Osprey Technologies, LLC

Quality Manual
ISO9001:2008
Rev -

February 8, 2015
Released by Dave Crockett
President

6100 S. Maple Avenue, Suite 117
Tempe, AZ 85283
www.osprey-tech.com

Acronyms

PM	Program Managers
QA	Quality Assurance
PDCA	Plan-Do-Check-Act
SPC	Statistical Process Control
VP/BM	Vice President/Business Manager

1. Introduction

Osprey Technologies is an engineering consulting company, with emphasis in composite material design, analysis, and fabrication.

With over 28 years of experience with structural composite materials, we have a proven reputation for excellence. Our expertise, along with our knowledge of the many fabrication processes, allows us to consider all aspects of project requirements to ensure optimum design and quality composite products.

This QA plan is the top level document controlling all QA procedures and processes for Osprey Technologies (herein referred to as Osprey).

The purpose of this plan is to provide all of the necessary QA guidance, rules, procedures, and processes for design, fabrication, and test of its engineering services and products.

Osprey uses the process based quality management system known as “Plan-Do-Check-Act” (PDCA) for all services and processes. This allows Osprey to be flexible with its customer needs. PDCA is described as:

Plan: Establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.
Do: Implement the processes.
Check: Monitor and measure processes and product against policies, objectives and requirements for the product and report the results.
Act: Take actions to continually improve process performance.

This QA plan is based on the requirements outlined in ISO:9001-2008 [1].

Exclusions: The QA Manager is responsible for identifying those requirements of ISO 9001 that do not apply to our organization or products, and to propose exclusions of such requirements from the scope of the quality system.

President has the responsibility and authority for evaluating whether the proposed exclusions are appropriate and for approving them.

Approved exclusions are noted in Appendix A. The excluded requirements are precisely identified with reference to specific clauses and/or statements in the standard. There is also a brief justification why the exclusion is taken and why it is appropriate.

Note: each customer project or program will maintain its own distinct QA manual. This manual will acknowledge the provisions of Osprey’s QA manual, any exclusions accepted by the customer, and any additional customer specific requirements.

Osprey has developed and implemented a quality management system to demonstrate its ability to consistently provide products and services that meet customer and applicable regulatory requirements, and to address customer satisfaction through the effective application of the system. This includes continual improvement and the prevention of nonconformity. The quality system complies with the international standard ISO 9001 (2008).

This manual is divided into five sections modeled on the sectional organization of the ISO 9001 (2008) standard. Sections are further subdivided into subsections, representing main quality system elements or activities. Each subsection starts with a general policy statement summarizing the basic principles of the pertinent quality system element or activity. The general policy statement is followed by more specific procedural policies outlining how the general policy is implemented, and referencing applicable operational procedures.

The purpose of this manual is to define and describe the quality system, to define authorities and responsibilities of the management personnel involved in the operation of the system, and to provide general procedures for all activities comprising the quality system. .

Another purpose of this manual is to present the quality system to our customers and other external interested parties, and to inform them of the specific controls that are implemented at Osprey to assure the quality of our products and services.

Regarding compliance to the latest revision of the Standard (IS09001:2008), it is the QA managers responsibility to ensure all applicable QA documentation, processes, and procedures are in conformance to latest ISO9001 revisions. All documentation is to show revisions level and issue date.

2. Quality Management System

2.1 General Requirements *(Section 4.1 [1])*

GENERAL POLICY
Osprey is committed to establish, document, implement and maintain a quality management system, and continually improve its effectiveness, in conformance with requirements of ISO 9000 (2008) International Standard. The scope of the quality management system includes all design and manufacturing operations.

PROCEDURAL POLICIES
2.1.1 Quality System Processes (Plan)

2.1.1.1 Processes needed for the quality management system are identified in this quality manual and in associated operational procedures and work instructions. The documentation defines these quality system processes and their sequence and interaction, and instructs on how to implement and apply them throughout the organization.

2.1.1.2 Quality system documentation also defines criteria and methods needed to ensure that the operation and control of quality system processes are effective. This usually includes assignment of responsibilities and allocation of resources for the process, instructions on how to carry out (or operate) the process, and definition of methods for monitoring and/or measuring the effectiveness of the process.

2.1.2 Resources and Information (Do)

2.1.2.1 The QA Manager is responsible for determining resource and information requirements necessary to support the operation and monitoring of quality system processes, and for communicating these requirements to the President. The President is responsible for ensuring the availability of necessary resources and information.

2.1.3. Monitoring and Measurement (Check)

2.1.3.1 The performance of quality system processes is systematically monitored and/or measured. This is to ensure their effectiveness and identify opportunities for improvement.

2.1.3.2 The performance of product realization processes is monitored by measuring process parameters and/or product characteristics resulting from the process; and through the program of inspections and tests applied to the product. The performance of processes required for quality management is monitored through internal quality audits. The overall performance of the quality system is monitored by measuring customer satisfaction.

2.1.4 Conformance and Continual Improvement (Act)

2.1.4.1 Quality management system processes are regularly reviewed by the President to identify any possible failures or breakdowns, as well as opportunities for improvement. Actions necessary to address actual or potential problems and to improve the quality system are implemented through corrective and preventive actions and management improvement projects.

2.1.5 Outsourced Processes

2.1.5.1 When processes that affect product conformity are outsourced, special controls are implemented to ensure that these processes meet specified requirements. Such controls may include; evaluation and pre-qualification of suppliers, assessment of supplier realization processes and quality system, monitoring of supplier quality performance, requirements for inspection, testing or other records demonstrating product conformity, or containment and verification of the supplied product.

PM for that process is responsible for defining special controls. PM is required to inform the QA manager and President of the special controls.

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2.2 Documentation Requirements *(Section 4.2 [1])*

GENERAL POLICY

The scope of quality system documentation is defined. Establishment and revision of documents, and their distribution, are controlled. New documents and revisions are reviewed and approved prior to issue; and are identified with respect to their revision level. Appropriate documents are available at locations where they are used. Obsolete documents are removed from points of use. Documents of external origin are identified and their distribution is controlled.

Quality records are identified and indexed to facilitate their retrieval. Records are stored in a suitable environment to minimize deterioration and are retained for a period of time equivalent to the lifetime of the product plus 5 years.

PROCEDURAL POLICIES

2.2.1 Scope

2.2.1.1 Osprey quality system documentation comprises the following types of documents:

- Company quality manual (this document);
- Company operational procedures;
- Program/project specific quality manual
- Work or fabrication procedures specific to each product line or customer program;
- Standards and other technical reference materials;
- Engineering documents, including drawings, specifications, procedures, and other documents defining products or customer programs;
- Product realization and control plans.

2.2.2 Quality Manual

2.2.2.1 This manual is the top level document defining the overall quality management system. It includes:

- The scope of the quality system, including details of and justification for any exclusions
- Description of quality system processes, their sequence, and interrelation
- References to documented procedures

2.2.3 Document Control

2.2.3.2 New documents and document changes may be initiated by anyone in the organization, but may only be issued by an authorized function. The authorized functions and the rules governing the issue of documents are defined as follows:

- PMs are responsible for their programs' documents including their project specific project QA manual
- QA is to be notified of all documents and changes requiring QA approval
- VP/BM and President are responsible for all company operational documents with QA notification/approval as required. All documents are reviewed and approved prior to issue.

2.2.3.3 Documents are distributed to personnel and locations where they are used. When appropriate, documents display a distribution list. All documents are maintained electronically via management documentation control.

2.2.3.4 Obsolete documents are removed from points of use. Retained masters or copies of obsolete documents are properly marked and are kept separate from active documents. Obsolete electronic documents are removed from the network and, if retained, are stored in directories that are only accessible to authorized personnel.

