Calyx RIM 7.0 Publishing

Contents

Calyx RIM Publishing **1**

Use eCTD Templates **2**

eCTD Template Files 2

Mapped eCTD Template Profiles 10

Publish Elements in eCTD Templates 15

Module 1 Regional Templates 16

Structured Product Labeling Files 16

Module Studies Folders 16

Study Tagging Files 17

Study Patient Information Folder 17

Study Data Folder 18

Publishing Settings Library Templates **19**

Publishing Settings Library Templates 19

Default Publishing Library Settings Template 19

Publishing Settings Library and License Modules 21

Publishing Settings Libraries and Security Permissions 21

Assembly Specific Publishing Settings Libraries 22

Create a Publishing Settings Library 23

Create a Publishing Settings Library Template from an Existing PLT 23

Special Sheet Publishing Settings 24

Special Sheets 24

Move Special Sheets 25

Special Sheets Commands 25

Promote or Demote a Special Sheet 25

Overlay Templates 25

Overlay Template File 26

Change an Overlay for a Document, Cover Page, or TOC 28

Modify an Existing Overlay 28

Hide Headers and Footers with an Overlay 29

Page Markers....29
Insert a Page Marker....29
Page Marker Attributes....29
Modify Publishing Settings Library Templates....30
Create Publishing Settings....30
XML Definition File Version Updates....31
Publishing Settings Attributes....32
XML Definition File Publishing Settings....33
Update eCTD XML Definition File Selections....33
eCTD Publishing Settings....34
Modify Default Publishing Values....34
Default Publishing Values Attributes....35
Default Study Folder....35
Default Study Folder Attributes....36
About PDF Properties....36
Add or Modify PDF Properties....37
Delete a PDF Property....38
PDF Property Attributes....38
Volumize....39
Define or Modify Volume Settings....41
Volumes....41
Volume Attributes....41
Bulk Volumization....43
Run a Bulk Volumization....43
Volume Icons....44
Revolumizing....44
Insert Manual Volume Breaks....44
Modify Volumes....45
Move TOCs to Volumes....46
Delete Volumes....46
Delete All Volumes from an Assembly....46

Delete Volumes in Bulk..... 47
Delete Assembly Tree Elements from the Volume Range..... 47
Cover Pages..... 48
Create or Modify Cover Pages..... 49
Cover Page Setting Attributes..... 49
Tabs..... 50
Create or Modify Tabs..... 51
Preview Tabs..... 51
Tab Sheet Attributes..... 52
Tab Attributes..... 52
Slip Sheets..... 53
Create or Modify Slip Sheets..... 53
Modify a Slip Sheet..... 54
Slip Sheet Attributes..... 54
TOCs..... 55
Add or Modify TOCs..... 55
TOC Attributes..... 56
Use TOC Defaults..... 58
Table of Contents Templates..... 59
Specify Element Level TOC Publishing Settings..... 60
Resolve Entries in TOCs..... 60
TOC Entries that Target Leaf, Folder, or Document Elements..... 60
TOC Entries that Target Other Tables of Contents..... 62
TOC Entries that Target Document Bookmarks (Extracts)..... 62
TOC Entries that Target Planned and Not Ready to Publish Assembly Elements..... 62
TOC Entries that Target Native Leafs and Descendents..... 63
Invalid Targeted Assembly Elements..... 64
Tables of Contents..... 64
Insert a TOC..... 65
Modify TOC Attributes..... 66
Modify a TOC..... 66

Select Contiguous TOC Nodes....67
Select Non-contiguous TOC Nodes....67
TOC Context Menu Options....67
Deactivate a TOC Entry....68
Modify TOC Entry Text....68
View TOC Entry Text....68
Duplicate a TOC....70
Delete a TOC....70
Move TOCs....70
Generate a TOC Manually....70
Generate a TOC Using Prepare to Publish....71
Preview TOC....71
Modify Generated TOC....72
Bookmarks....72
TOC Entry Links....82
Overlay Settings....82
Create or Modify Overlays....82
Overlay Attributes....83
Publication Variables....85
Delimiters....85
Create or Modify Variables....85
Delete a Publish Variable....86
Variable Attributes....86
Link Profiles and the System Profile....87
System Profile and Hyperlinks....87
PLT Link Options....88
Create or Modify Link Profiles....88
Link Profiles Attributes....89
Mass Insert/Update Publishing Elements....90
Insert a Publish Element....90
Delete a Publish Element....91

Types of Publish Variables....93
Variable Values....93
Variable Code Delimiters....93
Literal Text....93
Simple Variable Values....94
Formatted Variable Values....94
Variable Formats, Names, and Parameters....94
Date and Time Patterns....96
Multi-Line Variables....99
Variable Code Orientation....100
Multiple Values Within a Range....101
Multi-line Variable Alignment....101
Font Format in Multi-Line Variables....102
Line Breaks in Multi-Line Variables....102
Variables Within Variables....103
User-defined Variable Values....104
Calyx RIM Assembly Variable Values....105
Repository Variable Values....107
Publishing Elements and Effects....108
Assemblies....109
Assemblies....109
Assembly Templates....110
Create an Assembly Template....110
Create an Empty Assembly Template....110
Create an Assembly Template from a Template, Assembly, or View....111
Use the Search Tab to Locate an Assembly....112
Create an Assembly Template from an Assembly File....113
Create an Assembly Template from a Virtual Document....113
Assembly Template Attributes....114
Modify an Assembly Template....116
Delete an Assembly Template....116

Create an Assembly..... 117
New Assembly Created from a Template or an Assembly..... 117
New Assembly Created from an Assembly File..... 117
Standalone Assemblies..... 118
Create an Empty Standalone Assembly..... 118
Creating a Standalone Assembly from a Template, Assembly, or View..... 119
Create a Standalone Assembly from an Assembly File..... 120
Create a Standalone Assembly from a Virtual Document..... 120
Sequence Assemblies..... 121
Create an Empty Sequence Assembly..... 121
Create a Sequence Assembly from a Template, Assembly, or View..... 122
Create a Sequence Assembly from an Assembly File..... 123
Create a Sequence Assembly from a Virtual Document..... 124
Create Assemblies Based on Sequences..... 124
eCTD Assemblies..... 125
Import an Assembly Template..... 126
Supporting Assemblies..... 126
Create a Supporting Sequence Assembly..... 126
Assembly Attributes..... 127
Assembly Elements Context Menu..... 129
Auto Populate Output Folder..... 136
Modify Assembly Attributes..... 137
Assembly Structure..... 137
Assembly Structure Table..... 138
Automatic Leaf Creation..... 138
Reference Leaf Elements..... 139
Folder Elements..... 139
Add a Folder..... 140
Modify A Folder..... 140
Folder Attributes..... 140
Folder Element Type Attributes..... 141

Folder Element Types....142
Modify a Folder Element Type....142
Duplicate A Folder....142
Lock Folders....142
Lock a Folder....143
Unlock a Folder....143
Delete a Folder....143
Leaf Elements....144
Add a Leaf....144
Leaf Auto-Creation....144
Attribute Values for Auto-Created Leafs....145
Define Document Attributes in the `propertyMappings.xml` File....145
Document Attributes taken from Veeva DMS....147
Modify Leaf Elements....147
Modify a Leaf Element....148
Leaf Attributes....148
Duplicate a Leaf....150
Convert a Leaf to a Reference Leaf....150
Convert a Reference Leaf to a Standard Leaf....151
Deleted Leafs....151
Delete a Leaf....152
Reorder Leafs....152
Leaf Ordering Rules....152
Reorder Leafs....155
Add a Leaf PDF Property....155
Leaf PDF Property Attributes....156
Document Elements....157
Document Attributes....158
Document Placeholders....160
Document Binding....160
Modify Document Binding Rules for a Document Range....160

Apply Binding to All Children 161
Lock Binding 161
Reference Locations 162
Assign Documents 162
DMS Browse 163
DMS Browse Icons - Tree View 164
DMS Browse - Grid View 167
DMS Browse - Documents Tab 168
DMS Search 169
Assign a Document 174
Drag-and-Drop Documents from a Veeva Window 175
Drag-and-Drop Documents from a D2/LSRD Window 176
Assign a Virtual Document 177
Add a Document Placeholder 177
Locate Documents 178
Search for Documents 178
Create Missing Renditions and Extractions 179
Rules for a Veeva DMS Document Bound to the Standard Rendition Identifier 179
Rules for a File Share or for a Documentum Document Bound to the Standard Rendition Identifier 180
Missing Rendition Identifier Handling for a Documentum Document 180
Missing Rendition Identifier Handling for a Veeva Document 181
Create Missing Renditions and Extractions 181
Force New Renditions and Extractions 181
Force Renditions and Extractions with Rendition Identifiers 182
Force New Renditions and Extractions 182
Multiple Renditions Support 183
Document List Query 183
Generate a Document List Query 183
Select Document List Columns for Display 184
Document List Query Results 185
Document Status Indicators 186

Synchronize Document Attributes..... 187
Synchronize Documents with the DMS..... 187
View an Assigned Document..... 188
View Document Versions..... 188
Related Documents..... 188
Unassign Documents..... 189
Submission Readiness Report..... 189
Generate a Submission Readiness Report..... 190
View the Assembly Document List..... 190
Modify Document and Placeholder Attributes..... 191
Modify Document Attributes..... 191
Mass Update Properties..... 192
About Mass Update Properties..... 192
Apply Mass Update Properties..... 193
Apply Mass Update Properties - Extension..... 194
Apply Mass Update Properties - Extension Attributes..... 195
Mass Update Properties: Common Attributes..... 196
Mass Update Properties: Document/Placeholder Attributes..... 198
Mass Update Properties: Leaf Attributes..... 198
Mass Update Properties: Reference Leaf Attributes..... 200
Mass Update Properties: Folder Attributes..... 201
Move Assembly Elements..... 202
Move Assembly Elements Table..... 203
Move an Assembly Element..... 203
Move Leafs That Are Siblings in a Folder..... 203
Move Leafs That Are in Different Folders..... 204
Move Folders That Are Siblings in a Folder..... 204
Move Folders That Are in Different Folders..... 204
Move Different Element Types in Different Folders..... 205
New Assembly Tree..... 205
New Assembly Tree: Features..... 205

Assembly Tree..... 207
Move Assembly Elements Within an Assembly Tree..... 207
Move Volume and TOC onto Assembly Tree Elements..... 208
Move a Volume onto Assembly Tree Elements..... 208
Move a TOC onto Assembly Tree Elements..... 208
Add Assembly Elements from DMS Browse and Browse Assembly Windows..... 209
Assembly Tree Filter..... 209
Filter Assembly Tree Elements..... 212
Advanced Assembly Tree Filter..... 212
Advanced Assembly Tree Filter for all Nodes..... 212
Advanced Assembly Tree Filter for Folders..... 212
Advanced Assembly Tree Filter for Leafs..... 213
Advanced Assembly Tree Filter for Documents..... 213
Import Assemblies..... 213
Import Assembly Wizard..... 215
Search for an Assembly..... 216
Notes on Search for an Assembly..... 216
Assembly Baselines..... 216
View an Assembly Baseline..... 217
Replace Assembly Variables..... 217
Replace an Assembly Variable..... 218
Replaceable Assembly Variables..... 218
Lock Assemblies..... 219
eCTD and Standard Locks..... 219
Lock Volume Ranges..... 220
Lock a Volume Range..... 220
Unlock a Volume Range..... 220
Update Assembly Status..... 220
Update an Assembly Status..... 221
View an Assembly..... 221
Assembly Toolbar Icons..... 222

Export Assemblies..... 224
Export an Assembly.....224
Export an Assembly to Excel..... 225
Export an Assembly to a Virtual Document..... 226
Export to an Assembly File (XML).....227
Delete Assemblies.....227
Deleted Assemblies and Assembly Specific Publishing Settings Library (APL) 227
View Activities List.....228
Recalculate Checksums.....228
Prepare Cross-Reference Leafs.....229
Working Assemblies and Assembly Specific Publishing Settings Library (APL) 229
Lifecycle..... 230
Lock Sequence Assemblies.....231
Manually Lock an Assembly.....231
Add Sequence Assemblies to Lifecycle.....233
Add Sequence to Lifecycle..... 234
Remove Multiple Sequences from a Lifecycle.....234
Working Assemblies..... 235
Create A Working Assembly.....235
Modify Leaf Elements in the Working Assembly..... 236
Update a Working Assembly..... 238
Reorganize a Lifecycle Assembly.....238
Add Subsequent Sequences to Lifecycle..... 238
Modify Submission Statuses..... 240
Modify a Submission Status..... 240
View Submitted Sequences.....241
Manage Concurrently Planned Sequences..... 241
Generate an Assembly Comparison Query..... 242
Update an Unsubmitted Planned Sequence.....243
Parallel Submissions.....243
Synchronize Current Working View or Initial Assembly with Latest Submitted View.....243

Conflicting Operations Rules - Synchronization with Submitted View..... 244
Parallel Lifecycle..... 246
View Parallel Lifecycle..... 246
Submissions..... 247
Submissions..... 247
Submission Wizard Administrative Prerequisites..... 247
Create Submission Wizard..... 248
Initial Application Submission..... 248
Create an Initial Application Submission..... 249
Initial Application Submission Attributes..... 251
Major Update Submission..... 254
Create a Major Update Submission..... 254
Major Update Submission Attributes..... 256
Amendment Submission..... 257
Create an Amendment Submission..... 257
Amendment Submission Attributes..... 259
Create eCTD Wizard..... 260
Null Value and Swiss eCTD Assemblies..... 261
Create eCTD Submission..... 261
Add Metadata to Assembly..... 263
eCTD Attributes Australia..... 264
eCTD Attributes Canada..... 268
eCTD Attributes China..... 268
eCTD Attributes EAEU..... 269
eCTD Attributes European Union..... 270
eCTD Attributes Gulf Cooperation Council..... 273
eCTD Attributes Japan..... 275
eCTD Attributes Jordan..... 275
eCTD Attributes Switzerland..... 277
eCTD Attributes South Africa..... 281
eCTD Attributes Thailand..... 283

eCTD Attributes United States..... 284
Repeatable Assembly Sections.....286
Submission Metadata..... 286
Create Study Reports.....287
Use the Create Study Report Wizard.....287
Publish Submissions..... 289
EAEU Submissions Publish.....289
Electronic Publish..... 289
Paper Publish.....290
Publish Guidelines..... 290
General Publish Considerations.....291
PDF File Format..... 292
Document Structure..... 292
Major and Minor Divisions.....293
Page Size and Overlays..... 294
Publish Links.....295
Cross-References..... 295
Margin Stamp..... 296
Prepare to Publish..... 296
Run Prepare to Publish.....296
Cancel Prepare to Publish.....298
Maximum Job Message Length..... 299
Publishing Summary Query..... 299
Generate a Publishing Summary Query..... 299
Publishing Readiness Query..... 299
Publishing Readiness Query Filters..... 300
Publishing Readiness Query Attributes..... 301
Generate a Publishing Readiness Query..... 304
Browse for an Assembly..... 305
Publishing Requests.....305
Publish Job Requests..... 306

Submit an Electronic Publishing Request....306
Submit a Paper Publishing Request....308
Publish Commands and Volumes....309
Publishing Leaf Elements....310
After Submitting a Publishing Request....311
Viewing a Publishing Request....311
Publishing Request Results....312
View a Job Message....313
Cancel Publishing Requests....313
Cancel a Publishing Request....314
Export Submissions....314
Export a Published Submission....314
About Distribute Published Output as Rendition....315
Export a Source File to a Destination File as a Rendition....316
Review an eCTD....316
View XML in Internet Explorer....317
View Study Tagging Files (STFs)....317
Grouped Submissions....319
Submission Plans....319
Create Submission Plan Wizard....320
Create Submission Plans....322
Modify Submission Plans....322
Delete Submission Plans....323
Submission Plan Attributes....324
Assembly Plans....324
Create Assembly Plans....325
Modify Assembly Plan Attributes....325
Delete Assembly Plans....326
Lifecycle Operations in Assembly Plan....326
Associate Applications to Submission Plans....326
Attributes used while associating application....327

Disassociate Applications from Submission Plans..... 327
Associate Sequences to Submission Plans..... 328
Disassociate Sequences from Submission Plans..... 329
Associate Events to Submission Plans..... 329
Disassociate Events from Submission Plans..... 330
Use the Ready for Submission Wizard..... 330
Order of the copied elements in the target Assembly..... 332
Publishing Messages (Troubleshooting)..... 334
Repository Messages..... 334
Assembly Messages..... 334
Folder Messages..... 336
Leaf Messages..... 336
Document Messages..... 339
Page Marker Messages..... 341
TOC Messages..... 342
Cover Page Messages..... 342
Special Sheet Messages..... 342
Volume Messages..... 343
Checksum Messages..... 343
Other Messages..... 344
Linking..... 346
Authoring Links..... 346
Lifecycle Links..... 346
Create In-Process Lifecycle Links..... 347
Reference Leafs and Hyperlinks Between Applications..... 347
Reference Leafs..... 347
Hyperlinks..... 348
Post-Publishing Links..... 348
In-Process Links..... 349
Create In-Process Links..... 350
Comment Links..... 350

Linking Tools..... 350
Calyx RIM Link Types..... 352
Business Service Requests Sequence Example..... 352
Copy Links Between Assemblies..... 353
Get Started with Linking add-in (Word) 353
Modify In-Process Links..... 354
Link to Assembly Elements..... 354
Creating a Comment Link..... 355
Save Links to Calyx RIM..... 355
Modify Bookmarks..... 356
Modify a Bookmark..... 356
Link Inspector Query..... 357
Refresh the Link Inspector Query..... 358
Run the Link Inspector Query..... 358
Link Inspector Action Buttons..... 358
Link Statuses..... 359
View the Link Inspector Query..... 362
Character Encoding Status..... 364
Link Applicability..... 364
Extension Types and Usage..... 367
Extension Type: General Folders..... 368
Extension Type: Regional Folders..... 372
Extension Type:Leaf Types..... 399
Extended Attributes Name, Type, and Version..... 402
Assembly Node Creation by API Request..... 406
Calyx RIM Publishing Best Practices..... 407
Index..... 409

Calyx RIM Publishing

Calyx RIM Publishing enables you to create a complete submission package.

— Use submissions wizards to streamline the initiation of submissions that comply with ICH, Japanese, EU, US, STF, GCC, Swiss, AU, TH, Canadian, JO, CN, and EAEU specifications.

— Quickly create all the necessary components for a paper submission, compliant NeeS, or compliant eCTD submission, including the required ICH, STF, and regional XML files, the correctly named leaf files and folder structures, and any requisite navigation aids.

— Easily manage subsequent amendments, supplements and variations to your submissions using intuitive right-click menu options and simple drag-and-drop features, making all updates in the context of the full application.

— Create multiple submissions in multiple regions using comprehensive, built-in templates.

— Automatically transform documents in multiple file formats into enhanced PDFs with bookmarks and hyperlinks.

— Move seamlessly from product registration management to submissions management to publishing your submission to tracking your data.

— Enhance the efficiency of your organization, reduce your time to market, and be assured of compliance with the latest regulatory guidelines and specification.

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Use eCTD Templates

The eCTD templates include every leaf that can be included according to the ICH and regional specifications defined in the DTDs and the ICH granularity document.

You can easily modify the assemblies that use the template by deleting the unnecessary folders and leaf elements or adding additional leaf elements if more granularity is desired. Typical ways to use the eCTD templates include:

— Creating an assembly using the Create eCTD Wizard that is mapped to the Module 1 and eCTD ICH Module 2-5 template.
— Creating an assembly using a module 1 template, and then importing additional modules from the eCTD ICH Module 2-5 template.
— Creating a template based on a module 1 template, with the eCTD ICH Module 2-5 template imported and subsequently creating assemblies using this template.
— Creating an assembly using the eCTD ICH Module 2-5 template, and then importing the module 1 folder from an m1 template.

The following topics provide information about the specific eCTD templates provided with Calyx RIM.

eCTD Template Files

Calyx RIM includes ICH-compliant eCTD templates with preconfigured folder types to capture the metadata for the specific headings in the eCTD that require additional information: drug substance, drug product, excipient, clinical indication, and regional administrative information.

To ensure that you have the most current version of each listed template file on your system, refer to the New/Updated column in the table. This column contains information about the template status for each version in the Calyx RIM7.0 branch:

— **No** - template was not updated
— **Yes** - template was updated
— **New** - template is new with this Calyx RIM version
— Blank - template did not exist for the release

Template	New/Updated
templates\510k Template (Sep 2019).xml	Yes
\templates\510k template.xml	No
\templates \A4SampleTOCTemplate.docx	No

Template	New/Updated
\templates\ASEAN ACTD-NeeS.xml	No
\templates\AU eCTD Module 1 v0.90.xml	No
\templates\AU eCTD Module 1 v3.0.xml	No
\templates\AUS Module 1 CTD v2.1.xml	No
\templates\AUS Module 1 CTD-NeeS v2.0 2011.xml	No
\templates\AU Module 1 eCTD v3.1.xml	No
\templates\AU Module 1 NeeS v2.0.xml	No
\templates\Canadian eCTD Module 1 v1.0.xml	No
\templates\Canadian eCTD Module 1 v2.2.xml	No
\templates\Canadian electronic CTA CTA-A-29-May-2013.xml	No
\templates\Canadian electronic CTA.xml	No
\templates\CH eCTD Module 1 v1.0.1.xml	No
\templates\CH eCTD Module 1 v1.1.xml	No
\templates\CH eCTD Module 1 v1.2.xml	No
\templates\CH eCTD Module 1 v1.3.xml	No

Template	New/Updated
\templates\CH eCTD Module 1 v1.4.xml	No
\templates\CH eCTD Module 1 v1.5.xml	No
\templates\CN eCTD Module 1 v1.0.xml	No
\templates\CN eCTD ICH Module 2-5 v3.2.xml	No
\templates\CN Clinical Study Report (VV5-0).xml	No
\templates\CN Nonclinical Study Report (SEND Dataset).xml	No
\templates\CN Nonclinical Study Report.xml	No
\templates\eCTD ICH Module 2-5 v3.2.xml	No
\templates\EAEU Template v1.0.xml	No
\templates\EU CTA.xml	No
\templates\EU eCTD Module 1 v1.0 - CP.xml	No
\templates\EU eCTD Module 1 v1.0 - MRP-DCP.xml	No
\templates\EU eCTD Module 1 v1.0 - NP.xml	No
\templates\EU eCTD Module 1 v1.1 - CP.xml	No

Template	New/Updated
\templates\EU eCTD Module 1 v1.1 - MRP-DCP.xml	No
\templates\EU eCTD Module 1 v1.1 - NP.xml	No
\templates\EU eCTD Module 1 v1.2.1 - CP.xml	No
\templates\EU eCTD Module 1 v1.2.1 - MRP-DCP.xml	No
\templates\EU eCTD Module 1 v1.2.1 - NP.xml	No
\templates\EU eCTD Module 1 v1.3 - CP.xml	No
\templates\EU eCTD Module 1 v1.3 - MRP-DCP.xml	No
\templates\EU eCTD Module 1 v1.3 - NP.xml	No
\templates\EU eCTD Module 1 v1.4 - CP.xml	No
\templates\EU eCTD Module 1 v1.4 - MRP-DCP.xml	No
\templates\EU eCTD Module 1 v1.4 - NP.xml	No
\templates\EU eCTD Module 1 v2.0 - CP.xml	No

Template	New/Updated
\templates\EU eCTD Module 1 v2.0 - MRP-DCP.xml	No
\templates\EU eCTD Module 1 v2.0 - NP.xml	No
\templates\EU eCTD Module 1 v3.0 - CP.xml	No
\templates\EU eCTD Module 1 v3.0 - MRP-DCP.xml	No
\templates\EU eCTD Module 1 v3.0 - NP.xml	No
\templates\EU eCTD Module 1 v3.0.1 - CP.xml	No
\templates\EU eCTD Module 1 v3.0.1 - MRP-DCP.xml	No
\templates\EU eCTD Module 1 v3.0.1 - NP.xml	No
\templates\EU eCTD Module 1 v3.0.3 - CP.xml	No
\templates\EU eCTD Module 1 v3.0.3 - MRP-DCP.xml	No
\templates\EU eCTD Module 1 v3.0.3 - NP.xml	No
\templates\EU IMPD template.xml	No
\templates\EU PMF Submission in eCTD.xml	No

Template	New/Updated
\templates\EU VNeeS - Immunological.xml	No
\templates\EU VNeeS - Pharmaceutical.xml	No
\templates\EU VNeeS v2.2 - Immunological.xml	No
\templates\EU VNeeS v2.2 - MRL Maximum Residue Limits.xml	No
\templates\EU VNeeS v2.2- Pharmaceutical.xml	No
\templates\EU VNeeS v2.3 - Immunological.xml	No
\templates\EU VNeeS v2.3 - MRL Maximum Residue Limits.xml	No
\templates\EU VNeeS v2.3- Pharmaceutical.xml	No
\templates\GCC eCTD Module 1 v1.2 - GCC.xml	No
\templates\GCC eCTD Module 1 v1.2 - NP.xml	No
\templates\GCC eCTD Module 1 v1.5 - GCC.xml	No
\templates\GCC eCTD Module 1 v1.5 - NP.xml	No
\templates\HR eCTD Module 1 v1.4 - NP.xml	No

Template	New/Updated
\templates\ICH E3 Clinical Study Report (VV2-2).xml	No
\templates\ICH E3 Clinical Study Report (VV3-0).xml	No
\templates\ICH E3 Clinical Study Report (VV5-0).xml	No
\templates\JO eCTD Module 1 v1.0.xml	No
\templates\JP eCTD Module 1 v1.0.xml	No
\templates\JP eCTD Module 2-5 v3.2.xml	No
\templates\MD - IMDRF (HC) IVD Template.xml	Yes
\templates\MD - IMDRF nIVD Template.xml	Yes
\templates \Nonclinical Study Report (SEND Dataset).xml	No
\templates \Nonclinical Study Report.xml	No
\templates\PMA Template (Feb 2019).xml	Yes
\templates\PMA Template.xml	No
\templates\ROW CTD Module 1.xml	No

Template	New/Updated
\templates \SampleCoverPageTemplate.docx	No
\templates \SampleOverlayTemplate.docx	No
\templates \SampleTOCTemplate.docx	No
\templates\Saudi Arabia CTD Module 1 v1.0.xml	No
\templates\TH eCTD Module 1 v0.92.xml	No
\templates\TH eCTD Module 1 v1.0.xml	No
\templates \UCSampleCoverPageTemplate.docx	No
\templates \UCSampleOverlayTemplate.docx	No
\templates \UCSampleTOCTemplate.docx	No
\templates\US eCTD Module 1 v2.01.xml	No
\templates\US eCTD Module 1 v3.3.xml	No
\templates\ZA eCTD Module 1 v1.0.xml	No
\templates\ZA eCTD Module 1 v2.1.xml	No

Sample Templates

Calyx RIM includes additional assembly templates to enable the creation of reports or other electronic submission types. The following templates are samples for the publishing finishing options for overlays, Tables of Contents

(TOC), and cover pages. Unicode (UC) templates for TOC, cover pages, and overlays are available (for A4 paper size).

— A4SampleTOCTemplate.docx
— SampleCoverPageTemplate.docx
— SampleOverlayTemplate.docx
— SampleTOCTemplate.docx
— UCSampleCoverPageTemplate.docx
— UCSampleOverlayTemplate.docx
— UCSampleTOCTemplate.docx

Mapped eCTD Template Profiles

The standard mappings are used to configure eCTD templates and specifications with metadata entered in the wizards.

US

Region Abbreviation	Template Profile Name	Mapped Template Pair
US	U.S. 3.3 National (default)	US eCTD Module 1 v3.3 eCTD ICH Module 2-5 v3.2
	U.S. 2.01 National	US eCTD Module 1 v2.01 eCTD ICH Module 2-5 v3.2

EAEU

Region Abbreviation	Template Profile Name	Mapped Template Pair
EAEU	EAEU 1.0	EAEU Template v1.0

EU

Region Abbreviation	Template Profile Name	Mapped Template Pair
EU	E.U. 3.0.3 Centralised (default)	EU eCTD Module 1 v3.0.3 - CP eCTD ICH Module 2-5 v3.2
	E.U. 3.0.3 Mutual Recognition	EU eCTD Module 1 v3.0.3 - MRP-DCP eCTD ICH Module 2-5 v3.2
	E.U. 3.0.3 Decentralised	EU eCTD Module 1 v3.0.3 - MRP-DCP eCTD ICH Module 2-5 v3.2
	E.U. 3.0.3 National	EU eCTD Module 1 v3.0.3 - NP eCTD ICH Module 2-5 v3.2
	E.U. 3.0.1 Centralised	EU eCTD Module 1 v3.0.1 - CP eCTD ICH Module 2-5 v3.2
	E.U. 3.0.1 Mutual Recognition	EU eCTD Module 1 v3.0.1 - MRP-DCP eCTD ICH Module 2-5 v3.2
	E.U. 3.0.1 Decentralised	EU eCTD Module 1 v3.0.1 - MRP-DCP eCTD ICH Module 2-5 v3.2
	E.U. 3.0.1 National	EU eCTD Module 1 v3.0.1 - NP eCTD ICH Module 2-5 v3.2
	E.U. 3.0 Centralised	EU eCTD Module 1 v3.0 - CP eCTD ICH Module 2-5 v3.2
	E.U. 3.0 Mutual Recognition	EU eCTD Module 1 v3.0 - MRP-DCP eCTD ICH Module 2-5 v3.2
	E.U. 3.0 Decentralised	EU eCTD Module 1 v3.0 - MRP-DCP eCTD ICH Module 2-5 v3.2
	E.U. 3.0 National	EU eCTD Module 1 v3.0 - NP eCTD ICH Module 2-5 v3.2
	E.U. 2.0 Centralised	EU eCTD Module 1 v2.0 - CP eCTD ICH Module 2-5 v3.2
	E.U. 2.0 Mutual Recognition	EU eCTD Module 1 v2.0 - MRP-DCP eCTD ICH Module 2-5 v3.2
	E.U. 2.0 Decentralised	EU eCTD Module 1 v2.0 - MRP-DCP eCTD ICH Module 2-5 v3.2

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CAN

Region Abbreviation	Template Profile Name	Mapped Template Pair
CAN	Canada 2.2 National (default)	Canadian eCTD Module 1 v2.2 eCTD ICH Module 2-5 v3.2
	Canada 1.0 National	Canadian eCTD Module 1 v1.0 eCTD ICH Module 2-5 v3.2

JAP

Region Abbreviation	Template Profile Name	Mapped Template Pair
JAP	Japan 1.0 National (default)	JP eCTD Module 1 v1.0 JP eCTD Module 2-5 v3.2

Jordan

Region Abbreviation	Template Profile Name	Mapped Template Pair
JO	JO 1.0 National (default)	JO eCTD Module 1 v1.0 eCTD ICH Module 2-5 v3.2
	JO 1.1 National (default)	JO eCTD Module 1 v1.1 eCTD ICH Module 2-5 v3.2

CH

Region Abbreviation	Template Profile Name	Mapped Template Pair
CH	Swiss 1.5 National (default)	CH eCTD Module 1 v1.5 eCTD ICH Module 2-5 v3.2
	Swiss 1.4 National	CH eCTD Module 1 v1.4 eCTD ICH Module 2-5 v3.2
	Swiss 1.3 National	CH eCTD Module 1 v1.3 eCTD ICH Module 2-5 v3.2
	Swiss 1.2 National	CH eCTD Module 1 v1.2 eCTD ICH Module 2-5 v3.2
	Swiss 1.1 National	CH eCTD Module 1 v1.1 eCTD ICH Module 2-5 v3.2

CN

Region Abbreviation	Template Profile Name	Mapped Template Pair
CN	CN 1.0 National (default)	CN eCTD Module 1 v1.0 CN eCTD ICH Module 2-5 v3.2

GCC

Region Abbreviation	Template Profile Name	Mapped Template Pair
GCC	GCC 1.5 National (default)	GCC eCTD Module 1 v1.5 - NP eCTD ICH Module 2-5 v3.2
	GCC 1.5 GCC	GCC eCTD Module 1 v1.5 - GCC eCTD ICH Module 2-5 v3.2
	GCC 1.2 National	GCC eCTD Module 1 v1.2 - NP eCTD ICH Module 2-5 v3.2
	GCC 1.2 GCC	GCC eCTD Module 1 v1.2 - GCC eCTD ICH Module 2-5 v3.2

ROW

Region Abbreviation	Template Profile Name	Mapped Template Pair
ROW	Rest Of World (default)	ROW CTD Module 1.0 eCTD ICH Module 2-5 v3.2

UNDEFINED

Region Abbreviation	Template Profile Name	Mapped Template Pair
UNDEFINED	Undefined (default)	ROW CTD Module 1 eCTD ICH Module 2-5 v3.2

HR

Region Abbreviation	Template Profile Name	Mapped Template Pair
HR	Croatia 1.4 National (default)	HR eCTD Module 1 v1.4 eCTD ICH Module 2-5 v3.2

TH

Region Abbreviation	Template Profile Name	Mapped Template Pair
TH	TH 1.0 National (default)	TH eCTD Module 1 v1.0 eCTD ICH Module 2-5 v3.2
	TH 0.92 National	TH eCTD Module 1 v0.92 eCTD ICH Module 2-5 v3.2

AU

Region Abbreviation	Template Profile Name	Mapped Template Pair
AU	AU 3.1 National (default)	AU eCTD Module 1 v3.1 eCTD ICH Module 2-5 v3.2
	AU 3.0 National	AU eCTD Module 1 v3.0 eCTD ICH Module 2-5 v3.2
	AU 0.90 National	AU eCTD Module 1 v0.90 eCTD ICH Module 2-5 v3.2

ZA

Region Abbreviation	Template Profile Name	Mapped Template Pair
ZA	ZA 2.1 National (default)	ZA eCTD Module 1 v2.1 eCTD ICH Module 2-5 v3.2
	ZA 1.0 National	ZA eCTD Module 1 v1.0 eCTD ICH Module 2-5 v3.2

Publish Elements in eCTD Templates

The publishing elements are designed to facilitate the production of CTD paper and Non-electronic eCTD (NeeS). The folder and leaf types that you assign in an eCTD assembly are based on the current ICH and regional eCTD specification. These element types enable you to record eCTD-specified metadata attributes.

The eCTD templates also include sample publishing elements, including tables of contents, cover pages, slip sheets, tabs, overlays, and all applicable publishing settings.

In addition, the E3 Clinical Study Report template contains the elements necessary to generate a standard CSR publication.

Module 1 Regional Templates

Module 1 of the eCTD contains regional content and metadata about a submission, as defined by the regional regulatory authorities. Each regional template has special XML fields and attributes in the Module 1 folder to capture this additional metadata.

In addition, the EU requires envelope information for each country to which you are sending the submission. For each envelope, you create a folder to capture the relevant envelope information for each country under the EU Envelope Information leaf. Envelope folders are included in the EU Module 1 templates.

When an assembly is created using the Create eCTD Wizard, the wizard filters the template to only display structure for the countries already associated with that sequence.

Structured Product Labeling Files

Structured Product Labeling (SPL) files contain product labeling information in a structured XML format.

You can add these files to an assembly and specify whether they should be published in their native file format (`.xml`) or in PDF renditions. This includes the XML documents that reference style sheets, if the style sheets are located where they can be referenced by the XML.

You should place `.spl` files in a folder named SPL in the appropriate labeling folder according to the electronic labeling specification.

Module Studies Folders

The `Module 4` and `Module 5` folders are set as `Module Studies` folders. These folders include extra attributes that enable you to control how studies in that module are handled in the published XML and folder structure.

When a Study Folder is included in the assembly, Calyx RIM uses the setting at the Module level to determine whether it should create a Study Tagging File (STF), node-extension, or only the leaf elements of the study. You can also choose whether Calyx RIM should create a subfolder for the study content in the output.

When Create Study Folders is set to Yes, Calyx RIM uses the Study Folder name to create an additional folder in the output and places all the content for that study in the folder.

When STFs or node-extensions are created, the Study Folder Name is also used for the value of the *<leaf>* or *<node-extension>* title. If long values are used for the Folder Names, while shorter values are needed for the output folder name, the Create Study Folder option can be set to No, and the Study Folder Output Folder attribute populated with the shorter value.

Study Tagging Files

Study Tagging Files (STF) help identify files associated with a study and are required for U.S. submissions. Some of this information is included in the eCTD backbone, however, the STF provides more information on the content of these documents.

The eCTD templates provide two assembly element types to capture STF information:

— Study report folders capture the overall study information. This information is published as the study-information in the STF XML.

— Study report leaf elements capture the subject matter to be used as the value for the file-tag name in the study-document portion of the STF XML.

Different folder and leaf types contain special attributes that are incorporated into the STF XML when you publish the submission. Each leaf in the templates has the Subject Matter value populated according to the STF specification. If you use DMS mapping to populate the eCTD, you can map STF-related attributes to repository attributes.

Sample study report structures are included in the ICH eCTD template for Module 4 (section 4.2.1.1) and Module 5 (section 5.3.1.1). These examples are preconfigured with the expected subject matter values. You can duplicate these folders in an assembly and remove any unnecessary components on a study-by-study basis. Alternatively, studies can be added using the *Create Study Report* Wizard. All sections in Module 4 are mapped to the Nonclinical Study Report. All sections in Module 5 are mapped to the ICH E3 Clinical Study Report template. You can configure the wizard to use different study report templates for each lowest-level section in Modules 4 and 5, if different structures are used for different study types.

Two special element types provided with Calyx RIM are set in the template for CRFs and Datasets to make them easier to use. They are Study Patient Information and Study Data.

Study Patient Information Folder

Use the `Study Patient Information` folder type for case report forms and subject profiles for which the STF specification requires additional site information.

This folder type is applied to the `Case Report Forms` and `Subject Profiles` folders in the template and allows all child leaf elements to inherit the Subject Matter, preventing the need to enter the Subject Matter for each CRF or subject profile.

Adding Site folders to organize the CRFs and Subject Profiles enables Calyx RIM to automatically use the name of the `Site` folder to populate the site-identifier information for the child leaf elements during publishing. This completes the portion of the STF that includes those leaf elements and eliminates the need for you to enter this information for each leaf.

Study Data Folder

Use the `Study Data` folder type to organize datasets, which enables you to reset the output location for the folder's child leaf elements according to the FDA Study Data specification.

Datasets are organized in the *<module>*`/datasets` folder in the output rather than with the other components of the study report, so that you can manage them with the study report in the assembly.

The Dataset Type attribute controls the placement of the datasets in the *<module>*`/datasets` folder. Each child leaf element for this type of folder inherits the Subject Matter attribute.

For files that are not datasets, but other supportive files such as the Data Definition tables, the leaf elements included are set as Study Report Leaf elements. Their Subject Matter is populated to override the inheritance from the parent folder.

Publishing Settings Library Templates

Publishing Settings Library Templates

Calyx RIM Publisher provides the ability to create multiple Publishing Settings Library Templates (PLT).
The Calyx RIM Publishing Settings Library separates the publishing settings from the assembly structure, enabling you to control different overlay settings, cover page settings, TOC types, slip sheet settings, and tab settings for use within the assembly.

Publishing Settings Library Templates are stored and are accessible outside of an Assembly. With Calyx RIM licenses for Electronic Lifecycle Publishing and Paper Review Publishing, PLTs can be created, or modified and saved, for use when creating an assembly. Permitted administrators can create and modify PLTs. User roles may have NONE, READ, WRITE, or DELETE permissions for access to Publishing Settings Library Templates.

Default Publishing Library Settings Template

Calyx RIM includes a default Publishing Library Settings Template (PLT) that can be used with its existing settings, or it can be modified to create additional PLTs.
The default Calyx RIM Publishing Library Settings Template includes the following publishing element settings. An asterisk (*) indicates a required field.

Template	Field Name	Value
Publishing Settings Library	Name	Default

Template	Field Name	Value
Publishing Settings	*Printer	Generic PDF
	*Paper Size/Type	Letter
	*Tab paper Size/Type	Plain Letter 5 down Tab
	*Preview Location	blank
	XML Definitions	stf-2-2-5-0
	Default Rendition Identifier	Standard Rendition
	Missing Rendition Identifier Handling	Use Standard Rendition
	In-Process Rendition Location	blank
	TOC Destination Not Found Text	blank
	Cross-Reference Destination Not Found Text	blank
	Expand Bookmarks to Level	All
	PDF Version for Published Output	1.4, Acrobat 5
Volumes	*Volume File Naming Format	$VOLNAME
	*Begin at Volume Number	1
	*Total Sheets/Pages	300
	*Total Sheets/Pages Buffer	50
	Volumize by Size	No
	*Total Size (in MB)	100
	*Buffer Size (in MB)	10
	Volume Numbering	Assembly Relative
	Automatically Create Volume Tables of Contents	No
Link Profiles	*Link Profile Name	System Profile
	Default?	Yes
	*Electronic Hyperlink Style	Underline
	Electronic Hyperlink Color	Blue
	*Margin Cross-Reference Size	blank
	Margin Cross-Reference Text Font Style	blank
	Margin Cross-Reference Text Format	blank

Publishing Settings Library and License Modules

Publishing Settings Library Templates (PLT) are available with varying limitations according to your Calyx RIM license.

— Electronic Lifecycle Publishing (ELP) - PLT is included. Users with WRITE or greater permissions can:
  - create and modify Publishing Library Templates
  - access the Create Application wizard from the Wizards menu.
  - access to Events for the Create Application Wizard from the Wizards menu.

— Paper Review Publishing (PRP) - PLT is included. Users with WRITE or greater permissions can create and modify Publishing Library Templates.

— Submission Planning and Tracking (SPT) - Includes a default PLT that cannot be modified. Only the default PLT is available when creating an assembly. Users with WRITE permissions can access the Create Application Wizard and Events for the Create Application Wizard from the Wizards menu.

— Registered Document Analysis (RDA) - Includes a default PLT that cannot be modified. Only the default PLT is available when creating an assembly.

— Registration Planning and Tracking (RPT) - PLT is not available.

— Product Detail Management (PDM) - PLT is not available.

License Module	Available Tabs
Electronic Lifecycle Publishing (ELP)	— Publishing Settings — Default Values — Default Study Folder — TOCs — Variables — Link Profiles
Paper Review Publishing (PRP)	— Publishing Settings — Volumes — Cover Pages — Tabs — Slip Sheets — TOCs — Overlays — Variables — Link Profiles

Publishing Settings Libraries and Security Permissions

Access to PLTs and APLs is controlled by permission settings assigned to a user (or role) in the system.

Area	Permission Setting	Description
Publishing Settings Library Templates (PLT)	NONE	You have no access to, and cannot view, PLTs in the system.
	READ	You can only view PLTs in the system.
	WRITE	You can create, edit, and view PLTs, and all library elements can be created, edited, and viewed.
	DELETE	You can delete, create, edit, and view a PLT and all library elements.
Home Page Access to PLT	Yes	The PLT tab can be accessed on the Home page.
	No	The PLT tab is not available on the *Home* page. However, PLTs can be accessed via links from APLs, and can be created from the New menu.
Assembly Specific Publishing Library (APL)	NONE	You have no access to, and cannot view, APLs in the system.
	READ	You can only view APLs in the system.
	WRITE	You can create, edit, and view APLs and all library elements. WRITE or higher permissions are required to create a new Assembly and associate an APL. To use a PLT to create an APL, you must have READ or higher permissions on the PLT.
	DELETE	You can delete, create, edit, and view a APL and all library elements. To delete an Assembly, you must have DELETE permission.

Assembly Specific Publishing Settings Libraries

Assembly Specific Publishing Settings Libraries (APL) are created based on a Publishing Settings Library Templates (PLT) or on an APL from another Assembly.

Follow when you create an APL.

— An Assembly must have an associated APL.
— An APL is specific to the assembly that is being published.
— An APL can be saved as a PLT for use with other assemblies.
— A PLT cannot be modified at the assembly level.
— READ or higher system privileges are required to view, create, modify, or delete an APL.

Create a Publishing Settings Library

The Calyx RIM Publishing Settings Library separates the publishing settings from the assembly structure, enabling you to control different overlay settings, cover page settings, TOC types, slip sheet settings, and tab settings for use within the assembly.

To create a Publishing Settings Library Template (PLT) in Calyx RIM:

1. On the New menu, click Publishing Settings Library Template.
2. On the Create Publishing Settings Library page, enter a *Publishing Library Name*.
3. Optionally, add additional details for your new Publishing Library.

   This additional information may be useful search criteria when there are many PLTs in the system.
   - Publishing Library Owner (This field is automatically populated with the creation owner, but can be updated.)
   - Created From (This field is not populated at the Template level.)
   - Publishing Library Keywords
   - Publishing Library Description
   - Publishing Library Add Comment
4. Save.

   Your new Publishing Settings Library appears. The new Publishing Settings Library Template is ready for the publishing settings to be established.

Create a Publishing Settings Library Template from an Existing PLT

In a Paper Review Publishing (PRP) or an Electronic Lifecycle Publishing (ERP) licensed system, users with WRITE or greater permissions can create a new Publishing Settings Library Template (PLT) from an existing Publishing Settings Library Template.

1. On the Calyx RIM *Home* page, click Publishing Templates.
2. Choose an existing PLT in the Publishing Library Name list.
3. On the Publishing Settings Library toolbar, click Create Publishing Settings Library Template.
4. On the *Create Publishing Settings Library Template* page, change the Publishing Library Name for the new template and add additional information as needed.
   - The Publishing Library Name is required.
   - You can include Publishing Library Keywords, Description, and Comment. Existing Keywords and Descriptions are copied from the source PLT, Publishing Library Comments are removed.
5. Save.

   The new Publishing Settings Library Template inherits the publishing settings from the PLT from which it was created. These settings may be modified.

Special Sheet Publishing Settings

When you create a publication, you can insert special sheets, such as table of contents, cover pages, tab sheets, and slip sheets to aid navigation through your submission.

Special sheets can be inserted and deleted, individually or in bulk, where they are needed in the assembly. Special sheet settings control the properties of the paper on which the sheets are printed, and the text or content that pertains to the special sheet.

Special sheets and their settings are linked to the resource file update.

The printer publishing settings you choose control which paper types are available in the special sheets settings. Additionally, the general publishing settings control the preview file location where the tab and TOC preview files are stored.

Publishing settings are specific to the following modules:

— Electronic Lifecycle Publishing (ELP)
— Registered Document Analysis (RDA)
— Submission Planning and Tracking (SPT)
— Paper Review Publishing (PRP)

Special Sheets

Special sheets consist of cover pages, tab sheets, slip sheets, and TOCs. You can insert special sheets to aid navigation through a submission. Special sheets can be inserted individually or in bulk where they are needed in the assembly.

Special sheets settings control the properties of the paper on which the sheets are to be printed, and the text or content. Special sheets and their attributes are linked to the publishing settings for an assembly. The publishing settings control the printer, and therefore the paper types, that are available for printing special sheets.

You can insert special sheets for any of the following:

— Assembly
— Folders
— Leaf elements
— Documents
— Volumes

When you insert a special sheet for an element (for example, a folder), the sheet is inserted for all children of the element that meet the criteria of the chosen element type.

When adding special sheets in bulk, any leaf marked as a native file leaf or reference leaf is ignored. Special sheets cannot be added to native file leaf elements or reference leaf elements, and are ignored during publishing.

After inserting special sheets, click Volume to refresh the *Volume Special Sheets* pane and display the inserted special sheets.

Move Special Sheets

You can promote and demote cover pages, tabs, slip sheets, and TOCs that are assigned to assembly elements. Following assembly elements are:

— Assembly
— Folder
— Leaf elements
— Documents
— Page markers

Special Sheets Commands

You can reorganize the elements in the assembly tree. You can move elements up and down, and you can promote and demote elements.

Command	Description
Move Up	Moves an element to a location above its current position in the assembly tree, one position at a time.
Move Down	Moves an element to a location below its current position in the assembly tree, one position at a time.
Promote	Moves an element one level to the left in the assembly tree hierarchy.
Demote	Moves an element one level to the right in the assembly tree hierarchy.
Delete	Removes an element from the assembly tree structure; does not delete a document from the repository.

Promote or Demote a Special Sheet

You can promote a special sheet to earlier in the assembly, or demote a special sheet to later in the assembly.

Right-click the special sheet you want to move and choose one of the following:

Option	Description
Move Left:	Promotes the special sheet by moving it to the left.
Move Right:	Demotes the special sheet by moving it to the right.

The special sheet moves to the left or right of the adjacent element.

Overlay Templates

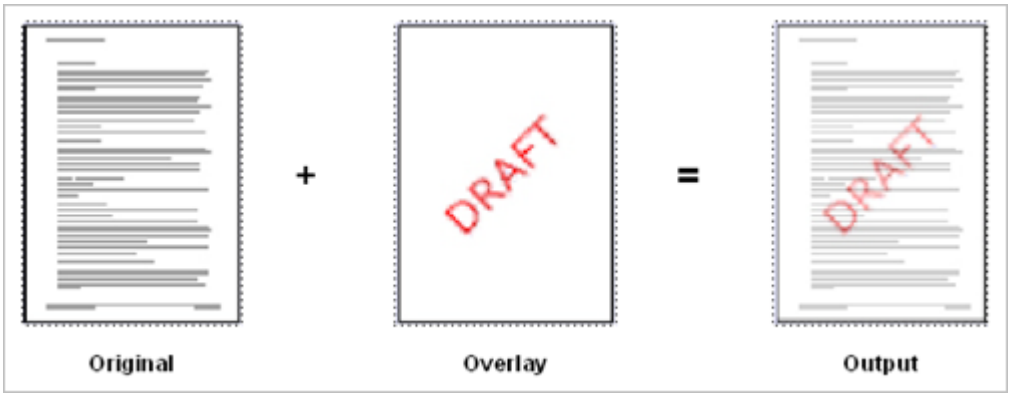
Overlay templates enable you to add headers, footers, and other elements to the pages of your publication. This includes page numbering and other variable data from Calyx RIM, resolved during publishing. Documents, TOCs, and cover pages may use the same or different overlay templates.

Cover page templates are similar to overlay templates, but they also allow variable placeholders in the body of the cover page.

Overlay Template File

Calyx RIM enables you to merge two PDF files so you can customize documents with headers and footers or apply a watermark.

You can apply different overlay templates to cover pages, TOCs, and documents in a submission. This effect is similar to that of a commonly used technique using transparencies and paper originals. The overlay information is printed onto a transparency, the transparency is placed onto a photocopier, and another document is placed on top of the transparency with the output being a merger of the two documents:



An overlay file is a PDF file that can contain a combination of fixed text and variables each page, including the following Assembly variables:

— Paper
— Electronic
— Variables that contain other variables
— Variables that contain formatting for other variables
— Data administration variables
— System-defined
— Calyx RIM
— Repository
— User-defined

You can create overlays in any document format that can be subsequently converted to PDF. Overlay files usually contain a single page, but you can define additional pages with an alternative page size or orientation that Calyx RIM can apply when source pages have different sizes. For examples of overlay files, refer to the samples provided for you in the installation files.

Variable Code and Delimiters

Variables are stamped on overlay files using the less-than sign or the greater-than sign, < and >, surrounding the variable's code. When a document is published, the delimiters and variable code are replaced with the resolved variable value. The space between the delimiters determines the size of the text to be placed at that position. Any text that extends beyond these limitations is clipped. You can align the final stamp of each variable as follows:

— <Left_Aligned >
— < Right_Aligned>

— < Centered >

The fonts used for variables in Overlay Templates must be installed on all Calyx RIM Rendering servers used to publish output with these overlays.

In addition to size and alignment, the delimiters and variable code specify the font, point size, and formatting of the text. In order to be correctly recognized and formatted, the delimiters and variable code must all share the same font, point size, and formatting.

Less-Than Sign (<) and Greater-Than Sign (>)

In an overlay template, do not use the less-than sign or the greater-than sign, except to enclose variables. Using these characters for any other purpose can cause undesired results.

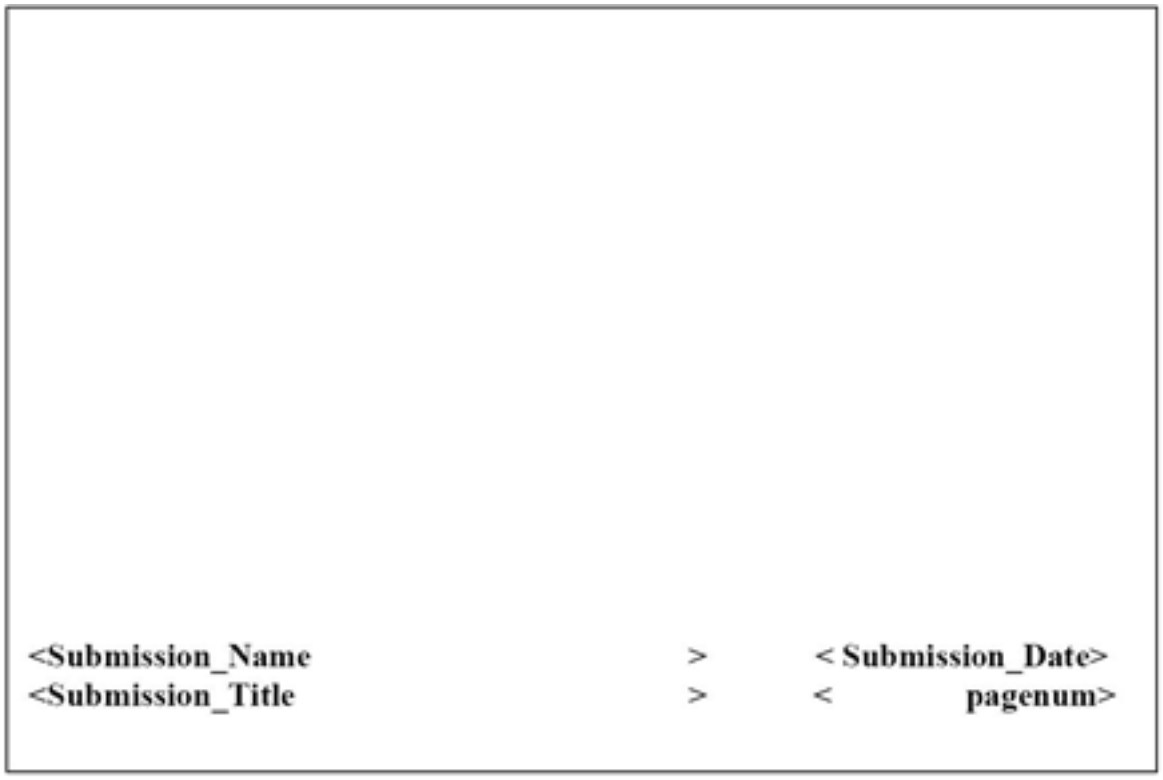
Japanese Characters

The font of the delimiters and variable code also determines which characters can be stamped. Most fonts do not contain all Unicode characters. If you intend to include Japanese characters in variable resolutions for example, you must make sure the font used for the delimiters and variable codes is MSMincho or another font containing Japanese characters. Arial Unicode MS is one of the few fonts containing almost all Unicode characters.

Overlay Footer Example

In this sample, the variables *Submission_Name* and *Submission_Title* are left aligned, and the variables *Submission_Date* and *pagenum* are right aligned. These variables are not predefined system variables, so you must define them at the assembly level or they must be defined by an administrator in data administration user-defined variables.

Portrait Overlay Footer



Change an Overlay for a Document, Cover Page, or TOC

Overlay templates enable you to add headers, footers, and other elements to the pages of your publication. This includes page numbering and other variable data from Calyx RIM, resolved during publishing. Documents, TOCs, and cover pages may use the same or different overlay templates.

To change an overlay for a document, cover page, or toc:

1. Select the element with an overlay you want to change.
2. Click Edit.
3. Choose an overlay from those available in the Overlay Setting list.
4. Save.

Modify an Existing Overlay

Overlay templates enable you to add headers, footers, and other elements to the pages of your publication. You can modify an existing overlay.
This includes page numbering and other variable data from Calyx RIM, resolved during publishing. Documents, TOCs, and cover pages may use the same or different overlay templates.

1. Go to the *Publishing Templates* page and choose a Publishing Library.
2. In the selected Publishing Library, open the Overlays tab to modify or add overlay settings.

3. Save.

Hide Headers and Footers with an Overlay

You can hide the headers and footers created by an assembly in Microsoft Word.

1. Open the overlay document in Word.
2. View headers and footers.
3. Insert a text box into the header and resize it to fill the width of the screen and desired depth from the top of the page.
4. Edit the text box and do the following:
   — Select White for the fill color for the text box.
   — Select either No Line or White for the line color.
5. Insert variables and/or images into the text box.

Page Markers

A page marker is an assembly element used to mark a specific page in a document.
This is most often used to indicate where a volume break may occur, but you can also use page markers to insert other publishing elements such as TOCs, tab sheets, and other publishing effects in a document.

Insert a Page Marker

You can insert a page marker to hold the place for a special sheet.

1. Right-click the assembly element where you want to insert a page marker and select Insert Page Marker. The *Add or Edit Page Marker* page appears.
2. Edit the attributes.
3. Save.

   For each element where a page marker has been inserted, appears on the assembly.

Page Marker Attributes

You can use the attributes to describe the details of a page marker.

Attribute	Description
Comments	Any additional information you want to save with the page marker.
Description	Describes why the Page Marker is needed.
Keywords	Keywords you can use to in a search for the page marker.
Page Marker Name	Name of the Page Marker.

Attribute	Description
Page Number	The page on which the page marker is applied. Any volume, special sheets, or TOC applied at this page marker are inserted just before this page.

Modify Publishing Settings Library Templates

You can access a Publishing Settings Library Template (PLT) from the Calyx RIM *Home* page and can modify it.

1. On the Calyx RIM *Home* page, click Publishing Templates.
2. In the Publishing Library Name list, choose a saved PLT.

   After opening the Publishing Settings Library Template, use the following procedures to modify the publishing settings.
3. On the selected *Publishing Settings Library* page, click the tabs on the *Publishing Settings Library* page to view, add, or modify the PLT settings.
   - Publishing Settings
   - Default Values
   - Default Study Folder
   - PDF Properties
   - Volumes
   - Cover Pages
   - Tabs
   - Slip Sheets
   - TOCs
   - Overlays
   - Variables
   - Link Profiles

   Note: *The procedures and attributes for each PLT tab are described in the corresponding topics and can be applied to both the Publishing Settings Library Templates (PLT) and the Assembly Specific Publishing Settings Library (APL).*
4. On each tab: click Create or Edit, add or modify the settings, and Save.

Create Publishing Settings

In the selected Publishing Settings Library, you can create or modify the Publishing Settings to adjust printer output settings and XML definitions.
This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL).

1. On the *Publishing Settings Library* window, select Publishing Settings .

2. Click Create: .
3. On the *Create Publishing Settings* page, use the drop-down lists to choose the following required settings:
   - Printer
   - Paper Size and Type
   - Tab Paper Size and Type
   - Preview Location (Click Browse to locate and select the location.)
4. Complete the remaining fields as needed:
   - XML Definitions
   - Default Rendition Identifier
   - Missing Rendition Identifier Handling
   - In-Process Rendition Location (Click Browse to locate and select the location.)
   - TOC Destination Not Found Text
   - Cross-Reference Destination Not Found Text
   - Expand Bookmarks to Level
   - PDF Version for Published Output
   - Optimize Fonts in Paper Output

Note: *Calyx RIM includes functionality to specify the rendition identifier to allow for a non-default Documentum or Veeva rendition to be used for publishing jobs. This value can be set in Publishing Settings Library Templates (PLT) and Assembly Specific Publishing Settings Libraries (APL). On the* Publishing Settings *tab, the option* Default Rendition Identifier *lists the values configured using the DMS Integration Rendition Identifier Values in Data Administration. See Maintaining a DMS Integration Value.*

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5. To save the new Publishing Settings, Save. To discard the changes, Cancel.

XML Definition File Version Updates

If the XML Definitions are set to a different XML definition than was previously used for the assembly, the system will initiate a renaming process when you save the file and the new XML Definition File is applied.

1. After the new XML Definition File is applied, refresh the assembly tree.
   Applying the new XML Definition File updates the assembly according to the new specification:
   - Values in extended attributes
   - Folder names
   - Leaf names. Abbreviated Name, Title, and Output File attributes are updated for leafs within a working assembly.
2. Check the following attributes of the leaf created as a result of any lifecycle operation, and update if necessary:
   - Abbreviated Name
   - Title
   - Output File

The Create eCTD Wizard can now be used for the Sequence. After the new XML definition file is applied, the changes within the current assembly cannot be rolled back. If it is necessary to roll back the changes, the working assembly must be deleted and recreated.

Publishing Settings Attributes

The attributes describe the details of the publishing settings used in a Publishing Settings Library Template (PLT). Required information is indicated by an asterisk (*).

Attribute	Description
Cross-Reference Destination Not Found Text	Specify the text to insert when Calyx RIM attempts to insert a margin cross-reference but cannot resolve the variable. If blank, no margin cross-reference is created for links that cannot be resolved.
Default Rendition Identifier	Specify the default rendition identifier for the document. The default is `Use Standard Rendition`.
Expand Bookmarks To Level	Specify the number of levels to which bookmarks are expanded on the initial opening of electronic (PDF) files published from Calyx RIM. You can choose to expand bookmarks from 1 to 20 levels, or expand ALL bookmarks, when the published PDF files are opened. The expansion of bookmarks applies to all Publish to eCTD/Electronic options except XML only.
In-Process Rendition Location	The location where in-process renditions are saved when creating and modifying in-process links in Calyx RIM. Periods and decimals cannot be used in folder names.
Missing Rendition Identifier Handling	Specify the rendition identifier to use when none is assigned to a document, or if the assigned rendition identifier does not exist in the system. The default is `Use Standard Rendition`.
Optimize Fonts in Paper Output	Minimizes the font compatibility issues and provides stability to the process of printing the paper output. The default value is No.
Paper Size/Type*	Select the paper size to use for publishing (Letter, A4, Color A4, Drilled A4, etc.). This list is dependent on the available printers.
PDF Version for Published Output	Select the PDF version for your published output. The default PDF version is `1.4, Acrobat 5`. Optional values are: 1.3, Acrobat 4; 1.4, Acrobat 5; 1.5, Acrobat 6; 1.6, Acrobat 7; 1.7, Acrobat 8.
Preview Location*	The storage location, used for tab preview locations and Microsoft Word-generated TOC files. — Tab preview files are not used in the final publication. — Periods and decimals cannot be used in the folder name.
Printer*	Select the printer that will be used for the paper publish. The selected printer defines the values available for the Paper Size/Type for Tabs, Cover Pages and Slip Sheets.

Attribute	Description
Tab Paper Size/ Type*	The Type and Size of the paper that will be used for the Tab when printed (e.g. Blue Letter). This list is dependent on the available printers.
TOC Destination Not Found Text	Specify the text that appears in TOCs when a TOC Entry cannot be resolved at publishing time. Destination Not Found Text is used in TOC right-columns where the target does not exist. This attribute is blank by default, but text may be entered to assist in the QC of invalid destinations or variables.
XML Definitions	Select XML definitions that are applicable to the Publishing Library and to the Assembly that uses the Publishing Library.

XML Definition File Publishing Settings

The XML Definitions settings determine the specification that is used for publishing your eCTD submission.
The XML (eXtensible Mark-up Language) DTD (document type definition) files indicate which specification your eCTD submission should use for publishing. These files are generally associated with a specific assembly template, but submissions based on earlier versions of the specification may be updated to newer specifications by selecting the latest definition file in the Publishing Settings of the active working assembly. These files are placed in a repository that is accessible to Calyx RIM, and new ones may be added to this location as a result of a new agency or ICH (International Conference on Harmonisation) specification.

For eCTD, you typically select a regional DTD, the standard ICH DTD, and the STF (Study Tagging File) DTD. The STF DTD can be activated even if STFs are not being created, as this enables global reuse by allowing you to specify how Study folders should be processed in the XML at the module-level.

Only one DTD file for each output XML file can be assigned in the DTD settings. If more than one is assigned, an error may occur during publishing (fixpoint error). Multiple DTDs are assigned if multiple XML files are generated, for example: `ICH index.xml`, `regional.xml`, and possibly `stf.xml`.

Update eCTD XML Definition File Selections

When XML definition settings are updated, Calyx RIM prompts you to verify that you want to make the change. If you agree to the change, Calyx RIM automatically changes the folder and leaf types throughout the assembly to the proper versions.
In some cases, metadata is removed if it is no longer needed by the new specification XML definition. In most cases, Calyx RIM only adds new attributes or changes the labels or selections of existing attributes. If new sections are required by the new XML definition specification, it may be recommended to add these attributes separately using the Create eCTD wizard.

In every case it is a best practice to run the Create eCTD wizard immediately after updating the XML specifications.

For EU specifications, keep in mind the following:

— When you include the electronic application form in EU module 1, section 1.2, ensure the form-1-1 rules are active in the publication settings to ensure the DTD and stylesheet are copied to the appropriate location during publishing.

— If you are using v1.1 of the EU specifications, and submitting PIM information in section 1.3.1, you also need to ensure the pim-2-1 rules are active to ensure the supportive files are correctly output.
— When you are using the v1.2.1 specification or later, these rules should not be active since the PIM information is provided as a single `.zip` file.

eCTD Publishing Settings

Specifying the general electronic eCTD publishing settings enables the entire eCTD assembly to inherit leaf element and study folder attributes. These settings contribute to default values for leaf elements in the eCTD XML files, and the default properties for study tagging or other study XML files.

The eCTD publishing settings are applicable to both the Default Values and the Default Study Folder in the Publishing Settings Library Template (PLT) and the Assembly Specific Publishing Settings Library (APL).

Generally, these settings are used to either:

— Set up a global value for an XML attribute that generally will not change, for example: the font library.
— Inherit this information from attributes that are already stored in your document repository. An administrator must have already configured repository variables (in Data Administration) so Calyx RIM can find the metadata, and placed these variables in the attributes on the settings page.

Any attributes defined on a particular leaf use the assigned values. Calyx RIM inherits only values from these settings if the value has been left blank on the element itself.

Modify Default Publishing Values

In the selected Publishing Settings Library, you can modify the default publishing values.
This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL). To modify the default publishing values:

1. On the *Publishing Settings Library* window, select Default Values.
2. Click Create .
3. Complete the fields, as needed:
   — Title
   — Leaf Owner
   — Language
   — Application Version
   — Font Library
   — Role
   — Actuate
   — Show
   — Use Native File
   — Leaf Due Date
   — Folder Owner
   — Folder Due Date

4. To save the new Default Publishing Values, Save. To discard the changes, Cancel.

Default Publishing Values Attributes

You can use the attributes to describe the details of the default publishing values.

Attribute	Description
Actuate	Choose the default Actuate setting for new leafs. Available values: onLoad, onRequest, other, none
Application Version	Specify the default application version for new leafs.
Folder Due Date	Specify the default due date for new folders.
Folder Owner	Specify the default owner for new folders.
Font Library	Specify the default font library for new leafs.
Keywords	Specify the default keywords for new leafs.
Language	Specify the default language for new leafs.
Leaf Due Date	Specify the default due date for new leafs.
Leaf Owner	Specify the default owner for new leafs.
Leaf Version	Specify the default version for new leafs.
Role	Specify the default role for new leafs.
Show	Choose the default Show setting for new leafs. Available values: new, replace, embed, other, none
Title	Specify the default title for new leafs.
Use Native File	Determine if new leafs should be created as Native Files. Available values: Yes, No

Default Study Folder

In the selected Publishing Settings Library, you can modify the Default Study Folder for the Publishing Library Template (PLT). The Default Study Folder tab is available only when an STF DTD definition is selected on the Publishing Settings tab of the PLT.
This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL).

1. On the *Publishing Settings Library* window, select Default Study Folder.
2. Click Create.
3. Complete the fields as needed. There are no required fields.
   - Full Report Title
   - Report Number
   - Operation

- Species
- Route of Administration
- Type of Control
- Duration
- Subject Matter

4. To save the new Default Study Folder, Save. To discard the changes, Cancel.

Default Study Folder Attributes

The Default Study Folder tab is available only when a study folder XML definition is selected on the Publishing Settings tab of the PLT. Values for Species, Route of Administration, Type of Control, Duration, and Subject Matter are controlled by the XML definition selected.

Attribute	Description
Duration	Choose the default duration for new studies.
Full Report Title	Specify the default full report title for new studies. (Limit 4000 bytes)
Operation	Choose the default operation for new studies. Available values: append, delete, replace, new
Report Number	Specify the default report number for new studies. (Limit 4000 bytes)
Route of Administration	Choose the default route of administration for new studies.
Species	Choose the default species for new studies.
Subject Matter	Choose the default subject matter for new studies.
Type of Control	Choose the default control type for new studies.

About PDF Properties

You can add PDF Property settings to the Publishing Settings Library Template (PLT) and to the Assembly Specific Publishing Settings Library (APL) to define the PDF properties of the electronic published output.

In addition to the PLT and APL PDF property settings, Calyx RIM enables you to create leaf-specific PDF property settings:

- While the APL and PLT PDF property settings are defined for the whole assembly, leaf PDF property settings are defined for an individual leaf element only.
- When importing or exporting an assembly, only APL PDF property settings are preserved. Any leaf-specific PDF property settings are automatically removed.
- Leaf PDF property settings are preserved in the duplicated leaf or folder.
- Adding or modifying leaf PDF property settings in the working assembly updates both working and publishing views.
- To use a specific property from the source document, set the PDF Property Source attribute to Use Source Document Property.
- If at least one PDF Property is defined, the submit.document.properties=true parameter in the `insight.var` is ignored.

Note: *Due to the additional information that is processed when using PDF Properties, the time needed to complete publishing can be increased.*

Leaf PDF properties are not available in:
— Approved, submitted, and sequence views.
— Publishing view of a locked assembly.

Add or Modify PDF Properties

PDF Properties are used to define the PDF properties of the electronic published output document.
In the selected Publishing Settings Library, you can add or modify the PDF Property settings. This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL).
You must have sufficient security permissions to be able to create or modify a PDF Property setting.

1. On the *Publishing Settings Library* window, select PDF Properties.
2. Click the Create icon .
   To edit an existing PDF Property setting, click a named PDF Property in the list on PDF Properties.
3. On the *Create PDF Property Settings* page, complete the required fields, and the optional fields as needed.
   Required information is indicated by an asterisk (*).
   — Output PDF Property*
   — Configuration*
   — Value*
   — Separator

   Note: *The set of attributes varies, depending on the value selected in the* PDF Property Source *field.*
4. To save the new PDF Property Settings, Save.

Option	Action
To create another PDF Property:	Click Create Another PDF Property. The current PDF Property will be saved automatically.
To discard the changes:	Click Cancel.
To return to the Publishing Settings Library after the updates are saved, if you are editing an existing PDF Property setting:	Click the name of the Publishing Settings Library on the *View* page at the top of the page.

Delete a PDF Property

You can delete a PDF Property Setting, as necessary. Use this procedure to delete a PDF Property Setting from the Publishing Settings Library (PLT), Assembly Specific Publishing Settings Library (APL) or a Leaf element.
You must have sufficient security permissions to be able to delete a PDF Property setting.

Note: *This procedure is not applicable for deleting a PDF Property setting inherited from the APL for a specific Leaf element. In order to not apply the inherited PDF Property setting for a specific Leaf, you should set the* PDF Property Source *value to* Do Not Populate *by modifying the PDF Property setting from this Leaf element.*

1. On the PDF Property Settings tab, select the PDF Property you want to delete.
2. On the *PDF Property Settings* view page, click Delete.
3. On the warning message that appears, click OK.

PDF Property Attributes

The attribute descriptions help you to enter the appropriate attribute values while creating a PDF Property setting for the Publishing Settings Library Template (PLT) or Assembly Specific Publishing Settings Library (APL).

Required information is indicated by an asterisk (*).

Attribute	Description
Output PDF Property*	Defines the target PDF Property in the output document. The value should be unique within a Publishing Settings Library (PLT) or Assembly Specific Publishing Settings Library (APL). Values available for selection are all active values from the Data Administration > PDF Properties section, where Target Property is set to `Yes`. If the Output PDF Property value for both the Leaf and the APL is the same, the Leaf-specific PDF Property setting will replace the inherited APL PDF Property setting.
PDF Property Source*	Defines the source for the PDF Property. The values available for selection are the following: — Define Repeatable Value - Applies a defined value as the PDF property, values are obtained from all assigned documents. The PDF Properties are distinguished by a defined separator. — Define Single Value - Applies a defined value as the PDF Properties, the value is obtained only from the first assigned document. — Use Source Document Property - Applies a defined PDF Property from all assigned documents. The PDF Properties are distinguished by a defined separator.

