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| O         | Updated 4.2.6 for retention times                                                                                                                                   | 12-11-03   | M.H.     |
| P         | Updated Organizational Chart                                                                                                                                        | 6/1/05     | M.H.     |
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| S         | Added Appendix AS9100.                                                                                                                                              | 6/28/06    | M.H.     |
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| U         | Removed Appendix TS16949                                                                                                                                            | 10/16/06   | M.H.     |
| V         | Updated language regarding references to management and updated process flow chart., update 4.2.6 record retention for aerospace products to 10 years               | 2/12/07    | M.H.     |
| W         | Updated Organizational Chart                                                                                                                                        | 8/2/07     | M.H.     |
| X         | Updated Organizational Chart                                                                                                                                        | 10/4/07    | M.H.     |

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## Introduction

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Vermont Composites developed and implemented a Quality Management System in order to document the company’s best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The Quality Management System of Vermont Composites meets the requirements of the international standard ISO 9001:2008, AS9100:2004. This system addresses the design, development, production, installation, and servicing of the company’s products.

The manual is divided into eight sections that correlate to the Quality Management System sections of ISO 9001:2008, AS9100:2004. Each section begins with a policy statement expressing Vermont Composites’ obligation to implement the basic requirements of the referenced Quality Management System section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

This manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company’s employees through the various requirements of the ISO standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

The original, signed, copy of this document is available in Vermont Composites’ Document Control. The document owner retains previous versions for legal purpose or preservation of knowledge for 10 years.

This document will be reviewed within 1 year of current version date. Updates will be made as significant changes occur in the quality management system and approved by the authorities.

Revisions are listed on the cover page, (page 1.)

Copies of this Quality Manual, distributed outside the organization ( e.g. to customer) are uncontrolled and clearly marked “ UNCONTROLLED COPY”.

## Section 1: Scope

### 1.1 General

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The quality manual outlines the policies, procedures and requirements of the Quality Management System. The system is structured to comply with the conditions set forth in the International Standard ISO 9001:2008, AS9100:2004.

Vermont Composites facilities are located at 25 Performance Drive. The company designs, develops, produces, delivers, products for the medical imaging, aerospace, aircraft, and other industries. Our products (services) include patient support devices for medical x-ray equipment, electronic enclosures for aircraft and spacecraft, and other components for various industries.

### 1.2 Application

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Vermont Composites has determined that the following requirements are not applicable to the operations at this site and are documented as exclusions:

- There are no exclusions

## Section 2: Normative Reference

### 2.0 Quality Management System References

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The following documents were used as reference during the preparation of the Quality Management System:

- American National Standard ANSI/ISO/ASQ Q9000:2008, Quality Management Systems - Vocabulary.
- American National Standard ANSI/ISO/ASQ Q9001:2008, Quality Management Systems – Requirements
- American National Standard ANSI/ISO/ASQ Q9004:2008, Quality Management Systems – Guidelines for performance Improvements
- SAE Aerospace SAE AS9100:2004, Quality Management Systems – Aerospace Requirements

## Section 3: Definitions

### 3.0 Quality Management System Definitions

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This section is for definitions unique to Vermont Composites.

- Customer owned property - Any type of instrumentation, accessories, manuals, or shipping containers that belong to a customer.
- Customer supplied product - Any type of service or material supplied to be utilized in the manufacture, modification or repair of customer-owned property.
- Product – The end item result of meeting all contracts terms and conditions. (eg: manufactured goods, merchandise, services etc.)
- Quality Records – Documentation of those activities wherein records of said activities must be maintained will be specified in the procedure or work instruction level documents, as applicable.
- Key Characteristics – The features of a material, process, or part whose variation has a significant influence on product fit, performance, service life or manufacturability.

## Section 4: General Requirements

### 4.1 General requirements

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- Vermont Composites has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of ISO 9001:2008, AS9100: 2004. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

To design and implement the QMS Vermont Composites has:

- Determined the processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram shown in Appendix C.
- Determined the sequence and interaction of these processes, and illustrated them on the Process Flow Diagram
- Determined criteria and methods needed to ensure that the operation and control of the processes are effective, and documented them in quality plans, work instructions and the measuring, monitoring and analysis procedures.
- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes
- Established systems to monitor, measure where applicable and analyze these processes, and
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes

### 4.2 Documentation Requirements

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#### 4.2.1 General

The QMS documentation includes:

- A documented Quality Policy
- This Quality Manual (Level 1)
- Documented Procedures and Records required by the International Standard (Level 2)
- Documents including records identified as needed for the effective planning, operation and control of our processes, (Level 3)
- Quality Records (Level 4)

#### 4.2.2 Quality manual

This Quality Manual has been prepared to describe Vermont Composites' QMS. The scope and permissible exclusions of the QMS are described in section one of this manual. Each section of the manual references documented QMS procedures relating to the requirements outlined in that section. The Process Flow Diagram (Appendix C) provides

a description of the interaction between the processes of the QMS system. This Quality Manual is reviewed annually and signed off in form CMF-0139 (see Appendix D for a copy of this form).

#### **4.2.3 Control of documents**

All of the QMS documents are controlled according to the Document Control Procedure (CPD-0500). This procedure defines the process for:

- Approving documents for adequacy prior to issue
- Reviewing and updating as necessary and re-approving documents
- Ensuring that changes and current revision status of documents are identified
- Ensuring that relevant versions of applicable documents are available at points of use
- Ensuring that documents remain legible and readily identifiable
- Ensuring that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
- Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose

For external regulations, codes and standards used in the Quality System, the specific version/year/release and/or edition is identified.

All electronic data Quality Records are backed up so that in the event of failure of a computer or hard drive, the data can be restored.

#### **4.2.4 Document and Data Approval, Issue and Review**

The document owner is responsible to ensure that documents and data are reviewed and approved by authorized personnel prior to issue. Document Control is responsible to ensure pertinent issues of documents and data are available at all required locations and to promptly remove invalid or obsolete documents and data.

Any copies retained for purposes of knowledge preservation or legal purposes are clearly marked “VOID” or “OBSOLETE”.

Unless otherwise dictated by customer requirements, documents distributed outside the organization (e.g. customer, subcontractor) are uncontrolled and clearly marked as such.

A master list, identifying the current revision status of the quality system documents, is maintained. The master list is readily available or accessible to all personnel in Document Control. The user needs to verify that hard copies being used are the current, approved issue by verifying with Master list of document version and issue dates.

All documented procedures (level 2) are to be reviewed annually as assigned in from CMF-0139, see Appendix D.

