 <b>NELSON PRECISION DRILLING CO.</b> <small>I N C O R P O R A T E D</small>	<b>Quality Management System Manual</b>		
	<b>QMS Rev 004</b>	<b>Date: 02/02/2020</b>	<b>Owner: President</b>

*This document is the Quality Management Systems Manual for Nelson Precision Drilling located at 103 Commerce Street, Glastonbury CT, 06033. It is based on AS9100D and internal company policies.*

*This is a controlled document. Approvals may be found on Page 29*

## Preface

This Quality Management Systems Manual summarizes the policies and commitments of Nelson Precision Drilling. It has been reviewed and approved by the company's President.

The format of this manual follows AS9100D.

Where applicable it calls out specific Standard Operating Procedures (SOPs), Quality Work Instructions (QWIs) and Quality Forms and Records (QRF's) that detailed information on a specific process. A complete index of these is found in **FM 4.0-01 "QMS Master Document Index"**

When describing specific employee titles in our documentation we have chosen to use Head of (Process / Function) instead of a specific title that may change. For example, the leader of the Quality function is referred to as the "Head of Quality" instead of a title such as Quality Director, Quality Manager, Quality Engineer, etc. The exception to this is the CEO who is referred to by title.

Nelson Precision Drilling may be referred to as "NPD" or "the company" in this manual.

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## Introduction

Nelson Precision Drilling (NPD) has been in business since 1970 performing deep drilling (aka gun barrel drilling) and honing for high tolerance customer requirements. We strive to assure customer satisfaction; continually improving to provide our customers, safe and reliable products and services that meet or exceed customer and applicable statutory and regulatory requirements.

This Quality Manual documents the standards for the company's AS9100D based Quality Management System (QMS) and is used at all levels of NPD to improve quality, cost and delivery performance.

## .01 General

The NPD QMS is a result of a strategic decision by the company that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.

The potential benefits to the company for implementing a QMS based on AS9100D are:

- a) the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;
- b) facilitating opportunities to enhance customer satisfaction;
- c) addressing risks and opportunities associated with its context and objectives;
- d) the ability to demonstrate conformity to specified QMS requirements.

The QMS requirements specified in this International Standard are complementary to requirements for products and services.

NPD employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking. The process approach enables a NPD to plan its processes and their interactions. The PDCA cycle enables NPD to ensure that its processes are adequately resourced and managed; and those opportunities for improvement are determined and acted on.

Risk-based thinking enables NPD to determine the factors that could cause its processes and its QMS to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise

Consistently meeting requirements and addressing future needs and expectations poses a challenge for NPD in an increasingly dynamic and complex environment. To achieve this objective, NPD finds it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation, and re-organization.

In this Quality Manual, the following verbal forms are used:

- **"shall" indicates** a requirement;
- **"should" indicates** a recommendation;
- **"may" indicates** a permission;
- **"can" indicates** a possibility or a capability.

## .02 Quality Management Principles

NPD quality management principles are:

- customer focus;
- leadership;
- engagement of people;

- process approach;
- improvement;
- evidence-based decision making;

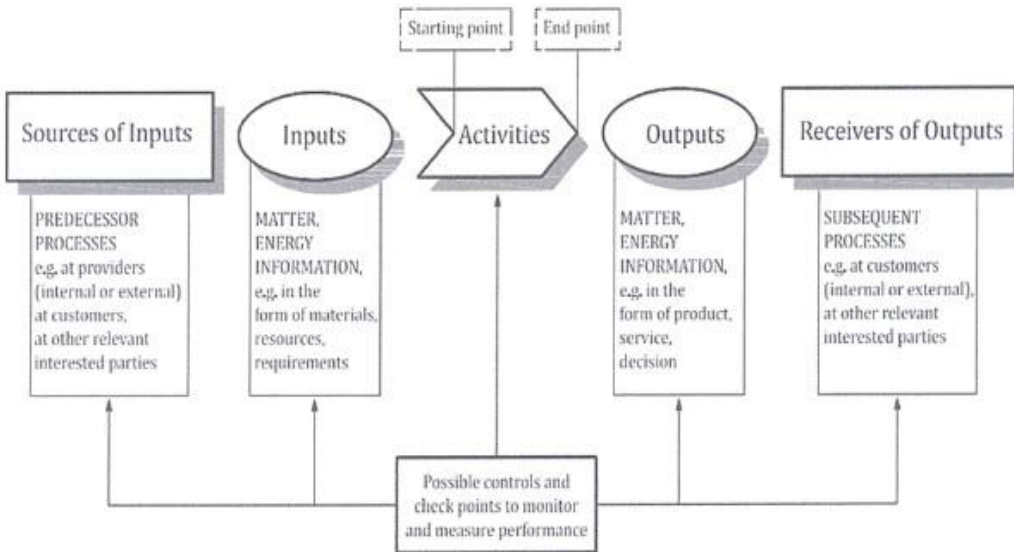
### .03 Process Approach

NPD uses the process approach to all its processes. We believe this provides the best opportunity to satisfy our customer's needs. The application of the integrated process approach in a QMS enables NPD to give strategic direction to the company; mitigate risks through critical thinking; take advantage of opportunities; and prevent undesirable effects.

The application of the process approach in the QMS enables:

- understanding and consistency in meeting requirements;
- the consideration of processes in terms of added value;
- the achievement of effective process performance;
- improvement of processes based on evaluation of data and information.

Figure 1 gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring check points, which are necessary for control, are specific to each process, and will vary depending on the related.



