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Quality Manual

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Title - Approval Page

Approved by _____

QUALITY MANUAL APPROVALS

Chairman - _____

President - _____

Executive Vice President - _____

V. P. of Operations - _____

V. P. of Administration - _____

Director of Quality - _____

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QUALITY MANUAL

APPROVALS

President - _____

Exec. Vice President - _____

V. P. of Operations - _____

V. P. of Finance - _____

Director of Quality - _____

2.0 REVISION HISTORY

<u>Rev #</u>	<u>Date</u>	<u>Changes, Section #</u>	<u>Written By</u>
	<u>Approved</u>		

1 WJensen	6/01/96	Original version	W. Jensen
2 WJensen	7/01/96	General typing corrections, changed Durex Co. to Durex Inc., All sections	W. Jensen
3 WJensen	11/10/97	Changes in Executive Management, Corrected the Approval page	W. Jensen
4 WJensen	6/15/98	Rewrote sections: 3.0, 4.1 - 4.20, & 5.0, Added reference to procedures and Responsibilities for each section. Instituted a revision for each section.	W. Jensen
5 WJensen	11/02/98	Corrected sections: 2.0, 4.1, & 4.4 per Perry Johnson audit.	W. Jensen
6 WJensen	4/15/99	Updated sections 1.0, 2.0, 4.1	W. Jensen

2.0 REVISION HISTORY

<u>Rev #</u>	<u>Date</u>	<u>Changes, Section #</u>	<u>Written By</u>
7 WJensen	8/12/99	Added statement to section 4.1 that the	W. Jensen

Management Rep. / Quality Director is responsible for the Quality System. Also added ISO element responsibility.

8 2/11/00 Updated Organization chart and W. Jensen
WJensen

Approval page.

9 6/15/00 Section 4.5.1 – Added two missing W. Jensen
WJensen

procedures to list. Section 4.2 – Added statements that records are documented & stored per the Record Retention List, FM 104-1

10 7/31/01 Updated the Organizational chart, and W. Jensen
WJensen

Section 4.1

Section 3.0	DureX, Inc. Union, N. J.	Rev. B
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Title - Quality Policy & Mission Statement	Approved by	_____

Quality Policy

Durex and Quality are synonymous. Quality is the key to success at Durex. Quality means fully satisfying the requirements of our internal and external customers. For every member of the Durex team, Quality is a way of life.

Mission Statement

Durex is a full service manufacturer dedicated to producing Quality metal stampings, assemblies, sheet metal fabrications, and finished products. We pride

ourselves in providing the best possible Quality and service environment for our employees, encouraging them to grow and prosper with the company.

General

A Quality system with all programmatic controls has been established which shall serve to communicate expectations, establish controls, and foster a culture committed to excellence in everything we do. The management of Durex, Inc. is firmly committed to a Quality process that serves our customers and helps us maintain a leadership position in our industry.

The Quality policy is posted throughout all departments of the Durex facility. All Durex employees are instructed and reminded through product reviews, Quality reviews, departmental meetings, and customer feedback concerning the implementation / maintenance of the Quality Policy

Achievement Through Teamwork And Quality (ATTAQ)

Robert Denholtz
President, Durex, inc

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Title - Organization		Approved by _____

General

The prime responsibility for quality is vested in that level of management responsible for those activities which affect quality characteristics in the products produced by Durex, Inc.

Responsibility

The elements of the quality system are outlined in this manual and meet the requirements of the ANSI/ASQC Q9001-1994.

The Director of Quality is directly responsible for all acceptance decisions of products released for delivery.

The ISO Management Representative shall be responsible for:

- 1) Developing the system, preparing and obtaining the approval of the quality manual.
- 2) The review and approval of all written procedures, and for monitoring all activities which affect quality.
- 3) Determining the status and adequacy of the program through audits.

When problems or differences of opinions on quality cannot be resolved within the line organization, these problems shall be referred to the attention of the Director of Quality. The resolution of the problem shall be within the quality system and design specifications requirements.

Whenever an activity in this manual is assigned to the manager of the responsible department, the department manager may delegate this activity as required. However, the department manager maintains responsibility for the complete execution of the activity.

The President of Durex and the ISO Management Representative shall be responsible for the overall effectiveness of this section.

The responsibility to establish the quality policy is vested on the President of Durex, Vice President of Operations, and ISO Management Representative, who shall assure the adequate understanding and application of the quality policy.

The Management Representative / Quality Director will be responsible for establishment, implementation, and maintenance of the quality system within the operation.

The Management Representative has the authority to take decisive action relative to system deficiencies in all quality contribution areas and disciplines.

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Title - Organization

The Quality Director will be responsible for the quality system, quality programs, continuous improvement, customer complaints, internal quality system audit schedule, verification / effectiveness of corrective / preventive actions, and all quality measurements.

The Executive Vice President (Sales) will be responsible for customer satisfaction through a solid communication network between all Durex departments and the customer.

The Director of Tooling & Mfg'ing Eng'ing will support the continuous improvement of quality by assuring a complete contract review process of the customer requirements.

The Administrative Manager will support the continuous improvement of quality by providing fiscal guidance, creating and monitoring internal controls, safeguarding corporate assets, and undertaking responsibility for all administrative functions.

The Customer Service Manager will be responsible for assuring that customer orders match Durex quotes, resolve order differences, coordinate orders with production control, and resolve delivery differences.

The Quality Engineering Manager will be responsible for design verification through first article inspection, customer sample approval, quality product plans, and customer interface as required.

The Controller will support the continuous improvement of quality by providing quality cost data for analysis as required.

The MIS Manager will be responsible for assuring the control and storage of all product and Quality records within the computer system.

The Engineering Manager will be responsible for product tool designs, and maintain design review records to ensure customer satisfaction.

The Quality Engineering Manager will be responsible for first article inspection, first piece inspection, receiving inspection, calibration program, quality process improvements, and customer satisfaction.

The Human Resource Manager will be responsible to maintain a work force capable of meeting customer needs, and maintain training programs / records for all Durex personnel.

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Title - Organization

The Manufacturing Supervision will be responsible for assuring proper identification and storage of raw material / work-in-process, manufacturing process control / improvements and corrective action responses to customer complaints as required.

The Production Control Manager will be responsible for planning incoming material delivery, and work order scheduling for manufacturing to assure product on-time delivery to customers.

The Director of Tooling and Manufacturing Engineering will be responsible for the scheduling for all internal or external tooling. He is also responsible for document control including, prints, new revisions, change orders, master specification sheets, and the coordination of change orders affecting tooling / gages / fixtures.

The Toolroom Manager will be responsible for building new tools / gages per specifications, modifying tools / gages, and repairing tools / gages as required.

The Director of Tooling & Mfg'ing Eng'ing will be responsible for manufacturing process improvements, tool analysis / troubleshooting, and rework processes.

The Purchasing Senior Buyer will be responsible for assuring that required materials are procured and documented per specifications. Purchasing is also responsible for vendor rating, control, and approved vendor lists.

The Maintenance Manager will be responsible for performing preventive maintenance on the manufacturing equipment and analyzing the effectiveness of the P.M. program.

The Manufacturing Departments will be responsible for building products to the customer specifications and requirements.

The Receiving Department will be responsible for the control and receipt of all incoming material based on purchase orders, and the coordination through receiving inspection.

The Warehouse Department will be responsible for proper packaging, storage, and control of incoming material, work-in-process, and finished goods.

The Shipping Department will be responsible for proper packaging, labeling, delivery, and records for product shipped to customers.

The Internal Audit Team shall be responsible through the internal audit system to assure that written procedures are prepared, followed, and conform to Durex, Inc. requirements.

