Surgi Manufacturing
Quality Manual

Surgi Manufacturing Company, Inc.
Quality Manual

Change Record

Revision	Date	Responsible Person	Description of Change
A	18Aug98	Engineering Manager	Development Release

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1. Introduction

This manual outlines the policy of the company relating to its Quality Management System. The Quality Manual is issued and controlled by Surgi Manufacturing, this manual defines the Quality Management System which is effective across all disciplines and at all levels within the company.

1.1 Scope

This Quality Manual Applies to stamping, forming, cutting, sawing, turning, and milling of metal of all grades and plastics and the Personnel of Surgi Manufacturing.

1.2 Purpose

The primary purpose of this Quality Manual is to describe and document the Quality Program currently in practice at Surgi Manufacturing. This Manual is the central source of general policies, procedures, and responsibilities that in turn authorize and govern creation of subsidiary quality related documentation and activities. This Manual provides comprehensive evidence to all customers, suppliers, and employees that Surgi Manufacturing is committed to establishing and maintaining acceptable levels of measurable Quality in its products and services. The requirements and procedures addressed in the Quality Manual are intended to meet the requirements of ISO 9002, (1994) and customer Quality Assurance specifications.

1.3 Authority

This manual is issued under the authority of the General Manager of Surgi Manufacturing.

1.4 Issue of the Manual

Controlled copies of the Manual will be numbered and registered. The master copy of the Manual will be held by the Quality Manager. The Quality Manager is responsible for the issue of amendments to the Manual, withdrawal of obsolete information and the maintenance of the master copy of the manual. Uncontrolled copies may be distributed to organizations or persons at the discretion of the Quality Manager. These will be current at the date of issue only and will not be subject to amendment action. These copies will be annotated “Uncontrolled Copy”.

1.5 Amendments

Controlled Manuals will be updated and revised as required. The issue of amendments requires approval by the Quality Manager.

1.6 Review

The Quality Manual will be reviewed annually by the Management staff to ensure that the policies set forth remain effective in the operation of the quality system. Evidence of the review will be indicated

Change Record

Revision	Date	Responsible Person	Description of Change
A	18Aug98	Engineering Manager	Development Release

by the signatures and dates as approved by the Management of Surgi Manufacturing. The Quality System will be audited over a twelve month period to affirm that the current practices conform to the policies set out in the manual. This Quality Manual is to be treated as confidential and must not be copied, re-printed or the contents divulged to a third party without the permission of the Quality Manager of Surgi Manufacturing.

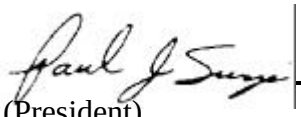
1.7 Cost of Quality

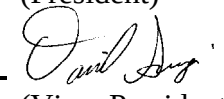
The cost of Quality is regularly addressed by the Controller and by management. Actual cost data is considered company confidential. This quality program is designed to produce continuous improvements in all operations. Improvements in quality are measured and evaluated using the cost of quality information.

Change Record

Revision	Date	Responsible Person	Description of Change
A	18Aug98	Engineering Manager	Development Release

2. Approvals

Paul Surgi _____  _____ Date 14 September 1998
(President)

David Surgi _____  _____ Date 14 September 1998
(Vice- President)

