



CALYX™

Best Practice: Management of Change

CALYX.AI

1 Best Practice Revision History

When Calyx releases a new version of Calyx RIM, they issue Release Notes which explain the new features and updates. Calyx reviews the Release Notes against each Best Practice to determine any impact to the document:

- Impact = Release notes-documented upgrade changes this Best Practice
- No Impact = Release notes-documented upgrade changes do not affect this Best Practice

When Release Notes impact Best Practice documentation, Calyx recommends that clients review the entire Release Notes for a full understanding of all changes associated with this Best Practice documentation.

Software Version	Release/Revision Date	Summary of Change(s) (Refer to Release Notes for Full Description)
v7.0	30-Apr-2021	Update Best Practice for v7.0 – No Impact
N/A	01-Apr-2021	Update Best Practice for Calyx Rebranding – No Impact
v6.2 CHF6	21-Oct-2020	Update Best Practice for v6.2 CHF6 – No Impact
v6.2 CHF5	03-Aug-2020	Update Best Practice for v6.2 CHF5 – Impact
v6.2 CHF4	28-Feb-2020	Update Best Practice for v6.2 CHF4 – No Impact
v6.2 CHF3	27-Jun-2019	Update Best Practice for v6.2 CHF3 – No Impact
v6.2 CHF2	15-Feb-2019	Update Best Practice for v6.2 CHF2 – No Impact

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3 Document Purpose

The purpose of this document is to provide best practice guidance on the use of the Management of Change features available in Registrations Component of Calyx RIM.

3.1 Scope

This document covers only the use of the Management of Change functionality, including the Change and Change Detail entities and associated GPP wizard. This document seeks to clarify the use of the functionality and how it supports standard regulatory processes.

4 Management of Change Entities

4.1 Change

A Change is typically aligned with a record created in a proprietary event tracking and action resolution tool (change control tool), although use of an external tool is not mandatory.

Calyx RIM has two-level Change tracking: Changes, and Change Details

When created in Calyx RIM, the Change:

- Can be categorized by capturing one or more configurable Change Types to identify the areas that the Change covers.
- Allows users to enter a high-level description of the change.
- Is automatically assigned a unique, internal six-digit Change Number to assist with tracking and managing. The Change Number is used as the primary identifier.

Other fields are available to capture additional Change information. It may also be possible to use Data Exchange functionality to create or update the record with information from an existing proprietary change control tool.

4.2 Change Detail

Since each Change may have multiple product impacts – which may require one or more Calyx RIM Events (regulatory objectives) – the system allows users to add one or more Change Details to each individual Change.

A Change Detail is a child of a Change and is itself assigned a Change Detail Number (a sequential suffix to the Change Number).

- Multiple Change Details can be associated to each Change to account for all individual changes that make up the overall Change.
- It is the Change Detail, and not the Change, that is associated with an Event. Associating at the Change Detail level allows these individual changes to be associated under the same or different Events (per Application).
- Each Change Detail has its own status which is relative to the Event it is associated with.

- The Event-Change Detail status should be used in conjunction with the relevant Event-Country Status in order to give the full picture of the approval in any one Event and Event - Country

Additional fields are available to capture specific information.

5 Management of Change Initiation

A Change Management Wizard is available in the Wizards drop-down list to support the Management of Change process activity. The wizard can guide you through either of the following processes:

- Create a new Change and one or more Change Details
- Associate existing Change Details

The wizard creates or associates the Change Details as part of the GPP wizard which has been integrated into the flow of the Change Management wizard.

