

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)
v6.2 CHF6	25-Mar-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 – Impact

1 Contents

- Revision History**1
- 1 Contents2
- 2 Document Purpose3
 - 2.1 Scope3
- 3 Event-Association Closed As Status, Event-Country Status, and Event–Change Detail Status3
- 4 Event-Country Status Definitions4
 - 4.1 Association Closed As, Event Change Detail, and Event-Country Statuses Set to APPROVED.....4
 - 4.2 Association Closed As Status and Event Change Detail Status Set to APPROVED, Event-Country Status Set to No Submission Required.....4
 - 4.3 Association Closed As and Event Change Detail Statuses Set to APPROVED, Event-Country Status Set to Implemented or Approved.....5
 - 4.4 Association Closed As and Event Change Detail Statuses Set to WITHDRAWN and Event-Country Status Set to Decision Not to File.....5
 - 4.5 Association Closed As and Event Change Detail Statuses Set to WITHDRAWN and Event-Country Status Set to Withdrawn.....5
 - 4.6 Association Closed As and Event Change Detail Statuses Set to NOT APPROVED and Event-Country Status Set to Not Approved:6
 - 4.7 Examples6
 - Example 16
 - Example 26
 - Example 37
 - Example 47
 - Example 57
 - Example 68
 - Example 78

2 Document Purpose

The purpose of this document is to provide best practice guidance on the use of the Association Closed As feature when closing an Event, particularly since the Association Closed As functionality must be completed regardless of a Product Detail Set (PDS) being associated, or there being any changes to the PDS. Guidance is also provided on the Association Closed As feature when an Event Change Detail is associated with an Event.

2.1 Scope

This document covers the use of the Association Closed As functionality and its impact on the PDS, Event-Change Detail and its relationship with the Event-Country Status. This document seeks to clarify the use of the Association Closed As functionality in conjunction with the Event Country Status, PDS status, and Event-Change Detail Status under a number of possible scenarios.

3 Event-Association Closed As Status, Event-Country Status, and Event-Change Detail Status

When an Event is closed, the Product Detail Set nodes modified by that Event become immutable and Calyx RIM applies one of three specific statuses to those nodes:

- APPROVED
- NOT APPROVED
- WITHDRAWN

At the time the Event is closed, the Event-Change Detail status is also updated based on the internal status mappings defined in Data Administration.

The Event-Association Closed As Status is used in Calyx RIM solely to capture the appropriate status to apply to all the PDS nodes (those of status Pending Modify, Pending Add, or Pending Withdraw) controlled by the Event and the Event-Change Detail(s). Should different statuses be needed on different Event Change Details or nodes of the PDS (as long as all are controlled by the same Event) e.g. one PDS change is Withdrawn or Not Approved and all other changes are Approved, those which are WITHDRAWN or NOT APPROVED should be manually updated on the Event-Change Detail and/or in the PDS before closing the Event.

Note: 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

The Event-Country Status defines the current status, including the final approval status of that Event (Regulatory objective) for all countries associated with the Event. This applies to all types of Events, not solely multi-country Events. The Event-Country Status should be used (in conjunction with the PDS node status, Event-Change Detail status, and the Registration status) to identify whether a particular Event Change or a PDS detail is Approved within that market.

Calyx does not recommend that Event-Association Closed As Status be used for reporting purposes.

4 Event-Country Status Definitions

When considering this document it is critical to understand the meanings of the Event-Country statuses used in the following statements. While the exact status name in each organisation may be different it is imperative that all users of the system understand the status definition and in which circumstances to apply them.

- No Submission Required (or similar status): the change can be implemented without informing the regulatory authority.
- Decision Not to File (or similar status): the change will not be filed and the change will not be implemented
- Implemented (or similar status): Before, or following, a submission to the health authority, the change can be implemented prior to receiving (e.g. Type IA IN) or without regulatory authority approval (notification only or implementation before notification). (The Action Type field may be used to further define the route of regulatory approval, e.g. Notification Only or Implementation Prior to Approval.)
- Withdrawn: The regulatory objective was withdrawn before a final Health Authority decision.
- Not Approved: The regulatory objective was not approved by the Health Authority.

