



QUALITY MANUAL

Revision K

JADE PRECISION MEDICAL COMPONENTS, LLC
3063-B Philmont Avenue
Huntingdon Valley, PA 19006

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1. Purpose & Scope

This manual describes the Quality Management System (QMS) established by and for

Jade Precision Medical Components LLC (JPMC).

The principles and policies on which this manual is based; along with operating procedures, work instructions, and other supporting documents; govern all processes that affect quality throughout the organization.

2. Applicable Standards

- 2.1 The QMS is structured and intended to be in compliance with the following standards.
ISO 13485:2016 · Medical Devices · Quality Management Systems · Requirements for Regulatory Purposes
21 CFR Part 820 · Quality System Regulation
(Exclusions and Exceptions noted below.)
- 2.2 Normative References
ISO 9000:2015 · Quality Management Systems · Fundamentals and Vocabulary
ISO 13485:2016 · Medical devices · Quality Management Systems · Guidance on the Application of ISO 13485:2016

3. Business Profile

3.1 Mission Statement

To deliver zero defects to our internal and external suppliers and customers.

- 3.2 JPMC, with one facility located at 3063·B Philmont Avenue, Huntingdon Valley, Pennsylvania, 19006, USA, is a contract manufacturer of precision medical components.
- 3.3 The organizational structure is described by RE-42-002 Organization Chart.

4. Authority & Responsibility

- 4.1 This manual is issued under the authority of the President.
- 4.2 It is the responsibility of the Director of Quality, who is the designated Management Representative, to ensure that the principles of this manual, the Quality Policy, quality objectives, customer requirements, applicable regulatory requirements, and quality management system requirements are promoted, communicated to and understood by all JPMC employees.

5. Terms & Definitions

- 5.1 Corrective Action
A process improvement methodology aimed at identifying and eliminating the causes of known non-conformities to prevent their recurrence. A problem solving process.
- 5.2 Customer
 1. A business entity and the individuals representing it that specify and purchase products produced by JPMC.
 2. A business entity considering JPMC as a potential supplier.
- 5.3 Customer Complaint
A communication from a customer expressing dissatisfaction with product or service or a concern based on observations or perceptions of JPMC; classified as Formal Complaint, Informal Complaint, or Customer Return.



- 5.4 Customer Feedback
Customer assessment of JPMC's performance as it relates to meeting customer requirements and/or expectations.
- 5.5 Process
A set of interrelated resources and activities; i.e. people, materials, equipment, environment, methods; used to transform specific inputs into specific outputs.
- 5.6 Product
1. The end result of activities performed and resources applied by JPMC; a process output.
 2. Purchased goods and services.
- 5.7 Preventive Action
A process improvement methodology aimed at identifying and eliminating potential causes of nonconformities before they occur.
A risk management process.
- 5.8 Qualified
Having attained the knowledge, skills, or other attributes necessary to perform a particular activity or task in accordance with specified requirements.

6. Policy & Objectives

6.1 Quality Policy

Our goal, at JPMC, is to provide products and services that comply with applicable requirements and exceed our customers' expectations. This will be accomplished through employee involvement and ongoing education to ensure continuous improvement of our processes.

This quality policy is communicated to all employees as part of their training, with the intent of providing a clear, common understanding, directly applicable to their work. The quality policy is reviewed at least once per year for continuing suitability and adequacy.

6.2 Quality Objectives

- Only Defect-Free Product and Services shipped/provided to customers/suppliers
- Continuous Improvement in Delivery Performance through the Utilization of Capable Processes
- Maintenance/Continuation of ISO 13485 Certification

7. Application

- 7.1 The QMS described in this manual is applicable in contractual situations entailing the manufacture of components/devices in accordance with customer specifications.

7.2 Exclusions

- 7.2.1 ISO 13485:2016 · Clause 7.3 · Design & Development · including all sub-clauses.
21 CFR Part 820 Subpart C · Design Controls · including all sub-sections.

JPMC is a contract manufacturer and does not design, develop, test, or market its own products/brand(s). All medical components/devices produced by JPMC are manufactured in accordance with specifications provided and authorized by our customers.

Planning, execution, and control of design and development activities are, therefore, not addressed in this manual and are excluded from the QMS.

- 7.2.2 ISO 13485:2016 · Clause 7.5.3 · Installation Activities
21 CFR §820.170 · Installation

JPMC does not perform or support any installation activities.

