NEPSI
Northeast Power Systems, Inc.

# Quality Manual

This manual complies with the requirements of the ISO 9001:2015 International Standard.

Northeast Power Systems, Inc.

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# 1 Introduction

## Our Quality Management System Commitment

As the President of Northeast Power Systems, Inc. I am committed to the quality management system, taking full accountability, and supporting other roles of leadership. Management uses the process approach and risk-based thinking to ensure the management system is integrated into our business processes to achieve intended results.

I am committed to provide the resources and training needed to ensure an effective quality management system that is necessary for our success and improvement. We provide a work environment that allows our employees to be successful in meeting our customers' needs.

The Quality Policy is established to be the driving force behind our quality management system, and I will continue to ensure that it remains compatible with the context and strategic direction of our organization.

Paul Steciuk, President

Northeast Power Systems, Inc.

### Quality Policy

NEPSI
Northeast Power Systems, Inc.

Northeast Power Systems, Inc. (NEPSI) is committed to be an established and recognized world leader in providing quality products and services to our customers. In pursuit of this goal, we will continually improve our products, processes and operating systems to enable us to meet customer needs and enhance customer satisfaction, while meeting the needs of our business and maintaining a safe and responsible work environment. Each member of the NEPSI organization will apply their talent, both individually and in teams to support our quality effort. NEPSI will be in compliance with all applicable regulatory and environmental requirements.

# 2 Management System Approach

Our approach to our quality management system is based on the Plan, Do, Check, Act cycle (PDCA). The basis of our business beliefs is represented in **three** pillars:

## Customer Focus

Our customers are the reason we exist. We aim to meet or exceed their needs and expectations to make them successful. We will even try to anticipate their needs and introduce solutions they've not seen before in the spirit of true partnership. Our success depends upon our customers' success.

## Process Approach

To deliver on our commitment to total customer focus we constantly work on our internal processes to maximize their effectiveness and efficiency. We recognize that it takes countless individual activities to deliver our products and services and that the process approach ties them all together. Our business is a process that transforms several inputs (customer requirements, resources, skilled employees, etc.) into an output that meets our customer's needs. Within our business are several key processes that make it all work. Our processes are dependent upon one another and individually need continual attention and improvement. We are constantly challenging ourselves to refine and change how we do things to reduce the time it takes to get something done with the least errors. When errors do occur, we use them as opportunities to learn and improve. We are never satisfied with how things are working now and strive to improve our organization every single day.


## Risk-based Thinking

Looking ahead to anticipate what could happen is the reason we employ risk-based thinking throughout our organization. At several points in our process we purposely stop and ask two probing questions:

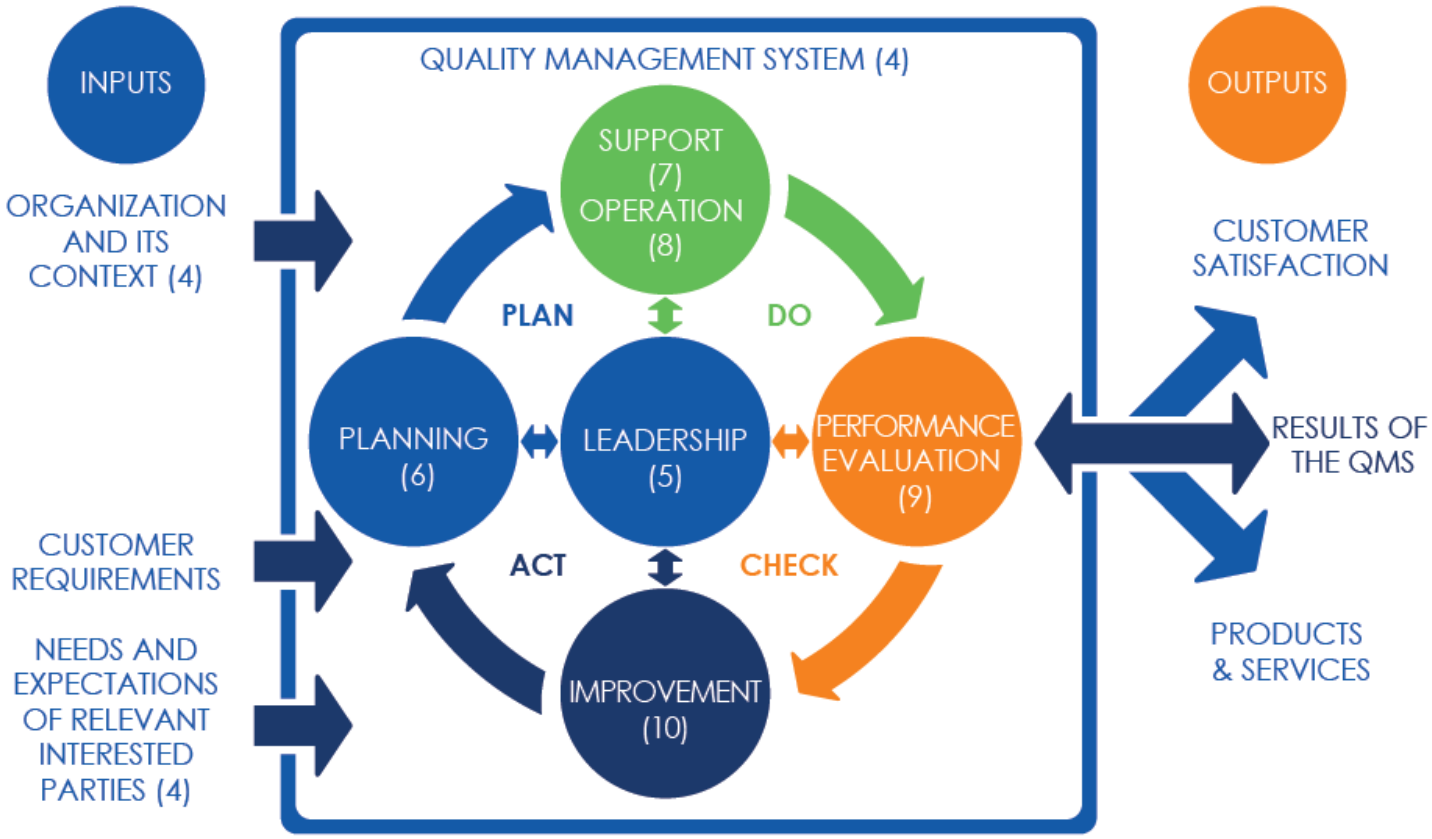
- "What could go wrong?"
- "Is there a way to improve?"