2.2.3.5 Document changes are reviewed and authorized by the same function that issued the original document. Revised documents are distributed with a change brief summarizing the changes. A master list specifying the latest issues and revisions of its documents is maintained. Only the latest issue and revision of a documents is available on the network. Obsolete documents are moved to an archived directory.

2.2.4 Control of Quality Records

2.2.4.1 Quality records are established and maintained to provide evidence that:

- Product designs satisfy design input requirements;
- Materials, components, and production processes meet specified requirements;
- Finished products conform to specifications: and
- The quality system is operated in accordance with documented procedures and that it is effective.

Where required, quality records also include traceability information.

2.2.4.2 Records are established by personnel performing the task, operation, or activity the results of which need to be recorded. Records are dated; and identify the product, person, or event to which they pertain.

2.2.4.3 Records are indexed and grouped to facilitate their retrieval. Storage media containing records are clearly labeled with identification of their content.

2.2.4.4 Records are normally stored by the same department that initially established the record. Records are stored in dry clean areas, and electronic records are regularly backed up. Quality records and documents may not be stored in private desk drawers, unauthorized computer drives, or other obscure locations that are not generally known.

2.2.4.5 Retention periods for quality records are determined on the basis the lifetime of the product or the event to which the record pertains, and on regulatory and contractual requirements.

3. Management Responsibilities

3.1 Management Commitment *(Section 5.1 [1])*

GENERAL POLICY
The President is ultimately responsible for establishing, implementing, maintaining, and improving the quality system. His commitment is demonstrated by communicating to the organization the importance of meeting requirements, establishing the quality policy and quality objectives, conducting management reviews of the quality system, and ensuring the availability of necessary resources. The president has final say in all matters of QA.

PROCEDURAL POLICIES
3.1.1 Top Management

3.1.1.1 For the purpose of administrating the quality management system, top management is defined to include the President and Vice President/Business Manager.

3.1.2 Customer Requirements

3.1.2.1 President is committed to communicate the importance of meeting customer as well as regulatory and legal requirements. The VP/BM and PMs are responsible for implementing this commitment by promoting awareness of customer requirements throughout the organization.

3.1.3 Quality Policy and Quality Objectives

3.1.3.1 President defines the purpose and objectives for the quality management system as outlined in this manual.

3.1.4 Management Reviews

3.1.4.1 President reviews the quality management system at least yearly to ensure its continuing suitability, adequacy, and effectiveness. The review evaluates current status and performance of the quality system and initiates actions for further improvement of the system.

3.1.5 Resources

3.1.5.1 President is committed to providing resources necessary for establishing, implementing, and improving the quality management system.

3.2 Customer Focus *(Section 5.2 [1])*

GENERAL POLICY

The principal objective of the quality management system is to focus the company organization on the customer, and in particular, on customer satisfaction. The key to achieving high customer satisfaction is a good understanding of customer requirements and a capability to consistently fulfill these requirements.

PROCEDURAL POLICIES

3.2.1 The PM is responsible for determining customer requirements for each specific project and conveying to QA via project specific QA documents.

3.2.1.1 Customer requirements are understood broadly to include all aspects of products, projects, and associated services that can influence customer satisfaction. When relevant, this may also include customer needs and expectations.

3.2.1.2 Customer requirements are determined and verified through the process of order review. Requirements are determined by Sales/Marketing and PM with top management final review and approval.

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3.2.2 Customer Needs and Expectations

3.2.2.1 When appropriate, customer needs and expectations are determined and are incorporated into product or service requirements. Marketing is responsible for collecting and analyzing information on customer needs and expectations. The purpose is to gain understanding of:

- How customers use (and misuse) the product and services;
- How the product interfaces with customer's other products and/or operations;
- Which product features and characteristics are most important to customers, and which are perceived to be the strengths and weaknesses of the product or service.

3.2.2.2 Information about customer needs and expectations is collected and developed from various sources. These include:

- Trends in stated customer requirements and developments in pertinent legal and regulatory requirements;
- Customer surveys and direct contacts with customers;
- Expressions of customer satisfaction and dissatisfaction, including customer complaints, and other customer feedback;
- Trade magazines, conferences, seminars, etc.; and
- Benchmarking against competitive products.

3.2.2.3 Information about customer needs and expectations is also extracted from customer feedback and complaints, and customer satisfaction data.

3.2.3 Fulfillment of Customer Requirements

3.2.3.1 The whole quality system is designed and implemented to ensure that customer requirements can be consistently fulfilled. Quality system processes that most directly contribute to achieving this objective are those related to the control of product realization processes and to monitoring and measuring of product.

3.3 Quality Policy *(Section 5.3 [1])*

QUALITY POLICY
Osprey is committed at all levels to meeting all customer requirements and increasing customer satisfaction through the continual measurement, review and improvement of our products, services, and the effectiveness of the quality management system. To meet our customer's needs and provide options for product and service improvement.

PROCEDURAL POLICIES
3.3.1 Authority

3.3.1.1 Quality policy is established by the President. Any changes to the policy must be likewise approved by the President.

3.3.2 Role of the Policy

3.3.2.1 The main role of the quality policy is to communicate the company's commitments with regard to quality, and to define principal objectives for the quality management system. The quality policy provides a framework for establishing specific quality objectives, and provides direction for the continual improvement effort.

3.3.3 Communication

3.3.3.1 The quality policy is posted throughout the company, and its role is explained and discussed at the general orientation training provided to all employees.

3.3.3.2 The quality policy is also communicated to customers, consumers and other interested parties. For this purpose, it is displayed in the reception area and posted on the company's internet site.

3.3.4 Review

3.3.4.1 The quality policy is periodically reviewed within the framework of management reviews of the quality system. This is to ensure its continual relevance and suitability.

3.4 Quality System Planning *(Section 5.4 [1])*

GENERAL POLICY

Quality objectives are established to support and implement the quality policy and continual improvement. Quality planning includes identification and determination of quality system processes (including any exclusions of ISO 9001 requirements); priorities for continual improvement; and resources needed to achieve quality objectives and to maintain and improve the quality system. Quality plans are periodically reviewed and updated to maintain the integrity of the quality system.

PROCEDURAL POLICIES

3.4.1 Quality Objectives

3.4.1.1 Top management is responsible to ensure quality objectives are established throughout the organization, to implement the quality policy, to meet requirements for products and processes, and to improve quality system and quality performance.

3.4.1.2 Quality objectives are classified into the following four categories:

- Policy objectives: These are principal, strategic objectives that apply to the whole organization. They are typically included in the quality policy itself, or may be communicated in memoranda from the top management. Policy objectives are authorized only by the President.
- Quality performance objectives: These objectives set specific, measurable targets for improving operational performance to ensure product conformity and customer satisfaction. They apply to departments and functions having direct responsibility for activities that require improvement. Performance objectives are established, documented, and monitored within the framework of management reviews of the quality system.
- Product quality objectives: These objectives pertain to improvement of products and associated services. Product objectives are established by the PM and Marketing. They can be documented in product briefs, memoranda, or minutes of meetings; and apply to functions responsible for research, design, and development of products and services.
- Quality system objectives: These objectives pertain to improvement of quality system processes and performance. Quality system objectives are established, documented, and monitored within the framework of management reviews of the quality system.

3.4.2 Quality System Planning

3.4.2.1 Quality system elements and processes are planned to ensure that the system is appropriate for its intended purpose, and that it is effective and efficient. The purpose of the quality system is:

- To achieve the quality policy;
- To ensure and demonstrate ability to provide consistent products and services that meet customer and regulatory requirements;
- To ensure high level of customer satisfaction;
- To facilitate continual improvement; and
- To comply with requirements of ISO 9001 standard.

3.4.2.2 The output of quality system planning is documented in this quality manual, in associated operational procedures, and in other referenced documents. These documents identify and define all elements and processes of the quality system.

