

Northern Technologies Corp.

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**1**

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**QUALITY MANUAL**

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**ORIGINATOR**

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**PURPOSE**

This Quality Manual details the overall policies and objectives of the Quality Management System of Northern Technologies. It specifically addresses the requirements of the International Standard; ISO 9002 Quality Systems - Model for quality assurance in production and installation.

**SCOPE**

This manual is applicable to all Quality Management System activities within Northern Technologies located at 95 Konrad Cres., Markham, Ontario.

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**REVISION CONTROL LOG**

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GENERAL

1.1 **Introduction**

This Quality Manual is the top level document in Northern Technologies' Quality Management System. It defines the policies and objectives for the administration of the system. The system has been modeled to conform to the requirements of International Standard - ISO 9002 "Quality systems - Model for quality assurance in production and installation". Appendix A of this manual cross references the ISO 9002 clauses to the applicable sections of this Quality Manual.

For clarity of use, the layout of this manual indicates, where applicable, for each major element in the Quality Management System;

- \* the policies and objectives.
- \* the responsibilities.
- \* any relevant lower level reference standards.
- \* any relevant lower level operating procedures or instructions.
- \* the basic process.
- \* the quality assurance activities.

1.2 **Company Profile**

In 1982, Northern Technologies was incorporated to engage in the supply of Plastic D-subminiature connector covers. A year later the company announced a line of metal connector covers which surpassed FCC requirements for regulating EMI/RFI emissions. By January 1985, Northern Technologies "NORTECH" connector covers were being supplied, under private label, to many of the Fortune Companies of North America. With its proprietary "NORTECH" Strain Relief System, Northern Technologies continued to expand into world markets. Operating from a 35,000 square foot facility, headquartered in Markham, Ontario, Canada, and a 7000 square foot warehouse in Wheatfield, New York, USA. Northern Technologies has become a leader in offering simple solutions to complex cable shielding requirements.

## 1.2 Basic Reference Documents

ISO 9002      1987 (E) International Standard. Quality systems - Model for quality assurance in production and installation.

QSTD-0001    Document Standard for Quality Management System documentation.

NOTE:        Individual Sections of this Quality Management Manual will reference documentation applicable to the Section.

## 1.3 Abbreviations / Definitions

CUSTOMER    For the purpose of this manual, the term "Customer" shall describe those organizations to whom Northern Technologies sells its products to.

MRB          Material Review Board

NPI          New Product Introduction

QA          Quality Assurance

SUPPLIER    For the purpose of this manual, the term "Supplier" shall describe those organizations that supply product to Northern Technologies.

## 2 MANAGEMENT RESPONSIBILITY

### 2.1 Purpose

The purpose of this section of the Quality Manual is to define the overall quality commitment of Northern Technologies and to indicate the functional responsibilities within the Quality Management System. It also covers the maintenance of the Quality Management System.

### 2.2 Reference Documents

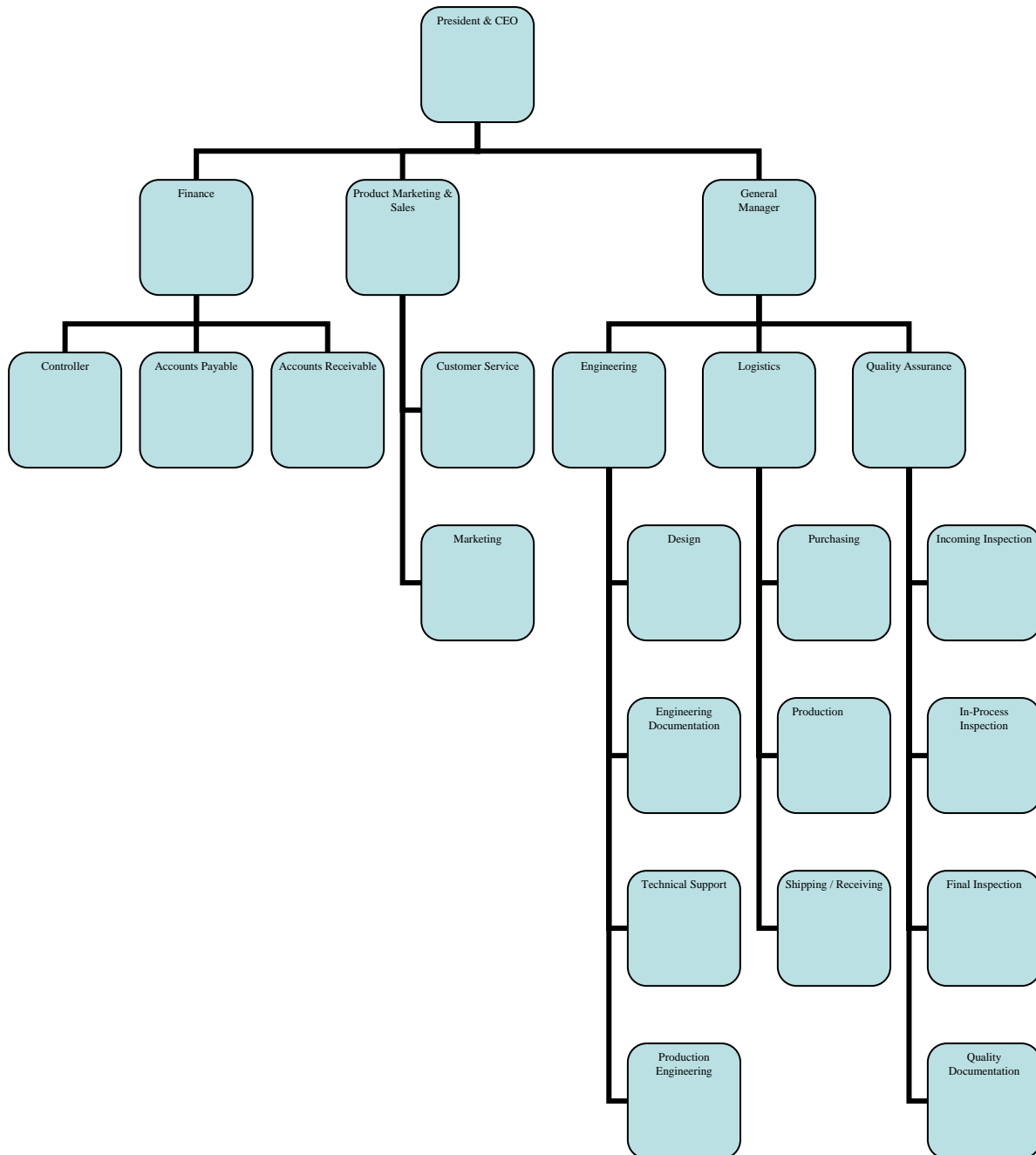
ISO 9002 Section 4.1 " Management Responsibility"

### 2.3 Company Commitment / Quality Policy

Northern Technologies is committed to the Quality Management System as detailed in this Quality Manual. The overall objectives to be attained, and maintained shall be:

- a) that the products and services supplied, meet or exceed our customer's requirements with respect to quality of design, workmanship, timely delivery, cost, and service.
- b) that all company employees will have adequate experience, or be trained for their specific functions in order that the requirements of the Quality Management System are met, and to adopt a philosophy of continual quality improvement to products, processes, and services.
- c) that a qualified quality monitoring function shall ensure that product, processes and services conform to requirements, and that actions are initiated to permanently correct any nonconformance.

