SOP 7.5.1 / Revision C

Owner: Quality System Management Representative

### 1.0 Purpose

To provide a documented procedure that defines the controls needed to create, update, and control documented information maintained by Fastener Depot, Inc. (FDI).

## 2.0 Scope

All Quality Management System (QMS) related documented information created and / or maintained by FDI.

### 3.0 References

- FDI Quality Management System Manual <7.5.1>
- FDI Quality Policy (Quality Management System Manual Addendum D)
- FDI SOP 7.5.2 Control of Records Documented Information Retained
- FDI SOP 9.2.1 Internal Audit
- FDI SOP 9.3.1 Management Review
- SAE AS9100, SAE AS9120
- IAQG Dictionary
- All documented information that is and should be maintained by FDI.

#### 4.0 Requirements

- 4.1 External documented information
- 4.1.1 Typical external documented information that is maintained by FDI may include:
  - Regulatory standards & regulations, such as "TSO", "PMA", "OSHA", and
  - Industry standards for materials & processes, such as "AS" & "ANSI", and
  - Industry standards for parts, such as "AN", "MS", "NAS", & "NASM", and
  - Customer drawings, blueprints, and
  - Manufacturer sales drawings, catalogs, etc.
- 4.1.2 Customers, end users, external providers, regulatory bodies or industry associations, authors typically maintain custody of external documented information.

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- 4.1.3 External custodians are responsible for approval, review, change and identification (including specific requirements for control, where applicable) of documented information, as applicable, ensuring their legible & controlled distribution to FDI.
- 4.1.3.1 Clarification of requirements is achieved through authoritative or other appropriate sources when external documented information contains illegible information, information needed to ensure that requirements are met. These clarifications are appropriately identified and traceable to the source of clarification and personnel assigning clarification.

Care is taken to protect internal documented information from damage. Electronic documented information maintained by FDI is stored in a cyber secure base, and hard copy documented information is maintained in folders, bankers' boxes and other appropriate containers to ensure their protection.

- 4.1.4 Regulatory or customer requirements for control and distribution of external documented information are complied with, as applicable.
- 4.1.5 Previous revisions are replaced by FDI with new revisions where appropriate and in a timely manner.
- 4.1.6 FDI ensures that appropriate versions of external documented information are used within associated processes of the QMS. Specified revision and configuration requirements are flowed down from regulatory bodies, customer RFQ and Orders, through the FDI QMS, through the external provider base to manufacturing.
- 4.1.7 FDI takes precautions in handling and storing external documented information to ensure they remain legible and identifiable.
- 4.1.8 Unless otherwise specified, FDI receives and ships product manufactured to the latest blueprint revision on file at time of FDI acceptance of customer order. If a requirement specifies a later or earlier revision of blueprint than that which is on file at FDI, the required blueprint is attained by FDI if acceptance of the order is considered. If the order is accepted, the required revision of the blueprint is used in all applicable aspects of the QMS in satisfying the requirements.

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- 4.2 Internal documented information
- 4.2.1 Typical internal documented information that is maintained by FDI includes:
  - FDI quality system policies
  - FDI QMS standard operating procedures (SOP)
  - FDI QMS standard work instructions (SWI)
  - FDI quality system forms
- 4.2.2 Creating internal documented information that is maintained by FDI is the Responsibility of, and may be delegated by, the Vice President of FDI. FDI policies, standard operating procedures and work instructions, forms and job descriptions are developed as needed. Prior to approval, documented information includes:
  - Title, Revision Blocks or Fields, and
  - Link or Specific Reference to other applicable documented information, as applicable

The FDI Vice President is responsible for the Approval, Re Approval and Update of all internal documented information.

- 4.2.3 To ensure continuing suitability of internal documented information and the documented QMS:
  - Internal audits are utilized to identify documented information which remain suitable, and therefore do not require Re approval.
  - Internal audits are also used to identify that documented information which may require change or Re approval.
- 4.2.4 Approved changes may be made to the FDI documented QMS as a result of internal audit results and reporting. Documented information is retained to identify changes to affected documented information (Refer to FDI documented procedure SOP 7.5.2 as needed).
- 4.2.5 Minutes of management review may describe changes made to the documented QMS as a result of internal audit results or other identification of need or desire.
- 4.2.6 To ensure legibility of internal documented information, the following requirements apply:
  - Corrections or clarifications to documented information that are used to ensure that requirements are met are neatly documented and traceable to the individual providing the correction or clarification

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- Originals and copies of internal documented information are reviewed by personnel making the copies, prior to copy, use or distribution, to ensure legibility and completeness.
- Care is taken to protect internal documented information from damage. Electronic documented information maintained by FDI is stored in a cyber secure base, and hard copy documented information is maintained in folders, bankers' boxes and other appropriate containers to ensure their protection.
- 4.2.7 FDI defines and considers an "Obsolete Document" as documented information that is "no longer in use" consistent with ISO 9001, SAE AS9100, SAE AS9120 and the IAQG Dictionary.

At FDI, this type of documented information would likely be manifested in:

- An externally controlled documented information identified by its recognized custodian as "Obsolete" (such as drawings & specifications), or
- An internal form, procedure, or other internal QMS documented information, that has been revised or cancelled (Exceptions include previous issues of documented information that are "in use" for the purposes of control, investigation or improvement, Or
- A "record" (documented information that has been retained) that has exceeded retention period requirement(s) and is no longer "in use" (retention requirements for documented information are included in FDI documented procedure SOP 7.5.2 and are considered "minimal" requirements).
- 4.2.8 All hard copy documented information classified as "Obsolete" IAW with criteria noted above will be identified (marked) conspicuously and positively as follows by the Vice President:
  - "Obsolete See Vice President for Authorization to use"
  - Printed name, initials or signature of the Vice President, and the date that the documented information has been considered "Obsolete"
- 4.2.9 All electronic documents classified as "Obsolete" IAW with criteria noted above will be identified as follows:
  - "Obsolete See Vice President for Authorization to use"
  - Printed name, initials or signature of the Vice President, and the date that the documented information has been considered "Obsolete"
- 4.2.9.1 This identification of "Obsolete" electronic documented information may be accomplished and demonstrated through documented information retained and that is directly and positively traceable to the electronic documented information being classified as "Obsolete".

NOTE 1: It is important to recognize that FDI routinely accepts customer requirements that require products or services that are not produced, certified or

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presented as meeting the most currently available issues or revisions of drawings, specifications, or other requirements.

NOTE 2: When documented information is identified with "Obsolete – See Vice President for Authorization to use", all FDI personnel are required to obtain written approval of the FDI Vice President prior to use.

- 4.3 FDI conducts weekly collection of hard copy Internal & External Documented Information for eventual Shredding. This activity includes temporary staging and eventual delivery of documented information to the Secured Container deployed for slightly longer storage, and the eventual hand off to the Disposal provider (every other month).
- 5.0 Documented information retained ("records")
- 51 Evidence of documented information issue can be verified in drafts and revision "records" related to forms, procedures and policies, contracts, shipping documented information, Purchase Orders, and other Purchasing information.
- 5.2 Records of changes to internal documented information are retained, identifiable to the affected documented information and personnel assigned authority for their change.
- 5.3 Documented information is retained in accordance with FDI documented procedure SOP 7.5.2.