3.4.3 Continual Improvement Planning

3.4.3.1 Improvements of the quality system are planned within the framework of management reviews. .

3.5 Responsibility, Authority, and Communication *(Section 5.5 [1])*

GENERAL POLICY

The President appoints a management representative responsible for establishment and maintenance of the quality system, and for reporting to the President on the performance of the system. Issues regarding the quality system are communicated internally though distribution of pertinent documents, meetings, training and awareness programs, and management reviews.

PROCEDURAL POLICIES

3.5.1 Responsibility and Authority

3.5.1.1 All departments and functions in the company are responsible for implementing, maintaining, and improving the quality system. Specific responsibilities and authorities are assigned as shown in Appendix B.

3.5.2 Management Representative (QA Manager)

3.5.2.1 The QA manager has the authority and responsibility to:

- Ensure that the quality management system is implemented, maintained and continually improved
- Promote awareness of customer requirements throughout the organization
- Report to the President on the performance of the quality system, including needs for improvement
- Coordinate communication with external parties on matters relating to the quality system and ISO 9001 registration
- Coordinate with PM for program specific QA requirements and documents

3.5.3 Internal Communication

3.5.3.1 Internal communication regarding the quality system flows two ways:

Top management communicates to the organization the quality policy and objectives; customer and regulatory requirements; product and process specifications; verification and validation requirements; and instructions on how to implement and use the quality system.

The organization communicates to the management information and data regarding customer needs and expectations, customer satisfaction, quality performance, the effectiveness of the quality system, and opportunities for improvement.

3.5.3.2 Information is communicated through manuals, procedures, instructions, drawings, specifications, quality records, reports, etc.; and through training, on-the job instruction, and meetings.

3.5.3.3 Management review meetings have a special role in ensuring proper communication between the President and the organization. The meeting provides the framework for the organization to report on the status of quality-related issues and activities, and for the management to formulate policies and directives to change and/or improve the quality system.

3.5.3.4 QA Manager has the overall responsibility for ensuring that all pertinent documents, reports and records are distributed to appropriate departments and functions, and that information and data about quality performance and the effectiveness of the quality system are reported to the top management.

3.6 Management Review *(Section 5.6 [1])*

GENERAL POLICY

The President conducts periodical reviews of the quality system. The review evaluates the suitability and effectiveness of the system, identifies opportunities for improvement, and considers the need for changes to the quality policy and quality objectives. Results of reviews are documented.

PROCEDURAL POLICIES

3.6.1 General

3.6.1.1 The purpose of management reviews is to:

- Evaluate the suitability, adequacy and effectiveness of the quality system;
- Consider changes to the quality management system and to the quality policy and quality objectives; and
- Identify opportunities for improvement of the quality system, processes and products.

3.6.1.2 Management reviews are chaired by the President

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3.6.1.3 Management reviews are conducted at least once a year. More frequent reviews are scheduled in periods when organizational or product changes, or other circumstances require increased attention and input from the top management.

3.6.2 Review Input

3.6.2.1 Input into the management reviews consists of information and data related to quality performance of the organization. At a minimum, this includes:

- Results of audits,
- Customer feedback and complaints,
- Process performance and product conformance data,
- Status of preventive and corrective actions,
- Organizational changes,
- Other changes that could affect the quality system,
- Follow-up actions from earlier management reviews, and
- Recommendations for improvement.

3.6.3 Review Output

3.6.3.1 Management reviews are concluded with actions related to improvement of the quality management system, and improvement of processes and products to better meet customer requirements. The review also identifies resource needs to implement these actions.

3.6.3.2 Results of management reviews are documented in minutes of the review meeting. The minutes include improvement actions, and assign responsibilities and allocate resources for implementation of these actions.

4. Resource Management

4.1 Provision of Resources *(Section 6.1 [1])*

GENERAL POLICY
Osprey is committed to provide adequate resources for the implementation and improvement of the quality system, and for addressing customer satisfaction.

PROCEDURAL POLICIES
4.1.1 General

4.1.1.1 Resources required for implementation and improvement of the quality system, and for addressing customer satisfaction, may include people, suppliers, information, infrastructure, work environment, and financial resources.

4.1.2 Determination of Resource Requirements

4.1.2.1 The President is responsible for determining resource requirements for the implementation and improvement of the system.

4.1.2.2 The President is responsible for determining resource requirements for addressing customer satisfaction. This is based on input from other management personnel responsible for activities relevant to particular aspects of customer satisfaction.

4.1.2.3 The principal forum for determining and communicating resource requirements are management reviews of the quality system.

4.1.3 Provision of Resources

4.1.3.1 The President has the responsibility and authority for provision of resources.

4.1.3.2 Allocation of resources for particular activities is integrated with the process of defining and initiating the activity. It may take the form of personnel assignments, allocation of space or equipment, training, procurement decisions, and budgets.

4.1.3.3 Allocation of resources may be documented in the quality manual, operational procedures, minutes of meetings, or memoranda. Approvals of resource allocations may also be communicated verbally.

4.1.3.4 Management review of the quality system is the principal forum for allocation of resources for the operation and improvement of the system. All actions initiated by the review are supported by allocation of specific resources necessary for their implementation.

4.2 Human Resources *(Section 6.2 [1])*

GENERAL POLICY

Osprey identifies personnel training needs, provides required training, and evaluates the effectiveness of the training provided. Personnel assigned to perform specific tasks, operations, and processes are qualified on the basis of appropriate education, experience, or training. Employees are made aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives. Records of personnel qualifications and training are maintained.

PROCEDURAL POLICIES

4.2.1 Identification of Training Needs and Awareness Programs

4.2.1.1 VP/BM is responsible for identifying training needs and awareness programs for company-wide participation, such as: general orientation, rules and regulations, quality system, safety, and other company-wide systems and issues.

4.2.1.2 VP/BM is responsible for identifying competency requirements and training needs in their departments, and for establishing departmental training programs. Departmental training is primarily focused on increasing the level of skills in operating equipment and processes, conducting inspections and testing, using analytical and statistical techniques, and so forth.

4.2.1.3 In addition, training needs are often identified in response to corrective or preventive action requests, as nonconformities may be caused by inadequate training.

4.2.2 Awareness and Training Programs

4.2.2.1 Osprey provides, or supports, the following categories of company-wide and departmental training and awareness programs:

- General orientation and quality system awareness training — Explains how the product is used and how the quality system works to ensure product quality.
- Safety training — Instructs in safe working practices, use of personal protective equipment, first aid, etc. Provided to all employees.
- External training — External seminars, conferences, and courses. Provided to individual employees on as-needed basis.
- Self-study — Reading magazines, books, and reports. While all employees are encouraged to broaden their knowledge through reading, in some cases self studying may be required as formal training.
- Skill training in engineering, production, and quality control — departmental training in specific skills. Often provided as on-the-job training.

4.2.3 Effectiveness of Training

4.2.3.1 Effectiveness of training is evaluated using the following approaches:

- Follow-up performance evaluation of trained employees
- Review of the overall performance in areas relevant to particular training programs
- Consideration of competency and training when investigating causes of quality system failures and product or process nonconformities
- A global review of all training and awareness programs, conducted within the framework of management reviews of the quality system

4.2.4. Training Records

4.2.4.1 Training records are established for all types of training. Human Resources (VP/BM) maintains as-hired qualification records.

4.3 Infrastructure *(Section 6.3 [1])*

4.3.1 Supporting Services and Maintenance of Facilities

4.3.1.1 Maintenance of buildings and facilities is the responsibility of the President with the exception of those items covered by the leasing agency as noted in the lease.

4.3.1.2 Production equipment maintenance and calibration are the responsibility of the President.

4.4 Work Environment *(Section 6.4 [1])*

4.4.1 The President and VP/BM are responsible for ensuring suitable working environment for personnel. This is to include both human and physical factors.