Attribute	Description
Source Document Property	Defines the PDF Property in source documents to be used as a source for the PDF Property in the output document. Values available for selection are all active values from the Data Administration > PDF Properties section, where Source Property is set to `Yes`. The following default values are available for selection: — Author — Keywords — Title — Subject This field appears and is required only when PDF Property Source is set to Use Source Document Property.
Separator	User defined separator to distinguish values from individual documents within a leaf. To support the use of spaces and newline breaks, the following text patterns must be used: — `//space` - Space character will be inserted as a separator — `//newline` - New line will be started. The effect of the new line break will be visible from the PDF viewer for multi-line fields only. This field does not appear when PDF Property Source is set to Define Single Value.
Value	Defines the value for the PDF Property in the output document. This field appears and is required only when PDF Property Source is set to Define Single Value or Define Repeatable Value.

Volumize

Volumization is the process by which assembly content is divided into multiple volumes for the purpose of publishing paper volumes. You can define the settings for splitting the assembly into volumes using the volume settings.

Volumization settings include:

— The number of pages that make up the volume.

— The size of the page buffer, which indicates the number of pages under the specified volume pages that would still be considered as a valid volume size.

— The total size of each volume.

— The buffer size of each volume, which indicates the number of MB under the specified volume total size that would still be considered as a valid volume size.

— Whether to automatically create volume TOCs for each volume.

— The name and numbering schema for each volume (specified by default as the variable $VOLNAME).

— Whether volumes should be counted relative to the assembly or the major division (module).

Volume settings are included in a Publishing Settings Library by default. When creating a new Publishing Library Template (PLT), or when creating a new PLT based on an existing PLT, the Begin at Volume Number setting is set to 1.

You can start a volumization from the start of an assembly, a subset folder, or a section in the assembly. Volumization will end when either a locked volume is encountered or the end of the assembly is reached.

Volumization may take a significant amount of time to accomplish, so the recommended way to volumize is by using the Prepare to Publish process.

Positioning your cursor over a volume indicates the number of current pages, but in certain cases it may be necessary to refresh the volume page count. This can be done with either the volumes refresh option or the Prepare to Publish process.

During volumization, the assembly is not locked. You must wait for volumization to complete before attempting to select any elements.

Calyx RIM provides the ability to create volumes in an assembly based on an estimated output file size.

Because Volumize by Size can be a time-consuming process, Calyx recommends completing all assembly creation steps (including Prepare to Publish) prior to invoking this functionality. An assembly paper output location is required when using the Volumize by Size option. There is a limitation of assembly content size that can be processed at once, so it is recommended to use Volumize by Size option in a reasonable time periods. See Memory Limits for Windows and Windows Server Releases.

For Volumize by Size, using the No option causes Volumize by Page to be enforced when the right-click menu option Volumize is invoked in the assembly. Volumize by Page provides faster performance than Volumize by Size.

When the Volumize by Size option is set to Yes, all volumes will be deleted and recreated, including locked volumes.

Use the Volumes tab in the Publishing Settings Library to set or modify the following options:
— Volumize by Size
— Total Size (in MB)
— Buffer Size (in MB)

Note: *1MB = 1,048,576 bytes*

Volumes also enable you to divide an assembly into logical sections that will be published to the paper output channel as separate files, one file for each volume.

If you choose to divide your assembly into paper volumes, you can create volumes in several ways:
— Bulk volumization
— Insert manual volumes

— Insert and manipulate existing volumes

Volume settings must be defined in the Publishing Settings Library prior to inserting volumes.

Define or Modify Volume Settings

Use the Modify Publishing Settings command to modify volume attributes for your assembly.

1. In an assembly view, click Edit Publishing Settings Library to open the *Publishing Settings*.
2. Select Volumes.
3. On the Volumes tab, click Edit to specify the Volume attribute settings.
4. Save.

Volumes

In the selected Publishing Settings Library, you can modify the Volumes settings. This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL).

To modify the Volumes settings:

1. On the *Publishing Settings Library* window, select Volumes.
   The default Volumes settings appear.
2. Click Edit.
3. On the *Edit Volume Settings* page complete the required fields, and the optional fields as needed.
   Required information is indicated by an asterisk (*).
   — Volume File Naming Format *
   — Begin at Volume Number *
   — Total Sheets/Pages *
   — Total Sheets/Pages Buffer *
   — Volumize by Size
   — Total Size (in MB) *
   — Buffer Size (in MB) *
   — Volume Numbering
   — Automatically Create Volume Tables of Contents
4. Save. To discard the changes, Cancel.

Volume Attributes

You can use the attributes to describe the details of a volume. Required information is indicated by an asterisk (*).

Attribute	Description
Automatically Create Volume Tables of Contents	Controls whether TOCs are created automatically and assigned to each volume. Choose Yes or No. Default is No. ***Note:*** *When automatically creating the table of contents for volumes using* Prepare to Publish *or* Volumize*, Calyx RIM may misname the table of contents. An incorrectly generated table of contents results if the $TITLE variable is used in the header or left column entry text. If file bookmarks are used in volumes with automatically generated tables of contents, a bookmark for the table contents is named* New TOC*. The bookmarks do not affect the printed output. To work around this issue: set* Automatically Create Volume Tables of Contents *to* No *on the* Volumes *page in* Publishing Settings*. After volumizing, create tables of contents on the newly created volumes by right-clicking on any element in the tree and selecting* Mass Insert/Update Publishing Elements*, selecting* Table of Contents *in the drop-down, and then selecting* Volumes*, and set* Use Default *for the type. You can also create tables of contents for individual volumes by selecting* This Element Only*.*
Begin at Volume Number*	Specify the number where you want your volume to begin. Must be a number greater than 0. Default is 1.
Buffer Size (in MB)*	Defines the additional buffer size allowed in a volume when running volumize by size. Must be a number, 10 or greater. Default is 10.
Total Sheets/ Pages*	Specify the total number of sheets or pages that make up your volume when running volumize by number of pages. Must be a number greater than 0. Default is 300.
Total Sheets/Pages Buffer*	The number of sheets or pages, plus or minus, that Calyx RIM uses to calculate logical volume breaks during bulk volume creation when running volumize by number of pages. The Total Sheets/Pages Buffer setting should always be less than the Total Sheets/Pages setting. Must be a number. Default is 50.
Total Size (in MB)*	Defines the maximum size of the volume when running volumize by size. Must be a number greater than 50. Default is 100.
Volume File Naming Format*	The default volume naming format that applies to all the volumes in your submission. This is set by default to $VOLNAME, which is a volume-naming variable included with every Calyx RIM installation. This attribute can be set only to a specific variable name, and it cannot contain additional text or variables. If different variable attributes are needed: changes should be made to the $VOLNAME variable in data administration, or you should use a new user-defined variable instead. (Limit 150 bytes)
Volume Numbering	The volume number scheme. Choose Assembly Relative or Major Division. Default is Assembly Relative.

Attribute	Description
Volumize by Size*	Determines if the volumization will be done by the number of pages in the volume or by the estimated size of the volume. Choose Yes or No. Default is No. For Volumize by Size, using the No option causes Volumize by Page to be enforced when the right-click menu option Volumize is invoked in the assembly. Volumize by Page provides faster performance than Volumize by Size.

Bulk Volumization

Bulk volumization enables you to divide assembly content into multiple volumes automatically.
Volume publishing settings identify how the assembly is divided into volumes including the default size and other characteristics of the volumes inserted during the bulk volumization process.

Content that has been rendered or has a planned page count, and that is specified for the paper output channel, is volumized. Content that is not intended for the paper channel is not included in volumization calculations.

You can volumize from an assembly root, a folder, or a section in the assembly. Bulk volumization may take a certain amount of time to perform, so the recommended way to volumize is by using Prepare To Publish.

Run a Bulk Volumization

Volumes you insert have a standard naming convention based on the volume publishing settings, which may be variable-based.

Prerequisites

Prior to running a bulk volumization, it is recommended that you verify the volume publishing settings before you insert volumes into the assembly.

To volumize an entire assembly:

1. Right-click the assembly root and select Volumize.
   A message prompts you to confirm the volumization.
2. Click OK.
   For each volume added, the book icon appears in the assembly tree.
3. Volumization creates volumes in the assembly according to the volume publishing settings.
   - If a document is too large to fit in a volume, volumization will break up the document, creating page markers and volume breaks where appropriate.
   - If you create your own page markers manually, volumization attempts to create volume breaks on those page markers if the page marker falls within the volume publishing page size, plus/minus the buffer.
4. Volumization ends when the process encounters a locked volume or the end of the assembly.

Volume Icons

When you create and manipulate volumes, icons in the assembly tree indicate volume statuses and features associated with the volumes. You can position the pointer over a volume in the assembly tree to see the number of pages in the volume. (It may be necessary to refresh the *Volume Attributes* page to see an accurate volume page count.)

Icons	Description
	Represents multiple volume breaks. Publishes all volumes where the starting range breaks fall under the collapsed multi-volume icon, including the last volume whose end break may fall past the specified range. To see all the individual volume breaks, right-click the element and choose Expand Range.
	Represents a single volume break. A volume begins at one volume break and ends at either the next volume break or at the end of the assembly. With this icon selected, when choosing Publish Request (Publish Paper > Volumes in Selected Range) only this volume will be published.
	Represents a volume where the starting and end points are fixed.

Revolumizing

Calyx RIM enables you to re-bulk volumize all the volumes that existed from the point where the volumization was invoked.

When you run bulk volumization again (revolumizing), the existing volumes, page markers created by previous volumizations, and any special sheets attached to those volumes and page markers, will be deleted.

If there are locked volumes, the revolumization process stops at the first locked volume it finds.

Insert Manual Volume Breaks

Use this procedure to insert a volume. During volumization, the assembly is not locked. You must wait for volumization to complete before attempting to select any elements.

Prerequisites

You must specify volume publishing settings before you insert volumes into the assembly. The Volumes will have a standard naming convention based on the volume setting, these may be variable based.

To insert a volume:

1. Right-click the element where you want to insert a volume and choose Insert Volume.
   If a volume break resides on the leaf you are deleting, you should move the volume break to the closest folder. Volume breaks that reside on a deleted leaf will not be published.
2. Save.
   Each volume added is displayed in the assembly tree. The volume break is added and the *Edit Volume* page appears.
3. Optionally change the name of the volume and Save.

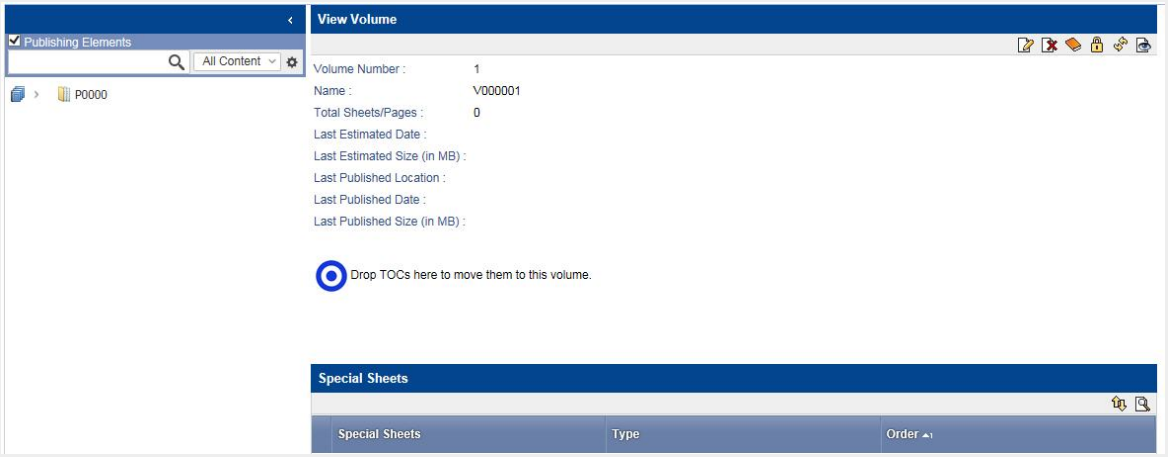
Modify Volumes

While you can change a volume's name and override the default, any changes to volume ordering (or the inclusion of new volumes) overwrites the change. Calyx RIM numbers the volumes correctly based on their order. If you overwrite a volume name, you can lock the volume to prevent additional changes.
During volumization, the assembly is not locked. You must wait for volumization to complete before attempting to select any elements.

To modify a volume:

1. In the assembly, click on the volume you want to modify.

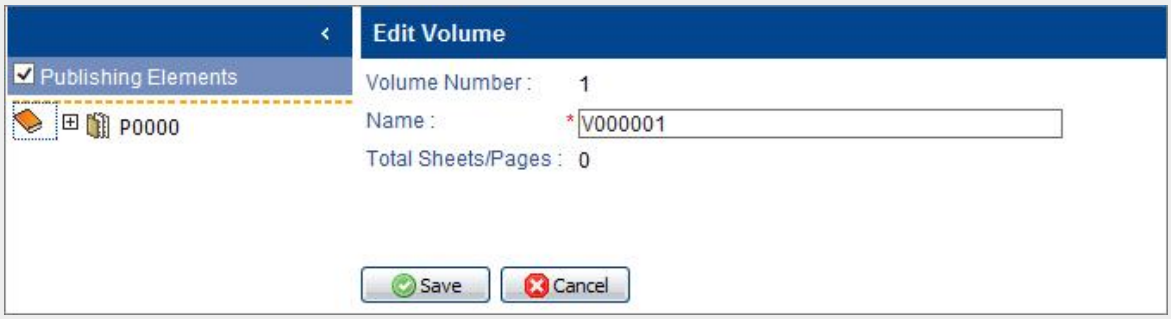
   Example

   The *View Volume* page appears.

2. Click .

   Example

   The *Edit Volume* page appears.

3. Enter a name for the volume.
4. Save.
5. To protect the volume name from changes, click .

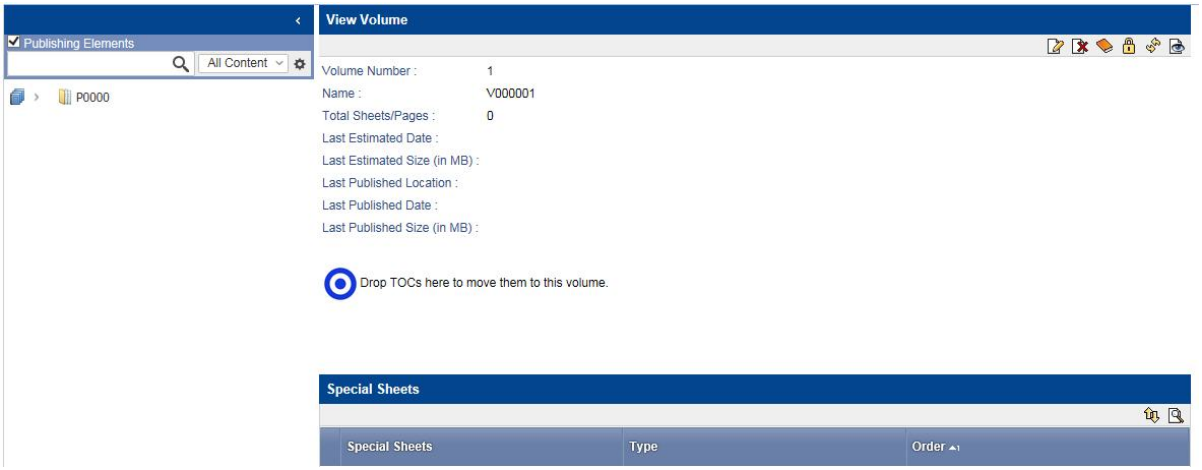
A message prompts you to confirm the lock.

6. Click **OK**.

   The volume icon changes to:

Move TOCs to Volumes

You can move TOCs from the assembly tree onto a volume by dragging them onto the volume icon.



Delete Volumes

After deleting a volume from an assembly tree, you may need to refresh the assembly tree or refresh the volume so that Calyx RIM displays the remaining volumes correctly.
After deleting a volume from an assembly tree, you may need to refresh the assembly tree or refresh the volume so that Calyx RIM displays the remaining volumes correctly.

To delete a single volume from an assembly:

1. Right-click the volume that you want to delete from the assembly.
2. Click **Delete**.

   The volume is deleted.

Delete All Volumes from an Assembly

Use this procedure to delete all volumes from an assembly.

To delete all volumes from an assembly:

1. Right-click the assembly root.
2. On the pop-up menu, click **Delete All Volumes**.
3. To confirm that you want to delete all volumes, click **Yes**.

Delete Volumes in Bulk

With appropriate permissions, you can delete multiple volumes simultaneously. To delete volumes in bulk, the selected volumes must be unlocked.

To delete volumes in bulk:

1. Expand the assembly sections that have the volumes under them.
2. Select multiple individual volumes or a range of volumes.
3. Right-click and select Delete.
4. In the confirmation message, click OK.
   The selected volumes are deleted.

Delete Assembly Tree Elements from the Volume Range

Assembly tree elements can be deleted from both locked and unlocked volumes. After the element is deleted from the volume range, the Volume structure will be adjusted automatically.
You can remove any assembly tree element from the Volume range:

— Folder
— Leaf
— Placeholder
— Assigned Document

Before deleting an assembly tree element from a volume range, you may need to refresh the volume so that the elements inside the volume range are up-to-date. After deleting a volume from an assembly tree, you may need to refresh the assembly tree so that Calyx RIM displays the volumes correctly.

To delete an assembly tree element from a volume range:

1. Right-click the assembly tree element in a volume that you want to delete.
2. On the pop-up message click OK to continue.
3. The assembly tree element is deleted and the elements structure in the volume is adjusted.

Option	Description
If the deleted element is the first element in the volume:	The structure is adjusted to start with the next element.
If the deleted element is the last element in the volume:	The structure is adjusted to finish with the previous element.

What to do next

Unlocked Volumes

You can delete any element inside the unlocked volume, even if the element is the first, or the last, inside the volume range.

If there is only one element in the unlocked volume, then that element and the volume are deleted.

Important: You cannot delete a volume that is located directly below a locked volume. When you attempt to delete the only element in an unlocked volume under a locked volume, a warning message appears and the element is not deleted.

Deleting a parent assembly tree element with child elements and volumes assigned to them causes the assembly tree and volumes structure to be adjusted. All entities are deleted, except the last volume. The last volume is automatically moved to start with the next element that is not a child element of the parent element. For example, if the parent Folder 1 element is deleted, all child elements including the first volume are deleted:

The second volume will start with the Leaf A element, that is not a child element of the Folder 1:

Locked Volumes

You can delete any element inside the locked volume, including the first and the last elements in the locked volume range. The exception is the locked volume that contains only one element.

When you attempt to delete the only element in a locked volume, a warning message appears and the element is not deleted. To delete the element, and the volume itself, the volume must be unlocked and must not be located directly under another locked volume.

When you are deleting a parent assembly tree element with child nodes that contain volumes, they are also deleted. The exception is a parent assembly tree element with child nodes that contain locked volumes. A warning message appears and the element is not deleted.

Note: *The locked volume can not be deleted.*

Cover Pages

You can insert cover pages anywhere in an assembly, in both paper and electronic output, to divide volumes into sections of information or reports.

Cover pages can be a special size or color. They can have text, variable text, and graphics. You can also apply overlays, which create headers and footers.

Cover pages, and tables of contents, can be included in both paper and electronic output.

Cover page templates define the text, variable text, and graphics that are applied to the cover page. For output that contains cover pages, you should specify publishing settings for the cover pages. You can override any publishing settings for specific cover pages, as needed.

Like documents, cover pages can be one or more pages. Unlike documents, Calyx RIM cover pages cannot be lifecycled.

You must specify printer Publishing Settings before you can select or insert special sheets in your assembly.

Cover pages operate similarly to overlay templates in their ability to contain variable placeholders and other page elements.

Create or Modify Cover Pages

In the selected Publishing Settings Library, you can modify the Cover Page settings. This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL).

1. On the *Publishing Settings Library* window, select Cover Pages.
2. Click the Create icon .
   To edit an existing cover page setting, click a named cover page in the list on the Cover Page tab.
3. On the *Create Cover Page Settings* page, complete the required fields, and the optional fields as needed.
   Required information is indicated by an asterisk (*).
   - Name *
   - Default?
   - Cover Page Template * (Click Browse to locate and select the location.)
   - Include in Page Numbering
   - Paper Type *
   - Output Channel *
4. Save.

Option	Action
To create another cover page, after saving the current cover page settings:	Click Create Another Cover Page.
To discard the changes:	Cancel.
If you are editing an existing Cover Pages setting:	Click the name of the Publishing Settings Library on the *View* page at the top of the page to return to the Publishing Settings Library.

Cover Page Setting Attributes

You can use the attributes to describe the details of the cover page settings.

Required information is indicated by an asterisk (*).

Attribute	Description
Name*	Specify a name for your Cover Page. The name must be unique within the Publishing Settings Library. (Limit 100 bytes.)
Default?	Determines if this is the default cover page. Choose Yes or No. Default is No. A default must exist. If a default already exists it is updated to be No, and the saved cover page setting becomes the default.

Attribute	Description
Cover Page Template*	Browse to select the cover page template you want to use for your cover pages.
Include In Page Numbering	Determines if the cover page is included in the page numbering and can impact the way overlay page numbers are calculated. Choose Yes or No. Default is `Yes`.
Paper Type*	Choose the paper type for your cover page. The paper type options are determined by the printer selected on the Publishing Settings tab.
Output Channel*	Select the output channel to publish to by default. You may default the cover page output channel to electronic, paper, or both. At least one channel must be selected. Default is `paper`.

Tabs

Like cover pages, tab sheets are used to divide content in a submission and serve as a navigational aid. Tab sheets are unique to the paper output channel and cannot be included in the electronic output channel.

With tab sheets, you can insert variable text, or up to three lines of manual text, to appear on the tab. Other configurable settings include text wrap, font type, font style, font size, and vertical or horizontal positioning.

Note: *You must specify printer publishing settings before you can select or insert special sheets in your assembly.*

Generating and Previewing Individual Tabs

Tabs can be generated and previewed individually from the tab itself. A tab preview must first be generated from the Generate File option; it can then be previewed using the View Tab option.

The preview function does not display the actual tab positions. Preview is meant to test for variable resolution, and to ensure that the tab text is not running over the side of the tab printable area. Your fully published output will show the tab text in the correct position as defined by your Tab Publishing Settings for the assembly.

Tab Review File

A Tab Review File can be generated from the Assembly root by selecting the Generate Tab Review File option. After review file has been created it can be viewed using the View Tab Review File option. Generating a tab review file creates a single file containing all of the tabs in the Assembly for review.

— Generating an individual tab will overwrite the bulk file when it creates the single file preview.

— You are not required to generate tabs prior to publishing. The publishing request executes this step automatically. Generating tabs prior to publish is only necessary for reviewing tab content.

Unicode Characters in Tabs

You must use the MS Mincho font to properly display Unicode characters in *Tab Preview*.

Create or Modify Tabs

In the selected Publishing Settings Library, you can modify the tab settings for the Publishing Library Template (PLT). This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL).

1. On the *Publishing Settings Library* window, select Tabs.
2. Click Create .
   To edit an existing tab setting, click named tab in the list on the Tabs tab.
3. On the *Create Tab Settings* page, complete the required fields, and the optional fields as needed.
   Required information is indicated by an asterisk (*).
   - Name*
   - Text
   - Default?
   - Auto Text Wrap
   - Font Definition
   - Font Bold
   - Font Italic
   - Font Size*
   - Vertical Text
4. Save.

Option	Action
To create another tab, after saving the current tab settings:	Click Create Another Tab.
To discard the changes:	Click Cancel.
If you are editing an existing Tab setting:	Click the name of the Publishing Settings Library on the *View* page at the top of the page to return to the Publishing Settings Library.

Preview Tabs

With tab preview, you can test for variable resolution and ensure that text is contained in the printable area. Preview does not show the actual tab positions. Your fully published output will show the tab text in the correct position as defined by your tab publishing settings for the assembly.

1. In the assembly tree, click the Tab icon.
2. In the Tab Sheet Attributes toolbar, click the View Tab icon to see an example of the selected Tab Sheet Attributes.

If the message `No preview exists. Generate a preview` appears, click the Generate File icon and then click View Tab.

Tab Sheet Attributes

You can use the attributes to describe the tab sheets after they have been included in an assembly. After a tab sheet has been included in an assembly, Publishing Setting is the only attribute that can be modified.

Required information is indicated by an asterisk (*).

Attribute	Description
Auto Text Wrap	Indicates whether to wrap text on the tab. The value displays as read-only and is based on the tab settings within the associated Publishing Settings Library.
Default?	Indicates whether to make the settings default.
Font Bold	Indicates whether the text is bold. The value displays as read-only and is based on the tab settings within the associated Publishing Settings Library.
Font Definition	The font used for the tab. The value displays as read-only and is based on the tab settings within the associated Publishing Settings Library.
Font Italic	Indicates whether the text is italic. The value displays as read-only and is based on the tab settings within the associated Publishing Settings Library.
Font Size	Indicates the text size (in points) for the tab. The value displays as read-only and is based on the tab settings within the associated Publishing Settings Library.
Last Generated Date	Date the tabs were last generated. You cannot change this value.
Name	Defines the name of the tab.
Overridden Tab Text	Defines the text that overrides the one taken from the Publishing Settings Library.
Publishing Setting *	Choose the default or a different saved publishing setting for the tab sheet.
Text	The text that is to appear on the tab. The value displays as read-only and is based on the tab settings within the associated Publishing Settings Library.
Vertical Text	Indicates whether to display text vertically on tabs. The value displays as read-only and is based on the tab settings within the associated Publishing Settings Library.

Tab Attributes

You can use the attributes to describe the Tab settings within a Publishing Library.

Required information is indicated by an asterisk (*).

Attribute	Description
Auto Text Wrap*	Determines whether or not to wrap text automatically. Default is No.
Default?*	Determines if the current tab is the default tab to be used when inserting tabs. Choose Yes or No. Default is No. If a default already exists it is updated to be No, and the saved tab setting become the default.
Font Bold*	Determines if the font appears in bold face. Default is No.
Font Definition*	Select a font for the tab. Available fonts: all active fonts defined in Data Administration, under Submission Maintenance.
Font Italic*	Determines if the font appears in italics. Default is No.
Font Size	Set the font size (points) for your tab. Default is 10.
Name*	Specify the name of the tab. Must be a unique name within the Publishing Settings Library. (Limit 200 bytes.)
Text	Specify the text to display on each tab. This can be text, or a variable (for example, ${NN}${LABBR}) can be used to create tab text. (The character count should not exceed 487 characters.) ***Note:*** *To make the first line of the tab blank, press the* `spacebar` *to enter a space, then press* `Enter` *to move to the next line.*
Vertical Text	Determines if the alignment of text on the tab is aligned vertically. Default is No.

Tab paper size is controlled by the Tab Paper Size field on the Publishing Settings tab of the Publishing Settings Library Templates (PLT) and Assembly Specific Publishing Settings Libraries (APL).

Slip Sheets

You can use slip sheets to divide content in a submission and serve as a navigational aid. Slip sheets are unique to the paper output channel and are not to be included in the electronic output channel.
Unlike cover pages and tab sheets, slip sheets cannot contain any text or graphics.

The only publishing setting you need to define for slip sheets is the paper type to use for the slip sheets. You must define publishing settings before you can select or insert special sheets in your assembly.

Create or Modify Slip Sheets

In the selected Publishing Settings Library, you can modify Slip Sheet settings. This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL).
Like cover pages and tab sheets, you can use slip sheets to divide content in a submission and serve as a navigational aid. Slip sheets are unique to the paper output channel and can never be included in the electronic output channel.
Unlike cover pages and tab sheets, slip sheets cannot contain any text or graphics.

The only publishing setting you need to define for slip sheets is the paper type to use for the slip sheets. You must define publishing settings before you can select or insert special sheets in your assembly.

To add a slip sheet to an assembly:

1. On the *Publishing Settings Library* window, select Slip Sheets.
2. Click Create.
   To edit an existing slip sheet setting, click a named slip sheet in the list on the Slip Sheets tab.
3. On the *Create Slip Sheet Settings* page, complete the required fields, and the optional fields as needed.
   Required information is indicated by an asterisk (*).
   — Name*
   — Default?
   — Paper Type*
4. Save.

Option	Action
To create another slip sheet, after saving the current slip sheet settings:	Click Create Another Slip Sheet.
To discard the changes:	Click Cancel.
If you are editing an existing Slip Sheet setting:	Click the name of the Publishing Settings Library on the *View* page at the top of the page to return to the Publishing Settings Library.

Modify a Slip Sheet

You can modify the name or paper type of a slip sheet placed in an assembly.

1. Select a slip sheet in the assembly.
2. On the *Slip Sheet Attributes* page, click Edit.
3. On the *Edit Slip Sheet* page, modify the attributes.
4. Save.

Slip Sheet Attributes

You can use the attributes to describe the details of slip sheet settings. Attributes are editable on a slip sheet setting, and visible (read-only) on a slip sheet. A slip sheet includes an editable field for choosing the slip sheet setting.

Required information is indicated by an asterisk (*).

Attribute	Description
Default?	Determines if this is the default slip sheet. Choose Yes or No. Default is No. A default must exist. If a default already exists it is updated to be No, and the saved slip sheet becomes the default.
Name*	Specify a name for your slip sheet. The name must be unique within the Publishing Settings Library. (Limit 100 bytes)
Paper Type*	Choose the paper type for your slip sheet. The paper type options are determined by the printer option selected on the Publishing Settings tab.

TOCs

Like special sheets, TOCs serve as navigation aids to facilitate review of the published assembly. TOC creation is a multiple step process that results in a final navigational aid.

To generate a TOC, Calyx RIM references a TOC template file. The TOC template file includes the following:

— Width of columns in the TOC
— Heading levels and styles
— General formatting

Calyx RIM includes two TOC templates, one letter and one A4. They are Microsoft Word documents you can copy and/or modify to meet your organization's needs. You can create TOCs for the paper output channel, electronic output channel, or both.

Only TOCs that are assigned to the paper output channel and that are included in a volume range are published during a paper publish request. TOCs that are assigned outside of a volume range or that are assigned only to the electronic output channel are not published during a paper publish request.

Add or Modify TOCs

In the selected *Publishing Settings Library*, you can modify the TOC Settings to adjust the default TOC formatting. This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL).
To add a TOC to an assembly:

1. On the *Publishing Settings Library* window, select TOC.
2. Click Create.
   To edit an existing TOC setting, click a named TOC in the list on the TOCs tab.
3. On the *Create/Edit TOC Type* page, complete the required fields, and the optional fields as needed.
   Required information is indicated by an asterisk (*).
   — Name*
   — TOC Definition File* (Click Browse to locate and select the location.)
   — TOC Overlay
   — Header

- Default TOC For (Move items from the Available box to the Selected box to apply the TOC settings by default for those items.)
- Tree Elements to Include in TOC (Move items from the Available Entry Generation Options box to the Selected Entry Generation Options box to apply them as default tree elements to include by default in the TOC.)
- Left Column Entry Text* (Leave blank to use the TOC tree values.)
- Right Column Entry Text*
- Leader
- Build TOCs to Level
- Including Bookmarks up to Level
- Include Only Bookmarks with the Text
- Exclude All Bookmarks with the Text
- Bookmark Handling
- Include in Page Numbering
- Output Channel* (move items from Output Channel Types to the Selected Output Channel Types box to apply the TOC to the selected output channel types by default)

4. Save. To discard the changes, click Cancel.

   If you are editing an existing TOC setting, click the name of the Publishing Settings Library on the *View* page at the top of the page to return to the Publishing Settings Library.

TOC Attributes

You can use the attributes to describe TOC settings for a PLT.

Required information is indicated by an asterisk (*).

Attribute	Description
Bookmark Handling	Indicates whether or not the entries from this TOC will be used to create the bookmarks in the Leaf, Volume, or Single File output file containing this TOC: — File Bookmarks Only - Do not use the entries from this TOC to create output file bookmarks. — All TOC Bookmarks - Use all of the entries from this TOC to create output file bookmarks.
Build TOCs to Level	Select the maximum number of levels of entries to build in the TOC, from 1 to 20.
Default TOC for	Select the Tree elements for which this TOC is used as the default TOC. A default must exist for every Tree element.
Exclude All Bookmarks with the Text	Specify text that will be used to designate the bookmarks to exclude from the TOC.

Attribute	Description
Header	Specify the text that will replace the word `header` in the TOC Definition File. (Limit 100 bytes)
Including Bookmarks up to Level	Select the maximum number of levels of entries in the TOC that can be created from bookmarks, from **1** to **20**.
Include In Page Numbering	Specify whether the TOC pages are included in the page numbering: **Yes** or **No**.
Include Only Bookmarks with the Text	Specify text that will be used to designate the bookmarks to include in the TOC.
Leader	Specify the characters to use to separate TOC entry text from the corresponding page number. If you select **Dash**, **Dot**, or **Underline**, the leader character is created for TOC entries at all levels. If you select **Space**, no leader is created. If you select **Use Template**, the iTOC 1 to iTOC 15 styles in the Word template specify the leaders for the corresponding TOC entry levels. Select this option if you want different leader characters for all the different TOC Entry levels or if you want leaders only for some levels. If you select **Use Template**, do the following to set up the iTOC styles in Microsoft Word: 1. Note the width of the left column of the single row table in the Word TOC Template. 2. Open the **Styles** pane. 3. Click **Options...**. 4. On the **Style Pane Options** box, for **Select styles to show**, click **All styles**. 5. To set up an iTOC style, right-click the iTOC Style, and click **Modify...**. 6. Click **Format > Tabs...**. 7. Do one of the following: — Create a tab stop for the left column width that you noted on step 1, for the right alignment, and for a leader character. — If you do not want leaders, clear all tab stops.

Attribute	Description
Left Column Entry Text	Specify the text that resolves in the left hand column of the TOC. If this is left blank, the values from the assembly tree (TOC Tree Values) populate the left column of the generated TOC. — In the TOC editor and the preview file, left column entry text resolves fully. — Volume variables, $VN and $VNAME, cannot be included in the Left Column Entry Text field for TOC Attributes. They do not resolve in published output. — Variables resolved only at publishing time will not be resolved in the Left Column Entry Text. For more information, see: *InSight System-Defined Variables*
Name*	Specify the name of the TOC. Must be a unique name within the Publishing Settings Library. (Limit 100 bytes.)
Output Channel*	Select the output channel to which this TOC is to be published. You must choose Electronic, Paper, or both. `Paper` is the default.
Right Column Entry Text*	Text that appears in the right column. Right Column Text fully resolves only in the published output. Right Column text contains the resolved value for any variable.
TOC Definition File*	Browse to select the TOC template you want to use for your table of contents. This provides the link to the Word file that defines the formatting and structure of the TOC.
Tree Elements to Include in TOC*	Specify the assembly elements to display in the generated TOC by moving items from Available Entry Generation Options to Selected Generation Options. A TOC entry for a leaf, folder, or document with a TOC or Cover Page that is included in the output channel and page numbering will stamp the page number of the TOC or Cover Page.

Use TOC Defaults

When creating a TOC, you can establish a default TOC setting. This tells Calyx RIM which TOC setting to use by default when a TOC is inserted for a particular kind of element.

For example, if TOC setting `ABC` is mapped to leaf elements, any time you insert a TOC for a leaf it will appear as the default TOC setting `ABC`. A single TOC setting can be the default for multiple elements at once.

Mapping	Sample TOC Setting
Assembly root	Table of contents
Volume	Volume table of contents
Document	Document table of contents
Leaf	Leaf table of contents

Mapping	Sample TOC Setting
Folder	Module table of contents
Extract	Table of figures

Table of Contents Templates

The layout of the TOC is defined in a TOC definition file, which must be in Word format. You can define a definition file for each TOC in the document, if required. This topic describes the basic TOC definition file.

You can modify a TOC template (which is a Microsoft Word document) to meet your publication submission needs. The text used for the final TOC entries is derived from two sources:

— The left column text specified for the TOC element, usually represented by a variable string containing the $NAME element name and $N element number of the elements included from the assembly tree

— The bookmark names contained in the actual document files

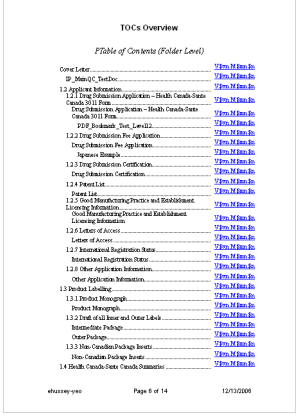
Heading level styles TOC1 (TOC20) defined in the Word document correspond to the heading levels created when the TOC is generated. Each new TOC entry is generated in its own row in the table. The first row included in the template provides a place for the generator to begin.

The heading level styles may contain Word formatting (numbering, indent, character style, color, box, outline letters, font, paragraph styles, leader text, and so on). In this way, most formatting options are supported. This information is placed in the first column of the table. The second column of the table is reserved for the right column text, and the style of this text is specified by the link text style. Again, this right column is resolved only during final publish, not during preview and editing. The left column is resolved during preview and editing.

The number of bookmark levels in the TOC element determines how many heading levels to use from all component documents in the TOC range. This should be the highest number of allowed levels in your document templates.

The number of TOC levels to include determines the total number of final heading levels that will be included in the TOC.

The location of the header text determines where the header attribute in the TOC element will be placed, and the style of that text. This text may wrap lines. If this is insufficient, you can use Word headers on the TOC template to express the TOC subject, and you can use the TOC overlay here as well to stamp additional information.


TOCs Overview

TTable of Contents (Folder Level)

Cover Letter ..... TFirm, M Imm, Rx
TP_MainQC_TestDoc ..... TFirm, M Imm, Rx
1.2 Applicant Information ..... TFirm, M Imm, Rx
1.2.1 Drug Submission Application – Health Canada Santa Canada 3011 Form ..... TFirm, M Imm, Rx
Drug Submission Application – Health Canada Santa Canada 3011 Form ..... TFirm, M Imm, Rx
PDR_Bookmark_Test_Level12 ..... TFirm, M Imm, Rx
1.2.2 Drug Submission Fee Application ..... TFirm, M Imm, Rx
Drug Submission Fee Application ..... TFirm, M Imm, Rx
Signature Example ..... TFirm, M Imm, Rx
1.2.3 Drug Submission Certification ..... TFirm, M Imm, Rx
Drug Submission Certification ..... TFirm, M Imm, Rx
1.2.4 Patent List ..... TFirm, M Imm, Rx
Patent List ..... TFirm, M Imm, Rx
1.2.5 Good Manufacturing Practice and Establishment Licence Information ..... TFirm, M Imm, Rx
Good Manufacturing Practice and Establishment Licence Information ..... TFirm, M Imm, Rx
1.2.6 Letter of Access ..... TFirm, M Imm, Rx
Letter of Access ..... TFirm, M Imm, Rx
1.2.7 International Registration Status ..... TFirm, M Imm, Rx
International Registration Status ..... TFirm, M Imm, Rx
1.2.8 Other Application Information ..... TFirm, M Imm, Rx
Other Application Information ..... TFirm, M Imm, Rx
1.3 Product Labelling ..... TFirm, M Imm, Rx
1.3.1 Product Monograph ..... TFirm, M Imm, Rx
Product Monograph ..... TFirm, M Imm, Rx
1.3.2 Draft of all Inner and Outer Labels ..... TFirm, M Imm, Rx
Intermediate Package ..... TFirm, M Imm, Rx
Outer Package ..... TFirm, M Imm, Rx
1.3.3 Non-Canadian Package Inserts ..... TFirm, M Imm, Rx
Non-Canadian Package Inserts ..... TFirm, M Imm, Rx
1.4 Health Canada Santa Canada Summaries ..... TFirm, M Imm, Rx

ehzzzzy-yuo Page 6 of 14 12/13/2006

Specify Element Level TOC Publishing Settings

You can add special sheets at any element level, including TOCs, Tabs, Cover Pages, or Slip Sheets.
Following elements are:

— Assembly
— Folder
— Leaf
— Document
— Bookmark

To specify element level TOC settings, right-click on the element and select Mass Insert/Update Publishing Elements and follow the procedure described in *Inserting a Publishing Element*.

Resolve Entries in TOCs

Calyx RIM calculates right column text and resolves electronic links for the entries in a TOC, based on the assembly items that are assigned to the publishing channel and the type of publish (Leaf, Volume, or Single File).

— Publishable - Publishable elements are those that can produce pages in the output (Leaf, Volume, or Single File). These are Documents, TOCs, and Cover Pages that are in-channel and in range of the type of publish. Elements attached to or descended from non-Leafs are unpublishable in electronic Leaf output.
— Placeholder - Placeholders may add to page numbering but are never resolved as TOC entry targets.
— Ready to publish - A publishable element with an extracted PDF rendition (either a PDF source or PDF rendition of the source). Entries targeting an element that is ready to publish will have resolved right column text and a working hyperlink.

The following assembly elements are resolved according to various business rules employed by Calyx RIM to calculate page numbering in TOCs.

TOC Entries that Target Leaf, Folder, or Document Elements

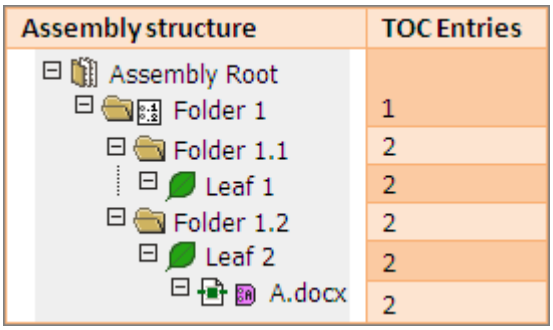
When a leaf, folder, or document that has a publishable TOC or cover page that is also assigned to be included in page numbering, the TOC entry for that leaf, folder, or document calculates the right column text for the first page of the publishable TOC or cover page. The link destination of the link under the right column TOC entry text is the first page of the publishable TOC or cover page.
When there are folders, leafs, and documents without elements attached to them (as described above), the TOC entries for those empty elements resolve to the first subsequent element in the assembly structure:

— Publishable included in page numbering TOC (see: *Sample TOC 1*.
— Publishable included in page numbering cover page, or (see: *Sample TOC 2*.
— Publishable document pages (see: *Sample TOC 3*.

An exception to this rule is that a paper channel cover page attached to a reference leaf is always targetable for TOC entries, even if the cover page is not included in page numbering. Electronic elements attached to a reference leaf are invalid. Tabs and Slip Sheets are never targeted because they are never included in Page Numbering.

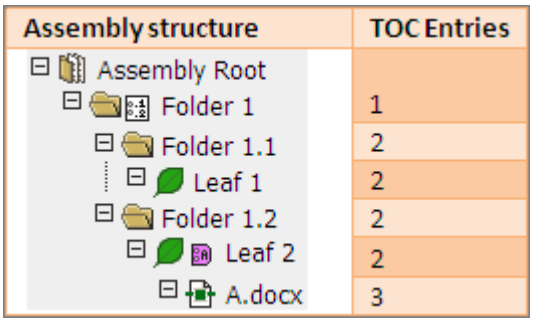
Sample TOC 1

— All elements are in-channel and included in page numbering
— All special sheets and documents are ready to publish



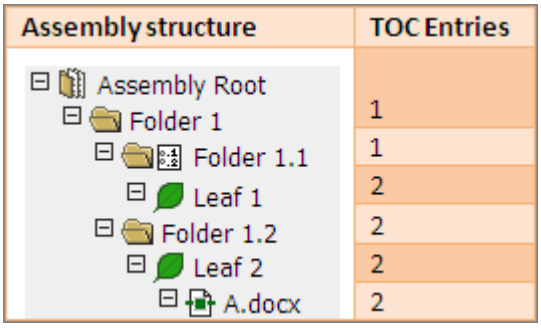
Sample TOC 2

— All elements are in-channel and included in page numbering.
— All special sheets and documents are ready to publish.



Sample TOC 3

— All elements are in-channel and included in page numbering.
— All special sheets and documents are ready to publish.



TOC Entries that Target Other Tables of Contents

For a TOC entry targeting a Table of Contents, the right-column text is calculated for the first page of the targeted TOC.
The link destination of the link, under right-column TOC entry text, is the first page of the TOC.

TOC Entries that Target Document Bookmarks (Extracts)

For a TOC entry targeting an extracted document bookmark, the right-column text is calculated for the targeted page of the including document.
The link destination of the link under right-column TOC entry text, is the document page.

PageMarker attached special sheets will not be targeted by these TOC entries.

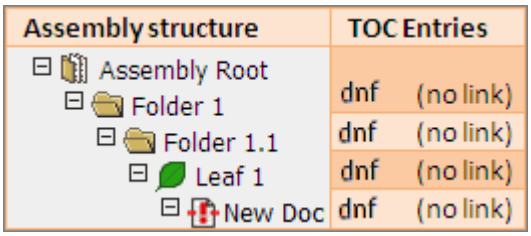
TOC Entries that Target Planned and Not Ready to Publish Assembly Elements

An assembly element (TOC, cover page, or document) that has not been rendered and extracted is not ready to publish.
No pages are created in the leaf, volume, or single output files for these pages. When an assembly contains unpublishable elements, the right-column text for TOC entries targeting these elements (or pages in them) is the `Destination Not Found Text`. There is no navigable link for these TOC entries.

The `Destination Not Found Text` setting is defined on the ***Publishing*** page of the ***Modify Publishing Settings*** dialog box. If the Destination Not Found Text setting is not defined, a single space is used.

Sample TOC 1

— All elements are in-channel and included in page numbering.
— Document& New Doc is planned and has not been assigned to a document in a DMS.



Sample TOC 2

— All elements are in-channel and included in page numbering.
— The template for the cover page attached to `A.docx` has not been rendered and extracted.
— Document `A.docx` is ready to publish. Entries targeting extracted bookmarks in `A.docx` are resolved.

Assembly structure	TOC Entries
Assembly Root	
Folder 1	dnf (no link)
Folder 1.1	dnf (no link)
Leaf 1	dnf (no link)
A.docx	dnf (no link)

Sample TOC 3

— All elements are in-channel and included in page numbering.
— Document `A.docx` is not ready to publish with a planned page count of 8.
— Document `AAA.docx` is ready to publish.

Assembly structure	TOC Entries
Assembly Root	
Folder 1	dnf (no link)
Folder 1.1	dnf (no link)
Leaf 1	dnf (no link)
Folder 1.2	dnf (no link)
Leaf 2	dnf (no link)
A.docx	dnf (no link)
Folder 1.3	9
Leaf 3	9
Folder 1.4	9
Leaf 4	9
AAA.docx	9

TOC Entries that Target Native Leafs and Descendents

A native leaf is a leaf with the Use Native File attribute set to YES. Because the output file of native leafs may be of any file type, Native leafs require special handling.

The following rules apply for native files:

— The page number for the first page is used for any page in a native leaf document. Page numbers and totals are always calculated using the Planned Number of Pages for native leaf documents. If you have not indicated a Planned Number of Pages for a native leaf document, one page will be used. Native leaf documents follow the usual rules of page numbering. If you do not want native leaf pages to be added to the page numbers and totals, set Include in page numbering to NO. If you do not want the native leaf document to affect the paper channel page numbers, remove it from the paper output channel.
— The PDF link for a link, TOC entry, or bookmark in published PDF output that targets a page in a native leaf appears as a Launch link. The targeted native leaf file is opened in its associated application. Because of this, individual pages in the native leaf file cannot be targeted. If Adobe Acrobat® is the default application for PDF files, links targeting pages in native leaf output will navigate to the first page.

Invalid Targeted Assembly Elements

Invalid targeted assembly elements are usually created in error, and are not included in the published assembly. Invalid targeted assembly elements can be caused for several reasons.

Possible reasons for invalid target assembly elements:

— Out-of-channel TOCs and documents (and their extracted bookmarks).
— Extracted bookmarks of documents with new bindings. This situation can occur by creating a TOC tree with extracts, followed by performing a DMS synchronization on the parent document without updating/regenerating/rendering the TOC.
— Extracted bookmarks out of page range. This situation can occur by creating a TOC tree with extracts, and then limiting the page range of the document to exclude some extracts without updating/regenerating/rendering the TOC.
— Target elements that have been deleted from the assembly. This situation can occur by creating a TOC tree, and then deleting some of the target elements without updating/regenerating/rendering the TOC.

When a TOC contains entries targeting invalid elements, the right column text for these TOC entries is the `Destination Not Found Text`. There is no navigable link for these TOC entries.

Tables of Contents

Tables of Contents (TOCs) enable you to find contextual information in a published assembly. The creation of TOCs is dependent on document structure, as each submission document can contain several levels of document structure elements in a familiar hierarchy. For CTD TOCs, the hierarchical structure roughly follows the eCTD hierarchy, but for other publications such as study reports, the structure may differ.

You can treat TOCs as additional assigned documents in the repository that are not part of the lifecycle or content, but are needed during electronic and paper publishing. These TOC documents can be generated into `.doc` format for use and modification in Microsoft Word or other word processing applications. Normal rendering processes can create final TOC documents in the publishing output file format.

When you insert a TOC into an assembly the default TOC type is used automatically, or you can choose an alternate TOC type. You specify the default TOC settings in the Publishing Settings Library Templates, and a default TOC is required. In the publishing settings, you may create an association between different TOC types and assembly elements or locations. This association is called mapping.

When publishing tables of contents that include a range to which all content has not yet been assigned, TOC entries that cannot be targeted. For example, when no content yet exists under the leaf, TOC entries are stamped with the `Destination Not Found Text` from the Publishing Settings. Once the content is assigned to the leaf, the TOC entry stamp correctly resolves to the destination.

If you are defining (mapping) a TOC for volumes, when you insert a TOC on a volume the TOC type associated (mapped) with a volume may be inserted automatically. As long as the TOC types are defined correctly for the appropriate elements before bulk insertion, little editing of the assembly is necessary to generate valid TOCs.

When you generate a TOC, a Word document is created from the information about the TOC in Calyx RIM. The TOC is combined with the style and format specified in the TOC template. The TOC is then rendered to a PDF and

the right-column text and hyperlink is resolved during final publishing. There are various ways to create a TOC, for example:

— Generate the TOC from the default range directly to a PDF during final publish; this is best suited for volume TOCs.
— Edit the TOC in the TOC editor, then generate the TOC from the TOC editor directly to a PDF during the final publishing.
— Generate the TOC from the default range to the Word document preview, edit the preview, then publish the Word document to a PDF during final publishing; this is best suited to submission TOCs.
— Edit the TOC in the TOC editor, generate the TOC from the TOC editor to a Word document preview, edit the preview, and then publish the Word document to a PDF during final publishing; this is best suited to a submission TOC.

Generated TOCs are saved to the preview location specified in the TOC publishing settings.

When you preview a generated TOC, the system makes a copy of the TOC in a temporary location (regardless of the defined preview location) and displays that copy for preview. Any changes you make to the previewed TOC are made on the temporary copy only, and are not made on the actual TOC that will be published.

Note: *In some desktop configurations you may have to save the TOC to a local file and open the local file to view the TOC.*

Insert a TOC

You can insert a TOC in an element for the contents of the element.
When adding a TOC to a tree element, the TOC name inherits the name of the element on which it was placed. This name is used to create the file name of the generated TOC.

Note: *If a TOC is placed on an element that includes a special character in its name (/ \ : * ? < > |), you must edit and update the TOC name so that it does not include special characters, otherwise it will not generate.*

To insert a TOC:

1. In the assembly, right-click the element where you want to insert the TOC and choose Mass Insert/Update Publishing Elements.
2. In the *Mass Insert/Update Elements* window, select Table of Contents.
3. Select one or more elements where you want to insert a TOC:

Option	Description
For this Element:	Inserts a TOC for the selected assembly element.
Volumes:	Inserts a TOC for each volume in the assembly.
Folders:	Inserts a TOC for each folder in the assembly.
Leaf Elements:	Inserts a TOC for each leaf element in the assembly.

Option	Description
Documents:	Inserts a TOC for each assigned document and document placeholder in the assembly.
Page Markers:	Inserts a TOC for each volume break in assigned documents.

4. In the Publishing Setting list, leave the Use Default setting, or choose an alternative TOC setting (if other TOC settings have been created in the PLT).
5. To set the Range Start option, select Entity and click Browse to specify the location in the Current Assembly to start the range of the new TOC.
6. Click Insert.
   A message prompts you to confirm the insertion.
7. Click OK.
   For each element where a TOC has been inserted, the TOC icon appears in the assembly tree.

Modify TOC Attributes

You can modify the attributes of a TOC placed in an assembly.

To modify TOC attributes:

1. Click Edit Publishing Settings Library to open the Publishing Settings Library for the assembly.
2. In the Publishing Settings Library, click TOC.
3. On the TOC tab, click the name of the TOC you want to modify.
4. On the *TOC Types* page, click Edit TOC Type.
5. On the Edit TOC Type page, modify the TOC attributes as needed.
6. Save. To close the *Edit TOC Type* page without saving any changes, click Cancel.

Modify a TOC

Use the TOC editor to modify folders, leafs, or files in a TOC by: deactivating or activating them, editing their names, moving them up or down, and promoting or demoting them in the hierarchy. You cannot modify the root of the assembly in the TOC editor.

To modify a TOC:

1. In the *Publishing Elements* view of an assembly tree, click TOC.
   The *TOC Attributes* window appears.
2. In the TOC Attributes toolbar, click Modify TOC Content.
   The Modify TOC Content view displays the entries of the selected TOC.

Note: *Using* Modify TOC Content *(the TOC entries editor) sets the* TOC Content Modified *flag to* `Yes` *on the* TOC Attributes *page. This gives you control of the TOC Content for making modifications. If you only want to view the TOC Content and do not want to make modifications, click* Reset TOC Content *to exit.*

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3. To modify an entry in the TOC, right-click on the entry and choose an option in the list. Multiple entries can be selected to perform an action.

The option list is contextual, depending on the location of the selected item in the TOC. Only the usable options will be available for the selected TOC entry.

4. To reset the TOC so that it includes all of your recent assembly changes, click Reset TOC Content.

   Using Reset TOC Content sets the TOC Content Modified flag to `No` on the *TOC Attributes* page. By clicking this button, you relinquish control of the TOC Content. Any changes you have made to the TOC Content will not be saved.

5. To save your changes, take control of the TOC Content and close the *Modify TOC Content* view, go back to the *TOC Attributes* view, and click Close.

Select Contiguous TOC Nodes

You can select multiple TOC entries, or nodes, either contiguously or non-contiguously.

To select contiguous TOC nodes:

1. Click the first TOC entry of the group of nodes you want to select.
2. Press and hold the `Shift` key on your keyboard.
3. Click the last TOC entry of the group of nodes you want to select.
   All of the nodes in your selected group should appear highlighted. You can now perform the following actions on the entire selected group at once:
   — Activate
   — Deactivate
   — Drag-and-drop

Select Non-contiguous TOC Nodes

You can select multiple TOC entries, or nodes, either contiguously or non-contiguously.

To select non-contiguous TOC nodes:

1. Press and hold the `Ctrl` key on your keyboard.
2. Click the TOC entries you want to select.
   The nodes that you selected should appear highlighted, although the group is not contiguous. All of the nodes in your selected group should appear highlighted. You can now perform the following actions on the entire selected group at once:
   — Activate
   — Deactivate
   — Drag-and-drop

TOC Context Menu Options

Use the TOC context menu options to manage elements in a table of contents.

Option	Description
Expand Range	Expand the selected entry to reveal its child entries.
Deactivate/Activate selected	Deactivate or activate the selected entry.

Option	Description
Deactivate/Activate selected + descendants	Deactivate or activate the selected entry plus its child nodes of the same active/inactive state.
Edit	Change the name of the selected entry.
Move Up	Move the selected entry up (within its node group).
Move Down	Move the selected entry down (within its node group).
Promote	Move the selected entry (and its child entries) to the left in the TOC.
Demote	Move the selected entry (and its child entries) to the right in the TOC.

Deactivate a TOC Entry

You can deactivate a TOC entry if is not needed in the submission.

To deactivate a TOC entry:

1. In the assembly, select a TOC and click Modify TOC Tree.
2. Right-click the TOC entry, and choose Deactivate.
   The TOC entry is not deleted, but it is made unavailable.
3. Save.
4. To activate a deactivated TOC entry, right-click it and choose Activate, then Save.

Modify TOC Entry Text

Use Edit TOC Entry to modify the text of an entry in the TOC tree.

To modify TOC entry text:

1. In the *Publishing Elements* view, click TOC.
2. On the *TOC Attributes* page, click Modify TOC Content.
3. Right-click a TOC level, and click Edit.
   The *Edit TOC Entry* dialog box appears.
4. Edit the text and Save.
   The TOC entry content is updated.

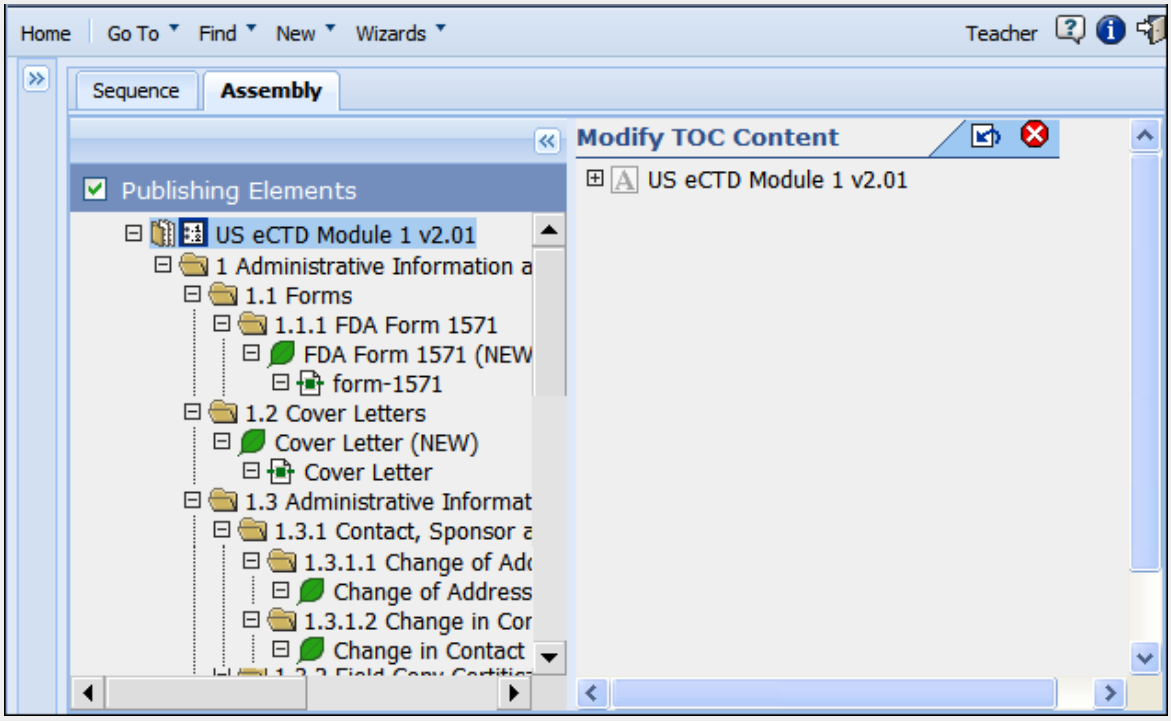
View TOC Entry Text

You can view the text for a TOC entry to verify it.

To view TOC entry text:

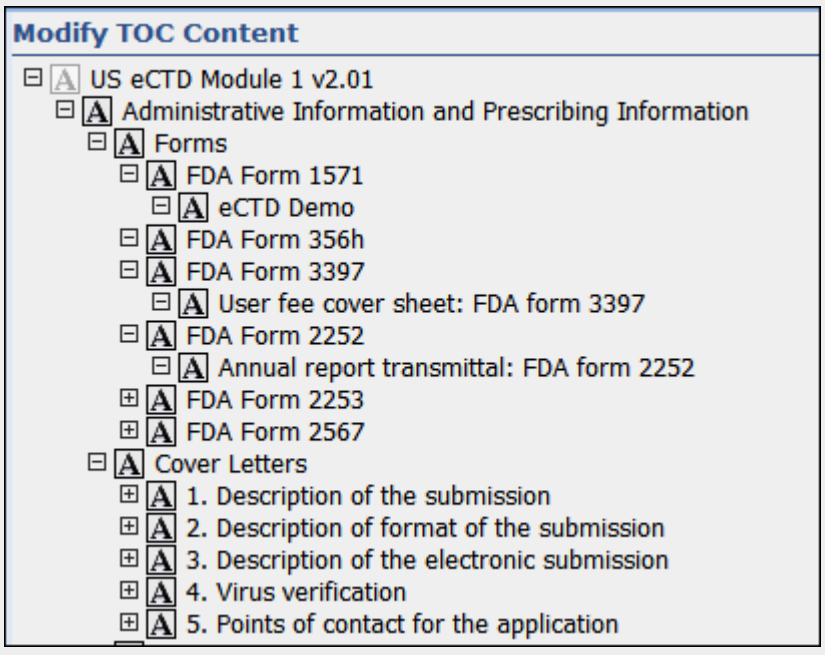
1. In the assembly, select a TOC and click Modify TOC Content to view the *Modify TOC Content* page.

Example



2. To expand the TOC content of any node with children (other than the root TOC content node) click Expand or right-click and select Expand Range. To collapse the TOC content of a node with children, click Collapse.

Example



Duplicate a TOC

You can duplicate a TOC within an entity and add it to the assembly.

To duplicate a TOC:

1. Right-click the TOC you want to duplicate, and choose Duplicate TOC.
   The new TOC is added to the element and the *Edit TOC* page appears.
2. In the *Edit TOC* view, specify the values to use and Save.
   The duplicated TOC is added to the assembly tree.

Delete a TOC

You can delete a TOC from an entity as needed.

To delete a TOC:

1. Right-click the TOC you want to delete, and choose Delete TOC.
   A message prompts you to confirm the deletion.
2. Click OK.

Note: *If you delete the Microsoft Word TOC document created by Calyx RIM directly in the DMS repository or file system, the publish may fail because Calyx RIM cannot rerender the Word TOC documents into PDF output. You must delete the TOC element and create a new one.*

Move TOCs

You can drag a TOC to an unlocked tree element in an assembly.

If the TOC Content Modify flag is not selected, the TOC range also moves to the new location. If the TOC Content Modify flag is selected, the TOC range does not move and your edits are preserved.

You can drag items to any element in the assembly tree, or to a volume, but you cannot drag items from a volume into an assembly tree.

Move a TOC

You can move a TOC to another place in the assembly.

Click the TOC that you want to move and drag it to an unlocked tree element.
The TOC is moved.

Generate a TOC Manually

Use this procedure to generate a TOC manually.

To generate a TOC manually:

1. In the assembly, click the icon for the TOC you want to generate.
2. Click Generate.

A job request is submitted to generate the TOC.

3. Choose Go To > Job Requests to monitor the progress of the request.
   When the job status is complete, you can preview the TOC.

Generate a TOC Using Prepare to Publish

Use this procedure to generate a TOC using Prepare to Publish.

To generate a TOC using Prepare to Publish:

1. From the assembly, select the entire assembly or the section for which you want to generate a TOC.
2. Choose Prepare to Publish from the action toolbar.
   The *Prepare to Publish* dialog box appears.
3. Select Generate TOCs only, and clear any other options that are selected.
4. Click OK.
   A message prompts you to confirm the publish.
5. Click OK.
   A job request is submitted to generate the TOCs.
6. Choose Go To > Job Requests to monitor the progress of the request.
7. When the job status is complete, click View File.

Preview TOC

You can preview a local, cached copy of a generated TOC in your Web browser.

A TOC must be generated before it can be previewed. Use the Generate TOCs option in the *Prepare to Publish* dialog to generate a TOC for preview.

When you preview a generated TOC, the system makes a copy of the TOC in a temporary location (regardless of the defined preview location) and displays that copy for preview. Any changes you make to the previewed TOC are made on the temporary copy only, and are not made on the actual TOC that will be published.

Preview a TOC

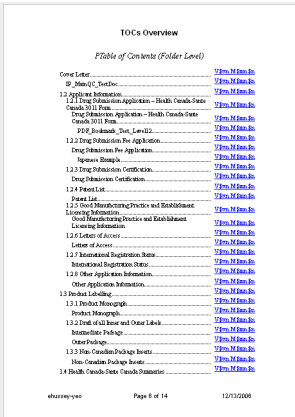
You can preview a local, cached copy of a generated TOC in your Web browser.

To preview a TOC:

1. When a job request to generate a TOC has completed, on the *assembly* page, click View File to preview the TOC.
2. When you are prompted, open the TOC.

Example

```
The preview is similar to the following:
```


TOCs Overview

TTable of Contents (Folder Level)

Cover Letter ..... V1pro, M Inter, Rn
TP_Main-QC_Test.Doc ..... V1pro, M Inter, Rn
1.2 Applicant Information ..... V1pro, M Inter, Rn
1.2.1 Drug Submission Application – Health Canada-Santé Canada 3011 Form ..... V1pro, M Inter, Rn
Drug Submission Application – Health Canada-Santé Canada 3011 Form ..... V1pro, M Inter, Rn
PDF_Bookmark_Test_Lev-II2 ..... V1pro, M Inter, Rn
1.2.2 Drug Submission Fee Application ..... V1pro, M Inter, Rn
Drug Submission Fee Application ..... V1pro, M Inter, Rn
Signature Example ..... V1pro, M Inter, Rn
1.2.3 Drug Submission Certification ..... V1pro, M Inter, Rn
Drug Submission Certification ..... V1pro, M Inter, Rn
1.2.4 Patent List ..... V1pro, M Inter, Rn
Patent List ..... V1pro, M Inter, Rn
1.2.5 Good Manufacturing Practice and Establishment Licensing Information ..... V1pro, M Inter, Rn
Good Manufacturing Practice and Establishment Licensing Information ..... V1pro, M Inter, Rn
1.2.6 Letter of Access ..... V1pro, M Inter, Rn
Letter of Access ..... V1pro, M Inter, Rn
1.2.7 International Registration Status ..... V1pro, M Inter, Rn
International Registration Status ..... V1pro, M Inter, Rn
1.2.8 Other Application Information ..... V1pro, M Inter, Rn
Other Application Information ..... V1pro, M Inter, Rn
1.3 Product Labelling ..... V1pro, M Inter, Rn
1.3.1 Product Monograph ..... V1pro, M Inter, Rn
Product Monograph ..... V1pro, M Inter, Rn
1.3.2 Draft of all Inner and Outer Labels ..... V1pro, M Inter, Rn
Intermediate Package ..... V1pro, M Inter, Rn
Outer Package ..... V1pro, M Inter, Rn
1.3.3 Non-Canadian Package Inserts ..... V1pro, M Inter, Rn
Non-Canadian Package Inserts ..... V1pro, M Inter, Rn
1.4 Health Canada-Santé Canada Summaries ..... V1pro, M Inter, Rn

eNumrny-yeo Page 6 of 14 12/13/2006

Modify Generated TOC

Make the changes to the generated TOC using the TOC editor.

Generated TOCs are created as Word documents and saved to the preview location specified in the TOC publishing settings for the assembly. These TOCs are complete except for the right column, which is generated during final publishing with cross-reference stamps and hyperlinks.

You can edit the TOC, including left column. You cannot edit the table and the right column links. These must be intact during final publishing, so they are stamped and linked appropriately.

Note: *In some cases the TOC editor does not resolve a left column variable immediately. This happens if the left column variable is complex and requires additional processing to define. You may need to first generate the TOC to preview it.*

Modify a Generated TOC

You can edit the TOC, including left column. You cannot edit the table and the right column links. These must be intact during final publishing, so they are stamped and linked appropriately.

To modify a generated TOC:

1. In the assembly, click the TOC you want to edit.
2. Verify the generated TOC `file name` and `location`.
3. Access the document repository in the normal manner and edit the TOC.

Bookmarks

Bookmarks are taken directly from the source files, unless they have been modified or changed in the bookmark editor. In this case, the bookmarks are used for all TOCs and file output.

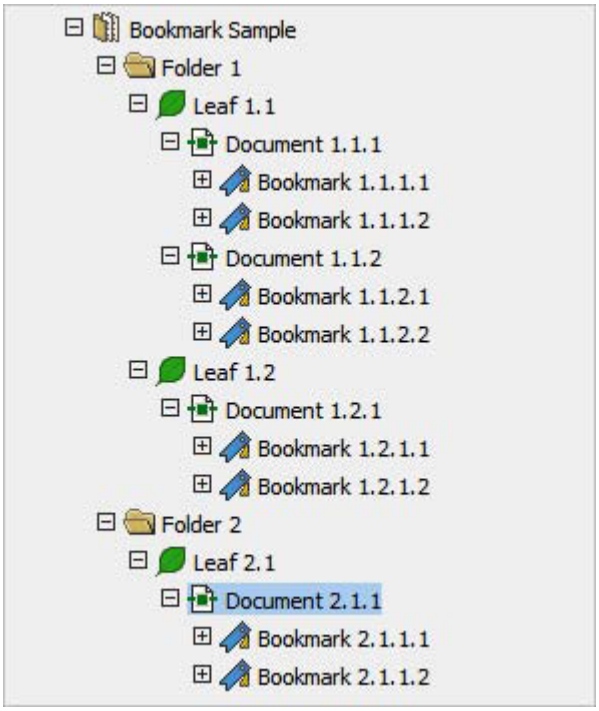
When the TOC is generated, either in the TOC editor or at publish time, Calyx RIM attempts to build a valid tree structure using the edited bookmarks or bookmarks extracted from source documents. If hierarchy levels are skipped or missed, Calyx RIM will 'compress' the bookmark tree in order to ensure valid published output.

During final TOC generation, two bookmark handling options are available: File Bookmarks and TOC Bookmarks.

File Bookmarks

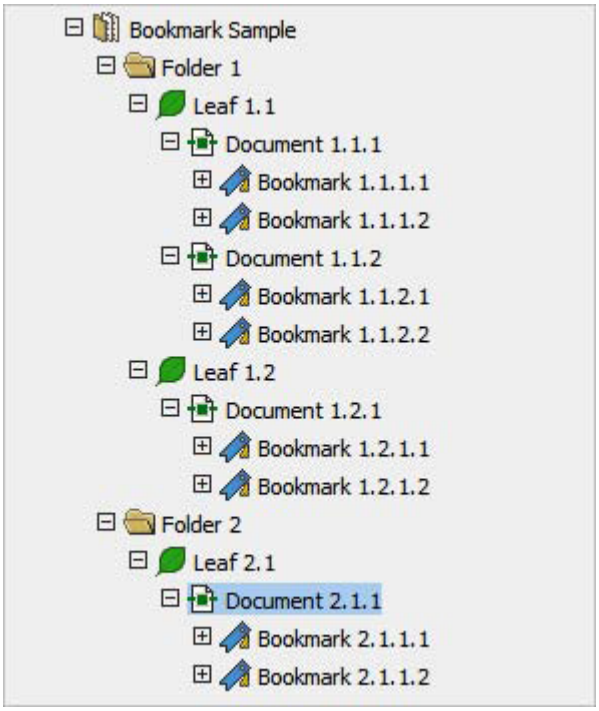
All final output files that span the range of a TOC contain their original bookmarks, and those bookmarks are used in the PDF output.
If multiple files are combined, they contain the bookmark trees of all source documents, plus a bookmark representing the document.

As shown in the example image, if you select File Bookmarks Only for all TOCs the final files contain the following (which is also the default for files that do not have tables of contents defined).