_____ Date _____
(Shop Floor Supervisor)

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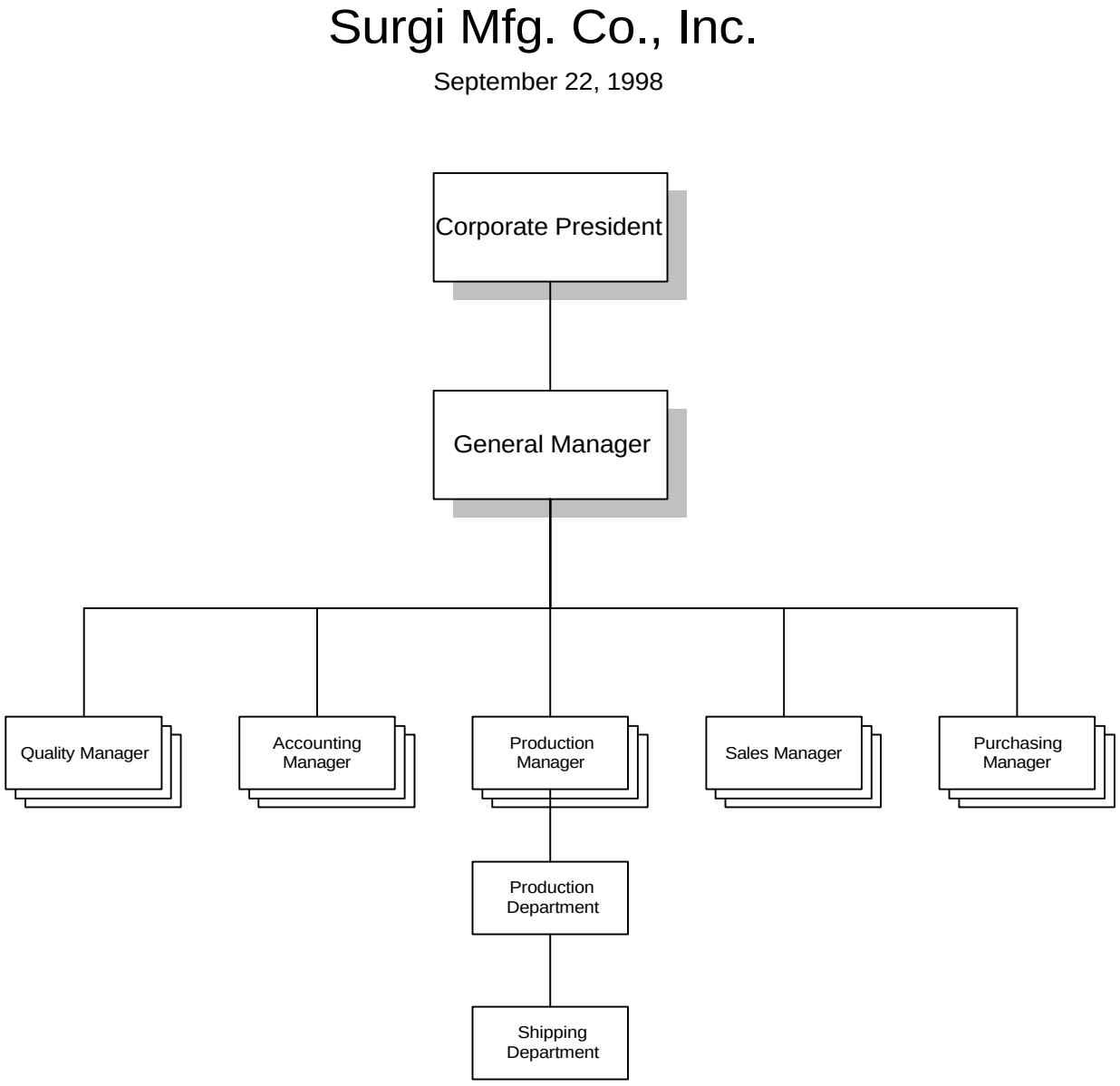
Change Record

Revision	Date	Responsible Person	Description of Change
A	18Aug98	Engineering Manager	Development Release



3. Company Organization

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Change Record

Revision	Date	Responsible Person	Description of Change
A	18Aug98	Engineering Manager	Development Release

4.1 Management Responsibility

4.1.1 Quality Policy

We clearly understand and conform to customer requirements and specifications. Our target is customer satisfaction. All employees within the. organization are responsible for understanding and the lamentation of the companies policy for quality.

4.1.2 Organization

The structure of the company will be defined within the organizational chart.

4.1.2.1 Responsibility and Authority

The General Manager is responsible for the verification that the policies and associated documents are implemented and performed. The department managers are responsible for the creation and implementation of documents procedures and work instructions. These documents shall be in line with the companies policy for quality.

The Production Manager is responsible for the creation of procedures and work instructions for the production process. These processes will be carried out to ensure product quality and to satisfy the requirements of the customer.

The Sales Manager is responsible for the creation of procedures and work instruction for the sales and contract review activity.

The Purchasing Manager is responsible for the creation of procedures and work instruction for the purchasing department and the verification that all purchased material consistently meets the specified requirements.

The Accounting Manager is responsible for the creation of procedures and work instruction for the Accounting Department and the cost of quality calculations.

The Quality Manager is responsible for establishing and maintaining an effective quality management system. The Quality Manager is responsible for the verification of the implementation of solutions and to control further processing, delivery of non-conforming product until the deficiency or unsatisfactory condition has been corrected.