2.4 Organizational Chart



## 2.5 **Function Responsibilities / Policies**

### a) Quality Assurance Function

The Quality Assurance Coordinator has the authority to:

- \* measure, record, and report quality problems that would jeopardize the overall objectives detailed in 2.3.
- \* control further processing, delivery, or installation, of nonconforming product or service until the deficiency or unsatisfactory condition has been corrected.
- \* initiate, in conjunction with other functions, corrective actions for noted nonconformance.
- \* verify the implementation of solutions to nonconformance.

### b) **Other Functions**

All other functional managers and/or supervisors in charge of the functions indicated in the Organization Chart are responsible for ensuring, in their area of responsibility, that not only the overall objectives are met as detailed in 2.3, but also the more specific functional ones as subsections of this Quality Manual.

### c) **Quality Management System Responsibility**

The Quality Assurance Coordinator shall be the management representative for the Quality Management System. This responsibility includes:

- \* ensuring that the requirements of this Quality Manual are implemented and maintained.
- \* ensuring that timely reviews (minimum yearly) are carried out, and published, on the Quality Management System itself in order to implement enhancements to the system as part of the philosophy of continual improvement. These reviews shall include inputs from the managers and supervisors of the functions detailed in the Organization Chart in 2.4.

### 3. QUALITY SYSTEM

#### 3.1 Purpose

The purpose of this section of the Quality Manual is to define, in an overview way, the Quality Management System within Northern Technologies. Detailed applications are covered in subsequent sections of this manual.

#### 3.2 Responsibility

As previously detailed in 2.5 a), the primary responsibility for ensuring that conforming products, processes and services occur, and that the requirements of this Quality Manual are met, rests with the Quality Assurance function.

#### 3.3 Policy

To ensure that the Quality Management System is clearly documented and adopted as standard operating practice as detailed in 2.3.

#### 3.4 Reference Documents

ISO 9002	Section 4.2 a) and b)	Quality System
QSTD-0001	Document Standard	
QPRO-0001	Document Control Procedure	

### 3.5 Processes

#### a) **The Quality Management System Documentation Process**

The Quality Management System is documented in accordance with Document Standard QSTD-0001. This standard defines the types and the revision control of documents to be used. In essence the types of documents are:

- POLICIES - are documents that state Northern Technologies' plan of action for a particular objective.
- STANDARDS - are documents that define the minimum requirements to achieve the objective of a Policy.
- PROCEDURES - are documents that detail the process steps to be followed to achieve the objectives of the Policies and Standards.
- INSTRUCTIONS - are documents that detail the process steps for a specific part of a Procedure.
- FORMS - are reproducible, full sized documents that may be referenced in the Procedures or Instructions.

This Quality Manual QPOL-0001 is the top level document in the Quality Management System and from it can be referenced lower level Standards, Procedures, and Instructions.

#### b) **Quality System Management Awareness**

To ensure all personnel are aware of the requirements of the Quality Management System, all will undergo overall awareness training plus specific training for their particular area(s) of application.

Controlled copies of the Quality System Documentation shall be prominently displayed for use at key locations throughout the organization. Control of these copies shall be in accordance with QPRO-0001 "Document Control Procedure".

**c) The Quality Assurance System Verification Process**

To ensure that functions within Northern Technologies are conforming with this Quality Manual, audits and/or direct involvement in the functional processes are carried out by Quality Assurance. In the subsequent sections of this Quality Manual, where applicable, this verification is covered by the "Quality Assurance Activities" clauses.

## 4. CONTRACT REVIEW

### 4.1 Purpose

The purpose of this section of the Quality Manual is to define the requirements and activities that ensure that customer's requirements are fully understood, acceptable, and communicated adequately to relevant Northern Technologies functions.

### 4.2 Responsibility

Tender and contract activities are the responsibility of the Sales Department and the Product Coordinator.

### 4.3 Policy

To ensure that customer's requirements are fully understood, acceptable, and communicated adequately to relevant Northern Technologies functions.

### 4.4 Reference Documents

ISO 9002	Section 4.3 Contract Review
QPRO-0002	Tender and Contract Review Procedure

### 4.5 Process

The Sales Department process quotations and sales in accordance with QPRO-0002 "Tender and Contract Review Procedure" when applicable..

**4.5 Quality Assurance Activities**

- a) The Quality Assurance Department shall include a sampling audit of tenders and/or contracts as part of their annual Quality Management System audit.
  
- b) In the event of Northern Technologies entering into a contract with a customer where that customer has their own Quality Management Representative the Northern Technologies' Quality Assurance function will act, as required, as a prime quality contact for quality communication. The prime responsibility on addressing customer requirements through the Sales Department will still be valid and they will be notified of all communications.

5

**DOCUMENT CONTROL**

**5.1 Purpose**

The purpose of this section of the Quality Manual is to define the system for controlling documentation.

**5.2 Scope**

Documentation, in this application, applies to:

- \* direct Quality Management System documentation.
- \* direct Product and Process Definition documentation.
- \* Engineering Change Order documentation.
- \* externally produced reference documentation.

Note: Other functional specific documentation shall be stored and controlled by the function.  
Details of storage and control are referenced in the procedures pertaining to the function.

**5.2 Responsibility**

The Documentation Control function of the Manufacturing Engineering Department is responsible for the storage, issuance and control of documentation.

#### 5.4 Policy

To ensure that documentation is adequately stored, maintained, controlled, and communicated, in order to effectively control the quality requirement of the products and/or process.

#### 5.5 Reference Documents

ISO 9002                      Section 4.4 Document Control

QPRO-0001                  Document Control Procedure

Note: All referenced documentation shall be submitted to, stored by, and distributed from, Documentation Control.

