in the SOP only the information relevant for the particular activity shall be available.

- A SOP shall clearly indicate which specific procedure/ method is to be used

Types of SOPs

- System SOPs

- Technical SOPs

NOTE:
General policy and procedures already described in the quality manual should not be mentioned again in the SOP to avoid redundancy and inconsistency.

System SOPs

- Document Control Procedure
- Training of new and experienced staff including recognition, training of new and experienced staff, procedure of warning, suspension etc
- Internal Audit Procedure
- Dealing with Customer Complaints
- Non conforming work and Corrective Action Procedure
- Preventive Action Procedure
- Purchasing of Services and Supplies
- Management Review Procedure
- Quality Control Procedure (Monitoring)
- Proficiency Testing Procedure

Technical SOPs

- Maintenance, repair, control or internal calibration for each item or group of equipment

- Storage and disposal of samples

- Control and disposal of chemicals

- Maintenance and description of seed collection(s) and how the verification of species is accomplished including a list of seeds

- Testing procedures (separate SOP for each type of test)

Other Quality Documents

- Include working instructions, forms & reports

- Working instructions give details on the standard procedure concerned.

- Working instructions or specimen forms may be directly attached to the respective SOP if applicable.

- Forms, checklists, reports related to a standard procedure should be provided where appropriate.

FLOW CHARTING

- Flow charts help to visualize a process and to represent the essential elements of a given procedure on a single page.

- A flow may be supplemented by explanatory notes or be itself the summary to a textual description.

- By general consensus a very limited number of symbols is used, which facilitates its generic application and makes it a tool that is easily understood

- Visual representation of each step in the process
- Graphically displays functional activity and provides a visual understanding of interrelated occurrences
- Provides an understanding of the entire process
- Modifications and disconnects can be identified
- Displays a clear relationship between customer and supplier

Flowchart Symbols
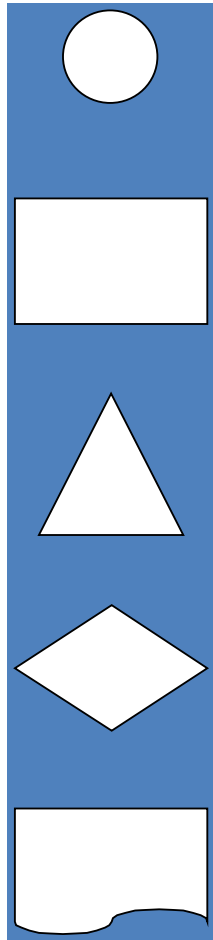
○   Begin/End/Linkage

▭   Activity/Process

△   Major Review

◇   Decision

⬓   Data and/or Document

Basic Flowcharting Guidelines

- Start at the top of the page and end at the bottom
- As a general rule do not exceed 20 symbols per page
- Describe activities with same level of process complexity
- To much detail will defeat the purpose of a flowchart
- Do not develop flowcharts without input from everyone involved in the process
- Use active terms - verb/noun
  - Schedule meeting
  - Develop plan
  - Conduct audit