Aras Quality Management System 12.0R1

Administrator Guide

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Copyright Information

Aras Corporation
100 Brickstone Square
Suite 100
Andover, MA 01810

Phone: 978-806-9400
Fax: 978-794-9826

E-mail: support@aras.com

Website: https://www.aras.com

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Document Conventions

The following table highlights the document conventions used in the document:

Table 1: Document Conventions

Convention	Description
Bold	This shows the names of menu items, dialog boxes, dialog box elements, and commands. Example: Click **OK**.
`Code`	Code examples appear in `courier` text. It may represent text you type or data you read.
`Yellow highlight`	Code with yellow highlight is used to draw attention to the code that is being indicated in the content.
`Yellow highlight with red text`	Red color text with yellow highlight is used to indicate the code parameter that needs to be changed or replaced.
Italics	Reference to other documents.
Note:	Notes contain additional useful information.
Warning	Warning contains important information. Pay special attention to information highlighted this way.
Successive menu choices	Successive menu choices may appear with a greater than sign (-->) between the items that you will select consecutively. Example: Navigate to **File** --> **Save** --> **OK**.

1 Overview of Quality Management System

The **Quality Management System** (**QMS**) is the name of the overarching application encompassing two Quality-related capabilities: Quality Planning and Quality Systems. **Quality Planning** will cover the *proactive* side of Quality; areas that involve design/process planning, risk analysis and risk mitigation. **Quality Systems** will cover the *reactive* side of Quality; areas that involve Issue Identification/Containment/Analysis and Corrective/Preventive Actions (CAPA).

Quality Management is an essential function in the set of functionality provided by a Product Lifecycle Management (PLM) system. In order for Quality-related information to be effective and relevant, it must be integrated with other PLM-managed data with information linked such that there's direct traceability between a product's requirements, design evolution, manufacturing, and its end use. The data authored and managed by the Quality Management System (QMS) should span all the applicable domains and be integral to the product planning, manufacturing process planning, and risk mitigation processes. To this end, the design of the QMS application strives to achieve the following:

1. Ease of Use

   The user interface and its associated functions should be intuitive to the broadest set of users that the system is intended to interact with.

2. Content linking

   The content managed by the system should allow direct reference to the relevant products (Parts), Processes (Manufacturing Operations), Users, Equipment, etc. that are managed by others parts of the PLM. When any these components change, the system should be able to alert the authors as to impact on the quality-related information.

3. Consistency and Reuse

   The information collected in various parts of Quality documents is rarely unique. Many times common descriptions are used and authors should be able to access managed repositories of quality data and reuse this information to ensure consistency and improve the efficiency with which the documents are created and maintained.

1.1 Glossary

The following Terms are used throughout this document:

Term	Definition
QMS	Quality Management System
QP	Quality Planning. The QP capability was introduced in the QMS 11.0R1 release
QS	Quality Systems. The QS capability was introduced in the QMS 11.0R2 release
PE	Product Engineering
APQP	Advanced Product Quality Planning
Business Object	Refers to any Item in Innovator that contains information, which may be referred to in a Quality Document
Context Menus	Pop-up menus, used mostly by Document Elements, that contain menu items used to invoke various functions on the Document Element instance. The term 'context' is used because the specific menu items displayed in the menu may be different depending on the specific Document Element instance selected.
Document Element	Refers to the components that make up a Quality Document. Each Document Element can have one or more Properties, the values of which are displayed in the Quality Document Table.
Candidate Document Element	A placeholder for a Document Element in a Structure Mapped Quality Document that represents a specific Business Object in the mapped and bound Business Object hierarchy but has not yet been created in the Quality Document.
Flagged Document Element	A Document Element in a Structure Mapped Quality Document that does not have an equivalent referenced Business Object in the mapped and bound Business Object hierarchy.
Quality Document	Any Document Item that can be produced using the Quality Document Editor and supporting data model configuration framework. When capitalized, Quality Document refers to the Quality Document Types provided by the Quality Planning application: **Design Quality Document (DQD)** and **Process Quality Document (PQD)**. When not capitalized, the term 'quality document' is used more generally; referring to any type of document produced in the Quality domain.
Quality Document Administrator	Describes the type of user responsible for the definition and management of Quality Document Types