#### **4.2.5 Document Change and Modification**

The document owner is responsible to provide pertinent information and to ensure all changes are appropriately reviewed and approved prior to issue. The changes are reviewed and approved by the same functions that performed the original review and approval, unless designated otherwise.

Where practical the nature of the change is identified in the document or via attachments.  
Revisions are issued at the discretion of the document owner, based on the number and significance of the change(s).

#### **4.2.6 Control of quality records**

Managers of each department are responsible for implementation of control of Quality Records in their respective department.

The Quality Records, maintained as objective evidence compliance to Quality System Procedures and effective functioning of the Quality System, are defined and listed in the associated process/procedure documentation, including record owner, location, indexing method, and retention time.

The document control requirements for quality records are defined in the Document Control procedures.

Retention times are generally 7yrs minimum with the exceptions of the following customers.

General Electric – The life of the part and/or GE requests the records.

Aerospace product – 10 years minimum

Records are legible and stored in clearly identified filing cabinets, which are readily accessible. At the end of the required retention time, records may be recycled as waste.

Records maintained as computer records are backed daily as described in CPD-0508.

Where required by contract (4.3) pertinent quality records are made available for evaluation by the customer or customer's representative.

Quality records include but are not limited to:

- Internal Audit plans and results
- Management reviews of the quality management system
- Corrective and Preventative Actions Request Forms (CAR's).
- Contracts, contract reviews
- Approved supplier list, supplier performance and purchase orders
- Product, process and equipment qualification results/data
- Customer satisfaction surveys and analysis
- Product, quality plans, design reviews and verification results.
- Calibration and maintenance records.
- Process control parameters.
- Inspection / test records
- Product waivers, off-specs, downgrades, rework and scrap
- Employee training and certification.
- And all other records required by procedures, policies and processes part of the Quality System.

## Section 5: Management Responsibility

### 5.1 Management commitment

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Management has been actively involved in implementing the quality management system (QMS). It has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the quality policy.

To continue to provide leadership and show commitment to the improvement of the QMS, management will do the following.

- Communicate the importance of meeting customer, statutory, and regulatory requirements.
- Establish quality objectives
- Establish the quality policy.
- Conduct management reviews at least twice per year.
- Ensure the availability of resources.

### 5.2 Customer focus

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Vermont Composites strives to identify current and future customer needs, to meet customer requirements and exceed customer expectations.

Management ensures that customer requirements are understood and met, by requiring compliance with documented customer communication procedures. Customer requirements are determined, converted into internal requirements, and communicated to the appropriate people in our organization.

### 5.3 Quality policy

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Management ensures that the quality policy is communicated to all employees. It is included in new employee training and training on the QMS. It is posted in prominent places throughout the facility to maintain high standards within our organization.

Management reviews the quality policy at each management review meeting to determine the policy's continuing suitability for our organization. The Quality Policy is as follows:

**Vermont Composites' policy is to provide customers with products which are fully compliant with agreed standards and specifications and which take into account all relevant contractual, technical, commercial, regulatory, statutory, safety and environmental requirements. All personnel within the organization are required to comply with the company's quality policy at all times and to continually improve all aspects of the quality management system and to work to surpass the Quality Goals of the Company.**

## 5.4 Planning

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### 5.4.1 Quality objectives

Quality objectives are established to support our organization's efforts in achieving our quality policy and reviewed annually for suitability. Quality objectives are measurable, and reviewed against performance goals at each management review meeting.

Specific Objectives of our Quality System are as follows:

- First Time Quality at the Customer to exceed 98%. First time quality is defined as acceptance of the product by the customer without quality discrepancies requiring additional disposition by the customer and measured by the ratio of customer returns in dollars divided by the total sales in dollars.
- On Time Delivery is to exceed 95%. One time delivery is defined as the percentage of deliveries that are delivered on time (to customers requested ship date).
- Material Scrap (dollar value as a percentage of sales) due to faulty manufacturing processes is to be less than 2%.

### 5.4.2 Quality management system planning

The quality system has been planned and implemented to meet our quality objectives and the requirements of 4.1 of the ISO 9001 standard. Quality planning takes place as changes that affect the quality system are planned and implemented.

## 5.5 Responsibility, authority and communication

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### 5.5.1 Responsibility and authority

An organizational chart has been established to show the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of each of the positions on the organizational chart. Job descriptions and the organizational chart are reviewed and approved by top management for adequacy. These documents are available throughout the organization to help employees understand responsibilities and authorities. An organizational chart is located in Appendix A of this manual.

### 5.5.2 Management representative

Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

- Ensure that processes needed for the quality management system are established and implemented.
- Report to top management on the performance of the quality management system, and note needed improvements.
- Promote awareness of customer requirements throughout the organization.
- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS.

### **5.5.3 Internal communication**

Processes are established for communication within the organization. Methods of communicating the effectiveness of the QMS include department and management meetings, management review, circulation of minutes of management review meetings, Internal Audit Closing meetings, and other routine business communication.

## **5.6 Management review**

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### **5.6.1 General**

Management reviews the QMS at least twice per year at management review meetings. This review assesses the continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement and needed changes. Records are maintained for each management review meeting.

### **5.6.2 Review input**

Assessment of the QMS is based on a review of information inputs to management review. These inputs include the following:

- Results of internal and external audits
- Customer feedback
- Process performance and product conformity as measured by performance measured against quality objectives
- Company level quality data
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Planned changes that could affect the quality management system
- Recommendations for improvement
- The integrity of the QMS as changes are considered and implemented.

### **5.6.3 Review output**

During these review meetings, management will identify appropriate actions to be taken regarding the following issues:

- Improvement of the effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements
- Resource needs

Responsibilities for required actions are assigned to members of the management review team. Any decisions made during the meeting, assigned actions are recorded in the minutes of management review.

## **Section 6: Resource Management**

### **6.1 Provision of resources**

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Vermont Composites has implemented a Quality Management System that complies with the ISO 9000:2008, AS9100:2004 standard. This implementation was achieved with management commitment and with sufficient resources for the implementation. To effectively maintain and continually improve the system, management determines and provides necessary resources.

### **6.2 Human resources**

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#### **6.2.1 General**

To ensure competence of our personnel, job descriptions have been prepared identifying the qualifications required for each position that affects conformity to product requirements. Qualifications include requirements for appropriate education, skills and experience. Appropriate qualifications, along with required training, provide the competence required for each position.