This perspective of constantly watching for risks and opportunities leads us to action which we carefully manage to ensure timely implementation and effective results. This gives us an attitude of being proactive to take advantage of every opportunity to improve.

We intend these three basic beliefs to cause our customers to stand up and take notice the difference we provide to them on a daily basis. Our quality management system described in this Quality Manual has been carefully crafted to make these three pillars a real part of what makes us work.

# 3 Quality Manual Structure

This Quality Manual is presented in a PDCA manner and describes our approach to the requirements of ISO 9001:2015. The manual is divided into four sections with all applicable sub-clauses represented in each section as below:




**NOTE**: In the sections that follow, **Bold Blue Text** refers to related documentation where additional documentation is maintained and/or records are retained.

# SECTION 1: PLAN

With an ever-changing world we are faced with new challenges on a continuing basis. The issues, changes, and trends within our industry and the broader economy present us with risks and opportunities from cultural, technological, competitive, regulatory, market, economic, and social factors. Not only can these factors affect our business, but there are also other interested parties and organizations that we deal with on a day-to-day basis and these present additional requirements that we must account for.

All of these factors may affect our business negatively (risks) or positively (opportunities). The risks may be relevant to us, and have the potential to affect our business or our customers in a negative way. These aspects of our business environment may also create opportunities for us to improve our organization or take advantage of expanded current or new business ventures.

Planning other aspects of our organization is also very important. Our planning process also includes people, their knowledge and training, infrastructure, environment, documented information, and communication. All planning efforts are structured, include decision-makers, and are documented when required.

Our extensive planning process puts us in the best position possible to forecast these challenges and take actions when necessary. It also establishes the needed foundations for us to provide our products and services.

# 4 Context of the Organization

## 4.1 Understanding the organization and its context

***Requirement***: *Determine the external and internal issues that are relevant to the purpose and strategic direction and that affect the ability to achieve the intended result(s) of the quality management system.*

**Our Approach:** Issues (4.1) stemming from trends and changes in our industry may affect our business purpose and strategic direction. Those that present risks and/or opportunities are initially addressed by top management, then monitored and reviewed on an annual basis by our **QMS Plan** review which occurs during Management Review.

## 4.2 Understanding the needs and expectations of interested parties

***Requirement:*** *Determine the interested parties, and their requirements that are relevant to the quality management system.*

**Our Approach:** Requirements from interested parties (4.2) that impact our ability to meet customer and applicable statutory and regulatory requirements may present risks and/or opportunities. These are reviewed to determine relevance and necessary actions. Subsequently, they are also monitored and reviewed on a quarterly basis by our **QMS Plan** review.

## 4.3 Determining the scope of the quality management system

***Requirement:*** *Determine the boundaries and applicability of the quality management system to establish the scope, considering:*

- *external and internal issues;*
- *requirements of relevant interested parties;*
- *products and services.*

*The scope is available and maintained as documented information stating the:*

- *products and services covered by the quality management system;*
- *justification for any instance where a requirement of ISO 9001 cannot be applied.*

**Our Approach:** The contextual issues and interested party requirements are considered to determine the scope (4.3) of our quality management system.

In light of these external and internal issues and requirements, we have established the scope of our quality management system as:

**Scope**

*This quality management system pertains to processes relating to: the design, manufacture, and service of capacitor banks (thyristor and conventionally switched), harmonic filter banks, and surge protections for power factor correction, harmonic mitigation, and voltage support / protection. There are no exclusions taken to the ISO 9001: 2015 standard.*

## 4.4 Quality management system and its processes

***Requirement:*** *Establish, implement, maintain and continually improve the quality management system, including the processes needed and their interactions*.

*For the processes needed, determine:*

- the inputs required and the outputs expected;
- their sequence and interaction;
- the criteria, methods, including monitoring, measurements and related performance indicators needed to ensure their effective operation, and control;
- the resources needed and their availability;
- the assignment of the responsibilities and authorities;
- the risks and opportunities, and plan and implement the appropriate actions to address them;
- the evaluation and, if needed, the changes to processes to ensure that they achieve intended results;
- and improvement.

**Our Approach:** The processes (4.4) needed to achieve intended outcomes, results, and to continually improve our quality management system are identified on the **QMS Plan**, are maintained on **Process Plans**, and reviewed during Management Review.

# 5 Leadership

## 5.1 Leadership and commitment

***Requirement:*** *Demonstrate leadership and commitment with respect to the quality management system by:*

- *taking accountability of its effectiveness;*
- *establishing a quality policy and objectives that are compatible with the context and strategic direction;*
- *integrating the QMS requirements into business processes;*
- *promoting the use of the process approach and risk-based thinking;*
- *ensuring that the resources needed are available;*
- *communicating its importance and of conforming to its requirements;*
- *achieving intended results;*
- *engaging, directing and supporting people to contribute to the QMS;*
- *promoting improvement;*
- *supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.*

**Our Approach:** Our top management holds the ultimate responsibility for the quality management system. Our top management is dedicated and committed (5.1) to ensuring that our quality management system is effective, understood and improved.

Top management includes the following members:

- President, co-founder
- Sales and marketing manager, co-founder
- Engineering and design manager, co-founder
- Project manager, Management Representative
- Shop Foreman

## 5.1.2 Customer focus

***Requirement:*** *Demonstrate leadership and commitment with respect to customer focus by ensuring that:*

- *applicable requirements are determined, understood and consistently met;*

- *risks and opportunities that can affect conformity of products; services and enhancement of customer satisfaction are determined and addressed;*
- *focus on enhancing customer satisfaction is maintained.*

**Our Approach:** Top management demonstrates leadership and commitment to ensure that all applicable requirements are met, risks and opportunities are addressed, and the focus on customer satisfaction is maintained (5.1.2) through our **QMS Plan**, **Process Plans** and **Quality Policy**.

