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PRODUCT RESOURCES

DESIGN – BUILD – SERVICE

**Quality Management
System Manual
for ISO 9001:2015**

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Introduction

.01   General

Product Resources is a product design, engineering and manufacturing company with expertise in designing and building complex scientific and industrial equipment.

Product Resources

4 Mulliken Way

Newburyport, MA 01950

www.prodres.com

This Quality Manual specifies requirements that Product Resources uses to address customer satisfaction, to meet customer and applicable regulatory and statutory requirements and to meet ISO 9001:2015 requirements and is supported by additional procedures where necessary. The quality management principles stated in ISO 9000, and ISO 9004, have been taken into consideration during the development of this Quality Policy Manual.

This Quality Manual specifies the general requirements for Product Resources competence towards a management system for quality, administrative and technical operations

Recognizing the importance of quality, Product Resources has earned and maintained the following quality certifications:

ISO 9001-approved for engineering design, development, manufacturing and service

1   Scope

This Quality Manual specifies requirements for a quality management system where Product Resources:

a) Needs to demonstrate its ability to consistently provide product and services that meet customer and applicable statutory and regulatory requirements, and

b) Aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

2   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.

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ISO 9001:2015, Quality management systems — Fundamentals and vocabulary

3 Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

Document Note: For the following document sections and elements of the standard, Product Resources' related Tier 2 procedures, which represent Product Resources' processes, will be given in [brackets].

4 Context of the Organization

4.1 Understanding the Organization and its Context [91-9001]

Product Resources has determined external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

Product Resources monitors and reviews information about these external and internal issues.

4.2 Understanding the Needs and Expectations of Interested Parties [91-1001, 91-9001]

Due to their effect or potential effect on Product Resource's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, Product Resources determined:

a) The interested parties that are relevant to the quality management system;

b) The requirements of these interested parties that are relevant to the quality management system.

Product Resources monitors and reviews the information about these interested parties and their relevant requirements.

4.3 Determining the Scope of the Quality Management System [91-9001]

Product Resources has determined the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, Product Resources 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 Product Resources.

Product Resources applies all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

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The scope of Product Resource's quality management system is available and maintained as documented information. The scope states the types of products and services covered and provides justification for any requirements that Product Resources has determined is not applicable to the scope of its quality management system.

Conformity to ISO 9001 are only claimed if the requirements determined as not being applicable do not affect Product Resource's ability to ensure the conformity of its product and services and the enhancement of customer satisfaction.

Scope of Registration

The Scope associated with Product Resources activities and registration is:

> Design, Development, Manufacture and Service of Custom Instrumentation, Devices, Controls and Integrated Systems Using Embedded Systems, Electronic, Precision Mechanical, Optical, and Pneumatic Technologies

4.4 Quality Management System and its Processes

4.4.1 Product Resources has established, implemented, maintains, and continually improves a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard. **[91-9003]**

Product Resources has determined the processes needed for the quality management system and their application throughout Product Resources, and

a) Determined the inputs required and the outputs expected from these processes;

b) Determined the sequence and interaction of these processes;

c) Determined and applied 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) Assigns the responsibilities and authorities for these processes;

f) Addresses the risks and opportunities as determined in accordance with the requirements of 6.1;

g) Evaluates these processes and implement any changes needed to ensure that these processes achieve their intended results.

h) Improves the processes and the quality management system.

4.4.2 To the extent necessary, Product Resources:

a) Maintains documented information to support the operation of its processes **[91-6001]**

b) Retain documented information to have confidence that the processes are being carried out as planned **[91-6002]**

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5 Leadership

5.1 Leadership and Commitment

5.1.1 General [91-9002, 91-9004, 91-9005]

Top management demonstrates leadership and commitment with respect to the quality management system by:

a) Taking accountability for the effectiveness of the quality management system;

b) Ensuring that the quality policy and quality objectiveness are established for the quality management system and are compatible with the context and strategic direction of Product Resources;

c) Ensuring the integration of the quality management system requirements into Product Resource's business process;

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 quality management system;

i) Promoting improvement; and

j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer Focus [91-1001, 91-1003, 91-9005]

Top management demonstrates 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; and

c) The focus on enhancing customer satisfaction is maintained.

5.2 Policy [91-9002]

5.2.1 Developing the Quality Policy [91-9005]

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

a) Is appropriate to the purpose and context of Product Resources and supports its strategic direction;

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b) Provides a framework for setting quality objectives;

c) Includes a commitment to satisfy applicable requirements; and

d) Includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the Quality Policy

The Quality Policy:

a) is available and maintained as documented information;

b) is communicated, understood and applied within the organization; and

c) is available to relevant interested parties, as appropriate.