#### **6.2.2 Competence, training and awareness**

Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position change. The Human Resource Manager maintains records of employee qualifications. If any differences between the employee's qualifications and the requirements for the job are found, training or other action is taken to provide the employee with the necessary competence for the job. The results are then evaluated to determine if they were effective. Training and evaluation are conducted according to the Training procedure. (CPD-1800)

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

### **6.3 Infrastructure**

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To meet quality objectives and product requirements Vermont Composites has determined the infrastructure needed. The infrastructure has been provided, and includes buildings, workspace, utilities, process equipment and supporting services (such as transport, communication or information systems). As new infrastructure requirements arise, they will be documented in quality plans. Existing infrastructure is maintained to ensure product conformity. Maintenance requirements are documented in:

- Preventive maintenance plans

### **6.4 Work Environment**

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A work environment suitable for achieving product conformance is maintained. The work environment is managed for continuing suitability. Data from the quality system is evaluated to determine if the work environment is sufficient for achieving product conformance, or if preventive or corrective action related to the work environment is required.

## Section 7: Product Realization

### 7.1 Planning of product realization

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Quality planning is required before new products or processes are implemented. The quality planning may take place as a design project, or according to the Design Control procedure (CPD-0400). During this planning, management or assigned personnel identify:

- The quality objectives and requirements for the product,
- Processes and documents, and to provide resources specific to the product
- Required verification, validation, monitoring, measurement, inspection and test activities specific to the product, and
- Criteria for product acceptance

The output of quality planning includes documented quality plans (manufacturing instructions, and bills of operation), processes, procedures and design outputs.

### 7.2 Customer-related processes

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#### 7.2.1 Determination of requirements related to the product

Vermont Composites determines customer requirements before acceptance of an order. Customer requirements include those:

- Requested by the customer
- Required for delivery and post-delivery activities
- Not stated by the customer but necessary for specified use or known and intended use
- Statutory and regulatory requirements applicable to the product
- Additional requirements considered necessary by Vermont Composites

Customer requirements are determined according to the Contract Review Processes Procedure. (CPD-0300)

#### 7.2.2 Review of requirements related to the product

Vermont Composites has a process in place for the review of requirements related to the product (CPD-0300). The review is conducted before the order is accepted. The process ensures that:

- Product requirements are defined
- Contract or order requirements differing from those previously expressed are resolved
- Vermont Composites has the ability to meet the defined requirements

- Quality records are maintained showing the results of the review and any actions arising from the review
- Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance
- When product requirements are changed, Vermont Composites communicates changes to relevant personnel and customers and amends relevant documents

### **7.2.3 Customer communication**

Vermont Composites has implemented an effective procedure (Ref CPD-0300) for communicating with customers in relation to:

- Product Information
- Enquiries, contracts and order handling, including amendments
- Customer Feedback, including customer complaints

## **7.3 Design and Development**

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### **7.3.1 Design and development planning**

The design and development procedure (CPD-0400) outlines the process for controlling the design and development process. Engineering plans design and development according to this procedure. The design plan includes:

- Design and development stages
- Required design reviews
- Verification and validation methods appropriate to each design and development stage
- Responsibilities and authorities for design and development
- Identification of the technical interfaces required for the project
- Updating of the design plan as the project progresses

### **7.3.2 Design and development inputs**

Inputs relating to product requirements are determined and documented according to the Design and Development procedure (CPD-0400). All inputs are reviewed for adequacy and completeness, and to resolve any ambiguous inputs. Inputs include:

- Functional and performance requirements
- Applicable statutory and regulatory requirements
- Where applicable, information derived from previous similar designs

- Other requirements essential for design and development

### **7.3.3 Design and development outputs**

Outputs of design and development are documented according to the Design and Development Procedure (CPD-0400). They are documented in a form suitable for verification against the inputs, and are approved prior to release. Outputs:

- Meet the input requirements
- Provide appropriate information for purchasing, production and service provision
- Contain or reference product acceptance criteria
- Specify the characteristics of the product that are essential for its safe and proper use.

### **7.3.4 Design and development review**

The design plan specifies suitable stages of the project to conduct design and development review. Reviews take place according to the design and development procedure; results of design review are recorded in minutes of the design review meetings which are maintained as a quality record. Design reviews:

- Evaluate the results of design and development activities and determine if they fulfill requirements
- Identify any problems and propose necessary actions
- Include representatives of functions concerned with the design and development stage being reviewed

### **7.3.5 Design and development verification**

Design verification is planned and performed to ensure that the design and development outputs have satisfied the design and development input requirements. Records of the results of the verification and any necessary actions are maintained according to the Design and Development procedure (CPD-0400).

### **7.3.6 Design and development validation**

Design and development validation is performed according to the design plan to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application. Validation is completed prior to delivery whenever practicable. Records of the validation activities are maintained according to the design and development procedure.

### **7.3.7 Control of design and development changes**

The Document Control procedure (CPD-0500) defines a process for identifying, recording, verifying, validating and approving design changes. The review of design and development changes includes an evaluation of the effect of the changes on constituent

parts and delivered product. Records are maintained to show the results of the review and any necessary actions identified during the review.

## **7.4 Purchasing**

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### **7.4.1 Purchasing process**

The Purchasing procedure (CPD-0600) is followed to ensure that purchased product conforms to the specified purchase requirements. The procedure outlines the extent of control required for suppliers. Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements as outlined in the procedure. Criteria for selection, evaluation and re-evaluation are documented in the procedure. Records of the evaluation and any necessary actions are maintained as quality records.

### **7.4.2 Purchasing information**

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

- Requirements for approval of product, processes and equipment
- Requirements for qualification of personnel
- Quality management system requirements

The purchasing documents are reviewed to ensure the adequacy of requirements before orders are placed with the supplier.

### **7.4.3 Verification of purchased product**

The Purchasing procedure (CPD-0600) describes the process used to verify that purchased product meets specified purchase requirements. If Vermont Composites or the customer will perform verification at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information.

## **7.5 Production and Service Provision**

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### **7.5.1 Control of production and service provision**

Vermont Composites plans and carries out production and service provision under controlled conditions according to documented Process Control procedure (CPD-0900). Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product
- The availability of work instructions
- The use of suitable equipment
- The availability and use of monitoring and measuring equipment.

- The implementation of monitoring and measurement
- The implementation of product release, delivery and post-delivery activities

**7.5.2 Validation of processes for production and service provision**

Vermont Composites validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results.