To invoke the wizard:

1. Select the Change Management wizard.
2. Select Create Change / Change Details (if the Change and Change details have been created, follow step 10).
3. Click Next.
4. On the Create Change page:
 - Change Type: associate 1 or more Change Type
 - Change Short Description: <insert description up to 100 characters>
 - Change Initiation Date: <insert date>
 - Complete other fields as required by corporate guidance
5. Click Next until the Create Change Detail page appears
6. On the Create Change Detail page:
 - Change Detail: retain proposed or modify as required
 - Change Detail Short Description: <insert description up to 100 characters>
 - Change Detail Initiation Date:<insert date>
 - Complete other fields as required by corporate guidance
7. Click Next.
8. On the Create Additional Change Details page, select Yes if additional Change Details should be created (go to step 6) or No if all Change Details have been created.
9. Click Next.
10. Select Associate Change / Change Details (if the Change and Change details have not been created, follow step 2).
11. On the Select Change Details to Associate page, use the Change Detail widget to Select one or more Change Details (across one or more Change).

12. Click Next.
13. On the Select Event-Change Detail Status page:
 - Change Detail Status: select according to corporate guidance*

14. Click Next.

15. Complete the Global Project Planning pages according to corporate guidance.

*Typically the Status selected would be Planned since the Events are most likely to be created in advance of dispatch or submission.

On the completion of the Wizard, the appropriate Events have been created and all Change / Change Details have been associated to the Events and can be verified through the Project's Event Change Details tab.

6 Management of Change: Affiliate Assessment

On completion of the Global Project Plan, affiliates can make an assessment to identify that the Change Details associated with the individual Event may need to be separated to comply with regulatory processes in that country. To manage this activity, the following process should be followed.

Disassociate the Change from the Event

1. Navigate to the created Event.
2. Navigate to the Change Details tab.
3. Select the checkboxes next to the Change Details to be disassociated.
4. Click the Associate / Disassociate Change Details button.
5. Click OK on the pop-up message.
 - The Change Detail is dissociated from the Event.

Reverse any Detail Changes in the Product Detail Set

A User with Admin rights to the PDS must perform these steps:

1. Navigate to the Product Detail Set tab.
2. Select the appropriate Product Detail Sets.
3. Navigate to any changes related to the dissociated Change Details (Pending Add / Pending Modify / Pending Withdraw).
 - Right-click each modified, added, withdrawn node, then click Delete.
4. Click OK on the pop-up message.
 - The changes have been rolled back in the Product Detail Sets.

Create a New Event and Update Product Details for the Disassociated Changes

1. Create a new Event to manage the disassociated Change Detail and complete fields according to corporate guidance.

2. Navigate to the Product Detail Set tab.
3. Select the appropriate Product Detail Sets.
4. Apply any changes required related to the associated Change Details (Add / Modify / Withdraw).

Associate the Change Detail with the New Event

1. From the Event, navigate to the Change Details tab.
2. Select the Associate / Disassociate Change Details button.
3. On the Associate Change Detail page, use the Select Change Detail widget to select the appropriate Change Details.
4. Click OK.
5. Modify the Event.
6. In the Project Name field, select the Project Name created in the Management of Change Initiation section, step 15 (see http://help.Liquent.com/InSight_6-1-0/GUID-DD4559DB-6773-41E8-A75C-410DE9CF8758.html for additional information on associating and disassociating Change Details).

Separate Change Details for Multiple Events

If the Change Details need to be separated for multiple Events, perform this procedure:

1. Create a Global Project Plan to mass create the Events.
2. Associate the new Events to the original Project from the Event page.
3. Follow Steps 1 – 4 (above).
4. From the Project, apply the Associate Change Detail(s) to Event function to associate the Change Detail to the new Events (therefore skipping Steps 1- 4).

7 Change and Change Detail at a Glance Views

Each Change record displays an Event tab that reflects the entire Event landscape as it relates to that Change (and all its Change Details). The Related Events tab displays:

- Event Name (all Events that are related to a Change Detail that is part of this Change)
- Related Change Details (the specific Change Detail(s) associated with the Event from the selected Change record)
 - Change Detail Short Description
 - Event-Change Detail current status
- All Event Change Details (all Change Detail(s) associated with the Event from any Change record)
 - Change Detail Short Description
 - Event-Change Detail current status

When an individual Change Detail record is selected, the Change Detail displays an Events tab that highlights the following information:

- Event Name
- Event-Change Detail current status

8 Updating Event Statuses and Status Dates

Where all Events are captured in the same Project, users can apply the Update Project Event Country Status wizard to update and modify multiple Event-Country status values at the same time (even within the same Application). This approach provides an easy way to manage and view the status of the Events and the associated Change Details.