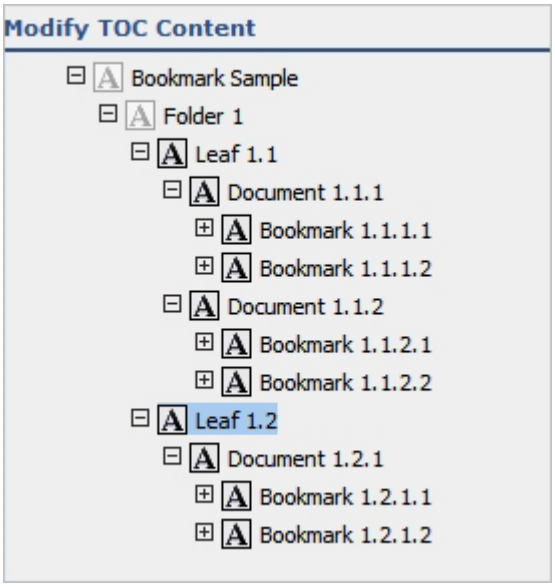


TOC Bookmarks

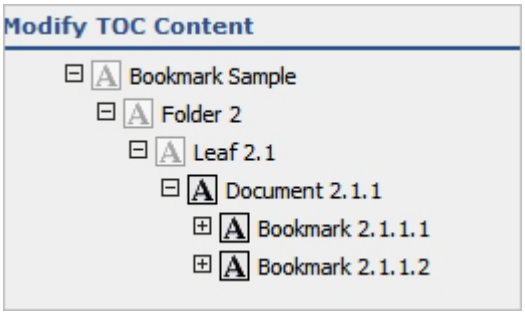
All final output files that span the range of the TOC contain the entire bookmark tree. For the output PDFs that fall within the range of that TOC, the bookmarks will match exactly what is shown in the generated TOC. Each TOC entry corresponds to a bookmark.
If multiple TOCs exist in this range and use this option, the TOCs are appended and the result is used as the bookmark tree. In the following example, if you select Use TOC Bookmarks for TOC #1 and TOC #2:



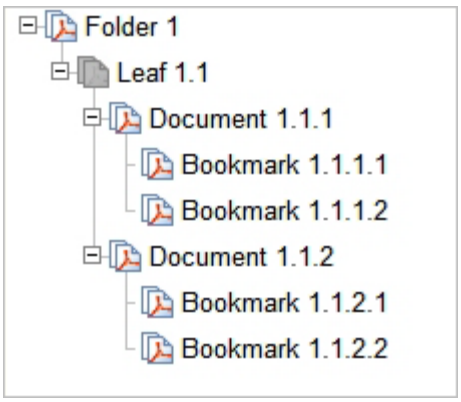
Use TOC bookmarks creates the following:



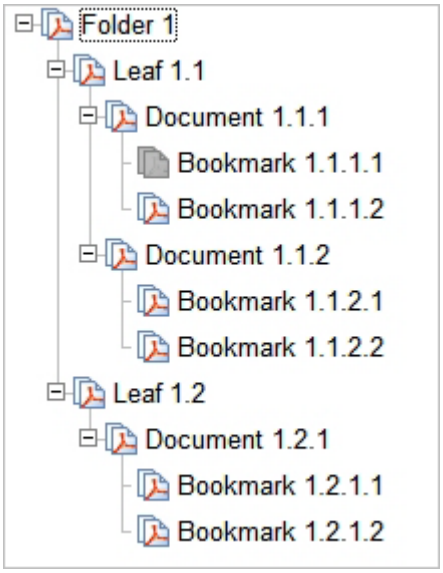
Use file bookmarks creates the following:



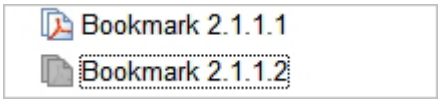
Leaf 1.1 file



Leaf 1.2 file



Leaf 2.1 file



Calyx RIM can generate bookmarks automatically for the output PDF file as part of TOC creation. The new bookmark text for each component document is determined from the left column text for the TOC element. With this function, the bookmarks for the final files can reflect exactly the content in the TOCs.

TOC Levels and Bookmark Levels

Bookmark levels are essentially a sub-setting of the TOC Levels setting. TOC levels defines how many levels will be displayed overall in the TOC and Bookmark levels determines how many levels of bookmarks are displayed within that number of TOC levels.
The following examples demonstrate the concept of TOC levels and Bookmark levels.

The first example shows how levels 3 and 4, although falling within the TOC level range, will not be included in the TOC because the number of levels of bookmarks to be included has been restricted to 2.

Example 1: TOC Levels = 7 Bookmark Levels = 2

LEVEL1	LEVEL2	LEVEL3	LEVEL4	LEVEL5	LEVEL6	LEVEL7	LEVEL8	LEVEL9	LEVEL10
Folder 1									
	Leaf 1								
		Doc 1							
			Bkm1						
				Bkm2					
					~~Bkm3~~				
						~~Bkm 4~~			
							Bkm5		
Folder 2									
	Folder 3								
		Folder 4							
			Leaf 2						
				Doc 2					
					Bkm1				
						Bkm2			
							Bkm3		
								Bkm4	
									Bkm 5
Folder 5									
	Leaf 3								
		Doc 3							
			Bkm1						
				Bkm2					
					~~Bkm3~~				
						~~Bkm 4~~			
							Bkm5		

Table of Contents (Folder Level)

Folder 1 ..... TOCRIGHTCOL
Leaf 1 ..... TOCRIGHTCOL
Doc 1 ..... TOCRIGHTCOL
Bkm1 ..... TOCRIGHTCOL
Bkm 2 ..... TOCRIGHTCOL
Folder 2 ..... TOCRIGHTCOL
Folder 3 ..... TOCRIGHTCOL
Folder 4 ..... TOCRIGHTCOL
Leaf 2 ..... TOCRIGHTCOL
Doc 2 ..... TOCRIGHTCOL
Bkm 1 ..... TOCRIGHTCOL
Bkm 2 ..... TOCRIGHTCOL
Folder 5 ..... TOCRIGHTCOL
Leaf 3 ..... TOCRIGHTCOL
Doc 3 ..... TOCRIGHTCOL
Bkm 1 ..... TOCRIGHTCOL
Bkm 2 ..... TOCRIGHTCOL

In the second example, Bookmarks at levels 8 and 9 in the assembly will not be included because TOC levels is restricted to 7.

Example 2: TOC Levels - 7 Bookmark Levels = 9

LEVEL1	LEVEL2	LEVEL3	LEVEL4	LEVEL5	LEVEL6	LEVEL7	LEVEL8	LEVEL9	LEVEL10
Folder 1									
	Leaf 1								
		Doc 1							
			Bkm1						
				Bkm2					
					Bkm3				
						Bkm4			
							Bkm5		
Folder 2									
	Folder 3								
		Folder 4							
			Leaf 2						
				Doc 2					
					Bkm1				
						Bkm2			
							Bkm3		
								Bkm 4	
									Bkm5
Folder 5									
	Leaf 3								
		Doc 3							
			Bkm1						
				Bkm2					
					Bkm3				
						Bkm4			
							Bkm5		

Table of Contents (Folder Level)

Folder 1 ..... TOCRIGHTCOL
Leaf 1 ..... TOCRIGHTCOL
Doc 1 ..... TOCRIGHTCOL
Bkm 1 ..... TOCRIGHTCOL
Bkm 2 ..... TOCRIGHTCOL
Bkm 3 ..... TOCRIGHTCOL
Bkm 4 ..... TOCRIGHTCOL
Folder 2 ..... TOCRIGHTCOL
Folder 3 ..... TOCRIGHTCOL
Folder 4 ..... TOCRIGHTCOL
Leaf 2 ..... TOCRIGHTCOL
Doc 2 ..... TOCRIGHTCOL
Bkm 1 ..... TOCRIGHTCOL
Bkm 2 ..... TOCRIGHTCOL
Folder 5 ..... TOCRIGHTCOL
Leaf 3 ..... TOCRIGHTCOL
Doc 3 ..... TOCRIGHTCOL
Bkm 1 ..... TOCRIGHTCOL

In the third example, only one level of bookmarks will be included because the TOC level count starts from the invoked element.

Example 3: TOC Levels = 4 Bookmark Levels = 4

LEVEL1	LEVEL2	LEVEL3	LEVEL4	LEVEL5	LEVEL6	LEVEL7	LEVEL8	LEVEL9	LEVEL10
Folder 1									
	Leaf 1								
		Doc 1							
			Bkm1						
				Bkm2					
					Bkm3				
						Bkm4			
							Bkm5		
Folder 2									
	Folder 3								
		Folder 4							
			Leaf 2						
				Doc 2					
					Bkm1				
						Bkm2			
							Bkm3		
								Bkm4	
									Bkm5
Folder 5									
	Leaf 3								
		Doc 3							
			Bkm1						
				Bkm2					
					Bkm3				
						Bkm4			
							Bkm5		

Table of Contents (Folder Level)

Folder 4 ..... TOCRIGHTCOL
Leaf 2 ..... TOCRIGHTCOL
Doc 2 ..... TOCRIGHTCOL
Bkm1 ..... TOCRIGHTCOL
Bkm 2 ..... TOCRIGHTCOL
Bkm3 ..... TOCRIGHTCOL
Bkm4 ..... TOCRIGHTCOL
Folder 2 ..... TOCRIGHTCOL
Folder 3 ..... TOCRIGHTCOL
Folder 4 ..... TOCRIGHTCOL
Leaf 2 ..... TOCRIGHTCOL
Doc 2 ..... TOCRIGHTCOL
Bkm1 ..... TOCRIGHTCOL
Bkm 2 ..... TOCRIGHTCOL
Folder 5 ..... TOCRIGHTCOL
Leaf 3 ..... TOCRIGHTCOL
Doc 3 ..... TOCRIGHTCOL
Bkm1 ..... TOCRIGHTCOL

TOC Entry Links

When a TOC entry is generated during final publishing, it is automatically hyperlinked to the page containing the TOC entry.

The destination is determined from the bookmark data that was used to create the TOC entry. The link area extends from the top left of the TOC link text column to the bottom right of the column. The link parameters are determined by the link publishing settings for the assembly.

Overlay Settings

With Calyx RIM, you can define headers and footers for certain elements in your assembly by creating and/or manipulating an overlay template file and specifying the overlay settings.

The overlay template is a file that you can create using Word. The overlay template can contain graphics, regular text, or variables that are resolved at publishing time. You can apply publication overlays to individual documents, cover pages, and TOCs. You can easily position graphics, text, or variables such as page numbers in the headers and footers of the document, and you can also specify font styles like you would in any other Word file.

You can create as many overlay files as needed. Calyx RIM enables you to define a default overlay file separately for each of the following types of elements in your assembly:

— All TOCs
— All cover pages
— All content documents

Calyx RIM can help you manipulate how overlay files are to be applied in multiple ways, including:

— Best fit - Used when working with overlay files that contain multiple pages. The multiple pages typically contain multiple page sizes (for example, A4 and US Letter) or multiple orientations (for example, portrait and landscape). Calyx RIM selects the best overlay page size and orientation to match the output page size and orientation after normalization.
— Rotation - Applied when there is a single orientation in an overlay file. You should choose to turn on overlay rotation when you have a portrait-oriented overlay that should be rotated to landscape orientation for landscape-oriented content documents. This results in all the headers and/or footers appearing at the same position on each page.
— Scaling - Enables you to indicate whether to scale the overlay to the output page.

When defining overlay publishing settings, many of the overlay values may already be populated, especially if you created your assembly by importing another assembly or template where overlay settings were applied. If this is the case, verify that your overlay settings meet the requirements for your new assembly.

Create or Modify Overlays

In the selected Publishing Settings Library, you can modify the Overlay Settings to adjust the default formatting of the overlay. This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL).

To modify the Overlay Settings:

1. On the *Publishing Settings Library* window, select Overlays.

2. Click Create .

   To edit an existing overlay setting, click a named overlay in the list on the Overlays tab.
3. On the *Create/Edit Overlay Settings* page, complete the required fields, and the optional fields as needed. Required information is indicated by an asterisk (*).
   - Name *
   - Overlay Template File (click Browse to locate and select the location)
   - Default Overlay For (move items from the Available box to the Selected box to apply the Overlay settings by default for those items)
   - Rotate Overlay to Content
   - Apply Best Fit Overlay
   - Scale Overlay to Content Page Size
   - Scale Content to Margins
   - Measurement Unit
   - Portrait Margin Left
   - Portrait Margin Right
   - Portrait Margin Top
   - Portrait Margin Bottom
   - Landscape Margin Left
   - Landscape Margin Right
   - Landscape Margin Top
   - Landscape Margin Bottom
4. Save.

Option	Action
To create another overlay setting, after saving the current settings:	Click Create Another Overlay.
To discard the changes:	Click Cancel.
To return to the Publishing Settings Library after editing an existing Overlay setting:	Click the name of the Publishing Settings Library on the *View* page at the top of the page.

Overlay Attributes

You can use the attributes to define the Overlay. Required information is indicated by an asterisk (*).

Attribute	Description
Apply Best Fit Overlay	Choose Yes to apply the best fitting overlay page from the overlay template. Default is No.

Attribute	Description
Default Overlay For	Move publishing elements to the Selected box to specify this as the default overlay for the selected publishing elements. At least one overlay must be defined as the default for Cover Pages, Documents, and TOCs. Available options: Cover Pages, Documents, TOCs
Landscape Margin Bottom	The bottom margin on a landscape page. Enter a numeric value from `.1` to `2` inches or `.03` to `5.1` centimeters.
Landscape Margin Left	The left margin on a landscape page. Enter a numeric value from `.1` to `2` inches or `.03` to `5.1` centimeters.
Landscape Margin Right	The right margin on a landscape page. Enter a numeric value from `.1` to `2` inches or `.03` to `5.1` centimeters.
Landscape Margin Top	The top margin on a landscape page. Enter a numeric value from `.1` to `2` inches or `.03` to `5.1` centimeters.
Measurement Unit	Measurement used to indicate margin sizes. Available options: Inches, Centimeters. Default is `Inches`.
Name*	Specify the name of the overlay. Must be a unique name within the Publishing Settings Library. (Limit 100 bytes.)
Overlay Template File	Browse to select the template file stored in the document repository that will be used to generate the overlay.
Portrait Margin Bottom	The bottom margin on a portrait page. Enter a numeric value from `.1` to `2` inches or `.03` to `5.1` centimeters.
Portrait Margin Left	The left margin on a portrait page. Enter a numeric value from `.1` to `2` inches or `.03` to `5.1` centimeters.
Portrait Margin Right	The right margin on a portrait page. Enter a numeric value from `.1` to `2` inches or `.03` to `5.1` centimeters.
Portrait Margin Top	The top margin on a portrait page. Enter a numeric value from `.1` to `2` inches or `.03` to `5.1` centimeters.
Rotate Overlay to Content	Choose Yes to rotate the overlay to fit the content correctly. Default is `No`.
Scale Content to Margins	Choose Yes to scale the content to the margins defined for the overlay. Default is `No`.
Scale Overlay to Content Page Size	Choose `Yes` to scale the overlay to fit the content correctly. Default is `No`.

Publication Variables

You can set and modify variables at the publication level for headers, footers, tabs, cover pages, overlays, cross references, TOCs, and assembly elements. You can create variables, which may contain existing variables defined either at the assembly level or system-wide.

— Assembly level variables - These are normally user-defined variables used in the assembly for both electronic and paper publications. These variables are set up by an administrator in data administration and specified with the assembly or in the paper or electronic output templates for publishing. Publication variable settings specify which of these variables are scanned for or resolved for a particular publication.
— Data administration variables - These are used in the assembly for both electronic and paper publication. These variables are set up by an administrator and specified with the assembly or in the paper or electronic output templates. Publication variable settings specify which of these variables are scanned for/resolved for a particular publication.

Once defined, these variables can be used in two places:

— Assembly attributes and metadata - Variables are specified using their name and the delimiters described below. These variables are resolved during publishing and used within the eCTD XML metadata, tabs, TOCs, and volume names.
— Published output - Variables are specified using their name and the delimiters described below. These variables are resolved as page stamps on TOCs, special sheets, cross references, and overlays.

Delimiters

When creating a variable you should be aware of the how Calyx RIM accepts variables and delimiters.

Calyx RIM uses the following types of delimiters:

— Dollar signs ($) and braces ({ }) are the delimiters used to describe how certain fields should be calculated in the system and/or resolved at publishing time. Always use these delimiters to describe, for example, how tab text should be resolved at publishing time. Dollar sign and braces delimiters are used in the assembly attributes and settings.
— Angle brackets (< >) are the delimiters used in Word to describe how the publishing engine should position variables in overlays and cover pages. You should always use these delimiters to insert variables that will be resolved directly as page stamps on overlays, cover pages, and other published output.

Create or Modify Variables

In the selected Publishing Settings Library, you can modify the variable settings. This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL).

1. On the *Publishing Settings Library* window, select Variables.
2. Click Create .

   To edit an existing variable setting, click a named variable in the list on the Variables tab, and click Edit.
3. On the *Create Variable* page, complete the required fields, and the optional fields as needed.

   Required information is indicated by an asterisk (*).

   — Variable Code *

- Variable Name *
- Variable Value *
- Variable Type *
- Description
- Output Channel * (Move items from Output Channel Types to the Selected Output Channel Types box to apply the variable to the selected output channel types by default.)

4. Save.

Option	Action
To create another variable, after saving the current variable settings:	Click Create Another Variable.
To discard the changes:	Click Cancel.
If you are editing an existing Variable setting:	Click the name of the Publishing Settings Library on the *View* page at the top of the page to return to the Publishing Settings Library.

Delete a Publish Variable

You can delete a publishing variable at any level, as necessary.

To delete a publishing variable:

1. On the *Variables* page select the variable you want to delete.
2. Click Delete.
3. Click Apply.

Variable Attributes

You can use the attributes to define the publishing variables. Required information is indicated by an asterisk (*).

Attribute	Description
Description	Enter a description of the variable. (Limit 500 bytes)
Is Active*	Determines if the variable is active. Choose Yes or No. Default is `Yes`.
Output Channel*	Choose output channels to specify this as the default variable for the selected output channel types. Default is both, Electronic and Paper.
Variable Code*	Specify the variable code that appears in the document or tree structure. The Variable Code and Output Channel combination must be unique within the Publishing Settings Library. The Variable Code must be different from any variable code defined in Assembly Repository Variables, Assembly System-Defined Variables, Assembly User-Defined Variables, or InSight Assembly Variables. (Limit 100 bytes.)
Variable Name*	Specify the human readable name of the variable. (Limit 100 bytes.)

Attribute	Description
Variable Value*	Specify the value to which the variable will resolve. This can be free text or another variable. (Limit 4000 bytes.)
Variable Type*	Choose the type of variable configuration. Available options: Single-Line Variable, Multi-Line Variable

Link Profiles and the System Profile

Link profiles enable you to define how links are handled during publishing. These profiles can be created in a Publishing Settings Library Template (PLT), enabling you to create publications by starting with the saved profile values; you do not have to respecify the settings.

Calyx RIM provides you with a default profile called the `System Profile`.

— The System Profile is assigned automatically to all imported links.
— The System Profile is always used to create electronic TOC links and margin cross-references.
— For Xrefs, SmartLinks, in-process links and other inter-document links (links between documents) the System Profile is always applied to electronic and paper output, that is, the old links are deleted and the new links are applied.
— For intra-document links (links within a document) the assigned System Profile indicates that Calyx RIM does not alter these links during Electronic publishes unless it must. Any intra-document link formatting in the original documents is preserved in its original form, including style, font, color, and target settings. If a profile other than the default is used, or during a Paper publish, these settings are overwritten just like they are for inter-document links.
— When publishing to paper, the stamp generated for margin cross-reference links is created with the defined font type and font size.

Note: *Not all formatting for old links can be deleted. For example, some underlines cannot be removed and text color cannot be changed. Also, intra-document links cannot be suppressed from published output. As a workaround, you can mask intra-document links by changing the link profile from the System profile to black text.*

System Profile and Hyperlinks

If you use the System Profile, there are specific rules that Calyx RIM follows when publishing links.

Calyx RIM writes out hyperlink settings and cross-reference stamp styles unless the link matches all of the following conditions:

— The link is an intra-document link (it points to another place in the document).
— The link is not published as part of a split document.
— The link has not been manually retargeted to another location.

The table of contents also always uses the System Profile for hyperlinks and the Table of Contents template for stamps. In all other situations, links that are set to the System Profile will always be written out exactly like the profile settings indicate. Also, when copying parts or an entire assembly to a new assembly, all link profiles are reverted to the System Profile.

When importing or copying assemblies from an assembly, all links are assigned automatically to the System Profile.

PLT Link Options

Link settings in a Publishing Settings Library Template (PLT) enable you to create hyperlink and margin cross-reference styles at the publication level. These predefined settings are applied to your publication and establish how Calyx RIM formats links that were created during Publish time.

— The electronic hyperlink settings control the formatting of the hyperlinks that are published to the electronic output channel.
— The margin cross-reference settings control the formatting of the margin cross-references that will appear for output published to the paper output channel.

You can create, modify and view link settings (including color, size, and style) by clicking Links in the *Publishing Settings* dialog box.

Select a previously-created profile and links will use the settings defined in the profile. You can create a new profile by clicking Create Link Profile on the Link Profiles tab.

For paper publications, a margin cross-reference stamp appears in the margin next to text that contains a hyperlink. The value used to format this margin cross-reference is based on the Margin Cross Reference Text Format field in the Link Profiles. You can create the variable name for the links in this field and enter any other data you would like to appear in the final publication.

Calyx RIM cannot remove underline styles from text when suppressing an existing hyperlink or cross-reference. Default Microsoft Word templates normally dictate that the link style is blue text, otherwise you will need to clean-up PDFs if they suppress, disable, or delete any hyperlinks or cross-references.

Links do not resolve correctly if they target a document page and the page in that document exists twice in the same assembly. Links work properly if the same document is assigned twice with two different page ranges for splitting up a document.

Create or Modify Link Profiles

In the selected Publishing Settings Library, you can modify the Link Profile settings. This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL).

To modify the Link Profile settings:

1. On the *Publishing Settings Library* window, select Link Profiles.
   The default Link Profiles appear.
2. Click Create .
   To edit an existing link profile setting, click a named link profile in the list on the Link Profiles tab.
3. On the *Create Link Profile* page, complete the required fields, and the optional fields as needed.
   Required information is indicated by an asterisk (*).
   — Link Profile Name*
   — Default?

- Electronic Hyperlink Style *
- Electronic Hyperlink Color
- Electronic Hyperlink Line Thickness (available when the selected Electronic Hyperlink Style is other than `None`)
- Margin Cross-Reference Size*
- Margin Cross-Reference Text Font Style
- Margin Cross-Reference Text Format
- Cross-Document Link Handling

4. Save.

Option	Action
To create another Link Profile, after saving the current Link Profile settings:	Click Create Another Link Profile.
To discard the changes:	Click Cancel.
If you are editing an existing Link Profile setting:	Click the name of the Publishing Settings Library on the *View* page at the top of the page to return to the Publishing Settings Library.

When you change the Default field for the link profile, it is important to remember:

- For a Link Profile with the Default value set to `yes`: if you set the Default field to No and try to save the changes, an error message appears.
- If the Default value is set to `Yes` for a link profile, but you want to assign another link profile to be the default, set the Default field to Yes for the preferred link profile. The profile that was previously marked as default will be updated automatically.

Link Profiles Attributes

You can use the attributes to define the Link Profiles. Required information is indicated by an asterisk (*).

Attribute	Description
Link Profile Name*	Specify a name for the link profile. The name must be unique within the Publishing Settings Library. (Limit 100 bytes.)
Default?	Determines if this is the default link profile. The system automatically generates the default Link Profile (named `System Profile`). The default profile cannot be deleted.
Electronic Hyperlink Style*	Choose the style of the hyperlink displayed in the published output. Available options: — Dashed Box — None — Solid Box — Underline

Attribute	Description
Electronic Hyperlink Color	Choose the color of the hyperlink displayed in the published output. Default is `Blue`. Available options: — Blue — Black
Margin Cross-Reference Size*	Specify the font size to use for Margin Cross-References. Default is `10`.
Margin Cross-Reference Text Font Style	Specify the font style to use for Margin Cross-References. Default is `Arial`. Available options: — Arial — Arial Narrow — Courier — Times New Roman — MS Mincho
Margin Cross-Reference Text Format	Specify the format to use for all Margin Cross-Reference links. Use variables.
Cross-Document Link Handling	Determines if cross-document links are opened in the same window or in a new window. Available options: — Default — Open in the Same Window — Open in a New Window The **Default** option opens the cross-document link according to the **Open Settings** applied in Adobe Acrobat or Reader (**Edit** > **Preferences** > **Documents**).

Mass Insert/Update Publishing Elements

Insert a Publish Element

Use the **Mass Insert/Update Publishing Elements** option to insert a special sheet or a table of contents in an assembly. Special sheets include cover pages, slip sheets, tab sheets, and tables of contents. This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL).

To insert a special sheet or a TOC publishing element into an assembly:

1. Right-click the assembly element where you want to insert a publishing element and choose **Mass Insert/Update Publishing Elements**.
2. In the *Mass Update Elements* window, choose a Publishing Element from the list:

Publishing Element	Description
Table of Contents	Inserts a TOC for the selected assembly element or set of elements.
Tab Sheet	Inserts a tab sheet for the selected assembly element or set of elements.
Cover Page	Inserts a tab sheet for the selected assembly element or set of elements.
Slip Sheet	Inserts a slip sheet for the selected assembly element or set of elements.

3. The *Mass Update Elements* window provides options to include the selected publishing element in one or more locations in the assembly:

Publishing Element	Description
For this Element	Inserts the selected publishing element for the selected assembly element.
Volumes	Inserts the selected publishing element for each volume in the assembly.
Folders	Inserts the selected publishing element for each folder in the assembly.
Leaf Elements	Inserts the selected publishing element for each leaf element in the assembly.
Documents	Inserts the selected publishing element for each assigned document and document placeholder in the assembly.
Page Markers	Inserts the selected publishing element for each volume break in assigned documents.

4. The Publishing Settings field is required. Use the default, or select a different saved publishing setting in the list.
5. The Range Start field is available only when Table of Contents is the selected Publishing Element. Browse to select the location for the start of the TOC range.

Delete a Publish Element

Use the Mass Insert/Update Publishing Elements option to delete cover pages, slip sheets, tab sheets, or tables of contents from an assembly. This procedure applies to both the Publishing Settings Library Template (PLT) and the Assembly Specific Publishing Settings Library (APL).

To delete a publishing element from an assembly:

1. Right-click the assembly element where you want to delete a publishing element and choose Mass Insert/Update Publishing Elements.
2. In the *Mass Update Elements* window, choose a Publishing Element from the list:

Option	Action
Table of Contents:	Deletes a TOC from the selected assembly element or set of elements.
Tab Sheet:	Deletes a tab sheet from the selected assembly element or set of elements.
Cover Page:	Deletes a cover page from the selected assembly element or set of elements.
Slip Sheet:	Deletes a slip sheet from the selected assembly element or set of elements.

3. The *Mass Update Elements* window provides options to delete the selected publishing element from one or more locations in the assembly:

Option	Action
For this Element:	Deletes the selected publishing element from the selected assembly element.
Volumes:	Deletes the selected publishing element from each volume in the assembly.
Folders:	Deletes the selected publishing element from each folder in the assembly.
Leaf Elements:	Deletes the selected publishing element from each leaf element in the assembly.
Documents:	Deletes the selected publishing element from each assigned document and document placeholder in the assembly.
Page Markers:	Deletes the selected publishing element from each volume break in assigned documents.

4. The Publishing Settings field is required. Use the default, or select a different saved publishing setting in the list.
5. The Range Start field is available only when Table of Contents is the selected Publishing Element. Browse to select the location for the start of the TOC range.

Types of Publish Variables

Publishing variables are placeholders publishers use to reserve space in documents for variable text. When the document is published, the value of the variable is resolved and entered into the published document.
Variables can be used in cover pages, overlays, and in the body of the submission.

There are several types of variables:
— Assembly user-defined variables
— Assembly system-defined variables
— Calyx RIM assembly variables
— Assembly repository variables

Variable Values

You can define Publishing variables using text or other variables.
A variable value is made up of any combination of the following:
— Variable code delimiters
— Literal text
— Simple variable values
— Formatted variable values

Variable Code Delimiters

Variable codes must have a starting and ending tag. The starting variable code and ending variable code tags are defined within angle bracket delimiters: < and > .

Starting Calyx RIM variable code: <my_variable_code>
— The first starting angle bracket is considered the left limit of the variable placeholder
— The top of the starting variable code is considered the upper limit of the variable placeholder

Ending Calyx RIM variable codes are prefixed with an exclamation: <!my_variable_code>
— The last angle bracket of the ending variable code is considered the right limit of the variable placeholder.
— The bottom of the ending variable code is considered the lower limit of the variable placeholder.

The variable code cannot contain spaces, however, spaces are permitted between the variable code and the delimiters. See Multi-Line variables - Alignment for more information about spaces and variable codes.

Literal Text

Any text that is not a variable value or formatted variable value is literal text.
The characters $ \ ( ) { } must be escaped with the backslash character (\) or 0x005C Unicode. For example, aaa resolves to bbb and `aaa\(bbb\)` resolves to aaa(bbb).

Simple Variable Values

A simple variable value is defined by a dollar sign ($) followed by the variable code of the variable whose value is to be substituted in the default format for the variable type.

For example, `$ANAME` resolves to the name of the current assembly; and `Assembly name: $ANAME` resolves to: Assembly name: My Assembly (where the name of the current assembly is My Assembly).

Formatted Variable Values

Use formatted variable values to calculate values or add the current date and time.

Formatted variable values must be resolved using either the `$VARIABLE` or `${VARIABLE}` forms. No spaces or special (escaped) characters can exist in the formulas or variables names. Formatted variable values have the following general format: `$format-name(simple-variable-value optional-param1 .. optional-paramN )`

Within an overlay or cover page, all variable codes should be the same case, regardless of variable stamp type. The variable code cannot contain spaces, however, spaces are permitted between the variable code and the delimiters.

Variable Formats, Names, and Parameters

You can format variables to calculate values or add the current date and time.

Formats	Names and parameters	Examples
Numeric	`$Bates(simple-variable-value, width) $RomanNum(simple-variable-value) $RomanNum(simple-variable-value, width) $RomanLowerNum(simple-variable-value) $RomanLowerNum(simple-variable-value, width) simple-variable-value, "increment-step") $Reverse (simple-variable-value, "increment-step") $Calculate (expression) may contain numeric values and other simple variable-values that are also numeric, characters + - * / ()` Where: `width: numeric-param, minimum width of number. $Bates numbers are padded with 0. $Roman… numbers are padded with space.`	On page 22 of a volume: `$Bates($VR, 6)` resolves to 000022 `$RomanNum($VR)` resolves to XXII `$RomanLowerNum($VR, 6)` resolves to xxii `$Calculate` - Calculates a start value by performing addition, subtraction, multiplication, or integer division. This function can accept any integer or variables that can be resolved as integers. The variables must be surrounded by curly braces ({}). Examples of variables are ARP and VT. This function can also accept the operands `+`, `-`, `*`, or `/`. $Calculate provides static value. It does the calculation once and no further increments happen based on a variable changing (LR in the following example). This example will create a page number defined by the LR variable plus 1: `$VAR = $Reverse($Calculate(${LR}+1),"1")` `$Reverse` - Submits a negative integer as the increment for a dynamic attribute. This function accepts two parameters: any integer as `Start Value`, and a negative integer as an increment. The negative integer must be in double quotes. Using reverse numbering for a document of 100 pages, the first page number will be 100 and the last page will be 1. This function can be applied in a user-defined variable, as in this example for numbering a document to comply with Mexico submission requirements: `$VOLRPGNUM = $Reverse($Calculate(${ARP}+${VT}-${VR}*2+1), "-1")`
String	n/a	n/a

Formats	Names and parameters	Examples
Date/ Time	The entire date/time value is formatted in a single call. `$DateTime(simple-variable-value format-string)` Where: `format-string`: A date and time pattern.	$DateTime(${CT}, "EEE dd MMM yyyy HH:mm:ss Z")

Date and Time Patterns

Date and time formats are specified by date and time pattern strings. Within date and time pattern strings, unquoted letters from A to Z and from a to z are interpreted as patterns representing the components of a date or time string.

Text surrounded by single quotes (') is interpreted as literal text. To include the text character for a single quote as literal text, use a double quote ("). All other characters are not interpreted; they are copied into the output string during formatting or matched against the input string during parsing.
The following pattern letters are defined (all other characters from A to Z and from a to z are reserved).

Letter	Date or Time Component	Presentation	Examples
G	Era designator	Text	AD
y	Year	Year	1996; 96
M	Month in year	Month	July; Jul; 07
w	Week in year	Number	27
W	Week in month	Number	2
D	Day in year	Number	189
d	Day in month	Number	10
F	Day of week in month	Number	2
E	Day in week	Text	Tuesday; Tue
a	AM/PM marker	Text	PM
H	Hour in day (0-23)	Number	0
k	Hour in day (1-24)	Number	24
K	Hour in am/pm (0-11)	Number	0
h	Hour in am/pm (1-12)	Number	12
m	Minute in hour	Number	30
s	Second in minute	Number	55
S	Millisecond	Number	978

Letter	Date or Time Component	Presentation	Examples
z	Time zone	General time zone	Pacific Standard Time; PST; GMT-08:00
Z	Time zone	RFC 822 time zone	-0800

Pattern letters are usually repeated as their number determines the exact presentation:

— Text: If the number of pattern letters is four or more, the full form is used; otherwise a short or abbreviated form is used if available.

— Number: The number of pattern letters is the minimum number of digits, and shorter numbers are zero-padded to this amount.

— Year: If the number of pattern letters is two, the year is truncated to two digits; otherwise it is interpreted as a number.

— Month: If the number of pattern letters is 3 or more the month is interpreted as text; otherwise it is interpreted as a number.

— General time zone: Time zones are interpreted as text if they have names. For time zones representing a GMT offset value, the syntax `GMT Sign Hours:mm` is used, where `Sign` is + or −; `Hours` is `H` or `HH` and must be between 0 and 23; and `mm` must be between 00 and 59. The format is locale-independent and digits must be taken from the Basic Latin block of the Unicode standard.

— RFC 822 time zone: The four-digit time zone format of `Sign Hours:mm` is used, where `Sign` is + or −; and `Hours` is `HH` and must be between 00 and 23. Other definitions are as for general time zone.

Examples

The following examples show how date and time patterns are interpreted in the U.S. locale. The date and time represented in these examples is 2001-07-04 12:08:56 local time in the U.S. Pacific Time time zone.

Date and Time Pattern	Result
"yyyy.MM.dd G 'at' HH:mm:ss z"	2001.07.04 AD at 12:08:56 PDT
"EEE MMM d ''yy"	Wed Jul 4 '01
"h:mm a"	12:08 PM
"hh 'o''clock' a zzzz"	12 o'clock PM Pacific Daylight Time
"K:mm a z"	0:08 PM PDT
"yyyyy.MMMMM.dd GGG hh:mm aaa"	02001.July.04 AD 12:08 PM
"EEE d MMM yyyy HH:mm:ss Z"	Wed 4 Jul 2001 12:08:56 -0700
"yyMMddHHmmssZ"	010704120856-0700

This example shows how the entire date/time value can be formatted in a single call:

```
$DateTime (simple-variable-value format-string)
```

Where: `format-string:` a date and time pattern

Note: *`$DateTime` does not include the parameter lang-code for presenting date and time patterns in a language other than the designated default language.*

Example:

```
$DateTime (${CT}, "EEE dd MMM yyyy HH:mm:ss Z")
```

Formal Grammar

The formal grammar presented below defines variable values in Extended BNF (Bakus-Naur Form):

— ' ' - literal value
— ( ) - group of values
— | - choice
— ? - multiplicity 0 or 1
— * - multiplicity 0 or more
— + - multiplicity 1 or more
— #xnnnn - 16 bit hexadecimal value

Variable	Value	Comments
variable-value ::==	(literal-string | variable-evaluation | function)*	
literal-string ::==	(unicode-character | character-escape)+	/* allows $VAR or $FUNC(...) or ${VAR} */
variable-evaluation :==	'$' (variable-name | '{' variable-name '}')	
variable-name :==	identifier	
function :==	function-name '(' parameters ')	
function-name :==	('$Bates' \| '$RomanNum' | '$RomanLowerNum')	
parameters :==	variable-evaluation (',' digit+)?	variable-evaluation must resolve to a numeric value
identifier :==	letter (letter | digit)*	
character-escape ::==	'\' ('$' | '\' | '(' | ')')	
letter ::==	['a' - 'z'] | ['A' - 'Z'] | '_'	
digit :==	['0'-'9']	

Variable	Value	Comments
unicode-character ::==	[#x0020 - #x0023] | [#x0025 - #x0026] | [#x0029 - #x005B] | [#x005D - #x007F] | [#x00A0 - #xD7FF] | [#xE000 - #xFFFD]	

Multi-Line Variables

You can create Multi-Line (multiline) variables within overlay or cover page templates by defining starting and ending variable codes within a Word document, which is then saved as a template.

The Multi-Line stamping functionality applies only to Assembly User-Defined Variables.

Assembly User-Defined Variables can be defined system-wide in Calyx RIM Data Administration. They can also be assembly specific, defined in Assembly Publishing Settings. For any other type of variable to be stamped as Multi-Line, it must be nested inside an Assembly User-Defined Variable.

For an Assembly User-Defined Variable to be stamped as Multi-Line on a cover page or overlay, the Variable Stamp Type must be set to Multi-Line text in Calyx RIM Data Administration or in the Assembly Publishing Settings. In addition, the Variable placeholder (or attribute) on the pages of the Cover Page or Overlay template must include beginning and ending placeholders.

The area of the template defined by the starting and ending variable codes is the variable placeholder where the variable value will be inserted. Variable codes are surrounded with angle bracket delimiters.

The variable code cannot contain spaces. However, spaces are permitted between the variable code and the delimiters.

— Starting variable code: <my_variable_code >
— Closing variable code: < !my_variable_code>

Starting Calyx RIM variable code: <my_variable_code>

— The first starting angle bracket is considered the left limit of the variable placeholder
— The top of the starting variable code is considered the upper limit of the variable placeholder

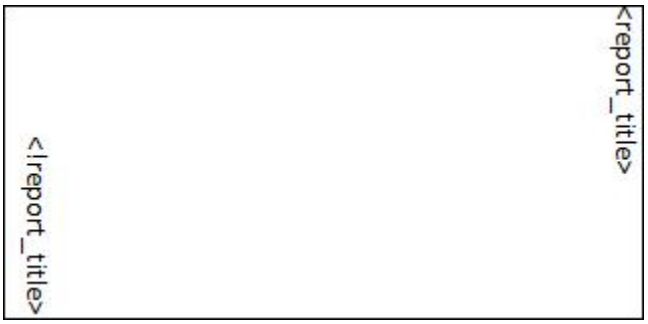
Ending Calyx RIM variable codes are prefixed with an exclamation: <!my_variable_code>

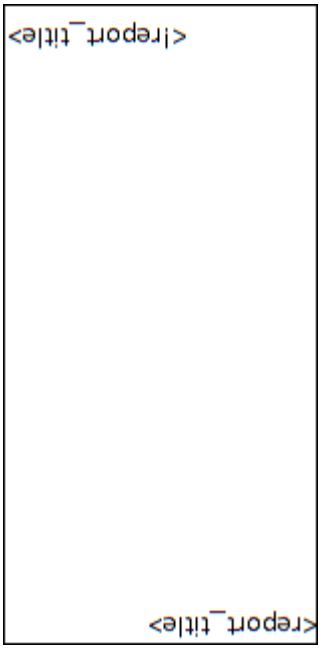
— The last angle bracket of the ending variable code is considered the right limit of the variable placeholder
— The bottom of the ending variable code is considered the lower limit of the variable placeholder

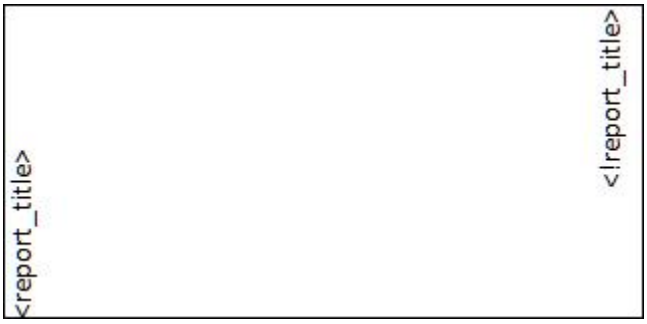
Variable Code Orientation

Variable codes can be included in the template at any 90-degree orientation: 0-, 90-, 180-, or 270-degrees. The system reads the variable codes from left to right within the orientation.

The starting variable code position and orientation determine the area - the inline and baseline - within which the system expects to find the ending variable code. The beginning of the ending variable code must be within the search area to be considered valid.







Multiple Values Within a Range

When multiple values exist within the same range, the closest ending variable code within the search area is used. In the following example the matching colors show the starting and ending variable codes found by the system:

<report_title>
<!report_title>
<report_title>
<report_title>

<report_title>
<!report_title>
<!report_title>

<report_title>
<!report_title>
<!report_title>

Multi-line Variable Alignment

You can define the desired alignment for Multi-Line variables. All alignment is controlled using the starting variable code. Formatting and spacing are not applied by manipulation of the closing variable code.

To left-align the text within the variable placeholder limit:

— Enter one or more spaces between the end of the starting variable code and the closing angle bracket (>) of the starting variable code, with no spaces between the opening angle bracket (<) and the starting variable code. Example: <report_title >

— No spaces between the variable code and either angle bracket. (The default variable alignment is left-align.) Example: <report_title>

To right-align the text within the variable placeholder limit:

— Enter one or more spaces between the opening angle bracket and the starting variable code, with no spaces between the closing angle bracket and the starting variable code. Example: < report_title>

To center align the text within the variable placeholder limit:

— Enter one or more spaces between the opening angle bracket and the starting variable code, AND enter one or more spaces between the end of the starting variable code and the closing angle bracket. Example: < report_title >

Font Format in Multi-Line Variables

Font style, case, color, and size can be controlled by applying effects to both the starting variable code and the ending variable code in Multi-Line variables.

When creating the Multi-Line variable in an overlay or cover page template in Word, apply the desired font style, case, color, and size to the starting and ending variable code of the variable. The starting and ending variable codes must be the same font style, case, color, and size.

If you apply bold, blue, 24pt font style to the variable code, the resulting output from the template will include that specified font formatting. The case of the variable code does not determine the case of the resulting output.

Note: *Within an overlay or cover page, all variable codes should be the same case, regardless of variable stamp type.*

Japanese Characters

The font of the delimiters and variable code also determines which characters can be stamped. Most fonts do not contain all Unicode characters. If you intend to include Japanese characters in variable resolutions for example, you must make sure the font used for the delimiters and variable codes is MSMincho or another font containing Japanese characters. Arial Unicode MS is one of the few fonts containing almost all Unicode characters.

Font Formatting That Is Not Supported

Underlined text and highlighted text are not supported. Adobe Acrobat does not recognize these styles as part of the font.

If underlining or highlighting happens to be applied to a variable in a template: During rendering and publishing, the space used by the starting and ending variable tags will remain highlighted or underlined, but the resulting output in the remaining space will not display underlining or highlighting.

Line Breaks in Multi-Line Variables

Each line space is determined by the starting variable. Text can be wrapped at line break characters.

Use the following characters:

— Hyphen
— Space
— Tab
— Carriage return (either a new line, or "/n")

If there are no line break characters in the variable, the text is truncated to fit each line - wrapped to fit the space outlined by the starting and ending variable codes. Hyphens are added at the end of each wrapped line.

Conditions When Words Are Split for a Line Break

The word (or portion of a hyphenated or split word) is longer than the width of the text box. A word is defined as a string of non-space characters between a Space `U+0020`, a Tab `0x0009`, a Line Feed `0x000A`, or an Ideographic Space `U+3000`. The word will be split so the maximum amount with a trailing hyphen fits within the width of the box.

The word contains a non-leading or non-trailing hyphen U+002D. The word will be split at the hyphen. The following are also recognized as hyphens for text boxes:

— U+2010 - hyphen
— U+2012 - figure dash
— U+2013 - en dash
— U+2014 - em dash
— U+2212 - minus

Variables Within Variables

Variables can contain other variables, or nested variables, as part of their definition. This enables you to concatenate and improve the spacing of text that is placed in published output.

— Variable text must be identical for the starting and ending tags of the variable. The variable text is case sensitive.
— Within an overlay or cover page, all variable codes should be the same case, regardless of variable stamp type.

Variables within variables: example 1

Place the following variables and text in the header or footer of a page in an overlay or cover page template:

```
Volume <VN      >, Page <  VR> of <VT  >
```

This will be the result in the published output:

```
Volume 12  , Page  4 of 350
```

Variables within variables: example 2

1. Place a single variable in the header or footer of the overlay or cover page template:

```
<PAGE_NUM                                                    >
```

2. Next, add the variable PAGE_NUM to the *Variables* tab in the Assembly Publishing settings:

```
Volume $Bates($VN,6), Page $VR of $VT
```

This will be the result in the published output:

```
Volume 00012, Page 4 of 350.
```

Warning: Nested variables must not contain page number system variables, as they will not resolve and may cause publishing issues. Assume there is a variable placeholder on your overlays, as in this example:

<PAGENUM >

On the Variables page in AsmPubSettings you cannot define:

PAGENUM = "Page $CHANNELPAGE"

CHANNELPAGE = "$LR of $LT" (Electronic variable)

CHANNELPAGE = "$VR of $VT" (Paper variable)

But you can define:

PAGENUM = "Page $LR of $LT" (Electronic variable)

PAGENUM = "Page $VR of $VT" (Paper variable)

Channel Specific Variables

User-defined variables may have different values depending on the output channel being published.

The PAGE_NUM variable in example 2 (above), is suitable for paper publishing.

If the assembly is to be published in both paper and eCTD electronic channels, the PAGE_NUM variable above could be assigned to the paper output channel. Another PAGE_NUM variable should be assigned to the electronic output channel with a more appropriate value such as: ${LABBR}, Page $LR of $LT.

The *${}* notation is required so that the comma directly follows the Abbreviated Leaf name when the variable is resolved.

User-defined Variable Values

You can define the value for specific variables.

Variable Name	Variable Code	Variable Value	Description	Active Flag	Variable Type
Company Name	UCN	Company Name	Company name	Active	Single-line variable
Volume Name Formula	VOLNAME	V$Bates($VN, 6)		Active	Single-line variable

Calyx RIM Assembly Variable Values

You can define variables for Calyx RIM Assemblies in Data Administration.

The table lists all the variables that you can define for assemblies.

Variable Name	Variable Code	Last User Updated	Last Changed Date	Description	Active Flag
Application Code	IAC	Username	d-m-y	Application code	Active
Application Internal Code	IIC			Application internal code	Active
Application Keywords	IAK			Application keywords	Active
Application Language	IAL			Application language	Active
Application Name	IAN			Application name	Active
Application Procedure Type	IPT			Application procedure type	Active
Application Type	IAT			Application type	Active
Assembly Category	IASC			Assembly category	Active
Assembly Keywords	IASK			Assembly keywords	Active
Assembly Name	INA			Assembly name	Active
Assembly Status	IASS			Assembly status	Active
Assembly Subcategory	IASSC			Assembly subcategory	Active
Country Name	ICN			Country name	Active

Variable Name	Variable Code	Last User Updated	Last Changed Date	Description	Active Flag
Country Regulatory Authority	ICA			Country regulatory authority	Active
Event Code	IEC			Event code	Active
Event Keywords	IEK			Event keywords	Active
Event Name	IEN			Event name	Active
Event Sequences	IER			Event sequences	Active
Event Type	IET			Event type	Active
Event Variation Number	IEV			Event variation number	Activ
Product Dosage Form	IPF1			Product dosage form	Active
Product Family Code	IPC			Product family code	Active
Product Family Name	IPN			Product family name	Active
Product Name 1	IP1			Product name 1	Active
Product Name 2	IP2			Product name 2	Active
Sequence Keywords	ISK			Sequence keywords	Active
Sequence Name	ISN			Sequence name	Active
Sequence Number/ Code	ISC			Sequence number/code	Active
Sequence Status	ISS			Sequence status	Active
Sequence Status Date	ISD			Sequence status date	Active

Variable Name	Variable Code	Last User Updated	Last Changed Date	Description	Active Flag
Sequence Submission Filing Type	ISF			Sequence submission filing type	Active

Repository Variable Values

You can define the values for Repository values.

Variable Name	Variable Code	Document Type	Repository Attribute	Description	Active Flag
Repository Author	RSA	Null	Author	Author of the mapped document author; repeating attribute; returns a comma delimited list	Active
Repository Subject	RSS	Null	Subject	Subject of the mapped document	Active

Publishing Elements and Effects

Apply different changes on a published document using publishing elements and their effects.

To view publishing elements in the assembly tree, select Publishing Elements (located above the assembly tree). To hide publishing elements, clear the Publishing Elements option.

During volumization, the assembly is not locked. You must wait for volumization to complete before attempting to select any elements.

Publishing Elements

— Special sheets - Special sheets enable you to organize and divide the sections of an assembly. You can insert, modify, or delete special sheets individually or in bulk wherever they are needed in the assembly.

— Tables of contents - In addition to being special sheets, tables of contents help reviewers to navigate through an assembly. You can insert, modify, or delete TOCs individually or in bulk within the assembly. Calyx RIM provides regulatory-compliant TOCs inserted in the assembly templates. Calyx RIM provides an ability to include links to TOCs.

Include Links to TOCs

The Include Links to TOCs field defines which TOC elements will be included in the TOC in addition to the elements defined in the Tree Elements to Include in TOC field.

— If you create a new assembly from an assembly file or from an existing assembly, all selected TOCs are cleared.

— When duplicating an element with a TOC, all TOCs are preserved.

— The display order of the links to TOCs will be the same as the TOCs order in the assembly.

— If a target TOC is deleted, the current TOC is automatically updated to exclude the link to the deleted TOC.

Publishing Effects

— Overlays - Use an overlay to apply headers and footers on a published document.

— Page markers - Use a page marker to divide a document at a particular page. Special sheets, TOCs, and volume breaks can be inserted as page markers.

— Volumes - Use volume breaks to divide the assembly into logical sections. Each volume represents a unique output PDF intended for the paper output channel.

Assemblies

Assemblies

An assembly is the logical bill of materials (BOM) or dossier as represented in a publishing product interface that represents one sequence.
When you create an assembly, you specify attributes like due date, owner, and output location. Some of these attributes are required, others are optional, and still others default to preconfigured values.

Calyx RIM supports the following types of assemblies:
— Standalone
— Sequence
— eCTD
— Supporting

You must have the following modules to perform assembly activities:
— Electronic Lifecycle Publishing (ELP)
— Submission Planning and Tracking (SPT)
— Registered Document Analysis (RDA)
— Paper Review Publishing (PRP)

Creating Assemblies
You can create an assembly by creating the folders, leaf elements and assigning documents, or you can create an assembly from another entity. When you create an assembly from a template, an existing assembly, an application view, or an assembly file, many of that entity's attributes are inherited by the new assembly.

Modifying Assemblies
You may want to change the attributes of an assembly, such as the name, the default binding rule, due date or description. In addition, you can set default folder and leaf attributes for the assembly and specify the referenced DTDs/schemas for assembly publishing.

Building Assemblies
When you build an assembly you create its structure. You can add the folders, leaf elements, documents and document placeholders that make up the hierarchical content of the assembly. Throughout the life of the assembly, it may go through numerous changes and updates.

Deleting Assemblies
Only an administrator can delete assemblies.

Assembly Templates

An assembly template enables you to set up an assembly structure that you can use to create similar assemblies. The template can include the elements and metadata that are common to the assemblies you create.

You must have any of the following modules to perform assembly template activities:
— Electronic Lifecycle Publishing (ELP)
— Registered Document Analysis (RDA)
— Submission Planning and Tracking (SPT)
— Paper Review Publishing (PRP)

Create an Assembly Template

You can create an assembly template by using the New menu or by using existing assembly elements.

On the Calyx RIM New menu, click Assembly Template to create an assembly template from one of the following sources:

— New (Empty) - to create a new template containing no existing assembly elements
— Existing Template, Assembly or View - create a new template from an existing template or assembly, or from a current or active view
— Assembly File - create a new template from an assembly or view that has been exported as an XML file
— Virtual Document - create a new template from a Documentum virtual document

Using a template, an existing assembly, or a virtual document to create a new assembly template streamlines the process because existing attribute values are inherited by any new assembly you create. A template or an existing assembly can contain publishing settings, the assembly structure, the hierarchical order of folders and leaf elements, documents, document placeholders, publishing elements, and default mappings to DMS attributes for leaf and study report attributes. This minimizes the need for you to enter data already captured in the DMS.

Note: *Creating a new assembly, or a new assembly template, will fail with a Null Pointer Exception if DMS repositories, including a file share repository, have not been configured for Calyx RIM.*

Create an Empty Assembly Template

You can create an empty assembly template from the home page. An empty assembly template provides the structure for a new assembly without existing documents.

Note: *To create an assembly template, you must have the appropriate security privileges.*

To create an empty assembly template:

1. On the home page, click New > Assembly Template.
2. On the *Create Template* page, select New (Empty) to create an empty assembly template.

3. Click and select the Publishing Settings Library to use with the assembly template.
4. Save.
   The *Create Assembly* window appears.
5. Enter attribute values for the assembly template.

   Note: *The* Created From *attribute is always blank.*

6. Click Create.

Create an Assembly Template from a Template, Assembly, or View

You create an assembly template from an existing template, assembly, or a submitted or approved view. The existing attribute values of the selected element is inherited to the new assembly template, minimizing the need for you to enter data.

To create an assembly template, you must have the appropriate security privileges.

To create an assembly template based on a template, assembly, or a submitted or approved view:

1. On the home page, click New > Assembly Template.
2. On the *Create Template* page, click Existing Template, Assembly or View.
3. Click Browse to find and select the template, assembly, or view using the Search Assembly Wizard.
4. On the *Search Options* window, choose an assembly type from the Assembly Type to Search list, and click Next.
5. On the *Assembly Query Parameters* window, use Search to find an assembly, or you can choose an assembly from one of the other tabs: Assembly Templates, Standalone Assemblies, Sequence Assemblies, or Views.
   - Columns in the grid can be sorted in ascending or descending order using the options for each column heading.
   - Columns in the grid can be shown or hidden using the options for each column heading.
   - Move your pointer over a column heading and click the arrow next to the heading name to view the options.
6. Select an assembly and click OK.
   On the *Create Template* window, the assembly you selected appears in the Browse field.
7. Choose a Use Source Assembly Publishing Settings Library option:

Option	Description
Yes :	The new assembly template inherits the Publishing Settings Library used in the source assembly you have selected. Selecting Yes also provides the option to Import Publishing Elements (choose Yes or No).
No :	You must select a PLT from the Publishing Settings Library field that appears when you choose No.

Note: *If an Approved View is selected as the source assembly for creation, the* Publishing Settings Library *option will appear in place of the* Use Source Assembly Publishing Settings Library *option. Choose a Publishing Settings Library from the list.*

8. In the Retarget Copied Reference Leafs field, set the option for reference leafs in your new assembly template:

Option
Retarget Copied Reference Leafs
Preserve Copied Reference Leafs

9. Save.
10. On the *Create Assembly* window, enter a name for your new assembly and enter attribute values for the assembly.

Use the Search Tab to Locate an Assembly

When creating a new assembly template from an Existing Template, Assembly or View, you can use the Search tab options to locate an assembly.

1. On the home page, click New > Assembly Template.
2. On the *Create Template* page, click Existing Template, Assembly or View .
3. Click Browse to find and select the template, assembly, or view using the Search Assembly Wizard.
4. On the Search tab, choose an assembly type from the Assembly Type to Search list, and click Next.
5. On the *Assembly Query Parameters* window, set your search parameters and click Next.
6. On the *Matching Assemblies* window, select an assembly.
7. After selecting an assembly, click Next.
8. On the *Selected Assembly* window, click OK.
   On the *Create Template* window, the assembly you selected appears in the Browse field.
9. Choose a Use Source Assembly Publishing Settings Library option:

Option	Description
Yes :	The new assembly template inherits the Publishing Settings Library used in the source assembly you have selected. Selecting Yes also provides the option to Import Publishing Elements (choose Yes or No).
No :	You must select a PLT from the Publishing Settings Library field that appears when you choose No.

Note: *If an* `Approved View` *is selected as the source assembly for creation, the* Publishing Settings Library *option will appear in place of the* Use Source Assembly Publishing Settings Library *option. Choose a Publishing Settings Library from the list.*

10. In the `Retarget Copied Reference Leafs` field, set the option for reference leafs in your new assembly template:
    - Retarget Copied Reference Leafs
    - Preserve Copied Reference Leafs
11. Save.
12. On the *Create Assembly* window, enter a name for your new assembly and enter attribute values for the assembly.

Create an Assembly Template from an Assembly File

When importing an assembly file, the documents in the file are not synchronized automatically with the mapped DMS.
They appear as placeholders, which prevents import failures if the referenced DMS does not exist in the current system. You must run a DMS synchronization immediately after importing to assign placeholders automatically to the DMS documents.

Note: *You must have the appropriate security privileges to create an assembly template.*

To create an assembly template based on an assembly exported as XML to an assembly file:

1. On the home page, click New > Assembly Template.
2. On the *Create Template* page, click Assembly File.
3. To find the assembly file, click Browse and do either of the following:

Option	Action
On the *Documents* tab, navigate to the assembly file:	Click OK.
On the *Search* tab, find the assembly file:	Click OK.

4. For Use Source Publishing Settings Library, click Yes or No to indicate whether the new assembly template will use the publishing settings library that the source assembly uses.

Option	Action
If you clicked Yes, then for Import Publishing Elements:	Click Yes or No to indicate whether the new assembly template will use the publishing elements that the source assembly uses.
If you clicked No for Use Source Publishing Settings Library, then:	Click the publishing settings library that the new assembly template will use.

5. Save.

Create an Assembly Template from a Virtual Document

You can create a standalone assembly template based on an assembly exported to a Documentum virtual document.

Note: *To create an assembly template, you must have the appropriate security privileges.*

To create a assembly template from a virtual document:

1. On the home page, choose New > Assembly Template.
2. On the *Create Template* page, click Virtual Document.
3. To find the virtual document, click Browse and do either of the following:

Option	Action
On the *Documents* tab, navigate to the virtual document:	Click OK.
On the *Search* tab, find the virtual document:	Click OK.

4. Click the publishing settings library to use with the assembly template.
5. Save.
6. Enter attribute values for the assembly template.
7. Click Create.

Assembly Template Attributes

You can use the assembly template attributes and descriptions to enter attribute values while creating assembly templates.

Attributes marked with an asterisk (*) are mandatory.

Attribute	Description
Assembly Type*	Defines the output type of the Assembly. Required. The default eCTD. When set to eCTD, all folder names, file names, and paths are normalized during publishing. When set to CN eCTD, all folder names, file names, and paths are normalized during publishing, but underscores are not replaced. When set to US eCTD, all folder names, file names, and paths are normalized during publishing, but capital letters and underscores are not replaced. When set to Standard, all paths are based on the entries for the output folder and file. All output files will maintain the original context of the source: — Source document name = Tabular_Listings-1.pdf — eCTD name = tabular-listings-1.pdf — CN eCTD name = tabular_listings-1.pdf — US eCTD name = Tabular_Listings-1.pdf — Standard name = Tabular_Listings-1.pdf
Auto Populate Output Folder	Determines whether the Output Folder attribute of a folder is populated with the name of the object used to create the folder when a vdoc structure, folder structure, Veeva binder, or Veeva section is assigned to an assembly.

Attribute	Description
Auxiliary Output Location	Alternate location for saving a published version.
Category	High level category associated with the assembly. The available Subcategory options are dependent on the selected category.
Comments	Comments about the assembly.
Create Leaf Elements	Determines if leaf elements are created automatically when you assign documents to assemblies you create from the template, as when using a drag-and-drop action to add files into folders. Default is Yes.
Created From	The name of the Assembly that was used to create the current Assembly. This field is blank if no Assembly was used to create the current Assembly.
Creation Date	The date the assembly was created.
Default Binding Rule	The binding rule that will be applied to documents from the DMS assigned to assemblies created using the template. — Bind to Label binds documents to a label you choose. — Bind to Status binds documents to a status you choose. — Bind to Version binds documents to the version number you enter. When you create a template from a virtual document or you assign a virtual document to a template, no warning is displayed if the virtual document contains binding rules that are not defined in Calyx RIM by the administrator.
Description	Text that describes the assembly.
Due Date	The date the assembly is due to be complete for submission.
Electronic Output Location	The specified storage location for electronic output.
Keywords	Words you can use to search for the assembly.
Last Repository Data Retrieval	The date the last DMS Sync was executed. View only, not available for editing.
Lock Indicator	Indicates if the assembly has been locked. If the standard lock has been applied to the assembly, set to Yes.
Name*	Name of the assembly, which appears in the assembly tree.
Owner	Person responsible for the assembly.
Paper Output Location	The specified storage location for paper output.

Attribute	Description
Reference Location	(SPT only) The location within the DMS of a reference to the assembly. If you try to create a reference location in a repository folder to which you do not have access, a message informs you that you do not have permission to write to the folder. This field is populated automatically when Set Reference Location is selected from the More menu, after an Assembly has been created.
Reference Location Name	The name of the reference object.
Status	The current status of the assembly. Default is In Draft (unless modified in Data Administration - Assembly Status Values). Can be updated using Update Assembly Status.
Status Date	The current status date of the assembly. Default is Date of Assembly Creation.
Subcategory	The subcategory to further classify the assembly.
Version Number	(SPT only) Indicates the version of the assembly. Default is 1.0, CURRENT.

Modify an Assembly Template

You can modify the assembly template attributes to create additional, reusable assembly templates.
You can also set default folder and leaf attributes for the assembly and specify the referenced DTDs/schemas for assembly publishing.

Note: *The assembly attributes that you can modify depend on your security privileges.*

To modify an assembly:

1. Click a link for the assembly template you want to modify.
2. Click Edit.
3. On the *Edit Assembly* page, enter your changes.
4. Save.

Delete an Assembly Template

Only an administrator user can delete an assembly template.

To delete an assembly template:

1. Click the link for the assembly template you want to delete.
2. Click Delete.
3. When you are prompted to confirm the deletion, click OK.

Create an Assembly

When you create a new assembly based on a template, an existing assembly, or an assembly file, the new assembly may be generated with settings that are different from your source file. It is a best practice to review the settings of your new assembly and manually adjust the settings as necessary.

Note: *Creating a new assembly, or a new assembly template, will fail with a Null Pointer Exception if DMS repositories, including a File Share repository, have not been configured for Calyx RIM.*

New Assembly Created from a Template or an Assembly

After creating a new assembly from an existing assembly, the following settings in your new assembly can be different from your source assembly, and may need to be modified:

Element	Description
Cover Page element	The planned number of pages is set to null.
TOC element	The comment, description, and keywords are set to null.
Document	— Output channel is reset to the default: both Paper and Electronic. — Include in page numbering is reset to YES (if it was set to NO in the existing assembly). — Category is set to null, rather than the entered value from the existing assembly.
Volumes	Volumes may be missing from your new assembly.

New Assembly Created from an Assembly File

After creating a new assembly from an assembly file, the following settings in your new assembly can be different from your source assembly, and may need to be modified:

Element	Description
Publishing settings	— Publishing – The in-process rendition location is reset to null. — Cover Pages – The Cover Pages template is reset to null. — TOCs – The TOC definition file is reset to null. — Overlays – The Overlays template is reset to null.
In the new Assembly	— Custom overlays is reset to the default, and Inherit Properties from Publishing Settings is set to YES. — Some volumes may be missing from your new assembly.

Note: *When an assembly is created from an assembly file, the locations included in the assembly file that do not match the repositories in Calyx RIM Technical Administrator will not be saved.*

Standalone Assemblies

A standalone assembly is an assembly that is not associated with an application or sequence.
It has no regulatory context and is not slated for submission to a specific agency, or part of an eCTD lifecycle.

Examples of standalone assemblies are reports, eCTD modules that will be submitted later, and assembly templates that are used to create assemblies submitted in different countries and regions.

After you have created a standalone assembly it becomes available in lists of standalone assemblies. The assembly is also available in various queries.

In the standalone assembly created from an `Assembly File`, or `Template`, `Assembly` or `View`, each imported Leaf Element is assigned automatically with the default `Leaf Status` value from *Data Administration*.

Note: *Only authorized users can access the assemblies.*

Create an Empty Standalone Assembly

An empty standalone assembly provides the structure for a new standalone assembly without existing documents. You can use the Home page to create a standalone empty assembly. You can also use the Create eCTD wizard.

Note: *You must have the appropriate security privileges to create a standalone assembly.*

To create an empty standalone assembly:

1. On the home page, click New > Standalone Assembly.
2. On the *Create Assembly* page, select New (Empty) to create an empty assembly.
3. Click the publishing settings library to use with the assembly.
4. Save.
5. Enter attribute values for the assembly. See *Assembly Attributes*.

   Note: *The* Created From *attribute is always blank.*

6. Click Create.

Creating a Standalone Assembly from a Template, Assembly, or View

You can use the Home page to create an assembly based on a template, assembly, submitted, or approved view. You can also use the *Create eCTD* wizard.

Note: *You must have the appropriate security privileges to create a standalone assembly.*

To create an assembly based on a template, assembly, or a submitted or approved view:

1. On the home page, click New > Standalone Assembly.
2. On the *Create Assembly* page, click Existing Template, Assembly or View.
3. Click Browse.
4. Find and select the template, assembly, or view. Do either of the following:

Option	Action
On the Search tab:	Use the *Search Assembly* wizard.
On any other tab:	Click the versions or view types from which you want to select an assembly. Select an assembly.

Note: *If you click* Show*, you can select only the assembly root. You cannot create an assembly from any other node.*

5. For Use Source Publishing Settings Library, click Yes or No to indicate whether the new assembly will use the publishing settings library that the source assembly uses.

Option	Action
If you clicked Yes, then for Import Publishing Elements:	Click Yes.
To indicate whether the new assembly will use the publishing elements that the source assembly uses:	Click No.
If you clicked No for Use Source Publishing Settings Library:	Click the publishing settings library that the new assembly will use.

6. For Retarget Copied Reference Leafs, click a value to retarget (change) or preserve the destinations of links in the reference leafs that are copied to the assembly that you create.
7. Save.
8. Enter attribute values for the assembly.
9. Click Create.

Create a Standalone Assembly from an Assembly File

When you import an assembly file, the documents in the file are not automatically synchronized with the mapped DMS.
They appear as placeholders which prevents import failures if the referenced DMS does not exist in the current system. Run a DMS synchronization immediately after importing to assign placeholders automatically to the DMS documents.

Note: *You must have the appropriate security privileges to create a standalone assembly.*

You can use the Home page to create a standalone from an assembly file. You can also use the Create eCTD wizard.

To create a standalone assembly based on an assembly file:

1. On the home page, click New > Standalone Assembly.
2. On the *Create Assembly* page, click Assembly File.
3. To find the assembly file, click Browse and do either of the following:

Option	Action
On the Documents tab, navigate to the assembly file:	Click OK.
On the Search tab, find the assembly file:	Click OK.

4. For Use Source Publishing Settings Library, click Yes or No to indicate whether the new assembly will use the publishing settings library that the source assembly uses.

Option	Action
If you clicked Yes, then for Import Publishing Elements:	Click Yes.
To indicate whether the new assembly will use the publishing elements that the source assembly uses:	Click No.
If you clicked No for Use Source Publishing Settings Library:	Click the publishing settings library that the new assembly will use.

5. Save.

Create a Standalone Assembly from a Virtual Document

You can use the Home page to create a standalone assembly based on a virtual document. You can also use the *eCTD* wizard.

Note: *You must have the appropriate security privileges to create a standalone assembly.*

To create a standalone assembly based on a virtual document:

1. On the home page, choose New > Standalone Assembly.

2. On the *Create Assembly* page, click Virtual Document.
3. To find the virtual document, click Browse and do either of the following:

Option	Action
To search for a virtual document:	On the Documents tab, navigate to the virtual document, and click OK.
To search for a virtual document:	On the Search tab, find the virtual document, and click OK.

4. Click the publishing settings library to use with the assembly.
5. Save.
6. Enter attribute values for the assembly. See *Assembly Attributes*.
7. Click Create.

Sequence Assemblies

Sequence assemblies represent a submission.
They are associated with a particular product, country, application, event, and sequence.

When you create a sequence assembly, you must specify its attributes. Some of these attributes are required, others are optional, and others are provided by Calyx RIM automatically.

If you create an assembly from a template, existing assembly, or application view, many attributes are maintained and saved in the new assembly. You can use these default values for the new assembly or you can overwrite them with different attribute values.

In the sequence assembly created from an `Assembly File`, or `Template`, `Assembly` or `View`, each imported Leaf Element is assigned automatically with the default `Leaf Status` value from Data Administration.

When you copy an assembly to another assembly, Calyx RIM does not clear the assembly, folder and leaf due dates. This is because these due dates may be templated before assembly creation for project planning purposes.

Once you have created a sequence assembly, it becomes available in lists of sequence assemblies and in the sequence it is associated with. Users who are authorized to work with assemblies can access the assembly from its sequence.

Create an Empty Sequence Assembly

You can create an empty sequence assembly from the View Sequence page.
You can create an empty sequence assembly from the View Sequence page. You can also use the Create eCTD wizard.

Note: *You must have the appropriate security privileges to create a sequence assembly.*

To create an empty sequence assembly:

1. Click a link for the sequence for which you are creating a sequence assembly.
2. On the *View Sequence* page, click the Assembly tab.
3. Click Create Assembly.
4. On the *Create Assembly* page, select New (Empty) to create an empty assembly.
5. Click the publishing settings library to use with the assembly.
6. Save.
7. Enter attribute values for the assembly.

Note: *The* Created From *attribute is always blank.*

8. Click Create.

Create a Sequence Assembly from a Template, Assembly, or View

You can create an empty sequence assembly from a template, assembly, or a submitted or approved view using the the *View Sequence* page.
You can also use the *Create eCTD* wizard.

Note: *You must have the appropriate security privileges to create a sequence assembly.*

To create an empty sequence assembly:

1. Click a link for the sequence for which you are creating a sequence assembly.
2. On the *View Sequence* page, click Assembly.
3. Click Create Assembly.
4. On the *Create Assembly* page, click Existing Template, Assembly or View .
5. Find and select the template, assembly, or view. Do either of the following:

Option	Action
On the Search tab:	Use the *Search Assembly* wizard.
On any other tab:	Click the versions or view types from which you want to select an assembly. Select an assembly.

Note: *If you click* Show*, you must select the Assembly root. You cannot create an assembly from any other node.*

6. For Use Source Publishing Settings Library, click Yes or No to indicate whether the new assembly will use the publishing settings library that the source assembly uses.

Option	Action
For Import Publishing Elements:	If you clicked Yes initially, then click Yes.

Option	Action
To indicate whether the new assembly will use the publishing elements that the source assembly uses:	Click No.
For Use Source Publishing Settings Library:	If you clicked No, then click the publishing settings library that the new assembly will use.

7. For Retarget Copied Reference Leafs, click a value to retarget (change) or preserve the destinations of links in the reference leafs that are copied to the assembly that you create.
8. Save.
9. Enter attribute values for the assembly.
10. Click Create.

Create a Sequence Assembly from an Assembly File

When importing an assembly file, the documents in the file are not automatically synchronized with the mapped DMS.
They will appear as placeholders which prevents import failures if the referenced DMS does not exist in the current system. Run a DMS synchronization immediately after importing to assign placeholders automatically to the DMS documents.

Note: *You can use the Create eCTD wizard (see You must have the appropriate security privileges to create a sequence assembly.*

You can use the *View Sequence* page to create a sequence assembly from an assembly file. You can also use the *Create eCTD* wizard.

To create a sequence assembly based on an assembly file:

1. Click a link for the sequence for which you are creating a sequence assembly.
2. On the *View Sequence* page, click Assembly.
3. Click Create Assembly.
4. On the *Create Assembly* page, click Assembly File.
5. To find the assembly file, click Browse and do either of the following:

Option	Action
On the Documents tab, navigate to the assembly file:	Click OK.
On the Search tab, find the assembly file:	Click OK.

6. For Use Source Publishing Settings Library, click Yes or No to indicate whether the new assembly will use the publishing settings library that the source assembly uses.

Option	Action
If you clicked Yes, then for Import Publishing Elements:	Click Yes.

Option	Action
To indicate whether the new assembly will use the publishing elements that the source assembly uses:	Click No.
If you clicked No for Use Source Publishing Settings Library:	Click the publishing settings library that the new assembly will use.

7. Save.

Create a Sequence Assembly from a Virtual Document

You can use the View Sequence page to create a sequence assembly based on a virtual document.
You can also use the *Create eCTD* wizard.

Note: *You must have the appropriate security privileges to create a sequence assembly.*

To create a sequence assembly based on a virtual document:

1. Click a link for the sequence for which you are creating a sequence assembly.
2. On the *View Sequence* page, click Assembly.
3. Click Create Assembly.
4. On the *Create Assembly* page, click Virtual Document.
5. To find the virtual document, click Browse and do either of the following:

Option	Action
On the Documents tab, navigate to the virtual document:	Click OK.
On the Search tab, find the virtual document:	Click OK.

6. Click the publishing settings library to use with the assembly.
7. Save.
8. Enter attribute values for the assembly. See *Assembly Attributes*.
9. Click Create.

Create Assemblies Based on Sequences

You can create an assembly template, a standalone assembly, or a sequence assembly based on sequences from another application.
For example, you might want to create an application for one country using an existing application for another country, and all the information available in its first three sequences.

Importing any one assembly from the first three sequences for the existing application does not produce a culmination of the three submissions. For example, if the third sequence of the application is a working assembly, it

includes the changes made to the previous sequences but not the content of those sequences. However, creating an application from the application view captures all content and all changes to date.

You can create the new application using submitted or approved sequences from the existing application. Submitted sequences have been submitted to the regulatory agency. Approved sequences have been approved by the regulatory agency.

Only Registered Document Analysis (RDA) module users can create a new application using an existing application's approved sequences.

eCTD Assemblies

Calyx RIM includes ICH-compliant eCTD templates. The assembly templates include all sections defined by the CTD/eCTD specification.
Folder types have been preconfigured to provide the metadata for specific headings in the eCTD that require additional information, for example: drug substance, drug product, excipients, clinical indication, and regional administrative information.