Vermont Composites has documented the process for validation including:

- Defined criteria for review and approval of the processes
- Approval of equipment and qualification of personnel
- Use of specific methods and procedures
- Requirements for records
- Revalidation

The following processes, the results of which cannot be verified with subsequent tests / inspections, are pre-qualified, executed by operators, continuous monitoring and/or control of critical process parameters. Records of pre-qualification, operator training and process monitoring are maintained as quality records. Specific requirements are detailed for each applicable process.

| Process name | Control method(s)   | Comments |
|--------------|---------------------|----------|
| Lay-up       | Qualified Operators | .....    |
| Bonding      | Qualified Operators | .....    |
| Painting     | Qualified Operators | .....    |
|              |                     |          |
|              |                     |          |

**7.5.3 Identification and traceability**

Vermont Composites identifies the product throughout product realization according to the Product Identification and Traceability procedure (CPD-0800). Product is identified with respect to monitoring and measurement requirements throughout product realization.

Vermont Composites controls the unique identification of the product and maintains records where ever traceability is a specified requirement and these records become Quality Records.

**7.5.4 Customer property**

Vermont Composites exercises care with customer property while it is under the organization's control or being used. Customer Supplied Product procedure (CPD-0700) outlines the Identification, verification, protection and safeguarding of customer property

provided for use. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records.

### **7.5.5 Preservation of product**

Vermont Composites preserves the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements per the Handling, Storage and Packaging procedure (CPD-1500). As applicable preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product. All material is checked by verification of inventory at least once per year.

## **7.6 Control of monitoring and measuring equipment**

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Vermont Composites has determined the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. The Inspection and Test Equipment procedure (CPD-1100) outlines the process used to ensure that monitoring and measurement to be carried out are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment is:

- Calibrated or verified, or both at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards
- Adjusted or re-adjusted as necessary;
- Have identification in order to determine its calibration status; (generally with dated stickers showing calibration dates)
- Safeguarded from adjustments that would invalidate the measurement result;
- Protected from damage and deterioration during handling, maintenance and storage.

In addition, Quality Control assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Vermont Composites takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained as Quality Records.

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

## **Section 8: Measurement, Analysis and Improvement**

### **8.1 General**

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Vermont Composites has plans and implements the monitoring, measurement, analysis and improvement processes as needed

- To demonstrate conformity to product requirements,

- To ensure conformity of the quality management system, and
- To continually improve the effectiveness of the quality management system.

These processes are identified in documented procedures and include determination of applicable methods, including statistical techniques, and the extent of their use.

## **8.2 Monitoring and Measurement**

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### **8.2.1 Customer Satisfaction**

As one of the measurements of the performance of the quality management system, Vermont Composites monitors information relating to customer perception as to whether the organization has fulfilled customer requirements. The method for obtaining and using this information is identified in the Customer Related Processes (CPD-0300).

### **8.2.2 Internal Audit**

Vermont Composites conducts internal audits at planned intervals to determine whether the quality management system

- Conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization
- Is effectively implemented and maintained.

An audit program has been designed and implemented and identifies an audit schedule based on the importance of the areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, methods, responsibilities and requirements for planning and conducting audits, and for establishing records, reporting results, are defined and documented in the Internal Audit procedure (CPD-1700).

The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process.

At least annually the QMS will be audited and documented to determine the effectiveness of the quality system.

Any Non-Compliance issues are documented on a NCR form CMF-031. The responsible management for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up evaluation or audit activity will verify the effectiveness of the corrective action.

Audit reports and completed NCR forms are maintained as Quality Records. The Quality Manager summarizes findings and the results of the Internal audit Program and report these at the Management Review Meetings.

### **8.2.3 Monitoring and measurement of processes**

Vermont Composites applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not

achieved, correction and corrective action is taken, as appropriate. The process for identifying and carrying out the required monitoring and measuring of processes is documented in the Inspection and Test Procedure (CPD-1000) and this Quality Manual (CPD-0100)

## **8.2.4 Monitoring and measurement of product**

Vermont Composites monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process identified in Inspection and Test Procedure (CPD-1000).

Evidence of conformity with the acceptance criteria is maintained as Quality Records. Records indicate the person authorizing release of product for delivery to the customer. The release of the product and delivery of service to the customer shall not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

### **8.2.4.1 Receiving Inspection and Testing**

Receiving inspection or testing is performed in accordance with documented procedures or as requested by the originator of the purchase requisition against which part/product/service are purchased. Responsibility for incoming inspection rests with the Quality function.

In determining the nature and amount of receiving inspection, consideration is given to the control exercised at the vendor and documented evidence of quality conformance provided (as defined by Quality Codes on the Purchase Order).

When incoming product or material is released, prior to receiving inspection, for urgent production purposes, it is positively identified, controlled and recorded to permit immediate recall and replacement in the event of non-conformance, when inspection is completed.

### **8.2.4.2 In-process Inspection and Testing**

In-process tests/inspections are performed in accordance with documented procedures on all product to ensure conformance to requirements and further enhanced by process and tool monitoring and control for those processes listed in section 7.5.2.

Responsibility for in-process inspection rests with the Quality function.

### **8.2.4.3 Final Inspection and Testing**

Final tests/inspections are performed in accordance with documented procedures on final product (or prior to service delivery) to ensure conformance to customer requirements.

Final test will also verify that all specified test, prior to this station have been carried out and that results meet specified requirements. Product is not dispatched until all required tests are completed and data or documents are available and approved.

Responsibility for final inspection rests with the Quality function.

### **8.2.4.4 Inspection and Test Records**

The Product Quality Plan or inspection procedures define the required records and data needed to demonstrate successful completion. These records clearly identify whether product passed or failed the inspections or tests and identify the authority responsible for release of the product.

Product that fails to pass any inspection or test will be identified, documented and dispositioned as defined in the Control of Nonconforming Product procedure. (Ref. CPD-1300)

### **8.3 Control of Nonconforming Product**

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Vermont Composites ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in the Control of Nonconforming Product procedure (CPD-1300).

To prevent unauthorized / unintended use or shipment of non-conforming product (service) and to prevent mixing with conforming material, non-conforming product is clearly marked “Rejected” and separated until problem analysis and proper disposition is determined. Concerned function(s) are notified of the existence of non-conforming product.

The Quality Manager has overall responsibility for the control of nonconforming product.

### **8.4 Analysis of Data**

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Vermont Composites determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. The process for determining, collecting and analyzing this data is defined in this Quality Manual (CPD-0100). Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to the following:

- Customer satisfaction
- Conformance to product requirements
- Characteristics and trends of processes and products including opportunities for preventive action
- Supplier performance.

### **8.5 Improvement**

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#### **8.5.1 Continual Improvement**

Vermont Composites continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

### 8.5.2 Corrective Action

Vermont Composites takes action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure (CPD-1400.1) defines requirements for

- Reviewing nonconformities (including customer complaints),

Customer complaints are logged and handled through the corrective action process. If required by the customer a corrective action is initiated immediately. If not required immediately they will follow the same procedure outlined in CPD-1400.1.