4.1 Association Closed As, Event Change Detail, and Event-Country Statuses Set to APPROVED

Association Closed As status, Event Change Detail status, and Event-Country status are set to APPROVED when:

- The final status is Approved, a Change Detail is associated to the Event, a PDS is associated to the Event (with or without changes).
- The final status is Approved, a Change Detail is associated to the Event, a PDS is not associated to the Event.
- The final status is Approved, no Change Detail is associated to the Event, a PDS is associated to the Event (with or without changes).
- The final status is Approved and no Change Detail or PDS is associated to the Event.

4.2 Association Closed As Status and Event Change Detail Status Set to APPROVED, Event-Country Status Set to No Submission Required

Association Closed As status and Event Change Detail status are set to APPROVED and Event-Country Status is set to No Submission Required when:

- The final status is No Submission Required, a Change Detail is associated to the Event, a PDS is associated to the Event (with or without PDS changes).
- The final status is No Submission Required, a Change Detail is associated to the Event, a PDS is not associated to the Event.
- The final status is No Submission Required, a Change Detail is not associated to the Event, a PDS is associated to the Event (with or without changes).
- The final status is No Submission Required and no Change Detail or PDS is associated to the Event.

4.3 Association Closed As and Event Change Detail Statuses Set to APPROVED, Event-Country Status Set to Implemented or Approved

Association Closed As status and Event Change Detail status are set to APPROVED and Event-Country status is set to Implemented or Approved when:

- The final status is either Implemented or Approved (when the Approval follows after Implementation), a Change Detail is associated to the Event, a PDS is associated to the Event (with or without PDS changes).
- The final status is either Implemented or Approved (when the Approval follows after Implementation), a Change Detail is associated to the Event, a PDS is not associated to the Event.
- The final status is either Implemented or Approved (when the Approval follows after Implementation), a Change Detail is not associated to the Event, a PDS is associated to the Event (with or without PDS changes).
- The final status is either Implemented or Approved (when the Approval follows after Implementation), no Change Detail or PDS is associated to the Event.

4.4 Association Closed As and Event Change Detail Statuses Set to WITHDRAWN and Event-Country Status Set to Decision Not to File

Association Closed As status and Event Change Detail status are set to WITHDRAWN and Event-Country Status is set to Decision Not to File when:

- The final status is Decision Not to File, a Change Detail is associated to the Event, a PDS is associated to the Event (with or without PDS changes).
- The final status is Decision Not to File, a Change Detail is associated to the Event, a PDS is not associated to the Event.
- The final status is Decision Not to File, a Change Detail is not associated to the Event, a PDS is associated to the Event (with or without PDS changes).
- The final status is Decision Not to File, no Change Detail or PDS is associated to the Event.

4.5 Association Closed As and Event Change Detail Statuses Set to WITHDRAWN and Event-Country Status Set to Withdrawn

Association Closed As status and Event Change Detail status is set to WITHDRAWN and Event-Country Status is set to Withdrawn when:

- The final status is Withdrawn, a Change Detail is associated to the Event, a PDS is associated to the Event (with or without PDS changes).
- The final status is Withdrawn, a Change Detail is associated to the Event, a PDS is not associated to the Event.
- The final status is Withdrawn, a Change Detail is not associated to the Event, a PDS is associated to the Event (with or without PDS changes).
- The final status is Withdrawn, no Change Detail or PDS is associated to the Event.

4.6 Association Closed As and Event Change Detail Statuses Set to NOT APPROVED and Event-Country Status Set to Not Approved:

Association Closed As status and Event Change Detail status is set to NOT APPROVED and Event-Country Status is set to Not Approved when:

- The final status is Not Approved, a Change Detail is associated to the Event, a PDS is associated to the Event (with or without PDS changes).
- The final status is Not Approved, a Change Detail is associated to the Event, a PDS is not associated to the Event.
- The final status is Not Approved, a Change Detail is not associated to the Event, a PDS is associated to the Event (with or without PDS changes).
- The final status is Not Approved, no Change Detail or PDS is associated to the Event.

4.7 Examples

Example 1

In a single country Event there are modifications to two of the PDS nodes, and two corresponding Event-Change Details. The Event has been approved by the Health Authority, but only one of the changes is approved, the other was Not Approved. The Actions in Calyx RIM are:

1. Navigate to the Product Detail Set:
 - a. Select the node which was Not Approved
 - b. Right-click and select Modify Status
 - c. Select: Not Approved
2. Navigate to the Event-Change Details:
 - a. Modify the Event-Change Detail that was Not Approved
 - b. Set the status to Not Approved, and then Save
3. Navigate to the Event:
 - a. Following the corporate processes, close the Event
 - b. Event Country Status: Approved
 - c. Association Closed As: APPROVED

Note: The Event Change Detail with the 'Not Approved' Status will automatically be available for association with another Event if a subsequent submission is progressed within the same Application.