Control and verification of installation activities is not applicable to JPMC.

7.2.3 ISO 13485:2016 · Clause 7.5.4 · Servicing Activities
 21 CFR §820.200 · Servicing
 JPMC does not perform or support any servicing activities.
 Control and verification of servicing activities is not applicable to JPMC.

7.2.4 ISO 13485:2016 · Clause 7.5.5 and Clause 7.5.7
 Particular Requirements for Sterile Medical Devices
 JPMC does not perform sterilization of any kind.
 Record maintenance of sterilization process parameters is not applicable to JPMC.

8. Quality Management System

8.1 General

- 8.1.1 JPMC has developed, documented, implemented, and maintains its QMS in accordance with ISO 13485:2016, and 21 CFR Part 820.
- 8.1.2 JPMC applies a risk-based approach to the control of appropriate processes needed for the quality management system utilizing the methods specified in *ISO/IEC 31010:2009, Risk management - Risk assessment techniques*, which is used as guidance on selection and application of systematic techniques for risk assessment.
- 8.1.3 The QMS is based on a process approach to quality management and JPMC applies continuous process improvement methodology, i.e. the Plan-Do-Check-Act Cycle (Figure 1), to ensure its on-going effectiveness.

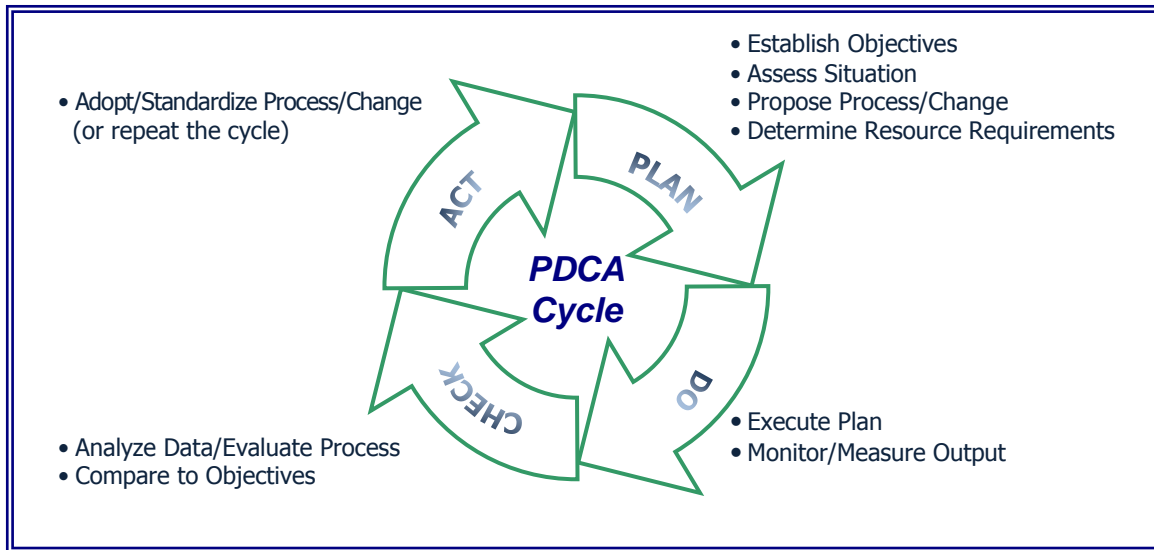


Figure 1

8.1.4 System processes, including their interrelationships and correlation to ISO 13485:2016 sub-clauses, are described in the appendices of this manual.