Term	Definition
Quality Document Author	Describes the type of user responsible for creating and managing Quality Documents
Quality Document Type	Either Design Quality Document or Process Quality Document
Structured Content	Refers to the general use of an underlying schema to define the content of a document. Structured Content is contrasted with unstructured (or freeform) content in which case there are no rules that define and control the content.
Structure Mapping	A configured binding between a hierarchy of Document Element Types in a Quality Document Type configuration and an equivalent hierarchy of Business Objects.
CAPA	Corrective Action Preventive Action
NCR	Non-Conformance Report – Used to report a problem with a part that does not meet the part specification.
RCA	Root Cause Analysis – Methodology used to investigate the root cause of a problem.

2 Overview of Quality Planning

2.1 APQP Documents

The Advanced Product Quality Planning (APQP) documents that can be created using the QMS - Quality Planning application include Design Failure Modes and Effects Analysis (FMEA), Process FMEA, Control Plan, and Process Flow Diagram. Each organization is expected to have variations in the underlying data model and potentially unique representations of these documents but they should all be based on the documents as specified by the AIAG FMEA Reference Manual and the AIAG APQP Reference Manual. As such, this document will refer to the data model and representation of APQP documents as described and illustrated in the AIAG specifications.

2.2 Structured Data

Each APQP Document will be composed of a self-contained hierarchy of distinct data elements (Document Elements), with individual properties that are displayed as a table. Instances of a Document's Elements exist solely for a single APQP Document; they are not shared across APQP Documents and the Document content evolves as a single entity. Each Document Element may have one or more *child* Document Elements resulting in a lineage, or tree-like, structure. Each parent/child relationship can be represented in the table whereby higher-level elements start at the left columns in the table and descend down the hierarchy towards the right of the table. The table cells containing properties of parent Documents Elements are extended to match each member of their direct child Document Elements.

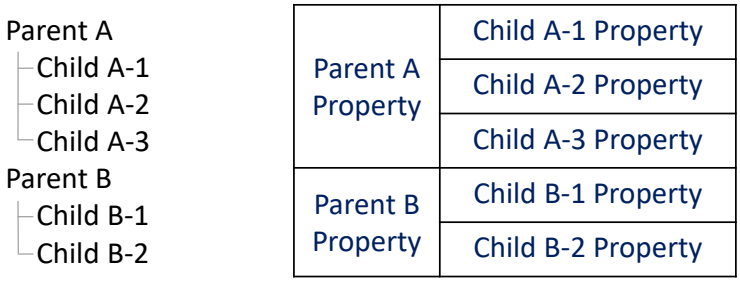

Figure 1.

2.3 APQP Data Model

The Document Elements that comprise the Design and Process Quality Documents are shown in the following diagram. The solid lines/arrows connecting the Document Elements represent a one-to-many relationship.