- Determining the causes of nonconformities,
- Evaluating the need for action to ensure that nonconformities do not recur,
- Determining and implementing action needed,
- Records of the results of action taken (see 4.2.4) as Quality Records, and
- Reviewing the effectiveness of the corrective action taken.

The Quality Manager in conjunction with the Internal Audit Program (ref CPD-1700) assesses the effectiveness of all corrective actions taken.

### 8.5.3 Preventive Action

Vermont Composites determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure (CPD-1400.2) defines requirements for:

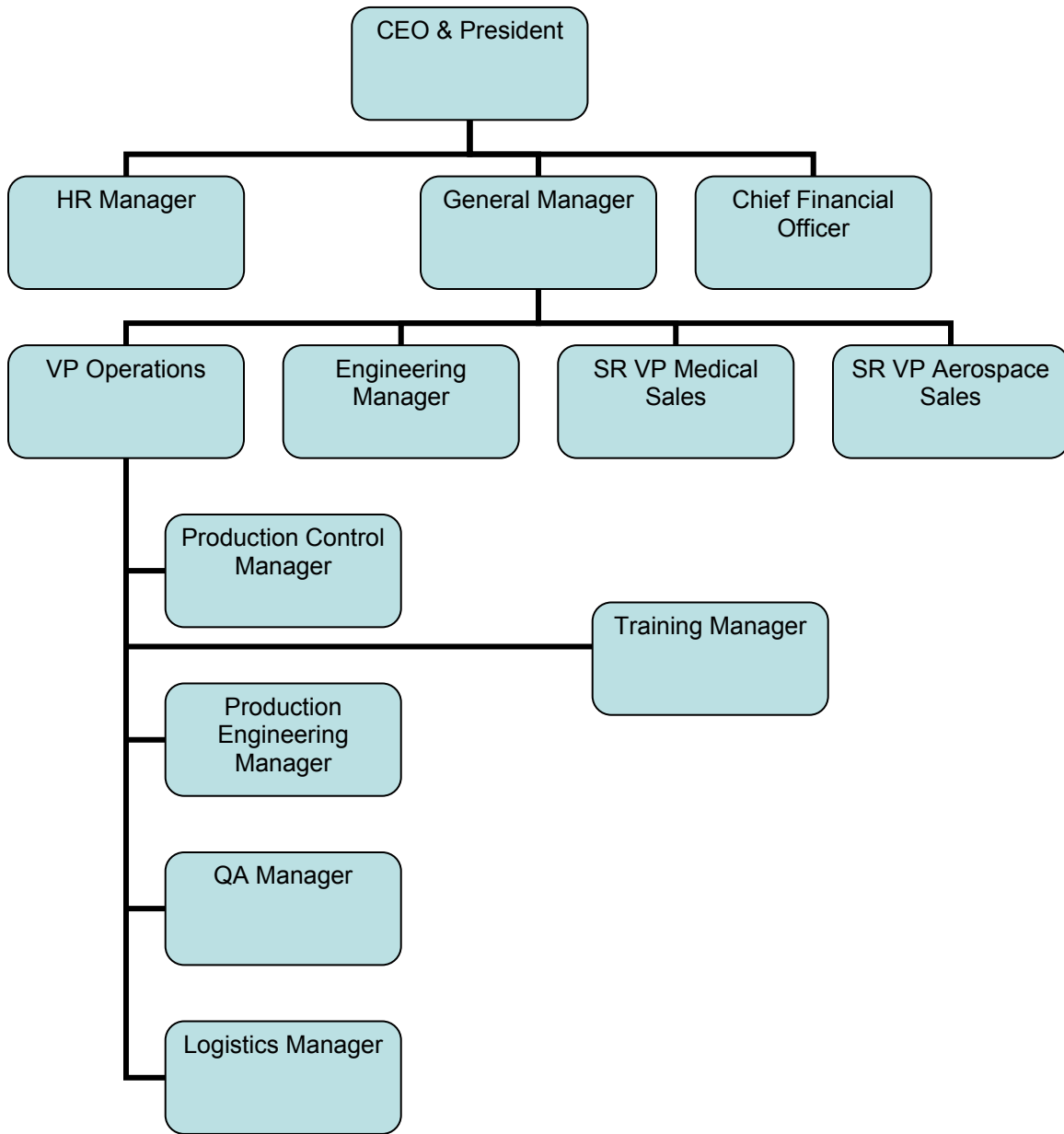
- Determining potential nonconformities and their causes
- Evaluating the need for action to prevent occurrence of nonconformities
- Determining and implementing action needed
- Records of results of action taken become Quality Records.
- Reviewing the effectiveness of the preventive action taken

The Quality Manager in conjunction with the Internal Audit Program (ref CPD-1700) assesses the effectiveness of all preventative actions taken.