#### 5.6 Quality Assurance Activities

There is no direct audit or monitoring of the Documentation Control function per se. Any nonconformance in released documentation will be identified via other function audits and by the Corrective Action process (seeSection14).

**6**

**PURCHASING**

**6.1 Purpose**

The purpose of this section of the Quality Manual is to define the system for purchasing and receiving compliant material from qualified vendors.

**6.2 Scope**

Material, in this application, applies to all material or services that are to be used either directly in, or in the manufacturing process, of an end product or service to be sold to the customer.

**6.3 Responsibility**

The Purchasing function of the Materials Department is responsible for all direct purchasing activities.

The Quality Assurance Department is responsible for:

- \* evaluating and approving vendors.
- \* the incoming inspection function.
- \* any vendor source inspection required relating to a purchase order.

The Manufacturing Engineering Department is responsible for the definition of material to be purchased.

The Receiving function of the Materials Department is responsible for receiving material into the manufacturing facility.

**6.4 Policy**

To ensure that required material is adequately define and procured from vendors who have demonstrated their ability to supply compliant material.

**6.5 Reference Documents**

ISO 9002                      Section 4.5                      Purchasing

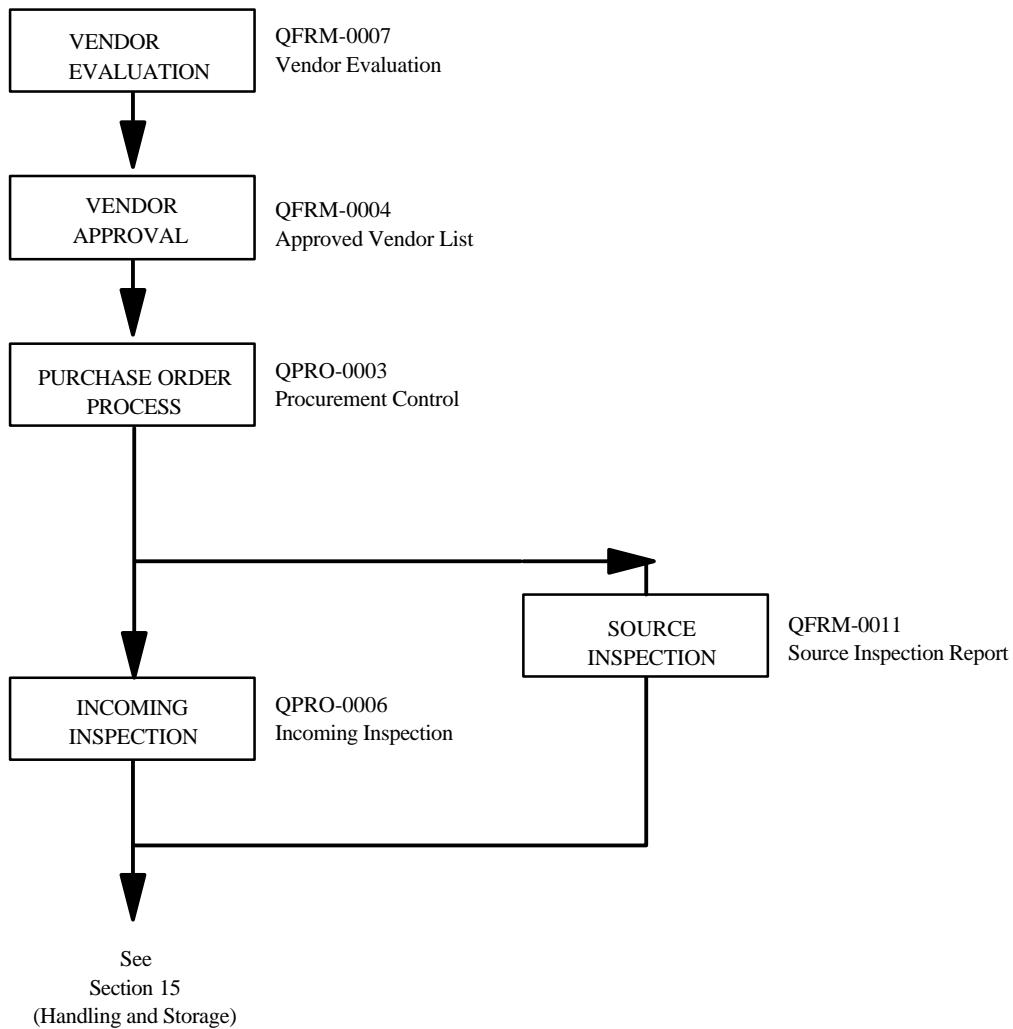
see also 6.7

**6.6 Quality Assurance Activities**

In addition to their direct involvement in vendor approvals, the Quality Assurance Department are also included in the approval sign-off process of; a Purchase Order as detailed in QPRO-0003 "Procurement Control". Vendor performance records shall be kept, see Section 17.

**6.7 Basic Process**

The basic process steps when purchasing and receiving material are:



Refer to the Quality Management System documents indicated above for more detailed process Steps within each of the functions.

## 7 CUSTOMER SUPPLIED PRODUCT

### 7.1 Purpose

The purpose of this section of the Quality Manual is to determine the process for handling, verifying and controlling a product that a customer has supplied for incorporation into goods being purchased by that customer.

Note: At this time nor is it contemplated in the foreseeable future will Clause 4.6 of ISO 9002 apply to product manufactured by Northern Technologies. This section has been included in the Quality Manual for reference purposes only. If and when the situation occurs, this section of the Quality Manual will be expanded to suit.

### 7.2 Responsibility

The Materials Department shall be responsible or controlling customer supplied product. The Manufacturing Engineering Department shall be responsible for defining the required parameters for specific customer supplied product utilizing a source controlled document described in Section 5 of this manual. The Incoming Inspection function of the Quality Assurance department shall be responsible for verifying that customer supplied product complies with relevant source control document. Any nonconformance shall be handled as per Section 13 of this manual.

### 7.3 Policy

To insure that customer supplied product is verified as suitable for inclusion into the end product, and handled/controlled in such a way as to insure the quality requirements of the product.

### 7.4 Reference Documents

ISO 9002

Section 4.6

Purchaser Supplied Product

**7.5 Process**

Not applicable at this time.

**7.6 Quality Assurance Activities**

Not applicable at this time.

8

**PRODUCT IDENTIFICATION**

**8.1 Purpose**

The purpose of this section of the Quality Manual is to define the system for insuring material, where required, can be traced to; source documentation, test results, product and processed information documentation, process control, and quality records.