8.2 Document Control

8.2.1 The document system is tiered as shown in Figure 2.

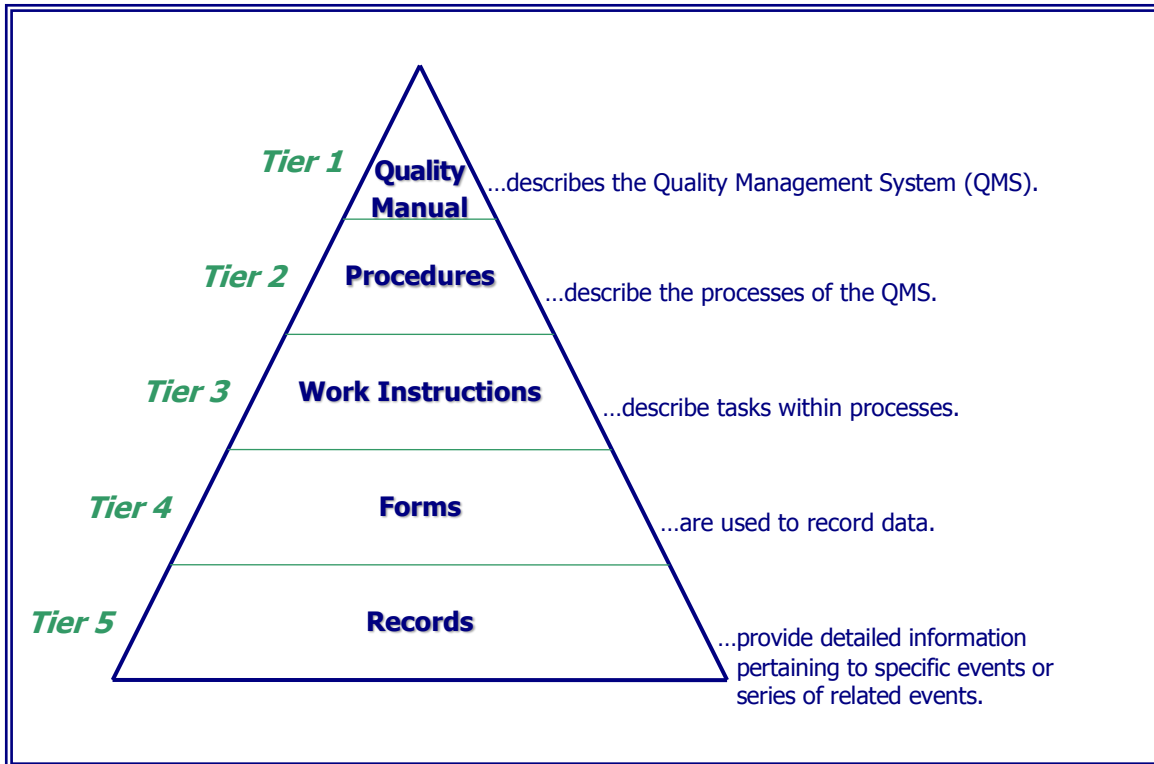


Figure 2

8.2.2 All documents comprising the QMS; i.e. this Quality Manual, Procedures, Work Instructions, Forms; their current revision level and file type are listed and controlled within IQS Quality Management Software.

8.2.3 QMS documents are controlled and revised as described in procedure *PR-42-001 Control of Documents*.

8.2.4 Records required by the QMS, ISO 13485:2016, and 21 CFR Part 820 are maintained in accordance with procedure *PR-42-002 Control of Records*.

8.3 References

PR-42-001 · Control of Documents

PR-42-002 · Control of Records

PR-42-003 · Document Map

IQS Quality Management Software

9. Management Responsibility

9.1 General

9.1.1 JPMC management is committed to the development and implementation of the QMS and fully supports maintaining its effectiveness by:

- communicating, to all functions and levels within JPMC, the importance of meeting customer, applicable regulatory, and statutory requirements.
- establishing an appropriate quality policy and measurable objectives and ensuring these are communicated and understood throughout the company.

- providing a framework for review of quality objectives and processes, including regularly scheduled Management Reviews to ensure continuing suitability, adequacy, and effectiveness of the QMS.
 - ensuring the integrity of the QMS as changes are planned and implemented.
 - allocating sufficient resources and providing education and/or training as required.
- 9.1.2 Management is ultimately responsible for determining and satisfying customer/product requirements.
- 9.1.3 Roles, responsibilities, authorities, and their interrelationships are clearly defined, documented, and communicated within JPMC.
Personnel who manage, perform, and/or verify work affecting quality have the authority and independence to perform these tasks effectively.
- 9.2 The Director of Quality serves as the **Management Representative** and, as such, is responsible and fully authorized to manage the QMS and related matters on an ongoing basis. Roles and responsibilities include the following.
- Interprets applicable standards and continually verifies QMS compliance.
 - Ensures that required processes are documented, implemented, and maintained.
 - Advises the management team regarding operation and effectiveness of the QMS and opportunities for improvement.
 - Serves as liaison to external parties regarding matters relating to the QMS.
 - Ensures that the principles of this manual, the Quality Policy, quality objectives, customer requirements, applicable regulatory requirements, and QMS requirements are promoted, communicated to and understood by all JPMC employees.
- 9.3 In the event the Director of Quality cannot serve as the **Management Representative**, for whatever reason, the Quality Assurance Manager serves as the **Management Representative** and will fulfill the roles and responsibilities outlined above.
- 9.4 **Management Review**
- 9.4.1 Management Review Meetings are conducted at regularly planned intervals to ensure continuing suitability, adequacy, and effectiveness of the QMS.
- 9.4.2 Input to management reviews may include, but is not limited to, the following.
- Quality Policy
 - Quality Objectives
 - Follow-Up Items From Previous Management Review(s)
 - Audit Results
 - Customer Input
 - Internal Non-Conformances (NCRs)
 - On-time Delivery Performance Data
 - Supplier Performance Data
 - Training Program Status
 - Internal Corrective & Preventive Actions Status
 - Changes that could affect the QMS
 - New or Revised Regulatory Requirements
 - Resource Issues/Requirements
 - Recommendations for Improvement
- 9.4.3 Output of management reviews is recorded and includes the input reviewed and any decisions and actions related to the following:
- Improvements needed to maintain the suitability, adequacy, and effectiveness of the QMS and its processes
 - Improvement of Product
 - Changes needed to respond to new or revised regulatory requirements
 - Resource Needs