Surgi personnel have the organization freedom to initiate action to prevent the occurrence of any non-conformities relating to the product, process and quality system; Identify and record any problems relating

Change Record

Revision	Date	Responsible Person	Description of Change
A	18Aug98	Engineering Manager	Development Release

to the product, process and quality system; To initiate, recommend or provide solutions through designated channels.

4.1.2.2 Resources

Surgi Manufacturing Company, Inc. has identified and provides adequate resources. Including the assignment of trained personnel for management, performance of work and verification activities including internal quality audits.

4.1.2.3 Management Representative

The General Manager has appointed the Quality Manager to serve as the Management representative for Surgi Manufacturing Company, Inc.. The Quality Manager has the authority for ensuing that a quality system is established, implemented and maintained in accordance with ISO 9002 (1994) standard. The Quality Manager has the authority for reporting on the performance of the quality system to Management for review and as a basis for improvement of the quality system.

4.1.3 Management Review

The General Manager is responsible for management review. The quality policy and objectives are reviewed on a quarterly basis to ensure continuing suitability and effectiveness. Relevant information regarding the performance of the quality system will be reviewed as a basis for improvement. Information on corrective and preventive actions will be submitted for management review. Management review records are maintained. Attachments may be used as evidence of such reviews.

4.2 Quality System

4.2.1 General

Surgi Manufacturing has an established documented quality system. The System is maintained as a means of ensuring that the products produced by Surgi Manufacturing conforms to specified requirements. The quality manual covers the requirements of ISO 9002 (1994). The quality system procedures and work instructions are identified in the procedure matrix of this manual.

4.2.2 Quality System Procedures

Surgi Manufacturing has prepared documented procedures which are consistent with the requirements of ISO 9002(1994) standard and the companies stated quality policy. The quality system and it's documented procedures have been effectively implemented. Surgi Manufacturing maintains a documented quality system as a means to ensure that all products conform to specified requirements. The following four levels of documentation are utilized and maintained to meet the requirements of the ISO 9002 (1994) Standard and, where it is necessary, to ensure adequate control.

Change Record

Revision	Date	Responsible Person	Description of Change
A	18Aug98	Engineering Manager	Development Release

Level I- Quality Manual

The quality manual describes Surgi Manufacturing quality policy and the general company structure and methods for maintaining the quality management system. The manual references the related quality system procedures followed to meet the specified policies and approaches.

Level 2- Quality System Procedures

Documented procedures are used to specify who does what, when it is done. and what documentation is used to verify that the quality activity was executed as required.

Level 3- Work Instructions

Work instructions are used by Surgi Manufacturing to detail how particular tasks are to be performed where the absence of such instructions would adversely affect quality. In particular, the following two types of work instructions are used.

System-related instructions- These supplement our procedures by giving detailed instructions on how to carry out the specified controls, inspections or tests, or how to process materials or documents.

Contract-related instructions- These include drawings, material lists, special inspection, testing, processing or packaging instructions, etc. which translate the specific requirements of a contract into working documents.

4.2.3 Quality Planning

Surgi Manufacturing has documented procedures, work instructions and related documents which define how the requirements for quality will be met. This also applies to new products. Consideration has been taken into account to meet the specified requirements of Quality plans, the identification and acquisition of controls, processes, equipment, test equipment, resources and skills. The compatibility of the production process, inspection and test procedures and supporting documentation. Updating of inspection and testing techniques, the identification of measuring requirements when applicable. The identification of suitable verification at appropriate stages, clarification of standards and requirements. The identification and preparation of quality records.

4.3 Contract Review

4.3.1 General

Documented procedures have been established and implemented for contract review.

Change Record

Revision	Date	Responsible Person	Description of Change
A	18Aug98	Engineering Manager	Development Release

4.3.2 Review

Orders that are received for production are reviewed in accordance to the contract review procedure. The orders are reviewed either by the sales representative, sales support, or by management (as needed). The review process will ensure that:

a. The requirements are adequately defined, documented and agreed before their acceptance.
b. Any differences between the requirements are resolved.
c. Surgi Manufacturing has the capabilities to meet the specified requirements.

4.3.3 Amendment to a Contract

When amendments to a contract is necessary, the inside sales representative will amend the contract and ensure the amendment is correctly transferred to the functions concerned.

4.3.4 Records

Records of contract reviews are maintained.

4.4 Design Control

Surgi Manufacturing does not design parts or products.