# Appendix A

## Organization Chart

Vermont Composites Organization Chart  
February 20, 2008



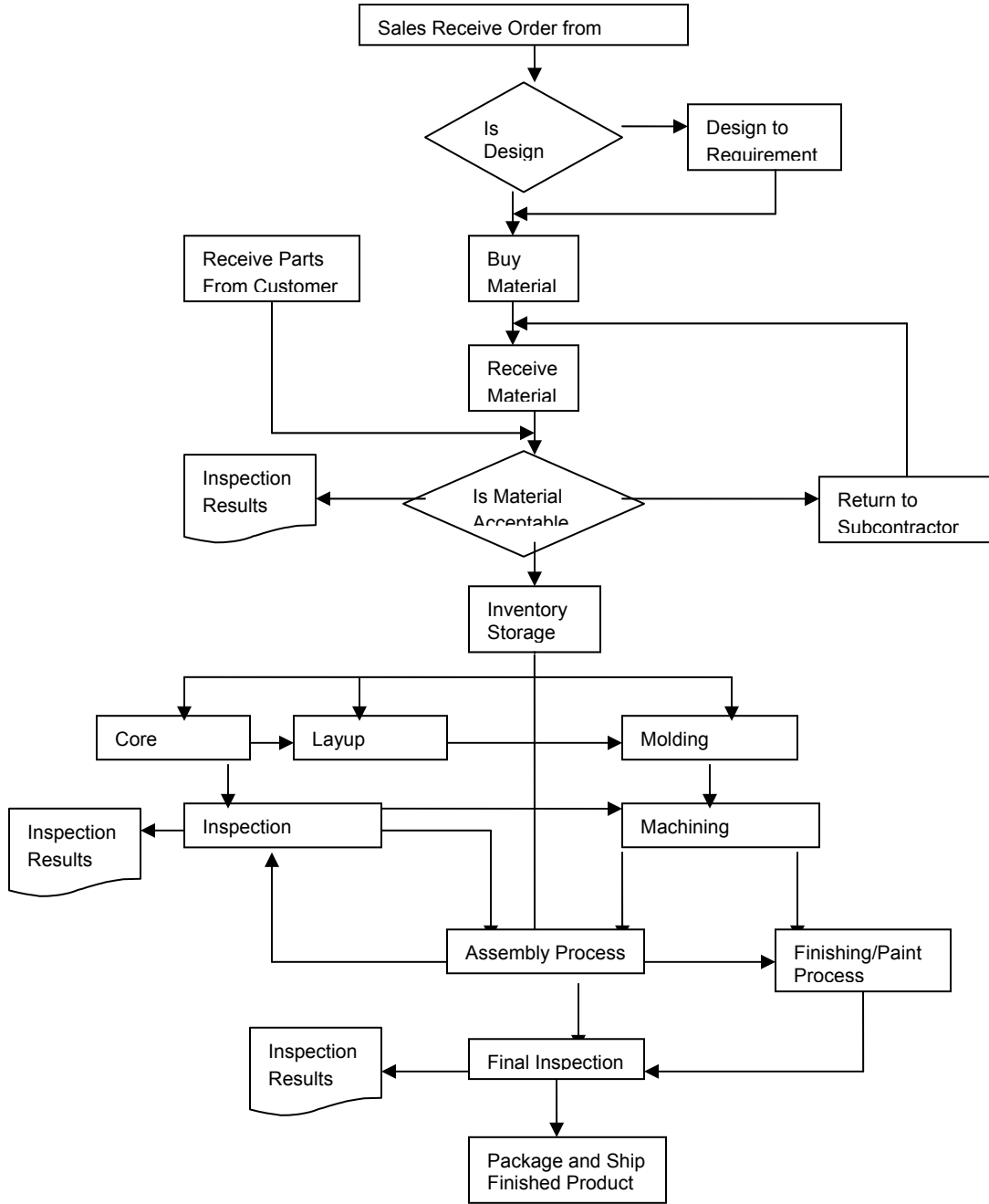
## Appendix B

### Quality Responsibilities

| ISO 9001:2008) Elements                                 | Manual Section | Document Title                    | Document Owner      | Person Responsible  |
|---------------------------------------------------------|----------------|-----------------------------------|---------------------|---------------------|
| 5.1, 5.3, 5.4.1, 5.5.1, 6.1, 6.2.1, 5.5.2, 5.6.1, 8.5.1 | par 4.1        | Management Responsibility         | President           | President           |
| 4.1, 4.2.2, 4.2.1, 5.4.2, 7.1                           | par 4.2        | Quality System                    | Quality Manager     | Quality Manager     |
| 5.2, 7.2.1, 7.2.2, 7.2.3                                | par 4.3        | Contract Review                   | Vice President      | Vice President      |
| 7.3.1, 7.2.1, 7.3.2, 7.3.3, 7.3.4, 7.3.5, 7.3.6, 7.3.7  | par 4.4        | Design Control                    | Engineering Manager | Engineering Manager |
| 4.2.3                                                   | par 4.5        | Document Control                  | Eng. Manager        | Eng. Manager        |
| 7.4.1, 7.4.2, 7.4.3                                     | par 4.6        | Purchasing                        | Logistics Manager   | Logistics Manager   |
| 7.5.4                                                   | par 4.7        | Customer Supplied Product         | Logistics Manager   | Logistics Manager   |
| 7.5.3                                                   | par 4.8        | Product ID & Traceability         | Logistics Manager   | Logistics Manager   |
| 6.3, 6.4, 7.5.1, 7.5.2                                  | par 4.9        | Process Control                   | Manufacturing       | Manufacturing       |
| 7.1, 8.1, 7.4.3, 8.2.4, 7.5.3                           | par 4.10       | Inspection and Test               | Quality             | Quality             |
| 7.6                                                     | par 4.11       | Inspection and Test Equipment     | Quality             | Quality             |
| 7.5.3                                                   | par 4.12       | Inspection and Test Status        | Quality             | Quality             |
| 8.3                                                     | par 4.13       | Control of nonconforming product  | Quality             | Quality             |
| 8.5.2, 8.5.3                                            | par 4.14       | Corrective and Preventive action  | President           | Quality             |
| 7.5.1, 7.5.5                                            | par 4.15       | Handling, Storage, Packaging etc. | Logistics Manager   | Logistics Manager   |
| 4.2.4                                                   | par 4.16       | Quality Records                   | All                 | All                 |
| 8.2.2, 8.2.3                                            | par 4.17       | Internal Quality Audits           | Quality             | Quality             |
| 6.2.2                                                   | par 4.18       | Training Records                  | Training Manager    | Training Manager    |
| 7.5.1                                                   | par 4.19       | Servicing                         | n/a                 | n/a                 |
| 8.1, 8.2.3, 8.2.4, 8.4                                  | par 4.20       | Statistical Techniques            | Quality             | Quality             |
|                                                         |                |                                   |                     |                     |

# Appendix C

## Manufacturing Process Flow



## Appendix D

### Document Review Records

| Document         | <u>Document Title</u>        | <u>Document Owner</u> | Annual Review Record:<br>By / Date Review<br>Complete. |
|------------------|------------------------------|-----------------------|--------------------------------------------------------|
| <b>CPD-0100</b>  | Quality Manual               | General Manager       |                                                        |
| <b>CPD-0300</b>  | Contract Review              | Vice President of S   |                                                        |
| <b>CPD-0400</b>  | Design Control               | Engineering Manag     |                                                        |
| <b>CPD-0500)</b> | Document Control             | Engineering Manag     |                                                        |
| <b>CPD-0600)</b> | Purchasing                   | Purchasing Manage     |                                                        |
| <b>CPD-0610</b>  | Vendor Rating                | Purchasing Manage     |                                                        |
| <b>CPD-0700</b>  | Customer Supplied Product    | Engineering Manag     |                                                        |
| <b>CPD-0800</b>  | Product ID & Traceability    | Manufacturing         |                                                        |
| <b>CPD-0900</b>  | Process Control              | Manufacturing         |                                                        |
| <b>CPD-1000</b>  | Inspection and Test          | Quality               |                                                        |
| <b>CPD-1100</b>  | Inspection and Test Equipmen | Quality               |                                                        |
| <b>CPD-1200</b>  | Inspection and Test Status   | Quality               |                                                        |
| <b>CPD-1300</b>  | Control of nonconforming pro | Quality               |                                                        |
| CPD-1400.1       | Corrective action            | Quality               |                                                        |
| CPD-1400.2       | Preventive action            | Quality               |                                                        |
| <b>CPD-1500</b>  | Handling, Storage, Packaging | Manufacturing         |                                                        |
| CPD-1700         | Internal Quality Audits      | Quality               |                                                        |
| <b>CPD-1800</b>  | Training Records             | Engineering Manag     |                                                        |