In Modules 4 and 5, only one sample study report is included in the first study report section. You should remove any sections that are not applicable to an individual submission. If you do not remove them, the published XML will include their corresponding elements. This XML will be valid against the DTD. However, these sections are not applicable and you should remove them prior to publishing for clarity per agency recommendations.

Typical ways to use the eCTD templates:
- Create an assembly using a module 1 template, then import additional modules from the eCTD ICH Module 2-5 template.
- Create a new template based on a module 1 template, with the eCTD ICH Module 2-5 template imported. You can subsequently create new assemblies using this template.
- Create an assembly using the eCTD ICH Module 2-5 template, then import the module 1 folder from a module 1 template.

When performing an import of an existing eCTD, the import progress is reported in the `server.log` file. The Job Request Details also show messages about each sequence that is imported. The administrator can monitor the server log to follow the overall progress of the import and see more detailed messages, such as timestamps and Oracle information.

You can also create an eCTD assembly using the Create eCTD wizard.

While you are allowed to include more than one set of DTDs, you must be sure to include only one DTD of each type. For example, do not include two versions of an EU Module regional DTD. This may cause errors during publishing.

Import an Assembly Template

You can create an assembly by importing an assembly template.

To configure an assembly template:

1. Import the template that contains the publishing settings for the new assembly and configure all of the settings in the template.
2. Apply every setting to make these settings effective in the new assembly created from that template.
3. Import the assembly template XML into a new assembly template in the system.
4. Choose a generic repository (DMS or File System) location to store all overlay, cover page, and TOC templates.
5. Choose a generic repository (DMS or File System) location to use as a temporary location for submissions.
6. Go to the Assembly Template settings and make sure every value on every page has a default setting.
7. Make sure every path required in the settings is pointed to the correct TOC, cover page, or overlay template.
8. Make sure the preview location is set to the chosen repository location.
9. On each page of settings, click APPLY.

Supporting Assemblies

A supporting assembly is an assembly that is part of an application, but is not part of an eCTD lifecycle for that application.
You can create as many supporting assemblies as you need. Circumstances when you might want to use supporting assemblies could include: making paper copies for CTD reviewers, or creating study reports.

For example, if you need to create a CTD reviewer copy in addition to the eCTD sequences, you can copy the publishing view of the eCTD sequence to a supporting assembly, and then publish to paper from the supporting assembly.

Create a Supporting Sequence Assembly

Use this procedure to create a supporting sequence assembly. You can import an assembly, add volumes, files, and folders.

To create a supporting sequence assembly:

1. Select the new assembly and click Assembly. Two options are available for the new assembly:

Option	Description
Create Working Assembly	Use this option to create a lifecycle sequence assembly. A working assembly contains everything previously dispatched to the authority, minus anything replaced or withdrawn. It also includes anything incremental to that sequence that is planned but not yet submitted.

Option	Description
Create Supporting Sequence Assembly	Use this option to create a supporting sequence assembly. This type of assembly may be created within an Application alongside an existing Sequence Lifecycle without having to be part of that Lifecycle. The supporting sequence assembly will have no relationship to the previous lifecycle, and will not contain any of the previously dispatched folders or files. You may use this type of assembly for any publications that are related to the Application, for example: paper submissions, or study reports.

2. In the Assembly tab, click Create Supporting Sequence Assembly.
3. Complete the necessary information and click Create.

Note: *It is recommended that you name the supporting sequence assembly appropriately to identify its relationship to the eCTD.*

The *Create Assembly* page appears.

4. The new supporting assembly is created, and you can now import an assembly, add volumes, files, and folders.

Assembly Attributes

You can use the attribute descriptions to enter the attribute values while creating the assemblies or assembly plans.

The table lists all the attributes that are available to you while creating an assembly or an assembly plan.

Attribute	Description
Assembly Type	Defines the output type of the Assembly. Required. The default eCTD. — When set to eCTD, all folder names, file names, and paths are normalized during publishing. — When set to US eCTD, all folder names, file names, and paths are normalized during publishing, but capital letters and underscores are not replaced. — When set to Standard, all paths are based on the entries for the output folder and file.
Assign Workflow	Defines the workflow that will be associated with the root of the assembly automatically when the assembly is created.
Auto Populate Output Folder	Determines whether the Output Folder attribute of a folder is populated with the name of the object used to create the folder when a vdoc structure, folder structure, Veeva binder, or Veeva section is assigned to an assembly.
Auxiliary Output Location	Alternate location for saving a published version.

Attribute	Description
Category	The Assembly high-level category.
Comments	Comments regarding the Assembly.
Create Leaf Elements	Determines if Leaf elements are created when dragging files onto folders. Default =Yes
Created From	The name of the Assembly that was used to create the current Assembly. — In lifecycle, this will be the previous sequence. — When versioning, this will be the name of the previous version.
Creation Date	The date the Assembly was created.
Default Binding Rule	The default rule used to bind documents from the DMS.
Default Leaf Workflow	Defines the workflow that will be associated with the leaf automatically when the leaf is created within the assembly.
Default Major Division Folder Workflow	Defines the workflow that will be associated with the major division folder automatically when major division folder is created within the assembly.
Description	A description of the Assembly.
Due Date	The date the Assembly is due to be complete for submission.
Electronic Output Location	The location for the electronic published output to be stored.
Keywords	Keywords that apply to the specific Assembly.
Last Repository Data Retrieval	The date the last DMS Sync was executed.
Lock Indicator	Indicates whether the Assembly is locked. If the Assembly has had the Standard lock applied, set to Yes.
Name	The name of the Assembly; appears in the Assembly Tree. *Required*
Owner	The owner of the assembly. Default = current user.
Paper Output Location	The location for the paper published output to be stored.
Reference Location	SPT Only. The location within the DMS of a reference to the assembly. This field is populated when the user selects "Set Reference Location".
Reference Location Name	The name of the reference object.
Status	The current Status of the Assembly, controlled by the Assembly Status Values Data Administration default. Updated using the "Update Assembly Status". Default = In Draft

Attribute	Description
Status Date	The current status date of the assembly. Default = Date of Assembly Creation
Subcategory	The Assembly low level category. The available options depend on the Category selected.
Version Number	The version of the Assembly. SPT only. Default = 1.0, CURRENT

Assembly Elements Context Menu

You can use the Assembly Elements Context Menu to add, modify, or perform actions on publishing elements.

The Assembly Elements Context Menu is dynamic, providing options relevant to the selected root, folder, leaf, or document element node.
The options in the context menu depend on the Locked/Unlocked status of the assembly and on the particular node, user license, security settings, and view of the assembly where it is invoked.

In the Assembly Elements tree of an assembly, right-click on a node in the tree to view the Assembly Elements Context Menu for that node. The following images show some (but not all) of the different Assembly Elements Context Menu options available for the different types of nodes. See *Icons* for descriptions.

Root Node Context Menu

Figure 1: Context menu for a root node

Folder Node Context Menu

The Promote, Demote, Move Up, and Move Down options availability depends on the position of the selected Folder element in the Assembly Tree. For example, if the folder element is the first in the range, then the Move Up option will not be presented in the context menu for such an element.

Figure 2: Context menu for a folder node

Leaf Node Context Menu

The Promote, Demote, Move Up, and Move Down options availability depends on the position of the selected Leaf element in the Assembly Tree. For example, if the leaf element is the first in the range, then the Move Up option will not be presented in the context menu for such an element.

Figure 3: Context menu for a leaf node

Reference Leaf Node Context Menu

The Promote, Demote, Move Up, and Move Down options availability depends on the position of the selected Reference Leaf element in the Assembly Tree. For example, if the reference leaf element is the first in the range, then the Move Up option will not be presented in the context menu for such an element.

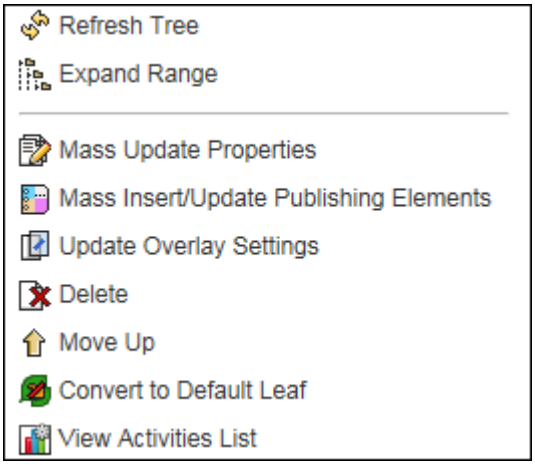


Figure 4: Context menu for a reference leaf node

Document Node Context Menu

The Promote, Demote, Move Up, and Move Down options availability depends on the position of the selected Document element in the Assembly Tree. For example, if the document element is the first in the range, then the Move Up option will not be presented in the context menu for such an element.

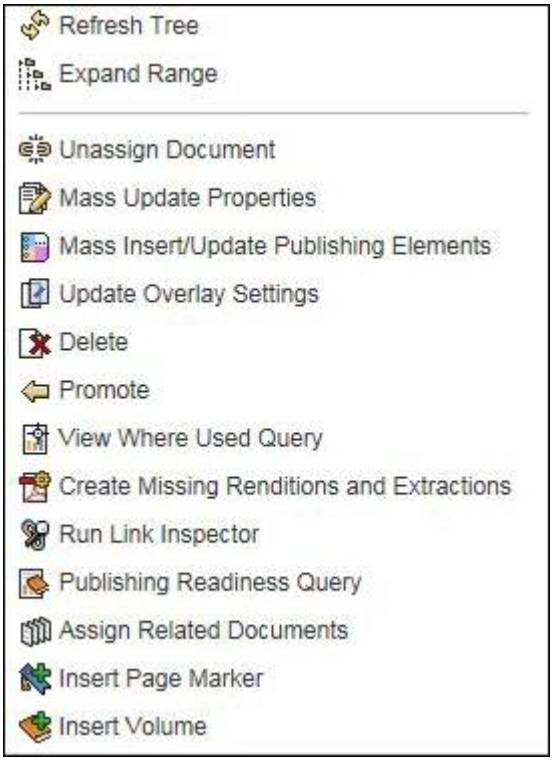


Figure 5: Context menu for a document node

Placeholder Node Context Menu

The Promote, Demote, Move Up, and Move Down options availability depends on the position of the selected Placeholder element in the Assembly Tree. For example, if the placeholder element is the first in the range, then the Move Up option will not be presented in the context menu for such an element.

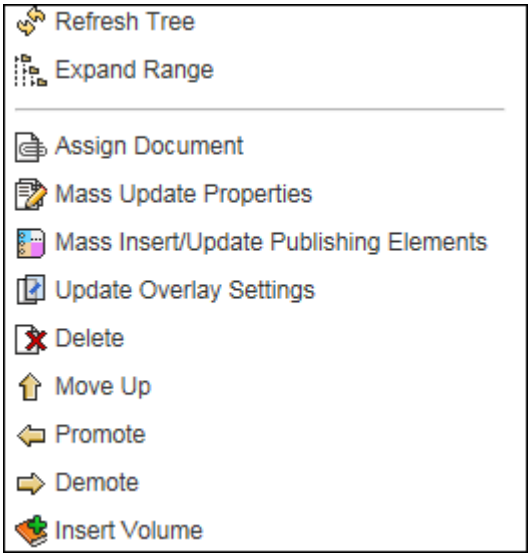


Figure 6: Context menu for a placeholder node

TOC Node Context Menu

The Move Left and Move Right options availability depends on the number of publishing elements assigned to the assembly tree element and the TOC position within this range. For example, if the TOC element is the first in the range, then the Move Left option will not be presented in the context menu.

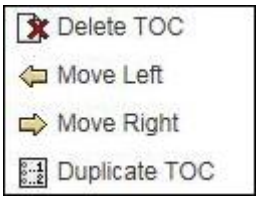


Figure 7: Context menu for a TOC node

Page Marker Node Context Menu

Figure 8: Context menu for a page marker node

Special Sheet Node Context Menu

Includes cover page, tab sheet, and slip sheet.

The Move Left and Move Right options availability depends on the number of publishing elements assigned to the assembly tree element and the special sheet position within this range. For example, if the special sheet element is the

first in the range, then the Move Left option will not be presented in the context menu. Includes cover page, tab sheet, and slip sheet.

Figure 9: Context menu for a special sheet node

Auto Populate Output Folder

This option enables the automatic population of the Output Folder field when folders, virtual documents, Veeva binders, or Veeva sections are assigned to the Assembly by using the DMS Browse window (such as when adding site folders).

The value used to populate this field is the name of the DMS folder, virtual document, binder, or section. This field will also be updated automatically in any nested folders. This preserves an internal structure and naming convention in published output.

You can set the Auto Populate Output Folder attribute for an existing assembly by editing the assembly attributes page or when creating a new assembly. You can also set this attribute on a Standalone Assembly, Sequence Assembly, or Template.

The following rules apply to the Auto Populate Output Folder option:

— An Assembly created using the Create eCTD wizard will inherit the Auto Populate Output Folder attribute from the value in the Module 1 template selected in the wizard.
— An Assembly created from a Submitted view will inherit the Auto Populate Output Folder attribute from the value in the Submitted view.
— An Assembly/Template created from another Assembly/Template will inherit the Auto Populate Output Folder attribute from the source Assembly/Template
— An Assembly created from an Approved view or a virtual document will have the Auto Populate Output Folder attribute set to No.
— An Assembly created with eCTD Import will have the Auto Populate Output Folder attribute set to No.
— The value of the Auto Populate Output Folder attribute will be preserved during Export to Assembly File/ Import from Assembly File.

When Auto Populate Output Folder is set to Yes:

— From the DMS Browse field, you can assign a folder or nested folders from any configured DMS repository that has folders to any module in the Assembly. (These repositories include File System and Documentum). You can also assign Veeva binders or Veeva sections to any module in the Assembly.
— When contents are assigned, the Output Folder attribute is populated on the folders and subfolders that are assigned to the Assembly.

— When assigning a virtual document without content from Documentum by choosing it in the DMS Browse tree or in the DMS Search window, a folder with all the virtual document descendants is created. The Output Folder attribute is populated on the folder and all subfolders created.

Modify Assembly Attributes

You modify the assembly attributes to change the attribute values for an assembly.

Note: *The attributes you can modify depend on your security privileges.*

To modify an assembly:

1. Click a link for the assembly you want to modify.
2. Click .
3. Choose and change attributes.
4. Save

Assembly Structure

When you build an assembly you create its structure. You can add the folders, leaf elements, documents, and document placeholders that make up the hierarchical content of the assembly.

As you add elements to the assembly tree, consider the following rules:

— An assembly can have major and minor divisions. The major and minor settings can be found on the *Folder Elements* in an assembly.
— You cannot add an element at the same level as the root.
— Documents you add to the assembly are saved as links to the document location in a repository or file system. No content is stored in Calyx RIM.
— An element you add is inserted as the last child of the selected element.
— You cannot add a leaf as a child of a leaf or as a child of another document.
— You cannot add a folder or a leaf as a child of a document or a document placeholder.
— To make an assigned document or document placeholder the child of another document or document placeholder, you must drag it from the document browse dialog box or promote or demote it.
— You cannot directly add an assigned document or document placeholder as a child of an assigned document or a document placeholder.
— When specifying the source location for a placeholder, do not end the source location with a backslash.
— You can only assign documents from one DMS at one time.
— To add multiple documents at the same time from the DMS browse window in Calyx RIM, do the following: - Shift+click adjacent documents to choose them. - Ctrl+click nonadjacent documents to choose them.
— When you add a specific version of a document to the assembly, the document binding rule for that document defaults to Bind to Version and the document's version number.

— When creating a new assembly, an error may occur if anything but the root is selected when previewing the assembly or template source.

Assembly Structure Table

The following guidelines may help you build an assembly.

This element	Can be added to this element
Folder	Assembly root, other folders and leaf elements
Leaf element	Assembly root and folders
Reference Leaf element	Assembly root and folders ***Note:*** *There is no option to add a reference leaf itself. The Reference Leaf element is a standard Leaf element that was previously converted to be a reference to a specific Leaf element.*
Assigned document	Assembly root, folders and leaf elements
Document placeholder	Assembly root, folders and leaf elements

Automatic Leaf Creation

You can create leaf elements automatically by dragging documents from the DMS browse window into an assembly folder or root node.

Based on the Create Leaf File attribute for an assembly, leaf creation behaves as follows when you add documents to the assembly.

When the Create Leaf Elements option is set to Yes and you drag documents to the root or a folder:

— A leaf element is added for each document.

— Each leaf element is created as the last child of the target element.

— Each leaf has the same name as the corresponding document.

— Automatically, the Leaf Status for each leaf element is set to the default `Leaf Status` value configured in *Data Administration*.

— The Use Native File attribute of a new leaf is set to Yes if your system administrator configured the extension for the corresponding document to generate this attribute value. Your system administrator can configure the extension in the `dms.nativeLeafExtension` property in the `insight.var` file. You can extend the list by modifying the `insight.var` file. The following example shows the list of extensions that are set forCalyx RIM by default. If additional extensions are needed, you must include the complete list of default extensions (shown below) along with the additional file types you are adding when using the `dms.nativeLeafExtension` property in the `Insight.var` configuration file.

Example:

```
dms.nativeLeafExtension=sas,xpt,xml,sc2,sct,sdq,sd2,ssd,ssp,stc,stx,sxs,sxx,sx,aml,dmn,imx,jmp,ecg
```

When the Create Leaf Element option is set to No and you drag a document to the root or a folder, you can expect the following behavior:

— A document you drag to an assigned document is added as the last child of that document.
— A document placeholder to which you drag a document becomes an assigned document.
— A document you drag to the root or a folder becomes the last child of that element.

Regardless of whether leaf elements are created automatically: when you drag a document or documents to a leaf, they are assigned to that leaf and no additional leaf elements are created.

When a leaf element is created automatically during document assignment, the leaf is named with the document file name. The extension on the leaf file name is stripped and Calyx RIM later assigns the appropriate extension during publishing.

Reference Leaf Elements

A reference leaf element has the same lifecycle requirements as a standard leaf element in the assembly. Both require a unique ID and lifecycle management to track modified file information.

Reference leaf element features:

— A reference leaf element allows multiple leaf elements to point to a single piece of content or another leaf in either a current or submitted assembly.
— A reference leaf cannot point to another leaf in a standalone assembly.
— A reference leaf must include the application number, prefix and the sequence number.
— To reference an entity across assemblies, the target leaf must be included in a lifecycle or supporting sequence.
— A reference leaf element does not have the Leaf Status attribute.

Unlocked Submitted View: Assembly

To modify a Reference Leaf element in the unlocked submitted assembly view, you must have the following set of access permissions in Security Administration:

— Application Country Rights set to at least WRITE.
— Entity Security > Sequence Assemblies set to ADMIN.

Unlocked Submitted View: Assembly Plan

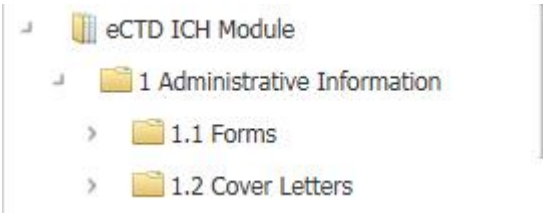
To modify a Reference Leaf element in the unlocked submitted assembly plan view, you must have the following set of access permissions in Security Administration:

— Entity Security > Submission Plans set to at least WRITE.
— Entity Security > Sequence Assemblies set to ADMIN.

Folder Elements

A folder element is the node beneath the root or another folder, and can contain other folders and leaf elements.

The root folder is represented by the icon and the folder element is represented by the icon in the tree view.



Add a Folder

You can add folders to the assembly structure under an assembly root.
To add a folder to an assembly:

1. Right-click the assembly root or the element on the assembly tree where you want to add a folder, and choose Add Folder.
   The folder is added to the assembly tree with the name New Folder and the *Edit Folder* page appears.
2. Enter values for the attributes.
3. Save.

Modify A Folder

You can modify the folder attributes in an assembly tree.
Before you modify the folder attributes, make sure that the DMS browse window is closed. Content for one pop-up window sometimes appears in another pop-up window. If this occurs, close the pop-up windows and try the operation again.

To modify a folder:

1. On the assembly tree, click the folder you want to modify.
   The *Edit Folder* page appears.
2. In the Edit Folder view, click .
3. Change attributes.
4. Save.

Folder Attributes

You can use the field descriptions to enter attribute values while adding a folder.

The table lists all the fields that appear while adding a folder.

Field	Description
Abbreviated Name	The short name for the folder.
Comments	The comments for the folder.
Creation Date	The date the folder was created.
Description	The description for the folder.

Field	Description
Division	Indicates if the folder is a major or minor division.
Due Date	The date all content within the folder is due.
Extension	The type of folder within the Assembly. Additional folder types open up additional attributes on the folder. Default = Default
Force New Volume	Indicates if a new volume should be created at this folder during volumize. Default = No
Keywords	The keywords for the folder.
Last Repository Retrieval Date	The last date a DMS Sync was run against this folder.
Leaf Id	A unique ID for the folder, generated by the system.
Lock Indicator	Indicates if the folder is locked.
Name	The name of the folder. Required
Number	The outline number for the folder. For eCTD submissions this is necessary for XML generation.
Output Folder	The folder name to be created in the output. This is used to override any automatically created eCTD folders, or where there is no folder to be created. Example: For a Study, a folder will be created. If the Assembly Type is set to eCTD, US eCTD or CN eCTD, this will be normalized during publishing. Default = blank.
Owner	The owner of the folder. Default = current user

Folder Element Type Attributes

You can enter values for additional eCTD attributes in the following ICH eCTD M2-5 folders:

— 2.3.S Drug Substance - Substance, Manufacturer
— 2.3.P Drug Product - Product Name, Manufacturer, Dosage Form
— 2.7.3 Summary of Clinical Efficacy - Indication
— 3.2.S Drug Substance - Substance, Manufacturer
— 3.2.P Drug Product - Product Name, Manufacturer, Dosage Form
— 3.2.P.4 Excipients - Excipient Name
— 3.2.A.1 Facilities and Equipment - Manufacturer, Substance, Dosage Form, Product Name
— 3.2.A.2 Adventitious Agents - Manufacturer, Substance, Dosage Form, Product Name
— 5.3.5 Reports of Efficacy and Safety Studies - Indication

Folder Element Types

You can change the element type for a folder in an eCTD assembly.

This enables you to specify additional publishing attributes for study tagging files (STFs), clinical indications, and other types of data required by the eCTD specification and by regulatory agencies. These attributes are used to create the XML backbone for eCTD submissions.

Modify a Folder Element Type

You can make changes to the Folder Type. The changes you make to the attributes for an extended element in a previous sequence assembly do not affect the current sequence.
You must have the appropriate security privileges to modify a folder element type.

To change the folder type:

1. On the assembly tree, select the folder you want to change.
2. In the More list, click Change Type .
3. On the *Modify Element Type* dialog box, click the Extension arrow and choose a folder type.
4. After you choose a folder type in the Extension list and click OK, attributes specific to the folder type you chose appear on the *Folder Attributes* page.
5. To specify values for the attributes, click Edit.

Duplicate A Folder

You can create a new folder by duplicating an existing folder and then changing its attributes as needed for the new folder type.

Note: *You must have the appropriate security privileges to duplicate folders.*

To duplicate a folder:

1. Right-click the folder you want to duplicate and choose Duplicate.
   The new folder is positioned as a sibling immediately below the folder you duplicated.
2. Select the duplicated folder in the assembly and click Edit to edit attributes for the duplicated folder.
   Automatically, each leaf element within the duplicated folder is assigned the default `Leaf Status` value from *Data Administration*. You can change the status, if needed.

Lock Folders

Locking a folder prevents any changes from being made to the content of the folder.
Before locking the folder, keep in mind the following:

— To unlock a locked folder, you must have License Modules > SPT (Submission Planning and Tracking) set to at least Write, and Functional Security > Review and Approval set to Yes in Security Administration. All child folders are also unlocked.
— The location of the locked folder in the assembly tree cannot be changed; that is, you cannot move the folder up or down, and you cannot promote or demote the folder.

— If you move the locked folder parent element, the folder moves with its parent.
— You cannot change elements in a locked folder.
— You cannot add elements to a locked folder.
— The locked folder and its contents cannot be duplicated directly or deleted.
— The locked folder parent element cannot be deleted.
— Structure locking an assembly will lock in place Folders, Leaf elements, documents, and special sheets. It will not lock Volumes or TOCs. Volumes have their own locking function, and TOCs cannot be locked.
— In the sequence view, when a folder and its contained elements are locked, the locked folder icon is not displayed, but the folder is shown as read-only.

Lock a Folder

You can lock the folder to prevent any changes from being made to its content.

To lock a folder:

1. On the assembly tree, choose the folder you want to lock.
2. On the action toolbar, click .
   A message prompts you to confirm the lock.
3. Click OK.

Unlock a Folder

You can unlock folders in an assembly tree from the working or publishing views, and enable users to modify the folders.

To unlock a locked folder:

1. Click a link for the assembly that has the locked folder.
2. Right-click the root and choose Expand All.
3. Click the locked folder you want to unlock.
4. Click .
5. Click OK when you are prompted to confirm the unlock.

Note: *When you unlock a parent folder, the first child of the last child folder of the parent folder is unlocked.*

Delete a Folder

A folder and all of its contents can be deleted from an assembly tree.

Note: *You must have the appropriate security privileges to delete folders.*

To delete a folder:

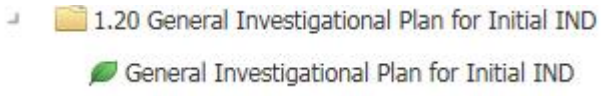
1. Right-click the folder you want to delete and choose Delete.
   A message prompts you to confirm the deletion.

2. Click OK.
   The folder and its contents are deleted.

Leaf Elements

A leaf element is a collection of individual, published files submitted to a regulatory agency per the eCTD guidance. A leaf node is included under a folder in an assembly tree. A folder can contain other folders and leaf elements.

A leaf node appears in an assembly tree as a green leaf icon.



The following tabs are present on the *Leaf Attributes* page:

— PDF Properties
— Activities (displayed for the user with permissions on activities within the Entity Security section of Security Administration)
— Workflows (displayed for the user with permissions on activities within the Entity Security section of Security Administration)

Add a Leaf

You can add a leaf element to an assembly under a folder.

Note: *You must have the appropriate security privileges to add leaf elements to an assembly.*

To add a leaf element to an assembly:

1. Right-click the assembly root or the element in the assembly where you want to add a leaf, and click Add Leaf. The leaf is added to the assembly tree with the name `New Leaf`.
2. On the *Edit Leaf* page, rename and enter attributes for the new leaf.
3. Save.
4. To undo modifications to the attributes, click Cancel. (The added leaf will remain, with the default attributes.)

Leaf Auto-Creation

When a document is assigned to an assembly, Calyx RIM automatically creates a leaf under an assembly section. For a leaf to be auto-created when assigning a document from a Document Management System (DMS) repository or a file system, the value of the assembly attribute Create Leaf Elements must be set to `Yes`. By default, the value of Create Leaf Elements is set to `Yes`. Some attributes of the auto-created leaf are populated with the source document attributes.

For more information, see `Attribute Values for Auto-Created Leafs`.

Attribute Values for Auto-Created Leafs

When a leaf is auto-created, the value of the leaf attributes such as the Name, Abbreviated Name, and Output File are taken from the attributes of a source document that is assigned.
A leaf gets the values of the Name, Abbreviated Name, and the Output File attributes from an assembly document.

Note: *For a Veeva document, it is possible to use a file name with and without an extension using the* `nameWithExtension` *and* `name__v` *attributes respectively. The attribute* `owner_v` *cannot be used for customization. This is disabled to avoid extra API calls to Veeva Vault.*

The following table lists the names of the attributes of a source document and their corresponding default names in different Document Management Systems (DMS) and the file system.

Document	DCTM Attribute by Default	File System Attribute by Default	Veeva Attribute by Default	SharePoint Attribute by Default	Livelink attribute by default
Name	object_name	name	nameWithExtension	Name	NAME
Abbreviated Name	object_name	name	nameWithExtension	Name	NAME
Title	title	n/a	title__v	n/a	n/a
Source Document	object_name	name	nameWithExtension	Name	NAME
Review Status	a_status	n/a	status__v	n/a	n/a
Owner	owner_name	n/a	n/a	n/a	n/a
Content Type	a_content_type	n/a	format__v	n/a	n/a
Keywords	keywords	n/a	n/a	n/a	n/a
Description	subject	n/a	n/a	n/a	n/a
Comments	log_entry	n/a	n/a	n/a	n/a

Define Document Attributes in the `propertyMappings.xml` *File*

Calyx RIM provides the ability to define auto-created leaf attributes as well as assembly document attributes that are taken from a source document in the `propertyMappings.xml` file.
By defining the Output File value, irrespective of whether a file with or without an extension is assigned, the extension for the native file remains unchanged. The extension of an Output File can be removed if the value of the attribute Use Native File is set to `No`. The same applies when a file is dragged within an assembly or imported from another assembly that results in leaf creation. Configuration can be made in the `propertyMappings.xml` file to enable removing of an extension from any leaf field. If such a configuration is applied and a leaf is updated, it is necessary to ensure the intended attribute value is taken. If the leaf attributes defined in the

propertyMappings.xml file fail to retrieve due to configuration discrepancies, the corresponding auto-created leaf attributes fields show blank values.

To define leaf attributes for an auto-created leaf:

1. Go to the <installation drive>:\InsightManager\server\all\conf\insight folder and open the propertyMappings.xml file in Notepad.
2. Locate the code section for the Document Management System or the file system that you use as repository for documents. Example of the code section for the file system:

Example

```
<!--These mappings indicate what attributes will be populated in an
Assembly Document when a File System document is assigned.WARNING:
This is the default property mapping. It must not be removed.Working
bean! --/>
    <bean id="file.file_object-assembly.leaf" parent="propertyMapper">
        <property name="retriever" ref="dmsContentRetriever" />
        <property name="populator" ref="metaObjectPopulator" />
        <property name="mappings">
```

3. To exclude the file extension for non-native files for auto-created leafs, locate the following section:

```
<bean parent="simpleMapping">
    <property name="source" value="name" />
    <property name="target" value="outputFileName" />
    </property>
</bean>
```

4. Add the following code lines after the code line <property name="target" value="outputFileName" />:

```
<property name="converter">
<bean parent="removeExtensionConverter"/>
```

Example

After adding the code lines, the code block will look like the following:

```
<bean parent="simpleMapping"/>
    <property name="source" value="name" />
    <property name="target" value="outputFileName" />
     <property name="converter">
     <bean parent="removeExtensionConverter"/>
    </property>
</bean>
```

5. Save and close the `propertyMappings.xml` file.
6. Restart the Calyx RIM service.

Document Attributes taken from Veeva DMS

Below is the list of Veeva DMS attributes that can be used to configure in the `propertyMappings.xml` file and to populate the same in Calyx RIM documents or auto-created leafs.

— id
— name__v
— title__v
— major_version_number__v
— minor_version_number__v
— type__v
— subtype__v
— classification__v
— binder__v
— document_number__v
— version_creation_date__v
— document_creation_date__v
— format__v
— filename__v
— status__v
— version_modified_date__v
— size__v
— product__v
— country__v
— description__v
— lifecycle__v
— locked__v
— locked_date__v
— export_filename__v
— md5checksum__v

Modify Leaf Elements

When you modify a leaf element, you need to know the type of leaf element and follow the procedure to modify according to the leaf element type.

There are two distinct types of leaf elements in Calyx RIM Publisher:

— A Standard leaf element is one that, upon eCTD publish or a publish of the electronic files, publishes to a unique PDF file. The published file has unique checksums and metadata.
— A Reference leaf element serves a different purpose. Often, when creating an eCTD, you may wish to submit to the agency an output leaf that is simply a reference or a pointer to either previously-submitted information or information that is present elsewhere in your assembly.

Changes you make to the attributes for an extended element in a previous sequence assembly do not affect the current sequence.

Before you modify leaf attributes, be sure the DMS browse window is closed. Content for one popup window sometimes appears in another popup window. If this occurs, close the pop-up windows and try the operation again.

Modify a Leaf Element

If you need to modify a reference leaf target location, first convert the leaf to a standard leaf, make the required edits, and then change it back to a reference leaf.

Note: *You must have the appropriate security privileges to modify a leaf element.*

To modify reference leaf attributes:

1. On the assembly tree, select a leaf.
2. Click Edit .
3. On the *Edit Leaf* page, modify the attributes.
4. Save

Leaf Attributes

The attribute descriptions help you to enter the appropriate attribute values while creating a leaf.
The table lists all the attributes that are available to you, while creating a leaf.

Attribute	Description
Abbreviated Name	Short name for the leaf.
Actuate	Reserved eCTD attribute.
Application Version	The PDF application version for the software (for example, PDF Ver 1.2).
Change Modified Leaf	Enables you to select and add attributes based on another leaf. When you select an assembly to use, you can click the Search tab to find the assembly that you want. See *Searching for an Assembly*.
Clear Modified Leaf	Clears leaf attributes.
Comments	Text to save with the leaf.
Creation Date	The date the leaf was created.
Description	Text that describes the leaf.
Due Date	The leaf's completion date.
Extension / Leaf Type	Defines the type of leaf in the Assembly.
Font Library	Commercial font or font set used to create the file.

Attribute	Description
Keywords	Words you can use to search for a leaf.
Language	The primary language that will be used for your electronic eCTD; can be a variable or text.
Leaf ID	Unique number that identifies the leaf; you cannot change this value.
Leaf Status	Leaf status for the specific leaf. The values available for selection are all active leaf statuses from Data Administration, the default status is Planned.
Leaf Type	Type of leaf, you cannot change this value.
Modified File	Name of changed file.
Modified Leaf	Name of changed leaf.
Modified Leaf Sequence	Name of changed leaf sequence.
Name	Name of the leaf.
Number	Number that helps you identify the leaf.
Operation	Action used to create this leaf (append, delete, replace, new).
Output File	Relative path and/or the file name of the published output for the leaf. — The value you enter cannot exceed 500 characters. — Avoid extra periods in the file name, such as `output.file.doc`, as this can result in an invalid file name in a DMS. ***Note:*** *For a reference leaf, this attribute is presented as a read-only field.*
Role	Indicates the regulatory role.
Show	Action used to show the leaf (embed, new, none or other).
Title	The title for the electronic eCTD.
Use Native File	Determines whether to use source files or renditions for publishing. — To include both the native SPL XML and a PDF rendition, create a second leaf, assign the same document and choose No for Use Native File. — Do not assign a publishing effect (special sheet, TOC) or more than one document to a leaf when Use Native File is set to Yes. During publication, the publishing effect or document will not be added to the leaf, and no error message will be generated to indicate this.

Attribute	Description
Version	To comply with Appendix 6 of the ICH eCTD Specification, this attribute is used to indicate the internal version number or version identification for the file. However, for leaf elements pointing to STF files, this attribute is used to identify the version of the STF specification against which they are constructed, for example, STF Version 2.2

Duplicate a Leaf

You can create a new leaf by duplicating an existing leaf.

Note: *You must have the appropriate security privileges to duplicate a leaf.*

To duplicate a leaf:

1. Right-click the leaf you want to duplicate and choose Duplicate.
   A new leaf appears below the duplicated leaf and the *Edit Leaf* page appears.
2. Enter attributes for the leaf.
3. Save
   The leaf status of the duplicated leaf is set to the default `Leaf Status` value configured in *Data Administration*. You can change the Leaf Status on the duplicated leaf, as needed.

Convert a Leaf to a Reference Leaf

For submission to an agency, output leafs that are references or pointers to previously-submitted information or to information that is present elsewhere in your assembly must be converted to reference leafs.

To convert a leaf to a reference leaf:

1. On the assembly tree, navigate to a leaf.
2. Right-click on the leaf and click Convert to Reference Leaf.
   A message prompts you to confirm that you want to delete any children that the leaf element has and convert the leaf.
3. Click OK.
4. On the next page, find the tab that displays the assembly that has the leaf that you want to reference, and select that assembly.

   If you want to search for an assembly, click Search.
5. Expand the assembly, and select a leaf.
6. Click OK.

   Note: *A reference leaf that points to an empty leaf will cause* Prepare to Publish *to fail.*

   The leaf appears in the assembly tree as a reference leaf with a reference leaf icon.

Note: *The Leaf Status attribute is not presented on the attributes page of a reference leaf.*

Convert a Reference Leaf to a Standard Leaf

To modify the target location of a reference leaf, you must convert a reference leaf to standard (default) leaf. After the target location has been changed, you can then convert it back to a reference leaf.

To convert a reference leaf to a standard leaf:

1. On the assembly tree, right-click the reference leaf you want to convert and select Convert to Default Leaf. The reference leaf changes to a default leaf.
2. When selecting the referenced leaf, Calyx RIM displays the current working assembly first, allowing you to choose a current leaf from the active assembly.

   The leaf status of the converted leaf is set to the default `Leaf Status` value configured in *Data Administration*. You can change the Leaf Status on the converted leaf, as needed.

Deleted Leafs

When you delete (withdraw) a leaf that was submitted in an earlier sequence, you are indicating that the leaf should be removed from the submitted view when the current sequence assembly is added to lifecycle.

— The deleted leaf is hidden in the working view.
— A new leaf with an operation of Delete is displayed in the assembly tree.
— The new leaf is positioned in the same location as the deleted leaf.
— The leaf and all its components are displayed with a line through them.
— Except for the leaf ID and operation, the new leaf has the same attributes as the deleted leaf.
— You cannot replace, append or delete the new leaf.
— You can revert the new leaf to undo the deletion.
— If the deleted leaf had content, the new leaf has the same content in the working view. In the sequence view however, the leaf is displayed with no content.
— The modified file for the new leaf references the deleted leaf. The modified file name is constructed as follows: Modified Leaf shows the leaf that is currently being modified by this leaf in the lifecycle. Modified Sequence shows the sequence that is currently being modified by this leaf in the lifecycle. Modified File Override is available to administrators only to allow an override of the modified leaf/sequence. This should only be used in certain situations because the change is not tracked in the lifecycle.
— Set Modified File is available in a working assembly to administrators, and in a standalone assembly to everyone. This allows the modified file to be manually set.
— Clear Modified File is available to administrators in a working assembly, and everyone in a standalone assembly. This allows the modified file to be manually cleared.
— You cannot change or move the new leaf, nor can you add elements to the new leaf.
— Deleted leaf elements are hidden in the submitted view after the current sequence assembly is added to lifecycle.

Delete a Leaf

You can delete a leaf from an assembly tree if it is not required to be published and submitted to the regulatory agency.

Note:

— *You must have the appropriate security privileges to delete leaf elements.*

— *If a volume break resides on the leaf you are deleting, you should move the volume break to the closest folder. Volume breaks that reside on a deleted leaf will not be published.*

To delete a leaf:

1. Right-click the leaf you want to delete and choose Delete.
   A message prompts you to confirm the deletion.
2. Click OK.
   The leaf and its contents are deleted.

Reorder Leafs

You can create leafs and assign documents to them as the documents become available and later you can reorder leafs in folders alphanumerically.

Reordering leafs can be useful, for example, with an assembly structure for literature references and study reports. Such a structure can contain hundreds of leafs.

You can reorder leafs only if they are in an unlocked assembly and folder or in an assembly and folder locked by using the eCTD lock. You cannot reorder leafs in an assembly or folder locked by using the standard lock.

What You Can Reorder

You can reorder:

— All leafs in one folder

— All leafs and reference leafs in a folder and in each subfolder

Where You Can Reorder

You can reorder leafs from:

— A standalone assembly folder

— An assembly template folder

— An initial working assembly folder

— A folder on the sequence view page of a lifecycled assembly

— A folder in the unlocked submitted view

Leaf Ordering Rules

In-order to reorder Leafs, you must follow specific rules.

— Reordering is case-insensitive.

— Values starting with numerals are placed before values starting with letters.

— If two leafs have the same value for the field on which the leafs are reordered, the leaf created earlier is placed first.
— Reordering leafs in folders and subfolders keeps each leaf in the same folder or subfolder.
— Reordering leafs in a folder containing subfolders places leafs that are on the same level as subfolders after those subfolders. This happens whether or not you reorder leafs in the subfolders.

Example: Reordering leafs in folders and subfolders

Orginal order:

New order:

```
Folder 1
        Folder 2
                Leaf 3
                Leaf 1
                Leaf 2
        Leaf b
        Leaf d
        Leaf c
        Leaf a
```

```
Folder 1
        Folder 2
                Leaf 1
                Leaf 2
                Leaf 3
        Leaf a
        Leaf b
        Leaf c
        Leaf d
```

Example: Reordering leafs in folders but not in subfolders

Orginal order:

New order:

```
Folder 1
        Leaf d
        Folder 2
        Folder 1
        Leaf c
        Leaf a
        Leaf b
```

```
Folder 1
        Folder 2
        Folder 1
        Leaf a
        Leaf b
        Leaf c
        Leaf d
```

— Reordering keeps each publishing element, such as a volume and or TOC, with the same leaf.
— Reordering does not change the positions of non-leaf nodes that are in the folder containing the leafs. Reordering places the leafs after non-leaf nodes.

Example:

Orginal order:

New order:

```
Folder 1
        Doc 4
        Leaf c
        Placeholder i
        Doc 1
        Folder 1.1
        Leaf a
```

```
Folder 1
        Doc 4
        Placeholder i
        Doc 1
        Folder 1.1
        Leaf a
        Leaf c
```

— If Include Lifecycle Items is set to Yes, reordering leafs in a folder containing lifecycled leafs reorders all leafs in the folder.

Example: Sequence 0001 tree

Orginal order:

New order:

```
Folder 1
        Leaf 4 (0000, NEW)
        Leaf 2 (0001, REPLACE)
        Leaf 1 (0001, NEW)
        Leaf 5 (0000, NEW)
                Leaf 3 (0001, APPEND)
```

```
Folder 1
        Leaf 1 (0000, NEW)
        Leaf 2 (0001, REPLACE)
        Leaf 4 (0000, NEW)
        Leaf 5 (0000, NEW)
                Leaf 3 (0001, APPEND)
```

Example: Sequence 0001 tree

Orginal order:

New order:

```
Folder 1
        Leaf 4 (0000, NEW)
        Leaf 2 (0001, REPLACE)
        Leaf 1 (0001, NEW)
        Leaf 5 (0000, NEW)
                Leaf 3 (0001, APPEND)
```

```
Folder 1
        Leaf 4 (0000, NEW)
        Leaf 5 (0000, NEW)
                Leaf 3 (0001, APPEND)
        Leaf 1 (0001, NEW)
        Leaf 2 (0001, REPLACE)
```

— Reordering a folder containing leafs and documents directly under the folder places the reordered leafs before the reordered documents.

Reorder Leafs

You can change the existing order of leafs in folders and subfolders. You can also reorder lifecycled leafs with other leafs.

Important: After you reorder leafs, you cannot change the order again. Before you perform this procedure, be sure of the result you want.

To reorder leafs, do the following:

1. Right-click the folder containing the leafs that you want to reorder, and click Reorder Child Leafs.
2. Click the field on which to reorder the leafs: Leaf Name, Leaf Title, or Leaf Output File.
3. If you want to reorder leafs in subfolders under the selected folder, for Include Subfolders?, click Yes. If not, for this field, click No.
4. If you want to reorder lifecyled leafs with other leafs, for Include Lifecyled Leafs?, click Yes. If not, for this field, click No.
5. Click OK.
6. When prompted to confirm that you really want to perform this reordering, click Yes.

Add a Leaf PDF Property

You can add or modify the PDF Property Setting for a selected Leaf from the *Leaf Attributes* view page. You must have sufficient security permissions to be able to create a PDF Property.

To add or modify the PDF Property:

1. On the view *Leaf Attributes* page, select PDF Properties.
2. Click Create .
   — To edit an existing PDF property setting, click the named PDF property in the list on the *PDF Properties* tab.
3. On the *Create PDF Property Settings* page, complete the required fields, and the optional fields as needed. Required information is indicated by an asterisk (*).
   — Output PDF Property*
   — PDF Property Source*
   — Source Document Property*
   — Value*
   — Separator

   Note: *The set of attributes varies on the value selected in the PDF Property Source field.*
4. To save the new PDF Property, Save.
   To discard the changes, Cancel.

Leaf PDF Property Attributes

The attribute descriptions help you to enter the appropriate attribute values while creating a PDF Property setting for a Leaf element. Required information is indicated by an asterisk (*).

Attribute	Description
Output PDF Property*	Defines the target PDF Property in the output document. Values available for selection are all active values from the Data Administration|PDF Properties section, where Target Property is set to Yes. The value should be unique within settings defined explicitly for the leaf. The value can be the same as the value inherited from the Assembly Specific Publishing Settings Library (APL). The Leaf-specific PDF Property setting will replace the inherited APL PDF Property setting, if the Output PDF Property value for both the Leaf and the APL is the same.
PDF Property Source*	Defines the source for the PDF Property. The values available for selection are the following: — Define Repeatable Value - Applies a defined value as the PDF property, values are obtained from all assigned documents. The PDF Properties are distinguished by a defined separator. — Define Single Value - Applies a defined value as the PDF Properties, the value is obtained only from the first assigned document. — Use Source Document Property - Applies a defined PDF Property from all assigned documents. The PDF Properties are distinguished by a defined separator.

Attribute	Description
Source Document Property	Defines the PDF Property in source documents to be used as a source for the PDF Property in the output document. Values available for selection are all active values from the Data Administration|PDF Properties section, where Source Property is set to Yes. The following default values are available for selection: — Author — Keywords — Title — Subject This field appears and is required only when PDF Property Source is set to Use Source Document Property.
Separator	User defined separator to distinguish values from individual documents within a leaf. To support the use of spaces and newline breaks, the following text patterns must be used: — //space - Space character will be inserted as a separator — //newline - New Line will be started. The effect of the new line break will be visible from the PDF viewer for multi-line fields only. This field does not appear when PDF Property Source is set to Define Single Value.
Value	Defines the value for the PDF Property in the output document. This field appears and is required only when PDF Property Source is set to Define Single Value or Define Repeatable Value.

Document Elements

Documents are placed under leaf elements in an assembly tree.
The features related to document elements include automatic leaf creation, document place holders, document binding, and reference locations.

You can perform the following actions:

— Automatic leaf creation - You can determine if leaf elements are created automatically when you drag documents from the DMS browse window into an Calyx RIM folder or root.
— Document placeholders - You can create document placeholders in an assembly where you expect to later assign documents.
— Document binding - When you create an assembly, you choose a default document binding. The documents you assign to the assembly assume the specified document binding.

— Reference locations - A reference location enables you to open an assembly from within a document management system (DMS) or repository.

Document Attributes

The attributes and descriptions help you to enter the appropriate attribute values when you create documents. The table list all the attribute values that are available to you when you create a document.

Attribute	Description
Abbreviated Name	Short name for the document.
Assignment Status	Indicates whether the document is available in the DMS. You cannot change this value.
Bound Version	Version of the document bound to the assembly. You cannot change this value. If a version of the document in the DMS supersedes the bound version, Newer Version Available is displayed.
Category	Descriptive information about the document.
Comments	Exceptions or clarifications about the document.
Content Type	Type of content in the document.
Copied From	If applicable, indicates the origin location of the copied document.
Default Binding Rule	Set Default Document Binding: — Bind to Label binds the document to the label you choose — Bind to Status binds the document to the status you choose — Bind to Version binds the document to the version number you enter ***Note:*** *For documents assigned to SharePoint in Calyx RIM, you cannot change the Label or Status attributes and can only bind to the file version. SharePoint supports minor and major file versions, but does not support labels and statuses.* ***Note:*** *For Veeva documents, binding to a label is supported only when the label is set to* `CURRENT`*. Veeva does not use labels. When the label is set to* `CURRENT`*, Veeva displays the latest version in the tree.*
Description	Text that describes the document.
Document Modified Date	When the document was last modified.

Attribute	Description
Document Type	DMS document type. You cannot change this value.
Due Date	Date document is due.
Extraction Exists	Indicates whether or not extractions exist for the document.
Has Relations	Indicates whether or not the document has any relations.
Include in Page Numbering	Include page numbering on document.
Keywords	Words you can use to search for the document.
Last Rendered	Displays the last known rendition date.
Last Repository Data Retrieval	Indicates the last time the document was synchronized with the DMS. You cannot change this value.
Latest Version	Current version of the document. You cannot change this value.
Name	Name of the document.
Number	Number to use with publishing tools that require section numbering.
Number of Pages	Displays the number of pages in the document.
Other	Information you want to save about the document.
Output Channel	Available publication output (electronic, paper).
Overlay Setting	Choose the overlay to apply to the document.
Owner	Person responsible for the document.
Page Range From	Define the start of the range of pages within the document to be used in the assembly.
Page Range To	Define the end of the range of pages within the document to be used in the assembly.
PDF Exists	Indicates whether a PDF rendition exists for the document. You cannot change this value.
Planned Number of Pages	This enables you to indicate the number of pages you are planning to include in the document; may be useful if you do not yet have a finalized document. For documents in native file leafs: **Planned number of pages** is always used, even if the document has been extracted at some point and **Extraction Exists = YES**, and **Number of Pages** has been extracted. If **Planned Number of Pages** is not set, one page is assumed.
Rendition Identifier	Choose the **Rendition Identifier** to use for the document.
Review Status	Text about the status of the document review process.

Attribute	Description
Source Document	Name of the source document. You cannot change this value.
Source Location	Indicates where the source document is located in the DMS or file system. You cannot change this value.
Title	Title that helps you identify the document.

Document Placeholders

You can create document placeholders in an assembly where you expect to assign documents at a later time.

A document placeholder has an assignment status of Unassigned. This status changes when you assign a document to the placeholder.

Document Binding

When you create an assembly, you choose a default document binding. The documents you assign to the assembly assume the specified document binding.

For example, if you set your document binding to a status of approved, Calyx RIM clearly indicates when the assigned documents are in or out of compliance with that rule.

Keep in mind the following about document binding:

- When you apply a document binding to all children, it is not applied to child documents that reference a branched version and that are set to 'Bind to Version'. In this case, after you navigate through any messages, the selected binding is applied to documents up to, but not including, the document that references the branched version. You can apply the version binding to documents individually, or you can select a more granular range that does not include the branched document versions.
- When you create an assembly from a virtual document or when you assign a virtual document to an assembly, no warning is displayed if the virtual document contains binding rules that are not defined in Calyx RIM by the administrator.
- Including the same document in an assembly twice when one of the documents is bound to a non-existent status (such as Approved) produces the inclusion of this document as a bound document in an exported virtual document.
- Binding cannot be removed after it is applied. However, it can be modified by using the *`Apply Binding to All Children`* option.
- Binding can be applied to DMS documents only, and does not apply to file system documents.
- Your options for applying binding rules are controlled by the configuration of Calyx RIM Data Administration, your DMS, and your permissions in the system.

Modify Document Binding Rules for a Document Range

You can change the binding rule for all documents in the root, a folder, or a leaf.

When you change the binding rule for a folder or a leaf, the binding rule for elements outside the folder or leaf remain unchanged. The new rule affects only the contents of the folder or leaf.

When you add any elements to the assembly tree, after you change the binding rule for the root, a folder, or a leaf use the default document binding rules set for the assembly.

You can also lock the binding rule to the current content so that the same document is referenced regardless of later versions that may become available. For example, if the binding rule for a document is set to Current and the current document version is 3.0, locking the binding will make the reference to version 3.0 permanent. Even if later versions of the document become available, the assembly will reference version 3.0.

Apply Binding to All Children

Use the Apply Binding to All Children option to apply or modify binding rules for assembly elements in a standalone assembly, a sequence assembly that is not lifecycle, an unfinalized lifecycle assembly, or an assembly template.

To apply or modify binding rules:

1. On the assembly tree, select the assembly root, a folder, or leaf.
   The binding rule you apply or modify will apply to the selected element and all children assigned to that element.
2. On the More menu, choose Apply Binding to All Children.
3. On the *Apply Binding to All Children* window, select a Rendition Identifier.
   The selected Rendition Identifier will apply to the selected assembly element and all of the children of that element.
4. Choose the Binding Rule that will apply to the selected assembly element and all of the children of that element and click OK.

Option	Action
Bind to Label	Select the option to provide a dynamic list of options for the binding rule after choosing the appropriate Label.
Bind to Status	Select the option to provide a dynamic list of options for the binding rule after choosing the appropriate Status.
Bind to Version	Select the option to provide a dynamic list of options for the binding rule after choosing the appropriate Version.
Lock Binding	Select the option to provide a dynamic list of options for the binding rule.

5. A message appears, warning that you are about to change the binding for all documents under the selected element and that the binding action cannot be undone. To complete the binding action, click OK. To quit the binding action, click Cancel.

Lock Binding

Lock Binding is an option of the Apply Binding to All Children function.

When you select Lock Binding from the Binding Rule options, a repository property retrieval is performed for each Placeholder or Assigned Document within the range and their mapped or calculated properties (including Assignment Status) are updated.

Bindings are changed on all Placeholders and Assigned Documents that:

— Are within the selected element or Root, except for Placeholders and Assigned Documents descended from a Standard locked Folder or Root.

— Have a binding option of Bind to Label or Bind to Status. Those set to Bind to Version are already locked and are not affected.
— Have an object that exists within a DMS (Documentum or Veeva) that fulfills the binding option and its value. If no object meets the current binding criteria, a version number cannot be determined and binding on these elements cannot be locked.

For Documentum, branched versions are not supported so bindings are not changed on any branched Assigned Document version.

Reference Locations

You can use reference locations to open an assembly from within a document management system (DMS) or repository.
The reference location is an HTML file that contains all the assembly attributes and a link that enables you to open the assembly automatically. When you click the reference location in the DMS, it opens a browse window with the attributes of the assembly, including a link to the assembly. Clicking this link takes you to the Calyx RIM login page. After you enter your login information, Calyx RIM opens the assembly.

The reference location name is the name you assign to the reference location.

Keep in mind the following:
— Calyx RIM maintains only one reference location for an assembly version. If a reference location exists in Documentum or the file system and it is moved or renamed, the original reference location is not deleted. Instead, another reference location is created for the same assembly version.
— You can create a reference location when the assembly is created by editing the assembly properties. Once an assembly exists, you must use the Set Reference Location action button to change it.
— When a reference location is created from the current active view, launching the reference location takes you to the first sequence assembly in the lifecycle. From there, you have to switch to the current active view.
— Calyx RIM References to DMS elements can go to documents only; they cannot reference a compound document, virtual document, or link.
— For an assembly with a reference location defined in Documentum, to avoid having multiple versions of the assembly showing as Current, you must not change the reference location for any of the assembly versions to a different directory in Documentum.

Assign Documents

When you add an assigned document to the assembly tree, you create a link from the assembly tree to the document in the repository or file system.
This link associates the document with the assembly.

You can add document assignments in the following ways:
— Assign a document to a placeholder
— Assign a document as a child of an element
— Add a virtual document to the assembly tree
— Replace an assigned document with a related document
— Add an entire file/folder structure to the assembly tree

— Adding a Veeva binder, classification folder, or section to the assembly tree

You can perform the drag-and-drop function with documents from the repository browse window only. You cannot drag-and-drop documents from Windows Explorer. To access a specific file system from Calyx RIM, it must be mapped by an administrator and accessed from the DMS Browse window as a file/folder repository.

DMS Browse

The DMS Browse function displays a tree structure used to access documents in the selected document management system (DMS).
You can use the tree from the following places in :

Location	DMSs with Accessible Document
Assigning documents	All
Attachment Values in Data Administration	All except Veeva
Auxilary Output Location	All except Veeva
Bulk eCTD Import	All except Veeva
Create Assembly or Create Assembly Template - from an assembly file	All
Create Assembly or Create Assembly Template - from a virtual document	All except Veeva
Electronic Output Location - on the Create Assembly, Edit Assembly Attributes, and Publish Request pages	All except Veeva
Export Assembly - to Excel, Virtual Document, or Assembly File	All except Veeva
Export Published Output	All except Veeva
Import eCTD	All except Veeva
Paper Output Location - on the Create Assembly, Edit Assembly Attributes, and Publish Request pages	All except Veeva
PDS Label	All
Publishing Settings Browse - Preview Location and Process Rendition Location	All except Veeva
Reference Location - on the Create Assembly page	All except Veeva
Set Reference Location	All except Veeva
XEVMPD Acknowledgement wizard	All except Veeva
XEVMPD Submission wizard	All except Veeva

Where the DMS Browse function is available, clicking the Browse button opens the DMS Browse window. The DMS Browse window displays the tree structure used to access documents in the DMS that you select.

Choosing any of the following in the tree view displays additional information about the selected item in the grid view to the right of the tree:

— Folder
— Document
— Virtual document
— Veeva binder
— Veeva section

For a description of the grid view, see *DMS Search Results – Grid View.*

The tree view displays all of the configured repositories that the logged on user has permission to access. User access to repositories is configured in Technical Administration.

DMS Browse Icons - Tree View

The DMS tree is used to access documents in document management systems (DMSs).
In the DMS Browse tree view, different icons are used for different types of nodes:

Icon	Node Type
	Documentum repository
	Documentum
	Standard document
	Documentum virtual document
	File system
	File system folder
	Server
	Secure file system
	Veeva Vault
	Veeva binder
	Veeva type, subtype, or classification
	Veeva section

Use The Tree

Expand the tree to view available documents.
Clicking the arrow icon next to a node will:
— Expand the node by one level if the selected node was collapsed
— Collapse the selected and all nodes under it if the selected node was expanded

A document displayed in the tree view is the:
— CURRENT document, for Documentum
— Latest version of the document, for any DMS except Documentum

Expanding the document node displays all available versions of the document.

A virtual document displayed in the tree view is the CURRENT version and not the latest version. Expanding the virtual document or binder node displays the content of the virtual document or binder, not all available versions.

DMS Browse - Select Multiple Rows In Tree View: Contiguous Nodes

You can select the multiple nodes in the DMS Browse tree view, contiguously, using the `SHIFT` keys.
Following are the multiple nodes in the DMS Browse tree view:
— Folders
— Documents
— Virtual documents
— Veeva placeholders, binders, classifications, and sections

To select contiguous nodes:

1. Click the first entry of the group of nodes that you want to select.
   Select the name of the node, not the icon.
2. Press and hold the Shift key on your keyboard.
3. Click the last entry that you want to select.
   All of the nodes in your selected group appear highlighted.

DMS Browse - Select Multiple Rows In Tree View: Non-Contiguous Nodes

You can select the multiple nodes in the DMS Browse tree view, non-contiguous, using the `CTRL` keys.
Following are the multiple nodes in the DMS Browse tree view:
— Folders
— Documents
— Virtual documents
— Veeva placeholders, binders, classifications, and sections

To select non-contiguous nodes:

1. Press and hold the Ctrl key on your keyboard.
2. Click each node that you want to select.

The nodes that you selected appear highlighted, although the group is not contiguous.

3. You can now drag-and-drop the nodes, or click OK to assign them.

DMS Browse - Tree View of a Veeva Repository

In DMS Browse, the tree for a Veeva repository has the following structure. Each node in this structure can contain one or more nodes of each type shown. Note the following:

— The tree shows documents, placeholders, and binders that you have permission to see.
— The tree does not show deactivated types, subtypes, and classifications.
— A binder can contain other binders.
— A section can contain other sections.
— A document, placeholder, or binder for which no classification is specified is at the same level as a subtype.
— A document, placeholder, or binder for which no subtype is specified is at the same level as a type.
— You can assign the following to assemblies: documents, placeholders, binders, classifications, and sections.

```
> Veeva Vault [server level}
 > Vault [repository label defined in Technical
   Administration]
    > type
      > subtype
        > classification
          > document
          > placeholder
          > binder
            > document
            > placeholder
            > binder
              ...
            > section
              > document
              > placeholder
              > binder
                ...
              > section
                ...
        > section
          ...
      > subtype
        > document
        > placeholder
              > binder
          ...
    > type
      > document
      > placeholder
      > binder
        ...
```

The following is an example of part of a DMS Browse tree for a Veeva repository:

```
> Veeva Vault [server level]
            >  Vault 1 [vault]
               > Clinical [type]
                  > Trial Management [subtype]
                    > Data Monitoring Committee classification]
                      > US binder [binder]
                        > Administrative Information [section]
                          > Forms [section]
                            > Initial Request.doc [document]
                            >  ...
```

DMS Browse - Grid View

The DMS Browse grid view displays different columns by default, depending on which repository type is accessed. The following attributes are configured to display, or are available to display, as columns within the grid view for the specified DMS. Additional attributes can be configured using the XML overrides.

DMS	Default Column Attributes	Optional Column Attributes
Documentum	— Name — Title — Date Modified — Version — Keywords — Path	— Subject — Date Created — Authors — Status — Document ID
Filesystem and Secure Filesystem	— Name — Document Modified Date	— Size — Absolute Path — Canonical Path — File Parent — File Path

DMS	Default Column Attributes	Optional Column Attributes
Veeva Vault	— Name — Title — Version — Last Modified Date — Created By — Product — Country	— Status — Created Date — Last Modified By — Document Number — Type — Subtype — Classification

DMS Browse - Modify Grid View Columns

You can add or remove columns in the grid view using the Columns list.

To modify the columns in the grid view:

1. Open the Columns list by clicking the arrow on any column heading.
2. Point to Columns and then select or clear the available column options.
3. The selected columns appear in your DMS Search Results grid view.

Option	Action
You can sort any column in ascending or descending order:	Click the sort arrow on the column heading. You can restore the grid view to the default sort by clicking Reset Sort at the bottom of the grid view.
DMS Search Results:	The DMS Search Results can display multiple pages of data in the grid view, but you cannot select items across multiple pages.
DMS Search Results:	You can export the DMS Search Results from the grid view as a spreadsheet by clicking Export to Excel at the bottom of the grid view.

DMS Browse - Documents Tab

DMS Browse - Documents Tab comes with two different options to complete your selection process.
The DMS Browse Documents tab consists of two panes: Browse Documents and Browse Recently Selected. Each pane can be expanded to show their respective lists and perform certain actions.

DMS Browse - Documents Tab Preview Document

The DMS Browse Documents tab consists of two panes: *Browse Documents* and *Browse Recently Selected*.
You can preview a document selected in either the tree view or the grid view by clicking Preview (located below the tree view).

If you select multiple documents in the grid view and click Preview, the document selected first will be previewed. If multiple documents are selected in the tree view, the last document selected will be previewed.

To preview a virtual document, the selected virtual document must have content.

DMS Browse - Documents Tab Recently Selected

When you are assigning documents in an assembly, the Browse Recently Selected pane is available on the Documents tab of the Browse window. This view helps you to keep track of the documents, virtual documents, Veeva placeholders, and Veeva binders that you have selected as you browse a DMS and choose entries to add to an assembly.

The Browse Recently Selected pane automatically lists all documents, virtual documents, Veeva placeholders, and Veeva binders that you select in the grid view, with the most recently selected added to the bottom of the list. To remove an entry from the Browse Recently Selected pane, select the root folder, and then clear the check box of the entry in the grid view.

The Browse Recently Selected list is expandable and collapsible at the root folder and at nodes for virtual documents and Veeva binders. The expanded view enables you to see all versions of a selected entry:

— To view an entry in the Browse Recently Selected pane, select the entry in the list and click Preview. The entry opens in the appropriate application for viewing.
— To add entries from the list of recently selected entries to an assembly, select the check box next to each entry that you want to add and click OK.
— To quit the DMS Search without assigning any of the recently selected entries to the assembly, click Close.

DMS Search

Use the Search tab on the *DMS Browse* window to search any of the following repositories for which you have access permission:

— Documentum
— Veeva

Warning: When searching against a Veeva repository using DMS Search in Calyx RIM, an error may appear about exceeding the API calls limit. By default, Veeva Vault has an API burst limit of 2,000 API calls within a 5-minute period, and 100,000 API calls daily. These limits help to prevent runaway script scenarios (e.g. where the logic creates an infinite loop that continuously calls the Vault APIs). To request an increase to this limit, please contact Veeva Support.

The available DMS Search options depend on the type of DMS repository you are searching. Different options are available for different DMS repositories. For example, the Advanced Query functionality is available only for Documentum and Veeva repositories.

By default, a DMS search returns only the first 50 objects found. If your company wishes to modify the default setting, please contact Technical Support.

Field	Description
DMS Repository	Select the DMS repository to search. Required.

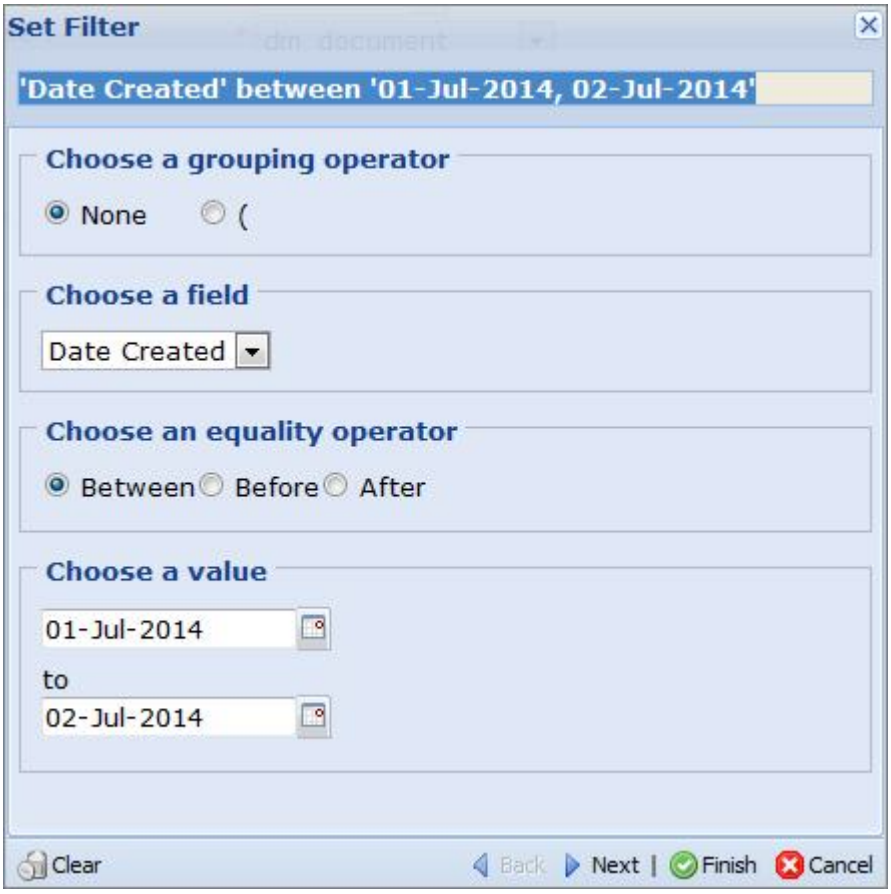
Field	Description
Repository	This field appears on the search tab after you select a DMS Repository. Select the name of the repository to search. Required.
Document Type	This field appears on the search tab after you select a Repository. Select the document type to search for in the repository. Required. ***Note:*** *The* Document Type *field in the Calyx RIM* DMS Search *function is not equal to the Document Type term in Veeva. Calyx RIM* DMS Search *treats the Veeva Document Type as a top level folder in the DMS folders/files tree.*
Search Folder	Click the Browse option to choose a folder in the repository to search. In addition to the required fields, you must choose a Search Folder or Advanced Query to complete a search.
Exclude Assigned Documents	Select this option to exclude assigned documents from the search.
Case Sensitive	Select this option to make the search case sensitive according to your filter criteria.

Field	Description
Advanced Query	Advanced Query is available only for Documentum and Veeva repositories. Click Build Query to open the *Set Filter* window and add operators to refine your search criteria. In addition to the required fields, you must choose a Search Folder or Advanced Query to complete a search. — Choose a grouping operator. Choose None, or choose to group multiple filter criteria within parentheses. — Choose a field. Select a field from the keywords list. This list, except for Path, corresponds to the columns in the grid view. If your company configures custom fields for the grid view, those fields also are available. — Choose an equality operator. The equality operators are dynamic and vary according to the selected field. — Choose a value. Enter text, or choose dates, if a date field was selected, to specify the equality operator. Example: To find all documents created on one specific date, in this example, July 1, 2014: 1. Choose the field Date Created. 2. Choose the operator Between. 3. Set the first date to 01-Jul-2014, and set the second date to 02-Jul-2014. The search filter looks like this: 'Date Created' between '01-Jul-2014, 02-Jul-2014'. 4. Click Finish, and then click Search. The *DMS Search Results* displays results for only July 1, 2014. The system retains the last search criteria specified in Advanced Query until those criteria are reset, regardless of whether the DMS Browse/Search window is closed/reopened, the user logs off from , or the browser window is closed.
Clear	Clears and closes the *Set Filter* window.
Back	To return to the previous criteria in your search filter, click Back.
Next	To add another item to your search filter, click Next.
Finish	When your search filter is completed, click Finish.
Cancel	To cancel your last selection while creating the search filter, click Cancel.
Reset	To remove all search criteria and start over, click Reset.
Search	To initiate the search using your selected criteria, click Search. The results appear in the *DMS Search Results* grid view.

DMS Search Examples

The following images show two different Advanced Query filter examples. The first image shows the filter for searching the repository for documents modified on a single, specific date. The second image shows the filter for searching the repository for documents modified by either of two authors within a date range.

Advanced Query – Set Filter – single date



Advanced Query – Set Filter – either of two authors within a date range

DMS Search Results - Grid View

The DMS Search Results grid view displays the documents for the node selected in the tree view.
When a selected node or folder consists of child folders and documents, then only the documents assigned to selected folder appear in the grid view.

The grid view displays additional attributes for the node selected in the tree view. Folders do not appear in the grid view.

If a repository or folder is selected:
— All documents in that repository or folder appear in the grid view.
— All versions of each document are displayed.
— All versions of each virtual documents are displayed.

If a document or virtual document is selected, all versions of the documents are displayed.

If a version of a document or virtual document is selected, all versions of that document are displayed. The selected version appears first in the grid view.

If multiple nodes are selected in the tree view, the grid view displays only the last node selected.

Assign a Document

You can assign documents to a folder from the assembly tree, or from the repository, using the DMS browse window. You can perform the drag-and-drop function for documents from the DMS browse window only. You cannot perform drag-and-drop with documents from Windows Explorer.

To access a file system from Calyx RIM, it must be mapped by an administrator and accessed from the DMS browse window as a file/folder repository.

To assign a document:

1. In the assembly tree do one of the following:

Option	Action
To select the element that you want to assign a document to	Right-click the element and choose **Assign Document**.
To select from a document placeholder	Right-click a document placeholder and choose **Assign Document**.
To select from different document placeholders	Choose a document placeholder and click **Assign Document** .

2. In the repository browse window, do one of the following:

Option	Action
To successfully drag the document to the assembly	Locate the document and click on the document name and drag it to the element or document placeholder. (You must click the text of the document name, not the icon preceding the text.)
Locate and choose the document	Click **OK**.

3. Continue to assign documents or click **Close** to close the repository browse dialog box.
   The ***DMS browse*** window is specific to the assembly from which it is launched and must be closed before assigning documents to another assembly. If you attempt to use the same ***DMS browse*** window for a different assembly, this message appears: `The open DMS Browse window was not opened for this Assembly, it will now be closed.`
4. When creating an assembly, if you click **Cancel** in the **DMS browse** window, you are not returned to the assembly tree.
   When importing a VDM, the ***DMS Import*** dialog box appears behind the browser window. You must minimize the browser window to continue.

Drag-and-Drop Documents from a Veeva Window

You can drag-and-drop documents from another browser instance with opened Veeva Vault page.

Prerequisites

Before you can use the feature, review the following procedures and make sure that the needed configurations are appropriately applied:

Configuring the Veeva Cache Timeout Setting	The procedure in this topic describes the changes that need to be performed in `insight.var` file to change the default Veeva cache timeout that is set to 3 minutes to be any other integer value.
Internet Explorer: Enabling the Drag-and-Drop from Veeva DMS	The procedure in this topic describes the changes that must be performed in the Internet Explorer browser to enable drag-and-drop from a separate Veeva window.

The file can be dragged from another browser window with Veeva Vault opened. You can drag a file or binder from the Veeva Vault Library to the:

— Assembly
— Template
— Working View

To drag-and-drop from Veeva Window:

1. From a separate browser window, navigate to the Veeva Vault window.
2. Select any file.
3. Drag-and-drop the selected file to the target assembly element.

Condition	Result
If the file dropped onto an assembly element belongs to Veeva Vault, configured and active in Technical Administration:	The file is assigned.
If the file dropped onto an assembly element belongs to Veeva Vault, deactivated or absent in Technical Administration:	The following warning message is displayed: `Repository is either invalid or deactivated.`
If the file or object dropped onto an assembly element does not belong to Veeva Vault:	The action is ignored.

4. Select any binder.
5. Drag-and-drop the selected binder to the target assembly element.

Condition	Result
If the binder dropped onto an assembly element belongs to Veeva Vault, configured and active in Technical Administration:	The file is assigned.
If the file is dropped onto an assembly element belongs to Veeva Vault, deactivated or absent in Technical Administration:	The following warning message is displayed: `Repository is either invalid or deactivated.`
If the file or object dropped onto assembly element does not belong to Veeva Vault:	The action is ignored.