**Figure 1 - Schematic representation of the elements of a single process**

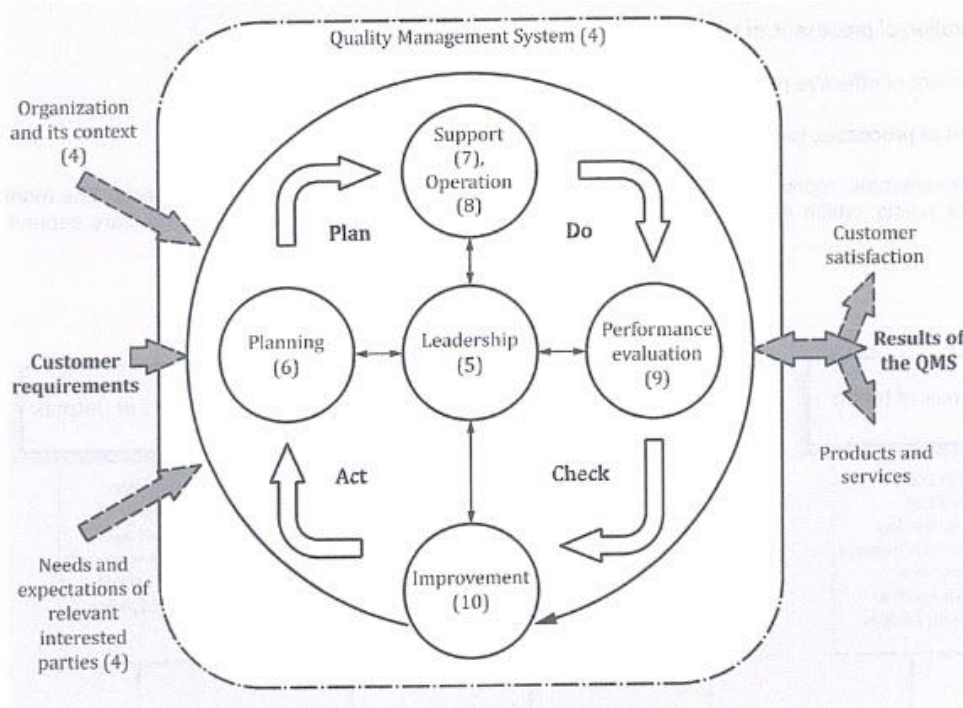
#### Plan-Do-Check-Act Cycle

The PDCA cycle can be applied to all processes and to the QMS as a whole. Figure 2 illustrates how AS9100D clauses 4 to 10 can be grouped in relation to the PDCA cycle.

The PDCA cycle can be briefly described as follows:

- **Plan:** establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and NPD 's policies, and identify and address risks and opportunities;
- **Do:** implement what was planned;

- **Check:** monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements, and planned activities, and report the results;
- **Act:** take actions to improve performance, as necessary.




**Figure 2 – Representation of the structure of AS9100D in the PDCA cycle**

### **Risk Based Thinking**

NPD understands risk-based thinking is essential for achieving an effective QMS. We have applied the concept of risk-based thinking to our processes to improve customer satisfaction by carrying out preventive action to eliminate potential nonconformities, analyzing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity. We understand that NPD needs to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the QMS, achieving improved results, and preventing negative effects.

We also understand opportunities can arise as a result of a situation favorable to achieving an intended result, for example, a set of circumstances that allow NPD to attract customers, develop new products and services, reduce waste, or improve productivity. Actions to address opportunities can also include consideration of associated risks. Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

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## **.04 Relationship with Other Management System Standards**

As other management systems are flowed in by contract, statute, or regulation NPD blends these requirements into our QMS. In all cases the Contract or Purchase Order take precedent over the AS9100D specifications. When a conflict does arise, management resolves it with the customer and or AS9100 registrar.

### **1.0 Scope**

The NPD QMS has been developed to be compliant to AS9100D (including ISO9001:2015), and any specific customer, statutory and regulatory requirements. Details and exceptions taken to AS9100D are noted in para 4.3 of this manual.

### **2.0 Normative References**

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

AS9100D Quality Management Systems - Requirements for Aviation, Space, and Defense Organizations

ISO 9000:2015 Quality Management Systems - Fundamentals and Vocabulary

ISO 9001:2015 Quality Management Systems - Requirements

### **3.0 Terms and Definitions**

For the purpose of this document the terms and definitions in ISO9001:2015 and AS9100D apply.

### **4.0 Context of Organization**

#### **4.1 Understanding Nelson Precision Drilling and Its Context**


NPD has determined the external and internal issues that are relevant to our purpose; our strategic direction; and the effect of these on our ability to achieve the intended result(s) of its QMS. We monitor and review information about these external and internal issues on a routine basis through various methods described in this manual.

#### **4.2 Understanding the Needs and Expectations of Interested Parties**

Due to their effect or potential effect on Nelson Precision Drilling's ability to consistently provide products and services that meet our customer's and applicable statutory and regulatory requirements, NPD has determined:

- a) the interested parties that are relevant to the QMS. These are listed in **FM 5.0-02 "Context and Interested Parties"**
- b) The requirements of these interested parties that are relevant to the QMS. These requirements are on our networks; flowed onto our drawings and other documents as necessary; and flowed down to our suppliers as necessary

NPD monitors and reviews information about these interested parties and their relevant requirements. This process is led by Sales but involves the entire company.

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### 4.3 Determining the Scope of the Quality Management System

NPD has determined the boundaries and applicability of the QMS to establish its scope. When determining this scope NPD has considered:

- a) the external and internal issues referred to in 4.1;
- b) the requirements of relevant interested parties referred to in 4.2;
- c) the products and services of NPD.

NPD applies all the requirements of AS9100D, if they are applicable, within the determined scope of its QMS.

The official registrar scope of Nelson Precision Drilling's QMS is: "**DEEP HOLE DRILLING, BORING AND HONING OF STANDARD AND EXOTIC MATERIALS FOR AEROSPACE AND OTHER INDUSTRIES**".

This scope is documented and maintained in **FM 5.3-01 "Quality Policy with Objectives"** and is available for general review on company bulletin boards and in our ASR Registration which is located on our bulletin boards and our website.

The following sections of AS9100D are not performed under our scope and are not documented in our QMS.

- Para 8.3 "Design and Developments of Product and Services." As a contract manufacturer NPD does not perform any design of product or services. Therefore, our QMS does not address these requirements.

### 4.4 Quality Management System and Its Processes

4.4.1 NPD has established, implemented, maintains, and continually improves a QMS, including the processes needed and their interactions, in accordance with the requirements of AS9100D. Our QMS also addresses customer and applicable statutory and regulatory requirements.