Example 2

In a single country Event there is a modification to one of the PDS nodes, and one corresponding Event-Change Detail. The specific change does not require Health Authority approval and may be implemented without any submission. In Calyx RIM:

Navigate to the Event and, following the corporate processes, close the Event.

- a. Event Country Status: No Submission Required

- b. Association Closed As: APPROVED

Example 3

In a multi country Event there are modifications to two of the PDS nodes, and two corresponding Event-Change Details. The Event has been approved by the Health Authority in one of the three countries. In Calyx RIM:

Navigate to the Event following the corporate processes.

- a. Event Country Status: Approved
- b. Association Closed As: <leave blank>

When the final approval is received for the last remaining country on the Event, the actions in Calyx RIM are:

Navigate to the Event following the corporate processes close the Event.

- a. Event Country Status: Approved
- b. Association Closed As: APPROVED

Example 4

GPP has been used to create multiple Events for a labelling change. In all Events there is a modification to one of the PDS nodes, and one corresponding Event-Change Detail. The affiliates review the Events to make an assessment of the change.

- In Country A the specific change does not require Health Authority approval and may be implemented without any submission.
- In Country B the specific change has been assessed by the affiliate as not acceptable by the Regulatory Authority (not in line with their regulations) and so will not be submitted and the change will not be implemented.

The Actions in Calyx RIM are:

1. Navigate to the Country A Event and, following the corporate processes, close the Event.
 - a. Event Country Status = No Submission Required
 - b. Association Closed As: APPROVED
2. Navigate to the Country B Event and, following the corporate processes, close the Event.
 - a. Event Country Status = Decision Not To File
 - b. Association Closed As: WITHDRAWN

Note: The Event Change Detail with the 'Withdrawn' Status will be automatically available for association with another Event if a subsequent submission is progressed within the same Application

Example 5

In a single country Event there is a modification to one of the PDS nodes and one corresponding Event-Change Detail. The specific change can be implemented prior to Health Authority approval but only after

submission of appropriate documentation. On submission of the appropriate documentation, the Actions in Calyx RIM are:

1. Navigate to the Event and, following the corporate processes, update the Event-Country Status.
 - a. Event Country Status: Submitted
 - b. Association Closed As: <leave blank>
2. Following implementation of the change, and following corporate processes, update the Event-Country Status.
 - a. Event Country Status: Implemented
 - b. Association Closed As: <leave blank>
3. Following Health Authority Approval navigate to the Event and, following the corporate processes, update the Event-Country Status.
 - a. Event-Country Status: Approved
 - b. Association Closed As: APPROVED

Example 6

In a single country Event there is a modification to one of the PDS nodes and one corresponding Event-Change Detail. The specific change can be implemented after a defined time period following submission to the Health Authority; no formal approval is expected.

1. Navigate to the Event and, following the corporate processes, update the Event-Country Status.
 - a. Event Country Status: Submitted
 - b. Association Closed As: <leave blank>
2. When the mandatory waiting time has elapsed navigate to the Event and, following the corporate processes, update the Event-Country Status.
 - a. Event Country Status: Implemented
 - b. Association Closed As: APPROVED

Example 7

In a single country Event there is a modification to one of the PDS nodes and one corresponding Event-Change Detail. The specific change can be implemented and the change will be included in an Annual Report (the AR Event already exists). The Actions in Calyx RIM are:

1. Navigate to the Event and, following the corporate processes, close the Event.
 - a. Event Country Status: Implemented
 - b. Association Closed As: APPROVED
2. Following Submission navigate to the Annual Report Event and update the Event-Country Status.
 - a. Event-Country Status: Submitted
 - b. Association Closed As: <leave blank>

3. When Approval is granted for the Annual Report, close the Annual Report Event and update the status of the change Event.
 - a. Annual Report Event Country Status: Approved
 - b. Annual Report Association Closed As: APPROVED
 - c. Change Event Country Status: Approved.