4.4.2 VP/BM is responsible for identifying those operations where extreme environmental conditions could impact quality performance of personnel and result in product nonconformities. Were appropriate, limits of exposure and/or mitigating measures shall be defined and implemented for these operations.

5.0 Product Realization

5.1 Planning of Product Realization *(Section 7.1 [1])*

GENERAL POLICY
Planning of product realization processes includes determination of quality objectives for products; development of required processes and process documentation; and establishment of product verification and validation programs. The plan also defines requirements for records necessary to demonstrate process and product conformity.

PROCEDURAL POLICIES
5.1.1 Product Quality Objectives

5.1.1.1 Quality objectives for products are defined in drawings, specifications, contract documents, internal and external standards, product samples and workmanship standards, and applicable legal and regulatory requirements.

5.1.1.2 QA, in working with PMs, is responsible for identifying product quality objectives and requirements. This may be integrated with the process of determining customer and product requirements

5.1.2. Product Realization Planning

5.1.2.1 Product realization planning includes, as applicable:

- Definition and evaluation of manufacturing operations and processes,
- Development of adequate and capable processes,
- Identification of special processes and consideration of associated risks and consequences,
- Establishment and implementation of appropriate process control measures,
- Development of instructions and training for process operators, and
- Requirements for records necessary to demonstrate process conformity.

5.1.2.2 Product realization plans are established in collaboration between Production, Engineering, and Quality Assurance. The plans are defined in various types of production documents, such as process flowcharts, production work orders, control plans, operator instructions, process validation reports, etc.

5.1.3. Product Verification and Validation Planning

5.1.3.1 Product verification and validation plans determine the inspection and testing program for a product, and for materials and components incorporated into the product. This includes:

- Identification of inspection and testing points,
- Inspection and testing scope, frequency, and method,
- Acceptance criteria, and
- Requirements for records necessary to demonstrate product conformity.

5.1.3.2 Engineering and QA are responsible for the development of product verification plans. The plans are defined in various types of documents, such as product drawings and specifications, production work orders, purchasing documents, inspection and testing procedures, and so forth. Documents defining the processing, inspection and testing program for a specific product are collectively referred to as manufacturing control plans.

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5.2 Customer Related Requirements *(Section 7.2 [1])*

GENERAL POLICY
Products or projects are determined to include customer requirements and legal, regulatory, and other necessary requirements that may not be specified by customers. Orders are reviewed to ensure that product and order requirements are defined and can be met, and to resolve any incomplete or conflicting requirements. Verbal orders are confirmed before acceptance. Order amendments and changes are likewise reviewed and are communicated to all relevant functions. Order reviews are recorded.

Arrangements for communication with customers relating to product information, order handling, and customer feedback and complaints are defined and implemented. Where appropriate, operational procedures and instructions for these activities are established and implemented.

5.2.1 Determination of Requirements Related to the Product
The projects PM is responsible for determining all requirements related to their program. These requirements are to include:

- Those specified by the customer, including the requirements for delivery and post-delivery activities. NOTE: Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal
- Requirements not stated by the customer but necessary for specified or intended use, where known
- Statutory and regulatory requirements applicable to the product
- Any additional requirements considered necessary by Osprey

5.2.1.1 Incomplete or Conflicting Requirements

5.2.1.1.1 Any incomplete or conflicting requirements are resolved with the customer before acceptance of the order.

5.2.1.2 Verbal Orders

5.2.1.2.1 Verbal orders are confirmed before acceptance. This may be by repeating the order requirements back to the customer by sending a confirming e-mail.

5.2.1.3 Amendments

5.2.1.3.1 Change orders are received and reviewed by the same functions that are responsible for the review of the initial orders. Change orders are communicated to all functions within the organization that may be affected by the change of customer requirements.

5.2.2 Review of Requirements Related to the Product

Review of requirements are done prior to start of design by the customer, QA, and top management in a program specific requirements review. The President will authorize the program to proceed after requirements review and approval. The review and approval process includes:

- Product requirements are defined
- Contract or order requirements differing from those previously expressed are resolved
- Company has the ability to meet the defined requirements
- Final acceptance by the customer

Records of the requirement review and actions arising are maintained.

Any future changes to requirements are documented, reviewed, and follow same approval process as original. All relevant personnel are made aware of the changed requirements.

5.2.3 Customer Communication

The PM is responsible for implementing effective arrangements for communicating with customers in relation to: .

- Product information
- Enquiries, contracts or order handling, including amendments
- Customer feedback, including customer complaints

The President is responsible to verify through periodic communication with the customers management.

5.3 Design and Development *(Section 7.3 [1])*

GENERAL POLICY

The design, development, and/or analysis processes are planned. Activities are identified, qualified personnel are assigned to specific design responsibilities, and organizational interfaces are defined and controlled. Input is formally documented and reviewed. The design and analysis are verified and, when applicable, validated with prototype testing or by other means. Output is documented and checked before it is released for production or review by the customer. Changes are controlled.

PROCEDURAL POLICIES

5.3.1 Design and Development Planning

The PM is responsible for the planning and control of their program or project. During the course of the design there will be periodic reviews (preliminary design review, critical design review, manufacturing readiness review, and test readiness review as required). At each of these milestone reviews the customer is invited. QA and the President will also attend. The reviews will present needed information which will include:

- Verification of requirements being met (including complete, unambiguous, and not conflicting with other requirements)
- Verification of the design and development for that stage
- Responsibilities and authorities for continued design, development, manufacture, test, etc
- Review of costs and schedule
- Verify communication between specific groups and personnel responsible
- Feedback on customer satisfaction
- Documentation of the review

Osprey designs and analyzes customer-specified products and modifications. Engineering is responsible for design and identification of QA requirements.

5.3.2 Design and Development Inputs

Inputs relating to product requirements are determined and recorded. Inputs include:

- Verification of functional and performance requirements
- Verification of applicable statutory and regulatory requirements
- Heritage of previous designs
- Any other requirements essential for design and development.

The PM is responsible for review of all inputs.

5.3.3 Design and Development Outputs

Program design and development outputs are documented in forms of drawings, reports, manuals, etc. These outputs will go through a signature verification process involving various applicable departments. Outputs, such as drawings and process manuals, are managed by configuration control process.

Design and development outputs include:

- Verification of input requirements for design and development
- 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.

5.3.4 Design and Development Review

At suitable stages, systematic reviews of design and development are performed in accordance with planned arrangements (see 5.3.1):

- To evaluate the ability of the results of design and development to meet requirements .
- To identify any problems and propose necessary actions

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

5.3.5 Design and Development Verification

Verification is performed in accordance with planned arrangements outlined in Section 5.3.1 to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions are maintained.

5.3.6 Design and Development Validation

Design and development validation are performed in accordance with planned arrangements outlined in Section 5.3.1 to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained.

5.3.7 Control of Design and Development Changes

Design and development changes are identified and records maintained. All changes are reviewed, verified and validated, as appropriate, and approved before implementation. Engineering will review design and development changes, including evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions are maintained through configuration management control.

5.3.7.1 Design changes are initiated using the Engineering Change Notice (ECN) system. Requests for engineering changes are evaluated, and are recommended or rejected, by Engineering, Production and Quality Assurance, and/or other designated personnel as applicable. The ECN provides design input for designing the change.

5.4 Purchasing *(Section 7.4 [1])*

GENERAL POLICY
Osprey evaluates its suppliers and purchases only from those that can satisfy quality requirements. Quality performance of suppliers is monitored and evaluated. Purchasing documents clearly and completely describe ordered products, including quality requirements. Purchasing documents are reviewed and approved prior to release. Purchased products are verified before they are used or shipped. As a note the President and VP/BM are the only personnel authorized to make purchases.

