Allentown's Quality Vision is to be incredibly customer focused and thereby improve customer satisfaction, growth and profit for both our customers and our company.

This manual is a controlled document. Copies distributed to customers and employees are considered to be "Uncontrolled". For the most current update, contact the company's Quality Department.

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<tr>
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<th>Latest Revision Date</th>
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<td>To check on or receive a current revision of the Quality Manual, contact the Quality Assurance Supervisor at the address or phone number provided here.</td>
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<td>ABB Inc.</td>
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</table>
Quality Management System Authorization Signatures

The following signatures indicate that the Quality Manual has been approved by the ABB Inc. Allentown site.

<table>
<thead>
<tr>
<th>Signature:</th>
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<tbody>
<tr>
<td>Dennis A. Haring</td>
<td>Dennis F. Batovsky</td>
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<tr>
<td>Approved - 03/25/2003 by Dennis A. Haring</td>
<td>Approved - 04/01/2003 by Dennis F. Batovsky</td>
</tr>
<tr>
<td>Title: QA Supervisor</td>
<td>Title: Quality Manager</td>
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</tbody>
</table>
The Substation Automation and Protection Group is committed to outrageous levels of customer service and quality. All employees strive to produce defect free products and are dedicated to continuous improvement of processes. Our Quality Objectives are determined by all employees and are approved, reviewed and maintained by the management team. Quality objectives are located in the Quality Plan.
Corporate Organization History and Background

POLICY:

PURPOSE:

To provide a brief overview of the Corporate Organization History and Background and the Protective Relay Operation.

RESPONSIBILITIES:

DESCRIPTION:

1889 Our roots go back to the founding of the Cutter Electric Company in Philadelphia, PA. This company originated the "Inverse Time Element" concept for circuit protection.

1927 The name I-T-E Circuit Breaker Company was adopted.

1968 The I-T-E Circuit Breaker Company merged with Imperial Eastman of Chicago, a fluid power components company, to form the I-T-E Imperial Corporation. The headquarters for this business resided in Springhouse PA.

1976 I-T-E Imperial corporation merged with Gould Incorporated, with headquarters in Rolling Meadows, Illinois.


1989 In February, Westinghouse Electric and Asea Brown Boveri entered into a joint venture known as Westinghouse ABB Power T&D Company.

1990 In January, ABB purchased the Westinghouse share to form the ABB Power T&D Company, Inc., with headquarters in Blue Bell, PA.

1998 In September the Power Automation and Protection Division of ABB Power T&D Company, Inc. became part of ABB Automation and was renamed the Substation Automation and Protection Division.

1999 In January we became part of ABB Automation Inc.

2002 In January we were renamed ABB Inc.

THE PROTECTIVE RELAY OPERATION:

1962 The Electronics Lab was formed by I-T-E at the Philadelphia plant as an engineering development group to design solid state relays.

1966 In August, the relay and control section was formed to produce and further develop a broad line of solid state protective relays.

1974 In February, the growing operation was moved to a larger facility in Horsham, PA.

1984 In June, the continued growth again required a move to larger facilities where we are now located near Allentown, PA.

1993 We became the headquarters for all Distribution Relay divisions in the US.

1995 We became the headquarters for all Distribution and Transmission Relay divisions in the US.

REFERENCE DOCUMENTATION:

None
List Of Abbreviations

POLICY:

PURPOSE:

To list the abbreviations commonly used in this manual.

RESPONSIBILITIES:

DESCRIPTION:

QAP        Quality Assurance Procedure
S.O.       Sales Order
IR         Incoming Rejection
EPL        Engineering Parts List
BOM        Bill of Material
P.O.       Purchase Order
ANSI       American National Standards Institute
NEMA       National Electrical Manufactures Association
NRC        Nuclear Regulatory Commission
NCMR       Non-conforming Material Report
PITs       Process Improvement Teams
ECR        Engineering Change Request
ECO        Engineering Change Order
CCRP       Customer Complaint Response Process
PIC        Product Integrity Committee
QMS        Quality Management System
FRY        First Run Yield
FPY        First Pass Yield
OOBA       Out of Box Audit

REFERENCE DOCUMENTATION:

None
Introduction

POLICY:

PURPOSE:
To introduce the Quality Assurance Manual and outline the intent of the Quality Assurance Program.

RESPONSIBILITIES:

DESCRIPTION:
This manual has been established to describe and demonstrate how the ABB Inc. Allentown site's Quality Assurance Program, currently in effect, complies with the requirements of NRC regulation 10CFR50 Appendix B, ANSI standard N45.2-1977 and ISO9001:2000.

The intent of the Quality Assurance Program is to provide assurance that our finished products and associated accessories perform and conform to all applicable specifications and drawings prior to shipment. The program also assures that all items will reach their destination in a condition ready for installation.

Uncontrolled copies of this Quality Assurance Manual are available to customers. Controlled copies are maintained by Quality Assurance. Holders of controlled copies (internal) will be notified of revisions and will be supplied revised copies from Quality Assurance.

REFERENCE DOCUMENTATION:
None
Purpose

POLICY:

PURPOSE:
To outline the purpose of the Quality Manual.

RESPONSIBILITIES:

DESCRIPTION:
The purpose of this manual is to present a description of the overall Quality Assurance Program and Quality Control System in effect within the ABB Inc. Allentown site.

It is company policy not to distribute detailed Quality Assurance Procedures outside the company. However, all detailed procedures will be made available for review at the time of a Quality Assurance program survey or audit.

The Quality Assurance Manual is augmented by the Quality Assurance Procedures. These are detailed procedures defining policy, and methods for Quality Assurance program implementation. These procedures relate to the criteria of 10CFR50 Appendix "B" and the ISO 9001:2000 standards.

REFERENCE DOCUMENTATION:
None
4.0 Quality Management System

POLICY:

PURPOSE:

To outline the Quality Management System used at ABB Inc. Allentown site.

RESPONSIBILITIES:

DESCRIPTION:

4.1 General Requirements:

Process Approach:

The ABB Inc. Allentown site takes a process approach to quality management. The status and adequacy of the Quality Assurance Program and Quality Manual is reviewed by the General Manager and his staff. The Quality Assurance Program is reviewed regularly by several means, some of which include:

Management Review - Review of Quality Policy and objectives (quarterly meetings) by the management staff and the Quality Assurance Supervisor. The management staff is ultimately responsible for:
  a) identifying the processes needed for the quality management system and their application throughout the ABB Inc. Allentown site,
  b) determining the sequence and interaction of processes,
  c) determining criteria and methods needed to ensure that both the operation and control of processes are effective,
  d) ensuring the availability of resources and information necessary to support the operation and monitoring of processes,
  e) monitoring, measuring and analyzing processes and
  f) implementing actions necessary to achieve planned results and continual improvement of processes.
Quality Council - Review of audit results, inspections, warranty information and a review of both internal and external reported conditions perceived to be adverse to quality. Corrective action assignments and follow up are reviewed at each meeting. (meeting every 2 weeks).

Non-conformance Material Report Review (NCMR) - Review of rejected material with reports distributed to appropriate management or supervision for review and corrective action.

External Audits - Review of audit findings and corrective action identified from customer or supplier audits (as required).

Internal Audits - Review of audit findings and corrective action identified during internal Quality System audits.

Product Integrity Committee - Review of product performance reports (as required). Records of meeting minutes, documentation or any resulting Product Advisory Letters (PAL) are maintained in files in the QA department.