## 5.2 Policy

***Requirement:*** *Establish, implement and maintain a quality policy that:*

- *is appropriate to the purpose and context and supports the strategic direction;*
- *provides a framework for setting quality objectives;*
- *includes a commitment to satisfy applicable requirements;*
- *includes a commitment to continual improvement of the QMS.*
- *is available and maintained;*
- *is communicated, understood and applied;*
- *is available to relevant interested parties.*

**Our Approach:** The top-level requirement that directs our entire quality management system is our **Quality Policy.** The quality policy (5.2) is maintained, available, communicated, and reviewed at least annually during Management Review. It is made available to interested parties through our website or upon request.

## 5.3 Organizational roles, responsibilities and authorities

***Requirement:*** *Ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood.*

*Assign quality management system responsibilities and authority for:*

- *ensuring that it conforms to the requirements of ISO 9001:2015;*
- *ensuring that processes are delivering their intended outputs;*
- *reporting on its performance, and opportunities for improvement, to top management;*
- *ensuring the promotion of customer focus;*
- *ensuring that its integrity is maintained when changes are planned and implemented.*

**Our Approach:** Responsibilities and authorities (5.3) for our process owners are assigned, communicated and understood on our **Process Plans.** The **Project Manager** has been appointed as the **Management Representative** of our QMS.

# 6 Planning

## 6.1 Actions to address risks and opportunities

***Requirement:*** *When planning for the QMS, consider the issues (4.1) and the requirements (4.2) and determine the risks and opportunities that need to be addressed to:*

- *assure that the QMS can achieve its intended result(s);*
- *enhance desirable effects;*
- *prevent, or reduce, undesired effects;*
- *achieve improvement.*

*Plan:*

- *actions to address these risks and opportunities;*
- *how to:*
  - *integrate and implement the actions into our processes;*
  - *evaluate their effectiveness.*

**Our Approach:** We address the risks and opportunities (6.1) identified in the **QMS Plan** and **Process Plans**, as well as other situations through the use of the **Action Item Form**.

The actions will be integrated into our quality management system process and will be evaluated for effectiveness during reviews.

## 6.2 Quality objectives and planning to achieve them

***Requirement:*** *Establish objectives at relevant functions, levels and processes that:*

- *are consistent with the quality policy,*
- *are measurable;*
- *take into account applicable requirements;*
- *are relevant to conformity of products and services and the enhancement of customer satisfaction;*
- *are monitored;*
- *are communicated;*
- *are updated as appropriate.*

*Retain documented information on the quality objectives.*

**Our Approach:** We establish objectives (6.2) at relevant functions, levels, and processes, and have plans to achieve them on our **Measurement Plans**. The results of these objectives and plans are reviewed annually and retained on the **Management Review Minutes**.

### 6.3 Planning of changes

***Requirement:*** *Where needed, carry out changes in a planned manner considering:*

- *the purpose of the change and any of its potential consequences;*
- *the integrity of the quality management system;*
- *the availability of resources;*
- *the allocation or reallocation of responsibilities and authorities.*

**Our Approach:** Changes (6.3) that are needed are planned and carried out carefully considering the consequences, the integrity of our QMS, resources and associated responsibilities. The changes are managed and are recorded in the **Management Review Minutes** if the change affects our organization as a whole, or in **Project Binders** if changes are to be made on an individual project, as appropriate for the change.

## 7 Support

### 7.1.1 General

***Requirement:*** *Determine and provide resources needed for maintenance and continual improvement of the QMS considering:*

- *capabilities, constraints and existing resources;*
- *needs from external providers.*

**Our Approach:** During our Management Reviews, our top management discusses all internal and externally provided resources needed (7.1.1) for maintenance and continual improvement of our quality management system, and ensures that they are provided.

## 7.1.2 People

***Requirement:*** *Determine and provide the people necessary to effectively implement the QMS and for the operation and control of processes.*

**Our Approach:** During our Management Reviews, our top management determines the persons necessary (7.1.2) for the effective implementation of our QMS and for the operation and control of our processes, and ensures that the resources are provided.

## 7.1.3 Infrastructure

***Requirement:*** *Provide and maintain the infrastructure for the operation of processes and conformity of products and services.*

**Our Approach:** To ensure that our infrastructure resources remain adequate, they are reviewed and discussed during Management Reviews. All heavy machine operators are provided with the applicable manufacturer preventative maintenance schedule and trained on their importance within our QMS, as outlined in our **Communication and Awareness Plan**. This includes discussing the risks associated with equipment downtime and how they affect customer satisfaction down the line.

## 7.1.4 Environment for the operation of processes

***Requirement:*** *Provide and maintain the environment necessary for the operation of processes and to achieve conformity of products and services.*

**Our Approach:** Our top management ensures that our work environment (7.1.4) is sufficient to achieve conformity of our products and services as discussed during Management Reviews.

## 7.1.5.1 Monitoring and measuring resources

***Requirement:*** *Provide the resources needed to ensure results when monitoring and measuring is used to verify conformity of products and services.*

**Our Approach:** We have determined, and provide the resources needed to monitor and measure (7.1.5.1) our products and services to ensure that they continue to meet requirements and specifications. These resources typically include: personnel resumes and training certificates, spreadsheets and formulas, and measuring tools such as scales, paint thickness gauges, and calipers.

We ensure these resources are:

- suitable for the specific type of monitoring and measurement activities;
- maintained to ensure fitness for purpose.

This is documented in the **Calibration Plan** and **Calibration Forms**.