Authority

Durex, Inc. has assigned the Director of Quality as the Management Representative for ISO9000 implementation.

- 1) The Director of Quality shall ensure that a quality system is established, implemented, and maintained.
- 2) The Director of Quality shall review regularly the performance of the quality system.

Authority for administration of the quality system is vested in the ISO Management Representative who shall be sufficiently independent from the pressure of production to perform this function, and shall report regularly to the President of Durex on the effectiveness of the program.

Personnel performing quality functions shall have sufficient authority and organizational freedom to

- 1) Identify non-conforming activities
- 2) Initiate action to prevent the occurrences of any non-conformities relating to production, process, and the quality system.
- 3) Collect or cause the collection of data necessary to measure the effectiveness of the quality system and its elements.
- 4) Verify implementation of solutions to identified problems.
- 5) Control further processing of non-conforming items until proper and effective corrective measures are accomplished.

Management Review

The quality system shall be reviewed regularly for effectiveness by the Executive staff. This review shall include, but not be limited to non-conformances, corrective action requests, preventive actions, customer complaints, internal quality system audit results, suppliers quality, product hold data, PPM data, training, Quality Policy, and other key quality measurements.

Reference procedure #102, Management Review.

Organizational Chart

Refer to page 6 of this section, 4.1.

Title - Organization

Resources

The ISO Management Representative shall assure that sufficient and appropriate resources essential to the implementation of the quality system are provided.

ISO Element Responsibility

- 4.1 Management Responsibility – Management Representative / V. P. of Operations
- 4.2 Quality System – Management Representative
- 4.3 Contract Review – Director of Tooling & Manufacturing Engineering
- 4.4 Design Control – Engineering Manager
- 4.5 Document & Data Control – Director of Tooling & Manufacturing Engineering
- 4.6 Purchasing – Senior Buyer
- 4.7 Control of Customer Supplied Product – Warehouse Manager
- 4.8 Product Identification & Traceability – Quality Engineering Manager
- 4.9 Process Control – Manufacturing Supervision
- 4.10 Inspection and Testing – Quality Engineering Manager
- 4.11 Control of Inspection, Measuring, & Test Equip. – Quality Engineering Manager
- 4.12 Inspection & Test Status – Quality Engineering Manager
- 4.13 Control of Nonconforming Products – Director of Quality
- 4.14 Corrective and Preventive Actions – Quality Eng. Manager / Director of Quality
- 4.15 Handling, Storage, Packaging, & Delivery – Warehouse Manager
- 4.16 Control of Quality Records – Director of Quality, Shipping Manager, MIS Manager
- 4.17 Internal Quality Audits – Director of Quality
- 4.18 Training – Human Resource Manager / V. P. of Operations
- 4.19 Servicing – Not Applicable
- 4.20 – Statistical Techniques – Quality Engineering Manager & Director of Quality

Purpose

To establish the methods and responsibilities for the receiving inspection of purchased materials and services, in-process inspection of components, and final inspection of completed products.

Scope

This section describes the controls and responsibilities for the receiving inspection of purchased materials and services, in-process inspection of components, and final inspection of completed products.

Procedure**Receiving Inspection**

All incoming material shall be inspected for conformance to the purchase order and referenced documents.

When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service.

Upon receipt of material, the Receiving department shall check the purchase order requirements for item identification and damage. Items requiring inspection shall be held in a specified area until released by incoming inspection.

Incoming inspection shall be notified of the arrival of material when the receiving clerk submits the applicable receiver documents and / or delivers samples to inspection.

Material shall be inspected by incoming inspection to procedure, #206 - Receiving Inspection. Items shall be identified for traceability as required.

All required documentation shall be examined for conformance to the purchase order requirements and the material specification for the material or services received.

Items which have successfully passed inspection shall be identified by a move ticket / acceptance stamp to provide evidence of compliance for movement of the material to the storage area.

A record of inspection shall be entered in the product history file for the part number.

Certificates of compliance shall be filed at incoming inspection, as required.

All non-conforming material shall be segregated and subject to the requirements of section 4.13, Control of Non-Conforming Product.

Incoming material released for urgent production purposes prior to inspection, shall be identified and recorded for recall in the event of a non-conformance.

In-Process and Final inspection

Inspections shall be performed as required on the process instructions (routers), and the specific product inspection instructions.

Product shall not progress to additional process stages until all activities specified in the quality plan, and / or router, and / or inspection instructions have been satisfactorily completed.

Product shall not progress to the Finished Goods warehouse or prepared for shipment to the customer until all activities specified in the quality plan, and / or router, and / or inspection instructions have been satisfactorily completed.

Items which have successfully passed inspection shall be identified by a move ticket / acceptance stamp to provide evidence of compliance for movement of the material to the next process / operation or Finished Goods warehouse or preparation for shipment to the customer.

Where possible, inspection records will be retained or stored by customer and / or part number. Reference procedure #209, First Piece, In-Process, & Final Audit Inspection.

Responsibility

The Receiving and Quality departments shall be responsible for the overall effectiveness of receiving, receiving inspection, in-process inspection, and final inspection.

The Quality Engineering Manager shall be responsible for the overall effectiveness of this section.

The Internal Audit Team shall be responsible to assure that written procedures are prepared, followed, and conform to Durex requirements, including the effectiveness of the inspection system.

Section 4.11

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Title - Control of Inspection, Measuring, and
Test Equipment

Approved by _____

Purpose

To establish a system for the use, control, calibration, and adjustment of measuring / test equipment.

Scope

This section outlines the controls and responsibilities for the calibration and adjustment of gauges, instruments, and other measuring devices used for product acceptance and development, to assure that an accuracy level necessary to verify conformance to specification requirements are maintained.

Procedure

All inspection, measuring, and test equipment used to determine an acceptance parameter of product or material shall be calibrated under controlled conditions, traceable to the National Standards (N.I.S.T.).

Determination of the measurements to be made and accuracy required for products shall be utilized to select the appropriate inspection, measuring, and test equipment that is capable of the necessary accuracy and precision.

Prior to use, all new inspection, measuring, and test equipment shall be calibrated and traceable to National Standards.

Calibration procedures shall be maintained, which include equipment type, identification, location, frequency of checks, check method, acceptance criteria, and action to be taken when the results are non-compliant.

The calibration schedule of each instrument shall be determined by industry standards, the Quality Engineering Manager, or as determined by previous calibration history of the instrument.

Results of calibration checks and necessary adjustments shall be entered in the calibration data base maintained by the Quality department.

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Title - Control of Inspection, Measuring, and
Test Equipment

All instruments shall have a calibration label listing the instrument number and calibration due date attached to the device or its container.

Equipment found to be out of calibration or of unknown calibration status shall be identified and removed from service.

When a device is found to be out of calibration, it shall be considered non-conforming. Disposition of material measured by a non-conforming device shall be determined in accordance with section 4.13, Control of Non-Conforming Material.

All measuring, and test equipment shall be properly handled and stored to maintain accuracy and preclude damage.

Subcontracted calibration services shall be controlled in accordance with section 4.6, Purchasing

Reference procedure # 219, Calibration System.

Responsibility

Calibration procedures shall be prepared, reviewed, and approved by the Quality Engineering Manager.

The Quality Engineering Manager shall establish a meaningful calibration schedule.

The Quality Director shall be responsible for the overall effectiveness of this section.

The Internal Audit team shall be responsible to assure that written procedures are prepared, followed, and conform to Durex requirements, including the effectiveness of the control of inspection, measuring, and test equipment system.

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Title - Inspection and Test Status Approved by _____

Purpose

To establish a controlled system for the identification of the quality status of a procured, manufactured, or assembled product.