Training - Quality Assurance training for Supervisors is accomplished by seminars and, or on-the-job training to cover those aspects of Quality Assurance and Quality Control programs applicable to fulfilling their responsibilities. Quality Assurance and Quality Control training for persons performing quality functions is primarily accomplished by on-the-job training. A log of QA/QC personnel is maintained to provide evidence of personnel qualifications.

The ABB Inc. Allentown site may choose to outsource processes that affect product conformity with requirements. If these types of processes are outsourced, the ABB Inc. Allentown site will oversee and maintain control over such processes.

It is the direction of the management to establish, implement and continually maintain an effective quality management system that complies with the ISO 9001:2000 international standard.

The QMS is implemented in practice by a process management approach. This pictorial representation and the table below depicts how the organization intends to translate requirements of the ISO 9001:2000 into its business processes.

**ISO 9001:2000**

*Model of a Process-based Quality Management System*
### ISO 9001:2000

#### ABB Business Processes (Interactions of Activities)

<table>
<thead>
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<th>ISO 9001:2000</th>
<th>ABB Business Processes (Interactions of Activities)</th>
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<td>Customer Requirements</td>
<td>Sell, Project/Order Execution</td>
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<td>Management Responsibility</td>
<td>Commitment to develop business processes</td>
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<td>Product Realization</td>
<td>Project execution, product delivery, supply and demand chain management</td>
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<td>Measurement, analysis and improvement</td>
<td>Develop performance indicators, nonconformance control, corrective and preventive actions, Internal audit and reviews</td>
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<tr>
<td>Continual Improvement of the QMS</td>
<td>Periodic review of the QMS and processes</td>
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<tr>
<td>Customer Satisfaction</td>
<td>Sales process, project execution, service and support, CCRP, SupportLine, survey process</td>
</tr>
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</table>

### 4.2 Documentation:

#### 4.2.1 General:

The quality system documentation includes the following:

**Quality Manual:**
Describes the scope of the Quality Management System at the ABB Allentown site.

**Quality Policy:**
Describes the organization's Quality Policy and provides a framework for establishing and reviewing quality objectives.

**Quality Assurance Procedures (QAPs):**
A compilation of procedures and instructions for all aspects of quality assurance programs, 10CFR 50 Appendix B, ISO 9001, quality control, test and inspection.

**Engineering Procedures (ESPs):**
Procedures for development of new products, design control, etc., including documentation for product qualification for Class 1E applications, mechanical and electrical standards.
Manufacturing Procedures (MSPs):
Procedures for manufacturing, process control, maintenance, production planning, etc. for production personnel. (RC 3000) - Detailed test and calibration procedures for all products to assure conformance to published specifications.

Supply Management Procedures (SMPs):
Procedures for procurement and control of purchased material.

Order Entry/Contract Review Procedures (MSPs):
Procedures for order entry and contract review for special customer requirements.

Quality Records:
Records that provide evidence of conformity to requirements and to the effective operation of the quality management system.

4.2.2 Quality Manual:

The Quality Manual includes the following:
a) the scope of the quality management system, including details of and justification for any exclusions,
b) the documented procedures established for the quality management system, or reference to them,
c) a description of the interaction between the processes of the quality management system.

Scope:

The scope of the Quality Management System in effect at the ABB Inc. Allentown site includes ISO 9001:2000 and 10CRF50 Appendix B and applies to the design, manufacture and application of protective relays and substation control equipment.

4.2.3 Control of Documents:

The procedures for control and distribution of documents (drawings, procedures, etc.) are intended to assure that the proper information is available when and where it is needed. The procedures provide an organized means of controlling changes to existing documents as well as the introduction of new documents. These procedures define the controls needed to:
a) approve documents for adequacy prior to issue,
b) review and update as necessary and re-approve documents,
c) ensure that changes and the current revision status of documents are identified,
d) ensure that relevant versions of applicable documents are available at points of use,
e) ensure that documents remain legible and readily identifiable,
f) ensure that documents of external origin are identified and their distribution controlled and
   g) prevent the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose.
The primary example of document control is with engineering designs, where engineering documentation is controlled according to the Engineering Standard Practices. Changes to existing designs and new designs are reviewed by the appropriate members of the organization to guide the engineering work being done. The Engineering Action Request (ECR) and Engineering Change Order (ECO) forms facilitate the process of engineering document control and provide for documentation of the change process. As documents are revised or created, they are again reviewed and after acceptance distributed throughout the organization.

Methods have been defined for control and tracking of Industry Standards used as reference documents by Design Engineering including ANSI, IEEE, UL, etc.

The individual departments of the organization are responsible for the proper maintenance of latest revision files, etc. as may be appropriate for the department.

Instructions, Procedures and Drawings:

Activities affecting quality are defined by documented instructions, procedures or drawings.

Management and supervisory personnel are responsible for assuring that activities affecting quality are prescribed in a documented form appropriate to the circumstances. The activity may be prescribed in job specifications, work instructions, drawings, manufacturing material, route cards, planning sheets, procedures, manuals, or any form that provides an adequate description of the activity.

Quantitative criteria, such as dimensions, electrical measurements, tolerances and operating limits; and where required, qualitative criteria such as workmanship samples are used to determine satisfactory work performance and quality compliance.

These procedures will be made available for review during a Quality Assurance Survey or a Quality Assurance Audit. It is management policy not to distribute these procedures outside the Company for review or approval.

Quality Assurance personnel review procedures and proposed changes to procedures, prior to their being approved and released.

4.2.4 Control of Records:

Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure (QAP 17.1) has been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

Quality Assurance and Quality System Records are maintained and stored in a manner and area that provides for normal protection from deterioration, fire, or flooding.
It is the responsibility of the area manager or supervisor to maintain the records in his/her area and review his/her files once each year for disposition of records.

Quality Assurance data and records for the products are submitted to the customer in accordance with their purchase order requirements. For Class 1E products a copy of this information is placed in the QA order file. If a customer desires to be notified prior to the destruction of these records, a note to this effect can be attached to the sales order file.

Class 1E records have a 40 year retention as identified in the Quality Assurance record index file.

Quality Assurance records other than Class 1E records do not require long term storage and protection. These records are retained for internal use such as warranty records, etc. The product itself carries permanent inspection and test verification in the form of Quality Assurance stamps. Other records such as sales orders, certificates, and/or required test data are delivered to the customer with the shipment of material as requested.

**REFERENCE DOCUMENTATION:**

- QAP 2.1 -- QUALITY ASSURANCE PROGRAM
- QAP 2.2 -- QUALITY PROGRAM REQUIREMENTS
- QAP 2.3 -- QA TRAINING
- QAP 2.4 -- ANNUAL REVIEW OF QUALITY ASSURANCE PROCEDURES
- QAP 6.1 -- PREPARATION AND CONTROL OF QUALITY ASSURANCE PROCEDURES
- QAP 6.2 -- ENGINEERING RELEASE PROCESSING
- QAP 6.3 -- QUALITY ASSURANCE MANUAL - CONTROLLED COPIES
- QAP 6.4 -- CONTROL OF INDUSTRY STANDARDS REFERENCE DOCUMENTS
- QAP 17.1 -- RETENTION AND STORAGE OF QUALITY RECORDS
- ESP-201 -- ENGINEERING CHANGE DATABASE
- ESP-202 -- ENGINEERING DRAWING RELEASE
- ESP-203 -- ENGINEERING DRAWING RELEASE
5.0 Management Responsibility

POLICY:

PURPOSE:

This section outlines the responsibilities of the management team at the ABB Inc. Allentown site.