PROCEDURAL POLICIES
5.4.1 Purchasing Process

5.4.1.1 Approved Supplier List

5.4.1.2 Osprey maintains an approved supplier list. Orders may only be placed with vendors that are on the list.

5.4.2 Supplier Evaluation

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5.4.2.1 Any vendor that has not been issued an approved vendor status is classified as a new vendor. When a purchase request is made for products or services from a vendor who is not on the Approved Vendor List, purchasing personnel place the vendor onto the vendor list when issuing the Purchase Order (mark with “New Vendor” designation). The Purchase Order specifies the vendor is new and requires special attention at the time of receiving.

5.4.2.2 Those new vendors who supply products that require only a general inspection (1st stage) will be placed on the Approved Vendor List only after inspection has been completed. New vendors supplying products which require a 2nd stage inspection (inspection of facilities and QA review) will be placed on the Approved Vendor List only after inspection has been completed.

5.4.3 Supplier Quality Performance Monitoring

5.4.3.1 Quality performance of suppliers is monitored. Suppliers showing inadequate performance may be asked to implement corrective actions, and be downgraded to the PROVISIONAL rating. If the requested corrective actions are not implemented and there is no improvement, the supplier is further downgraded to the NOT APPROVED rating and is discontinued. Records of suppler monitoring and reevaluations are maintained.

5.4.4 Purchasing Information

5.4.4.1 Purchasing documents are prepared by the President or VP/BM. The documents clearly and completely describe ordered products, including precise product identification and quality requirements.

5.4.4.2 Engineering specifies the purchase requirements.

5.4.5 Verification of Purchased Product

5.4.5.1 Purchased products are inspected by President, VP/BM, or PM of that specific program. This includes verification of product identity and quantity, visual inspection and, where applicable, verification that all requested certificates and quality records are available. President may designate products for further inspection or testing by QA.

5.4.5.2 QA inspection or testing may not be necessary when products are supplied with records or certificates demonstrating conformity; or when the supplier is qualified based on their quality system certification or supplier audits, and a satisfactory quality performance history.

5.4.5.3 Engineering is responsible for selecting appropriate methods for purchased product verification and acceptance.

5.4.5.4 When verification of purchased product is to be performed at supplier's premises, purchasing documents specify the intended verification arrangements and method of product release.

5.5 Production and Service Provisions *(Section 7.5 [1])*

GENERAL POLICY

Product and process information and appropriate work instructions are established and are communicated to relevant personnel. Operations and production processes are monitored and controlled, and are validated where appropriate. Machines and equipment used in production and for monitoring and measurement activities are maintained. Methods for product release and delivery are defined.

Materials, components, parts, subassemblies, and finished products are identified. When required, traceability of materials and processes is recorded and maintained. Inspection and test status of product is identified to ensure that only product that has passed the required inspections is used, installed, or dispatched.

Customer-supplied products are normally controlled in the same manner as are purchased products. Customer-owned tools, equipment, software, or other property are marked to indicate ownership. Loss, damage, or unsuitability of a customer's product is recorded and reported to the customer.

Appropriate handling, storage and preservation methods are implemented to prevent product damage or deterioration. Receipt and dispatch to and from storage areas are controlled. The condition of products in stock is regularly assessed. Product packaging materials and methods are specified and controlled.

PROCEDURAL POLICIES

5.5.1 Control of Production and Service Provision

Osprey plans and carries out production and service provision under controlled conditions. This includes:

- Documentation of information that describes the characteristics of the product
- Use of work instructions or procedures for all fabrication, test, and repair
- Use of calibrated of monitoring and measuring equipment
- Documentation of product release, delivery and post-delivery activities.

5.5.2 Validation of Processes for Production and Service Provision

Osprey validates all 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. Arrangements to establish these processes include:

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

5.5.2.1 Processes where the resulting output cannot be verified by subsequent measurement or monitoring are designated as special processes.

5.5.2.2 Engineering and QA are responsible for identifying, validating, and documenting special processes. Engineering will establish validation specifications and testing of samples.

5.5.2.3 Special processes are validated and controlled by applicable methods, such as destructive testing of product samples, equipment and personnel qualification, and work instructions and process procedures.

5.5.2.4 Engineering and QA are responsible for selecting and implementing appropriate process validation and control measures for each special process. At a minimum, all special processes are documented in work instructions.

5.5.2.5 Special process records are established and maintained as appropriate. Depending on the control measures implemented, these records may include process qualification and validation reports, equipment qualification and maintenance records, SPC data, first article inspections and tests, operator qualification and training records.

5.5.3 Identification and Traceability

All identification and traceability are maintained through the company's configuration management control system.

5.5.3.1 Product Identification

5.5.3.1.1 Purchased products are identified with unique numbers, codes, or names. The identification is the same as, or is cross-referenced with, the designations used in drawings, specifications, bills of materials, parts lists, purchase orders, etc. Purchased products are identified by marking, labeling, or tagging the products or their packaging, or by identification of the area where the products are held.

5.5.3.1.2 During all stages of production, products are identified by work orders and other documents that accompany them through the production cycle. Parts and components are also be identified by labels or tags, or the containers in which they are held.

5.5.3.1.3 Final products are identified by their name and model number, which is labeled or marked on the products and/or is printed on the primary product packaging.

5.5.3.2 Traceability

5.5.3.2.1 When required by contracts, laws and regulations, or voluntary standards traceability is implemented to the extent specified. Traceability are also be implemented for internal reasons, to facilitate corrective action.

5.5.3.2.2 As required, traceability applies to materials, components, parts, production processes, environmental conditions, inspection and testing, and personnel responsible for processing and verification of products. The scope of traceability is documented in product manufacturing specifications or the production work order.

5.5.3.3 Inspection Status Identification

5.5.3.3.1 Following every inspection or test, products are identified to indicate whether they have passed or failed the inspection. This is to prevent nonconforming product from being used or dispatched.

5.5.3.3.2 QA inspectors and production personnel authorized to carry out inspections and testing are responsible for identifying product inspection status. All personnel handling products are responsible for maintaining the identification.

5.5.3.3.3 Products that have passed the receiving inspection are moved to the material stockroom or designated material staging areas in production. Where intermingling with other product is a possibility, the inspected items are also appropriately tagged or labeled.

5.5.3.3.4 Status of an in-process inspection is identified by a sign-off in the work order accompanying the product. The status may be also identify by tagging or labeling, or holding products in designated containers.

5.5.3.3.5 Products that pass the final inspection are placed in the finished product area that is designated and used only for this purpose. In addition, finished products are identified as ACCEPTED, and their release is signed off in the work order on the line where the final inspection is called out.

5.5.3.3.6 Products that fail any inspections or tests are identified as REJECTED, and are segregated and/or quarantined. Whenever a nonconforming product is identified, the nonconformity is documented using a product nonconformity report

5.5.4 Customer Property

All customer property is logged in, labeled, and inspected for condition at time of receiving. Any damage is reported to the customer. Any property damaged during use is recorded in log and reported to the customer for disposition.

5.5.4.1 Receiving

5.5.4.1.1 Customer-supplied products are received and inspected following the same procedure that applies to purchased products. In the event the supplied products fail receiving inspection, or are not suitable for any other reason, the customer is contacted.

5.5.4.2 Marking, Storage, and Handling

5.5.4.2.1 Marking, storage, handling, and preservation of customer supplied products follow the same procedures that apply to purchased products.

5.5.4.2.2 Customer-owned tooling and returnable packaging are permanently marked so that ownership of each item is visually apparent.

5.5.4.2.3 Customer's software, documents, and other intellectual property are protected to the same extent, as would Osprey's internal documents of similar content, unless there are contractual requirements for special measure to protect customer's intellectual property.

5.5.4.3 Special Requirements

5.5.4.3.1 When specified in a contract, special handling instructions from customers will take precedent over the company's standard procedures.

