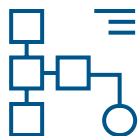


# Exception Management



Provides the mean to define and track workflows that are triggered as a response to an exception or deviation

## Overview

During manufacturing operations, it's inevitable that some problems, exceptions, and deviations will occur. It's important to address these problems quickly and systematically. Some problems will fall within defined patterns and pre-defined workflows can guide the operators on their resolution, such as SPC violations which can be addressed by Out-of-Control Action Plans (OCAPs). Other problems need a more thorough analysis to identify the root cause and to take actions to address the root cause in order to prevent these problems from occurring again, such as Corrective and Preventive Actions (CAPA).

The Exception Management module provides the capability to defined and execute workflows to guide the user in capturing problems and issues and responding to them. Being an integrated module, exceptions can be triggered automatically by system under certain conditions (e.g.: SPC violation). An exception can also be opened manually at any time in response to a certain condition.

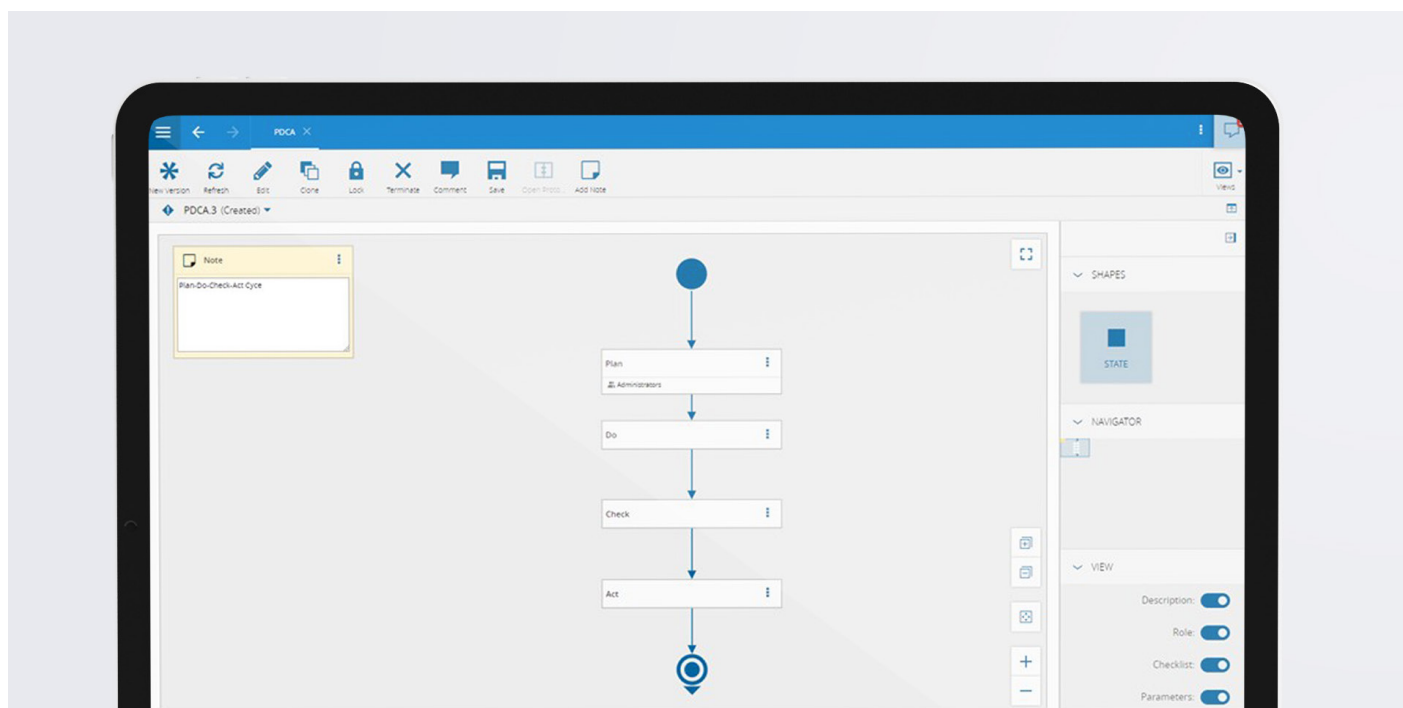


Figure 1 Exception Protocol workflow example

## Key Features

- Provision of a graphical user interface designer to create exception workflows.
- Support for change control and versioning of exception workflows.
- Capability to open exception workflows manually or automatically in case that SPC rules are violated or Data Collection limits are exceeded.
- Capability to prevent a Material from moving from the current Step or from being shipped to another facility while it's associated with an open exception.
- Capability to assign roles, parameters, and checklists for every state of the exception workflow.
- Support for material dispositions as part of an exception workflow. For example, if a certain problem affects several lots, it's possible to open an exception workflow for the affected lots and then decide on a lot by lot basis, what is the action to be taken lot (e.g.: Scrap or Rework).
- Capability to create tasks as part of an exception workflow and to track the progress and state of those tasks (action items) until the completion.
- Integration with Material Tracking, SPC and Data Collection.

## Benefits

- Improved process repeatability and consistency
- Reduction of problem resolution time
- Reduction of problem re-occurrence
- Improved quality
- Improved regulatory compliance
- Reduction of customer complaints
- Reduction of downtime
- Reduction of scrap

The screenshot displays the Critical Manufacturing software interface. On the left is a navigation menu with categories: Administration, Business Data, Manufacturing, Maintenance, Quality, Planning and Logistics, Business Intelligence, and Automation. Below this are 'My Notifications', 'My Tasks', and 'System'. The main workspace is titled 'PDCA-00000007 (Active)'. It features a toolbar with icons for Refresh, Terminate, Comment, Edit, Perform, Change State, Adjust State, Close, Take Owner, Manage, Approve, Execute Dis., and Create Task. The workspace is divided into three panels:

- States:** A list of states including Plan (with a green checkmark), Do (with a green checkmark), and Check (with a clock icon).
- DO (Performed):** A section titled 'NOTES' containing a note from user 'CMF1' dated '10/16/2018 05:51 PM' stating: 'The material mass flow rate seems to be below nominal constantly. Is it a calibration issue?'.
- Protocol:** A section showing 'MATERIALS (0)' with 'No Materials found', 'TASKS (0)' with 'No Tasks found', and 'CONTEXT' with fields for Product, Step, Facility, Flow, and Resource. Below this is 'DOCUMENTS (0)'.

Figure 2 Protocol execution example