RESPONSIBILITIES:

DESCRIPTION:

5.1 Management Commitment:

Top management is committed to the development and implementation of the quality management system and to continually improving its effectiveness through the following:

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

b) establishing the quality policy and quality objectives,

c) conducting management reviews and ensuring the availability of resources.

5.2 Customer Focus:

Top management is responsible for ensuring that customer requirements are determined and are met with the aim of enhancing customer satisfaction. The ABB Inc. Allentown site recognizes the fact that partnering (developing long term quality relationships with customers) is the best way to ensure customer satisfaction and get repeat business from our customers. The management team regularly contacts customers directly to maintain two way communication with our customers. The object of this two-way communication is to listen to customer complaints, concerns and requirements with the intent of providing solutions and for promoting our product, service, features and enhancements.

5.3 Quality Policy:

Top Management ensures that the Quality Policy:

a) is appropriate to the purpose of the organization,
b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
c) provides a framework for establishing and reviewing quality objectives,
d) is communicated and understood within the organization, and
e) is reviewed for continuing suitability.

See page five of this manual to read the Quality Policy.

5.4 Planning:

5.4.1 Quality Objectives:

The management team ensures that quality objectives, including those needed to meet requirements for product are established at relevant functions and levels of the organization. The quality objectives are measurable and consistent with the quality policy.

5.4.2 Quality Management System Planning:

The management team is responsible for the planning of the quality management system with the intent of meeting system requirements and quality objectives. The management team is also responsible to ensure that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, Authority and Communication:

5.5.1 Responsibility and Authority:

The ABB Inc. Allentown site Organization Chart illustrates that the Quality representative functions have direct access to responsible management, where appropriate quality assurance corrective actions can be taken. The Quality functions are independent and separate from manufacturing operations. The Quality Assurance Supervisor is responsible for maintaining the Quality System. See page 11 of this manual to view the Organization Chart.

The Quality Assurance Organization is responsible for establishing and monitoring the Quality Assurance Program for the ABB Inc. Allentown site. This scope includes those functions that directly affect product quality, the related product processes and the associated product information. In addition to assuring that the Division is properly employing the correct quality procedures for product and process quality, the Quality Assurance Organization is also responsible for challenging our quality programs and assumptions for the purpose of improving both our quality performance and expectations for the benefit of our customers and ourselves. Any individual in the organization who detects a condition that may compromise product quality is expected to stop the process and seek immediate assistance to analyze and correct the condition.
Personnel requirements and qualifications are specified in job descriptions and training requirements. Personnel job descriptions define responsibilities. Qualification of personnel is determined by management, with emphasis being placed on obtaining the maximum education and job related experience for the position. Personnel are evaluated periodically to review their qualifications and progress.

5.5.2 Management Representative:

The ISO 9001 Management Representative at this facility is the Quality Assurance Supervisor. The Quality Assurance Supervisor reports directly to the Division Quality Manager on all quality issues. In his/her absence the Division Quality Manager will assume or delegate this responsibility.

The Quality Assurance Supervisor has responsibility and authority that includes:

a) ensuring that processes needed for the quality management system are established, implemented and maintained,

b) reporting to top management on the performance of the quality management system and any need for improvement and

c) ensuring the promotion of awareness of customer requirements throughout the organization.

5.5.3 Internal Communication:

A number of Internal Communication processes and mediums are used within the organization to ensure that communication takes place regarding the effectiveness of the quality management system. Some of these include:

a) Quarterly Management Review meetings,

b) Quarterly Business Status meetings,

c) Lotus Notes (Internal E-Mail communication system),

d) Team meetings and

e) Manufacturing performance measures and process charts

5.6 Management Review:

5.6.1 General:

Two management review formats are used at the ABB Inc. Allentown site. The Quality Council which meets approximately every 2 weeks and Management Reviews which take place quarterly. Reviews include assessing opportunities for improvement and the need for changes to the quality system, including the quality policy and quality objectives.

5.6.2 Review Inputs:

Review inputs include the following:

a) Results of internal and external quality audits - (Quality Council)

b) Customer feedback - (Quality Council, Management Reviews)

c) Process performance and product conformity (Quality Council, Management Reviews)
d) Status of preventive and corrective actions (Quality Council)
e) Follow-up actions of previous management reviews (Quality Council, Management Reviews)
f) Changes that could affect the quality management system (Management Reviews)
g) Recommendations for improvement (Quality Council, Management Reviews)

5.6.3 Review Output:

Review output includes any decisions and actions related to:
a) Improvement of the effectiveness of the quality management system and its processes (Management Reviews)
b) Improvement of product related to customer requirements (Quality Council) and
c) Resource needs (Quality Council, Management Review)

REFERENCE DOCUMENTATION:

QAP 2.1 -- QUALITY ASSURANCE PROGRAM
QAP 16.2 -- PRODUCT RELIABILITY COMMITTEE (PRC) CORRECTIVE ACTION
QAP 17.1 -- RETENTION AND STORAGE OF QUALITY RECORDS
QAP 20.2 -- STATISTICAL MEASURES
6.0 Resource Management

POLICY:

PURPOSE:

This section outlines how the management of resources is handled at the ABB Inc. Allentown site.

RESPONSIBILITIES:

DESCRIPTION:

6.1 Provision of Resources:

The management staff determines and provides the resources needed to implement and maintain the quality management system and continually improve its effectiveness and to enhance customer satisfaction by meeting customer requirements.

Design, development, inspection, manufacturing and equipment resources are established by Development and Manufacturing Engineering to ensure that product quality requirements are maintained. Verification methods shall include product inspection, testing and monitoring of the product design to specifications, procedures and manufacturing workmanship standards.

6.2 Human Resources:

6.2.1 General:

Personnel performing work affecting product quality must be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, Awareness and Training:

Quality, Operations and Human Resources with input from other departments are responsible for:

a) determining the necessary competence for personnel performing work affecting product quality,
b) providing training or take other actions to satisfy these needs,
c) evaluate the effectiveness of the actions taken,
d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives and
e) maintain appropriate records of education, training, skills and experience.

Procedures are established for identifying training requirements and for providing scheduled training of all personnel performing activities that directly affect Quality.

The training requirements are accomplished by seminars, class room sessions, and on the job training. This training is designed to cover all aspects of the Quality Assurance Program and various workmanship standard procedures.

A list of Quality Assurance Personnel and qualification records are maintained in the QA Department. Job requirements and qualification are based upon appropriate education, training, experience and physical abilities. Job requirements are outlined in the Job Descriptions book maintained and located in the Human Resources Department.

Personnel files are maintained by the Human Resources Department. Personnel training/job certification records are maintained by the QA Department and/or department managers or supervisors.

6.3 Infrastructure:

Quality, Operations and Human Resources with input from other departments are responsible for determining, providing and maintaining the infrastructure needed to achieve conformity to product requirements. This includes buildings, workspace and associated utilities, process equipment (both hardware and software) and supporting services (transport and communication).

The manufacturing operations employed in the manufacturing of solid-state and microprocessor relays are all standard high quality industrial processes. No unique or special processes are in use at this location.

Controlled processes are used for the soldering of electronic components to printed circuit boards. This process is performed both with automatic soldering equipment (Wave Solder and SMT) and with hand soldering equipment. Procedures and controls have been established for both.

General machinery maintenance is scheduled daily, weekly and quarterly, etc. depending upon complexity and use of the machine.

6.4 Work Environment:

The work environment is determined and managed to achieve conformity to product requirements. Controlled processes are used in storage and handling of electro-static
discharge (ESD) sensitive parts and assemblies. Production and test equipment processes and procedures are documented and maintained.

