# Change History

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<td>8/22/06</td>
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<td>Revisions to complement and be consistent with QMS procedures</td>
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<td>B</td>
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<td>Revisions after BSI Audit to detail permissible exclusions; fix typos; add Appendix A</td>
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<td>C</td>
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<td>Updated the “Proprietary and Confidential” statement</td>
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<td>8/15/12</td>
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<td>Update to Hart’s current processes and procedures</td>
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<td>D.01</td>
<td>1/4/2013</td>
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<td>Align document revision numbering as stated in the Hart’s Document Control process</td>
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Statement of Policy

Hart InterCivic operates and maintains a documented QUALITY MANAGEMENT SYSTEM (QMS) implemented from the intentions defined in ISO 9001:2000 Quality Management Systems – Requirements.

The requirements of the QUALITY MANUAL extend to all employees who have responsibility for implementing and maintaining the procedures detailed or referenced.

The SENIOR STAFF with executive responsibility has approved the QUALITY MANUAL for issue and implementation within Hart InterCivic.

All Hart InterCivic employees are given the responsibility and authority to identify and resolve problems, and to control further processing of potentially affected product including preventing shipment of potentially non-conforming products, until satisfactory corrective action has been taken.

This QUALITY MANUAL is the property of Hart InterCivic and shall not be copied in whole or in part without written permission of the SENIOR STAFF.

Hart’s Quality Statement

“Hart InterCivic is committed to consistently providing high quality products and services for its customers through adherence to its established Quality Management System, complying with customer, statutory and regulatory requirements, and a commitment to continual improvement.

Hart InterCivic is committed to the capability, integrity, and the security of our product development process as well as the capability, integrity, and security of Hart Products.”
1 INTRODUCTION

Hart InterCivic designs, develops, integrates, and oversees the contract manufacturer of government solutions, including records and election management applications, election systems software and hardware products that improve, or make possible, cost effective government processes.

2 SCOPE

The QUALITY MANUAL is an “executive summary” of the Quality Management System (QMS) that demonstrates Hart InterCivic's capability to safely and effectively design, develop, integrate, publish and oversee the contract manufacturer of government solution products. The QMS covers all internal operations, and the control of external operations, required to meet the requirements specified in the Statement of Policy and customer and product requirements.

3 DEFINITIONS

Please see Terminology for standard definitions.

4 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

Hart InterCivic has established, documented, implemented and maintained a QMS in accordance with the applicable requirements of the Standards and regulations identified in the Statement of Policy. The QMS includes:

- identification of processes needed for the QMS and their application through the organization;
- determining the sequence and interaction of these processes;
- determining criteria and methods needed to ensure that both the operation and control of these processes are effective;
- ensuring the availability of resources and information necessary to support the operation and monitoring of these processes;
- monitoring, measuring and analysis of these processes, and
- implementing actions necessary to achieve planned results and maintaining the effectiveness and continual improvement of these processes.

These processes are managed in accordance with the QMS and the requirements of those Standards and regulations. Any processes that are outsourced are appropriately controlled and identified within the QMS.

Hart InterCivic's CHANGE CONTROL BOARD is informed of any major changes in the QUALITY SYSTEM.
4.2 QMS Process Overview

Hart InterCivic – Main Process Flowchart

Processes with red background depict outsourced processes.

4.3 Documentation Requirements

4.3.1 General

Hart InterCivic has established QMS documentation that includes:

- a documented statement of Quality Policy and quality objectives;
- a QUALITY MANUAL;
- procedures, forms, work instructions, specifications, etc. to meet the Quality Policy, quality objectives, customer and product requirements;
- records to demonstrate conformance to specified requirements and effectiveness of the QMS; and
- any other documentation specified by national or regional regulations.