5.5.4.4 Loss or Damage

5.5.4.4.1 Customers are contacted in the event of loss, damage, deterioration, or unsuitability of their products.

5.5.5 Preservation of Product

Osprey puts in processes to preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

5.5.5.1 Product Handling and Preservation

5.5.5.1.1 Production is responsible for product handling and preservation; and in particular for ensuring that containers holding products are suitable and are in good condition, that equipment used for internal transportation of products is well maintained and is properly operated, and that products are adequately protected during production and storage.

5.5.5.1 Product and Process Specifications

5.5.5.1.1 Information specifying product characteristics is communicated to production in the form of drawings, specifications, samples, instructions, work orders, and product specific templates and other tooling. Engineering, Production and QA determine the scope, form, and distribution of product specifications.

5.5.5.1.2 Product and process information required by process operators is communicated through the work order or is included in work instructions. Where required for custom products, engineering drawings and specifications may be enclosed with the work order.

5.5.5.2 Storage

5.5.5.2.1 Stockrooms and storage, staging and holding areas are controlled.

5.5.5.2.2 When special storage conditions are specified (for example, temperature or humidity), products are stored in special rooms, boxes, or containers where the specified conditions can be continuously maintained. These special conditions are monitored to ensure that they are maintained without interruption and that the product is not compromised at anytime.

5.5.5.2.3 Products with limited shelf life are identified with expiration dates. These perishable products are also rotated to ensure that the oldest product is used first.

5.5.5.3 Packaging and Labeling

5.5.5.3.1 Primary packaging are boxes, bags or other packaging in which products are presented to the end-users.

5.5.5.3.2 Secondary packaging are cardboard boxes, crates, or other additional packaging intended to contain and protect products for shipping and transportation.

5.5.5.3.3 Primary packaging and labeling operations are controlled following the same policies and procedures that apply to production operations and processes. Product packaging and labeling are defined in drawings, specifications and artwork. These documents are issued and controlled in the same manner as other engineering documents. When appropriate, personnel involved with these processes are provided with work instructions and/or special training.

5.5.5.3.4 Shipping department is responsible for establishing specifications for secondary packaging and labeling. The specifications are compatible with requirements of commonly used carriers and for intended means of delivery (ground, sea, air). Packaging specifications are documented in drawings, written standards, and/or packaging instructions. Packaging specifications are maintained and controlled by Shipping.

5.5.5.4 Shipping and Delivery

5.5.5.4.1 Shipping of finished products is initiated by the shipping order. The order identifies the shipping consignee address, shipping due date, products to be shipped, labeling requirements, and transportation mode or carrier. Before products are dispatched, the shipping supervisor verifies that the shipment contains the same products and quantities as specified in the shipping order, and that packaging and labeling conform with customer and/or carrier requirements. Only orders that have been verified and signed off by the President or VP/BM can be loaded for shipment.

5.5.5.5 Work Instructions

Work instructions and workmanship standards may be in the form of manuals, procedures, sheets, posted signs, or samples. They instruct on how to carry out a process or perform an operation or task. The need for work instructions is evaluated on the basis of criticality, importance and complexity of the process; the ability to verify results of the process; operator qualifications; and history of quality problems associated with the process. Workmanship standards are provided when acceptability of the process output can only be determined by comparison with a standard sample.

5.5.5.6 Equipment Maintenance

Key process equipment, machines, hardware, and software are regularly maintained in accordance with maintenance plans specified by equipment manufacturers or departmental managers responsible for the equipment.

5.5.5.7 Measuring and Monitoring Equipment

Requirements for measuring and monitoring equipment are determined by Quality Assurance. Equipment is calibrated in accordance with ANSI/NCSL Z540-1-1994 Part 1 and be traceable to NIST standards

5.5.5.8 Process Monitoring and Control

Processes are monitored and controlled through variety of approaches, activities and techniques. The system is designed to control:

- Information, material and human (operator) input into the process;
- Technology, tools and equipment used;
- Process environment and performance; and
- Process output.

5.5.5.9 Product Release and Delivery

Products are released for delivery only after all specified activities have been satisfactorily completed and conformity of the product has been verified.

5.6 Control of Monitoring and Measuring Equipment *(Section 7.6 [1])*

GENERAL POLICY

Osprey maintains measuring and monitoring instruments to ensure that capability is consistent with the requirements. Equipment used for assuring product conformity is calibrated using calibration standards traceable to the national standard. Calibration status of measuring equipment is identified with calibration stickers. Measuring equipment is properly maintained and its placement and use are controlled.

Osprey determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. Osprey establishes processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. Where necessary to ensure valid results, measuring equipment is:

- Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification is recorded.
- Adjusted or re-adjusted as necessary
- Identified in order to determine its calibration status
- Safeguarded from adjustments that would invalidate the measurement result
- Protected from damage and deterioration during handling, maintenance and storage

In the event that equipment is found not to conform to requirements Osprey assesses and records the validity of previous measuring results to ensure conformance of products delivered.

PROCEDURAL POLICIES
Note covered by other sections. In future revision consolidate this to more applicable and organized sections.

5.6.1 Controlled and Uncontrolled Equipment

5.6.1.1 The scope of the calibration control system extends to the measuring and test equipment, comparative reference hardware (such as gauges and templates), and test software used for:

- Setup and monitoring of production processes;
- Monitoring of environmental conditions;
- Verification of product conformity; and
- Operations where defined accuracy of a measurement is required to assure product conformity.

5.6.1.2 Equipment used for other purposes may be exempted from calibration. Such equipment is labeled with stickers warning that it is not calibrated. Uncontrolled measuring equipment is prohibited in QC inspection areas.

5.6.2. Measurement Identification and Selection of Equipment

5.6.2.1 Identification of measurements to be made and the tolerance of the measured characteristics are documented in control plans and/or in product drawings and specifications.

5.6.2.2 Gauges, instruments, and other measuring and monitoring equipment are selected on the basis of their capability to provide the necessary accuracy of the measurement. QA is responsible for selecting appropriate measuring and monitoring equipment.

5.6.3. Equipment Calibration and Maintenance

5.6.3.1 Tools and equipment used for product acceptance shall be calibrated in accordance with ANSI/NCSL Z540-1-1994 Part 1 and be traceable to NIST standards.

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5.6.3.2 QA is responsible for calibrating and maintaining measuring and monitoring equipment. All active equipment is inventoried in a controlled list, indicating equipment calibration status and location.

5.6.3.3 Measuring equipment is calibrated using written instructions, unless calibration is simple and obvious. Only calibration instruments and standards having known relationship to the nationally recognized standards are used for calibrating measuring and test equipment.

5.6.3.4 Calibration is recorded in a calibration certificate and the calibrated equipment is labeled with a calibration sticker.

5.6.4. Validation of Software

5.6.4.1 In-house developed inspection, test, and monitoring software is validated before it is used for product assurance or verification. Commercial software is purchased with validation certificates where available. Software is revalidated or recertified when conditions for which it was initially validated are materially changed.

6. Measurement, Analysis, and Improvement

6.1 General *(Section 8.1 [1])*

GENERAL POLICY
Measurement and monitoring activities required to assure product conformity, and to achieve improvement, are planned and defined. When applicable, statistical techniques are used for analyzing measurement data.

PROCEDURAL POLICIES
6.1.1Planning

6.1.1.1 Measurement and monitoring activities to assure and verify product conformity are defined in engineering specifications and drawings, production work orders, inspection and testing procedures, and process control procedures.

6.1.1.2 The effectiveness of the quality system is monitored by internal audits and by measuring quality performance and customer satisfaction. Results of these activities are reported to the President and are used to identify opportunities for improvement.