**REFERENCE DOCUMENTATION:**

- QAP 2.3 -- QA TRAINING
- QAP 9.2 -- CONTROLLED PROCESSES
- QAP 20.1 -- EMPLOYEE TRAINING/JOBT CERTIFICATION
- QAP 9.1 -- CONTROL OF PROCESSES
7.0 Product Realization

POLICY:

PURPOSE:

This section outlines how product realization is conducted at the ABB Inc. Allentown site.

RESPONSIBILITIES:

DESCRIPTION:

7.1 Planning of Product Realization:

Product development teams plan and develop the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the quality management system. Product Development teams consist of representatives of each department relevant to the development of complete product. These departments include but are not limited to Finance, Supply Management, Development, Quality, Operations, Manufacturing, Marketing and Customer Support.

In planning product realization, product development teams determine the following as appropriate:

a) quality objectives and requirements for the product,
b) the need to establish processes, documents and provide resources specific to the product,
c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance,
d) records needed to provide evidence that the realization processes and resulting product meet requirements.

The output of this planning shall be in a form suitable for the method of operations at the ABB Inc. Allentown site.

7.2 Customer Related Processes:

7.2.1 Determination of Requirements Related to the Product:
Marketing (with input from Development and Quality) is responsible for determining:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
b) requirements not stated by the customer but necessary for specified or intended use, where known,
c) statutory and regulatory requirements related to the product and
d) any additional requirements determined by the ABB Inc. Allentown site.

### 7.2.2 Review of Requirements Related to the Product:

Marketing and the Marketing Channel Representative review the requirements related to the product. This review is conducted prior to our commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and ensures that:

a) product requirements are defined,
b) contract or order requirements differing from those previously expressed are resolved and
c) ABB Inc. has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review are maintained. Where the customer provides no documented statement of requirement, the customer requirements are confirmed by Marketing or the Marketing Channel Representative before acceptance. Where product requirements are changed, Marketing or the Marketing Channel Representative ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

The majority of the business at the ABB Inc. Allentown facility is for standard catalog items defined by specific catalog numbers for each product variation. All requests for quotation and orders received which are not based strictly upon published catalog numbers and documented pricing and selling policies are considered as having special requirements and are reviewed by a Marketing Department Application Engineer. The Application Engineer keeps records of the customer's inquiry and the resulting quotation.

The Marketing Channel Representative has the responsibility for interpreting the purchase order then keying and electronically transmitting the information to the appropriate division for production. The electronic transmission is reviewed by the division Order Entry Coordinator for accuracy of the information. When all parameters are met, the order is downloaded into the Division Internal Business System.

If the inquiry or order requirements call for a new product or a new non-trivial variation of an existing product, the Application Engineer informs and obtains approval of the Product Line manager. A new catalog number must be assigned to new product variations no later than the time of order entry into the business computer system at the ABB Inc. Allentown facility. The requirements for amendments and changes are documented by revision levels on customer purchase orders and internal shop orders.

### 7.2.3 Customer Communication:

**Quality Policy for: 7.0 Product Realization - Revision: 1**
Marketing, Quality and Customer Support determine and implement effective arrangements for communicating with customers in relation to:

a) product information,
b) enquiries, contracts or order handling, including amendments and
c) customer feedback, including customer complaints.

7.3 Design and Development:

The development of each design is according to the six development process phases:

1.0 Design Requirements
2.0 Design to Requirements
3.0 Implement Design
4.0 Verify Design
5.0 Validate Design
6.0 Product Launch

Each phase has a required set of inputs and a set of deliverables upon completion of the phase.

Development, Design control, component and material qualification procedures and specifications are described in the Engineering Standard Practices (ESPs).

Drawing approval, change control, and distribution are controlled by Engineering Standard Practices (ESPs) which detail a system of sign-offs for preparation, review, and approvals for all types of controlled documents.

Customer specifications for non-catalog models will be assigned new catalog numbers and will be added to the engineering design base through the Engineering Standard Practices.

7.3.1 Design and Development Planning:

Development is responsible for planning and controlling design and development of product. During the design and development planning, Development determines:

a) the design and development stages,
b) the review, verification and validation that are appropriate to each design and development stage and
c) the responsibilities and authorities for design and development.

The Program manager and Project Manager manages the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output is updated, as appropriate, as the design and development progresses.

7.3.2 Design and Development Inputs:

Inputs relating to product requirements are determined and recorded. These inputs include:
a) functional and performance requirements,
b) applicable statutory and regulatory requirements,
c) where applicable, information derived from previous similar designs and
d) other requirements essential for design and development.

The inputs are reviewed for adequacy. Requirements must be complete, unambiguous and not in conflict with each other. Design input requirements are contained in Marketing Requirement Specifications and includes customer requirements, applicable industry and regulatory standards.

The primary sources for design requirements are contained in the applicable UL and ANSI standards. Additional design criteria may be included in Engineering standards or procedures. As an example, Protective Relays' performance criteria are specified in ANSI C37.90 and C37.90.1. These standards define rating requirements, design test and production test requirements.

**7.3.3 Design and Development Outputs:**

The outputs of design and development process are provided in a form that enables verification against the design and development input and are approved prior to release. Design and development outputs must:

a) meet the input requirements for design and development,
b) provide appropriate information for purchasing, production and for service provision,
c) contain or reference product acceptance criteria and
d) specify the characteristics of the product that are essential for its safe and proper use.

**7.3.4 Design and Development Review:**

At suitable stages, systematic reviews of design and development are performed in accordance with planned arrangements:

a) to evaluate the ability of the results of design and development to meet requirements and
b) to identify any problems and propose necessary actions.

Participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions are maintained.

During the development of new products, or during an evaluation of significant engineering changes to existing products, design reviews will be conducted with qualified independent personnel, which may include Field Service, Marketing, Quality Assurance and others as required.

**7.3.5 Design and Development Verification:**

Verification is performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions are maintained.
The primary means of design verification for products is by means of analysis, simulation, development testing and qualification testing.

**7.3.6 Design and Development Validation:**

Design and development validation is performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained.

**7.3.7 Control of Design and Development Changes:**

Design and development changes are identified and records maintained. The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes includes evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions are maintained.

**7.4 Purchasing:**

**7.4.1 Purchasing Process:**

Supply Management ensures that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

Supply Management, Development and Quality evaluate and select suppliers based on their ability to supply product in accordance with ABB Inc. Allentown requirements. Criteria for selection, evaluation and re-evaluation are established by Supply Management, Development and Quality. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.

A Procurement Documentation Control System has been established to control activities for the procurement of items or services that affect the quality or performance of our products. The system is organized as a series of drawings that describe items, materials, or components and approved suppliers. These drawings are considered part of the purchasing documents.
Suppliers and their products are evaluated to assure that the quality and technical performance are such that they satisfy the requirements of the specifications, standards, and expected end use of the product. The extent of the supplier evaluation may vary, depending upon the complexity of design, manufacture or test, the difficulty of verifying quality characteristics after delivery, the end use of the item, the cost, or other factors. The evaluation process often involves the integrated actions of several organizational elements (i.e. Quality Assurance, Engineering, Supply Management, Manufacturing, etc.) based upon the nature of the item.

**Vendor Evaluation:** All vendors and their products are evaluated by one or more of the following methods:

- **Quality Assurance Audit** - This is accomplished by a Quality Assurance visit to the vendor's facility to evaluate their conformance to industry standards and, or quality levels required for use in our products. As an alternative, audits performed by other operations within the ABB organization may be used to establish acceptability.

