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	Operational Procedure: SOP-424	Revision: 1/08/09

Control of Quality Records

1.0 Purpose and Scope

- 1.1 The purpose of this procedure is to define the system for the maintenance, identification, indexing, storage and control of quality records to ensure:
- Record controls established satisfy all regulatory and customer requirements.
 - Records controlled include customer-specified records.
 - Disposition of records also includes their disposal.
- 1.2 This procedure applies to all Widget Works Co. functions and operations and encompasses all records used to demonstrate conformance to product and quality system requirements including those specified in our Quality Manual, Operating Procedures (SOPs), Work Instructions (WI), etc.

2.0 Responsibilities

- 2.1 The Management Representative has overall responsibility for the record control system, including the issuance and maintenance of this procedure. All proposed changes and other suggestions for improvement should be submitted to the Management Representative in accordance with SOP-423. The Management Representative reviews all proposed changes as they are submitted and otherwise reviews this document annually for compliance with *ISO 9000* requirements and consistency with established policy, objectives and other QMS processes/systems. The Management Representative maintains a master copy of this document and controls its electronic and hard copy distribution as well as any Damen Carbide Tool Forms and/or record formats required by the provisions of this SOP.

3.0 Definitions

- 3.1 Quality Records: information generated from the processes described in quality system documents, and retained as indicated in this procedure.

4.0 Equipment/Software

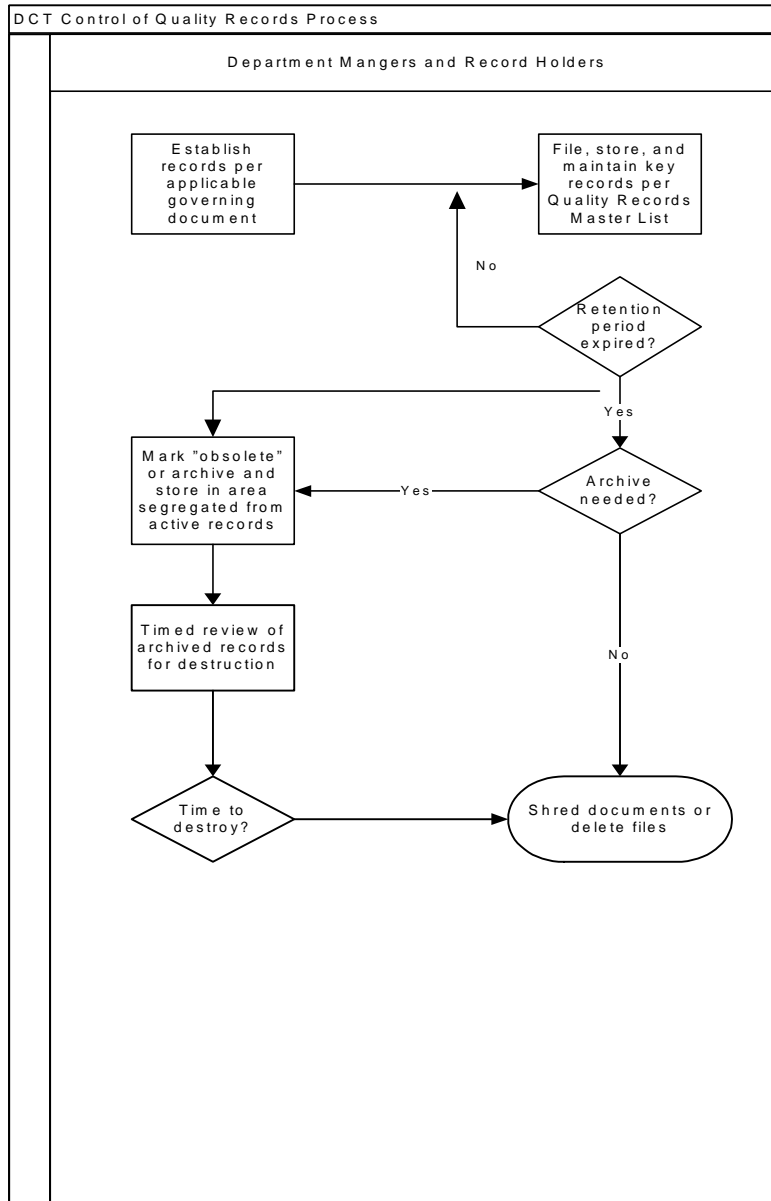
- 4.1 Not Applicable.