**8.2 Scope**

Material, in this application, applies to component or subassembly material that is to be used either directly in, or in the manufacturing process of, and end product to be sold to the customer. It also includes the end product itself. It does not include component material or assemblies that are being used for design engineering purposes.

Note: Material that has been designated for, or used in, design engineering work will be segregated from material that has been designated for sale to a customer.

**8.2 Responsibility**

All personnel involved in the functions shown on the flowchart in 8.6 are responsible for insuring that material identification is in accordance with the relevant procedures indicated.

**8.4 Policy**

To ensure that non conforming product is not delivered to the customer.

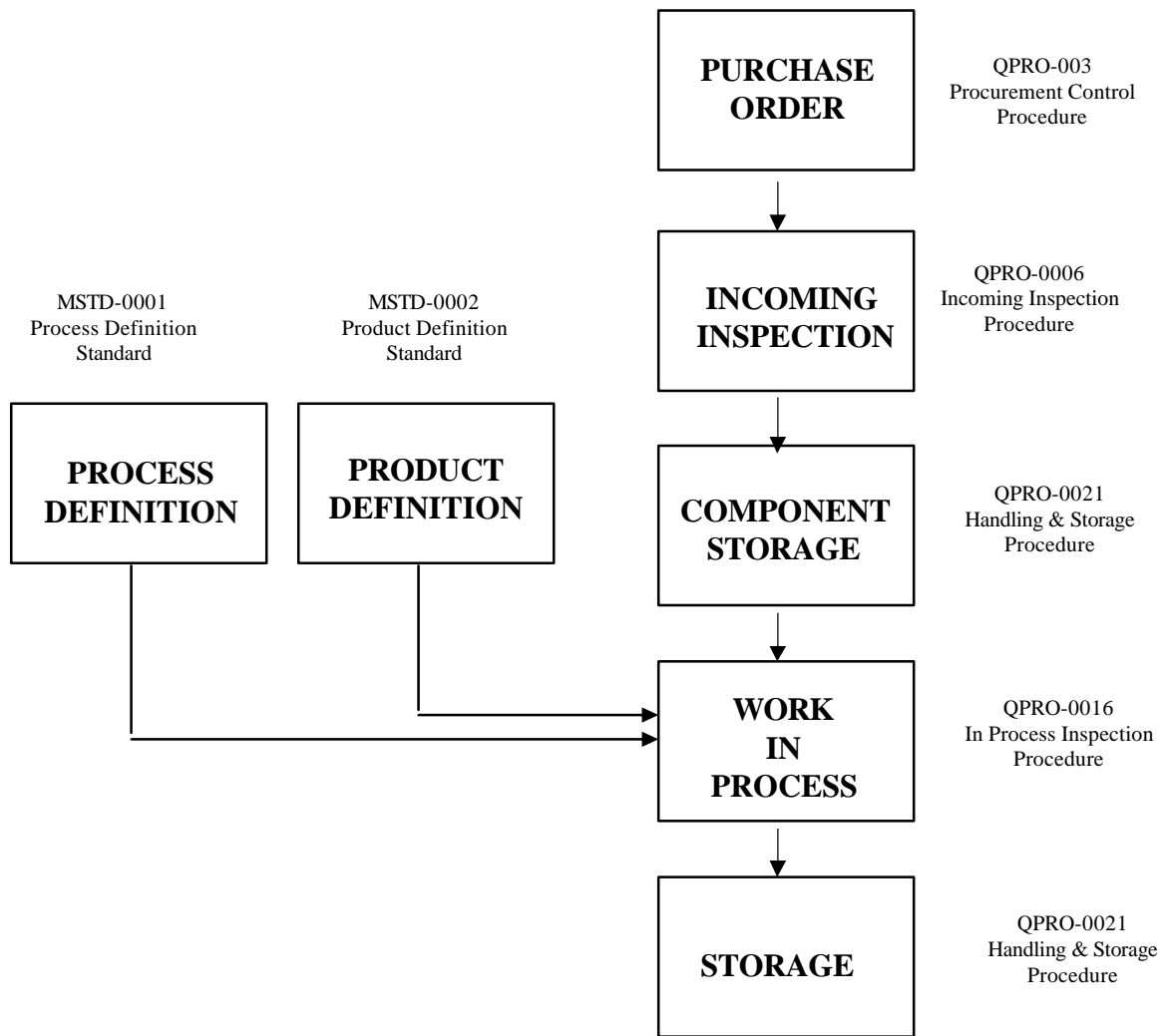
**8.5 Reference Documents**

ISO 9002  
QPRO-0020  
see also 8.6

Section 4.7 Product Identification and Traceability  
Electrostatic Sensitive Devices Handling Procedure

**8.6 Basic Process**

Where applicable, the requirements for material traceability are noted in the Quality Management System Documentation indicated on the following flow chart:



**8.7 Quality Assurance Activities**

Where applicable the Quality Management System Documents are indicated in 8.6 will detail any Quality Assurance activity.

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**PROCESS CONTROL**

9.1 **Purpose**

The purpose of this section of the Quality Manual is to define the system for ensuring that product is manufactured in accordance with specific requirements. Specific requirements shall include; compliance in workmanship standards, compliance to design, and compliance to a documented manufacturing process.

9.2 **Responsibility**

The Production Control function of the Materials Department is responsible for ensuring a production schedule is formulated that takes into account the capacity parameters of Northern Technologies.

The Manufacturing Engineering function is responsible for providing Product or Process Definition in accordance with design requirements and the production schedule.

The Inventory Control function of the Materials Department is responsible for ensuring that the correct materials supplied in accordance with the Product Definition and the production schedule.

The Production Department is responsible for ensuring that the product is built in accordance with the Product and Process Definitions and in accordance with the production schedule.

9.3 **Policy**

To build product that meets or exceeds specified requirements in accordance with the production schedule.

#### 9.4 Reference Documents

ISO 9002	Section 4.8	Process Control
MSTD-0001		Product Definition Standard
MSTD-0002		Process Definition Standard

#### 9.5 Quality Assurance Activities

The Quality Assurance Department shall periodically (see Section 20) audit the compliance to requirements of work in process. Any nonconformance shall cause a "Correction Action Request" (see Section 14) to be initiated.

Note: When a nonconformance is detected by the Quality Assurance Department and/or others, the nonconforming process is put on hold and no further process shall occur until the nonconformance is resolved.