5.3 Organizational Roles, Responsibilities, and Authorities

Top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within Product Resources.

Top management assigns the responsibility and authority for:

a) Ensuring that the quality management system 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 quality management system and on opportunities for improvement (see 10.1), in particular to top management;

d) Ensuring the promotion of customer focus throughout Product Resources; and

e) Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

6 Planning

6.1 Actions to Address Risks and Opportunities

6.1.1 When planning for the quality management system, Product Resources considered the issues referred to in 4.1 and the requirements referred to in 4.2 and determined the risks and opportunities that need to be addressed to:

a) Give assurance that the quality management system can achieve its intended results;

b) Enhance desirable effects;

c) Prevent, or reduce, undesired effects; and

d) Achieve improvement.

6.1.2 Product Resources plans:

a) Actions to address these risks and opportunities;

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b) How to:

    1. Integrate and implement the actions into its quality management system processes (See 4.4)

    2. Evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of products and services.

6.2 Quality Objectives and Planning to Achieve Them [91-9004, 91-9005]

6.2.1 Product Resources has established quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives are:

a) Consistent with the quality policy;

b) Measurable;

c) Taken into account applicable requirements;

d) Relevant to conformity of products and services and to enhancement of customer satisfaction;

e) Monitored;

f) Communicated; and

g) Updated as appropriate.

Product Resources maintains documented information on the quality objectives.

6.2.2 When planning how to achieve its quality objectives, Product Resources has determined:

a) What will be done;

b) What resources will be required;

c) Who will be responsible;

d) When it will be completed; and

e) How the results will be evaluated.

When the quality objective is a significant change to the QMS, see also **[91-9001]** for guidance that Product Resources has put in place.

6.3 Planning of Changes [91-9001, 91-9005]

When Product Resources determines the need for changes to the quality management system, the changes are carried out in a planned manner (see 4.4).

Product Resources considers:

a) The purpose of the changes and their potential consequences;

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b) The integrity of the quality management system;

c) The availability of resources; and

d) The allocation or reallocation of responsibilities and authorities.

7   Support

7.1   Resources

7.1.1   General [91-9005]

Product Resources determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

Product Resources considers:

a) The capabilities of, and constraints on, existing internal resources; and

b) What needs to be obtained from the external providers.

7.1.2   People [91-9005]

Product Resources determines and provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3   Infrastructure [91-7005, 91-8001, 91-9005]

Product Resources determines, provides, and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services.

a) Buildings and associated utilities;

b) Equipment, including hardware and software;

c) Transportation resources; and

d) Information and communication technology.

7.1.4   Environment for the Operation of Processes [91-4004]

Product Resources determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services.

a) Social (e.g. non-discriminatory, calm, non-confrontational);

b) Psychological (e.g. stress reducing, burnout prevention, emotionally protective);

c) Physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

7.1.5   Monitoring and Measuring Resources

7.1.5.1   General [91-4001, 91-7004]

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Product Resources determines and provides 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.

Product Resources ensures that the resources provided:

a) Are suitable for the specific type of monitoring and measurement activities being undertaken; and

b) Are maintained to ensure their continuing fitness for their purpose.

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

7.1.5.2 Measurement Traceability [91-7004]

When measurement traceability is a requirement, or is considered by Product Resources to be an essential part of providing confidence in the validity of measurement results, measuring equipment are:

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 is retained as documented information;

b) Identified in order to determine their status; and

c) Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

Product Resources determines if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose and takes appropriate action as necessary.

7.1.6 Organizational Knowledge [91-8002]

Product Resources determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge is maintained and made available to the extent necessary.

When addressing changing needs and trends, Product Resources considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence [91-8002]

Product Resources:

a) Determines the competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;

b) Ensures that these persons are competent on the basis of appropriate education, training, or experience;

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c) Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; and

d) Retain appropriate documented information as evidence of competence.

7.3   Awareness [91-8002]

Product Resources ensures that persons doing work under Product Resources control are aware of:

a) The Quality Policy;

b) Relevant quality objectives;

c) **Their contribution to the effectiveness of the quality management system, including the benefits of improved performance**; and

d) **The implication of not conforming with the quality management system requirements.**

7.4   Communication [91-1003]

Product Resources determines the internal and external communications relevant to the quality management system, including:

a) On what it will communicate;

b) When to communicate;

c) With whom to communicate;

d) How to communicate; and

e) Who communicates.