Form CMF -0139

# APPENDIX AS9100

## Section 4 QUALITY MANAGEMENT SYSTEM

**4.2.1** The QMS documentation must include quality system requirements imposed by the applicable regulatory authorities. The organization shall ensure that personnel have access to quality management system documentation and are aware of relevant procedures. Customer and/or regulatory authorities' representatives shall have access to quality management system documentation.

**4.2.2** When referencing the documented procedures in the Quality Manual, the relationship between the requirements of this International Standard and the documented procedures shall be clearly shown.

**4.2.3** The organization shall coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.

**4.2.4** The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers. Records shall be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements

**4.3** Configuration Management:

- The organization shall establish, document and maintain a configuration management process appropriate to the product.

## Section 5 MANAGEMENT RESPONSIBILITY

**5.5.2** Management Representative must have the organizational freedom to resolve matters pertaining to quality.

## Section 6 RESOURCE MANAGEMENT

No significant additions to ISO 9001:2000 requirements

## Section 7 PRODUCT REALIZATION

**7.1** Quality planning includes identifying the identification of resources to support operation and maintenance of the product.

**7.3.7** When product requirements are changed, Vermont Composites, Inc. communicates changes to relevant personnel and amends relevant documents

**7.2.2** Risks (e.g., new technology, short delivery time scale) have been evaluated.

**7.3.1** Design and development stages are based on organization, task sequence, mandatory steps, significant stages and method of configuration control,

- 7.3.1** Required design reviews specific to each element shall be reviewed to ensure consistency with requirements
- a. Where appropriate, due to complexity, the organization shall give consideration to the following activities:
    - i. Structuring the design effort into significant elements
    - ii. For each element, analyzing the tasks and the necessary resources for its design and development. This analysis shall consider an identified responsible person, design content, input data, planning constraints, and performance conditions. The input data specific to each element shall be reviewed to ensure consistency with requirements.
  - b. Updating of the design plan as the project progresses
  - c. The different design and development tasks to be carried out shall be defined according to specified safety or functional objectives of the product in accordance with customer and/or regulatory authority requirements.

**7.3.3** Design outputs

- a. specify the characteristics of the product that are essential for its safe and proper use.
- b. Identify key characteristics, when applicable, in accordance with design or contract requirements.
- c. All pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained shall be defined by the organization; for example:
  - drawings, part lists, specifications;
  - a listing of those drawings, part lists, and specifications necessary to define the configuration and the design features of the product;
  - information on material, processes, type of manufacturing and assembly of the product necessary to ensure the conformity of the product.

**7.3.4** Design Reviews

- Include representatives of functions concerned with the design and development stage being reviewed to authorize progression to the next stage.

**7.3.5** NOTE Design and/or development verification may include activities such as:

- performing alternative calculations,
  - comparing the new design with a similar proven design, if available,
  - undertaking tests and demonstrations, and
  - reviewing the design stage documents before release.
- Validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion.
- Multiple validations may be performed if there are different intended uses.

**7.3.6.1** Documentation of Design and/or Development Verification and Validation:

- At the completion of design and/or development, the organization shall ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions.

**7.3.6.2** Design and/or Development Verification and Validation Testing:

- Where tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed, and documented to ensure and prove the following:
  - a. test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria;
  - b. test procedures describe the method of operation, the performance of the test, and the recording of the results;
  - c. the correct configuration standard of the product is submitted for the test;
  - d. the requirements of the test plan and the test procedures are observed;
  - e. the acceptance criteria are met.

The organization's change control process shall provide for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement.

**7.4 Purchasing**

The organization shall be responsible for the quality of all products purchased from suppliers, including customer-designated sources.

The organization shall:

- a. maintain a register of approved suppliers that includes the scope of the approval;
- b. periodically review supplier performance; records of these reviews shall be used as a basis for establishing the level of controls to be implemented;
- c. define the necessary actions to take when dealing with suppliers that do not meet requirements;
- d. ensure where required that both the organization and all suppliers use customer approved special process sources;
- e. ensure that the function having responsibility for approving supplier quality systems has the authority to disapprove the use of sources.

- Supplier quality management system requirements

**7.4.2** The name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data, requirements for design, test, examination, inspection and related instructions for acceptance by the organization,

- a. requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing,

- b. requirements relative to
- c. supplier notification to organization of nonconforming product and
- d. arrangements for organization approval of supplier nonconforming material,
- e. requirements for the supplier to notify the organization of changes in product and/or process definition and, where required, obtain organization approval,
- f. right of access by the organization, their customer, and regulatory authorities to all facilities involved in the order and to all applicable records, and
- g. requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required.

**7.4.3** Verification activities may include

- a. obtaining objective evidence of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control),
- b. inspection and audit at supplier's premises,
- c. review of the required documentation,
- d. inspection of products upon receipt, and
- e. delegation of verification to the supplier, or supplier certification.

Purchased product shall not be used or processed until it has been verified as conforming to specified requirements unless it is released under positive recall procedure.

Where the organization utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. The organization shall periodically validate test reports for raw material.

Where the organization delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.

If Vermont Composites, Inc. or the customer will perform verification at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information. Where specified in the contract, the customer or the customer's representative shall be afforded the right to verify at the supplier's premises and the organization's premises that:

- subcontracted product conforms to specified requirements. Verification by the customer shall not be used by the organization as evidence of effective
- control of quality by the supplier and shall not absolve the organization of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

**7.5.1** Control of production and service provision

Vermont Composites, Inc. plans and carries out production and service provision under

controlled conditions according to documented procedure (MP-750). Planning shall consider, as applicable,

- a. the establishment of process controls and development of control plans where key characteristics have been identified,
- b. the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization,
- c. the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and
- d. special processes (see 7.5.2).

The implementation of release, delivery and post-delivery activities

- Accountability for all product during manufacture (e.g., parts quantities, split orders, nonconforming product),
  - a. evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized,
  - b. provision for the prevention, detection, and removal of foreign objects,
  - c. monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality, and criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations).