## 10 INSPECTION AND TESTING

### 10.1 Purpose

The purpose of this section of the Quality Manual is to define the inspection and/or test parameters during the manufacturing process.

### 10.2 Responsibility

The responsibility for inspection and/or testing shall be upon those personnel involved in the stages outlined in 10.5.

### 10.3 Policy

All material and product shall be inspected and/or tested to ensure its compliance to requirements.

### 10.4 Reference Documents

ISO 9002	Section 4.9	Inspection and Testing
QPRO-0006		Incoming Inspection Procedure
QPRO-0016		In-Process Inspection Procedure
QPRO-0017		Final Inspection Procedure

### 10.5 Basic Process

There are three basic stages for Material/Product verification against a reference standard.

#### a) Incoming Inspection

- 1) The inspection and/or test requirements for that material are indicated as per QPRO-0006 Incoming Inspection Procedure. It also indicates whether a Certificate of Conformance or Test Results are required to be supplied by the Vendor.

- 2) Compliant material shall have an "Accept" tag affixed to it prior to that material being placed in stock.
  - 3) Non compliant material shall be processed in accordance with Sections 13 and 14 of this manual (Control of Nonconforming Material/Correction Action).
- b) Work In Process
- 1) The inspection and/or test points are indicated in QPRO-0016 In-Process Inspection Procedure. This document may in turn reference; specifications, test procedures, etc. contained in the Product Definition document.
  - 2) Noncompliant material shall be processed in accordance with Sections 13 and 14 of this manual (Control of Nonconforming Material/Correction Action).
- c) Final Inspection
- 1) The inspection and/or test requirements shall be in accordance to Northern Technologies QPRO-0017 Final Inspection Procedure.
  - 2) Non compliant material shall be processed in accordance with Sections 13 and 14 of this manual (Control of Nonconforming Material/Correction Action).

Note: At the conclusion of all three stages, verification results shall be kept on file in order to provide evidence of inspection and test if required.

## 10.6 Positive Recall

For material in stages a) and b) of 10.5, noncompliant material may be allowed to proceed in the manufacturing process under certain specific conditions. These conditions are:

- a) that the material is evaluated and authorized for processing by the customer.
- b) that the reason for the noncompliance is a minor paperwork or specification problem that is easily resolved.
- c) that the material can be easily retrieved, if necessary, from the manufacturing process.

Positive Recall application does not negate a Corrective Action being processed.

## 10.7 Quality Assurance Activities

The Quality Assurance Department are directly involved in the Incoming Inspection function (see Section 6). They also are directly involved in the Correction Action process (see Section 14). In addition, periodic audits are carried out on Work in Process and Final Inspection (see Section 20).

## 11 INSPECTION, MEASURING AND TEST EQUIPMENT

### 11.1 Purpose

The purpose of this section of the Quality Manual is to define the maintenance and serviceability of all measurement and test equipment.

### 11.2 Responsibility

The Incoming Inspection function of the Quality Assurance Department is responsible for monitoring and controlling all measuring and test equipment. The function using the measuring or test equipment is responsible for arranging the recalibration of test equipment in conjunction with the incoming inspection function.

### 11.3 Policy

All measuring and test equipment utilized in the inspection and testing of material and product shall be subject to calibration controls. These controls shall be specific usability parameters on the equipment.

### 11.4 Reference Documents

ISO 9002  
QPRO-0009

Section 4.10 Inspection, Measuring and Test Equipment  
Measuring and Test Equipment Procedure

### 11.5 Process

Full details of the control process are shown in QPRO-0009 (Measuring and Test Equipment Procedure).

In brief this procedure:

- a) Insures that each piece of measuring and test equipment is suitably labelled indicating a control number and a calibration expiry date for the equipment.
- b) Insures that a calibration record is kept for each piece of measuring or test equipment.
- c) Directs that measuring or test equipment that is past due its recalibration date is removed from the manufacturing process and not returned until it has been recalibrated.
- d) That a general listing be maintained of all measuring and test equipment showing location, control number and calibration expiry date. This listing to be published monthly to all personnel involved in the usage, maintenance and inspection of the equipment.

### 11.6 Quality Assurance Activities

From the general listing of the measuring and test equipment, the Quality Assurance Department shall carry out periodic audits (see Section 20). Corrective Action Requests (see Section 14) shall be initiated for any nonconformance.

12

**INSPECTION AND TEST STATUS**

**12.1 Purpose**

The purpose of this section of the Quality Manual is to define the method(s) of identifying conforming material and end product.

**12.2 Responsibility**

Material

The identification of conforming received vendor material is the responsibility of the incoming inspection function of the Quality Assurance Department using an "Accept" tag.

Product

The identification that production process steps have been completed and/or conformed to requirements is the responsibility of the person completing the process step.

**12.3 Policy**

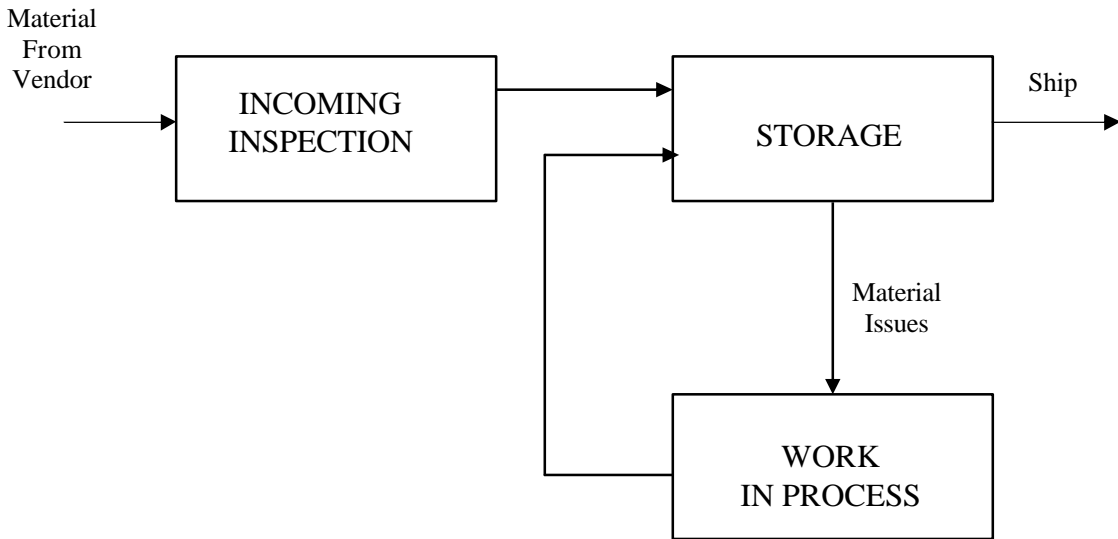
To insure that all conforming material and product are identified as such.