Drag-and-Drop Documents from a D2/LSRD Window

You can drag-and-drop documents from another browser instance with an opened D2/LSRD window.

Prerequisites

Before you use the feature, review the following procedure and make sure that the proper configurations are applied:

Internet Explorer: Enable Drag-and-Drop from D2/LSRD	The procedure in this topic describes the changes that must be performed in the Internet Explorer browser to enable drag-and-drop from a separate D2/LSRD window.

Note: *Drag-and-drop of multiple objects is not supported. Drag-and-drop is supported if the D2/LSRD window is opened in Java mode only. Make sure that you are aware of the product-specific notes that may apply to the requirements for OpenText Documentum D2 16.4. Please refer to D2 Release Notes for more details.*

Any Virtual document, file, or folder can be dragged from another browser window when the D2 window is open. You can drag a Virtual document, file, or folder from the D2 window to the:

— Assembly
— Template
— Working View

To drag-and-drop from a D2/LSRD window:

1. From a separate browser window, navigate to the D2/LSRD window.
2. Select any Virtual document, file, or folder.
3. Hold the `Alt+Shift` keyboard combination, drag-and-drop the selected Virtual document, file, or folder to the target assembly element.

Condition	Result
If the Virtual document, file, or folder dropped onto an assembly element belongs to D2, configured and active in Technical Administration:	The file is assigned.
If the Virtual document, file, or folder dropped onto an assembly element belongs to D2, deactivated in Technical Administration:	The following warning message appears: `Repository is either invalid or deactivated.`
If the Virtual document, file, or folder dropped onto an assembly element does not belong to D2:	The action is ignored.

Assign a Virtual Document

You can assign a virtual document from a DMS repository to an assembly tree.
You can assign either the root as an assigned document or assign the root with all the child folders and documents with the same hierarchy to the assembly tree.

To assign a virtual document:

1. In the assembly tree, right-click the root, folder or leaf where you want to assign the virtual document.
2. Choose Assign Document.
3. In the *Browse* dialog box that opens, locate and choose the virtual document.
4. Choose one of the following:

Option	Action
To add the root as an assigned document to the assembly tree without its children	Click Only the root node.
To add the assembly root and its children, maintaining the same hierarchy as the virtual document	Click All child nodes.

Note: *Assigning a virtual document with all child nodes converts no-content objects in the virtual document to documents with a* `MISSING CONTENT` *assignment status in Calyx RIM.*

5. Click OK.
   The virtual document is added to the assembly tree.

Add a Document Placeholder

You can add a document placeholder to an assembly tree to indicate where a document will be added when it becomes available.

To add placeholder elements to an assembly:

1. Right-click the assembly root, or the target element on the assembly tree, and choose Add Placeholder.

Note: *When leaf elements are created automatically for the assembly, a new leaf (named* New Leaf*) is created.*

A document placeholder, named New Document, is added to the assembly tree and the *Edit Document* page appears.

2. Enter attributes.
3. Save.

Locate Documents

You can locate documents in the browse dialog box and add them to an element you select in the assembly.
You can also use a drag-and-drop action to move documents from a repository or file system to Calyx RIM.

If no repositories have been configured by the Calyx RIM system administrator, an HTTP 500 error will occur when you try to open the DMS browser.

Note: *It may be necessary to turn off the pop-up blocker in Internet Explorer (*Tools > Pop-up Blocker*) to enable the drag-and-drop function for moving documents to the assembly from the document browse window.*

Search for Documents

To find the DMS location of a document you want to add to the assembly, you can perform a search using the Search tab in the DMS Browse window.
Keep in mind the following as you enter search criteria:

— Calyx RIM searches for a date exactly as you enter it.
— Calyx RIM searches for text exactly as you enter it. You can use wildcard characters (* or %) to search for documents that contain the text you enter.

Search Criteria Options

When performing a search using the Search tab in *DMS Browse* window, the search option descriptions will help you to enter appropriate search criteria.
The table list all the options that are available to you while performing search in the *DMS Browse* window.

Option	Description
Authors	Authors whose documents you are searching for.
Created Date	The creation date of the document you are searching for.
Repository	The repository you want to search.
Document Type	The repository document type you are searching for.
Keywords	Text to search for.
Modified Date	Date the document you are searching for was last modified.

Option	Description
Name	Name of the document you are searching for.
Status	Status of the document you are searching for.
Subject	Subject of the document you are searching for.
Title	Title of the document you are searching for.
Version	Version of the document you are searching for.

Search for a Document in a Repository

Calyx RIM search functionality enables you to locate a document in a DMS repository and then assign it to an assembly tree.

To find documents to assign to an assembly:

1. In the *browse repository* dialog box, click Search.
2. Enter the criteria with which you want to perform the search. You must enter some selection criteria in addition to the required DMS Repository, Repository, and Document Type search criteria fields to receive search results.
3. Do either of the following:

Option	Action
To clear your entries and re-enter search criteria:	Click Reset.
To find documents that meet the search criteria.	Click Search.

4. Choose one or more documents from the search results on the right side of the browse dialog box and do one of the following:

Action
Click Assign.
Drag them to the target location in the assembly and drop them.

Create Missing Renditions and Extractions

Calyx RIM enables you to create new and missing renditions and extractions of the source documents for an assembly.

Rendering retains the content and layout of the source document while transforming it into a PDF file. The extracts, such as bookmarks and headings, of the source documents are copied to the PDF file.

The following rules apply to all documents that have the Use Native File option set to No and that are in the section where you create missing renditions and extractions.

Rules for a Veeva DMS Document Bound to the Standard Rendition Identifier

You must follow specific rules for a Veeva DMS Document.

— If the PDF document does not exist, the job request for creating renditions and extractions is sent.

— If the PDF document exists but an extraction does not exist, the job request for the extraction is sent, and the current rendition is not changed.
— If no documents require renditions or extractions to be created in the section where you try to create missing renditions and extractions, the appropriate job request is set to Completed with the message No Documents to Render in the job details.

Rules for a File Share or for a Documentum Document Bound to the Standard Rendition Identifier

Rules are applied for all documents with Use Native File set to No within the section where the option was invoked from, if the document is from Documentum and is bound to Standard Rendition, or if a document is from File Share.
The following rules are:
— If PDF Exists is set to Yes, but Extraction Exists is set to No, the request for extraction is sent, and the currently existing rendition is not changed.
— If both PDF Exists and Extraction Exists are set to Yes, Calyx RIM compares the `.pdf` file size of a rendition with the one that is stored internally. If they are different, for example the rendition has been changed outside of Calyx RIM, only extraction request is sent.
— If there are no documents that require renditions/extractions to be created in the section where the option was invoked from, the appropriate job request is set to Completed with `No Documents to Render` message in job details.

Missing Rendition Identifier Handling for a Documentum Document

The following Missing Rendition Identifier Handling rules apply only to documents assigned from a Documentum DMS.
There are specific business rules for documents assigned from a Documentum DMS when using the Rendition Identifier functionality. LIQUENT InSight will only create renditions for the Standard Rendition Identifier.

Renditions and extractions are created when the Missing Rendition Identifier Handling setting is Use Standard Rendition, and no rendition exists.

Renditions are not created:
— When the Missing Rendition Identifier Handling setting is Use Standard Rendition, and a rendition exists for the non-standard Rendition Identifier value
— When the Missing Rendition Identifier Handling setting is Do Nothing, and no rendition exists for the non-standard Rendition Identifier value

Only extractions are created when the following conditions are met:
— When the Missing Rendition Identifier Handling setting is Use Standard Rendition, and a rendition exists for the non-standard Rendition Identifier value, but no extractions currently exist
— When the Missing Rendition Identifier Handling setting is Use Standard Rendition, and a rendition exists for the non-standard Rendition Identifier value, and the rendition file size has changed
— When the Missing Rendition Identifier Handling setting is Do Nothing and a rendition exists for the non-standard Rendition Identifier value, but no extractions currently exist

— When the Missing Rendition Identifier Handling setting is Do Nothing and a rendition exists for the non-standard Rendition Identifier value, and the rendition file size has changed

Missing Rendition Identifier Handling for a Veeva Document

The following Missing Rendition Identifier Handling rules apply only to documents assigned from a Veeva DMS.

Renditions and extractions are created when the Missing Rendition Identifier Handling setting is Use Standard Rendition, no PDF rendition exists, and no rendition with the rendition identifier value Calyx exists.

No renditions or extractions are created when the Missing Rendition Identifier Handling setting is Do Nothing and no PDF rendition exists.

Only extractions are created:

— When the Missing Rendition Identifier Handling setting is Use Standard Rendition, no PDF rendition exists, and a rendition with the rendition identifier value parexel exists, but no extractions for the latter rendition exists.

— When a PDF rendition exists, but no extractions for that rendition exists.

Create Missing Renditions and Extractions

Use the procedure to create missing renditions and extractions of the source documents for an assembly. You can also track the progress of the process from the *Job Request* page.

Note: *You must have the appropriate security privileges to create new/missing renditions and extractions.*

To create missing renditions and extractions:

1. Right-click on a node in the assembly tree.
2. In the menu, click Create Missing Renditions and Extractions.
3. To track the progress of the process, chose Go To > Job Requests.
4. On the *Job Requests* page, set the filtering information and click Search.

Force New Renditions and Extractions

Force New Renditions and Extractions overwrites all existing renditions and extractions, and creates missing renditions and extractions for the selected node and all of its child nodes.

Forcing new renditions and extractions will cause custom bookmarks, modified TOC entries, in-process links, and (depending on your DMS configuration) signature pages to be lost.

Note: *Access to this functionality is dependent on your user role and permissions in the system, and on your permissions within the repository.*

Force Renditions and Extractions with Rendition Identifiers

The following Missing Rendition Identifier Handling rules apply only to documents assigned from a Documentum or Veeva DMS.
Specific business rules for documents assigned from a Documentum or Veeva DMS apply when using the rendition identifier functionality. Calyx RIM creates renditions only for the Standard Rendition Identifier.

Note: *In a Documentum DMS, the Standard Rendition identifier (NULL) identifies renditions with PAGE_MODIFIER set to NULL. In a Veeva repository, the Standard Rendition identifier (parexel) identifies the same kind of renditions.*

Renditions and extractions are created/overwritten when the Missing Rendition Identifier Handling setting is Use Standard Rendition.

Renditions are not created when the following conditions exist:

— When the Missing Rendition Identifier Handling setting is Use Standard Rendition and a rendition exists for the non-standard Rendition Identifier value.
— When the Missing Rendition Identifier Handling setting is Do Nothing.

Only Extractions are created when the following conditions are met:

— When the Missing Rendition Identifier Handling setting is Use Standard Rendition and a rendition exists for the non-standard Rendition Identifier value.
— When the Missing Rendition Identifier Handling setting is Do Nothing and a rendition exists for the non-standard Rendition Identifier value.

Force New Renditions and Extractions

You can use the Force New Renditions and Extractions option to overwrite existing renditions and extractions, creating missing renditions and extractions for the selected node and all of its child nodes.
Forcing new renditions and extractions causes custom bookmarks, modified TOC entries, in-process links, and (depending on your DMS configuration) signature pages to be lost.

To force new renditions and extractions:

1. On the assembly tree, select the assembly root, a folder, or leaf.

   The Force New Renditions and Extractions function applies to the selected element and all children assigned to that element.

2. On the *More* menu, choose Force New Renditions and Extractions .
3. Read the CAUTION message, and make sure that you want to proceed.

   Force New Renditions and Extractions creates missing renditions and extractions, overwrites all existing renditions and extractions for the selected node and all of its child nodes, and will result in the loss of:

   — Custom bookmarks
   — Modified TOC entries
   — In-process links
   — Signature pages (depending on your DMS configuration

4. To complete the Force New Renditions and Extractions action, click OK.
   Existing renditions and extractions will be overwritten. Missing renditions and extractions will be created.
5. To quit the Force New Renditions and Extractions action, click Cancel.
6. To track the progress of the action, choose Go To > Job Requests.
7. On the *Job Requests* page, enter appropriate information and click Search.
8. After the Force New Renditions and Extractions action is completed, refresh the assembly (or reselect the document elements) to see that the following options are set to Yes:
   — PDF Exists
   — Extraction Exists

Multiple Renditions Support

provides support for associating and publishing renditions using custom Rendition Identifiers (page_modifier) for documents in a Documentum DMS.
All documents assigned within an assembly are bound to the default Rendition Identifier that is set in the Publishing Settings for the assembly. After documents have been assigned to an assembly, the Rendition Identifier can be updated for a single document or for a group of documents (the selected assembly element and all of its children) using Apply Binding to All Children.

If the rendition with the defined Rendition Identifier does not exist, you can set the Missing Rendition Identifier Handling option to control how the document will be included during publishing. This option is available in the Publishing Settings Library, on the Publishing Settings tab. The Missing Rendition Identifier Handling option on the Publishing Settings tab provides two options: Use Standard Rendition (this is the default option) or Do Nothing.

If Use Standard Rendition is selected, Calyx RIM searches for a rendition with page_modifier set to NULL and uses it for publishing. If Do Nothing is selected, a missing rendition message will be logged.

Document List Query

The Document List query provides a view of the placeholders and assigned documents associated with an assembly structure.
This view is a non-hierarchical view of the placeholders and assigned documents in the submission. You can use the query to perform ad-hoc querying, tracking, and planning of placeholders and assigned documents.

Note: *The* Document List *query is specific to the current assembly, not the current active view.*

Generate a Document List Query

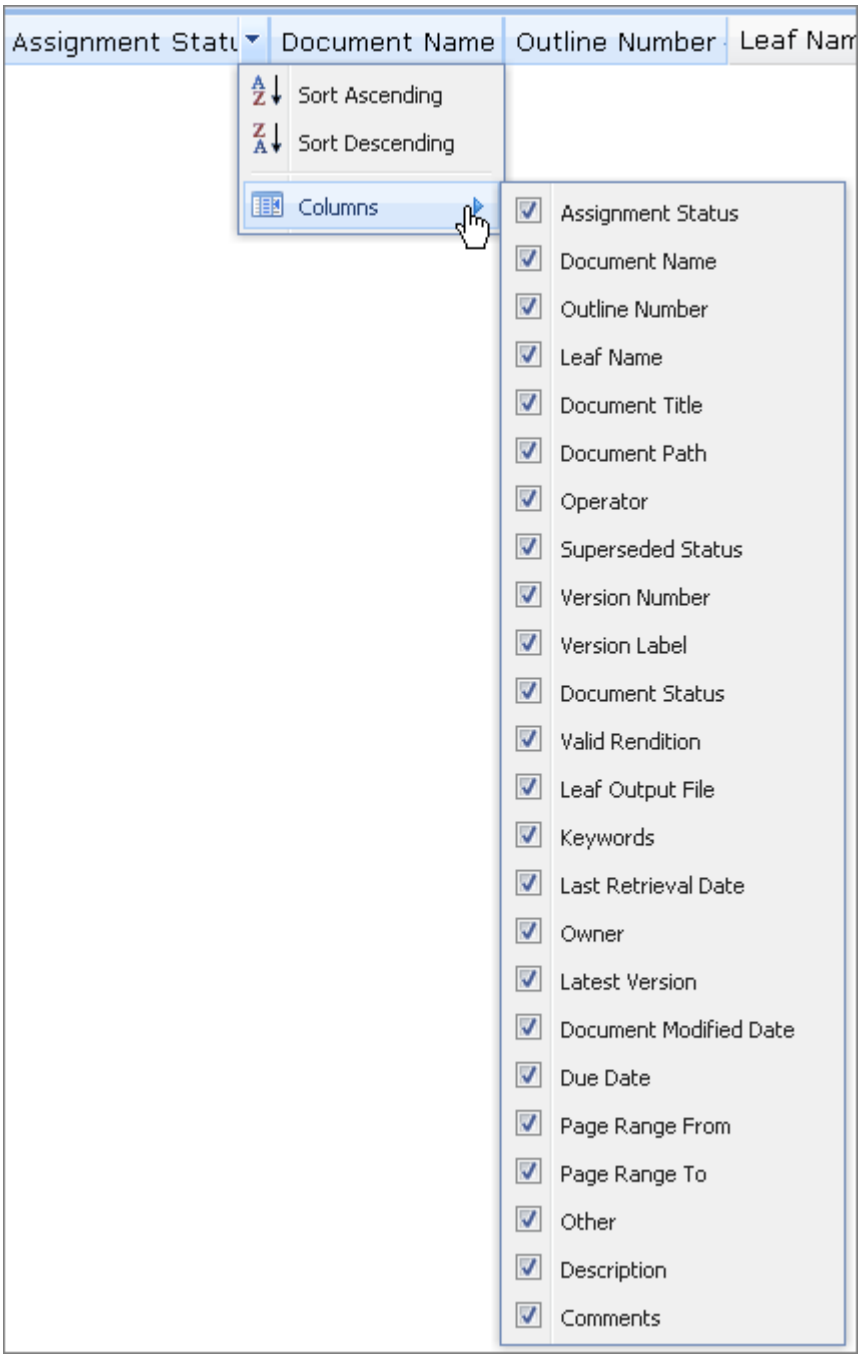
Use the Document List query to generate a table that displays assigned documents and their attributes for the assembly.

On the assembly root, right-click and select View Document List.

The resulting table lists all of the documents that are assigned to the assembly.

Select Document List Columns for Display

By default, all of the available columns are displayed in the generated Document List. You can choose to view fewer columns by opening the Columns list and clearing the check boxes next to the column names. To add an omitted column back to the Document List view, select the check box for that column.



Document List Query Results

The descriptions of column names helps you to understand the information displayed in the Document List query results.

This table contains all of the columns and describes the information displayed in the Document List query results.

Column Name	Description
Assignment Status	Lists documents that meet binding or missing binding or no longer exist in the data repository. Leaf elements that have no documents are not displayed.
Comments	Exceptions or clarifications about the document
Description	A brief description of the document
Document Family ID	The reference code for the document family
Document ID	The reference code for a document
Document Modified Date	When the document was last modified
Document Name	The name of the document.
Document Path	The location of the document in your system
Document Status	The status of the document
Document Title	The title given to the document
Due Date	The date that the document is due
Has Open Activities	Indicates whether there are active activities associated with the document
Keywords	Words that help to identify or describe the content of the document
Last Retrieval Date	Last time the document was synchronized with the DMS
Latest Version	Most current version of the document
Leaf Name	The name of the leaf where the document is located
Leaf Name	The name of the leaf where the document is located
Leaf Output File	Relative path and / or the file name of the published output for the leaf
Leaf Status	The value of the Leaf Status attribute from the leaf element
Operator	The eCTD lifecycle status for the leaf
Other	Additional information about the document that was saved
Outline Number	The eCTD outline number for the leaf
Owner	Person responsible for the document

Column Name	Description
Page Range From	Start of the range of pages in the source document that are used in the assembly
Page Range To	End of the range of pages in the source document that are used in the assembly
Superseded Status	Indicates if a more recent version of the specified file is available in the repository
Valid Rendition	Indicates that a valid rendition of the document exists
Version Label	The status of the version (Current, Superseded)
Version Number	Version of the document

Document Status Indicators

You can view the assignment status of an assigned document or a document placeholder, and the superseded status of an assigned document. A document with a superseded status is identified by the red label: Newer Version Available. The assignment status is determined by the binding options and the values and availability of documents in the repository, as follows:

— The assignment status indicates whether the file you want to bind to the assembly is available in the repository.
— The superseded status, indicated by a red label that says Newer Version Available, indicates whether a document available in the repository is more recent than the document assigned in the assembly.

When you assign a document to an assembly, it is added to the assembly tree and its icon indicates its status. The following table identifies the document status icons.

Icon	Meaning	Description
	Bound	The document exists, it has content and the binding rule has been satisfied.
	Unassigned	This is a document placeholder; it indicates that no document has been assigned.
	Superseded	The document exists, it has content and the binding rule has been satisfied, however a newer version of the document exists.
	Missing version	A version of the document exists that is different from the one specified by the binding rule.
	Missing	No version of the assigned document exists.
	Missing content	The document exists and the binding rule has been satisfied, however the document has no content associated with it. This can occur if a virtual document has been assigned from the repository.

Synchronize Document Attributes

As the documents change in the DMS, synchronizing document attributes enables you to see the current DMS attributes in Calyx RIM.

Attributes that map to DMS values are indicated by on the ***Document Attributes*** page.

When a DMS synchronization occurs, the following happen:

— The value for Last Repository Data Retrieval (on the ***Document Attributes*** page) is updated for the root, all folders, leaf elements, documents, and document placeholders.
— All calculated and mapped attributes (for example, assignment status and version numbers) are updated.
— Any other attributes for which you changed the values in Calyx RIM revert to their DMS attribute values.

Keep in mind the following:

— HTML text strings enclosed in angle brackets (< >) that map to Calyx RIM attributes do not appear in document attributes. HTML numeric strings map correctly.
— Running a DMS Synchronization on the root of a lifecycle working view performs a synchronization on documents from the previous sequence. Updates to documents from previous sequences do not become part of the current active view. Be aware, however, that if you synchronize the root and thereafter find unexpected attribute values on documents from previous sequences, you should check the same document in the current active view to determine the values of the document in the previous sequence.
— Running a DMS Synchronization from the Working View sends all previous sequences for Rendition & Extraction. Only documents for which there are no renditions and extractions are sent.
— Synchronizing large assemblies can slow the repository's performance and prevent other users from accessing it temporarily.
— Synchronization may be slower than expected if the DMS has limited space.
— Calyx RIM binds directly to specific versions of documents in a DMS repository. Because of this, Calyx RIM does not support the automatic or manual deletion of previous versions in a DMS. If you delete versions in your repository, Calyx RIM may generate an error when you attempt to synchronize to a version that no longer exists. You can avoid this by reassigning the document through the binding rule to a version that still exists.

Synchronize Documents with the DMS

You can run a DMS Synchronization from the Working View to send all previous sequences for Rendition & Extraction. Only documents for which there are no renditions and extractions are sent for Rendition & Extraction.

To synchronize document attributes with the DMS:

1. In the assembly tree, do one of the following to open the attributes page for the element:

Action
Choose the root to synchronize the entire assembly.
Choose an individual element to synchronize.

2. Click . A message prompts you to confirm the synchronization. Click Yes for one of the following:

Option	Action
Update the InSight document properties from the attributes:	Replaces the assembly attributes with those values in the DMS.
Update the Reference Location attributes from InSight:	Updates the existing reference location in the DMS with the latest version, label, and status information from the assembly, as well as additional configured attributes.

Note: *The Calyx RIM hourglass does not appear as the DMS synchronization occurs, however, synchronization can sometimes take several minutes to complete, depending on the speed of the associated DMS.*

Attributes preceded with are updated with the current values in the DMS.

View an Assigned Document

Use the procedure to view the content of an assigned document in the assembly tree.

To view the content of an assigned document:

1. In the assembly tree, click the assigned document whose content you want to view.
   The *Document Attributes* page appears.
2. Click on the action toolbar. The document opens in the appropriate application.

View Document Versions

You can view the version of a document from the assembly tree.

To view document versions:

1. Click a link for the assembly whose document versions you want to view.
2. On the assembly tree, click the document whose versions you want to view.
   The document versions appear in the lower-right corner under the document attributes.

Related Documents

You can replace an assigned document in an assembly tree with one of its related documents.
Calyx RIM provides a list of related documents, if they exist, for each assigned document.

Related documents are defined by document relations, a concept defined and supported by Documentum. When you replace a document with a related document, the link from the assembly tree to the original document is deleted and a link is created between the assembly tree and the related document.

Note: *Replacing a document with a virtual document is not currently supported.*

Assign a Related Document

Use the procedure to replace an assigned document with one of its related documents in an assembly tree.

To replace a document with a related document:

1. In the assembly tree, right-click the document you want to replace and choose Assign Related Documents. The list of related documents appears.
2. Choose a related document from the list and click Assign Document.

Unassign Documents

You can remove the link to a document from the assembly tree by unassigning the document.
When you unassign a document, the following happen:

— Selected attributes (as specified by your administrator) are cleared from the *Document Attributes* page.
— The assignment status on the *Document Attributes* page changes.
— The icon next to the document in the assembly tree changes to

Unassign a Document

Use the procedure to remove the link to a document from the assembly tree by unassigning a document.

To unassign a document:

1. Do one of the following:

Action
Choose the document in the assembly tree and click .
Right-click the document in the assembly tree and choose Unassign Document. A message prompts you to confirm the change.

2. Click OK.
3. If does not replace the document icon in the assembly tree, right-click the assembly root and choose Refresh Tree.

Submission Readiness Report

The Submission Readiness report shows, for each module in an assembly, the number and percentage of documents that fall into each of ten categories.
Each category is related to a document assignment status, approval status if assigned, due date of the parent leaf, and whether a document is in Documentum.

Your SPT license must be enabled to provide access to the Submission Readiness report.

Key questions answered by this report include:

— How many documents are assigned?
— How many documents have been approved?

— How many leafs are on time, and how many are late?
— How many documents are located on a file share?

If a document is in Documentum, the document is in one of the following categories:
— Assigned, Approved, Not Yet Due
— Assigned, Not Approved, Not Yet Due
— Assigned, Approved, No Due Date
— Assigned, Not Approved, No Due Date
— Not Assigned, Not Yet Due
— Assigned, Approved, Past Due
— Assigned, Not Approved, Past Due
— Not Assigned, Past Due
— Not Assigned, No Due Date

If a document is not in Documentum, the document is in the category Outside Documentum.

Synchronize the documents with the DMS before running this report.

A chart shows the categories for each module.

Generate a Submission Readiness Report

You can generate the Submission Readiness report to show categories of documents and the number of documents in each category.

To generate a Submission Readiness report:

1. Display the *Assembly Attributes* page for the assembly.
2. Click More in the top right corner of the page.
3. Click Submission Readiness Report.

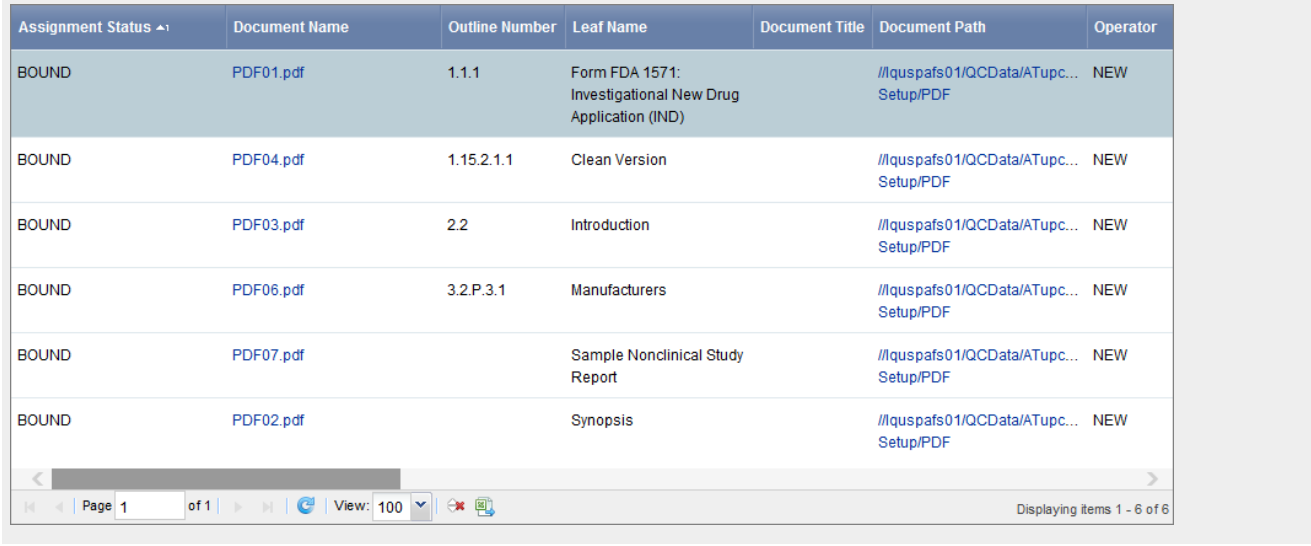
View the Assembly Document List

You can view the list of documents in the assembly tree.

To view a document list:

1. Right-click the assembly root and choose View Document List.

Example



Assignment Status	Document Name	Outline Number	Leaf Name	Document Title	Document Path	Operator
BOUND	PDF01.pdf	1.1.1	Form FDA 1571: Investigational New Drug Application (IND)		//lquspafs01/QCData/ATupc... Setup/PDF	NEW
BOUND	PDF04.pdf	1.15.2.1.1	Clean Version		//lquspafs01/QCData/ATupc... Setup/PDF	NEW
BOUND	PDF03.pdf	2.2	Introduction		//lquspafs01/QCData/ATupc... Setup/PDF	NEW
BOUND	PDF06.pdf	3.2.P.3.1	Manufacturers		//lquspafs01/QCData/ATupc... Setup/PDF	NEW
BOUND	PDF07.pdf		Sample Nonclinical Study Report		//lquspafs01/QCData/ATupc... Setup/PDF	NEW
BOUND	PDF02.pdf		Synopsis		//lquspafs01/QCData/ATupc... Setup/PDF	NEW

Page 1 of 1 | View: 100 | Displaying items 1 - 6 of 6

Attributes for each document assigned to the assembly appear.

2. Click Back to Outline View to return to the assembly tree.

Modify Document and Placeholder Attributes

Modifying documents in the assembly tree can cause unexpected results.

— You can change the pathname or file name of an assigned document with a status of missing content, missing version, or bound.

— Many attributes are mapped to their DMS repository or file system attributes when you assign a document to an assembly. The attribute that is stored in Documentum or the file system is displayed in . When you synchronize with a DMS repository, the DMS attributes overwrite any mapped attributes you have changed in InSight. appears next to attributes that are mapped to their DMS repository or file system attributes.

When you assign a document to a placeholder, the placeholder is not bound to the assigned document until you perform a DMS synchronization.

Modify Document Attributes

You can modify attributes for a document in the assembly tree.

To modify the attributes for a document:

1. On the assembly tree, select the document you want to modify.
2. On the *Document Attributes* page, click Edit.
3. Change attributes, then Save.

Mass Update Properties

About Mass Update Properties

The Mass Update Properties functionality is designed to simplify the process of updating properties of a defined list of Assembly tree elements. Instead of updating properties for one element type at a time, the properties can be updated in bulk for all elements of the same type.

Using the Mass Update Properties feature, you can also:

— update common properties for a combination of elements with different types

— set extensions or extension attributes for folders and leafs within a section of an assembly in bulk

Before using the Mass Update Properties feature, make sure you have read the following information on security restrictions, invocation points, and the assembly types for which this functionality can be invoked.

Security Information

To be able to apply the Mass Update Properties functionality you should have the SPT (Submission Planning and Tracking) license in Security Administration > License Modules section set to at least `Write`.

Assembly Types

The Mass Update Properties functionality is supported for the following assembly types:

— Sequence Assemblies: Initial Sequence Assemblies, Working View, Publishing View

— Standalone Assemblies

— Assembly Templates

Assembly Tree Elements

There is a defined list of Assembly Tree Elements that the Mass Update Properties functionality can be invoked from:

— Assembly Root - Right-click and select Mass Update Properties from the root of the specific assembly to select an element type to be updated within this assembly. You can also select a combination of element types, or all element types to be updated.

— Folder - Right-click and select Mass Update Properties from the specific assembly folder to select an element type to be updated within this folder range. You can also select a combination of element types, or all element types to be updated within the folder range.

— Leaf - Right-click and select Mass Update Properties from the specific leaf to select an element type to be updated within this leaf range. You can also select a combination of element types, or all element types to be updated within the leaf range.

— Reference Leaf - Right-click and select Mass Update Properties from the specific reference leaf to select an element type to be updated within this reference leaf range. You can also select a combination of element types, or all element types to be updated within the reference leaf range.

— Document - Right-click and select Mass Update Properties from the specific document to select an element type to be updated within this document range. You can also select a combination of element types, or all element types to be updated within the document range.

— Placeholder - Right-click and select Mass Update Properties from the specific placeholder to select an element type to be updated within this placeholder range. You can also select a combination of element types, or all element types to be updated within this placeholder range.

Element Types

There is a defined list of Element Types that can be updated using the Mass Update Properties functionality:

— Document
— Placeholder
— Leaf
— Reference Leaf
— Folder

Available Options

The following options are available on the *Select an Assembly Tree Element to Update* page:

— Update and Overwrite - When you select an element type to update you also select the properties you would like to update. If you select this option, the specified properties are overwritten by the system with the values you have entered, even if those properties for some elements are already populated with values.
— Update and Preserve - Unlike the Update and Overwrite option, the Update and Preserve option enables you to update only those properties without any existing values. If the property you have selected to update is already populated with value, that value is preserved and the system only adds the values where the selected property is either blank or set to `[Select]`. This is applicable to all field types.

Apply Mass Update Properties

You can apply the Mass Update Properties functionality to bulk update properties of the defined list of elements with the same type across the Assembly, or across the defined Assembly Tree Element. It also can be applied to bulk update the common properties either for a combination, or for all element types.

Prerequisites

If you need to update properties of a defined element type, or a combination of element types, for the whole assembly at once you should invoke the Mass Update Properties functionality from the Assembly Root. If you already know a specific assembly tree element range to update, you should invoke the Mass Update Properties functionality from that specific assembly tree element.

Note: *When using the Mass Update Properties, updating fields with inappropriate value or creating a number of envelope elements in an assembly, may corrupt data.*

To mass update properties:

1. Navigate to an assembly you need to update.
2. Depending on the update action you would like to perform, select one of the following invocation points:
   — Assembly Root
   — Folder

— Leaf
— Reference Leaf
— Document
— Placeholder

3. Right-click the selected assembly tree element.
The menu appears.
4. Select Mass Update Properties from the menu.
The *Select an Assembly Tree Element to Update* window appears.
5. On the *Select an Assembly Tree Element to Update* page, select the check box next to the element you need to update. The list of properties to update appears on the same page.
You can select one or multiple elements to update. The list of properties that appears after you select the check box depends on the selected element or combination of selected elements.
6. Select the check box next to each property you need to update and enter the values.
7. When all the needed updates are performed, do one of the following:

Option	Action
To cancel the changes:	Click Cancel.
To save the changes and overwrite the values of the element properties that existed before your updates:	Click Save and Overwrite.
To save the changes and preserve the values for the element properties that existed before your updates:	Click Save and Preserve.

Apply Mass Update Properties - Extension

You can apply the Mass Update Properties functionality to bulk update extension.

Prerequisites

To update extensions of an entire assembly at once, invoke the Mass Update Properties functionality from an assembly root. To update extension of an assembly tree element range at once, invoke the Mass Update Properties functionality from that specific assembly tree element.

To mass update extension:

1. Navigate to an assembly you need to update.
2. Depending on the update action you would like to perform, select one of the following innovation points:
— Assembly Root
— Folder
— Leaf
— Reference Leaf
— Document
— Placeholder
3. Right-click the selected assembly tree element.
The menu appears.

4. Select Mass Update Properties from the menu.
   The *Select an Assembly Tree Element to Update* window appears.
5. Do one of the following:

Option	Action
To update a leaf extension:	Select Leaf.
To update a folder extension:	Select Folder.

6. Select Extension and select an extension value from the drop-down list.

Note: *No elements will be updated if the option* Default *is selected and then the option* Update and Preserve *is used.*

7. Do one of the following:

Option	Action
To cancel the changes:	Click Cancel.
To save the changes and overwrite the values of the element properties that existed before your updates:	Click Update and Overwrite.
To save the changes and preserve the values for the element properties that existed before your updates:	Click Update and Preserve.

Apply Mass Update Properties - Extension Attributes

You can apply the Mass Update Properties functionality to bulk update extension attributes.

Prerequisites

To update extension attributes of an entire assembly at once, invoke the Mass Update Properties functionality from an assembly root. To update extension attributes of an assembly tree element range at once, invoke the Mass Update Properties functionality from that specific assembly tree element.

Note: *Exercise caution when using the* Mass Update Properties *feature, as updating fields with inappropriate values or creating a number of envelope elements in an assembly can corrupt data.*

To mass update extension attributes:

1. Navigate to the assembly to which you want to update extension attributes.
2. Depending on the update action you would like to perform, select one of the following innovation points:
   — Assembly Root
   — Folder
   — Leaf
   — Reference Leaf

— Document
— Placeholder

3. Right-click the selected assembly tree element.
The menu appears.
4. Select **Mass Update Properties** from the menu.
The *Select an Assembly Tree Element to Update* window appears.
5. Do one of the following:

Option	Action
To update folders with extensions:	Select **Folder with Extension**.
To update leafs with extensions:	Select **Leaf with Extension**.

The list of properties to update appears on the same page.
6. Select an element to update. The list of properties that appears after you select the check box depends on the selected element or combination of selected elements. Enter values in the text box where necessary.
7. Do one of the following:

Option	Action
To cancel the changes:	Click **Cancel**.
To save the changes and overwrite the values of the element properties that existed before your updates:	Click **Update and Overwrite**.
To save the changes and preserve the values for the element properties that existed before your updates:	Click **Update and Preserve**.

Mass Update Properties: Common Attributes

When you apply the **Mass Update Properties** functionality for all element types, or for a combination of different element types, the system filters properties of the selected element types and returns only those properties common for all of them. This topic describes the attributes being displayed when all element types, or some combinations of them have been selected.

The following list describes the properties displayed when all element types are selected on the *Select an Assembly Tree Element to Update* page:

— Due Date
— Owner
— Keywords
— Description
— Comments

The following table describes the attributes displayed on the *Select an Assembly Tree Element to Update* if a combination of element types has been selected.

Element Types Combination	Properties Displayed
Leaf and Reference Leaf	— Title — Owner — Language — Application Version — Version — Font library — Role — Actuate — Show — Use Native File — Due Date — Link Text — Keywords — Description — Comments
Document and Placeholder	— Title — Category — Review Status — Due Date — Owner — Output Channel — Other — Keywords — Description — Comments
— Folder, Leaf, and Reference Leaf — Folder, Document, and Placeholder	— Due Date — Owner — Keywords — Description — Comments
Document, Placeholder, Leaf, and Reference Leaf	— Title — Due Date — Owner — Keywords — Description — Comments

Mass Update Properties: Document/Placeholder Attributes

The list of attributes displayed for Document and Placeholder element types on the *Select an Assembly Tree Element to Update* page does not depend on the selected invocation point.

The following table describes the properties displayed on the *Select an Assembly Tree Element to Update* page when a Document or Placeholder element type has been selected:

Property	Field Type
Title	Text field
Category	Text field
Review Status	Text field
Due Date	Date field
Owner	Text field
Output Channel	Multiselect field. Available values: — Electronic — Paper
Other	Text field
Keywords	Text field
Description	Text field
Comments	Text field

Mass Update Properties: Leaf Attributes

The list of attributes displayed for a Leaf element type on the *Select an Assembly Tree Element to Update* page does not depend on the selected invocation point.

The following table describes the properties displayed on the *Select an Assembly Tree Element to Update* page when a Leaf element type has been selected:

Property	Field Type
Title	Text field
Owner	Text field
Leaf Status	Drop-down list. Values available for selection are all active leaf statuses from Data Administration. The `Planned` status is set by default.
Language	Text field

Property	Field Type
Application Version	Text field
Version	Text field
Font Library	Text field
Role	Text field
Actuate	Drop-down list. The `[Select]` value is set by default.
Show	Drop-down list. Available values: — New — Replace — Embed — Other — None The `[Select]` value is set by default.
Leaf with Extension	Drop-down list. Available values: — Study Patient Information — Study Report
Use Native File	Drop-down list. Available values: — Yes — No The `[No]` value is set by default.
Due Date	Date field
Link Text	Text field
Keywords	Text field
Description	Text field
Comments	Text field

Mass Update Properties: Reference Leaf Attributes

The list of attributes displayed for a Reference Leaf element type on the *Select an Assembly Tree Element to Update* page does not depend on the selected invocation point.

The following table describes the properties displayed on the *Select an Assembly Tree Element to Update* page when a Reference Leaf element type has been selected:

Property	Field Type
Title	Text field
Owner	Text field
Language	Text field
Application Version	Text field
Version	Text field
Font Library	Text field
Role	Text field
Actuate	Drop-down list. The `[Select]` value is set by default.
Show	Drop-down list. Available values: — New — Replace — Embed — Other — None The `[Select]` value is set by default.
Use Native File	Drop-down list. Available values: — Yes — No The `[No]` value is set by default.
Due Date	Date field
Link Text	Text field
Keywords	Text field

Property	Field Type
Description	Text field
Comments	Text field

Mass Update Properties: Folder Attributes

The list of attributes displayed for a Folder element type on the *Select an Assembly Tree Element to Update* page does not depend on the selected invocation point.

The following table describes the properties displayed on the *Select an Assembly Tree Element to Update* page when a Folder element type has been selected:

Property	Field Type
Owner	Text field
Due Date	Date field
Keywords	Text field
Description	Text field
Comments	Text field
Division	Drop-down list. Available values: — NONE — MAJOR — MINOR The `[Select]` value is set by default.

Property	Field Type
Folder with Extension	Drop-down list. Available values: — Clinical Indication — Drug Product — Drug Substance — Excipient — Promotional Material Type — Promotional Material Doc Type — Promotional Material Audience Type — US Admin Forms — US Forms — US Module 1 v3.3 — Quality Introduction — Quality Overall Summary — Module Studies — Node-Extension — Quality Appendix — Study Report — Study Data — Study Patient Information
Force New Volume	Drop-down list. Available values: — Yes — No The `[No]` value is set by default.

Move Assembly Elements

Moving the location of an element can cause unexpected results.

As you move elements around in the assembly tree, keep in mind the following:

— A leaf cannot be moved, promoted, or demoted to a level where it becomes a parent or child of another leaf.

— A document or document placeholder cannot be the parent of a leaf.

— You cannot move or demote elements into a locked folder.

— When you promote an element, it becomes a sibling of its previous parent.

— When you demote an element, it becomes the last child of its next higher sibling.

— Additional reorganization guidelines apply to assemblies in lifecycle applications.

Move Assembly Elements Table

You can move elements up and down and you can promote and demote elements in the following ways:

Choose this	To do this
Move Up	Move an element to a location above its current position in the assembly tree, one position at a time
Move Down	Move an element to a location below its current position in the assembly tree, one position at a time
Promote	Move an element one level to the left in the assembly tree hierarchy
Demote	Move an element one level to the right in the assembly tree hierarchy
Delete	Remove an element from the assembly tree structure; does not delete a document from the repository

Move an Assembly Element

You can move the location of a single element or multiple elements in the assembly tree.

To move an element in the assembly tree:

1. On the assembly tree, right-click the element you want to move and choose one of the following:

Option	Action
Move up :	Moves the element one position up.
Move down:	move the element one position down.
Promote :	move the element one position to the left.
Demote:	move the element one position to the right.

2. To move multiple elements in the assembly tree:

Option	Action
Shift+click:	To select contiguous elements, then drag the elements to a new location in the assembly.
Ctrl+click:	To select non-contiguous elements, then drag the elements to a new location in the assembly.

Move Leafs That Are Siblings in a Folder

Use this procedure to move leafs that are siblings within a folder.

To move leafs that are siblings within a folder:

1. To select a range of leafs:

Action
Click the first leaf in the range.
Hold down the Shift key and click the last leaf in the range.
Drag one of the selected leafs onto a folder.

When you let go of the mouse the dragged leafs will become children of the folder.

2. To select specific leafs:

Action
Click the first leaf to be selected.
Hold down the Ctrl key, and select the rest of the leafs.
Drag one of the selected leafs onto a folder.

When you let go of the mouse the dragged leafs will become children of the folder.

Move Leafs That Are in Different Folders

Use this procedure to move leafs that are in different folders.

To move leafs that are in different folders:

1. Hold the Shift key down and click on leafs one at a time. While still holding down Shift, click one of the selected leafs and drag it onto a folder.
   When you let go of the mouse and Shift key the dragged leafs will become children of the folder.
2. Hold the Shift key down and click on leafs one at a time. While still holding down Shift, click one of the selected leafs and drag it onto another leaf.
   When you let go of the mouse and Shift key the dragged leafs will become siblings to the leaf.

Move Folders That Are Siblings in a Folder

Use this procedure to move folders that are siblings in another folder.

To move folders that are siblings in another folder:

1. Hold the Shift key down and click the first and last folder.
2. While still holding down Shift, click one of the selected folders and drag it onto a folder.
   When you let go of the mouse and Shift key the dragged folders will become children of the folder.

Move Folders That Are in Different Folders

Use this procedure to move folders from a different folder.

To move a folder from a different folder:

1. Hold the Shift key down and click on folders one at a time.
2. While still holding down Shift, click one of the selected folders and drag it onto a folder.
   When you let go of the mouse and Shift key the dragged folders will become children of the folder.

Move Different Element Types in Different Folders

Use this procedure to move different element types in different folders.

To move different element types in different folders:

1. Hold the Ctrl key down and click on different non-contiguous elements one at a time.
2. While still holding down Ctrl, click one of the selected elements and drag it onto a folder.
   When you let go of the mouse and Ctrl key the dragged elements will become children of the folder.

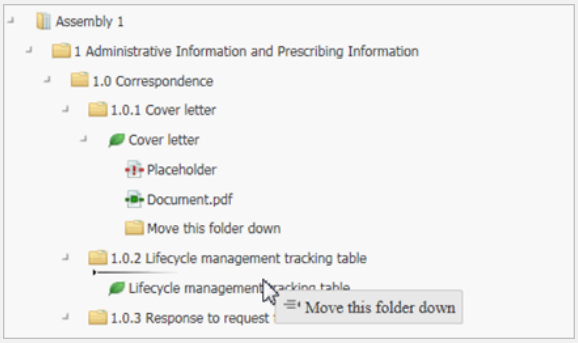
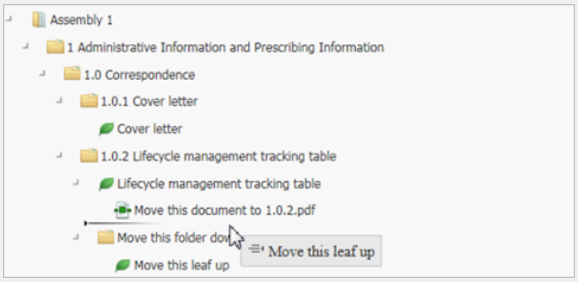
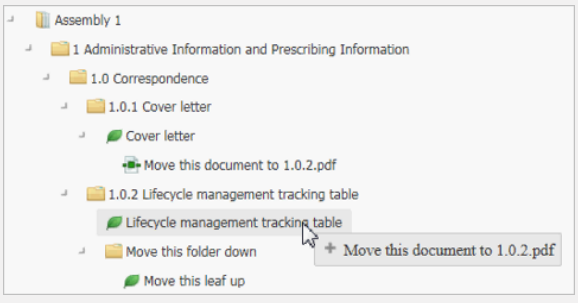
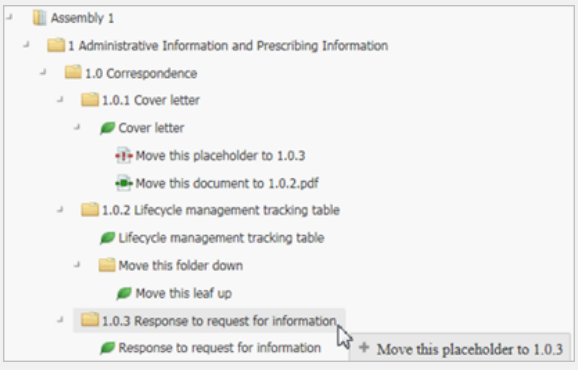
New Assembly Tree

New Assembly Tree: Features

With the new version of the Assembly Tree, you can drag assembly elements to place them between Assembly Tree nodes and also filter the Assembly Tree elements using the new Assembly Tree search option.

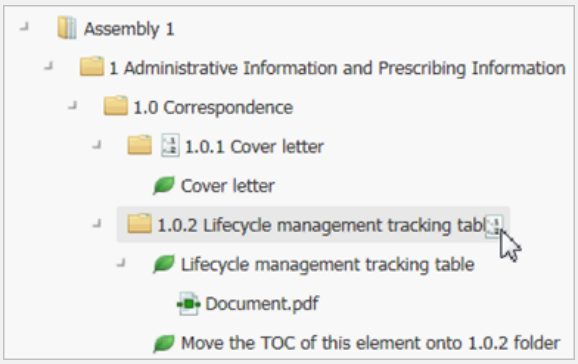
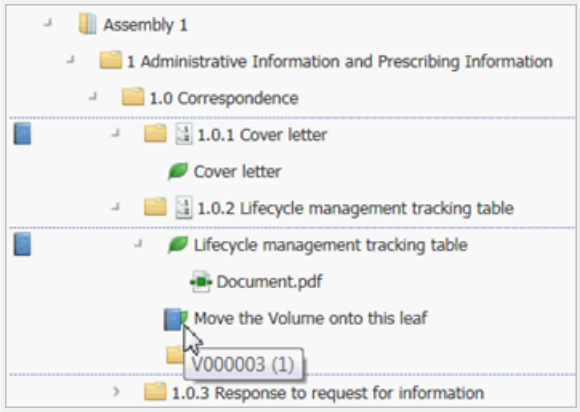
You can perform the following actions within the New Assembly Tree:

— Use the drag-and-drop feature to move the Assembly Tree elements within an Assembly Tree.

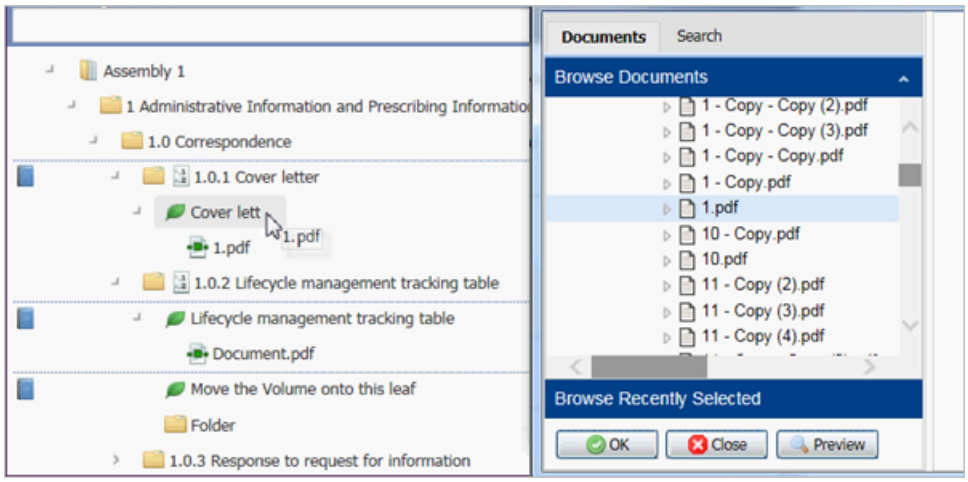
Drag-and-Drop Folder	Drag-and-Drop Leaf
	
Drag-and-Drop Document	**Drag-and-Drop Placeholder**
	

Note: *Only a single node can be moved.*

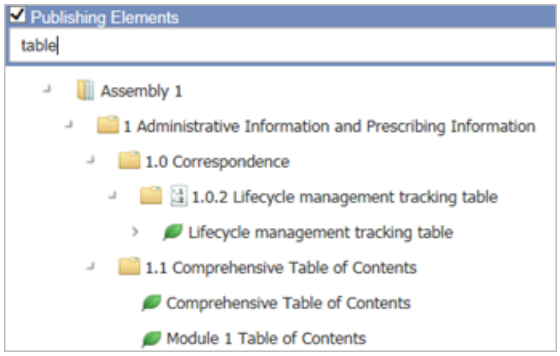
— Use the drag-and-drop feature to move volumes and TOCs onto the Assembly Tree elements.

Drag-and-Drop TOC	Drag-and-Drop Volume
	

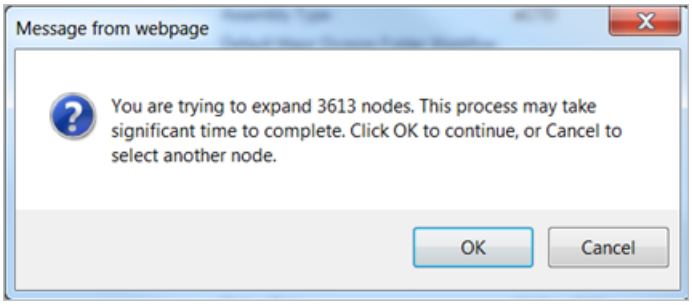
— Use the drag-and-drop feature to add folders, documents, and leafs from the *DMS Browse* and *Browse Assembly* windows to an Assembly Tree.



— Use the Search option to filter the Assembly Tree elements by the text entered in the Search field.



As an additional feature, you can select Right-click > Expand Range for an Assembly that has a complicated structure and contains an extensive amount of elements. A confirmation prompt appears and you can confirm that you want to proceed.



See *Limiting Assembly Tree Expand Range*.

Assembly Tree

For better system performance, please consider the following when your Assembly has a complicated structure and contains an extensive amount of elements:

— Assembly Tree Search functionality can be used to help in navigation through complex and large assemblies.
— The number of displayed assembly tree elements that match the search criteria can be restricted by defining an upper limit in the `insight.var` file. See *Limiting the Assembly Tree Search Results*.
— If the requested range exceeds the value defined in the `insight.var`, a confirmation prompt appears and you can confirm that you want to proceed.
— If the desired node is placed under a folder with a large number of nodes located at the same level, it is recommended to create a copy of that node and make a custom template including the node.

Move Assembly Elements Within an Assembly Tree

Calyx RIM enables you to perform drag-and-drop actions on assembly elements within an assembly tree. To perform drag-and-drop operations in an assembly tree, you must have the WRITE permission for those assemblies.

A single node of the following elements can be dragged onto an assembly tree.

— Folder
— Leaf
— Document
— Placeholder
— Reference Leaf

The following rules apply when using the drag-and-drop feature.

— You can drag single elements within the standalone assembly, initial sequence assembly, assembly template, working view of the sequence assembly or assembly plan, and submitted view of the sequence assembly or assembly plan.
— Dragging elements within the publishing or sequence views of the sequence assembly or assembly plan is not allowed.

The following nodes cannot be dragged onto an assemble tree.

— Withdrawn (Delete) leaf and withdrawn elements in the range under it.
— Replaced or appended leaf.

— Folder, leaf, reference leaf, document, or a placeholder within the lock range of a standard locked root or folder.
— Page Marker.
— Folder in the eCTD locked assembly, except dragging a folder under a leaf within the leaf range.
— Root of the assembly.
— Old folder, leaf, document. or a placeholder onto the new assembly tree elements.
— Leaf to another Leaf or document including missing document, document with missing content, document with the missing version, or superseded document.
— Leaf to placeholder.
— Folder to placeholder.
— Folder to document, document including missing document, document with missing content, document with the missing version, or superseded document.
— Parent node to its child node.

Move Volume and TOC onto Assembly Tree Elements

Moving Volume and TOC onto Assembly Tree Elements

Calyx RIM enables you perform drag-and-drop operations to move the volume and TOC publishing elements onto assembly tree elements. The volume and TOC elements can be moved onto the following assembly tree elements.

— Root
— Folder
— Leaf
— Document
— Placeholder
— Page Marker
— Volume (only TOC can be moved onto a volume)

Move a Volume onto Assembly Tree Elements

The following conditions apply when moving a volume onto assembly tree elements:

— Volume cannot be moved onto a locked tree element or a range (standard lock).
— Locked volume cannot be moved.
— Volume cannot be moved to a tree node which already has a volume.
— Volume cannot be moved onto the range of a locked volume.
— Volume cannot be moved onto the publishing elements and volume.
— Volume cannot be moved from a locked range, except eCTD lock.

Note: *Only a single volume node can be moved at a time onto assembly tree elements.*

Move a TOC onto Assembly Tree Elements

You can move a TOC onto Assembly Tree Elements with some conditions.

The following conditions apply when moving a TOC onto assembly tree elements:

— TOC cannot be moved onto publishing elements, except volume.

— TOC cannot be moved onto a locked tree element or a range (standard lock), except the range of a locked volume.
— TOC cannot be moved from a locked range, except eCTD lock.

Note: *In the new version of the assembly tree, to move a TOC that is attached to a volume using the drag-and-drop feature, a TOC must be dragged onto the icon corresponding to a volume.*

Add Assembly Elements from DMS Browse and Browse Assembly Windows

Calyx RIM enables you to perform drag-and-drop actions to add folders, documents and leafs from the DMS Browse and Browse Assembly windows to an assembly tree. To add folders, documents, and leafs you must have the WRITE permission for those assemblies.
The following rules apply when using the drag-and-drop function:
— Folders or documents cannot be moved on to a locked assembly node or range.
— Folders or documents cannot be moved from the DMS Browse window on to a page marker.
— A folder cannot be moved on to a document if assembly has Create Leaf Elements set to Yes.
— A folder or document cannot be moved on to an old leaf that has an appended leaf.
— A folder or leaf cannot be moved on to a withdrawn (deleted) leaf.
— A folder or document cannot be moved on to reference leaf.

You must click the text of the name, not the icon preceding the text, to successfully drag a folder, document, or leaf to a new location.

Assembly Tree Filter

Calyx RIM enables you to filter the assembly tree elements using the search option on the new version of the assembly tree.
Using the search drop-down list, you can also select a node type as a criterion to narrow your search results. The results appear in the same order as they are in the assembly. The maximum number of matching elements displayed depends on the limit set in the `insight.var` file. When the results exceed the number defined in the `insight.var` file, a message is displayed with the number of matching elements and the number of elements that will be displayed in the assembly tree. By default, the maximum number for displaying the matching elements defined in the `insight.var` file is 500.

The following assembly elements can be searched using the search option:
— Assembly root
— Folder
— Leaf
— Reference leaf
— Document
— Placeholder

The search option is available for the following when the new version of the assembly tree is enabled. For procedure on enabling the new version of the assembly tree, see the topic *Enabling New Version of the Assembly Tree* in the Installation Guide.

— Standalone Assembly
— Assembly Template
— Sequence Assembly (Initial, Working View, Submitted View, Publishing View, Sequence View)
— Supporting Sequence Assembly
— Assembly Plan (Initial, Working View, Publishing View, Sequence View, Submitted View)
— Lifecycle Assembly/Assembly Plan (Submitted View, Sequence View, Publishing View)
— Import Assembly Wizard
— Assembly Comparison Query
— Assembly Status Query
— Change Modified Leaf on the Leaf attributes window
— Convert to Reference Leaf
— Reference Link to an Assembly
— Assembly tree in SmartLink for PDF tool
— Retarget Links in Link Inspector
— Create Assembly from Existing Template, Assembly or View

You will be able to filter an assembly tree based on the search text that matches the values in the following fields:

	Name	Abbreviated Name	Title	Number	Owner	Keywords
Assembly Root	+				+	+
Folder	+	+		+	+	+
Leaf	+	+	+	+	+	+
Document/Placeholder	+	+	+	+	+	+

You can also filter an assembly tree based on the search text that matches the values of the following extended attributes:

	Extension Type	Associated Attributes
Folder	Drug Substance	— Drug Substance Name — Drug Substance Manufacturer
	Drug Product	— Drug Product Name — Dosage Form — Drug Product Manufacturer
	Clinical Indication	Indication
	Excipient	Excipient
	Quality Appendix	— Manufacturer — Substance — Dosage Form — Product Name
	Study Report	— Full Report Title — Report Number — Operation — Species — Route of Administration — Duration — Type of Control — Subject Matter
	Study Data	— Dataset Type — Subject Matter
Leaf	Study Patient Information	— Subject Matter — Site
	Study Report	Subject Matter

Use the following wildcard characters to filter the assembly tree elements:

Wildcard Character	Description
%	Use % to specify that characters can occur in multiple positions.
_ (Underscore)	Use _ to specify a single position in which a character can occur.

Filter Assembly Tree Elements

Use this procedure to filter an assembly tree elements.

To filter the assembly tree elements:

1. Navigate to an assembly
2. In the search text field, enter the criterion and do the following:

Option	Action
To filter an assembly tree based on the search criterion across all node types:	Select All Content from the search drop-down list.
To filter an assembly tree based on the search criterion for a specific node type:	Select a node type from the search drop-down list.

3. Click the search icon.
   The assembly tree is refreshed and shows the branches with the nodes that match the search criteria. Each branch can be expanded up to the matching node.

Advanced Assembly Tree Filter

The Advanced Assembly Tree Filter feature enables you to filter an assembly tree with the available options.
The Advanced Assembly Tree Filter feature enables you to filter an assembly tree for:

— Empty folders and leafs
— Leafs with the lifecycle Replace, Append, or Delete and that are being operated in a parallel sequence
— Leafs with leaf status
— Documents with assignment status

Advanced Assembly Tree Filter for all Nodes

The Advanced Search provides you with the numerous options to filter down an assembly for all the Nodes.

To filter an assembly for all node types:

1. Navigate to an assembly.
2. Click the Advanced Search icon.
3. To filter an assembly tree across all node types, select All Content from the search drop-down list.
4. In the Search in All Fields field, enter the search criteria.
5. Click Search.

Advanced Assembly Tree Filter for Folders

The Advanced Search provides you with the numerous options to filter down an assembly for Folders.

To filter an assembly for empty folders:

1. Navigate to an assembly.
2. Click the Advanced Search icon.
3. From the search drop-down list, select Folders.

4. In the Search in All Fields field, enter the search criteria.
5. To view only the empty folders that match the search criteria, select Show only empty Folders.
6. Click Search.

Advanced Assembly Tree Filter for Leafs

The Advanced Search provides you with the numerous options to filter down an assembly for Leafs.

To filter an assembly for leafs:

1. Navigate to an assembly.
2. Click the Advanced Search icon.
3. From the search drop-down list, select Leafs.
4. In the Search in All Fields field, enter the search criteria.
5. To filter leafs based on the status, select a status from the Leaf Status drop-down list.
6. To view only the empty leafs that match the search criteria, select Show only empty Leafs.
7. To view leafs that are being operated in one or more parallel sequences, select Show leafs operated in parallel sequences. The option Show leafs operated in parallel sequences is available only in the Working view of a sequence assembly.
8. Click Search.

Advanced Assembly Tree Filter for Documents

The Advanced Search provides you with the numerous options to filter down an assembly for documents.

To filter an assembly for documents:

1. Navigate to an assembly.
2. Click the Advanced Search icon.
3. From the search drop-down list, select Documents.
4. In the Search in All Fields field, enter the search criteria.
5. To filter documents based on the document assignment status, select a status from the Assignment Status drop-down list.

   For information about the document statuses, refer to the topic *Document Status Indicators*.
6. Click Search.

Import Assemblies

You can only import assemblies using the Import Assemblies Wizard. Other content can be added to an assembly using different methods.

When importing an assembly file, the documents in the file are not automatically synchronized with the mapped DMS - they will appear as placeholders. This prevents import failures should the referenced DMS not exist in the current system. Run a DMS synchronization immediately after importing to assign placeholders automatically to the DMS documents.

You can import any of the following:

— An existing standalone or sequence assembly
— Part of a standalone or sequence assembly
— An entire template or part of a template
— An application view of the following types:
  - Submitted
  - Working
  - Sequence
  - Approved

Keep in mind the following:

— If you are importing an assembly that used versions 2.0 or earlier of the Study Tagging File specification, these are imported and the appropriate assembly is created, but any subsequent sequences must use the latest (v2.2) DTD.
— You can import an assembly root or folder into an assembly root or a folder only, as long as the target folder is not the child of a leaf.
— When you right-click a folder to import it, the whole assembly is imported, not just the selected folder. To import only part of an assembly, you must use the drag-and-drop function.
— Paper elements cannot be imported using a drag-and-drop operation from the import dialog.
— When exporting and then importing an assembly or template, TOC elements must be moved to the correct location in order to inherit any predefined values.
— You must re-target in-process links to leaf elements when using an imported assembly file that contains previously defined in-process links that target leaf elements.
— Leaf status assigned to each leaf element is automatically set to the default `Leaf Status` value configured in *Data Administration*.

When you import an entire assembly or part of an assembly, the following occur:

— If you import one assembly into a new assembly, the settings in the imported assembly are copied into the new assembly.
— The source assembly or assembly folder you import becomes a child of the target element in the target assembly.
— Element attributes of the imported assembly or folder are referenced.
— If you import the assembly root, a folder that represents the source assembly's root is created in the target assembly, which contains the children of the imported root.
— Locks are not maintained; elements that are locked in the imported assembly are not locked in the target assembly.
— All leaf elements contained in the imported assembly root or folder are added to the target assembly with the NEW operator and a blank modified file value.
— Volume breaks that are imported are not maintained.
— Documents in the imported assembly do not have a value for the Created From attribute.
— You cannot import individual leaf elements, documents or document placeholders.
— A document will not change to a placeholder when importing a source assembly where it is assigned.
— The Site attribute for the Study Information Leaf does not inherit a value from its parent folder, which also has a Site attribute.

Import Assembly Wizard

Use the *Import Assembly Wizard* to import an assembly into the assembly tree.
Publishing settings must be specified for the assembly into which you are importing an assembly.

To use the *Import Assembly Wizard*:

1. On the assembly tree, right-click the root or folder where you want to import the assembly and choose Import Assembly Wizard.
2. For the option How would you like to find the assembly?, use Browse to select the assembly location, or select Search to find the assembly based on the search criteria.

Option	Action
If you choose to select the assembly by browsing:	Click the Browse button. Select the assembly type tab, select the assembly and click OK.
If you are using the Search option to find the assembly:	Select the assembly type under Assembly Type to Search.

3. Choose the following options. Selecting the option = Yes, clearing the check box for the option = No.

Option	Action
Copy Paper Publishing Elements:	Select this option to include paper publishing elements from the source assembly in the new assembly.
Reset Lifecycle Information:	Select this option to reset the lifecycle information for the new assembly. If this option is not selected, the lifecycle from the source assembly will be included in the new assembly.
Retarget copied Reference Leafs:	Select this option to retarget the reference links copied from the source assembly to link to their targets in the new assembly. If the Reference Leaf points to a leaf that is also part of the import, the Reference Leaf will be updated to the copied target instead of the source assembly. If the Reference Leaf points to a leaf that was not included in the import, but a leaf in the target assembly matches the source assembly and was created from the same template, then the leaf will be retargeted.

Note: *You must retarget in-process links to leaf elements when using an imported assembly file that contains previously defined in-process links that target leaf elements.*

4. Click Next.
   If you have selected the assembly by using the browse option, move to step 9.
5. Enter the search criteria and click Next.
6. Select the assembly from the matching assemblies and click Next.
7. Expand the assembly, then click the root or part of the assembly to import, and click Next.
   The *Import Completed* window appears, listing the actions taken.
8. Click Finish.

The updated Assembly is displayed.

9. Right-click the root or the folder and choose Expand Range to see the full assembly with the imported assembly.

Search for an Assembly

The wizard launches when you click whichever is available on the page that you are viewing: the Search tab or the Browse button.

To search for an assembly:

1. Select the type of assembly you are searching for and click Next.
2. Enter the assembly query parameters. Only the display columns are required, and they have default values.
3. Click Next.
4. On the *Matching Assemblies* page, select the assembly that you want to use.
5. On the *Selected Assembly* page, select the assembly element that you want to use, and click OK.

Notes on Search for an Assembly

You can use the *Search Assembly* wizard to search for an assembly when you take specific actions.

— Change a modified leaf
— Convert a leaf to a reference leaf
— Create an assembly template from an existing template, assembly, or view
— Create a standalone assembly from a template, assembly, or view
— Create an assembly after you create an initial application submission, an amendment submission, or a major update submission
— Retarget links while running the Link Inspector query

The wizard launches when you click either the Search tab or the Browse button.

Assembly Baselines

You can track the changes of an assembly by multiple user groups to establish a baseline.
Once an assembly is in a semi-completed state, you can begin to track changes to its structure and content. This enables multiple groups of users to track changes before the assembly is approved. It also enables an assembly group and publishing group to synchronize changes to the assembly with an external publishing application.

The current assembly outline becomes the baseline when the baseline is set; any existing baseline for that version is erased. After you begin to make changes to the assembly, you can view differences between the updated assembly and the baseline.

Note: *Only an administrator can set the baseline for an assembly.*

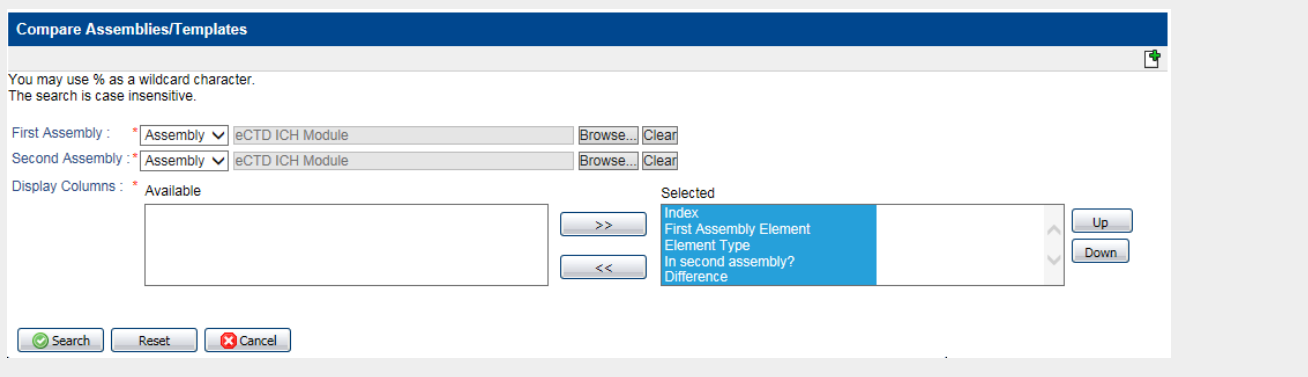
View an Assembly Baseline

You can track the changes of an assembly by multiple user groups to establish a baseline.

To view baseline differences:

1. Click a link for the assembly whose baseline differences you want to view.
2. Right-click the assembly root and choose View Baseline Differences.

Example



The *Compare Assemblies/Templates* page opens with the baseline assembly in the *First Assembly* box and the current assembly in the *Second Assembly* box.

3. In the *Available Columns* box, select the columns to include in the query and move them to the *Selected Columns* box.

   To remove columns from the *Selected Columns* box, select them and move them to the *Available Columns* box.

4. To change the order of the columns as they appear from left to right in the query results, select a column in the *Selected Columns* box and click up or down.
5. Click Search.
   The comparison query results are displayed.
6. To return to the *Assembly Attributes* page, click Back.

Replace Assembly Variables

You can use Find and Replace to update delimited variables to text values for a specific assembly.
Find and Replace is available for the assembly root and folder-level elements. All folders, leaf elements, and documents that are children of the root or a folder on which you perform a find and replace are searched and instances of the search criteria are replaced.

When you create an assembly from a template that contains delimited variables, you can use Find and Replace to replace those variables with unique values for the assembly. For example, if a template contains `[docbase]/regulatory/[product]/substance` for the document path, you could search for [docbase] and replace it with the name of your repository.

When you perform a find and replace:
— The find and replace values are limited to 500 characters.
— Values must be text values.
— No validation is performed on the values you enter.

For find and replace in a working view:
— Attributes of folders from previous sequences are searched.
— Attributes of read-only leaf elements from previous sequences are not searched.

Note: *Although some attributes in folders from previous sequences appear to be read-only, they are modified by the find and replace because some of the attributes affect publication of XML for the current sequence.*

Replace an Assembly Variable

You can use Find and Replace to update delimited variables to text values for a specific assembly.
You cannot undo a find-and-replace action. To restore changed values, you must perform another find-and-replace action.

It is strongly recommended that you create an assembly version before using Find and Replace, so you can revert to the original version if something is replaced in error. It is also recommended that you carefully choose the text to replace.

To find and replace a variable in an assembly:

1. Click a link for the assembly you want to search.
2. Right-click the element you want to search.
3. Choose Find and Replace.
4. In the *Find and Replace* dialog box, choose one of the following:

Option	Description
Text Search:	Searches all text attributes.
Date Search :	Searches date attributes.

5. In the *Find what* box enter the text value or date to find.
6. In the *Replace with* box, enter the replacement value or date.
7. Click OK.
8. To view the replaced values, click .

Replaceable Assembly Variables

You can use Find and Replace to update delimited variables to text values for assembly root and folder-level elements.

Element	Attribute
Folder	Name
	Output folder
	Keywords
	Extended publishing attributes
Leaf	Name
	Output file
	Keywords
	Extended publishing attributes
Document	Name
	Title
	Category
	Source Location
	Source Document
	Due Date
	Owner
	Keywords

Lock Assemblies

With the proper permissions, you can lock assemblies at various levels.

eCTD and Standard Locks

In addition to locking folders, you can create eCTD and standard locks.

