

Document Control Lesson

1. Policy

- 1.1. All management system documents (e.g., policies, procedures, specifications, food safety plans, work instructions), plus any other operational reference documents (e.g., external codes, regulations, customer requirements, equipment instructions, etc.), are controlled to ensure their currency and relevance. This includes the templates for records used to report tests, inspections, and audit results.
- 1.2. Documents are stored electronically or be paper-based, or a blend of both. The current copy of the relevant documents is available to staff and employees that need to use them.
- 1.3. A list of documents and amendments to documents are maintained to identify the current records in use.
 - 1.3.1. Refer to *Master Document Register*

2. Procedure

- 2.1. The following procedure describes how documents are maintained, updated, and replaced.
 - 2.1.1. Document Control Number– a written, printed, or electronic file that provides a control number for program, policy, procedures, and instructions or evidence such as forms, statements, verification, and validation or serves as an official record in the following format “PCQI-QMS-SQF#.P#-Title – Revision date. R# (P, F, L, SWS, WI).#...”
 - 2.1.1.1. Example : PCQI-QMS-X.X.X.PX-Document Control Program – YYYYMMDD
 - 2.1.1.2. [COMPANY INITIALS] = [COMPANY NAME] (Company Initials)
 - 2.1.1.3. QMS = Quality Management System
 - 2.1.1.4. SQF# (e.g. 2.1.1) = Numbering Sequence (Reflects SQF Module System Elements)
 - 2.1.1.5. P0, P1, P2, = Programs, Policies, and Procedures
 - 2.1.1.6. F0, F1, F2, = Forms utilized for verification, validation, and statements
 - 2.1.1.7. L0, L1, L2, = Lesson utilized for training materials and general learning lessons.
 - 2.1.1.8. SWS = Standard Work Sheet
 - 2.1.1.9. ES = Spanish
 - 2.1.1.10. Revision date = format is YYYYMMDD (e.g. 20220515)
 - 2.1.1.11. R1, R2, R3, = Revision number (original documents will not have revision number)
 - 2.1.2. Title – a descriptive general heading that distinguishes the name of written or printed material.
 - 2.1.3. Effective Date – The date the document was signed and approved.
 - 2.1.4. Publication Date – The date the P, F, L, SWS, WI is published for distribution and initiated training.
 - 2.1.5. Implemented Date – The date the P, F, L, SWS, WI is distributed, and training is completed.
 - 2.1.6. Supersedes - Put ORIGINAL for initial issuance of the document. For any revisions, reflect the initial revision date before the current revision.

2.2. Authorities / Responsibilities

- 2.2.1. Reviewer - QMS Management Personnel
 - 2.2.1.1.1. Reviews the document or its revision for accuracy and implementation
 - 2.2.1.1.2. Reviews and recommends final document approval, disapproval, or approval with revision and presents to the Approval Officer
 - 2.2.1.1.3. Ensures resources are available to accomplish requirements specified within the documents
- 2.2.2. Approval - Company Officer
 - 2.2.2.1.1. Final Approval Authority
 - 2.2.2.1.2. The approval represents the acceptance of liability on behalf of the company

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2.2.2.1.3. Ensures funds and resources are available to accomplish requirements specified within the documents

- 2.3. Registers – The following registers are maintained by the document controller or [ENTER POSITION TITLE - Food Safety Team Lead, PCQI, or SQF Practitioner]. Registers are available at the Quality, Compliance, Production Offices.
- 2.3.1. SQF Documents
 - 2.3.2. HACCP Food Safety Plans
 - 2.3.3. SSOPs
 - 2.3.4. SOPs
 - 2.3.5. Other Work Instructions
 - 2.3.6. Raw Material Specifications
 - 2.3.7. Finish Product Specifications
 - 2.3.8. Approved Company
 - 2.3.9. Approved Service Providers
 - 2.3.10. Training
 - 2.3.11. Verification and Validation
- 2.4. Any requirements for corrections or maintenance of records are recorded in document control procedures, including the appropriate methods for addressing corrections.
- 2.5. New document proposal, change request, revised document development, and approval.
- 2.6. Personnel creating a new document and making a change to SOPs and Forms will report all changes requests to the Quality Department, Quality Supervisor, and Senior Manager to approve the required change.
- 2.7. Changes shall be documented under the History section or Change History Document
- 2.7.1. Refer to *Change History Document*
- 2.8. Methods of Addressing Corrections.
- 2.8.1. Correction fluid, white-out, and correction tape shall not be used on records.
 - 2.8.2. Erasures shall not be used to correct records.
 - 2.8.3. Corrections shall consist of a single line drawn through erroneous material and legible printing of the changes above it or at the end of that line where the corrections occur. The person making each change shall initial and date the change, and in the event, the change is a part of a CCP, the time will be added to annotate the change.
 - 2.8.4. Document Control may only correct administrative errors after consultation with the originator.
 - 2.8.5. Sticky notes (e.g., Post-it notes) to correct the entry in GMP documents are not permitted.
- 2.9. General Good Documentation Practice
- 2.9.1. An indelible ballpoint pen shall be used to record data. A pencil or erasable or water-soluble ink pen shall not be used. A pencil may be used in an extreme cold area if an ink pen does not work in that environment.
 - 2.9.2. Highlighting original documentation is allowed only if it does not obliterate the information once scanned. Yellow highlighting will usually not appear on the scanned image; therefore, other methods of indicating special attention should be used (clouding, asterisks, and so forth).
 - 2.9.3. Notes or other annotations shall be relative and be completely legible. Notes or markings of any sort must not obscure additional information.
 - 2.9.4. Never use Dittos and Arrows when entering repetitive data.
 - 2.9.5. Abbreviation “N/A” = Not Available or Not Applicable
 - 2.9.6. Abbreviation “N/S” = Not Specified
 - 2.9.7. Abbreviation “N/P” = Not Performed
- 2.10. Document Retention

