Procedure: [Control of Records Proc. Title]

1. SUMMARY
   1. This procedure defines the requirements for the identification, storage, protection, retrieval, retention time and disposition of controlled quality records.
   2. “Quality records” are those records which provide evidence of [Short Client Name] having met – or not met – requirements. This may include requirements related to inspection requirements, purchasing requirements, contractual requirements, etc. The full listing of records affected by this procedure is given in the table at the end of this procedure.
   3. Records outside of this scope do not require control, but may be controlled at the discretion of management.
2. REVISION AND APPROVAL

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| --- | --- | --- | --- |
| **Rev.** | **Date** | **Nature of Changes** | **Approved By** |
| [Rev Number] | [Date of Issue] | Original issue. | [Procedure Approver Name] |
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|  |  |  |  |

1. PROCEDURE
   1. **Identification**
      1. [Short Client Name] maintains records that are needed to provide evidence of conformity to requirements and of the effective operation of the quality management system. The records are identified in the table below, along with the controls for each record type.
   2. **Storage**
      1. Storage methods are indicated in the table below, for each record type.
      2. Softcopy records and data are stored on the company server or computers; in all cases, computers are subject to backup.
      3. Hardcopy records are stored in suitable cabinets that prevent damage or deterioration.
   3. **Retention, Retrieval & Disposition**
      1. Records shall be maintained a minimum of XX years [🡨 define actual retention time; should not be less than 3 years due to ISO audit cycle requirements] unless otherwise indicated below or as defined by customer, statutory or regulatory requirements.
      2. Training records and other records pertaining to employees must be retained at least one year beyond that employee’s end of employment.
      3. Records that are discarded after retention shall be permanently destroyed.
      4. When archived records are stored offsite or in another location, these shall be stored in a controlled environment that also protects them from damage or deterioration.
      5. As required by customer contract or regulatory requirements, quality records shall be made readily available for review by the requesting authority. Such review is limited to those records applicable to the customer or regulatory authority, and shall not allow for the accidental or intentional release of confidential information to an unauthorized party.
   4. **Protection**
      1. The listed “controller” shown in the table below must ensure their assigned records remain legible, readily identifiable and retrievable.
      2. In order to ensure protection of records, electronic records are subject to periodic backups, with the backup stored on a separate server. [Add details of backup procedures and methods here; if complex, a separate procedure may be required.]
      3. The [who?] is responsible for backup of data.
      4. Quality records data stored on individuals’ computers must either be backed up through the server (as above), or backed up manually onto the server. The individual users of such data are responsible when data is not backed up by the server. [Delete if not applicable.]
      5. Entries made by hand on hardcopy forms shall be made in ink.
      6. White-out or correction tape is not to be used on any quality records. The correct procedure for making corrections is to cross the error out, make the correction and initial it. Optionally, date-sensitive corrections should be dated as well.

**Example:**

*126*

# parts accepted = ~~124~~ ***S.P . 12/12/2020***

**QUALITY RECORDS MATRIX**

Edit table as required; data entered is provided only as examples

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Required Record or Document Type** | **[Short Client Name] Record** | **Responsible Controller** | **Type of Record** | **Storage Location** | **Discard Method** |
| Management Review Records | Management Review Meeting Minutes | QA Manager | Softcopy | Server | Secure delete |
| Customer Satisfaction records | QA Manager | Hardcopy | QA Manager’s Office | Shred and discard |
| Employee Opinion Surveys |  |  |  |  |
| Training Records | Training Matrix |  |  |  |  |
| Employee Training Records |  |  |  |  |
| Statements of Training |  |  |  |  |
| Applications, resumes |  |  |  |  |
| Authority Roster |  |  |  |  |
| Records of realization process meeting requirements | Preventive Maintenance Records |  |  |  |  |
| Stamp & Signature Control Log |  |  |  |  |
| Work Orders |  |  |  |  |
| Travelers |  |  |  |  |
| Purchase Orders |  |  |  |  |
| Packing Lists / Packing Slips |  |  |  |  |
| Process control records (incl. temp charts) |  |  |  |  |
| Design and Development Records | Design plans |  |  |  |  |
| Design drawings |  |  |  |  |
| Design models |  |  |  |  |
| Specifications |  |  |  |  |
| Design change records |  |  |  |  |
| Design verification records |  |  |  |  |
| Design validation records |  |  |  |  |
| Contract Review Records | Customer RFQs |  |  |  |  |
| Quotes |  |  |  |  |
| Customer POs |  |  |  |  |
| Customer drawings |  |  |  |  |
| Customer specifications |  |  |  |  |
| Vendor Evaluation | AVL |  |  |  |  |
| Vendor survey reports |  |  |  |  |
| Suppler evaluation records |  |  |  |  |
| Calibration Records | Calibration Master List |  |  |  |  |
| Calibration Records |  |  |  |  |
| Certificates of Calibration |  |  |  |  |
| Traceability records | Travelers |  |  |  |  |
| Record of release of product | First Article Inspection Reports |  |  |  |  |
| Receiving Inspection Forms |  |  |  |  |
| Final Inspection Sheets |  |  |  |  |
| Nonconforming Product Dispositions |  |  |  |  |
| Nonconformance Log |  |  |  |  |
| Record of nonconforming customer property | Nonconforming Product Dispositions |  |  |  |  |
| Corrective & Preventive Actions | CARs |  |  |  |  |
| CAR Log |  |  |  |  |
| Internal Audit records | Internal audit Reports |  |  |  |  |
| Internal Audit Schedule |  |  |  |  |