Cardinal Systems, Inc.

# Quality, Inspection and Calibration Standards

**3.1 Quality Managment System Planning.**

**3.1.1** Quality Planning is an integral part of the Management System and is used to define and document how Cardinal Systems Inc. will meet customer requirements. The elements of Quality Planning exist throughout the various Management System Procedures and Work Instructions at the facilities and are used to ensure that:

3.1.1.1 The Quality Management System enables Cardinal to meet internal and external customer requirements, as well as the quality objectives.

3.1.1.2 The integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented.

**3.1.2** Quality Plans will be developed, as necessary to help communicate the results of Quality Planning activities.

3.1.2.1 Quality Plans will define inspection requirements, acceptance criteria and documentation requirements not included in the Management System Procedures.

**3.1.3** Where appropriate, these plans will be combined with Production Plans (refer to Level 1 Policy QMS-7.1) into a single reference document.

**3.1.4** Each facility is responsible for developing and implementing effective Quality Planning.

**3.2 All employees are responsible for recognizing, identifying, and notifying management of conditions that can lead to, or have created, nonconforming materials.**

**3.3 Cardinal has established Level 2 Management System Procedures for ensuring that materials and products not conforming to specified requirements are prevented from inadvertent use or shipment. Controls include:**

**3.3.1** Identification of nonconforming materials with appropriate tags, labels, or reports.

**3.3.2** Segregation of nonconforming materials from conforming materials by moving to a clearly identified hold area, when practical. When this is not practical, other means will be taken to prevent inadvertent use.

**3.3.3** Identification of responsibilities for handling nonconforming materials.

**3.3.4** Review and disposition to be made as soon as possible, through a formal Material Review Process. Effective reviews (and if necessary, corrective action) should be performed in order to prevent reoccurrence. Disposition for the nonconforming product may be as follows:

3.3.4.1 Accepted "as is" with concession when appropriate.

3.3.4.2 Reworked to meet customer specifications.

3.3.4.2.1 Products that have been repaired or reworked will be inspected and tested per established Inspection and Testing Management System Procedures.

3.3.4.3 Re-graded for alternative application.

3.3.4.4 Rejected or scrapped.

**3.3.5** Notification and Approval from the customer, where required by contract, for accepting "as is" or for reworking products that do not conform to original requirements.

**3.3.6** Documentation of the nonconformance with information on the nature and extent of the problem, any corrective or preventive action taken, the final disposition, and if reworked, evidence that the items have passed original requirements.

**3.4 Records of non-conformances are to be kept on file and used as a basis for corrective action, if appropriate.**

**3.5 Cardinal has established Level 2 Management System Procedures for control, calibration, and maintenance of inspection, measuring, and test equipment. Calibration is performed on calipers, micrometers, PI tapes, and other measuring equipment used in daily production every 6 months. Smaller daily checks are also performed by QA. Scales and Surface Plates are calibrated by outside sources on a yearly basis.**

**3.5.1** Inspection, measuring, and testing equipment is defined as that which determines conformance of a product or a process to specified requirements.

**3.5.2** Inspection, measuring, and testing equipment uncertainty will be known and consistent with the required measurement capability. Technical data (if available), verifying the functionality of inspection, measuring and testing equipment used, may be reviewed by any customer if contractually required.

**3.6 Measuring and testing equipment within the Cardinal calibration system will be:**

**3.6.1** Selected based on measurements to be made, required accuracy, degree of traceability, past serviceability, and reliability history.

**3.6.2** Identified utilizing a unique number prior to being placed into service, assigned a calibration cycle based on manufacturers recommendation or historical knowledge, and labeled showing the calibration status.

**3.6.3** Placed into service only after having accuracy verified or a certificate of calibration included with the item.

**3.6.4** Calibrated according to manufacturer's calibration specifications and procedures (if available), otherwise to established Management System Procedures or Work Instructions based on the manufacturer's specifications. Equipment will be calibrated and adjusted against equipment having a traceable relationship to nationally recognized standards, such as the National Institute of Standards and Technology (NIST) or equivalent.

3.6.4.1 Where certified calibration standards do not exist, calibration methods used will be documented.

**3.6.5** Documented to show the details of equipment, identification number, frequency of calibration, calibration due date, calibration method, calibration source (in-house, equipment supplier or calibration service), traceable certified calibration standard, acceptance criteria, equipment calibration history, and any action taken when results were not acceptable.

3.6.5.1 Records of calibration certificates accompanying new equipment and from subsequent calibrations by external sources shall be maintained.

3.6.5.2 The data generated from the internal calibration program or supplied from an approved calibration service supplier will be used to adjust any equipment calibration frequencies, as necessary.

**3.6.6** Verified for the required precision prior to use between the specified calibration frequency.

**3.6.7** Removed from service when found to be damaged, questionable, or out of calibration, with the degree of the out of calibration condition to be assessed. Previous inspection results will be verified, and any product found to be questionable shall be reviewed prior to release.
The equipment shall not be returned to service until calibration is verified.

**3.6.8** Used, handled, and stored in locations where: environmental conditions are suitable, protection from adjustments that would invalidate calibration (if necessary), and accuracy/fitness for use is maintained.