DOCUMENTATION STRUCTURE AND WRITING

SEMIS COURSE ON

SEED QUALITY ASSURANCE, MANAGEMENT AND CONTROL PROCESSES

PRESENTED ON 3RD MAY 2017

BY

Stellamaris Ndinda Mulika

smulika@kephis.org

Documentation Structure

- Quality manual – previews of business operations including policy and reference to support documentation.
- In documentation – write procedures and work instructions, attach applicable forms e.g. inspection application, inspection forms and the flow chart at the end.

Documentation Structure

- References are input items e.g. seed certification standards, rules, regulations, samples that make processes function. References are pre-set and cannot be changed just anyhow for example, responsibility of a seed inspector on fake seeds is to issue stop sale order, seek police assistance on seizure and accusation and inform superiors by report on the findings.

How to structure your QMS documentation

1. **Quality manual**

- The quality manual should include the following elements:
  - ✓Title and table of contents;
  - ✓Scope of the QMS;
  - ✓Versioning information and approval;
  - ✓Quality policy and objectives; QMS description,

How to structure your QMS documentation

- ✓ the business process model of the organization;
- ✓ definition of responsibilities for all personnel;
- ✓ references to relevant documents and relevant appendices.

2. **Quality policy.**

- ✓ A policy represents a declarative statement by an organization. A Quality policy should state the commitment of the organization to quality and continual improvement.

How to structure your QMS documentation

- ✓ The Quality policy defines the quality objectives to which the organization strives. The quality goals of organizations are defined by quantifying the quality objectives

3. **Quality procedures.**

- Quality procedures can have different formats and structures. Quality procedures should include the following elements:
- Title – for identification of the procedure;

How to structure your QMS documentation

- Purpose – describing the rationale behind the procedure;
- Scope – to explain what aspects will be covered in the procedure, and which aspects will not be covered;
- Responsibilities and authorities of all people/functions included in any part of the procedure;
- Records that result from the activities described in the procedure should be defined and listed;

How to structure your QMS documentation

- Document control – identification of changes, date of review, approval and version of the document should be included in accordance with the established practice for document control;
- Description of activities – this is the main section of the procedure; it relates all the other elements of the procedure and describes;
  - ✓ What should be done
  - ✓ By whom

How to structure your QMS documentation

- How
- When
- Where
- In some cases, “why” should be clarified as well.
- Additionally, the inputs and the outputs of the activities should be explained, including the needed resources.

- Appendices may be included, if needed.

How to structure your QMS documentation

4. **Work instructions.**

- Work instructions can be part of a procedure, or they can be referenced in a procedure. Generally, work instructions have a similar structure to the procedures and cover the same elements; however, the work instructions include details of activities that need to be realized, focusing on the sequencing of the steps, tools, and methods to be used and required accuracy.

Levels of Documents

Quality Manual (first tier)

Procedures (second tier)

Work Instructions (third tier)

Documents, Forms, Records (fourth tier)

How to prepare SOP‘s

- Standard operating procedures shall enable users to perform the work by following the description.
- The volume and degree of detail should be adapted to the needs of the personnel.
- General design
  - 1. Purpose.

How to prepare SOP's

- 2. Scope.
- 3. Definitions and abbreviations.
- 4. Related documents and references
- 5. Responsibilities
- 6. Process description
- 7. Records

- The same structure may be followed for technical and non-technical procedures.

Importance of good documentation

- Correct, complete, current, and consistent information effectively meet customer and stakeholder requirements
- Helps to reduce observations raised on inadequate documentation practices
- Good documentation practice is an expected practice

What constitutes Good Documentation

- Approve, review and update documents
- Changes & current revision status of documents identified
- Relevant versions of applicable documents available at points of use
- Documents remain legible and readily identifiable
- Documents of external origin identified and their distribution controlled
- Prevent unintended use of obsolete documents, and archiving

Observations on poor documentation practices

- Document error correction not signed/dated, and didn't include a reason for the correction
- Write-overs, multiple line-through and use of "White-out" or other masking device
- Sample sequence table and audit trail not documented (*if its not documented, it didn't happen*)

Observations on poor documentation practices

- SOP related to production, calibration, storage and maintenance not authorized by the QA head.
- The delegation for batch release, in case of absence of the QA manager, not recorded / documented.
- Specification procedure not detailed enough; flow chart and /or check-list not available.

Thank you

smulika@kephis.org