NPD has determined the processes needed for the QMS and its application throughout the company. We have:

- a) determined the inputs required and the outputs expected from these processes;
- b) determined the sequence and interaction of these processes;
- c) determined and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
- d) determined the resources needed for these processes and ensure their availability;
- e) assigned the responsibilities and authorities for these processes;
- f) addressed the risks and opportunities as determined in accordance with the requirements of 6.1;
- g) evaluated these processes and implement any changes needed to ensure that these processes achieve their intended results;
- h) improved the processes and the QMS.

4.4.2 To the extent necessary, NPD:

- a) maintains documented information to support the operation of its processes;
- b) retains documented information to have confidence that the processes are being carried out as planned.

NPD has established and maintains documented information that includes:

- a) a general description of relevant interested parties (see 4.2 a);

- b) the scope of the quality management system, including boundaries and applicability (see 4.3);
- c) a description of the processes needed for the QMS and their application throughout the company (see Fig 3)
- d) the sequence and interaction of these processes (see Fig 3);
- e) assignment of the responsibilities and authorities for these processes (see 5.3).

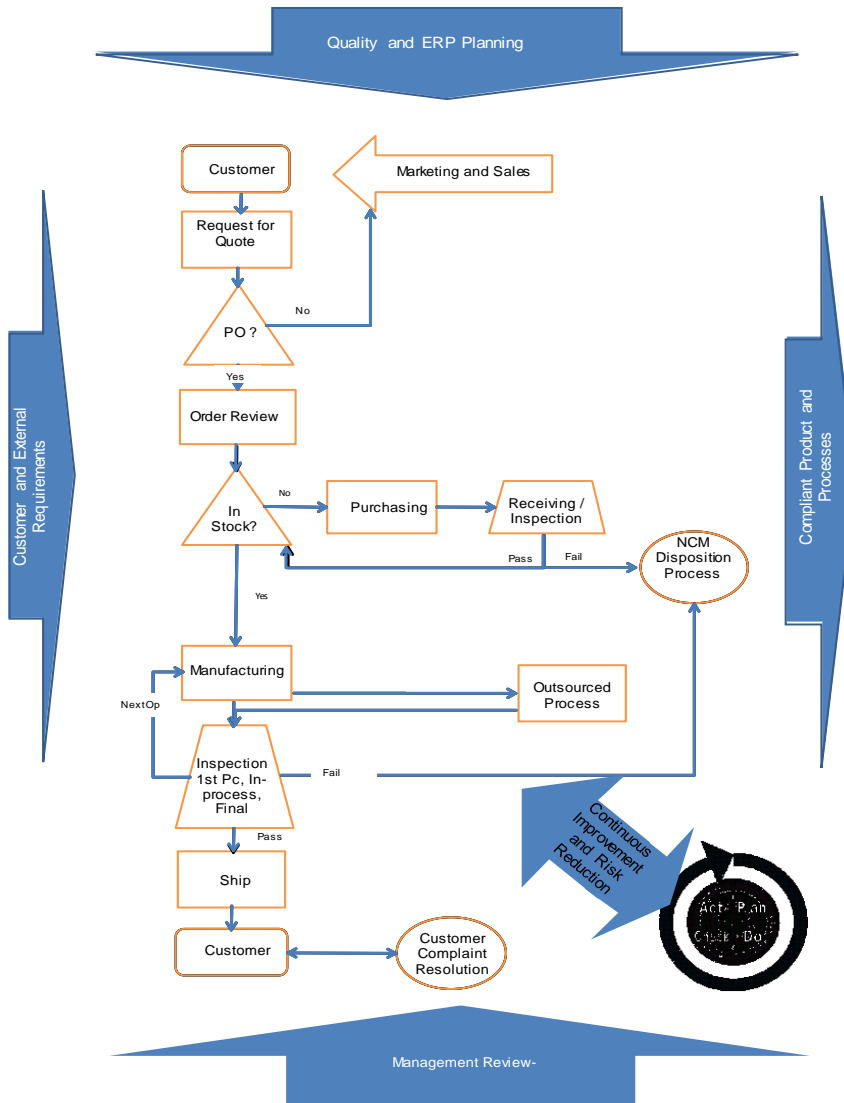


Figure 3



## 5. Leadership

### 5.1 Leadership and Commitment

#### 5.1.1 General

Top management shall demonstrate leadership and commitment with respect to the QMS by:

- a) taking accountability for the effectiveness of the QMS;
- b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the company;
- c) ensuring the integration of the QMS requirements into NPD 's business processes;
- d) promoting the use of the process approach and risk-based thinking;
- e) ensuring that the resources needed for the quality management system are available;
- f) communicating the importance of effective quality management and of conforming to the quality management system requirements;
- g) ensuring that the quality management system achieves its intended results;
- h) engaging, directing, and supporting persons to contribute to the effectiveness of the QMS;
- i) promoting improvement;
- j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

#### 5.1.2 Customer Focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

- a) customer and applicable statutory and regulatory requirements are determined, understood, and consistently met;
- b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- c) the focus on enhancing customer satisfaction is maintained;
- d) product and service conformity and on-time delivery performance are measured, and appropriate action is taken if planned results are not, or will not be, achieved.

## 5.2 Policy

#### 5.2.1 Establishing the Quality Policy

Top management has established, implemented and maintains a quality policy that:

- a) is appropriate to the purpose and context of NPD and supports its strategic direction;
- b) provides a framework for setting quality objectives;
- c) includes a commitment to satisfy applicable requirements;
- d) includes a commitment to continual improvement of the quality management system.

#### 5.2.2 Communicating the Quality Policy

The quality policy is:

- a) available and maintained as documented information;
- b) communicated, understood, and applied within the NPD;
- c) available to relevant interested parties, as appropriate.

#### 5.2.3 NPD's Quality Policy is

**Top management and its employees are committed to meeting customer requirements and supplying products that meet or exceed expectations for quality, on time deliveries, and conformity.**

**It is our policy to achieve customer satisfaction through continuous improvement programs that ensure the effectiveness of our quality management systems goals and objectives.**

**We shall meet the requirements of our customer policy by using teamwork and ethical behavior.**

### 5.3 Nelson Precision Drilling Roles, Responsibilities and Authorities.

Top management has documented the responsibilities and authorities for relevant roles and ensured these are assigned, communicated, and understood within NPD.