9.5 References

PR-56-001 · Management Review

10. Resource Management

10.1 The JPMC management team is responsible for identifying, obtaining, allocating, and/or training appropriate resources to ensure effective implementation and management of the QMS and to satisfy customer and regulatory requirements.

10.2 Human Resources · Training & Competence

10.2.1 Personnel who manage, perform, and/or verify work affecting quality are fully competent on the basis of education, training, skills, and experience.

10.2.2 New employees are provided with the following essentials and are subsequently deemed fully qualified for a position or job function.

- Review of Company Policies & Best Practices
- Review of the Quality Manual, including Quality Policy & Objectives
- Review of Relevant Procedures and Work Instructions
- Familiarization with Equipment and/or Software
- Facility Tour & Introductions

10.2.3 All changes to the QMS are reviewed with appropriate personnel when they are put into place.

10.2.4 Competencies are re-evaluated, with respect to current and future requirements, on an ongoing basis to determine if/when/what additional training is necessary. Appropriate training is provided if a deficiency is identified.

10.3 The **Infrastructure** is designed and maintained to enable conformity with product requirements, prevent product mix-up, and ensure orderly handling of product. JPMC's infrastructure includes:

- Buildings, workspace, and associated utilities
- Process equipment (both hardware and software)
- Supporting services (transport, communication, or information systems)

10.4 References

PR-62-001 · Personnel Qualifications & Training

PR-63-001 · Facility & Equipment Maintenance

PR-64-001 · Pest Control

PR-75-003 · Shipping & Receiving

PR-75-006 · Product Identification & Traceability

11. Product Realization

11.1 Product Realization at JPMC encompasses the following.

- Request for Quotation (RFQ) · from customer
- Initial Assessment · to determine if:
 - work is suitable and within JPMC capabilities,
 - customer delivery and price targets are realistic,
 - requirements, specifications, acceptance criteria are adequately defined.
- Quotation · based on material cost, labor estimates, workload and schedule.
- Order Processing · including review and confirmation of requirements
- Job Planning & Scheduling
- Purchasing
- Manufacturing
- Measurement/Inspection
- Documentation



- Delivery · to customer

11.2 Risk Management

11.2.1 JPMC is a contract manufacturer and does not design, develop, or market its own products/brand(s). Risk management, as it pertains to product realization, is limited to analysis of customer and regulatory requirements/specifications and assessment and control of product realization processes (above).

11.2.2 Product realization processes and manufacturing plans are designed to minimize risk.

11.3 References

- PR-72-001 · Quoting
- PR-72-002 · Job Planning
- PR-72-003 · Order Review & Entry
- PR-75-001 · Manufacturing
- PR-75-003 · Shipping & Receiving
- PR-75-006 · Product Identification & Traceability
- PR-82-001 · Inspection
- PR-83-001 · Control of Non-Conforming Material

12. Purchasing

12.1 Suppliers are evaluated and selected based on:

- Their ability to provide products and/or services that meet specific requirements,
- The performance of the supplier, and
- The effect of the purchased product on the quality of the medical device.

12.2 The criteria by which suppliers are evaluated and selected is proportionate to the risk associated with the medical device.

12.3 Supplier performance is monitored regularly to ensure ongoing control over purchased products and outsourced services. Evaluation/selection/review criteria and procedures have been established and documented.