4.5 Document and Data Control

4.5.1 General

Documented procedures have been established and maintained for the control of documents and data that relate to the requirements of ISO. 9002,1994 Standard, Including as applicable, documents of external origin such as standards and customer drawings.

4.5.2 Document and Data Approval and Issue

Documents and data are reviewed and approved for adequacy by authorized personnel prior to issue. A master list which identifies the current revision level of the document has been established and is readily available. Pertinent issues of appropriate documents are available at locations are essential to the effective functioning of the Quality System. Invalid or obsolete documents are removed from areas of issue or use. Obsolete documents that are retained are suitably identified.

4.5.3 Document and Data Changes

Document and data changes will be reviewed and approved by the same function which conducted the original review and approval unless specifically designated, otherwise. The designated functions will have access to the pertinent background data. The nature of the change will be documented.

Change Record

Revision	Date	Responsible Person	Description of Change
A	18Aug98	Engineering Manager	Development Release

4.6 Purchasing

4.6.1 General

Documented procedures are maintained for purchasing.

4.6.2 Evaluation of Subcontractors

Purchasing will evaluate and select the subcontractors based upon their abilities to meet the requirements, including the Quality System, and Quality Assurance requirements. The type and extent of control over the subcontractors is based on the type of the product and the impact of the subcontractors product on the quality of the final product. Quality records are established and maintained of acceptable subcontractors.

4.6.3 Purchasing Data

Purchasing documents contain the data which clearly describe the product ordered, including where applicable, the type class, grade, or other precise information. The positive identification and applicable issues of specifications, process requirements, inspection, and other technical data. The requirements for approval or qualification of products, process equipment, procedures, and personnel. The description of the title, number and issue of the Quality system standard to be applied, (as applicable). Purchasing documents are reviewed and approved for adequacy of the specified requirements, the review is performed by Management prior to release.

4.6.4 Verification of Purchased Product

4.6.4.1 Supplier Verification at Subcontractors Premises

Verification of purchased product at the subcontractors premises is not performed by Surgi Manufacturing.

4.6.4.2 Customer Verification of Subcontracted Product

The customer and /or customer representative has the right to verify our subcontractors premises to ensure the product conforms to specified requirements. Such verification is not to be used as evidence of the effective control of the quality by the subcontractor. Verification by the customer does not absolve Surgi Manufacturing of the responsibility to supply acceptable product, or will it preclude subsequent rejection by the customer.

4.7 Control of Customer Supplied Product

Surgi Manufacturing has established and maintains documented procedures for the control of verification, storage, and maintenance of customer supplied product for processing. Any product that is damaged, lost, or is otherwise unsuitable for use will be recorded and the customer will be notified. Verification by Surgi Manufacturing does not absolve the customer of the responsibility to supply acceptable product.

Change Record

Revision	Date	Responsible Person	Description of Change
A	18Aug98	Engineering Manager	Development Release

4.8 Product Identification and Traceability

Surgi Manufacturing has established and maintains documented procedures for the identification of products by suitable means from receipt and during all stages of production and delivery. Surgi Manufacturing has established and maintains documented procedures for unique identification of individual product, this information will be recorded.

4.9 Process Control

Surgi Manufacturing has identified and carries out the planning of production which can directly affect Quality. Surgi Manufacturing will ensure that the processes will be carried out under controlled conditions. Controlled conditions will include the following.

A.) Documented procedures which define the manner of production, where the absence of such procedures could adversely affect quality.
B.) The usage of appropriate production equipment and a suitable working environment.
C.) The compliance with reference standards and/or documented procedures.
D.) To monitor and control of suitable process parameters and product characteristics.
E.) The approval of processes and equipment, as appropriate.
F.) Criteria for workmanship in the form of written standards and/or illustrations.
G.) Suitable maintenance of equipment to ensure continuing process capability.

In the areas where the results of processes cannot be fully verified by subsequent inspection and testing will be monitored and controlled by qualified operators. Surgi Manufacturing will maintain records for equipment and personnel, as appropriate.

4.10 Inspection and Testing

4.10.1 General

Surgi Manufacturing has established and maintains documented procedures for inspection and testing processes in order to verify the requirements for the product have been met. The required inspection and testing is stated within documented procedures and / or process control plans, records of such inspections and tests are established and maintained

4.10.2 Receiving Inspection and Testing

Surgi Manufacturing ensures that incoming strip product is not used or processed until the product has been inspected or otherwise verified as meeting the specified requirements. The verification of compliance of the specified requirements will be carried out in accordance to documented procedures, work instructions, and / or process control plans. To define the extent of receiving inspection, Surgi

Change Record

Revision	Date	Responsible Person	Description of Change
A	18Aug98	Engineering Manager	Development Release

Manufacturing has given consideration to the amount of control exercised at the subcontractors premises and the recorded evidence of compliance provided. Positive recall activities are not performed, all incoming strip product is verified prior to production release.