Scope

This section describes the control and responsibilities for assuring that the inspection and test status of a product is maintained throughout manufacturing.

Procedure

All manufactured items requiring inspection shall have the requirements listed on the process instructions (routers) and / or inspection instructions.

Completed move tickets that are stamped ‘Approved’ and placed on or attached to the container of parts shall indicate the quality inspection status.

Reference procedure #211, Production Acceptance

All items failing inspection and test shall be tagged with a hold ticket. Disposition of failed material shall be in accordance with section 4.13, Control of Non-conforming Products.

Inspection approval stamps shall be controlled and traceable to the individual, when used to indicate acceptance of product.

Responsibility

The Quality Engineering Manager shall be responsible for qualifying all quality inspection personnel.

The Quality Director shall be responsible for the overall effectiveness of this section.

The Quality Audit team shall be responsible to assure that written procedures are prepared, followed, and conform to Durex requirements, including the effectiveness of the inspection and test status system.

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Title - Control of Non-Conforming Product	Approved by	_____

Purpose

To establish a system to prevent the inadvertent use of material / product which does not conform to specified requirements.

Scope

This section describes the control and responsibilities for identification, segregation, documentation, and disposition of all non-conformances of products and processes.

Procedure

Non-conformances are normally identified during the manufacturing process, but may be detected by observation or other means. All items thought to be non-conforming shall be brought to the attention of the appropriate authority.

All items or activities judged to be non-conforming and / or require MRB disposition shall be reported on the Quality Control Hold Ticket. These Hold tickets shall be numbered and controlled by the Quality department.

Non-conforming items shall be removed / segregated from the manufacturing area, and held for disposition.

When segregation is impractical or impossible due to physical conditions, such as size, weight, or access limitations, the items shall be clearly marked "Rejected, Material On Hold" to preclude the inadvertent use of the items.

Non-conforming material / items that requires obvious disposition will be routinely handled by the Quality / Quarantine department.

Reference procedure # 214, Non-Conforming Material

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Title - Control of Non-Conforming Product

The Material Review Board (MRB) functions as an evaluation team to determine the disposition of non-conforming material / items, and to initiate corrective action as necessary.

The MRB shall consist of representatives from Quality, Manufacturing, Manufacturing Engineering, and Executive Management.

Reference procedure # 215, Material Review Board.

Items that are judged to be beyond repair shall be scrapped by the MRB or Executive Management / Quality.

A disposition decision for rework, repair, or accept as is shall require a technical justification.

Repaired and / or reworked items shall be re-examined and documented in accordance with the applicable procedures to the original acceptance criteria.

When the product does not conform to the specified requirements, the Quality department shall obtain approval from the customer for use or repair. This shall be documented in the Quality product folder.

Responsibility

Anyone can identify and report non-conformances, place items into a non-conforming status, and notify the Quality department for action.

The chairman of the Material Review Board shall be the Quality Director, who is responsible for convening the MRB to act effectively on all non-conformances.

The Material Review Board shall review Internal Production Rejection reports (IPRR) for possible corrective action. If corrective action is required, the corrective action section is completed on the IPRR form.

The Quality Director shall be responsible for the overall effectiveness of this section.

The Internal Audit team shall be responsible to assure that written procedures are prepared, followed, and conform to Durex requirements, including the effectiveness of the non- conformance system.

Section 4.14

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Title - Corrective and Preventive Action

Approved by _____

Purpose

To establish a controlled system to assure that causes of actual or potential non-conformities are identified and corrected.

Scope

This section describes the controls and responsibilities to assure that the cause of recurring non-conformances, or any significant condition considered adverse to quality is determined, and that corrective or preventive action is taken to preclude repetition or occurrence.

Procedure

Corrective Action

Request for corrective action can originate from any department. Any condition considered adverse to quality shall be identified and documented to the Quality department.

Procedures for corrective action shall include the effective handling of customer complaints regarding product non-conformities.

Procedures for corrective action shall include non-conformities found during the manufacturing process.

Corrective actions shall include the investigation and the action needed to eliminate the cause of non-conformities.

Procedures shall include verification and effectiveness of the corrective action implementation.

Reference procedure #213, Corrective Action - Internal

#220, Customer Quality Feedback System

Procedures for corrective action shall include subcontractor non-conformances, as required. Reference procedure #208, Subcontractor Corrective Action.

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Title - Corrective and Preventive Action

Preventive Action

Corrective Action follow-up is the first step in preventive action.

Procedures for preventive action shall include the following information to detect, analyze, and eliminate potential causes of non-conformities.

- 1) Manufacturing process
- 2) Audit results
- 3) Quality records
- 4) Customer complaints

Procedures for preventive action shall include action regarding potential non-conformities, verification and effectiveness of the preventive action, and management review.

Reference procedure #223, Preventive Action

Responsibilities

Every employee at Durex has the responsibility to request corrective or preventive action on conditions adverse to Quality.

The Quality Director shall be responsible for the overall effectiveness of this section.

The Internal Audit Team shall be responsible to assure that written procedures are prepared, followed, and conform to Durex requirements, including the effectiveness of the corrective and preventive action system.

Section 4.15	DureX, Inc. Union, N. J.	Rev. B
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Title - Handling, Storage, Packaging, Preservation & Delivery		Approved by _____

Purpose

To establish controls for handling, storage, packaging, preservation, and delivery of products to assure design integrity and maintain functionality.

Scope

This section outline the controls and responsibilities for handling, storage, packaging, preservation, and delivery of all items and parts to prevent loss, damage, or deterioration.

Procedure

Procedures shall be maintained to describe the methods of handling product to prevent damage / deterioration during the manufacturing process.

Secure and appropriate storage facilities shall be maintained to prevent damage or deterioration of product. The receipt and transfer for goods stored in designated areas shall be through the use of move tickets and material requisitions. Product audits will be conducted within the storage facilities.

Move tickets placed with each container and / or production lot shall correctly identify, preserve, and segregate all product.

Reference procedure #304, Handling and Storage, In-process

All finished products shall be packed in such a manner as to ensure conformance to specified requirements. Requirements for packaging shall be stated on the production work orders (routers).

Reference procedure #703, Packing, Handling, Storage - Finished Goods.

Procedures shall be maintained to define the marking and labeling of product for identification in Finished Goods.

Reference procedure #702, Product Label Shipping

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Title - Handling, Storage, Packaging, Preservation & Delivery		

Durex shall be responsible for the safe delivery of goods and shall extend to the time goods are placed on the carrier vehicle. The carrier shall be responsible to ensure the material integrity during transport.

Reference procedure #701, Shipping Process

Responsibility

The Receiving and Shipping Managers shall be responsible for the overall effectiveness of this section.

The Internal Audit Team shall be responsible to assure that written procedures are prepared, followed, and conform to Durex requirements, including the effectiveness of the handling, storage, packaging, presentation, and delivery system.

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Title - Control of Quality Records		Approved by _____

Purpose

To establish the responsibility for the retention and maintenance of quality records.

Scope

This section defines the procedures for retention of quality records for orders processed to the requirements of ANSI / ASQC Q9001 - 1994.

Procedure

Quality Records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system.

Documents which are designated to become records shall be legible, accurate, complete, and identifiable to the product involved.

The records management system shall be maintained by the ISO Management Representative.

The minimum retention period of records shall be specified on the records retention list, (form 104-1).

At the end of the required retention period, the records shall be destroyed. Storage beyond the retention period shall be allowed.

Records shall be indexed and filed in a manner which permits retrieval of any record within a forty-eight hour period. Storage shall prevent damage, deterioration, and loss.