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- 2.10.1. Procedures, SOPs, SSOPs, Policies, Work Instructions, and Forms that are signed and implemented but are now obsolete will be retained for **two (2) years** before destruction.
- 2.10.2. The company will retain equipment manuals and all applicable documents and forms for two (2) years after the equipment was deemed unusable, sold or discarded.
- 2.10.3. Facility documents such as maintenance records and service contracts will be retained indefinitely while the company is at the facility location. If the company no longer utilizes said facility, documents will be retained for two (2) years before document destruction.
- 2.10.4. Laboratory test results documents will be retained for two (2) years commencing on the expiry date, best used by, or distribution date of the material tested.
- 2.10.5. Scientific testing (clinical, shelf-life studies, etc.) documents will be retained for two (2) years commencing on the last calendar year the product is no longer distributed for commerce.
- 2.10.6. The employment records, such as job applications and resumes of non-hired individuals, will be retained for two years following the date the hiring process is completed for a position. This includes applications for permanent and temporary positions.
- 2.10.7. Other documents such as accounting, finance, personnel's training records, and legal contracts will be retained for seven (7) years and up to the maximum allowable by law of 10 years. Reference: Sarbanes–Oxley Act of 2002.
- 2.10.8. The company will retain finished product records for one (1) year after the expiration date
- 2.11. Document Destruction
 - 2.11.1. Documents will be destroyed by;
 - 2.11.2. Shredding - **A plastic trash liner will secure shredded documents before placing them in the dumpster.** Black trash liner is recommended for this purpose but not mandatory.
 - 2.11.3. Utilized a 3rd party company to perform this procedure is authorized.
 - 2.11.4. Refer to *Document Destruction Record*.

3. Responsibility

- 3.1. Designated Staff- Quality Compliance Personnel, Document Controller
 - 3.1.1. Document storage and security;
 - 3.1.2. Documents are controlled;
 - 3.1.3. Distributing current versions to relevant employees on time;
 - 3.1.4. Ensuring that documents are up-to-date;
 - 3.1.5. Worn, illegible, or out-of-date documents must be replaced;

4. Corrective Action

- 4.1. Any inefficiencies detected in complying with Document Control Program shall be addressed immediately by the FSMS management.
- 4.2. In the event of corrupted electronic records and paper-based records being present, electronic records shall be manually recorded based on the paper-based documents.

5. Review

- 5.1. Review of the document control procedure;
- 5.2. Review of the document register and list of amendments and their accuracy;
- 5.3. Availability and currency of documents in use;
- 5.4. Security and storage of records;
- 5.5. All personnel who need access to specific documents such as food safety plans, procedures, customer specifications, and applicable food regulations have such access.

6. History

Revision No.:	Revision Date:	Description of Change:	Originator / Author Name:	Title / Department:
0	YYYYMMDD	Original	ENTER ORIGINATOR/AUTHOR	ENTER TITLE/DEPARTMENT

Requirements:

- (1) The trainee (employee/visitor) has read or received a verbal translation of all or part of the policy, procedure, method, and/or SOP for which they are being trained.
- (2) The trainee has observed a demonstration of the task they are to perform or the procedure for which they are being trained as required.
- (3) The trainee has demonstrated the ability to perform the task with acceptable proficiency and minimal supervision.