**12.4 Reference Documents**

ISO 9002      Section 4.11    Inspection and Test Status  
QPRO-0016    In-Process Inspection Procedure  
QPRO-0017    Final Inspection Procedure  
QPRO-0006    Incoming Inspection Procedure

**12.5 Basic Process**

The following basic process indicates where inspection and test acceptance notations are made.



## 13 CONTROL OF NONCONFORMING MATERIAL

### 13.1 Purpose

The purpose of this section of the Quality Manual is to define the system for documenting, handling and dispositioning material that does not conform to requirements.

### 13.2 Scope

Material, in this application, applies to component or sub-assembly material that is to be used either directly in, or in the manufacturing process of, an end product to be sold to a customer, it also includes the end product itself. It does include component material or assemblies that are being used for design and engineering purpose.

Note: Material that has been designated for, or used in, design engineering work will be segregated from product that has been designated for sale to a customer.

### 13.3 Responsibility

All functions indicated in the Organizational Chart in 2.4 that handle product are responsible for identifying nonconforming product, and initiating corrective action, when it is observed in their area of application. The Quality Assurance Department shall be responsible for determining the disposition decision of non-conforming product via a Material Review Board (MRB).

### 13.4 Policy

To insure that nonconforming product is not delivered to a customer.



## 14 CORRECTIVE ACTION

### 14.1 Purpose

The purpose of this section of the Quality Manual is to define the system for recording, tracking, and resolving errors.

### 14.2 Scope

An error is defined as a nonconformance to a specified requirement.

### 14.3 Responsibility

Upon discovery of an error, all personnel in the functions indicated in the Organization Function

Chart in 2.4 are responsible for initiated error correction activities in accordance with QPRO-0014 "Corrective Action Procedure". The Quality Assurance Department are responsible for coordinating the error correction system detailed in QPRO-0014 "Corrective Action Procedure".

### 14.4 Policy

To insure that nonconformances in products, processes and services are documented and corrected permanently in a timely manner.

### 14.5 Reference Documents

ISO 9002	Section 4.13 Corrective Action
QPRO-0014	Corrective Action Procedure

#### **14.6 Process**

The functional process steps for error correction are detailed in QPRO-0014 "Corrective Action Procedure" in brief this procedure:

- a) Provides a formal mechanism for anyone within Northern Technologies to initiate an error correction activity by completing a "Corrective Action Request" form and introducing it into a pro-active error correction process.
- b) Provide a close looped system whereby the originator, and Quality Assurance, are informed of the resolution to a nonconformance.
- c) Provide a recording mechanism whereby error correction data can be collected and analyzed in order to identify any error trends.

#### **14.7 Quality Assurance Activities**

In addition to coordinating the error correction process, the Quality Assurance Department also monitor the errors recorded, and the resolutions proposed, in order to analyze and report on pertinent quality parameters (see Section 20 - Statistical Techniques).

## 15 MATERIAL HANDLING AND STORAGE

### 15.1 Purpose

The purpose of this section of the Quality Manual is to define the system for insuring that material used in the manufacturing process is handled, stored, and controlled in such a way that the quality requirements of the end product conform.

### 15.2 Scope

Material, in this application, applies to component or subassembly material that is to be used either directly in or in the manufactured process of, an end product to be sold to a customer. It also includes the end product itself. It does not include component material or assemblies that are being used for design and engineering purposes.

Note: Material that has been designated for, or used in, design engineering work will be segregated from product that has been designated for sale to a customer.

### 15.3 Responsibility

The materials department is responsible for the handling, storage, and control, of material while it resides in their storage, incoming goods receiving, and shipping areas. The production department is responsible for the handling, storage, and control, of material while it resides in their direct manufacturing application areas. The quality assurance department is responsible for the handling, storage, and control, of material while it resides in the incoming inspection area.

### 15.4 Policy

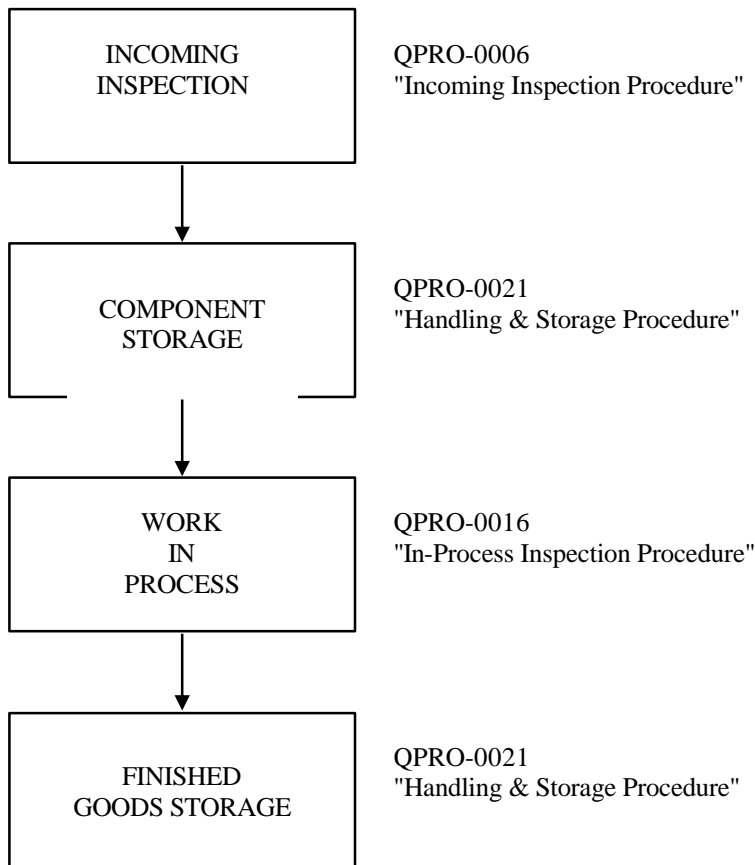
All material shall be handled, stored and controlled to insure that quality requirements of the end product are not jeopardized.

**15.5 Reference Documents**

ISO 9002	Section 4.14.1	General
	Section 4.14.2	Handling
	Section 4.14.3	Storage
	Section 4.14.4	Packaging
QPRO-0020	Electrostatic Sensitive Devices Handling Procedure	
See also 15.6	Basic Process	

**15.6 Basic Process**

The basic material flow handling steps are:



Refer to the Quality Management System documents indicated above for more detailed process steps within each of the functions.