Top management has assigned the Head of Quality the responsibility and authority for:

- a) ensuring that the QMS conforms to the requirements of this International Standard;
- b) ensuring that the processes are delivering their intended outputs;
- c) reporting on the performance of the QMS and on opportunities for improvement (see 10.1), to top management;
- d) ensuring the promotion of customer focus throughout NPD;
- e) ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

Top management has appointed the NPD Head of Quality as the management representative. This position has the responsibility and authority for oversight of the above requirements. The management representative's name can be found in **FM 5.0-01 "Organizational Matrix"**

The NPD management representative has organizational freedom and unrestricted access to top management to resolve quality management issues.

NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the QMS.

## 6. Planning

### 6.1 Actions to Address Risks and Opportunities

6.1.1 When planning for the QMS, Nelson Precision Drilling considers the issues referred to in para 4.1 and the requirements referred to in para 4.2 and determines the risks and opportunities that need to be addressed to:

- a) give assurance that the quality management system can achieve its intended result(s);
- b) enhance desirable effects;
- c) prevent, or reduce, undesired effects;
- d) achieve improvement.

Each major or critical process is documented in the QMS to satisfy these requirements either directly or indirectly.

6.1.2 Nelson Precision Drilling plans:


- a) actions to address these risks and opportunities;
- b) and how to:
  - integrate and implement the actions into its QMS processes (see 4.4);
  - evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services. These actions are addressed, in part, using form **FM 7.1-01 "Risk Management Matrix"**

For Detailed information on how this is accomplished go to the Specific SP listed in **FM 4.0-01 "QMS Master Document Index"**

### 6.2 Quality Objectives and Planning to Achieve Them

6.2.1 NPD has established quality objectives at relevant functions, levels, and processes needed for the QMS.

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The quality objectives are:

- a) consistent with the quality policy;
- b) measurable;
- c) take into account applicable requirements;
- d) relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) monitored;
- f) communicated;
- g) updated, as appropriate.

NPD maintains documented information on the Quality Objectives (reference document **FM 5.3-01 "Quality Policy with Quality Objectives"** for current objectives)

6.2.2 When planning how to achieve its quality objectives, NPD determines:

- a) what will be done;
- b) what resources will be required;
- c) who will be responsible;
- d) when it will be completed;
- e) how the results will be evaluated.

The Quality Policy and Objectives are reviewed at Management Review and updated as needed.

## 6.3 Planning of Changes

When NPD determines the need for changes to the QMS, the changes are carried out in a planned manner (see 4.4).

NPD considers:

- a. the purpose of the changes and their potential consequences;
- b. the integrity of the QMS;
- b) the availability of resources;
- a. the allocation or reallocation of responsibilities and authorities.

The process for changing the QMS is documented in **SP 4.2-01 "Control of QMS Documents and Records"**

## 7. Support

### 7.1 Resources

#### 7.1.1 General

NPD has determined and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS. When reviewing for resources we consider

- a) the capabilities of, and constraints on, existing internal resources;
- b) what needs to be obtained from external providers

#### 7.1.2 People

NPD has determined and provides the persons necessary for the effective implementation of its QMS and for the operation and control of its processes.

#### 7.1.3 Infrastructure

NPD has determined, provided, and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. The Infrastructure includes

- a. buildings and associated utilities;

- b. equipment, including hardware and software;
- c. transportation resources;
- d. information and communication technology.

7.1.4 Environment for the Operation of Processes

NPD has determined, provided, and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services. We strive to have a robust, friendly and productive workforce located in a in a temperature controlled, well lit, clean and organized facility.

7.1.5 **Monitoring and Measuring Resources**

See **SP 7.6-01 “Control of Monitoring & Measuring (Calibration)”** for detailed process documentation.

7.1.5.1 General

NPD has determined and provided the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

NPD ensures that the resources provided:

- a. are suitable for the specific type of monitoring and measurement activities being undertaken;
- b. are maintained to ensure their continuing fitness for their purpose.

NPD retains appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement Traceability

When measurement traceability (calibration) is a requirement or is considered by NPD to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

- a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;
- b) identified in order to determine their status;
- c) safeguarded from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results

NPD has established, implemented, and maintains a process for the recall of monitoring and measuring equipment requiring calibration or verification.

NPD maintains a register of the monitoring and measuring equipment. The register includes the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.

Calibration and verification of monitoring and measuring equipment is carried out under suitable environmental conditions (see 7.1.4).

NPD takes the appropriate action (as necessary) when it has been determined that the validity of previous measurement results have been adversely affected or when measuring equipment is found to be unfit for its intended purpose.

7.1.6 Nelson Precision Drilling Knowledge

NPD shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge shall be maintained and be made available to the extent necessary. Knowledge is maintained in Drawings, Job Travelers, Work Instructions, etc.

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

## 7.2 Competence

Nelson Precision Drilling:

- a. determines the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the QMS;
- b. ensures that these persons are competent on the basis of appropriate education, training, or experience;
- c. where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- d. retains appropriate documented information as evidence of competence.

Competence is determined and recorded in Employee performance evaluations, training evaluations, metrics, corrective actions and observations.

## 7.3 Awareness

The NPD ensures that persons doing work under the company's QMS control are aware of:

- a) the quality policy;
- b) relevant quality objectives;
- c) their contribution to the effectiveness of the QMS, including the benefits of improved performance;
- d) the implications of not conforming with the QMS requirements;
- e) relevant QMS documented information and changes thereto;
- f) their contribution to product or service conformity;
- g) their contribution to product safety;
- h) the importance of ethical behavior.

Awareness is ensured through an employee handbook that all new hires receive. Training (including annual refresher training) bulletin boards, production meetings, work instructions and day to day interaction with employees.

## 7.4 Communication

NPD has determined the internal and external communications relevant to the QMS, including:

- a) on what it will communicate;
- b) when to communicate;
- c) with whom to communicate;
- d) how to communicate;
- e) who communicates.

Communication at NPD starts with the President and includes formal and informal methods such as employee feedback, written information and company meetings, employee handbook, bulletin boards, etc. External communication includes sharing scope, manual, etc. with

customers, registrar, etc. As well as communication via website, brochures and promotional materials.