When the terminal status is achieved, use the Update Event Status wizard or the Update Project Event Country Status feature to apply the terminal status to the Event.

- After selecting Yes to the Close Event option, the Event Closed As selection will appear.
- The status selected in the Event Closed As field will be applied to the Event-Change Detail entity as well as the Product Detail Set node. (See the Additional Reading section for links to the specific rules relating to the Event Closed As functionality).

Note: The terminal status of an Event Change Detail can be managed independent of the overall Event e.g. to manage partial approvals. Event Change Details assigned either a 'Not Approved' or 'Withdrawn' status will be automatically available for association with another Event if a subsequent submission is progressed within the same Application

9 Additional Reading

Please refer to the Calyx RIM® Best Practice on the use of Event Closed As Functionality document, which provides further detail on the functionality of the Event Closed As feature and its impact on the Change Detail status.

Please also refer to the following online help topics for additional information on the Event Closed As Functionality.

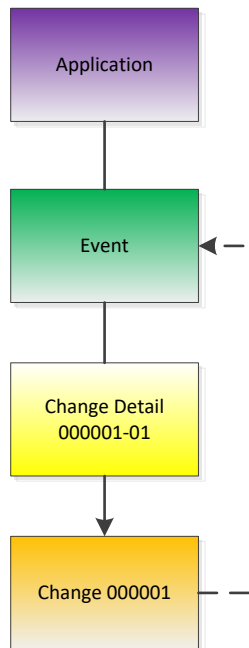
- If the Event is Closed with the Event-Closure Status of Approved:
http://help.Liquent.com/InSight_6-1-0/GUID-36C5C70B-C9DE-4FE2-80B9-10A5195DD948.html
- If the Event is Closed with the Event-Closure Status of Not Approved:
http://help.Liquent.com/InSight_6-1-0/GUID-BE182358-41E3-4C97-8267-AFA18A172174.html
- If the Event is Closed with the Event-Closure Status of Not Approved:
http://help.Liquent.com/InSight_6-1-0/GUID-EB08E4AA-3DAA-4E14-90B7-4AFACD05F937.html

10 Scenarios for Change and Change Detail Associations with Events and Applications

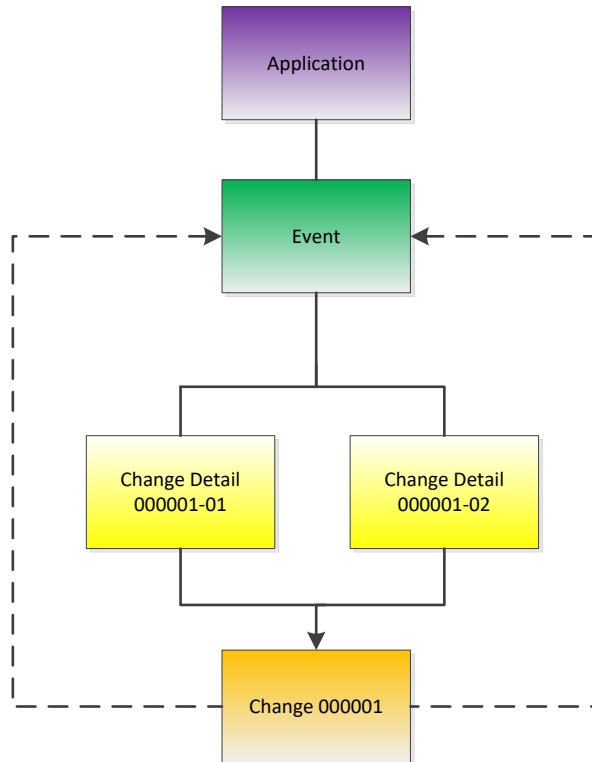
The following examples illustrate some potential relationships for Applications, Events, Changes, and Change Details. The examples are illustrative only and are not intended to be an exhaustive list.