12.4 Purchasing documents describe products/services clearly and completely.

(Information may include technical specifications, acceptance criteria, certification requirements, traceability, etc.)

12.5 Incoming product is controlled in accordance with referenced procedures to ensure that:

- receipts are properly recorded and relevant information is retained,
- purchase requirements have been met,
- non-conformities are handled correctly, promptly and consistently.

12.6 References

- PR-74-001 · Purchasing
- PR-74-002 · Supplier Approval & Evaluation
- PR-75-003 · Shipping & Receiving
- PR-75-006 · Product Identification & Traceability
- PR-82-001 · Inspection
- PR-83-001 · Control of Non-Conforming Material

13. Production Control / Product Identification & Traceability

13.1 The manufacture of JPMC products is planned and carried out under the following controlled conditions.

- Requirements, procedures, work instructions, reference materials, etc. are available, as needed.



- Product is manufactured and verified using suitable tools and equipment.
 - Material/product identity and status is clearly discernible at all times throughout the manufacturing process.
 - Product is adequately protected while in-process or in storage and packaged to prevent damage during shipment.
- 13.2 A record containing relevant manufacturing information is established and maintained for each lot of manufactured product. Records include the following information to enable product identification and traceability.
- Product Specifications/Requirements
 - Raw Material Information; including certifications and heat numbers.
 - Lot Size; i.e. quantity of product manufactured.
 - Manufacturing Details; including job/lot numbers, sequence of operations, start and completion dates.
 - Purchasing Information
 - Inspection Reports
 - Shipping Information
- 13.3 When the output of a manufacturing process cannot be verified by subsequent measurement or monitoring and, as a consequence, deficiencies become apparent only after the product is in use, the process is validated according to industry best practices that are acceptable to the customer.
- 13.4 **Customer Property**
Acquisition and control of customer-supplied materials is addressed in *PR-75-006 Product Identification & Traceability*, *PR-76-001 Calibration & Control of Inspection, Measuring, and Test Equipment*, and *WI-82-002 Receiving, Inspection, and Labeling of Raw Materials*. Such material that is lost, damaged, or otherwise deemed unsuitable for use, is handled in accordance with *PR-83-001 Control of Non-Conforming Material* and the customer is notified promptly.
- 13.5 **Preservation of Product**
- 13.5.1 Employees, contractors, and suppliers who come into contact with work-in-process or finished goods are provided with the proper instructions, tools, and supplies to protect the materials during production, handling, and while in transit.
- 13.5.2 Products manufactured by JPMC do not require special storage conditions and do not have limited shelf life.
- 13.6 **References**
- PR-42-002 · Control of Records
 - PR-72-001 · Quoting
 - PR-72-002 · Job Planning
 - PR-72-003 · Order Review & Entry
 - PR-74-001 · Purchasing
 - PR-74-002 · Supplier Approval & Evaluation
 - PR-75-001 · Manufacturing
 - PR-75-003 · Shipping & Receiving
 - PR-75-006 · Product Identification & Traceability
 - PR-75-009 · Validation
 - PR-76-001 · Calibration & Control of Inspection, Measuring, and Test Equipment
 - PR-82-001 · Inspection
 - PR-83-001 · Control of Non-Conforming Material

14. Control of Inspection, Measuring, and Test Equipment

- 14.1 Inspection, measuring, and test equipment (IMTE) is controlled, calibrated and/or verified in accordance with a documented procedure.
- 14.2 A Calibration Log (Record) has been established and is updated on an ongoing basis to track the calibration history, status, and schedule of all IMTE. Each piece of IMTE as well as the calibration standards are identified by a unique ID number and detailed description.
- 14.3 IMTE is further identified by calibration labels (corresponding to the log) and is handled and stored to maintain accuracy.
- 14.4 Calibrations are performed at predetermined intervals that are subject to periodic review and adjustment.
- 14.5 Any piece of IMTE found to be in use past its calibration due date shall be returned to the QA Department and calibrated immediately. In such cases, affected material is considered to be non-conforming, i.e. handled in accordance with PR-83-001 Control of Non-Conforming Material, until the validity of measurements is determined.
- 14.6 Calibration laboratories and service providers contracted by JPMC are required to use standards traceable to the National Institute of Standards and Technology (NIST).
- 14.7 **References**
PR-76-001 · Calibration & Control of Inspection, Measuring, and Test Equipment
PR-83-001 · Control of Non-Conforming Material
RE-76-001 · Calibration Log

15. Measurement, Analysis, Improvement

15.1 Customer Communications, Complaints, Feedback

- 15.1.1 Communications related to customer requirements, product quality, and process improvement may include:
- Customer Complaints
 - Customer Feedback
 - Advisory Notices
- 15.1.2 Customer complaints and feedback are communicated, documented, and tracked according to procedures for control of non-conforming material, corrective & preventive action, and management review.
- 15.1.3 Advisory Notices are issued as needed.

