



QAD Adaptive Applications

User Guide
QAD EQMS Applications:
Design Control

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Design Control User Guide

Change Summary

The following table summarizes significant differences between this document and previous versions.

Date/Version	Description	Reference	Changed By
MAY 2020/v2020	Initial upload	--	RQT
OCT 2020/v2020.1	<p>Rebranded for 2020.1;</p> <p>Added new processes (Design Risk Analysis Library; Design Risk Structural Analysis Library, Design Risk Systems Library, Risk Action Priority, Process Risk Structural Analysis Library, Project Identification Question Design Risk, Project Identification Question Process Risk);</p> <p>Renamed existing processes (Design Risk Mode Control Library >> Design Risk Control Methods, Control Methods >> Process Risk Control Methods, Library Process Risk >> Process Risk Failure Analysis Library);</p> <p>Removed processes that no longer exist (Design Risk Library Functions, Design Risk Function Requirements Library);</p> <p>Added information about changes that support the harmonized 2019 AIAG/VDA risk plan handbook design risk and process risk functionality (AIAG 4th Edition is still supported)</p>	p. 104, p. 101, p. 85, p. 79, p. 108, p. 49, p. 50, p. 52, p. 52, p. 111, p. 116, p. 134, p. 20, p. 66, p. 83, p. 212	RQT
MAR 2021/v2021	Updated linkage	--	RQT
MAY 2021/v2021	Added a section for Commands	p. 243	RQT
SEPT 2021/v2021.1	<p>Updated versioning;</p> <p>Added ITAR information to Processes, Library Specifications, Process Risk Structural Analysis Library, Process Risk Failure Analysis Library, Family Templates, and Manufacturing Documents.</p>	p. 87, p. 95, p. 108, p. 111, p. 116, p. 134	RQT
MAR 2022/v2022	<p>Updated versioning;</p> <p>Added a section for the Graphical Risk Tree View;</p> <p>Updated Manufacturing Documents.</p>	p. 83, p. 134	RQT

Date/Version	Description	Reference	Changed By
SEPT 2022/v2022.1	Updated versioning; Added new processes (Project Identification Question FMEA-MSR; FMEA-MSR Monitoring Control Methods; FMEA-MSR System Responses; FMEA-MSR Frequency Criteria; FMEA-MSR Monitoring Criteria; FMEA-MSR Action Priority); Updated Manufacturing Documents	p. 51, p. 53, p. 59, p. 77, p. 78, p. 80, p. 134	RQT
MAR 2023/v2023	Updated versioning	--	RQT
MAR 2024/v2024	Updated versioning	--	RQT
SEPT 2024/v2024.1	Updated versioning; Updated Manufacturing Documents	p. 134	RQT
MAR 2025/v2025	Updated versioning; Updated Manufacturing Documents; Updated Commands	p. 134, p. 243	RQT
SEPT 2025/v2025.1	Updated versioning; Listed new tree view: Control Plan Only PFMEA	p. 83,	F6J
SEPT 2026/v2026	Updated versioning		F6J

Chapter 1

Introduction

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Overview

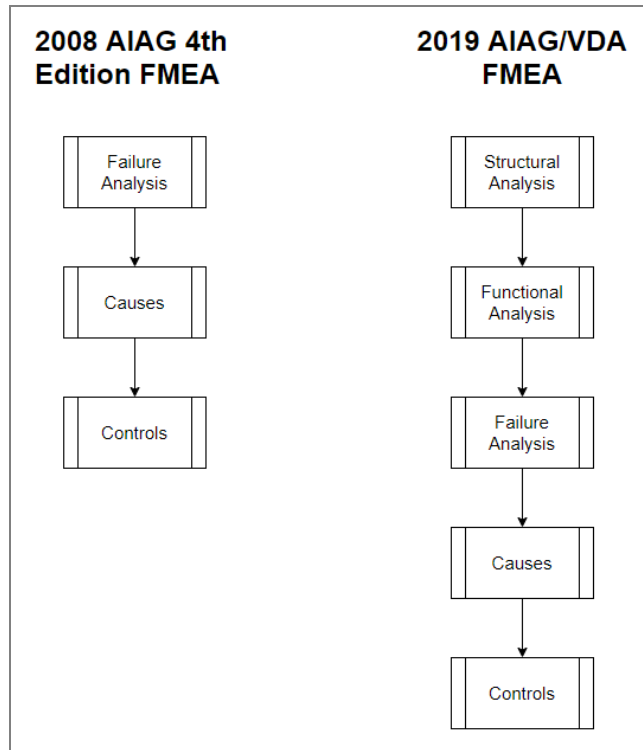
Design Control is a structured method of defining and establishing the steps necessary to ensure that a product satisfies the customer's requirements for performance and timing. Communication should be facilitated with everyone involved to assure that all required steps are completed on time. Design Control depends on a company's top management commitment to the effort required in achieving customer satisfaction.

Design Control is important because the bulk of a product's cost is committed to the early stages; creating an effective design and avoiding faulty decisions is essential to avoid incurring costs due to changes later. Not only is it costly to fix a design after product launch, but the opportunity costs of being late to market are very high. Additionally, cross-functional teams provide a better quality solution to complex product development problems than individuals.

Today, it is impossible to manage quality or meet Production Part Approval Process (PPAP) requirements using disconnected spreadsheets that are manually updated, printed, and stored in folders. Documentation needs to be linked to consistently reflect real-time data and communicate changes to stakeholders quickly. In addition, project management teams need the ability to track program status, measure against a project plan, and control new product development risks.

Some EQMS processes within the Design Control module allow users to decide whether they want to work with the 2008 AIAG 4th Edition risk formats or the 2019 AIAG/VDA risk formats. The starting point for these two formats differ; 4th edition risks begin at the Failure Analysis level, while risks using the new AIAG/VDA mode begin at the Structural Analysis level and complete the Functional Analysis before moving on to the Failure Analysis. In both formats, after the analyses are complete, users proceed to Causes, then Concerns. See "Design Control Level 2 Libraries" on page 83 for a more detailed explanation of each workflow.

Fig. 1: Work flow comparison



About This Guide

This user guide focuses on:

- Setup required for the Design Control module
- Different forms of document organization in the Design Control module
- Security and roles for the Design Control module
- Instructions for the various Design Control tasks

The Design Control module in the EQMS system is separated into three categories: Design Control , Design Control Libraries, and Design Control Setup. A majority of the processes that make up Design Control are included in this user guide; however, a secondary user guide contains processes specifically for [Project Management](#).

Note: This guide does not provide field descriptions for the Design Control module fields. Field help is provided in the software.

Design Control Module Setup Guide

This section describes the processes of the Design Control module. The list below is arranged by the order in which the processes should be completed, starting with the setup operations and continuing with the main functions.

Setting Up the Design Control Module

Frequency Event

Use Frequency Events to define the list of events that can be selected for event-based inspections. See "Frequency Event" on page 30.

Sample Sizes

Use Sample Sizes to define a list of standard sample sizes from both a numeric and an alphanumeric value. See "Sample Sizes" on page 30.

Units of Measure

Use Units of Measure to identify quantities when used throughout the module. See "Unit of Measures" on page 31.

Gauge Types

Use Gauge Types to categorize generic types of gauges that have similar characteristics. See "Gauge Types" on page 33.

Gauge Sub-Types

Use Gauge Sub-Types for more specific gauge categorization, which can include sizes, tolerances, calibers, and more. See "Gauge Sub-Types" on page 33.

Gauges

Use Gauges for asset tracking of individual gauges, as well as recording of calibrations and R&R studies for individual gauges. See "Gauges" on page 34.

Tooling and Equipment Types

Use Tooling and Equipment Types to categorize pieces of equipment that have similar characteristics and allow for standardized reporting on equipment categories. See "Tooling and Equipment Types" on page 34.

Tooling and Equipment

Use Tooling and Equipment to document the pieces of equipment in an organization. Typically, the equipment also contains the associated maintenance information, both preventive and reactive, for tracking purposes. See "Tooling and Equipment" on page 34.

Process Symbols

Use Process Symbols to create a library of process images or symbols that can be used on reports as an indicator of the process. See "Process Symbols" on page 37.

Special Symbols

Use Special Symbols to create unique images that are typically used to identify special characteristics or hazards. See "Special Symbols" on page 38.

Drawing Types

Use Drawing Types to set up the default list of approvers for a type of drawing, such as Customer or Supplier drawings. See "Drawing Types" on page 39.

Item Types

Use Item Types to distinguish between different items, such as purchased versus manufactured. See "Item Types" on page 41.

Item Groups

Use Item Groups to subdivide product lines. For items that are purchased, item groups might be created for each commodity type. See "Item Groups" on page 43.

Product Lines

Use Product Lines to group items or products with similar characteristics. Marking usually breaks products into product lines to allow consumers to better understand their offerings or capabilities. See "Product Lines" on page 45.

Reaction Plans

Use Reaction Plans to define a list of standard reaction plans that can be used when defining controls for inspection. See "Reaction Plans" on page 46.

AQL Level

Use AQL Levels to define the list of numerical levels that can be selected on each AQL detail record. See "AQL Level" on page 47.

AQL

Use AQL to define a single table such as ANSI/ASQ Z1.4 and Z1.9, and all of the detail records that define that standard. See "AQL" on page 47.

Project Identification Question Design Risk

Use Project Identification Question Design Risk to provide questions that should be answered during the Planning and Preparation step of a design risk. See "Project Identification Question Design Risk" on page 49.

Project Identification Question Process Risk

Use Project Identification Question Process Risk to provide questions that should be answered during the Planning and Preparation step of a process risk. See "Project Identification Question Process Risk" on page 50.

Project Identification Question FMEA-MSR

Use Project Identification Question FMEA-MSR to provide questions that should be answered during the Planning and Preparation step of a FMEA-MSR. See "Project Identification Question FMEA-MSR" on page 51.

Design Risk Control Methods

Use Design Risk Control Methods to identify failure control methods that can be applied to a design risk. See "Design Risk Control Methods" on page 52.

Process Risk Control Methods

Use Process Risk Control Methods to identify hazard control methods that can be applied to a process risk. See "Process Risk Control Methods" on page 52.

FMEA-MSR Monitoring Control Methods

Use FMEA-MSR Monitoring Control Methods to identify control methods that can be applied to a FMEA-MSR. See "FMEA-MSR Monitoring Control Methods" on page 53.

Specification Categories

Use Specification Categories to group specification by a common name, typically for presentation on a report such as a certificate of conformity or certificate of analysis. See "Specification Categories" on page 54.

Specification Names

Use Specification Names to provide consistency with specification naming to help avoid naming problems such as having many different values that really mean the same thing. See "Specification Names" on page 55.

Specification Date Ranges

Use Specification Date Ranges to define the acceptable number of days for specifications that use the type Date, such as a chemical with a shelf life. See "Specification Date Ranges" on page 56.

Inspection Types

Use Inspection Types to prompt an operator/inspector with the appropriate characteristics/specifications and sample sizes at the right frequencies for that type of inspection. See "Inspection Types" on page 57.

Inspection Stations

Use Inspection Stations to prompt an operator/inspector with the appropriate characteristics/specifications and sample sizes at the right frequencies for the location of the inspection. See "Inspection Stations" on page 58.

FMEA-MSR System Responses

Use FMEA-MSR System Responses to provide a library of ways in which a system may respond to a detected risk cause. See "FMEA-MSR System Responses" on page 59.

PPAP Requirement Status

Use PPAP Requirement Status to define the status of the link between a PPAP requirement and a PPAP level. See "PPAP Requirement Status" on page 60.

PPAP Requirements

Use PPAP Requirements to define a full list of requirements for PPAP submission. See "PPAP Requirements" on page 61.

PPAP Submission Requirement Sets

Use PPAP Submission Requirement Sets to define groups of PPAP requirements per customer. See "PPAP Submission Requirement Sets" on page 63.

Design Risk Severity Criteria

Use the Design Risk Severity Criteria table when creating a design risk. The severity ratings are a relative indication of how severe an effect is to the customer if it happens. See "Design Risk Severity Criteria" on page 67.

Design Risk Occurrence Criteria

Use the Design Risk Occurrence Criteria table when creating a design risk. The occurrence ratings are a relative indication of how likely a design risk is to happen. See "Design Risk Occurrence Criteria" on page 68.

Design Risk Detection Criteria

Use the Design Risk Detection Criteria table when creating a design risk. The detection ratings are a relative indication of how likely a current control is going to detect a design risk if it happens. See "Design Risk Detection Criteria" on page 69.

Design Risk Occurrence Zone

Use the Design Risk Occurrence Zone to define all of the combinations of severity and occurrence and assign each a priority level. See "Design Risk Occurrence Zone" on page 70.

Design Risk Detection Zone

Use the Design Risk Detection Zone to define all of the combinations of severity and detection and assign each a priority level. See "Design Risk Detection Zone" on page 70.

Design Risk Priority Levels

Use Design Risk Priority Levels to define all of the combinations of the occurrence zone and detection zone and assign each a priority level. See "Design Risk Priority Levels" on page 71.

Process Risk Severity Criteria

Use the Process Risk Severity Criteria table when creating a process risk. The severity ratings are a relative indication of how severe an effect is to the customer if it happens. See "Process Risk Severity Criteria" on page 72.

Process Risk Occurrence Criteria

Use the Process Risk Occurrence Criteria table when creating a process risk. The occurrence ratings are a relative indication of how likely a process risk is to happen. See "Process Risk Occurrence Criteria" on page 73.

Process Risk Detection Criteria

Use the Process Risk Detection Criteria table when creating a process risk. The detection ratings are a relative indication of how likely a current control is going to detect a process risk if it happens. See "Process Risk Detection Criteria" on page 73.

Process Risk Priority Levels

Use Process Risk Priority Levels to define the list of risk levels that can be selected for the occurrence zone, detection zone, or overall priority level. See "Process Risk Priority Levels" on page 74.

Process Risk Occurrence Zone

Use the Process Risk Occurrence Zone to define all of the combinations of severity and occurrence and assign each a priority level. See "Process Risk Occurrence Zone" on page 75.

Process Risk Detection Zone

Use the Process Risk Detection Zone to define all of the combinations of severity and detection and assign each a priority level. See "Process Risk Detection Zone" on page 76.

Process Risk Priority Levels

Use Process Risk Priority Levels to define all of the combinations of the occurrence zone and detection zone and assign each a priority level. See "Process Risk Zone Priority Levels" on page 76.

FMEA-MSR Frequency Criteria

Use FMEA-MSR Frequency Criteria to provide a frequency rating representative of the effectiveness of preventive controls. This is used when building a FMEA-MSR. See "FMEA-MSR Frequency Criteria" on page 77.

FMEA-MSR Monitoring Criteria

Use FMEA-MSR Monitoring Criteria to provide a monitoring rating representative of the effectiveness of the diagnostic detection controls. This is used when building a FMEA-MSR. See "FMEA-MSR Monitoring Criteria" on page 78.

Risk Action Priority

Use the Risk Action Priority table to prioritize actions for risk reduction. See "Risk Action Priority" on page 79.

FMEA-MSR Action Priority

Use the FMEA-MSR Action Priority table to describe a risk effect and assigns an action priority to determine the importance of taking action. See "FMEA-MSR Action Priority" on page 80.

Using The Design Control Module

Design Risk Systems Library

Use Design Risk Systems Library to identify the systems or subsystems within your product lines. See "Design Risk Systems Library" on page 85.

Processes

Use Processes to document specific business or manufacturing processes that make up a process flow. See "Processes" on page 87.

Library Specifications

Use Library Specifications to document the acceptance criteria, including (where appropriate) the tolerances of an attribute or characteristic. See "Library Specifications" on page 95.

Control Library

Use Control Library to control quality related to product or process specifications. See "Control Library" on page 98.

Design Risk Structural Analysis Library

Use Design Risk Structural Analysis Library to determine structural and functional examinations for design risks. See "Design Risk Structural Analysis Library" on page 101.

Design Risk Analysis Library

Use Design Risk Analysis Library to determine hazards that can generally occur in a design. See "Design Risk Analysis Library" on page 104.

Design Risk Causes Library

Use Design Risk Causes Library to describe a potential hazardous situation in a design risk. See "Design Risk Causes Library" on page 105.

Process Risk Structural Analysis Library

Use Process Risk Structural Analysis Library to determine structural and functional examinations for process risks. See "Process Risk Structural Analysis Library" on page 108.

Process Risk Analysis Library

Use Process Risk Analysis Library to determine hazards that can generally occur in the process. See "Process Risk Analysis Library" on page 111.

Process Risk Causes Library

Use Process Risk Causes Library to describe a potential cause of hazard in a process risk. See "Process Risk Causes Library" on page 113.

Family Templates

Use Family Templates to house the risk plan, process flow, controls plans, and specifications for a product family, which can be used as a starting point for new manufacturing documents. See "Family Templates" on page 116.

Drawings

Use Drawings to control the drawings typically associated with products or items. See "Drawings" on page 124.

Items

Use Items to identify things that you stock in inventory, purchase, manufacture, sell, or service. See "Items" on page 130.

Manufacturing Documents

Use Manufacturing Documents to provide controlled copies of documentation used to produce part-specific design and process control documentation. See "Manufacturing Documents" on page 134.

Design Verification Reports

Use Design Verification Reports to document the performance of the product against the Design Verification Plan. See "Design Verification Reports" on page 164.

PPAP Submissions

Use PPAP Submissions to track submissions to your customer as part of the PPAP. See "PPAP Submissions" on page 165.

Getting Started

Before you can begin using the Design Control module, it is important to understand the basics of how to navigate and use the EQMS system. The system is intuitive, but some layouts, features, and best practices require a more thorough understanding. See the [User Interface](#) user guide for additional information about the EQMS software.

Chapter 2

Base Setup Tasks

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Introduction

Some processes housed in the Design Control module are used across multiple modules of the EQMS system. While these processes are important to Design Control functions, they are not exclusive to this module. The Base Setup Tasks chapter covers the most common and basic processes within this category.

Some processes in this chapter belong primarily to another module, where they are explained more thoroughly with appropriate contexts and required setup tasks. These processes are introduced in this user guide, but users should refer to the corresponding user guide for more detailed information. A link to the appropriate user guide is supplied after each introduction.

Frequency Event

When identifying an inspection's occurrence frequency for a process risk control plan item, there are two options: time-based and event-based. This process is used to define the list of events that can be selected for event-based inspections. Examples include per lot, per inspection, and per order.

Fig. 2: Frequency Event process screen



Frequency Event

Event Frequency Name ⓘ

Per Inspection

Frequency Event States

This section defines each state available in the workflow for the Frequency Event process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

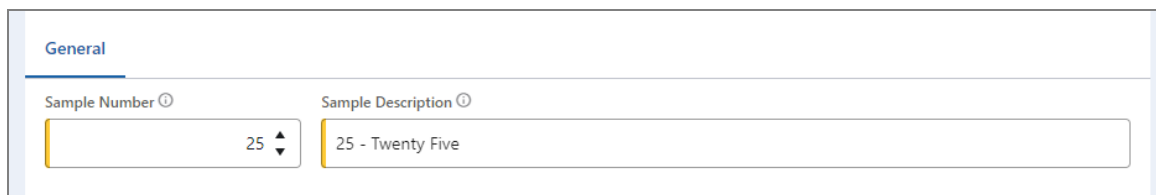
Frequency Event Tasks

Adding a New Frequency Event

1. Select Frequency Event from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter a name for the frequency event.
3. Click Save to save the new record.

Sample Sizes

Sample sizes is a simple process that allows you to define a list of standard sample sizes – both from a numeric value and an alphanumeric value – that can be used when defining controls for inspection.

Fig. 3: Sample Sizes process screen

The screenshot shows the 'General' tab of the 'Sample Sizes' process screen. It contains two input fields: 'Sample Number' with a value of 25 and 'Sample Description' with the text '25 - Twenty Five'.

Sample Sizes States

This section defines each state available in the workflow for the Sample Sizes process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Sample Sizes Tasks

Adding a New Sample Size

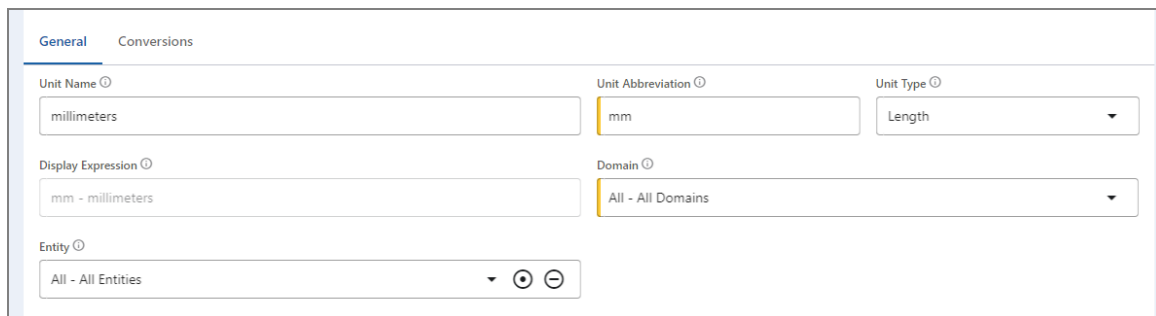
1. Select Sample Sizes from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Select a number value that defines the sample size.
3. Enter a description of the sample size.
4. Click Save to save the new record.

Unit of Measures

The Unit of Measures process helps identify quantities. A conversion table is also associated with each unit of measure, which defines the conversion factor when converting from one unit of measure to another.

Unit of measures is used in the following processes of the Design Control module:

- By Library Specifications to determine the tolerance values of a specification. See "Library Specifications" on page 95.
- By Items to identify the quantity or measurement associated with a specific item. See "Items" on page 130.

Fig. 4: Unit of Measures screen, General tab

The screenshot shows the 'General' tab of the 'Unit of Measures' screen. It contains several input fields and dropdown menus: 'Unit Name' (millimeters), 'Unit Abbreviation' (mm), 'Unit Type' (Length), 'Display Expression' (mm - millimeters), 'Domain' (All - All Domains), and 'Entity' (All - All Entities).

The General tab is used to define the basic information of a unit of measure.

Fig. 5: Unit of Measures screen, Conversions tab

General

Conversions

Unit of Measure Conversion(s) ⓘ

☐	Unit Name	Unit Abbreviation	Conversion Factor	Notes	
☐	yard	yd	0.00109361		⌵
☐	mile	mi	0.00000062		⌵
☐	inch	in	0.03937010		⌵
☐	foot	ft	0.00328084		⌵
☐	kilometer	km	0.00000100		⌵
☐	Meter	M	0.00100000		⌵
☐	Cubic Meter	CM	0.10000000		⌵

⏮◀1▶⏭

1 - 7 of 7 items

+

☰

The Conversion tab contains a list of other units of measure that the current unit of measure can be converted to, along with the conversion factor.

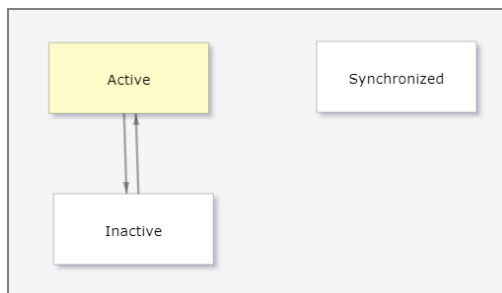
Unit of Measures States

This section defines each state available in the workflow for the Unit of Measures process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A unit of measure that is actively used.

Inactive. A unit of measure that is no longer in use.

Synchronized. The state is automatically set if the item is created or updated from integration with another system (e.g. ERP). Synchronized fields are read-only.



Unit of Measures Tasks

Adding a New Unit of Measure

1. Select Unit of Measures from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter a unit name and abbreviation.
3. Select a unit type.
4. Select a domain that this unit belongs to.

Note: You can select All Domains if you want the unit to pertain to each domain in the system.

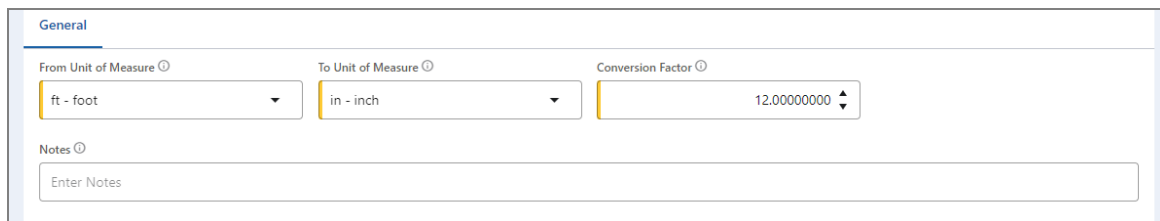
5. Click Save to save the new record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the unit of measure cannot be used for new records.

Adding a New Conversion

1. In the Unit of Measures detail screen, navigate to the Conversion tab.
2. Click the Add New Item  button in the Unit of Measure Conversions field.
3. In the To Unit of Measure field, select the measurement that the current unit of measure can be converted to.
4. In the Conversion Factor field, enter the numerical factor used to convert the "from" unit of measure to the "to" unit of measure. See the figure below for an example.
5. Enter any notes about the conversion if necessary.
6. Click Save to save the record.

Fig. 6: Unit Conversions screen



The screenshot shows a web interface for adding a new conversion. It has a 'General' tab selected. There are three main fields: 'From Unit of Measure' with a dropdown menu showing 'ft - foot', 'To Unit of Measure' with a dropdown menu showing 'in - inch', and 'Conversion Factor' with a text input field containing '12.00000000'. Below these fields is a 'Notes' section with a text input field labeled 'Enter Notes'.

Gauge Types

Gauge types allow you to categorize generic types of gauges that have similar characteristics. Examples of this general categorization could be micrometer, caliper, or plug gauge.

Within these types, you can configure calibration procedures and reference documentation. Gauge types are used in the Gauge module. See "Gauges" below.

Information about the Gauge Types process (including state transitions, security roles, tasks, and more) can be found in the [Gauge Management](#) user guide.

Gauge Sub-Types

Gauge sub-types exist for more specific categorization of gauges, which can include sizes, tolerances, calibers, and more. Gauges of the same sub-type should have the same calibration standards.

Gauge sub-types are used in the Gauge module and to configure calibrations. See "Gauges" below.

Information about the Gauge Sub-Types process (including state transitions, security roles, tasks, and more) can be found in the [Gauge Management](#) user guide.

Gauges

The Gauges process provides asset tracking of individual gauges and records calibrations, as well as bias, linearity, and R&R studies for individual gauges. With this process, you will know where a gauge came from, its purpose, where it is assigned and located, whether it is active or out of service, and more. Gauges are organized by type and sub-type.

Information about the Gauges process (including state transitions, security roles, tasks, and more) can be found in the [Gauge Management](#) user guide.

Tooling and Equipment Types

The first step to setting up pieces of equipment in the system is separating them into different types for better organization. The Tooling and Equipment Types process enables you to categorize pieces of equipment that have similar characteristics, such as conveyors, and allow for standardized reporting on tooling and equipment categories, which can optionally be broken down further into tooling and equipment sub-types. Tooling and equipment sub-types are more precise, such as flat-belt conveyor, and are typically used for tracking and categorizing purposes.

Information about the Tooling and Equipment Types process (including state transitions, security roles, tasks, and more) can be found in the [Equipment Management](#) user guide.

Tooling and Equipment

Tooling and Equipment allows you to document the pieces of equipment in the organization. Typically the equipment also contains the associated maintenance information, both preventive and reactive for tracking purposes.

Information about the Tooling and Equipment process (including state transitions, security roles, tasks, and more) can be found in the [Equipment Management](#) user guide.

Chapter 3

Setting Up the Design Control Module

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Process Symbols

Process symbols allow you to create a library of process images or symbols that can be used on reports as an indicator of the process, such as on the process flow report.

Process symbols are used in the Processes process. See "Processes" on page 87.

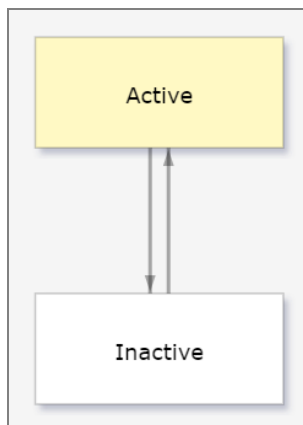
Fig. 7: Process Symbols process screen

Process Symbols States

This section defines each state available in the workflow for the Process Symbols process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A process symbol that is actively used.

Inactive. A process symbol that is no longer in use.



Process Symbols Tasks

Adding a New Process Symbol

1. Select Process Symbols from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter a brief description for the process symbol.
3. Click the Browse button in the Process Symbol Image field. A new window appears.

4. Navigate the files of your computer until you find the image that you want. Then select that image and click Open.
5. To save the image, click the Save Local button.
6. Click Save to save the new record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the process symbol cannot be used for new records.

Special Symbols

Special symbols allows users to create unique images that are typically used to identify special characteristics or hazards.

Special symbols are used in the Library Specification process as a special classification as required by the customer. See "Library Specifications" on page 95.

Fig. 8: Special Symbols process screen

The screenshot shows a web application interface for managing special symbols. It features a 'General' tab with the following elements:

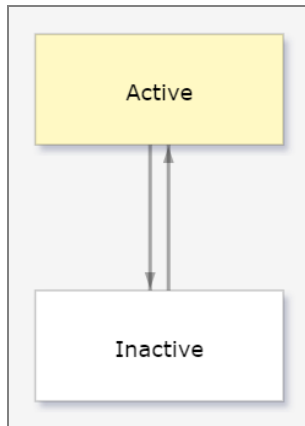
- Special Symbol Code**: A text input field containing the value 'OS'.
- Special Symbol Description**: A text input field containing the value 'Operator Safety Characteristic'.
- Special Symbol Image**: A large rectangular area displaying a square icon with a white 'S' inside a blue triangle. Below this area is a link that says 'Click here to add description' and three small icons: a trash can, a download arrow, and a plus sign in a square.
- Display Expression**: A text input field containing the value 'OS - Operator Safety Characteristic'.

Special Symbols States

This section defines each state available in the workflow for the Special Symbols process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A special symbol that is actively used.

Inactive. A special symbol that is no longer in use.



Special Symbols Tasks

Adding a New Special Symbol

1. Select Special Symbols from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the special symbol code and name. Notice how the Display Expression field combines the two values; this is how users will look up this symbol.
3. Click the Browse button in the Special Symbol Image field. A new window appears.
4. Navigate the files of your computer until you find the image that you want. Then select that image and click Open.
5. To save the image, click the Save Local button.
6. Click Save to save the new record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the symbol cannot be used for new records.

Drawing Types

Drawing types gather similar drawings together and are used to set up the default list of approvers for a type of drawing. Drawing types can be set up by the different types of products being created or even by the different areas of the engineering department. Another example for the use of drawing types is the source of the drawing, such as Customer or Supplier drawings.

Drawing types can be linked to one or several sites, which are filtered by the selected domain. If any of these sites contain an ITAR (International Traffic in Arms Regulation) requirement, then drawings created from this type can be ITAR restricted. This means only employees who are ITAR compliant can view, access, and interact with the drawing.

See "Drawings" on page 124 to learn more about the Drawings process.

Fig. 9: Drawing Types screen, General tab

The screenshot shows the 'General' tab of the 'Drawing Types' screen. It contains the following fields and lists:

- Drawing Type Code:** LS-01
- Drawing Type:** Finished assembly
- Domain(s):** A list with three items: 'Display Expression', '10USA - USA Domain', and 'All - All Domains'. The first item is selected.
- Entities:** A list with three items: 'Display Expression', '10USACO - USA DIVISION', and 'All - All Entities'. The first item is selected.
- Site(s):** A list with four items: 'Display Expression', '10-201 - Lean Manufacturing Site', '10-100 - Site 100 USA', and 'All - All Sites'. The first item is selected.
- Display Expression:** LS-01 - Finished assembly

The General tab contains the naming convention for the drawing type. If one of the sites listed in the Sites field are ITAR restricted, then the "ITAR Restricted" toggle field is automatically set to YES.

Fig. 10: Drawing Types screen, Approval Setup tab

The screenshot shows the 'Approval Setup' tab of the 'Drawing Types' screen. It contains the following fields and lists:

- Drawing Type Approvers:** A list with two items: 'Display Expression' and 'Gene Nakimura'. The second item is selected.
- Default Approval Days:** 7

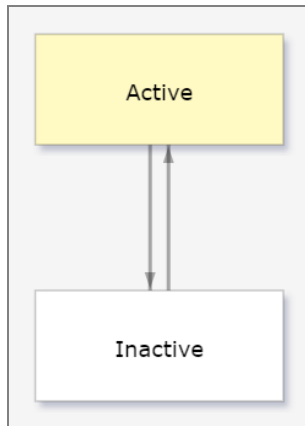
The Approval Setup tab allows you to assign employees as approvers for drawings of this type, as well as set the default number of days for approval.

Drawing Types States

This section defines each state available in the workflow for the Drawing Types process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A drawing type that is actively used.

Inactive. A drawing type that is no longer in use.



Drawing Types Tasks

Adding a New Drawing Type

1. Select Drawing Types from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the drawing type code and name. Notice how the Display Expression field combines the two values; this is how users will look up this drawing type.
3. Add the domains, entities, and sites associated with this drawing type.
 - a. Click the Link  button. A small window appears.
 - b. Select all items that apply.
 - c. Click OK.

Note: If any of the selected sites contain an ITAR restriction, then the drawing type's "ITAR Restricted" check box automatically becomes selected.

4. Navigate to the Approval Setup tab. Select approvers for this drawing type in the Drawing Type Approvers field.
5. Select the default number of days that approvers should have to approve a drawing of this type. This number is just a default and can be changed per drawing.
6. Click Save to save the new record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the drawing type cannot be used for new records.

Item Types

Item types are the most general grouping level for items. Item types are generally used to distinguish between items that are purchased versus items that are manufactured, although there may be additional item types to help break down a very large item database. Examples of item types might be finished goods, component, purchased product, spare part, and so on.

Item types are used in the Family Templates and Items processes for categorization. See "Family Templates" on page 116 and "Items" on page 130.

Fig. 11: Item Types process screen

The screenshot shows the 'General' tab of the Item Types process screen. It contains the following fields and controls:

- Item Type Code**: A text field containing 'BRK'.
- Item Type Name**: A text field containing 'Brake Assembly'.
- Domain**: A dropdown menu showing 'All - All Domains'.
- Entity**: A dropdown menu showing 'All - All Entities'.
- Approvers**: A table with columns 'First Name', 'Last Name', and 'Default Site'. It contains one row with 'demo', 'superuser', and 'HQ - Farmington Hills'. There is a checkbox in the first column and a 'Link' button in the last column.
- Spare Part Default**: A toggle switch with 'YES' and 'NO' options, currently set to 'NO'.
- Display Expression**: A text field containing 'BRK - Brake Assembly'.

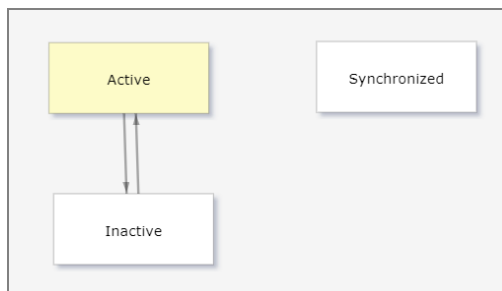
Item Types States

This section defines each state available in the workflow for the Item Types process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). An item type that is actively used.

Inactive. An item type that is no longer in use.

Synchronized. The state is automatically set if the item is created or updated from integration with another system (e.g. ERP). Synchronized fields are read-only.



Item Types Tasks

Adding a New Item Types

1. Select Item Types from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the item type code and name. Notice how the Display Expression field combines the two values; this is how users will look up this item type.
3. In the Approvers field, click the Link  button. A new window appears.
4. Select the check box next to each user that should be a default approver for the item type. Then click OK.
5. If the item type will be used for maintenance spare parts, then select the "Spare Part

Default" check box.

6. Click Save to save the new record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the item type cannot be used for new records.

Item Groups

Item groups allow you to subdivide product lines. Items are often grouped based on similar characteristics, such as end user function. For items that are purchased, item groups might be created for each commodity type. Examples include round bar stock, tie rods, plate steel, bearings, and lug nuts.

Item groups are used in the following processes of the Design Control module:

- By Library Specifications to categorize product specifications. See "Library Specifications" on page 95.
- By Family Templates to subdivide product lines. See "Family Templates" on page 116.
- By Items to categorize an item. See "Items" on page 130.

Fig. 12: Item Groups screen, General tab

The screenshot shows the 'General' tab of the 'Item Groups' screen. It contains several input fields and lists:

- Item Group Code:** AUTO
- Item Group Name:** Automotive Items
- Domain:** 10USA - USA Domain
- Entity:** All - All Entities
- Notification List:** A table with columns First Name, Last Name, and Title. It contains one entry: Lauren Bastian, PEMGR - Process Engineering Manager.
- Buyer(s):** A table with columns Site and Buyer. It contains one entry: 10-200 - Auto Industrial Mfg, Stan Ford-Buyer.
- Global Item Group Manager:** A text input field with the placeholder 'Enter Global Item Group Manager'.
- Display Expression:** AUTO - Automotive Items

The General tab contains the basic information of an item group, including the code and name, notification list, buyers list, and more.

Fig. 13: Item Groups screen, Approval Setup tab

The screenshot shows the 'Approval Setup' tab of the 'Item Groups' screen. It contains:

- Approvers:** A table with columns First Name, Last Name, and Title. It contains one entry: Mark Feathers, M007 - EMEA VP of Marketing.
- Default Approval Days:** A numeric input field with the value 7.

The Approval Setup tab allows you to assign employees as approvers for items of this group, as well as set the default number of days for approval.

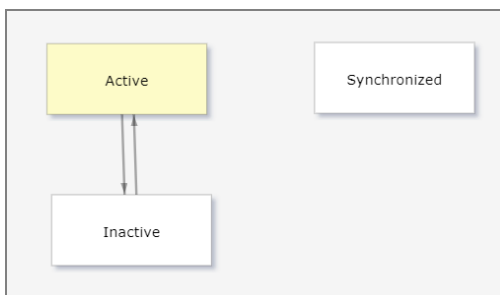
Item Groups States

This section defines each state available in the workflow for the Item Groups process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). An item group that is actively used.

Inactive. An item group that is no longer in use.

Synchronized. The state is automatically set if the item is created or updated from integration with another system (e.g. ERP). Synchronized fields are read-only.



Adding a New Item Group

1. Select Item Groups from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the item group code and name. Notice how the Display Expression field combines the two values; this is how users will look up this group.
3. In the Notification List field, click the Link  button. A new window appears.
4. Select the check box next to each user that should be notified if a non-conformance is found for a safety-related item. Then click OK.
5. In the Buyers field, click the Add New Item  button. A new tab opens.
6. Use the Site and Buyer drop-down fields to create a record that identifies the buyer for this item group. Click Save to save the record when finished.
7. Back at the Item Group process screen, click Save to save the new record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the item group cannot be used for new records.

Adding Approval Setup to an Item Group

1. Select Item Groups from the left navigation panel. Then, double-click the record that you want to open.
2. Navigate to the Approval Setup tab and click on the Link button in the Approvers field. A new window opens.

3. Select the check box next to each user that should be a default approver for the item type. Then click OK.
4. Select the default number of days that approvers have to approve manufacturing documents associated with this group.

Product Lines

Product lines are used to group items or products with similar characteristics. These products are usually grouped by similarities of manufacture, use, module, cost analysis, or revenue analysis. Marketing usually breaks products into product lines to allow consumers to better understand their offerings or capabilities.

Product lines are used in the Item process. See "Items" on page 130.

Fig. 14: Product Lines process screen

The screenshot shows the 'General' tab of the Product Lines process screen. It contains the following fields:

- Product Line Code**: A text input field containing the value '10'.
- Product Line Name**: A text input field containing the value 'Finished Goods (FGI)'.
- Domain**: A dropdown menu showing '10USA - USA Domain'.
- Entity**: A dropdown menu showing '10USACO - USA DIVISION'.
- Display Expression**: A text input field containing the value '10 - Finished Goods (FGI)'.

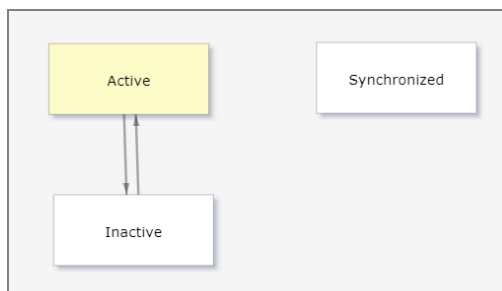
Product Lines States

This section defines each state available in the workflow for the Product Lines process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A product line that is actively used.

Inactive. A product line that is no longer in use.

Synchronized. The state is automatically set if the item is created or updated from integration with another system (e.g. ERP). Synchronized fields are read-only.



Product Lines Tasks

Adding a New Product Line

1. Select Product Lines from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the product line code and name. Notice how the Display Expression field combines the two values; this is how users will look up this product line.
3. Click Save to save the new record. When selecting the next state, click Active.

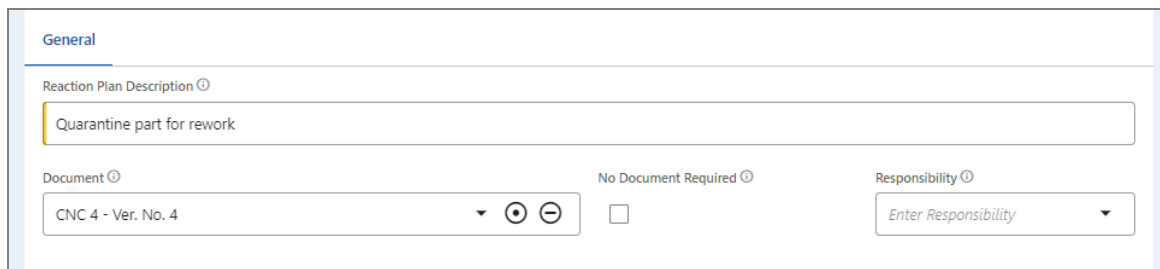
Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the product line cannot be used for new records.

Reaction Plans

The reaction plans process allows you to define a list of standard reaction plans that can be used when defining controls for inspection.

Reaction plans are used by the Library Controls process to document what actions should be taken in a process begins to go out of control. See "Control Library" on page 98.

Fig. 15: Reaction Plans process screen



The screenshot shows a web form for creating a reaction plan. It has a 'General' tab selected. The 'Reaction Plan Description' field is a text box containing 'Quarantine part for rework'. Below it, there are three fields: 'Document' with a dropdown menu showing 'CNC 4 - Ver. No. 4', a 'No Document Required' checkbox, and a 'Responsibility' dropdown menu with the text 'Enter Responsibility'.

Reaction Plans States

This section defines each state available in the workflow for the Reaction Plans process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Reaction Plans Tasks

Adding a New Reaction Plan

1. Select Reaction Plans from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter a description of the reaction plan.
3. If the reaction plan requires a document, use the Document drop-down field to select the appropriate document.
4. If the reaction plan does not require a document, then select the "No Document

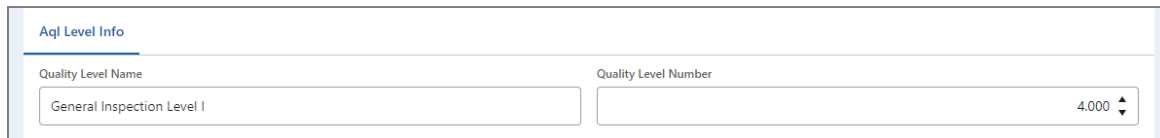
- Required" check box.
- Click Save to save the new record.

AQL Level

The AQL is the quality level considered to be the "worst tolerable". It represents the maximum number of defective units, beyond which a batch is rejected. See "AQL" below.

AQL levels are typically classified into three levels: critical, major, and minor. The more critical the defect, the smaller the number of acceptable defects within a batch. A minor defect may be as simple as some chipped paint; a major defect can affect its marketability or usability, such as a misspelled logo; a critical defect would render the product unsafe for users or fail mandatory regulations, such as broken glass or leaking fluid.

Fig. 16: AQL Level process screen



AQL Level States

This section defines each state available in the workflow for the AQL Level process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

AQL Level Tasks

Adding a New AQL Level

- Select AQL from the left navigation panel. Then, click the Add Item  button in the toolbar.
- Enter a quality level name.
- Enter a quality level number.
- Click Save to save the new record.