All quality records shall be made available for evaluation by the customer or customer's representative, when specified by contact.

All records shall be stored in folders, binders, or containers and placed in an area which minimizes deterioration and damage.

Reference procedure #104, Records Retention.

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Title - Control of Quality Records		

Responsibility

All quality system records shall be retained under the supervision of the ISO Management Representative.

The ISO Management Representative shall be responsible for the overall effectiveness of this section.

The Internal Audit Team shall be responsible to assure that written procedures are prepared, followed, and conform to Durex requirements, including the effectiveness of the control of quality records system.

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Title - Internal Quality Audits	Approved by	_____

Purpose

To establish a comprehensive system for the performance of internal quality audits.

Scope

This section outlines the controls and responsibilities for conducting planned and periodic audits to determine compliance and effectiveness of all elements of the quality system.

Procedure

Audits shall include examination of program elements, and shall verify by objective evidence, compliance with the quality program.

The ISO Management Representative shall prepare a calendar for auditing which shall provide for the entire program to the audited.

The lead auditor shall complete an audit plan prior to each audit. The audit plan shall reviewed by the ISO Management Representative. The audit plan shall identify requirements, audit personnel, activities to be audited, schedule, and written procedures.

Audits shall be conducted by qualified audit personnel, assigned by the ISO Management Representative. Audit personnel shall not have direct responsibility in the area being audited.

The audit report shall be issued by the lead auditor and / or ISO Management Representative, and shall include the following:

- 1) Description of audit plan
- 2) Identification of auditors
- 3) Identification of persons contracted during the audit
- 4) Summary of the audit results, including a statement of effectiveness of the quality system elements that were audited.
- 5) Description of reported adverse findings in sufficient detail to enable corrective action to be taken.

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Title - Internal Quality Audit

The completed audit report shall be sent to the ISO Management Representative for review, with recommendations for corrective action.

Activities which show a deficiency through an audit shall require a corrective action request be sent to the responsible manager. The manager shall report when the deficiency has been corrected.

Confirmation of corrected deficiencies shall be accomplished by a follow-up audit.

The ISO Management Representative shall select individuals for auditing assignments who have been trained for the audit function.

Reference procedure #217, Internal Quality System Audit Process

Responsibilities

The ISO Management Representative shall have responsibility for the conduct and effectiveness of the audit function.

The ISO Management Representative shall review all audit records with executive management.

The ISO management Representative shall be responsible for the overall effectiveness of this section.

The Internal Audit Team shall be responsible to assure that written procedures are prepared, followed, and conform to Durex requirements, including the effectiveness of the internal quality audit system.

Section 4.18	DureX, Inc. Union, N. J.	Rev. B
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Title - Training	Approved by _____
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Purpose

To establish a program for training and indoctrination of personnel in the correct performance of job activities.

Scope

Durex personnel shall receive training and indoctrination in the performance of their activities, as required.

Procedure

Support and direction for training shall be through Executive Management and Human Resources.

Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training, and / or experience.

Training needs will be identified through:

- 1) Executive staff meetings
- 2) Corrective Action Program
- 3) Recommendations of supervisors, managers, employees, and the quality department

- 4) Response to customer requests
- 5) Change in process instructions
- 6) Recommendations of the Safety Team

The training program shall serve to instruct in basic job skills and responsibilities in quality related activities.

Training in job skills may be accomplished through lectures, video programs, on-the-job training, formalized written instructions, group discussion, seminars, or sponsored outside courses.

Refresher training shall be conducted, as required, to assure that the achieved proficiency is maintained.

Section 4.18	DureX, Inc. Union, N. J.	Rev. B
Page 2 of 2	Quality Manual	Effectivity - 6/15/98
Title - Training		

Each employee's personal file shall contain all records of training.

Training documentation shall be monitored and controlled by the Human Resource Manager.

Personnel involved in special processes which requires specific qualifications, such as fork lift operations and internal audits, shall have special training and qualification, as required by procedures.

Reference procedure #601, Training Program

#602, Operator Certification

#603, Orientation of New Employees.

The Human Resource department shall assist in the preparation of training program outlines, and shall monitor the presentation of the training.

It shall be the responsibility of each department supervisor / manager to ensure the indoctrination of all new employees, and promoted / transferred employees, including the need for additional training.

The Human Resource Manager shall be responsible for the overall effectiveness of the section.

The Internal Audit Team shall be responsible to assure that written procedures are prepared, followed, and conform to Durex requirements, including the effectiveness of the training system.

Section 4.19	DureX, Inc. Union, N. J.	Rev. A
Page 1 of 1	Quality Manual	Effectivity - 6/15/98
Title - Servicing		Approved by _____

The Durex, Inc. quality system does not include requirements for Servicing

Section 4.2	DureX, Inc. Union, N. J.	Rev. C
Page 1 of 4	Quality Manual	Effectivity - 4/12/00
Title - Quality System		Approved by _____

Purpose

To establish a system of policies, procedures, standards, and controls to assure the planned and controlled actions necessary to produce quality products for Durex customers.

Scope

The quality system encompasses all of the functions which are necessary to effectively assure the production of a quality product in compliance with the Durex customer requirements.

Quality System

The quality system structure shall be defined as follows:

- 1) Tier 1 - Quality Manual A written document which describes the Durex ISO9001-94 quality system. Controlled copies of the Quality Manual are distributed according to a master list maintained by the ISO Management Representative.
- 2) Tier 2 - Quality Procedures Procedures which detail the method for implementing the quality requirements as set forth in the Quality Manual. These procedures shall provide sufficient detail to assure activity completeness and standardization. The

quality procedures have been developed to cover all applicable elements of the quality system and are arranged in accordance with the elements of ANSI / ASQC 9001-94. Controlled copies are distributed according to a master list maintained by the ISO Management Representative. Applicable system level procedures are referenced in the table of contents of the Quality Procedure Manual.

- 3) Tier 3 - Operating Work instructions Individual department procedures which detail the method for complementing specific functions within the department or work area. These work instructions shall provide sufficient detail to assure activity completeness and standardization.

Reference procedure #105, Standard Operating Procedure, Creation and Control

Section 4.2	DureX, Inc. Union, N. J.	Rev. C
Page 2 of 4	Quality Manual	Effectivity - 4/12/00
Title - Quality System		

Quality System (Cont'd)

Work instruction locations by department are as follows :

- 1) Press Department - Primary / Secondary - Routers / Operating instructions maintained at each press as specific job runs. Routers are stored in the Visual Mfg'ing System.
- 2) Assembly - Work instructions (master) stored in the Quality Department. Controlled copies kept in the Assembly department. Routers maintained at each operation as each specific job runs. Routers are stored in the Visual Mfg'ing System.
- 3) Paint - Routers maintained within department as jobs are run. Work instructions (master & controlled copies) stored in the Quality department.
- 4) Shipping - Work instructions / routers are stored in the Visual Manufacturing system.

Durex, in general, performs quality planning on all customer products.

Quality planning is accomplished through the use of the Quality Manual, Quality procedures, Operating Instruction Documents, and Work Instructions.

Reference procedure #109, Quality Planning

Records are documented and maintained to support our Quality system.

Quality System Records are retained / stored per the Record Retention List, FM104-1

Reference procedure # 104, Record Retention

Manual Revisions

As ANSI / ASQC 9001-94 revisions are issued, they shall be revised by the ISO Management Representative for revisions affecting the quality system. The quality manual shall be revised using the SOP Change Notice Form 105-1 to incorporate the required changes.

Suggestions for manual revisions shall be presented to the ISO Management Representative for consideration.

When any part of a subsection requires revision the entire subsection shall be re-issued. Personnel affected by the revisions shall have training as required.