## 7.5 Documented Information

7.5.1 General – **Refer to SOP -401, “Documents and Records Control” for documented process information.**

NPD 's QMS includes:

- a) documented information required by this International Standard;
- b) documented information determined by the company as being necessary for the effectiveness of the QMS.

7.5.2 Creating and Updating QMS documentation

When creating and updating documented information, NPD ensures appropriate:

- a) identification and description (e.g., a title, date, author, or reference number);
- b) format (e.g., language, software version, graphics) and media (e.g., paper, electronic);
- c) review and approval for suitability and adequacy.

7.5.3 Control of Documented Information

7.5.3.1 Documented information required by the QMS is controlled to ensure:

- a. it is available and suitable for use, where and when it is needed;
- b. it is adequately protected (e.g., from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, the NPD has addressed the following activities, as applicable:

- a. distribution, access, retrieval, and use;
- b. storage and preservation, including preservation of legibility;
- c. control of changes (e.g., version control);
- d. retention and disposition;
- e. prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

Documented information of external origin determined by NPD to be necessary for the planning and operation of the QMS is identified as appropriate and controlled.

Documented information retained as evidence of conformity is protected from unintended alterations.

Documented information and data that is managed electronically is protected from loss, unauthorized changes, unintended alteration, corruption and physical damage.

## 8. Operation

### 8.1 Operational Planning and Control

Refer to **SP 7.1-01 “Product Realization Planning”** and **SP 7.2-01 “Customer Related Processes”** for detail process documentation.

NPD plans, implements, and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in clause 6, by determining the requirements for the products and services. When determining the requirements NPD takes into consideration:

- a) personal and product safety;
- b) producibility and inspectability;

- c) reliability, availability, and maintainability;
- d) suitability of parts and materials used in the product;
- e) selection and development of embedded software (if applicable);
- f) product obsolescence (if applicable);
- g) prevention, detection, and removal of foreign objects;
- h) handling, packaging, and preservation;
- i) recycling or final disposal of the product at the end of its life (if applicable.)

NPD establishes criteria for:

- a) the processes;
- b) the acceptance of products and services;
- c) statistical techniques (if applicable)
- d) selection and verification of key characteristics (if applicable);
- e) process capability measurements (if applicable);
- f) statistical process control (if applicable);
- g) design of experiments (if applicable);
- h) verification;
- i) failure mode, effects, and criticality analysis (if applicable).

NPD plans also include:

- a) determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of products and services;
- b) implementing control of the processes in accordance with the criteria;
- c) determining, maintaining, and retaining documented information to the extent necessary:
  - to have confidence that the processes have been carried out as planned;
  - to demonstrate the conformity of products and services to their requirements;
- d) determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;
- e) engaging representatives of affected NPD functions for operational planning and control;
- f) determining the process and resources to support the use and maintenance of the products and services;
- g) determining the products and services to be obtained from external providers;
- h) establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

As appropriate to NPD, customer requirements, and products and services, NPD plans and manages product and service provisions in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints.


The output of this planning shall be suitable for the NPD 's operations. This is also referred to a part number specific Quality Plan

The NPD controls planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

NPD ensures that outsourced processes are controlled (see 8.4).

NPD has established, implemented, and maintains a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements. The process ensures that work transfer impacts and risks are managed.

NOTE: See 8.4 for the control of work transfer from one NPD facility to another; see 8.5 for work transfer between NPD and an external provider to the NPD.

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### 8.1.1 Operational Risk Management

NPD has planned, implemented, and controls a process for managing operational risks to the achievement of applicable requirements. the scope of this clause (8.1.1) is limited to the risks associated to the operational processes needed for the provision of products and services (clause 8). This includes as appropriate to the NPD and its products and services:

- a) assignment of responsibilities for operational risk management;
- b) definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance);
- c) identification, assessment, and communication of risks throughout operations;
- d) identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;
- e) acceptance of risks remaining after implementation of mitigating actions.

### 8.1.2 Configuration Management

NPD has planned, implemented, and controls a process for configuration management as appropriate to NPD and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process:

- a) controls product identity and traceability to requirements, including the implementation of identified changes;
- b) ensures that the documented information (e.g., requirements, design, verification, validation and acceptance documentation) is consistent with the actual attributes of the products and services.

### 8.1.3 Product Safety

NPD plans, implements, and controls the processes needed to assure product safety during the entire product life cycle, as appropriate to the NPD and the product. Examples of these actions are:

- a) assessment of hazards and management of associated risks (see 8.1.1);
- b) management of safety critical items;
- c) analysis and reporting of occurred events affecting safety;
- d) communication of these events and training of persons.

### 8.1.4 Prevention of Counterfeit Parts

NPD plans, implements, and controls processes, appropriate to NPD and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer. This process includes consideration of:

- a) training of appropriate persons in the awareness and prevention of counterfeit parts;
- b) application of a parts obsolescence monitoring program;
- c) controls for acquiring externally provided product from original or authorized manufacturers, authorized distributors, or other approved sources;
- d) requirements for assuring traceability of parts and components to their original or authorized manufacturers;
- e) verification and test methodologies to detect counterfeit parts;
- f) monitoring of counterfeit parts reporting from external sources;
- g) quarantine and reporting of suspect or detected counterfeit parts.

For more information on this see **WI 7.1-01 “Assuring Acquisition of Authentic and Conforming Material (Counterfeit Material)”**

## 8.2 Requirements for Products and Services

### 8.2.1 Customer Communication

Communications with customers includes:

- a) providing information relating to products and services;



- b) handling enquiries, contracts, or orders, including changes;
- c) obtaining customer feedback relating to products and services, including customer complaints;
- d) handling or controlling customer property;
- e) establishing specific requirements for contingency actions, when relevant.

Generally, customer communication is typically handled by the President or customer support personnel.

#### 8.2.2 Determining the Requirements for Products and Services

When determining the requirements for the products and services to be offered to customers, NPD ensures that:

- a) the requirements for the products and services are defined, including:
  - 1. any applicable statutory and regulatory requirements;
  - 2. those considered necessary by NPD
- b) NPD can meet the claims for the products and services it offers;
  - 1. special requirements of the products and services are determined;
  - 2. operational risks (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified.