AQL

Acceptable quality limit (AQL) defines the range between accepting and rejecting components of a product during the random sampling process of an inspection. When adding details to an AQL record, you must define the minimum and maximum size of a batch, how many samples should be taken from that batch, the AQL level, and the quantity of defects that is acceptable from those samples. See "AQL Level" above.

AQL Tables are used for process risk control plans and inspection events. See "Control Library" on page 98.

Fig. 17: AQL process screen

AQL Info

Title ⓘ

BEMIS Sampling Plan

Aql Detail ⓘ

Batch Size Minimum	Batch Size Maximum	AQL Level	Number of Samples to Take	Acceptable Defe	⊕
500,001	10,000,000	1.000	102		⊖
150,000	500,000	1.000	90		
10,001	35,000	1.000	60		
3,201	10,000	1.000	50		
1,201	3,200	1.000	42		
501	1,200	1.000	34		
281	500	1.000	29		
151	280	1.000	20		
1	150	1.000	13		

AQL States

This section defines each state available in the workflow for the AQL process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

AQL Tasks

Adding a New AQL Table

1. Select AQL from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter a title for the AQL table.
3. In the AQL Detail field, click the Add New Item  button. A new row appears.
4. Use the first two number toggle fields to set the batch size minimum and maximum parameters.
5. Select the AQL level.
6. Select the number of samples that should be taken within the batch size parameters to be tested for quality.
7. Select the acceptable defect quantity, which determines how many samples are allowed to be defective before the whole batch is declared rejected.
8. Repeat steps 4-7 to add as many rows as are necessary.
9. Click Save to save the new record.

Project Identification Question Design Risk

The Project Identification Question Design Risk process provides questions that should be answered during the Planning and Preparation step of a design risk. These questions populate the Project Identification field in the Design Risk Analysis tab of manufacturing documents. See "Manufacturing Documents" on page 134.

Fig. 18: Project Identification Question Design Risk process screen

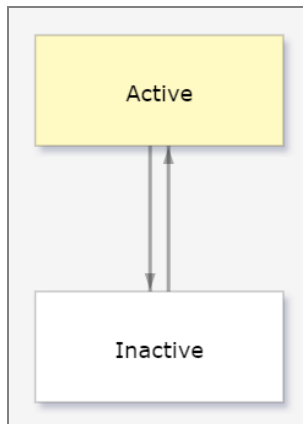


Project Identification Question Design Risk States

This section defines each state available in the workflow for the Project Identification Question Design Risk process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A project identification question that is actively used.

Inactive. A project identification question that is no longer in use.



Project Identification Question Design Risk Tasks

Adding a New Project Identification Question Design Risk

1. Select Project Identification Question Design Risk from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter the project identification question.
3. Click Save to save the new record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the project identification question cannot be used for new records.

Project Identification Question Process Risk

The Project Identification Question Process Risk process provides questions that should be answered during the Planning and Preparation step of a process risk. These questions populate the Project Identification field in the Process Risk Planning tab of manufacturing documents. See "Manufacturing Documents" on page 134.

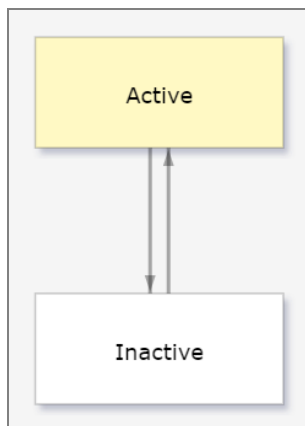
Fig. 19: Project Identification Question Process Risk process screen

Project Identification Question Process Risk States

This section defines each state available in the workflow for the Project Identification Question Process Risk process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A project identification question that is actively used.

Inactive. A project identification question that is no longer in use.



Project Identification Question Process Risk Tasks

Adding a New Project Identification Question Process Risk

1. Select Project Identification Question Process Risk from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter the project identification question.
3. Click Save to save the new record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the project identification question cannot be used for new records.

Project Identification Question FMEA-MSR

The Project Identification Question FMEA-MSR process provides questions that should be answered during the Planning and Preparation step of a FMEA-MSR. These questions populate the Project Identification field in the FMEA-MSR Analysis tab of manufacturing documents. See "Manufacturing Documents" on page 134.

Fig. 20: Project Identification Question Design Risk process screen

General

Project Identification Question ⓘ

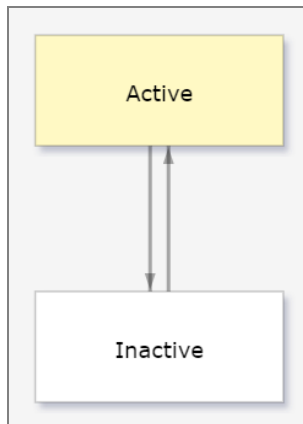
Did the DFMEA indicate that all of the causes which lead to harm or noncompliance can be detected by direct sensing, and/or plausibility algorithms?

Project Identification Question FMEA-MSR States

This section defines each state available in the workflow for the Project Identification Question FMEA-MSR process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A project identification question that is actively used.

Inactive. A project identification question that is no longer in use.



Project Identification Question FMEA-MSR Tasks

Adding a New Project Identification Question FMEA-MSR

1. Select Project Identification Question FMEA-MSR from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter the project identification question.
3. Click Save to save the new record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the project identification question cannot be used for new records.

Design Risk Control Methods

The Design Risk Control Methods process identifies control methods that can be applied to a design risk. Control methods can be used to detect a hazardous situation, to prevent a hazardous situation, or both.

Once a control method is created, it can be used when building a design risk in a manufacturing document. See "Manufacturing Documents" on page 134.

Fig. 21: Design Risk Control Methods screen, General tab



Design Risk Control Methods States

There are no states identified for this process.

Design Risk Control Methods Tasks

Adding a New Design Risk Control Method

1. Select Design Risk Control Methods from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter a description of the control method.
3. Set the "Detection" and "Prevention" toggles to indicate whether this control method is used for detecting hazards, preventing hazards, or both.
4. Click Save to save the new record.

Process Risk Control Methods

The Process Risk Control Methods process identifies control methods that can be applied to a process risk. Control methods can be used to detect a hazardous situation, to prevent a hazardous situation, or both.

Once a control method is created, it can be used when building a process risk in a manufacturing document. See "Manufacturing Documents" on page 134. Process risk control methods are also used in the Control Library process and the Process Risk Failure Analysis Library process to explain the method of detection or prevention of hazards. See "Process Risk Analysis Library" on page 111 and "Control Library" on page 98.

Fig. 22: Process Risk Control Methods process screen

Process Risk Control Methods States

This section defines each state available in the workflow for the Process Risk Control Methods process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Process Risk Control Methods Tasks

Adding a New Process Risk Control Method

1. Select Process Risk Control Methods from the left navigation panel. Then, click the Add Item button in the toolbar.
2. Enter a name for the control method.
3. Set the "Detection" and "Prevention" toggles to indicate whether this control method is used for detecting hazards, preventing hazards, or both.
4. Use the Document drop-down field to select a document associated with the control method.
5. Click Save to save the new record.

FMEA-MSR Monitoring Control Methods

The FMEA-MSR Monitoring Control Methods process identifies control methods that can be applied to a FMEA-MSR. These control methods should be monitored for the cause or mode of a failure.

Once a control method is created, it can be used when building a FMEA-MSR in a manufacturing document. See "Manufacturing Documents" on page 134.

Fig. 23: FMEA-MSR Monitoring Control Methods screen

FMEA-MSR Monitoring Control Methods States

There are no states identified for this process.

FMEA-MSR Monitoring Control Methods Tasks

Adding a New FMEA-MSR Monitoring Control Method

1. Select FMEA-MSR Monitoring Control Methods from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter a description of the control method.
3. Click Save to save the new record.

Specification Categories

Specification categories allow you to group specifications by a common name, typically for presentation on a report such as a certificate of conformity or certificate of analysis. Examples of categories include electronic properties, electrical properties, physical properties, or chemical properties.

Fig. 24: Specification Categories process screen



The screenshot shows a web application interface for 'Specification Categories'. The 'General' tab is selected. There are three input fields: 'Category Code' containing 'ELCT', 'Category Name' containing 'Electrical', and 'Display Expression' containing 'ELCT - Electrical'. Each field has a small circular icon with an 'i' next to it, likely for information or help.

Specification Categories States

This section defines each state available in the workflow for the Specification Categories process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Adding a New Specification Category

1. Select Specification Categories from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the category code and name. Notice how the Display Expression field combines the two values; this is how users will look up this category.
3. Click Save to save the new record.

Specification Names

Specification names provide consistency with specification titles in order to avoid naming problems such as having many different values that really mean the same thing. For example, it is common to see a value such as width be entered as width, widths, wd, or w. To help avoid this problem the specification names process was created to provide a level of security control over who can create specification names.

Specification names should be specific. For instance, if you are making a motor shaft, there are likely several outer diameters. Each unique diameter should have its own unique name. This allows for unique control of each diameter and better matching with the Drawing Features.

Fig. 25: Specification Names process screen

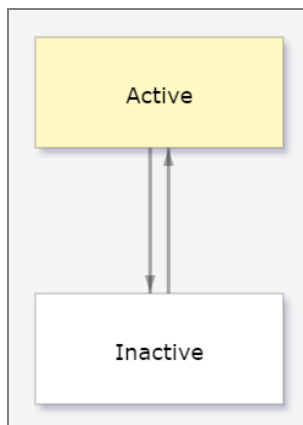
The screenshot shows a web form with a 'General' tab. Below the tab, there are two input fields. The first is labeled 'Specification Name' with a help icon, and it contains the text 'Internal diameter'. The second is labeled 'Specification Category' with a help icon, and it is a dropdown menu currently showing 'DIM - Dimensional'. To the right of the dropdown are three small icons: a downward arrow, a plus sign, and a minus sign.

Specification Names States

This section defines each state available in the workflow for the Specification Names process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A specification name that is actively used.

Inactive. A specification name that is no longer in use.



Specification Names Tasks

Adding a New Specification Name

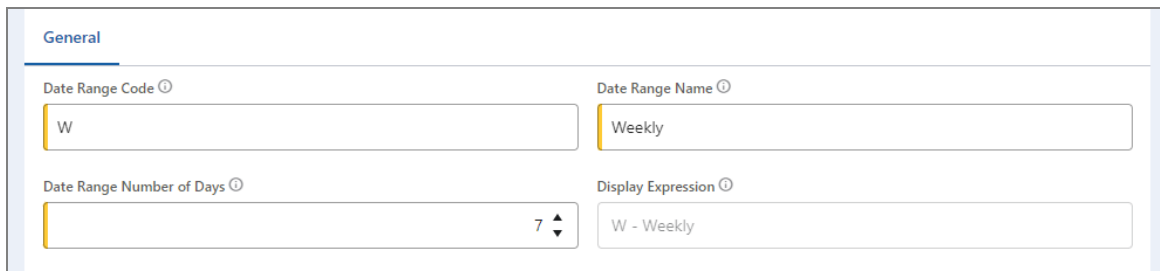
1. Select Specification Names from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter a name for the specification.
3. Select a category that the specification belongs to.
4. Click Save to save the new record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the specification name cannot be used for new records.

Specification Date Ranges

Specification date ranges are used to define the acceptable number of days for specifications that use the type Date. For example, the name of the range might be "1 Year" and the number of days would be 365.

Fig. 26: Specification Date Ranges process screen



General	
Date Range Code ⓘ	Date Range Name ⓘ
W	Weekly
Date Range Number of Days ⓘ	Display Expression ⓘ
7	W - Weekly

Specification Date Ranges States

This section defines each state available in the workflow for the Specification Date Ranges process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Specification Date Ranges Tasks

Adding a New Specification Date Range

1. Select Specification Date Ranges from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the date range code and name. Notice how the Display Expression field combines the two values; this is how users will look up this range.
3. Enter a numerical value in the Date Range Number of Days field that represents the date range. For example, if the date range is Weekly, then enter 7 days.
4. Click Save to save the new record. When selecting the next state, click Active.

Inspection Types

Inspection types make up a list of possible types of inspections that may be conducted, such as setup, in-process, or FAI (first article inspection). They are used to present an inspector with the appropriate specifications to verify based on the type of inspection they are performing.

Within the Design Control module, inspection types are linked to library controls to default on family template and manufacturing document process risk control plans in order to specify if the process risk control plan item will appear on inspections related to the type of inspection. The process risk control plans that an inspection type is linked to will appear in the Process Risk Control Plan cross-reference field.

- See "Control Library" on page 98.
- See "Family Templates" on page 116.
- See "Manufacturing Documents" on page 134.

An additional cross-reference field displays which, if any, inspection plan items are connected to the inspection type. Inspection plans are part of the Inspection & SPC module. See the [Inspection & SPC](#) user guide for more information.

Fig. 27: Inspection Types process screen

The screenshot shows the 'General' tab of the 'Inspection Types' process screen. It includes the following elements:

- Inspection Type Code:** A text field containing the value '5'.
- Inspection Type Name:** A text field containing the value 'Final Inspection'.
- Process Risk Quality Plan:** A table with columns: Obsolete - Process, Specification, Detection, Prevention, Control Description, Sample Size Description, and Reaction Plan. It lists three entries for 'Product Testing' with specifications '05 - Amplitude', '04 - Amperage', and '04 - Amperage'. Each entry has 'Yes' for Detection, 'No' for Prevention, and a reaction plan of 'Quarantine gauge and inform quality r...'. The table is paginated with 10 items shown out of 120.
- Inspection Plan Items:** A table with columns: Process, Specification, and a checkbox. It lists three items: 'PKF - Picking Fruit' (Specification: '2383-2 - Height - 2383-2 Test'), 'SPC 2 - Visual Inspect' (Specification: 'Color'), and 'SPC 2 - Visual Inspect' (Specification: 'Label Position'). The table is paginated with 10 items shown out of 73.

Inspection Types States

This section defines each state available in the workflow for the Inspection Types process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Inspection Types Tasks

Adding a New Inspection Type

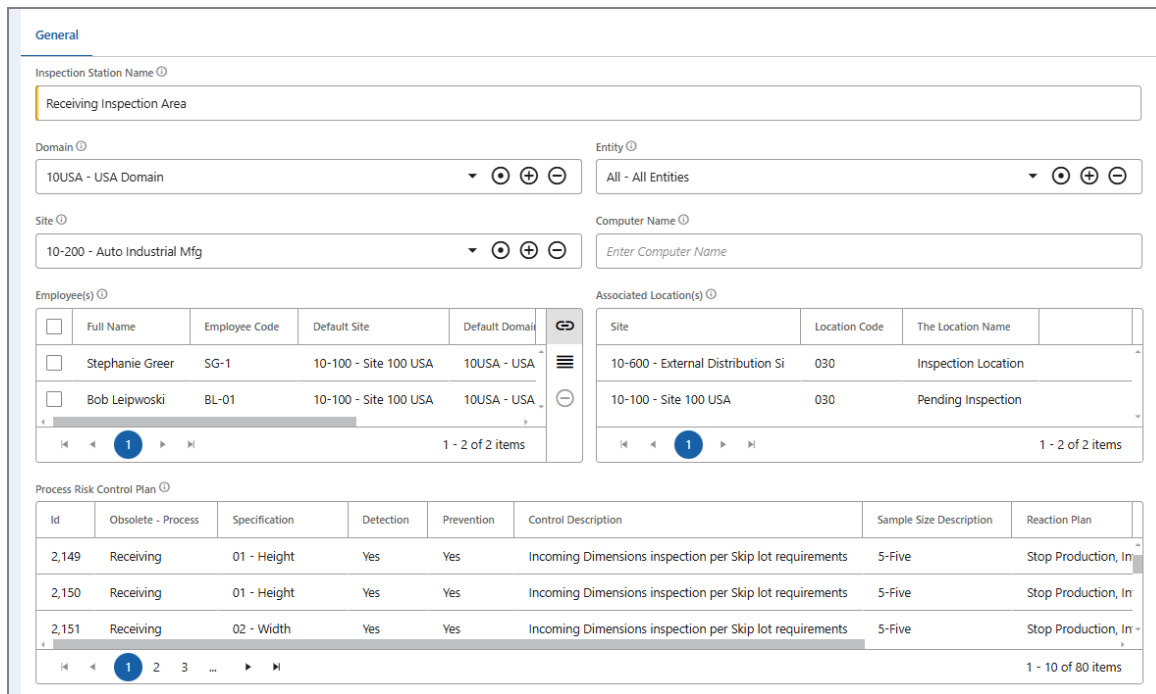
1. Select Inspection Types from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the inspect type name and code.
3. Click Save to save the new record.

Inspection Stations

Inspection stations are used to identify locations where inspections take place. Process risk control plan items can be assigned one or more inspection stations and then be used to limit which process risk control plan items show up for an inspection event based on a selected station.

Inspection stations are used in the Library Controls process to filter SPC collection events for inspection stations. See "Control Library" on page 98 for more information.

Fig. 28: Inspection Stations process screen



General

Inspection Station Name 
 Receiving Inspection Area

Domain  10USA - USA Domain   

Entity  All - All Entities   

Site  10-200 - Auto Industrial Mfg   

Computer Name  Enter Computer Name

Employee(s) 

☐	Full Name	Employee Code	Default Site	Default Domain	
☐	Stephanie Greer	SG-1	10-100 - Site 100 USA	10USA - USA	
☐	Bob Leipwoski	BL-01	10-100 - Site 100 USA	10USA - USA	

1 - 2 of 2 items

Associated Location(s) 

Site	Location Code	The Location Name
10-600 - External Distribution Si	030	Inspection Location
10-100 - Site 100 USA	030	Pending Inspection

1 - 2 of 2 items

Process Risk Control Plan 

Id	Obsolete - Process	Specification	Detection	Prevention	Control Description	Sample Size Description	Reaction Plan
2,149	Receiving	01 - Height	Yes	Yes	Incoming Dimensions inspection per Skip lot requirements	5-Five	Stop Production, In
2,150	Receiving	01 - Height	Yes	Yes	Incoming Dimensions inspection per Skip lot requirements	5-Five	Stop Production, In
2,151	Receiving	02 - Width	Yes	Yes	Incoming Dimensions inspection per Skip lot requirements	5-Five	Stop Production, In

1 - 10 of 80 items

Inspection Stations States

This section defines each state available in the workflow for the Inspection Stations process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Inspection Stations Tasks

Adding a New Inspection Station

1. Select Inspection Stations from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter a name for the inspection station and select the appropriate domain and site.
3. Enter the network name of the computer for the station.
4. In the Employees field, click the Link  button. A new window appears.
5. Select the check box beside each employee that you want to assign to the station. Then click OK.
6. Click Save to save the new record.

FMEA-MSR System Responses

The FMEA-MSR System Responses process provides a library of ways in which a system may respond to a detected risk cause.

Fig. 29: FMEA-MSR System Responses process screen



The screenshot shows a web-based form for 'FMEA-MSR System Responses'. The 'General' tab is active. There are three main input areas:

- System Response Code:** A text box containing 'WIN-002'.
- System Response:** A text box containing 'Comfort closing mode disabled'.
- Notes:** A text box containing 'Window will NOT close itself with one touch of a button.'

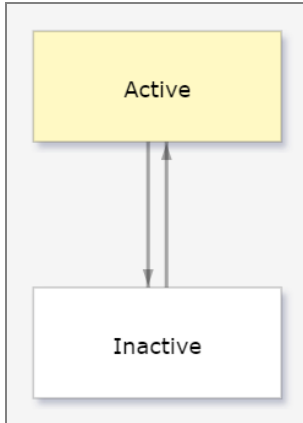
Each input field has a small circular icon with an 'i' (help) to its right.

FMEA-MSR System Responses States

This section defines each state available in the workflow for the FMEA-MSR System Responses process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A system response that is actively used.

Inactive. A system response that is no longer in use.



FMEA-MSR System Responses Tasks

Adding a New FMEA-MSR System Response

1. Select FMEA-MSR System Responses from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter a code and name for the system response.
3. Enter any notes about the system response, if necessary.
4. Click Save to save the new record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the specification name cannot be used for new records.

PPAP Requirement Status

Production Part Approval Process (PPAP) is an approach that supports a customer's decision-making process when determining if a supplier:

- Understands the customer's product requirements and specifications
- Is ready to supply product at the required quality and rate

PPAP requirement statuses are used to define the status of the link between a PPAP requirement and a PPAP level. Examples include:

- S = the organization shall submit
- R = the organization shall retain
- * = the organization shall retain and submit upon request

PPAP requirement statuses are used in the PPAP Submissions process. See "PPAP Submissions" on page 165.

Fig. 30: PPAP Requirement Status process screen

The screenshot shows a web form titled "General" for creating a PPAP Requirement Status. It includes the following fields:

- Code**: A text box containing the letter "R".
- Name**: A text box containing the word "Retain".
- Description**: A larger text box containing the sentence "The organization shall retain at appropriate locations and make available to the customer upon request."
- Display Expression**: A text box containing the text "R - Retain".

PPAP Requirement Status States

This section defines each state available in the workflow for the PPAP Requirement Status process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

PPAP Requirement Status Tasks

Adding a New PPAP Requirement Status

1. Select PPAP Requirement Status from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the requirement status code and name. Notice how the Display Expression field combines the two values; this is how users will look up this status.
3. Enter a full description of the requirement status.
4. Click Save to save the new record.

PPAP Requirements

PPAP requirements define a full list of requirements for PPAP submission. The default list comes from the AIAG (Automotive Industry Action Group) PPAP manual, but customer-specific requirements can be added to the list as required.

Fig. 31: PPAP Requirements process screen

General

Requirement Number ⓘ
06

Requirement Description ⓘ
Process FMEA

Requirement Set(s) ⓘ

☐	Requirement Set	Status
☐	NQC Test 2021	S - Submit
☐	BB AP	S - Submit
☐	Taco PPAP	S - Submit
☐	Level 5	R - Retain
☐	Level 4	* - Upon Request
☐	Level 2	R - Retain
☐	Level 1	R - Retain

1 - 7 of 7 items

Include Process Flow Report? ⓘ YES NO

Include Design FMEA Report? ⓘ YES NO

Include Process FMEA Report? ⓘ YES NO

Include Control Plan Report? ⓘ YES NO

PPAP Requirements States

This section defines each state available in the workflow for the PPAP Requirements process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

PPAP Requirements Tasks

Adding a New PPAP Requirement

1. Select PPAP Requirements from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter the requirement number.
Note: This field is alphanumeric. If you want a proper sort, then pad the numbers with leading zeros.
3. Enter a full description of the requirement.
4. Click the Add New Item  button in the Requirement Submission Levels field. A new tab opens.
5. In the new tab, enter the sequence of the requirement/submission level combination. The sequence is for sorting purposes only.
6. Select the submission level and appropriate submission status for this relationship.

7. Click Save to save the requirement submission level.
8. Back in the PPAP Requirement screen, use the toggle fields to determine which reports should be included in the PPAP requirement. These reports include:
 - a. Process Flow
 - b. Design FMEA
 - c. Process FMEA
 - d. Control Plan
 - e. Work Instruction

Note: At least one report should be selected to fulfill the PPAP requirement.

9. Click Save to save the new record.

PPAP Submission Requirement Sets

PPAP submission requirement sets define groups of PPAP requirements per customer. These sets are used by PPAP Submissions to determine the set of requirements needed for a PPAP. See "PPAP Submissions" on page 165.

Fig. 32: PPAP Submission Requirement Sets screen

General

Set Name ⓘ
Level 3

Customer(s) ⓘ
☐ Display Expression Site Domain Domain Set
No records available

Description ⓘ
Warrant with product samples and complete supporting data submitted to customer.

Requirements ⓘ

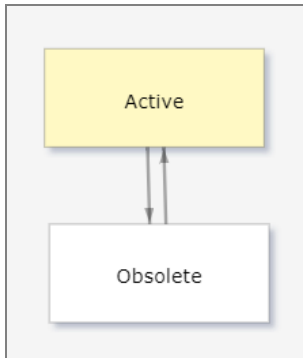
☐	Sequence ↑	Submission Requirement	Status	
☐	1.0	Design Record for all other components/details	S - Submit	
☐	2.0	Engineering Change Documents, if any	S - Submit	
☐	3.0	Customer Engineering approval, if required	S - Submit	
☐	4.0	Design FMEA	S - Submit	
☐	5.0	Process Flow Diagrams	S - Submit	
☐	6.0	Process FMEA	S - Submit	
☐	7.0	Control Plan	S - Submit	
☐	8.0	Measurement System Analysis Studies	S - Submit	

PPAP Submission Requirement Sets States

This section defines each state available in the workflow for the PPAP Submission Requirement Sets process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A PPAP submission requirement that is actively used.

Obsolete. The PPAP submission requirement set has expired or is obsolete.



PPAP Submission Requirement Sets Tasks

Adding a New PPAP Submission Requirement Set

1. Select PPAP Submission Requirement Set from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter a value for the set name. This is often the submission level.
3. Enter a description of the PPAP submission level.
4. Click the Add New Item  button in the Requirements field. A new screen opens.
5. Select the sequence, status, and submission requirement. The submission level defaults.
6. Click Save to save the requirement.
7. Back in the main process screen, click Save to save the new record. When selecting the next state, click Active.

Chapter 4

Design and Process Risks

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Introduction to Risk Plans

Risk plans are design tools for assessing risk associated with the different ways in which a part or system can fail; identifying the effects of those failures; and providing a structure for revising the design, process, or controls to mitigate risk where necessary. Essentially, the risk plan asks, "If this hazard occurred, then what would happen? And how can we reduce the risk of this hazard?"

Design Risk concerns the design of a part (pre-production), while Process Risk concerns the process of creating a part (production). See examples of these in the tables below.

The AIAG & VDA risk plan handbook defines seven steps in the risk plan process:

1. **Planning and Preparation.** Why, When, Who, What, How.
2. **Structure Analysis.** Breakdown of the structural items/systems in the design.
3. **Functional Analysis.** Breaks down the function of the different systems.
4. **Failure Analysis.** Defines the potential hazards that could occur as a result of the design.
5. **Risk Analysis.** Assigning controls and assessing risk.
6. **Optimization.** Identify actions to reduce risk (using action priority as a guide).
7. **Results Documentation.** Summarize the results of the risk activity.

Fig. 33: Design Risk Example

Design Failure Mode and Effects Analysis (Design FMEA)					PLANNING & PREPARATION (STEP 1)													
STRUCTURAL ANALYSIS (STEP 2)					Company Name:		Subject:											
					Engineering Location:		DFMEA Start Date:		DFMEA ID Number:									
							2/25/2020		DFMEA-0000020									
					Customer Name:		DFMEA Revision Date:		Change Responsibility:									
									Andy Leroy									
FUNCTIONAL ANALYSIS (STEP 3)					Model Year / Platform:		Cross-Functional Team:		Confidentiality Level:									
					2021		Jack Welch-Quality											
FAILURE ANALYSIS (STEP 4)					DFMEA RISK ANALYSIS (STEP 5) and DFMEA OPTIMIZATION (STEP 6)													
Issue #	History / Change Authorization	1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Prevention Controls (PC) of the FC	Occurrence (O) of FC	Detection Controls (DC) of the FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Remarks	
30	Jack Welch-Quality, Jack Welch-Quality	Seat will lock in position and will not be able to move	4	Plate twists when exposed to forces less than 1000Nm	Plate hardness not to spec			2	Test per Test Spec MP. 128537	3	L							
DFMEA CURRENT CONTROLS																		
Metal plate spec based on ASTM-D 19919162-0																		
DFMEA OPTIMIZATION																		
-																		
No Action Taken																		

Fig. 35: Design Risk Severity Criteria process screen

General

Severity Rank ⓘ Effect ⓘ

Severity Criteria ⓘ

Corporate or Product Lines Examples ⓘ

Design Risk Severity Criteria States

This section defines each state available in the workflow for the Design Risk Severity Criteria process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Design Risk Severity Criteria Tasks

There are no tasks for this process.

Design Risk Occurrence Criteria

The design risk occurrence criteria table is used when creating a design risk in a manufacturing document. The occurrence ratings are a relative indication of how likely a design risk is to happen.

This process is locked to prevent records from being added or deleted; however, current records can be edited. You can provide examples relevant to your business for each level of occurrence to help others better understand that level.

Fig. 36: Design Risk Occurrence Criteria process screen

General

Rank ⓘ Prediction of Failure Cause Occurring ⓘ Incidents per 1000 Items/Vehicles ⓘ Time Based Failure Cause Prediction ⓘ

Occurrence Criteria ⓘ

Corporate or Product Line Examples ⓘ

Probability of Failure ⓘ Occurrence criteria - Time Based ⓘ

Design Risk Occurrence Criteria States

This section defines each state available in the workflow for the Design Risk Occurrence Criteria process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Design Risk Occurrence Criteria Tasks

There are no tasks for this process.

Design Risk Detection Criteria

The design risk detection criteria table is used when creating a design risk in a manufacturing document. The detection ratings are a relative indication of how likely a current control will detect a design risk if it occurs.

This process is locked to prevent records from being added or deleted; however, current records can be edited. You can provide examples relevant to your business for each level of detection to help others better understand that level.

Fig. 37: Design Risk Detection Criteria process screen

General

Rank ⓘ Ability to Detect ⓘ

4 High

Detection Method Maturity ⓘ

Proven test method for verification of functionality or validation for performance quality, reliability and durability' planned timing is sufficient to modify production tools before release for production

Opportunity for Detection ⓘ

Pass-Fail Testing

Corporate or Product Line Examples ⓘ

Enter Corporate or Product Line Examples

Design Risk Detection Criteria States

This section defines each state available in the workflow for the Design Risk Detection Criteria process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Design Risk Detection Criteria Tasks

There are no tasks for this process.

Design Risk Occurrence Zone

Associated with the risk priority level (RPL) method of identifying risk, this process defines all of the combinations of severity and occurrence and assigns each a priority level.

Fig. 38: Design Risk Occurrence Zone process screen

Design Risk Occurrence Zone States

This section defines each state available in the workflow for the Design Risk Occurrence Zone process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Design Risk Occurrence Zone Tasks

Adding a New Design Risk Occurrence Zone

1. Select Design Risk Occurrence Zone from the left navigation panel. Then, click the Add Item button in the toolbar.
2. Select a numerical value to gauge the severity of the occurrence zone.
3. Select a numerical value to gauge the occurrence of the occurrence zone.
4. Select the priority level that represents the occurrence zone.
5. Select the color that represents the occurrence zone.
6. Click Save to save the new record.

Design Risk Detection Zone

Associated with the risk priority level (RPL) method of identifying risk, this process defines all of the combinations of severity and detection and assigns each a priority level.

Fig. 39: Design Risk Detection Zone process screen

Design Risk Detection Zone States

This section defines each state available in the workflow for the Design Risk Detection Zone process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Design Risk Detection Zone Tasks

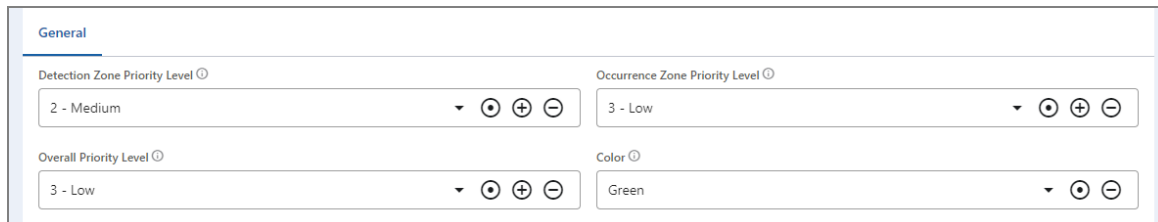
Adding a New Design Risk Detection Zone

1. Select Design Risk Detection Zone from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Select a numerical value to gauge the severity of the detection zone.
3. Select a numerical value to gauge the occurrence of the detection zone.
4. Select the priority level that represents the detection zone.
5. Select the color that represents the detection zone.
6. Click Save to save the new record.

Design Risk Priority Levels

Associated with the risk priority level (RPL) method of identifying risk, this process defines all of the combinations of the occurrence zone and detection zone and assigns each a priority level. The result of identifying where in this matrix that a failure falls is the assigned RPL.

Fig. 40: Design Risk Priority Levels process screen



General	
Detection Zone Priority Level ⓘ	Occurrence Zone Priority Level ⓘ
2 - Medium ▼ ⓘ + -	3 - Low ▼ ⓘ + -
Overall Priority Level ⓘ	Color ⓘ
3 - Low ▼ ⓘ + -	Green ▼ ⓘ -

Design Risk Priority Levels States

This section defines each state available in the workflow for the Design Risk Priority Levels process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Design Risk Priority Levels Tasks

Adding a New Design Priority Levels Zone

1. Select Design Risk Priority Levels from the left navigation panel. Then, click the Add Item  button in the toolbar.

2. Select a numerical value to gauge the detection zone priority level that represents this item.
3. Select a numerical value rank to set the occurrence zone priority level that represents this item.
4. Select the overall priority level of this item.
5. Select the color that represents this item.
6. Click Save to save the new record.

Process Risk Severity Criteria

The process risk severity criteria table is used when creating a process risk. The severity ratings are a relative indication of how severe an effect is to the customer if it happens.

This process is locked to prevent records from being added or deleted; however, current records can be edited. You can provide examples relevant to your business for each level of severity to help others better understand that level.

Fig. 41: Process Risk Severity Criteria process screen

General

Severity Rank 7 Effect Moderately high

Impact to Your Plant
Product may have to be sorted and a portion (less than 100%) scrapped; deviation from primary process; decreased line speed or added manpower

Impact to Ship-to Plant (when known)
Line shutdown from 1 hour up to full production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance

Impact to End User (when known)
Degradation of primary vehicle function necessary for normal driving during expected service life.

Corporate or Product Lines Examples
Specify examples relevant to your business for this level of severity to help others better understand this level

Description
Moderate Loss or Degradation of Primary Function

Customer Effect
Degradation of primary function (vehicle operable, but at reduced level of performance.)

Manufacturing/Assembly Effect
Significant Disruption - A portion of the production run may have to be scrapped. Deviation from primary process including decreased line speed or added manpower.

Process Risk Severity Criteria States

This section defines each state available in the workflow for the Process Risk Severity Criteria process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Process Risk Severity Criteria Tasks

There are no tasks for this process.

Process Risk Occurrence Criteria

The process risk occurrence criteria table is used when creating a process risk. The occurrence ratings are a relative indication of how likely a process risk is to happen.

This process is locked to prevent records from being added or deleted; however, current records can be edited. You can provide examples relevant to your business for each level of occurrence to help others better understand that level.

Fig. 42: Process Risk Occurrence Criteria process screen

General

Rank ⓘ
6

Prediction of Failure Cause Occurring ⓘ
High

Incidents per 1000 Items/Vehicles ⓘ
2 per thousand - 1 in 500

Time Based Failure Cause Prediction ⓘ
More than once per week

Type of Control ⓘ
Behavioral or Technical

Prevention Controls ⓘ
Prevention controls somewhat effective in preventing failure cause.

Corporate or Product Line Examples ⓘ
Enter Corporate or Product Line Examples

Description ⓘ
Moderate

Process Risk Occurrence Criteria States

This section defines each state available in the workflow for the Process Risk Occurrence Criteria process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Process Risk Occurrence Criteria Tasks

There are no tasks for this process.

Process Risk Detection Criteria

The process Risk detection criteria table is used when creating a process risk. The detection ratings are a relative indication of how likely a current control is going to detect a process risk if it happens.

This process is locked to prevent records from being added or deleted; however, current records can be edited. You can provide examples relevant to your business for each level of detection to help others better understand that level.

Fig. 43: Process Risk Detection Criteria process screen

General

Rank ⓘ

7

Ability to Detect ⓘ

Low

Detection Method Maturity ⓘ

Test or inspection method has not been proven to be effective and reliable (e.g. plant has little or no experience with method, gauge R&R results marginal on comparable process or this application, etc.).

Opportunity for Detection ⓘ

Machine-based detection (automated or semi-automated with notification by like, buzzer, etc.), or use of inspection equipment such as a coordinate measuring machine that should detect failure mode or failure cause.

Corporate or Product Line Examples ⓘ

Enter Corporate or Product Line Examples

Description ⓘ

Very Low

Criteria ⓘ

Failure Mode detection in-station by operator through visual/tactile/audible means or post-processing through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.).

Range of Detection Methods ⓘ

Problem Detection at Source

Process Risk Detection Criteria States

This section defines each state available in the workflow for the Process Risk Detection Criteria process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Process Risk Detection Criteria Tasks

There are no tasks for this process.

Process Risk Priority Levels

Risk Priority Level (RPL) is an alternative method for identifying opportunities to reduce risk. This process defines the list of risk levels that can be selected for the occurrence zone, detection zone, or overall priority level.

Fig. 44: Process Risk Priority Levels process screen

General

Priority ⓘ

2

Description ⓘ

Medium

Notes ⓘ

Enter Notes

Display Expression ⓘ

2 - Medium

Process Risk Priority Levels States

This section defines each state available in the workflow for the Process Risk Priority Levels process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Process Risk Priority Level Tasks

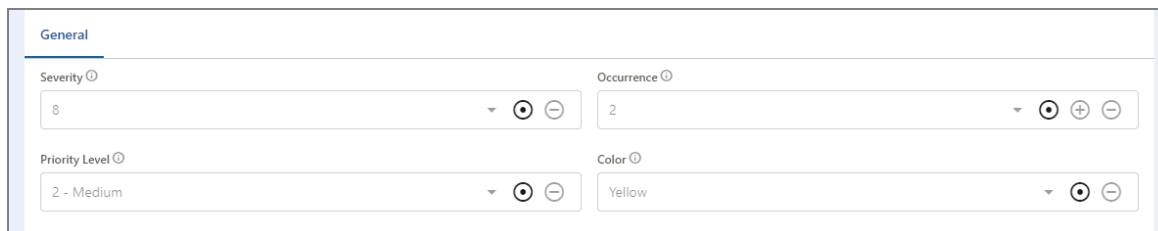
Adding a New Process Risk Priority Level

1. Select Process Risk Priority Levels from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Select a numerical rank for the priority level. Generally this is either 1, 2, or 3.
3. Enter a description of the priority level.
4. Enter any notes about the priority level.
5. Click Save to save the new record. When selecting the next state, click Active.

Process Risk Occurrence Zone

Associated with the RPL method of identifying risk, this process defines all of the combinations of severity and occurrence and assigns each a priority level.

Fig. 45: Process Risk Occurrence Zone process screen



General	
Severity ⓘ 8	Occurrence ⓘ 2
Priority Level ⓘ 2 - Medium	Color ⓘ Yellow

Process Risk Occurrence Zone States

This section defines each state available in the workflow for the Process Risk Occurrence Zone process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Process Risk Occurrence Zone Tasks

Adding a New Process Risk Occurrence Zone

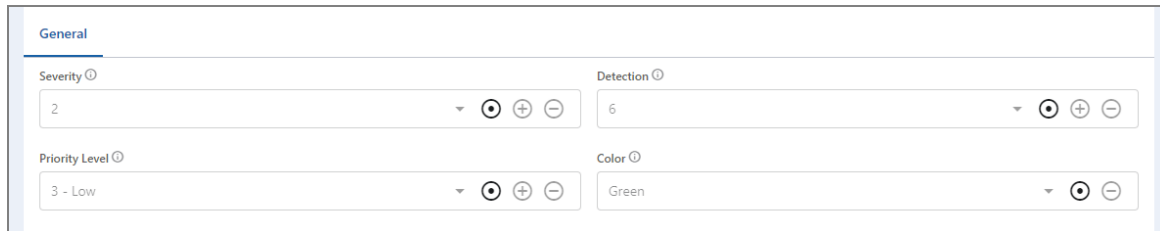
1. Select Process Risk Occurrence Zone from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Select a numerical value to gauge the severity of the occurrence zone.
3. Select a numerical value to gauge the occurrence of the occurrence zone.

4. Select the priority level that represents the occurrence zone.
5. Select the color that represents the occurrence zone.
6. Click Save to save the new record.

Process Risk Detection Zone

Associated with the RPL method of identifying risk, this process defines all of the combinations of severity and detection and assigns each a priority level.

Fig. 46: Process Risk Detection Zone process screen



Process Risk Detection Zone States

This section defines each state available in the workflow for the Process Risk Detection Zone process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Process Risk Detection Zone Tasks

Adding a New Process Risk Detection Zone

1. Select Process Risk Detection Zone from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Select a numerical value to gauge the severity of the detection zone.
3. Select a numerical value to gauge the occurrence of the detection zone.
4. Select the priority level that represents the detection zone.
5. Select the color that represents the detection zone.
6. Click Save to save the new record.

Process Risk Zone Priority Levels

Associated with the RPL method of identifying risk, this process defines all of the combinations of the occurrence zone and detection zone and assigns each a priority level. The result of identifying where in this matrix that a failure falls is the assigned RPL.

Fig. 47: Process Risk Zone Priority Levels process screen

The screenshot shows a web interface for configuring Process Risk Zone Priority Levels. It features a 'General' tab with four input fields, each with a dropdown menu and three circular control buttons (minus, plus, and a central dot). The fields are: 'Detection Zone Priority Level' (2 - Medium), 'Occurrence Zone Priority Level' (3 - Low), 'Overall Priority Level' (3 - Low), and 'Color' (Green).

Process Risk Zone Priority Levels States

This section defines each state available in the workflow for the Process Risk Zone Priority Levels process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Process Risk Zone Priority Levels Tasks

Adding a New Process Risk Zone Priority Level

1. Select Process Risk Zone Priority Levels from the left navigation panel. Then, click the Add Item button in the toolbar.
2. Select a numerical value to gauge the detection zone priority level that represents this item.
3. Select a numerical value rank to set the occurrence zone priority level that represents this item.
4. Select the overall priority level of this item.
5. Select the color that represents this item.
6. Click Save to save the new record.

FMEA-MSR Frequency Criteria

The FMEA-MSR frequency criteria provides a frequency rating representative of the effectiveness of preventive controls. This is used when building a FMEA-MSR.

This process is locked to prevent records from being added or deleted; however, current records can be edited. You can provide examples relevant to your business for each level of frequency to help others better understand that level.

Fig. 48: FMEA-MSR Frequency Criteria process screen

General

Estimated Frequency ⓘ

Frequency Rank ⓘ

Frequency Criteria ⓘ

Corporate or Product Line Examples ⓘ

FMEA-MSR Frequency Criteria States

This section defines each state available in the workflow for the FMEA-MSR Frequency Criteria process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

FMEA-MSR Frequency Criteria Tasks

There are no tasks for this process.

FMEA-MSR Monitoring Criteria

The FMEA-MSR monitoring criteria provides a monitoring rating representative of the effectiveness of the diagnostic detection controls. This is used when building a FMEA-MSR.

This process is locked to prevent records from being added or deleted; however, current records can be edited. You can provide examples relevant to your business for each level of monitoring to help others better understand that level.

Fig. 49: FMEA-MSR Monitoring Criteria process screen

General

Effectiveness of Monitoring Controls & System Response ⓘ

Monitoring Rank ⓘ

Diagnostic Monitoring / Sensory Perception Criteria ⓘ

System Response / Human Reaction Criteria ⓘ

Corporate or Product Line Examples ⓘ

FMEA-MSR Monitoring Criteria States

This section defines each state available in the workflow for the FMEA-MSR Monitoring Criteria process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

FMEA-MSR Monitoring Criteria Tasks

There are no tasks for this process.

Risk Action Priority

The Risk Action Priority process describes a hazard effect and assigns an action priority to determine the importance of taking action. Action priority is based on combinations of severity, occurrence, and detection ratings in order to prioritize actions for risk reduction.

The action priority calculations and effect are pre-populated to reflect AIAG & VDA risk plan standards. However, you can comment to provide examples relevant to your business to help others better understand the action priority.

Fig. 50: Risk Action Priority process screen

The screenshot displays a web form titled "General" for the Risk Action Priority process. It contains several input fields and dropdown menus:

- S (Severity):** A dropdown menu with the value "10" selected.
- Harm:** A text input field containing "Product or Plant Effect Very high".
- O (Occurrence):** A dropdown menu with the value "9" selected.
- Prediction of Hazard Cause Occurring:** A text input field containing "Very high".
- D (Detection):** A dropdown menu with the value "6" selected.
- Ability to Detect:** A text input field containing "Moderate".
- Action Priority:** A dropdown menu with the value "H" selected.
- Comments:** A text input field with the placeholder text "Enter Comments".