**15.7 Quality Assurance Activities**

The Quality Assurance Department shall audit, on a periodical basic, various handling, storage, and control parameters in the process steps detailed in 15.6. A more detailed explanation of these audits is shown in the procedures listed in 15.6. Each procedure listed, where applicable, shall have a "Quality Assurance Activity" section detailing the parameter(s) and scope of the audit. Audit results shall be recorded and published. See Section 20 Statistical Techniques.

## 16

## SHIPPING PRODUCT

### 16.1 Purpose

The purpose of this section of the Quality Manual is to define the system when shipping product to a customer.

### 16.2 Scope

Product, in this application, applies to completed assemblies or components.

### 16.3 Responsibility

The shipping function of the materials department is responsible for packing and shipping product.

### 16.4 Policy

All product to be shipped to a customer shall be processed expeditiously, and packaged adequately, in order to satisfy customer and company requirements.

### 16.5 Reference Documents

ISO 9002      Section 4.14.5    Delivery  
QPRO-0021    Handling and Storage Procedure  
QPRO-0020    Electrostatic Sensitive Device Handling Procedure

## **16.6 Basic Process**

The functional process steps when shipping product are detailed in QPRO-0021 "Handling and Storage Procedure" in brief this procedure:

- a) describes the documentation process when shipping product
- b) details the responsibilities of functions in the shipping process
- c) provides responsibility sign-off to insure that requirements have been met

## **16.7 Quality Assurance Activities**

The Quality Assurance Department are included in the sign-off process in the QPRO-0021 "Handling and Storage Procedure". Incidences of nonconformances noted in the shipping process shall be recorded via Corrective Action process.  
(see Section 14)

17

**QUALITY RECORDS**

**17.1 Purpose**

The Purpose of this section of the Quality Manual is to define the content, and requirement for storage of records that relate to conformance to requirements.

**17.2 Scope**

A quality record for the purpose of this application includes, but is not limited to the following:

- a) Design Records
  - design documentation, including phase meeting minutes and design correspondence with customer.
  - Design Engineering
- b) Sales Records
  - tenders, contracts, sales orders, plus any associated documentation.
  - Sales
- c) Purchase Records
  - purchase orders, plus any associated documentation.
  - Purchasing
- d) Incoming Inspection Records
  - incoming inspection documentation that relates to a particular receipt of material.
  - vendor performance records shall also be calculated.
  - Incoming Inspection

- e) Work In Process Records - work orders, plus any associated build and test documentation that relates to a particular build batch.
  - Production Control
- f) Shipment Records - any associated documentation relating to a shipment.
  - Production Control
- g) Product/Process Definition Records - product/process definition, source control, and engineering change, documentation.
  - Manufacturing Engineering

Held by the Quality Assurance Department:

- a) Corrective Action Documentation
- b) Measuring and Test Equipment Records
- c) Audit Reports
- d) Miscellaneous Quality Records

### 17.3 Policy

Records relating to quality shall be kept secure, easily retrievable, on file for a minimum period of three years or be in accordance with contractual requirements.

### 17.4 Reference Documents

ISO 9002	Section 4.15 Quality Records
QPRO-0001	Document Control Procedure
QPRO-0002	Tender and Contract Review Procedure
QPRO-0003	Procurement Control Procedure
QPRO-0006	Incoming Inspection Procedure
QPRO-0016	Inprocess Inspection Procedure
QPRO-0017	Final Inspection Procedure

**17.5 Process**

The requirement process steps for the filing of Quality Records are defined in the function procedures listed in 17.4.

**17.6 Quality Assurance Activities**

The Quality Assurance Department shall include a sampling audit of record keeping as part of their annual Quality Management System audit.

## 18 INTERNAL QUALITY AUDITS

### 18.1 Purpose

The purpose of this section of the Quality Manual is to define the process for insuring that functional practices and procedures comply with the quality requirements of this manual.

### 18.2 Responsibility

The Quality Assurance Department are responsible for ensuring that internal audits are conducted and that corrective action has been completed.

### 18.3 Policy

All internal processes and procedures are to be independently accessed as to their effectiveness and compliance to defined requirements.

### 18.4 Reference Documents

ISO 9002	Section 4.16 Internal Quality Audits
QPRO-0023	Management System Audit Procedure

### 18.5 Process

The process steps for the audit are detailed in QPRO-0023 "Management System Audit Procedure". In brief this procedure directs that:

- a) an audit schedule shall be prepared identifying the quality elements to be audited and when. (Minimum yearly)
- b) follow-up corrective actions are implemented in a timely manner by the appropriate functional manager/supervisor.
- c) an audit report shall be published and made available for management use as part of the management system review (see Section 2.5 c). Copy is also submitted to the registrar.

**18.6 Quality Assurance Activities**

The Quality Assurance Department organize, carry-out, and report on, the audit as detailed in QPRO-0023 "Management System Audit Procedure".

### 19.1 Purpose

The purpose of this section of the Quality Manual is to define the system for insuring that personnel are suitably skilled for the job functions they are assigned to.

### 19.2 Responsibility

It is the responsibility of the manager/supervisors of the functions detailed in the Function Organizational Chart in 2.4 to:

- a) document the required actions within the job functions in their area of responsibility.
- b) define the minimum qualifications required for the job functions.
- c) select personnel suitable for the job functions.
- d) insure that, where necessary, adequate training is provided for personnel in order to achieve or enhance the skill levels for the job functions.

It is the responsibility of the Human Resources Department to:

- a) maintain, in conjunction with the functional managers/supervisors the job descriptions.
- b) keep records of the qualifications of personnel employed.
- c) organize, in conjunction with the functional managers/supervisors, any training requirements.

### 19.3 Policy

All personnel shall be qualified, and trained where necessary, to achieve the quality requirements within their functions as detailed in this manual.

#### **19.4 Reference Documents**

ISO 9002      Section 4.17   Training  
HSTD-0001    Job Function Description Standard

#### **19.5 Process**

The process steps for analyzing the requirements for job functions are detailed in HSTD-0001 "Job Function Description Standard". In brief this standard:

- a) provides a generic template form unto which specific job functions are described together with the qualification requirements.
- b) provides the guidelines for documenting and analyzing the job functions.

#### **19.6 Quality Assurance Activities**

As part of their annual Quality Management System audit the Quality Assurance Department shall include a sampling of the job descriptions versus the personnel within those jobs, to insure that adequate skill level and cognizance of the quality requirements exists.