7.5   Documented Information [91-6001, 91-6002, 91-6005]

7.5.1   General

Product Resource's quality management system includes:

a) Documented information required by ISO 9001:2015; and

b) Documented information determined by Product Resources as being necessary for the effectiveness of the quality management system.

7.5.2   Creating and Updating

When creating and updating documented information, Product Resources ensures appropriate:

a) Identification and description (e.g. title, date, author, or reference number);

b) Format (e.g. language, software version, graphics) and media (e.g. paper, electronic); and

c) Review and approval for suitability and adequacy.

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7.5.3 Control of Documented Information

7.5.3.1 Documented information required by the quality management system and by ISO 9001:2015 are controlled to ensure:

   a) Availability and suitable for use, where and when it is needed; and

   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, Product Resources 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); and

   d) Retention and disposition.

Documented information of external origin determined by Product Resources to be necessary for the planning and operation of the quality management system is identified as appropriate and controlled.

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

8 Operation

8.1 Operational Planning and Control

Product Resources planned, implemented and controls the processes (see 4.4) needed to meet the requirements for the provision of products and services, and implemented the actions determined in Clause 6, by:

   a) Determining the requirements for the products and services;

   b) Establishing criteria for:

      1. The processes;

      2. The acceptance of products and services;

   c) Determining the resources needed to achieve conformity to the product and service requirements;

   d) Implementing control of the processes in accordance with the criteria; and

   e) Determining and keeping documented information to the extent necessary:

      1. To have confidence that the processes have been carried out as planned;

      2. To demonstrate the conformity of products and services to their requirements.

The output of this planning is in a form suitable to Product Resource's method of operations.

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Product Resources ensures that outsourced processes are controlled (See 8.4).

8.2   Requirements for Products and Services

8.2.1   Customer Communication [91-1003]

Communication with Customers includes:

a)   Providing information relating to products and services;

b)   Handling inquiries, contracts or orders, including changes;

c)   Obtaining customer feedback relating to products and services, including customer complaints;

d)   Handling or controlling customer property; and

e)   Establishing specific requirements for contingency actions, when relevant.

8.2.2   Determining the Requirements Related to Products and Services [91-1001]

When determining the requirements for the product and services to be offered to customers, Product Resources ensures that:

a)   The requirements for the product and services are defined, including:

    a)   Any applicable statutory and regulatory requirements;

    b)   Those considered necessary by Product Resources;

b)   Product Resources can meet the claims for the product and services it offers.

8.2.3   Review of Requirements Related to Products and Services [91-1002]

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

a)   Requirements specified by customer, including the requirements for delivery and post-delivery activities;

b)   Requirements not stated by the customer, but necessary for the specified intended use, when known;

c)   Requirements specified by Product Resources;

d)   Statutory and regulatory requirements applicable to the products and services; and

e)   Contract or order requirements differing from those previously expressed.

Product Resources ensures that the contract or order requirements differing from those previously defined are resolved.

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

8.2.3.2 Product Resources retains documented information, as applicable:

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a) On the results of the review; and

b) On any new requirements for the products and services;

8.2.4 Changes to Requirements for Products and Services [91-1002, 91-1003]

Product Resources 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 [91-2001, 91-2002, 91-2003]

8.3.1 General [91-2001]

Product Resources has established, implemented, and maintains a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.2 Design and Development Planning [91-2001]

In determining the stages and controls for design and development, Product Resources considers:

a) The nature, duration, and complexity of the design and development activities;

b) The required process stages, including applicable design and development reviews;

c) The required design and development verification and validation activities; **[91-2002]**

d) The responsibilities and authorities involved in the design and development process; **[91-2002, 91-2003]**

e) The internal and external resource needs for the design and development of products and services;

f) The need to control interfaces between persons involved in the design and development process;

g) The need for involvement of customers and users in the design and development process;

h) The requirements for subsequent provisions of products and services;

i) The level of control expected for the design and development process by customer and other relevant interested parties; and

j) The documented information needed to demonstrate that design and development requirements have been met.

8.3.3 Design and Development Inputs [91-2001]

Product Resources determines the requirements essential for the specific types of products and services to be designed and developed. Product Resources considers:

a) Functional and performance requirements;

b) Information derived from previous similar design and development activities;

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    c) Statutory and regulatory requirements;

    d) Standards or codes of practice that Product Resources has committed to implement; and

    e) Potential consequences of failure due to the nature of the products and services. **[91-2003]**

Inputs are adequate for design and development purposes, complete, and unambiguous. Conflicting design and development inputs are resolved.

Product Resources retains documented information on design and development inputs.