### 7.1.5.2 Measurement Traceability

***Requirement:*** *If required or considered essential to provide confidence in the validity of the measurement results, the measurements are traceable.*

**Our Approach:** Measurement traceability is essential to providing confidence in the validity of the measurement results. Details of this process are maintained within the **Calibration Plan** and **Calibration Form,** and a list of monitoring and measurement equipment is maintained on the **Calibration Log.**

### 7.1.6 Organizational Knowledge

***Requirement:*** *Determine the knowledge necessary for the operation of processes and to achieve conformity of products and services. Maintain this knowledge and, make it available to the extent necessary.*

*When addressing changing needs and trends, consider current knowledge and determine how to acquire or access the necessary additional knowledge and required updates.*

**Our Approach:** All current knowledge (7.1.6) sources, requirements, changes, needs and trends are determined by top management, maintained and discussed during Management Reviews. Transfer of current knowledge occurs within our organization through the use of one-on-one training, internally generated training documentation, software onboarding videos and documents, and job shadowing. We constantly strive to acquire new applicable knowledge which enhances our ability to meet customer requirements and improve our quality management system. Acquisition of this organizational knowledge occurs when employees attend live training seminars, enroll in web-based courses, pursue certifications, or enroll in accredited universities.

## 7.2 Competence

***Requirement:*** *Determine the necessary competence of people doing work under organizational control that affects the performance and effectiveness of the QMS and:*

- *ensure they are competent on the basis of education, training, or experience;*
- *where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;*
- *retain appropriate documented information as evidence of competence.*

**Our Approach:** We determine the required competencies (7.2) for our employees, whose work may impact the effectiveness and performance of our QMS. We hire employees with specific knowledge, skills and education that best fit our needs and provide training to fulfill any missing competencies. Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position change. Human Resources maintain 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 all employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives. Employees will be trained to perform the duties required of the job position they are currently holding. The level of training required is commensurate with the education, experience, certification, and skill level required of the job. Employees may receive specific, documented training for particular jobs. This training may consist both of practical and procedural training. It can be accomplished through demonstration and practice where method, quality, and safety are monitored by the foreman in the work area. All employees hired will receive induction training. This program will cover safety, quality, and plant rules. This training will be documented. Where required, tests, certification, or college degrees may be required to demonstrate proficiency, in accordance with various job descriptions. Records of these shall be maintained in the employee personnel file.

Evidence of this process is retained in **employee personnel files** and maintained by the **Human resources and compliance manager**

As of the initial release of this document, all current employees are considered to be competent.

## 7.3 Awareness

***Requirement:*** *Make people doing work under organizational control aware of:*

- *the quality policy;*
- *relevant quality objectives;*
- *their contribution to the QMS and the benefits of an improved system;*
- *the implications of not conforming to the QMS requirements.*

**Our Approach:** People doing work under our control are made aware (7.3) of our quality policy, objectives, how our quality management system works and the implications of not working within our quality management system as defined on the **Communication and Awareness Plan**, and is reviewed during Management Review.

## 7.4 Communication

***Requirement:*** *Determine all elements of internal and external communications relevant to the quality management system.*

**Our Approach:** Communication (7.4) is very important to our operation's success. Our communication methods are maintained on the **Communication and Awareness Plan**, which is reviewed periodically during Management Review.

## 7.5 Documented Information

***Requirement:*** *Determine the documented information necessary for an effective QMS, and apply controls to ensure it is:*

- *available and suitable, where and when it's needed;*
- *protected from loss of confidentiality, integrity and improper use;*
- *properly identified;*
- *used in the proper format and media;*
- *reviewed for suitability and adequacy.*

*Control the documented information, including necessary external documents, with regards to (as applicable):*

- *distribution, access, retrieval and use;*
- *storage and preservation, including preservation of legibility;*
- *control of changes (e.g. version control);*
- *retention and disposition.*

*Protect all retained documentation used as evidence of conformity from unintended alterations.*

**Our Approach:** We have determined which internal and external documented information (7.5) is necessary for the effectiveness of our quality management system. This documented information is created, approved, and controlled according to applicable requirements primarily through the use of our **CORE ISO Compliance Platform®.**

CORE® ISO COMPLIANCE PLATFORM

# SECTION 2: DO

Providing our customers with products and services that meet their requirements and expectations is why we are in business. This takes planning, reviewing, as well as execution of these processes to ensure that all requirements are identified and met.

In this section of the handbook, we will be describing our methods for conforming to the operational planning, requirements determination and review, design and development, purchasing, product and service provision, post-delivery activities, and what we do when something doesn't go quite as we expected.

# 8 Operation

## 8.1 Operational Planning and Control

***Requirement:*** *Plan, implement and control the processes needed to meet requirements for products and services and to implement the actions determined in 6.1, by:*

- *determining requirements for the product and services;*
- *establishing criteria for the processes and for the acceptance of products and services;*
- *determining the resources needed to achieve conformity to product and service requirements;*
- *implementing control of the processes in accordance with the criteria;*
- *maintaining and retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate conformity of products and services to requirements.*

*The output of this planning is suitable for the organization's operations.*

**Our Approach:** The processes, including outsourced processes that affect our products and services are controlled (8.1). The details and evidence of our processes are maintained within the **QMS Plan** and **Process Plans**. All planned changes are controlled, un-planned changes are reviewed and actions to mitigate are taken for any adverse effects.

## 8.2.1 Customer communication

***Requirement:*** *Communication with customers includes:*

- *information relating to products and services;*
- *inquiries, contracts or order handling, including changes;*

- *obtaining customer feedback relating to products and services, including customer complaints;*
- *the handling or controlling of customer property, if applicable;*
- *specific requirements for contingency actions, when relevant.*

**Our Approach:** Open, and efficient communication with our customers (8.2.1) is very important for communicating information relevant to products and services, contract information, customer complaints, changes, property, requirements and contingency actions. Our methods and controls for ensuring accurate and reliable communications with our customers are laid out in our **Process Plans.**

## 8.2.2 Determining the requirements for products and services

***Requirement:*** *When determining the requirements for the products and services to be offered to customers, ensure that:*

- *the requirements for the products and services are defined, including; applicable statutory and regulatory requirements, and those considered necessary;*
- *the organization has the ability to meet the claims for the products and services offered.*

**Our Approach:** Northeast Power Systems, Inc. (NEPSI) determines customer requirements before acceptance of an order per our **Process Plans** and in conjunction with our **QSP – Customer Related Processes**. 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 related to the product, if applicable.
- Additional requirements determined by Northeast Power Systems, Inc. based on the particular application.