### 20.1 Purpose

The purpose of this section of the Quality Manual is to define the requirement for analyzing quality parameters in order to identify quality trends.

### 20.2 Responsibility

The Quality Assurance Department is responsible for analyzing and reporting quality parameters.

### 20.3 Policy

To insure quality trends are identified and reported on in order to take affirmative action if required.

### 20.4 Reference Documents

ISO 9002      Section 4.18   Statistical Techniques

### 20.5 Process

On a monthly basis the Quality Assurance Department shall issue a quality report that covers:

- a) analysis of the corrective action process
- b) vendor performance

- c) results of sampling audits on:
  - 1) work in process
  - 2) shipments
  - 3) measuring and test equipment
  - 4) stock room control
    - shelf life material
    - deterioration
    - security
    - protective packaging

**APPENDIX A**

ISO 9002 to QUALITY MANUAL - CROSS REFERENCE

Clause	Title	Section	Title	Lower Level Quality Management Documentation
4.1	MANAGEMENT RESPONSIBILITY	2	MANAGEMENT RESPONSIBILITY	
4.1.1	Quality Policy	2.3	Quality Policy	
4.1.2	Organization	2.4	Organization Function Chart	
4.1.2.1	Responsibility and authority	2.5.b	Function Responsibilities and Policies	
4.1.2.2	Verification resources and personnel	2.5.a	Quality Assurance Function	
4.1.2.3	Management representative	2.5.c	Quality Management System Responsibility	
4.1.3	Management review	2.5.c	Quality Management System Responsibility	
4.2	QUALITY SYSTEM	3	QUALITY SYSTEM	
a)		3.5.a	Quality Management System Documentation	QSTD-0001 Document Standard
b)		3.5.b	Quality Management System Awareness	SPRO-0001 Document Control Procedure
		3.5.c	Quality Management System Verification Process	
4.3	CONTRACT REVIEW	4	CONTRACT REVIEW	QPRO-0002 Tender & Contract Review Procedure

**APPENDIX A**

ISO 9002 to QUALITY MANUAL - CROSS REFERENCE

4.4	DOCUMENT CONTROL	5	DOCUMENT CONTROL	
4.4.1	Document approval and issue			
4.4.2	Document changes / modifications			QPRO-0001 Document Control Procedure
4.5	PURCHASING	6	PURCHASING	
4.5.1	General	6.7	Basic Process	QFRM-0007 Vendor Evaluation
4.5.2	Assessment of subcontractors	6.7	Basic Process	QFRM-0004 Approved Vendor List
4.5.3	Purchasing data	6.7	Basic Process	QPRO-0003 Procurement Control Procedure
4.5.4	Verification of purchased product	6.7	Basic Process	QPRO-0006 Incoming Inspection Procedure QFRM-0011 Source Inspection Report
4.6	PURCHASER SUPPLIED PRODUCT	7	CUSTOMER SUPPLIED PRODUCT	not applicable

**APPENDIX A**

ISO 9002 to QUALITY MANUAL - CROSS REFERENCE

4.7	PRODUCT IDENTIFICATION AND TRACEABILITY	8	PRODUCT IDENTIFICATION	
		8.6	Basic Process	MSTD-0001 Product Definition Standard MSTD-0002 Process Definition Standard QPRO-0003 Procurement Control Procedure QPRO-0006 Incoming Inspection Procedure QPRO-0021 Handling & Storage Procedure QPRO-00061 In-Process Inspection Procedure
4.8	PROCESS CONTROL	9	PROCESS CONTROL	
4.8.1	General			MSTD-0001 Product Definition Standard
4.8.2	Special Process			MSTD-0002 Process Definition Standard

**APPENDIX A**

ISO 9002 to QUALITY MANUAL - CROSS REFERENCE

4.9	INSPECTION AND TESTING	10	INSPECTION AND TESTING	
4.9.1	Receiving inspection and testing	10.5	Basic Process	QPRO-0006 Incoming Inspection Procedure
4.9.2	In-process inspection and testing	10.5	Basic Process	QPRO-0016 In-Process Inspection Procedure
4.9.3	Final inspection and testing	10.5	Basic Process	QPRO-0017 Final Inspection Procedure
4.9.4	Inspection and test records	10.5	Basic Process	
4.10	INSPECTION, MEASURING AND TEST EQUIPMENT	11	INSPECTION, MEASURING AND TEST EQUIPMENT	QPRO-0009 Measuring & Test Equipment Procedure
4.11	INSPECTION AND TEST STATUS	12	INSPECTION AND TEST STATUS	QPRO-0016 In-Process Inspection Procedure QPRO-0017 Final Inspection Procedure QPRO-0006 Incoming Inspection Procedure
4.12	CONTROL OF NONCONFORMING PRODUCT	13	CONTROL OF NONCONFORMING MATERIAL	
4.12.1	Nonconformity review and disposition	13.6	Process	QPRO-0014 Corrective Action Procedure

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ISO 9002 to QUALITY MANUAL - CROSS REFERENCE

4.14	HANDLING, STORAGE, PACKAGING AND DELIVERY	15	MATERIAL HANDLING & STORAGE	
4.14.1	General	15.6	Basic Process	QPRO-0020 Electrostatic Sensitive Device Handling Procedure
4.14.2	Handling	15.6	Basic Process	QPRO-0006 Incoming Inspection Procedure
4.14.3	Storage	15.6	Basic Process	QPRO-0021 Handling & Storage Procedure
4.14.4	Packaging	15.6	Basic Process	QPRO-0016 In-Process Inspection Procedure
4.14.5	Delivery	16	Shipping Product	QPRO-0021 Handling & Storage Procedure
4.15	QUALITY RECORDS	17	QUALITY RECORDS	QPRO-0020 Electrostatic Sensitive Device Handling Procedure  QPRO-0006 Incoming Inspection Procedure  QPRO-0002 Tender & Contract Review Procedure  QPRO-0003 Procurement Control Procedure  QPRO-0016 In-Process Inspection Procedure  QPRO-0017 Final Inspection Procedure

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ISO 9002 to QUALITY MANUAL - CROSS REFERENCE

4.16	INTERNAL QUALITY AUDITS	18	INTERNAL QUALITY AUDITS	QPRO-0023 Management System Audit Procedure
4.17	TRAINING	19	TRAINING	HSTD-0001 Job Function Description Standard
4.18	STATISTICAL TECHNIQUES	20	STATISTICAL TECHNIQUES	