Risk Action Priority States

This section defines each state available in the workflow for the Risk Action Priority process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

Risk Action Priority Tasks

There are no tasks for this process.

FMEA-MSR Action Priority

The FMEA-MSR Action Priority process describes a risk effect and assigns an action priority to determine the importance of taking action. Action priority is based on combinations of severity, frequency, and monitoring ratings in order to prioritize actions for risk reduction.

The action priority calculations and effect are pre-populated to reflect AIAG & VDA FMEA standards. However, you can comment to provide examples relevant to your business to help others better understand the action priority.

Fig. 51: FMEA-MSR Action Priority process screen

General

S ⓘ

10 ▴ ▾

F ⓘ

9 ▴ ▾

M ⓘ

7 ▴ ▾

Action Priority ⓘ

H

Effect ⓘ

Product Effect High

Prediction of Failure Cause Occurring ⓘ

Medium - Extremely high

Effectiveness of Monitoring ⓘ

Reliable - Not effective

Comments ⓘ

Enter Comments

FMEA-MSR Action Priority States

This section defines each state available in the workflow for the FMEA-MSR Action Priority process. See "State Change Security" on page 206 to learn more about how these states transition.

There are no states available.

FMEA-MSR Action Priority Tasks

There are no tasks for this process.

Chapter 5

Design Control Library

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Design Control Level 2 Libraries

Libraries in the Design Control module are separated into two groups: level 1 and level 2. Level 1 libraries create data that is used to populate level 2 libraries. The Design Control Libraries section of the Design Control module is made up of level 2 processes that will be used to ultimately create a manufacturing document.

An overview of the Design Control Libraries begins with developing a process flow, in which you determine each step that must be completed to produce a part. Once this flow is developed, look at each step – or Process – and determine what failures can occur.

Process Risk identifies where the risks are within a process. If there is a risk, a control must be put in place. Controls determine what characteristics must be measured to reduce, eliminate, or detect the defined hazards. This is your Process Risk Control Plan.

Once all of these processes have been completed, they are connected within a Family Template in the order of Process Flow, Specifications, Process Risks, and Process Risk Control Plan.

Graphical Risk Tree View

Risk is an intricate concept that can be complex to manage within software, especially during the brainstorming stage. To ease this difficulty, the Family Templates and Manufacturing Documents processes contain a graphical risk tree view, which allows users to add, edit, delete, link, and sort risk records within a visual context. See "Family Templates" on page 116 and "Manufacturing Documents" on page 134.

The tree view button appears when a process is saved to the Draft state for the first time. To open the tree view, click the triple line icon  in the lower left corner of the screen. The tree view slides out, but does not cover the process screen.

Fig. 52: Family Templates screen, Tree View

The screenshot shows the EQMS Family Templates screen. The left sidebar contains a tree view with the following structure:

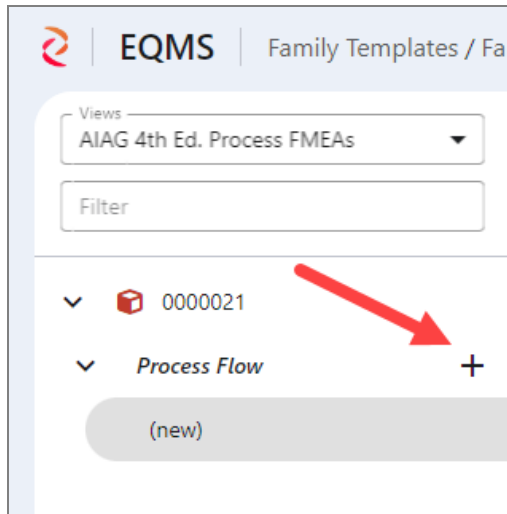
- Views: AIAG 4th Ed. Process FMEAs
 - Filter
 - 0000003
 - Process Flow
 - Casting - Pattern Making
 - Casting - Coremaking & Molding
 - Casting - Alloy Melting and Pouring
 - Process FMEA
 - Metal is overheated
 - The pour speed is too high
 - Failure Causes
 - Ladle tilt mechanism is obstructed
 - Controls
 - Furnace does not get the temperature high enough
 - Casting Cleaning
 - Machining

The main area displays the 'Process Flow' tab with the following table:

Flow Sequence	Process No	Process	Specification ID	Specification Name
1.0	CST-2	Casting - Pattern Making		
2.0	CST-3	Casting - Coremaking & Molding		
3.0	CST-4	Casting - Alloy Melting and Pouring	02, 01, 01	Temperature, F
4.0	CST-5	Casting Cleaning		
5.0	MCH-1	Machining	SFC-1, 01, 02, 03	Surface Finish

A red box highlights the 'Process Flow' section in the sidebar and the 'Process Flow' tab in the main area. A red arrow points to the 'Process Flow' tab.

To begin, choose the format in which you will be working: AIAG 4th Ed. Process FMEAs or AIAG/VDA Process FMEAs (or Design FMEA or Control Plan Only PFMEA for manufacturing documents). Then click the plus icon beside the Process Flow line item. A new line item appears, and the process screen transitions to a blank process flow screen.

Fig. 53: Tree View, adding a new process flow

As you build and save each step of the risk, a new line item will appear and allow you to add the next step. Double-click a line item to open its detail screen, or drag-and-drop a line item to rearrange the order within the process. You can search for keywords within the tree view, which can be useful as the number of records grows.

Note: All APQP risk reports will sort in the order as they are displayed in the tree view.

Design Risk Systems Library

The Design Risk Systems Library process identifies the systems or subsystems within your product lines. An example of a system might be an infusion pump system for a medical device or an electric window actuator system for a vehicle. After the design risk system is added to the library, you can define the structural, functional, and failure analysis of that system in a foundation or family design risk. See "Design Risk Structural Analysis Library" on page 101.

On a specific part's manufacturing document, you can specify the systems in play for that part and link the design risk structural, functional, and failure analysis so you do not have to reinvent it. See "Manufacturing Documents" on page 134.

Fig. 54: Design Risk Systems Library screen, General tab

General

System/Subsystem Code ⓘ
TRSDR

System/Subsystem Name ⓘ
Transducer

Domain ⓘ
10USA - USA Domain

Entity ⓘ
10USACO - USA DIVISION

Site(s) ⓘ

☐	Site Code	Site Name	
☐	10-100	Site 100 USA	

1 - 1 of 1 items

Boundary Diagram ⓘ

Block Diagram ⓘ

Interface Analysis ⓘ

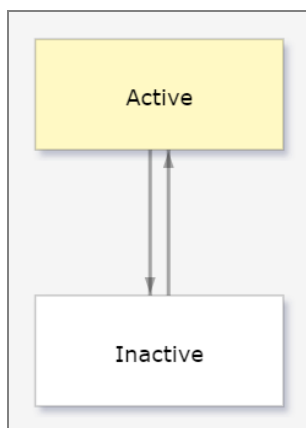
Structure Tree ⓘ

Design Risk Systems Library States

This section defines each state available in the workflow for the Design Risk Systems Library process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A design risk system that is actively used.

Inactive. A design risk system that is no longer in use.



Design Risk Systems Library Tasks

Adding a New Design Risk Systems Library

1. Select Design Risk Systems Library from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter a name and a code for the system or subsystem.
3. Select a domain and entity.
4. Select one or more sites.
 - a. Click the Link  button. A new window opens.
 - b. Select one or more sites.
 - c. Click OK.
5. If you have a diagram, interface analysis, or structure tree for the system structure, then drag and drop or upload the file to the applicable field.
6. Click Save to save the new record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the design risk systems library cannot be used for new records.

Processes

Use process records to document specific business or manufacturing processes that make up a process flow. Documenting a process provides benefits in several areas, including auditing, product design, product development, product corrective action, and non-conformance.

Process records are the main repository for information on your organization's business and manufacturing processes, and are used by the Auditing, CAPA, Inspection & SPC, and Design Control modules. In the Auditing module, processes are used to identify which processes have been audited and when, which is important to track given the process-based auditing approach. In the Design Control module, the list of processes serves as a way to standardize the name of processes used on manufacturing-related documentation. The information from a process that has been documented in one module can be re-used in another module.

Generally, processes fall into three categories:

- **Customer-oriented processes.** Core processes to the business such as design and development, order management, and production.
- **Management-oriented processes.** Processes that define areas of management responsibility and, typically, have an indirect impact on the customer such as quality policy and objectives, resource management, and planning.
- **Support-oriented processes.** Processes that enable other processes such as purchasing, finance, and information technology.

Processes may be linked to a responsible site with an ITAR (International Traffic in Arms Regulation) requirement. If this is true, then a new field appears on the General tab titled ITAR Restricted. Setting this toggle to YES means that only employees who are ITAR compliant can view, access, and interact with the process.

Processes are used in the following processes of the Design Control module:

- By Family Templates and Manufacturing Documents to build the process flow, which represents the flow of processes used to manufacture a product. See "Family Templates" on page 116 and "Manufacturing Documents" on page 134.
- By Library Specifications to link a process specification to a process. This link is essential to build a family template. See "Library Specifications" on page 95.
- By Process Risk Failure Analysis Library, which is linked to a process and determines what can go wrong during that process. See "Process Risk Analysis Library" on page 111.

Fig. 55: Processes screen, General tab

Process Code ⓘ STMP

Process Name ⓘ Stamping

Process Owner ⓘ demo superuser

Process Category ⓘ COP

General Manufacturing Information Work Elements Auditing Information Requires Review Skill and Training Risks

Process Description ⓘ
Place flat sheet metal into stamping press

Domain ⓘ 10USA - USA Domain

Entity ⓘ 10USACO - USA DIVISION

Site ⓘ 10-201 - Lean Manufacturing Site

Process Symbol ⓘ Operation

Parent Process ⓘ Enter Parent Process

Top Management Reviewer ⓘ VP-OPS - VP of Operations

Responsibilities ⓘ

☐	Display Expression	
☐	TM - Training Manager	
☐	INSP-OP1 - Inspection Operator Level 1	

1 - 2 of 2 items

Authorities ⓘ

☐	Display Expression	
☐	TM - Training Manager	

1 - 1 of 1 items

Related Document(s) ⓘ

Document Number	Document Title	Version Number	Current State	Document Type

The General tab is used to define the basic details of a process, including the description, parent process, process owner, responsibilities, and more.

Fig. 56: Processes screen, Manufacturing Information tab

Process Code Process Name Process Owner Process Category

General **Manufacturing Information** Work Elements Auditing Information Requires Review Skill and Training Risks

Inspection Requires Approval ☐ YES ☒ NO List Process in APQP ☐ YES ☒ NO

Sources of Variation

Process Failure Mode(s)

Process Control(s)

Process Specification(s)

☐	Specification Name	Acceptance Criteria / Notes	Lower Limit	Target	Upper Limit	Unit of Measure	
☐	Plate Thickness	Measured					

1 - 1 of 1 items

Process FMEA Analysis Library (AIAG & VDA)

☐	Process Item System/Subsystem	Process Step Name	Process Work Elements	
☐				

No records available

Use the Manufacturing Information tab to link the process to process specifications and process risk analysis library. This tab contains a "List Process in Device Control" check box; this box must be selected in order for this process to be linked in a family template or manufacturing document via the Actions button.

Fig. 57: Processes screen, Work Elements tab

Process Code Process Name Process Owner Process Category

General Manufacturing Information **Work Elements** Auditing Information Requires Review Skill and Training Risks

Process Work Elements

☐	Element	
☐	Material	
☐	Man	
☐	Machine	

1 - 3 of 3 items

The Work Elements tab allows you to link work elements to the process that should be considered when contemplating potential hazards and controls. These elements include Man, Machine, Material, Environment, Method, and Measurement.

Fig. 58: Processes screen, Auditing Information tab

Process Code ⓘ STMP Process Name ⓘ Stamping Process Owner ⓘ demo superuser Process Category ⓘ COP

General Manufacturing Information Work Elements **Auditing Information** Requires Review Skill and Training Risks

Related Management System Standard Sections/Requirements ⓘ

Management System Standard	Section/Requirement Number	Section/Requirement Name	Related Processes
ISO 13485:2003 - Quality Management for Medical Devices	7.0	Product Realization	STMP - Stamping
IATF 16949:2016 - Quality Management for Automotive	8.0	Operation	STMP - Stamping

1 - 2 of 2 items

Process Input(s) ⓘ

Display Expression	Process Interaction Description
☐ LS-REC - Receiving	Receive materials for stamping and manufacture

1 - 1 of 1 items

Process Output(s) ⓘ

Display Expression	Process Interaction Description
☐ INS - Inspection	Inspect parts for quality

1 - 1 of 1 items

Use the Auditing Information tab to record auditing information for the process, such as:

- **Process Category.** Indicate whether the process is customer-oriented or another type of process.
- **Process Inputs.** These are the processes that the manufactured item goes through before it reaches the process currently being defined.
- **Process Output.** The next process that the item moves to after the process currently being defined.
- **Equipment.** The equipment used in the process.

Note that this tab is used more in the Auditing module than it is in the Design Control module. See the [Auditing](#) user guide for information on how to use this tab.

Fig. 59: Processes screen, Requires Review tab

Process Code ⓘ STMP Process Name ⓘ Stamping Process Owner ⓘ demo superuser Process Category ⓘ COP

General Manufacturing Information Work Elements Auditing Information **Requires Review** Skill and Training Risks

Last Review ⓘ 4/18/2023 Next Review Due ⓘ 4/17/2024 Review Frequency ⓘ 1Y - Every year

Review Completed By ⓘ Enter Review Completed By Review Notes ⓘ Enter Review Notes

If a process requires review, then the Requires Review tab allows you to supply details regarding the process' last review, review frequency, review notes, and more.

Fig. 60: Processes screen, Skill and Training tab

Process Code ⓘ FAB - 1

Process Name ⓘ Fabrication

Process Owner ⓘ Jane First-MgrQual

Process Category ⓘ MAN - Manufacturing

General Manufacturing Information Work Elements Auditing Information Requires Review **Skill and Training** Risks

Instructional Video ⓘ

Enter a URL to link a video

Link Video

Skill ⓘ FAB - 1 - Fabrication of Motor Mount Assembly

Training Aid ⓘ

Drop files here to upload or

Browse Files

Skill Training Questions ⓘ

☐	Question Number	Question
☐	0000014	How many stampings make up a batch?
☐	0000013	What two specifications should be checked before stamping?
☐	0000012	Can you stamp more than one part at a time?

1 - 3 of 3 items

Training Event(s) ⓘ

Use the Skill and Training tab to enhance training management for the process. Select or create a skill, create questions that will evaluate a person's knowledge of changes to the process, and optionally upload a video and file to be used as training aids.

Fig. 61: Processes screen, Risks tab

Process Code ⓘ STMP

Process Name ⓘ Stamping

Process Owner ⓘ demo superuser

Process Category ⓘ COP

General Manufacturing Information Work Elements Auditing Information Requires Review Skill and Training **Risks**

Risks ⓘ

☐	Risk Number	Title	Owner	Risk Level	Risk Evaluation
☐	0000105	The impact of changes have not been identified and addressed	demo superuser	0	
☐	0000104	Failure modes are not identified for the process	demo superuser	0	
☐	0000103	Controls are not established for the identified failure modes	demo superuser	0	

1 - 3 of 3 items

Use the Risks tab to create a list of risks associated with the process. See the [Risk Management](#) user guide to learn more about creating risks.

Processes States

This section defines each state available in the workflow for the Processes process. See "State Change Security" on page 206 to learn more about how these states transition.

Draft (Default). The process is still being drafted and not yet ready for approval.

Ready for Approval. The process is waiting to be approved.

Awaiting Effective Date. The process is approved but waiting until the effective date to be marked as official.

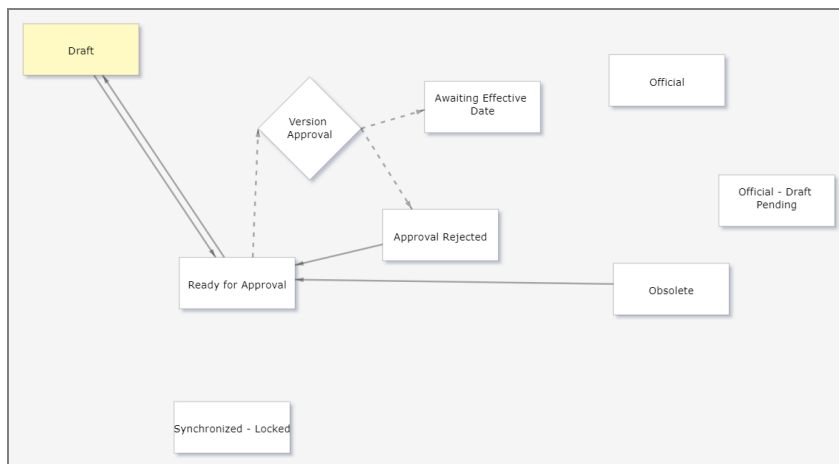
Approval Rejected. The process approval was rejected.

Official. The official version of the process.

Official – Draft Pending. The official version of a process, which also has a new version being drafted.

Obsolete. An obsolete version of the process. This version shall not be used.

Synchronized - Locked. This state is used if the process was created based on an integration to an ERP system.



Processes Tasks

Adding a New Process

1. Select Processes from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the Process Code, Process Name, Process Category, and Process Description fields.
3. Select a Process Owner and Top Management Reviewer.

Note: The Top Management Reviewer field is filtered based on employee titles where Top Management is checked.

4. In the Responsibilities field, click the Link  button to select one or more Training Roles who are responsible for this process.
5. Navigate to the Requires review tab. Click the calendar icon in the Last Review field to select the date when this process was last reviewed.
6. Use the Review Frequency drop-down field to determine how often the process should be reviewed, and the Review Completed By drop-down field to declare who completed the last review.
7. Click Save to save the new record. When selecting the next state, click Draft or Ready for Approval as needed.

Adding Process Manufacturing Information

1. In the Process detail screen, navigate to the Manufacturing Information tab.
2. Select the "List Process in Design Control" check box to ensure this process can be selected in other Design Control processes, such as Family Templates. If necessary, set the "Inspection Requires Approval" toggle field to YES.
3. Use the Sources of Variation field to describe any known sources of variation that may affect the process.
4. Use the Process Hazards/Hazardous Situations field to identify any potential failures that could happen with the process.

Note: This information may be reflected in the Process Risk Failure Analysis Library field at the bottom of the screen, which is automatically populated. See "Process Risk Analysis Library" on page 111 for more information.

5. Use the Process Controls field to identify anything currently being done to help control the potential failures from happening.
6. The Process Specifications field may contain process specifications that are already linked to the process. You can add more by clicking the Add New Item  button. See "Library Specifications" on page 95 for more information.
7. Navigate to the Work Elements tab. Link one or more process work elements that apply to this process.
 - a. Click the Link  button.
 - b. Select one or more work elements.
 - c. Click OK.
8. Click Save to save the record. When selecting the next state, click Draft.

Approving a Process

1. The person responsible for approving a process is automatically notified when it is time for approval through the inbox or optionally from an e-mail notification (clicking the link in that message takes you to the process for approval).
2. Open the inbox, either through the Home Page dashboard or by clicking the Inbox icon in the toolbar.
3. Upon opening the inbox, click the approval item under the Design Control group to show the action icons. Then click the Open icon. The screen navigates to the process' detail screen.

4. In the detail screen, scroll down to the Version Approval field and click the Approve/Reject button. A small window appears.
5. In the Sign Off window, enter your password and either approve or reject the change. Use the comments field to document any information about your decision. Comments are required for rejection.

Note: Once all members of the approval process have finished, the process becomes official and ready for use.

Starting a New Version of a Process

The Start New Version command in the Processes process should be used for small-impact changes that do not affect other departments or people, such as fixing a typo or changing a symbol. If the process requires a bigger change, then a change request must be initiated. See "Change Requests" in the [Document Control](#) user guide for more information.

Note: Revisions can only be made if the process is in the Official state.

1. Open the detail screen of the process you wish to change. If the process does not already have a change initiated, then click the Actions  button and select Start New Version.

Note: If a process already has a change initiated, then contact the Process Owner to see if the changes you want to make can be included in the current change.

2. In the General tab, use the Change Description field to summarize what has changed and set the effective date.
3. Select the "Synchronized" and "Requires Training" check boxes as appropriate. Minor changes may not require additional training.
4. Click Save to save the record. Select Ready for Approval if you are finished with the changes or select Draft to save the process as a draft and continue working.

When this version is approved, it becomes official and all previous versions become obsolete.

It can be helpful to see a historical version of the process. You can quickly access historical versions from any version of the process by clicking More in the toolbar and selecting Versions to expand the Versioning panel. Click one of these versions to switch your detail screen view to the selected version.

Fig. 62: List of Versions

Versions	
Number: F	Date: 1/8/2024, 11:02 AM
Number: E	Date: 7/31/2023, 11:18 AM
Number: D	Date: 5/4/2023, 3:32 PM
Number: C	Date: 4/28/2023, 1:18 PM
Number: B	Date: 4/28/2023, 1:17 PM
Number: A	Date: 4/12/2023, 3:05 PM

Library Specifications

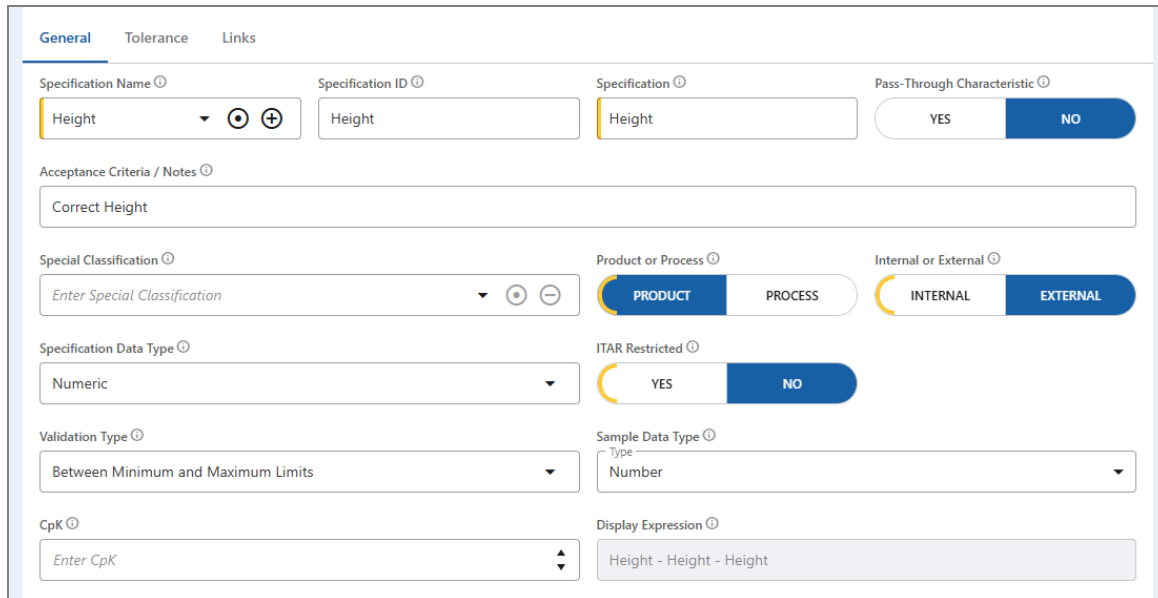
Library specifications document the acceptance criteria of a product or process, including (where appropriate) the tolerances of an attribute or characteristic. Each specification is associated with a specification group and linked to additional data (item, process, drawing, etc.), which defines the applicability of the specification.

Library specifications may be ITAR restricted, meaning that only employees who are ITAR compliant can view, access, and interact with the specification.

Process library specifications are linked to a specific process and can be found on that process' detail screen. See "Processes" on page 87.

Library specifications are linked to Family Templates and Manufacturing Documents to document acceptance criteria for a process flow and library process. See "Family Templates" on page 116 and "Manufacturing Documents" on page 134.

Fig. 63: Library Specification screen, General tab

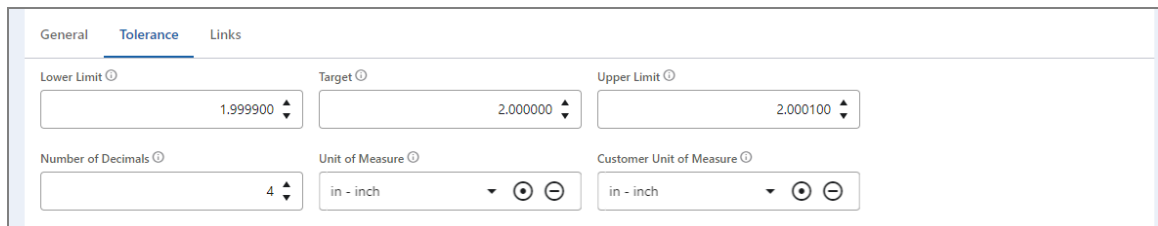


The General tab is used to define the basic details of a specification, including whether it is a product or process specification, the specification and sample data types, validation type and more.

The General tab is used to define the basic details of a specification, including whether it is a product or process specification, the specification and sample data types, validation type and more.

The Validation Type and Sample Data Type fields are dependent on the Specification Data Type field.

Fig. 64: Library Specifications screen, Tolerance tab



The Tolerance tab changes depending on the Specification Data Type field:

The Tolerance tab changes depending on the Specification Data Type field:

- **Numeric.** Set the numerical target, parameters, and unit of measure (see above).
- **Date.** Specify the date range.
- **Logical.** The Tolerance tab is hidden when Logical is selected.

Fig. 65: Library Specifications screen, Links tab

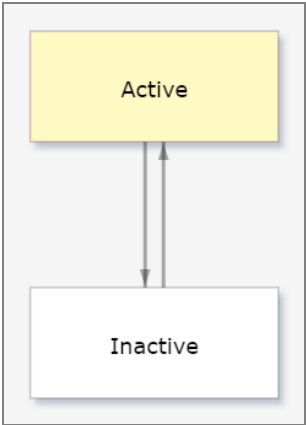
The Links tab contains fields to link the specification to multiple processes and item groups. Generally, the Process field is only used for process specifications and the Item Groups field is only used for product specifications.

Library Specifications States

This section defines each state available in the workflow for the Library Specifications process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A library specification that is actively used.

Inactive. A library specification that is no longer in use.



Library Specifications Tasks

Adding a New Library Specification

1. Select Library Specifications from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the specification name, ID, and description. Notice how the Display Expression field combines the three values; this is how users will look up this library specification.

3. If the specification applies to a special class, then select the special classification as required by the customer.
4. Select whether this specification applies to a product or a process, as well as whether it is internal or external.

Note: Setting the specification to internal will prevent it from appearing on related PPAP reports.

5. Select the specification data type:
 - a. **Numeric.** Select when using lower/target/upper limit data.
 - b. **Logical.** Select when entering acceptance criteria.
 - c. **Date.** Select when capturing a date.
6. Select the sample data type:
 - a. **Alphanumeric.** Data consists of numbers and letters.
 - b. **Boolean.** Used for logical specifications, boolean has two possible values: true and false.
 - c. **Number.** Data consists of only numbers.

Note: If the record is saved prior to the data type selection, the sample data type changes automatically based on what was selected in the Specification Data Type field.

7. Select the type of validation to use when evaluating if an inspection result passes or fails. Select None if you do not want the system to automatically determine a pass or fail result.
8. For the acceptance criteria:
 - a. If the specification is not defined by a numerical tolerance, enter a description of the acceptance criteria for the specification.
 - b. If the specification is defined by a numerical tolerance, navigate to the Tolerance tab and set the parameters for the acceptance criteria.
9. Navigate to the Links tab. Select the processes and item groups that the library specification belongs to.
10. Click Save to save the new record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the library specification cannot be used for new records.

Control Library

Once a process risk has determined the failures that can occur in a process flow, controls determine what characteristics must be measured to reduce, eliminate, or detect the defined hazards. Examples include what to measure with, how to measure the parts, how many samples to take and how often, and so on. These controls make up the Process Risk Quality Plan.

The Control Library process is a library of methods used to control quality that is related to product or process specifications. These can then be brought in to manufacturing documents and family templates.

Control libraries are used in the following processes of the Design Control module:

- By Process Risk Failure Analysis Library and Process Risk Causes Library to provide methods to prevent or detect a failure. See "Process Risk Analysis Library" on page 111 and "Process Risk Causes Library" on page 113.
- By Family Templates to connect process risk control plans to a template and, ultimately, a manufacturing document. See "Family Templates" on page 116.
- By Manufacturing Documents to connect process risk control plans to a controlled copy of documentation used for the manufacture of an item. See "Manufacturing Documents" on page 134.

Fig. 66: Control Library screen, General tab

The screenshot shows the 'General' tab of the Control Library screen. The form is organized into several sections:

- Control Method:** A dropdown menu with 'In-process check sheet' selected.
- Control Description:** A text field containing 'Product test for Torque in-process'.
- Evaluation/Measurement Technique:** A text field containing 'Check product via Torque gauge'.
- Machine, Device, Jig, Tools for Manufacturing:** A text field containing 'Assembly station'.
- Tooling and Equipment Type:** A dropdown menu with 'Enter Tooling and Equipment Type' selected.
- Tooling and Equipment Number:** A dropdown menu with 'Enter Tooling and Equipment Number' selected.
- Gauge Type:** A dropdown menu with 'TQ - Torque Gauge' selected.
- Gauge Number:** A dropdown menu with 'Enter Gauge Number' selected.
- Reaction Plan:** A dropdown menu with 'Correct/Repair and Report' selected.
- Inspect:** A toggle switch with 'YES' selected.
- Inspection Type(s):** A table with columns 'Inspection Type Code' and 'Inspection Type Name'. It contains one row with code '3' and name 'In-Process Inspection'.
- Inspection Station(s):** A table with columns 'Inspection Station Name', 'Site', and 'Domain'. It contains one row with station name 'General Assembly', site '10-100 - Site 100 USA', and domain '10USA - USA D'.
- Notes:** A text area at the bottom of the form.

The General tab is used to define the basic details of a control library and includes multiple fields that allow you to be as specific as you want regarding the techniques, equipment, locations, and more that are used in a control.

Fig. 67: Library Controls screen, Sampling tab

The screenshot shows the 'Sampling' tab of the Library Controls screen. The form contains the following fields:

- Sampling Technique:** A dropdown menu with '100% Inspection - Known Batch Size' selected.
- Sample Frequency:** A dropdown menu with 'Per Lot' selected.
- Collection Frequency Option:** Two radio buttons: 'Time based' (unselected) and 'Event based' (selected).
- Frequency Events:** A dropdown menu with 'Per Lot' selected.
- Sample Frequency Description:** A text field containing 'Per Lot'.

Use the Sampling tab to specify the technique and frequency for sampling product and process components. The Sampling Technique field determines what fields appear after the Sample Frequency field.

The Sampling Technique field has four choices:

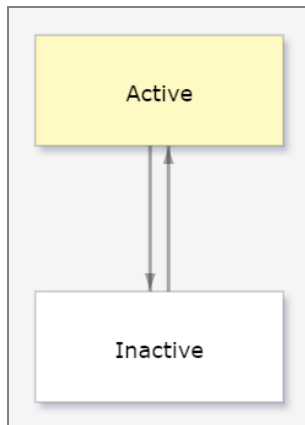
- **Fixed.** Use for cases with a set/static number of samples (e.g. 2 samples, 5 samples, etc.)
- **100% Known Sample Size.** Use for cases where all parts should be inspected.
- **AQL.** Use for cases where, based on the batch/lot size, it is best to use an Acceptable Quality Limit table to dynamically determine the number of samples.
- **Manual.** Use for cases where the operator/inspector must specify the sample size. Rarely used for cases such as an engineering study.

Control Library States

This section defines each state available in the workflow for the Control Library process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A control library that is actively used.

Inactive. A control library that is no longer in use.



Control Library Tasks

Adding a New Control Library

1. Select Control Library from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Select a control method of detection or prevention failure.
3. Enter descriptions for the control, the evaluation/measurement technique, and the machine, device, jig, or tools that would be used in manufacturing.
4. Select the tooling and equipment type and number gauge type and number, and a reaction plan.
5. If this control library will be used in conjunction with inspection events, then set the "Inspect" toggle field to YES. Two new fields appear: Inspection Types and Inspection Stations.

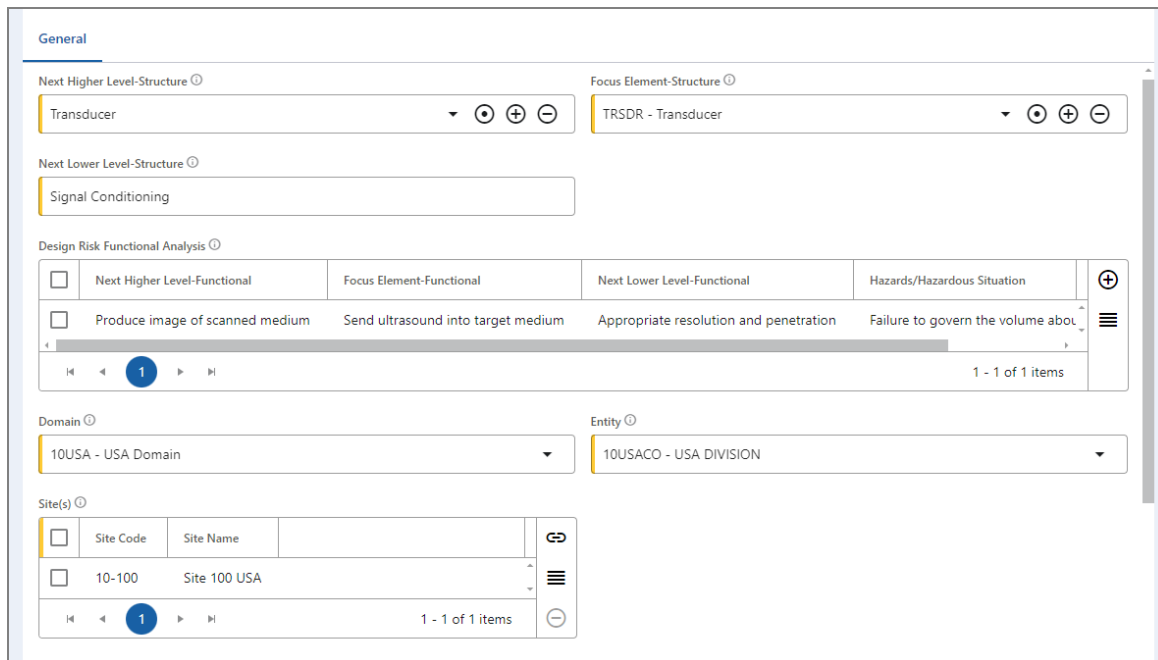
6. Use the Link  or Add New Item  button in the Inspection Types and Inspection Stations fields to add inspection data.
7. Navigate to the Sampling tab. Select the appropriate sampling technique. If you chose Fixed, then select or create a sample size description.
8. Set up the sampling frequency for this control:
 - a. **Time based.** Enter the number of hours in between inspections.
 - b. **Event based.** Select the event that requires inspection for the control.
9. Click Save to save the new record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the Control Library cannot be used for new records.

Design Risk Structural Analysis Library

The Design Risk Structural Analysis Library process provides a library of structural and functional examinations for design risks. It dissects the structural items or systems in a design, then breaks down the function of those systems; this fulfills the second and third steps in the design risk process. These details can then be linked to the Design Risk Analysis Library process so they may be investigated for hazardous situations and controls. See "Design Risk Analysis Library" on page 104 for more information.

Fig. 68: Design Risk Structural Analysis Library process screen



General

Next Higher Level-Structure : Transducer    

Focus Element-Structure : TRSDR - Transducer    

Next Lower Level-Structure : Signal Conditioning

Design Risk Functional Analysis 

☐	Next Higher Level-Functional	Focus Element-Functional	Next Lower Level-Functional	Hazards/Hazardous Situation	
☐	Produce image of scanned medium	Send ultrasound into target medium	Appropriate resolution and penetration	Failure to govern the volume about	

1 - 1 of 1 items

Domain : 10USA - USA Domain 

Entity : 10USACO - USA DIVISION 

Site(s) 

☐	Site Code	Site Name	
☐	10-100	Site 100 USA	

1 - 1 of 1 items

The first level of this process involves determining focus and next level structures, which are tied to the Design Risk Systems Library process (see page 85 for more details). Additionally, you can upload boundary and block diagrams, an interface analysis, and a structure tree.

Once the structural analysis is complete, the functional analysis can begin.

Fig. 69: Design Risk Functional Analysis Library process, General tab

General P-Diagram

Next Higher Level-Structural ⓘ
Transducer

Next Higher Level-Functional ⓘ
Produce image of scanned medium

Focus Element-Structural ⓘ
TRSDR - Transducer

Focus Element-Functional ⓘ
Send ultrasound into target medium

Next Lower Level-Structural ⓘ
Signal Conditioning

Next Lower Level-Functional ⓘ
Appropriate resolution and penetration

Design Risk Analysis ⓘ

☐	Hazards/Hazardous Situation	Hazard Harms	Hazard Cause(s) of the Work Elements	
☐	Failure to govern the volume about 155DB threshold	Overheating of the target medium	Amplitude regulation not present or effective	

1 - 1 of 1 items

Display Expression ⓘ
Produce image of scanned medium - Send ultrasound into target medium - Appropriate resolution and penetration

When a new record is added to the Design Risk Functional Analysis field, the screen shown above appears. Use this screen to describe the function of each level and focus structure. You can also create a Design Risk Analysis Library record directly from this screen.

Fig. 70: Design Risk Functional Analysis Library process, P-Diagram tab

General **P-Diagram**

Input ⓘ
Pulse generator

Functional Requirements ⓘ
Transducer produces the ultrasound in a known frequency and known amplitude

Control Factors ⓘ
Piezoelectric crystal thickness, Acoustic lens profile, Matching layer thickness

Non-Functional Requirements ⓘ
cable lead is 8"

Intended Output ⓘ
ultrasound of the expected frequency and amplitude is produced

Unintended Output ⓘ
Enter Unintended Output

Noise Factors

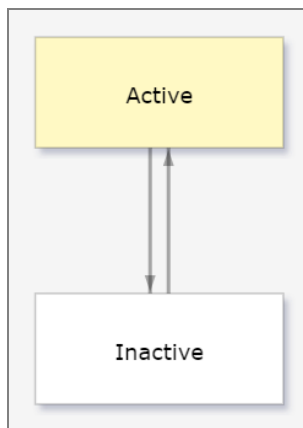
Use the P-Diagram tab of the design risk functional analysis to provide additional details of the focus element's intended functions, such as control factors, intended output, piece to piece variation, customer usage, and more.

Design Risk Structural Analysis Library States

This section defines each state available in the workflow for the Design Risk Structural Analysis Library process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A design risk structural analysis that is actively used.

Inactive. A design risk structural analysis that is no longer in use.



Design Risk Structural Analysis Library Tasks

Adding a New Design Risk Structural Analysis Library Record

1. Select Design Risk Structural Analysis Library from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Select the focus element and the next higher level of the structure.
3. Enter the element that is the next level down the structure from the focus element.
4. If you have a diagram, interface analysis, or structure tree for the design risk, then drag and drop or upload the file to the applicable field.
5. Click Save to save the record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the design risk structural analysis cannot be used for new records.

Adding a New Design Risk Functional Analysis

1. In the Design Risk Structural Analysis Library record, click the Add New Item  button in the Design Risk Functional Analysis field. A new screen appears.
2. For each level and focus of the system, describe its function and the requirement or intended output it must fulfill.

3. Navigate to the P-Diagram tab. In each field, provide additional details of the focus element's intended functions
4. Click Save to save the record. When selecting the next state, click Active.

Design Risk Analysis Library

The Design Risk Analysis Library process is the fourth step in the design risk process. Wherever a risk is identified, a hazard analysis should be put in place. Hazard analyses determine what characteristics must be controlled (measurements, required specifications, and so on) in order to mitigate or detect the hazardous situation and harm defined. This is your design risk quality plan; see "Control Library" on page 98 for more information.

Design Risk Analysis Library records are linked to manufacturing documents to supply potential risks for the design risk. See "Manufacturing Documents" on page 134.

Fig. 71: Design Risk Analysis Library process screen

General

Next Higher Level-Structural ⓘ
Transducer

Next Higher Level-Functional ⓘ
Produce image of scanned medium

Hazard Harms ⓘ
Overheating of the target medium

Focus Element-Structural ⓘ
TRSDR - Transducer

Focus Element-Functional ⓘ
Send ultrasound into target medium

Hazards/Hazardous Situation ⓘ
Failure to govern the volume about 155DB threshold

Next Lower Level-Structural ⓘ
Signal Conditioning

Next Lower Level-Functional ⓘ
Appropriate resolution and penetration

Hazard Cause(s) of the Work Elements ⓘ

☐	Potential Cause of Hazard	Best Occurrence	Best Detection	Control(s)	
☐	Amplitude regulation not present or effective	2	2		

1 - 1 of 1 items

Severity ⓘ
4

Best Occurrence ⓘ
2

Best Detection ⓘ
2

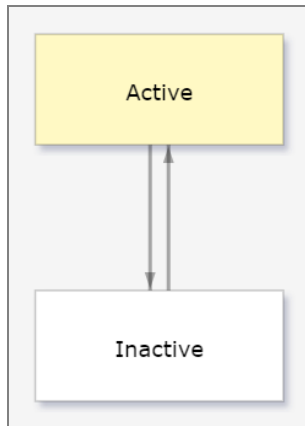
RPN Level ⓘ
16

Design Risk Analysis Library States

This section defines each state available in the workflow for the Design Risk Analysis Library process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A design risk analysis that is actively used.

Inactive. A design risk analysis that is no longer in use.



Design Risk Analysis Library Tasks

Adding a New Design Risk Analysis Library Record

1. In a Design Risk Structural Analysis Library record, open the relevant Design Risk Functional Analysis record. Then, click the Add New Item  button in the Design Risk Analysis field.
2. Describe how the system or subsystem could fail to perform the function described at the next higher level.
3. Describe the potential hazardous situation of the focus element. Use a noun followed by a hazard description (e.g. seal twisted, diameter undersized).
4. Select the severity of the hazardous situation.
5. Click Save to save the new record. When selecting the next state, click Active.
6. Add hazard causes of the work elements. See "Design Risk Causes Library" below for more information.
7. Note that the Best Occurrence, Best Detection, and RPN Level fields have been populated. This information comes from the potential causes and the controls linked to those causes.
8. If needed, click Save to save the record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the design risk analysis cannot be used for new records.

Design Risk Causes Library

The Design Risk Causes Library process describes the potential causes of hazard for each hazardous situation in a design risk. By identifying potential root causes, you can aim control methods appropriately and calculate the best occurrence and detection ratings. You can also add optimizations to be completed in order to reduce the risk of the hazard.

Design risk causes are added directly to a Design Risk Failure Analysis Library record in the Failure Causes of the Work Elements field. See "Design Risk Analysis Library" on the previous page.

Fig. 72: Design Risk Causes Library screen

General

Potential Cause of Hazard ⓘ
 Plate hardness not to spec

Problem Cause Code(s) ⓘ

☐	Problem Cause Code	Problem Cause
☐	MN-1	Machine not set correctly to spec
☐	PC-02	Material Issue
☐	PC-07	Out of calibration

1 - 3 of 3 items

Control(s) ⓘ

☐	Occurrence of Hazard Cause	Detection of Hazard Cause	Current Prev
☐	2	3	Metal plate

1 - 1 of 1 items

Best Occurrence ⓘ
 2

Best Detection ⓘ
 3

Optimization(s) ⓘ

☐	Design Risk Preventive Action	Design Risk Detection Action	Target Completion Date	Status	Completion Date	Residual Severity (S)	Residual Occurrence
No records available							

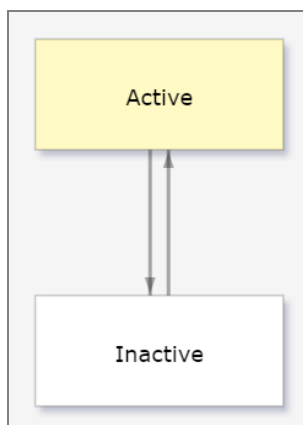
Design Hazard/Hazardous Situation ⓘ
 Plate twists when exposed to forces less than 1000Nm

Design Risk Causes Library States

This section defines each state available in the workflow for the Design Risk Causes Library process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A design risk cause that is actively used.