Section 4.2

DureX, Inc. Union, N. J.

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Quality Manual

Effectivity - 4/12/00

Title - Quality System

Manual Distribution

Quality manuals shall be identified as **“Controlled Document”** in red ink.

Controlled copies shall be issued to Durex personnel.

Controlled copies shall be sequentially numbered.

Printed copies are considered uncontrolled unless stamped “Controlled”.

The ISO Management Representative shall be responsible for maintaining and updating all controlled copies of the manual. The ISO Management Representative shall maintain a log of all holders of controlled manuals.

Uncontrolled copies shall be issued on request for sales promotional purposes only.

Uncontrolled copies shall not be issued to Durex personnel.

Uncontrolled copies shall be current at the time of issue, and shall receive no future revisions.

Issuance of the manual and revised sections of the manual shall be distributed by the ISO Management Representative.

Manufacturing Department Description

Primary Department - Press department, progressive dies or first stage press operation for a product.

Secondary Department - Press department, secondary, third, or fourth press operations, forming, etc. for a product.

Assembly Department - Welding, tapping, pem insertion, riveting, silk-screen and assembly operations.

Finishing Department - Wet and powder paint line operations.

Tumbling / Degreasing Department – Removal of sharp edges and burrs. Removal of oils and contaminants.

Packaging Department – Prepare the product for shipment to the customer.

Section 4.2	DureX, Inc. Union, N. J.	Rev. C
Page 4 of 4	Quality Manual	Effectivity - 4/12/00
Title - Quality System		

Scope of Registration

All products manufactured at Durex, Inc.

Responsibility

The ISO Management Representative shall be responsible for the overall effectiveness of this section

The Internal Audit Team shall be responsible through the internal audit system, to assure written procedures are prepared, followed, and conform to the Durex requirements.

The Internal Audit Team shall evaluate the effectiveness of the Quality System.

Section 4.20	DureX, Inc. Union, N. J.	Rev. B
Page 1 of 1	Quality Manual	Effectivity - 6/15/98

Purpose

To establish the controls for the application of statistical techniques.

Scope

This section describes the controls and responsibilities for the use of statistical techniques throughout the organization.

Procedure

Statistical techniques are components of an overall continuous process improvement program. Some of these techniques include control charting, sample plans, and trend charts. The training of personnel in the techniques of continuous process improvement shall be constant and on going.

Where statistical techniques have been implemented, the quality procedure for that product will indicate the implemented statistical technique.

Data collection for process measurements shall be performed by trained individuals.

Results of statistical data collection shall be formatted appropriately.

SPC results shall be maintained within the guideline of the quality records system.

Internal applications for statistical techniques shall be utilized in the following areas:

- 1) Vendor Quality
- 2) Manufacturing Department Quality
- 3) Specified Product by Customer request.

Responsibility

The Quality Engineering Manager shall be responsible for the overall effectiveness of this section.

The Internal Audit Team shall be responsible to assure written procedures are prepared, followed, and conform to Durex requirements, including the effectiveness of the statistical techniques system.

Section 4.3

DureX, Inc. Union, N. J.

Rev. B

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Quality Manual

Effectivity - 6/15/98

Title - Contract Review

Approved by _____

Purpose

To establish the procedures used in managing and coordinating a quote request / order from a customer.

Scope

This section describes the control and responsibilities for the translation of customer contract requirements into complete work orders.

Procedures

Request for quotes on new products will be reviewed by the sales, engineering, and management of Durex per procedure # 402, Request for Quote.

Engineering shall review and verify that all applicable documentation is received and complete. Any missing documentation shall be requested from the customer.

Manufacturing Engineering maintains the customer print files and shall be responsible for updating existing customer documents and drawings when required.

Each contract will be reviewed to ensure that:

- 1) The product requirements are defined and documented.
- 2) A method is established to handle differences between the contract and the accepted order.
- 3) Durex has the ability to meet the requirements.
- 4) Clear communication interface with the customer must be defined.

Reference procedure # 401, Contract Review

The Sales, Customer Service, and Manufacturing Engineering departments will ensure proper control for amendments to a contract. Procedure # 802, Change Order/ Document Control shall define how an amendment to a contract is made and communicated to all affected departments at Durex.

Section 4.3

DureX, Inc. Union, N. J.

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Quality Manual

Effectivity - 6/15/98

Title - Contract Review

The formal quotation is mailed to the customer confirming agreed terms. If the customer does not agree with the quotation, they may communicate the disagreement either in writing or verbally until an agreement is met.

Records of all contact reviews will be maintained in the administrative office by customer and product.

Upon acceptance of the order by the customer, a sales order is created and entered into the computer system per procedure # 501, Sales Order Creation.

Responsibility

The Sales, Engineering, Manufacturing Engineering, and Customer Service departments are responsible for handling all customer orders and ensuring the requirements of the customer specifications are accurately documented.

The Internal Audit Team shall be responsible to assure that written procedures are prepared, followed, and conform to Durex requirements, including the effectiveness of the contract review system.

Section 4.4	DureX, Inc. Union, N. J.	Rev. C
Page 1 of 2	Quality Manual	Effectivity - 11/02/98
Title - Design Control		Approved by _____

Purpose

Engineering will maintain procedures to ensure the design of the product meets program goals, launch schedule, and customer expectations.

Scope

This section describes the methods, controls, and responsibilities for the translation of customer requirements into completed designs.

Design and Development Planning

Engineering will maintain plans for each design and development activity. The plans shall define responsibility, qualified personnel, and required resources. Reference procedure # 403, Engineering Tooling Design Process.

Organizational and Technical Interface

Procedures will be maintained to ensure that department participation and interface in the design process shall consist of Engineering, Sales, Quality, Tooling, and Production Reference procedure #403, Engineering Tooling Design Process.

Design Input

Procedures will be maintained to define the input of the design project with specifications, objectives, and performance requirements. Reference procedure #403, Engineering Tooling Design Process.

Design Output

Procedures will be maintained to verify the design output through the, measurement against design input requirements. Verification of the design output is maintained through procedure #205, First Article Inspection.

Section 4.4

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Quality Manual

Effectivity - 11/02/98

Title - Design Control

Design review

Procedures and methods for design reviews will be maintained. Design reviews will be conducted regularly and department representation will include Engineering, Manufacturing Engineering, Quality, Sales, Tooling, and Production. Records of reviews will be maintained. Reference procedure #403, Engineering Tool Design Process.

Design Verification

Procedures will be maintained to perform design verification to ensure that the design output meets the design input. Verification may include product submission to the customer. Verification measures will be recorded. Reference procedure #205, First Article Inspection.

Design Validation

Design validation will be maintained to ensure that the product conforms to the customers requirements by sending sample parts to the customer for review. Reference procedure #205, First Article Inspection.

Design Changes

Procedures will be maintained for all design changes and modifications. These changes will be identified, documented, reviewed, and approved by authorized personnel. Reference procedures #803, Design / Process Change Request

Responsibility

Engineering, Toolroom, and Quality departments are responsible for the product design to meet the customer expectations.

The Internal Audit Team shall be responsible to ensure that written procedures are prepared, followed, and conform to Durex requirements, including the effectiveness of the design control system.

Section 4.5	DureX, Inc. Union, N. J.	Rev. B
Page 1 of 2	Quality Manual	Effectivity - 6/15/98
Title - Document and Data Control		Approved by _____

Purpose

To establish the procedure for documents which defines the product, controls the release, and distribution of product documents.

Scope

This section describes the controls and responsibilities for the origin, content, review, approval, distribution, and revision of documents. This includes internal documents and customer documents.