- **Quality Assurance Manual Review** - The vendor's Quality Assurance Manual is reviewed by Quality Assurance to assure that it meets industry standards and, or quality levels required for use in our products.

- **Quality/Engineering Evaluation of Products** - This is accomplished by the analysis of data or actual test and approval of samples.

- **Evaluation of Performance Data and Supplier History** - Our internal inspection system allows us to collect data on a part by part basis. Thus, we measure monthly supplier performance. Some of our supplier data may also come from other ABB locations, industry surveys, or the supplier.

- **Source Surveillance** - This method is used in conjunction with the other methods in order to provide a continuing evaluation of each vendor.

- **Approved Supplier Listings** - Standard purchased part drawings include listings of manufacturers or processors qualified to supply that component. A supplier approved for one item is not automatically approved for other or similar items. Standard hardware and fittings such as brackets, spacers, etc., are controlled by the Supply Management department and do not require source approval. The Supply Management department maintains an approved supplier list.

- **Supplier Certification** - Supplier Certification is recognition that the supplier has demonstrated a high level of performance and has appropriate process controls in place to eliminate redundant testing, provide a guarantee of product quality and on-time delivery, and improve response time by reducing delays in production, all to ensure continued excellence. Once a supplier has met the criteria for certification, receipt inspection confirms that one part from a lot matches the part number purchased and records the data related to the shipment.

### 7.4.2 Purchasing Information:
Purchasing information describes the product to be purchased, including where appropriate:

a) requirements for approval of product, procedures, processes and equipment,

b) requirements for qualification of personnel and

 c) quality management system requirements.

Supply Management ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

Purchase Order Placement and Approval:

Purchase requisitions are prepared from the materials plan. A purchasing agent evaluates price and delivery and prepares a purchase order. A copy of the purchased part drawings and applicable specifications and standards are forwarded to the supplier with the purchase order. Any special part or service requirement for class 1E products is detailed on our part drawing and noted on the Purchase Order sent to the supplier, i.e. UL recognized, no Mercury etc.

Components manufactured by approved manufacturers may be obtained directly or through intermediate representatives or distributors.

The Purchase Order is reviewed by appropriate personnel and, once approved, is placed with the selected supplier. The Purchase Order information is placed on the business computer system, which is accessible in Inventory Control and Receiving.

The Quality Assurance requirements of 10CFR50 Appendix B are not passed on to material suppliers. All materials are purchased as standard parts and are not designated as Class 1E. Purchases of Engineering or QA services related to products sold to Nuclear Utilities are considered as Class 1E and the requirement of 10CFR part 21 or ANSI/NCSL Z540 are imposed on those suppliers.

7.4.3 Verification of Purchased Product:

Quality Assurance establishes and implements inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

If ABB Inc. or its customer intends to perform verification at the supplier's premises, then ABB Inc. will state the intended verification arrangements and method of product release in the purchasing information.

Receiving Purchased Material - The Purchase Order number and quantity received are verified by the receiving personnel and input into the computer system. A copy of the receipt traveller is attached to the material and given to incoming inspection.
Incoming Inspection of Purchased Material - Inspection procedures define the method for verifying quality and assuring compliance to the drawings and specifications of incoming purchased materials. The purchased material is inspected and, or tested to specifications on the drawing for that part. If the material lot is rejected, the material is reviewed via the Nonconforming Material Report process. Rejected material is identified and stored in a segregated area when practical. It may be stored in others areas if appropriately marked or tagged.

When received material is found to be acceptable, a Computer receipt record is completed by the inspector and the material is released to the Stockroom accompanied by a Receiving Report marked with the inspection approval, the inspector's initials, the Purchase Order number and the date. The accepted items are then placed in stock or on the production floor for general use.

The history of purchased parts is maintained in Receiving Inspection for all components. This History Record lists information such as Engineering Drawing Number and Revision, Manufacturers and Suppliers, AQL, Inspection Criteria, Date Received, Purchase Order Number, and Lot Number. The inspection department also maintains history on supplier quality performance and on time shipments.

Where possible, inspection and acceptance are based on industry standards such as ANSI and IPC for various inspection criteria.

Changes or revisions to procured items are subject to the same procedures and approvals as were the original items.

7.5 Product and Service Provision:

7.5.1 Control of Production and Service Provision:

The ABB Inc. Allentown site plans and carries out production and service provisions under controlled conditions. Controlled conditions include the following where applicable:

a) the availability of information that describes the characteristics of the product,
b) the availability of work instructions, as necessary,
c) the use of suitable equipment,
d) the availability and use of monitoring and measuring devices and
e) the implementation of monitoring and measurement, and the implementation of release, delivery and post-delivery activities.

7.5.2 Validation of Processes for Production and Service Provision:

The ABB Inc. Allentown site will validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.
Validation must demonstrate the ability of the processes to achieve planned results. Arrangements for these processes include, as applicable:

a) defined criteria for review and approval of the processes,
b) approval of equipment and qualification of personnel,
c) use of specific methods and procedures,
d) requirements for records and
e) revalidation.

The scope of servicing is limited to field upgrades and repairs performed by Customer Support or Repair Department Technicians. These technicians are qualified to perform product upgrades and repairs.

The manufacturing operations employed in the manufacturing of solid-state and microprocessor based relays are all standard high quality industrial processes. No unique or special processes are in use at this location.

Controlled processes are used for the soldering of electronic components to printed circuit boards. This process is performed with both automatic soldering equipment (Wave Solder and SMT) and with hand soldering equipment. Procedures and controls have been established for both.

Environment

Controlled processes are used in storage and handling of electro-static discharge (ESD) sensitive parts and assemblies. Production and test equipment processes and procedures are documented and maintained.

Process Quality

Internal product Quality evaluation is measured by Process Improvement Teams (PITs). These measures include process First Run Yield (FRY) in many areas including wave solder, SMT solder, Teradyne, 1st and 2nd stage assembly, calibration, Burn-in and Final Test. Additional measures come from production floor rejects and Warranty returns. Process Improvement Teams re-design processes with the goal of increased FRY, FPY and decreased throughput/value added time ratio.

Preventative Maintenance

General machinery maintenance is scheduled daily, weekly and quarterly, etc. depending upon complexity and use of the machine.

7.5.3 Identification and Traceability:

Where appropriate, the ABB Inc. Allentown site identifies the product by suitable means throughout product realization.
Product status is identified with respect to monitoring and measurement requirements. Where traceability is a requirement, the ABB Inc. Allentown site controls and records the unique identification of the product.

Order entry personnel prepare shop orders which specify to the Operations Department the required material in terms of the catalog number used in published literature and drawing number for the required Bill Of Material.

Production and Storeroom personnel use "pull" instructions which detail all required components for all subassembly stages and the quantities of each required. These documents tie together the following material identifications:

a) The manufacturing part number (Bill of Material) and the revision number.
b) The assigned manufacturing release number. (1E products only)
c) The quantity and type to be built.
d) The identity of stock deductions for each component by its purchased part number and inspection lot number or date of pull. (1E products only)
e) The cross reference from component purchased part number to the schematic identification name (i.e. R99, C101, etc.) by which the component is then identified in the assembly stock bins and by which its location in the printed circuit board is identified.
f) The date issued to the stockroom and the scheduler's initials. (1E products only)
g) The date material is pulled from stock and the stock person's initials. (1E products only)

All material is identified by part number or catalog number during all stages, from receipt through product delivery. Identification is maintained for Class 1E relays, through assembly, by stamping a release number on the Printed Circuit Assembly.