A PRODUCT RECORD is established and maintained for each product that either contains or identifies QMS DOCUMENTS defining product specifications and quality management system requirements. These QMS DOCUMENTS define, if applicable, the development process, installation and servicing.
4.3.2 Control of Documents

Procedures are established and maintained to control QMS DOCUMENTS, including EXTERNAL DOCUMENTS. QMS documents can be in the form of any type of media such as hard copy or electronic media. Controls ensure that documents remain legible and readily identifiable at all times.

QMS DOCUMENTS are reviewed and approved for adequacy by authorized personnel prior to issue. Changes to controlled QMS DOCUMENTS are reviewed, approved and issued in accordance with current procedures. The designated functions/organizations have access to pertinent background information with which to base their review and approval. Approved changes are communicated to the appropriate personnel in a timely manner.

Controls ensure that pertinent revisions of appropriate QMS DOCUMENTS are available on the network to personnel or locations where operations are performed. Obsolete QMS DOCUMENTS retained for legal and/or knowledge preservation purposes are suitably identified.

Obsolete QMS DOCUMENT retention times are established in the RECORDS RETENTION MATRIX.

Records of document changes are maintained by Hart’s Product Lifecycle Management process, Software Versioning process, and Product Documentation processes.

4.3.3 Control of Records

Procedures are established and maintained for the identification, storage, protection, retrieval, retention and disposition of QUALITY RECORDS. QUALITY RECORDS are maintained to demonstrate conformance to specified requirements and effectiveness of the QMS.

QUALITY RECORDS are captured and stored electronically whenever possible to be readily retrievable. Hardcopy QUALITY RECORDS are legible, and are stored in facilities that provide a suitable environment to minimize damage, deterioration and loss.

QUALITY RECORD retention times are established in the RECORDS RETENTION MATRIX.

5 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

Hart InterCivic SENIOR STAFF is committed to the development and implementation of the QMS, and maintaining and continually improving its effectiveness by:

- communicating to employees the importance of meeting customer, statutory and regulatory requirements;
- observing the Quality Policy;
- ensuring that quality objectives are established;
- conducting management reviews; and
- ensuring that resources are available as necessary.

5.2 Customer Focus

Procedures are established and maintained for the determination of customer and product requirements, to ensure that these requirements are met and that customer satisfaction is maximized.
5.3 Quality Policy

Hart InterCivic’s SENIOR STAFF has developed and agreed upon the following policy for quality and information security that is understood, implemented and maintained by all employees:

“Hart InterCivic is committed to consistently providing high quality products and services for its customers through adherence to its established Quality Management System, complying with customer, statutory and regulatory requirements, and a commitment to continual improvement.

Hart InterCivic is committed to the capability, integrity, and the security of our product development process as well as the capability, integrity, and security of Hart Products.”

The Quality Policy is posted within the Hart InterCivic facility.

5.4 Planning

5.4.1 Quality Objectives

Hart InterCivic SENIOR STAFF defines and documents quality objectives. These include, but are not limited to, management review quality objectives and customer design requirements. Quality objectives are consistent with the Quality Policy.

5.4.2 Quality Management System Planning

Quality planning is performed to define and document how quality requirements and objectives are met. This includes, but is not limited to, the QUALITY MANUAL and Procedures, product realization planning, supplier evaluation, and product documentation.

The generation of QUALITY RECORDS to provide objective evidence of compliance is an integral part of the quality planning process.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Hart InterCivic SENIOR STAFF defines, documents and communicates employee responsibility and authority in job descriptions that are structured within an organization chart as presented in Figure 2: Hart InterCivic Organization Structure.

![Hart InterCivic Organization Chart Title](image)

CEO  President  CFO

Business Development  Vice President, Development  Sales and Marketing

Research and Development  Quality Administration and Software Quality Assurance  Operations Production Support

Figure 1: Hart InterCivic Organization Structure
Primary functional area responsibilities are provided in Table 1: Functional Area Primary Responsibilities.