Inactive. A design risk cause that is no longer in use.



Design Risk Causes Library Tasks

Adding a New Design Risk Causes Library Record

1. In the Design Risk Analysis Library record, click the Add New Item  button in the Hazard Causes of the Work Elements field. A new screen appears.
2. Enter a description of the potential cause of hazard.
3. In the Problem Cause Codes field, use the Link  or Add New Item  button to add one or more problem cause codes.

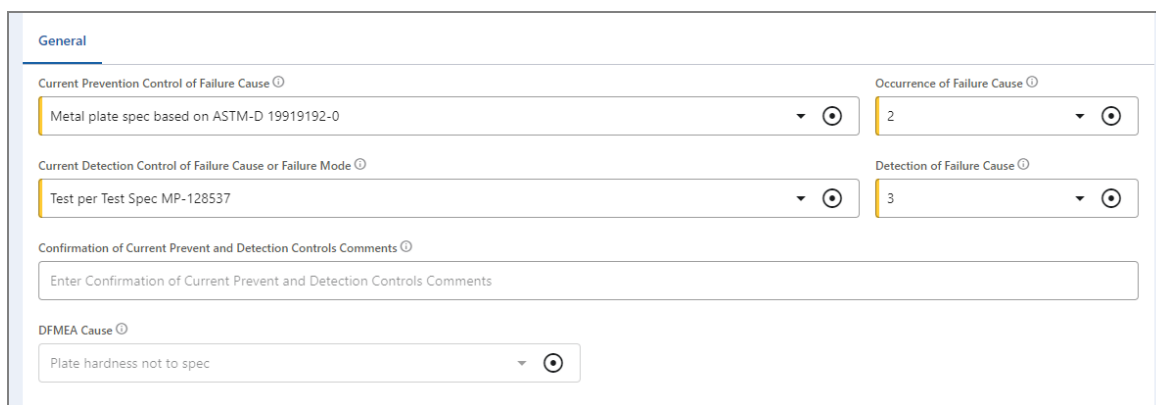
Note: Problem causes originate from the NCR & CAPA module. See the [NCR & CAPA](#) user guide for more information.

4. Click Save to save the new record. When selecting the state, click Active.
5. Add one or more controls. See "Adding a Control to the Design Risk Causes Library" below for more information.
6. Add Optimizations to recommend actions to be taken in order to reduce the risk of the failure. See "Adding a New Optimization for Design Risk" on the next page for more information.
7. Click Save to save the record.

Adding a Control to the Design Risk Causes Library

It is important to document the current preventive and detection controls of a hazard cause in order to finish up the measurement of the level of risk associated with the hazard cause. To properly calculate the action priority number, at least one detection control is required. See "Control Library" on page 98.

Fig. 73: Design Risk Controls Library screen



The screenshot shows the 'Design Risk Controls Library' screen. It features a 'General' tab at the top. Below the tab, there are several input fields and dropdown menus. The first row contains 'Current Prevention Control of Failure Cause' (dropdown: 'Metal plate spec based on ASTM-D 19919192-0') and 'Occurrence of Failure Cause' (dropdown: '2'). The second row contains 'Current Detection Control of Failure Cause or Failure Mode' (dropdown: 'Test per Test Spec MP-128537') and 'Detection of Failure Cause' (dropdown: '3'). Below these is a text area for 'Confirmation of Current Prevent and Detection Controls Comments' with the placeholder text 'Enter Confirmation of Current Prevent and Detection Controls Comments'. At the bottom is a dropdown for 'DFMEA Cause' with the value 'Plate hardness not to spec'.

1. In the Design Risk Causes Library process screen, click the Add New Item  button in the Controls field. A new screen appears.
2. Select the current control methods to prevent and detect the cause of the hazard.
3. Select the occurrence and detection ratings that represent the effectiveness of each control.
4. Enter any notes about the confirmation of the current controls effectiveness.
5. Click Save to save the record. When selecting the next state, click Active.

Adding a New Optimization for Design Risk

1. In the Design Risk Causes Library record, click the Add New Item  button in the Optimizations field. A new screen appears.
2. Describe the recommended action that should be taken to help reduce the action priority number.

Note: Typically the rankings should be reduced in the order of severity, occurrence, and then detection (although only a design or process revision can reduce the severity ranking). Preventive actions are preferable to detection actions.

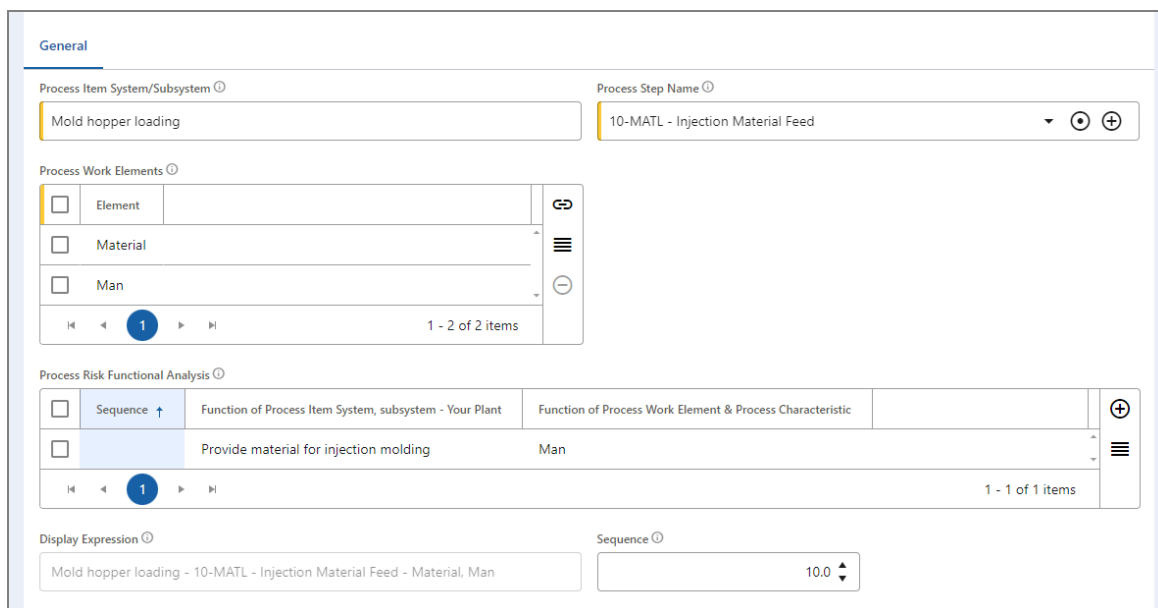
3. Select the user responsible for completing the action and the target date of completion.
4. Select the residual severity, occurrence, and detection as needed; these indicate how the ratings are affected as a result of the action taken.
5. Click Save to save the record.

Process Risk Structural Analysis Library

The Process Risk Structural Analysis Library process provides a library of structural and functional examinations for process risks. It dissects the structural items or systems in a design, then breaks down the function of those systems; this fulfills the second and third steps in the process risk process. These details can then be linked to the Process Risk Analysis Library process so they may be investigated for hazardous situations and controls. See "Process Risk Analysis Library" on page 111 for more information.

The process risk structural analysis library may be ITAR restricted, meaning that only employees who are ITAR compliant can view, access, and interact with the record.

Fig. 74: Process Risk Structural Analysis Library process screen



General

Process Item System/Subsystem 

Process Step Name 

Process Work Elements 

☐	Element	
☐	Material	
☐	Man	

1 - 2 of 2 items

Process Risk Functional Analysis 

☐	Sequence 	Function of Process Item System, subsystem - Your Plant	Function of Process Work Element & Process Characteristic	
☐		Provide material for injection molding	Man	

1 - 1 of 1 items

Display Expression 

Sequence 

The first level of this process involves selecting a Process record and describing the item system/subsystem being analyzed. Additionally, the process risk structural analysis identifies work elements involved in the process that should be considered when contemplating potential hazards. These elements include Man, Machine, Material, Environment, Method, and Measurement.

Once the structural analysis is complete, the functional analysis can begin.

Fig. 75: Process Risk Functional Analysis Library process screen

General

Process Item System/Subsystem - Structural

Mold hopper loading - 10-MATL - Injection Material Feed - Material, Man

Function of Process Item System, subsystem - Your Plant

Provide material for injection molding

Function of Process Item System, subsystem - Ship to Plant

Assembly of connector

Function of Process Item System, subsystem - End User

Provide secure connection

Process Step Name - Structural

10-MATL - Injection Material Feed

Function of Process Step & Product Characteristic

Material properties - type/grade

Process Work Elements - Structural

Material, Man

Function of Process Work Element & Process Characteristic

☐	Process Work Element	Function of the Process Work Elements	Process Characteristic/Specification	
☐	Man	Selection of the proper material	Material	

1 - 1 of 1 items

Process Risk Analysis

☐	Sequence	Hazards/Hazardous Situation	Hazard Harm - Your Plant	Hazard Cause(s) of the Work Elements	
☐	1.0	Wrong Material loaded	Defective part	Cause 3, Raw Material Labeling	
☐	2.0	Failure Mode	Plant failure		

1 - 2 of 2 items

When a new record is added to the Process Risk Functional Analysis field, the screen shown above appears. Use this screen to describe the function of the structure in relation to your plant, the ship to plant, and the end user. Additionally, you can specify the function of each process work element.

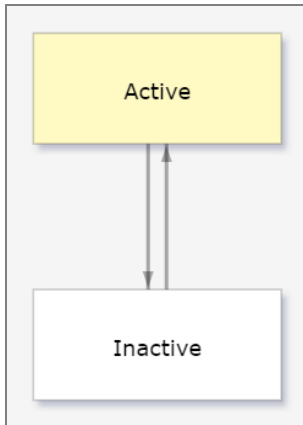
Process Risk Analysis Library records are created directly from this screen. Also available is a list of Process Risk Analysis Library records that are not currently linked to a function analysis. When a user is transitioning to the new AIAG/VDA format from the old 4th edition, they need to add the Structural and Functional Risk levels above the hazardous situations, then link the hazardous situations to the appropriate Functional Analysis level. To do this, users must create the Structural level, create the Functional level below Structural, then double-click the unlinked Analysis record that applies to the new Structural/Functional chain in order to link it to the Functional Analysis record. This creates the full chain: Structural, Functional, Hazard Cause, and Controls.

Process Risk Structural Analysis Library States

This section defines each state available in the workflow for the Process Risk Structural Analysis Library process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A process risk structural analysis that is actively used.

Inactive. A process risk structural analysis that is no longer in use.



Process Risk Structural Analysis Library Tasks

Adding a New Process Risk Structural Analysis Library Record

1. Select Process Risk Structural Analysis Library from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Select whether this record is ITAR restricted.
3. Select a process.
4. Enter an item system, subsystem, part element, or name of the process.
5. Add process work elements that affect the process.
 - a. Click the Link  button. A new window opens.
 - b. Select one or more work elements.
 - c. Click OK.
6. Click Save to save the record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the process risk structural analysis cannot be used for new records.

Adding a New Process Risk Functional Analysis

1. In the Process Risk Structural Analysis Library record, click the Add New Item  button in the Process Risk Functional Analysis field. A new screen appears.
2. Enter the function of the process item system/subsystem in the context of your plant, the ship to plant, and the end user. These functions should be in a "Do this to that" format (e.g. drill hole, apply coating, weld joint).

3. Describe the function of the process step name from the structural analysis and the product characteristic.
4. Click Save to save the record. When selecting the next state, click Active.
5. Return to the Process Risk Functional Analysis record. Click the Add New Item button in the Function of Process Work Element & Process Characteristic field. A new screen appears.

Fig. 76: Process Risk Functional Analysis Work Elements Library screen

6. Select the process work element and the process characteristic/specification.
7. Enter the function of the work element.
8. Click Save. When selecting the next state, click Active. Repeat this step in the screen that follows.

Process Risk Analysis Library

The Process Risk Analysis Library process is the fourth step in the process risk process. Wherever a risk is identified, a hazard analysis should be put in place. Hazard analyses determine what characteristics must be controlled (measurements, required specifications, and so on) in order to mitigate or detect the hazardous situations defined. This is your process risk quality plan; see "Control Library" on page 98 for more information.

Before a process risk analysis can be filled out, you must know what process, specification, and potential hazardous are involved. These items are identified in the process flow. As stated in "Design Control Level 2 Libraries" on page 83, the process risk analysis is completed at each step of the process flow to determine what can go wrong at that step.

The process risk analysis library may be ITAR restricted, meaning that only employees who are ITAR compliant can view, access, and interact with the record.

Process Risk Analysis Library records are linked to a specific process and can be found on that process' detail screen. See "Processes" on page 87.

Process Risk Analysis Library records are also linked to family templates and manufacturing documents to supply potential risk for the process flow. See "Family Templates" on page 116 and "Manufacturing Documents" on page 134.

Fig. 77: Process Risk Analysis Library process screen

General

Process Item System/Subsystem - Structural ⓘ
 Mold hopper loading - 10-MATL - Injection Material Feed - Material, Man ▼ ⓘ

Function of Process Item System, subsystem - Your Plant ⓘ
 Provide material for injection molding

Function of Process Item System, subsystem - Ship to Plant ⓘ
 Assembly of connector

Function of Process Item System, subsystem - End User ⓘ
 Provide secure connection

Hazard Harm - Your Plant ⓘ
 Defective part

Hazard Harm - Ship to Plant ⓘ
 Assembly failure

Hazard Harm - End User ⓘ
 Connection failure

Process Step Name - Structural ⓘ
 10-MATL - Injection Material Feed ▼ ⓘ

Function of Process Step & Product Characteristic ⓘ
 Material properties - type/grade

Hazards/Hazardous Situation ⓘ
 Wrong Material loaded

Function of Process Work Element - Functional ⓘ
 Enter Function of Process Work Element - Functional ▼ ⓘ

Requirement ⓘ
 15-MAT - Material - ▼ ⓘ +

Special Classification ⓘ
 Enter Special Classification ▼ ⓘ -

Safety/Regulatory ⓘ
 YES NO

Hazard Cause(s) of the Work Elements ⓘ

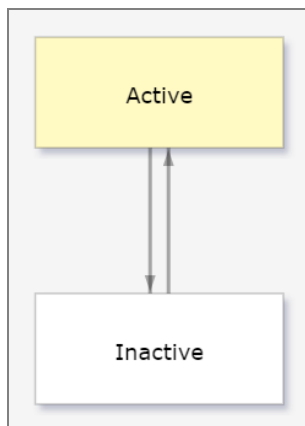
☐	Sequence ↑	Potential Cause of Hazard	Best Occurrence	Best Detection	Control(s)	
☐						+

Process Risk Analysis Library States

This section defines each state available in the workflow for the Process Risk Analysis Library process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A process risk analysis that is actively used.

Inactive. A process risk analysis that is no longer in use.



Process Risk Analysis Library Tasks

Adding a New Process Risk Analysis Library Record

1. In a Process Risk Structural Analysis Library record, open the relevant Process Risk Functional Analysis record. Then, click the Add New Item  button in the Process Risk Analysis field.
2. Select whether this record is ITAR restricted.
3. Describe the potential hazardous situation and the harm hazardss for your plant, the ship to plant, and the end user.
4. Select the requirement that could fail (see "Library Specifications" on page 95) and the severity of the hazardous situation.
5. Click Save to save the new record. When selecting the next state, click Active.
6. Add hazard causes of the work elements. See "Process Risk Causes Library" below for more information.
7. Note that the Best Occurrence, Best Detection, RPN, and Priority Level fields have been populated. This information comes from the potential causes and the controls linked to those causes.
8. Add Optimizations to recommend actions to be taken in order to reduce the risk of the hazard. See "Adding a New Optimization for Process Risk" below for more information.
9. If needed, click Save to save the record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the Process Risk Analysis Library record cannot be used for new records.

Adding a New Optimization for Process Risk

1. In the Process Risk Analysis Library record, click the Add New Item  button in the Optimizations field. A new screen appears.
2. Describe the recommended action that should be taken to help reduce the RPN rankings.

Note: Typically the rankings should be reduced in the order of severity, occurrence, and then detection (although only a design or process revision can reduce the severity ranking). Preventive actions are preferable to detection actions.

3. Enter the user responsible for completing the action and the target date of completion.
4. Select the residual severity, occurrence, and detection as needed; these indicate how the ratings are affected as a result of the action taken.
5. If applicable, select the relevant non-conformance or document change request.
6. Click Save to save the record.

Process Risk Causes Library

The Process Risk Causes Library process describes the potential manufacturing, assembly, and process causes for each hazardous situation in a process risk. By identifying potential root causes, you can aim control methods appropriately and calculate the best occurrence and detection ratings.

Process risk causes are added directly to a Process Risk Analysis Library record in the Failure Causes of the Work Elements field. See "Process Risk Analysis Library" on page 111.

Fig. 78: Process Risk Causes Library screen

General

Hazard Harm, Hazard/Hazardous Situation
Defective part - Wrong Material loaded

Applicable Work Element
Enter Applicable Work Element

Potential Cause of Hazard
Raw Material Labeling

Problem Cause Code(s)

☐	Problem Cause Code	Problem Cause	Site Name
☐	PC-06	Skills/Training	All Sites

1 - 1 of 1 items

Control(s)

☐	Sequence	Control Method	Prevention	Rank	Detection	Rank
☐		Check Sheet	No		Yes	5
☐		Check Sheet	No		Yes	7

1 - 2 of 2 items

Best Occurrence
Enter Best Occurrence

Best Detection
5

Baseline Occurrence
Enter Baseline Occurrence

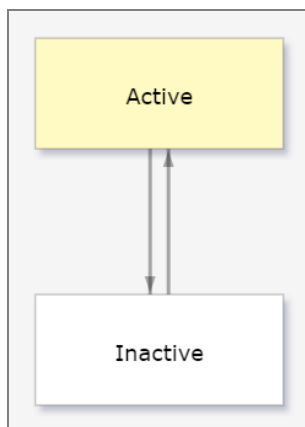
Sequence
Enter Sequence

Process Risk Causes Library States

This section defines each state available in the workflow for the Process Risk Causes Library process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). A process risk cause that is actively used.

Inactive. A process risk cause that is no longer in use.



Process Risk Causes Library Tasks

Adding a New Process Risk Causes Library Record

1. In the Process Risk Analysis Library record, click the Add New Item  button in the Hazard Causes of the Work Elements field. A new screen appears.
2. Enter a description of the potential cause of hazard.
3. Select an occurrence ranking for the cause of hazard.
4. In the Problem Cause Codes field, use the Link  or Add New Item  button to add one or more problem cause codes.

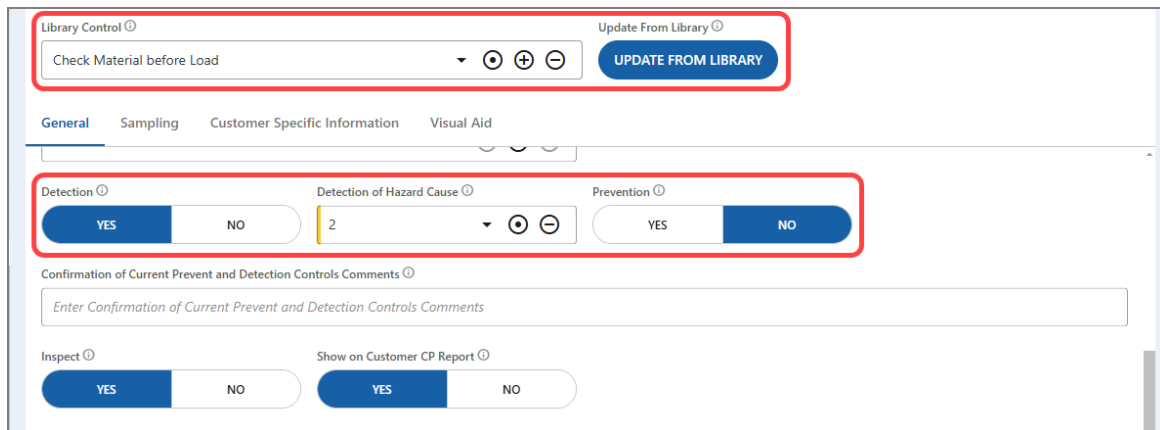
Note: Problem causes originate from the NCR & CAPA module. See the [NCR & CAPA](#) user guide for more information.

5. Click Save to save the new record. When selecting the state, click Active.
6. Add one or more controls. See "Adding a Control to the Process Risk Causes Library" below for more information.
7. Click Save to save the record.

Adding a Control to the Process Risk Causes Library

It is important to document the current preventive and detection controls of a hazard cause in order to finish up the measurement of the level of risk associated with the hazard cause. To properly calculate the action priority number, at least one detection control is required. See "Control Library" on page 98.

Fig. 79: Process Risk Controls Library screen



1. In the Process Risk Causes Library process screen, click the Add New Item  button in the Controls field. A new screen appears.
2. Complete all required fields, then select a library control from the drop-down list.
3. Click the "Update From Library" button. The selected library control record's information is imported, populating any field that contains a value in the linked record.
4. If the library control did not set the "Detection" and "Prevention" toggles, then adjust them appropriately, depending on the type of control you are adding. When a toggle is set to YES, a new field appears.

5. In the new field, select the level that corresponds with the selected toggle fields.
6. Click Save to save the record. When selecting the next state, click Active.

Family Templates

A family template is a non-part-specific manufacturing document that can be used to create manufacturing documents. You may think of it as a manufacturing document template. A family template will house the process flow, specifications, process risk, and process risk control plan for a product family, which can be used as a starting point for new manufacturing documents. The new AIAG/VDA risk plan handbook embraces and recommends Foundation and Family risk plans. In QAD EQMS, Foundation risk plan is the baseline risk plan defined in the libraries described earlier in this user guide, while the Family Templates process is the Family risk plan for a group of similar parts.

The advantages of a family template is that it drives standardization, reduces effort and increases speed to produce part-specific documentation, and allows changes to cascade.

This process is designed to be populated with command buttons. These buttons are located at the top of the appropriate tab, but can also be found within the Actions button  in the toolbar. However, if the Specifications, Process Risk Plans, and Process Risk Control Plans were not set up ahead of time, then they can be completed manually from their respective tabs in the family template.

Family templates may be linked to a site with an ITAR requirement. If this is true, then a new field appears on the General tab titled ITAR Restricted. Setting this toggle to YES means that only employees who are ITAR compliant can view, access, and interact with the template.

EQMS contains a grid control displaying data stored in multiple relational levels within a single screen, allowing you to see all fields for a risk plan, process risk control plan, and so on. Details within each tab are presented in two formats:

1. A grid where you can double-click within a level to open the detail screen associated with that level (for example, clicking Process Risk will open the process risk detail screen, clicking Cause will open the risk cause detail screen, etc.).
2. A cross-reference list of the highest level record. This field is where you add new records, but they are better to view in the grid.

This process contains a "Show AIAG 4th Edition" toggle that, when set to YES, shows the 2008 AIAG 4th Edition risk plan formats for family templates. If this toggle is set to NO, then the process is formatted to comply with the 2019 AIAG & VDA risk plan format. Note that 4th edition process risks begin at the Failure Analysis level, while process risks using the new AIAG/VDA mode begin at the Structural Analysis level. If you switch from the old 4th edition to the new AIAG/VDA edition, you will need to create the structural and functional levels first, then open the appropriate failure analysis record not yet linked to a functional analysis and link them to the functional analysis.

Family Templates are used in the Manufacturing Documents process to copy details to populate several tabs and fields. See "Manufacturing Documents" on page 134.

Fig. 80: Family Templates screen, General tab

General | Process Flow | Specifications | Process FMEA | Process Control Plan

Family Template Number: 0000001 | Name: Plastic Injected Connector frame

Item Group: CONNECTR - Connector | Item Type: AUTO - Automotive Products

Owner: Mark Leroy-MgrEng | Customer: Enter Customer

Supplier: Enter Supplier | Domain: 10USA - USA Domain | Entity: 10USACO - USA DIVISION

Site(s):

☐	Site Code	Site Name
☐	All	All Sites

1 - 1 of 1 items

Show AIAG 4th Edition: YES (selected) | NO

Notes: Enter Notes

The General tab is used to define the basic details of a family template, including the item group and type, linked customer and supplier, and more.

This tab features a toggle that, when set to YES, shows the 2008 AIAIG 4th Edition risk plan formats for Family Templates. If this toggle is set to NO, then the process is formatted to comply with the 2019 AIAG & VDA risk plan handbook. These formats can be seen on the Process Risk tab.

Fig. 81: Family Templates screen, Process Flow tab

General | **Process Flow** | Specifications | Process Risk | Process Risk Quality Plan

Process Flow

☐	Flow Sequence ↑	Process No	Process	Specification ID	Specification Name
☐	10.0	10-MATL	Injection Material Feed	15-MAT	Material
☐	20.0	10-INJ	Plastic Injection	70-Inj, 51-VISU	Temperature, Visual Aspect
☐	30.0	10-INSP	Plastic Injection Inspection	51-VISU, 42-W, 41-L, 40-H, 11-Wgt	Visual Aspect, Width, Length, Height, Weight
☐	40.0	10-STO	Injected parts storage	50-Pack	Packaging

1 - 4 of 4 items

The Process Flow tab documents the routing that will be used to manufacture the product. Process Flow is the first step to populating the family template. This tab is populated by the Import and Link Process Specs command, which can be executed from the Specifications tab or the Actions button in the toolbar.

Fig. 82: Family Templates screen, Specifications tab

General Process Flow Specifications Process Risk Process Risk Quality Plan						
Specification(s) ⓘ						
☐	Specification ID	Specification Name	Special Classification	Library Specification	Product or Process	Acceptance Criteria / Notes
☐	50-Pack	Packaging		50-Pack - Packaging	Process	No defect visible on external pac
☐	70-Inj	Temperature	HI - High Impact Characteristic	70-Inj - Temperature	Process	
☐	51-VISU	Visual Aspect		51-VISU - Visual Aspect	Product	No visible defect on surfaces
☐	42-W	Width	CC - Critical Characteristic	42-W - Width	Product	
☐	41-L	Length	CC - Critical Characteristic	41-L - Length	Product	
☐	40-H	Height	CC - Critical Characteristic	40-H - Height	Product	
☐	15-MAT	Material		15-MAT - Material -	Product	Check Material loaded against Pr
☐	11-Wgt	Weight	SC - Significant Characteristic	11-Wgt - Weight	Product	
<div> ⏪ ⏴ 1 ⏵ ⏩ </div> <div>1 - 8 of 8 items</div>						

The Specifications tab documents the acceptance criteria, including tolerances of an attribute or characteristic. Each specification is associated with a specification group, and is linked to additional data that defines the applicability of the specification. This tab is populated by the Import and Link Process Specs command, which can be executed by clicking the Import Specs button or the Actions  button in the toolbar.

When manually adding records via the Specifications cross-reference field, you can use the Library Specification drop-down field to select a pre-made specification that will auto-populate the required data upon saving the process.

Fig. 83: Family Templates screen, Process Risk tab

General Process Flow Specifications **Process Risk** Process Risk Quality Plan

Process Risk Analysis ⓘ

☐	Flow Sequence	Process Item System/Subsystem	Process Step Name	Process Work Elements	Function of Process Item System, subsystem - Your Plant	Function
☐	10.0	Mold hopper loading	10-MATL - Injection Material Feed	Material, Man	Provide material for injection molding	Ass...
☐	20.0	Injection Molding	10-INJ - Plastic Injection	Man, Machine	Provide appropriate temperature for injection molding	Ass...

1 - 2 of 2 items

Results Documentation

Intent Results Comments ⓘ

We determined the failures that can occur during the injection molding of the plastic connector frame as we intended.

Timing Results Comments - Risk due date ⓘ

This is a library and did not have a specific due date, but we completed before we intended.

Team Results Comments - List of Participants ⓘ

Jack Welch, Mark Leroy

Document the Status to the Original Team goals ⓘ

Process Flow, Process FMEA, and Process Control Plan are complete for this family.

Tool Results Comments - How Do We Conduct Analysis - Method Used ⓘ

Structure tree and process steps

How the Functions Were Developed Summary ⓘ

Functions of the processes were based on this family.

The Process Risk tab supplies a list of potential risk plans for the processes in the family template's process flow. Once the Process Flow and Specifications tabs have been populated and linked, this tab can be auto-populated with the Generate Risk Plan button. If the "Show AIAG 4th Edition" toggle is set to YES, then the fields under the Results Documentation header are hidden; the "Step 2 – Structural Analysis" header is hidden as well.

When manually adding process risks via the Process Risk Analysis cross-reference field, you can use the Process Risk Structural Analysis Library drop-down field to select a pre-made risk plan that will auto-populate the required data upon saving the process. If the "Show AIAG 4th Edition" toggle is set to YES, then use the Process Risk Failure Analysis Library drop-down field.

Fig. 84: Family Templates screen, Process Risk Control Plan tab

General Process Flow Specifications Process Risk <u>Process Risk Quality Plan</u>						
Process Risk Control Plan ⓘ						
☐	Flow Sequence	Machine, Device, Jig, Tools for Manu.	Specification	Product or Process	Special Classification	Product/Process Specification/T
☐			Packaging	Process		No defect visible on externa
☐			Visual Aspect	Product		No visible defect on surface
☐			Visual Aspect	Product		No visible defect on surface
☐			Temperature	Process	HI - High Impact Characteristic	Control Process parameters
☐		Barcode reader	Material	Product		Check Material before Load
☐		Caliper	Height	Product	CC - Critical Characteristic	Min: 22.9 Target: 23 Max: 23
☐			Visual Aspect	Product		No visible defect on surface
☐		Caliper	Length	Product	CC - Critical Characteristic	Min: 44.9 Target: 45 Max: 45
☐		Caliper	Width	Product	CC - Critical Characteristic	Min: 29.9 Target: 30 Max: 30
☐		Caliper	Weight	Product	SC - Significant Characteristic	Min: 11.9 Target: 12 Max: 12

The Process Risk Control Plan tab contains a collection of controls aimed at mitigating process risks through the control of process and product specifications. Once the Process Risk tab has been completed, this tab can be auto-populated with the Add Controls button. See "Adding a Control to the Process Risk Causes Library" on page 115 to learn how to connect controls to process risks.

When manually adding process risk control plans, you must select a specification before you can select a process.

Family Templates States

This section defines each state available in the workflow for the Family Templates process. See "State Change Security" on page 206 to learn more about how these states transition.

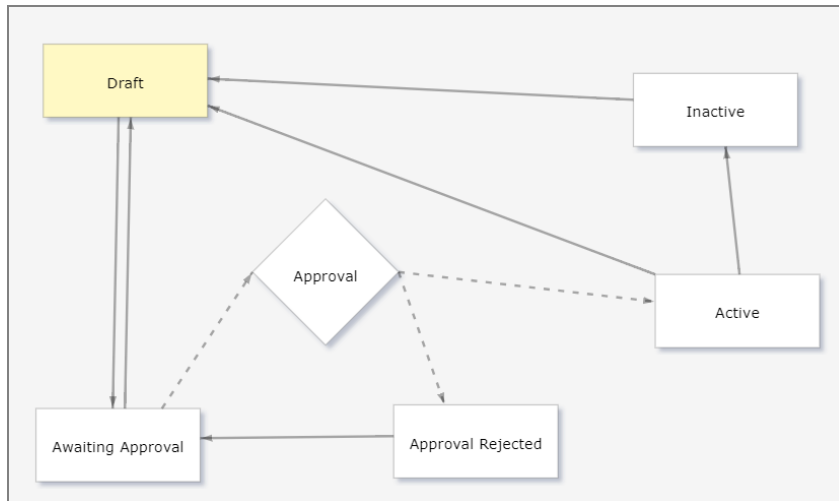
Draft (Default). The template is still being drafted and not yet ready for approval.

Awaiting Approval. The template must be approved before it can be made Active.

Active. A template that is actively used.

Approval Rejected. Approval for the template has been rejected.

Inactive. A template that is no longer in use.



Family Templates Tasks

Adding a New Family Template

1. Select Family Templates from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter a name for the family template.
3. If necessary, select whether this record is ITAR restricted.
4. Select an item group, item type, owner, and domain. You can also select a customer and supplier that the family template applies to, if applicable.
5. Click Save to save the new record. When selecting the next state, click Draft.
6. Navigate to the Process Flow tab. Select the Add New Item  button in the Process Flow cross-reference field. A new screen appears.
7. Select a library process and the process sort. The Library Process field will automatically populate the other fields. Repeat this step until all processes for the process flow have been added.
8. Complete the remaining three tabs (Specifications, Process Risk, and Process Risk Control Plan). You can complete the information manually or use the designated button in each tab to import the information.
 - a. **Import and Link Process Specs.** Adds new process specifications based on the processes added to the family template. Current process specifications on the family template are linked with matching process specifications linked to processes. Note that product specifications will have to be manually added to the Specifications tab.
 - b. **Generate Suggested Process Risk Plan.** Adds suggested process hazards/hazardous situations based on the processes linked within the process flow. Controls are assigned to the family template based on the risk controls in the Process Risk tab.
9. Click Save to save the new record. When selecting the next state, click Awaiting Approval.

Approving a Family Template

1. The person responsible for approving a family template is automatically notified when it is time for approval through the inbox or optionally from an e-mail notification (clicking the link in that message takes you to the document for approval).
2. Open the inbox, either through the Home Page dashboard or by clicking the Inbox icon in the toolbar.
3. Upon opening the inbox, click the approval item under the Design Control group to show the inbox action icons. Then click the Open icon. The screen navigates to the family template's detail screen.
4. In the detail screen, scroll down to the Approval field and click the Approve/Reject button. A small window appears.
5. In the Sign Off window, enter your password and either approve or reject the change. Use the comments field to document any information about your decision. Comments are required for rejection.

Note: Once all members of the approval process have finished, the family template becomes active and ready for use.

Making a Family Template Inactive

1. Open the active family template to be made inactive.
2. Click the state button, which should currently say "Active".
3. In the drop-down list, select Inactive.
4. Click Save to save the record. The family template is now inactive and cannot be used in manufacturing documents.

Note: The family template can be made active again, but it must go through the approval process first. Repeat the steps above but select Draft instead of Inactive in step 3 to reroute the family template through the approval process.

Chapter 6

Design Control Tasks

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Drawings

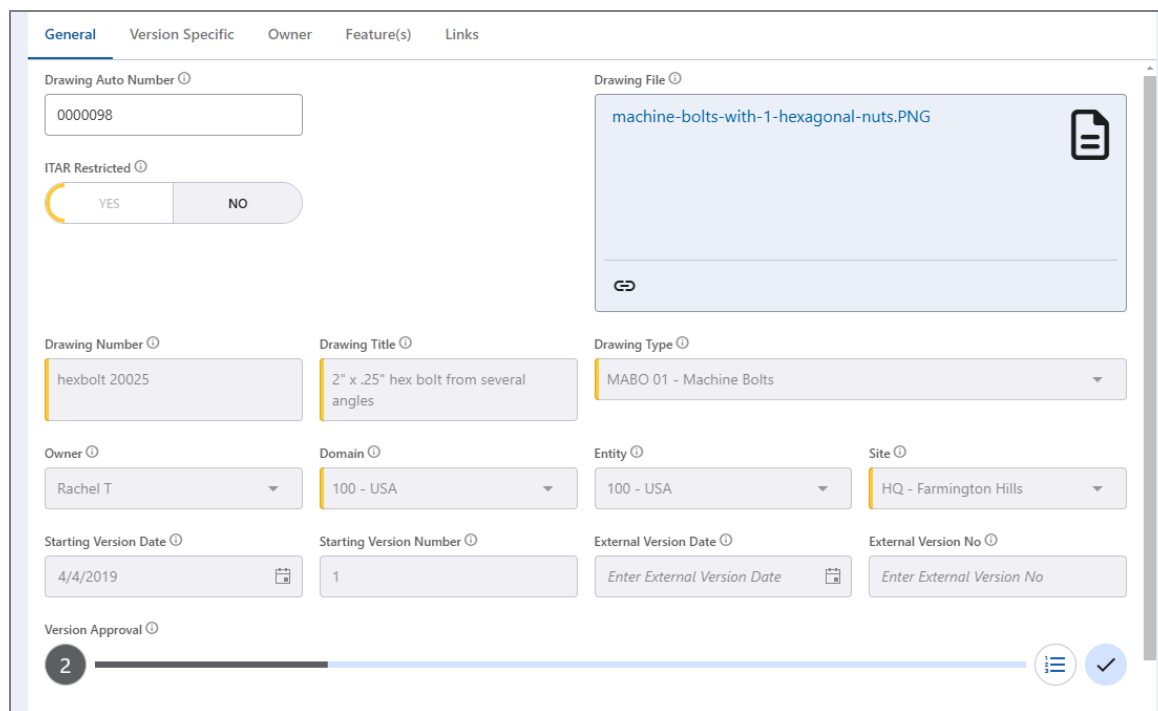
Drawings are used by engineers to control the drawings typically associated with products or items. It is recommended that the drawings are loaded as PDF files to allow approval routing and reference use when creating production documentation. PDF files are recommended because engineering departments typically have their own file management system that integrates into their design environment for managing all of the files that could make up a single CAD drawing.

Drawings differ from documents in that they allow you to define specifications associated with the drawing. These specifications will then be available to "import" into a manufacturing documentation so that the proper control information can be established when producing the Process Risk Control Plan.

Drawings may be linked to a drawing type with an ITAR requirement. If this is true, then a new field appears on the General tab titled ITAR Restricted. Setting this toggle to YES means that only employees who are ITAR compliant can view, access, and interact with the drawing.

Drawings may be associated with manufacturing documents or items. See "Manufacturing Documents" on page 134 and "Items" on page 130.

Fig. 85: Drawings screen, General tab



The screenshot shows the 'General' tab of a 'Drawings' screen. The interface includes a top navigation bar with tabs: 'General', 'Version Specific', 'Owner', 'Feature(s)', and 'Links'. The 'General' tab is active. The form contains the following fields and controls:

- Drawing Auto Number**: Text input field with value '0000098'.
- ITAR Restricted**: Toggle switch set to 'YES'.
- Drawing File**: File upload area showing 'machine-bolts-with-1-hexagonal-nuts.PNG' with a document icon and a link icon below it.
- Drawing Number**: Text input field with value 'hexbolt 20025'.
- Drawing Title**: Text input field with value '2" x .25" hex bolt from several angles'.
- Drawing Type**: Dropdown menu with value 'MABO 01 - Machine Bolts'.
- Owner**: Dropdown menu with value 'Rachel T'.
- Domain**: Dropdown menu with value '100 - USA'.
- Entity**: Dropdown menu with value '100 - USA'.
- Site**: Dropdown menu with value 'HQ - Farmington Hills'.
- Starting Version Date**: Date input field with value '4/4/2019' and a calendar icon.
- Starting Version Number**: Text input field with value '1'.
- External Version Date**: Text input field with placeholder 'Enter External Version Date' and a calendar icon.
- External Version No**: Text input field with placeholder 'Enter External Version No'.
- Version Approval**: A progress bar with a circular indicator showing '2' and a checkmark icon.

The General tab is used to define the basic details of a drawing, including the drawing title and type. This tab also contains the version approval and the drawing file itself.

Additionally, this tab indicates whether the drawing is ITAR restricted, meaning that only employees who are ITAR compliant can view, access, and interact with the drawing.

Fig. 86: Drawings screen, Version Specific tab

General

Version Specific

Owner

Feature(s)

Links

Change Description ⓘ

New

Reason for Change ⓘ

Enter Reason for Change

Effective Date ⓘ

4/4/2019

Approval Start Date ⓘ

4/15/2025

Approval Due Date ⓘ

4/22/2025

Received Date ⓘ

Enter Received Date

Change Request ⓘ

Enter Change Request

Change Order ⓘ

Enter Change Order

Change Due Date ⓘ

Enter Change Due Date

Change Owner ⓘ

Rachel T

The Version Specific tab allows you to document specific changes made to the drawing.

Fig. 87: Drawings screen, Owner tab

General

Version Specific

Owner

Feature(s)

Links

Additional Approver(s) ⓘ

☐	First Name	Last Name	Title
☐	Michael	Mallen	150-QE - Quality Engineer
☐	Brian	Brooks	PSE - Professional Services Engin

1 - 2 of 2 items

Number of Days for Approval ⓘ

7

Notification Role ⓘ

Enter Notification Rol

The Owner tab contains approver information, such as additional approvers, number of days for approval, and a list of people to notify when the drawing becomes official.

Fig. 88: Drawings screen, Features tab

General

Version Specific

Owner

Feature(s)

Links

Drawing Feature(s) ⓘ

☐	Code	Specification Name	Special Classification	Acceptance Criteria / Notes	Lower Limit	Target	Upper Limit	Unit of Measure
☐	CL	Color	SC - Significant Characteristic					
☐	L1	Length	CC - Critical Characteristic		1.950000	2.000000	2.050000	in - inch
☐	F1	Surface Finish	SC - Significant Characteristic	Visual Pass/Fail				

1 - 3 of 3 items

Use the Features tab to document any specifications or characteristics defined on the drawing, such as measurements or quality characteristics.

Fig. 89: Drawings screen, Links tab

General Version Specific Owner Feature(s) **Links**

Customer ⓘ
10-300 - QMI - USA Division

Share With All Suppliers ⓘ
YES NO

Item(s) ⓘ

Item Number	Item Type	Item Description	
02001-1	AUTO - Automotive Products	Automotive Connector	+
01040-012	DEVICES - Devices	Industrial Ultrasound	
01070	DEVICES - Devices	Medical Cart	

1 - 6 of 6 items

Drawing Reference(s) ⓘ

Reference To	
No records available	

Tooling and Equipment ⓘ

Tooling & Equipment Number	Tooling & Equipment Description	Site	Department	
No records available				

In the Links tab, associate relevant items, equipment, and other drawings with the selected drawing. Additionally, select which suppliers can view the drawing.

Drawings States

This section defines each state available in the workflow for the Drawings process. See "State Change Security" on page 206 to learn more about how these states transition.

Draft (Default). The drawing is still being drafted and not yet ready for approval.

Awaiting Approval. The drawing is waiting to be approved.

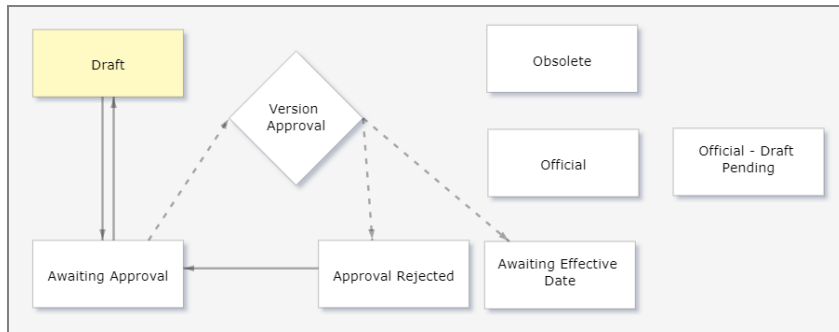
Awaiting Effective Date. The drawing is approved but waiting until the effective date to be marked as official

Approval Rejected. The drawing approval was rejected.

Official. The official version of the drawing.

Official – Draft Pending. The official version of a drawing, which also has a new version being drafted.

Obsolete. An obsolete version of the drawing. This version shall not be used.



Drawings Tasks

Adding a New Drawing

1. Select Drawings from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the drawing number and title. Then click "Select File to Upload" in the Drawing File field to upload the drawing file.
3. Select a drawing type, which also determines the level 1 approvers for the drawing.
4. Select whether the drawing is ITAR restricted. If access of the drawing is dependent on the ITAR compliance of the user, then select YES.
5. Navigate to the Owner tab. Click the Link  button to select any additional approvers for the drawing. If applicable, select a notification role, which defines a list of people to notify when the drawing becomes official.
6. Click Save to save the record. When selecting the next state, click Draft.
7. Navigate to the Features tab. Use the Drawing Features field to document any specifications or characteristics defined on the drawing. See "Adding a Drawing Feature" on the facing page to learn more about this process.
8. Navigate to the Links tab. Select the relevant customer, items, tooling and equipment, and other drawings.
9. In the Share With These Suppliers field, select or add suppliers to allow them to view the drawing with the appropriate security. If you want to allow all suppliers to view the drawing, then select the "Share With All Suppliers" check box. See the [Supplier Quality](#) user guide for more information.
10. Click Save to save the record. When selecting the next state, click Awaiting Approval.

