

	Agricultural Marketing Service Federal Grain Inspection Service Quality Assurance and Compliance Division Quality Management Program	Document Control: QACD XXXX
		Version Number: 1.0
Document Control Guidance		Effective Date: TBD

What is Document Control?

The definition of document control is the act of controlling documents that your organization uses to perform official services and achieve compliance.

Why is Document Control important?

Effective document control ensures the integrity of a system. This includes the integrity of your organization's individual quality management program and the integrity of the FGIS Official System.

Who is responsible for Document Control?

Personnel at all levels have a responsibility relating to document control. Outlined below are examples of responsibility relating to document control at varying levels in an organization:

- Top management – Ensures that your organization has a document control procedure and provides adequate resources so your organization can carry out the procedure. This includes, but is not limited to, software, computers, cabinets, pens, paper, etc. Ultimately, top management is accountable for ensuring that roles and responsibilities associated with document control are defined and implemented according to your QMP.
- Document Control Manager/Quality Management Representative – Analyzes your document control procedure for effectiveness and ensures that employees are trained on your document control procedure. Additionally, personnel at this level may review, approve, and makes changes to your document control procedure, as necessary.
- Supervisors/Team Leaders/Location Managers – Ensures that your document control procedure is being followed and communicates suggestions for procedure improvement when identified.
- Graders/Technicians – Follows your document control procedure and makes suggestions for procedural improvement when identified.

NOTE: It is not required to have a different person at each level of responsibility. Your organization may require, or be structured in such a way, that one person occupies multiple roles or one person may occupy all the roles listed above.

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Benefits of Document Control

Outlined below are benefits that your organization may observe as a result of having an effective document control procedure:

- **Time Efficiency**: Personnel at all levels will be able to access and retrieve all documents in a more timely manner if an effective document control procedure has been established and employees are adequately trained. Creating a single point for all personnel to access documents is vital for your document control procedure to be effective. Additionally, ease of access and retrieval of documents may allow your employees to make better informed and timely decisions when performing official services. This same benefit may be observed when top management is attempting to make timely decisions. The opposite of this, not having a document control procedure or having an ineffective procedure, may cost your organization time and/or money.
- **Process Consistency**: When your organization has an effective document control procedure in place it ensures consistency in the processes you perform. This may mean process consistency in providing and recording official services, performing internal audits, conducting root cause analysis and corrective action, etc.
- **Outdated Documents/Incorrect Outputs**: Having an effective document control procedure which is verified during internal and external audits, decreases the probability that your organization is using outdated documents (internal or external documents). Lowering this probability also decreases the chances that a procedure will be performed incorrectly yielding incorrect procedural outputs (i.e. incorrect certificates, incorrect calibration, incorrect procedure performing tests (test weight, moisture, falling number, check testing, aflatoxin, etc.)).
- **Encourages Communication, Collaboration, Trust, and Morale**: Having an effective document control procedure encourages personnel at all levels to communicate and collaborate about changes (of any kind) which can ultimately lead to process improvement. Additionally, an effective document control procedure encourages trust within your organization and with external stakeholders. Finally, a document control procedure that encourages communication, collaboration, and trust leads to increased morale in your organization at all levels.
- **Makes QMP Relevant**: Having an effective document control procedure makes your QMP relevant to personnel that were not involved in its development or would otherwise be involved. Document control is something that touches each person in your organization and is a way to empower and encourage employees which can ultimately lead to process improvement.

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Internal Documents vs. External Documents

Section 4.2.3 of the Quality Management Program (QMP) outlines requirements for document control. More specifically, this section requires your organization to control internal documents and external documents. Means of control for each of these document types is different.

What is an Internal Document?

Internal documents are documents that your organization uses to perform official services and comply with your QMP where **you control the content**. Examples of these documents are the procedures you create, your Quality Manual, checklists, logs, or reminders that you create to aid your organization's personnel in performing official services correctly and in compliance with your QMP.

You control internal documents by ensuring these documents have appropriate headers/footers/identification (which you determine), have a date/version number/document control number (which you determine) and are present on your organization's master list of documents. During your annual internal audit your organization will ensure that all internal documents in use, no matter their format, are in accordance with your master list of documents and your document control procedure. Your organization may also choose to verify the control of internal documents more frequently, at planned intervals, or simply as needed.

What is an External Document?

External documents are documents that your organization uses to perform official services and comply with your QMP but **you do not control the content**. Examples of these documents are FGIS handbooks, directives, notices, bulletins, posters, and work instructions/procedures you receive from equipment manufactures.

The reason for the requirement to control external documents is not to control their content, but rather to ensure that your organization is using the most current version of these documents. You verify this at your annual internal audit, at minimum, and as necessary when updated versions of external documents are issued by the person/organization that controls its content. When updated versions become available, it is vital that your organization has a process to inform relevant parties. Your organization may also choose to verify the control of external documents more frequently, at planned intervals, or simply as needed. It is not required for your organization to list external documents on your master list of documents.