An eCTD lock prevents you from changing the folder structure and metadata of an assembly. You can create new leaf elements, but you must use the Create eCTD wizard to add, move, and delete folders. In addition, you must use the wizard to change folder metadata. All changes must be made by either unlocking the assembly or using the Create eCTD wizard. This prevents accidental or unauthorized changes that would cause issues with eCTD publishing, but still enables document assignment and leaf manipulation.

A standard lock prevents most changes to the assembly, including changes to folders, leaf elements, documents, and publishing elements. However, you may still change document binding; binding must be locked separately.

Note: *Only an administrator or the owner of the assembly can unlock an eCTD lock.*

Lock Volume Ranges

A volume lock defines the beginning and ending points of a volume.
You can think of this as bookends for a volume. The beginning and ending points of the volume are locked in place, but the contents in the middle can be altered.

When a volume is locked, bypasses it when you volumize an assembly range that includes the locked volume.

An assembly must be refreshed when locking or unlocking volumes for a "non-first" lifecycle sequence assembly in order to display the assembly correctly.

Lock a Volume Range

When you lock a volume, you define the beginning point and end point of the volume.

To lock a volume range:

1. In the assembly click the volume at the beginning of the volume range you want to lock.
2. Click .
   A message prompts you to confirm the lock.
3. Click OK.
   The volume icon changes to .

Unlock a Volume Range

You can remove a lock on a volume range to change the beginning and ending points of the volume.

To unlock a volume range:

1. Select a locked volume and click .
2. Click OK.

Update Assembly Status

.When you update an assembly status to the effective status as defined by your system administrator, the assembly is locked and its version label is set to Current, which may already be assigned to another assembly version in the version tree.
Updating as assembly status to the effective status has limitations and consequences. Once the assembly version has an effective status, only an administrator can change the assembly status and status date. If the administrator changes an effective status to a non-effective status, the assembly remains locked until the administrator unlocks it. To work around this, you can create a new assembly version and make changes to the new version.

If after the administrator unlocks a non-effective status assembly you change the assembly to an effective status again the assembly is not relocked. You must lock the assembly.

If you change a noneffective status to an effective status on an assembly version, the version label of the assembly version is set to CURRENT.

If the assembly version being set to the effective status is not the latest version for the assembly, the version label for the latest version of the assembly with the CURRENT version is set to blank, or if a previous version of the assembly has the effective status, its version label is set to SUPERSEDED.

If the administrator changes an assembly version's effective status to a noneffective status:

— The assembly version label changes to blank unless the assembly is the latest version and no other version has an effective status.
— The CURRENT version label is assigned to an effective assembly with the most recent version number in the version tree.
— The label is set to blank if the assembly version had a label of SUPERSEDED.

If a reference location exists in the DMS repository for the version of the assembly, the reference location that corresponds to the CURRENT assembly version is made current in the DMS repository. In some instances, this may require the creation of a new version of the reference location.

Update an Assembly Status

You must have the appropriate security privileges to update the status of an assembly. You should be aware of the limitations and consequences before updating the assembly status.

To update an assembly status:

1. Click a link for the assembly version whose status you want to update.
2. On the *Assembly Attributes* page, click .
3. Click the New Status arrow and choose the updated status.
4. For Status Date, choose the effective date for the new status.
5. Save.

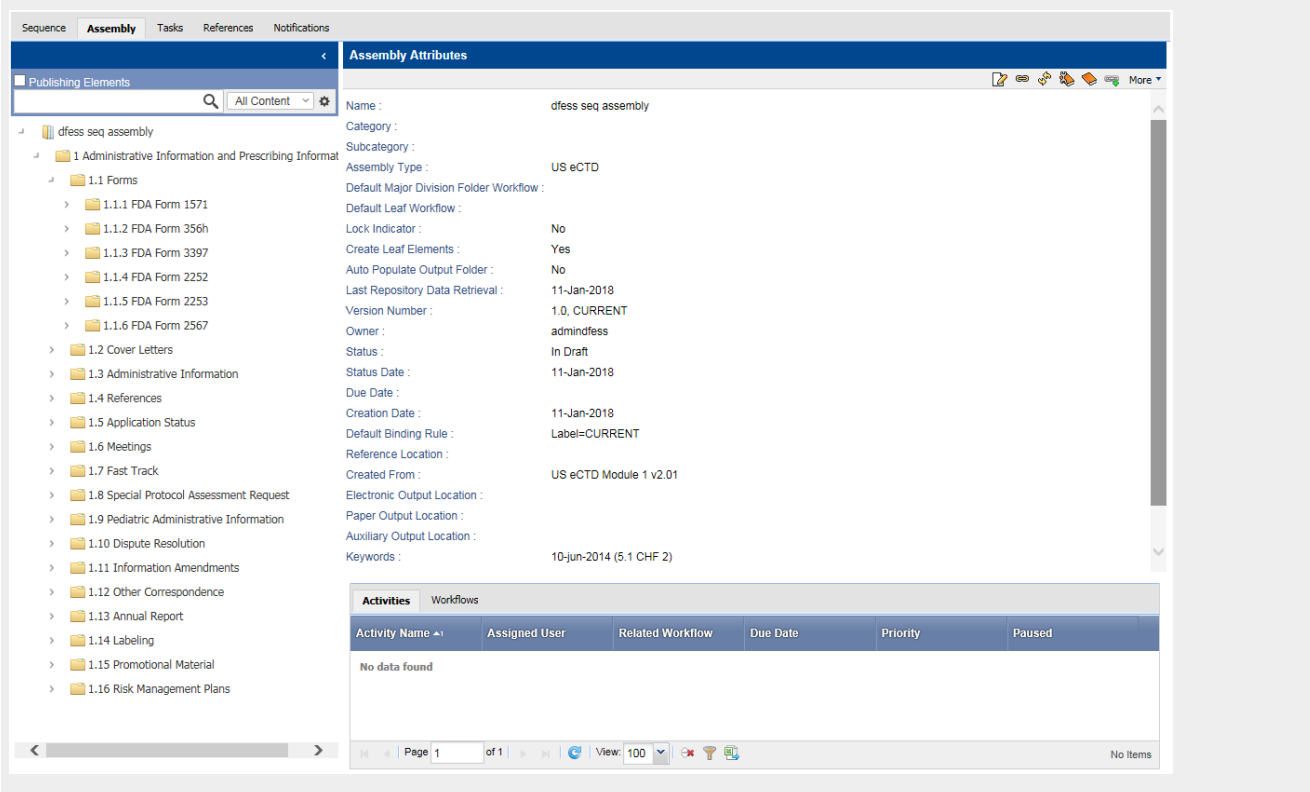
View an Assembly

You must have the appropriate security privileges to view and take action on an assembly and its attributes.

To view attributes for an assembly:

1. Click a link for the assembly you want to view.

Example



The *Assembly Attributes* page opens.

2. Do any of the following:
   - Click an action button to perform an action on the entire assembly.
   - Right-click the root, then choose Expand Range to expand the assembly so you can choose an element on which to perform an action.
3. Click the toolbar icons to perform an action. Do any of the following:
   - To view the sequence with which the assembly is associated, click the Sequence tab and click a sequence link.
   - To view tasks and sub-tasks associated with the sequence, click the Tasks tab and click a task link.
   - To view references associated with the sequence, click the References tab and click a reference link.
   - To view notifications associated with the sequence, click the Notifications tab and click a notification link.
   - To view a version of an assembly document, click the document in the assembly tree, then click the version at the bottom of the page.

Assembly Toolbar Icons

You can take action on assemblies using the icons in the toolbar.

Icon	Description
	Edit enables you to change the assembly or element attributes.

Icon	Description
	Assign Document enables you to assign a document to the assembly tree.
	DMS Synchronization enables you to synchronize the InSight attributes with the DMS repository mappings for documents in the assembly.
	Publishing Settings Library enables you to specify leaf and default study file attributes for publishing. This button is for ELP users only.
	Publish Request enables you to: choose a submission output location and document type, specify whether to create renditions automatically, and what to publish. This button is available for ELP users only.
	Associate Workflow enables you to associate workflows to entities.
	Metadata Library enables you to view the metadata library page.
	Copy URL enables you to copy the URL for the assembly or an element to the Clipboard.
	Lock Sequence locks the assembly from further changes.
	Unlock Sequence releases the assembly from a locked state.
	Update Status enables you to change the assembly status.
	Export Assembly to... enables you to export the assembly to a Microsoft Excel spreadsheet, an assembly file, or a virtual document.
	Create Version enables you to create a version of the assembly.
	Delete enables you to delete a document placeholder.
	Set Reference Location enables you to specify a different location for the assembly reference location.
	Apply Binding to all Children enables you to apply the binding rule for documents that are currently assigned to the assembly. If you first choose an element, the binding changes only for the children in the selected element.
	Force New Renditions and Extractions creates renditions and extractions, overwriting all existing renditions and extractions.
	Prepare to Publish opens the dialog box to prepare the assembly element for publishing.
	View Tab Review File enables you to open the PDF file with the generated tab review.
	Generate Tab Review File generates the assembly tabs in a PDF file.
	Publishing Summary Query displays each component in the assembly, its types and sub-types, and indicates whether a leaf has at least one child document and whether the leaf has any overridden attributes with renditions.

Icon	Description
	Submission Readiness Report. For each module in an assembly, the Submission Readiness report shows the number and percentage of documents that fall into each of ten categories. Each category is related to a document assignment status, approval status if assigned, due date of the parent leaf, and whether a document is in Documentum.
	Recalculate Checksums enables you to recalculate checksums for content that has been changed post publishing.
For folders and leaf elements	
	Change Type enables you choose an element type which includes additional properties specific to the element; these properties are used to create the XML backbone for eCTD submissions.
	Add Metadata enables you to add metadata to an entity.
For documents	
	Unassign Document enables you to remove the selected assigned document from the assembly tree.
	Prepare Documents for Linking enables you to prepare documents for use in linking tools.
	View File enables you to open an assigned document.
	Edit Document Bookmarks enables you to edit the extracted bookmarks of the selected document.
	Edit Document Links enables you to edit the hyperlinks of the selected document.

Export Assemblies

Exporting Assemblies provides you details in different formats.

You can export an assembly to any of three formats.

— Microsoft Excel spreadsheet (SPT users only)
— DMS repository virtual document (sometimes known as a compound document, depending on the repository type)
— XML file

Export an Assembly

You cannot view the assembly in the Approved Status View when exporting an assembly.

To export an assembly:

1. Click a link for the assembly you want to export.
2. In the More menu, click the Export Assembly to... .

3. On the *Export Assembly* page, enter a name for the export file.
4. In the Export Type field, choose one of the following:

Option	Description
Excel Spreadsheet:	Exports to a Excel spreadsheet.
Assembly File:	Exports to an XML file.
Virtual Document:	Exports to a virtual document.

5. In the Output Location field, click the Browse button to choose where to save the exported document.
6. In the Please select a document type list (optional), you may choose the document type in which to save the exported document, and click Next.
   A message prompts you to confirm the export.
7. Click OK.
   A message confirms the export was successful.
8. Click Done.

Export an Assembly to Excel

When you export an assembly to Excel, automatically formats the resulting spreadsheet.

The spreadsheet contains the following:

— The Excel file name is the same as the assembly name.
— First-level folders (major divisions or modules) become the spreadsheet tabs. One sheet is created for each first-level folder. First-level folder names are truncated at 31 characters.
— One row for each folder, leaf and document element is created. The rows are in the order of the assembly. The Excel spreadsheet is not hierarchical but a Level column is provided which indicates the hierarchy.
— Folder attribute names become the column names.
— Folder attribute values become the column contents.
— Leaf attribute names that differ from the folder attribute names become additional column names.
— Leaf attribute values become the column contents.
— Assigned document and placeholder attribute names that differ from the folder or leaf attribute names become column names.
— Assigned document and placeholder attribute values become the column contents.
— Leading zeros are stripped during the export process. To work around this, rename the file with a .txt extension rather than a .csv extension. Open the file in Excel. Use the Text Import wizard to make the initial cells text cells instead of general cells, and choose a comma delimiter.

Note: *Occasionally Excel may prompt you to make repairs. This is an errant message; you can click Close to ignore the message.*

Export an Assembly to a Virtual Document

Exporting an assembly to a virtual document enables you to generate a virtual document you can use in a submission publishing tool.

Due to the nature of DMS repository virtual documents, you can unintentionally convert a document to a virtual document, change the structure of an existing virtual document, or check in a checked-out document by exporting an assembly as a virtual document.

— Assigning children to an assigned document in and then exporting the assembly as a virtual document forces to convert the assigned document into a virtual document.
— If the assigned document was already a virtual document, is forced to change the virtual document so it reflects the assembly hierarchy.
— If the assigned document was checked out, is forced to check the assigned document back in to convert it to a virtual document, or to change its virtual document structure.

Before you export an assembly containing assigned documents that have children, you should evaluate the effects of converting those documents to virtual documents or changing the structure of the assigned virtual document. This is generally applicable; it is not specific to InSight and applies equally when working with virtual documents through any means.

When you export an assembly to a virtual document:

— You can export only from the root level. You cannot export from the folder, leaf or document levels.
— Each time you export an assembly to a virtual document, a new virtual document is created; you cannot re-export to an existing virtual document.
— If a document in the assembly is a child of another document, the parent document is converted to a virtual document.
— The virtual document name in the DMS repository must be unique.
— The assembly name cannot contain characters that are illegal on the file system (slashes, asterisks, etc.).
— A new folder is created in the destination folder you choose and is assigned the following name: <User-Defined Virtual Document Name> Supporting Documents.
— A new DMS repository object is added for each assembly element that is not already in the DMS (that is, root, folders, leaf elements, document placeholders, and file system documents). These new objects are placed in the supporting documents folder.
— For the assembly root, folders, leaf elements and document placeholders, the object in the virtual document is a no-content object.
— Any bound document that is already checked out is checked back in during the export.
— For each document that links to content in a different repository, a link to that content object is created in the Supporting Documents folder.
— For each document in the target export repository, the existing DMS objects are linked to the virtual document.
— For documents that link to content in the file system, a new object is created as a no-content object.
— The document type you specify is applied to all new objects created in the DMS.

The assembly version bindings are mapped to the virtual document as follows:

— If the assembly has version number binding, the virtual document bindings are set to the same number.

— If the assembly binding is version status binding, the virtual document binding defaults to the version label Current.
— If the assembly binding is version label binding, the virtual document bindings are the same.
— Currently the export will fail if there are any documents set to MISSING_VERSION (no binding).

Export to an Assembly File (XML)

When you export to an assembly file, the resulting file is an XML file. The XML file can be imported to create new assemblies.
When Export Assembly to Assembly File is performed the Rendition Identifier values set in the Assembly Specific Publishing Settings Libraries (APL), and those set on each element, are exported.
— When creating an Assembly from an Assembly file, the Rendition Identifier values are restored.
— If a Rendition Identifier value does not exist in the database, the Standard Rendition is used.
— If the Rendition Identifier information does not exist in the XML, the Standard Rendition is used.

Delete Assemblies

The information provides you detailed unintended consequences when deleting an assembly.
When administrators delete an assembly or assembly template, there can be unintended consequences.

When you delete an assembly or template the following occur:
— The reference location is deleted.
— The assembly or template is no longer available in lists of assemblies and templates.
— For a working assembly, the Sequence attributes page is displayed where you can create another assembly.
— For a single-version standalone assembly, the standalone assemblies list is displayed.
— For a single-version sequence assembly, the Sequence attributes page is displayed where you can create another assembly.
— For a multiple-version standalone or sequence assembly, the current version is displayed in the assembly tree pane.
— For the system current assembly (TIP) that has no former version with an effective status, the previous version of the assembly is unlocked and assigned the TIP status.
— For the current assembly with the effective status, checks for a previous superseded version with the effective status and makes that the current version. If there is no previous superseded version with an effective status, the TIP version becomes the current version.

You cannot delete the following:
— An assembly in current active view
— A locked assembly
— A lifecycle assembly that is finalized

Deleted Assemblies and Assembly Specific Publishing Settings Library (APL)

With some exceptions, deleting an assembly from deletes the associated APL.
The APL is deleted if the deleted assembly type is:

— Template
— Standalone Assembly
— Supporting Sequence Assembly

If the deleted assembly is a Sequence Assembly or a Working Assembly, the APL is deleted only if the APL is not referenced by a Submitted View.

View Activities List

You can view the list of activities across the assembly entities, or a for a selection of the assembly entities. For the sequence assembly, the list displays the activities associated to a selected section and all sub-sections in the Working view.
You must have at least READ permission for Activities within the entity security to be able to view the activities list.

To view an activities list:

1. Right-click on an assembly root, a folder, or a leaf and select View Activities List.
   A list of activities with activity attributes is displayed.
2. Do any of the following:

Option	Action
To find specific activities:	You can use the Set Filter option. For information on using Set Filter, see *Set Filter*.
To view the details of an activity:	Click on the activity name.
To view the details of an associated entity:	Click on the entity under Related Entity.

Recalculate Checksums

Calyx RIM provides users with the ability to recalculate checksums for content that has been changed post publishing. Using the Recalculate Checksums functionality will ensure that Calyx RIM contains the correct checksums which are submitted to the agency.
You can use recalculate checksums for any assembly.

Upon executing the **Recalculate Checksums** functionality, Calyx RIM verifies that the electronic output location is the same that the assembly was last published to. When all published output is correctly located, the system sends a job request to recalculate checksums. After the recalculated checksums are saved, the assembly will be republished using the XML only option, ensuring the XML contains the updated checksums, as well as recalculating the checksum for the XMLs.

Note: *The* Recalculate Checksums *functionality for lifecycle sequence assemblies and assembly plans is available from the publishing and sequence view only.*

To recalculate checksums do the following:

1. Navigate to the defined assembly root, folder or leaf level.
2. Select More > Recalculate Checksums.
3. Click OK. The request is sent.
4. Select Go To > Job Requests. Confirm that the job is completed.
5. The checksums in the XML file are updated.

Note: *If there is a cross reference leaf in the assembly, then you must execute the* Prepare Cross-Reference Leafs *functionality first.*

Prepare Cross-Reference Leafs

The Prepare Cross-Reference Leafs functionality enables you to ensure that the checksum is correct, and is available when publishing any cross-reference leafs that point to content outside of the current sequence.

Note: *Prepare Cross-Reference Leafs can only be executed from the* Prepare to Publish *window.*

To prepare cross-reference leafs:

1. On the assembly root, click More > Prepare to Publish.
2. In the prepare to publish window click the Prepare Cross-Reference Leafs checkbox, and click OK.
   The prepare to publish request is sent.
3. Navigate to the Job Requests window.
4. Confirm that the jobs are completed.
5. Click Close.
6. To submit the publishing request, click More > Publishing Request.
7. Select Publishing Output Channel: Electronic and Publish eCTD/Electronic: All leaf elements and XML, and click OK.
   The Prepare Cross-Reference Leafs functionality pulls the database value for the target of the cross reference leaf, ensuring that the correct checksum value is used at publish time.

Working Assemblies and Assembly Specific Publishing Settings Library (APL)

When a working assembly is created, it copies the APL of the submitted view and it updates the submitted view to use the new copy of the APL

The previous sequence view still uses the previous APL. When you create multiple working assemblies, the submitted view is updated to the last created working assembly.

Lifecycle

Lifecycle enables you to track changes you make to a submission as it progresses through the approval process.

When you are ready to submit an application to a regulatory agency for approval you must lock it to prevent additional changes. In addition, because the regulatory agency may require changes throughout the approval process, Calyx RIM enables you to track changes as they occur. You do this by creating a lifecycle. A lifecycle begins with the first sequence you submit for approval and continues through each additional sequence until the end of the drug's life for that application. The lifecycle and change tracking in the lifecycle are compliant with the ICH eCTD specification.

When you lock and add the first sequence assembly to lifecycle, it becomes the finalized assembly. Keep in mind the following:

— Any assembly versions are rendered non-useable after you add the first sequence assembly to lifecycle.
— The application's submitted view is the accumulation of all sequence assemblies that have been added to the lifecycle for the application. The submitted view, like all views, cannot be changed.

When the application lifecycle contains only the first finalized lifecycle assembly, the submitted view and sequence view look the same. After you add another assembly lifecycle, the sequence view and the submitted view differ.

— The working view is the submitted view plus any changes you have made. These changes can include new folders, leaf elements, documents and document placeholders, appended, withdrawn and replaced leaf elements, and deletions. Sections of the working view that were added to lifecycle in previous sequences (that is, the submitted view) cannot be changed. The working view initially represents a snapshot of the application's submitted view when the current sequence was created. If additional parallel sequences are created in the application, their changes are not included in the working view for the sequence.
— Only envelope information that is added to a lifecycle will carry through to newly created lifecycle assemblies. Planned lifecycle assemblies created from a specific submitted view will not upgrade to the latest submitted view: they will not be placed in the context of the latest sequence until they are added to a lifecycle, and they will not contain more recently added EU envelope information. However, any sequence added to a lifecycle that shares leaf replaces with other sequence(s) in the same application will always have assigned the correct modified file for published output.
— The application's sequence view contains only the changes that comprise the current sequence. As changes are made to the working view, these changes are reflected in the sequence view that represents exactly what will be submitted as part of that sequence.
— Once there is a lifecycle, you can create several supporting sequences. These can be separate assemblies that have no relation to the application lifecycle, but instead support it. For example, you might create a Clinical Study Report to support an existing lifecycle, or perhaps a paper reviewer's copy of the an eCTD sequence.
— You can add to lifecycle only assemblies with leaf elements. Leaf elements represent the final, published documents. You can use assemblies without leaf elements for study reports or paper output, but you cannot used them for eCTD or other regulated output that requires a document lifecycle.
— If you are adding documents from a DMS (such as Documentum), you must log on to the DMS before you can add a sequence assembly to a lifecycle.

Note: *When using the Duplicate command on a folder that contains leafs with lifecycle append operations, the duplicated structure is "flattened" and the appended documents are displayed as siblings (rather than as children) of the original source document.*

Until a submission is added to a lifecycle, the workflows associated to assembly nodes are displayed under the Working, Sequence and Publishing views of the sequence assembly. When a submission is added to a lifecyle, the incomplete workflows associated with the assembly nodes are canceled. All current activities of the canceled workflows are deleted. All canceled and completed workflows for the sequence assembly will be available from the Sequence and Publishing View of the lifecycled assembly.

Lifecycle procedures are applicable to the following Calyx RIM modules:
— Electronic Lifecycle Publishing (ELP)
— Registered Document Analysis (RDA)
— Submission Planning and Tracking (SPT)

Lock Sequence Assemblies

When you are ready to add a sequence assembly to lifecycle, you must lock it to prevent additional changes. Then you can add the sequence to lifecycle. This creates the lifecycle and makes the sequence assembly you used to create it the first finalized lifecycle assembly.
Once an assembly is locked, only an administrator can make changes and synchronize the assembly with the DMS. It is recommended, however, that you lock the binding of all documents used in the assembly, thus preventing binding changes should the assembly be unlocked and synchronized.

You can manually lock an assembly or you can use the *Change Submittal Status* wizard to mark the assembly as submitted. This locks the assembly automatically. The *Change Submittal Status* wizard enables you to update a submission status after a sequence assembly has been received by the regulatory agency. When you change the status, the submission is finalized and you can use it in subsequent submission lifecycle updates by adding it to the submitted view. In addition, the statuses of related entities (application, event, sequence, assembly) and key status attributes such as first submittal date are updated automatically.

Note: *Only an administrator can unlock a locked assembly.*

Manually Lock an Assembly

You can manually lock a sequence assembly to add it to a lifecycle.

To manually lock a sequence assembly:
1. Click a link for the sequence whose assembly you want to lock.
2. Click the Assembly tab to open the *Assembly Attributes* page.
3. Optionally, review the assembly tree and any of its attributes.
4. Click the assembly root.

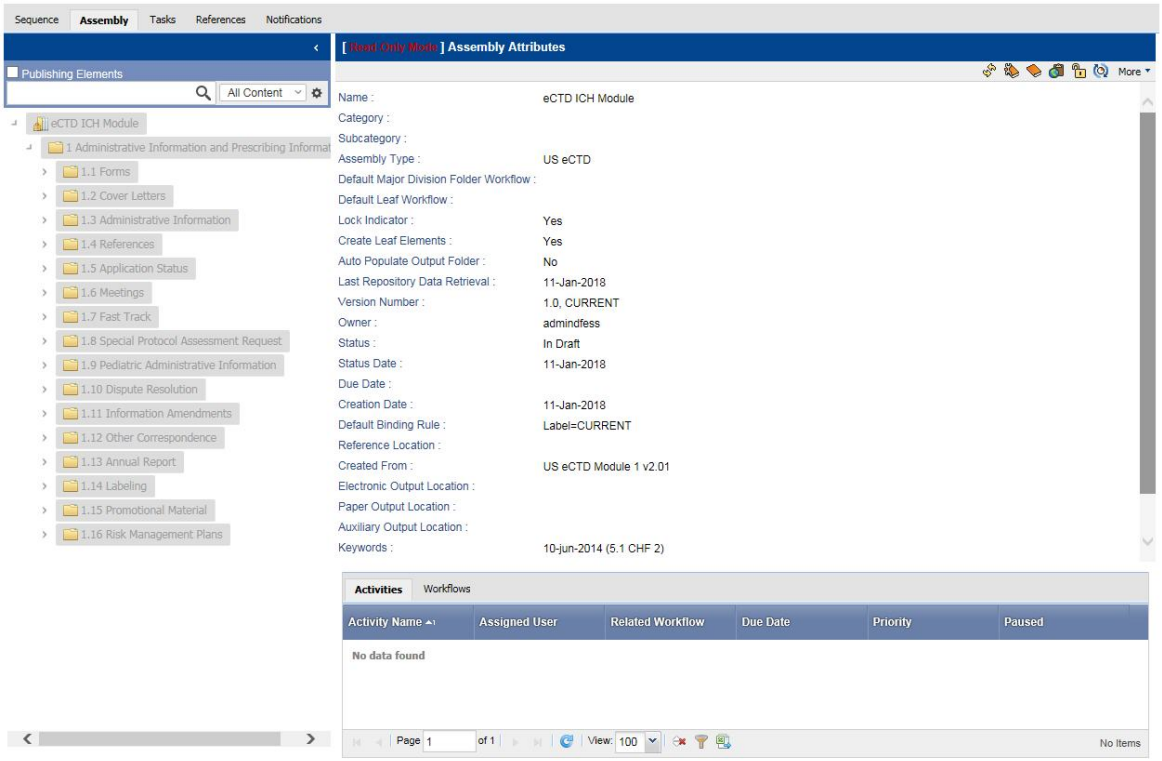
5. Click on the action button toolbar.
   A message prompts you to select the lock type.
6. Select Standard to lock the entire assembly.

   Example

7. Click OK.
   — `Read-Only Mode` appears before *Assembly Attributes*.
   — Lock Indicator is set to `Yes`.
   — A lock appears on the root in the assembly tree.
   — When you expand the assembly tree, the elements are grayed out to show they cannot be changed.

   Note: *Although the sequence assembly is locked, you can still change attributes for the assembly root.*

8. You can now add the locked sequence assembly to lifecycle.



Add Sequence Assemblies to Lifecycle

After adding an assembly to lifecycle, any other assembly versions are deleted. Before you add the first assembly to lifecycle, you can export the assembly to save the data.

Also, when an assembly or an assembly plan is added to a lifecycle all the incomplete workflows of an assembly or an assembly plan are canceled. See *Lifecycle*.

The sequence view and the submitted view are the same when you add the first locked sequence to lifecycle. You can add subsequent sequences to lifecycle just as you add the first sequence. You can also use the *Create Submission* wizard to add sequences.

When a submission is added to lifecycle, the leaf statuses of leaf elements are not updated.

Note: *Only an administrator can remove a sequence that has been added to lifecycle.*

Add Sequence to Lifecycle

You can add a sequence to lifecycle to create new versions of a sequnece.

Prerequisites

Before you add the first assembly to lifecycle, you can export the assembly to save the data. Other assembly versions are deleted when assemblies are added to lifecycle.

To add the first sequence to lifecycle:

1. On the action toolbar, select Add Sequence to Lifecycle.
   A message prompts you to confirm the addition.
2. Click OK.

Remove Multiple Sequences from a Lifecycle

Calyx RIM enables administrators to remove one or more sequences from a lifecycle back to a selected point within the lifecycle. This functionality helps to make corrections within the lifecycle.
You can remove the last sequence added to lifecycle by using the Remove Sequence from Lifecycle functionality. The same icon is used for both functionalities, and the system will determine which to use based on the sequence order.
If an assembly, that had updated submitted available set to Yes before adding to lifecycle, is removed from a lifecycle, the Updated Submitted Available flag value changes from No to Yes.

When you view job details on the Job Request window, messages indicate when the system removes sequences. If the Submitted View does not exist, or if the system encounters a reference leaf for one of the sequence assemblies that you want to remove, the failure message appears and the job fails.

To remove multiple sequences from a lifecycle:

1. Navigate to the sequence in the lifecycle.
2. On the entity view page, click the toolbar option Remove Submissions from Lifecycle to this Sequence.
3. When the system message appears, click OK to proceed.
   The system verifies that each sequence assembly that you want to remove has a corresponding associated *Submitted* View.
   - If the removed sequence was the first in the lifecycle, then the assembly is unlocked and the Current Active View, the Working View, and the Sequence View are no longer available.
   - If the removed sequence was not the first in the lifecycle, then you can see the assembly in the Sequence View. The changes that you made are seen in the Working view, and it is locked. The Submitted (Current Active) View is not changed. The removed assembly was added to lifecycle. The system returns you to the Application window related to the sequence.

Working Assemblies

After you have added the first sequence assembly to lifecycle, you can create planned sequence assemblies to include updates and changes required by the regulatory agency. These sequence assemblies are referred to as working assemblies, the assemblies you are working on in the lifecycle.

You update a working assembly in the working view. In the working view, normally the modified file and operation attributes cannot be changed; changes are managed by the lifecycle change control process. In limited cases, however, it may be necessary to change these values. In this case, an administrator may use the Reset and Change Modified Leaf buttons on individual leaf elements to make changes. Calyx RIM calculates the correct modified file values based on the specified leaf element.

Working Assemblies and Assembly Specific Publishing Settings Library (APL)

When a working assembly is created, it copies the APL of the submitted view and it updates the submitted view to use the new copy of the APL. The previous sequence view still uses the previous APL. When you create multiple working assemblies, the submitted view is updated to the last created working assembly.

Create A Working Assembly

After you add sequence assemblies to lifecycle, you can create working assemblies that include updates and changes required by the regulatory agency.

To create a working assembly:

1. Click the link for the application for which you want to create the working assembly.
2. Click the Sequences tab, and then click .
3. Enter the required information for the sequence and Save.
4. Click the Assembly tab.
5. Click Create Working Assembly.
6. Provide the information for the working assembly and click Create.
   The working assembly is created and displayed on the Assembly tab.
7. Above the assembly tree, choose one of the following:

Option	Action
Submitted:	Shows the most recent sequence submitted to the regulatory agency; its folders, leaf elements and documents are shown in gray.
Sequence:	Shows you the folders, leaf elements and documents in this sequence only; these are also shown in gray.
Working:	Shows the assembly in which you make changes and updates to the submission. It is the combination of the last submitted sequence (in gray) and the current sequence you have just added (in black).

Option	Action
Publishing:	Shows you the folders, leaf elements, documents and publishing elements in this sequence only. The non-editable elements are shown in gray, but publishing elements may still be modified.

Modify Leaf Elements in the Working Assembly

You can perform leaf operations, including add (New), replace, append, and delete from the working view. You cannot perform replace, append, or delete operations on a leaf that is part of an open Submission Plan.

Replacing a Leaf

- You can replace a leaf only once per sequence.
- You can replace directly from the assignment page by dragging one or more documents to an old leaf. This will automatically assign these documents to the leaf and change the leaf to an active Replace leaf.
- When you replace a leaf, the replaced leaf is hidden and the replacement leaf is displayed.
- The replacement leaf appears at the same location in the assembly tree as the leaf you replaced and you cannot move it.
- The replacement leaf has an operation of Replace.
- The replacement leaf has the default leaf status.
- When a reference leaf is replaced, it is converted back to a normal leaf. It must be manually converted again into a reference leaf, and it will need to be re-targeted to the new, replaced, version of the referenced document.
- The modified file for the replacement leaf references the replaced leaf. The modified file name is formatted as `../<replaced leaf sequence number>/index.xml#<letter><numeric identifierGUID>`. For example, `../0001/index.xml#a9f5078464791677a9934ae330536bffa`
- You cannot replace, append, withdraw, or delete the replacement leaf in the current sequence.
- You can revert the replacement leaf to undo the replacement. The leaf status is automatically reverted to the status that was set before the Replace operation.
- The replacement leaf assumes the content that was assigned to the replaced leaf. You can add, reorganize, or delete some or all of this content.
- The only content the replacement leaf has is the content you assign.
- According to the ICH eCTD specification, when you replace a leaf, the leaf in the `index.xml` is created automatically for each region's regional XML. For the `us-regional.xml`, `eu-regional.xml`, and `ca-regional.xml`, the operation on the leaf element in the `index.xml` is always New with no value for modified file. This is done per agency recommendation. For the `jp-regional-index.xml`, the operation on the leaf in the `index.xml` is New in the first sequence and Replace in subsequent sequences. The modified file automatically refers back to the previous sequence's regional leaf.
- If there are links that target the document assigned under the replaced leaf, they are re-targeted to point to the document assigned under the replacing leaf in the new sequence.

Appending a Leaf

- The new leaf has an operation of Append.
- The new appendee leaf has default leaf status.
- The new appendee leaf is represented as the last child of the appended leaf.

— The new appendee leaf is created in the same folder as the appended leaf, and it appears as a child of the appended leaf.
— You can append a leaf more than once.
— The modified file for the new appendee leaf references the appended leaf. The modified file name is formatted as `../<appended leaf sequence number>/index.xml#<letter><numeric identifierGUID>`. For example, `../0001/index.xml#a9f5078464791677a9934ae330536bffa`
— You cannot replace or delete the appended leaf in the current sequence. Calyx RIM does not allow a NEW leaf to be APPENDED in the same sequence. The appending document instead can be assigned below the first document under the NEW leaf, which will trigger Calyx RIM to perform a Leaf Roll-up of the two documents. This provides greater clarity to the reviewer and limits the use of Appends in the lifecycle.

Duplicating a Folder

When you duplicate a leaf element, an identical leaf is created in the new sequence. The attributes are the same, except for the leaf ID, modified file, and any assigned documents.

Deleting a leaf

When you delete (withdraw) a leaf that was submitted in an earlier sequence, you are indicating that the leaf should be removed from the submitted view when the current sequence assembly is added to lifecycle.

— The deleted leaf is hidden in the working view.
— A new leaf with an operation of Delete is displayed in the assembly tree.
— The new leaf has the default leaf status.
— The new leaf is positioned in the same location as the deleted leaf.
— The leaf and all its components are displayed with a line through them.
— Except for the leaf ID and operation, the new leaf has the same attributes as the deleted leaf.
— You cannot replace, append or delete the new leaf.
— You can revert the new leaf to undo the deletion. The leaf status is automatically reverted to the status that was set before the Delete operation.
— If the deleted leaf had content, the new leaf has the same content in the working view. In the sequence view however, the leaf is displayed with no content.
— The modified file for the new leaf references the deleted leaf. The modified file name is constructed as follows: Modified Leaf shows the leaf that is currently being modified by this leaf in the lifecycle. Modified Sequence shows the sequence that is currently being modified by this leaf in the lifecycle. Modified File Override is available to administrators only to allow an override of the modified leaf/sequence. This should only be used in certain situations because the change is not tracked in the lifecycle.
— Set Modified File is available in a working assembly to administrators, and in a standalone assembly to everyone. This allows the modified file to be manually set.
— Clear Modified File is available to administrators in a working assembly, and everyone in a standalone assembly. This allows the modified file to be manually cleared.
— You cannot change or move the new leaf, nor can you add elements to the new leaf.
— Deleted leaf elements are hidden in the submitted view after the current sequence assembly is added to lifecycle.

Reverting a Leaf Action

If you mistakenly perform a leaf operation, you can undo it by choosing the leaf for which you want to undo the operation, and then right-clicking the leaf and choosing Revert. To revert an appended leaf, choose the appended leaf, not the appendee leaf.

Update a Working Assembly

You can perform actions to update a working assembly such as replacing a leaf, updating a leaf, or deleting a leaf.

To change and update the working assembly:

1. At the top of the assembly tree, choose Working from the drop-down menu.
2. Expand the folder or leaf you want to change and update.

   Note: *You cannot change the submitted view elements; you can update only the working assembly with new information.*

3. Update the working assembly with new elements as needed.

   To undo an action, right-click the appropriate leaf, choose Revert, and confirm the action when you are prompted.
4. When you are ready to add the working assembly to lifecycle (adding the new leaf elements, their operations and their modified file references) lock the assembly in the working view and add it to lifecycle.

Reorganize a Lifecycle Assembly

You can reorganize a lifecycle assembly under specific limitations.

Following limitations are:

- New documents should not be added directly under the assembly root. They should always be added to leaf elements, which are children of folders.
- Folders in the current sequence can be moved up or down.
- An element cannot be demoted when the leaf directly above it is in a previous sequence.
- When you drag an element to another element, it becomes the last child in the target element with the following exception: A leaf dragged to another leaf becomes the next sibling of the target leaf.
- An element you promote becomes the next sibling of its previous parent.
- An element you demote becomes the last child of its previous sibling.
- To satisfy eCTD compliance, appended or modified leaf elements should not be placed under new leaf elements.
- When an assembly is removed from the current active view, slip sheets that were added to the leaf and folder no longer appear in the assembly.

Add Subsequent Sequences to Lifecycle

You can add subsequent sequences to lifecycle just as you add the first sequence. You can also use the Create Submission wizard to add sequences. For details, see Creating submissions.

To add subsequent sequences to lifecycle:

1. Click a link for the sequence you want to add to lifecycle.
   The *Sequence View* page opens.
2. Click the Assembly tab.
   The *Assembly Attributes* page opens.
3. Click on the action button toolbar.
   A message prompts you to select the lock type.
4. Select Standard to lock the entire assembly.

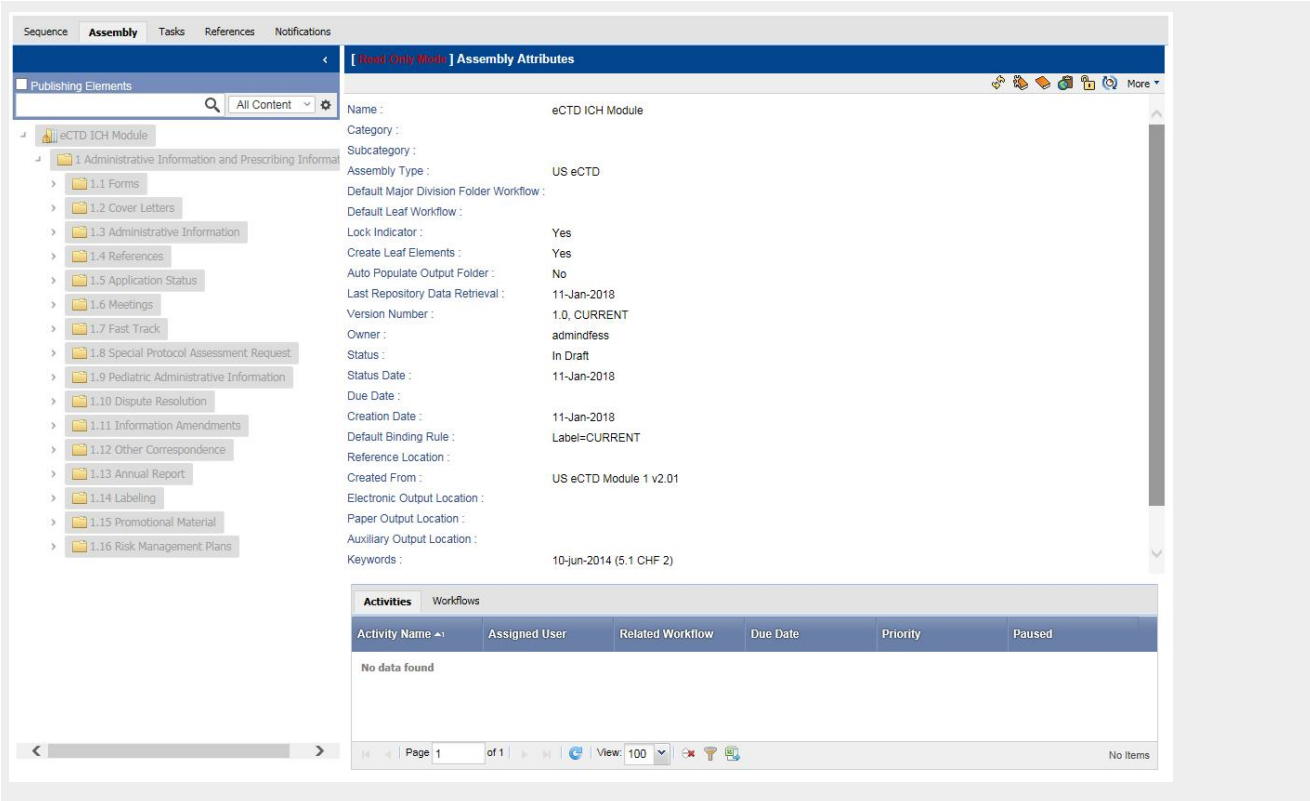
Example

5. Click OK.
   — Read-Only Mode appears above Assembly Attributes.
   — Lock Indicator is set to Yes.
   — A lock appears on the root in the assembly tree.
   — When you expand the assembly tree, the elements are grayed out to show they cannot be changed.

Note: *Although the sequence assembly is locked, you can still change attributes for the assembly root.*

6. To add the assembly to lifecycle, click .
7. When you are prompted to confirm the addition, click OK.

Example



Modify Submission Statuses

When you have submitted a lifecycle sequence to the regulatory agency for approval, you can change its submission status to help track its progress through the approval process.

You can change the submission status in either of two ways:

— By modifying the sequence attributes manually

— Using the *Change Submittal Status* wizard

Modify a Submission Status

When you have submitted a lifecycle sequence to the regulatory agency for approval, you can change its submission status to help track its progress through the approval process.

To manually change the status for a lifecycle sequence:

1. Click the link of the sequence you want to modify.
2. On the Sequence View page, click Edit.
3. On the Modify Sequence page, click the Status arrow and choose Submitted.
4. For the Status Date, do one of the following to choose when the sequence was submitted:

— Enter the date in the format appropriate for the language preferences of your Web browser.
— Click the calendar icon and choose a date.

5. Save.
   The new status appears under Status Dates at the bottom of the *Sequence View* page.

View Submitted Sequences

You can view all sequences that have a submitted status.

To view submitted sequences:

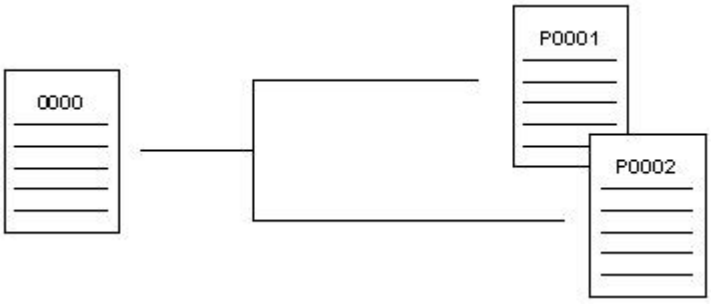
1. On the home page, click the Submitted Views tab.
2. Do one of the following:

Option	Action
To view the *Assembly Attributes* page:	Click a link in the Status View column.
To view the *Event Attributes* page for the event associated with the sequence:	Click a link in the Event Name column.

Manage Concurrently Planned Sequences

As you work on multiple planned sequences, it is important to understand how the submitted view is created. When you create the working assembly, the submitted view is a cumulative snapshot of all the sequences you have submitted. Once a submitted view is created for a planned assembly, it does not change.

If you are working on two planned sequences at the same time, they are both based on the same submitted sequence. In the example below, the submitted view of both P0001 and P0002 are based on 0000, which is the only submitted sequence.



You may submit P0002 to the regulatory agency before you submit P0001. The approved view is based on what has already been submitted, and enables you to make and view your changes. Both of these sequences may modify the same eCTD sections, and in fact they may modify the same eCTD leaf elements.

In the example above, when P0001 is submitted, it does not show the changes in the P0002 Submitted and working views. However, sequences P0001 and P0002 may still be submitted in any order. As each sequence is submitted, it looks for other planned sequences that have leafs in common with it. If these other planned sequence's leafs all have REPLACE leaf operations, they are automatically updated to point to the common leafs in the current sequence. It is extremely important to confirm leafs that are in common between the sequences after submittal, to make sure the correct document versions have been included in each case.

For a more specific example, suppose that in P0001 a leaf containing drug product information is updated in section 3.2.P.1. This information is also updated in P0002 with different data. The change in P0001 is an APPEND to the 3.2.P.1 leaf, and the change in P0002 is a replace to the 3.2.P.1 leaf. If P0002 is submitted before P0001, the REPLACE leaf in 3.2.P.1 updates the NEW 3.2.P.1 leaf in sequence 0000. If sequence P0001 were published before running the submittal wizard, its APPEND to the 3.2.P.1 leaf would point to the leaf in sequence 0000. If this is incorrect, P0001 would have to be submitted first and synchronized with the lifecycle. Once this was done, the APPEND leaf in 3.2.P.1 would point to the REPLACE 3.2.P.1 leaf in P0002.

In a similar example suppose that in P0001 a leaf containing drug product information is updated in section 3.2.P.1. This information is also updated in P0002 with different data. The change in P0001 is a REPLACE to the 3.2.P.1 leaf, and the change in P0002 is also a REPLACE to the 3.2.P.1 leaf. If P0002 is submitted before P0001, the REPLACE leaf in 3.2.P.1 updates the NEW 3.2.P.1 leaf in sequence 0000, and then updates the REPLACE leaf in sequence P0001. If sequence P0001 were published before running the submittal wizard, its REPLACE to the 3.2.P.1 leaf would point to the leaf in sequence P0001.

In this way, the eCTD XML is verified to be 100% correct with a valid lifecycle. Of course, in the act of submitting P0002 forces the sequence code to change to 0001, and when P0001 is submitted, the wizard again forces the sequence code to change to 0002. This is how Calyx RIM enforces consistency of the lifecycle to help prevent compliance issues later.

If many changes have been made to P0001 that you must compare with what is showing in P0002, you can use the *Assembly Comparison* query to view the differences between the planned sequences. This can help you determine the changes you need to make in the unsubmitted planned sequence.

As implied in the second example above, more than one planned sequence may be created and added in any order. The same leaf files may even be REPLACED, and as long as both are added to the submitted view and the XML is republished, both are valid sequences. The only situation that cannot be handled is if sequence P0002 has a DELETE operation on a leaf, and sequence P0001 attempts to REPLACE or APPEND on that same leaf. This will trigger an error when sequence P0001 is added to lifecycle, because it is an illegal eCTD operation. You can use the *Assembly Comparison* query to view the differences between the planned sequences. This can help you determine the changes you need to make in the unsubmitted planned sequence.

Generate an Assembly Comparison Query

The Assembly Comparison query is available to Submission Planning and Tracking (SPT) users only.

To generate an assembly comparison query:

1. Choose Go To > Querying.
2. Click the Submission Planning and Tracking tab.

3. Choose Assembly Comparison.
4. Choose the assemblies to compare and the columns to include in the query results.
5. Click Search.
   The comparison query results are returned.

Update an Unsubmitted Planned Sequence

You can update an unsubmitted planned sequence manually by creating a working assembly and importing parts of the unsubmitted planned sequence.

To update an unsubmitted planned sequence manually:

1. Create a sequence for the application.
2. On the *Sequence View* page, click the Assembly tab.
3. Click Create Working Assembly.
4. Enter the appropriate information to create the assembly and click Create.
5. Right-click the root in the assembly tree and choose Import to import parts of the unsubmitted planned sequence.
6. When you finish creating the working assembly, delete the unsubmitted planned working assembly.

Parallel Submissions

Synchronize Current Working View or Initial Assembly with Latest Submitted View

Calyx RIM enables you to synchronize the current Working view or an initial assembly with the updates made in a Submitted view. To use the option to synchronize, you must have WRITE permissions to an ELP or SPT License, at least READ permissions for parent entities (for Sequence Assembly: Sequences, for Assembly Plan: Submission Plans), and WRITE permissions to Sequence Assemblies.

Prerequisites

Prerequisites for synchronizing the Working view or an Initial Assembly with the Submitted view:

— Changes must have been made in a Submitted view. Changes made in the Submitted view are indicated by the status Yes for the Updated Submitted Available attribute on the Assembly Attributes page.
— The Working Assembly as well as the folders in an assembly must be unlocked.

To synchronize a current Working view or an initial assembly with updates of the Submitted view:

1. In the Working View or an initial assembly, choose the root to synchronize the entire assembly.
2. On the More menu, click Synchronize with the Submitted View.
3. On the confirmation message, click OK.
   The synchronization process starts. While the synchronization process is in progress, some assembly actions are unavailable.
4. To view the status of the synchronization process, use the Job Requests feature.

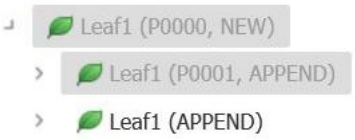
When the synchronization process is complete, the status of the Updated Submitted Available attribute is set to No.

Note: *Synchronization does not make any changes to APL. APL remains, irrespective of the changes made in parallel sequences.*

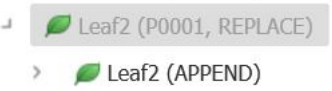
Conflicting Operations Rules - Synchronization with Submitted View

The following rules are applied during synchronization with Submitted view to conflicting operations.

— If a leaf has Append status in the Planned Submission and Append status in the latest Submitted view then after synchronization the current Working View will have the following structure.

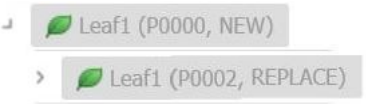


— If a leaf has Append status in the Planned Submission and Replace status in the latest Submitted View then after synchronization the current Working View will have the following structure.



— If a leaf has Append status in the Planned Submission and the Delete/Withdrawn status in the latest Submitted view then after synchronization the current Working view will have the following structure.

— If a leaf has Replace status in the Planned Submission and Append status in the latest Submitted view then after synchronization the current Working view will have the following structure.



— If a leaf has Replace status in the Planned Submission and Replace status in the latest Submitted view then after synchronization the current Working view will have the following structure.

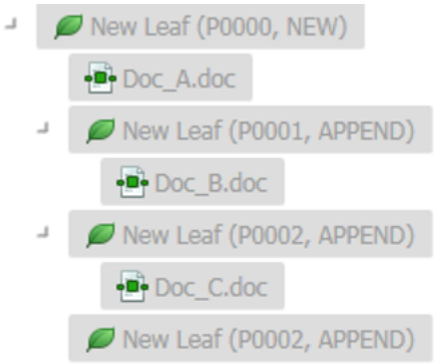
— If a leaf has Replace status in the Planned Submission and Delete/Withdrawn status in the latest Submitted view then after synchronization the current Working view will have the following structure.

— If a leaf has Delete/Withdrawn status in the Planned Submission and Append status in the latest Submitted view then after synchronization the current Working view will have the following structure.

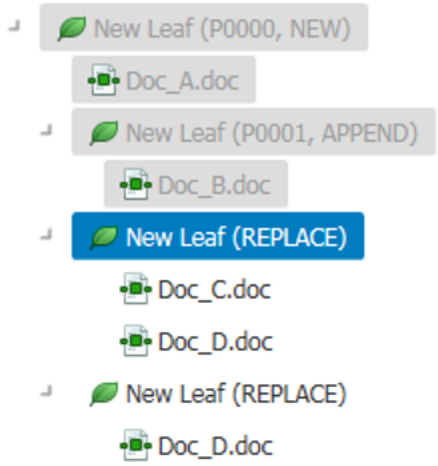
— If a leaf has Delete/Withdrawn status in the Planned Submission and Replace status in the latest Submitted view then after synchronization the current Working view will have the following structure.

— If a leaf has Delete/Withdrawn status in the Planned Submission and Delete/Withdrawn status in the latest Submitted view then after synchronization the leaf in current Working view will not be displayed (the leaf is deleted from the structure).

— Consider a submission with multiple Appends to a leaf. The tree structure will be as below.



If we now apply Replace or Withdrawn operation to the initial leaf (P0000), the Replace or Withdrawn operation is applied to all the appended leaf from the last lifecycled sequence.



After synchronization, the documents are retained in different views as per the rules noted below:

— If final operation is Append, the documents from Planned submission are retained.
— If final operation is Replace, the documents from both the Planned Submission and the Submitted View are retained.
— If final operation is Withdrawn, the documents from the Submitted view are retained.

All Workflows added to nodes in the Working view are retained. If a leaf with assigned Workflow is re-targeted to several leaves from Submitted view, a Workflow is retained for the first resulting leaf only.

Note:

— *If the operation is an Append/Withdraw, all the documents from all of the sequences appear under the resulting leaf.*
— *It is recommended that you avoid synchronization with Submitted view for submissions that have too many changes between Working and Submitted views, as it could result in unpredictable results. For example, if we have P0001 created from P0000 and it is in Working view, and if 10 assemblies are added to lifecycle, P0001 will have to be synchronized with P0011.*
— *Synchronization with the Submitted View is not supported when the selected XML definitions are changed.*
— *Publishing Settings Library and US M1 Metadata Submitted View updates are not synchronized with the current Working View.*
— *Some conflicting operations, such as lifecycle operations resulting in different leaf locations in cross-specification applications, cannot be resolved by the* Synchronize with the Submitted View *feature. The synchronization process skips the conflicting leafs and logs the details of the leaf name and ID in the Job Requests.*

Parallel Lifecycle

You can use the View Parallel Lifecycle option to view a report of the concurrent changes of a leaf across planned sequences.
This report is available in the working view of a sequence assembly and an assembly plan.

View Parallel Lifecycle

Using the Advanced Assembly Filter feature, an assembly can be filtered to get a list of lifecycled leafs in parallel sequences. You can use the View Parallel Lifecycle feature to view a report of the concurrent changes of the lifecycled leafs across a planned submission.

To view the parallel lifecycle of a leaf:

1. In the Working View of a sequence assembly or an assembly plan, choose a leaf to view its parallel lifecycle.
2. Right-click on the leaf and select View Parallel Lifecycle.
   The report is displayed in the *Parallel Lifecycle Operations* pane.
3. To view the attributes of a leaf in the report, click the leaf name hyperlink.
   The leaf attributes are displayed on the *Leaf Attributes* page.

Submissions

Submissions

The Calyx RIM submission wizards help you to create and modify submissions.

— Create eCTD provides an alternate way for you to create and organize standalone and sequence assemblies.
— Create Study Reports enables you to add study report structures (for example, folders, leaf elements) to existing assemblies.
— Create Submission enables you to create an application, its associated event, and sequence.
— Change Submittal Status enables you to mark a submission as submitted and protect it from further changes.

You must have the following modules to perform submission activities:

— Electronic Lifecycle Publishing (ELP)
— Paper Review Publishing (PRP)
— Registered Document Analysis (RDA)
— Submission Planning and Tracking (SPT)

Submission Wizard Administrative Prerequisites

Before you can use the submission wizards, certain fields and information types must already be set up and configured in data administration.

Includes the following :

— Product family type values
— Product family name
— Product family code
— Country values
— Default application status
— Default event status
— Default sequence status
— Default application type
— Default procedure type
— Event type
— Sequence filing type
— Products

Create Submission Wizard

The Create Submission wizard enables you to create an assembly within the context of its appropriate Calyx RIM relationship. The submission wizards facilitate the creation and/or confirmation of the application event (or activity) and sequence that correspond to the assembly you are creating.

To create an assembly, you must first determine its relationship in Calyx RIM. Except for template assemblies, every assembly in Calyx RIM has a relationship to other entities. Specifically, every assembly has an associated application, event, and sequence number.

The Create Submission wizard enables you to create an application and its associated event and sequence. You can create any of three types of submissions using the wizard:

— An initial application is the original filing event (request for marketing) in the history of a submission application. After a product family and its associated products have been created, you can create a submission.
— A major update is a variation or supplement to an original application. A new request for approval against the application is being made, for example, a new indication or a manufacturing change. Alternatively, a major update can be used for renewals or PSUR reporting. The major update is used for all event types other than the original application.
— An amendment is a change to filing content that supports an existing approval objective for which the application and event already exist. For example, you may be asked to clarify a statement in a previously-submitted document.

The Create Submission wizard controls which countries can be assigned to a sequence based on the submission type for MRP and DCP procedures. For major updates, all countries for the procedure are listed. For an amendment, only countries associated with the application are listed. If a new country is needed in an amendment, it must be added by modifying the application.

You cannot complete the Create Submission wizard without associating a Product.

For European submissions, the wizard displays only the countries that have been selected as part of the sequence. For certain submission procedures such as Centralized, only one country (EMEA) will be available. The common country is treated in a special way by the Create eCTD wizard. It is not included in normal country selections when creating submissions. However, if the common country is found in a section of the regional templates, it is always included as a possible selection in the Create eCTD wizard.

Note: *Only the MRP/DCP templates include any folders where the country is common. These appear in the following sections: 1.0, 1.2, 1.3.2, 1.3.3, 1.3.4, 1.3.5, Responses to Questions, and Additional Data. The common option does not apply to CP or NP submissions, which is why separate templates are required for the different procedure types.*

Initial Application Submission

You must have at least Write security permissions for one of the following Calyx RIM modules to create an initial application submission using the *Create Submission* wizard:

— Submission Planning and Tracking (SPT)

— Registration Planning and Tracking (RPT)
— Electronic Lifecycle Publishing (ELP)
— Paper Review Publishing (PRP)

When you create a submission using the wizard, you choose a product family with which to associate the submission, and assign several other required properties. The *Create Submission* wizard automatically creates:

— An application
— An event
— A sequence (optional)

If you are a product detail management (PDM) user, you can also associate products with the application. For PDM users, a link is created so you can create a product detail set (PDS). For submission planning and tracking (SPT) users, a link is created that takes you to the *Create Assembly* page, so you can create the assembly associated with the sequence. Application countries are set to:

— For MRP, RMS country plus selected CMS countries
— For CP, all countries selected. Role=Other

The Countries attribute on the event is set as follows:

— For National internal procedure type applications, automatically associate the user selected reviewing country with the event
— For CP internal procedure type applications, automatically associate the EU Country with the event
— For MRP internal procedure type applications, countries is set to the RMS and the CMS countries selected in the wizard

Create an Initial Application Submission

se the Create Submission wizard to create an initial application submission for a specific country, set of countries, or region. When an initial application is created, the event-country status schedules will be created for each country included in the application.

Note: *The wizard for creating a submission for an initial application does not use the default* Application Type *and* Procedure Type *values for the selected* Reviewing Country*. These defaults are for Copying Applications and the Global Project Planning (GPP) wizard.*

To create an initial application submission:

1. Select Wizards > Create Submission.
   The *Create Submission* wizard opens to the *Choose Submission Type* page.
2. Click Initial Application.
3. Click Next.
   The *Complete Submission Properties* (application) page appears.
4. Enter the application properties for the submission.

5. Click Next. The *Complete Submission Properties (event/sequence)* page appears.
6. On the *Complete Submission Properties (event/sequence)* page, do any of the following:

Option	Action
To create an event:	Enter an `Event Code`, `Keywords` and `Description`. If no entry is made to the event-related fields, the event will still be created with default values.
To use a timeline/event plan to create the event:	Select a **Timeline/Event Plan** from the drop-down list.
To change the event type:	Select the value from **Event Type** drop-down list. The New Application value is selected by default.
To create a sequence:	Select the **Create sequence?** check box.

Note: *If you choose to create a sequence, you can change the default sequence numbering of a P followed by four digits. This numbering scheme is the format recommended for an eCTD submission. The sequence code must be unique within the application. If you change default numbering format, the wizard will issue a message requesting confirmation that you accept the deviation from the default sequence numbering format.*

7. Click Next.
   The *Create Submission Confirmation* page opens, confirming the actions that will be performed based on your selections.
8. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature and SSO are enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.
When electronic signature is enabled and SSO is disabled	a. Select a reason and enter comments for the reason. b. Enter user ID and password and click Next.

9. On the *Create Submission Confirmation* page, do any of the following:

Option	Action
To confirm your selections:	Click **Next**. The *Create Submission Summary* page opens, listing the created items. Additional items you can add to the submission may also be listed.
To return to the previous pages to change your selections:	Click **Back**.

Option	Action
To cancel the submission entirely and return to the view form which you invoked the wizard:	Click **Cancel**.

10. On the *Create Submission Summary* page, do any of the following:

Option	Action
To view the created event:	Click the event link.
If you created a sequence and want to view it:	Click the sequence link.
To update a PDS associated with the event:	Click the PDS link. This option is available for PDM users.
To create an assembly:	Click the first assembly link. This options is available for SPT users. If you create an assembly from an existing template, assembly, or view, to find an assembly, click **Browse** and use the Search Assembly wizard. See Searching for an Assembly.
To create an eCTD:	Click the second assembly link to start the Create eCTD wizard.
To return to the location from which you invoked the Create Submission wizard:	Click **Finish**.

Initial Application Submission Attributes

You can use the attributes to describe the details of the initial application submission.

Attribute	Description
Applicant ID	Identifies the entity that submits the application to regulatory authorities.
Application	The Application field now shows the value as a concatenation of [Application Code + Application Name].

Attribute	Description
Application Code	The agency-identified application number (or identifier). This number may not be known until the time of submission, so it may be the same as the internal code. Keep in mind the following when you enter an application code or number: — For US applications, the application code is always a 6-digit number. — For Canadian applications, the application is generally an *e* followed by a 6-digit number (for example, e123456). — For Japan the application code is generally ectd- followed by a 6-digit number (for example, ectd-123456). — For the EU, applications numbers are generally not available until you have filed and numbers may vary by country. It is best to enter an application number that is unique and meaningful according to the specification. Samples may include a country abbreviation or an internal drug code abbreviation or number, for example, uk-h-323-001.
Application Name	The name of the application that will be associated with the submission event.
Application Type	The type of application for which you are creating the submission. The list of available options depends on the Reviewing Country selected.
Associated Products	Products included in the Product Family that are available to include in the application.
Co-Rapporteur	Used when the Reviewing Country is a member of the European Union (EU) and the submission involves a Centralised Procedure (CP).
Countries	Used when the submission involves a member of the European Union (EU) and the Procedure Type is Mutual Recognition Procedure (EU MRP) or a Decentralised Procedure (EU DCP), the Countries attribute appears and enables you to select multiple countries for the submission. When an EU country is selected, European Union is automatically included in the countries selected for the submission for CP applications.
Create Sequence	Determines whether the wizard will create a sequence for the application.
Description	Text that describes an entity within a submission.
Event Code	The code used to identify the event.
Event Type	The drop-down list displays all Active values from Data Administration > Event Maintenance > Event Type Values. The New Application value is selected by default in the Event Type field.
Timeline/Event Plan	A preset plan that determines the ordered progression of primary event statuses that will apply for events created from the plan.

Attribute	Description
Timeline/Event Plan Type	The type of timeline/event plan used to create or update the event. The timeline/event plan type can be procedure type, event type, or none. An event created or updated by using the procedure type of timeline/event plan has a sequence of statuses that are relevant to the procedure type selected for the event. An event created or updated by using the event type of timeline/event plan has a sequence of statuses that are relevant to the event type selected for the event. An event created or updated by specifying none for the timeline/event plan type can have any sequence of active statuses. The sequence of statuses for a timeline/event plan type is defined in Data Administration.
Filing type	The filing type (for example, original filing, extension filing, reformatting filing) for the application, which is required only if sequences will be created with the submission.
Keywords	Words used to enable a search for entities associated with the submission.
Procedure Type	The procedure type for the application, such as National, CP, DCP, or MRP. The list of available options depends on the reviewing country for the submission.
Registration Type	This attribute specifies whether the registrations you associate with the application will be of a registration type that is mapped to an internal value of either package set or product. This attribute can be configured to default to one registration type and be non-editable.
Reviewing Country	The country responsible for performing the submission review. When the submission involves a member of the European Union (EU) and the Procedure Type is Mutual Recognition Procedure (EU MRP) or a Decentralised Procedure (EU DCP), the Countries attribute appears and enables you to select multiple member countries from the EU for the submission. The Reviewing Country is automatically assigned for National procedure types.
Sequence Code	The identifier for the sequence associated with the application, which is required only if a sequence will be created. The sequence code defaults to the next available four-digit sequence number, prepended with the letter P to indicate that this is the planned sequence number. This enables working on multiple planned sequences concurrently. When you mark the sequence as submitted, Calyx RIM Manager reconfirms the next available sequence number and removes the P. If you enter a value that deviates from the default format, the wizard displays a message requiring you to confirm that you want to deviate from the default numbering format. For the first sequence in an application, the start sequence code from the application is always used. For subsequent sequences, all the sequences in the application are considered. When the highest existing sequence number has been determined, the default sequence number for the new sequence is the highest plus one. For example, if there are four sequences with the codes P0000, 0001, 0005, and R0006-512, the next sequence number by default is P0006.

Major Update Submission

When you create a major update submission, you create an event and, optionally, a sequence. Links to create assemblies and edit PDSs (for all but ELP-only users) are provided as well. To create a major update submission, an application must exist for the product family and country.

Application countries:

— If additional CMS countries have been added that are not already part of the application, they are added to the application.

— If CMS countries that are part of the application are removed from the CMS list, they are not removed from the application.

The Countries attribute on the event is set as follows:

— For national internal procedure type applications, automatically associate the reviewing country on the selected application with the event.

— For CP internal procedure type applications, automatically associate the EU Country with the event.

— For MRP internal procedure type applications, the Reviewing Country/RMS on the selected application and the CMSs selected in the wizard are associated with the event.

Create a Major Update Submission

You can update an existing application for a new business objective or regulatory activity. When creating a major update submission, an event is created and you can create a sequence, if needed.

Note: *To create a major update submission, an application must exist for the product family and associated country, and you must have the appropriate security permissions.*

To create a major update submission:

1. Click Wizards > Create Submission.
   The *Create Submission* wizard opens to the *Choose Submission Type* page.
2. Click Major Update.
3. Click Next.
   The *Complete Submission Properties* page appears.
4. Enter the required information for creating an event.
   Creating a sequence is optional.

   Note: *If you choose to create a sequence, you can change the default sequence numbering of a P followed by four digits. This numbering scheme is the format recommended for an eCTD submission. If you change, the format, Calyx RIM will issue a message requesting confirmation that you accept the deviation from the default sequence numbering format.*
5. Click Next to confirm your selections.
   The *Create Submission Confirmation* page appears.
6. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature and SSO are enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.
When electronic signature is enabled and SSO is disabled	a. Select a reason and enter comments for the reason. b. Enter user ID and password and click Next.

7. Do one of the following:

Option	Action
To confirm your selections.:	Click **Next**. The *Create Submission Summary* page opens, listing the created items. Additional items you can add to the submission may also be listed. Proceed to step 8.
To return to previous pages to change your selections:	Click **Back**.
To cancel the submission entirely and return to the view from which you invoked the wizard:	Click **Cancel**.

8. On the *Create Submission Summary* page, do any of the following:

Option	Action
To view the created event:	Click the event link.
If you created a sequence and want to view it:	Click the sequence link.
To update a PDS associated with the event. This option is available for PDM users:	Click the **PDS link**.
To create an assembly:	Click the first assembly link. This link is available for SPT, ELP, and RDA users.
If you create an assembly from an existing template, assembly, or view, to find an assembly:	Click **Browse** and use the **Search Assembly** wizard.
To create an eCTD:	Click the second assembly link to start the eCTD wizard.
To return to the location where you invoked the Create Submission Wizard:	Click **Finish**.

Major Update Submission Attributes

You can use the attributes to modify submission attributes.

Attribute	Description
Application Code	The agency-identified application number (or identifier), which may not be known until the time of submission, so it may be the same as the internal code
Application Name	The name of the application that is associated with the submission event. The value is a concatenation of [Application Code + Application Name].
Countries	When the Reviewing Country is a member of the European Union (EU), the Concerned Member States attribute appears and enables you to select multiple countries for the submission. This section does not appear if the Reviewing Country is not a member of the EU or for applications of national procedure type.
Create Sequence	Determines whether the wizard will create a sequence for the application
Description	Text that describes the submission
Event Code	The code your organization uses to identify the event. ***Note:*** *The event code and event name as a combination for an event must be unique within an application.*
Event Name	The name of the event. ***Note:*** *The event code and event name as a combination for an event must be unique within an application.*
Timeline/Event Plan	A timeline/event plan determines the ordered progression of event statuses that will apply for events created from the plan
Timeline/Event Plan Typ	The type of timeline/event plan used to create or update the event. The timeline/event plan type can be procedure type, event type, or none. An event created or updated by using the procedure type of timeline/event plan has a sequence of statuses that are relevant to the procedure type selected for the event. An event created or updated by using the event type of timeline/event plan has a sequence of statuses that are relevant to the event type selected for the event. An event created or updated by specifying none for the timeline/event plan type can have any sequence of active statuses. The sequence of statuses for a timeline/event plan type is defined in Data Administration.
Event Type	The type of event
Family Name/ Code	The product family with which to associate application you are updating

Attribute	Description
Filing Type	The filing type for the application
Keywords	Words used to search for when creating a submission
Reason	Reason for creating, modifying or deleting a submission
Reason for Comments	Comments related to reason entered by users
Reviewing Country	The country performing the submission review. Only the countries associated with the application will be listed. When the Reviewing Country is a member of the European Union (EU), the Concerned Member States attribute appears and enables you to select multiple countries for the submission except for EU national procedure type applications. The wizard automatically sets the Reviewing Country for national applications.
Sequence Code	The identifier for the sequence associated with the application, which is required only if a sequence will be created. The sequence code defaults to the next available four-digit sequence number, prepended with the letter P to indicate that this is the planned sequence number. This enables working on multiple planned sequences concurrently. When you mark the sequence as submitted, Calyx RIM Manager reconfirms the next available sequence number and removes the P. If you enter a value that deviates from the default format, the wizard displays a message requiring you to confirm that you want to deviate from the default numbering format. For the very first sequence in an application, the start sequence code from the application is always used. For subsequent sequences, all the sequences in the application are considered. When the highest existing sequence number has been determined, the default sequence number for the new sequence is the highest plus one. For example, if there are four sequences with the codes P0000, 0001, 0005, and R0006-512, the next sequence number by default is P0006.
User ID	The user name to validate user identity.
Password	The user password to validate user identity.

Amendment Submission

You can create an amendment submission to change the filing content of an existing approval objective.

When you create an amendment submission, you change the filing content of an existing approval objective. For example, you may be asked to clarify a statement in a previously submitted document. A sequence is created to support the amendment.

Create an Amendment Submission

You can create a new sequence for an existing application and event. You must have the appropriate security permissions to create an amendment using the *Create Submission* wizard.

To create an amendment submission:

1. Click Wizards > Create Submission.
   The *Create Submission* wizard opens to the *Choose Submission Type* page.
2. Click Amendment.
3. Click Next.
   The *Complete Submission Properties* page appears.
4. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature and SSO are enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click Next. c. Validate your identity by entering your user credentials in the dialog box.
When electronic signature is enabled and SSO is disabled	a. Select a reason and enter comments for the reason. b. Enter user ID and password and click Next.

5. Enter the properties for the submission.
   `Concerned Member States` will display only if the procedure type is MRP.

Note: *If you choose to create a sequence, you can change the default sequence numbering of a P followed by four digits. This numbering scheme is the format recommended for an eCTD submission. The sequence code must be unique within the application. If you change default numbering format, the wizard will issue a message requesting confirmation that you accept the deviation from the default sequence numbering format.*

6. Click Next.
   The *Create Submission Confirmation* page appears.
7. On the *Create Submission Confirmation* page, do one of the following:

Option	Action
To confirm your selections:	Click Next . The *Create Submission Summary* page appears, indicating that a sequence has been created. Additional items that you can add to the submission may also be listed. Proceed to step 8.
To return to previous pages to change your selections:	Click Back.
To cancel the submission and return to the view form which you invoked the wizard:	Click Cancel..

8. On the *Create Submission Summary* page, do any of the following:

Option	Action
To view the newly created sequence attributes:	Click the sequence link.
To create an assembly:	click the first assembly link. This link is available for or SPT, ELP, and RDA users. If you create an assembly from an existing template, assembly, or view, to find an assembly, click Browse and use the *Search Assembly* wizard. See *Searching for an Assembly*
To create an eCTD:	Click the second assembly link to start the eCTD wizard.
To return to the location from which you invoked the *Create Submission* wizard:	Click Finish.

Amendment Submission Attributes

You can use the attributes to modify an existing submission.