Note: If you want to make the drawing become official at a future date instead of allowing it to become official immediately upon approval, then select a date in the Effective Date field, located in the Version Specific tab.

Adding a Drawing Feature

Fig. 90: Drawing Features screen

The screenshot shows the 'Drawing Features' screen with the following fields and values:

- Library Specification:** Enter Library Specification (dropdown with add and minus buttons)
- General Tab:**
 - Drawing:** hexbolt 20025 - 2" x .25" hex bolt from several angles - Ver. No. 1 (dropdown with add button)
 - Code:** L1 (text field)
 - Specification Name:** MF-Length (dropdown with add button)
 - Pass-Through Characteristic:** YES (radio button selected), NO (radio button)
 - Special Classification:** CC - Critical Characteristic (dropdown with add, minus, and plus buttons)
 - Acceptance Criteria / Notes:** Enter Acceptance Criteria / Notes (text field)
 - Specification Data Type:** Numeric (dropdown)
 - Validation Type:** Between Minimum and Maximum Limits (dropdown)
 - Lower Limit:** 1.950000 (text field with up/down arrows)
 - Target:** 2.000000 (text field with up/down arrows)
 - Upper Limit:** 2.050000 (text field with up/down arrows)
 - Unit of Measure:** in - inch (dropdown with minus button)
 - Number of Decimals:** 3 (text field with up/down arrows)
 - Internal or External:** INTERNAL (radio button selected), EXTERNAL (radio button)

1. In the Drawing record, navigate to the Features tab. In the Drawing Features field, click the Add New Item  button.
2. Select a specification name and special classification.
3. Select a specification data type, then a validation type. If the specification data type is not numerical:
 - a. Use the Acceptance Criteria/Notes field to describe the acceptance criteria in detail.
 - b. The following fields are hidden:
 - Lower Limit
 - Target
 - Upper Limit
 - Unit of Measure
 - Number of Decimals
4. If the specification data type is numerical, then use the Lower Limit, Target, and Upper Limit fields to describe the range of acceptable measurement for the drawing feature.
5. Select the unit of measure and number of decimals for the lower, target, and upper tolerance values.
6. Determine if the drawing feature is internal or external. Setting this field to Internal will prevent the feature from showing on related PPAP reports.
7. Click Save to save the record.

Approving a Drawing

1. The person responsible for approving a drawing is automatically notified when it is time for approval through the inbox or optionally from an e-mail notification (clicking the link in that message takes you to the drawing for approval).
2. Open the inbox, either through the Home Page dashboard or by clicking the Inbox icon in the toolbar.
3. Upon opening the inbox, click the approval item under the Design Control group to show the inbox action icons. Then click the Open icon. The screen navigates to the drawing's detail screen.
4. In the detail screen, scroll down to the Version Approval field and click the Approve/Reject button. A small window appears.
5. In the Sign Off window, enter your password and either approve or reject the change. Use the comments field to document any information about your decision. Comments are required for rejection.

Note: Once all members of the approval process have finished, the drawing becomes official and ready for use.

Starting a New Version of a Drawing

The "Start New Version" command in the Drawings process should be used for small-impact changes that do not affect other departments or people, such as fixing a typo or adding a tag. If the drawing requires a bigger change, then a change request must be initiated. See "Change Requests" in the [Document Control](#) user guide for more information.

Note: Revisions can only be made if the Drawing is in the Official state.

1. Open the detail screen of the drawing you wish to change. If the drawing does not already have a change initiated, then click the Actions  button and select "Start New Version".

Note: If a drawing already has a change initiated, then contact the Change Owner to see if the changes you want to make can be included in the current change.

2. Navigate to the Version Specific tab. Use the Change Description field to summarize what has changed and set the effective date.
3. Click Save to save the record. Select Awaiting Approval if you are finished with the changes or select Draft to save the drawing as a draft and continue working.

When this version is approved, it becomes official and all previous versions become obsolete.

It can be helpful to see a historical version of the drawing. You can quickly access historical versions from any version of the drawing by clicking More in the toolbar and selecting Versions to expand the Versioning panel. Click one of these versions to switch your detail screen view to the selected version.

Fig. 91: List of Versions

Versions	
Number: F	Date: 1/8/2024, 11:02 AM
Number: E	Date: 7/31/2023, 11:18 AM
Number: D	Date: 5/4/2023, 3:32 PM
Number: C	Date: 4/28/2023, 1:18 PM
Number: B	Date: 4/28/2023, 1:17 PM
Number: A	Date: 4/12/2023, 3:05 PM

Items

Items identify things that you stock in inventory, purchase, manufacture, sell, or service. Items can identify raw materials, purchased or manufactured intermediates, finished items, packaging materials, planning items, configured products, service kits, and repair parts used in service activities.

Items are linked to the following processes of the Design Control module:

- "Manufacturing Documents" on page 134.
- "PPAP Submissions" on page 165.
- "Drawings" on page 124.
- "Library Specifications" on page 95.

Fig. 92: Items screen, General tab

The screenshot displays the 'General' tab of the 'Items' screen. The interface includes a top navigation bar with tabs: 'General', 'Drawings & Documents', 'Inventory', 'Marketing', and 'Customer and Supplier Items'. The 'General' tab is active. The form is organized into two main columns. The left column contains fields for 'Item Number' (12345), 'Product Line' (10 - Finished Goods (FG)), 'Item Group' (ACCESSOR - Accessory), 'Item Picture(s)' (showing a funnel image), 'Site' (HQ - Farmington Hills), and 'Out of Service Date' (with a calendar icon). The right column contains fields for 'Item Description' (304 Stainless Steel 6\" Funnel), 'Item Type' (CAR - Car Part), 'Unit of Measure' (EA - Each), 'Spare Part' (YES/NO buttons), 'Product Safety Related' (YES/NO buttons), 'Domain' (100 - USA), 'Entity' (100 - USA), 'Price' (6.00000), and 'Currency' (USD). A 'Click here to add description' link is located below the item picture.

The General tab is used to define the basic details of an item, including the item type and group, unit of measure, picture, price, and more.

Fig. 93: Items screen, Drawings tab

General **Drawings & Documents** Inventory Marketing Customer and Supplier Items

Drawing(s) ⓘ

☐	Drawing Number	Drawing Title	Version Number	Drawing Type	Current State	
☐	12345	304 Stainless Steel 6" Funnel	1	Product Drawings	Official - Draft Pending	

1 - 1 of 1 items

ADD NEW MFG DOCUMENT

Manufacturing Document(s) ⓘ

Manufacturing Document Number	Version Number	Version Date	Current State	
0000249	1	12/16/2017, 4:39 AM	Draft	
0000250	1	12/20/2017, 8:59 AM	Draft	
0000264	1	3/8/2018, 10:26 AM	Draft	
0000265	1	3/8/2018, 1:58 PM	Draft	
0000267	1	3/10/2018, 5:04 AM	Draft	
0000504	1	11/10/2018, 8:59 AM	Official	
0000602	1	4/12/2019, 5:55 PM	Official	

1 - 7 of 7 items

The Drawings tab allows you to link related drawings to the item or create a new manufacturing document that applies to the item.

Fig. 94: Items screen, Inventory tab

General Drawings & Documents **Inventory** Marketing Customer and Supplier Items

Inventory Location(s) ⓘ

☐	Location	Inventory Quantity	
☐	01 - Warehouse 1	20.00	
☐	010 - Finished Goods	50.00	

1 - 2 of 2 items

Inspection Required ⓘ

YES NO

The Inventory tab shows the running inventory level for the item. It is linked to an integration with ERP that updates the current inventory and location of the inventory.

Fig. 95: Items screen, Marketing tab

General	Drawings & Documents	Inventory	Marketing	Customer and Supplier Items
Brand Name ⓘ		Common Name ⓘ		
H Auto Stainless Steel Funnel		Stainless Steel Funnel		
Model Number ⓘ		Product Code ⓘ		
8027-F		12345		
Catalog Number ⓘ		Unique Number ⓘ		
75-070		Enter Unique Number		

The Marketing tab is completed by customers when submitting a complaint. It records the item's brand name, model number, catalog number, and more.

Fig. 96: Items screen, Customer and Supplier Items tab

General	Drawings & Documents	Inventory	Marketing	Customer and Supplier Items
Customer Item(s) ⓘ				
☐	Customer	Customer Item Number	+	
☐	10C3002 - Houston Automotive Group	2203-6		
1 - 1 of 1 items				
Supplier Item(s) ⓘ				
☐	Supplier	Supplier Item Number	Do	+
☐	10S1002 - Bridgeville Industries	70288	10	
☐	10-200 - QMI - USA Division	4022-68	30	
☐	10-200 - QMI - USA Division	4056-33	12	
1 - 3 of 3 items				
Program Item(s)				
Item Number	Item Description	Program Code		
12345	304 Stainless Steel 6" Funnel			
1 - 1 of 1 items				

If any customer or supplier items are associated with this item, then they are recorded in the Customer and Supplier item tab. The Add New Item ⓘ button in each field allows you to select the appropriate information without having to re-enter all of the item's information.

Items States

This section defines each state available in the workflow for the Items process. See "State Change Security" on page 206 to learn more about how these states transition.

Active (Default). An item that is actively used.

Synchronized. The state is automatically set if the item is created or updated from integration to another system (e.g. EPR system). Synchronized fields are read-only.



Items Tasks

Adding a New Item

1. Select Items from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the item number and description. Notice how the Display Expression field combines the two values; this is how users will look up this item.
3. Select the product line, item type, item group, and unit of measure for the item.
4. Click Browse in the Item Picture field to upload a picture of the item.
5. Enter the item's price and a secondary description. If the item is product safety-related, then select the "Product Safety Related" check box to enable increased notifications.
6. Navigate to the Drawings tab. Use the Add New Item  buttons in the Drawings and Manufacturing Documents fields to add the associated records.

Note: The Drawings field allows you to link a currently existing drawing, but the Manufacturing Documents field requires that you create a new manufacturing document. See "Manufacturing Documents" below.

7. Click Save to save the new record.

Manufacturing Documents

Manufacturing documents provide controlled copies of documentation used for the manufacture of an item. Typically these documents include the process flow, process risk, process risk control plan, and additional work instructions.

Manufacturing documents allow for the development of part-specific:

- Bill of Materials
- Design Systems, Design Risk Plan, Design Verification Plan & Report
- Process Flow, Process Risk Planning, Process Risk, Quality Plan
- Work Instructions
- PPAP Submissions

Similar to family templates, manufacturing documents utilize command buttons to automatically complete several tabs in the detail screen. These buttons are located at the top of the appropriate tab, but can also be found within the Actions button  in the toolbar. The commands include:

- **Generate Suggested Design Risk Plan.** Adds new items to the Design Risk for each design system. The System or Subsystem, Function, and Requirement fields are populated.
- **Generate Suggested Design Verification Plans.** Generates the Design Verification Plan using the information from the Design Risk Plan. Multiple items may be created from one design risk if there is more than one control, but duplicate data will not transfer.
- **Copy from Family Template.** Copy initial setup (Process Flow, Specifications, Process Risk, and Process Risk Control Plan) from the Family Template selected in the "Copy from Family Template" field.

- **Copy from Manufacturing Document.** Copy initial setup (Associated Drawings, Drawing Features, Process Flow, Specifications, Process Risk, and Quality Plan) from the Manufacturing Document selected in the "Copy from Manufacturing Document" field.
- **Import Drawing Features.** Adds specification data to the Specifications tab based on data from the linked drawing's Features tab.
- **Update Suggested Drawing Features.** Updates the tolerance data for the Specifications tab of the Manufacturing Document with values from the Manufacturing Document.
- **Import and Link Process Specifications.** Imports Library Specifications that are linked to Processes in the Process Specifications field into the Specifications tab of the Manufacturing Document. Additionally, the manufacturing document specifications are linked to the processes in the Process Flow tab, based on the specifications linked to that process.
- **Generate Suggested Process Risk Plan.** Imports Process Risk Analysis Libraries that are linked to processes in the Process Flow tab into the Process Risk tab of the Family Template. Additionally, controls are added to the Quality Plan based on the current risk list.
- **Create Inspection Event Questions.** Create inspection event questions for all process risk control plans that are marked for inspection and have inspection type and stations defined. Then make these questions available to inspection events. This command is located in the Actions icon.
- **Start New Version.** Creates a blank manufacturing document detail screen. This command is located in the Actions icon.

EQMS contains a grid control displaying data stored in multiple relational levels within a single screen, allowing you to see all fields for a risk plan, process risk control plan, and so on. Details within each tab are presented in two formats:

1. A grid where you can double-click within a level to open the detail screen associated with that level (for example, clicking Process Risk will open the process risk detail screen, clicking Cause will open the risk cause detail screen, etc.).
2. A cross-reference list of the highest level record. This field is where you add new records, but they are better to view in the grid.

This process contains a "Show AIAG 4th Edition" toggle that, when set to YES, shows the 2008 AIAG 4th Edition risk formats for manufacturing documents. If this toggle is set to NO, then the process risk is formatted to comply with the 2019 AIAG & VDA risk handbook. Note that 4th edition risks begin at the Failure Analysis level, while risks using the new AIAG/VDA mode begin at the Structural Analysis level. If you switch from the old 4th edition to the new AIAG/VDA edition, you will need to create the structural and functional levels first, then link them to the existing failure analysis.

Manufacturing documents may be ITAR restricted, meaning that only employees who are ITAR compliant can view, access, and interact with the record.

Manufacturing documents are listed in PPAP submissions and items. See "PPAP Submissions" on page 165 and "Items" on page 130.

Fig. 97: Manufacturing Documents screen, General tab

Item ①: 52299 - Motor Mounting Plate MD

Owner ①: demo superuser

General | Version Specific | Skill and Training | Bill of Materials | Design Risk Analysis | Design Risk | Design Verification Plan & Report | Risk Planning

Manufacturing Document Number ①: 0000208

Starting Version Date ①: 3/1/2024

Use Document for Receiving Inspection? ①: YES NO

Requires Customer Approval ①: YES NO

Family Template ①: 0000003

Copy From Family Template ①: COPY FAMILY TEMPLATE

Source Manufacturing Document ①: Enter Source Manufacturing Document

Copy From Manufacturing Document ①: COPY MFG DOCUMENT

Domain ①: 10USA - USA Domain

Entity ①: 10USACO - USA DIVISION

Show AIAG 4th Edition ①: YES NO

Site(s) ①:

☐	Site Code	Site Name
☐	10-202	Automotive Mfg Site 2
☐	10-200	Auto Industrial Mfg

1 - 2 of 2 items

Related Item(s) ①:

☐	Display Expression
No records available	

Customer ①: Enter Customer

Customer Addresses ①:

☐	Display Expression
--------------------------	--------------------

The General tab is used to define the basic details of a manufacturing document, including the applicable and related items, connected family template or manufacturing document, customer or supplier, and more. Several fields on this tab, such as Core Team, Device, and Process Responsibility, are completed to be used in reports.

Fig. 98: Manufacturing Documents screen, General tab alternate

Supplier ①: ABC Componentes Electronic

Supplier Item ①: LS-Ultra

Owner ①: Glen Milburn

General | Version Specific | Skill and Training | Process Flow | Specifications | Process Risk Planning | Process Risk | Process Risk Quality Plan | W

Manufacturing Document Number ①: 0000201

Starting Version Date ①: 12/11/2023

Use Document for Receiving Inspection? ①: YES NO

Requires Customer Approval ①: YES NO

Family Template ①: 0000041

Copy From Family Template ①: COPY FAMILY TEMPLATE

Source Manufacturing Document ①: 3277

Copy From Manufacturing Document ①: COPY MFG DOCUMENT

If you set the "Use Document for Receiving Inspection?" toggle field to Yes, two new required fields appear: Supplier and Supplier Item. Additionally, the following tabs are removed from the process screen:

- Bill of Materials
- Design System

- Design Risk
- Design Verification Plan & Report

Fig. 99: Manufacturing Documents screen, Version Specific tab

Item ⓘ
52299 - Motor Mounting Plate MD
Owner ⓘ
demo superuser

General
Version Specific
Skill and Training
Bill of Materials
Design Risk Analysis
Design Risk
Design Verification Plan & Report
Risk Planning

Approval Start Date ⓘ
3/1/2024
Approval Due Date ⓘ
3/8/2024
Requires Training ⓘ
YES NO

Reason for Change ⓘ
N/A

Change Description ⓘ
New Document

Effective Date ⓘ
3/1/2024
Change Request ⓘ
Enter Change Request
Change Order ⓘ
Enter Change Order
Change Due Date ⓘ
Enter Change Due Date

Change Owner ⓘ
demo superuser

Associated Drawing(s) ⓘ

☐	Drawing Type	Drawing Number	Drawing Title	Site	Current State	
☐	007 - Bag drawing type	ENG-0010	Engine Block	10-200 - Auto Industrial Mfg	Official	
☐	LS-01 - Finished assembly	123987	304 Stainless Steel 6" Funnel	All - All Sites	Draft	
☐	LS-01 - Finished assembly	Connect-001	Automotive Connector 001	10-200 - Auto Industrial Mfg	Official	

The Version Specific tab contains approval start and due dates, change descriptions, associated drawings, and the ability to require training and create a training event.

Fig. 100: Manufacturing Documents screen, Skill and Training tab

Supplier ABC Componentes Electronic Supplier Item LS-Ultra Owner Glen Milburn

< General Version Specific **Skill and Training** Bill of Materials Design Risk Analysis Design Risk Design Verification Plan & Report Risk Planning >

Skill MFR 304F - Manufacture of 304 Stainless Steel Funnel

Training Aid Quality Manual.docx

Skill Training Questions

☐	Question Number	Question	
☐	0000060	Which departments are involved with the manufacture of 304 stainless steel 6" funnel?	
☐	0000059	How much weight can the 304 stainless steel 6" funnel hold?	
☐	0000058	What are the potential effects of failure when the sheet chemistry is out of spec?	

1 - 3 of 3 items

Training Event(s)

Training Event Number	Completed Date	Training Event Description	Current State
No records available			

Use the Skill and Training tab to enhance training management for the manufacturing document. Select or create a skill, create questions that will evaluate a person's knowledge of changes to the document, and optionally upload a file to be used as a training aid.

Fig. 101: Manufacturing Documents screen, Bill of Materials tab

Item 52299 - Motor Mounting Plate MD Owner demo superuser

< General Version Specific Skill and Training **Bill of Materials** Design Risk Analysis Design Risk Design Verification Plan & Report Risk Planning >

Material/Components

☐	Process Step	Material/Component	Quantity	Unit of Measure	Notes	
☐		62204 - Titanium Pem Nut #4 1/3	1.0000			
☐		62205 - Titanium PresFit #3 1/2	1.0000			
☐		52229 - Motor Mtg Plate Asm MD	1.0000			

1 - 3 of 3 items

Use the Bill of Materials tab to compile a list of the materials and components required to build the item associated with the manufacturing document.

Fig. 102: Manufacturing Documents screen, Design Risk Analysis tab

Item ① 52299 - Motor Mounting Plate MD Owner ① demo superuser

< General Version Specific Skill and Training Bill of Materials **Design Risk Analysis** Design Risk Design Verification Plan & Report Risk Planning >

Step 1 - Planning and Preparation

Project Identification ①

	Question	Comments
✓	What is our customer buying from us?	
✓	Are there new requirements we have not dealt with before?	
✓	Is a DFMEA required by customer or internally?	
✓	Do we make the product and have design control of it?	
✓	Do we buy the product or sub-component and still have design control of it?	

1 - 5 of 8 items

Intent ①

Analyse the structure, function and determine failures and the risks

Design Risk Start Date ① Enter Design Risk Start Date

Design Risk Due Date ① Enter Design Risk Due Date

Non-employee Team ① Enter Non-employee Team

The Design Risk Analysis tab functions as the first two steps in the design risk process: Planning and Preparation, and Structural Analysis. Answer questions to identify the project scope, define the design team, select the systems involved, and add other details that organize the features of the design risk.

This tab is the design risk equivalent of the Process Risk Planning tab.

Fig. 103: Manufacturing Documents screen, Design Risk tab

Item 52299 - Motor Mounting Plate MD Owner demo superuser

General Version Specific Skill and Training Bill of Materials Design Risk Analysis **Design Risk** Design Verification Plan & Report Risk Planning

Generate Design Risks

GENERATE DESIGN RISKS

Design Risk

System Sequence	Next Higher Level-Structure	Focus Element-Structure	Next Lower Level-Structure
WIN_LIFT - Window Lift System	WIN_LIFT-02.010D - Electronic Control Unit (ECU) for Window Lifter	Transmit signal frc	
TRSDR - Transducer	TRSDR - Transducer	Signal Conditionir	
3.0 Seat Motor Assembly - Seat Motor Assembly	Seat Motor Assembly - Seat Motor Assembly	Test 2792-1	
3.0 Seat Motor Assembly - Seat Motor Assembly	Seat Motor Assembly - Seat Motor Assembly	Motor and Motor	

Results Documentation

InTent Results Comments- Purpose of DFMEA

Use the Design Risk tab to provide hazardous situation information for the design phase of production. After the design risk is complete, use the Results Documentation section to document the status of the original design risk goals and compare them with the actual results. See "Introduction to Risk Plans" on page 66 for more information about design risk plans.

Fig. 104: Manufacturing Documents screen, Design Verification Plan & Report tab

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General Version Specific Skill and Training Bill of Materials Design Risk Analysis Design Risk **Design Verification Plan & Report** Risk Planning

Generate Suggested Design Verification Plans

GENERATE DVP&R

Design Verification Plan(s)

Test Number	Specification & Test Method	Test Description	Acceptance Criteria	Test Stage	Test Requirement
0000006	Test per Test Spec MP-128537				
0000007	Test per Test Spec MP-128537				
0000008	Visual Inspection	Seat Motor Assembly Focus Element-Functional - 2792			
0000009	Visual Inspection	Seat Motor Assembly Focus Element-Functional - 2792			

Results Documentation

InTent Results Comments- Purpose of DFMEA

Use the Design Verification Plan & Report tab to create the design verification plan & report (DVP&R). The DVP&R is a summary of every test performed on a part for a design risk plan. See "Design Verification Reports" on page 164 for more information about the DVP&R.

Fig. 105: Manufacturing Documents screen, Risk Planning-MSR Analysis tab

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Design Risk Analysis Design Risk Design Verification Plan & Report **Risk Planning-MSR Analysis** Risk Planning-MSR Process Flow Specification

Step 1 - Planning and Preparation

Project Identification

Question	Comments
After completing a DFMEA on an Electrical/Electronic/Programmable Electronic System, are there effects that may be harmful to persons or involve regulatory noncompliance?	
Did the DFMEA indicate that all of the causes which lead to harm or noncompliance can be detected by direct sensing, and/or plausibility algorithms?	
Did the DFMEA indicate that the intended system response to any and all of the detected causes is to switch to a degraded operational state (including disabling the vehicle), inform the driver and/or write a Diagnostic Trouble Code (DTC) into the control unit for service purposes?	

1 - 3 of 3 items

Risk Planning-MSR Start Date Risk Planning-MSR Due Date

Enter Risk Planning-MSR Start Date Enter Risk Planning-MSR Due Date

Use the Risk Planning-MSRS Analysis tab to complete Step 1 (Planning & Preparation) of the Risk Planning-MSR. This step includes documenting a plan, team, scope, and the approach to be taken for the Risk Planning-MSR.

Risk Planning-MSR is an organized approach to evaluate the high severity design risk items that can impact the vehicle and occupants, and determine if suitable monitoring systems can be used as inputs to provide a system response that reduces the overall risk (including risk of harm, risk of noncompliance, or risk of not fulfilling expectations).

Fig. 106: Manufacturing Documents screen, Risk Planning-MSR tab

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Design Risk Analysis

Design Risk

Design Verification Plan & Report

Risk Planning-MSR Analysis

Risk Planning-MSR

Process Flow

Specification >

Step 2 - Structural Analysis

Supplemental Risk Planning for Monitoring & System Response ⓘ

☐	System Sequence	Next Higher Level-Structure	Focus Element-Structure	Next Lower Level-St	⊕
☐		WIN_LIFT - Window Lift System	WIN_LIFT-02.010D - Electronic Control Unit (ECU) for Window Lifter	Transmit signal fr	⋮
☐	3.0	Seat Motor Assembly - Seat Motor Assembly	Seat Motor Assembly - Seat Motor Assembly	Next Lower Level	⋮

1

1 - 2 of 2 items

Results Documentation

InTent Results Comments - Purpose of Risk Planning-MSR ⓘ

Enter InTent Results Comments - Purpose of Risk Planning-MSR

Timing Results Comments - Risk Planning-MSR due date ⓘ

Enter Timing Results Comments - Risk Planning-MSR due date

Team Results Comments - List of MSR participants ⓘ

Use the Risk Planning-MSR tab to complete Steps 2-6 of the Risk Planning-MSR. These steps are a series of cascading steps that move from Structural Analysis, to Functional Analysis, to Hazard Analysis, to Risk Analysis, to Optimization, and finally Results Documentation.

Fig. 107: Manufacturing Documents screen, Process Flow tab

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< Design Risk Analysis

Design Risk

Design Verification Plan & Report

Risk Planning-MSR Analysis

Risk Planning-MSR

Process Flow

Specification >

Process Flow ⓘ

☐	Flow Sequence ↑	Process No	Process Symbol Image	Process	Unit Name	Item Number	Item Description	Sort	⊕
☐	1.0	CST-2		Casting - Pattern Making					⋮
☐	2.0	CST-3		Casting - Coremaking & Molding					
☐	3.0	CST-4		Casting - Alloy Melting and Pouring					
☐	4.0	CST-5		Casting Cleaning					
									

The Process Flow tab documents the routing that will be used to manufacture the product. It is essentially a process flow diagram for the processes involved in manufacturing a particular product without the actual diagram.

This tab is typically populated when a manufacturing document is created using the “Copy from Family Templates” or “Copy from Manufacturing Document” commands, but it can be completed manually as well.

Fig. 108: Manufacturing Documents screen, Specifications tab

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< Specification Plan & Report

Risk Planning-MSR Analysis

Risk Planning-MSR

Process Flow

Specifications

Process Risk Planning

Process Risk

Process >

Import Drawing Features ⓘ
IMPORT FEATURES

Update Suggested Drawing Features ⓘ
UPDATE FEATURES

Import and Link Process Spec ⓘ
IMPORT SPECS

Specifications ⓘ

☐	Flow Sequence ↑	Specification Id	Specification	Special Classification	Product or Process	Acceptance Criteria / Notes
☐		01	Metal Temperature	CC - Critical Characteristic	Prod	
☐		01	Metal Pouring speed		Proc	
☐		SFC-1	Surface finish		Prod	There are no visible defects and surface
☐		03	Cylinder Bore ID	CC - Critical Characteristic	Prod	
☐	3.0	02	Metal Temperature	CC - Critical Characteristic	Prod	
☐	5.0	02	Height of Block	SC - Significant Characteristic	Prod	
☐	5.0	01	Width of block	CC - Critical Characteristic	Prod	

1

1 - 7 of 7 items

The Specifications tab documents the acceptance criteria, including tolerances of an attribute or characteristic. Each specification is linked to additional data that defines the applicability of the specification.

This tab is typically populated using the command buttons, but can be completed manually as well.

Fig. 109: Manufacturing Documents screen, Process Risk Planning tab

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< ication Plan & Report Risk Planning-MSR Analysis Risk Planning-MSR Process Flow Specifications **Process Risk Planning** Process Risk Proces >

Step 1 - Planning and Preparation

Project Identification ①

	Question	Comments
✓	What is our customer buying from us?	
✓	Are there new requirements we have not dealt with before?	
✓	What are the specific process/elements that cause risk in fulfilling a requirement/characteristic?	
✓	Is a PFMEA required by customer or internally?	
✓	Do we make the product and have design control of it?	

1 - 5 of 9 items

InTent ① Enter InTent

Process Risk Start Date ① Enter Process Risk Start Date
 Process Risk Due Date ① Enter Process Risk Due Date
 Non-employee Team ① Enter Non-employee Team

The Process Risk Planning tab functions as the first step in the process risk process: Planning and Preparation. Answer questions to identify the project scope, define the process team, and add other details that organize the features of the process risk.

This tab is the process risk equivalent of the Design Risk Analysis tab.

Fig. 110: Manufacturing Documents screen, Process Risk tab

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< Location Plan & Report

Risk Planning-MSR Analysis

Risk Planning-MSR

Process Flow

Specifications

Process Risk Planning

Process Risk

Proces >

Step 2 - Structural Analysis

Generate Process Risks

Generate Risks - Current Specifications

GENERATE PROCESS RISKS

GENERATE RISKS - CURRENT SPECS

Process Risk

☐	Flow Sequence	Process Step Name	Process Work Elements	Function of Process Item System, subsystem - Your Plant	Function of P	
☐	3.0	CST-4 - Casting - Alloy Melting and Pouring	Man. Machine	Heat alloy mix	Engine bloc	
☐	3.0	CST-4 - Casting - Alloy Melting and Pouring	Man	Fill the mold with alloy	Engine bloc	
☐	3.0	CST-4 - Casting - Alloy Melting and Pouring	Man. Machine	It Works	It Kind Of V	
☐	3.0	CST-4 - Casting - Alloy Melting and Pouring	Man. Machine	Heat allow to temperature	Engine bloc	
☐	5.0	MCH-1 - Machining	Machine	Hone/polish cylinder wall surface	Engine asse	
☐	5.0	MCH-1 - Machining	Machine	Bore cylinder to diameter	Engine Asse	

1

1 - 6 of 6 items

Results Documentation

The Process Risk tab supplies a list of potential risk plans for the processes in the family template's process flow. After the process risk is complete, use the Results Documentation section to document the status of the original process risk goals and compare them with the actual results.

This tab is typically populated using the command button, but can be completed manually as well.

Fig. 111: Manufacturing Documents screen, Process Risk Quality Plan tab

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Process Risk Quality Plan Number CP-0000020 Supplier Code QMI-0001

Flow Sequence	Evaluation/Measurement Technique	Process	Product/Process Specification/Tolerance	Product or Process
3.0	Manual check	Casting - Alloy Melting and Pouring		Prod
3.0	Manual check	Casting - Alloy Melting and Pouring		Prod
3.0	Visual and manual start up	Casting - Alloy Melting and Pouring		Proc
3.0	Manual check	Casting - Alloy Melting and Pouring	Min: Target: Max: 112.000000 F	Prod
3.0	Manual check	Casting - Alloy Melting and Pouring		Prod
3.0	Visual and manual start up	Casting - Alloy Melting and Pouring	Min: 500.000000 Target: Max: s	Proc
3.0	Manual check	Casting - Alloy Melting and Pouring	Min: Target: Max: 112.000000 F	Prod
3.0	Manual check	Casting - Alloy Melting and Pouring		Prod
3.0	Manual check	Casting - Alloy Melting and Pouring	Min: Target: Max: 112.000000 F	Prod
5.0	Visual Check of Part against master	Machining		Prod

1 - 10 of 15 items

The Process Risk Quality Plan tab contains a collection of controls aimed at mitigating risks through the control of process and product specifications.

This tab is typically populated using the command button, but can be completed manually as well.

Fig. 112: Manufacturing Documents screen, Work Instructions tab

Item 52299 - Placa de montagem do mot Owner Jack Welch-Quality

Work Instructions

Flow Sequence	Process	Step Number	Step Title	Step Instructions
1.0	FAB - 1	3.0	First piece check - Hole Diameter	Check hole diameter and index using dimensional jig
1.0	FAB - 1	2.0	First piece check - Thickness	Complete first Piece machining and check thickness before releasing to p
1.0	FAB - 1	1.0	Plate Mounting	Mount Titanium stock into jig and check machine set up parameters

1 - 3 of 3 items

Use the Work Instructions tab to provide step instructions for each process in the process flow. The work instructions may include an image and related process risk control plan item.

Fig. 113: Manufacturing Documents screen, PPAP Submissions tab

The PPAP Submissions tab contains links to generated PPAP submission records and allows you to create new ones. You can create multiple PPAP submissions for the same manufacturing document, i.e. for an annual PPAP. See "PPAP Submissions" on page 165 for more information on how to add a PPAP submission.

Fig. 114: Manufacturing Documents screen, Document Review tab

If a manufacturing document requires review, then the Document Review tab allows you to supply details regarding the document's last review, review frequency, review notes, and more.

Manufacturing Documents States

This section defines each state available in the workflow for the Manufacturing Documents process. See "State Change Security" on page 206 to learn more about how these states transition.

Draft (Default). The document is still being drafted and not yet ready for approval.

Ready for Approval. The document is ready for approval. The system performs an assessment to determine if any skip lot rules are impacted. If so, the state changes to Skip Lot Review; if not, the state changes to Awaiting Approval.

Awaiting Approval. The document is waiting to be approved.

Awaiting Effective Date. The document has been approved but is waiting until the effective date to be marked as official.

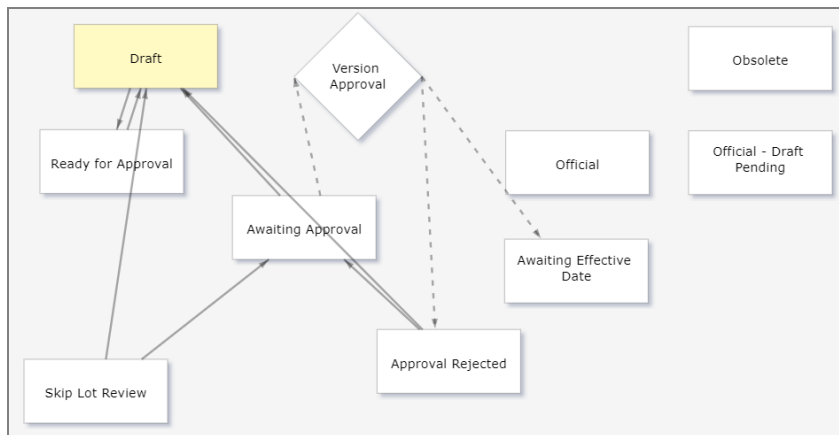
Approval Rejected. The approval of the document was rejected.

Official. The official version of the document.

Official – Draft Pending. The official version of the document, which also has a new version being drafted.

Obsolete. An obsolete version of the document. This version shall not be used.

Skip Lot Review. The process risk control plan has changed and the skip lot rule is impacted. This state is used when the process risk control plan is linked to one or more skip lot rules.



Manufacturing Documents Tasks

Adding a New Manufacturing Document

1. Select Manufacturing Documents from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Select a site and an item that the manufacturing documents apply to. The site field determines the item selection list.
3. Select whether this record is ITAR restricted.
4. If the manufacturing document is intended for receiving inspection, then set the "Use Document for Receiving Inspection?" toggle field to YES. Otherwise, select NO.
 - a. If YES was selected, then two fields become required: Supplier and Supplier Item.
 - b. The Bill of Materials, Design Systems, Design Risk, and Design Verification Plan & Report fields disappear from view.
5. Select a family template or manufacturing document whose details will be copied over.

Note: It is not absolutely necessary to select a family template or manufacturing document, as manufacturing documents can be built from scratch. However, it is considered a best practice for users to use family templates to drive standardization, efficiency, and ease of maintenance.

6. Click one of two command buttons: "Copy from Family Template" or "Copy from Manufacturing Document". These commands use the information from the linked

template or document to automatically populate the following tabs:

- General
 - Process Flow
 - Specifications
 - Process Risk
 - Process Risk Quality Plan
7. Navigate to the Version Specific tab. Click the Link  button in the Associated Drawings field. Select the drawing related to the item from the Item field.
 8. Navigate to the Specifications tab. Click the command button labeled "Update Suggested Drawing Features". This command uses the data in the linked drawing's Features tab to add measurement specification data to the Specifications tab.
 9. Click Save to save the new record. When selecting the next state, click Draft.

Setting Up Skill and Training

1. In the Manufacturing Document detail screen, navigate to the Version Specific tab.
2. Set the "Requires Training" toggle field to YES if necessary. A new field appears titled "Create Training Event"; set this toggle field to YES to automatically create a training event for the document once the new version has been approved.
3. Navigate to the Skill and Training tab. Select or create a skill that represents the manufacturing document for the purposes of managing training.

Note: To learn more about adding skills, see the [Training Management](#) user guide.

4. Click the Add New Item  button in the Skill Training Questions field. A new screen appears.
5. Create a question that will be used to evaluate a person's knowledge of changes to the manufacturing document. Include any additional reference information.

Note: If you have questions to ask that would be common from revision to revision, you can add those questions on the Skill screen.

6. Create multiple choice or true/false answer choices.
 - a. **Use Global Choice.** You can select a pre-made answer choice from a list of very common choice scenarios, such as Yes/No, Scale 1-5, Pass/Fail, and more. This menu of answer types originates from the Global Choice process.
 - b. **Create Specific Choice List.** You can create a list of choices specific to the record you are creating. For example, if the question is "Which shift is responsible for the AKP shipment?" you can create a specific choice list such as "1st Shift/2nd Shift/3rd Shift". Add a new choice by clicking the Add button under Choice Details.
7. Enter details for the answer choice. The score value for each choice must be unique.

Fig. 115: Answer Choices

Choice	Score	Acceptance	Req. Comment	Req.
Red	1.00	Unfavorable	☐	
Yellow	2.00	Neutral	☐	
Green	3.00	Favorable	☐	

8. Click Add New Record to keep adding choices. To remove a row, highlight the row and click Remove.

Note: The Maximum Score field is automatically calculated to the highest numeric score from the choice list.

9. Click Save to save the new record. When selecting the next state, click Active.
10. Back at the Manufacturing Document detail screen, click Save to save the record as a draft.

Completing the Design Risk Analysis and Design Risk

1. In the Manufacturing Document detail screen, navigate to the Design Risk Analysis tab. For each question in the Project Identification field, click the Comments column and add your answer.
2. Specify the intent of the design risk and enter start and due dates.
3. Add members to the design team.
 - a. Click the Add New Item button in the Design Team field. A new screen opens.
 - b. Select a role and the employee who will fulfill the role.
 - c. Click Save.
 - d. Repeat for each member of the team.

Fig. 116: Manufacturing Document Design Risk Team screen

4. Back in the main process screen, use the Task and Tool fields to describe the work that needs to be done for design risk and any tools that will be used to conduct the analysis.
5. Select the systems that are part of the scope.
 - a. Click the Add New Item button in the Design Systems Scope field. A new screen opens.
 - b. Select a system involved in the design risk (see "Design Risk Systems Library" on page 85 for more information).
 - c. Enter the sequence of this system.

- d. Click Save.
- e. Repeat for each system involved in the design risk.

Fig. 117: Manufacturing Document Systems screen

The screenshot shows the 'Manufacturing Document Systems' screen with the 'General' tab selected. The form contains several fields: 'System Sequence' is set to 3.0; 'System' is 'Seat Motor Assembly - Seat Motor Assembly'; 'Domain' is '10USA - USA Domain'; 'Entity' is '10USACO - USA DIVISION'; 'Site(s)' is 'All Sites'; and 'Manufacturing Document' is '0000208'. Below these fields is a table with 3 columns: 'Site Code', 'Site Name', and a link icon. The table contains one row with 'All' in the 'Site Code' column and 'All Sites' in the 'Site Name' column. At the bottom of the table, it says '1 - 1 of 1 items'.

6. Back in the main process screen, use the fields under the Design Risk Header to provide additional details about the design risk, including the design risk project name, customer name, design responsibility, confidentiality level, and more.
7. Click Save to save the manufacturing document . When selecting the next state, click Draft.
8. Navigate to the Design Risk tab. Click the command button 'Generate Design Risk'. The Design Risk and Design Risk Grid fields are now populated with the Structural and Functional Analysis information.
9. Click Save to save the manufacturing document. When selecting the next state, click Draft.

Adding a New Design Verification Plan

1. In the Manufacturing Document detail screen, navigate to the Design Verification Plan & Report tab. Click the command button "Generate Suggested Design Verification Plans". The Design Verification Plans field now contains a new line item.
2. Double-click the design verification plan. A new screen opens.
3. In the General tab of the new screen, enter values for the acceptance criteria and test requirements.
4. Select a test stage and the employee responsible for executing the test.
5. Set up the remaining parameters of the verification plan: target start and completion date, sample quantity, and sample type.
6. If there are any relevant non-conformances, click the Link  button to link to an existing non-conformance or the Add New Item  button to create a new one. See the [NCR & CAPA](#) user guide for more information about creating non-conformances.
7. Click Save to save the new record.

Note: To learn more about completing the Test Reports tab of the Design Verification Plan & Report detail screen, see "Design Verification Reports" on page 164.

Completing a Risk Planning-MSR

Risk Planning-MSR is an organized approach to evaluate the high severity design risk items that can impact the vehicle and occupants, and determine if suitable monitoring systems can be used as inputs to provide a system response that reduces the overall risk (including risk of harm, risk of noncompliance, or risk of not fulfilling expectations).

1. In the Manufacturing Document detail screen, navigate to the Risk Planning-MSR Analysis tab. For each question in the Project Identification field, click the Comments column and add your answer.
2. Specify the intent of the Risk Planning-MSR and enter start and due dates.
3. Use the Task and Tool fields to describe the work that needs to be done for Risk Planning-MSR and any tools that will be used to conduct the analysis.
4. Navigate to the Risk Planning-MSR tab. Click the Add New Item button in the Supplemental Risk Planning for Monitoring & System Response field; a new screen opens.

Fig. 118: Mfg Document Risk Planning-MSR Structural Analysis screen

The screenshot shows the 'Mfg Document Risk Planning-MSR Structural Analysis' screen. It features a 'General' tab at the top. Below it, there are several input fields and sections:

- Next Higher Level-Structure:** A dropdown menu showing 'WIN_LIFT - Window Lift System'.
- Focus Element-Structure:** A dropdown menu showing 'WIN_LIFT-02.010D - Electronic Control Unit (ECU) for Window Lifter'.
- Next Lower Level-Structure:** A text input field containing 'Transmit signal from Hall effect sensor to ECU'.
- Design Failure:** A dropdown menu showing 'No anti-pinch protection in comfort closing mode (Hand or neck may e pir'.
- Cause(s) of Design Failure:** A list of potential causes with checkboxes:
 - ☐ Potential Cause of Failure
 - ☐ Signal of Hall effect sensor is not transmitted to ECU due to poor conn
- Functional Analysis:** A table with columns for 'Next Higher Level-Functional', 'Focus Element-Functional', and 'Next Lower Level-Fu'. It contains one row:

Next Higher Level-Functional	Focus Element-Functional	Next Lower Level-Fu
☐ Provide anti-pinch protection for comfort closing mode	Provide signal to stop and reverse window lift motor in case of pinch situation	Transmit signal fro
- Diagram Upload Areas:** Four boxes at the bottom labeled 'Boundary Diagram', 'Block Diagram', 'Interface Analysis', and 'Structure Tree', each with a 'Drop files here to upload' instruction.

5. Define the system structures that are being evaluated. Then select the Design Risk failure analysis being addressed by this Risk Planning-MSR.
6. Select at least one cause of design failure. Then click Save.
7. Click the Add New Item button in the Functional Analysis field. A new screen opens.

Fig. 119: Mfg Document Risk Planning-MSR Functional Analysis screen

GeneralP-Diagram

Next Higher Level-Structural ⓘ

WIN_LIFT - Window Lift System

Next Higher Level-Functional ⓘ

Provide anti-pinch protection for comfort closing mode

Focus Element-Structural ⓘ

WIN_LIFT-02.010D - Electronic Control Unit (ECU) for Window Lifter

Focus Element-Functional ⓘ

Provide signal to stop and reverse window lift motor in case of pinch situation

Next Lower Level-Structural ⓘ

Transmit signal from Hall effect sensor to ECU

Next Lower Level-Functional ⓘ

Transmit signal from Hall effect sensor to ECU

Risk Analysis ⓘ

☐ Hazards/Hazardous Situation	Hazard Harms	Hazard Causes	
☐ No signal to stop and reverse window lift motor in case of pinch situation	No anti-pinch protection in comfort closing mode	Signal of Hall effect sensor is	<div><div>+</div><div>≡</div></div>

1

1 - 1 of 1 items

Design Failure ⓘ

No anti-pinch protection in comfort closing mode (Hand or neck may e pin

Manufacturing Document ⓘ

0000208

Sequence ⓘ

Enter Sequence

- 8. Define the functions of the system structures. Then click Save.
- 9. Click the Add New Item button in the Risk Analysis field. A new screen opens.