Document and Data Approval and Issue

Engineering / Manufacturing Engineering is responsible for the preparation of all products documentation including, but not limited to, parts list, master specifications, products drawings, including customer drawings. These documents establish the

manufacturing requirements, dimensional standards, materials, and part numbers of the product / components.

Master specifications and master product drawing are stored in the customer folder in the administrative office.

Controlled drawings and documents are distributed to the Quality department for retention in the customer Quality folder.

Invalid and / or obsolete documents shall be promptly removed from the master customer file and the customer quality file. Obsolete documents are stamped obsolete and placed in the obsolete file in the Quality department.

Reference procedure #108, Documentation Control and procedure #801 New Order Entry Process / Document Control.

Section 4.5

DureX, Inc. Union, N. J.

Rev. B

Page 2 of 2

Quality Manual

Effectivity - 6/15/98

Title - Document and Data Control

Document and Data Changes

Revision to documents shall be reviewed and approval by manufacturing engineering per procedure #802, Change Order / Document Control.

The document change procedure will include:

- 1) Review and approval
- 2) Access to background information
- 3) Nature of the changes identified
- 4) After several number of changes, re-issue the document.

New master documents are placed in the master sales folder.

Controlled documents are distributed to the Quality department for retention in the customer quality folder.

Obsolete documents are stamped obsolete, destroyed, or placed in the obsolete file in the Quality department.

Responsibility

Manufacturing Engineering shall be responsible for the control and distribution of specifications and drawings.

The ISO Management Representative shall be responsible for the control and distribution of all other documents referenced in the manual.

The Internal Audit Team shall be responsible to ensure written procedures are prepared, followed, and conform to Durex requirements, including the effectiveness of the document and data control system.

Section 4.5.1	DureX, Inc. Union, N. J.	Rev. C
Page 1 of 3	Quality Manual	Effectivity - 6/15/00
Title - Quality Procedures		Approved by _____

Purpose

To establish a means for documenting procedures and instructions relating to the quality system.

Scope

This section describes the control and responsibilities for the origin, content, review, approval, distribution, and revision of the documented procedures required for the implementation and control of activities affecting quality.

Procedure

Written procedures shall be prepared for all activities affecting the quality system.

The ISO Management Representative, V. P. of Operations, and department manager or designee shall approve all procedures after review for conformance to the requirements of the quality system. This review shall look for adequacy, completeness, and correctness prior to approval and issuance.

The ISO Management Representative shall assign a defining number for distribution to the authorized holder of the quality system procedures manual. The procedure manual shall contain all detailed procedures in the quality system.

The master copy of the Quality procedure manual is controlled and stored by the ISO Management Representative in the Quality department.

All revisions to these documents shall be subjected to the same review as the original documents.

Operating instruction documents / work instructions shall be controlled by the assigned department and the Quality department.

Reference procedure #105, Standard Operating Procedure, Creation and Control.

Section 4.5.1	DureX, Inc. Union, N. J.	Rev. C
Page 2 of 3	Quality Manual	Effectivity - 6/15/00
Title - Quality Procedures		

Distribution

Quality system procedure manuals shall be assigned to individuals, and shall be controlled by a unique number. The ISO Management Representative shall maintain a log of all manuals and revisions issued.

Documents shall be distributed by the ISO Management Representative using the quality procedures log. Recipients will sign for the quality system procedure manual.

Updating of the quality system procedure manuals is the responsibility of the ISO Management Representative.

Responsibility

Each department manager shall be responsible for preparing documented procedures as necessary to meet the requirements of their functions.

The ISO Management Representative shall be responsible for assuring documents conform to requirements of the quality system and that all documents required to implement the system are prepared.

The ISO Management Representative shall be responsible for the distribution of all quality procedures and the overall effectiveness of the section.

<u>4.5</u> <u>Docume</u> <u>nt and</u> <u>Data</u> <u>Control</u>				
104	Records Retention	A	3	09/01/96
105	Standard Operating Procedure Creation and Control	A	5	09/05/96
107	Identification of Meeting Attendees	A	2	02/15/97
108	Documentation Control	A	3	08/01/96
801	New Order Entry Process / Document Control	B	3	02/19/98
802	Change Order / Document Control	A	3	09/01/96
<u>4.6</u> <u>Purchasi</u> <u>ng</u>				
201	Supplier Selection and Approval	A	3	09/01/96
202	Supplier Quality Rating and Control	A	3	09/01/97
203	Approved Suppliers	A	3	09/01/97
302	Purchase Order Process	A	3	08/01/96
<u>4.7</u> <u>Control</u> <u>of</u> <u>Custome</u> <u>r</u> <u>Supplied</u> <u>Product</u>				
207	Customer Supplied Product	A	3	08/01/96

		Rev.	Pages	Date
<u>4.8</u> <u>Products</u> <u>Identifica</u> <u>tion and</u> <u>Traceabil</u> <u>ity</u>				
307	Move Ticket Process	A	3	01/01/97
702	Product Label - Shipping	A	4	01/01/97
<u>4.9</u> <u>Process</u> <u>Control</u>				
210	Special Process	A	3	09/01/96
301	Material Receiving	A	7	07/01/96
303	Work Order Creation	A	4	07/01/96
305	Work Order Process Manufacturing	A	5	01/01/97
306	Scrap Control Process	A	3	01/01/97

805	Sample / Trial Run	A	4	11/01/97
852	Tooling Identification / Storage	A	3	09/01/97
1001	Preventative Maintenance	A	36	05/27/97
4.10				
<u>Inspection and Testing</u>				
205	First Article Inspection	A	4	07/01/96
206	Receiving Inspection	A	7	10/01/96
209	First Piece, In-Process, & Final Audit Inspection	B	6	10/17/97
222	Operator Inspection	A	3	10/15/97
4.11				
<u>Control of Inspection, Measuring, Test Equipment</u>				
219	Calibration System	B	7	10/17/97
4.12				
<u>Inspection and Test Status</u>				
211	Production Acceptance	A	3	01/01/97
212	Quality Inspection Identification Stamps	A	4	10/01/96
4.13				
<u>Control of Nonconforming Products</u>				
214	Non-Conforming Material	A	4	08/01/96
215	Material Review Board	A	3	08/01/96
218	Control of Finished Products - Hold	A	3	08/01/96
4.14				
<u>Corrective and Preventive Actions</u>				
208	Supplier Corrective Action	A	3	08/01/97

213	Corrective Action - Internal	A	3	08/01/97
853	Tooling Maintenance / Repair	A	3	09/01/96
4.15				
<u>Handling</u>				
<u>Storage,</u>				
<u>Packing,</u>				
<u>ng, and</u>				
<u>Delivery</u>				
304	Handling and Storage In-Process	A	3	01/01/97
701	Shipping Process	A	4	08/01/96
703	Packing, Handling, Storage Finished Goods	A	3	01/01/97
704	Shipping Records	A	3	01/01/97

		Rev.	Pages	Dates
4.16				
<u>Control</u>				
<u>of</u>				
<u>Quality</u>				
<u>Records</u>				
106	Quality Documentation and Records	A	3	09/01/96
4.17				
<u>Internal</u>				
<u>Quality</u>				
<u>Audits</u>				
216	Finished Goods - Quality Audits	A	3	09/01/97
217	Internal Quality System Audits process	B	3	10/17/97
4.18				
<u>Training</u>				
601	Training Needs Employees	A	3	08/01/97
602	Operator Certification	A	3	08/01/97
603	Orientation of New Employees	A	3	08/01/97
4.19				
<u>Servicing</u>				
4.20				
<u>Statistica</u>				
<u>l</u>				
<u>Techniqu</u>				
<u>es</u>				
221	Statistical Process Control	B	3	10/17/97