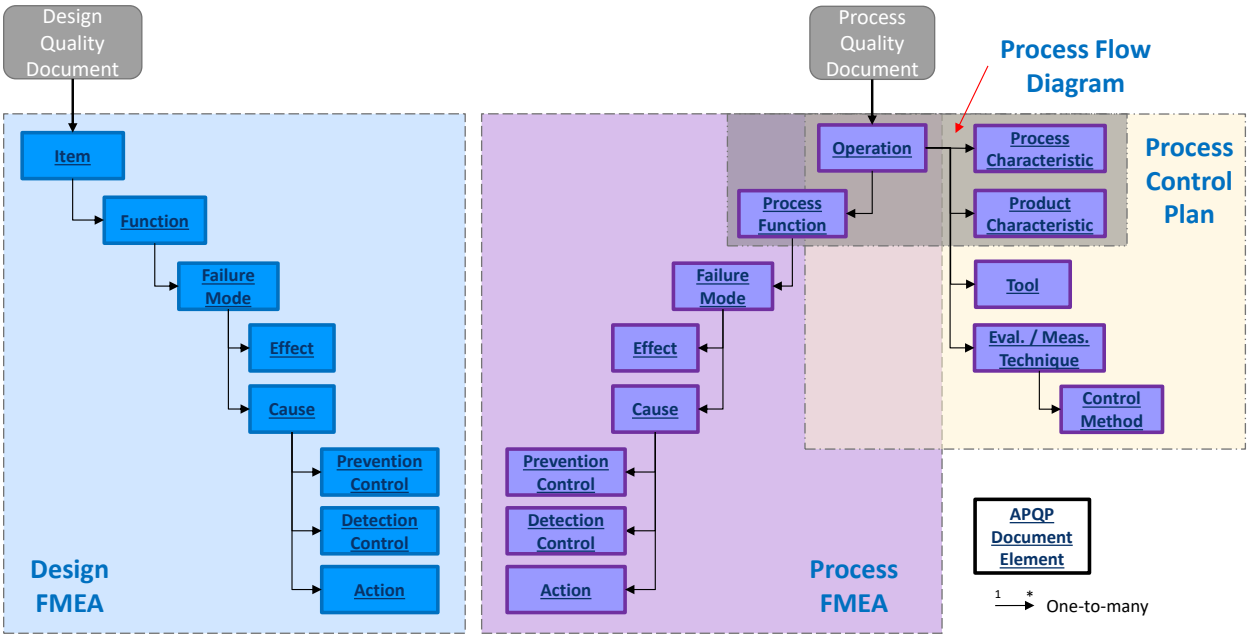

Figure 2.

The Design Quality Document will contain a single view – Design FMEA. The Process Quality Document will contain three views: Process FMEA, Process Control Plan, and Process Flow Diagram. Any instances of Document Elements that are contained in multiple views will be shared. For example an Operation added in a Process FMEA view, will show up in the Process Flow Diagram and Process Control Plan of the same Process Quality Document. The above figure identifies the Document Elements for each view.

2.3.1 Design Quality Document

The Design Quality Document contains a single View for a Design FMEA (DFMEA). The term 'Design Quality Document' and DFMEA are used interchangeably in this document. The DFMEA collects information from an analysis process performed on a product, identifies and quantifies any associated risk, and identifies various mitigation procedures that are in place or that need to be put in place. Each Design Quality Document is maintained as a separate Design Quality Document Item instance. A Design Quality Document ItemType is the overarching container for each DFMEA.

The AIAG FMEA Reference Manual describes each of the Document Elements for the DFMEA in depth.

Table 2: Design Quality Document Elements

Name	Description
Item	Represents a Part, Assembly, or component of a Part
Function	Describes a particular function of the Item
Failure Mode	Describes a manner in which the Item could fail to meet its associated function / requirement
Effect	Identifies the consequence of the Failure. Effects have an associated *severity ranking* value, which provides an indication of the severity of the Effect.

Name	Description
Cause	Identifies the potential causes of the Failure. Causes have an associated *occurrence ranking* value, which provides an indication of the likelihood of the Cause.
Prevention Control	Identifies existing mechanisms / processes in place to prevent the Cause from occurring
Detection Control	Identifies existing mechanisms / processes in place to detect the existence of the Cause. Detection Controls have an associated *detection ranking* value, which provides an indication of the likelihood of the associated Detection Control of discovering the Cause.
Action	Describes a recommended action / task that should be executed to address one or more shortcomings in current processes for prevention and/or detection

2.3.2 Process Quality Document

Similar to the DFMEA, the Process Quality Document collects information from an analysis process performed on a *process*, identifies and quantifies any associated risk, and describes various mitigation procedures in place or that need to be put in place. In addition, the Process Quality Document includes the sequence of Operations, the associated manufacturing equipment, and the controls in place to ensure each Operation performs the necessary tasks for producing an associated part or assembly component as dictated by the design and/or governing standards or procedures. Each Document is maintained as a separate Process Quality Document Item instance. A Process Quality Document ItemType is the overarching container for each Process Plan.

In the Process Quality Document, the document Elements on the right (in the light purple, dotted box) show the hierarchy of Document Elements for a PFMEA, the light brown box for the Process Control Plan, and the light grey box for the Process Flow Diagram. The AIAG FMEA Reference Manual and the AIAG APQP and Control Plan Reference Manual describes each of these elements in depth.