## 8.2.3 Review of the requirements for products and services

***Requirement:*** *Ensure that the ability to meet the requirements for products and services to be offered to customers is present. Conduct a review before committing to supply products and services to a customer, to include:*

- *customer requirements, including requirements for delivery and post-delivery activities;*
- *requirements not stated by the customer, but necessary for the customers' specified or intended use, when known;*
- *requirements specified by us;*
- *statutory and regulatory requirements applicable to the products and services;*
- *contract or order requirements differing from those previously expressed.*

*Ensure that contract or order requirements differing from those previously defined are resolved.*

**Our Approach:** After the requirements are determined, Northeast Power Systems, Inc. has a process in place for the review of requirements related to the product. The review is conducted before an order is accepted. The process ensures that:

- Product requirements are defined to the extent required for customer approval of the design.
- Contract or order requirements differing from those previously expressed are resolved.
- Northeast Power Systems, Inc. has the ability to meet the defined requirements.
- Records are maintained showing the results of the review and any actions arising from the review. Each individual project is assigned its own project binder, which includes all information (including the customer's RFQ and NEPSI's quote) applicable to that specific project.
- Where a customer does not provide a documented statement of requirements, the customer requirements are confirmed before acceptance.
- When product requirements are changed, Northeast Power Systems, Inc. communicates changes to relevant personnel and amends relevant documents, such as submittal drawings.

## 8.2.4 Changes to requirements for products and services

***Requirement:*** *Ensure relevant documented information is amended and that relevant persons are aware of changes.*

**Our Approach**: When the requirements for products and services are changed (8.2.4), the **Sales and Marketing Manager** ensures that relevant documented information is amended and that relevant personnel are made aware of the changed requirements. This documented information is usually in the form of a request for information (RFI) from either NEPSI or the customer, a contractually agreed upon change order to the existing purchase order, and the equipment drawings.

## 8.3 Design and development

***Requirement:*** *Establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of our products and services.*

**Our Approach:** We maintain a design and development process that is appropriate to the products and services that we offer.

Our design and development process is performed in controlled stages for:

- inputs,
- controls,
- outputs, and
- changes

## 8.3.2 Design and development planning

***Requirement:*** *Determine the stages and controls for design and development, considering:*

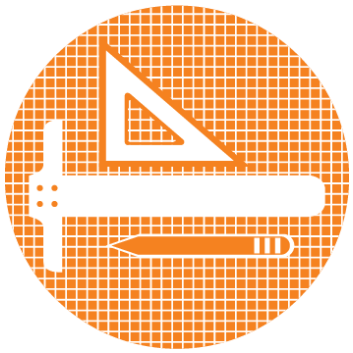
- *the nature, duration and complexity of the activities;*
- *the required process stages, including applicable reviews;*
- *the required verification and validation activities;*
- *the responsibilities and authorities involved;*
- *the internal and external resource needs;*
- *the need to control interfaces between individuals and parties involved;*
- *the need for involvement of customer and user;*
- *the requirements for subsequent provision of products and services;*
- *the level of control expected for the processes by customers and other relevant interested parties;*
- *the necessary documented information to confirm that design and development requirements have been met.*

**Our Approach:** We have determined the stages and controls for our design and development process (8.3.2). The **Design Plan and Schedule** controls all stages of the design and development process. The documented information is retained in the **Design Plan and Schedule.**

## 8.3.3 Design and development Inputs

***Requirement:*** *Determine the requirements essential for the specific types of products and services being designed and developed, considering:*

- *functional and performance requirements;*
- *information derived from previous similar activities;*
- *applicable statutory and regulatory requirements;*
- *standards or codes of practice that we have committed to implement;*
- *the potential consequences of failure due to the nature of the products and services;*



*Inputs are adequate for design and development purposes, complete, and unambiguous. Conflicts among inputs are resolved.*

*Documented information on design and development inputs is retained.*

**Our Approach:** We determine our requirements taking into consideration all input elements. Our design and development inputs (8.3.3) are included within the **Design Plan and Schedule**.

## 8.3.4 Design and development controls

***Requirement:*** *Apply design and development controls that ensure:*

- *the results to be achieved are defined;*
- *reviews are conducted to evaluate the ability of the results of design and development to meet requirements;*
- *verification activities are conducted to ensure that the outputs meet the input requirements;*
- *validation activities are conducted to ensure the products and services meet the requirements for the application or intended use;*
- *any actions are taken on problems determined during the reviews, or verification and validation activities;*
- *documented information of these activities is retained.*

**Our Approach:** We apply controls (8.3.4) to our design and development process to ensure that we:

- achieve defined results;
- review and evaluate our D/D requirements;
- ensure that outputs meet input requirements;
- meet requirements for application or intended use;
- resolve problems that may arise during design and development
- retain documented information.

Our design and development controls include the **Design Plan and Schedule**.

### 8.3.5 Design and development outputs

***Requirement:*** *Ensure that design and development outputs:*

- *meet input requirements;*
- *are adequate for the processes for the provision of products and services;*
- *include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;*
- *specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.*

*Retain documented information resulting from the design and development outputs.*

**Our Approach:** Our design and development outputs (8.3.5) are adequate, and include essential information needed to ensure that all input requirements are met. The design and development outputs are retained on the **Design Plan and Schedule**.

### 8.3.6 Design and development changes

***Requirement:*** *Review, control and identify changes made during, or subsequent to the design and development of the products and services, to ensure that there is no adverse impact on conformity to requirements.*

*Retain documented information on:*

- *design and development changes;*
- *the results of reviews;*
- *the authorization of the changes;*
- *the actions taken to prevent adverse impacts.*

**Our Approach:** Any changes (8.3.6) that are made during the design and development stages of the products and services are controlled and identified. We retain documented information of the changes, reviews, authorizations and adverse impact actions through **Design Plan and Schedule**.

