



CALYX™

CALYX™
Best Practice:
CE Mark
Applications

CALYX.AI

1 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 change this Best Practice
- No Impact = Release notes do not change 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 – Impact
N/A	09-Apr-2021	Update Best Practice for Calyx Rebranding – No Impact
N/A	21-Oct-2020	Update Best Practice for v6.2 CHF6 – No Impact
N/A	03-Aug-2020	Update Best Practice for v6.2 CHF5 – No Impact
N/A	28-Feb-2020	Update Best Practice for v6.2 CHF4 – No Impact
N/A	27-Jun-2019	Update Best Practice for v6.2 CHF3 – No Impact
N/A	15-Feb-2019	Update Best Practice for v6.2 CHF2 – No Impact

2 Contents

1	Revision History.....	1
2	Contents.....	2
3	Document Purpose.....	3
4	Scope	3
5	Data Administration Activities.....	3
5.1	Application Category	3
5.2	Application Type	3
5.3	Procedure Type.....	3
6	CE Mark Process	3

3 Document Purpose

The purpose of this document is to provide a Best Practice defining the process of capturing CE Mark Applications and Events.

4 Scope

Capturing CE Mark Applications and Events in Calyx RIM for Registrations.

5 Data Administration Activities

5.1 Application Category

A new Application Category should be created named Device.

5.2 Application Type

A new Application Type should be created named CE Mark, this should be mapped to the Default Application Type (Entity XML Type) and to the Device Application Category; countries assigned should be all countries appropriate for the CE Mark (typically all of EU plus Switzerland and Turkey).

5.3 Procedure Type

A new Procedure Type should be created named CE Mark, this should be mapped to the Internal Procedure Code CP, all appropriate EU countries (plus Switzerland and Turkey if appropriate) should be added.

If no Data Administration changes are preferred, the Application Type of MAA and Procedure Type of CP may be selected in Step 1 (below). However, it should be noted that Switzerland and Turkey may not, by default be included in the Application. If Turkey and Switzerland were added to the MAA Application Type / CP Procedure Type, this may cause undesirable issues when creating Centralised Procedure Applications.

6 CE Mark Process

1. An Application should be created within the appropriate Product Family with the following attributes:
 - *Application Name:* Product Family Name> <Type of Application> <Country/Region>
(e.g. Product Family Name> < CE Mark > <EU>)
 - *Application Type:* CE Mark
 - *Procedure Type:* CE Mark
 - *Reviewing Country:* <as appropriate>
 - *Countries:* <as appropriate>
 - *Products* <as appropriate>
 - Complete other fields as required by your organisation
2. Create an Event with the following attributes:
 - *Event Name:* follow organisation naming convention (e.g. New CE Mark Certification)
 - Complete other fields as required by your organisation

3. Create a Sequence as required by your organization.
4. Create an Assembly as required by your organization.
5. Application Country Attributes will support country specific date data since this will vary from country to country.

Planning and Tracking activities will follow standard Calyx RIM processes.