Table 3: Process Quality Document Elements

Name	Description
Operation	Represents a task or operation within a manufacturing process
Product Characteristic	Aspects or features about the design of a Part that require special attention including, but not limited to, its color, size, surface finish, strength, etc.
Process Characteristic	Aspects or features about a Process/Operation that require special attention including, but not limited to, size/dimension, surface finish, strength, etc.
Function	Describes the purpose of the Operation
Failure Mode	Describes a manner in which a process could fail to meet its associated function / requirement
Effect	Identifies the consequence of the Failure. Effects have an associated *severity ranking* value, which provides an indication of the severity of the Effect.

Name	Description
Cause	Identifies the potential causes of the Failure. Causes have an associated *occurrence ranking* value, which provides an indication of the likelihood of the Cause.
Prevention Control	Identifies existing mechanisms / processes in place to prevent the Cause from occurring
Detection Control	Identifies existing mechanisms / processes in place to detect the existence of the Cause. Detection Controls have an associated *detection ranking* value, which provides an indication of the likelihood of the associated Detection Control of discovering the Cause.
Action	Describes a recommended action / task that should be executed to address one or more shortcomings in current processes for prevention and/or detection
Tool	Equipment used in the process
Evaluation / Measurement Technique	Identifies the method to be used to measure or evaluate the results of a process in its output
Control Method	Identifies the method, procedure, specification, that governs the process(s) used

2.4 Enabling Printing and Exporting Options

The Quality Management Systems solution is based on the configuration management framework in the Aras Innovator core. The configuration management framework has publishing features available to Subscribers for use with the Quality Management Systems documents. Before the end users will be able to take advantage of these features, the administrator will need to install and activate these features.

There are 2 separate documents that should be reviewed to enable these options:

- *Aras Innovator - Conversion Server Setup Guide* – The conversion server is used for generating the outputs. This will need to be installed before the features can be enabled
- *Aras Innovator - Content Modeling Framework Guide* – Once the Conversion Server is installed, the publishing features must be configured and activated. Please reference section 3.3 “Enabling Printing and Exporting Options” for enabling this core feature for use with the solution.

3 Overview of Quality Systems

The set of functions called Quality Systems (QS) deals with the reactive side of Quality. The application provides the following listed capabilities:

- Manage closed-loop CAPA data and processes in PLM.
- Identify, contain, and analyze issues.
- Perform corrective and preventive actions.
- Manage Quality data with Product and Manufacturing data.
- Track Quality affected Items.
- Leverage PLM core capabilities – Workflow, Document Management, Search, Change, Reporting, Security etc.

3.1 Data Model

Quality Systems is based on the **Corrective Action Plan** ItemType which has five PolyItems related to it. Each PolyItem has its own Polysource Items as shown in the figure below.