### 8.4 Control of externally provided processes, products and services (Purchasing)

***Requirement:*** *Ensure that externally provided processes, products, and services conform to requirements.*

*Apply controls to externally provided processes, products and services when:*

- *products and services are provided for incorporation into the organization's products and services;*
- *products and services are provided directly to the customer(s) on behalf of the organization;*
- *a process, or part of a process, is provided as a result of our decision.*

*Establish and apply criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers based on their ability to provide processes or products and services in accordance with specified requirements.*

*Retain documented information of the results of the evaluations, monitoring of the performance and re-evaluations.*

**Our Approach**: We ensure that all of our suppliers of processes, products and services (8.4) conform to all applicable requirements. We apply sufficient controls, as laid out in the **Process Plans**, to any provider of products or services that:

- are directly incorporated into our products or services;
- are provided directly to the customer on our behalf; or
- provide a process, or part of a process requested by us.

Our criteria for selection, evaluation, performance and re-evaluation practices, is described in the table below:

| Criteria | Selection | Evaluation/Re-evaluation |
|---|---|---|
| Customer specified supplier | X | |
| Sole Provider | X | |
| Project completion | | X |
| Technical specifications | X | X |
| Compliance with industry and regulatory standards | X | X |
| Price and availability | X | X |
| Product quality | X | X |
| On time delivery | | X |
| Any adverse effect on our QMS | X | X |

The **Project manager** is responsible for controlling the purchasing process and for maintaining appropriate records. Approved suppliers are listed in our **Approved Supplier List**. External providers are evaluated during our Management Reviews.

As of the initial release of this document, all current suppliers in good standing are considered to be approved.

## 8.4.2 Type and extent of control

***Requirement:*** *Ensure that externally provided processes, products and services do not adversely affect the ability to consistently deliver conforming products and services to customers by:*

- *ensuring that externally provided processes remain within the control of the QMS;*
- *defining both the controls that is intend to be applied to an external provider and those intend to be applied to the resulting output;*
- *taking into consideration the potential impact of the externally provided processes, products and services on the ability to consistently meet customer and applicable statutory and regulatory requirements; and the effectiveness of the controls by the external provider;*
- *determining the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.*

**Our Approach:** The controls (8.4.2) that we apply to our external providers are decided on an individual basis. We ensure all suppliers remain in control in our quality management system and apply other controls as necessary by product, service or situation.

## 8.4.3 Information for external providers

***Requirement:*** *Ensure adequate requirements prior to communicating to the external provider, and communicate the requirements for:*

- *the processes, products and services to be provided;*
- *approval or release of products and services, methods, processes or equipment;*
- *competence of personnel, including necessary qualification;*
- *their interactions with the QMS;*
- *the control and monitoring of the external provider's performance to be applied;*
- *verification or validation activities that the organization, or customers, intend to perform at the external provider's premises.*

*Ensure the adequacy of specified requirements prior to communicating to the external provider.*

**Our Approach:** Prior to communicating with suppliers, we ensure that all applicable requirements are clearly identified. These may include requirements relating to products, services, supplier processes, certifications or personnel, and any verification or validation that the supplier provides at their premises. Primary suppliers must be approved by way of our "key supplier quality system assessment form". Purchasing information such as purchase orders, banking information, terms, etc. are communicated through email delivery.

The purchasing information (8.4.3) is communicated to suppliers via purchase orders and/or contracts.

## 8.5.1 Control of production and service provision

***Requirement:*** *Implement controlled conditions, including, as applicable:*

- *the availability of documented information that defines the characteristics of the products and services, and the results to be achieved;*
- *monitoring and measurement activities at appropriate stages to verify that criteria for control of processes and process outputs, and acceptance criteria for products and services, have been met.*
- *the use, and control of suitable infrastructure and process environment;*
- *the availability and use of suitable monitoring and measuring resources;*
- *the competence and, where applicable, required qualification of people;*
- *the validation, and periodic revalidation, of the ability to achieve planned results of any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement;*
- *the implementation of actions to prevent human error;*
- *the implementation of products and services release, delivery and post-delivery activities.*

**Our Approach:** We control all phases of our product or service realization (8.5.1). These controls may include; documented characteristics, monitoring and measurement, validations or reviews of products and/or processes, and release and post-delivery activities.

The Management Team is responsible for controlling all phases of product and service provision and for maintaining appropriate records.

## 8.5.2 Identification and traceability

***Requirement:*** *Use suitable means to identify outputs when it is necessary to ensure the conformity of products and services. Identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. Control the unique identification of the outputs when traceability is a requirement, and retain the documented information necessary to enable traceability.*

**Our Approach:** Where traceability (8.5.2) is a requirement, we use methods suitable to identify outputs to ensure conformity of our products or services. The method(s) used for traceability is determined by the **Project manager** and is accomplished as follows. When NEPSI receives a new purchase order, that order is entered in to our project management software and assigned a sales order number. This sales order number represents the entirety of the project and is used to track the outputs of that project. The sales order number is associated with numerous traceability processes including: creating the individual project binder, invoicing and accounting, product labeling, inspection and testing, and shipping.

## 8.5.3 Property belonging to customers or external providers

***Requirement:*** *Exercise care with property belonging to the customer or external providers while it is under organizational control or being used. Also, identify, verify, protect and safeguard the customer's or external provider's property provided for use or incorporation into our products and services.*

*Property of the customer or external provider which is lost, damaged or found to be unsuitable, is reported to the customer or external provider and retain documented information of what occurred.*

**Our Approach:** There may be times that we use property belonging to customers or external providers (8.5.3). When this occurs, we identify, verify and protect the provider's property.

The **President** is responsible for controlling and recording customer property.

In the rare occurrence of customer or provider's property becoming lost, damaged or unusable, the **President** will contact the provider. The record of communication is retained in the specific project binder.

