Controls to Prevent Delivery of Nonconforming Product and Services

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Agenda

- Nonconformance Definition? Nonconformance versus Noncompliance

- View Nonconforming as an Output either in a Product or Services context

- Control of Nonconforming Outputs Requirements

- Detecting the Nonconforming Outputs

- Control of Nonconforming Output Responsibility & Authority

- Control of Nonconforming Output – Determination of Disposition

- Risk Management and Philosophies

What is the definition of Nonconformance?

Merriam-Webster Dictionary:

- Failure to conform.

International Aerospace Quality Group:

- A condition of any article, material or service in which one or more characteristics do not conform to requirements specified in the contract, drawings, specifications, or other approved product description. Includes failures, discrepancies, defects, anomalies, and malfunctions.

- Parts or materials that do not meet specifications or requirements. The failure of a characteristic to conform to the requirements specified in the contract, drawings, specifications, or other approved product description.

Nonconformance versus Noncompliance

Non-conformance:

- Is the failure to comply with a requirement (internal or external), standard or process/procedure.

Non-compliance:

- Is the failure to adhere to an Act or its Regulations.

Control of Nonconforming Outputs Requirements

As soon as nonconforming outputs are detected within the organization, they must be identified, recorded, and controlled; and most importantly, they must be treated. The objective is to prevent the release, delivery, or use of nonconformed products or services by the customers. Treating and managing nonconformities should be one of the basic objectives of any organization.

Nonconforming outputs refer to the outputs of processes that do not fulfill a requirement that is a need or an expectation of one of the interested parties of the organization that is stated, implied, or obligated. Controlling the nonconforming outputs is planning activities for detecting nonconforming outputs and deciding what is to be done with them.

Control of Nonconforming Outputs Requirements

When planning the process for handling nonconforming products, the next issues are expected:

- The organization should maintain a documented procedure that describes the method of detecting and controlling non conforming products/service. The documentation of the procedure must be controlled and introduced to the documents control process in the organization as required in paragraph 4.2.4 – control of documents

- As soon as a non conforming product/service was detected and must be segregated from other products/services. The organization must initiate an action in order to identify and eliminate the use of non conforming product/service.

- Releasing a non conforming product/service must be approved by a prior authorized function. The release would be under concession. Concession can be made by an authorized person or by the customer but anyway documented

Control of Nonconforming Outputs Requirements

- The organization is required to maintain records that describe the nonconformities detected and the actions that were taken to eliminate them. The records are to be introduced to the records control process as required in paragraph 4.2.5– control of records

- When nonconformity is detected after delivering the product/service, actions must be taken relevant to the nature of the nonconformities

- When a nonconforming product/service was re-processed, it must be re-validated in order to ensure that it meets the requirements (customer's or regulatory).

Detecting the Nonconforming Outputs

- A Nonconforming output: a product or process result that does not conform to its specified requirements:

- Customer's requirements: Functionality or intended use requirements

- Regulatory requirements

We may look at it in another way: nonconformity is where a result was not achieved according to a specific requirement. The requirement refers to both products that were detected in house and products that were already delivered to the customer.

Controlling the nonconforming outputs will allow the organization to minimize their effect. Nonconformance can occur in raw materials, components, in goods that are in process or finished goods, or service operations. When nonconforming outputs are detected, the first step is to identify them. In order to effectively identify nonconforming outputs, one must understand which quality tools will indicate that a process output is nonconforming.

Detecting the Nonconforming Outputs

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Typical we see the following controls within an organization.

- Verification activities

- Monitoring, measurement, analysis, and evaluation activities

- Controls of external providers

- Release activities

Identifying the Nonconforming Outputs

After identifying the nonconforming outputs, the organization must identify them as a means of classifying them. The standards specifically demand the identification of nonconforming outputs in an objective manner. This means that each nonconforming product or service will be identified independently (physically as well as logically). The objective of the classification is to prevent the use of those outputs before it is decided what is to be done with them

Control of Nonconforming Output Responsibility & Authority

The organization is required to determine the authorities and responsible parties to handle nonconforming products/services. The definition shall refer to all stages of the process; from the detection of the nonconforming product/service until the closure of the case. The definition should be documented in the required procedure mentioned in the previous slide. (6)

Control of Nonconforming Output – Determination of Disposition

An organization shall take immediate necessary action regarding the nonconforming product/service. The following are examples of disposition:

- Segregation of the nonconforming product

- Notification to the customer

- Notifications to the relevant parties; organizational, internal, external, or governmental

- Short term and long term corrective action

You may determine the method according to the nature of your product or service but you must document it. Everybody must know what they are required to do when a nonconforming product/service is detected; service call center, the logistics, salesmen, production manager, quality manager – everybody who is related and has a part in the realization of the product/service.

Risk Management Concepts & Philosophies

What is risks?

An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence. (ISO 31000)

The organization should deploy is risk management process, concepts and/or philosophies to address potential and past nonconformance outputs for product/service.

What is risk management?

An iterative process to identify, assess, reduce, accept, and control risks in a systematic, proactive, comprehensive and cost effective manner, taking into account the business, costs, technical, quality and schedule programmatic constraints.

Risk Management Concepts & Philosophies

Why do you want risk management?

To reduce the chances of something harmful happening to the business. This involves a focus on the risks to meeting customer requirements, and preventing product non conformance escapes. The absence of a Risk Management program can result in known, unknown, and unknowable /unforeseen problems for the Customer and Stakeholders concerning the cost, schedule, and technical performance of programs and concerning the quality and on-delivery performance of products and services.

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Risk Management Concepts & Philosophies

Why does your "Risk Management Program" do?

Describes your organization's attitude and approach towards risks, how it conducts risk management, the risks it is prepared to accept and how it plans on dealing with those it chooses not to accept and defines the main requirements for a risk management plan.

Your Risk Management Program will help in the following:

- to identify risks

- to reduce occurrences and impacts of risks

- to understand significance/severity of risks

- to promote organizational behaviors focused on risk management

- to increase effectiveness of product and service delivery to customer

Risk Management Concepts & Philosophies

Why does your "Risk Management Program" do?

- Helps your organization maintain information on historic issues

- Helps capitalize on historic issues to prevent future issues

- Helps your organization bring out hidden risk knowledge, so it can be managed

Risk Management Concepts & Philosophies

What are the elements of a "Risk Management Program"?

Risk Management Concepts & Philosophies

Types of identification tools

- Checklist for process assessment

- Key process indicators

- Design process audit

- FMEA (Failure Modes and Effect Analysis)

- Lesson's Learned

- Design of Experiments

- Review of current development plan

- Review of operational plan for product realization.

- Tolerance analysis

Risk Management Concepts & Philosophies

- Regardless of any other considerations, an organization can decide that the business risk or potential liability is great enough to treat products/services as nonconforming at any particular stage of the process.

- Even given these guidelines, an organization may discover a considerable amount of gray area regarding what is or isn't nonconforming product/service. This is only natural and a reflection of the real-life complexities of business. The organization must look objectively at its own operations, analyze its unique risk factors and decide what will be included within its system for nonconforming products/services. Some situations will be quite obvious, and others won't. But, remember, these interpretations are only opinions, and common sense should always prevail.

Do You Have Any Questions?