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<tr>
<th>Functional Area</th>
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<tr>
<td>Sales and Marketing</td>
<td>Market definition and profile analysis, product planning, requirements development, product life cycle management, customer service, advertising and sales, pricing, communications, and POST-MARKET SURVEILLANCE.</td>
</tr>
<tr>
<td>Operations and Production Support</td>
<td>Process development and documentation, product technical support, sustaining engineering and production support, equipment maintenance and calibration, purchasing, MATERIAL control, shipping and receiving, and COMPLAINT investigation.</td>
</tr>
<tr>
<td>Quality Administration and Software Quality Assurance</td>
<td>QUALITY MANAGEMENT SYSTEM development and management, incoming INSPECTION, document change processing, national standards representation, product compliance, COMPLAINT administration, product surveillance and field actions.</td>
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<tr>
<td>Research and Development</td>
<td>New product and technology development, product planning and release management, hardware and software design and development, product certification and approvals, COMPLAINT investigation, research and reliability engineering.</td>
</tr>
<tr>
<td>Administration</td>
<td>General and network administration, facilities management and financial activities.</td>
</tr>
<tr>
<td>All Functions</td>
<td>Job descriptions and training record retention, recruiting, hiring and co-worker relations, and information security.</td>
</tr>
</tbody>
</table>

Table 1: Functional Area Primary Responsibilities

When an employee is not available for signature, the employee’s direct supervisor has signing authority in the employee’s absence.

5.5.2 Management Representative

The specific responsibilities of the Management Representative are:

- ensuring that processes needed for the QMS are established, implemented and maintained;
- reporting to SENIOR STAFF on the performance of the QMS and any need for improvement, and
- ensuring the promotion of awareness of regulatory, customer and product requirements throughout the organization.

5.5.3 Internal Communication

Hart InterCivic SENIOR STAFF ensures that communication processes are established, and that communication regarding QMS effectiveness occurs. These communication processes may include, but are not limited to meetings, project status reports, the company website, the CAPA process, etc.
5.6 Management Review

5.6.1 General

Hart InterCivic SENIOR STAFF reviews the suitability, adequacy and effectiveness of the QMS at least annually. During the reviews, quality objectives are defined and documented in support of the Quality Policy, and progress toward achievement is evaluated and tracked. Hart InterCivic SENIOR STAFF assigns responsibility for tracking and reporting on quality objectives.

Records of management reviews are maintained as QUALITY RECORDS.

5.6.2 Review Input

Management review agenda items to be reviewed annually include, but are not limited to:

- Internally generated data, process and product quality trends, NONCONFORMING MATERIAL reports (NMRs), corrective and preventive action status, previous management review minutes, recommendations for QMS improvement, supplier issues and quality performance measures; and
- Externally generated data such as customer feedback, service reports, field information, regulatory changes and other surveillance data that may affect the QMS.

5.6.3 Review output

Management review minutes are generated to document management decisions and actions which include, but are not limited to:

- QMS process improvements;
- customer requirement improvements to enhance customer satisfaction; and
- resource requirements.

6 RESOURCE MANAGEMENT

6.1 Provision of Resources

Adequate resources are determined and provided to:

- meet and enhance customer satisfaction by meeting customer and product requirements.

6.2 Human Resources

6.2.1 General

Employee competency is determined based on education, skills, background, training, and/or experience, as required by job descriptions.

All individuals have the education, training, skills and/or experience required to perform their job function unsupervised. Individuals who have not yet completed the minimum job requirements must work under the supervision of a trained employee.

If the work of a contractor or consultant affects the QMS and is unsupervised and/or not reviewed by an employee, a job description and training record is maintained for that contractor or consultant. If the work is supervised and/or reviewed by an employee, the employee is
responsible for the work and a job description and training record is not required for the contractor or consultant.

6.3 **Work Environment**

The work environment at Hart InterCivic is determined and managed to ensure that customer, safety, and product requirements are successfully fulfilled.

Procedures and requirements are established and maintained, if necessary, for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions if work environment conditions can have an adverse effect on product quality.

All personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person.

Records for qualified processes, equipment and personnel are maintained.