Attribute	Description
Application Code	The agency-identified application number (or identifier), which may not be known until the time of submission, so it may be the same as the internal code.
Application Name	The name of the application that is associated with the submission event. The value is a concatenation of [Application Code + Application Name].
Application Type	The type of application associated with the submission event
Concerned Member States	When the Reviewing Country is a member of the European Union (EU), the Concerned Member States attribute appears and enables you to select multiple countries for the submission. This section does not appear if the Reviewing Country is not a member of the EU.
Event Code	The code your organization uses to identify the event.
Event Name	The name of the event.
Event Type	The type of event.
Family Name/Code	The product family with which to associate the application you are updating.
Filing Type	The filing type for the application.
Reason	Reason for creating, modifying or deleting a submission.
Reason for Comments	Comments related to reason entered by users.

Attribute	Description
Reviewing Country	The country performing the submission review. Only the countries associated with the application will be listed. When the Reviewing Country is a member of the European Union (EU), the Concerned Member States attribute appears and enables you to select multiple countries for the submission.
Sequence Code	The identifier for the sequence associated with the application, which is required only if a sequence will be created. The sequence code defaults to the next available four-digit sequence number, prepended with the letter P to indicate that this is the planned sequence number. This enables working on multiple planned sequences concurrently. When you mark the sequence as submitted, InSight Manager reconfirms the next available sequence number and removes the P. If you enter a value that deviates from the default format, the wizard displays a message requiring you to confirm that you want to deviate from the default numbering format. For the first sequence in an application, the start sequence code from the application is always used. For subsequent sequences, all the sequences in the application are considered. When the highest existing sequence number has been determined, the default sequence number for the new sequence is the highest plus one. For example, if there are four sequences with the codes P0000, 0001, 0005, and R0006-512, the next sequence number by default is P0006.
Sequence Description	Text that describes an entity within the submission.
Sequence Keywords	Words used to search for when creating a submission.
User ID	The user name to validate user identity.
Password	The user password to validate user identity.

Create eCTD Wizard

The *Create eCTD* wizard enables you to create and organize structured and compliant eCTD assemblies. Using standard templates, you can create folder structure, leaf elements, and metadata in an assembly.

You can run the wizard multiple times to ensure the metadata is up to date, to add new sections, or to refresh structures. The *eCTD wizard* shows all eCTD components that are available for inclusion in the submission.

The *eCTD wizard* enables you to perform the following tasks:

— Create the assembly for the first sequence or a standalone assembly.

— Build the assembly with the correct eCTD components based upon region, specifications, template, configuration, and user selections.

— Create the assembly structure with selected or confirmed metadata.

You can use the *Create eCTD* wizard with:
— Existing standalone assemblies
— Existing sequence assemblies (both lifecycle and non-lifecycle)
— Existing sequences with no assembly created
— Applications or events

Using the *Create eCTD* Wizard, you can select a template other than the default template to use with the assembly, and that selected template will persist as the default whenever you run the *Create eCTD* Wizard for that assembly.

When you create an eCTD using the wizard, all attributes display the default values from the assembly template you are using. The assembly templates provide all available sections for an eCTD.

Automatically, each leaf element created using the *Create eCTD Wizard* is assigned the default `Leaf Status` value configured in *Data Administration*.

Based on the module you select (US, Canada, Europe. Switzerland, Japan, Rest of World), some of the properties are different. For example, United States does not require a country.

When creating an eCTD from an existing sequence and application, the region, application number, sequence number, and countries attributes are pre-populated based on the information stored in those entities.

When running the *Create eCTD* wizard for a new standalone assembly, the regions available for selection in the Region drop-down list are all active regions of the Regulatory Region type. The list is alphabetically sorted.

When running the *Create eCTD* wizard, or editing the M1 or envelope folders:
— The current sequence code for the sequence entity is always updated in the eCTD metadata in the folder extension.
— The sequence code is always used when publishing.

Null Value and Swiss eCTD Assemblies

When using the *Create eCTD* wizard to create a Swiss eCTD assembly, you are prompted for the number of Galenic Forms included in the sequence, the name of the form, and Swissmedic Number. A separate folder is created for each Galenic Form indicated in the resulting assembly and includes the value 'null' in the Name attribute.
You MUST edit the extended attributes of each folder to provide the Galenic Form's translation languages and values (the Galenic Language Name attribute pair).

You may also update the folder name to remove the 'null' value, but this has no effect on the published output. At least one Galenic Language Name pair must be provided in order to produce valid XML.

Create eCTD Submission

The *Create eCTD* wizard enables you to create, update, and organize structured and compliant eCTD assemblies. Using standard templates, you can create folder structure, leaf elements, and metadata in an assembly.

To create an eCTD assembly:

1. Click a link for the sequence, assembly, standalone assembly, or assembly plan from which you want to create an eCTD assembly.
2. Choose Wizards > Create eCTD.
   The *Create eCTD* wizard appears.
3. Do the following:

Option	Action
In the *Assembly Name* box:	Enter a name for the assembly. For assembly plans, the name of the submission plan associated with the assembly plan is populated automatically as the name for the assembly.
To import the TOC and special sheet values from the publication settings of the template on which you are basing the eCTD:	Select Copy TOCs and Special Sheets.
From the *Available* countries box:	Select the appropriate countries and move them to the *Selected* box.
To remove countries from the *Selected* box:	Select them and move them back to the *Available* box.
Next to Template Selection:	Select the template on which to base the eCTD.

Note: *Using the Create eCTD Wizard, you can select a template other than the default template to use with the assembly, and that selected template will persist as the default whenever you run the Create eCTD Wizard for that assembly.*

4. Click Next .
   The *Select Attributes* page appears. The region for which you are creating the eCTD determines the attributes that appear in the wizard. Enter details as necessary.
5. Click Next.
   The *Set Application Metadata* page appears. The type of assembly for which you are creating the eCTD determines the attributes that appear in the wizard. Enter details as necessary.
6. Click Next.
   The *Select Sections* page displays all of the available CTD sections you can add to the assembly.
7. Select the individual folders and subfolders for the eCTD.
   - For existing standalone, lifecycle or non-lifecycle sequence assemblies, any section folders that already exist in the assembly are not available.
   - Selecting a top-level section automatically includes all the subsections for that folder.
   - To update the metadata values in sections that already exist, or to add the subsections to existing sections, select the checkbox next to the existing sections that need to be updated

Tip: Folders that are copied from the template appear in the same order as in template. New sections or folders that do not belong to any template are placed at the top of the list.

8. Click Next.
   The Select *Sets of Submission Metadata* page appears. If you have included any of the repeatable assembly sections, they are displayed.
9. Enter the number of sets of information for each repeatable section. In some instances, the metadata may be dependent on a section being created or on one that already exists.

Note: *When running the eCTD wizard or editing the M1 or envelope folders, the current sequence code for the sequence entity is always updated in the eCTD metadata in the folder extension. This is because this code is always used when publishing.*

10. Click Next.
    The *Set Submission Metadata* page appears.
11. Enter the submission metadata. For descriptions of the metadata, see Submission Metadata.
12. Click Next.
    The *Confirmation* page appears.
13. Click Next.
    The *Summary* page displays a message indicating that the eCTD information has been saved to the assembly.
14. Do one of the following:

Option	Action
To view the assembly that was created:	Click the first assembly link.
To start the Create Study Reports wizard for the assembly:	Click the second assembly link.
To close the wizard:	Click Finish.

Add Metadata to Assembly

Calyx RIM enables you to add metadata such as application number, cross-reference application details, sequence number, and submission ID to US DTD v3.3 submissions.

To add metadata to an assembly:

1. Navigate to the assembly to which you want to add metadata.
2. Expand the assembly tree and select the module level folder to which you want to add the metadata.
3. Click More > Add Metadata.
4. Select the metadata type from the drop-down list.
5. Enter relevant details in their corresponding fields.
   For an assembly plan with multiple applications associated to it, only one application containing files can be configured.
6. Save.

The metadata is added to the assembly.

eCTD Attributes Australia

You can use the following attributes to describe eCTD submissions for Australia.

Australia-v0.90

Attribute	Description
Applicant	The applicant name as listed in the eBS client database.
ARTG Number	The Australian Register of Therapeutic Goods number. The ARTG can be a four, five or six digit number. Multiple comma-separated values can be provided.
Australian Approved Name(s)	The name of the active ingredients that are accepted for inclusion in the Australian Approved Name list. Multiple comma-separated values can be provided.
eSubmission Identifier	The Application Number as provided by the agency.
Product Name	The name or proposed product (trade) name to be used on the Certificate of Registration. Multiple comma-separated values can be provided.
Regulatory Activity Lead	Identifies the group within the TGA which is expected to take the lead in the review process.
Related Sequence Number	Four digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity.
Sequence Description	Content description for the submitted sequence.
Sequence Number	Four digit sequence number matching the sequence folder being submitted.

Australia-v3.0

Attribute	Description
Applicant	The applicant name as listed in the eBS client database.
ARTG Number	The Australian Register of Therapeutic Goods number. The ARTG can be a four, five or six digit number. Multiple comma-separated values can be provided.
Australian Approved Name(s)	The name of the active ingredients that are accepted for inclusion in the Australian Approved Name list. Multiple comma-separated values can be provided.
eSubmission Identifier	The Application Number as provided by the agency.
Product Name	The name or proposed product (trade) name to be used on the Certificate of Registration. Multiple comma-separated values can be provided.

Attribute	Description
Regulatory Activity Lead	Identifies the group within the TGA which is expected to take the lead in the review process.
Related Sequence Number	Four digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity.
Sequence Description	Content description for the submitted sequence.
Sequence Number	Four digit sequence number matching the sequence folder being submitted.
Sequence Type	Identifies the type of activity that is being submitted with the sequence, either the regulatory activity type if it is the first sequence of the regulatory activity or supplementary information if it is a follow-up to information already submitted for the regulatory activity.

Australia-v3.1

Attribute	Description
Approved Name(s)	The name of the active ingredients that are accepted for inclusion in the Australian Approved Name list. You can enter up to 500 characters. Multiple comma-separated values can be provided.
ARTG Number(s)	The Australian Register of Therapeutic Goods number. The ARTG can be a four, five, or six digit number. Multiple comma-separated values can be provided.
Contact Email	Results of the sequence validation are sent to the email addresses provided. You can enter up to 500 characters. Multiple comma-separated values can be provided.
e-Identifier	The Application Number as provided by the agency. The value must be a lowercase letter followed by six digits. Example: `a123456`
eBS Client ID	The client ID as listed in the eBS client database. You can enter up to 200 characters.
Regulatory Activity Lead	Identifies the group within the TGA that is expected to take the lead in the review process.
Related Sequence Number	Four-digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity.
Sequence Description	Content description for the submitted sequence.
Sequence Number	Four-digit sequence number matching the sequence folder being submitted.

Attribute	Description
Sequence Type	Identifies the type of activity that is being submitted with the sequence, either the regulatory activity type if it is the first sequence of the regulatory activity or supplementary information if it is a follow-up to information already submitted for the regulatory activity.
Submission or Application Number(s)	The submission number(s) or application number(s) applicable to the sequence being submitted. You can enter up to 500 characters. Multiple comma-separated values can be provided.
Submission Mode	The value can be set to `Single`, `Work-grouping`, or `Work-sharing`. Until the work grouping and work sharing functions are sufficiently developed, the only valid mode is Single which denotes a single regulatory activity.
Trade Name(s)	The name or proposed product (trade) name to be used on the Certificate of Registration. You can enter up to 500 characters. Multiple comma-separated values can be provided.

The following table describes are recommendation for providing the Submission Number values:

Submission Number Value	Description	Allowable Combinations
PM-2017-12345-1-5 Prescription medicines submission numbers	Prefix PM followed by the submission number and stream. — If the submission number is not yet known it is appropriate to only include the prefix and the stream. Example: `PM-1` ***Note:*** *This will apply whether the activity refers to a biological medicine or other molecular type ('chemical' medicine).*	— PM with PV or MF — BA with PV or MF — OM with PV — PV with PM, BA, or OM — MF with PM or BA
BA-2017-12345-1 Biologicals submission numbers	Prefix BA followed by the submission number. — If the submission number is not yet known it is appropriate to only include the prefix. Example: `BA`.	
OM-2017-12345-1 OTC medicines submission numbers	Prefix OM followed by the submission number. — If the submission number is not yet known it is appropriate to only include the prefix. Example: `OM`.	
Complementary Medicines	For registered complementary medicines the same protocol applies as for OTC medicines as detailed above. For listed complementary medicines no validation is planned at this time.	
PV Pharmacovigilance	No submission number is assigned. PV should be entered for all sequences where pharmacovigilance information is submitted.	
MF Master Files	No submission number is assigned. MF should be entered for all sequences where master file information is submitted.	
MD Medical Devices	Depending on whether the eCTD application is a device application or a conformity assessment, the prefix should be DA or DC. Example: `DA-2017-12345-1`.	

eCTD Attributes Canada

You can use the following attributes to describe eCTD submissions for Canada.

Canada-v2.2

Attribute	Description
Applicant	The company that is submitting the regulatory transaction.
Dossier Identifier	The unique identifier assigned to the dossier by Health Canada. The Dossier Identifier is 7 characters: a lower case letter followed by 6 digits.
Dossier Type	The dossier type: Biologic Dossier, Drug Master File Dossier, or Pharmaceutical Dossier.
Product Name	The product or products that are being addressed in the application
Regulatory Activity Lead	Defines which group within Health Canada is expected to take the lead in reviewing the regulatory activity supported by the regulatory transaction.
Regulatory Activity Type	The type of regulatory activity: i.e. what regulatory purpose the filing is addressing.
Related Sequence Number	The four digit sequence number of the first sequence in the regulatory activity.
Sequence Number	The four digit number that is the unique identifier for the sequence (regulatory transaction) inside the overall dossier.
Sequence Description	The description of the sequence (regulatory transaction) based upon a series of possibilities defined by Health Canada.

eCTD Attributes China

You can use the following attributes to describe eCTD submissions for China.

China-v1.0

Attribute	Description
Application Number	Unique identification number for an application in its full lifecycle, assigned by the regulatory agency. The applicant obtains the application number from the regulatory agency when it submits eCTD applications for IND, NDA, ANDA for the first time. The application number format: Letter (x = NDA; y = ANDA; l = IND) + year (4 digits) + 5 digit serial number. Example: x201912345.
Application Type	Describes the application purpose. Example: IND, NDA, ANDA

Attribute	Description
Product Type	Describes the product classification information. Example: Chemical Product, Biological Product.
Original Number	The basic and permanent number given to a drug entering the registration approval process. The original number is assigned by the regulatory agency and is used as the unique code to identify the applicant, active ingredient (API), and dosage form. The original number format: year (4 digits) + 6-digit serial number. Example: *2019123456*.
Related Sequence	Used to group the sequences in one application according to the regulatory activity. The first sequence in one regulatory activity is the related sequence for all other sequences submitted in the regulatory activity.
Regulatory Activity Type	Describes the purpose of the regulatory activity.
Sequence Number	A unique 4-digit character string in the application, a unique identifier that distinguishes different submitted sequences. The applicant shall submit the application from 0000 and the sequence number shall be incremented by 1 for each submission. The application shall be submitted based on sequence.
Sequence Type	Describes the purpose of the sequence.
Sequence Description	Brief description of the sequence purpose, used to distinguish the sequence of similar type. The sequence description length shall be controlled within 120 Chinese characters. The sequence description shall not substitute the reply and cover letter to the request raised by the regulatory agency, and shall not be used to raise questions to the regulatory agency.
Sequence Contact Name	Name of the contact person responsible for the sequence.
Sequence Contact Telephone	Telephone number of the contact person responsible for the sequence.
Sequence Contact Email	Email address of the contact person responsible for the sequence.

eCTD Attributes EAEU

You can use the following attributes to describe eCTD submissions for the EAEU.

EAEU-v.1.0

Attribute	Description
Country	List of country codes associated to the EAEU region.
EDoc Id	Electronic Document ID. UUID format.
EDoc Reference Id	Electronic Document ID of the document the current document is referred to. UUID format.
EDoc Date Time	Creation timestamp. Date of the assembly creation. Date format - Unix Timestamp.
Registration Number Id	Registration Number. Six digits.
Application Id	Application Id.
Registration Kind Code	Defines a procedure: — 01 – mutual recognition: MRP. — 02 - decentralized: DCP.
Submission Sequence	Defines a current sequence code for all the leafs in the assembly. Four digits.

eCTD Attributes European Union

European Union-v2.0

Attribute	Description
Agency Name	The name of the receiving agency for the submission. The default is based on the country for the application.
Applicant	The name of the company submitting the eCTD.
Application Tracking Number	The number used by an agency or applicant to track the submission, in any procedure, in relation to a particular product. There must be at least one tracking number identified from the regulators. The applicant can choose to include an internal tracking number.
Country	The country to which the envelope applies (or 'ema'). The default is the country of the application.
High Level/ Worksharing Submission Number	The high-level submission number, either a 'worksharing' number or the high-level submission number to be used when grouping Type IA variations for multiple marketing authorisations. It is used when the submission mode is either Grouping or Worksharing.
INN	International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients.
Invented Name	The name of the medicinal product.

Attribute	Description
Procedure Type	The type of procedure for the submission. The default is based on the application Country.
Related Sequence	The sequence number(s) of previous submission(s) to which this submission relates.
Sequence	The sequence number of the submission.
Submission Description	The description of the submission to be included in the XML.
Submission Mode	The mode of the submission, either Single, Grouping, or Worksharing. The submission mode should only be used in variation or line extension regulatory activities and must be included in every sequence of that activity.
Submission Type	The type of submission material sent to the regulatory agency.

European Union-v3.0

Attribute	Description
Agency Name	The name of the receiving agency for the submission. The default is based on the country for the application.
Applicant	The name of the company submitting the eCTD.
Application Tracking Number	The number used by an agency or applicant to track the submission, in any procedure, in relation to a particular product. There must be at least one tracking number identified from the regulators. The applicant can choose to include an internal tracking number.
Country	The country to which the envelope applies (or 'ema'). The default is the country of the application.
High Level/ Worksharing Submission Number	The high-level submission number, either a 'worksharing' number or the high-level submission number to be used when grouping Type IA variations for multiple marketing authorisations. It is used when the submission mode is either Grouping or Worksharing.
INN	International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients.
Invented Name	The name of the medicinal product.
Procedure Type	The type of procedure for the submission. The default is based on the application Country.
Related Sequence	The sequence number(s) of previous submission(s) to which this submission relates.
Sequence	The sequence number of the submission.

Attribute	Description
Submission Description	The description of the submission to be included in the XML.
Submission Mode	The mode of the submission, either Single, Grouping, or Worksharing. The submission mode should only be used in variation or line extension regulatory activities and must be included in every sequence of that activity.
Submission Type	The type of submission material sent to the regulatory agency.
Submission Unit Type	Submission unit type describes the content at a lower level (a “sub-activity”) which is submitted in relation to a defined regulatory activity.
UUID	A UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 | ISO/IEC 9834-8:2005. The same UUID is used for all sequences of an eCTD applications. UUID is a universal unique identifier. Through the eCTD wizard, users with appropriate permissions are able to modify the UUID to support Sequences that may require a different UUID than the remainder of the Application. In most cases, the UUID value should not change.

European Union-v3.0.1

Attribute	Description
Agency Name	The name of the receiving agency for the submission. The default is based on the country for the application.
Applicant	The name of the company submitting the eCTD.
Application Tracking Number	The number used by an agency or applicant to track the submission, in any procedure, in relation to a particular product. There must be at least one tracking number identified from the regulators. The applicant can choose to include an internal tracking number.
Country	The country to which the envelope applies. The default is the country of the application.
High Level/ Worksharing Submission Number	The high-level submission number, either a 'worksharing' number or the high-level submission number to be used when grouping Type IA variations for multiple marketing authorisations. It is used when the submission mode is either Grouping or Worksharing.
INN	International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients.
Invented Name	The invented name of the medicinal product which is submitting for an approval.
Procedure Type	The type of procedure for the submission. The default is based on the application Country.

Attribute	Description
Related Sequence	The sequence number(s) of previous submission(s) to which this submission relates.
Sequence	The sequence number of the submission.
Submission Description	The description of the submission to be included in the XML.
Submission Mode	The mode of the submission, either Single, Grouping, or Worksharing. The submission mode should only be used in variation or line extension regulatory activities and must be included in every sequence of that activity.
Submission Type	The type of submission material sent to the regulatory agency.
Submission Unit Type	Submission unit type describes the content at a lower level (a “sub-activity”) which is submitted in relation to a defined regulatory activity.
UUID	A UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 | ISO/IEC 9834-8:2005. The same UUID is used for all sequences of an eCTD applications. UUID is a universal unique identifier. Through the eCTD wizard, users with appropriate permissions are able to modify the UUID to support Sequences that may require a different UUID than the remainder of the Application. In most cases, the UUID value should not change.

eCTD Attributes Gulf Cooperation Council

You can use the following attributes to describe eCTD submissions for Gulf Cooperation Council (GCC).

Gulf Cooperation Council-v1.2

Attribute	Description
Agency Name	The name of the receiving agency for the submission.
Applicant	The name of the company submitting the eCTD.
Application Number	The number issued for the sponsor and the product by the GCC (Gulf Cooperation Council). The Application Number remains from the first data submission for the full lifecycle of the product. Multiple comma-separated values can be provided.
ATC	The ATC (Anatomical Therapeutic Chemical) code. Multiple comma-separated values can be provided.
Country	The GCC country for which the envelope information is related.
INN	The International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. Multiple comma-separated values can be provided.

Attribute	Description
Invented Name	The name of the medicinal product. Multiple comma-separated values can be provided.
Procedure Type	The procedure type for the product. Available values: gcc, national
Related Sequence	The sequence number of a previous submission to which this submission relates. Multiple comma-separated values can be provided.
Sequence	The sequence number of the submission. The default is from the Sequence Code, but can be overridden.
Submission Description	The description of the Submission to be included in the XML.
Submission Type	The filing type of the submission.

Gulf Cooperation Council-v1.5

Attribute	Description
Agency Name	The name of the receiving agency for the submission.
Applicant	The name of the company submitting the eCTD.
Application Number	The number issued for the sponsor and the product by the GCC. The Application Number remains from the first data submission for the full lifecycle of the product. Multiple comma-separated values can be provided.
ATC	The ATC (Anatomical Therapeutic Chemical) code. Multiple comma-separated values can be provided.
Country	The GCC country for which the envelope information is related.
INN	The International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. Multiple comma-separated values can be provided.
Invented Name	The name of the medicinal product. Multiple comma-separated values can be provided.
Procedure Type	The procedure type for the product. Available values: gcc, national
Related Sequence	The sequence number of a previous submission to which this submission relates. Multiple comma-separated values can be provided.
Sequence	The sequence number of the submission. The default is from the Sequence Code, but can be overridden.
Submission Description	The description of the Submission to be included in the XML.
Submission Type	The filing type of the submission.

Attribute	Description
Submission Unit Type	The actions within the regulatory activity (initial submission, update, responses to questions, any additional information or consolidation submission respectively when closing a regulatory activity).

eCTD Attributes Japan

You can use the following attributes to describe eCTD submissions for Japan.

Japan-v1.0

Attribute	Description
Applicant	The name of the entity presenting the submission.
Brand Name	The marketing name for the product.
Generic Name	The generic name for the product.
Operation	The operation used for the submission (for example, new, append, replace).
Sequence Number	The number for the initial sequence for filing.
Submission Date	The effective date for the submission.
Submission Number	The number used to identify the submission, must be numeric. See Application Code Guidelines.
Submission Type	The filing type of the submission.

eCTD Attributes Jordan

You can use the following attributes to describe eCTD submissions for Jordan.

Jordan-v1.0.2.

Attribute	Description
Country	Country Code
Application Reference Number	Element for the reference number of the product as taken from eJDWS. Multiple comma-separated values can be provided.
Number	Reference number of the product allocated by the regulatory authority. If the number is not yet allocated at the time point of submission, 'to be advised' should be added instead and replaced by the number in follow-up submissions when registered.

Attribute	Description
UUID	UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 | ISO/IEC 9834-8:2005. The same UUID is used for all sequences of an eCTD Application. UUID is a universal unique identifier. Using the eCTD wizard, users with appropriate permissions are able to modify the UUID to support Sequences that may require a different UUID than the remainder of the Application. In most cases, the UUID value should not change.
Applicant	Name of the company submitting the eCTD.
Agency	Name of the receiving agency for the submission.
MAH	Marketing Authorisation Holder.
ATC	ATC (Anatomical Therapeutic Chemical) code. Multiple comma-separated values can be provided.
Submission Type	Filing type of the submission.
Submission Unit	Actions within the regulatory activity: initial submission, update, responses to questions, any additional information or consolidation submission respectively when closing a regulatory activity.
Procedure	Procedure type for the product. Available values: jo, national.
Invented Name	Name of the medicinal product. Multiple comma-separated values can be provided.
INN	International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. Multiple comma-separated values can be provided.
Sequence	Sequence number of the submission. The default is from the Sequence Code, but can be overridden.
Related Sequence	Sequence number of a previous submission to which this submission relates. Multiple comma-separated values can be provided.
Submission Description	Description of the Submission to be included in the XML.

Jordan-v1.1.

Attribute	Description
Country	Country Code
Application Reference Number	Element for the reference number of the product as taken from eJDWS. Multiple comma-separated values can be provided.

Attribute	Description
Number	Reference number of the product allocated by the regulatory authority. If the number is not yet allocated at the time point of submission, 'to be advised' should be added instead and replaced by the number in follow-up submissions when registered.
UUID	UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 | ISO/IEC 9834-8:2005. The same UUID is used for all sequences of an eCTD Application. UUID is a universal unique identifier. Using the eCTD wizard, users with appropriate permissions are able to modify the UUID to support Sequences that may require a different UUID than the remainder of the Application. In most cases, the UUID value should not change.
Applicant	Name of the company submitting the eCTD.
Agency	Name of the receiving agency for the submission.
MAH	Marketing Authorisation Holder.
ATC	ATC (Anatomical Therapeutic Chemical) code. Multiple comma-separated values can be provided.
Submission Type	Filing type of the submission.
Submission Unit	Actions within the regulatory activity: initial submission, update, responses to questions, any additional information or consolidation submission respectively when closing a regulatory activity.
Procedure	Procedure type for the product. Available values: jo, national.
Invented Name	Name of the medicinal product. Multiple comma-separated values can be provided.
INN	International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. Multiple comma-separated values can be provided.
Sequence	Sequence number of the submission. The default is from the Sequence Code, but can be overridden.
Related Sequence	Sequence number of a previous submission to which this submission relates. Multiple comma-separated values can be provided.
Submission Description	Description of the Submission to be included in the XML.

eCTD Attributes Switzerland

You can use the following attributes to describe eCTD submissions for Switzerland.

Switzerland-v1.2

Attribute	Description
Agency	The name of the receiving agency for the submission: Swissmedic
Applicant	The name of the company submitting the eCTD. Entered as "n/a" (case sensitive) if the submission is a DMF (Drug Master File) or PMF (Plasma Master File).
Application Number	The application number as provided by the agency. Multiple comma-separated values can be provided.
DMF Holder	The name of the company submitting the DMF. Entered as "n/a" (case sensitive) if the submission is not a DMF.
DMF Number	The number assigned to the DMF. Entered as "pending" (case sensitive) if the assigned DMF number is not known. Entered as "n/a" (case sensitive) if the submission is not a DMF.
INN	International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. Multiple comma-separated values can be provided.
Invented Name	The name of the medicinal product. Enter an invented name even if it is not yet definitive. Entered as "pending" (case sensitive) only as a last choice. Multiple comma-separated values can be provided.
Paragraph 13 TPA	Identifies the submission as Paragraph 13 TPA.
PMF Holder	The name of the company submitting the PMF. Entered as "n/a" (case sensitive) if the submission is not a PMF.
PMF Number	The number assigned to the PMF. Entered as "pending" (case sensitive) if the assigned PMF number is not known. Entered as "n/a" (case sensitive) if the submission is not a PMF.
Related Sequence	The sequence number of a previous submission to which the submission is related. Enter the numeric value (must have 4 digits) or, if there is no related sequence, enter "none" (case sensitive). Multiple comma-separated values can be provided.
Sequence Number	The sequence number of the submission. The default is from the sequence code, but can be overridden.
Submission Description	The description of the submission to be included in the XML.
Submission Type	The type of procedure for the submission.

Switzerland-v1.3

Attribute	Description
Agency	The name of the receiving agency for the submission: Swissmedic

Attribute	Description
Applicant	The name of the company submitting the eCTD. Entered as "n/a" (case sensitive) if the submission is a DMF (Drug Master File) or PMF (Plasma Master File).
Application Number	The application number as provided by the agency. Multiple comma-separated values can be provided.
DMF Holder	The name of the company submitting the DMF. Entered as "n/a" (case sensitive) if the submission is not a DMF.
DMF Number	The number assigned to the DMF. Entered as "pending" (case sensitive) if the assigned DMF number is not known. Entered as "n/a" (case sensitive) if the submission is not a DMF.
INN	International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. Multiple comma-separated values can be provided.
Invented Name	The name of the medicinal product. Enter an invented name even if it is not yet definitive. Entered as "pending" (case sensitive) only as a last choice. Multiple comma-separated values can be provided.
Paragraph 13 TPA	Identifies the submission as Paragraph 13 TPA.
PMF Holder	The name of the company submitting the PMF. Entered as "n/a" (case sensitive) if the submission is not a PMF.
PMF Number	The number assigned to the PMF. Entered as "pending" (case sensitive) if the assigned PMF number is not known. Entered as "n/a" (case sensitive) if the submission is not a PMF.
Related Sequence	The sequence number of a previous submission to which the submission is related. Enter the numeric value (must have 4 digits) or, if there is no related sequence, enter "none" (case sensitive). Multiple comma-separated values can be provided.
Sequence Number	The sequence number of the submission. The default is from the sequence code, but can be overridden.
Submission Description	The description of the submission to be included in the XML.
Submission Type	The type of procedure for the submission.

Switzerland-v1.4

Attribute	Description
Agency	The name of the receiving agency for the submission: Swissmedic
Applicant	The name of the company submitting the eCTD. Entered as "n/a" (case sensitive) if the submission is a DMF (Drug Master File) or PMF (Plasma Master File).

Attribute	Description
Application Number	The application number as provided by the agency. Multiple comma-separated values can be provided.
DMF Holder	The name of the company submitting the DMF. Entered as "n/a" (case sensitive) if the submission is not a DMF.
DMF Number	The number assigned to the DMF. Entered as "pending" (case sensitive) if the assigned DMF number is not known. Entered as "n/a" (case sensitive) if the submission is not a DMF.
INN	International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. Multiple comma-separated values can be provided.
Invented Name	The name of the medicinal product. Enter an invented name even if it is not yet definitive. Entered as "pending" (case sensitive) only as a last choice. Multiple comma-separated values can be provided.
Paragraph 13 TPA	Identifies the submission as Article 13 TPA.
PMF Holder	The name of the company submitting the PMF. Entered as "n/a" (case sensitive) if the submission is not a PMF.
PMF Number	The number assigned to the PMF. Entered as "pending" (case sensitive) if the assigned PMF number is not known. Entered as "n/a" (case sensitive) if the submission is not a PMF.
Related Sequence	The sequence number of a previous submission to which the submission is related. Enter the numeric value (must have 4 digits) or, if there is no related sequence, enter "none" (case sensitive). Multiple comma-separated values can be provided.
Sequence Number	The sequence number of the submission. The default is from the sequence code, but can be overridden.
Submission Description	The description of the submission to be included in the XML.
Submission Type	The type of procedure for the submission.

Switzerland-v1.5

Attribute	Description
Agency	The name of the receiving agency for the submission: Swissmedic
Applicant	The name of the company submitting the eCTD. Entered as "n/a" (case sensitive) if the submission is a DMF (Drug Master File) or PMF (Plasma Master File).
Application Number	The application number as provided by the agency. Multiple comma-separated values can be provided.

Attribute	Description
DMF Holder	The name of the company submitting the DMF. Entered as "n/a" (case sensitive) if the submission is not a DMF.
DMF Number	The number assigned to the DMF. Entered as "pending" (case sensitive) if the assigned DMF number is not known. Entered as "n/a" (case sensitive) if the submission is not a DMF.
INN	International Nonproprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. Multiple comma-separated values can be provided.
Invented Name	The name of the medicinal product. Enter an invented name even if it is not yet definitive. Entered as "pending" (case sensitive) only as a last choice. Multiple comma-separated values can be provided.
Article 13 TPA	Identifies the submission as Article 13 TPA.
PMF Holder	The name of the company submitting the PMF. Entered as "n/a" (case sensitive) if the submission is not a PMF.
PMF Number	The number assigned to the PMF. Entered as "pending" (case sensitive) if the assigned PMF number is not known. Entered as "n/a" (case sensitive) if the submission is not a PMF.
Related Sequence	The sequence number of a previous submission to which the submission is related. Enter the numeric value (must have 4 digits) or, if there is no related sequence, enter "none" (case sensitive). Multiple comma-separated values can be provided.
Sequence Number	The sequence number of the submission. The default is from the sequence code, but can be overridden.
Submission Description	The description of the submission to be included in the XML.
Submission Type	The type of procedure for the submission.

eCTD Attributes South Africa

You can use the following attributes to describe eCTD submissions for South Africa.

South Africa-v1.0

Attribute	Description
Applicant	The name of the applicant/HCR (Holder of Certificate of Registration) submitting the eCTD.
Application Number	The number issued for the product by the MCC (Medicines Control Council). The Application Number remains from the first data submission for the full lifecycle of the product. Multiple comma-separated values can be provided.

Attribute	Description
Dosage Form	The dosage form of the medicinal product. Multiple comma-separated values can be provided.
Duplicated Applications (Proprietary Names/ Dates of Application)	The name of the multiple/duplicate applications of the medicinal product (include, even if the name is not yet approved) plus the application date of the duplicate applications. Multiple paired values can be provided.
eCTD Sequence	The sequence number of the data submission. The default is from the Sequence Code, but can be overridden.
INN	The INN of the API(s) accompanied by its salt or hydrate form (if relevant) or chemical description of the API(s). Multiple comma-separated values can be provided.
Proof of Efficacy	The data type submitted as proof of efficacy, and a description of the data type if "other" is selected as data type. Multiple paired values can be provided.
Proprietary Name	The name of the medicinal product. Include even if not yet approved. Multiple comma-separated values can be provided.
Related Sequence	The sequence number of a previous submission to which the submission relates. Multiple comma-separated values can be provided.
Submission Type	The type of regulatory submission to which the data submission relates.

South Africa-v2.1

Attribute	Description
Applicant	The name of the applicant/HCR (Holder of Certificate of Registration) submitting the eCTD.
Application Number	The number issued for the product by the MCC (Medicines Control Council). The Application Number remains from the first data submission for the full lifecycle of the product. Multiple comma-separated values can be provided.
Dosage Form	The dosage form of the medicinal product. Multiple comma-separated values can be provided.
Duplicated Applications (Proprietary Names/Application Numbers)	The name of the multiple/duplicate applications of the medicinal product (include, even if the name is not yet approved) plus the application number(s) of the duplicate applications. Multiple paired values can be provided.
eCTD Sequence	The sequence number of the data submission. The default is from the Sequence Code, but can be overridden.

Attribute	Description
INN	The INN of the API(s) accompanied by its salt or hydrate form (if relevant) or chemical description of the API(s). Multiple comma-separated values can be provided.
Proprietary Name	The name of the medicinal product. Include even if not yet approved. Multiple comma-separated values can be provided.
Related Sequence	The sequence number of a previous submission to which the submission relates. Multiple comma-separated values can be provided.
Submission Type / Proof of Efficacy	The type of regulatory submission to which the data submission relates followed. The type of regulatory submission is followed by data type submitted as proof of efficacy, and a description of the data type if "other" is selected as data type. Multiple paired values can be provided for the Proof of Efficacy, each bound to the specific submission type.

eCTD Attributes Thailand

You can use the following attributes to describe eCTD submissions for Thailand.

Thailand-v0.92

Attribute	Description
eSubmission Identifier	The Application Number as provided by the agency.
INN/Generic Name	The INN or Generic Name of the active ingredients used in the product. Multiple comma-separated values can be provided.
Licensee	The licensee name that is legally responsible for the application in Thailand.
Product Name	The name or proposed product (trade) name to be used on the Certificate of Registration. Multiple comma-separated values can be provided.
Regulatory Activity Lead	Identifies the group within the THAI FDA which is expected to take the lead in the review process.
Related Sequence Number	Four digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity.
Sequence Description	Free text description of the submission. The description provided here should also be used in the node title for 1.0 Cover Letter and 1.R Response to Questions.
Sequence Number	Four digit sequence number matching the sequence folder being submitted.
Sequence Type	Identifies the type of activity that is being submitted with the sequence, either the regulatory activity type if it is the first sequence of the regulatory activity or supplementary information if it is a follow-up to information already submitted for the regulatory activity.

Thailand-v1.0

Attribute	Description
Contact Email	The email address used to notify the applicant of a change in application status.
eSubmission Identifier	The Application Number as provided by the agency.
INN/Generic Name	The INN or Generic Name of the active ingredients used in the product. Multiple comma-separated values can be provided.
Licensee Name	The licensee name that is legally responsible for the application in Thailand.
Licensee Number	The licensee number of the company that is legally responsible for the application in Thailand.
Licensee Type	The licensee type of Licensee Number for the application in Thailand.
Product Name	The name or proposed product (trade) name to be used on the Certificate of Registration. Multiple comma-separated values can be provided.
Regulatory Activity Lead	Identifies the group within the THAI FDA which is expected to take the lead in the review process.
Related Sequence Number	Four digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity.
Sequence Description	Free text description of the submission. The description provided here should also be used in the node title for 1.0 Cover Letter and 1.R Response to Questions.
Sequence Number	Four digit sequence number matching the sequence folder being submitted.
Sequence Type	Identifies the type of activity that is being submitted with the sequence, either the regulatory activity type if it is the first sequence of the regulatory activity or supplementary information if it is a follow-up to information already submitted for the regulatory activity.

eCTD Attributes United States

You can use the following attributes to describe eCTD submissions for the United States.

United States-v2.01

Attribute	Description
Application Number	The number assigned to the application.
Application Type	The type of the application.
Company Name	The company presenting the submission.
Product Name	The product or products that are being addressed in the application.

Attribute	Description
Related Sequence Number	Any sequence related to the registered product name. Click Add to create additional rows for adding more related sequences.
Sequence Number	The number for the initial sequence for filing.
Submission Date	The effective date for the submission.
Submission Type	The type of the submission.

United States-v3.3

Attribute	Description
Applicant Contact	The Applicant Contact for the submission.
Applicant ID	The D-U-N-S® number identifier for the business entity that is the sponsor, applicant, or holder of the submission.The same D-U-N-S number should be used for all submissions to an application, unless there is a change in ownership of the application. The default value is taken from the Application level value. If not defined at the Application level, the default for United States region in Data Administration is used.
Application Contains Files?	Indicates if the application contains the files in a grouped submission.
Application Number	The application number provided by the agency.
Application Type	The type of application.
Company Name	The sponsor or applicant name.
Cross-Reference Application	The application number and type of cross-reference applications. Should only be provided when an application makes reference to other application. Multiple paired values can be provided.
Sequence Number	The sequence number of the submission. It should start at 0001, and should not exceed 9999.
Submission Description	The description of the submission to be included in the XML.
Submission ID	The sequence number of the first submission that refers to the same regulatory activity as the sequence that is being submitted.
Submission Sub-Type	The filing/submission sub-type for the submission. Dependent on the value selected for Submission Type.
Submission Type	The filing/submission type for the submission. Dependent on the selected Application Type.
Supplement Effective Date Type	The supplement effective date type for the submission. Dependent on the selected Submission Type.

Repeatable Assembly Sections

The eCTD assembly contains repeatable sections and captures section-specific metadata for their associated extended type.

Assembly section number	Assembly section name	Associated extended type
1.15.2.1	Material	Promotional Material Type
N/A	Galenic Form	CH Galenic Form
2.3.S	Drug Substance	Drug Substance
2.3.P	Drug Product	Drug Product
2.7.3	Clinical Indication	Clinical Indication
3.2.S	Drug Substance	Drug Substance
3.2.P	Drug Product	Drug Product
3.2.P.4	Excipient	Excipient
3.2.A.1	Quality Appendix	Quality Appendix
3.2.A.2	Quality Appendix	Quality Appendix
3.2.A.3	Excipient	Excipient
5.3.5	Clinical Indication	Clinical Indication

Submission Metadata

You can use the attributes to enter submission metadata on the *Set Submission Metadata* page in the *Create eCTD* wizard.

Metadata	Description
Dosage Form	The dosage form (e.g.: liquid, capsules).
Drug Product Manufacturer	Enter the name of the manufacturer for the marketing name product.
Drug Product Name	The Marketing Name for the product.
Drug Substance Manufacturer	The name of the manufacturer for the active ingredient of the product.
Drug Substance Name	The active ingredient for the product.
Excipient	The nonactive substance for the product.
Galenic Form Name	The name of the galenic form.
Galenic Language Name	The language of the galenic form.
Galenic Language Text	The galenic language text.
Indication	The disease or medical problem for which the drug is used.

Metadata	Description
Manufacturer	The name for the marketing manufacturer.
Product Name	The marketing name for the product.
Promotional Material ID	The applicant identification code or other designation of the specific promotional material.
Promotional Material Type	Defines the promotional material document type.
Substance	The active ingredients for the product.
SwissMedic Number	The number for the galenic form from the SwissMedic agency. 5-digits, or 'pending'.
Update the sub-folder structure for	If selected, set submission structure for selected nodes is updated with missing folders and their children. If no folders are missing but leaf elements are missing in the assembly, the update has no effect. The wizard checks for folders only.

Create Study Reports

The Create Study Reports wizard enables you to add study report structures (folders and leaf elements) to an existing eCTD or CTD. You can run the wizard one or more times as you obtain information about the study reports to include in the assembly.

Note: *The* Create Study Reports *wizard does not support EAEU submissions.*

The wizard is designed to be run after using the Create eCTD wizard, but you can use it any time after an eCTD is created. It enables you to do the following:

— Insert the appropriate study reports into an existing sequence or standalone assembly based on specification, template configuration, and user selections
— Insert a study report into an assembly structure with selected or confirmed metadata

Before creating a study report:

— An assembly must already exist and cannot be locked.
— The XML definitions must be applied for the assembly in the publishing settings.

Use the Create Study Report Wizard

The *Create Study Reports* wizard enables you to add study report structures (folders and leaf elements) to an existing eCTD or CTD. You can run the wizard one or more times as you obtain information about the study reports to include in the assembly.

Note: *The* Create Study Reports *wizard does not support EAEU submissions.*

To create a study report:

1. In the selected eCTD assembly, choose Wizards > Create Study Reports.
   The *Create Study Reports* wizard appears and the *Select Subsections* page lists the available report sub-sections.
2. Select the sub-section options to include in your study report.
   - To use the default values specified in the template, select Default Study Report Values from Template.
   - To copy the TOCs and special sheets from the template, select Copy TOCs and Special Sheets.
   - Select the individual folders and subfolders for the eCTD.
   - To remove a section, select it.
   - For existing standalone, lifecycle or non-lifecycle sequence assemblies, any section folders that already exist in the assembly are not available.
   - Selecting a top-level section automatically includes all the subsections for that folder.

   Note: *In the* Create Study Reports *wizard, if you click* Back *to return to the* Select Sub-Sections *page your checkbox selections are not retained.*
3. Click Next.
   The *Enter Quantities* page appears.
4. Enter the study report quantities per subsection.
5. Click Next.
   The *Enter Properties* page appears.
6. To add study reports to Indication folders, select the Update the sub-folder structure for 5.3.5 Reports of Efficacy and Safety Studies option specific to the indication folder.
   The study reports are added to the selected Indication folders. If no Indication folders are selected, an error is shown.
7. Enter the property values for the study report. These values are normally populated automatically based on the template.
   - A Study Name value is initially populated with the name of the section that it is in. You must change the name value to avoid having folders in the section with the same name as the section.
   - If you selected Default Values from Template, any changes you make to the metadata that would reflect a deviation from the metadata values in the template are ignored when you complete the wizard.
8. Click Next.
   The *Confirmation* page appears, confirming the information has been saved permanently to the assembly.
9. Click Next.
   The Summary page appears.
10. Click Finish.

Publish Submissions

Calyx RIM offers several publishing options for assemblies.
You can publish an assembly, in whole or in part, to the electronic output channel, to the paper output channel, or to both.

EAEU Submissions Publish

EAEU submission has specific publishing rules that differ from other eCTD submissions.
The specific things you must be aware of:

1. Calyx RIM 7.0 enables you to publish XML with PDF files placed nearby. For using the PDFs built into XML, use the export functionality. See *Export a Published Submission*.
2. You must populate Document Creation Date for every leaf in the assembly.

   Note: *To define the same date for the set of leafs, use the* Mass Update Properties *functionality.*

3. EAEU output has no `util` folder.
4. As there is no stylesheet provided, raw XML is displayed if it is opened in a web browser.
5. To keep the submission format required by a regulatory agency for EAEU submissions, XML validation is disabled at the process of publishing.

Electronic Publish

There are a number of ways you can create electronic output. You will need to determine which options to select based on your publishing needs. These needs are likely to change throughout your submission process.
You can create different kinds of electronic output, including:

— Leaf elements
— eCTD XML
— A single file

Leaf Elements

When you publish leaf elements, you create a PDF file for each standard leaf. Calyx RIM creates a file in the native format (for example, Microsoft Word) for any published leaf elements that were flagged in the assembly to use the native file. You can choose to publish a full set or a subset of leaf elements in the assembly. You can use the `Leaf Status` values to identify the leaf elements in an assembly that need to be published.

eCTD XML

Calyx RIM is designed to publish eCTD XML. You have the ability to publish an eCTD XML backbone independently, or in conjunction with publishing leaf elements.

Single File Output

Publishing to single file output is by its nature an electronic publish, not paper. When publishing to a single file, all electronic output including sheets (TOCs, cover pages, etc.) and documents outside of the leaf are published, with the exception of native files. If a document belongs to a native leaf, it is not be included in the single file output.

Single file report publishing to paper or electronic ignores the location from where it was run; the entire assembly is always published in these cases. A single output PDF file is created by the publishing engine. Unlike electronic or paper publishing, this option is not sensitive to the section from which the publish was executed.

Note: *For single file electronic output, elements both within and without leafs are included in the published output. Only native files are excluded from the published output. The leaf statuses selected in the* Publish Request *page do not affect the* Publish to a Single File *option, all leafs are included in the published output.*

Paper Publish

You can publish a CTD-compliant paper and paper reports. You can manipulate your assembly and publishing elements and effects to meet the requirements for your paper output.

For example you can separate content into paper volumes, create module and document levels, create tables of contents, use tab sheets, slip sheets, and cover pages, and create cross-reference stamps.

High-Speed Printer Support

Calyx RIM supports the use of a high-speed printer for printing the final output. Setting up the printer may require a specific configuration and this configuration may require certain printer attributes to accept the use of certain paper weights, sizes, tabs, colors and so on. For additional information and a complete list of compatible printers, see your system administrator.

Note: *If your printer supports the printing of special characters (UNICODE), Calyx RIM should be able to produce those characters specified in the publication.*

Publish Guidelines

Folders

You can avoid errors in your publishing jobs by following these guidelines.

— Some publishing attributes in folders may accept or require multiple values. Delimit multiple values for publishing attributes with commas.

Documents

— Some publishing attributes in documents may accept or require multiple values. Delimit multiple values for publishing attributes with commas.

— Encrypted PDFs can cause errors during publishing. An encrypted PDF cannot be concatenated with other files and may cause an error for that volume or leaf. For the paper output channel, you will need to remove the encryption prior to successfully publishing the document. For the electronic output channel, you can either remove the encryption, or simply change the Use Native File leaf attribute to Yes on the parent leaf.

— When output contains a PDF document which is under a leaf set with Use Native File, and then it is Published to a Single File, the TOC generates as expected in that the native leaf and PDF TOC are unchanged in a single file output.
— Documents in your assembly must be uniquely named in the document repository, relative to other documents in your assembly. If they cannot be uniquely named, they must be stored in uniquely named folders in the repository.

Warning: You should not attempt to manipulate or delete an assigned document or publishing element while it is being published.

Document Placeholders

— When publishing, document placeholders are flagged as errors, but the publish completes successfully. This is expected behavior.

Leaf Elements

— Some publishing attributes in leaf elements may accept or require multiple values. Delimit multiple values for publishing attributes with commas.
— Leaf elements that are to be created in the same output folder cannot have the same output file name. If two leaf elements have the same output file name and are in different folders that have the same output folder locations, the publish log reports duplicate folder/file paths.
— The Output File attribute must have a value. The file name must include the appropriate extension (for example, `outputfile.pdf`). The submission cannot be published without a file name.
— The Output File attribute must include the correct extension. For example, when you choose Yes for the Use Native File attribute to publish a Word document and you enter `outputfile.pdf` for the Output Filename attribute, you cannot open the file with Acrobat. You can change the file name extension to .doc to open it in Word.
— If you choose Yes for the Use Native File attribute for a leaf element containing two or more non-PDF documents, a message warns you that Calyx RIM cannot concatenate non-PDF documents.
— If a leaf element contains multiple documents and one but not all the documents are encrypted or password protected, the output for the leaf comprises only the non-encrypted documents. The encrypted documents are overwritten by the non-encrypted documents.
— When a leaf element contains multiple encrypted documents, the final output comprises the last encrypted document in the leaf definition.
— The output file on a leaf must contain content. Otherwise, the following error will occur: unable to calculate attribute checksum for leaf...exception detected...access denied.
— If a volume break resides on the leaf you are deleting, you should move the volume break to the closest folder. Volume breaks that reside on a deleted leaf will not be published.

General Publish Considerations

Publishing helps you with your details in a formatted document. However, you must have file format for your document to be published.

When publishing from Calyx RIM, you should consider the following:

— PDF File format
— Document Structure
— Major and Minor Divisions
— Page Scaling and Overlays

PDF File Format

Calyx RIM publishes to PDF version 1.4 by default, which is compatible with Acrobat version 5 and later. This can be changed on an assembly-by-assembly basis within the Publishing Settings.

It is useful to understand Acrobat, the way PDF files are created and used, and the Adobe Acrobat products. You can find information about Acrobat at the Adobe Web site.

Note: *In certain cases, links created with Acrobat 8 or 9 will not resolve to the correct file if viewed with an earlier version of Acrobat (7 or previous). This is due to changes to the Adobe Acrobat PDF version that are not backwards compatible.*

Document Structure

A composite document, or document roll-up is an ordered list of files comprised of multiple subdocuments, each maintained in their own right. Calyx RIM is specifically designed to compile and publish these documents as single, seamless entities that are a complete package ready for printing, distributing or saving as separate documents. You can publish electronically, retaining the original structure of the document list. You can also define a complete folder hierarchy for this, which is independent of the original document locations.

The composite document can be thought of as having three key parts:

— The cover page comprises previously prepared sheets that are usually placed at the front of the document, for example, title and copyright information. Cover pages can be added anywhere in an assembly.
— The table of contents (TOC) is prepared from a TOC definition template that defines the layout of the TOC pages, and is compiled from a combination of assembly elements and document extracts or bookmarks held in the constituent documents. The TOC may have up to 20 levels and has no limit on the number of entries. All TOC entries can be automatically numbered. Calyx RIM can also automatically enter the page numbers and a series of roughly fifty page-counting variables associated with TOC entries. Several TOCs can appear in a single publication, each with its own scope of pages. Tables of equations, figures and tables can also be defined separately.
— The document, sometimes called body matter, comprises constituent documents or specified page ranges from within constituent documents. Documents may be in any format supported by rendering, but must be in a repository Calyx RIM can access. The resulting output is a new document, eCTD XML structure, set of volumes for printing, or set of electronic files in a folder hierarchy defined as part of the publish process. Page ranges are useful for dividing a single document into multiple pieces, and for omitting or replacing pages in a source document that do not apply. In the case of dividing a single document into multiple parts, all links between pages are maintained during publishing. When copying placeholders between assemblies, these page ranges are maintained. A complex document may consist of several volumes, each with its own TOC and with an overall master TOC. Any page in the output document can be overlaid by a previously designed overlay template. This provides for the addition to the document of custom headers and footers, watermarks and other information.

Different templates can be applied to the cover page, TOC and individual major divisions, minor divisions, volumes, folders, leafs elements, documents, and pages.

Keep in mind that any document that has security or requires a password will fail to render, and may cause a long delay as rendering attempts to complete.

Warning: While you can create documents that are children of other documents within the assembly, this is for viewing only and may cause issues during publish. To roll up documents under a leaf, simply include all documents in the proper order as children of the leaf.

Major and Minor Divisions

Any folder in the assembly can be set as a major or minor division. These divisions can represent modules, sections, items, parts, chapters, and other standard subdivisions of a publication, depending on the type that is published. These divisions are used for page counting and to support variables such as major division name and minor division number.

There are three major and minor division variables available to access the Name, Abbreviated Name, and Number of the previous folder of each division type:

Division name	Major division variable	Minor division variable
Name	*$MNAME*	*$NNAME*
Abbreviated Name	*$MABBR*	*$NABBR*
Number	*$MN*	*$NN*

— Name = *$MNAME*
— Abbreviated Name = *$MABBR*
— Number - *$MN*

These major division variables (*$MNAME*, *$MABBR*, *$MN*) resolve the corresponding attribute of the previous folder in the tree marked as a major division. The minor division variables, *$NNAME $NABBR*, *$NN*, resolve the corresponding attribute of the previous folder in the tree marked as a minor division. Major and minor divisions do not follow parent/child hierarchy, the previous major or minor division is the next one encountered in bottom-to-top order in the navigation tree. A major division also ends the current minor division. You can control the major and minor divisions on the folder attributes.

Any folder may be set with a major or minor division, but for standard publications the first level folder should be set as a major division, and the second level folder as the minor division, for example items and sections in a legacy electronic submission.

Note: *When using Major Division Relative Volume breaking and the default volume file naming format ($VOLNAME), the system will overwrite the volume named* `V000001.pdf` *for each major relative division it encounters. When using this scheme, you should either substitute or add an additional variable to the volume name format to prevent overwriting.*

For eCTD submissions, the first level folder is set to major division to represent the current module name and number, and each folder containing leaf elements is set to the minor division. In this way, any leaf may refer to the minor division to reference the current eCTD section.

In the following example, for a leaf in the 3 Quality folder, the minor division number $NN will be set to 3.2.P.4.1 and the major division name will always be set to Quality, as shown in this example:

3 Quality

3.2 Body of Data

3.2.P Drug Product

3.2.P.4 Control of Excipient (Non-Compendia)

3.2.P.4.1 Specifications

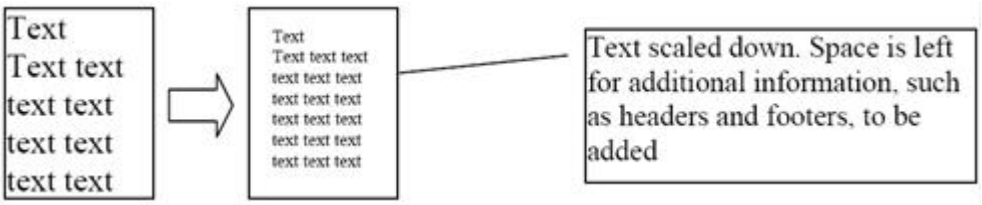
The minor division (*$NN*) resolves as expected, after the folder is set as minor division, and that number is then used for that element.

Page Size and Overlays

You can customize your electronic output by adding paper effects and setting a common page size.

With appropriate licensing, you can include some paper effects in electronic assemblies. Paper effects that might be appropriate for the electronic output channel include the following: TOCs, overlays and cover pages.

When publishing PDF content, Calyx RIM supports the normalization of final page sizes. The page size is automatically determined based on the output paper type. For example, if the constituent documents comprise both A4 and US sized paper, and the target output is A4, the US pages are scaled to fit. Calyx RIM enables you to scale down a page to a set of standard margins to leave space for additional information you might add, for example, headers and footers.



This enables you to use a single overlay for all page sizes in the publication. The overlay file can only be made smaller, so if you use this option, you must ensure that the overlay is at least as large as the largest page of your publication. For example, a US letter sized overlay applied to an A4 page will not be scaled to account for the longer dimension of the A4 page.

Overlay Handling

Selecting the best fit overlay option searches for the closest match in the overlay file on a page-by-page basis. If an exact match is not found, or you do not choose best fit, Calyx RIM rotates an overlay to get an exact or close match

for the page. If an exact match is not found with best-fit or rotation or neither has been set, then the closest match is scaled to fit.

— Selecting Best Fit overlays will increase the time to publish due to the extra processing required for matching each page. If the page size is known, this option should be avoided.
— Before publishing to different page sizes with overlays, you must define the appropriate page sizes in your overlays and have best fit enabled. If this is not properly set up in your overlay files, you may get improper stamps; Calyx RIM requires these settings in order to choose the correct overlay to fit the output page.

Publish Links

Intra-document links (links within documents) are treated differently by Calyx RIM than inter-document links (links between documents). These links are read into the Calyx RIM database during extraction but in many cases they should not be rewritten during publish time.

These links are often verified during document finalization and any manipulation of these in the final rendition would require additional quality control of the published output.

For this reason, any internal link set to the System Profile is not rewritten to documents during publishing unless absolutely necessary. The System Profile only writes inter-document links (because the relative paths have all changed) and writes intra-document links in cases where documents are split during publishing.

If you want the intra-document links to be rewritten, you must set all links to publish with a different link profile, one that you have defined in the assembly link settings. For paper cross-references, all links are rewritten during the process of stamping the final cross-reference text on the page.

Cross-References

Cross-references are the paper-publication equivalent of hyperlinks. Since output to paper does not contain hyperlinks, Calyx RIM stamps text in the right margin of the published documents. The text of these page stamps is defined for the link's profile in the link publishing settings.

Note: *By default, only inter-documents links are set to the paper output channel for the creation of a cross-reference.*

If there are too many cross-references to fit on one page, the stamps extend past the end of the page. You must reduce the number of cross-references so that they can all fit.

To use the cross-reference variables, you must first set up the variable publishing settings. After setting up the variable publishing settings, you can enter the variables enclosed in brackets on the applicable location. See the topic Calyx RIM variables more information about system, Calyx RIM, repository, and user-defined variables.

For cross-references, margin stamps appear in the right margin (regardless of page orientation) starting at the top and are listed sequentially down the page. The link box still exists but does not show in the paper copy output. The link box still works but it does not work outside the current volume. Each cross-reference is tagged with a number at the link box next to the referenced text and next to the margin page stamp.

Margin Stamp

Use the document overlay attributes to adjust the area used by the margin stamp. The document overlay settings control the allowable space used by margin stamps. Setting the Scale contents to margins option to Yes will scale the document to fit the parameters defined by the document overlay settings.

Note: *You are not required to set an overlay template file when setting document overlay margins.*

Prepare to Publish

Preparing to publish is an optional but recommended step in the publishing process. It is a flexible function that enables you to prepare your assembly for publishing.

Following are the publishing ways as follows:

— It ensures that you have all the files, renditions, and extractions that will be necessary for a successful publish.
— It updates data used in queries so you can see predicted issues.
— It refreshes your volume and page count information to ensure that your page number variables resolve correctly.

Note: *When using variables for tab text, certain variables cannot be used as they will not resolve: element number, element name, element title. Instead, it is recommended that you use the leaf number, leaf name, minor division number, and minor division name variables to represent the current tab location. If you use minor division variables, be sure to verify that minor divisions have been appropriately assigned to folders in the current assembly, or they will not resolve correctly and may cause previews to fail.*

Before you publish a submission, be sure that:

— All required fields are completed.
— All output filenames on leafs are completed.
— Leaf names are unique within an output folder.
— Reference leaf elements point to leaf elements that are not empty.
— eCTD Definition Files are defined in the Publication Settings.
— For paper output, at least one volume was created.
— For paper or electronic output, at least one document is assigned.

Failure to verify any of these items may result in a failed publish.

Run Prepare to Publish

Use the Prepare to Publish option to prepare your assembly for publishing.

To prepare to publish:

1. On the action toolbar, choose Prepare to Publish.
2. On the Prepare to Publish dialog box, select the options you want to perform for the publication.

Option	Description
Publishing Output Channel:	Choose Electronic or Paper output.
Generate Missing Renditions and Extractions:	You must have a license for Calyx RIM rendering and publishing services to generate missing renditions.
Remove Empty Assembly Folders:	This removes any empty folder elements from the assembly.
Remove Empty Assembly Leafs:	This removes any leaf elements that have no content from the assembly. It skips reference leaf elements and elements with metadata.
Prepare Cross-Reference Leafs:	This ensures that the checksum is correct and is available when you are publishing any cross-reference leafs that point to content outside of the current sequence.
Render Generated TOCs and Special Sheet Templates:	If TOCs or special sheets are missing, they are created.
Generate TOCs:	If you have not generated TOCs or if the TOC is outdated, this generates the TOCs. After generation is complete, the TOC is available as a Word document and can be previewed in Calyx RIM. (The text in the right column of a TOC will not resolve for a leaf element that has no document assigned.)
Generate Volumes:	If you have not inserted or locked volumes, this function recalculates all volumes in the assembly. If there are locked volumes in the assembly, this refreshes the page counts and volume names prior to publishing.
Update Volume Page Counts:	When selected, this function updates the page count for each volume within an assembly. The number is shown on the *Volume View* page as a Total Sheets/Pages attribute. It is also shown in brackets on the tooltip that appears on the Volume icon in the assembly.
Refresh Publishing Readiness Data:	This refreshes the information in the Publishing Readiness Report based on the selected output channel. To see the report, this must be run at least once.
Refresh Link Inspector Data:	This is required if you want to run the Link Inspector report. This is necessary to create in-process links or perform in-process link retargeting.
Refresh Link Inspector View:	Choose Current Sequence View Only (refreshes only the current sequence), or Entire Working Assembly (refreshes the current sequence and all previous sequences).

3. Click OK.
   A message indicates that some of the processes may take awhile.

4. Click OK.
5. Choose Go To > Job Requests to view the log file to check for any errors.

Cancel Prepare to Publish

You can cancel a Prepare to Publish action after the process is started. When canceled, the Prepare to Publish will complete the current phase and then stop, and no other selected Prepare to Publish phases will be run.
Use the following procedure to cancel a Prepare to Publish before it is completed.

To cancel a Prepare to Publish:

1. After Prepare to Publish has started, open GO TO > Job Requests.
2. On the *Job Requests* Search page, click Search.
3. On the *Search Results* page, find the row for your Prepare to Publish job in the list and click Cancel Job.
4. In the *Cancel Job* dialog box, click OK to cancel the Prepare to Publish.

Example

```
Phase 0: Prepare for Publish: constructs context
Phase 1: Validate and Remove Empty Content
Phase 2: Traverse and build context Phase 3A: Perform extractions
(concurrent with 3B)
Phase 3B: Perform renditions (concurrent with 3A)
Phase 4: Generate TOCs
Phase 5: Render and Extract Generated TOCs
Phase 6: Recalculate Checksums
Phase 7: Bulk Volumize and Refresh Volumes
Phase 8: Generate Auto TOCs on Volumes
Phase 9: Render and Extract generated auto TOCs on Volumes
Phase 10A: Generate Publish Readiness Report (concurrent with 10B)
Phase 10B: Generate Link Inspector Report (concurrent with 10A)
Phase 11: Finish Prepare for Publish: update statuses, determine overall
success
```

The Prepare to Publish phases (options) run in the order shown in the list (which can be seen in the Job Request page - phases that can run at the same time are labeled a/b of the same number). When the Prepare to Publish is canceled, the currently running phase will finish and then the Prepare to Publish will stop and any subsequent selected phases will not be executed. The exceptions to this are the pairs of phases, which must both be completed before the Prepare to Publish will be canceled.

Maximum Job Message Length

Be aware that some information in job messages is cut due to limit in characters. All job messages are truncated at 2000 characters. Because of this limit, you may not see the entire set of information that is generated by a job message.

For example, if you run Remove Empty Assembly Leaf Elements a job message listing all of the empty leafs and folders that were deleted is generated. Calyx RIM can only display the first 2000 characters in the job message, so you may not see the entire list of deleted empty leafs and folders.

Publishing Summary Query

The *Publishing Summary Query* displays the assembly elements in a tree hierarchy that you can export to a comma-separated file (CSV). You can import the CSV file into Microsoft Excel spreadsheet for further analysis.

The *Publishing Summary Query* displays each component in the assembly, its types and sub-types, and indicates leaf options:

— Whether a leaf has at least one child document
— Whether the leaf has any overridden attributes with renditions

Generate a Publishing Summary Query

The *Publishing Summary* Query displays the assembly elements in a tree hierarchy that you can export to a comma-separated file (CSV). You can import the CSV file into Microsoft Excel spreadsheet for further analysis.

To generate a Publishing Summary query:

1. Click a link for the assembly you want to publish.
2. From the action toolbar, choose Publishing Summary Query.
   The *Publishing Summary* query opens.
3. When you are finished reviewing the summary query, click Back.

Publishing Readiness Query

The Publishing Readiness Query enables you to view your assembly metadata at a glance and find predicted errors and warnings that may occur during publishing if an issue is not remedied.

The following information is included in the query results:

— The assembly name
— Element types and subtypes
— Default attributes that have been overridden
— Whether each leaf element includes at least one assigned document
— Whether documents are set to Use Native File
— Whether PDF renditions are available for each assigned document
— Output location information
— Number of bound documents and total documents

When you generate the query, you choose the columns that appear in the query results. You can export the query results to a Microsoft Excel spreadsheet for further analysis. The table in Publishing Readiness Query Attributes describes the information you can include in the query.

Warning: Always run a DMS Synchronization before refreshing the Publishing Readiness *query,* Link Inspector *query, and other queries. Calyx RIM uses the data available in the Calyx RIM database, and relies on DMS Synchronization to ensure this information matches what is in the DMS for each document.*

Publishing Readiness Query Filters

You use the filters in the Publishing Readiness query to return details about the assembly. The required filters are indicated by an asterisk (*).

Column	Description
Assembly *	The current assembly is selected by default. You can select the other assembly, if needed.
Query Type	The following types are available for selection: — Electronic — Paper The Electronic type is selected by default. Deselect, or add the other type, if needed.
Leaf Operation	The following operation types are available for selection: — append — delete — new — replace You can select multiple operations.
Object Type	All types are selected by default: — Cover Page — Document Folder — Leaf — Slip Sheet — Table of Contents — Volume You can deselect any type, if needed.
Filter on Elements that have Errors	The Yes and No values are available for selection, Yes is selected by default. You can change the value, if needed.
Display Columns *	You can select the columns you want to be displayed in the *Publishing Readiness Query* results. You also can change the columns order.

Column	Description
Sort Order	You can select how to sort the columns in the query results table. The values available for selection are: — The list of all columns with an ascending or descending options. For example: Element Type - DESC. — Order - ASC — Order - DESC The ascending order (Order - ASC) is selected by default. You can deselect or add the other types, is needed.

Publishing Readiness Query Attributes

You can use the attributes to describe the Publishing Readiness of an assembly. The attributes are valid for all elements of an assembly, unless otherwise noted.

Column Name	Description
Actual Page Count	The actual number of pages in the element.
All Pages Included	Indicates whether all pages in documents are to be published.
Application Version	An eCTD attribute.
Assembly Level	The relative level in the assembly where the element has been assigned. For example: the assembly root is 0, folders under the root are 1, the first element in folders is 2, and so on. Aligned TOCs and special sheets are assigned numerically, immediately after the element to which they are assigned in the order they appear, from left to right. Volumes are level 1 for a Paper Report Type, and folders are level 1 for an eCTD Report Type.
Element Empty	Indicates whether the folder or leaf element contains children. If a leaf or folder is empty, it is a candidate for deletion during Prepare To Publish. Leaf files are considered by the system to be empty when they are “default” type, as opposed to “reference” type. Default leafs are considered by the system to be empty when the leaf contains no child documents. — If a default type leaf contains a planned or placeholder document, it is considered not empty. — If a default type leaf has aligned TOCs or Special Sheets, it is still considered empty. — A Leaf Operation with a value of DELETE will be marked as empty, but will not be deleted as part of Prepare for Publishing (both eCTD and Paper). Valid for Folders and Leafs and Volumes.

Column Name	Description
Element Name	Inherited from the Element Name provided in the element attributes. If there is no “Element Name” the system provides a value of NA.
Element Number	Elements may contain an element number in addition to the element name, and sometimes instead of an element name. In these instances, an element number is provided. Element Number is valid for volumes, folders and leaf elements only. For leaf elements, the value should also contain the parent folder number.
Element Path	The location of the element in the assembly, including ancestry. (Element Path is similar in concept to "breadcrumbs".) Generations (levels in the assembly) are separated by backslashes (or some other character) in the Element Path. Valid for all elements except volumes.
Element Type	Describes the element. For example: Assembly Root, Folder, Leaf, Reference Leaf, Volume, Document, TOC, Cover Page, Tab, Slip Sheet, Placeholder.
Error and Warning Count	Indicates the number of errors detected.
Error and Warning Details	Detailed information about errors and warnings.
Extended Attributes	Lists extended attributes for the element.
Extended Subtype	Describes the subtype for the element.
Extracts Exist	The “Extracts Exist” value pertains to the system’s captured data about the document’s PDF Rendition bookmarks. This value is assigned by the system as a default value and can be overridden in document element attributes. — If the Extracts Exist value is set to Y (Yes), the system pulls the extracts from the PDF Rendition and populates those values for use in TOC generation. — If the Extracts Exist value is set to N (No), the system does not pull the extracts from the PDF Rendition; any previously pulled extracts are used in the creation of TOCs.
Font Library	The repository data file for the fonts.
Has Open Activities	Indicates whether there are active activities associated with the node.
Included in Page Numbering	Indicates the application of page numbers to the documents, cover pages, TOCs, and the system’s inclusion of those elements in page number calculations for other elements.
Inherited Attributes	Lists the inherited attributes for an element.

Column Name	Description
In Process Rendition Status	Indicates that status of an in-process rendition for: — Bound documents (in the case of leafs) — Bound documents encapsulated by a leaf element Leaf Elements flagged for native file will have a value of N/A or blank. Reference Leaf Elements will have a value of N/A or blank. A value of Yes indicates that the in-process rendition is current, while a value of No indicates that a new in-process rendition should be created to reflect changes to the documents.
Language	The language used in the assembly.
Leaf ID	An eCTD attribute, valid for leaf elements only. The leaf ID number.
Leaf Status	The value of the Leaf Status attribute from the leaf element. Valid for a leaf element only.
Modified File	An eCTD attribute, valid for leaf elements only. Indicates that a file has been modified.
Operation	An eCTD attribute, valid for leaf elements only. New, Replace, Append, and Delete are leaf operations. If the operation on a leaf is New and the leaf has a value for modified file, an error is reported indicating Inconsistent Lifecycle; a new leaf cannot have a modified file value. If the operation on a leaf is Replace, Append, or Delete, and the modified file attribute does not have a value, an error is reported indicating Inconsistent Lifecycle; a modified leaf must indicate its modified file.
Order	A system generated value depicting the order from top to bottom for the element.
Output Filename	The name the output file receives at publishing time. Inherited from the Element Name provided in the element attributes. If there is no “Output Filename” associated with the element, the system will provide a value of NA. Valid for Volumes and Leaf Files. ***Note:*** *Underscores are stripped out of file names instead of being converted into dashes in the output file name.*
Output Path	Lists the repository path to where the element is published. Inherited from the Element Name provided in the element attributes. If there is no “Output Path” associated with the element, the system provides a value of NA. Output Path is valid for Volumes and Leaf Files.
Output Channel	Indicates the output channel: Paper Output Channel, Electronic Output Channel, eCTD Output Channel.

Column Name	Description
Overwritten Attributes	Indicates the values for Folder and Leaf attributes that would otherwise be inherited from a parent or root defined attributes, but have been overwritten by the user.
Planned Page Count	Indicates the total number of planned pages represented by this element.
Rendition Exists	Indicates whether a PDF rendition is associated with the element. The "Rendition Exists" value pertains to the presence of a current PDF Rendition for the bound document. This value is assigned by the system in document element attributes. The value of "Rendition Exists" is set by the system for PDF renditions created. Valid for documents.
Rendition File Size	Indicates the file size of the leaf file or volume.
Section	The folder or leaf in the assembly that is being queried.
Tab Text	Provides the resolved Tab Text (if known by the system).
Use Native File	Indicates whether to use native file format or to create a PDF for output.

Generate a Publishing Readiness Query

The ***Publishing Readiness*** Query enables you to view your assembly metadata at a glance and find predicted errors and warnings that may occur during publishing if an issue is not remedied.