This review is done at Quotation and again at Contract Review. See **SP 7.1-01 "Product Realization Planning"** and **SP 7.2-01 "Customer Related Processes"**

#### 8.2.3 Review of the Requirements for Products and Services

##### 8.2.3.1 NPD ensures that it has the ability to meet the requirements for products and services to be offered to customers. NPD conducts a review before committing to supply products and services to the customer, to include:

- a. requirements specified by the customer, including the requirements for delivery and post-delivery activities;
- b. requirements not stated by the customer, but necessary for the specified or intended use, when known;
- c. requirements specified by the NPD;
- d. statutory and regulatory requirements applicable to the products and services;
- e. contract or order requirements differing from those previously expressed.

This review is coordinated with applicable functions of the NPD to the extent necessary to ensure customer satisfaction.

If upon review NPD determines that some customer requirements cannot be met or can only partially be met, the NPD will negotiate a mutually acceptable requirement with the customer.


NPD ensures that contract or purchase order requirements differing from those previously defined are resolved.

The customer requirements are confirmed by the NPD before acceptance, when the customer does not provide a documented statement of their requirements.

This review is done at Contract Review. See **SP 7.1-01 "Product Realization Planning"** and **SP 7.2-01 "Customer Related Processes"**

##### 8.2.3.2 NPD retains documented information, as applicable:

- a. on the results of the review;
- b. on any new requirements for the products and services.

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- 8.2.4 Changes to Requirements for Products and Services  
 NPD ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

### 8.3 Design and Development of Products and Services – Not in Scope

See 4.3 for reason this is not in scope.

### 8.4 Control of Externally Provided Processes, Products, and Services

- 8.4.1 General (This NPD process is called Purchasing). See **SP 7.4-01 “Purchasing”** for detailed documentation.  
 NPD ensures that externally provided processes, products, and services conform to requirements. NPD is responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer (directed sources).
- NPD ensures, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.
- NPD identifies and manages the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers.
- NPD requires that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.
- NPD determines the controls to be applied to externally provided processes, products, and services when:
- a) products and services from external providers are intended for incorporation into the NPD 's own products and services;
  - b) products and services are provided directly to the customer(s) by external providers on behalf of the NPD;
  - c) a process, or part of a process, is provided by an external provider as a result of a decision by the NPD.
- NPD determines and applies 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 requirements. NPD retains documented information of these activities and any necessary actions arising from the evaluations.
- 8.4.1.1 NPD:
- a) defines the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status;
  - b) maintains a register of its external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);
  - c) periodically reviews external provider performance including process, product and service conformity, and on-time delivery performance;
  - d) defines the necessary actions to take when dealing with external providers that do not meet requirements;
  - e) defines the requirements for controlling documented information created by and/or retained by external providers.

#### 8.4.2 Type and Extent of Control

NPD ensures that externally provided processes, products, and services do not adversely affect NPD's ability to consistently deliver conforming products and services to its customers.

NPD:

- a) ensures that externally provided processes remain within the control of its QMS;
- b) defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
- c) takes into consideration:
  1. the potential impact of the externally provided processes, products, and services on the NPD's ability to consistently meet customer and applicable statutory and regulatory requirements;
  2. the effectiveness of the controls applied by the external provider;
  3. the results of the periodic review of external provider performance (see 8.4.1.1 c);
- d) determines the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements.

Verification activities of externally provided processes, products, and services are performed according to the risks identified by the NPD. These include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts.

NOTE 2: Verification activities can include:

- review of objective evidence of the conformity of the processes, products, and services from the external provider (e.g., accompanying documentation, certificate of conformity, test documentation, statistical documentation, process control documentation, results of production process verification and assessment of changes to the production process thereafter);
- inspection and audit at the external provider's premises;
- review of the required documentation;
- review of production part approval process data;
- inspection of products or verification of services upon receipt;
- review of delegations of product verification to the external provider.

When externally provided product is released for production use pending completion of all required verification activities, it is identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

When NPD delegates verification activities to the external provider, the scope and requirements for delegation is defined and a register of delegations is maintained. NPD periodically monitor the external provider's delegated verification activities.

When external provider test reports are utilized to verify externally provided products, NPD implements a process to evaluate the data in the test reports to confirm that the product meets requirements. When a customer or NPD identifies raw material as a significant operational risk (e.g., critical items), NPD implements a process to validate the accuracy of test reports.

#### 8.4.3 Information for External Providers

NPD ensures the adequacy of requirements prior to their communication to the external provider. The NPD communicates to external providers its requirements for:

- a) the processes, products, and services to be provided including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions);
- b) the approval of:
  1. products and services;
  2. methods, processes, and equipment;

3. the release of products and services;
- c) competence, including any required qualification of persons;
  - d) the external providers' interactions with the NPD;
  - e) control and monitoring of the external providers' performance to be applied by the NPD;
  - f) verification or validation activities that the NPD, or its customer, intends to perform at the external providers' premises;
  - g) design and development control;
  - h) special requirements, critical items, or key characteristics;
  - i) test, inspection, and verification (including production process verification);
  - j) the use of statistical techniques for product acceptance and related instructions for acceptance by the NPD;
  - k) the need to:
    - implement a quality management system;
    - use customer-designated or approved external providers, including process sources (e.g., special processes);
    - notify the NPD of nonconforming processes, products, or services and obtain approval for their disposition;
    - prevent the use of counterfeit parts (see 8.1.4);
    - notify the NPD of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the NPD 's approval;
    - flow down to external providers applicable requirements including customer requirements; provide test specimens for design approval, inspection/verification, investigation, or auditing; retain documented information, including retention periods and disposition requirements;
  - l) the right of access by the NPD, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;
  - m) ensuring that persons are aware of:
    - their contribution to product or service conformity;
    - their contribution to product safety;
    - the importance of ethical behavior.

## 8.5 Production and Service Provision

Refer to **SP 7.5-01 "Production of Product "**for more detailed process documentation

### 8.5.1 Control of Production and Service Provision

The NPD has implemented the production and service provision under controlled conditions.