Fig. 120: Mfg Document Risk Planning-MSR Risk Analysis screen

General | **P-Diagram**

Next Higher Level-Structural
WIN_LIFT - Window Lift System

Next Higher Level-Functional
Provide anti-pinch protection for comfort closing mode

Hazard Harms
No anti-pinch protection in comfort closing mode

Focus Element-Structural
WIN_LIFT-02.010D - Electronic Control Unit (ECU) for Window Lifter

Focus Element-Functional
Provide signal to stop and reverse window lift motor in case of pinch situation

Hazards/Hazardous Situation
No signal to stop and reverse window lift motor in case of pinch situation

Next Lower Level-Structural
Transmit signal from Hall effect sensor to ECU

Next Lower Level-Functional
Transmit signal from Hall effect sensor to ECU

Hazard Causes

Potential Cause of Hazard	Best Frequency Potential (F)	Best Diagnostic Monitoring (M)
Signal of Hall effect sensor is not transmitted to ECU due to poor connection of Hall effect sensor	3	3

1 - 1 of 1 items

Failure Network Diagram

Severity
10

Best Frequency Potential (F)
3

Best Diagnostic Monitoring (M)
3

10. Define the hazard harms and hazardous situations that could occur during the functioning. Then click Save.
11. Click the Add New Item button in the Failure Causes field. A new screen opens.

Fig. 121: Mfg Document Risk Planning-MSR Causes screen

General

Potential Cause of Hazard ⓘ
Signal of Hall effect sensor is not transmitted to ECU due to poor connection of Hall effect sensor

Problem Cause Code(s) ⓘ

☐	Problem Cause Code	Problem Cause		
☐	CONNECT	Insufficient Connection		

1 - 1 of 1 items

Monitoring & Response ⓘ

☐	Rationale for Frequency	
☐	The connection principle of the Hall effect sensor and ECU is according	

1 - 1 of 1 items

Best Frequency Potential (F) ⓘ
3

Best Diagnostic Monitoring (M) ⓘ
3

MSR Optimization(s) ⓘ

☐	MSR Preventative Action	Diagnostic Monitoring Action	Target Completion Date	Status	
☐	None	Introduction of plausibility check b/w motor current and loss of signal from Hall effect sensor	3/15/2024	Open	

1 - 1 of 1 items

MSR Hazard/Hazardous Situation ⓘ
No signal to stop and reverse window lift motor in case of pinch situation

Design Failure ⓘ
No anti-pinch protection in comfort closing mode (Hand or neck may e pir

Manufacturing Document ⓘ

Sequence ⓘ

12. Define the potential cause of failure. Then click Save.
13. Use the Link button in the Problem Cause Codes field to identify what could cause such a failure. Then use the Add New Item button in the Monitoring & Response field to list the current MSR controls.

Fig. 122: Mfg Document Risk Planning-MSR Monitoring & Response screen

General

Frequency (F) of Hazard Cause ⓘ
3 ▼ ⓘ

Rationale for Frequency ⓘ
The connection principle of the Hall effect sensor and ECU is according to standard xyz

Current Monitoring Control Method ⓘ
No Monitoring ▼ ⓘ

Monitoring (M) of Hazard Cause ⓘ
10 ▼ ⓘ

Current System Response ⓘ
WIN-001 - Window will close with full clamping force ▼ ⓘ

Most Severe Hazard Harm after System Response ⓘ
Hand or neck may be pinched between glass and frame

Severity (S) of Hazard Harm After MSR ⓘ
10 ▼ ⓘ

MSR Cause ⓘ
Signal of Hall effect sensor is not transmitted to ECU due to poor connection ▼ ⓘ

Design Failure ⓘ
No anti-pinch protection in comfort closing mode (Hand or neck may be pinched) ▼ ⓘ

Manufacturing Document ⓘ
0000208 ▼ ⓘ

Sequence ⓘ
Enter Sequence ▼

14. Click Save, then click the Add New Item button in the MSR Optimizations field. A new screen opens.

Fig. 123: Mfg Document Risk Planning-MSR Optimization screen

General

Mfg Document Risk Planning-MSR Cause ⓘ
Signal of Hall effect sensor is not transmitted to ECU due to poor connectik ▼ ⓘ

Action Type ⓘ
Enter Action Type ▼

MSR Preventative Action ⓘ
None

Diagnostic Monitoring Action ⓘ
Introduction of plausibility check b/w motor current and loss of signal from Hall effect sensor

System Response ⓘ
WIN-002 - Comfort closing mode disabled ▼ ⓘ ⊕

Most Severe Hazard Harm after System Response ⓘ
Loss of convenience function "Comfort closing". The window only moves in manual mode

Responsible Person's Name ⓘ
Bob Leipwoski ▼ ⓘ ⊖

Target Completion Date ⓘ
3/15/2024 📅

Status ⓘ
Open ▼ ⓘ

Action Taken with Pointer to Evidence ⓘ
Enter Action Taken with Pointer to Evidence

Completion Date ⓘ
Enter Completion Date 📅

Residual Severity (S) ⓘ
6 ▼ ⓘ ⊕

Residual Frequency (F) ⓘ
2 ▼ ⓘ ⊕

Residual Monitoring (M) ⓘ
1 ▼ ⓘ ⊕

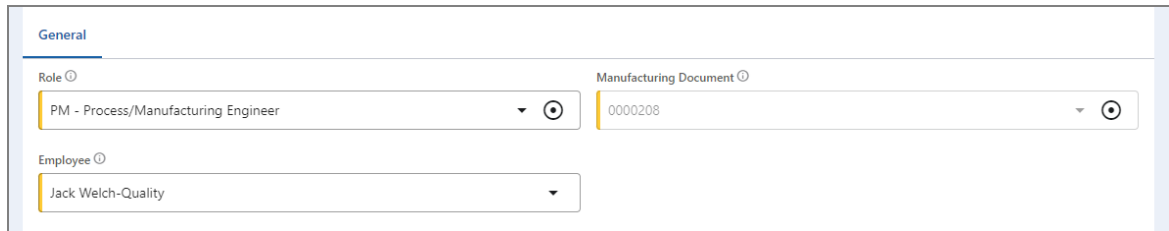
Residual MSR Action Priority (AP) ⓘ
L ▼ ⓘ ⊕

Remarks ⓘ
New monitoring

15. Use each field to look at the monitoring capabilities you have or want that would help reduce risk or severity through some automatic system response. This includes assigning an individual to take the improvement actions defined by a target completion date.
16. Click Save, then exit each screen until you return to the main Manufacturing Documents screen. You can also use the breadcrumb trail to navigate to this screen directly.
17. Back in the Risk Planning-MSR tab, use the fields under the Results Documentation header to record the results of the Risk Planning-MSR. When finished, click Save.

Completing the Process Risk Planning

1. In the Manufacturing Document detail screen, navigate to the Process Risk Planning tab. For each question in the Project Identification field, click the Comments column and add your answer.
2. Specify the intent of the process risk and enter start and due dates.
3. Add members to the process team.
 1. Click the Add New Item button in the Process Team field. A new screen opens.
 2. Select a role and the employee who will fulfill the role.
 3. Click Save.
 4. Repeat for each member of the team.

Fig. 124: Manufacturing Documents Process Risk Team screen

4. Back in the main process screen, use the Task and Tool fields to describe the work that needs to be done for the process risk and any tools that will be used to conduct the analysis.
5. Under the Process Risk Header, use each field to provide additional details about the process risk, including the process risk project name, customer name, process responsibility, confidentiality level, and more.
6. Click Save to save the manufacturing document. When selecting the next state, click Draft.

Reviewing a New Manufacturing Document with Copied Information

When a manufacturing document is created using the “Copy from Family Templates” or “Copy from Manufacturing Document” commands, the Process Flow, Specifications, Process Risk, and Process Risk Quality Plan tabs are automatically completed using data from the copied record. It is considered good practice to review these tabs and ensure their information is accurate and, if needed, part-specific.

As you navigate through each of these tabs, review the items in the lists. If the list is missing an important item, then the item should be added.

In the Process Flow tab, review the items in the process flow list and ensure each item is in the proper sequence.

1. If an item is in the wrong order, double-click it to open the detail screen.
2. In the Process Sort field, toggle to the correct sequence order.
3. Click Save.

In the Specifications tab, review the Lower Limit/Target/Upper Limit tolerances for each line item. If these values are blank or not accurate, then use the “Update Suggested Drawing Features” command to refresh that data from the Associated Drawings field.

Note: This command only updates data for specifications whose names match the specifications in the associated drawings.

On each process risk quality plan record, you can specify up to two graphics with an instruction for each graphic in the Visual Aid tab. These graphics and descriptions are visible to the operator/inspector when using the Inspection module.

Once all four tabs have been reviewed and updated as needed, continue to the next task.

Note: If any new specifications or process risk list items were added, then you may have to add a new process risk control plan as well.

Creating a Control Plan Without a Risk

1. In the Manufacturing Document detail screen, navigate to the Process Flow tab.
2. Click the Add New Item button in the Process Flow field. A new screen opens.

Fig. 125: Mfg Document Process Flow screen

General

Library Process ⓘ CST-4 - Casting - Alloy Melting and Pouring

Process No ⓘ CST-4

Flow Sequence ⓘ 3.0

Process Symbol ⓘ Operation

Inspection Requires Approval ⓘ YES NO

Process ⓘ Casting - Alloy Melting and Pouring

Sources of Variation ⓘ Enter Sources of Variation

Related Components ⓘ

Material/Component	Quantity	Unit of Measure	Notes
No records available			

Specification(s) ⓘ

Specification Id	Specification	Product or Process
02	Metal Temperature	Prod

1 - 1 of 1 items

3. Select a library process and the process sort. The Library Process field will automatically populate the other fields.
4. Determine whether the inspection requires approval.
5. Click the Link button in the Specifications field. Select each specification that is relevant to the process flow.
6. Click Save to save the record. Then click the Close button to return to the Manufacturing Document detail screen.
7. Repeat steps 2-6 until all processes for the process flow have been added.
8. Navigate to the Specifications tab. Execute the Import and Link Process Specs command; the Specifications field is populated.
9. Navigate to the Control Plan tab. Click the Add New Item button in the Control Plan field. A new screen opens.

Fig. 126: Mfg Document Process Risk Controls screen

Library Control ⓘ

Enter Library Control

Update From Library ⓘ

UPDATE FROM LIBRARY

General Sampling Customer Specific Information Visual Aid

Implementation Date ⓘ

3/1/2024

Process ⓘ

Casting - Alloy Melting and Pouring

Control Method ⓘ

Check Sheet

Specification ⓘ

01 - Temperature

Control Description ⓘ

Machine set up check for correct settings

Product/Process Specification/Tolerance ⓘ

Min: Target: Max: 112.000000 F

Evaluation/Measurement Technique ⓘ

Manual check

Machine, Device, Jig, Tools for Manu. ⓘ

Furnace

Tooling and Equipment Type ⓘ

FNC - Furnace

Tooling and Equipment Number ⓘ

Enter Tooling and Equipment Number

Gauge Type ⓘ

Enter Gauge Type

Gauge Number ⓘ

Enter Gauge Number

10. Choose a control method. Then, depending on your selection, choose a detection of hazard cause and/or an occurrence of hazard cause.
11. Navigate to the Sampling tab. Select a sampling technique and set the sample frequency.
12. Navigate to the General tab. Populate the relevant fields. You may also select a library control, then execute the Update from Library command; this copies the relevant information from the selected library control to the control plan.
13. Click Save to save the record. Then click the Close button to return to the Manufacturing Document detail screen.
14. Click Save to save the Manufacturing Document.

Linking a Design Risk to a Process Risk

1. In the Manufacturing Document, navigate to the Process Risk tab.
2. Open the Process Risk record you want to modify (4th Edition) or navigate through the structural and functional levels to the Process Risk record you want to modify (AIAG/VDA). A new screen opens.
3. In the Mfg Document Process Risk Structural Analysis screen, open a record in the Process Risk Functional Analysis field. A new screen opens.
4. In the Mfg Document Process Risk Functional Analysis screen, open a record in the Risk Analysis field. A new screen opens.
5. In the Mfg Document Process Risk Analysis screen, select a design system. A new field appears titled Design Risk Analysis.

Fig. 127: Design System and Design Risk Failure Analysis fields, Mfg Document Process Risk Failure Analysis screen

6. Use the Design Risk Analysis drop-down to select a hazard/hazardous situation with the same Failure Harm as the process risk.
7. Save the record.
8. Scroll down to the Severity field. Note that the severity of the process hazard will be limited to be greater than or equal to the severity of the design hazard.
9. Return to the main Manufacturing screen, saving each record as you close it.

Adding a New Work Instruction

1. In the Manufacturing Document detail screen, navigate to the Work Instructions tab. Click the Add New Item  button. A new screen appears.
2. In the new screen, select the process and process risk quality plan.
3. Select a step number
4. Enter a title for this step.
5. Enter detailed instructions for this step.
6. If you have a relevant image for this step, then click the Browse button in the Step Image field to add the image.
7. Click Save to save the record.
8. Repeat this task for all work instructions.

Approving a Manufacturing Document

1. The person responsible for approving a manufacturing document is automatically notified when it is time for approval through the inbox or optionally from an e-mail notification (clicking the link in that message takes you to the document for approval).
2. Open the inbox, either through the Home Page dashboard or by clicking the Inbox icon in the toolbar.
3. Upon opening the inbox, click the approval item under the Design Control group to show the action icons. Then click the Open icon. The screen navigates to the manufacturing document's detail screen.
4. In the detail screen, navigate to the Version Specific tab, scroll down to the Approval field, and click the Approve/Reject button. A small window appears.
5. In the Sign Off window, enter your password and either approve or reject the change. Use the comments field to document any information about your decision. Comments are required for rejection.

Note: Once all members of the approval process have finished, the manufacturing document becomes official and ready for use.

Starting a New Version of a Manufacturing Document

The Start New Version command in the Manufacturing Documents process should be used for small-impact changes that do not affect other departments or people, such as fixing a typo or changing a tag. If the document requires a bigger change, then a change request must be initiated. See "Change Requests" in the [Document Control](#) user guide for more information.

Note: Revisions can only be made if the manufacturing document is in the Official state.

1. Open the detail screen of the manufacturing document you wish to change. If the document does not already have a change initiated, then click the Actions  button and select Start New Version.

Note: If a manufacturing document already has a change initiated, then contact the Owner to see if the changes you want to make can be included in the current change.

2. In the Version Specific tab, use the Change Description field to summarize what has changed and set the effective date.
3. Select the "Requires Training" check box as appropriate. Minor changes may not require additional training.
4. Click Save to save the record. Select Awaiting Approval if you are finished with the changes or select Draft to save the document as a draft and continue working.

When this version is approved, it becomes official and all previous versions become obsolete.

It can be helpful to see a historical version of the manufacturing document. You can quickly access historical versions from any version of the document by clicking More in the toolbar and selecting Versions to expand the Versioning panel. Click one of these versions to switch your detail screen view to the selected version.

Fig. 128: List of Versions

Versions	
Number: F	Date: 1/8/2024, 11:02 AM
Number: E	Date: 7/31/2023, 11:18 AM
Number: D	Date: 5/4/2023, 3:32 PM
Number: C	Date: 4/28/2023, 1:18 PM
Number: B	Date: 4/28/2023, 1:17 PM
Number: A	Date: 4/12/2023, 3:05 PM

Design Verification Reports

During the design cycle of a product, tests are planned and conducted to ensure issues will not arise as a result of a product's design – that is, verifying that the design meets the basic design specifications and the design itself will not be the cause of any issues.

The design verification plan and report (DVP&R) are combined in the Manufacturing Documents process. See "Manufacturing Documents" on page 134 for more information.

Fig. 129: Design Verification Report screen

General

Report Number ⓘ

Verification Plan ⓘ

Sample Type ⓘ

Sample Quantity ⓘ

Completed By ⓘ

Actual Completion Date ⓘ

Test Passed ⓘ

PASSED
FAILED
UNDECID...

Actual Results ⓘ

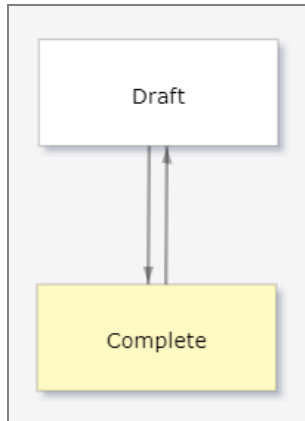
Notes ⓘ

Design Verification Reports States

This section defines each state available in the workflow for the Design Verification Reports process. See "State Change Security" on page 206 to learn more about how these states transition.

Draft (Default). The design verification report is being drafted and is not yet complete.

Complete. The design verification report is complete.



Design Verification Reports Tasks

Adding a New Design Verification Report

1. Select Design Verification Reports from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter a report number for the verification report.
3. Select the related verification plan in the appropriate drop-down field.
4. Select the sample type and quantity, if they did not automatically populate from the Verification Plan field selection.
5. Select the actual completion date and the employee who completed the test.
6. If the test passed inspection, then set the "Test Passed" toggle field to PASSED.
7. Document the actual results of the testing and any additional notes as needed.
8. Click Save to save the new record. When selecting the next state, click Complete.

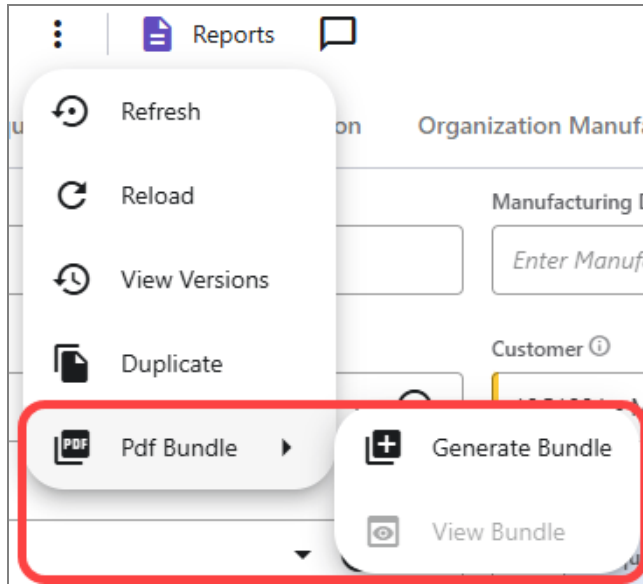
PPAP Submissions

The Design Control process concludes with the Production Part Approval Process (PPAP), which verifies that the supplier understands all customer product specifications and is ready to supply product at the required quality and production rate. PPAP is required for any new part submission or change to an existing part or process.

The PPAP Submissions process is a culmination of the documentation to be sent to the customer for approval or rejection. By approving the PPAP submission, the customer approves the product for mass production. The process contains a unique PDF Bundle selection under the More icon in the toolbar, which takes the following:

1. Documents and records linked to a requirement that has the submission status set to Submit.
2. Associated Project Task file on a requirement.
3. A rendering of Design Control reports for the associated Manufacturing Document linked to a requirement.

Clicking "Generate Bundle" creates the PDF, and clicking "View Bundle" opens the PDF.



PPAP submissions are linked to manufacturing documents. See "Manufacturing Documents" on page 134.

Fig. 130: PPAP Submissions screen, General tab

General | Submission Information | Requirements | Part Information | Organization Manufacturing Information | Submission Results | Cancellation

PPAP Submission Number ①: 9

Manufacturing Document ①: 0000021

Item ①: 02290 - AV Seat Motor Assembly

Customer ①: 10C1002 - Houston Automotive Group

Owner ①: Jack Welch-Quality

Additional Manufacturing Documents ①

☐	Sequence ↑	Manufacturing Document
☐	1	0000019
☐	2	0000020

1 - 2 of 2 items

Domain ①: 10USA - USA Domain

Entity ①: 10USACO - USA DIVISION

Site ①: 10-200 - Auto Industrial Mfg

Buyer / Buyer Code ①: HAG-001

Application ①: Seating

Tags ①

☐	Process	X-Ref	Notes
No records available			

The General tab is used to define the basic details of a PPAP submission, including the relevant manufacturing document, item, customer, owner, and additional manufacturing documents.

Fig. 131: PPAP Submissions screen, Submission Information tab

General | **Submission Information** | Requirements | Part Information | Organization Manufacturing Information | Submission Results | Cancellation

Substances of Concern ①: YES NO N/A

IMDS / Other Customer Format ①: IMDS-Node 030021

Polymeric Parts ①: YES NO N/A

Reason for Submission (check at least one)

Initial Submission ①: ☒

Engineering Change(s) ①: ☐

Tooling: Transfer, Replacement, Refurbishment, or Additional ①: ☐

Correction of Discrepancy ①: ☐

Tooling Inactive > Than 1 Year ①: ☐

Change to Optional Construction or Material ①: ☐

Supplier or Material Source Change ①: ☐

Change in Part Processing ①: ☐

Parts Produced at Additional Location ①: ☐

Other - Please Specify ①: ☐

The Submission Information tab describes the reason for submission, along with other submission information.

Fig. 132: PPAP Submissions screen, Requirements tab

General Submission Information **Requirements** Part Information Organization Manufacturing Information Submission Results Cancellation

PPAP Requirement Set Level 3

Currently Meets All PPAP Requirements YES NO

Requirement Status

	Sequence	PPAP Requirement	Requirement Met	Comment
	1.0	Design Record for all other components/details	No	
	2.0	Engineering Change Documents, if any	Yes	Not applicable
	3.0	Customer Engineering approval, if required	Yes	Not Applicable
	4.0	Design FMEA	Yes	
	5.0	Process Flow Diagrams	Yes	

1 - 5 of 19 items

In the Requirements tab, select a PPAP requirement set and save the record. This supplies a list of PPAP requirements, links to documents and records, and more. See "PPAP Requirement Status" on page 60 for more information.

Fig. 133: PPAP Submissions screen, Part Information tab

General Submission Information Requirements **Part Information** Organization Manufacturing Information Submission Results Cancellation

Part Name AV Seat Motor Assembly1

Customer Part Number 022900

Original Part Number NA

Shown on Drawing Number 02290-AA

Engineering Change Level AA

Engineering Change Date 4 Aug 2019

Additional Engineering Date NA

Additional Engineering Changes NA

PO Number PO-19930482

Safety and/or Govt. YES NO

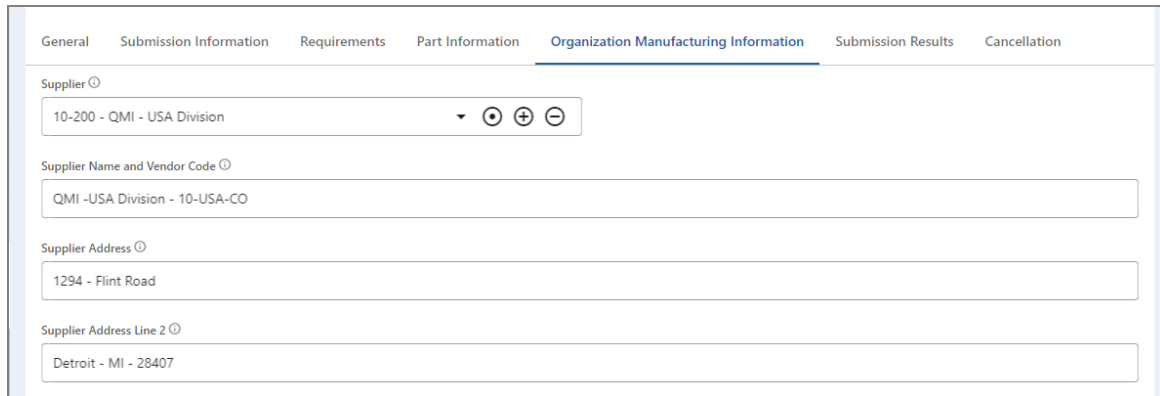
Weight 2.5000

Checking Aid Number NA

Checking Aid Change Level NA

Checking Aid Change Date NA

The Part Information tab supplies specific information of the part being submitted, including the name and part number, engineering changes, weight, and more.

Fig. 134: PPAP Submissions screen, Organization Manufacturing/Customer Information tab


General Submission Information Requirements Part Information **Organization Manufacturing Information** Submission Results Cancellation

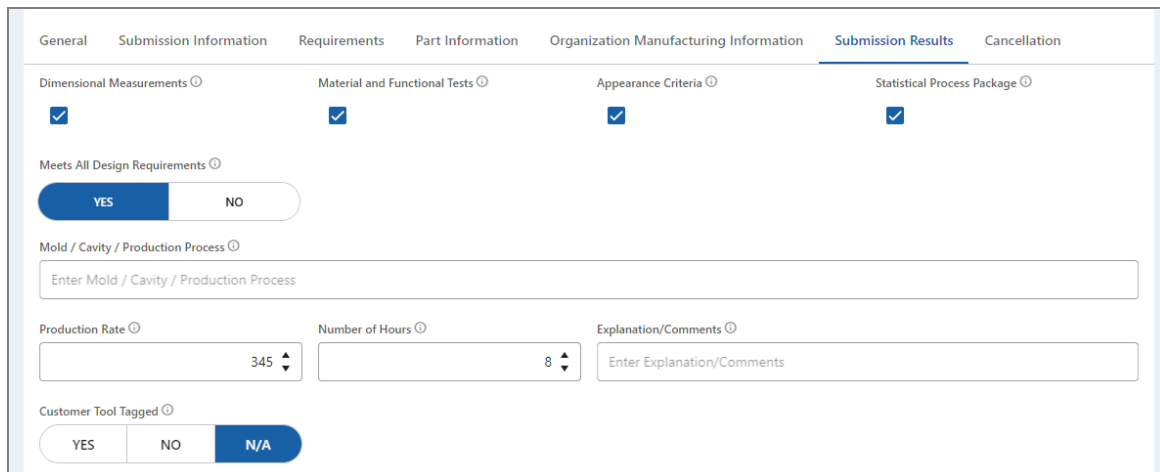
Supplier ⓘ
10-200 - QMI - USA Division

Supplier Name and Vendor Code ⓘ
QMI -USA Division - 10-USA-CO

Supplier Address ⓘ
1294 - Flint Road

Supplier Address Line 2 ⓘ
Detroit - MI - 28407

The Organization Manufacturing/Customer Information tab contains the name, vendor code, and address of the supplier.

Fig. 135: PPAP Submissions screen, Submission Results tab


General Submission Information Requirements Part Information Organization Manufacturing Information **Submission Results** Cancellation

Dimensional Measurements ⓘ ☒

Material and Functional Tests ⓘ ☒

Appearance Criteria ⓘ ☒

Statistical Process Package ⓘ ☒

Meets All Design Requirements ⓘ
YES NO

Mold / Cavity / Production Process ⓘ
Enter Mold / Cavity / Production Process

Production Rate ⓘ 345 Number of Hours ⓘ 8 Explanation/Comments ⓘ
Enter Explanation/Comments

Customer Tool Tagged ⓘ
YES NO **N/A**

The Submission Results tab signifies whether certain items are included in the submission, such as material and functional tests.

Fig. 136: PPAP Submissions screen, Approval tab

Internal Approval ①

2

Customer Approval Submission Date ① 2/9/2024

Customer Approval Target Date ① 2/9/2024

Customer Approval Date ① 2/8/2024

Customer Approval Notes ①

Enter Customer Approval Notes

Customer Approval Proof ①

HFA_Approval03062020.docx

Explanation or Comments ①

Enter Explanation or Comments

Use the Approval tab to track internal and customer approval dates. Once customer approval is obtained, attach a file that contains proof of the approval to this tab.

Fig. 137: PPAP Submissions screen, Cancellation tab

General Submission Information Requirements Part Information Organization Manufacturing Information Submission Results **Cancellation**

Cancelled? ①

YES NO

Cancellation Reason ①

No longer needed by customer

Sometimes a PPAP submission must be canceled before it reaches customer approval. In cases such as this, use the Cancellation tab to cancel and obsolete the submission.

To perform a cancellation, select the "Cancelled?" check box, enter a cancellation reason, then click the Save button to save the record.

PPAP Submissions States

This section defines each state available in the workflow for the PPAP Submissions process. See "State Change Security" on page 206 to learn more about how these states transition.

Draft (Default). The PPAP submission is still being drafted and is not yet ready for approval.

Ready for Approval. The PPAP submission is waiting to be approved internally.

Approval Rejected. The PPAP submission was rejected.

Submit for Customer Approval. The PPAP submission is approved and is waiting to be submitted to the customer for approval.

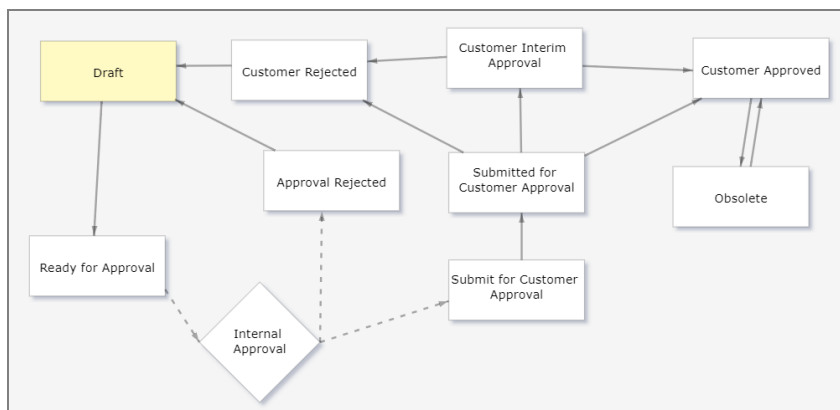
Submitted for Customer Approval. The PPAP submission is submitted for customer approval.

Customer Interim Approval. The PPAP submission was approved by the customer, but the project is still in the prototype stage.

Customer Approved. The PPAP submission was approved by the customer.

Customer Rejected. The PPAP submission was rejected by the customer.

Obsolete. An obsolete version of the PPAP submission. This version shall not be used.



PPAP Submissions Tasks

Adding a New PPAP Submission

1. There are two ways to add a new PPAP submission:
 1. Select PPAP Submissions from the left navigation panel. Then, click the Add Item  button in the toolbar.
 2. In a manufacturing document, navigate to the PPAP Submissions tab and click the Add New Item  button.
2. Select the manufacturing document. The Item, Customer, Owner, Domain, Entity, and Site fields automatically populate.

Note: If the submission is added through a manufacturing document, then the Manufacturing Document field is automatically populated.

3. Navigate to the Submission Information tab. Select any check box relevant to the reason for submission.
4. Indicate whether any substances of concern information have been reported. Also indicate whether any polymeric parts have been identified with the appropriate ISO marking codes.
5. Navigate to the Requirements tab. Select a level in the PPAP Requirement Set field.

6. Navigate to the Part Information tab. Complete each field that pertains to the part being submitted. If the design record indicates a safety or government regulation for the part being submitted, then select the "Safety and/or Govt." check box.
7. Navigate to the Organization Manufacturing/Customer Information tab. Enter the supplier's information.
8. Navigate to the Submission Results tab. Select all check boxes and toggle fields that indicate details covered in the submission.

Note: The "Meets all Design Requirements" toggle field is typically set to TRUE, but if not, the reasons why should be detailed in the Explanation/Comments field.

9. Click Save to save the new record. When selecting the next state, click Ready for Approval.

Approving a PPAP Submission

1. The person responsible for approving a PPAP submission is automatically notified when it is time for approval through the inbox or optionally from an e-mail notification (clicking the link in that message takes you to the document for approval).
2. Open the inbox, either through the Home Page dashboard or by clicking the Inbox icon in the toolbar.
3. Upon opening the inbox, click the approval item under the Design Control group to show the inbox action icons. Then click the Open icon. The screen navigates to the submission's detail screen.
4. In the detail screen, navigate to the Approval tab and click the Approve/Reject button in the Internal Approval field. A small window appears.
5. In the Sign Off window, enter your password and either approve or reject the change. Use the comments field to document any information about your decision. Comments are required for rejection.
6. Once all internal approvals are complete, the state automatically changes to Submit for Customer Approval. Click the state and select Submitted for Customer Approval to signify that the customer has received the PPAP submission.
7. After the customer has reviewed the PPAP submission, you can move the state to one of three options:
 - **Customer Rejected.** The customer rejects the submission. The record returns to the Draft state.
 - **Customer Approved.** The customer approves the submission. The record is complete.
 - **Customer Interim Approval.** The customer approves the submission but the project is still in the prototype stage.
8. Once the state is Customer Approved or Customer Interim Approval, enter the customer approval date and notes in the Approval tab. You can also upload a file that contains proof of customer approval, such as a PDF of the signed warrant form.
9. Click Save to save the record.

Starting a New Version of a PPAP Submission

Note: Revisions can only be made if the PPAP submission is in the Official state.

1. Open the detail screen of the PPAP submission you wish to change. If the submission does not already have a change initiated, then click the Actions  button and select Start New Version.

Note: If a submission already has a change initiated, then contact the Owner to see if the changes you want to make can be included in the current change.

2. Click Save to save the record. Select Ready for Approval if you are finished with the changes or select Draft to save the submission as a draft and continue working.

When this version is approved, it becomes official and all previous versions become obsolete.

Note: You can also make a PPAP submission record obsolete by moving the state to Obsolete and saving the record.

It can be helpful to see a historical version of the PPAP submission. You can quickly access historical versions from any version of the submission by clicking More in the toolbar and selecting Versions to expand the Versioning panel. Click one of these versions to switch your detail screen view to the selected version.

Fig. 138: List of Versions

Versions	
Number: F	Date: 1/8/2024, 11:02 AM
Number: E	Date: 7/31/2023, 11:18 AM
Number: D	Date: 5/4/2023, 3:32 PM
Number: C	Date: 4/28/2023, 1:18 PM
Number: B	Date: 4/28/2023, 1:17 PM
Number: A	Date: 4/12/2023, 3:05 PM

Chapter 7

Inbox Messages

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Inbox Messages...175

Introduction to Inbox Messages

Most processes in the system require multiple people, departments, or groups to coordinate on completing a process. The inbox automates notifications sent to the appropriate users at specific times in the process.

An individual inbox action item represents a single task, approval, or notification that has been sent to you. This task will remain in your inbox until the necessary steps have been taken for completion.

Inbox messages can be separated into three different inbox action types:

- **Assignment.** You are required to take some action in the system to move it beyond your workflow.
- **Approval.** Your approval is requested. You must approve or reject the process item.
- **Acknowledgment.** This is only for your information. You can acknowledge the notification to remove it from your inbox.

See the [User Interface](#) user guide to learn how to access inbox messages.

Inbox Messages

The table below describes each inbox action item involved in the Design Control Libraries module. In addition to title and description, the table indicates which process each item comes from, who receives the message, and when it is sent. See the [User Interface](#) user guide to learn more about inbox messages.

Process	Title	Message	Action Type	Sent To / Sent When
Processes	Owner – Approval Approved	The following process approval has been approved. This is just a notification of the approval.	Assignment	Sent to the process owner when the process has been approved.
Processes	Owner – Requires Review	The following process requires review. Please review the process and start a new change if changes are required or move the state back to official if no changes are required.	Assignment	Sent to the process owner when the state moves to Requires Review.
Processes	Owner – Approval Rejected	The following process approval has been rejected. This is just a notification of the rejection	Assignment	Sent to the process owner when the state moves to Approval Rejected.

Process	Title	Message	Action Type	Sent To / Sent When
Processes	Change Owner – Affected Process Ready for Change	Process {ProcessCode_f} is ready for change Reason: {ReasonforChange_f} Due date: {ChangeDueDate_f}	Assignment	Sent to the change owner when the change owner is changed.
Processes	Change Owner – Change Overdue	Process {ProcessCode_f} is past due for change Reason: {ReasonforChange_f} Due date: {ChangeDueDate_f}	Assignment	Sent to the change owner when the record is not complete and the current due date is past the change due date.
Processes	Change Owner > Reports to – Change Overdue – Escalation	Process {ProcessCode_f} is past due for change - Escalation Please address this with {ChangeOwner_f} Reason: {ReasonforChange_f} Due date: {ChangeDueDate_f}.	Assignment	Sent to the user that the change owner reports to when the record is not in the Complete state and the current date is 7 days past the change due date.
Processes	Past Effective Date and Not Approved	Process {ProcessCode_f} is past effective date and has not been approved Reason: {ReasonforChange_f} Due date: {ChangeDueDate_f}.	Assignment	Sent to the process owner when the current date is past the effective date and the process has not been approved.
Processes	Past Effective Date and Not Approved – Escalation	Process {ProcessCode_f} is past effective date and has not been approved - Please address with {ProcessOwner_f} Reason: {ReasonforChange_f} Due date: {ChangeDueDate_f}.	Assignment	Sent to the user that the process owner reports to when the current date is 7 days past the effective date and the process has not been approved.
Processes	Approvers – Awaiting Approval	The following process is ready for approval, please approve or reject the change.	Approval	Sent to approvers when the process is ready for approval.

Process	Title	Message	Action Type	Sent To / Sent When
Family Templates	Owner – Approval Rejected	<p>The following template's approval has been rejected. Please review the comments from the approvers, make the necessary changes and then re-submit the template for approval.</p> <p>Item Group: {ItemGroup_f}</p> <p>Item Type: {ItemType_f}</p> <p>Notes: {Notes_f}</p>	Assignment	Sent to the owner when the template has been rejected.
Family Templates	Owner – Approval Complete	<p>The following template's approval has been approved. This is just a notification of the approval.</p> <p>Item Group: {ItemGroup_f}</p> <p>Item Type: {ItemType_f}</p> <p>Notes: {Notes_f}</p>	Assignment	Sent to the owner when the template has been approved.
Family Templates	Approvers – Awaiting Approval	<p>The following template is ready for approval, please approve or reject the change</p> <p>Item Group: {ItemGroup_f}</p> <p>Item Type: {ItemType_f}</p> <p>Owner: {Owner_f}</p> <p>Notes: {Notes_f}</p>	Approval	Sent to the approvers when the template is ready for approval.
Drawings	Owner – Approval Rejected	<p>The following drawing's approval has been rejected. Please review the comments from the approvers, make the necessary changes and then re-submit the drawing for approval.</p> <p>Title: {DrawingTitle_f}</p> <p>Change Description: {ChangeDescription_f}</p>	Assignment	Sent to the drawing owner when the state becomes Approval Rejected.

Process	Title	Message	Action Type	Sent To / Sent When
Drawings	Owner – Approval Approved	The following drawing's approval has been approved. This is just a notification of the approval. Title: {DrawingTitle_f} Change Description: {ChangeDescription_f}	Assignment	Sent to the drawing owner when the drawing has been approved.
Drawings	Owner – Approver Escalation	The approval for the following drawing's is past due. This is just a notification that the approval is past due. To view the approvers who have not yet approved or rejected the current change, please view the drawing's details. Title: {DrawingTitle_f} Change Description: {ChangeDescription_f}	Assignment	Sent to the drawing owner when the current state is Awaiting Approval and the current date is past the approval due date.
Drawings	Notification – Drawing Official State	The following document's current state has become official. Title: {DrawingTitle_f} Change Description: {ChangeDescription_f}	Assignment	Sent to the drawing viewers when the current state moves to Official.
Drawings	Change Owner – Affected Drawing Ready for Change	Drawing {DrawingNumber_f} is ready for change Reason: {ReasonforChange_f} Due date: {ChangeDueDate_f}	Assignment	Sent to the change owner when the current change owner is changed and the record is not linked to a change request.
Drawings	Change Owner – Change Overdue	Drawing {DrawingNumber_f} is past due for change Reason: {ReasonforChange_f} Due date: {ChangeDueDate_f}	Assignment	Sent to the change owner when the record is not complete and the current date is past the change due date.

Process	Title	Message	Action Type	Sent To / Sent When
Drawings	Change Owner > Reports to – Change Overdue – Escalation	Drawing {DrawingNumber_f} is past due for change - Escalation Please address this with {ChangeOwner_f} Reason: {ReasonforChange_f} Due date: {ChangeDueDate_f}	Assignment	Sent to the user that the change owner reports to when the record is not complete and the current date is 7 days past the due date.
Drawings	Owners Supervisor – Approver Escalation	Drawing {DrawingNumber_f} is past due for change - Please address with the Reason: {ReasonforChange_f} Due date: {ChangeDueDate_f}	Assignment	Sent to the drawing owner's supervisor when the current date is Awaiting Approval and the current date is 7 days past the due date.
Drawings	Approvers – Awaiting Approval	The following drawing is ready for approval, please approve or reject the change by {ApprovalDueDate_f}. Title: {DrawingTitle_f} Owner: {Owner_f} Change Description: {ChangeDescription_f}	Approval	Sent to approvers when the drawing is ready for approval.
Manufacturing Documents	Owner – Approval Rejected	The following document's approval has been rejected. Please review the comments from the approvers, make the necessary changes and then re-submit the document for approval. Item: {Item_f} Change Description: {ChangeDescription_f}	Assignment	Sent to the document owner when the state becomes Approval Rejected.
Manufacturing Documents	Owner – Approval Approved	The following document's approval has been approved. This is just a notification of the approval. Item: {Item_f} Change Description: {ChangeDescription_f}	Assignment	Sent to the document owner when the record is approved.

Process	Title	Message	Action Type	Sent To / Sent When
Manufacturing Documents	Owner – Approver Escalation	<p>The approval for the following document's is past due. This is just a notification that the approval is past due. To view the approvers who have not yet approved or rejected the current change, please view the document's details.</p> <p>Item: {Item_f}</p> <p>Change Description: {ChangeDescription_f}</p>	Assignment	Sent to the document owner when the record requires approval and the current date is beyond the due date.
Manufacturing Documents	Owner – Requires Review	<p>The following document requires review. Please review the document and start a new change if changes are required or move the state back to official if no changes are required. If the document no longer applies, then move the state of the document to Obsolete.</p>	Assignment	Sent to the document owner when the state moves to Requires Review.
Manufacturing Documents	Skip Lot Review	<p>A Manufacturing Document that has recently been moved to Approval has broken some Skip Lot rules.</p> <p>The owners of the Skip Lot rules have been notified and they'll need to correct. Once corrected the Manufacturing Document will need to be moved to Awaiting Approval.</p> <p>Item: {Item_f}</p> <p>Change Description: {ChangeDescription_f}</p>	Assignment	Sent to the document owner when the current state moves to Skip Lot Review.
Manufacturing Documents	Change Owner – Affected Document Ready for Change	<p>Manufacturing Document {ManufacturingDocumentNumber_f} is ready for change</p> <p>Reason: {ReasonforChange_f}</p> <p>Due date: {ChangeDueDate_f}</p>	Assignment	Sent to the change owner when the current change owner is changed and the record is not linked to a change request.

Process	Title	Message	Action Type	Sent To / Sent When
Manufacturing Documents	Change Owner – Change Overdue	Manufacturing Document {ManufacturingDocumentNumber_f} is past due for change Reason: {ReasonforChange_f} Due date: {ChangeDueDate_f}	Assignment	Sent to the change owner when the record is not complete and the current date is past the due date.
Manufacturing Documents	Change Owner > Reports to – Change Overdue – Escalation	Manufacturing Document {ManufacturingDocumentNumber_f} is past due for change - Escalation Please address this with {ChangeOwner_f} Reason: {ReasonforChange_f} Due date: {ChangeDueDate_f}	Assignment	Sent to the user that the change owner reports to when the record is not complete and the current date is 7 days past the due date.
Manufacturing Documents	Approvers – Awaiting Approval	The following document is ready for approval, please approve or reject the change by {ApprovalDueDate_f}. Item: {Item_f} Owner: {Owner_f} Change Description: {ChangeDescription_f}	Approval	Sent to approvers when the document is ready for approval.
PPAP Submissions	Customer Has Not Approved PPAP	PPAP {PPAPSubmissionNumber_f} for item {Item_f} belonging to customer {Customer_f} is past due. The customer was expected to approve this PPAP on {CustomerApprovalTargetDate_f}.	Assignment	Sent to the PPAP submission owner when the customer has not approved the PPAP and the current date is past the customer target approval date.
PPAP Submissions	Owner – Approval Rejected	The following PPAP Submission's approval has been rejected. Please review the comments from the approvers, make the necessary changes and then re-submit the PPAP Submission for approval.	Assignment	Sent to the owner when the current state moves to Approval Rejected.