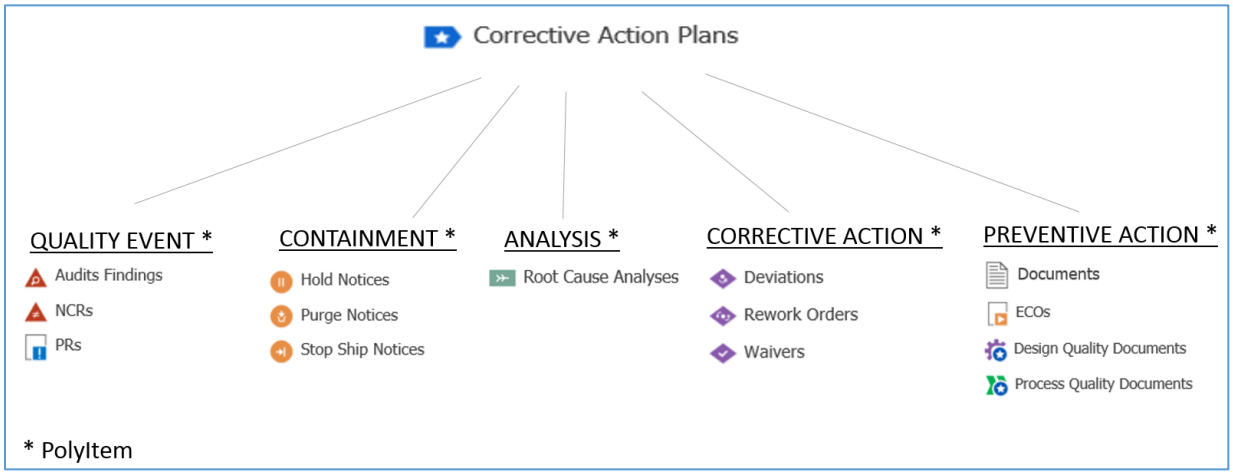

Figure 3.

3.2 Quality Identity

Aras Quality Management System includes the **Quality** Identity item. **Quality** is used in OOTB Permission structures, Workflow Assignments, and Life Cycle Promotions.

3.3 QMS Life Cycles

The Aras Quality Management System uses the following OOTB Life Cycles to help manage components of the application. Administrators have the option to customize these Life Cycles to meet business requirements.

3.3.1 Corrective Action Plan Life Cycle

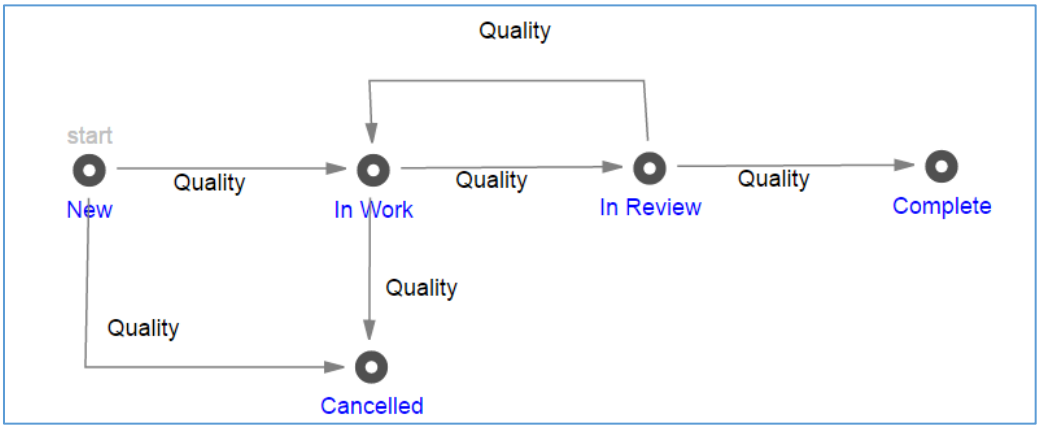

Figure 4.

3.3.2 Audit Finding Life Cycle

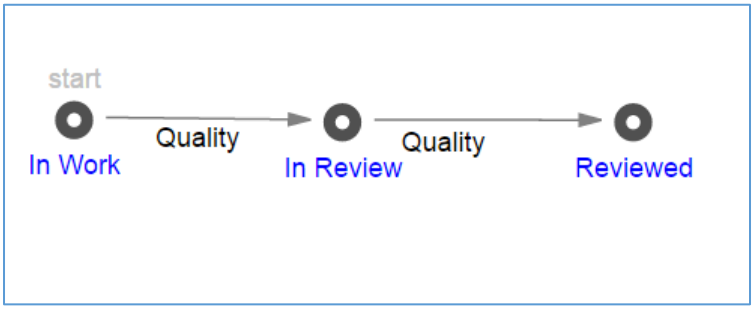

Figure 5.

3.3.3 Hold Notice, Purge Notice, and Stop Ship Notice Life Cycles

Although **Hold Notice**, **Purge Notice**, and **Stop Ship Notice** ItemTypes each have their individual Life Cycles, they share the same outline shown in the figure below.

For the Hold Notice, Purge Notice and Stop Ship Notice Items, their individual workflows control the automatic promotion between the various lifecycle states except for promotion from “Active” to “Expired” state. This promotion must be done manually from the UI by a member of the Quality identity.