## 8.5.4 Preservation

***Requirement:*** *Ensure preservation of process outputs during production and service provision, to the extent necessary to maintain conformity to requirements.*

**Our Approach:** We use methods necessary to ensure that our products maintain integrity, conformance, and identity throughout the order fulfillment processes. All orders are subject to electronic file-backup for applicable records preservation. Additional physical preservation requirements, such as packaging and transportation, are reviewed and agreed upon on a per-project basis. Controls include but are not limited to: crating finished equipment, shrink-wrapping finished equipment, and storage in climate-controlled environment.

## 8.5.5 Post-delivery activities

***Requirement:*** *Meet requirements for post-delivery activities associated with products and services, considering:*

- *customer requirements;*
- *the nature, use and intended lifetime of the products and services;*
- *customer feedback;*
- *statutory and regulatory requirements;*
- *the potential, undesired consequences associated with its products and services.*

**Our Approach:** NEPSI consistently performs post-delivery support such as: startup and commissioning of equipment, preventative maintenance, troubleshooting, site service, repairs, and warranty assessments. The requirements for these activities are developed and reviewed on a per-project basis and consider customer expectations, product usage, and customer feedback and potential risks. Details of the controls employed can be found on the corresponding **Process Plans.**

## 8.5.6 Control of changes

***Requirement:*** *Review and control changes for production or service to the extent necessary to ensure conformity with specified requirements.*

*Retain documented information describing the results of the review of changes, the personnel authorizing the change, and any necessary actions arising from the review.*

**Our Approach:** If the change occurs prior to fabrication, that change is usually documented on the schematic drawing and transmitted to the customer (usually through email) for approval. Oftentimes, required changes are submitted through requests for information (RFI) NEPSI never begins fabrication of equipment until schematic drawings are approved by the customer. If the change occurs during order fulfillment – for instance making a correction to something that failed inspection criteria – this change would be noted on the **Final Inspection and Test Form** in the section labeled "in-process corrections' and recorded on the mark-up drawings if applicable.

## 8.6 Release of products and services

***Requirement:*** *Implement planned arrangements at appropriate stages to verify that product/service requirements have been met.*

*Release of products/services to the customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. Retain documented information on the release of products/services includes:*

- *evidence of conformity with acceptance criteria*
- *traceability to the person(s) authorizing the release.*

**Our Approach:** Prior to release, equipment must be verified via our **Final Inspection and Test Form**. This form is completed or delegated by the **Shop Foreman**. Once the final inspection form is completed, it moves to the **Project Manager** – who then double checks that all inspection criteria were met. If yes, the project manager gives a final sign-off for release and arranges for shipment of the equipment. Records of this final release are maintained in the applicable **Project Binder**.

## 8.7 Control of nonconforming process outputs, products and services

***Requirement:*** *Ensure process outputs that do not conform to requirements are identified and controlled to prevent unintended use or delivery.*

*Take action based on the nature of the nonconformity and its effect on the conformity of products/services. This applies also to nonconforming products/services detected after delivery of the products or during or after the provision of the service.*

*As applicable, deal with nonconforming outputs in one or more of the following ways:*


- *correction;*
- *segregation, containment, return or suspension of products and services;*
- *informing the customer;*
- *obtaining authorization for acceptance under concession.*

*Where nonconforming outputs are corrected, conformity to the requirements is verified.*

*Retain documented information that:*

- *describes the nonconformity;*
- *describes the actions taken;*
- *describes any concessions obtained;*
- *identifies the authority deciding the action in respect of the nonconformity.*

**Our Approach:** Throughout the order fulfillment processes, we use numerous controls to verify in-process product(s). These controls include checking the product itself, using inspection forms to monitor enclosure and paint conformance, and performing incoming inspections on all received products from vendors. Any process output that does not conform (8.7) to requirements is properly identified and controlled to prevent unintended use or delivery.

We take appropriate action to deal with any nonconformities found. Resolutions are described on the **Nonconformance Form**, **Customer Complaint Form**, and/or **Corrective Action Form**.

# SECTION 3: CHECK

We make great efforts to be data-driven decision makers. This can only be accomplished by ensuring that we maintain accurate data and that the data is properly interpreted.

We take the time to analyze data from various areas that supplies us with data on:

- customer satisfaction;
- process effectiveness;
- product/service conformity;
- effectiveness of our QMS;
- external providers;
- our planning efforts;
- external providers; and
- the associated risks and opportunities.

Our thorough "checking" process allows us to have confidence in our quality management system and identify improvement areas.

# 9 Performance Evaluation

## 9.1 Monitoring, measurement, analysis and evaluation

***Requirement:*** *Determine:*

- *what needs to be monitored and measured;*
- *the methods for monitoring, measurement, analysis and evaluation to ensure valid results;*
- *when the monitoring and measuring will be performed;*
- *when the results from monitoring and measurement will be analyzed and evaluated. Evaluate the performance and effectiveness of the quality management system through the Management Review process, and retain documented information as evidence of the results.*

**Our Approach:** Our method of monitoring, measurement, analysis and evaluation is maintained within our **Measurement Plans**. The review of this plan is retained in our **Management Review** minutes.

### 9.1.2 Customer satisfaction

***Requirement:*** *Monitor customer perceptions of the degree to which their needs and expectations have been fulfilled.*

**Our Approach:** Customer survey forms are periodically emailed to customer project managers involved in the order. When returned, the scores are recorded into an excel spreadsheet and kept on file electronically. Hard copies of the completed forms are kept on record in a binder specific to customer satisfaction.

We also include a QR code on all of our shipped products. When scanned in the field, this code redirects the user to a website where they can share feedback and leave any comments about their experience with the equipment. When submitted, these forms are automatically processed through our website and into our electronic records. The customer satisfaction data is discussed during Management Reviews.