**7.5.1.1** Production Documentation:

Production operations shall be carried out in accordance with approved data. This data shall contain as necessary

- a. drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards); and inspection documents (see 8.2.4.1), and
- b. a list of specific or non-specific tools and numerical control (NC) machine programs required and any specific instructions associated with their use.

**7.5.1.2** Control of Production Process Changes:

- a. Persons authorized to approve changes to production processes shall be identified.
- b. The organization shall identify and obtain acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.
- c. Changes affecting processes, production equipment, tools and programs shall be documented. Procedures shall be available to control their implementation.
- d. The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product quality.

**7.5.1.3** Control of Production Equipment, Tools and Numerical Control (N.C.) Machine Programs:

- a. Production equipment, tools and programs shall be validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to production use shall include verification of the first article

- produced to the design
- b. data/specification.
- c. Storage requirements, including periodic preservation/condition checks, shall be established for production equipment or tooling in storage.

**7.5.1.4** Control of Work Transferred, on a Temporary Basis, Outside the Organization's Facilities:

When planning to temporarily transfer work to a location outside the organization's facilities, the organization shall define the process to control and validate the quality of the work.

**7.5.1.5** Control of Service Operations: Where servicing is a specified requirement, service operation processes shall provide for

- a. a method of collecting and analyzing in-service data,
- b. actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements,
- c. the control and updating of technical documentation,
- d. the approval, control, and use of repair schemes, and
- e. the controls required for off-site work (e.g., organization's work undertaken at the customer's facilities).

**7.5.2 Special processes**

- Defined criteria for review and approval of the processes, qualification and approval of special processes prior to use,
- Use of specific methods and procedures, control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto,

**7.5.3 ID and traceability**

- Vermont Composites, Inc. identifies the product throughout product realization according to the Identification and Traceability procedure (CPD-0800). The organization shall maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.
- Product is identified with respect to monitoring and measurement requirements. When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish and document controls for the media.
- According to the level of traceability required by contract, regulatory, or other established requirement, the organization's system shall provide for:
  - a. identification to be maintained throughout the product life;
  - b. all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch;
  - c. for an assembly, the identity of its components and those of the next higher assembly to be traced;
  - d. for a given product, a sequential record of its production (manufacture,

assembly, inspection) to be retrieved.

#### **7.5.4 Customer property:**

Includes customer furnished data used for design, production and/or inspection.

#### **7.5.5 Preservation of Product:**

Preservation of product shall also include, where applicable in accordance with product specifications and/or applicable regulations, provisions for:

- a. cleaning;
- b. prevention, detection and removal of foreign objects;
- c. special handling for sensitive products;
- d. marking and labeling including safety warnings;
- e. shelf life control and stock rotation;
- f. special handling for hazardous materials.

The organization shall ensure that documents required by the contract / order to accompany the product are present at delivery and are protected against loss and deterioration.

### **7.6 Measuring and monitoring devices**

- a. Are recalled to a defined method when requiring calibration.
- b. In addition, Quality Control assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Vermont Composites, Inc. takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained
- c. The organization shall maintain a register of these monitoring and measuring devices, and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

NOTE Monitoring and measuring devices include, but are not limited to: test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.

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

The organization shall ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.

## **Section 8 MEASUREMENT, ANALYSIS AND IMPROVEMENT**

**8.1** According to the nature of the product and depending on the specified requirements, Statistical techniques may be used to support:

- a. Design verification (e.g., reliability, maintainability, safety);
- b. Process control;
- c. Selection and inspection of key characteristics;
- d. Process capability measurements;
- e. Statistical process control;
- f. Design of experiment;
- g. Inspection - matching sampling rate to the criticality of the product and to the process capability;
- h. Failure mode and effect analysis.

### **8.2.2 Internal audits**

- a. Detailed tools and techniques shall be developed such as check sheets, process flowcharts, or any similar method to support audit of the quality management system requirements.
- b. The acceptability of the selected tools will be measured against the effectiveness of the internal audit process and overall organization performance.
- c. Internal audits shall also meet contract and/or regulatory requirements.

### **8.2.3 Monitoring processes**

In the event of process nonconformity, the organization shall

- a. take appropriate action to correct the nonconforming process,
- b. evaluate whether the process nonconformity has resulted in product nonconformity, and
- c. identify and control the nonconforming product in accordance with clause 8.3.

### **8.2.4 Key characteristics**

- a. When key characteristics have been identified, they shall be monitored and controlled.
- b. When the organization uses sampling inspection as a means of product acceptance, the plan shall be statistically valid and appropriate for use. The plan shall preclude the acceptance of lots whose samples have known nonconformities. When required, the plan shall be submitted for customer approval.
- c. Product shall not be used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities.

**8.2.4.1** Inspection Documentation: Measurement requirements for product or service acceptance shall be documented. This documentation may be part of the production

documentation, but shall include

- a. criteria for acceptance and/or rejection,
- b. where in the sequence measurement and testing operations are performed,
- c. a record of the measurement results, and
- d. type of measurement instruments required and any specific instructions associated with their use.

Test records shall show actual test results data when required by specification or acceptance test plan.

Where required to demonstrate product qualification the organization shall ensure that records provide evidence that the product meets the defined requirements.

#### **8.2.4.2 First Article Inspection:**

The organization's system shall provide a process for the inspection, verification, and documentation of a representative item from the first production run of a new part, or following any subsequent change that invalidates the previous first article inspection result.

### **8.3 Nonconforming product**

- a. The organization's documented procedure shall define the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions.
- b. The organization shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if
  - the product is produced to customer design, or
  - the nonconformity results in a departure from the contract requirements.
- c. Unless otherwise restricted in the contract, organization-designed product which is controlled via a customer specification may be dispositioned by the organization as use-as-is or repair, provided the nonconformity does not result in a departure from customer-specified requirements.
- d. Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.
- e. In addition to any contract or regulatory authority reporting requirements, the organization's system shall provide for timely reporting of delivered nonconforming product that may affect reliability or safety. Notification shall include a clear description of the nonconformity, which includes as necessary parts affected, customer and/or organization part numbers, quantity and date(s) delivered.

NOTE Parties requiring notification of nonconforming product may include suppliers, internal organizations, customers, distributors, and regulatory authorities.

#### **8.5.2 Reviewing corrective action taken includes**

- a. flow down of the corrective action requirement to a supplier, when it is determined that
- b. the supplier is responsible for the root cause, and
- c. specific actions where timely and/or effective corrective actions are not achieved.