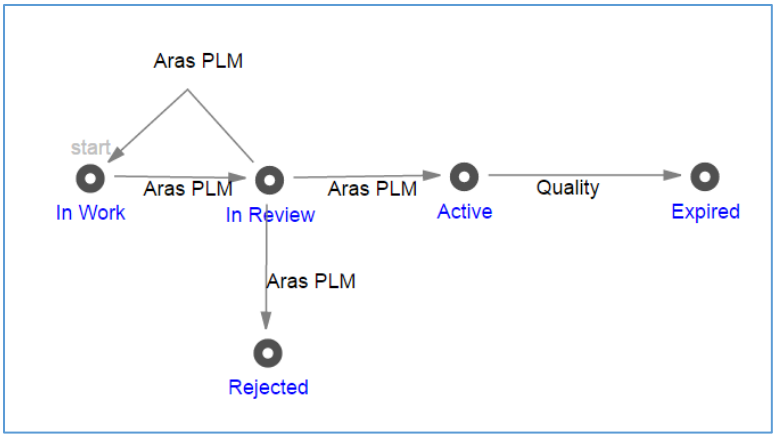

Figure 6.

3.3.4 Root Cause Analysis Life Cycle

For the Root Cause Analysis Item, its workflow controls the automatic promotion between the various lifecycles.

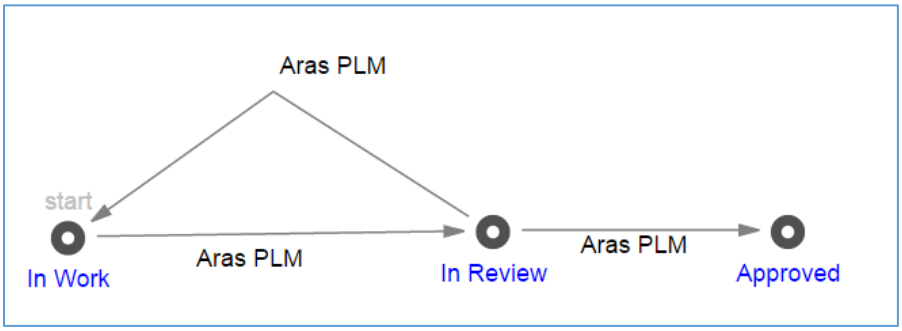

Figure 7.

3.3.5 Cause Life Cycle

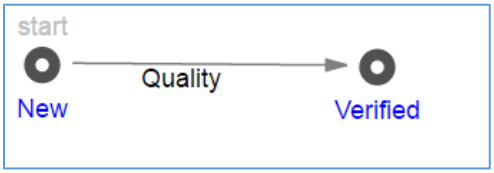

Figure 8.

3.4 QMS Workflows

The Aras Quality Management System uses the following OOTB Workflows to help manage components of the application. Administrators have the option to customize these Workflows and their Assignments to meet business requirements.

3.4.1 NCR, Hold Notice, Purge Notice, and Stop Ship Notice Workflows

Although **NCR**, **Hold Notice**, **Purge Notice**, and **Stop Ship Notice** ItemTypes each have their individual Workflows, they share the same basic outline shown in the following figure.