5.0 Instructions

- 5.1 The following process map defines the general method for the Control of Records process.

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6.0 Forms and Records

6.1 Key Records, Record Holders and Retention Periods

- **Management Review Records:** Outputs of management review meetings retained by the Management Representative for a period of three years; see SOP-560
- **Competency Records:** Personnel qualification and training records and retained by the Vice President of Administration for a

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period of three years after termination of employment; see *SOP-622*

- **Purchased Products and Services Review Records:** Offers, quotes and other documents established in the course of negotiating and implementing contracts retained by the Vice President of Administration for a period of 10 years after its completion; see *SOP-722*
- **Supplier Evaluation and Performance Records:** Documents demonstrating supplier capability and on-going performance retained by the Operations Manager while the supplier is active plus three calendar years; see *SOP-741*.
- **Purchasing Documents and Records:** Purchasing documents for procurement of materials, components, products, and services to be incorporated into the finished product retained by the Operations Manager while the production part for which the materials were purchased is active plus one calendar year; see *SOP-742*.
- **Production Part and Process Approval Records:** All records and documents required for product or process approvals and validations are retained by the Quality Manager while the production part is active plus one calendar year; see *SOP-710 and SOP-752*.
- **Product Quality Records:** Job travelers, traceability records, material certificates, inspection and test results, etc., retained by the Quality Manager for one calendar year after the year in which they were created; see *SOP-751, SOP-810 and SOP-824*.
- **Calibration Records:** Inspection, measuring, and test equipment calibration certificates retained by the Quality Manager for a period of three years; see *SOP-760*
- **Customer Satisfaction Data and Complaint Records:** Files with customer complaints and records together with customer satisfaction data retained by the Vice President of Administration for a period of three years; see *SOP-821*

6.2 Records are normally stored by the same department that initially established the record (see Section 6.1 of this procedure). Records are stored in a dry and clean environment. Cabinets containing records are clearly labeled to display their contents. Records and other quality documents may not be stored in private desk drawers or other obscure locations that are not generally known. Records are retained by record holders in either their active location or their final storage locations as identified in DCT Form 424.

6.3 Disposal. Records retained beyond their specified retention period must be clearly marked "archive or obsolete records" and placed in the archive location.

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Records not retained must be destroyed (i.e. shredded or deleted) as soon as practical after the retention period has lapsed.

7.0 Attachments

7.1 None

8.0 Related Documents

8.1 Quality System Procedures and Work Instructions

9.0 References

- 9.1 Damen Carbide Tool Quality Policy Manual Section 4.2.4 Control of Quality Records
- 9.2 SOP-423—Control of Documents
- 9.3 SOP-560—Management Review
- 9.4 SOP-822—Internal Audit
- 9.5 SOP-850-01—Corrective Action
- 9.6 SOP-850-02—Preventive Action
- 9.7 DCT Form 424—Index of Quality Forms and Records

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	Operational Procedure: SOP- 760	Revision: Draft

Control of Monitoring and Measuring Devices

1.0 Purpose and Scope

- 1.1 This procedure outlines the requirements for control of measuring and monitoring devices.
- 1.2 This procedure applies to inspection, measuring and test equipment used to control the product realization process.

2.0 Responsibilities

- 2.1 The Quality Control Manager is responsible for this procedure.

3.0 Definitions

- 3.1 Calibration—the comparison of a measurement instrument or system of unverified accuracy with a measurement instrument or system of known accuracy, to detect any variation from the required performance specifications.

