Step 6

ISO9001:2015 -Risk Based Planning Construct a Risk Based Planning Management Procedure

Introduction

In this fifth workshop module we will look at how to construct a documented risk based planning management procedure

By the end of this module you will be able to

- Format a document
- Define the document objective
- Define the document purpose
- State the document scope
- Construct a document procedure

Define the Objective

The first element is to define a clear and transparent objective

Objective example

To ensure a risk based planning approach is carried for the introduction of new or a changed to a product is formally planned, in order to control the input risks and mitigate the output impacts so the customer's and stake holders requirements are meet.

State the Purpose

The second element is to state the purpose

Purpose example

The purpose of this procedure is to define the methods by which the company identifies the activities within the Program Management Quality System

Define the Scope

The third element is to define the scope

Scope example

This document applies to all new and changes to products introduced and also all changes which take place to existing products and processes during their manufacturing .

Management Review Board

The forth element is to define the procedure

Procedure example

Step 1

The management review board will sit every two weeks to review the programme and assess new opportunities.

The board will consists of the following members:

Managing Director, Sales Director, Production Director, Design Product Director , Purchase Director & Customer H R Director

Feasibility study

Step 2

The management review board appoints a project leader

Project Leader

Step 3

All projects must under go a feasibility study.

Resource Support

Step 4

The management review board reviews the resources required and gives approval for tooling and equipment.

Risk Evaluation Assessment

Step 5

All critical product and processes will go through a risk evaluation assessment process. Refer to slide 12

Review Meeting Minutes

Step 6

Minutes from the management review board meetings will be issued to all attendees and relevant personnel nominated for the action

Risk Evaluation Process

Purpose

The purposes of this documented to define the methodology that is used and the controls that are in place for carrying out a risk evaluation of a process, to establish what type of risk enablers are in place and to prioritie these risk enablers, to put in place improvement actions that will remove, reduce or control the process risk enablers.

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Terms and Definitions

A risk evaluation will be carried out when the following takes place:

- When a new process is introduced.
- When a change to a process takes place.
- When a deviation from a process is requested.
- When process non-conformity is found.
- A process risk evaluation is carried out by a competent person who understands the process inputs and outputs and has under gone risk evaluation training.

Terms and Definitions

A process risk evaluation is carried out by a competent person who understands the process inputs and outputs and has under gone risk evaluation training.

A process risk evaluation can only take place when the process inputs and outputs have been mapped out and the input supplier and output customer are known.

The risk evaluation must be documented on form FMEA

Risk Enablers

A risk enabler is a process activity that is not controlled or that the controls in place are not effective at controlling the risk before it happens. There are two types of risk enablers a people enabler and a systems enabler

Risk Methodology Vocabulary

The methodology that will be used will be based on the following vocabulary:

- **Severity** - the seriousness of the effect of the failure mode to the process output
- **Occurrence** – rate of the likelihood that the specific causes will happen while the process performs
- **Detection -** the current process controls will detect the failure mode before it is too late (e.g., the risk will be stopped before it moves onto the next process step)

Risk Methodology Scoring

- On Severity, Occurrence and Detection a scoring of 1 - 10 rating is used.
- A score of 1 there is less than a 1% chance that the risk enabler will not be activated.
- A score of 10 there is a 99% chance that the risk enabler will be activated.
- NB: **Detection:**
- where there are people controls in place the score rating is 6-10.
- where there is a system controls in place the score rating is 1-5.

Risk Priority Number (RPN)

- The risk priority number or RPN; is the product of the severity x occurrence x detection
- When the all RPNs have been calculated and failure modes have been rank ordered.
- Corrective actions must be initiated against a RPN of 100 or agreed by the interested parties
- The objective of the actions is to reduce any one or all of the severity, occurrence and
- detection scoring ratings.

Process Risk Evaluation

When a process risk evaluation is activated it must be managed and controlled by the process holder who must be trained and competent in carrying out a risk evaluation.

Where required, the process holder will call cross-functional representations from the input supplier, outgoing customers and also the QMS manager. This is to ensure full process transparency has been covered.

When a RPN is greater than 100 or is greater than the score agreed by the output customer then actions must be put in place to reduce the RPN and a time frame agreed, when this will be implemented and re-scored

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When the process risk evaluation has been completed the FMEA documented must be sent to the QMS manager for review and approval.

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Example of a Documented Risk Based Planning Procedure

Ridgeway Ltd	**Title: Risk Based Planning**		
	Procedure No: 4.2 (Level 2)	**Revision Date:**	**Issue Number: 1**
	Department: All Departments	**Approval: MD**	**Page: 1 of 8**
Objective	To ensure that the implement of a quality risk based planning system is documented for the introduction of new or changed products are formally planned, in order to mitigate risk and meet the customer's requirements		
Purpose	The purpose of this procedure is to define the methods by which the company identifies the activities within the Program Management Quality System		
Scope	This procedure applies to all new processes/products introduced and also all changes which take place to existing products/processes during their manufacturing .		
Authority	Managing Director		

Responsibility		Flow		Remarks
1	Management Review Team	1	Management Board (MRB) sit every two weeks	1/2. The Management Review Broad Consists of the following members Managing Director, Sales Director, Production Manager, Product Manager, Purchase Manager & Customer Service Manager & H R Manager The teams review the programme every2 Weeks
2	Management Review Team	2	MRB review current or new projects	
3	Management Review Team	3	Does project follow TS16949 Route → YES: refer to QP 4.2. Page 4 APQP; NO	3. When the project is to follow Refto APQP page 4 and (APQP manual)
4	Management Review Team	4	Is a Feasibility Study required → YES: Referto QP 4.2 Page 3 Feasibility Study; NO	4. All projects must under go a feasibility study Ref to4.2 page 3 and WI 1234 level 3
5	Management Review Team	5	MRB appoint Project Leader Ref to Program Management 4.2 page 2	5. MRB appoints reviews management program and appoints project leader Refto: 4.2 page 2
6	Management Review Team	6	Allocates Resources and Approval & Installation of Tooling & Equipment Refto 4.2 page 8	6. The MRB reviews the resources required and gives approval for tooling and equipment.
7	Production Control/ Relevant Departments	7	All Changes to product and processes. Ref to: Control of Product & Process Changes 4.2 page 8	7 All critical product and processes will go through a control process. Refto 4.2 page 8
8	Management Review Team	8	Meeting Minutes issued to all attendees & other personnel nominated for action	8 Minutes of all MRB meetings are issued to all attendees and relevant personnel nominated for the action
9	Management Review Team	9	Relevant Board member report on progress at next review meeting	9 The nominated personnel report on progress at next meeting
10	Product Engineering Administrator	10	All meeting minutes of MRB are issued and retained by	10 All minutes are retained within MRB file

Audits	Is subject to Audit as listed in procedure xxxx		
Records	Amendment requests and the master manual and Procedures are stored in the Quality Department (refer to QP xxxx)		
Reference	BS EN ISO 9001:2015 Section XYZ, and Procedure Manual (level 2) section 4.2		
Procedure No: XYZ (Level 2)	**Operation Director.....**	**Date:**	**Issue No: 1**

End of Workshop

This now completes the risk based planning, right first time workshop.

I hope you enjoyed and found the workshop useful

Please do not hastate to contact me if you require my service in implementing ISO9001:2015 or a risk based planning process.

My contact details are

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