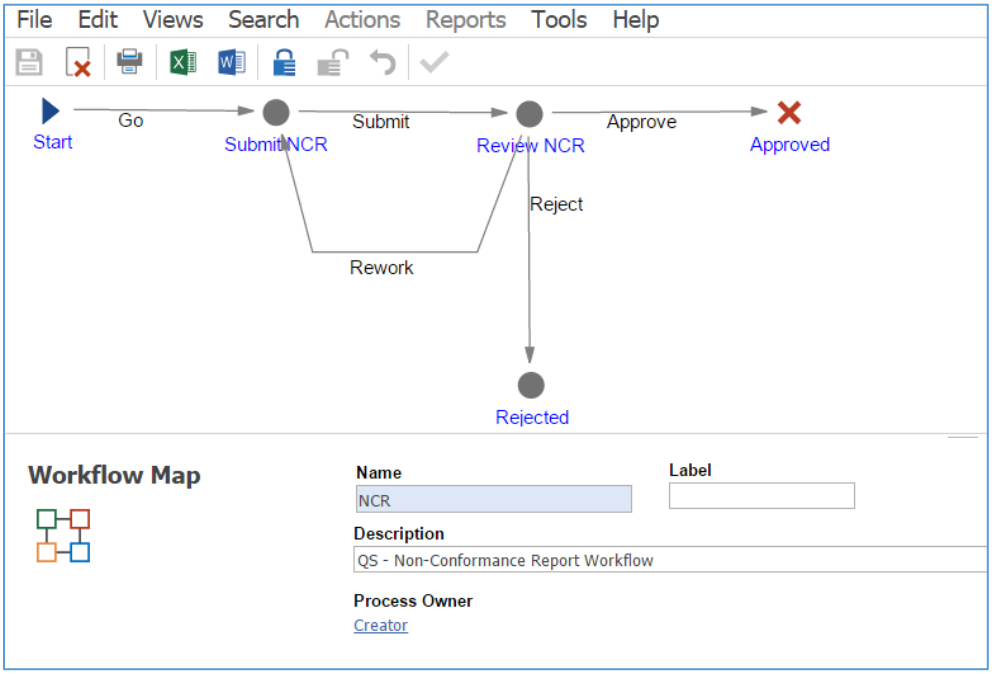

Figure 9.

3.4.2 Root Cause Analysis Workflow

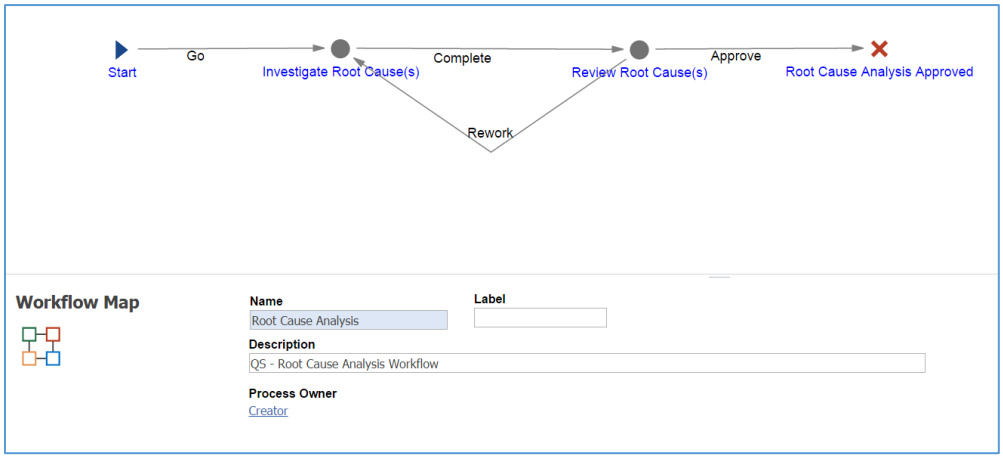

Figure 10.

3.5 Corrective Actions

The **Corrective Actions** Relationship tab on the **Corrective Action Plan** ItemType makes use of three ItemTypes – **Deviations**, **Rework Orders**, and **Waivers** – that come from the Product Engineering Application. These ItemTypes are intended to be used across multiple Aras Applications.

Each of these **Corrective Actions** has a Life Cycle and a Workflow similar to **Hold Notice**, **Purge Notice**, etc. shown above.

An Identity called “Manufacturing” is included.

3.6 Visual Collaboration

Visual Collaboration is a feature available to all Aras Subscribers. To take advantage of this feature, Subscribers need to activate a valid Feature License, available with their subscription. For more information about the Visual Collaboration Feature and License Activation, see *Visual Collaboration Administrator Guide* included in the Aras Innovator CD Image.

Once the Feature License is activated, Visual Collaboration is enabled by default for all ItemTypes (except for **Cause**) that are part of the **Corrective Action Plan**. This includes sharing messages and images related to each item. The messages that appear on the child items are aggregated on the parent **Corrective Action Plan**.