4.10.3 In-process Inspection and Testing

Surgi Manufacturing will inspect and test the product in accordance to documented procedures, work instructions, and / or the process control plan. Surgi Manufacturing will hold product until the required inspection and tests have been completed and verified, positive recall activities are not performed.

4.10.4 Final inspection and Testing

Surgi Manufacturing will perform all final inspection and testing in accordance to the process control plan and / or documented procedures to complete the evidence of conformance of the finished product to the requirements. The process control plan and / or documented procedures for final inspection and testing require that the specified inspection and tests, including those specified for receipt of product or in-process, have been performed and conform to the specified requirements. Product will not be dispatched prior to all the activities specified within the process control plan and / or documented procedures have been completed and the associated data and documentation are available and authorized.

4.10.5 Inspection and Test Records

Surgi Manufacturing has established and maintains records which provide evidence that the product has been inspected and / or tested. The records will clearly indicate whether the product has passed or failed the inspections and / or tests according to the defined acceptance criteria. In the event the product fail to pass any inspection and / or tests, the control of nonconforming product procedure will apply.

4.11 Control of Inspection, Measuring, and Test Equipment

4.11.1 General

Surgi Manufacturing has established and maintains documented procedures to control calibrate and maintain inspection, measuring and test equipment used by Surgi Manufacturing to demonstrate the conformance of product to the specified requirements. Inspection, measuring and test equipment is used in a manner which ensures that the measurement uncertainly is known and is consistent with the required measurement capability. Where comparative references such as test hardware are used as suitable forms of inspection, they will be checked to prove that they are capable of verifying the acceptability of the problem prior to release for use during production, and will rechecked at prescribed intervals. Surgi Manufacturing has established the extent and the frequency of such checks and records will be maintained as evidence of control. Where available, technical data relating to the inspection, measuring and test equipment is a specified requirement, the data will be made available to the customer for verification that

Change Record

Revision	Date	Responsible Person	Description of Change
A	18Aug98	Engineering Manager	Development Release

the equipment is functionally adequate.

4.11.2 Control Procedure

Surgi Manufacturing has determined the measurements to be made as with the accuracy required. The appropriate measuring and test equipment that is capable of the necessary accuracy has been selected.

Surgi Manufacturing identifies all measuring and test equipment that can affect the product quality and calibrates the equipment at prescribed intervals prior to use, the calibrations will be carried out against certified equipment having a known valid relationship to internationally or nationally recognized standards, in the absence of a recognized standard the basis used for calibration will be documented. Surgi Manufacturing has defined the process for calibrations of the measuring and test equipment. The details of the equipment type, unique identification, assigned location, frequency of checks, and the method of verification. The acceptance criteria is established as with the actions that will be taken when the results are unsatisfactory. Surgi Manufacturing identifies the measuring and test equipment with a suitable indicator which provides the calibration status. Calibration records are maintained for measuring and test equipment. Surgi Manufacturing accesses and documents the validity of previous inspection and test results when. equipment is found to out of calibration. Surgi Manufacturing ensures that the environmental conditions are suitable when the calibrations are being performed. Surgi Manufacturing ensures that the handling, preservation and storage of measuring and test equipment is such that the accuracy and fitness for use is maintained. Surgi Manufacturing provides safeguards for measuring and test facilities, including test hardware which would invalidate the calibration setting.

4.12 Inspection and Test Status

The inspection and test status of product is identified by suitable means, which indicates the acceptance or non-acceptance of product with regard to inspection and tests performed. The identification of inspection and test status is maintained as defined in the control plan and procedures throughout production of the product to ensure that only product that has passed the necessary inspections and tests, or released under an authorized concession is dispatched or used.

4.13 Control of Nonconforming Product

4.13.1 General

Surgi Manufacturing has established and maintains documented procedures to ensure that any product that does not meet the specified requirements is prevented from unintended use. Such controls include identification, documentation, evaluation, segregation, disposition, and notification to the functions concerned.