NOTE: Some organizations may choose to simply list the names of the external documents they use as a reminder to check for the most recent version during an internal audit, or more often, as necessary.

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Examples of Internal Documents and External Documents

Outlined below are examples of internal documents and external documents for FGIS OSPs.

Examples of Internal Documents for OSPs	Examples of External Documents OSPs
<p>Procedures required by the QMP Standard</p> <ul style="list-style-type: none"> Document control, record control, training, internal audit, corrective action, preventive action <p>Documents created using information extracted from FGIS handbooks, directives, notices, bulletins, etc.</p> <ul style="list-style-type: none"> Sample breakdown sheet, tolerances for moisture/test weight, grading references, dockage cheat sheet, test weight cheat sheet, sieving wheat/barley cheat sheet, pea sieving cheat sheet, etc. <p>Certificate accuracy procedure</p> <p>DT Lockout procedure</p> <p>Logs</p> <ul style="list-style-type: none"> Training log, supervision log, protein monitoring log, aflatoxin log, daily falling number temperature and barometric pressure log, etc. <p>Forms</p> <ul style="list-style-type: none"> Pea grading form, lentil grading form, hulless barley form, falling number monitoring form, corrective action form, management review meeting form, training forms, etc. 	<p>FGIS Documents</p> <ul style="list-style-type: none"> Handbooks, directives, program notices, policy bulletins, reference posters, VRIs, etc. <p>Equipment Manufacturer Procedures</p> <ul style="list-style-type: none"> Charm EZ aflatoxin procedure, Dickey John and/or Perten moisture machine procedures, Perten falling number procedures <p>Equipment Manufacturer Reference Material</p> <ul style="list-style-type: none"> Perten falling number reference poster <p>Elevator/Customer Documents</p> <ul style="list-style-type: none"> Reminders, contract specifications, customer requirements for operating in their facility

NOTE: A procedure can be imbedded in a form. This does not change the responsibility your organization has to control the document. Regardless if your document is a documented procedure or a form, if you create it you have to control it (internal documents). If you use it, you

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have a responsibility to control it (external documents). The type of document is not important. The important point is the way you control the document.

NOTE: Procedures **do not** have to be a collection of words. Your organization may choose to have procedures embedded in the forms in which work outcomes are recorded or outlined in a flow chart format. Procedure format can be anything that fits your business. Auditors, internal or external, should only seek to verify that the procedure is being followed (first by record evidence second by observation) and is properly controlled.

Living Documents vs. Historical Records

Documents, no matter internal or external, are considered “living documents”. Documents are an editable file and can be changed and revised as needed, according to your document control procedure. Documents can be stored as paper or digitally. A record acts as proof of existence or completion of a procedure. A record is either created or received by an organization as a result of providing an official service or completing a task within your organization. Records are used as proof of compliance with both QMP requirements and FGIS regulations. Records can be stored as paper or digitally.

Many records start out as documents and then become records when they are finalized. For example, an empty form is a document and then after it is filled in becomes a record. Records must adhere to specified retention times as spelled out by your organization and/or a regulatory authority.

FGIS regulations require that OSPs maintain records according to 7 CFR §800.145-159

Examples of Documents	Examples of Records
Procedures required by the QMP Standard <ul style="list-style-type: none"> Document control, record control, training, internal audit, corrective action, preventive action 	Internal Audit reports External Audit reports Completed Corrective/Preventive Action forms
Documents created using information extracted from FGIS handbooks, directives, notices, bulletins, etc. <ul style="list-style-type: none"> Sample breakdown sheet, tolerances for moisture/test weight, grading references, dockage cheat sheet, test weight cheat sheet, sieving wheat/barley cheat sheet, pea sieving cheat sheet, etc. 	Completed logs Completed forms Official Service Delivery Records Pan tickets, service requests, certificates, contracts, load orders, etc.

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<p>Logs</p> <ul style="list-style-type: none"> • Training log, supervision log, protein monitoring log, aflatoxin log, daily falling number temperature and barometric pressure log, etc. <p>Forms</p> <ul style="list-style-type: none"> • Pea grading form, lentil grading form, hulless barley form, falling number monitoring form, corrective action form, management review meeting form, training forms, etc. 	
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Other Talking/Clarification Points

- Control is defined differently for internal documents vs. external documents.
- Format is not a consideration when making a control determination.
- Your organization should not allow the integrity of the process (providing official services or otherwise) to be compromised for fear of printing, displaying, or creating documents.
- The QMP only requires 6 procedures. Your organization may choose to document additional procedures and should feel comfortable to if a need arises. If your organization chooses to document additional procedures it is not a grounds for a noncompliance. However, any procedures that your organization develops must be controlled according to your document control procedure.
- Your organization must ensure that when using equipment manufacturer procedures/reference materials to ensure that the industry developed information on said materials is not contradictory to requirements found in FGIS handbooks/notices/bulletins/instructions.