### 9.1.3 Analysis and evaluation

***Requirement:*** *Analyze and evaluate appropriate data and information arising from monitoring, measurement and other sources to evaluate:*

- *conformity of products and services;*
- *the degree of customer satisfaction;*
- *the performance and effectiveness of the QMS;*
- *planning implementation;*
- *the effectiveness of actions taken to address risks and opportunities;*
- *the performance of external provider(s);*
- *need or opportunities for improvements to the QMS.*

**Our Approach:** Our sources and evaluations (9.1.3) are described within our **Measurement Plans** and also retained within our **Management Review meeting minutes**.

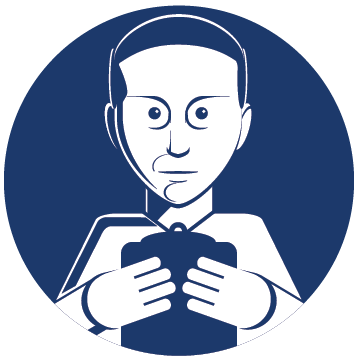
## 9.2 Internal audit

***Requirement:*** *Conduct internal audits at planned intervals to provide information on whether the QMS conforms to requirements, is implemented and maintained.*

*The organization shall:*

- *plan, establish, implement and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which takes into consideration, the importance of the processes concerned, changes affecting on the organization, and the results of previous audits;*
- *define the audit criteria and scope for each audit;*
- *select auditors and conduct audits to ensure objectivity and impartiality of the audit process;*
- *ensure that the results of the audits are reported to relevant management;*
- *take appropriate correction and corrective actions without undue delay;*
- *retain documented information as evidence of the implementation of the audit program and audit results.*

**Our Approach:** Our internal audit program is implemented and maintained and is used to ensure that our QMS is maintained and effective. Our internal audits are planned according to importance on our **Internal Audit Plan and Schedule**. Our auditors are objective and impartial and report the results to management. Auditors are qualified based on completion of an auditor training course or previous experience. Records of this training are maintained by the **Management Representative.** Corrective Actions resulting from internal audits are taken without undue delay.



The **Management Representative** is responsible to oversee the internal auditing system and for retaining appropriate documented information. Internal audit results and status are discussed during Management Review.

## 9.3 Management review

***Requirement:*** *Top management conduct planned reviews of the QMS to ensure its suitability, adequacy, effectiveness and alignment with the strategic direction considering:*

- *the status of actions from previous management reviews;*
- *changes in external and internal issues that are relevant to the QMS;*

- *information on the performance and effectiveness of the quality management system, including trends in:*
  - *customer satisfaction and feedback from relevant interested parties;*
  - *the extent to which quality objectives have been met;*
  - *process performance and conformity of products and services;*
  - *nonconformities and corrective actions;*
  - *monitoring and measurement results;*
  - *audit results;*
  - *the performance of external providers;*
  - *the adequacy of resources;*
  - *the effectiveness of actions taken to address risks and opportunities;*
  - *opportunities for improvement.*

*The outputs of management review are to include decisions and actions related to:*

- *opportunities for improvement;*
- *any need for changes to the quality management system;*
- *resource needs.*

*Retain documented information as evidence of the results of management reviews.*

**Our Approach:** Our management reviews are planned and occur on a quarterly basis. At a minimum, these reviews are attended by

- *President*
- *Project Manager (MREP)*
- *Sales and Marketing Manager*
- *Engineering and Design Manager*
- *Shop Foreman*
- *Automation Engineer*
- *Financial Controller*
- *HR and Compliance Mgr.*

The Management Reviews are planned using a schedule and meeting agenda consisting of all required inputs. The meetings are retained on the **Management Review meeting minutes**.

Outputs from our Management Reviews include the actions and decisions relating to any opportunities for improvement, needed changes to the QMS and resource needs. Outputs are also retained on the **Management Review meeting minutes**.

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# SECTION 4: ACT

This final step within our Plan, Do, Check and Act quality management system serves two purposes. First, it is the step which is used to make the decision of taking or not taking action based on the analysis and evaluations that occur during the "check" step. Whether we decide to take action or not, the decision will always be metric-driven, and risk-based.

The second purpose of the "Act" step is that it serves as the pivoting step that guides our QMS back to the Plan phase to begin the PDCA cycle and support continual improvement.

This last section of our manual covers our approach to improvements and corrective actions.

# 10 Improvement

## 10.1 General

***Requirement:*** *Determine and select opportunities for improvement and implement actions to meet customer requirements and enhance customer satisfaction, including (as appropriate):*

- *improving products and services to meet requirements as well as to address future needs and expectations;*
- *correcting, preventing or reducing undesired effects;*
- *improving the performance and effectiveness of the quality management system.*

**Our Approach:** We select opportunities relating to:

- improve our products and services;
- correct, prevent or reduce undesired effects;
- improve our QMS.

We retain the documented information regarding improvements on our **Measurement Plans** and **Corrective Action Forms**.

## 10.2 Nonconformity and corrective action

***Requirement:*** *When a nonconformity occurs, including those arising from complaints:*

- *react to the nonconformity, and as applicable:*
  - *take action to control and correct it;*

- *deal with the consequences;*

- *evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere:*
  - *review and analyze the nonconformity;*
  - *determine the causes of the nonconformity;*
  - *determine if similar nonconformities exist, or could potentially occur;*
- *implement any action needed;*
- *review the effectiveness of any corrective action taken;*
- *update risks and opportunities determined during planning, if necessary;*
- *make changes to the quality management system, if necessary.*

*Corrective actions are appropriate to the effects of the nonconformities encountered.*

*Retain documented information as evidence of:*

- *the nature of the nonconformities and any subsequent actions taken;*
- *the results of any corrective action.*

**Our Approach:** Nonconformities are taken seriously and are reacted to as applicable. We take any actions necessary to ensure that the nonconformity does not recur or occur elsewhere. Nonconformities are documented on our **Nonconformance Form** and/or **Corrective Action Form**, are tracked over time to help identify trends, and are discussed during Management Review.

## 10.3 Continual improvement

***Requirement:*** *Continually improve the suitability, adequacy, and effectiveness of the QMS.*

**Our Approach:** We consider the results of analysis and evaluation, and the outputs from Management Review, to confirm if there are needs or opportunities to be addresses as part of continual improvement.