Process	Title	Message	Action Type	Sent To / Sent When
PPAP Submissions	Customer Has Not Approved PPAP – Escalation	<p>The following PPAP Submission has not been approved by the customer and no action has been taken to address this. Please work with the PPAP owner to address this situation.</p> <p>Item: {Item_f}</p> <p>Manufacturing Document: {Manufacturing Document_f}</p>	Assignment	Sent to the owner's supervisor if the customer has not approved the PPAP and the current state is past the customer target approval date.
PPAP Submissions	Approvers Ready for Approval	<p>The following PPAP Submission is ready for approval, please approve or reject the change</p> <p>Item: {Item_f}</p> <p>Manufacturing Document: {ManufacturingDocument_f}</p> <p>Notes: {Notes_f}</p>	Approval	Sent to the approvers when the current state moves to Ready for Approval.

Chapter 8

Metrics and Reports

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Introduction to Metrics and Reports

The QMS system includes reporting and metric features that let you analyze the data in each process, measuring efficiency and effectiveness. The metrics and reports available differ between each process.

Report are generated within each process, either from the search screen or the detail screen. Metrics and key process indicators (KPIs) are gadgets that can be placed on one of your dashboards.

See the [User Interface](#) user guide to learn how to access reports, metrics, and KPIs.

Reports

Pre-set reports have been set up to be pulled on a process by process basis, though not every process has a pre-set report. Certain reports require additional parameters in order to be previewed. The parameters are listed on the right side of the preview window. If a report requires parameters, then this pane will automatically appear. Once you have selected the desired parameters, click the Preview button to see the report preview.

Below is a table that describes each report available in the Design Control module. In addition to title and description, the table indicates which process each report comes from and whether it is pulled from the search screen or detail screen. Lastly, if the report requires specific parameters in order to be generated properly, a description of those parameters is included below that report. See the [User Interface](#) user guide to learn more about reports.

Process	Pulls From	Title	Description
Sample Sizes	Detail Screen	Audit Trail – Sample Sizes	Provides a path of how the record has progressed over time with changes (who, what, and when).
Unit of Measures	Detail Screen	Audit Trail – Unit of Measures	Provides a path of how the record has progressed over time with changes (who, what, and when).
Process Symbols	Detail Screen	Audit Trail – Process Symbols	Provides a path of how the record has progressed over time with changes (who, what, and when).
Special Symbols	Detail Screen	Audit Trail – Special Symbols	Provides a path of how the record has progressed over time with changes (who, what, and when).
Drawing Types	Detail Screen	Audit Trail – Drawing Types	Provides a path of how the record has progressed over time with changes (who, what, and when).
Item Types	Detail Screen	Audit Trail – Item Types	Provides a path of how the record has progressed over time with changes (who, what, and when).

Process	Pulls From	Title	Description
Item Groups	Detail Screen	Audit Trail – Item Groups	Provides a path of how the record has progressed over time with changes (who, what, and when).
Product Lines	Detail Screen	Audit Trail – Product Lines	Provides a path of how the record has progressed over time with changes (who, what, and when).
Reaction Plans	Detail Screen	Audit Trail – Reaction Plans	Provides a path of how the record has progressed over time with changes (who, what, and when).
Control Methods	Detail Screen	Audit Trail – Control Methods	Provides a path of how the record has progressed over time with changes (who, what, and when).
Project Identification Question Design Risk	Detail Screen	Audit Trail – Project Identification Question Design Risk	Provides a path of how the record has progressed over time with changes (who, what, and when).
Project Identification Question Process Risk	Detail Screen	Audit Trail – Project Identification Question Process Risk	Provides a path of how the record has progressed over time with changes (who, what, and when).
Project Identification Question FMEA-MSR	Detail Screen	Audit Trail – Project Identification Question FMEA-MSR	Provides a path of how the record has progressed over time with changes (who, what, and when).
Design Risk Control Methods	Detail Screen	Audit Trail – Design Risk Control Methods	Provides a path of how the record has progressed over time with changes (who, what, and when).
Process Risk Control Methods	Detail Screen	Audit Trail – Process Risk Control Methods	Provides a path of how the record has progressed over time with changes (who, what, and when).
FMEA-MSR Monitoring Control Methods	Detail Screen	Audit Trail – FMEA-MSR Monitoring Control Methods	Provides a path of how the record has progressed over time with changes (who, what, and when).
Specification Categories	Detail Screen	Audit Trail – Specification Categories	Provides a path of how the record has progressed over time with changes (who, what, and when).
Specification Names	Detail Screen	Audit Trail – Specification Names	Provides a path of how the record has progressed over time with changes (who, what, and when).
Specification Date Ranges	Detail Screen	Audit Trail – Specification Date Ranges	Provides a path of how the record has progressed over time with changes (who, what, and when).

Process	Pulls From	Title	Description
Inspection Types	Detail Screen	Audit Trail – Inspection Types	Provides a path of how the record has progressed over time with changes (who, what, and when).
Inspection Stations	Detail Screen	Audit Trail – Inspection Stations	Provides a path of how the record has progressed over time with changes (who, what, and when).
FMEA-MSR System Responses	Detail Screen	Audit Trail – FMEA-MSR System Responses	Provides a path of how the record has progressed over time with changes (who, what, and when).
PPAP Requirement Status	Detail Screen	Audit Trail – PPAP Requirement Status	Provides a path of how the record has progressed over time with changes (who, what, and when).
PPAP Requirements	Detail Screen	Audit Trail – PPAP Requirements	Provides a path of how the record has progressed over time with changes (who, what, and when).
PPAP Submission Requirement Sets	Detail Screen	Audit Trail – PPAP Submission Requirement Sets	Provides a path of how the record has progressed over time with changes (who, what, and when).
Design Risk Severity Criteria	Detail Screen	Audit Trail – Design Risk Severity Criteria	Provides a path of how the record has progressed over time with changes (who, what, and when).
Design Risk Occurrence Criteria	Detail Screen	Audit Trail – Design Risk Occurrence Criteria	Provides a path of how the record has progressed over time with changes (who, what, and when).
Design Risk Detection Criteria	Detail Screen	Audit Trail – Design Risk Detection Criteria	Provides a path of how the record has progressed over time with changes (who, what, and when).
Design Risk Detection Zone	Detail Screen	Audit Trail – Design Risk Detection Zone	Provides a path of how the record has progressed over time with changes (who, what, and when).
Design Risk Priority Levels	Detail Screen	Audit Trail – Design Risk Priority Levels	Provides a path of how the record has progressed over time with changes (who, what, and when).
Design Risk Priority Levels	Detail Screen & Search Screen	Design FMEA Risk Limiting Method Setup	Displays the occurrence zone, detection zone, and priority zone tables that are used to determine the design FMEA risk limiting method.
Process Risk Severity Criteria	Detail Screen	Audit Trail – Process Risk Severity Criteria	Provides a path of how the record has progressed over time with changes (who, what, and when).
Process Risk Occurrence Criteria	Detail Screen	Audit Trail – Process Risk Occurrence Criteria	Provides a path of how the record has progressed over time with changes (who, what, and when).

Process	Pulls From	Title	Description
Process Risk Detection Criteria	Detail Screen	Audit Trail – Process Risk Detection Criteria	Provides a path of how the record has progressed over time with changes (who, what, and when).
Process Risk Priority Levels	Detail Screen	Audit Trail – Process Risk Priority Levels	Provides a path of how the record has progressed over time with changes (who, what, and when).
Process Risk Occurrence Zone	Detail Screen	Audit Trail – Process Risk Occurrence Zone	Provides a path of how the record has progressed over time with changes (who, what, and when).
Process Risk Detection Zone	Detail Screen	Audit Trail – Process Risk Detection Zone	Provides a path of how the record has progressed over time with changes (who, what, and when).
Design Risk Detection Zone; Process Risk Occurrence Zone; Process Risk Detection Zone; Process Risk Priority Levels	Search/Detail Screen	Process Risk Limiting Method Setup	Provides a report that shows the severity and detection zone set up for Risk Limiting Method setup.
FMEA-MSR Frequency Criteria	Detail Screen	Audit Trail – FMEA-MSR Frequency Criteria	Provides a path of how the record has progressed over time with changes (who, what, and when).
FMEA-MSR Monitoring Criteria	Detail Screen	Audit Trail – FMEA-MSR Monitoring Criteria	Provides a path of how the record has progressed over time with changes (who, what, and when).
Risk Action Priority	Detail Screen	Audit Trail – Risk Action Priority	Provides a path of how the record has progressed over time with changes (who, what, and when).
FMEA-MSR Action Priority	Detail Screen	Audit Trail – FMEA-MSR Action Priority	Provides a path of how the record has progressed over time with changes (who, what, and when).
Design Risk Systems Library	Detail Screen	Audit Trail – Design Risk Systems Library	Provides a path of how the record has progressed over time with changes (who, what, and when).
Processes	Detail Screen	Audit Trail – Processes	Provides a path of how the record has progressed over time with changes (who, what, and when).
Processes	Search/Detail Screen	Management System Standard Coverage	Provides a report by Management Standards that shows which process support the standard.

Process	Pulls From	Title	Description
Processes	Search/Detail Screen	Process Audit Coverage	Displays each process for a selected site and whether or not the process has been audited in the last 12 months from the current date.
Processes	Detail Screen	Process Card	Displays the details of a process in a convenient card format.
Processes	Detail Screen	Process Turtle Diagram	Displays the details of a process in a turtle diagram format. Typically the turtle diagram is the starting point for conducting a process-based audit.
Library Specifications	Detail Screen	Audit Trail – Library Specifications	Provides a path of how the record has progressed over time with changes (who, what, and when).
Control Library	Detail Screen	Audit Trail – Library Controls	Provides a path of how the record has progressed over time with changes (who, what, and when).
Design Risk Structural Analysis Library	Detail Screen	Audit Trail – Design Risk Structural Analysis Library	Provides a path of how the record has progressed over time with changes (who, what, and when).
Design Risk Failure Analysis Library	Detail Screen	Audit Trail – Design Risk Failure Analysis Library	Provides a path of how the record has progressed over time with changes (who, what, and when).
Design Risk Causes Library	Detail Screen	Audit Trail – Design Risk Causes Library	Provides a path of how the record has progressed over time with changes (who, what, and when).
Process Risk Structural Analysis Library	Detail Screen	Audit Trail – Process Risk Structural Analysis Library	Provides a path of how the record has progressed over time with changes (who, what, and when).
Process Risk Failure Analysis Library	Detail Screen	Audit Trail – Process Risk Failure Analysis Library	Provides a path of how the record has progressed over time with changes (who, what, and when).
Process Risk Causes Library	Detail Screen	Audit Trail – Process Risk Causes Library	Provides a path of how the record has progressed over time with changes (who, what, and when).
Family Templates	Detail Screen	Audit Trail – Family Templates	Provides a path of how the record has progressed over time with changes (who, what, and when).
Family Templates	Detail Screen	Family Template Differences	Shows the differences between the family template and the manufacturing documents created from this template.

Process	Pulls From	Title	Description
Family Templates	Detail Screen	Uncontrolled Specification	Provides a report that shows specifications that are not currently controlled on the process risk control plan.
Drawings	Detail Screen	Audit Trail – Drawings	Provides a path of how the record has progressed over time with changes (who, what, and when).
Items	Detail Screen	Audit Trail – Items	Provides a path of how the record has progressed over time with changes (who, what, and when).
Manufacturing Documents	Detail Screen	AIAG Format Document Set	Provides a report with the process flow, process risk, and process risk control plan in one report.
Manufacturing Documents	Detail Screen	AIAG & VDA Design FMEA	Displays the design risk in the AIAG & VDA format.
Manufacturing Documents	Detail Screen	AIAG & VDA DFMEA Software View	Displays the design risk in the AIAG & VDA format, software view.
Manufacturing Documents	Detail Screen	AIAG & VDA FMEA-MSR Software View	Displays Design Risk with the inclusion of a summary of the associated Supplemental FMEA-MSR Controls and Optimizations for those design risk items with high severity (9 or 10) or those specifically linked to an MSR chain.
Manufacturing Documents	Detail Screen	AIAG & VDA FMEA-MSR Standard Form	Displays Design Risk with the inclusion of the details of the associated Supplemental FMEA-MSR Control and Optimizations for those design risk items with high severity (9 or 10) or those specifically linked to an MSR chain.
Manufacturing Documents	Detail Screen	AIAG & VDA FMEA-MSR Stand-Alone	Displays FMEA-MSR results alone without referencing the design risk chain.
Manufacturing Documents	Detail Screen	AIAG & VDA PFMEA Software View	Displays the process risk in the AIAG & VDA format, software view.
Manufacturing Documents	Detail Screen	AIAG Format Document Set (4th Edition)	Displays the Process Flow, Process Risk, and Process Control Plan in the AIAG format for the current Manufacturing Document as one report.

Process	Pulls From	Title	Description
Manufacturing Documents	Detail Screen	Audit Trail – Manufacturing Document	Provides a path of how the record has progressed over time with changes (who, what, and when).
Manufacturing Documents	Detail Screen	Checksheet Report	Provides a report of the items to be controlled at a particular inspection station on the process risk control plan.
Manufacturing Documents	Detail Screen	Command Log	Provides feedback from a selected command so a user can troubleshoot if the command does not populate the record as expected.
Manufacturing Documents	Detail Screen	Design FMEA (4th Edition)	Displays the design risk in 4th edition format.
Manufacturing Documents	Detail Screen	Design Risk Limiting Method Setup	Shows the setup for the severity versus occurrence and the severity versus detection zones and the associated priority zones.
Manufacturing Documents	Detail Screen	Design Verification Plan and Report	Provides a report of DVP&R set up for the related manufacturing document.
Manufacturing Documents	Detail Screen	Family Template Difference Report	Displays differences between the Family Template and the Manufacturing Document.
Manufacturing Documents	Detail Screen	GM Design Risk Report	Provides a design risk plan report using the GM RPL setup.
Manufacturing Documents	Detail Screen	GM Process Risk Report	Provides a report using the GM Risk report with RPL setup.
Manufacturing Documents	Search & Detail Screen	Manufacturing Document Difference Report	Displays differences between the current manufacturing document and the manufacturing document used to create it.
Manufacturing Documents	Detail Screen	Manufacturing Document Process Risk Control Plan Report	Provides an AIAG compliant process risk control plan report.
Manufacturing Documents	Detail Screen	Manufacturing Document Process Flow Report	Provides an AIAG compliant process flow report.
Manufacturing Documents	Detail Screen	Manufacturing Document Process Risk Plan Report	Provides an AIAG complaint process risk plan report.
Manufacturing Documents	Detail Screen	Manufacturing Document Work Instruction Report	Provides a report showing the work instructions related to the manufacturing document.

Process	Pulls From	Title	Description
Manufacturing Documents	Search Screen	Process Risk Limiting Method Setup	Provides a report that shows the severity and detection zone set up for Risk Limiting Method setup.
Manufacturing Documents	Detail Screen	PQCT Format Document Set	Displays the process quality control in the PQCT format, a format created by Honda.
Manufacturing Documents	Detail Screen	Specification Report	Provides a report that shows specifications that are controlled on the process risk control plan.
Manufacturing Documents	Detail Screen	Uncontrolled Specification	Provides a report that shows specifications that are not currently controlled on the process risk control plan.
Manufacturing Documents	Detail Screen	VDA Product Risk	Provides a VDA compliant product risk report.
Manufacturing Documents	Detail Screen	VDA Process Risk	Provides a VDA compliant process risk report.
Design Verification Reports	Detail Screen	Audit Trail – Design Verification Reports	Provides a path of how the record has progressed over time with changes (who, what, and when).
PPAP Submissions	Detail Screen	Audit Trail – PPAP Submissions	Provides a path of how the record has progressed over time with changes (who, what, and when).
PPAP Submissions	Detail Screen	AIAG Part Submission Warrant 4th Edition	Provides a report of the PSW for signing and submission to the customer.
PPAP Submissions	Detail Screen	PPAP Submission Coverpage	Provides a cover page for the PPAP submissions report that is used with the PPAP bundle option.

Metrics

Below is a table that describes each metric available in the Design Control module. In addition to title and description, the table indicates which process each metric comes from. Lastly, if the metric requires specific parameters in order to be generated properly, a description of those parameters is included below that metric. See the [User Interface](#) user guide to learn more about metrics.

Process	Pulls From	Title	Description
Drawings	Gadget	Total Official Drawings	The total number of official drawings in the system.
Drawings	Gadget	Total Official Drawings by Drawing Type	The total number of official drawings grouped by drawing type.

Process	Pulls From	Title	Description
Drawings	Gadget	Total Official Drawings by Site	The total number of official drawings grouped by site.
Manufacturing Document	Gadget	Average Days to Complete Change	The average of the number of days between draft and approved states, divided by how many versions the document has gone through.
Manufacturing Document	Gadget	Maximum Revision Number	The maximum revision number the document has completed.
Manufacturing Document	Gadget	Revision Count	The number of revisions the document has gone through.

KPIs

See the [User Interface](#) user guide to learn more about KPIs.

There are no KPIs available for this module.

Chapter 9

Security Settings

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Security Roles

Security roles define how various users access and control different types of processes and data. These roles are then assigned to each user. Some roles are used by many users, while others may only be applied to one or two individuals.

The following security roles apply in the Design Control module.

All Roles

This security role is system-controlled. Any security applied to this special system role grants that security access to all users of the system.

APQP Administrator

This security role allows you to add, edit, and remove records in any process in the Design Control module.

APQP Champion

This security role allows you to add records in any process in the Design Control module.

APQP Library Maintenance

This security role allows you to add, edit, and remove records in Specifications, Process Risk Analysis Library, and Library Controls.

APQP Maintenance

This security role allows you to add, edit, and remove specification names, process symbols, special symbols, risk detection/occurrence/severity ratings, frequency events, drawing types, and control methods. Besides being able to add and remove items for those processes, you can also view and edit all of the fields of the processes noted. Typically this maintenance account is only given to one or two individuals who are responsible for setting up this data for others to use.

APQP Navigation

This security role allows you to navigate to the Design Control module.

Connect Maintenance

This security role allows you to add and remove company types. Besides being able to add and remove items for those processes, you can also view and edit all of the fields of the processes noted. Typically this maintenance account is only given to one or two individuals responsible for setting up this data for others to use.

Design Engineer

This role allows you to add and adjust records related to Manufacturing Documents, Family Templates, and Design Risk Effects Analysis.

Document Maintenance

This security role allows you to add and remove document types, drawing types, document templates, and record types, as well as add review frequencies. Besides being able to add and remove items for those processes, you can also view and edit all of the fields of the processes noted. Typically this maintenance account is only given to one or two individuals responsible for setting up this data for others to use.

Documents Administrator

This security role allows you to add, edit, and remove records in any process in the Document Control module.

Documents Champion

This security role allows you to add records in any process in the Document Control module.

Drawing Add/Edit

This security role allows you to add and edit new Drawings and Specifications. Upon adding a drawing, you become the drawing owner by default. The drawing owner and the Drawing Administrator security role are the only users who can edit the drawing.

Drawing Administrator

This security role allows you to add new drawings and drawing features. The drawing administrator also has the ability to edit any drawing as if he or she were the owner of the drawing owner.

Equipment Add

This security role allows you to add new and edit equipment.

Equipment Administrator

This security role allows you to add, edit, and remove records in any process in the Equipment module.

Equipment Champion

This security role allows you to add records in any process in the Equipment module.

Equipment Maintenance

This security role allows you to add, edit, and remove equipment types, equipment sub-types, equipment status, equipment cavity, equipment downtime logs, and asset meters. Typically this maintenance account is only given to one or two individuals responsible for setting up this data for others to use.

Equipment Maintenance Administrator

This security role allows you to add and remove maintenance work order types, maintenance fault codes, and maintenance teams. The Worksheet Administrator is also assigned as an approver to maintenance work orders that require approval.

Equipment Navigation

This security role allows you to navigate to the Equipment module.

Equipment Type Maintenance

Allows users to maintain equipment types and equipment sub-types.

Family Template Maintenance

This security role allows you to add, edit, and remove records in processes related to family templates. This includes family templates, family template process flow, family template process risk plan, family template specifications, family template process risk control plan, and more.

Gauge Add/Edit

This security role allows you to add new and edit gauges.

Gauge Administrator

This security role allows you to add new, edit, and remove gauges, gauge calibrations, and gauge R&R studies.

Gauge Champion

This security role allows you to add records in any process in the Gauge module.

Gauge Maintenance

This security role allows you to add, edit, and remove gauge types, gauge sub-types, gauge sub-type calibration standards, and gauge statuses. Typically, this maintenance account is only given to one or two individuals responsible for setting up this data for others to use.

Gauge Navigation

This security role allows you to navigate to the Gauge module.

Inspection & SPC Administrator

This security role allows you to add records in any process in the Inspection & SPC module.

Items Maintenance

This security role allows you to add, edit, and remove items and item types.

Manufacturing Documents Add/Edit

This security role allows you to add and edit the following data based on work flow security rules: manufacturing documents, manufacturing documents BOM, manufacturing documents process control plan, manufacturing documents process flow, manufacturing documents process risk, manufacturing document specifications, and manufacturing document work instructions.

Manufacturing Documents Maintenance

This security role allows you to add, edit, and remove the following data: manufacturing documents, manufacturing documents BOM, manufacturing documents process control plan, manufacturing documents process flow, manufacturing documents process risk, manufacturing document specifications, and manufacturing document work instructions.

Meetings Add/Edit

This security role allows you to add and edit meetings.

PO Item Log Maintenance

This security role allows you to add new, edit, and remove PO item logs.

PPAP Maintenance

This security role allows you to add, edit, and remove the following data: PPAP Submissions, PPAP Submission Levels, PPAP Requirements, PPAP Requirement Status.

PPAP Submissions Add/Edit

This security role allows you to add and edit PPAP Submissions based on work flow security rules.

Quality Engineer

This role allows you to add and adjust records related to Manufacturing Documents, Family Templates, and Process Hazards/Hazardous Situation Effects Analysis.

Quality Manager

This role allows you to add and adjust records related to Manufacturing Documents, Family Templates, and Process and Design Risk Effects Analysis.

System Administrator

This maintenance security role allows you to add and remove security roles, domains, entities, sites, locations, generalized code types and codes, product lines, item groups, item types, review frequencies, company types, cost accounts, and units of measure. Besides being able to add and remove items, you can also view and edit all of the fields for the processes noted. Typically this maintenance security role is only given to one or two individuals who are responsible for setting up the data for others to use.

System View

System view is a generic role that most users and modules use. This role allows you to view (but in most cases not edit) much of the non-sensitive data in the system. being able to view the data is still subject to you having the ability to navigate to, and open, a process.

Every user should have this security role because it allows users to view non-secure data for most processes. For users who typically only have to approve data, but do not have to add or edit data, this System View role is what they need.

Process Security Roles

Each list below displays the security roles that provide you with permissions to add items for the indicated individual process.

Frequency Event

- APQP Maintenance

Sample Sizes

- APQP Administrator
- APQP Champion
- APQP Maintenance

Unit of Measures

- System Administrator

Process Symbols

- APQP Administrator
- APQP Champion
- APQP Maintenance

Special Symbols

- APQP Administrator
- APQP Champion
- APQP Maintenance

Drawing Types

- APQP Administrator
- APQP Champion
- APQP Maintenance
- Document Maintenance
- Documents Administrator
- Drawing Administrator

Item Types

- APQP Administrator
- APQP Champion
- APQP Maintenance
- Items Maintenance
- Systems Administrator

Item Groups

- APQP Administrator
- APQP Champion
- APQP Maintenance
- Items Maintenance
- RFQ Administrator
- RFQ Planner
- System Administrator

Product Lines

- APQP Administrator
- APQP Champion
- APQP Maintenance
- Items Maintenance
- System Administrator

Reaction Plans

- APQP Administrator
- APQP Champion
- APQP Maintenance
- Quality Engineer

AQL

- APQP Administrator
- APQP Champion
- APQP Maintenance

AQL Level

- APQP Administrator
- APQP Champion
- APQP Maintenance

Project Identification Question Design Risk

- APQP Administrator
- APQP Champion

- Design Engineer
- Manufacturing Documents Add/Edit
- Manufacturing Documents Maintenance

Project Identification Question Process Risk

- APQP Administrator
- APQP Champion
- Design Engineer
- Manufacturing Documents Add/Edit
- Manufacturing Documents Maintenance

Project Identification Question FMEA-MSR

- APQP Administrator
- APQP Champion
- Design Engineer
- Manufacturing Documents Add/Edit
- Manufacturing Documents Maintenance

Design Risk Control Methods

- APQP Administrator
- Design Engineer

Process Risk Control Methods

- APQP Administrator
- APQP Champion
- APQP Maintenance
- Manufacturing Documents Add/Edit
- Manufacturing Documents Maintenance
- Process Engineer

FMEA-MSR Monitoring Control Methods

- APQP Administrator
- APQP Champion
- Design Engineer
- Manufacturing Documents Add/Edit
- Manufacturing Documents Maintenance

Specification Categories

- APQP Administrator
- APQP Champion
- APQP Maintenance

Specification Names

- APQP Administrator
- APQP Champion
- APQP Maintenance

Specification Date Ranges

- APQP Administrator
- APQP Champion
- APQP Maintenance

Inspection Types

- APQP Maintenance
- APQP Administrator
- APQP Champion
- Inspection & SPC Administrator
- Inspection & SPC Champion

Inspection Stations

- APQP Maintenance
- APQP Administrator
- APQP Champion
- Inspection & SPC Administrator
- Inspection & SPC Champion

FMEA-MSR System Responses

- APQP Administrator
- APQP Champion
- Design Engineer
- Manufacturing Documents Add/Edit
- Manufacturing Documents Maintenance

PPAP Requirement Status

- APQP Administrator
- APQP Champion
- APQP Library Maintenance
- APQP Maintenance
- PPAP Maintenance

PPAP Submission Requirement Sets

- APQP Administrator
- APQP Champion
- PPAP Maintenance

PPAP Requirements

- APQP Administrator
- APQP Champion
- PPAP Maintenance

Design Risk Severity Criteria

- APQP Maintenance
- APQP Administrator
- APQP Champion

Design Risk Occurrence Criteria

- APQP Maintenance
- APQP Administrator
- APQP Champion

Design Risk Detection Criteria

- APQP Maintenance
- APQP Administrator
- APQP Champion
- Manufacturing Documents Maintenance
- Manufacturing Documents Add/Edit

Design Risk Occurrence Zone

- APQP Administrator
- APQP Champion
- APQP Maintenance

Design Risk Detection Zone

- APQP Administrator
- APQP Champion
- APQP Maintenance

Design Risk Priority Levels

- APQP Administrator
- APQP Champion
- APQP Maintenance

Process Risk Severity Criteria

- APQP Administrator
- APQP Champion
- APQP Maintenance

Process Risk Occurrence Criteria

- APQP Administrator
- APQP Champion
- APQP Maintenance

Process Risk Detection Criteria

- APQP Maintenance
- APQP Administrator
- APQP Champion

Process Risk Zone Priority Levels

- APQP Administrator
- APQP Champion
- APQP Maintenance

Process Risk Occurrence Zone

- APQP Administrator
- APQP Champion
- APQP Maintenance

Process Risk Detection Zone

- APQP Administrator
- APQP Champion
- APQP Maintenance

Process Risk Priority Levels

- APQP Administrator
- APQP Champion
- APQP Maintenance

Design Risk Systems Library

- APQP Administrator
- APQP Champion
- Design Engineer
- Manufacturing Documents Add/Edit
- Manufacturing Documents Maintenance

Processes

- APQP Administrator
- APQP Champion
- APQP Maintenance

- Auditing Administrator
- Auditing Champion
- Auditing Maintenance

Library Specifications

- APQP Administrator
- APQP Champion
- APQP Library Maintenance
- APQP Maintenance
- Drawing Add/Edit
- Drawing Administrator

Control Library

- APQP Administrator
- APQP Champion
- APQP Library Maintenance
- APQP Maintenance
- Quality Engineer

Design Risk Structural Analysis Library

- APQP Administrator
- APQP Champion
- Design Engineer
- Manufacturing Documents Add/Edit
- Manufacturing Documents Maintenance

Design Risk Analysis Library

- APQP Administrator
- APQP Champion
- Design Engineer
- Manufacturing Documents Add/Edit
- Manufacturing Documents Maintenance

Design Risk Causes Library

- APQP Administrator
- APQP Champion
- Design Engineer
- Manufacturing Documents Add/Edit
- Manufacturing Documents Maintenance

Process Risk Structural Analysis Library

- APQP Administrator
- APQP Champion

- Manufacturing Documents Add/Edit
- Manufacturing Documents Maintenance
- Process Engineer

Process Risk Analysis Library

- APQP Administrator
- APQP Champion
- APQP Library Maintenance
- APQP Maintenance
- Quality Engineer

Process Risk Causes Library

- APQP Administrator
- APQP Champion
- Manufacturing Documents Add/Edit
- Manufacturing Documents Maintenance
- Process Engineer

Family Templates

- APQP Administrator
- APQP Champion
- Manufacturing Documents Add/Edit
- Manufacturing Documents Maintenance
- Process Engineer

Drawings

- APQP Administrator
- APQP Champion
- Documents Administrator
- Drawing Add/Edit
- Drawing Administrator

Items

- APQP Administrator
- APQP Champion
- Drawing Add/Edit
- Drawing Administrator
- Items Maintenance
- RFQ Administrator

Manufacturing Documents.

- APQP Administrator
- APQP Champion

- Manufacturing Documents Add/Edit
- Manufacturing Documents
- Quality Engineer
- Quality Manager

Design Verification Reports

- APQP Administrator
- APQP Champion
- APQP Maintenance
- Manufacturing Documents Add/Edit

PPAP Submissions

- APQP Administrator
- APQP Champion
- PPAP Maintenance
- PPAP Submissions Add/Edit
- Quality Engineer
- Quality Manager

State Change Security

As you complete tasks in the system, changes occur based on your activities (such as changing a record's state) and when other events occur (such as a specific amount of time passing). The changes based on your activities are called **actions**, while the event-based changes are called **transactions**. The main difference between the two is the initiator: actions are performed by users, and transactions are managed by the system.

Each system change may depend on a number of factors, including where you are in the system, who is involved, which fields are populated, and more. It is important to know the actions and transactions for each process because these affect your ability to complete a task.

The following sections describe two main pieces of information for each process:

1. **Security.** Which users (by security role or field role) can change the state of a record. Field roles are indicated with an asterisk*.
2. **Transactions.** The conditions that must be met to initiate a transaction.

Security

Unit of Measures

Transitions	APQP Administrator	System Administrator
Active >> Inactive	✓	✓
Inactive >> Active	✓	✓

Process Symbols

Transitions	APQP Administrator	APQP Maintenance
Active >> Inactive	✓	✓
Inactive >> Active	✓	✓

Special Symbols

Transitions	APQP Administrator	APQP Maintenance
Active >> Inactive	✓	✓
Inactive >> Active	✓	✓

Drawing Types

Transitions	APQP Administrator	Drawing Administrator
Active >> Inactive	✓	✓
Inactive >> Active	✓	✓

Item Types

Transitions	APQP Administrator	Items Maintenance	System Administrator
Active >> Inactive	✓	✓	✓
Inactive >> Active	✓	✓	✓

Item Groups

Transitions	APQP Administrator	RFQ Administrator	System Administrator
Active >> Inactive	✓	✓	✓
Inactive >> Active	✓	✓	✓

Product Lines

Transitions	APQP Administrator	APQP Maintenance	System Administrator
Active >> Inactive	✓	✓	✓
Inactive >> Active	✓	✓	✓

Project Identification Question Design Risk

Transitions	APQP Administrator	APQP Champion	Design Engineer	Manufacturing Documents Add/Edit	Manufacturing Documents Maintenance
Active >> Inactive	✓	✓	✓	✓	✓
Inactive >> Active	✓	✓	✓	✓	✓

Project Identification Question Process Risk

Transitions	APQP Administrator	APQP Champion	Manufacturing Documents Add/Edit	Manufacturing Documents Maintenance	Process Engineer
Active >> Inactive	✓	✓	✓	✓	✓
Inactive >> Active	✓	✓	✓	✓	✓

Project Identification Question FMEA-MSR

Transitions	APQP Administrator	APQP Champion	Design Engineer	Manufacturing Documents Add/Edit	Manufacturing Documents Maintenance
Active >> Inactive	✓	✓	✓	✓	✓
Inactive >> Active	✓	✓	✓	✓	✓

Design Risk Control Methods

Transitions	Active >> Inactive	Inactive >> Active
APQP Administrator	✓	✓
APQP Library Maintenance	✓	✓
APQP Maintenance	✓	✓
Drawing Administrator	✓	✓

Specification Names

Transitions	APQP Administrator	APQP Maintenance
Active >> Inactive	✓	✓
Inactive >> Active	✓	✓

FMEA-MSR System Responses

Transitions	APQP Administrator	APQP Champion	Design Engineer
Active >> Inactive	✓	✓	✓
Inactive >> Active	✓	✓	✓

PPAP Submission Requirement Sets

Transitions	APQP Administrator	PPAP Maintenance
Active >> Inactive	✓	✓
Inactive >> Active	✓	✓

Design Risk Systems Library

Transitions	APQP Administrator	Design Engineer
Active >> Inactive	✓	✓
Inactive >> Active	✓	✓

Processes

Transitions	APQP Administrator	APQP Champion	APQP Maintenance	Auditing Administrator	Auditing Champion	Auditing Maintenance	Change Coordinator*	Change Owner*
Approval Rejected >> Ready for Approval	✓	X	✓	✓	X	✓	✓	✓
Draft >> Ready for Approval	✓	✓	✓	✓	✓	✓	✓	✓
Obsolete >> Ready for Approval	✓	X	X	✓	X	X	✓	X
Ready for Approval >> Draft	✓	X	✓	✓	X	✓	✓	✓

Library Specifications

Transitions	APQP Administrator	APQP Library Maintenance	APQP Maintenance	Drawing Administrator
Active >> Inactive	✓	✓	✓	✓
Inactive >> Active	✓	✓	✓	✓

Control Library

Transitions	APQP Administrator	APQP Library Maintenance	APQP Maintenance
Active >> Inactive	✓	✓	✓
Inactive >> Active	✓	✓	✓

Design Risk Structural Analysis Library

Transitions	APQP Administrator	APQP Champion	Design Engineer
Active >> Inactive	✓	✓	✓
Inactive >> Active	✓	✓	✓

Design Risk Analysis Library

Transitions	APQP Administrator	APQP Champion	Design Engineer
Active >> Inactive	✓	✓	✓
Inactive >> Active	✓	✓	✓

Design Risk Causes Library

Transitions	APQP Administrator	APQP Champion	Design Engineer
Active >> Inactive	✓	✓	✓
Inactive >> Active	✓	✓	✓

Process Risk Structural Analysis Library

Transitions	APQP Administrator	APQP Champion	Process Engineer
Active >> Inactive	✓	✓	✓
Inactive >> Active	✓	✓	✓

Process Risk Analysis Library

Transitions	APQP Administrator	APQP Champion	Process Engineer
Active >> Inactive	✓	✓	✓
Inactive >> Active	✓	✓	✓

Process Risk Causes Library

Transitions	APQP Administrator	APQP Champion	Process Engineer
Active >> Inactive	✓	✓	✓
Inactive >> Active	✓	✓	✓

Family Template

Transitions	APQP Administrator	Manufacturing Documents Maintenance	Owner*
Active >> Draft	✓	✓	✓
Active >> Inactive	✓	✓	✓
Approval Rejected >> Awaiting Approval	✓	✓	✓
Awaiting Approval >> Draft	✓	✓	✓

Transitions	APQP Administrator	Manufacturing Documents Maintenance	Owner*
Draft >> Awaiting Approval	✓	✓	✓
Inactive >> Draft	✓	✓	✓

Drawings

Transactions	APQP Administrator	Change Owner*	Drawing Add/Edit	Drawing Administrator	Owner*
Approval Rejected >> Awaiting Approval	✓	✓	✓	✓	✓
Awaiting Approval >> Draft	✓	X	✓	✓	✓
Draft >> Awaiting Approval	✓	✓	✓	✓	✓

Manufacturing Documents

Transitions	APQP Administrator	Change Owner*	Manufacturing Documents Add/Edit	Manufacturing Documents Maintenance	Quality Engineer	Quality Manager
Approval Rejected >> Awaiting Approval	✓	X	✓	✓	✓	✓
Approval Rejected >> Draft	✓	✓	✓	✓	✓	✓
Awaiting Approval >> Draft	✓	✓	✓	✓	✓	✓
Draft >> Ready for Approval	✓	✓	✓	✓	✓	✓
Ready for Approval >> Draft	✓	✓	✓	✓	✓	✓
Skip Lot Review >> Awaiting Approval	✓	X	✓	✓	✓	✓
Skip Lot Review >> Draft	✓	X	✓	✓	✓	✓

Design Verification Reports

Transactions	APQP Administrator	APQP Champion	APQP Maintenance	Manufacturing Documents Add/Edit
Complete >> Draft	✓	X	✓	✓
Draft >> Complete	✓	✓	✓	✓

PPAP Submissions

Transitions	APQP Administrator	PPAP Maintenance	PPAP Submissions Add/Edit	Quality Engineer	Quality Manager
Approval Rejected >> Ready for Approval	✓	✓	✓	✓	✓
Customer Approved >> Obsolete	✓	✓	X	✓	✓
Customer Interim Approval >> Customer Approved	✓	✓	X	✓	✓
Customer Interim Approval >> Customer Rejected	✓	✓	X	✓	✓
Customer Rejected >> Draft	✓	✓	X	✓	✓
Draft >> Ready for Approval	✓	✓	✓	✓	✓
Obsolete >> Customer Approved	✓	✓	X	X	X
Submit for Customer Approval >> Submitted for Customer Approval	✓	✓	X	✓	✓
Submitted for Customer Approval >> Customer Approved	✓	✓	X	✓	✓
Submitted for Customer Approval >> Customer Interim Approval	✓	✓	✓	✓	✓
Submitted for Customer Approval >> Customer Rejected	✓	✓	X	✓	✓

Transactions

Drawing Types

Current User Isn't ITAR Compliant

When the current user is not ITAR compliant, the ITAR Restricted field is hidden.

First Save

Upon the first save, the system links the employee who created the drawing type to the Approvers list.

Site Isn't ITAR Restricted

When the selected site is not ITAR restricted, the ITAR Restricted field is set to FALSE and is hidden.

Reaction Plans

Hide Document Field if No Document Required is true.

The Document Cross-reference field is hidden when the "No Document Required" check box is empty.

Design Risk Control Methods

Detection and Prevention are not null

When either the Detection or Prevention field contains a value other than null, the field "Yes must be selected for Detection and/or Prevention" is hidden.

Design Risk System Library

Current User Isn't ITAR Compliant

When the current user is not ITAR compliant, the ITAR Restricted field is hidden.

Site Isn't ITAR Restricted

When the site is not ITAR restricted, the ITAR Restricted field is set to False and hidden.

Processes

Approval Rejected

When the current state changes to Approval Rejected, a notification is sent to the Process Owner to notify them that a review of the process is rejected.

Awaiting Effective Date

When the current state changes to Awaiting Effective Date, the following changes occur:

- A notification is sent to the Process Owner to notify them that the approval for the process has been approved.
- The linked Change Order is saved and its state is updated to Ready for Release.
- The current Process record is saved.
- The linked Change Item's state is updated to Complete.

Awaiting Obsolescence Approval Rejected

When the current state changes from Awaiting Obsolescence Approval to Official, a notification is sent to the Process Owner to notify them that the obsolescence approval for the process has been rejected.

Change Due Date Changed

When the Process record's overall change due date is changed, the system updates the change due date on the linked change items.

Change Order is NULL

When no change orders are linked to the process, the Update from Change Order Effective Date field is hidden.

Change Owner Changed

When the Change Owner is changed and the current state is Draft, the Change Owner is updated on the linked change items.

Additionally, a notification is sent to the new Change Owner informing them that the process is ready for change.

Change Request is NULL

When no change requests are linked to the process, the Change Coordinator field is hidden.

Created from Process Request

When the current record is created from a new process request, the process request is updated.

Current Date 7 Days Greater or Equal to Effective Date and Not Approved

When the current state is Ready for Approval and the current date is seven days past or equal to the effective date, a notification is sent to the user to whom the Process Owner reports, notifying them that the process is late and requires approval.

Current Date Greater or Equal to Effective Date and Not Approved

When the current state is Ready for Approval and the current date is one day past or equal to the effective date, a notification is sent to the Process Owner, notifying them that the process is late and requires approval.

Current Date Greater Than or Equal to Effective Date

When the current state is Awaiting Effective Date and the Effective Date field is before or equal to the current date, the system updates the current state to Official.

If the Effective Date field is blank, then once the current state is changed to Awaiting Effective Date, it automatically transitions to Official.

Current Date Greater Than or Equal to Next Review Date

When the current state is Official and the Next Review Due is before or equal to the current date, the system selects the "Requires Review" check box.

Current User Isn't ITAR Compliant

When the current user is not ITAR compliant, the ITAR Restricted field is hidden.

Draft

When a new version is created, the previous version's state becomes Official – Draft Pending and the current version's state becomes Draft.

Draft Created from New Process Request

When a new Process record is created from a new process request and is in the Draft state, a notification is sent to the Process Owner to notify them that a draft process was created as a result of a new process request.

Draft, No Change Request

When the record is in the Draft state and is not linked to a change request, a notification is sent to the Change Owner to inform them that the process is ready for a change.

First Save

When the process is saved for the first time, the system creates a risk associated with the process for each record in the Risk Library linked to a risk driver that is ultimately linked to the System Driver "Processes".

Note that the system should insert a record if it is not found based on the key match of Title.

List Process Risk in Design Control is False then Process Risk Analysis Library is Not Null

The Risk Label field is visible if the "List Process in Design Control " check box is selected and the Process Risk Analysis Library is null.

Not Completed, No Change Request, 1 Day Past the Change Due Date

The Change Owner receives a notification that the process is past due for a change when the following rules are met:

- The record is not in the Complete state.
- The current date is one day past the change due date.
- The record is not linked to a change request.

Not Completed, No Change Request, 7 Day Past the Change Due Date

The person to whom the Change Owner reports receives a notification that the process is past due for a change when the following rules are true:

- The record is not in the Complete state.
- The current date is seven days past the change due date.
- The record is not linked to a change request.

Obsolescence Fields

When the current state is NOT Obsolete, the following fields are hidden:

- Reason for Obsoleting
- Obsolescence Approval

Official

When the current state changes to Official, the following changes occur:

- The linked change order is saved and can create action notifications.
- The linked change item is updated to the Complete state.
- The Library Specification Process field is updated to the new Official version of the process.

Official – Create Training Event Checkbox is Checked

When the "Create Training Event" check box is selected and the state is changed to Official, the system creates a new training event based on the Progress information.

Process Owner Changed

When the Process Owner field changes and the current state is Draft or Approval Rejected, the system updates the Risk Owner field based on the Process Owner.

Processes Risk Field is Not Null then Processes Control Field is Hidden

The Process Controls field is hidden when the Processes Risk field is not null.

Ready for Approval

When the current state is Ready for Approval, the system unlinks employees **without** training roles selected in the Authorities field and links employees **with** training roles selected in the Authorities field.

In addition, the process approvers receive a notification when the process is ready for approval.

This action will remain on your action manager until you either approve or reject it.

Requires Review

When the "Flag for Requires Review" check box is selected and review was not previously required, the process owner receives a notification that a review of the process is required.

Responsible Site Changed to non-ITAR Compliant and ITAR Restricted is True

When the site is changed to a non-ITAR compliant site and the ITAR Restricted field is True, the ITAR Site Warning field is hidden.

Responsible Site Isn't ITAR Restricted

When the linked site is not ITAR restricted, the ITAR Restricted field is set to False and hidden.