Change Record

Revision	Date	Responsible Person	Description of Change
A	18Aug98	Engineering Manager	Development Release

4.13.2 Review and Disposition of Non-conforming Product

The responsibility for review and authority for disposition of non-conforming product is defined in documented procedures. Non-conforming product is reviewed in accordance to documented procedures. Non-conforming product may be,

*Reworked to meet the specified requirements.
*Accepted with or without repair by concession.
*Re-graded for alternative applications.
*Rejected or scrapped

When required by contract, the proposed use or repair of product which does not meet the specified requirements will be reported to the customer. A description of the nonconformity accepted and the repairs will be recorded to denote the actual condition. Repaired and / or reworked product will be reinspected in accordance to the process control plan and/ or documented procedures.

4.14 Corrective and Preventive Action

4.14.1 General

Surgi Manufacturing has established and maintains documented procedures for implementing corrective and preventative action, any changes will be implemented and recorded to the documented procedures, processing notes, or process control plans which resulted from corrective and preventive actions that were taken.

4.14.2 Corrective Action

Corrective action procedures will include; Product non-conformities and customer complaints will be handled effectively. Investigation of the cause of the nonconformance relating to the product, process and quality system. The results of the investigation will be recorded. The determination of the corrective action needed to eliminate the cause of the non conformance. The application of controls to ensure that corrective action is taken and that it is effective.

4.14.3 Preventive Action

Preventive actions will include; The use of appropriate sources of information such as processes and work operations which affect product quality, audit results, quality records, and customer complaints to detect, analyze and eliminate the potential causes of the non conformance. The determination of the steps needed to deal with any problems requiring preventative action. The initiation of preventive action and the application of controls to ensure that it is effective. Ensuring that the relevant information on the actions taken are submitted for management review.

4.15 Handling, Storage, Packaging, Preservation, and Delivery

4.15.1 General
Surgi Manufacturing has established and maintains documented procedures for handling, storage, packaging, preservation, and delivery of product.

4.15.2 Handling
Surgi Manufacturing has established methods of handling product that prevent damage or deterioration.

4.15.3 Storage
Surgi Manufacturing utilizes designated storage areas to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas are stipulated.

4.15.4 Packaging
Surgi Manufacturing has established methods to control packaging and the marking processes (including the materials used) to the extent necessary to ensure conformance to specified requirements.

4.15.5 Preservation
Surgi Manufacturing applies appropriate methods for preservation and segregation of product when the product is under the suppliers control.

4.15.6 Delivery
Surgi Manufacturing arranges for the protection of the quality of the product after final inspection and test. Where contractually specified, this protection will be extended to include delivery to destination.

4.16 Control of Quality Records
Surgi Manufacturing has established and maintains documented procedures for identification, collection, indexing, access, filling, storage, maintenance, and disposition of quality records. Quality records are maintained to demonstrate conformance to the specified requirement, applicable quality records from subcontractors are maintained. Quality records are legible and readily retrievable, such records are stored in a suitable environment. When agreed by contract, quality records will be made available for evaluation to our customers. Quality records are retained in accordance with the predetermined time frame.

4.17 Internal Quality Audits
Surgi Manufacturing has established and maintains documented procedures for planning and implementing internal quality audits to verify the quality activity complies with the effectiveness of the quality system. Internal quality audits are scheduled on the basis of importance of the activity, audits win be carried out

Change Record

Revision	Date	Responsible Person	Description of Change
A	18Aug98	Engineering Manager	Development Release

by personnel independent of the activity being audited. The results of the internal quality audits are recorded and are brought to the attention of personnel having responsibility in the area audited. The Management personnel that is responsible for the area will take timely corrective action on any deficiencies found during the audit. Follow-up audit activities will verify and record the implementation and effectiveness of the corrective actions that have been taken.

4.18 Training

Surgi Manufacturing has established and maintains documented procedures for the identification of training needs and provide training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks are qualified on the basis of knowledge, on the job training, and / or experience, as required. Records of training are maintained.

4.19 Servicing

Servicing is not a specified requirement of Surgi Manufacturing

4.20 Statistical Techniques

Surgi Manufacturing employs the method of continuously monitoring processes for the need of application of statistical monitoring controls. Surgi Manufacturing has established and maintains documented procedures to implement and control the application of the statistical techniques.

Change Record

Revision	Date	Responsible Person	Description of Change
A	18Aug98	Engineering Manager	Development Release