6.1.2. Statistical Techniques

6.1.2.1 Statistical techniques are applied to:

- Testing and validation of designs for specified programs
- Set up of process equipment for specified programs
- Testing and validation of processes for specified programs
- Control of process stability and performance for specified programs
- Establishment of sampling plans for inspections and testing for specified programs
- Evaluation of measurement systems
- Analysis of quality performance and other company-level data

6.1.2.2 Engineering and QA are responsible for identifying the need for using statistical techniques.

6.2 Monitoring and Measurement *(Section 8.2 [1])*

GENERAL POLICY

Customer satisfaction is the principal objective of the quality system, and the level of customer satisfaction is the most important measure of the effectiveness of the system. Customer satisfaction is measured by collecting and analyzing direct customer feedback and by measuring secondary indicators of customer satisfaction. Customer satisfaction data is used by the President to identify opportunities and priorities for improvement. All activities and areas relevant to the quality system are audited at least once a year. Audits are scheduled on the basis of the status and importance of the activity. Internal auditors are independent of those having direct responsibility for the audited activity. Identified nonconforming conditions are brought to the attention of the responsible managers and corrective actions are implemented in response to audit findings. Quality system processes are monitored to ensure that they achieve planned results. Relevant product characteristics are measured through inspections, tests, and other product verification activities as specified in control plans. Evidence of product conformity is recorded. Products are released for delivery only after all specified activities have been satisfactorily completed and verified.

PROCEDURAL POLICIES

6.2.1 Customer Satisfaction

6.2.1.1 General

6.2.1.1.1 VP/BM is responsible for developing suitable indicators of customer satisfaction, and for defining methods for collecting and analyzing the pertinent information.

6.2.1.1.2 Information and data pertaining to customer satisfaction are collected from several sources. Specifically, these are:

- Customer feedback and surveys,
- Awards and recognitions,
- Product returns and warranty claims,
- Repeat customer rates

6.2.1.2 Customer Feedback and Surveys

6.2.1.2.1 Customer complaints, spontaneous expressions of satisfaction, and other unsolicited customer feedback are collected and processed by the VP/BM. The resulting data is periodically analyzed by the VP/BM and presented to the President.

6.2.1.3 Awards and Recognitions

6.2.1.3.1 Osprey presents its products at conferences, competitions, and fairs, for independent evaluations and assessments. It also encourages customers to rate its performance and seeks to participate in customer's award and recognition programs. These recognitions and ratings are considered an important input for determining customer satisfaction.

6.2.1.4 Product Returns and Warranty Claims

6.2.1.4.1 Information about the rate of product returns and warranty claims is extracted from quality records. Results and trends are reported and analyzed by the VP/BM and President

6.2.1.5 Repeat Customers

6.2.1.5.1 Sales records are periodically analyzed to identify repeat customers and track their ordering frequencies and patterns. The ratio of repeat customers is one of the most important indicators of customer satisfaction. Statistics on repeat customers frequencies and trends are presented and reviewed by the President.

6.2.2. Internal Audit

6.2.2.1 Planning and Scheduling

6.2.2.1.1 The VP/BM establishes an internal audit plan and schedule. Every activity and area is audited at least once a year. Selected activities are audited more frequently, depending on their importance and quality performance history.

6.2.2.2 Audit Team and Preparation for Audit

6.2.2.2.1 Only personnel independent of the audited activities are assigned to conduct internal audits. Normally, QA leads the audit team except when QA activities are being audited. Audits of QA activities are usually conducted by Engineering.

6.2.2.2.2 Auditors prepare for audits by reviewing applicable standards and procedures, analyzing quality records, and establishing questionnaires and checklists.

6.2.2.3 Conducting the Audit

6.2.2.3.1 Conducting the audit, auditors seek objective evidence indicating whether the audited activities comply with the requirements of the documented quality system and ISO 9001:2008, and whether the quality system is effective. The evidence is collected by observing activities, interviewing personnel, and examining records.

6.2.2.3.2 Nonconforming conditions are documented and recorded using the audit nonconformity report form.

6.2.2.3.3 Audits are conducted in a way that minimizes disruption of the audited activities.

6.2.2.4 Corrective Action and Follow Up

6.2.2.4.1 When nonconforming conditions are identified, the manager responsible for the affected area or activity is requested to propose and implement a corrective action. Implementation and effectiveness of the action are verified by a follow-up audit.

6.2.2.5 Reporting

6.2.2.5.1 When the auditing cycle is completed, all nonconformity reports established during the cycle are compiled and analyzed, and are presented at the management review meeting.

6.2.3. Monitoring of Quality System Processes

6.2.3.1 Process Monitoring

6.2.3.1.1 Quality system processes are monitored by variety of approaches and techniques, as appropriate for a particular process and its importance. These include:

- Conducting internal audits of the quality system;
- Monitoring trends in corrective and preventive action requests;
- Analyzing product conformity and other quality performance data and trends;
- Measuring and monitoring customer satisfaction;

6.2.3.2 Response Actions

6.2.3.2.1 When a quality system process does not conform with requirements, Quality Assurance will request the manager responsible for the process to implement a corrective action.

6.2.4. Monitoring and Measurement of Product

6.2.4.1 Product Verification

6.2.4.1.1 Inspection and testing program for a product is defined in various types of documents, such as product drawings and specifications, production work orders, purchasing documents, inspection and testing procedures, and control plans. Documents defining the inspection and testing program for a product are collectively referred to as control plans.

6.2.4.1.2 Verification of purchased product: All purchased products are subjected to a visual inspection by receiving, and then some designated products are subjected to a more detailed and technical QA inspection.

6.2.4.1.3 In-process inspections: In-process inspections may be in the form of first article inspections, operator or QA inspections, continuous product verification by automated inspection equipment, or statistical process control (SPC). The focus is on defect prevention rather than detection.

6.2.4.1.4 Final inspection: Finished products are subjected to final QA inspection. First, inspectors verify that all specified receiving and in-process inspections have been carried out satisfactorily. Then they perform the remaining inspections and tests necessary to complete the evidence of product conformity. Only products that pass the final inspection can be shipped.

6.2.4.2 Inspection, Test and Monitoring Records

6.2.4.2.1 Results of inspections and tests are recorded.

6.2.4.3 Product Release

6.2.4.3.1 Products are released for delivery only after all specified activities have been satisfactorily completed and conformity of the product has been verified. Only personnel performing final product inspections and tests have the authority to release products. The identity of the person authorizing product release is recorded.

6.3 Control of Nonconforming Products *(Section 8.3 [1])*

GENERAL POLICY
Nonconforming product is identified, documented, evaluated, and prevented from being used or shipped. Repaired or reworked products are re-inspected. Appropriate actions are taken when product nonconformity is identified after delivery. When appropriate, corrective and preventive actions are implemented to prevent recurrence of identified nonconformities.

PROCEDURAL POLICIES
6.3.1 Identification and Documentation

6.3.1.1 Osprey identifies and documents all product nonconformities, regardless of how insignificant they seem to be or how easily they can be repaired or reworked. Product nonconformity records are invaluable for tracking performance and trends, and for identifying areas where corrective or preventive actions should be implemented.

6.3.1.2 Nonconforming products are documented using a nonconformity report. It describes the nonconformity, documents the disposition decision, and records close-out of follow-up activities (re-inspection, concessions, corrective actions, etc.).

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6.3.1.3 To prevent nonconforming products from being used or shipped, the products are marked as REJECTED and red tagged. They are then segregated from conformal parts.

6.3.2 Nonconformity Review and Disposition

6.3.2.1 Engineering makes all disposition decisions for a nonconforming parts or products.

6.3.2.2 The disposition decision may be: Rework or Repair, Accept As-Is, or Scrap.

6.3.3 Re-Verification of Repaired or Reworked Product

6.3.3.1 Repaired or reworked products are re-inspected in accordance with applicable procedures and instructions

6.3.4 Product Returns and Recalls

6.3.4.1 When product nonconformity is detected by the customer after delivery or use has started, the President or VP/BM will instruct the customer on return of product and resolution.