Reverse Cross Reference Process Risk is Not Filled Then it Should Be Hidden

The Process Risk Analysis Library field is hidden when empty.

Review Frequency = None

When the Review Frequency is set to 0, the following fields are hidden:

- Last Review
- Next Review Due
- Review Completed By

State is Obsolete

When the current state is Obsolete, the Process Specifications field is hidden.

Sys: Create Change Order is True

When the current Sys: Create Change Order is changed to True, the system creates a change order for the current process. This only takes place if the process is in the Draft state and already has a change request with no linked change order.

Once the new change order is saved, it can create action notifications.

Training is Not Required

When the "Requires Training" check box is not selected, the Create Training Event field is hidden.

Update From CO is True and Effective Date Doesn't Match CO

When the "Update Effective Date from Change Order" field is set to true and the effective date does not match the effective date from the linked change order, the current record's effective date is set to the linked change order's date.

Library Specifications

Active

When the current state is Active, the system updates the value of the Sample Data Type field based on the value of the Specification Data Type field.

Current User Isn't ITAR Compliant

When the current user is not ITAR compliant, the ITAR Restricted field is hidden.

Data Type = Date

When the Specification Data Type field is set to Date, the following fields are hidden:

- Customer Unit of Measure
- Lower Limit
- Number of Decimals
- Target
- Unit of Measure
- Upper Limit

Data Type = Logical

When the Specification Data Type field is set to Logical, the following fields are hidden:

- Customer Unit of Measure
- Lower Days
- Lower Limit
- Number of Decimals
- Target
- Unit of measure
- Upper Days
- Upper Limit

Data Type = Numeric

When the Specification Data Type field is set to Numeric, the following fields are hidden:

- Lower Days
- Upper Days

Data Type Changed to Date

When the data type changes to Date, the numeric fields are null.

Data Type Changed to Logical

When the data type changes to Logical, the numeric and date fields are null.

Data Type Changed to Numeric

When the data type changes to Numeric, the date fields are null.

Special Classification Updated

When the special classification is updated, the Process Risk Special Classification and Process Risk Custom Symbol Calculation fields are updated.

Control Library***Current User Isn't ITAR Compliant***

When the current user is not ITAR compliant, the ITAR Restricted field is hidden.

Inspect is Unchecked

When the "Inspect" toggle field is set to NO, the following fields are hidden:

- Inspection Stations
- Inspection Types

Sampling Technique = AQL and Batch Size

When the Sampling Technique field is set to AQL and Batch size, the following fields are hidden:

- Sample Size
- Sample Size Description

Sampling Technique = Fixed

When the Sampling Technique field is set to Fixed, the following fields are hidden:

- AQL Level
- AQL Table

Sampling Technique = Other

When the Sampling Technique field is not set to Fixed or AQL and Batch Size, the following fields are hidden:

Design Risk Structural Analysis Library

Current User Isn't ITAR Compliant

When the current user is not ITAR compliant, the ITAR Restricted field is hidden.

ITAR Restricted Changed

When the ITAR Restricted field is changed, the ITAR Restricted field is updated on the linked Design Risk Functional Analysis Library record.

ITAR Restricted Site Checkbox is Null or True

When the linked site's ITAR Restricted field is set to NULL or TRUE, the following fields are hidden:

- Acknowledge ITAR Restricted Change
- ITAR Site Warning

Site Isn't ITAR Restricted

When the current site is not ITAR restricted, the ITAR Restricted field is set to False and hidden.

Design Risk Failure Analysis Library

Cause(s) Exist

When the record contains causes, the Occurrence and Detection fields are updated.

Current User Isn't ITAR Compliant

When the current user is not ITAR compliant, the ITAR Restricted field is hidden.

Functionality Analysis Not is Null

When the Next Higher Level-Functional field is not null, the ITAR Restricted field is hidden.

ITAR Restricted Changed

When the ITAR restricted is changed, the ITAR restrictions are updated on the linked causes.

Design Risk Causes Library***Controls Added***

When controls are added to the Controls field, the following changes occur:

- The Detection level is updated
- The Occurrence level is updated
- A save is initiated on the linked Design Risk Failure Analysis

Controls Have Been Added

When a control is added to the Controls field, the field "It is recommended to have at least one control so Best Occurrence and Best Detection levels are assessed" is hidden.

ITAR Restricted Changed

When the ITAR Restricted field is changed, the ITAR restrictions on the linked Controls records are updated.

Process Risk Structural Analysis Library***Current User isn't ITAR Compliant***

When the current user is not ITAR compliant, the ITAR Restricted field is hidden.

ITAR Restricted Changed

When the ITAR Restricted field value changes, the ITAR restrictions are updated on the linked functional analysis.

Process Risk Failure Analysis Library***Cause(s) Exist***

When the record contains causes, the Detection and Occurrence fields are updated.

Changes in Occurrence, Detection, Severity

When a change occurs in the Occurrence, Detection, or Severity fields, the system calculates the priority level and adjusts the coloring in the Priority Level field accordingly.

Current User Isn't ITAR Compliant

When the current user is not ITAR compliant, the ITAR Restricted field is hidden.

Functional Analysis Not is Null

When the process Item System/Subsystem - Structural field is populated, the ITAR Restricted field is hidden.

Green

When the Sys: Priority Levels color is green, the Priority Level field's background color is set.

ITAR Restricted Changed

When the ITAR Restricted field value changes, the ITAR restrictions are updated on the linked Process Risk Causes Library.

Process Item System/Subsystem – Structural is Null

When the Process Item System/Subsystem – Structural field is empty, the following fields are hidden:

- Function of Process Item System, Subsystem – Your Plant
- Function of Process Item System, Subsystem – Ship To Plant
- Function of Process Item System, Subsystem – End User
- Failure Effect – End User
- Failure Effect – Ship to Plant
- Function of Process Step & Product Characteristic
- Function of Process Work Element – Functional

Process Step Name was Changed and is Not Equal to the Functional Value Above

When the Process Step Name – Structural field in the Process Risk Functional Analysis Library is changed and not null, the field is updated to match the field of the same name on the Failure Analysis.

Process Work Element – Structural is Null

The Process Work Element – Structural field is hidden when empty.

Red

When the Sys: Priority Levels color is red, the Priority Level field's background color is set.

Requirement Not Updated, Special Classification Updated

When the Requirement field is maintained and the Special Classification field is updated, the custom symbol is calculated.

Requirement Updated, Linked Special Classification is Not Null

The Special Classification field is updated when the following conditions are met:

- The Requirement field's value is changed
- The linked Library Specification record's Special Classification field is not null

Requirement Updated, No New Special Classification, No Old Custom Special Classification

The Special Classification field is updated when the following conditions are met:

- The Requirement field is updated
- The new requirement's Special Classification field is null
- The old record's Special Classification field is equal to the old linked Requirements Special Classification field

Yellow

When the Sys: Priority Levels color is yellow, the Priority Level field's background color is set.

Process Risk Causes Library***Controls are Added***

When a control is added, the Occurrence and Detection fields are updated in the following process:

- Process Risk Failure Analysis Library
- Process Risk Causes Library

Failure Analysis Library: Process Item System/Subsystem – Structural is Null

When the Process Item System/Subsystem – Structural field is empty, the Applicable Work Element field is hidden.

Hide Label

The Occurrence and Detection levels Label field is hidden before the first record save, or when detection controls exist.

ITAR Restricted Changed

When the ITAR Restricted field is changed, the ITAR restrictions on the linked Process Risk Controls Library record are updated.

Family Template

Active

When the current state changes to Active, a notification is sent to the Owner to inform them that approval for the template has been approved.

Approval Rejected

When the current state changes to Approval Rejected, a notification is sent to the Owner to inform them that approval for the template has been rejected.

Auto Fill Current Owner Site

When the Site field is empty and the current state is Draft, the system automatically fills the Site field using the selected owner's site.

Awaiting Approval

When the current state changes to Awaiting Approval, the system updates the current state to Locked for the following linked processes:

- Family Template Process Risk Control Plan
- Family Template Process Flow
- Family Template Process Risk Plan
- Family Template Specifications
- Family Template Process Risk Causes
- Family Template Process Risk Functional Analysis
- Family Template Process Risk Function Analysis Work Elements
- Family Template Process Risk Structural Analysis

Current State Not Equal Draft

When the current state is **not** Draft, the following fields are hidden:

- Item Group Approvers
- Item Type Approvers

Current User Isn't ITAR Compliant

When the current user is not ITAR compliant, the ITAR Restricted field is hidden.

Family Template is 2019 AIAG/VDA FMEA

When the Show AIAG 4th Edition toggle field is set to NO, the following fields are hidden:

- Process Risks
- Process Risks Grid

Family Template is AIAG 4th Edition

When the Show AIAG 4th Edition toggle field is set to YES, the following fields are hidden:

- Step 2 – Structural Analysis
- Process Risk Analysis
- RESULTS DOCUMENTATION
- InTent Results Comments
- Team Results Comments – List of participants
- Timing Results Comments – Risk due date
- Document the status to the original Team goals
- Tool Results Comments – How do we conduct analysis – method used
- How the Functions were Developed Summary
- High-risk Failure Actions Taken/Planned Summary
- Summary of actions taken or planned to address high-risk failures and status
- Process Risk Analysis Grid
- High-risk Failure Summary

ITAR Restricted or Item or Site Changed

When the ITAR Restricted field is changed, the Item Group field is changed, or the Sites field is changed, the ITAR Restricted field is updated on the following linked records:

- Process Risk Causes
- Process Risk Controls
- Process Risk Failure
- Process Risk Functional
- Process Risk Structural
- Process Flow
- Specifications

ITAR Restricted or Item Type or Site Changed

The system generates a list of approvers based on the Item Group approvers when the following items are true:

- The ITAR Restricted field is changed
- The Item Type field is changed
- The Sites field is changed
- The current state is **not** Active

Note that if the record is ITAR restricted, then only ITAR compliant users will be added to the approval. If the Item or ITAR Restricted fields are modified, then the list of employees will be updated.

ITAR Restricted Site Checkbox is Null or True

When the linked site's ITAR Restricted field is set to Null or True, the following fields are hidden:

- Acknowledge ITAR Restriction Change
- ITAR Site Warning

Link Current User Site

When the site from the Old Site field is absent from Sites, the system automatically fills the Sites field using the current user's site.

Not Awaiting Approval or Active

When the current state was Awaiting Approval or Active but is no longer one of these states, the system updates the current state to Unlocked for the following linked processes:

- Family Template Process Risk Control Plan
- Family Template Process Flow
- Family Template Process Risk Plan
- Family Template Specifications
- Family Template Process Risk Causes
- Family Template Process Risk Functional Analysis
- Family Template Process Risk Function Analysis Work Elements
- Family Template Process Risk Structural Analysis

Site Isn't ITAR Restricted

When the site linked to the record is not ITAR restricted, the Family Template's ITAR Restricted field is set to FALSE and hidden.

Site Isn't ITAR Restricted and ITAR Restricted is True

When the site linked to the record is not ITAR restricted but the Family Template's ITAR Restricted field is set to TRUE, the Family Template's ITAR Restricted field is updated to FALSE.

Drawings

Approval Past Due

When the current state is Awaiting Approval and the approval due date is past the current date, a notification is sent to the Owner to notify them that not all approvers have approved or rejected the current change and it is beyond the approval due date.

Approval Past Due – Escalation

When the current state is Awaiting Approval and the current date is seven days past the approval due date, a notification is sent to the user the Owner reports to, notifying them that not all approvers have approved or rejected the current change and it is beyond the approval due date.

Approval Rejected

When the current state changes to Approval Rejected, the system updates all features associated with this drawing to the Unlocked state.

Additionally, the drawing owner receives a notification that the approval for the drawing has been rejected. This action will remain on your list until you move the drawing state to another state besides Approval Rejected.

Awaiting Approval

When the current state changes to Awaiting Approval, the system updates all features associated with the drawing to the Locked state. Additionally, the Approval Start Date field is updated to the current date and time.

Awaiting Effective Date

When the current state changes to Awaiting Effective Date, the following changes occur:

- The system saves the linked change order after initial creation; this allows the change order to send action notifications, as it was originally created by stored procedure.
- The associated change order's state is updated to Ready for Release.
- The current record is saved.
- The associated change items' state is updated to Complete.
- A notification is sent to the Owner to inform them that approval for the drawing has been approved.

Awaiting Obsolete Approval Rejected

When the current state changes from Awaiting Obsolete Approval to Official, the Owner receives a notification that the approval for the drawing has been rejected.

Change Due Date Changed

When the record's change due date is changed, the change due date is updated on all change items.

Change Order is NULL

The Update from Change Order Effective Date field is hidden when there is no linked change order.

Change Owner Changed

When the drawing's Change Owner is changed, it is updated on linked change items.

Change Request is NULL

The Change Coordinator field is hidden when there is no change request.

Changed to Draft

When the current state changes to Draft, the following transactions occur:

- All features associated with this drawing are updated to the state of Unlocked.
- The items linked to this drawing series are updated with this drawing version.

- The Change Item field is set.
- The current state is updated to Official – Draft Pending.

Created from New Drawing Request

When the drawing record is created as a result of a new drawing request, the linked change item is updated.

Current Date greater than Effective Date

When the current state is Awaiting Effective Date and the Effective Date field is before or equal to the current date, the system updates the current state to Official. If the Effective Date field is blank, then once the current state is changed to Awaiting Effective Date, it automatically transitions to Official.

If the Effective Date field is blank, then the drawing state moves directly from Awaiting Effective Date to Official.

Current User Isn't ITAR Compliant

When the current user is not an ITAR compliant employee, the ITAR Restricted field is hidden.

Draft Created from New Drawing Request

When the drawing is in the Draft state and was created as a result of a new drawing request, a notification is sent to the Owner to notify them that a new drawing has been created.

Draft, No Change Request, Change Owner Changed

When the Change Owner is changed, the record is in the Draft state, and the record is NOT linked to a change request, the Change Owner receives a notification that the drawing is ready for change.

First Time Official and Initial Version

When the current state changes to Official, the previous state was not Requires Review, and the VersionMasterID is equal to zero, the system updates the Version Date field with the previous version date.

Note: The VersionMasterID field is equal to zero for a new document created using the Add Item  button.

ITAR Restricted and Current User Has Permission

If the record is ITAR restricted and the current user is ITAR compliant, then the ITAR Restricted warning is hidden.

ITAR Restricted and Current User Isn't ITAR Compliant

If the current user is not ITAR compliant, then all fields are hidden.

ITAR Restricted, Current User Isn't ITAR Compliant, and Not Draft or Rejected

The ITAR Restricted field is hidden when the following conditions are met:

- The drawing is ITAR restricted.
- The current user is not an ITAR compliant employee.
- The current state is not Draft or Approval Rejected.

New Draft, Not the First Version

When a draft is created and it is not the first version, the "Inspection Plans – Requires Review" check box is selected.

Not Completed, No Change Request, 1 Day Past the Change Due Date

A notification is sent to the Change Owner to inform them that the drawing is past due for a change when the following items are true:

- The state is either Draft, Awaiting Approval, Approval Rejected, or Awaiting Effective Date
- The current date is equal to or past the change due date
- The drawing is not linked to a change request

Not Completed, No Change Request, 7 Day Past the Change Due Date

A notification is sent to the person that the Change Owner reports to, which informs them that the drawing is past due for a change when the following items are true:

- The state is either Draft, Awaiting Approval, Approval Rejected, or Awaiting Effective Date
- The current date is past the change due date by 7 days
- The drawing is not linked to a change request

Not the Initial Version

When the VersionMasterID is not equal to zero, the following fields are hidden:

- Starting Version Date
- Starting Version Number

Note: The VersionMasterID field is equal to zero for a new document created using the Add Item  button.

Obsolescence Fields

When the current state is NOT Obsolete, the following fields are hidden:

- Obsolescence Approval
- Reason for Obsolescing

Official

When the current state changes to Official, the following changes occur:

- The change items are updated to Complete
- The drawing version is updated on any manual documents that include the drawing
- Items linked to the drawing are unlinked and then re-linked to the latest version
- The state of the associated change order moves to Closed

Responsible Site Changed to non-ITAR Compliant and ITAR Restricted is True

When the responsible site is changed to a site that is not ITAR compliant, and ITAR Restricted is True, the ITAR Site Warning field is hidden.

Share with All Suppliers is True

When the Share with All Suppliers field is True, the Share With These Suppliers field is hidden.

Share with All Suppliers is True and Drawing Becomes Official

When the current state changes to Official and the Share With All Suppliers field is true, a notification is sent to the External Supplier role to inform them that the drawing's current state is Official.

Share with These Suppliers is Not Null and Drawing Becomes Official

When the current state changes to Official and the Share With These Suppliers field is populated, a notification is sent to the External Supplier contacts to inform them that the drawing's current state is Official.

Site isn't ITAR Restricted

When the site connected to the drawing is not ITAR restricted, the following fields are hidden:

- ITAR Restricted
- ITAR Restricted Warning

State is Not Draft, Source Drawing is Null

The Source Drawing field is hidden when it is empty and the current state is not Draft.

Sys: Create Change Order is True

When the current Sys: Create Change Order is changed to True, the system creates a change order for the current drawing. This only takes place if the drawing is in the Draft state and already has a change request with no linked change order.

Once the new change order is saved, it can create action notifications.

Update from CO is True and Effective Date Doesn't Match CO

The current record's effective date is set to match the effective date on the linked change order when the "Update Effective Date from Change Order" field is selected and the drawing's effective date does not match the linked change order's effective date.

Items

Out of Service Date is filled in

When the Out of Service Date field is filled in, the system adds a year to the Disposal Date of all linked records.

There are no Program Items or First Save

When there is no value in the Program Item reverse cross-reference field, the system automatically creates a program item for the current Item upon its initial creation. Each item should have a single Program Item associated with it.

Manufacturing Document

Accept Warning equals True

When the "Accept Warning?" field is true, information is copied from the selected manufacturing document or family template to the current manufacturing document.

Approval Past Due

When the current state is Awaiting Approval and the field labeled Approval Due Date is past the current date, a notification is sent to the Owner to inform them that not all approvers have approved or rejected the current change and it is beyond the approval due date.

Approval Rejected

When the current state changes to Approval Rejected, a notification is sent to the Owner to notify them that approval has been rejected.

Associated Drawings is Null

When the Associated Drawings field is empty, the following fields are hidden:

- Import Drawing Features
- Update Suggested Drawing Features

Auto Fill Current Owner Site

When the Sites field is empty and the current state is Draft, the system automatically fills the Sites field using the current user's information.

Awaiting Approval

When the current state changes to Awaiting Approval, the following items are updated to the Locked state:

- All related BOM records
- All related Process Risk Causes records
- All related Control Plan records

- All related Design Risk Team records
- All related Design Risk Causes records
- All related Design Risk Controls records
- All related Design Risk Hazard Analysis records
- All related Design Risk Functional Analysis records
- All related Design Risk Structural Analysis records
- All related Design Risk Systems records
- All related FMEA-MSR Causes records
- All related FMEA-MSR Controls records
- All related FMEA-MSR Failure Analysis records
- All related FMEA-MSR Functional Analysis records
- All related FMEA-MSR Structural Analysis records
- All related Process Risk 4th Ed. Hazard Analysis records
- All related Process Risk Causes records
- All related Process Risk Hazard Analysis records
- All related Process Risk Functional Analysis records
- All related Process Risk Structural Analysis records
- All related Process Flow records
- All related Process Risk Team records
- All related Specs records
- All related Work Ins. records

Additionally, the Approval Start Date field is updated to the current date/time and the Versioning field is updated to properly populate the new version of the document after the "Start New Version" command.

Awaiting Effective Date

When the current state changes to Awaiting Effective Date, the following changes occur:

- The system saves the linked change order after initial creation; this allows the change order to send action notifications, as it was originally created by stored procedure
- A notification is sent to the Owner to inform them that the approval for the document has been approved
- The linked change order is updated to the Ready for Release state
- The current manufacturing document is saved
- The linked change items record(s) are updated to the Complete state

Awaiting Obsolescence Approval Rejected

When the current state changes from Awaiting Obsolescing Approval to Official, a notification is sent to the Owner to inform them that the obsolescence approval has been rejected.

Change Due Date Changed

When the record's change due date is changed, the system updates the change due date on all linked change items.

Change Order for New Mfg Document Request

When the record is created from a new manufacturing document request, the draft document is inserted into a change order.

Change Order is NULL

When there is no linked change order, the Update from Change Order Effective Date field is hidden.

Change Owner Changed

When the change owner is changed, the system updates the current change owner on all linked change items.

Change Request is NULL

When there is no change request, the Change Coordinator field is hidden.

Copy from Family Template Command Check is True and Previous Version Data is not True

When the "Copy from Family Template" command is used and the record does not use a previous version's data, the system copies information from the selected family template to the current manufacturing document.

Copy from FT Changed

When the "Copy from Family Template" field is changed, the record must be saved.

Copy from Mfg Document Command Check is True and Previous Version Data is not True

When the "Copy from Manufacturing Document" command is used and the record does not use a previous version's data, the system copies information from the selected manufacturing document to the current manufacturing document.

Created from New Mfg Document Request

When the record is created from a new manufacturing document request, the relevant change item is updated.

Current Date greater than Effective Date

When the current state is Awaiting Effective Date and the effective date is before or equal to the current date, the following changes occur:

- The current state is updated to Official
- The linked change item(s) are updated to the Complete state
- The latest Skip Lot Inspection Event Definitions are updated to Active, and the previous Skip Lot Inspection Event Definitions are set to Obsolete.
- The linked part skip lot rules are updated
- The linked change order is updated to the Closed state

- All existing inspection event questions currently linked to the manufacturing document are removed, and new ones are created

If the Effective Date field is blank, then once the current state is changed to Awaiting Effective Date, it automatically transitions to Official.

Current State is Not Draft

When the current state is not Draft, the following fields are hidden:

- Copy from Family Template
- Copy from Manufacturing Document
- Generate Design Risk
- Generate Suggested Design Verification Plans
- Import Drawing Features
- Update Suggested Drawing Features
- Import and Link Process Spec
- Generate Risk
- Item Group Approvers

Current State is Not Official or Official Draft Pending

When the current state is not Official or Official – Draft Pending, the Create Inspection Event Questions field is hidden.

Current User Isn't ITAR Compliant

When the current user is not ITAR compliant, the ITAR Restricted field is hidden.

Customer Approval is not Required

When the "Requires Customer Approval" check box is not selected, the following fields are hidden:

- Customer Approval Documentation – Process Risk Control Plan
- Customer Approval Documentation
- Customer Process Risk Approval Date
- Engineering Approval Date
- Engineering Approval Owner
- Engineering Approval Spacer
- Risk Customer Approval Documentation
- Quality Approval Date
- Quality Approval Owner
- Quality Approval Spacer

Customer entered or changed after initial save

When the Customer field is populated or changed after the initial save, the system defaults to the source customer name value.

Design Risk Company Name entered or change after initial save

When the Design Risk Company Name field is populated or changed after the initial save, the system defaults to the source company name value.

Design Risk Revision Date is Null

When the Design Risk/Process Risk Revision Date fields are empty, the system defaults to the source version date value.

Draft

When the current state changes to Draft, the following items are updated to the Unlocked state:

- All related BOM records
- All related Process Risk Causes records
- All related Control Plan records
- All related Design Risk Team records
- All related Design Risk Causes records
- All related Design Risk Controls records
- All related Design Risk Failure Analysis records
- All related Design Risk Functional Analysis records
- All related Design Risk Structural Analysis records
- All related Design Risk Systems records
- All related FMEA-MSR Causes records
- All related FMEA-MSR Controls records
- All related FMEA-MSR Failure Analysis records
- All related FMEA-MSR Functional Analysis records
- All related FMEA-MSR Structural Analysis records
- All related Process Risk 4th Ed. Failure Analysis records
- All related Process Risk Causes records
- All related Process Risk Failure Analysis records
- All related Process Risk Functional Analysis records
- All related Process Risk Structural Analysis records
- All related Process Flow records
- All related Process Risk Team records
- All related Specs records
- All related Work Ins. records

Draft Created from New Mfg Document Request

When a draft record is created from a new manufacturing document request, a notification is sent to the Owner to notify them of the creation.

Draft with Skip Lot Rules

When the current state is Draft and the count of the Utilized Skip Lots is greater than zero, the Utilized Skip Lots field is cleared.

Draft, No Change Request, and Not Initial Version

When the current state is Draft, the record is not the initial version, and the record is not linked to a change request, a notification is sent to the Change Owner to inform them that the affected document is ready for change.

Enable FMEA-MSR is not True

When the Show FMEA-MSR field is not set to TRUE, the following fields are hidden:

- FMEA-MSR Due Date
- FMEA-MSR Grid
- FMEA-MSR Start Date
- High-Risk Failure Actions Taken/Planned Summary
- High-Risk MSR Failure Summary
- How the MSR Functions were Developed Summary
- InTent
- InTent Results Comments – Purpose of FMEA-MSR
- Ongoing FMEA-MSR Improvement Actions Summary
- Project Identification
- RESULTS DOCUMENTATION
- Scope Analysis Summary
- Spacer FMEA-MSR 1
- STEP 1 – PLANNING AND PREPARATION
- Supplemental FMEA for Monitoring & System Response
- Task
- Task Results Comments – Scope of this FMEA-MSR
- Team Results Comments – List of MSR Participants
- Timing Results Comments – FMEA-MSR Due Date
- Tool
- Tool Results Comments – How do we conduct analysis – Method used

First Time Official and Initial Version

When the current state changes to Official, the previous state was not Requires Review, and the VersionMasterID is equal to zero, the system updates the version number and date for the selected document ID. This transition is only used for the initial version of a document.

Note: The VersionMasterID field is equal to zero for a new document created using the Add Item  button.

First Time Official and Starting Version is being used

When the current state becomes Official for the first time, the Starting Version field is updated.

Hide: Obsolescence Fields

When the current state is not Obsolete, the following fields are hidden:

- Obsolescing Approval
- Reason for Obsolescing

ITAR Restricted Modified

When the ITAR Restricted field is modified, the ITAR Restricted field is updated on the relevant sub-processes.

ITAR Restricted or Item or Site Changed

Item Group approvers are added based on the item selected when one of the following fields are changed:

- ITAR Restricted
- Item
- Site

Users that are not ITAR compliant will be excluded if the record is set to be ITAR Restricted.

ITAR Restricted Site Checkbox is Null or True

When the ITAR Restricted field is set to Null or True, the following fields are hidden:

- Acknowledge ITAR Restriction Change
- ITAR Site Warning

Item field entered or changed after initial save

When the Item field is changed or populated for the first time after the initial save, the system defaults the Subject field with the item number and description.

Label Backcolor

The following fields are set with a blue backcolor:

- STEP 1 – PLANNING AND PREPARATION
 - *This item applies to design risk and process risk*
- DESIGN RISK HEADER
- RESULTS DOCUMENTATION
 - *This item applies to design risk and process risk*
- STEP 2 – STRUCTURAL ANALYSIS
- PROCESS RISK HEADER

The following fields are set with an orange backcolor:

- Warning Label Copy Mfg Document
- Warning Label Copy Family Template

Manufacturing Document is 2019 AIAG/VDA FMEA

When the "Show AIAG 4th Edition" toggle field is set to NO, the following fields are hidden:

- Process Risk
- Process Risk Grid

Manufacturing Document is AIAG 4th Edition

When the "Show AIAG 4th Edition" toggle field is set to YES, the following fields are hidden:

- High-risk Failure Summary
- STEP 1 – PLANNING AND PREPARATION
 - *This item applies to design risk and process risk*
- Project Identification
 - *This item applies to design risk and process risk*
- InTent
 - *This item applies to design risk and process risk*
- Design Risk Start Date
- Design Risk Due Date
- FMEA-MSR Due Date
- FMEA-MSR Grid
- FMEA-MSR Start Date
- Non-employee Team
 - *This item applies to design risk and process risk*
- Design Team
- Task
 - *This item applies to design risk and process risk*
- Tool
 - *This item applies to design risk and process risk*
- STEP 2 – STRUCTURAL ANALYSIS
- DESIGN RISK HEADER
- Company Name
 - *This item applies to design risk and process risk*
- Subject
 - *This item applies to design risk and process risk*
- Engineering Location
- Design Risk Number
- Design Risk Revision Date
- Cross-Functional Team – Design Risk
- Cross-Function Team – Process Risk
- Confidentiality Level
 - *This item applies to design risk and process risk*
- RESULTS DOCUMENTATION
 - *This item applies to design risk and process risk*
- Scope Analysis Summary
 - *This item applies to design risk and process risk*
- Show FMEA-MSR
- Tool Results Comments – How do we conduct analysis – method used
 - *This item applies to design risk and process risk*
- Task Results Comments – Scope of this Risk
- Task Results Comments – Scope of this FMEA-MSR
- Team Results Comments – List of MSR participants
- Team Results Comments – List of Participants
 - *This item applies to design risk and process risk*
- Timing Results Comments – FMEA-MSR due date

- Timing Results Comments – Risk due date
 - *This item applies to design risk and process risk*
- InTent Results Comments – Purpose of Process Risk
- InTent Results Comments – Purpose of Design Risk
- InTent Results Comments – Purpose of FMEA-MSR
- How the Functions were Developed Summary
 - *This item applies to design risk and process risk*
- High-risk Failure Actions Taken/Planned Summary
 - *This item applies to design risk and process risk*
- High-Risk MSR Failure Summary
- How the MSR Functions were Developed Summary
- Ongoing Design Risk Improvement Actions Summary
- Ongoing Process Risk Improvement Actions Summary
- Ongoing FMEA-MSR Improvement Actions Summary
- Process Risk Header
- Process Risk Grid
- Process Risk
- Model Year / Programs
 - *This item applies to design risk and process risk*
- Customer Name
 - *This item applies to design risk and process risk*
- Process Risk Revision Date
- Manufacturing Location
- Task Results Comments – Scope of this Risk

Model Years / Programs entered or changed after initial save

The Model Year(s) / Program(s) field self-updates when it is changed or populated after the initial save.

New Draft

When the current state is Draft, the system updates the current state of the manufacturing document to Official – Draft Pending and selects the "Was Draft" check box.

Not Completed, No Change Request, 1 day past the change due date

When the record is not in the Complete state, is not linked to a change request, and the current date is one day past the change due date, a notification is sent to the Change Owner to inform them that the manufacturing document is past due for change.

Not Completed, No Change Request, 7 days past the change due date

When the record is not in the Complete state, is not linked to a change request, and the current date is seven days past the change due date, a notification is sent to the person to whom the Change Owner reports to inform them that the manufacturing document is past due for change.

Not Official

When the current state is not Official, or is not becoming Official through a self-update transaction related to the Effective Date, the Requires Review field is set to False.

Not Received Inspection Document

When the "Use Document for Receiving Inspections?" toggle field is **not** set to "Yes", the following fields are hidden:

- Supplier
- Supplier Item
- Utilized Skip Lots
- Valid Skip Lot Rules

Not the Initial Version

When the VersionMasterID is not equal to zero, the following fields are hidden:

- Starting Version Date
- Starting Version Number

Note: The VersionMasterID field is equal to zero for a new document created using the Add Item  button.

Official or Awaiting Effective Date, Create Training Event, Skill not Null

A new Training Event is created based on the manufacturing document's information when the following rules are met:

- The current state changes to Official or Awaiting Effective Date
- The Create Training Event checkbox is true
- The Skill field contains a value

On Start New Version

When starting a new version of a manufacturing document, the following changes occur:

- All cross-references are updated
- Linked Design and Process Risk processes are versioned with the Start New Version command
- The linked Change Item process is updated

Ready for Approval

When the state moves to Ready for Approval, the state changes to Skip Lot Review if this document is used for skip lot inspection, otherwise it moves to Awaiting Approval. Additionally, affected skip lots are populated for the new manufacturing document version.

Received Inspection Document

When the "Use Document for Receiving Inspections?" toggle field is set to "Yes", the following fields are hidden:

- Company Name
- Confidentiality Level
- Cross-Functional Team - Design Risk

- Customer
- Customer Addresses
- Customer Name
- Design Risk
- Design Risk Grid
- Design Responsibility
- Design Systems Scope
- Design Team
- Design Verification Plans
- Design Risk Due Date
- Design Risk Header
- Design Risk Number
- Design Risk Revision Date
- Design Risk Start Date
- Engineering Location
- FMEA-MSR Due Date
- FMEA-MSR Grid
- FMEA-MSR Start Date
- Generate Design Risk
- Generate Suggested Design Verification Plans
- High-risk Failure Actions Taken/Planned Summary
- High-Risk MSR Failure Summary
- How the Functions were Developed Summary
- How the MSR Functions were Developed Summary
- InTent
- InTent Results Comments – Purpose of Design Risk
- InTent Results Comments – Purpose of FMEA-MSR
- Item
- Material/Components
- Model Year/Programs
- Non-Employee Team
- Ongoing Design Risk Improvement Actions Summary
- Ongoing FMEA-MSR Improvement Actions Summary
- Project Identification
- Related Items
- Results Documentation
- Scope Analysis Summary
- Show FMEA-MSR
- Spacer
- Spacer 3
- Spacer 4
- STEP 1 - PLANNING AND PREPARATION
- STEP 2 - STRUCTURAL ANALYSIS
- Subject
- Supplemental FMEA for Monitoring & System Response
- Task
- Task Results Comments – Scope of this Risk
- Task Results Comments – Scope of this FMEA-MSR
- Team Results Comments – List of Participants

- Team Results Comments – List of MSR Participants
- Timing Results Comments – Risk due date
- Timing Results Comments – FMEA-MSR due date
- Tool
- Tool Results Comments – How do we conduct analysis – Method used

Review Complete

When the current date is less than or equal to the Next Review Date, the Requires Review field is set to False.

Review Frequency = None

When there is no review frequency, the following fields are hidden:

- Last Review
- Next Review
- Review Completed By

Review Required

When the current date is greater than the Next Review Date and the current state is Official, the Requires Review field is set to True. Additionally, a notification is sent to the Owner to inform them that the manufacturing document requires review.

Site Isn't ITAR Restricted

When the site linked to the manufacturing document is not ITAR restricted, the ITAR Restricted field is set to False and hidden.

Site Isn't ITAR Restricted and ITAR Restricted is True

When the site linked to the manufacturing document is not ITAR restricted and the ITAR Restricted field is set to True, the system updates the ITAR Restricted field to False.

Skill is Null

When the Skill field is null, the following fields are hidden:

- Create Training Event
- Requires Training

Skip Lot Review and All Skip Lots Are Valid

When the current state is Skip Lot Review and all skip lots are valid, the system moves the state to Awaiting Approval.

Skip Lot Review and Now Valid

When the current state moves to Skip Lot Review and the Valid Skip Lot Rules field is changed, the system moves the state to Awaiting Approval.

Sys: Create Change Order is True

When the current Sys: Create Change Order is changed to True, the system creates a change order for the current manufacturing document. This only takes place if the manufacturing document is in the Draft state and already has a change request with no linked change order.

Once the new change order is saved, it can create action notifications.

Training is not Required

When the "Requires Training" check box is not selected, the Create Training Event field is hidden.

Under Skip Lot Review

When the current state is Skip Lot Review, the owner is set to the Skip Lot Owner.

Update from CO is True and Effective Date Doesn't Match CO

When the Update Effective Date from Change Order field is set to true, and the effective date does not match the effective date from the linked change order, it is adjusted so that the two values match.

PPAP Submissions***All Requirements Met and State is Draft***

The state is changed to Ready for Approval when the following items are met:

- At least one requirement exists
- All requirements have the "Requirement Met" check box selected
- The current state is Draft

Approval Rejected

When the current state changes to Approval Rejected, a notification is sent to the Owner to inform them of the approval rejection.

Canceled

The state is changed to Obsolete when the "Canceled" check box is selected.

Check for Internal Approvers

The Missing Internal Approvers field is hidden when the following conditions are met:

- The item group approvers is greater than zero.
- The Quality Manager on the selected site is populated.
- The state is **not** Ready for Approval.

Customer Approval Due

When the current state is Submitted for Customer Approval and the customer approval target date is past due, a notification is sent to the Owner to inform them that the PPAP is past due.

Customer Approval Due – Escalation

When the current date is Submitted for Customer Approval and the customer approval target date is seven days past due, a notification is sent to the person to whom the Owner reports to inform them that the PPAP is past due.

Manufacturing Document Changed

When the manufacturing Document field is changed, the manufacturing document is re-saved and the Requirement Status field is updated.

Meets All Design Requirements is not set to No

The Explanation/Comments field is hidden unless the "Meets all design requirements" field is set to NO.

New Requirements Added

When a new PPAP requirement is added, the requirement is linked to the Design Control project tasks. Additionally, its sequence is set in the PPAP Submission record.

No Design Control Project

The Project field is hidden when empty.

Not Canceled

When the "Canceled" check box is not selected, the Cancellation Reason field is hidden.

Other – Please Specify is Not Checked

The Other Description field is hidden unless the "Other - Please Specify" check box is selected.

PPAP Requirement Set Changes

When the PPAP Requirement Set field changes, the system removes the record from the PPAP Submission Requirement Status process and reloads the requirement status.

Submitted for Customer Approval

When the current state is changed to Submitted for Customer Approval, the system updates the customer approval submission date with the current date.

Commands

Some processes utilize command buttons to perform pre-defined actions. Commands can be found under the Actions icon in the top toolbar of the appropriate process.

Below is a table that describes each command available in the Design Control module. In addition to title and description, the table indicates which process each command comes from, the roles that can execute the command, and the states when the command can be executed.

Process	Title	Description	Used By	State When Used
Processes	Update Risks from Library	Adds a Risk record associated with the process for each record in the risk library linked to a risk driver with the system driver Processes.	All Roles	Draft
Processes	Start New Version	Initiates a new draft version of the record. The state of the previous version moves to Official – Draft Pending.	APQP Administrator; APQP Champion; APQP Maintenance; Auditing Administrator; Auditing Champion; Auditing Maintenance	Official
Processes	Obsolete Process?	Select Yes and save the record to move the process to the Awaiting Obsolescence Approval state.	Owner; APQP Administrator	Official
Processes	Delete Current Draft Process	Removes the current draft process from the system. Previous versions of this process are updated from Official – Draft Pending to Official.	All Roles	Official
Family Templates	Import and Link Process Specs	Imports library specifications (linked to processes in the family template process flow) to the family template specifications.	Owner; APQP Administrator; Family Template Maintenance	Draft
Family Templates	Generate Suggested PFMEA	Imports library process risk items to family template-process risk based on the current process flow.	Owner; APQP Administrator; Family Template Maintenance	Draft

Process	Title	Description	Used By	State When Used
Drawings	Delete Current Draft Drawing	Removes the current draft drawing from the system. Previous versions of this drawing are updated from Official – Draft Pending to Official.	Owner; APQP Administrator	Draft
Drawings	Start New Version	Initiates a new draft version of the drawing. The state of the previous version moves to Official – Draft Pending.	Owner; APQP Administrator; APQP Champion; Drawing Add/Edit; Drawing Administrator	Official
Drawings	Copy Drawing Features	Copies drawing features from the drawing in the Source Drawing field.	Owner; APQP Administrator; Drawing Add/Edit; Drawing Administrator	Draft
Drawings	Delete Current Drawing	Removes the current obsolete drawing from the system.	APQP Administrator	Obsolete
Drawings	Obsolete Drawing?	Select Yes and save the record to move the drawing to the Awaiting Obsolescence Approval state.	Owner; APQP Administrator; Drawing Administrator	Official
Manufacturing Documents	Generate Suggested Design Failure Modes	Adds new items to the Design Failure Mode for each design system. The System or Subsystem, Function, and Requirement fields are populated.	APQP Administrator; Design Engineer	Draft
Manufacturing Documents	Generate Suggested Design Verification Plans	Generates the Design Verification Plan using the information from the Design Risk . Multiple items may be created from one Design Risk if there is more than one control, but duplicate data will not transfer.	Owner; APQP Administrator; APQP Champion; Design Engineer; Manufacturing Documents Add/Edit	Draft

Process	Title	Description	Used By	State When Used
Manufacturing Documents	Copy from Family Template	Copy initial setup (Process Flow, Specifications, Process Risk, and Control Plan) from the Family Template selected in the "Copy from Family Template" field.	Owner; APQP Administrator; Manufacturing Documents Add/Edit; Manufacturing Documents Maintenance	Draft
Manufacturing Documents	Copy from Manufacturing Document	Copy initial setup (Associated Drawings, Drawing Features, Process Flow, Specifications, Process Risk, and Control Plan) from the Manufacturing Document selected in the "Copy from Manufacturing Document" field.	Owner; APQP Administrator; Manufacturing Documents Add/Edit; Manufacturing Documents Maintenance	Draft
Manufacturing Documents	Import Drawing Features	Adds specification data to the Specifications tab based on data from the linked drawing's Features tab.	Owner; APQP Administrator; Manufacturing Documents Add/Edit	Draft
Manufacturing Documents	Update Suggested Drawing Features	Updates the tolerance data for the Specifications tab of the Manufacturing Document with values from the Manufacturing Document.	Owner; APQP Administrator; Manufacturing Documents Add/Edit; Manufacturing Documents Maintenance	Draft
Manufacturing Documents	Import and Link Process Specs	Imports Library Specifications that are linked to Processes in the Process Specifications field into the Specifications tab of the Manufacturing Document. Additionally, the manufacturing document specifications are linked to the processes in the Process Flow tab, based on the specifications linked to that process.	Owner; APQP Administrator; Manufacturing Documents Add/Edit; Manufacturing Documents Maintenance	Draft

Process	Title	Description	Used By	State When Used
Manufacturing Documents	Generate Suggested PFMEA	Imports Process Risk Structural Analysis Library records that are linked to processes in the Process Flow tab into the Process Risk tab of the Family Template. Additionally, controls are added to the Control Plan based on the current Risk list.	Owner; APQP Administrator; Manufacturing Documents Add/Edit; Manufacturing Documents Maintenance	Draft
Manufacturing Documents	Create Inspection Event Questions	Creates inspection event questions for all control plans that are marked for inspection and have inspection type and stations defined. Then make these questions available to inspection events.	Owner; APQP Administrator; Manufacturing Documents Add/Edit; Manufacturing Documents Maintenance	All States
Manufacturing Documents	Start New Version	Initiates a new draft version of the manufacturing document. The state of the previous version moves to Official – Draft Pending.	Owner; APQP Administrator; Manufacturing Documents Add/Edit; Manufacturing Documents Maintenance	Official
Manufacturing Documents	Delete Current Draft Manufacturing Document	Removes the current draft manufacturing document from the system. Previous versions of this document are updated from Official – Draft Pending to Official.	Owner; APQP Administrator; Manufacturing Documents Maintenance	Draft
Manufacturing Documents	Obsolete Mfg Document?	Select Yes and save the record to move the manufacturing document to the Awaiting Obsolescence Approval" state.	Owner; APQP Administrator	Official
PPAP Submissions	Start New Version	Initiates a new draft version of the PPAP submission.	APQP Administrator; APQP Champion; PPAP Maintenance; PPAP Submissions Add/Edit	All States

Chapter 10

Module Frequently Asked Questions

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Frequently Asked Questions

Why shouldn't I delete items?

Records should only be deleted when you are sure that they are no longer needed. Even though records use a soft delete mechanism, there is still work that must be done to restore an item once it has been deleted.

The best thing to do with an item that is no longer needed is to set it to Inactive, Retired, or Obsolete, whichever state is applicable. This way, the item historically remains in the system but cannot be used.

If you do need to delete an item for good, then use the Trash button in the toolbar. Typically, only the system administrator can delete items.

I just changed the state of a process. What happens now?

When a process' state makes a transition, the system typically takes some automated steps. Details about these steps are listed in the State Transitions section of each process in this user guide.

Typically, state transition steps perform one of three functions:

1. **Notifications.** Notifications are sent to the users that are responsible for the next state of a process.
2. **Field Update.** Fields that depend on a state, date, or action are updated.
3. **Another State Transition.** A process' state may be transitioned automatically by the system, depending on a state, date, or action update.

Some processes may not have any automatic state transitions. In that case, it is useful to check the States section (listed before the State Transitions section) to view the process' state map and read the definitions of each state.

You can also review the Task list for that process. Each list typically describes which state to select when saving a process record.