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5	6	7	8
19	10	11	12
13	14	15	16
17	18	20	21
22	23		

DEPARTMENT	ASSIGNED TO NUMB
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Human Resources	Mike Wenzel	1
Sales	Bill Meringer	2
Engineering	Bahir Abrihim	3
Shipping / Rec'ing	Rene Rich	4
Quality	Don Nalupta	5
Toolroom	Ed Kuehnle	16
Primary	Jim Castiglione	7
Secondary	Al Stoia	19
Assembly	John Wright	8
Paint	Doug Ruppel	9
Purchasing	Steve Schoenbach	10
MIS		11
Tumble / Degreasing	John Liska	12
Maintenance	Paul Powell	13
Prod. Control	Roy MacPherson	14
Manager	Ed Denholtz	15
	Bob Denholtz	17
	Sandy Schoenbach	21
	B. Cohen	18
	B. Jensen	20
	Steve Schertz	6
	Stu Robinson	22

TOTAL - 22 BOOKS

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DEPARTMENT	NO.	ASSIGNED TO...	SIGNATURE
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Human Resources	1	Mike Wenzel	-----
Sales	2	Bill Meringer	-----
Engineering	3	Bahir Abraham	-----
Shipping / Reciving	4	Rene Rich	-----
Quality	5	Don Nalupta	-----
Executive Management	6	Steve Schertz	-----
Primary	7	Jim Castiglione	-----
Assembly	8	John Wright	-----
Paint	9	Doug Ruppel	-----
Purchasing	10	Steve Schoenbach	-----
MIS	11	Aaron Tenenbaum	-----
Tumble / Degreasing	12	John Liska	-----
Maintenance	13	Paul Powell	-----
Prod. Control	14	Roy MacPherson	-----
Manager	15	Ed Denholtz	-----
Toolroom	16	Ed Kuehnle	-----
Executive Management	17	Bob Denholtz	-----
Executive Management	18	Barry Cohen	-----
Secondary	19	AL Stoia	-----
Quality	20	Bill Jensen	-----

Executive Management 21 Sandy Schoenbach

Plant Manager 22 Stu Robinson

Receiving 23 Bob McGee

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Name	Date
Elvin	24-Jan
Asteria	17-Feb
Fausto	Feb-29
Nancy	8-Jun
Ruby	27-Jun
Freda	2-Jul
Alice	17-Jul
Elba	21-Oct
Raquel	21-Oct
Angel	25-Oct
Irma	30-Oct
Dora	18-Nov
Howard	29-Nov

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DureX,

<u>4.1</u>			
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<u>ent</u>			
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101	Company Organization and Management Responsibility.		
102	Management Review		
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105	Standard Operating Procedure Creation and Control		
<u>4.3</u>			
<u>Contract</u>			
<u>Review</u>			
401	Contract Review		
402	Request for Quote Process		
501	Sales Order Creation		
<u>4.4</u>			
<u>Design</u>			
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403	Engineering Tooling Design Process		
803	Design / Process Change Request		
804	Deviation Process		

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<u>and</u>			
<u>Testing</u>			
206	Receiving Inspect		
209	First Piece, In-Process, & Final Audit Inspect		
222	Operator Inspect		
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<u>Inspection</u>			
<u>Measuring</u>			
<u>Test</u>			
<u>Equipment</u>			
219	Calibration Syst		
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<u>and Test</u>			
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211	Production Accepta		
212	Quality Inspection Identification Stan		
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<u>Nonconfor</u>			
<u>ming</u>			
<u>Products</u>			
214	Non-Conforming Mate		
215	Material Review Bo		
218	Control of Finished Products - H		

850	Tool and Die Quote Process	<u>4.14</u> <u>Corrective</u> <u>and</u> <u>Preventati</u> <u>ve Actions</u>	
851	Tooling Acceptance	208	Subcontractor Corrective Act
854	New Tooling - Creation	213	Corrective Action - Inter
855	Die Construction Specifications	853	Tooling Maintenance / Rep
205	First Article Inspection	220	Customer Quality Feedback Syst
		223	Preventive Act
<u>4.5</u> <u>Document</u> <u>and Data</u> <u>Control</u>		<u>4.15</u> <u>Handling</u> <u>Storage,</u> <u>Packaging,</u> <u>and</u> <u>Delivery</u>	
108	Documentation Control	304	Handling and Storage In-Proc
801	New Order Entry Process / Document Control	701	Shipping Proc
802	Change Order / Document Control	703	Packing, Handling, Storage Finished Go
<u>4.6</u> <u>Purchasin</u> <u>g</u>		<u>4.16</u> <u>Control of</u> <u>Quality</u> <u>Records</u>	
201	Supplier Selection and Approval	106	Quality Documentation and Reco
202	Supplier Quality Rating and Control	104	Records Retent
203	Approved Suppliers	704	Shipping Reco
302	Purchase Order Process	1101	Personal Computer Back
		1102	Computer System Record Retent
		1103	Personal Computer Virus Protect
<u>4.7</u> <u>Control of</u> <u>Customer</u> <u>Supplied</u> <u>Product</u>		<u>4.17</u> <u>Internal</u> <u>Quality</u> <u>Audits</u>	
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<u>4.8</u> <u>Products</u> <u>Identificati</u> <u>on and</u> <u>Traceabilit</u> <u>y</u>		<u>4.18</u> <u>Training</u>	
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702	Product Label - Shipping	602	Operator Certificat
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<u>4.9</u> <u>Process</u> <u>Control</u>		<u>4.19</u> <u>Servicing</u>	
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303	Work Order Creation		
305	Work Order Process Manufacturing		
306	Scrap Control Process	<u>4.20</u> <u>Statistical</u> <u>Technique</u>	

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Sample / Trial Run
Tooling Identification / Storage
Preventative Maintenance

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Statistical Process Control

Section 4.6

DureX, Inc. Union, N. J.

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Quality Manual

Effectivity - 6/15/98

Title - Purchasing

Approved by _____

Purpose

To establish a controlled system for the purchasing of materials and services.

Scope

This section describes the control and responsibilities for the selection of suppliers and the preparation and approval of purchasing documents for materials and services.

Procedure

Durex, Inc. is responsible for ensuring that purchased parts meet its requirements and specifications.

Durex will evaluate and select subcontractors on the basis of price, delivery, quantity, Quality system, and suppliers evaluation criteria. Suppliers / subcontractors who consistently are rated below 75% on the supplier rating system will be limited or suspended as suppliers. Quality records will be maintained on all suppliers.

Purchasing documents will include a clean definition of the product requirements including drawings, specifications, process requirements, test requirements, inspection criteria, physical / chemical requirements, cosmetic standards, and quality system standards that apply. The purchasing document will be approved prior to use.

Durex will specify arrangements and method of product release when purchased product is verified at the subcontractors premises.

Durex's customer will verify at the subcontractor's premises that the product conforms to specified requirements when specified in the contract. Verification may include inspection, supplier certification, or functional validation.

Reference procedure: #201 - Supplier Selection and Approval, procedure

#202 - Supplier Quality Rating and Control

#203 - Approved Suppliers

#302 - Purchase Order Process

Section 4.6 **DureX, Inc. Union, N. J.** Rev. B

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Title - Purchasing

Responsibility

Purchasing shall be responsible for selecting prospective suppliers and negotiating all purchase agreements.

Purchasing shall assure material is available to support Durex production requirements.

The Purchasing and Quality departments shall be responsible for approval, disapproval, and participation in the supplier rating system.