7 **PRODUCT REALIZATION**

7.1 **Planning of Product Realization**

Procedures are established and maintained for product realization planning activities to ensure that customer and product requirements are met. As part of the product realization planning activities, the following are determined:

- product quality objectives and requirements
- necessary processes, documents and resources specific to the product
- verification, validation, monitoring, inspection and test activities specific to the product
- product acceptance criteria

Records of product realization activities are maintained.

7.2 **Customer-Related Processes**

7.2.1 **Determination of Requirements Related to the Product**

The Hart Product Management team is responsible for managing the process that determines customer and product requirements, stated and unstated, necessary in the development of its products.

7.2.2 **Review of Requirements Related to the Product**

The Hart Product Management team is responsible for managing the review of requirements related to its products prior to the commitment to supply a product to the customer.

7.2.3 **Customer Communication**

Effective arrangements for customer communications are determined and implemented with customers regarding the following:

- product information;
- enquiries, contracts or order handling including amendments;
- customer feedback, including customer complaints; and
- field actions.
7.3 Design and Development

7.3.1 Design and Development Planning

Procedures are established and maintained to plan and control product and process design and development activities.

Hart InterCivic implements a stage gate design and development process that guides concurrent development of the product and the associated production processes and support services. A cross-functional project team led by a Project or Program Manager executes projects within the process and Hart InterCivic senior staff reviews, analyzes and approves the project throughout the stage gate process.

Project plans are established and maintained that describe the design and development activities and define responsibility for their implementation. Design and development activities are assigned to qualified personnel equipped with adequate resources. Project plans are reviewed, updated, and approved as the design and development evolves.

Project management using cross-functional teams requires organizational and technical interfaces between various functional departments involved in design and verification activities. These interfaces are identified in the project plan.

7.3.2 Design and Development Inputs

Procedures are established and maintained to ensure that product requirements are appropriate, address functional, performance, safety requirements, risk management, and project impact is well understood and agreed upon by major stakeholders.

A review process for addressing incomplete, ambiguous, or conflicting requirements is provided.

The products requirements are reviewed and approved by designated individuals and include the date and the person(s) approving the document.

7.3.3 Design and Development Outputs

Procedures are established and maintained to ensure that design output meets design input requirements for design and development, provide appropriate information for purchasing, production and for service provision, contains or references acceptance criteria, conforms to appropriate regulatory requirements and identifies those design characteristics that are crucial to safe, reliable, and proper functioning of the product. Design outputs are established and maintained in a form that enables verification against design and development inputs.

The product record, verification and validation results, when necessary the product Technical Data Package, and the declaration of certification, comprise the design outputs that establish the specifications and procedures of the finished product, and show compliance with the product requirements.

Design outputs are reviewed and approved prior to release.

7.3.4 Design and Development Review

Procedures are established and maintained to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the product’s design development. The procedures ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed, as well as specialists or third parties such as suppliers where appropriate. Appropriately skilled individuals are assigned to participate in the design reviews.

Records of design reviews and any necessary actions are maintained.
7.3.5 Design and Development Verification

Procedures are established and maintained for design verification at appropriate stages of the design to ensure that the design stage output meets the design stage input requirements.

Records of verification activities and any necessary actions are maintained.

7.3.6 Design and Development Validation

Procedures are established and maintained for design validation to ensure that product conforms to defined user needs and intended uses. Design validation is performed in accordance with the project plan, under defined operating conditions and on initial production units or their equivalents.

Design validation activities are successfully completed prior to the distribution of product.

Records of validation activities and any necessary actions are maintained.

7.3.7 Control of Design and Development Changes

The prerelease section of the Document Controls procedure is used for the review and approval of design changes prior to implementation.

Records of design changes and any necessary actions are maintained.

7.3.8 Design Transfer

The Document Controls procedure is used for design transfer to ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications.

Records of design transfer activities and any necessary actions are maintained.