Controlled conditions shall include, as applicable:

- a) the availability of documented information that defines:
  - the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
  - the results to be achieved;

NOTE 1: Documented information that defines characteristics of products and services can include digital product definition data, drawings, parts lists, materials, and process specifications.

NOTE 2: Documented information for activities to be performed and results to be achieved can include process flow charts, control plans, production documents (e.g., manufacturing plans, travelers, routers, work orders, process cards), and verification documents.

- b) the availability and use of suitable monitoring and measuring resources;
- c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;



1. ensuring that documented information for monitoring and measurement activity for product acceptance includes:

- criteria for acceptance and rejection;
  - where in the sequence verification operations are to be performed;
  - measurement results to be retained (at a minimum an indication of acceptance or rejection);
  - any specific monitoring and measurement equipment required, and instructions associated with their use;
- d) ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).
- e) the use of suitable infrastructure and environment for the operation of processes;
- f) NOTE: Suitable infrastructure can include product specific tools (e.g., jigs, fixtures, molds) and software programs.
- g) the appointment of competent persons, including any required qualification;
- h) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- i) NOTE: These processes can be referred to as special processes (see 8.5.1.2).
- j) the implementation of actions to prevent human error;
- k) the implementation of release, delivery, and post-delivery activities;
- l) the establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);
- m) the accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);
- n) the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;
- o) the determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);
- p) the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;
- q) the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;
- r) the provision for the prevention, detection, and removal of foreign objects;
- s) the control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products)
- t) to the extent they affect conformity to product requirements (see 7.1.3);
- u) the identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.

#### 8.5.1.1 Control of Equipment, Tools, and Software Programs

Equipment, tools, and software programs used to automate, control, monitor, or measure production processes shall be validated prior to final release for production and shall be maintained.

Storage requirements is defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.

#### 8.5.1.2 Validation and Control of Special Processes

For processes where the resulting output cannot be verified by subsequent monitoring or measurement, NPD establishes arrangements for these processes including, as applicable:

- a. definition of criteria for the review and approval of the processes;
- b. determination of conditions to maintain the approval;
- c. approval of facilities and equipment;

- d. qualification of persons;
- e. use of specific methods and procedures for implementation and monitoring the processes;
- f. requirements for documented information to be retained.

#### 8.5.1.3 Production Process Verification

NPD has implemented production process verification activities to ensure the production process is able to produce products that meet requirements.

NOTE: These activities can include risk assessments, capacity studies, capability studies, and control plans.

NPD uses a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation, and tooling are able to produce parts and assemblies that meet requirements. This activity shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, production process changes, tooling changes). This activity is referred to as First Article Inspection (FAI) or Production Part Acceptance Process (PPAP.) NPD retains this documented information on the results of production process verification.

#### 8.5.2 Identification and Traceability

NPD uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

NPD maintains the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.

NPD identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

Where acceptance authority media is used (e.g., stamps, electronic signatures, passwords), NPD has established controls for the media.

NPD controls the unique identification of the outputs when traceability is a requirement, and retains the documented information necessary to enable traceability.

NOTE: Traceability requirements can include:

- the identification to be maintained throughout the product life;
- the ability to trace all products manufactured from the same batch of raw material, or from the same
- manufacturing batch, to the destination (e.g., delivery, scrap);
- for an assembly, the ability to trace its components to the assembly and then to the next higher assembly;
- for a product, a sequential record of its production (manufacture, assembly, inspection / verification) to be retrievable.

#### 8.5.3 Property Belonging to Customers or External Providers

NPD exercises care with property belonging to customers or external providers while it is under the NPD 's control or being used by the NPD.

NPD identifies, verifies, protects, and safeguards customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged, or otherwise found to be unsuitable for use, NPD reports this to the customer or external provider and retains documented information on what has occurred.

NOTE: A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property, and personal data.

#### 8.5.4 Preservation

NPD shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

NOTE: Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

Preservation of outputs also includes, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:

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

#### 8.5.5 Post-Delivery Activities

NPD meets the requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, the NPD considers:

- a) statutory and regulatory requirements;
- b) the potential undesired consequences associated with its products and services;
- c) the nature, use, and intended lifetime of its products and services;
- d) customer requirements;
- e) customer feedback;
- f) collection and analysis of in-service data (e.g., performance, reliability, lessons learned);
- g) control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul;
- h) controls required for work undertaken external to NPD (e.g., off-site work); product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).

When problems are detected after delivery, NPD takes appropriate action including investigation and reporting.

NOTE: Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

### 8.5.6 Control of Changes

NPD reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

Persons authorized to approve production or service provision changes are identified.

NOTE: Production or service provision changes are included in the changes affecting processes, production equipment, tools, or software programs.

NPD retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

## 8.6 Release of Products and Services

NPD has implemented planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and 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.

NPD retains documented information on the release of products and services. The documented information shall include:

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

When required to demonstrate product qualification, NPD ensures that retained documented information provides evidence that the products and services have met the defined requirements.

NPD ensures that all documented information required to accompany the products and services are present at delivery.

This process is managed by the head of Quality and it confirms all parts are in specification ( unless identified as not) and all required documentation is completed and sent to the customer as directed.

## 8.7 Control of Nonconforming Outputs

8.7.1 NPD ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

NOTE: The term "nonconforming outputs" includes nonconforming product or service generated internally, received from an external provider, or identified by a customer.

NPD takes the appropriate actions based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of products, during or after the provision of services.

NPD 's nonconformity control process is maintained as documented information including the provisions for:

- a) defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;
- b) taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;
- c) timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;
- d) defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2).

NOTE: Interested parties requiring notification of nonconforming products and services can include external providers, customers, distributors, and regulatory authorities.

NPD deals with nonconforming outputs in one or more of the following ways:

- a) correction;
- b) segregation, containment, return, or suspension of provision of products and services;



- c) informing the customer;
- d) obtaining authorization for acceptance under concession by a relevant authority and, when applicable, by the customer.