At the calibration, inspection and test station, the serial number is assigned, placed on the unit and a data sheet is used for each individual unit. (Except for products tested on automated equipment with only a "go/no go" response in which case the same information is recorded into a log book). This data sheet or log book provides a cross-reference for the following identifications which are recorded on the data sheet:

a) The assigned serial number
b) The release number stamped on the Printed Circuit Assembly
c) The catalog number from the front panel of the relay

After final test and inspection, the unit is forwarded to the packing area where it is placed in a carton marked with the catalog number, type number and serial number. At this point the unit is linked to the appropriate sales order.

Various measures have been established for indicating the inspection and test status of equipment during the assembly and test processes. Coded inspection/test stamps or specific employee identification symbols are used for test and inspection to indicate acceptance and completion of basic inspection and test steps. Various tags and labels are used to indicate equipment status or to provide information for equipment or personnel safety.
Inspection and Test personnel are responsible for the care, integrity and the use of assigned, coded inspection/test stamps. Inspection/test stamps shall not be used by other than assigned personnel.

Certification procedures for Protective Relays manufactured at Allentown for nuclear Class 1E applications are detailed in QAP Section 14.2. 100% inspection and test are performed prior to shipment on all customer orders requiring a certificate of conformance. This procedure is documented on audit check lists and conformance test reports.

7.5.4 Customer Property:

If and when material or products are furnished by the customer, then care shall be exercised with this property, while it is under our control or being used by the ABB Inc. Allentown site. The ABB Inc. Allentown site will identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this will be reported to the customer and records maintained.

7.5.5 Preservation of Product:

The ABB Inc., Allentown site is committed to preserving the conformity of product during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

All material to be shipped shall show evidence of authority to ship. A copy of this authorization shall be maintained on file. Authorization to ship is a Sales Order (S.O.), or a Purchase Disposition (P.D.). Prior to forwarding products to the packaging and shipping area, they shall be clean, physically inspected, and tested by manufacturing personnel. For class 1E equipment orders, products are tested and inspected by Quality Assurance personnel. Presence of a QC stamp shows verification that the inspection and test took place.

All material to be shipped must have all instruction books or CDs, engineering drawings, reports, and paperwork as required by the sales order or other authorizing documents. The requirements and instructions for receiving, handling, and storage at the job site are included in the appropriate instruction books or CDs. Copies of these books or CDs are included with the shipment.

Upon release of the sales order, the Shipping Department shall review the sales order to determine that materials, drawings, etc. are available to meet the packaging and shipping requirements of the sales order. If special packaging is required, arrangements shall be made to have the work performed by a qualified packaging house.
Packaging and marking shall be accomplished in accordance with the sales order requirements. Standard protective relays are packed in specially designed cartons to protect relays during normal handling and shipping. Odd items or subassemblies are packed in anti-static containers with suitable loose fill material.

Shipping makes the following checks prior to release for shipments:
  a) Check product identification information for compliance with shipping documents.
  b) Check method of packaging against sales order requirements.
  c) Check type and quantities of containers against shipping documents.
  d) Check accuracy and completeness of marking for compliance to sales order and specification requirements.

**Conformance to ANSI N45.2.2:**

If required by contract, relay products are classified in this standard as Level B items.

**Handling, Storage:**

All material is received, stored and issued according to documented Supply Management Procedures.

**Preservation:**

The products manufactured at this location do not have shelf life limitations and do not require segregation.

**7.6 Control of Monitoring and Measuring Devices:**

Development, Quality and Operations determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements. Processes have been established to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment is:
  a) calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification is recorded:
  b) adjusted or re-adjusted as necessary,
  c) identified to enable the calibration status to be determined,
  d) safeguarded from adjustments that would invalidate the measurement result,
  e) protected from damage and deterioration during handling, maintenance and storage.

Quality Assurance assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements and takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are
maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This confirmation is undertaken prior to initial use and reconfirmed as necessary.

The calibration system has been established and is maintained in accordance with the requirements of ANSI/NCSL Z540-1-1994

The following methods have been established to assure that measuring and test equipment are of the proper range, stability, type, and accuracy to assure conformance to established specifications:

a) Traceability to the NIST for all production standards is maintained.
b) Any calibration frequency change is based upon a review of the history record for that instrument.
c) The calibration records include a record of repairs.
d) Equipment is identified by means of an Instrumentation Certification Tag showing classification, test instrument number, calibration date, calibration expiration date, and inspector's initials.
e) A recall system for calibration updating is used.
f) Special environmental control is not required, as work areas are maintained for worker comfort and test equipment is not subjected to environmental extremes.
g) The calibration procedures used are those specified by the equipment manufacture's instructions.
h) The acceptance and rejection criteria are the specifications published by the equipment manufacturer, or as modified by Quality Assurance.
i) Preventive maintenance is used where practical.
j) The use of personal measuring equipment is not permitted.

All measuring and test equipment is classified as follows:

a) Development standard  
b) Production standard  
c) Customer Support standard  
d) Quality Assurance standard  
e) Utility grade

Mechanical measurement equipment, standard common scales, verniers, etc., used in the incoming inspection area are included in the calibration system.

Calibration verification for standards is accomplished by our own personnel or qualified outside sources. Outside sources perform certification or repair services for our standards. The sources used are qualified and use standards traceable to the NIST and verification of their certification is maintained on file.

If measuring and test equipment is found to be out of calibration it is reported to Quality Assurance. The nature of the problem is documented. This documentation is submitted
to Quality Assurance for disposition. An evaluation is conducted and a course of corrective action is documented and initiated as required. If corrective action is required for products that have already been shipped from the plant, documentation is provided to Marketing for notification and corrective action with the customer or user of the equipment, detailed procedures for reporting product defects is described in QAP 15.2 (Includes 10CFR-Part 21).

**REFERENCE DOCUMENTATION:**

- QAP 3.1 -- DESIGN CONTROL PROCEDURES
- ESP-1009 -- A Guide to the Product Development Process
- QAP 7.1 -- RECEIVING INSPECTION PROCEDURES
- QAP 4.1 -- PROCUREMENT DOCUMENTATION CONTROL SYSTEM - GENERAL
- QAP 19.2 -- CONTRACT REVIEW
- SMP - 04.010 -- Purchasing Procedures
- QAP 8.1 -- IDENTIFICATION AND CONTROL OF MATERIAL FOR CLASS 1E RELAYS
- QAP 14.1 -- INDICATION OF PRODUCT INSPECTION AND TEST STATUS
- QAP 8.1.2 Trace Markings For Production - Doc Link Unavailable
- QAP 9.2 -- CONTROLLED PROCESSES
- QAP 9.1 -- CONTROL OF PROCESSES
- QAP 10.1 -- INSPECTION POLICY AND REQUIREMENTS
- QAP 10.2 -- IN-PROCESS TOUCH UP
- QAP 11.1 -- TEST PROCEDURES
- QAP 12.3 -- TEST INSTRUMENT LOGS
- QAP 12.2 -- CONTROL OF ELECTRICAL TEST EQUIPMENT
- QAP 12.4 -- CERTIFICATION OF CRIMPING TOOLS
- QAP 12.1 -- CONTROL OF MECHANICAL TEST EQUIPMENT
- QAP 14.2 -- CERTIFICATION PROCEDURE
- QAP 14.3 -- OPERATING STATUS
- QAP 13.1 -- PACKAGING, HANDLING, STORAGE, AND SHIPPING
8.0 Measurement, Analysis and Improvement

POLICY:

PURPOSE:

This section outlines how measurement, analysis and improvement are conducted at the ABB Inc. Allentown site.