Visual Collaboration is enabled for the following **ItemTypes** – CAP, Audit Finding, NCR, Hold Notice, Purge Notice, Stop Ship Notice, Root Cause Analysis, Hold Notice, Purge Notice, Stop Ship Notice, Design Quality Document, and Process Quality Document.

The settings that are configured for the Visual Collaboration feature are for File Selection Depth, Item Selection Depth, Feed Template, File Selector Template and Discussion Template View.

3.7 Reports

Aras Quality Management System includes two OOTB Reports that end users can use to review data in Quality System – **8D Report** and **Cap Closed/Due Report**.

3.7.1 8D Report

The **8D Report** is intended to be used for information on items related to a selected **Corrective Action Plan**. OOTB Report includes the following information:

- CAP general information
- Problem Description
- Quality Event
- Containment
- Analysis
- Corrective Action
- Preventive Action
- CAPA Effectiveness

3.7.2 CAP Closed/Due Report

The **CAP Closed/Due Report** is intended to show a summary of **Corrective Action Plans** in various Life Cycle States. OOTB Report includes the following information:

- Total Number of CAP = Total number of CAP Items in the system
- Number of CAP closed = Number of CAP in **Complete** Life Cycle State
- Number of CAP Due = Number of CAP in **New** + **In Work** + **In Review** Life Cycle States
- Number of CAP Cancelled = Number of CAP in **Cancelled** Life Cycle State

4 Integration with Aras Office Connector

Aras Quality Management System includes an optional component that integrates with Aras Office Connector. The Office Connector is an application available to Aras Subscribers at no additional cost. More information about the Aras Office Connector can be obtained from the Aras website: https://www.aras.com/applications/microsoft-office-connector.

Integration with Aras Office Connector includes Document Types for 3 classes used with the **Root Cause Analysis** ItemType that link to the **native_file** and **viewable_file** Properties. The 3 classes mapped in the OOTB setup are:

- Fault Tree Analysis
- Fishbone Analysis
- Five Whys

Using Aras Office Connector provides the option of updating **Root Cause Analysis** items directly from Microsoft Office Applications.

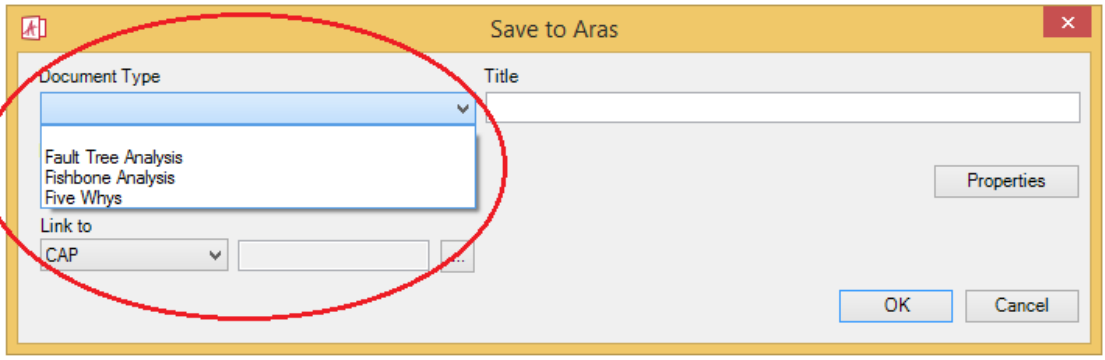

Figure 11.

For more information how Aras Office Connector setup works, refer to *Aras Office Connector – Administrator Guide*.

The 3 Office Document Types (MSO_DocumentType) - Fault Tree Analysis, Fishbone Analysis and Five Whys have property mapping as described here.

Office Property	Aras Property	Use Template	Direction	Create	Update
Title	description	false	Office to Aras	true	false
Title	description	false	Aras to Office	false	true
$MSO_User	owned_by_id	false	Office to Aras	true	false

5 Business Object Binding

Content Modeling Framework (CMF) binding is configured between the **Description** property of the **Cause** ItemType and the **DQD Cause Description** property of the **DQD Cause** Document Element**.**

Also, CMF binding is configured between the **Description** property of the **Cause** ItemType and the **PQD Cause description** property of the **PQD Cause** Document Element**.**