7.3.9 Design History File

A SharePoint Project File (SPF) or design history file is established and maintained for each product or project. The SPF contains or references the records necessary to demonstrate the design was developed in accordance with the approved project plan and the requirements of the Quality Manual.

7.4 Purchasing

7.4.1 Purchasing Process

Procedures are established and maintained to ensure purchased or otherwise received products and services conform to specified requirements. The requirements, including quality requirements, which suppliers, subcontractors and consultants must meet, are established and maintained.

Procedures are established and maintained to evaluate and select suppliers based on their ability to meet specified requirements, including quality requirements, and define the type and extent of control exercised over the product, services, suppliers, subcontractors, and consultants based on the evaluation results. Criteria for selection, evaluation and maintenance are established.

7.4.2 Purchasing Information

Purchasing information is established and maintained that clearly describes or references the specified requirements, including quality requirements, for purchased MATERIAL. The purchasing information includes a description of the MATERIAL ordered, and information on quantity,
delivery, test, and specification and performance requirements as necessary. Purchasing documents are reviewed and approved for adequacy prior to release.

Records of purchasing information are maintained.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

7.5.1.1 General Requirements

Procedures are established and maintained to plan and control any service activities under controlled conditions to ensure that product and equipment conforms to its specifications. Controlled conditions may include, but are not limited to product characteristics information, work instructions (WIs), suitable equipment, monitoring and measuring devices, process monitoring and/or measurement, release, delivery and post-delivery activities and defined operations for labeling and packaging.

Procedures are also established and maintained to provide direction and control of all external contract manufacturing to ensure that product conforms to its specifications.

DEVICE HISTORY RECORDS (DHRs) and/or LOT HISTORY RECORDS (LHRs) are established and maintained by the party responsible for the manufacture of each product or batch of products to provide evidence the product(s) was manufactured according to the PRODUCT RECORD, and identifies the amount manufactured and amount approved for distribution.

7.5.1.2 Specific Requirements

7.5.1.2.1 Installation Activities

Procedures are established and maintained for installing and verifying the installation of the products, component devices and software applications. These procedures include acceptance criteria.

If installation is performed other than by the organization or its authorized agent, the organization provides documented requirements for installation and verification.

Records of installation and verification performed by the organization or its authorized agent are maintained.

7.5.1.2.2 Servicing Activities

Procedures are established and maintained for servicing, if necessary. These procedures include documented procedures, work instructions and reference materials and reference measurement procedures, as necessary, for performing servicing activities and verifying that they meet the specified requirements.

Records of servicing activities carried out by the organization are maintained.

7.5.2 Identification and Traceability

7.5.2.1 Identification

Procedures are established and maintained for identifying product during all stages of product realization to prevent mix-ups. Serial or lot numbers are used to identify each unit or lot of components that Hart InterCivic chooses to track. The procedure to assign serial and/or lot numbers helps facilitate corrective action.

Records of serial and lot numbers are maintained in the DHR.
7.5.2.2 Traceability

Procedures are established and maintained for identifying product after product realization and during distribution. Serial or lot numbers are used to identify each individual or batch of finished products. The procedure to assign serial and/or lot numbers helps facilitate corrective action.

Records of serial and lot numbers are maintained in the DHRs and LHRs.

7.5.2.3 Status Identification

Procedures are established and maintained for identifying product status during all stages of product realization, installation and servicing to ensure that only product compliant with published specifications is distributed.

7.5.3 Customer Property

If necessary, procedures are established and maintained for handling customer property, including intellectual property, with care while it is within Hart InterCivic’s facility. Customer property is identified, verified, protected and safeguarded. If customer property is lost, damaged or otherwise found to be unsuitable for use, the customer is notified and records are maintained.

7.5.4 Preservation of Product

Procedures are established and maintained for identification, handling, packaging, storage, protection, preservation and delivery of purchased and finished product to preserve product conformity to specified requirements.

If purchased and finished product has a limited shelf life, procedures are established and maintained for special handling and control.

Records of special storage conditions, if necessary, are maintained.