8.3.4 Design and Development Controls [91-2001, 91-2002]

Product Resources applies controls to the design and development process to ensure that:

    a) The results achieved are defined,

    b) Reviews are conducted to evaluate the ability of the results of design and development meet requirements;

    c) Verification activities are conducted to ensure that the design and development outputs meet the input requirements;

    d) Validation activities are conducted to ensure that the resulting products and service meet the requirements for the specified application or intended use;

    Note that, while Product Resources has put in place procedures addressing validation, Product Resources performs little validation, as validation is typically in our customer's scope of work. As for verification and validation, Product Resources primarily performs verification.

    Note further that validation of process is handled separately; the above refers to validation of product.

    e) Any necessary actions are taken on problems determined during the reviews, or verification and validation activities; and

    f) Documented information of these activities is retained.

8.3.5 Design and Development Outputs

Product Resources ensures that design and development outputs:

    a) meet the input requirements; **[91-2002]**

    b) are adequate for the subsequent processes for the provision of products and services; **[91-2002]**

    c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;

    d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

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The Product Resources retains documented information on design and development outputs.

8.3.6 Design and development changes

Product Resources identifies, reviews, and controls changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

Product Resources retains documented information on:

a) Design and development changes;

b) The results of reviews;

c) The authorization of the changes; and

d) The actions taken to prevent adverse impacts. **[91-2003]**

8.4 Control of Externally Provided Processes, Products, and Services [91-3001, 91-3002, 91-3003]

8.4.1 General [91-3001]

Product Resources ensures that externally provided processes, products, and services conform to requirements.

Product Resources determines the control applied to externally provided processes, products, and services when:

a) Products and services from external providers are intended for incorporation into Product Resource's own products and services;

b) Products and services are provided directly to the customer(s) by external providers on behalf of Product Resources; and

c) A process, or part of a process, is provided by an external provider as a result of a decision by Product Resources.

Product Resources 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. Product Resources retains documented information of these activities and any necessary actions arising from the evaluations.

8.4.2 Type and Extent of Control [91-3001]

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

Product Resources:

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a) Ensures that externally provided processes remain within the control of its quality management system;

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 Product Resource's ability to consistently meet customer and applicable statutory and regulatory requirements;

2. The effectiveness of the controls applied by the external provider;

d) Determines the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3 Information for External Providers [91-3002]

Product Resources ensures the adequacy of requirements prior to their communication to the external provider.

Product Resources communicates to external providers its requirements for:

a) The processes, products and services to be provided;

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 Product Resources;

e) Control and monitoring of the external providers' performance to be applied by Product Resources; and

f) Verification or validation activities that Product Resources, or its customer, intends to perform at the external providers' premises.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision [91-1004, 91-4001, 91-5001, 91-6004, 91-7006]

Product Resources implements production and service provision under controlled conditions.

Controlled conditions include, as applicable:

a) The availability of documented information that defines:

1. The characteristics of the products to be produced, the services to be provided, or the activities to be performed;

2. The results to be achieved;

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;

d) The use of suitable infrastructure and environment for the operation of processes; **[91-4004, 91-8001]**

e) The appointment of competent persons, including any required qualification;

f) 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;

g) The implementation of actions to prevent human error; and

h) The implementation of release, delivery and post-delivery activities.

Note that Product Resources does not perform installation, and installation is excluded from its scope.

Product Resources does provide service depot and field service services; these are in Product Resources' scope.

8.5.2 Identification and Traceability [91-6003]

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

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

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

8.5.3 Property Belonging to Customers or External Providers [91-1003, 91-3001, 91-3002]

Product Resources exercises care with property belonging to customer or external providers while it is under Product Resource's control or being used by Product Resources.

Product Resources identifies, verifies, protects and safeguards customer's 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, Product Resources reports this to the customer or external provider and retains documented information on what has occurred.

8.5.4 Preservation [91-4003]

Product Resources preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

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8.5.5   Post-delivery Activities [91-5001]

Product Resources meets requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, Product Resources 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; and

e)   Customer Feedback.

8.5.6   Control of Changes

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

Product Resources 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 Service [91-4001, 91-5001]

Product Resources 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, do not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

Product Resources retains documented information on the release of products and services. The documented information includes:

a)   Evidence of conformity with the acceptance criteria;

b)   Traceability to the person(s) authorizing the release.

8.7   Control of Nonconforming Outputs [91-4002]

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

Product Resources takes appropriate action 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.

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

a)   Correction;

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b) Segregation, containment, return or suspension of provision of products and services;

c) Informing the customer; and

d) Obtaining authorization for acceptance under concession.

