

BUREAU OF ANIMAL INDUSTRY

OUALITY MANUAL

Document Name:

Documented Information

QM 7.5

Rev. No.: 04 October 31, 2022

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7.5.1 General

The management system documentation includes both documents and records. The ISO 9001:2015 standard uses the term "documented information". BAI does not use this term, but instead relies on the terms "document" and "record" to avoid confusion. In this context the terms are defined by BAI as provided for in QM 3.0 Terms and Definition. Documents and records undergo different controls as defined herein.

The extent of the management system documentation has been developed based on the following:

- a) The size of BAI
- b) Complexity and interaction of the processes
- c) Risks and opportunities
- d) Competence of personnel

Documents required for the management system are controlled in accordance with procedure GP BAI-01 Control of Documents. The purpose of document control is to ensure that staff have access to the latest, approved information, and to restrict the use of obsolete information. All documented procedures are established, documented, implemented and maintained.

A documented procedure GP BAI-05 Control of Records has been established to define the controls needed for the identification, storage, retrieval, protection, retention time, and disposition of quality records. This procedure also defines the methods for controlling records that are created by and/or retained by suppliers.

These controls are applicable to those records which provide evidence of conformance to requirements; this may be evidence of Product or Service requirements, contractual requirements, procedural requirements, or statutory/regulatory compliance. In addition, quality records include any records which provide evidence of the effective operation of the management system.

7.5.2 Creating and Updating

When creating and updating documented information, we ensure appropriate:

- a. identification (there shall be document control number, title, effectivity date, revision number)
- b. format (language shall be in English, in Verdana font and generally 10 font size of body text). All templates shall have appropriate footnote based on the agreed templates and or format. There shall be a prescribed BAI logo, internal and external look and feel of templates for compliance at all times.
- c. Review and approval for suitability and adequacy as defined in the matrix under QM0.3 Updating & Distribution of the Manuals and Documents.



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7.5.3 Control of Documented Information

The BAI QMS include documented information on:

- a. External and internal issues (monitoring and review)
- Criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure effective operation and control of processes;
- c. Quality objectives (monitoring)
- d. External providers (selection, monitoring of performance, evaluation, and reevaluation based on their ability to provide services in accordance with their requirements and communication regarding their performance)
- e. Service provision (monitoring and measurement activities)
- f. Customer's perception (obtaining, monitoring and reviewing)

The management system documentation includes both documents and records.

Documented information of external origin determined by BAI to be necessary for the planning and operation of the QMS is identified as appropriated and controlled.

Prepared by:	Reviewed/Approved by:
FELIPE P. REOLALAS, JR.	PAUL C. LIMSON, DVM
Quality Management Representative	Top Management