4.0 Equipment/Software

- 4.1 Not Applicable

5.0 Instructions

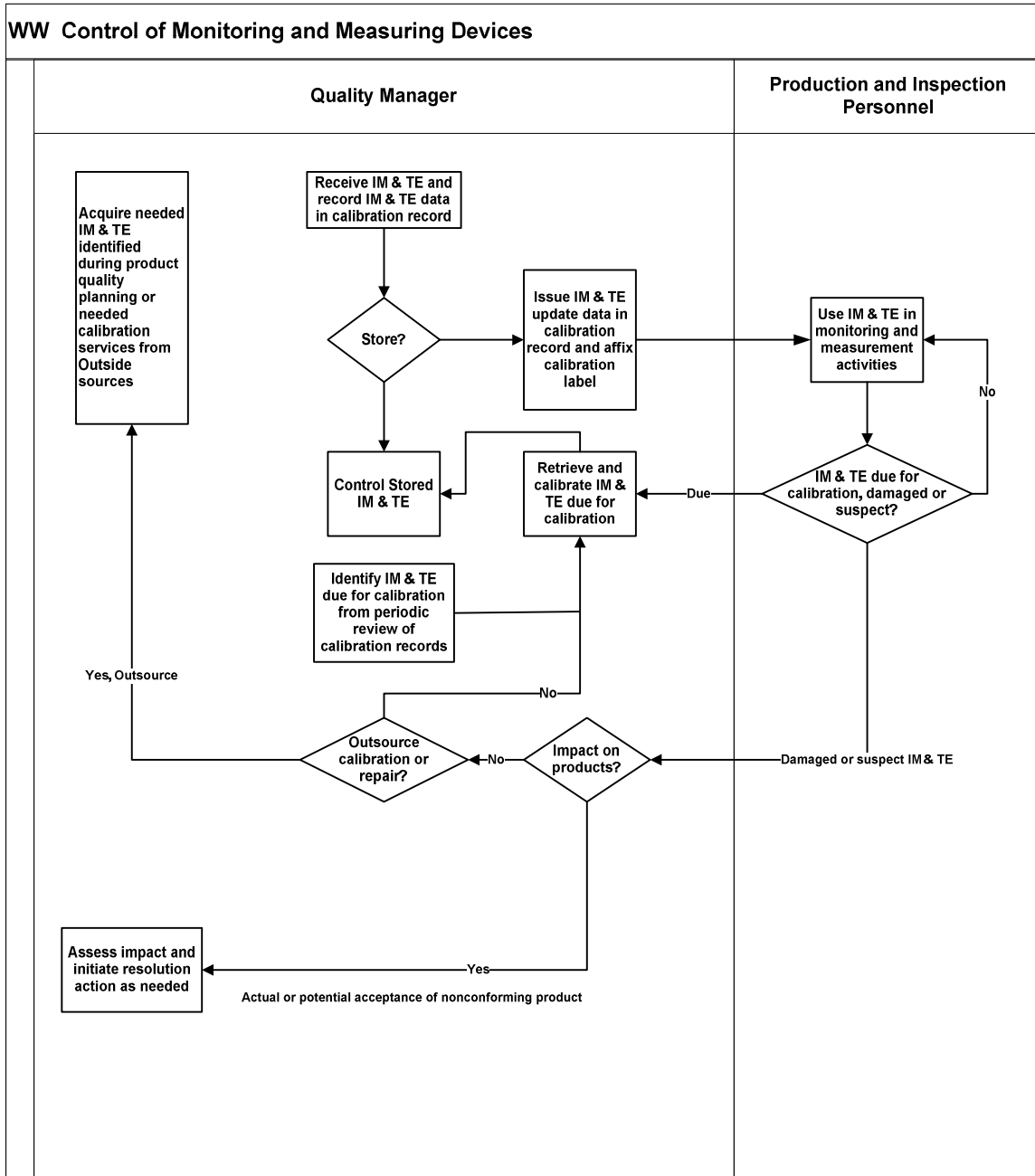
- 5.1 The quality procedure SOP -824 determines actual monitoring and measurement performed throughout production
- 5.2 The process map contained in **6.0 Method** defines the methods used at Widget Works for control of inspection, measuring and test equipment.
- 5.3 Software used to verify the acceptability of product is confirmed at prescribed intervals

6.0 Method

- 6.1 Control of Inspection, Measurement and Test Equipment (IM & TE).

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7.0 Forms and Records

7.1 Form 760-1 Calibration Record

8.0 Related Documents

8.1 DCT SOP – 824 Monitoring and Measurement of Product

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9.0 References

- 9.1 Widget Works Quality Policy Manual section 7.6 Control of Monitoring and Measuring Devices

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