Dispositions of use-as-is or repair for the acceptance of nonconforming can only be implemented:

- a) after approval by an authorized representative responsible for design or by persons who have delegated authority from the design authority;
- b) after authorization by the customer, if the nonconformity results in a departure from the contract requirements.

Product dispositioned for scrap are conspicuously and permanently marked, and positively controlled until physically rendered unusable.


Counterfeit, or suspect counterfeit, parts are controlled to prevent reentry into the supply chain.

Conformity to the requirements is verified after nonconforming outputs are corrected.

8.7.2 NPD retains documented information that:

- a) describes the nonconformity;
- b) describes the actions taken;
- c) describes any concessions obtained;
- d) identifies the authority deciding the action in respect of the nonconformity.

This process is managed by the head of Quality. See **SP 8.3-01 “Control of Non Conforming Material and Product”**

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## 9. Performance Evaluation

### 9.1 Monitoring, Measurement, Analysis, and Evaluation

#### 9.1.1 General

NPD determines:

- a) what needs to be monitored and measured;
- b) the methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results;
- c) when the monitoring and measuring shall be performed;
- d) when the results from monitoring and measurement shall be analyzed and evaluated.

NPD evaluates the performance and the effectiveness of the QMS.

NPD retains the appropriate documented information as evidence of the results.

#### 9.1.2 Customer Satisfaction

NPD monitors customers' perceptions to the degree to which their needs and expectations have been fulfilled. NPD has determined the methods for obtaining, monitoring, and reviewing this information.

NOTE: Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims, and dealer reports.

Information to be monitored and used for the evaluation of customer satisfaction includes, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests. NPD has developed and implemented plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

#### 9.1.3 Analysis and Evaluation

NPD analyzes and evaluates appropriate data and information arising from monitoring and measurement.

NOTE: Appropriate data can include information on product and service problems reported by external sources (e.g., government/industry alerts, advisories).

The results of analysis are used to evaluate:

- a) conformity of products and services;
- b) the degree of customer satisfaction;
- c) the performance and effectiveness of the QMS;
- d) if planning has been implemented effectively;
- e) the effectiveness of actions taken to address risks and opportunities;
- f) the performance of external providers;
- g) the need for improvements to the QMS.


NOTE: Methods to analyze data can include statistical techniques.

See SOP-801, "Measurement, Analysis and Improvement"

### 9.2 Internal Audit

9.2.1 NPD conducts internal audits at planned intervals to provide information on whether the QMS;

- a) conforms to:

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- 1) the NPD 's own requirements for its QMS including customer and applicable statutory and regulatory QMS requirements.
  - 2) the requirements of this AS9100
- b) is effectively implemented and maintained.

NOTE: When conducting internal audits, performance indicators can be evaluated to determine whether the QMS is effectively implemented and maintained.

#### 9.2.2 NPD:

- a) plans, establishes, implements, and maintains an audit program that includes the frequency, methods, responsibilities, planning requirements, and reporting, that takes into consideration the importance of the processes concerned, changes affecting NPD, and the results of previous audits;
  - 1) define the audit criteria and scope for each audit;
  - 2) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
  - 3) ensure that the results of the audits are reported to relevant management;
  - 4) take appropriate correction and corrective actions without undue delay;
- b) retains documented information as evidence of the implementation of the audit program and the audit results.

See **WI 8.2-02 "Internal Auditing"**

## 9.3 Management Review

### 9.3.1 General

Top management reviews NPD's QMS, at least annually to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of NPD.

### 9.3.2 Management Review Inputs

The management review is planned and carried out taking into consideration:


- a) the status of actions from previous management reviews;
- b) changes in external and internal issues that are relevant to the QMS;
- c) information on the performance and effectiveness of the QMS, 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;
  - on-time delivery performance;
- d) the adequacy of resources;
- e) the effectiveness of actions taken to address risks and opportunities (see 6.1);
- f) opportunities for improvement.

### 9.3.3 Management Review Outputs

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

- a) opportunities for improvement;
- b) any need for changes to the quality management system;
- c) resource needs;
- d) risks identified.

NPD retains documented information as evidence of the results of management reviews.

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See **SP 5.0-01 “Management Responsibility”**

## 10. Improvement

See **SP 8.4-01 “Analysis of Data, Continuous Improvement and Preventive Action”**

### 10.1 General

NPD determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction.

These include:

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

NOTE: Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation, and re-organization.

### 10.2 Nonconformity and Corrective Action

10.2.1 When a nonconformity occurs, including any arising from complaints, NPD:

- a) reacts to the nonconformity and, as applicable:
  - 1) takes action to control and correct it;
  - 2) deals with the consequences;
- b) evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
  - 1) reviewing and analyzing the nonconformity;
  - 2) determining the causes of the nonconformity, including, as applicable, those related to human factors;
  - 3) determining if similar nonconformities exist, or could potentially occur
- c) implement any action needed;
- d) review the effectiveness of any corrective action taken;
- e) update risks and opportunities determined during planning, if necessary;
- f) make changes to the QMS, if necessary;
- g) flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;
- h) take specific actions when timely and effective corrective actions are not achieved.

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

NPD maintains documented information that defines the nonconformity and corrective action management processes.

10.2.2 NPD retains documented information as evidence of:

- a) the nature of the nonconformities and any subsequent actions taken;
- b) the results of any corrective action.

See **SP 8.3-01 “Control of Non Conforming Material and Product”** for detailed information

### 10.3 Continual Improvement

NPD continually improves the suitability, adequacy, and effectiveness of the QMS. NPD considers the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that need to be addressed as part of continual improvement.

NPD monitors the implementation of improvement activities and evaluates the effectiveness of the results.

NOTE: Examples of continual improvement opportunities can include lessons learned, problem resolutions, and the benchmarking of best practices.

### Change History

Revised Date	Issue #	Change	Approved By
05/20/2014	001	Initial Issue	Sam Oliva
10/23/2017	002	Updated to AS9100D, completely rewritten	Sam Oliva
01/08/2020	003	Minor corrections to address internal audit findings per Management Review 1/8/2020	Sam Oliva
02/02/2021	004	Minor clerical corrections when referencing NPD policies, forms and work instructions	Sam Oliva