The Quality Engineering Manager shall establish guidelines for all supplier quality programs.

The Internal Audit Team shall be responsible to assure that written procedures are prepared, followed, and conform to Durex requirements, including the effectiveness of the purchasing system.

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Title - Control of Customer Supplied Product Approved by _____

Purpose

To establish the procedure for the control of customer supplied product.

Scope

This section describes the controls and responsibilities for the verification, storage, and maintenance of product supplied by a customer to Durex.

Procedure

Durex will maintain procedures for the verification, storage, and maintenance of a product supplied by a customer that Durex adds value to and returns to the customer.

All damaged or lost product shall be reported to the customer.

Reference procedure #207 - Customer Supplied Product

Responsibility

The Quality department is responsible for the quality acceptance of customer supplied product.

Warehouse management is responsible for proper control and storage of customer supplied product.

The Internal Audit Team shall be responsible to assure written procedures are prepared, followed, and conform to Durex requirements, including the effectiveness of the customer supplied product system.

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Title - Product Identification and Traceability	Approved by	_____

Purpose

To establish a controlled system to assure item identification and traceability is established and maintained for items in stock, in-process, and finished product.

Scope

This section describes the controls and responsibilities for the identification and traceability of items during all stages of production and delivery.

Procedure

All items used for the manufacturing of finished product shall be identified.

Durex will maintain procedures for the identification of the product, from receipt throughout all stages of production and delivery.

Move tickets are utilized for the identification of all accepted products. Reference procedure #207 - Move Ticket Process.

Items which cannot be identified using move tickets due to product non-conformance, shall be segregated and handled in accordance with procedure #214, Non-Conforming Material.

Durex will maintain procedures for unique identification of products that require traceability. This identification will be recorded. Reference procedure #308 - Special Lot Identification.

Responsibility

Manufacturing Engineering shall be responsible for the control and issuance of all part numbers.

Each manufacturing department shall be responsible for identification of material.

The Quality department and each manufacturing department shall be responsible for the identification and segregation of all non-conforming items.

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The Quality Engineering Manager shall be responsible for the overall effectiveness of this section.

The Internal Audit Team shall be responsible to assure written procedures are prepared, followed, and conform to Durex requirements, including the effectiveness of the product identification and traceability system.

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Title - Process Control	Approved by	_____

Purpose

To establish a system for the control of the manufacturing process.

Scope

The section describes the control and responsibilities for the preparation, distribution, and control of material manufactured and assembled at Durex, Inc.

Procedure

Production processes which directly affect quality shall be carried out under controlled conditions through the use of work instructions / routers. These work instructions / routers shall be written and issued for all processes which directly affect quality. These conditions shall include, but are not limited to the following:

- 1) Procedures defining the production process and activities.
- 2) Use of proper production equipment within a suitable working environment.
- 3) Compliance with reference standards, quality plans, and documented procedures.
- 4) Monitor and control all appropriate process parameters and product characteristics.
- 5) The approval of processes and equipment, as appropriate.
- 6) Product acceptability defined through workmanship standards, and cosmetic standards.
- 7) Preventive maintenance to ensure process capability.
- 8) Critical processes defined with SPC control plans as required.
- 9) Error - proofing of processes, as appropriate.

Processes where the results cannot be tested until after the product is completed will be continually monitored, and documented in order to comply with product requirements.

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Title - Process Control

Special processes will be defined as qualified process. Records will be maintained for qualified processes.

Work instructions / routers shall be controlled and distributed in accordance with section 4.5 - Document and Data Control.

Revisions to work instructions / routers shall be generated as a result of a process change, engineering change, equipment upgrade, or technology improvements.

All changes shall be subject to the same review and approval as the original document.

Reference procedure: #303 - Work Order Creation

#305 - Work Order Process Manufacturing

Responsibility

The Production Control Manager shall be responsible for initiating and processing all production work orders.

The V. P. of Operations shall be responsible for the overall effectiveness of the section.

The Internal Audit team shall be responsible to assure that written procedures are prepared, followed, and conform to Durex requirements, including the effectiveness of the process control system.

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Title - Glossary of Terms		Approved by _____

Purpose

To establish operational definitions for the terms referenced in this manual.

Scope

This section defines the terms used throughout the manual and is established as a reference document.

Definitions

Acceptance Criteria: Specified limits placed on characteristics of an item, process, or service defined in standards, or other requirement documents.

Accept-As-Is: A disposition permitted for a non-conforming item when it can be established that the item is satisfactory for its intended use without violating safety or functional requirements.

Audit: A documented evaluation performed to verify, by examination of objective evidence, that those selected elements of a previously approved quality program have been developed, documented, and implemented in accordance with specified requirements.

Certification: The act of verifying and attesting in writing that documents, processes, procedures, items, or the qualifications of personnel are in accordance with specified requirements.

Material Certification: A document attesting that the material is in accordance with specified requirements, including the actual results of all required chemical analyses, test, and examinations.

Characteristic: Any property or attribute of an item, process, or service that is distinct, describable, and measurable.

Condition Adverse to Quality: An all inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and non-conformances. A significant condition adverse to quality is one which, if uncorrected, could have a serious affect on the safety of operability of the product.

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Title - Glossary of Terms

Contract: Agreed requirements between a supplier and customer transmitted by any means.

Corrective Action: Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

Customer: The organization that purchases our products and is responsible for establishment of procurement.

Design Drawings: Drawings which are prepared, either electronically or by hand, to illustrate the mechanical details necessary to comply with the design specification.

Deviation: A departure from specified requirements.

Document: Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a quality record until it satisfies the definition of a quality record as defined in this manual.

Document Control: Those measures established to control the preparation, review, release, issuance, and disposition of documents, such as design calculations, purchase orders, specifications, instructions, procedures, and drawings, including changes, thereto, which describe or document activities affecting quality.

Guideline: A suggested practice that is not mandatory in programs intended to comply with standard. The word “should” denoted a guideline; the word “shall” denotes a requirement.

Inspection: Examination or measurement to verify whether an item or activity conforms to specified requirements.

Internal Audit: An audit of those portions of the quality system retained under its direct control and within its organizational structure.

Item: An inclusive term used in place of any of the following: assembly, component part, equipment, material, structure, subassembly, or unit.

Measuring and Test Equipment: Devices or systems used to calibrate, measure, gauge, test, or inspect, in order to control or to acquire data to verify conformance to specified requirements.

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Title - Glossary of Terms

MRB: Material Review Board.

Non-conformance: A deficiency in a characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

Objective Evidence: Any documented statement of fact, other information or record, either quantitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests, which can be verified.

Part: An item which is attached to or becomes a portion of a component before completion.

Preventive Action: Measures taken to eliminate potential problems.

Procedure: A document that specifies or describes how any activity is to be performed.

Process Instruction: A written procedure which details the interrelated resources and activities required to transform inputs into outputs with the aim to add value. Resources include personnel, facilities, equipment, technology, and methodology.

Quality Control: Measurement of the characteristic of an item or process to determine conformance to specified requirements.

Quality Procedure: An approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.

Quality Record: A completed document that furnishes evidence of the quality of items and/or activities affecting quality.

Quality System: A controlled system of planned and systematic actions required to provide adequate confidence that items designed and constructed are in accordance with the design specification.

Receiving: Taking delivery of an item at a designated location.

Rework: The reprocessing of product to conform to the originally specified requirement.

Subcontractor / Vendor: Any individual or organization who furnishes items or services to a procurement document. An all inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and sub-tier levels.

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Title - Glossary of Terms

Traceability: The ability to trace the history, application, or location of an item and like items, or activities by means of recorded identification.

Verification: The act of reviewing, inspection, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.