RESPONSIBILITIES:

DESCRIPTION:

8.1 General:

The ABB Inc. Allentown site plans and implements the monitoring, measurement, analysis and improvement processes needed:

a) to demonstrate conformity of the product,
b) to ensure conformity of the quality management system and
c) to continually improve the effectiveness of the quality management system.

This includes determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and Measurement:

8.2.1 Customer Satisfaction:

As one of the measurements of performance of the quality management system, the ABB Inc. Allentown site shall monitor information relating to customer perception as to whether the ABB Inc. Allentown site has met customer requirements. The methods for obtaining and using this information are:

a) Customer Complaint Resolution Process (CCRP),
b) SupportLine Process,
c) Customer Satisfaction Surveys and
d) Warranty return analysis.
8.2.2 Internal Audit:

Quality Assurance conducts internal audits at planned intervals to determine whether the quality management system:

a) conforms to the planned arrangements to the requirements of the ISO 9001:2000 International Standard, and to the quality management system requirements established by the ABB Inc. Allentown site, and

b) is effectively implemented and maintained.

An audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors cannot audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records are defined in a documented procedure (QAP 18.2). The management responsible for the area being audited ensures that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

Methods have been established for performing and documenting audits of the quality assurance and quality control systems. Internal Quality Audits are performed at least once each calendar year for each element of the quality system. Internal Quality Audits are performed as defined in the Quality Assurance Procedures. Audits are performed by trained personnel having no direct responsibility in the area being audited. Procedures or checklists are discussed with supervisory personnel in the areas audited and the findings are documented and reviewed with management.

The purpose of the audit program is to provide the best possible evaluation and assessment of our Quality Assurance Program permitting management and supervisory personnel to provide continuous monitoring, improvement and upgrading of our system, and to assure that appropriate corrective action is applied in a timely manner.

8.2.3 Monitoring and Measurement of Processes:

The ABB Inc. Allentown site applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product.

Process measures include but are not limited to:

a) Order schedule
b) Surface Mount assembly
c) Thru-hole assembly
d) Wave solder assembly
e) 2nd stage assembly  
f) Sub-assembly  
g) Final assembly  
h) Final test  
i) Out of Box Audit  
j) Packaging and Shipping  
k) Repair process  

8.2.4 Monitoring and Measurement of Product:  

The ABB Inc. Allentown site monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing release of product.

Product release and service delivery shall not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

In Process Inspection:

Inspections are conducted in accordance with documented instructions, procedures, or engineering drawings. Coded inspection/test stamps or specified employee identification (i.e. signature or initials) are used on test or inspection forms. Finished products are required to be stamped with the coded stamps for verification of test and inspection. Manufacturing assembly personnel perform self-inspection on their work. Coded stamps are not used on this process.

When modifications, repairs or replacements are required, re-inspection and/or re-testing of all characteristics are performed. Completed item inspection and testing are such that they provide a measure of overall quality of the completed product and are performed so that they simulate product end use and functioning. Where applicable and specified, inspections or tests are performed in accordance with the requirements of the appropriate standards or specifications. When the product fails to pass any inspection and/or test, the procedures for control of nonconforming product apply.

Product Testing:

Protective Relays are tested in accordance with detailed procedures based upon the applicable industry standards (ANSI C37.90), Underwriters Laboratory specifications etc. and published product specifications for standard catalog items.

Testing is done with calibrated test and measurement equipment that is maintained traceable to the National Institute of Standards and Technology (NIST) or other National
Standards. Where no traceable standards exist, equipment calibration is verified by use of procedures provided by the equipment manufacturer or developed by Quality Assurance. Equipment used for production and inspection test and calibration work is under Quality Assurance surveillance.

Each product is tested in accordance with a production test procedure derived from engineering specifications. The procedures identify the characteristics to be tested and the required calibrations. The procedures and test data sheets are prepared and controlled by the Engineering Release Form procedure. Data sheets or computer test files provide for recording of actual test results and show acceptable limits for each measurement. Coded test stamps are used on the product and data sheets upon completion of this process.

Some products are tested on automated equipment that operates on a "GO/NO-GO" basis using built-in tolerance control. Test records for these products are recorded in log books.

Internal on-line procedures are designed to verify proper functioning of subcircuits as well as the total unit and as such, may be used only with the specific production equipment, hence such procedures and data may not be available for use outside the plant, however, they are available for on-premises survey or audit.

For Class 1E Equipment orders, the Quality Assurance Certification includes an independent verification procedure by Quality Assurance personnel. Certified conformance test sheets can be supplied if specified by customer requirements.

8.3 Control of Nonconforming Product:

The ABB Inc. Allentown site ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in Quality Assurance Procedures shown in the reference documentation section of this Quality Assurance Manual.

The ABB Inc. Allentown site deals with nonconforming product by one or more of the following ways:
a) by taking action to eliminate the detected nonconformity,
b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer,
c) by taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained. When nonconforming product is corrected it is re-verified to demonstrate conformity to the requirements. When nonconforming product is detected after delivery or use has started, Quality Assurance takes action appropriate to the effects, or potential effects, of the nonconformity.
Receipt Inspection:

Nonconforming materials are segregated in a separate area, where practical, and identified as "nonconforming material". Nonconforming material items are documented on a Nonconforming Material Report (NCMR).

Disposition of nonconforming materials includes the following:
- Return to Vendor - Wrong material, defective, etc.
- Rework - Material that can be reworked to conform to the drawing.
- Repair - Materials that can be made to conform to drawings or meet the intended requirements of the end item. Modifications must be made to written procedures approved by Engineering and/or Quality Assurance.
- Scrap - Material that cannot be returned to vendor, reworked, or repaired shall be scrapped.
- Use As Is - The Nonconforming Material Report may be closed out only after a review by engineering and, or quality has determined that the material deviation does not affect the form, fit or function of the end item.

Test and Assembly Areas:

In the test and assembly areas, it is not practical to identify each nonconformance by means of a Rejected Tag or segregate it. Corrections are made on-line as needed. Relays and relay assemblies which cannot be promptly corrected in the normal production flow are tagged or segregated by the responsible team member.

The Quality Assurance Program provides methods for reporting of product defects, deficiencies or nonconformances in accordance with 10CFR Part 21.

8.4 Analysis of Data:

The ABB Inc. Allentown site determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:
- customer satisfaction,
- conformity to product requirements,
- characteristics and trends of processes and products including opportunities for preventive action and
- suppliers.

Data for analysis comes from (but is not limited to) the following sources:
- Customer Complaints (CCRP)
b) First Run Yield (FRY)
c) Warranty Returns
d) On-time Delivery
e) Supplier On-time Delivery
f) Supplier Quality
g) Cost Of Poor Quality (COPQ)
h) Inventory Accuracy
i) SupportLine database
j) Out of Box Audit (OOBA)

8.5 Improvement:

8.5.1 Continual Improvement:

The ABB Inc. Allentown site continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective Action:

The ABB Inc. Allentown site takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

Documented procedures are established to define requirements for:

a) reviewing nonconformities (including customer complaints),
b) determining the causes of nonconformities,
c) evaluating the need for action to ensure that nonconformities do not recur,
d) determining and implementing action needed,
e) records of the results of action taken and
f) reviewing corrective action taken.