15.2 Internal Audits

- 15.2.1 The purpose of internal audits is to verify that process activities and work practices are in conformance with QMS procedures.
- 15.2.2 Audits are planned and conducted in accordance with a documented procedure.
- 15.2.3 Auditors are drawn from various functional areas and departments and qualified according to relevant QMS procedures. Because auditors must maintain independence, they do not audit their own work, functional area or department.
- 15.2.4 Audit results are reviewed with personnel working in audited areas and in management reviews. Findings and observations are addressed through corrective or preventive action.

15.3 Process Monitoring & Evaluation

QMS processes are monitored and evaluated by comparing planned results to actual outputs. Deficiencies are addressed through management review and subsequent corrective or preventive action.

15.4 Product Monitoring & Measurement

- 15.4.1 Raw materials and work-in-process are subject to Receiving, First Article, and In-Process Inspections as they progress through manufacturing operations; and finished goods must undergo Final Inspection before they are released for shipment to customers.
- 15.4.2 All inspections are performed in accordance with documented procedures and work instructions to ensure that evidence of conformity with requirements is recorded and maintained. Inspection data includes measurements, inspection methods and IMTE used, inspectors' identities.

15.5 Control of Non-Conforming Product

- 15.5.1 Product that does not conform to requirements is identified and controlled to prevent its unintended use or delivery in accordance with documented procedures.
- 15.5.2 JPMC employees have the responsibility and authority to report nonconformities promptly and take appropriate action. Responsibility and authority for review, investigation, and disposition of non-conforming product is also defined.
- 15.5.3 The following steps are taken when a non-conformity is identified.
- Review to determine the disposition of non-conforming product.
 - Corrective Action (if necessary) to investigate and eliminate the cause of the non-conformity.
 - Advisory Notice (if necessary).

15.6 Data Analysis & Improvement

- 15.6.1 To ensure continuing suitability, adequacy, and effectiveness of the QMS and demonstrate product conformity, JPMC has established, documented, and implemented procedures to monitor, measure, analyze, and improve its processes. Information collected and used for this purpose includes:
- Customer Complaints & Feedback
 - Audit Results
 - Product Conformity/Inspection Data
 - Other Measurable Process Outputs/Results (such as delivery performance, supplier evaluations, etc.)
- 15.6.2 Results of analyses are used to identify trends, determine causes of existing or potential problems, guide decisions pertaining to corrective/preventive actions, and assess process effectiveness and supplier performance.

15.7 Corrective & Preventive Action

- 15.7.1 The process for initiating, investigating, planning, implementing, verifying and closing corrective and preventive actions is described in *PR-85-001 Corrective & Preventive Action*.
- 15.7.2 Corrective or Preventive Action is required in the following situations.

Corrective Action

- A SCAR is issued by a customer
- An audit finding is reported by a customer or third party as a result of a quality system audit.
- A non-conformance is issued by a customer as a result of defective material being shipped to a customer
- A non-conformance is reported as a result of an internal quality system audit.
- An action item that emanates from a management review meeting
- A non-conformance is determined to be a major or critical risk, per *PR-83-001 Control of Non-Conforming Material*

Preventive Action

- The reliability or effectiveness of a process is called into question.
- A potential cause of a nonconformity is identified.
- An opportunity for improvement is identified.
- A safety concern is raised or a potential hazard is identified.

- 15.7.3 Corrective or Preventive Action may also be initiated for isolated incidents as deemed necessary.



15.8 **References**

PR-56-001 · Management Review

PR-82-001 · Inspection

PR-82-003 · Internal Audits

PR-82-007 · Customer Feedback

PR-83-001 · Control of Non-Conforming Material

PR-83-002 · Customer Complaints and Medical Device Reporting Procedure

PR-84-002 · Data Collection, Analysis, & Statistical Techniques

PR-85-001 · Corrective & Preventive Action