8 ANALYSIS AND IMPROVEMENT

8.1 General

Procedures are established and maintained for monitoring, measurement, analysis and improvement processes to:

- demonstrate product conformity;
- ensure QMS conformity; and
- maintain and continually improve QMS effectiveness.

These procedures may include, if necessary, the identification and application of statistical techniques.

8.1.1 Customer Feedback and Satisfaction

Procedures are established and maintained for monitoring customer perception and whether the product has met customer requirements. Potential sources of customer data may include, but are not limited to customer complaints, customer and user surveys, market needs, competitive information and POST-MARKET SURVEILLANCE activities.

8.2 Control of Nonconforming Material

Procedures are established and maintained to ensure that product that does not conform to requirements is prevented from unintended use or distribution. NONCONFORMING MATERIAL is
identified, segregated, documented, evaluated and removed from use. Appropriate functional areas are notified of NONCONFORMING MATERIAL.

Procedures are established and maintained for the responsibility, review and disposition of NONCONFORMING MATERIAL. When required, the proposed use or repair of product that does not conform to specified requirements is reported for concession to the customer or relevant authority. NONCONFORMING MATERIAL is only accepted by concession if all regulatory requirements are met.

Rework of NONCONFORMING MATERIAL, if necessary, is performed according to documented rework instructions reviewed and approved by the same functions as the original work instructions. As part of the review and approval process, a determination of any adverse effect of the rework upon product is made and documented. Reworked product is reevaluated as required by the product documentation.

When NONCONFORMING MATERIAL is detected after distribution, action is taken appropriate to the effects, or potential effects, or the nonconformity including when necessary, field actions.

Records of NONCONFORMING MATERIAL activities, including the individual(s) authorizing disposition of NONCONFORMING MATERIALS, are maintained.

8.3 Analysis of Data

Procedures are established and maintained to determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the QMS, and to evaluate where continual improvement of the QMS may occur. Data analysis provides information relating to customer feedback and satisfaction, conformity to product requirements, process and product characteristics and trends, and suppliers.

Records of the results of data analysis are maintained.

8.4 Improvement

8.4.1 General

Procedures are established and maintained to identify and implement changes necessary to maintain the effectiveness of the QMS, and to continually improve the effectiveness of the QMS, through the use of the Quality Policy, quality objectives, audit results, data analysis, corrective and preventive actions and management review.

Procedures are established and maintained to perform field actions when deemed necessary to ensure the appropriate use of Hart InterCivic’s products by customers.

Procedures are established and maintained for administration, determination and investigation of customer complaints, including the evaluation of each customer complaint for adverse events. If an adverse event is noted, appropriate regulatory agencies are notified.

If customer complaint investigations require contributions from outside Hart InterCivic, relevant information is exchanged as necessary. Complaints not followed by corrective and/or preventive action have a documented rationale.

Records of complaint administration, determination and investigation are maintained.

8.4.2 Corrective and Preventive Action

Procedures are established and maintained to eliminate the causes of existing and potential nonconformities in order to prevent recurrence. Corrective and preventative actions taken to
eliminate causes of nonconformities are appropriate with regards to the problems and risks that may be encountered.

The procedure defines requirements for reviewing existing and potential nonconformities, investigating the causes of the nonconformities, evaluating whether corrective or preventive action is needed to prevent reoccurrence, determining and implementing needed corrective or preventive action including updating documentation if necessary, recording the results of investigation and corrective or preventive action, and reviewing the effectiveness of corrective or preventive action taken.
### Appendix A: HART QUALITY MANUAL MATRIX

<table>
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<tr>
<th>Quality Manual</th>
<th>Reference</th>
<th>Procedures/Documentation</th>
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<td>2.0 Scope</td>
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<td>Quality Manual</td>
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<td>3.0 Definitions</td>
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### Table 8.3 Control of Nonconforming Material

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### Table 8.4 Analysis of Data

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### Table 8.5.1 General

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