Nonconformances or conditions adverse to quality are initiated and documented on Nonconforming Material Reports, audit reports, Corrective Action Requests, Customer Complaints, SupportLine cases and Engineering Change Requests. The purpose of the documentation is to promptly identify the problem to the individual or the department responsible for corrective and preventative actions.

Wherever possible, nonconformances are identified as to their causes. Any corrective/preventative action is reviewed with appropriate levels of management.

Reports from Audit Findings, Corrective Action Requests, and Customer Feedback will be followed up by Quality Assurance and corrective action will be implemented as necessary.

Product Integrity Committee (PIC):
The scope and responsibilities of the Product Integrity Committee (PIC) is to document and determine the actions to be taken regarding reports of potential or actual improper operation of protective relay products.

**8.5.3 Preventive Action:**

The ABB Inc. Allentown site determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

Documented procedures are established to define requirements for:
- determining potential nonconformities and their causes,
- evaluating the need for action to prevent occurrence of nonconformities,
- determining and implementing action needed,
- records of results of action taken and
- reviewing preventive action taken.

The primary means of preventive action is the Engineering Change Request process. Requests for preventive action not related to product engineering changes are handled via the Quality Council and Preventive Action Request (PAR) process.

**REFERENCE DOCUMENTATION:**

- QAP 18.2 -- INTERNAL QUALITY ASSURANCE AUDITS
- QAP 9.2 -- CONTROLLED PROCESSES
- QAP 15.2 -- REPORTING OF PRODUCT DEFECTS
- QAP 16.5 -- HOLD SHIPMENT PROCEDURE
- QAP 16.11 -- FIELD REPAIR AND UPGRADE
- QAP 10.1 -- INSPECTION POLICY AND REQUIREMENTS
- QAP 16.2 -- PRODUCT RELIABILITY COMMITTEE (PRC) CORRECTIVE ACTION
- QAP 20.2 -- STATISTICAL MEASURES
- QAP 18.6 -- PITs (PROCESS IMPROVEMENT TEAMS)
- QAP 9.1 -- CONTROL OF PROCESSES
- QAP 15.1 -- NONCONFORMING MATERIAL
- QAP 15.3 -- CONTROL OF IN-PROCESS NONCONFORMANCES
- QAP 7.1 -- RECEIVING INSPECTION PROCEDURES
- QAP 16.1 -- RETURNED MATERIAL HANDLING
<table>
<thead>
<tr>
<th>Manual Revision:</th>
<th>Document, Section, Paragraph Changed</th>
<th>Page</th>
<th>Change Made</th>
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<tr>
<td>12</td>
<td>All Quality Manual Documents</td>
<td>All</td>
<td>Initial issue of Document on QSI database and added purpose to each element.</td>
<td>08/16/99</td>
<td>Dennis Haring</td>
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<td>Cover page</td>
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<td>Changed name to ABB Automation and format</td>
<td>08/16/99</td>
<td>Dennis Haring</td>
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<td>12</td>
<td>Quality Manual Authorizations</td>
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<td>Removed Cheryl Dahle, replaced with Dennis Batovsky, added Richard Fritz</td>
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<td>Updated Quality Policy</td>
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<tr>
<td>12</td>
<td>Corporate Organization History and Background</td>
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<td>Dennis Haring</td>
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<td>12</td>
<td>List of Abbreviations</td>
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<td>Add BOM Bill of Material, ECR Engineering Change Request, ECN Engineering Change Notice, ECO Engineering Change Order, and CCRP Customer Complaint Response Process</td>
<td>08/16/99</td>
<td>Dennis Haring</td>
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<tr>
<td>12</td>
<td>Introduction</td>
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<td>Clarified controlled copies of QAM for internal holders only.</td>
<td>08/16/99</td>
<td>Dennis Haring</td>
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<td>12</td>
<td>Organization and Management Responsibilities</td>
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<td>Removed Quality Policy from this section. Updated Organization chart to show current organization.</td>
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<td>Quality Assurance Program</td>
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<td>Changed Quality Council meetings to every 2 weeks. Changed MRB to weekly meetings. Changed Marketing/Contract Review Procedure to Order Entry/Contract Review Procedure.</td>
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<td>Dennis Haring</td>
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<td>Design Control</td>
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<td>Replaced old Development process with new process.</td>
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<td>12</td>
<td>Purchasing/Supply Management Control System</td>
<td></td>
<td>Replaced Procurement Documentation with Purchasing/Supply Management in title. Removed inspection per MIL-STD-105 for every 10th lot of certified suppliers. Added requirement of ANSI/NCSL Z540 to QA services related to Class 1E product.</td>
<td>08/16/99</td>
<td>Dennis Haring</td>
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<td>12</td>
<td>Identification and Control of Material</td>
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<td>In paragraph 1 replaced &quot;Engineering Parts List&quot; with &quot;Bill of Material&quot;. Removed reference to 1st, 2nd and Final assembly stages. In section added information recorded in log book for go/no go testing.</td>
<td>9/11/99</td>
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<td>Process Control</td>
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<td>Added wave solder and SMT descriptions to solder equipment. Under Process Quality - removed daily audits of finished product and replaced with PITs, FRY and RMR warranty.</td>
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<td>Nonconforming Material</td>
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<td>Changed from MRB reviews list &quot;daily&quot; as needed to &quot;weekly&quot; as needed</td>
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<td>Dennis Haring</td>
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<td>12</td>
<td>Corrective and Preventive Action</td>
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<td>Added &quot;and, or higher management&quot; to the 6th paragraph.</td>
<td>08/24/99</td>
<td>Dennis Haring</td>
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<td>12</td>
<td>Internal Quality Audits</td>
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<td>Title was previously &quot;Audits&quot;. Change the word function to system in paragraph 1. Replaced yearly audits with audit once each calendar year in paragraph 2.</td>
<td>08/24/99</td>
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<td>Training</td>
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<td>Added &quot;Job requirements are outlined in the Job Descriptions book maintained and located in the Human Resources Department&quot; to the third paragraph.</td>
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<td>Changed Paragraph 2 to say defined in ratio/fractions or discreet numbers. Updated performance measures. Dennis Haring</td>
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<td>Added Servicing requirement to Quality Manual now that the Customer Support Department performs field repairs and upgrades. Dennis Haring</td>
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<td>3/24/03</td>
<td>Updated entire manual to reflect ISO 9001:2000. Removed elements not included in the revised standard and replaced with new standard format. Dennis Haring</td>
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<td>Updated Organization History. Remove &quot;the purpose of this page&quot; in Purpose. Dennis Haring</td>
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<td>Replaced IQ TIP with NCMS, removed MRB and added PIC, QMS, FRY, FPY and OOB. Dennis Haring</td>
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<td>Changed ISO 9001-1994 to ISO 9001-2000, removed UL from first paragraph as it was not appropriate here. Removed &quot;the purpose of this page&quot; in Purpose and added ABB Inc. Allentown site to 1st paragraph in description. Dennis Haring</td>
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<td>Changed name to ABB Inc. and updated revision date, removed &quot;the&quot; and &quot;facility's&quot;. Dennis Haring</td>
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<td>3/8/03</td>
<td>Updated organization chart to include Customer Support Department. Dennis Haring</td>
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<td>Cross over appropriate information from sections 4.2, 4.5 and 4.16 from ISO 9001:1994 and added new requirements from ISO 9001:2000. Dennis Haring</td>
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Latest Revision Date: 03/24/2003  Revision Number: 14