6.3.4.2 When product nonconformity is detected internally after delivery or use has started, customers are informed and instructed what to do with the product. In situations when the nonconformity may create a safety or other hazard, the product may be recalled. Only the President of the company is authorized to make recall decisions.

6.4 Analysis of Data *(Section 8.4 [1])*

GENERAL POLICY
Osprey collects, complies, and analyzes information and data required for evaluating the effectiveness of the quality system and identifies opportunities for improvement.

PROCEDURAL POLICIES
6.4.1 General

6.4.1.1 Data and information recorded in quality records are compiled and analyzed periodically (at least annually) to determine trends in the performance and effectiveness of the quality system and to identify opportunities for improvement.

6.4.1.2 QA is responsible for coordinating these activities, and for reporting conclusions and trends to the President.

6.4.2 Scope: Following categories of information/data are recorded, compiled, and analyzed:

6.4.2.1 Characteristics of processes and products:
- Process performance variation — recorded in process control and evaluated by Engineering.

6.4.2.2 Conformance to customer requirements:
- Scrap, rework — recorded in product yield data and nonconformity reports and reviewed for trends by QA.
- On-time delivery performance — recorded in program performance reports and evaluated for trends by QA.

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6.4.2.3 Suppliers
- Supplier quality performance — as noted in approved vendor list.

6.4.2.4 Customer Satisfaction:
- Customer satisfaction levels — recorded in customer satisfaction surveys and evaluated for trends by the President.
- Customer complaints — recorded in customer complaints and evaluated for trends by the President.

6.4.2.5 Quality System:
- Effectiveness of training — recorded in training evaluation and evaluated for trends by the VP/BM.
- Effectiveness of quality system — recorded in internal audit and evaluated for trends by President.

6.5 Improvement *(Section 8.5 [1])*

GENERAL POLICY

Osprey uses a continual improvement philosophy throughout the entire organization. The improvement effort is driven by goals defined in the quality policy and quality objectives. Improvement opportunities are identified by analyzing quality performance data and information. Improvement projects are defined and implemented through the system of corrective and preventive actions and management review actions. Causes of identified nonconformities are investigated and, where appropriate, corrective actions are implemented to ensure that nonconformities do not recur. Preventive actions are implemented to eliminate the causes of potential nonconformities. Corrective and preventive actions taken are recorded and are followed up to ensure that they have been properly implemented and that they are effective.

PROCEDURAL POLICIES

6.5.1 Continual Improvement

6.5.1.1 Opportunities for Improvement

6.5.1.1.1 Opportunities and priorities for improvement are identified by comparing present quality performance to objectives defined in the quality policy and quality objectives.

6.5.1.1.2 Quality performance is determined by analyzing information about customer satisfaction, records of product and process nonconformity, results of internal audits, and other data and information relevant to quality performance.

6.5.1.1.3 Quality performance is evaluated by management reviews of the quality system. Where quality performance falls short of a defined objective, the management review identifies specific improvement actions to reach the objective. When a quality objective is reached, the management review may set a new, higher objective in this area and specify new improvement actions for reaching it.

6.5.1.1.5 In addition to management reviews employees are encouraged to come forward with ideas for improving products, processes, systems, productivity, and working environment. These improvement opportunities are evaluated and prioritized by QA and, where appropriate, are implemented though the system of corrective and preventive actions.

6.5.1.2 Implementation of Improvement Projects

6.5.1.2.1 Improvement projects are implemented through management review actions and through corrective and preventive actions. Where appropriate, improvement projects are also initiated by management directives, such as policy statements, announcements, memoranda, and so forth.

6.5.2. Corrective Action

Osprey identifies nonconformities via its numerous methods of product verification. Corrective action is identified in nonconformance report. QA reviews and analyzes nonconformities for trends and implement corrective action with the appropriate PM for that product or project. QA also reviews other programs to verify they are also not subject to the same problem to prevent recurrence.

Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure is established to define requirements for:

- Reviewing nonconformities (including customer complaints)
- 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
- Reviewing the effectiveness of the corrective action taken

6.5.3 Preventive Action

Osprey 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 is established to define requirements for:

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

6.5.4 Processing of Corrective and Preventive Actions

6.5.4.1 Preventive and corrective actions are initiated, processed and followed up using the CAR (Corrective Action Request) system. The system documents the unsatisfactory condition and the corrective or preventive action to be taken, and is used to record the verification and closure of the action. Open CARs are reviewed regularly to ensure that the actions are implemented and followed up in a timely manner.

7.0 References

1. ISO9001:2008 (E), Quality Management Systems - Requirements

Appendix A Exclusions

Following requirements are excluded from Osprey's QA plan. All listed exclusions are approved by the President.

Table A-1. Exclusion list of QA requirements

No.	Title	Description
	None at this time.	

Appendix B

Specific responsibilities and authorities are assigned as follows:

Top Management (President and VP/BM)

- Formulates the quality policy
- Provides resources necessary to maintain and improve the quality system
- Conducts management reviews of the quality system

Program Managers

- Manages specific programs or projects
- Responsible for program cost, schedule, and technical oversight
- Responsible for all interfacing with programs customer
- Reports directly to the President
- Develops program specific QA documentation and requirements

Engineering

- Develops design and prototype quality plans
- Prepares (or reviews) design input specifications
- Designs products and product improvements
- Conducts design reviews
- Verifies and tests designs
- Documents design outputs.
- Assists in product realization and verification planning

Production

- Schedules production
- Established production work orders
- Plans production facilities, equipment, and processes
- Develops production processes
- Develops process operator and set-up instructions
- Controls and monitors processes
- Conducts in-process inspections
- Applies and maintains in-process product identification
- Maintains production equipment
- Provides training for its personnel

Purchasing and Receiving and Shipping

- Selects qualified supplies and subcontractors
- Prepares and approves purchasing documents
- Monitors and evaluates supplier performance
- Receives purchased products
- Performs first-stage receiving inspection
- Applies or verifies product identification for purchased products
- Operates the material stockroom
- Packages products (secondary packaging)
- Ships products to customers
- Operates the finished product stockroom

Appendix B (continued)

Marketing and Sales, Customer Service

- Conducts market research to anticipate customer expectations
- Determines customer satisfaction
- Establishes specifications for new products (product briefs)
- Advertises and promotes company's products
- Monitors the quality performance of competitors
- Carries out contract and order reviews
- Provides customer liaison and service
- Provides product information
- Handles customer feedback and complaints

Human Resources (VP/BM)

- Defines personnel qualification requirements
- Implements measures to motivate personnel
- Conducts company-wide training

Quality Assurance

- Establishes and maintains the quality management system
- Audits implementation and effectiveness of the quality system
- Identifies opportunities for improvement of the quality system
- Develops quality plans and control plans
- Initiates corrective and preventive actions
- Maintains and calibrates measuring and test equipment
- Carries out subcontractor quality surveys and audits
- Performs inspections and testing
- Identifies the need for the use of statistical techniques
- Handles nonconforming products
- Coordinates document control activities
- Maintains, or coordinates the maintenance of quality records
- Coordinates collection of quality performance data
- Provides required training for its personnel.

Appendix C Listing of QA Documents

Following is a listing of QA documents used at Osprey.

Table C-1. Quality Assurance Documents

Doc No.	Document Title	Purpose/Description
QA-001	Audit Nonconformity Report	
QA-002	Nonconformity Report	Used to identify products that do not meet requirements
QA-003	Annual President Review of QA System	
QA-004-X	Project QA Requirements Document	Specified for each individual project
QA-005	Approved Vendor List	
QA-006	Equipment Calibration	Provides for control and calibration of all plant metrology equipment