Conformity to the requirements are verified when nonconforming outputs are corrected.

8.7.2 Product Resources retains documented information that:

a) Describes the nonconformity;

b) Describes the actions taken;

c) Describes any concessions obtained; and

d) Identifies the authority deciding the action in respect of the nonconformity.

9 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General [91-7001, 91-9004]

Product Resources 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 is performed;

d) When the results form monitoring and measurement are analyzed and evaluated.

Product Resources evaluates the performance and the effectiveness of the quality management system.

Product Resources retains appropriate documented information as evidence of the results.

9.1.2 Customer Satisfaction [91-1003]

Product Resources monitors customers' perceptions of the degree to which their needs and expectation have been fulfilled. Product Resources determines the methods for obtaining, monitoring and reviewing this information.

9.1.3 Analysis and Evaluation [91-9004]

Product Resources analyzes and evaluates appropriate data and information arising from monitoring and measurement.

The results of analysis are used to evaluate:

a) Conformity of products and services;

b) The degree of customer satisfaction;

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    c) The performance and effectiveness of the quality management system;

    d) If planning has been implemented effectively;

    e) The effectiveness of actions taken to address risks and opportunities;

    f) The performance of external providers; and

    g) The need for improvements to the quality management system.

9.2   Internal Audit [91-7001]

9.2.1   Product Resources conducts internal audits at planned intervals to provide information on whether the quality management system:

    a) Conforms to:

        1. Product Resources' own requirements for its quality management system;

        2. The requirements of ISO 9001:2015

    b) Is effectively implemented and maintained.

9.2.2   Product Resources has:

    a) Planned, established, implemented and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which is taken into consideration the importance of the processes concerned, changes affecting Product Resources, and the results of previous audits;

    b) Defined the audit criteria and scope of each audit;

    c) Selected auditors and conducts audits to ensure objectively and the impartiality of the audit process;

    d) Ensured that the results of the audits are reported to relevant management;

    e) Take appropriate correction and corrective actions without undue delay; and

    f) Retain documented information as evidence of the implementation of the audit program and the audit results.

9.3   Management Review [91-9005]

9.3.1   General

Top management reviews Product Resources' quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of Product Resources.

9.3.2   Management Review Inputs

Management review is planned and carried out taking into consideration:

    a) The status of actions from previous management reviews; (91-9005: 4.6.1)

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b) Changes in external and internal issues that are relevant to the quality management system; (91-9005: 4.6.8, 4.6.9, 4.6.10)

c) Information on the performance and effectiveness of the quality management system, including trends in:

1. Customer satisfaction and feedback from relevant interested parties; (91-9005: 4.6.3, 4.6.4, 4.6.9, 4.6.10)

2. The extent to which quality objectives have been met; (91-9005: 4.6.5, 4.6.6)

3. Process performance and conformity of products and services; (91-9005: 4.6.5, 4.6.6)

4. Nonconformities and corrective actions; (91-9005: 4.6.6, 4.6.7)

5. Monitoring and measurement results; (91-9005: 4.6.5, 4.6.6)

6. Audit results; (91-9005: 4.6.2, 4.6.3, 4.6.9, 4.6.10)

7. The performance of external providers; (91-9005: 4.6.5, 4.6.6)

d) The adequacy of resources; (91-9005: 4.6)

e) The effectiveness of actions taken to address risks and opportunities (see 6.1); (91-9005: 4.6.13) and

f) Opportunities for improvement (91-9005: 4.6)

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; and

c) Resource needs.

Product Resources retains documented information as evidence of the results of management reviews.

10 Improvement

10.1 General [91-9005]

Product Resources 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; and

c) Improving the performance and effectiveness of the quality management system.

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10.2 Nonconformity and Corrective Action [91-4002, 91-7002, 91-7003]

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

    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;

        3. Determining if similar nonconformities exist, or could potentially occur;

    c) Implements any action needed;

    d) Reviews the effectiveness of any corrective action taken;

    e) Updates risks and opportunities determined during planning, if necessary; and

    f) Makes changes to the quality management system, if necessary.

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

10.2.2 Product Resources retains documented information as evidence of:

    a) The nature of the nonconformities and any subsequent actions taken; and

    b) The results of any corrective action.

10.3 Continual Improvement [91-7002, 91-7003, 91-9005]

Product Resources continually improves the suitability, adequacy and effectiveness of the quality management system.

Product Resources considers the results of analysis and evaluations, and the outputs from the management review, to determine if there are needs or opportunities that are addressed as part of the continual improvement.