Note that in all instances, the Event *directly links* to the Change Detail, which provides an association between the Event and the Change.

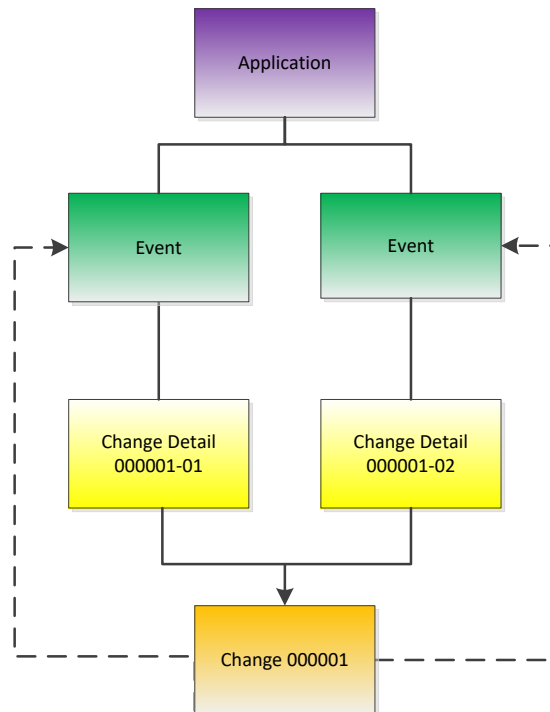
10.1 An Application with one Event, one Change Detail and one Change



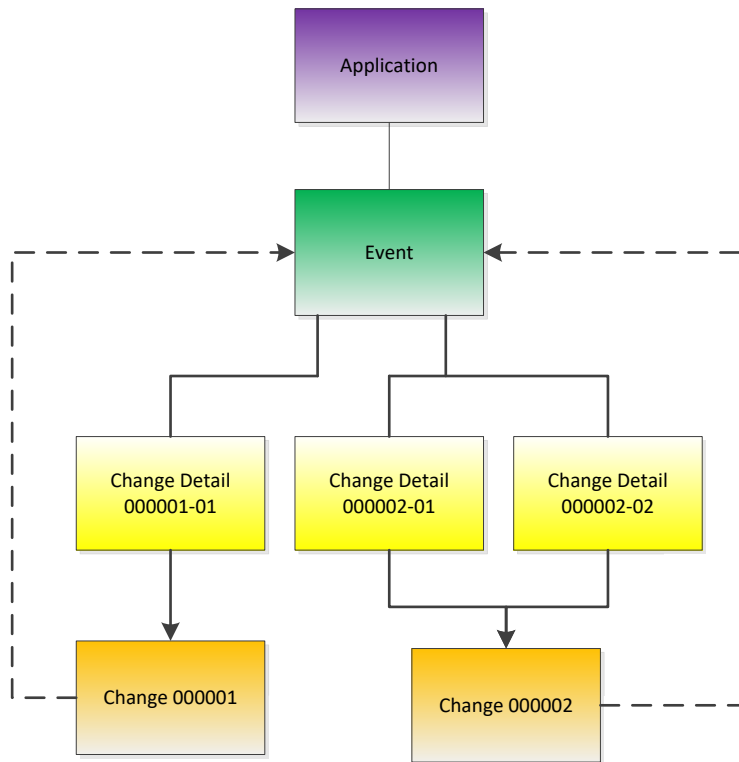
10.2 An Application with one Event, multiple Change Details and one Change



10.3 An Application with two Events, multiple Change Details and one Change



10.4 An Application with one Event, multiple Change Details and multiple Changes



10.5 Multiple Applications with single or multiple Events, multiple Change Details and one Change