Warning: Always run a DMS synchronization before refreshing the **Publishing Readiness** *query,* **Link Inspector** *query, and other queries. Calyx RIM uses the data available in the Calyx RIM database, and relies on DMS synchronization to ensure this information matches what is in the DMS for each document.*

To generate a Publishing Readiness query:

1. Click a link for the assembly you want to publish.
   The ***Assembly Attributes*** page opens.
2. Right-click the assembly root and choose **Publishing Readiness Query**.
   The ***Publishing Readiness Query*** dialog box opens.
3. Under **Selected Columns**, choose any data you do not want to include in the query and move it to the ***Available Columns*** box.
4. Optionally choose selected columns and click **up** or **down** to change the order in which columns appear in the query.
5. Do one of the following:

Option	Action
To generate the query results:	Click **Search**.
To clear your choices and start again:	Click **Reset**.

Option	Action
To save your choices as a query that you can use again:	Click .

6. Do one of the following:

Option	Action
To return to the *Publishing Readiness Query* page:	Click **Back**.
To export the query results to a comma-separated file:	Click .

Browse for an Assembly

Use the tabs and buttons in the dialog box to locate and select the assembly for which you want to generate the Publishing Readiness query.

To select an assembly:

1. Click the tab for the entity type you want to choose.
2. Select the entity, and then do one of the following:

Option	Action
To choose one of the following: — **All** shows all entities. — **Current** includes all entities with a status of current. — **Submitted** includes all entities that have been submitted to the regulatory agency. — **Approved** includes all entities that have been approved by the regulatory agency.	Click the **Show Versions** arrow.
To see the content of the entity you choose:	Click the **Show** button.

Publishing Requests

This feature enables you to query tasks that are directly or indirectly associated with publishing. You can use Job requests to view the status of the operations such as publishing jobs and print or view an output log from a completed job list.

For all publishing jobs:

— Documents are rendered (for customers who have licenses for rendering and publishing services).
— Links are resolved.
— Rendered documents are concatenated.
— Variables are resolved.
— TOCs may be regenerated.
— Overlay preferences are calculated and applied.
— Special sheets are inserted as appropriate.
— Output files are created in the document repository with the appropriate names, locations, and metadata.

— Any errors and warnings are noted in the job requests.
— Calyx RIM Publisher will not re-render or re-extract documents that have been checked in as the same version in a DMS. However, you can manually re-render and re-extract documents by right-clicking on any document and creating renditions and extractions or using Force New Renditions and Extractions functionality. This will refresh all links, bookmarks, and page count data as well as rendering the document.
— When you publish `.pdf` document that has a rendition, source `.pdf` document, not the rendition is used for publishing.

Electronic/eCTD Publishing

— XML files are created and validated against their specified XML definition files.
— Checksums for all published files are calculated and are included in the values in their respective leaf elements.
— Files are concatenated for each standard leaf element.
— Cross-references are converted to hyperlinks. See the chart in the *Linking Tools* section.

Paper Publishing

— Volumes are refreshed.
— Files are concatenated as per defined volume ranges.
— Cross-references are converted to margin cross-references. See the chart in the *Linking Tools* section.

Publish Job Requests

This feature enables you to query tasks that are directly or indirectly associated with publishing. You can determine the status of each publishing job, and print or view an output log from a completed job list.

Submit an Electronic Publishing Request

Before submitting an electronic publishing request, you should be aware of the limitations.
— All electronic publish requests must be made from assemblies that have leaf elements. Leaf elements represent output documents to Calyx RIM. Electronic publishes without leaf elements in the assembly will not generate output.
— For single file electronic output, all content and sheets (such as TOCs and cover pages), with the exception of native files, are included in the published output.

To submit an electronic publishing request:

1. On the ***Assembly Attributes*** page, do the following:

Option	Action
For a sequence assembly:	Choose **Publishing** above the assembly tree.
To publish the entire assembly or choose a folder to publish:	Click the assembly root.

2. Click .
3. On the ***Publish Request*** page, choose **Electronic** from the **Publishing Output Channel** list.
4. To choose the repository location to publish the electronic submission, click **Browse**.

When choosing a folder for a published output location, the name of the folder cannot contain both Unicode characters and a space character, as this will cause an invalid path error. If you are using Documentum as the repository location, move to the next step. Else, go to step 6.

5. Under Output Document Type, choose the document type.
6. Check Append Application and Sequence Number to create subfolders in the output location.

   The subfolder names comprise the application followed by the sequence number.

   — You must check this box to avoid having an invalid relative path in the `STF.xml` file.

   — Because Calyx RIM automatically appends the application number and sequence code to the folder path during publishing, you should always use legal file system characters in these attributes. The following characters are not legal on a file system: \ / : * ? " < > |

Warning: For Assembly Plans, the values are taken from the Application Number and Sequence Number values of the Metadata Library (US Module 1 Application metadata type).

7. Check the Prepare to Publish box to create PDF renditions if you are using Calyx RIM Rendering.

   This option is available only if you have a license for Calyx RIM Rendering.
8. Choose one of the following to indicate what should be published:

Option	Description
Publish to a Single File:	Publishes to one PDF file all elements in the entire assembly that are flagged for the electronic output channel. All content and sheets (TOCs, cover pages, etc) are included in the published output, except native files. Native files are omitted.
All Leaf Elements:	Publishes all the leaf elements in the assembly to individual output files.
Selected Leaf Elements:	publishes only those leaf elements that are included in the selected folder.
All Leaf Elements and XML:	Publishes all the leaf elements in the assembly to individual output files. The eCTD XML backbone is published according to the appropriate XML definition file.
Selected Leaf Elements and XML:	Publishes only those leaf elements that are included in the selected folder. The eCTD XML backbone is published according to the appropriate XML definition file.
XML Only:	Publishes the eCTD backbone XML based on the appropriate XML definition file. None of the leaf elements are published.

Note: *Reference leaf elements publish their xlink:href path as the minimum necessary relative path required to take the reviewer to the correct document. References to other sequences do not contain the application number; references outside the application contain the application number.*

9. If Publish to a Single File is selected, in the *Single File Output Filename* box, enter the output file name for the assembly.

10. In the Include Leafs with Status multi-select box, select the leaf statuses of leafs you want to be published.
    By default, all active Leaf Statuses from Data Administration|Submission Maintenance section are listed in the Selected box. Deselect, if needed. The leafs with selected statuses are included in the electronic publish to generate output leaf files. This option does not affect the XML generation. For XML, all leafs are included, independent from the status assigned.
11. Next to DMS Versioning Scheme, choose one of the following for the published output files:

Option	Description
Same:	Indicates the published output files should have the same version number as previous output. (Choose this when you are publishing to a file system.)
Minor Version:	Indicates the published output files should be increments to a minor version.
Major Version:	Indicates the published output files should be increments to a major version.

12. Click OK to submit a publish request.
    A message confirms the publish request has been successfully sent.
13. Chose Go To > Job Requests to view the status of your publication request.
14. Once the job is complete, navigate to the publish output location and confirm publication.

Submit a Paper Publishing Request

You can submit a paper publishing request and customize its details such as page counts and versions.

To submit a paper publishing request:

1. On the Assembly tree, do the following:

Action
For a lifecycled sequence assembly, choose Publishing view above the assembly tree.
Click the assembly root, a volume, a folder, a leaf, or a document.

2. From the action bar on the right, click .
   The *Publish Request* window opens.
3. Under Publishing Output Channel, choose Paper.
4. To choose the repository location to publish the paper publication, click Browse. If you are using Documentum as the repository location, move to the next step. Else, go to step 6.

   Note: *If this is a Standalone assembly, do not check* Append Application and Sequence Number.

5. Under Output Document Type, choose the document type.
6. Check Prepare to Publish to create PDF renditions if you are using the Calyx RIM rendering and publishing services.
7. Use the Update Volume Page Count option to update the volume page counts from the publish request screen.
8. Next to Publish Paper, select which volumes to publish:

Option	Description
All Volumes:	Publishes all volumes in the submission.
Volumes in Selected Range:	Publishes only those volumes that start in the node you have selected to publish.

9. Next to DMS Versioning Scheme, choose one of the following for the published output files:

Option	Description
Same:	Indicates the published output files should have the same version number as previous output. (Choose this when you are publishing to a file system.)
Minor Version:	Indicates the published output files should be increments to a minor version.
Major Version:	Indicates the published output files should be increments to a major version.

10. Click OK to submit a publish request. A message confirms the publish request has been successfully sent.
11. Choose Go To > Job Requests to view the status of your publication request.
12. When the job is complete, navigate to the publish output location and confirm publication.

    When publishing paper volumes, regardless of where invoked, the Publish All Volumes option will output all publishable volumes in your assembly.

Publish Commands and Volumes

For publishing volumes in the selected range, the output produced is dependent on where the publishing command was invoked.

Selected range	Description
Assembly root	Publishes all volumes.
Volume	(Single volume icon) Publishes this volume only. With this icon selected, when choosing Publish Request (Publish Paper > Volumes in Selected Range) only this volume will be published. (Multi-volume icon) Publishes all volumes where the starting range break falls under the collapsed multi-volume icon, including the last volume whose start break falls under the icon, up to the next volume break following the collapsed multi-volume icon.
Folder	Publishes all volumes where the volume begins (is attached to) or is under (is attached to a descendant of) the selected folder. If no volumes fit this criteria, no volumes will be produced.

Selected range	Description
Leaf	Publishes all volumes where the volume begins (is attached to) or is under (is attached to a descendant of) the selected leaf. If no volumes fit this criteria, no volumes will be produced.
Document	Publishes all volumes where the volume begins (is attached to) or is under (is attached to a descendant of) the selected document. If no volumes fit this criteria, no volumes will be produced.

Publishing Leaf Elements

During publishing, if a leaf has no content, it will be published with a checksum of null (empty checksum attribute) in the XML.
A final run of the Calyx RIM Validator tool will correctly set all checksums and confirm XML validity.

After publishing, when you choose View File for an empty SPL XML leaf element, an error message appears in the assembly. This is expected behavior.

You cannot preview cover pages. You can preview only source document renditions, TOCs, and tabs.

Leaf Statuses

You can select the leaf elements to be published. When the ***Publish Request*** page is initiated, in the Include Leafs with Status box select the leaf statuses of leafs you want to be published. The leafs with selected statuses are included in the electronic publish to generate output leaf files.

— This option does not affect the XML generation. For XML, all leafs are included, independent from the status assigned.
— After publishing is completed, the leaf statuses of leafs that have publishable elements are changed automatically to `Published`.
— For the Publish to a Single File option, all leafs are published to a single file, independent from the selected statuses.
— For the All Leaf Elements or Selected Leaf Elements options, only leafs with the selected leaf statuses are published.
— For the All Leaf Elements and XML and Selected Leaf Elements and XML, the backbone files and only leafs with the selected leaf statuses are published. When you do not specify the leaf statuses in the ***Publish Request***, then only the backbone files are published.
— For the Paper Publish only, all leafs under volumes are published, independent from the selected statuses.

The publishing job fails, if:
— All leafs have no publishable elements.
— There are no leafs in the assembly with the selected leaf statuses.

After Submitting a Publishing Request

When you create a publish request, a confirmation message indicates whether the request was successful and an audit trail is created.

The publish request is sent to and processed by the server as follows:

— If you chose to prepare for publishing automatically, Calyx RIM checks the rendition status of each source document before trying to publish the submission.
— Any renditions that are missing or out-dated are queued for processing.
— Calyx RIM holds the publishing request until all renditions are created for source files in the submission.
— If a rendition fails, a message is saved in the publish log and the leaf including that document is not published
— If a rendition fails for one or more source files, a message is saved in the publish log and the submission is not processed.
— If all renditions are created successfully, they are written to the DMS as renditions of their respective documents and the system continues to process the submission.
— You are notified when the job is completed and whether it was successful.

Note: *When a job has left the queue to be processed, it cannot be cancelled from the* InSight job *requests window. Jobs must be cancelled immediately if they are to be stopped, in the Web interface.*

Viewing a Publishing Request

You can generate a Publishing Request query to view all or specific publishing requests.

To view a publishing requests:

1. Choose Go To > Job Requests.
   The *Job Requests* page opens.
2. Do any of the following:

Option	Action
To view the job request:	Click the User Name arrow and choose the user who submitted the job requests.
To choose the date range during which the requests were submitted:	Click the date arrows.
To view the specific publishing request: Enter the name of the specific publishing request you want to view:	In the Job Name box, enter the name of the specific publishing request.
To view the publishing request:	In the Job Status box, choose the statuses of the publishing request.
If you do not want to include in the query:	Under Selected Columns, choose any data and click <-- to move it to the *Available Columns* box.

Option	Action
To change the order in which columns appear in the query results:	Choose Selected Columns and click up or down.
To sort the job requests:	Under Available Sort Orders, choose the columns and click <-- to move it to the *Available Columns* box.
To change the order in which columns appear in the query results:	Choose selected sort orders and click up or down.

3. Do one of the following:

Option	Action
To generate the query:	Click Search.
To clear your choices and start again:	Click Reset.
To save your choices as a query you can use again:	Click .

4. Do any of the following:

Option	Action
To return to the Job Requests page:	Click Back.
To export the query results to a comma-separated file:	Click .

Publishing Request Results

Each publishing request that fits the criteria you specify on the *Job Requests* page appears on a row in the resulting report. If an error has occurred during publishing, an error message is returned. The message that appears in the Job Message column is a link you can click to view the details of the message.

When publishing, if Prepare To Publish has been selected, the process is initiated before the publish function. The *Job Requests* page shows the prepare to publish running prior to showing the publish execution.

Suspended Calyx RIM Rendering processes (either purposefully or through an error) may cause Calyx RIM to incorrectly report jobs as completed in the job requests report. For all jobs that require Calyx RIM Rendering to be involved, the following Job Statuses exist to identify the job progress:

— Scheduled
— Started
— Waiting for Calyx RIM
— Waiting for Calyx RIM Rendering
— Processing Calyx RIM Rendering Results
— Completed
— Failed
— Canceled

The following table describes the different statuses of the publishing job results.

Status Description	Result
Publishing job is complete but with at least one error in job details.	Completed with Errors
Publishing job is complete but with at least one warning is present in job details.	Completed with Warnings
Publishing job is complete but with at least a warning and an error present in job details.	Completed with Errors
Publishing job is complete but without any warning and error in job details.	Completed
Publishing job is complete but at least a critical error present in job details.	Failed

View a Job Message

You can track the progress of your publishing job on the *Job Message* page.

To view a job message:

1. Click a link in the Job Message column in the *Job Requests* query results.
2. On the *Job Message* page, do any of the following:

Option	Action
To save the content of the message to the Windows Clipboard:	Click Copy to Clipboard.
To print the message:	Click Print.
To close the *Job Message* page and return to the *Job Requests* query results:	Click Close.

Note: *Suspended processes may cause Calyx RIM to incorrectly show jobs as completed in the* Job Request *query results.*

Cancel Publishing Requests

Only an administrator can delete a publishing request submitted by another user.
You can cancel your own publishing requests under certain conditions.
— You have the appropriate security privileges.
— The job has not already been completed.

You can only cancel in-progress jobs that have reached the Calyx RIM Rendering server, which is indicated by the Job Details. When doing so, the currently processing sub-task is completed and then the parent job is canceled.

Warning: If you attempt to cancel while the job is still being processed by Calyx RIM (before you see any Job Details), then resubmit the same job, you could cause the database to lock.

Cancel a Publishing Request

You can cancel a publishing job before processing if you have the appropriate security permissions.

To cancel a publishing request:

1. Click Go To > Job Requests.
2. On the Job Requests page, enter the information for the publishing request you want to cancel.
3. Click Search.
4. In the query results, click Cancel Job in the Cancel Job column for the publishing request.
5. Click OK when you are prompted to confirm the cancellation.

Export Submissions

From Calyx RIM, you can export published output from one repository location to another repository location. When you publish a submission, Calyx RIM creates eCTD files at the submission output location you specified in the publish request. This enables you to copy completed publications to their final storage, archival, or dispatch location in the repository.

Export a Published Submission

You can export a published submission from the repository you specified in the publish request to another repository.

To export a published submission:

1. Click a link for the assembly you want to export.
2. Right-click the root and choose Export Published Output.
   The *Export Published Output* dialog box opens.
3. In the *Source Location* box, specify the output location for the assembly. You can click Browse under the *Source Location* box to choose the published output from a DMS repository or a file system.
4. In the *Destination Location* box, specify the DMS repository or file system to which you want to copy the published output. You can click Browse under the *Destination Location* box to choose a location in a DMS repository or a file system.

   Note: *When exporting published output, you can only export to an existing location within the DMS repository or file system. If the path that is entered in the output location attribute does not exist, the export will fail.*

   Note: *For EAEU submissions, provide the valid values for the* Source Location *and* Destination Location *fields. For* Source Location*, a folder containing the* `index-r-022.xml` *file must be specified. See: EAEU Submissions Best Practices document for details.*

5. If you are exporting to a DMS repository, do the following:

Option	Action
In the Output Document Type drop-down list:	Select the object type to be created for the exported documents. Use dm_document for Documentum.
For DMS Versioning Scheme:	Select either Minor to version existing documents as a minor version, for example 1.1, or Major to version existing documents as a major version, for example 2.0.

6. Click OK.

Note: *For EAEU submissions, select* Embed PDFs into EAEU XML? *and proceed further. See: EAEU Submissions Best Practices document for details.*

Calyx RIM processes the export as a batch job and the following occur:

- A new document/file is created for each repository document that is a descendant of the source folder.
- A new folder is created for each repository folder that is a descendant of the selected folder.
- Only the CURRENT version of a particular source repository's document or folder is exported.
- The document or folder name attribute is set to the repository object name for the document file.
- The documents are placed as children of the matching folders to mirror the hierarchy in the repository.
- Virtual documents (with and without content) and objects with no content are ignored.
- Destination Not Found text will be used to stamp TOC entries or cross-references where the destination is undefined. By default it is set to blank, but in some processes it may be helpful to set it to some text indicating an issue with a TOC entry or cross-reference.

About Distribute Published Output as Rendition

The Export Published Output functionality includes the ability to distribute published output as a rendition of a virtual document or a file system document.

To distribute published output as a rendition, the source must be a single PDF file, such as the resulting PDF from performing a Publish to Single File publish, and the destination file cannot be a PDF (since that would be a rendition of itself).

If the destination file is a virtual document, it cannot be an object with no content. If you are exporting to a file system, there must be an existing pub folder in the same directory as the destination file.

Calyx RIM will distribute the PDF to the `pub` folder. Existing PDF renditions are overwritten when performing subsequent distributions.

Distributing Published Output as a Rendition

You can distribute the published output as a rendition of a virtual document or a file system document using the Export Published Output.

To distribute published output as a rendition:

1. Right-click on the root node of an assembly and select Export Published Output.

2. In the *Source Location* box, browse to select a PDF file.
3. In the *Destination Location* box, browse to select a virtual document or file system file.
4. Click OK.

Note: *The options for* Output Document Type, Status of Documents, *and* DMS Versioning Scheme *are only applicable when exporting folders. They do not apply to exported files.*

Export a Source File to a Destination File as a Rendition

Using the Export Published Output function you can specify and export a source file to a destination file (publish a rendition), with certain limitations. The source must be a PDF file, and the destination file cannot be a PDF (since that would be a rendition of itself). If the destination file is a virtual document, the root must already have content.

To export a source file to a destination file as a rendition:

1. On the root node of the assembly, right-click and select Export Published Output.
2. In the Export Published Output window, browse to select a PDF file for the Source Location.
3. For the Destination Location, browse to select either a non-PDF file or a Virtual Document (VDM).

   The options for Output Document Type, Status of Documents, and DMS Versioning Scheme are applicable only when exporting folders. They do not apply to exported files.
4. To export the selected file to the specified destination, click OK.

   If the source file and the destination file have the same name, the source file will overwrite the destination file without notice.

Review an eCTD

You can review an eCTD using tools such as Calyx RIM Validator and Internet Explorer to check the XML files and folder/file structure.

See the topic *Viewing Index and Regional XML Files in a Web Browser* in the Calyx RIM Validator User Guide.

You should still perform a typical electronic submission PDF validation by opening files in Acrobat and checking bookmarks and links.

Note: *PDF files launched from the Internet Explorer view of the* `index.xml` *or* `xx-regional.xml` *might not open to bookmarks and page because of how Acrobat is embedded in Explorer. Use the XML links only to verify that the file can be opened. Do not rely on this to verify the PDF files.*

Calyx RIM Validator is licensed at no cost to Calyx RIM customers. For more information, see the *Calyx RIM Validator User Guide.*

View XML in Internet Explorer

Internet Explorer is recommended for viewing generated .xml files in your Web browser.

Note: *For opening and viewing published XML files, PAREXEL recommends using the Microsoft Internet Explorer Web browser. Although Calyx RIM 7.0 supports other Web browsers, opening published XML files is best accomplished using Internet Explorer.*

To view an `index.xml` file or `xx-regional.xml` file in Internet Explorer:

1. Open the `index.xml` in Internet Explorer.
   - If XML files do not open in Internet Explorer, check that the `util` folder exists as a sibling to the module folders.
   - There should be two folders in the `util` folder: `Dtd`, which holds the DTD files against which the XML files are validated, and `Style`, which holds stylesheets that determine how the XML files will be displayed in Internet Explorer
2. Click the blue links to verify that leaf files can be launched from the `index.xml.` There should be no errors saying that a file cannot be located.
   - PDF files should open in Acrobat
   - XML files should open in Internet Explorer
   - XPT files should open in SAS Viewer (if available)
3. Open the `xx-regional.xml` in Internet Explorer and review it following the procedure for the `index.xml`.
4. In the `xx-regional.xml`, verify the application metadata at the top of the page, which typically includes company name, date of submission, application number, and so on. It may also show the number of leaf files in the XML file, depending on the region and the stylesheet.

View Study Tagging Files (STFs)

To view STF XML files in Internet Explorer:

1. Open files in IE by right-clicking them in Windows Explorer and choosing Open With > Internet Explorer. Alternatively, you can open STFs by clicking their links while viewing the `index.xml` in Internet Explorer.
2. For each STF, verify that the Study Title and Study ID are populated and correct. If the study is in a section that requires extra STF category metadata, verify that as well.

   Note: *Only studies contained in 4.2.3.1, 4.2.3.2, 4.2.3.4.1, and 5.3.5.1 require various combinations of the four category elements (species, route of administration, duration, type of control). Studies in other sections can omit the category metadata.*

   Each leaf referenced in the STF needs to correctly point to the leaf ID in the `index.xml` file. When the leaf ID is correctly referenced, both the Document Title and Relative Filename are populated on the STF. If the ID is not referenced properly to the `index.xml`, these fields are blank.
3. Click the blue Relative Filename links to ensure that leaf files can be launched.

Each leaf in the STF must have a valid file-tag as described in the STF implementation guide. Tags are displayed in the STF as [us] nonclinical-data or [ich] study-report-body. The text in square brackets is the info-type tag and the rest of the text is the file-tag. Any tags that are misspelled or use the wrong info-type are highlighted in red.

Grouped Submissions

A grouped submission is a submission type that is created and managed using submission plans. It is an eCTD submission where all files referenced in it are applicable to multiple applications identified as parts of the group.

Content of the grouped submission physically resides in one application. This is considered the Application Containing Files, or primary application, and remains constant in future sequences. Consider the following constraints while grouping a submission:

— Grouped submissions are supported using US DTD 3.3 or higher versions only.

— All submissions within a group must have the same application and submission type.

Note: *The application type and submission type of the submission are limited by the agency. Please check the latest version of the specification for the list of types applicable for grouped submissions.*

— The initial submission within a grouped submission can only contain new leafs.

— Subsequent submissions within a grouped submission can only contain new leafs or lifecycle operations against previous submissions within that group.

In Calyx RIM, all data related to the grouped submission is maintained in the submission plan entity with the Grouped Submission type. This includes:

— Applications, events, and sequences included in the grouped submission.

— Tasks and references related to the grouped submission.

— Assembly Plans that keep the structure, lifecycle, content, and metadata of the eCTD submission.

Submission Plans

Submission Plans facilitate the creation of submissions for multiple similar applications.

In Calyx RIM, the submission plan is a single source scheme used to eliminate redundant tasks of creating similar submissions while working with identical applications.

At this time, Submission Plans are for use with Grouped Submissions only.

To use the *Submission Plan* wizard, you must meet the following security requirements:

— An Electronic Lifecycle Publishing (ELP) and Submission Planning and Tracking (SPT) license modules with at least WRITE privileges.

— At least WRITE privileges on Submission Plan to be able to create a Submission Plan entity from the New menu.

— At least WRITE privileges on Submission Plan to be able to modify a Submission Plan entity.

— At least ADMIN privileges on Submission Plan to be able to delete a Submission Plan entity.

— At least READ privileges on Submission Plan to be able to view a Submission Plan entity.

— At least WRITE privileges to Submission Plans to be able to disassociate an Application.

— At least WRITE privileges to Submission Plans to be able to disassociate an Event.
— At least WRITE privileges to Submission Plans to be able to disassociate a Sequence.
— Home Page Access for Submission Plan set to YES to access the Submission Plan from the Home Page tab. An Assembly Plan can be created with at least WRITE privileges on Submission Plan.

Submissions Plans are available with the Electronic Lifecycle Publishing (ELP) and Submission Planning and Tracking (SPT) license modules.

With a submission plan, you can:
— Scheme the submission structure and the content.
— Automatically transfer the structure and documents to the applications.

To create a submission plan, you must have appropriate privileges from your application security administrator.

Create Submission Plan Wizard

The Create Submission Plan wizard guides you through the process to create a submission plan and associate entities such as applications, events, and sequences to the submission plan.
To use the Create Submission Plan wizard, you must have appropriate privileges from your application security administrator.
Using the Create Submission Plan wizard, you can:
— Create submission plan
— Associate existing applications to the submission plan
— Create new events and associate them with the submission plans, or associate existing events to the submission plan
— Create new sequences and associate them with the submission plans, or associate existing sequences to the submission plan

To create submission plan using the wizard:

1. On the home page, click Wizard > Create Submission Plan.
2. On the *Submission Plan Creation* page, enter the attribute values for the submission plan and click Next. The application page appears.
   — For description of the submission plan attributes, see the topic *Submission Plan Attributes*.
3. Do one of the following:

Option	Action
To search for the application to associate:	Enter the relevant details in the respective fields (for description of the attributes in the *Search for Applications to Associate* page, see the topic *Associating Applications to Submission Plans*. Click Next.
To view the list of existing US applications that have the application type selected for the submission plan:	Click Next.

4. Select the application and click **Next**.
5. On the confirmation page, click **Next**.

   The ***Confirmation*** pages appear during the execution of the wizard that indicate entities are being created, even though the wizard is still in progress. If the wizard prematurely terminates after a confirmation screen is displayed, the entities created continue to exist in Calyx RIM.
6. On the ***Summary*** page, to create or associate events and sequences, click **Next** and move to next step. Otherwise, click **Finish** to create the submission plan.
7. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature and SSO are enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.
When electronic signature is enabled and SSO is disabled	a. Select a reason and enter comments for the reason. b. Enter user ID and password and click Next.

8. On the ***Create/Associate Events*** page, select an appropriate option and follow the wizard to associate new or existing events to the submission plan.

   For the description of the event attributes, see the topic *Event Attributes*.
9. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature and SSO are enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.
When electronic signature is enabled and SSO is disabled	a. Select a reason and enter comments for the reason. b. Enter user ID and password and click Next.

10. On the ***Create/Associate Sequences*** page, select an appropriate option and follow the wizard to associate new or existing sequences to the submission plan.

    For the description of the sequence attributes, see the topic *Sequence Attributes*.
11. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature and SSO are enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click Next. c. Validate your identity by entering your user credentials in the dialog box.
When electronic signature is enabled and SSO is disabled	a. Select a reason and enter comments for the reason. b. Enter user ID and password and click Next.

12. Click Finish.
    The submission plan is created.

Create Submission Plans

Calyx RIM enables you to create submission plans and associate entities such as applications and sequences to the submission plans.
To create a submission plan, you must have appropriate privileges from your application security administrator.

To create a submission plan:

1. On the home page, click New > Submission Plan.
2. On the *Create Submission Plan* page, enter the attribute values for the submission plan.
3. Save.
4. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature and SSO are enabled	a. Select a reason and enter comments for the reason. b. Select Save. c. Validate your identity by entering your user credentials in the dialog box.
When electronic signature is enabled and SSO is disabled	a. Select a reason and enter comments for the reason. b. Enter user ID and password and click Save.

Modify Submission Plans

You can modify a submission plan to make edits to the attributes that were entered when the submission plan was created.

Note: *When modifying the values for the submission plan it is not possible to modify the following fields: Submission Plan Type, DTD/Schema, Filing Type, and Submission Plan Countries.*

To modify a submission plan:

1. On the home page left panel, click Submission Plans.
2. Click a link for the submission plan you want to modify.
3. On the View Submission Plan page, click the Edit icon.
4. On the Edit Submission Plan page, enter your changes to the submission plan attributes.
5. Click Save.
6. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature and SSO are enabled	a. Select a reason and enter comments for the reason. b. Select Save. c. Validate your identity by entering your user credentials in the dialog box.
When electronic signature is enabled and SSO is disabled	a. Select a reason and enter comments for the reason. b. Enter user ID and password and click Save.

Delete Submission Plans

Users with administrator privileges can delete a submission plan from Calyx RIM. When a submission plan is deleted, its associated tasks and references will be deleted.
A submission plan with an associated assembly plan cannot be deleted. To delete a submission plan, the assembly plan associated to it must be deleted first.

To delete a submission plan:

1. Navigate to the submission plan you want to delete.
2. Click the link for the submission plan.
3. On the *View Submission Plan* page, click the Delete icon.
4. Select a reason and enter comments for the reason.
5. Click Next.
6. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature and SSO are enabled	a. Select a reason and enter comments for the reason. b. Select Save. c. Validate your identity by entering your user credentials in the dialog box.
When electronic signature is enabled and SSO is disabled	a. Select a reason and enter comments for the reason. b. Enter user ID and password and click Save.

Submission Plan Attributes

You can use the attribute descriptions to enter the attribute values while creating the submission plans.

Attribute	Description
Submission Plan Name	The name of the submission plan.
Submission Plan Code	The code of the submission plan.
Submission Plan Owner	The person responsible for managing the submission plan.
Submission Plan Type	The type of submission plan you are creating. ***Note:*** *At this time, only Grouped Submission is available.*
DTD/Schema	The DTD/Schema version for the submission.
Application Type	The type of the application which will be associated with the submission plan.
Filing Type	The submission filing type.
Submission Plan Countries	The countries for which the submission is planned.
Submission Plan Status	The status of the submission plan.
Submission Plan Status Date	The date the current submission plan status is effective.
Submission Plan Keywords	Keywords that apply to the specific submission plan.
Submission Plan Description	A description of the submission plan.
Submission Plan Add Comment	Comments regarding the submission plan.
Reason	Reason for creating, modifying or deleting a submission plan.
Reason for Comments	Comments related to reason entered by users.
User ID	The user name to validate user identity.
Password	The user password to validate user identity.

Assembly Plans

An assembly plan enables you to create an assembly that can be used for multiple applications. An assembly plan helps in eliminating the redundant effort required in creating identical assemblies for similar applications.

Note: *Assembly Plans are for use within a Submission Plan only. See Grouped Submissions for usage constraints.*

For grouped submissions, the initial assembly plan that is created has no relationship to the already submitted assembly. Any subsequent assembly plans are built on top of the existing assembly plans.

With the assembly plan having no relation to the other assemblies, the lifecycle operations are contained within the submission plan until the sequence assembly is created.

See the following topics for information and procedures related to assemblies and assembly plans.

Create Assembly Plans

Calyx RIM enables you to create assembly plans within submission plans. Assembly Plans can only be created if the Submission Plan has associated Applications.

To create an assembly plan:

1. On the Home page, click Submission Plan.
2. In the Submission Plans list, click the submission plan under which you want to create an assembly plan.
3. On the *View Submission Plan* window, select Assembly Plans tab.
4. Click the Create icon.
5. In the *Create Assembly* page, select an appropriate option to create an assembly.
   - New (Empty) - to create a new assembly containing no existing assembly elements.
   - Existing Template, Assembly or View - create a new assembly from an existing template or assembly, or from a current or active view.
   - Assembly File - create a new assembly from an assembly or view that has been exported as an XML file.
   - Virtual Document - create a new assembly from a Documentum virtual document.
6. For the selected mode, follow the wizard and enter details where necessary.
7. Click Save.
8. Enter details as necessary.
   - If the method chosen to create an assembly plan is other than the one using the assembly file, the Applicable Applications field automatically shows the applications associated to the submission plan under the Selected box on the *Create Assembly* page.
   - The list of the applications applicable for the assembly plan can be changed after an assembly plan is created.
9. Click Create.
   The assembly plan is created.

Modify Assembly Plan Attributes

You can make edits to the attributes of an assembly plan.

To modify an assembly plan:

1. On the home page left panel, click Submission Plans.
2. Click the link for the submission plan which includes the assembly plan you want to modify.
3. On the View Submission Plan page, select the Assembly Plans tab.
4. Click the link for the assembly plan that you want to modify.
5. Click the Edit icon.
6. On the *Edit Assembly* page, enter your changes to the assembly plan attributes.

7. Click Save.
   The new attributes of assembly plan are saved.

Delete Assembly Plans

Deleting an assembly plan removes its sub-entities, such as folders and leafs.
You can delete an unlocked assembly plan from Calyx RIM.

To delete an assembly plan:

1. Go to the submission plan that contains the assembly plan you want to delete.
2. On the *View Submission Plan* page, go to the Assembly Plans tab and select the assembly plan that you want to delete.
3. On the *Assembly Attributes* page, click More.
4. Click Delete.
5. When you are prompted to confirm the deletion, click OK.
   The assembly plan is deleted.

Lifecycle Operations in Assembly Plan

Lifecycle operations are performed similarly in sequence assemblies and assembly plans. However, in an assembly plan, the target leaf of the operation will be set to the leaf on the sequence assembly of the Application Containing Files, as defined within the Assembly Plan metadata of the previously lifecycled Assembly Plan.
Lifecycle operations on leafs (replace, append, and delete) can be performed from the assembly plan working view.

— To perform any operation, the operated leaf should reside in the assembly plan that is already merged to the sequence assemblies.
— Though the operation is performed on the leaf from the previous assembly plan, the modified leaf and modified sequence attributes will be populated with the links targeting this leaf in the sequence assembly of the application containing files.
— The modified file path references the application number, sequence number, and leaf id for the application where the leaf was submitted with the application-containing-files element value indicating “true.”. The modified file attribute is formatted as `../../<application prefix><operated leaf application code>/<operated leaf sequence code>/index.xml#<leafid>`. For example, `../../nda678901/0004/index.xml#a08f474cfe3cad534c64843a54c534382`

Associate Applications to Submission Plans

Calyx RIM enables applications to be associated to submission plans.
Applications available for association are those which:

— are not assigned to the submission plan
— have the same application type and country as the submission plan
— have at least the Read permission enabled

Note: *When an application associated with a submission plan is deleted, the association of the application with that submission plan ends automatically.*

To associate applications to submission plans:

1. On the Home page, click Submission Plan.
2. In the submission plans list, click the submission plan to which you want to associate applications.
3. On the *View Submission Plan* window, select Associated Applications tab.
4. Click the Associate/Disassociate Application(s) icon.
   The *Associate Applications* window opens.
5. Enter relevant details of the application you want to associate in their respective fields and click Next.
   The applications matching the details entered are displayed in the *Select Application* window.
6. Select the applications and click Next.
7. Click Finish.
   The applications are associated with the submission plan.

Attributes used while associating application

Use the following attribute descriptions to enter the attribute values while associating applications to submission plans.

Attribute	Description
Application Name	The name of the application.
Application Owner	The person responsible for managing the application.
Application Status	The status of the application.
Display Columns	The application related columns you want displayed in the grid.
Sort Order	The display of applications based on the order of the application attributes set in the *Associate Applications* window.

Disassociate Applications from Submission Plans

Applications affiliated to submission plans can be disassociated. Events and sequences that are associated with the application will also be disassociated when the application is disassociated from the submission plan. Applications that have existing association with assembly plans cannot be disassociated.

To disassociate applications from submission plan:

1. On the Home page, click Submission Plan.
2. In the submission plans list, click the submission plan from which you want to disassociate the application.
3. On the *View Submission Plan* window, select Associated Applications tab.
4. Select the checkbox for the application you want to disassociate from the submission plan.
5. Click the Associate/Disassociate Application(s) icon.

6. Click OK on the confirmation message.
   The association of the application with the submission plan is removed.

Associate Sequences to Submission Plans

Calyx RIM enables sequences to be associated to submission plans. To associate a sequence to a submission plan, an application must already be associated to the submission plan.
Existing sequences will be available for association when:

— the sequence filing type matches the filing type of the submission plan to which it is being associated
— it is not already associated to any submission plan
— it does not have an assembly
— its application does not have a sequence without an assembly already associated to the submission plan to which it is being associated
— its application has Read permission based on the Application/Country rights

To associate sequences to submission plans:

1. On the Home page, click Submission Plan.
2. In the Submission Plans list, click the submission plan to which you want to associate sequences.
3. On the *View Submission Plan* window, select Associated Sequences tab.
4. Click the Associate/Disassociate Sequence(s) icon.
   The *Create/Associate Sequences* window opens.
5. Proceed as follows:
   — If a sequence you want to associate already exists, select Associate.
   — If no sequence exists, select Create.
6. Click Next.
7. Proceed as follows:

Option	Action
If Create was selected:	Skip to step 9.
If Associate was selected:	Enter the search criteria to find the sequences. Click Next.

   Only sequences matching the entered criteria, and with the same filing type listed on the Submission Plan, are returned.
8. Select the Sequence you wish to associate and click Next. Skip to step 11.
9. If Create was selected, select the Events to associate the sequence to, and click Next.
10. Complete the *Sequence Details* screen, and click Next.
    The Sequence Filing Type is automatically set to the same filing type as listed on the Submission Plan.
11. On the *Confirmation* screen click Next to save the associated Sequences.
    The *Summary* page confirms the association of the sequences.
12. Click Finish.

The sequences are associated to the submission plan. The Included in Grouped Submission field in the *View Sequence* window displays the submission plan to which the sequence is associated.

Note: *Creating assemblies manually in sequences associated to submission plans is not allowed.*

Disassociate Sequences from Submission Plans

Sequences without assemblies can be disassociated from submission plans.

To disassociate sequences from submission plans:

1. On the Home page, click Submission Plan.
2. In the submission plans list, click the submission plan from which you want to disassociate a sequence.
3. On the *View Submission Plan* window, click the Associated Sequences tab.
4. Select the check box next to the sequence you want to disassociate from the submission plan.
5. Click the Associate/Disassociate Sequence(s) icon.
6. Click OK on the confirmation message.
   The association of the sequence with the submission plan is removed. Assemblies can be manually created for sequences that are no longer associated with the submission plans.

Associate Events to Submission Plans

Calyx RIM enables you to associate events to submission plans.
To associate an event to a submission plan, an application must already be associated to the submission plan. An existing event cannot be associated if it is:

— already associated to the submission plan
— related to the application which has other event(s) associated to the submission plan
— associated to other submission plans
— related to the applications for which the user does not have at least the Read permissions based on the Application/Country rights.

To associate sequences to submission plans:

1. On the Home page, click Submission Plan.
2. In the *Submission Plans* list, click the submission plan to which you want to associate events.
3. On the *View Submission Plan* window, select Associated Events tab.
4. Click the Associate/Disassociate Event(s) icon.
   The *Associate Events* window opens.
5. Proceed as follows:
   — If an event you want to associate already exists, select Associate.
   — If no event exists, select Create.
6. Click Next.

7. Proceed as follows:

Option	Action
If **Create** was selected:	Skip to step 9.
If **Associate** was selected:	Enter the search criteria for the events to find, and click **Next**.

8. Select the event you wish to associate and click **Next**. Skip to step 12.
9. If **Create** was selected, select the applications to associate the event to. Click **Next**.
10. Complete the *Events Details* screen, and click **Next**.
11. Select the timeline/event plan from the drop-down list.
12. On the *Confirmation* screen click **Next** to save the associated events.
    The *Summary* page confirms the association of the events.
13. Click **Finish**.
    The events are associated to the submission plan.

Disassociate Events from Submission Plans

You can disassociate events associated with submission plans.

To disassociate events from submission plans:

1. On the Home page, click **Submission Plan**.
2. In the submission plans list, click the submission plan from which you want to disassociate an event.
3. On the *View Submission Plan* window, select **Associated Events** tab.
4. Select the event you want to disassociate from the submission plan.
5. Click the **Associate/Disassociate Event(s)** icon.
6. Click **OK** on the confirmation message.
   The association of the event with the submission plan is removed.

Note: *Even after an event is disassociated, the sequence belonging to the event will continue to be associated with the submission plan.*

Use the Ready for Submission Wizard

The *Ready for Submission* wizard enables an assembly plan to be merged into the lifecycle of the existing applications applicable to the assembly plan. Merging the assembly plan copies all of its files into the lifecycle. Using this wizard, you can also copy paper publishing elements and create events and sequences if they are not already associated with the submission plan.

Note: *You must have the appropriate security privileges of sequences and sequence assemblies to use the* ***Ready for Submission*** *wizard*

To prepare an assembly plan for submission:

1. On the homepage, click Submission Plans.
2. Click the link of the submission plan which includes the assembly plan that you want to prepare for submission.
3. Select the assembly plans tab and click the link of the assembly plan.
4. Click Wizards from the menu.
5. Click Ready for Submission.
   The *Ready for Submission* wizard opens.
6. Do the following:

Option	Action
To add submissions to lifecycle:	Select the option Add Submissions to Lifecycle?.
To copy paper publishing elements:	Select the option Copy Paper Publishing Elements?. Selecting this option copies all the publishing elements in the assembly plan to the corresponding nodes of the created sequence assembly. The source Assembly Specific Publishing Settings Libraries (APL) settings for the publishing elements that are copied, will be merged into the target APL(s).

7. Click Next.
8. Do one of the following:

Option	Action
If the events are already associated with the submission plan, in the *Event creation* page:	Click Next. Move to step 13.
If the events are not already associated with the submission plan, in the *Enter Event Details* page:	Enter details for the event and click Next.

9. In the select *Event Plan* page, select an appropriate plan from the Timeline/Event Plan option and click Next.
10. Select a reason and enter comments for the reason.
11. Click Next.
12. If eSignature is enabled, validate your identify by entering your user credentials and click Sign in.
13. If the sequences from the applicable applications on the assembly plan are already associated, in the *Sequence Verification* and *Sequence creation* pages, click Next. Move to step 20. Else, move to next step.
14. If the sequences from the applicable applications on the assembly plan are not associated, in the *Enter Sequence Details* page, enter details for the sequence. Click Next.
15. Select a reason and enter comments for the reason.
16. Click Next.
17. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature and SSO are enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click Next. c. Validate your identity by entering your user credentials in the dialog box.
When electronic signature is enabled and SSO is disabled	a. Select a reason and enter comments for the reason. b. Enter user ID and password and click Next.

18. In the *Confirmation* page, click Next.
    - A sequence will be created for every application listed as an associated application on the assembly plan, that does not have a currently associated sequence.
    - The created sequence will be associated to the event listed as the associated event for that application.
    - If no events are associated, the sequence will only be associated to the applications on the assembly plan.
    - If an existing sequence is associated and already has an assembly associated, the system will create a new sequence using the next available sequence code.
    - The sequence code for created sequences will be automatically set to the next available number, within the associated application, with a prefix of 'P'.
19. In the next *Confirmation* page, click Next.
20. In the *summary* page, click Finish.
    To know the status of the submitted job, click GO TO from the menu and click Job Requests. Upon the completion of the job request, the files are merged into the lifecycle.

Note:

- *If merging any application from the list of applicable applications into the lifecycle fails, all changes to all applications will be automatically reverted.*
- *If the changes are successfully merged and you then want to make changes to the submission that was merged, all the created sequence assemblies must be deleted and the changes must be made in the assembly plan. Sequence assemblies must be created again using the Ready for Submission Wizard to reflect the changes made to the submission.*
- *When an assembly plan is merged to sequence assemblies, there will be no synchronization between that assembly plan and the sequence assemblies.*
- *The leaf statuses of leaf elements in the assembly plan are not updated during the* Ready for Submission *wizard execution and after the wizard is finished.*

Order of the copied elements in the target Assembly

The order of the copied elements in the target Assembly will be based on the number attribute.

If there are several nodes with the same number, the newly copied ones will be added to the end under the appropriate parent. The nodes with the number attribute which ends with a letter (Example: 2.3.S, 2.3.P, 2.3.A, 2.3.R) will be placed in the following order:

1. x.x.S
2. x.x.P
3. x.x.A
4. x.x.R

Publishing Messages (Troubleshooting)

During publishing, messages related to the publishing process are noted in either the publishing log or the *Publishing Readiness* query.
An error message that starts with ERROR or WARNING is an error reported in the publishing log. Many of the other errors and warnings are strictly reported in the Publishing Readiness query.

These publishing messages do not include messages from the rendering and publishing servers, including the fusion business service, internal error messages caused by build or installation failures, or messages related to an incorrect engineering configuration.

Repository Messages

You can view repository error messages in either the publishing log or the *Publishing Readiness* query.

Message	Description
`Document Repository {name} does not appear to be available.`	A DMS is not working or the Calyx RIM login credentials are wrong.
`Credentials not available for repository {name}.`	The system has not received the user name and password for logging in to the DMS specified in a document cross-reference in the assembly. The cross-reference cannot be resolved.
`LoginInfo and Principal for {name} docbase are not defined or wrong.`	The specified Docbase is shut down.

Assembly Messages

You can view assembly error messages in either the publishing log or the *Publishing Readiness* query.

Message	Description
`Missing Rendition/Rendition does not exist`	A rendition does not exist and must be created to successfully publish the assembly as you expect. Documents that are missing renditions will not publish. When this warning appears at the assembly level, an overlay file rendition is missing.

Message	Description
Assembly doesn't have any volumes associated with.	The assembly has been prepared for the paper output channel, however, there are no volumes in the assembly. There must be at least one volume to publish to paper.
Missing DTD Settings	The assembly is missing assigned DTDs. These should be assigned in the publishing settings before performing an eCTD publish.
No Document associated with the assembly	There are no documents in the assembly. No content documents will be included in the publish job.
ERROR: Not all publish options set for prepare for publish	One or more options in the publishing settings have not been set. Access Publishing Settings and verify that all settings have been applied. This is noted in the publishing log.
At least one XML definition is required. Please use Publication Settings to select XML Definition	At least one DTD XML mapping has not been set in the publishing settings. Access Publishing Settings and verify that at least one DTD has been applied.
ERROR: com.liquent.ip.ectd.EctdException: ectd_1004 Error detected in trying to parse the ectd rules file >path to rules file (The system cannot find the file specified)	The DTD XML mapping files cannot be found. Verify with your system administrator that they have been correctly installed and configured. This is noted in the publishing log.
Has no major division.	The assembly contains no folders flagged for major division. This is important if you are using any variables that resolve to major division. In this case, you would see unresolvable variables in your output.
Has no minor division.	The assembly contains no folders flagged for minor division. This is important if you are using any variables that resolve to minor division. In this case, you would see unresolvable variables in your output.
Minor division is defined before the first major division folder.	The assembly contains a minor division folder that appears higher in the assembly tree than a folder flagged for major division. In this instance, the minor division variable may not resolve properly.

Message	Description
ERROR: Unable to calculate the attribute xlink:href for folder on object null. Exception detected String index out of range: 1.	When the DTD does not have a mapping for folders added to an assembly, this error appears in the job requests job message log during publishing.

Folder Messages

You can view folder error messages in either the publishing log or the *Publishing Readiness* query.

Message	Description
Supplied publish folder of name {name} is not found	Internal error; contact Technical Support.
The folder output path includes invalid characters.	Invalid characters are specified for the output path. Valid characters include only lowercase letters (a-z), numbers (0-9) and hyphens. If these are not adjusted prior to publishing time, the publishing engine will make the correction according to normalization rules.
Required metadata on a folder has a missing value:	The folder has a required attribute value that is currently blank. This should be corrected before attempting an eCTD publish.
The extended attributes, output folder, or leaf output file name contain non-substitutable characters that contribute to eCTD the output path.	You can override this manually by changing the output folder or leaf output file name to use only valid eCTD characters.
The max length exceeded.	The output file path exceeds maximum regulation file length. This should be corrected before a final publish.
Missing output file location.	The folder is missing an output file location. The eCTD will not publish fully without the file location defined.

Leaf Messages

You can view leaf error messages in either the publishing log or the *Publishing Readiness* query.

Message	Description
There is no policy called '{name}' in the DMS {name}	You have chosen a Documentum business policy to attach published documents to, but the policy does not exist.

Message	Description
Cannot find attribute '{name}' on element '(name)' when importing into DMS	You have specified attributes that should be copied from leaf elements to published results, but the attributes specified in this message cannot be found.
Could not find an ICH definition.	No DTD/schema has been specified; one is required to publish an eCTD.
Leafs {name 1} and {name 2} produce documents at the same location {location}.	Change one of the leaf output paths to resolve this issue.
Native file leaf {name} contains multiple documents that cannot be concatenated. Excluding the documents from the publication.	You chose Yes for the Use Native File attribute but the parent leaf contains more than one source document. Change Use Native File to No or remove the necessary documents from the leaf.
No Documents detected in Assembly, Executing ECTD XML Backbone only publish.	The assembly contains no documents to publish. Only the XML backbone will be published.
Cannot find attribute {name} on element {name} when importing into DMS	You have specified attributes that should be copied from leaf elements to published results, but an attribute of this name cannot be found.
Invalid input error: {error description}	The specified XML file or one of its dependencies (for example, a DTD or stylesheet) does not exist or cannot be read.
Cannot find the Insight configuration file {name}	An installation fault has occurred.
The leaf with assembly path {name} has no output file defined.	You did not enter a path for the leaf. Each leaf requires a resulting file name. A temporary name is generated and publishing continues.
You have not defined any agency definitions for your assembly.	You have not chosen the XML definition files in the publishing options.
ERROR: Error with Component 4	Occurs when Calyx RIM is unable to put multiple files together, often because one is encrypted or contains invalid data. This is noted in the publishing log.

Message	Description
ERROR: XML structure error: line 155, column 25: The content of element type m1-5-specific"" must match ((m1-5-1-bibliographic|m1-5-2-abridged)?,(leaf|node-extension)*)"	Elements m1-5-1-bibliographic and m1-5-2-abridged are both present in your assembly structure. Remove one to create a valid xml. This is noted in the publishing log.
ERROR: NVPair has no attribute name	NONE is not a valid selection for country. Please assign all related sequences to a specific country. This is noted in the publishing log.
WARNING: Page number is missing	Indicates that a native file leaf is included in publishing and will not be counted in page numbering. This is noted in the publishing log.
WARNING: FileNameRule: leaf output path ../../../../JCS 24-17 AppC1/0000/m1/eu/16-environrisk/162-gmo/1-6-2-nodeext-01.pdf contains invalid characters: `J', `C', `S', ` `, `A'. [XPath: /eu:eu-backbone/m1-eu/m1-9-clinical-trials/leaf/@xlink:href]	Indicates that an output folder, output file name, or eCTD metadata used for XML paths contains illegal characters. Most illegal characters are normalized for valid output, but these must be confirmed in the output. This is noted in the publishing log.
Missing Content, no children.	The leaf has no content documents assigned to it. This warning is only valid on standard leaf elements, and not applicable to reference leaf elements.
The extended attributes, output folder, or leaf output file name contain non-substitutable characters that contribute to the eCTD output path.	Override manually by changing the output folder or leaf output file name to use only valid eCTD characters.
File name is blank	A file name is not specified. At publishing time, if this is not corrected, the publishing engine will use the leaf name as the file name.
File extension on the leaf file name doesn't match the type of document.	The leaf output file name extension does not agree with the file type for the first document under the leaf. This should be corrected prior to performing an eCTD publish.
Only one document will be published	This warning appears when a native file leaf has more than one child beneath it. In this instance, only the first child document will be included.

Message	Description
`Two leafs cannot have same output file`	If two leaf elements in your assembly have the same output file, there is a risk the file will be overwritten. This should be corrected prior to publishing.
`File extensions are missing.`	Special required leaf attributes are missing. Values should be entered prior to performing an eCTD publish.
`This native formatted document will be published without page numbers.`	It is possible to mark a leaf as native or to have a reference leaf that has an associated overlay. However, in these special cases of leaf elements, no overlay will be applied, and the element will not be included in the page count.
`The max length exceeded.`	The output file path exceeds maximum regulation file length. This should be corrected before a final publish.
`The maximum leaf file size has been exceeded.`	The leaf file size exceeds regulatory guidance.
`Inconsistent Lifecycle; Modified leaf must indicate its modified file.`	A leaf operation is something other than NEW, but its modified file value is missing. This is a discrepancy that may need to be resolved by your administrator in order to successfully publish your eCTD.
`Inconsistent lifecycle; a new leaf cannot have a modified file value.`	A leaf operation is NEW, but the leaf contains a value for modified file. This is a discrepancy that may need to be resolved by your administrator in order to successfully publish your eCTD.
`Excluded from Volume Range.`	You have volumes defined, but this element is not included in a volume. Therefore, it will not be published.
`ERROR: Unable to distribute`	Generally caused by failure to remove a file that already exists, failure to classify/register published output in a DMS repository, or failure to save the published output or version on a DMS or file system repository. This is noted in the publishing log.

Document Messages

You can view document error messages in either the publishing log or the *Publishing Readiness* query.

Message	Description
`There is no policy called {name} in the DMS {name}`	You have chosen a Documentum business policy to attach published documents to, but the policy does not exist.

Message	Description
Failed to create the checksum file {name} for backbone file {name}	You may not have access to the file or folder. Save the log file information and see your system administrator.
Native file leaf {name} contains multiple documents that cannot be concatenated. Excluding the documents from the publication.	You chose Yes for the Use Native File attribute but the parent leaf contains more than one source document. Change Use Native File to No or remove the necessary documents from the leaf.
No Documents detected in Assembly, Executing ECTD XML Backbone only publish.	The assembly contains no documents to publish. Only the XML backbone will be published.
Cannot find the file system extension of document {name}: {error description}.	Calyx RIM Publisher failed to find the file extension of a document in a DMS repository. The extension is required to save the results in the DMS repository.
Cannot find attribute {name} on element {name} when importing into DMS	You have specified attributes that should be copied from leafs to published results, but an attribute of this name cannot be found.
There is no policy called {name}" in the DMS {name}	You have specified a Documentum business policy to attach published documents to, but the policy does not exist.
An exception has been detected in resolving attribute {name}, Exception: {description}	Internal error; contact Technical Support.
{validation rule class}: {target Xpath}: missing leaf content file {file name}	The specified leaf document does not exist or cannot be read. The document may not exist (for example, because of an incremental publish).
There is no attribute named {name} defined on an element of type {name}	The attribute may be incorrectly named. Check attribute mappings and see if the attribute exists.
Failed to read content file {PDF file name} : {error description}	The PDF document has not been published or does not exist. Please verify the PDF document exists.
Input error: missing or invalid input file {file name}"	The document specified does not exist or cannot be accessed. Please verify that the document exists and is readable.
Input error: unable to parse XML file {file name}": {error type}: {error description}	The file specified cannot be accessed or its content is invalid. Please verify that the file specified is readable and that its content is valid.

Message	Description
`Assembly document {name} does not have an attached DMS document`	Warning to users that they have forgotten to attach a repository document to an IMA document.
`Failed to read content file {name}": {error description}`	The PDF document has not been published or does not exist.
`Input error: missing or invalid input file {name}"`	This is an installation fault.
`No output channel has been specified`	This element does not have an output channel associated with it. Therefore, it will not be published.
`Missing Rendition/Rendition does not exist`	A rendition does not exist and must be created to successfully publish the assembly as you expect. Documents that are missing renditions will not publish.
`This is a placeholder and it is not going to be published.`	The element is a placeholder. Placeholders cannot be published, and will therefore not be included in the published output.
`Unable to set properties for documents in folder {file path}: Unable to find document`	The distribute sub-job on the Calyx RIM Rendering server attempts to set properties on placeholders. When there is no document to accept the properties, the sub-job reports an error. This error can safely be ignored for placeholders.
`Document are not assigned and a DMS synch is required`	The document is not assigned. A DMS Sync is required for these documents to publish successfully.
`ERROR: ESPSLoadContainer`	This message is informational and may be safely ignored. This is noted in the Publishing Log.
`ERROR: Odd Page Overlay`	This message is informational and may be safely ignored. This is noted in the Publishing Log.
`Excluded from Volume Range`	You have volumes defined, but this element is not included in a volume. Therefore, it will not be published.

Page Marker Messages

You can view page marker error messages in either the publishing log or the *Publishing Readiness* query.

Message	Description
`Page Marker out of range.`	The page marker does not fall within the page range of the document that it is associated with. The system will assume that the page marker is intended for the final page of the content document.

TOC Messages

You can view TOC error messages in either the publishing log or the *Publishing Readiness* query.

Message	Description
`No output channel has been specified`	This element does not have an output channel associated with it. Therefore, it will not be published.
`Excluded from Volume Range.`	You have defined volumes but this element is not included in a volume. Therefore, it will not be published.
`Missing Rendition/ Rendition does not exist`	A rendition does not exist and must be created to successfully publish the assembly as you expect. Documents that are missing renditions will not publish.
`This TOC will not publish to paper if it is assigned to an element that is set only to the electronic output channel`	There is a discrepancy between the TOC output channel designation (paper) and the output channel associated with the element the TOC is assigned to. The TOC will not publish to the paper output channel.
`ERROR: Unable to Distribute`	Generally caused by failure to remove a file that already exists, failure to classify/register published output in a DMS repository, or failure to save the published output or version in a DMS or file system repository. This is noted in the Publishing Log

Cover Page Messages

You can view cover page error messages in either the publishing log or the *Publishing Readiness* query.

Message	Description
`No output channel has been specified.`	This element does not have an output channel associated with it. Therefore, it will not be published.
`Missing Rendition/ Rendition does not exist`	A rendition does not exist and must be created in order to successfully publish the assembly as you expect. Documents that are missing renditions will not publish.

Special Sheet Messages

You can view special sheet error messages in either the publishing log or the *Publishing Readiness* query.

Message	Description
`Excluded from Volume Range`	You have defined volumes but this element is not included in a volume. Therefore, it will not be published.
`No paper type defined`	The element does not have a paper type defined. This is necessary before proceeding with a paper publish.

Volume Messages

You can view volume error messages in either the publishing log or the *Publishing Readiness* query.

Message	Description
`Volumes have no documents.`	The volume is in the assembly, but it contains no content documents. It may contain placeholders, TOCs and special sheets. The volume will publish with any associated TOCs and special sheets.
`Volume page counts are over the maximum volume count plus buffer.`	The volume exceeds the maximum size as indicated in your settings. It can still publish successfully, however.
`Volume page counts are under the minimum volume count minus the buffer.`	The volume is too small to meet the minimum size as indicated in your settings. It can still publish successfully, however.
`Some documents in this volume has UNASSIGNED status and will not publish.`	There is at least one document in the volume that has a status of unassigned. If you want to publish all your documents that appear in this volume, you perform a DMS sync.

Checksum Messages

You can view checksum error messages in either the publishing log or the *Publishing Readiness* query.

Message	Description
`Failed to create the checksum file {name} for backbone file {name}`	You may not have access to the file or folder. Save your error log and see your system administrator.
`Cannot export the checksum values to the job definition: {name}: {error description}`	Internal error. Contact Technical Support.
`Failed to create the checksum file {name} for backbone file {name}`	There may be a file system permission issue. Save the log information and contact your system administrator.

Message	Description
`Error in creating checksum file: {name} for backbone {name}`	You may not have access to the file or folder. See your system administrator.

Other Messages

You can view other error messages in either the publishing log or the *Publishing Readiness* query.

Message	Description
`There was a problem while submitting the publish request, please refer to the server log for more details.`	This is an incorrect error message when publishing the M2-M5 template without changes. If the sample study reports found in sections 5.3.5.1 and other locations in 4.2 and 5.3 are removed, everything publishes fine.
`Problem storing job results to database: {error description}`	Most likely the Calyx RIM database is not available.
`Problem determining the id of the job {name}, unable to store the job results.`	Calyx RIM service has probably stopped working.
`No schemas have been defined in the assembly.`	You must choose XML definition files for the assembly.
`Failed to find validation.properties file. Exception {error description}`	This is an installation fault.
`Error finding jobs for assembly with ID {name}: {error description}`	The database may be inaccessible. Check the database connection and password.
`ERROR: org.hibernate.LazyInitializationException`	Generally caused by a server timing issue due to heavy workload or network latency. Try the operation again. This is noted in the publishing log.
`There was a problem while submitting the publish request, please refer to the server log for more details`	Generally caused by a server timing issue due to heavy workload or network latency. Try the operation again.

Message	Description
`Cannot use a task file reference before it has been evaluated`	This can happen when: — Publishing an empty structure — There are no publishable documents — Volumes have not been setup Do a DMS synch to make sure the extraction requests are up to date and that each document has renditions and extractions. To troubleshoot the assembly: — For a paper publish, check that you have a volume. — Check that you have publishable documents. — Check that you have output channels. — Check that you have a file under a native leaf. — Check that you do not have more than one file under a native leaf. — Check that each volume has at least one publishable document, output channel, renditions, extractions.

Linking

Linking activities are available depending on the license modules available to the user.
You must have the following Calyx RIM modules to perform linking activities:
— Electronic Lifecycle Publishing (ELP)
— Paper Review Publishing (PRP)

Four kinds of links are supported by Calyx RIM.
— Authoring
— Lifecycle
— Post-publishing
— In-process

Authoring Links

Authoring links are hyperlinks created by authors in source documents. These links may point to documents in the DMS or file system. These links may also go to versions, pages, and bookmarks, or may be comments that indicate to the publisher how the link should be created.
Authoring links may be reused freely, and will automatically persist in new versions of modified documents within a source DMS repository or file system.

You can create authoring links in most content-editing software (such as Microsoft Word or Adobe Acrobat) as long as they are relative paths to target documents. While creating authoring links:
— You can use tools such as Microsoft Word and Linking add-in (Word) to generate both in-document links and cross-document links.
— Calyx RIM can interpret and understand links embedded in a document that point to other areas of the same document as well as links that point to other documents.
— Links may be targeted across servers and file shares, and DMS repositories of the same or different types.
— Links may target documents, specific page numbers within documents, and in the case of and Linking add-in (Word), they may target bookmarks or headings within documents.
— Links may target specific versions of documents, or by default the current (latest) version.
— Links may also consist of just a comment that indicates where the link should eventually be targeted.

Lifecycle Links

Lifecycle links are links that target documents across sequences in the same application.
Lifecycle links are automatically updated in the Calyx RIM link database to always point to the most current or specific version of a document in the application for published output. All lifecycle linking in Calyx RIM is done through the Link Inspector.

Lifecycle links have three basic types: broken, stale, and historical.

— Broken links point to content that does not exist or has moved due to lifecycle operations. They occur when a leaf is replaced in a new sequence with a new document, but that document's links are still targeting the old content and must be updated with new path information.
— Stale links are links where the source document and target document reside in different sequences, and Calyx RIM has not needed to update the link to insure a valid target during publishing. These links start in the old sequence targeting the current sequence. Any link marked as stale should be evaluated by the publisher for the correct target, because the target document may need to be operated on in the current sequence to resolve the link correctly, or you may need to verify that the historical target of the link is still valid for the reviewer.
— Historical links point from updated documents in newer sequences back to documents in old sequences.

Create In-Process Lifecycle Links

You can create lifecycle links by targeting a link to a document that exists in an assembly outside the current assembly. This includes an assembly in any other sequence and is not restricted to the current application.

For historical in-process links pointing to a submitted sequence, you can target a leaf, a document or bookmark. To create historical links from a working assembly to previously submitted content, the target assembly must have been published prior to adding to lifecycle. This sets the published output location on those leaf elements so that the appropriate relative path to the target may be determined.

Unless links are set to a document or a bookmark and any links targeting the old document get moved automatically to target the new document you assign under that leaf. The link is modified to point to the new location. In-process links created to a document or a bookmark will target to the location in previous sequence like it was selected when the link was created.

While links going to documents cannot target outside the current assembly/sequence, links going to leaf elements may target both old sequences and targets outside the current application. These links will have a status of Targeted even if the source document is not in the same assembly as the target document. They will be published as cross-application links according to the same rules that govern reference leaf elements.

Reference Leafs and Hyperlinks Between Applications

You can link to content between different application lifecycles using reference leafs or hyperlinks. Links or references pointing to separate applications must navigate back to the root of the output, below the application number.

For example, you might want to make reference to content in your IND application from your new NDA application by either reference links or hyperlinks, as shown in the following scenarios.

Reference Leafs

Any reference leaf can point to any other leaf in a separate application. The reference will navigate back to the root of the output under the application number. This example shows a target (Leaf 1) in a IND application that is referenced from Leaf 2 in the NDA application.

Leaf	Application number	Prefix*	Sequence	HREF
1	123456	ind	0000	`m1\mydoc.pdf`
2	234567	nda	0001	`m1\mydoc2.pdf`

*For the US, a 3-letter Application Prefix attribute is added to the application number.

In this example, the target document in the reference leaf is two levels removed from the root of the application.
— The navigation path of the href from Leaf 2 to Leaf 1 is: `..\..\ind123456\0000\m1\mydoc.pdf`
— The navigation path of the href from Leaf 1 to Leaf 2 is: `..\..\nda234567\0001\m1\mydoc2.pdf`

Hyperlinks

Any hyperlink can point to content in any other leaf in a separate application. The hyperlink will navigate back to the root of the output under the application number. This example shows a hyperlink target (in Leaf 1) in a IND application that is referenced from Leaf 2 in the NDA application.

Leaf	Application number	Prefix*	Sequence	HREF
1	123456	ind	0000	`m1\test\mydoc.pdf`
2	234567	nda	0001	`m1\mydoc2.pdf`

*For the US, a 3-letter Application Prefix attribute is added to the application number.

In this example, the target document in the reference leaf is three levels removed from the root of the application.
— The navigation path of the href from Leaf 2 to Leaf 1 is: `..\..\..\ind123456\0000\m1\test\mydoc.pdf`
— The navigation path of the href from Leaf 1 to Leaf 2 is: `..\..\nda234567\0001\m1\mydoc2.pdf`

Post-Publishing Links

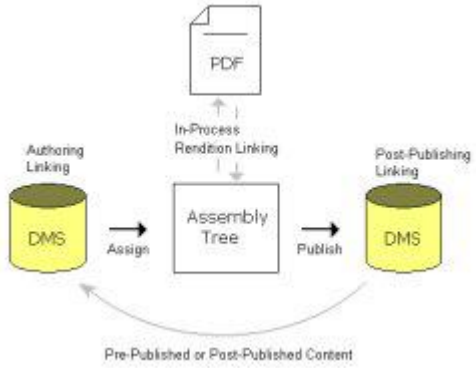
Post-publishing links are hyperlinks created by publishers after the publishing has completed. Most links cannot be reused in their current state, but can be edited for reuse.

These links cannot be reused automatically across documents or assemblies, but they may be exported, imported, repaired or updated. Post-publishing links may be reused if output documents are used as new source documents, as in the case of published reports that are used within a submission.

After publishing the documents in an assembly, if they are on different file shares or DMS repositories, Linking plug-in (PDF) creates a link that can be read only by Calyx RIM. Starting with Calyx RIM Linking plug-in (PDF) 1.8, the create and update support for post-publishing links is discontinued.

Note: *Be sure you are always linking documents on the same file share when creating post-publishing links.*

Published documents can be used again by Calyx RIM as though they were original source documents. Once PDFs have been published from the assembly, Calyx RIM can reuse these published documents in an entirely new assembly just like it would original source documents. You can use Linking plug-in (PDF) again to create in-process renditions of the documents and create, update, and delete links in Calyx RIM.



As shown above, the source documents from the DMS repository are assigned to Calyx RIM's assembly tree. During assignment, all the links contained in the source documents are extracted and stored in Calyx RIM. Once there, you can adjust the links through Linking plug-in (PDF) using a PDF rendition of the documents. The links may also be viewed and edited using the Link Inspector. Afterwards, you can publish the documents back to the DMS repository, and modify the links after publishing. The published content can be used again as the original if you need to reuse content in another publication. In this way, Calyx RIM can support your own best-practice linking processes, as links may be updated at each phase as needed.

In-Process Links

In-process links are content that is approved and finalized; they cannot be directly modified in the DMS. In-process links can be reused between documents and submissions/regions as well as automatically reconciled between document versions.

These links can be:

— Created in a final, non-editable PDF

— Retargeted in a final or draft document

Calyx RIM enables you to insert, modify, and delete in-process links and bookmarks in documents that are assigned to assembly leafs from Calyx RIM. Calyx RIM uses a database-centric approach to manage both lifecycle links and links found in documents assigned to an assembly.

Calyx RIM also enables you to link to a leaf, document, or a bookmark of a document from the previous sequence.

Link to a document in a previous sequence is not updated if there is a newer copy of target document in current assembly. If target is not valid, links become broken and do not appear in the output. It reflects in Link Inspector, thereby allowing to select an appropriate target.

When creating an in-process link it is possible to restrict the presence of the in-process link to an application. Not imposing any restriction makes the in-process links appear for all copies of source document in the system.

After a document is assigned to a leaf in an assembly, the linking information is extracted, stored, and manipulated in a secure database. Calyx RIM publishes a temporary rendition (called an in-process rendition) of each document

in PDF format. You can use this viewable copy of the rendition prior to publication to create new links or modify links created during the authoring stage and target them to other locations in the current submission.

When editing links in an in-process document rendition, only changes to links are stored in Calyx RIM. While Acrobat enables you to change other items (text, bookmarks, etc.), they are not saved.

Note: *In-process linking with Linking plug-in (PDF) in Calyx RIM is enabled by using the supported versions of Acrobat. Be sure to select the system viewer option (Acrobat) when opening a document for in-process linking, not the Web browser's viewing option. See the Linking plug-in (PDF) 1.8 System Support Document (SSD) for details.*

Create In-Process Links

To use in-process linking, your assembly must be a standalone assembly, a sequence assembly, or a working assembly that has not been locked and lifecyled.

To create an in-process link, a PDF rendition must exist, and the document must be prepared for linking.

— You can request that a particular document in the assembly tree be rendered and then be prepared for linking.

— You can select a folder or the assembly root and indicate that all documents be prepared for linking.

— You can specify the link applicability for new links to Global or Application.

A temporary PDF rendition is created when a document is prepared, and you can use Linking plug-in (PDF) to create links. The rendition is only available in the assembly for creating and modifying links prior to publishing. Also, you can only create links in in-process renditions. Any text modifications made in an in-process rendition will not be saved.

The standard Calyx RIM tool for creating and modifying links in PDF documents is Linking plug-in (PDF). When creating or modifying in-process links using Linking plug-in (PDF), if you want to create an internal link to a different page of the current document, you must choose the current document in the assembly tree as your destination with a different page number. Linking plug-in (PDF) defaults to the current document to make this easier.

Comment Links

A comment link is a placeholder for a link to a document that does not yet exist in an assembly.

The comment reminds publishers that a link must be created once the document exists. You can create comment links using Linking plug-in (PDF).

Linking Tools

Calyx RIM supports a number of tools that can be used to create links from source to target content on authored documents.

— Internal native Adobe links

— External native Adobe links

— Word cross-references

— Linking plug-in (PDF)
— Linking add-in (Word)

These links are treated distinctly in the following ways:

Linking Type	Electronic Output Channel	Paper Output Channel
Internal native Adobe	Links published to retain the behavior and format of the authored document.	Links stripped from the output; no margin cross-reference is created for these links
External native Adobe	Native external links created within the PDF source document by any product other than Linking plug-in (PDF) will not display in the electronic output channel.	Links stripped from the output, no margin cross-reference is created for these links.
Native Word cross-references	Links converted to Adobe hyperlinks; the Calyx RIM Rendering server controls the formatting of these links. See the Calyx RIM Rendering server documentation to configure this to meet your requirement for formatting links.	These links are converted to margin cross-references. If the variable for the margin cross-reference text cannot be resolved, it will display the "Cross-Reference Text" from the link profile. ***Note:*** *These types of links are recommended only for users who have a license for Calyx RIM Rendering.*
Linking plug-in (PDF) (in-process)	Links are published, and are formatted based on the characteristics established in the Publishing Settings.	These links are converted to margin cross-references. If the variable for the margin cross-reference text cannot be resolved, it will display the "Cross-Reference Text" from the link profile.
(Linking add-in (Word) is not provided with Calyx RIM, it must be purchased separately.)	Links converted to Adobe hyperlinks; the Calyx RIM Rendering server controls the formatting of these links; see the Calyx RIM Rendering server documentation to configure this to meet your requirement for formatting the links.	These links are converted to margin cross-references. If the variable for the margin cross-reference text cannot be resolved, it will display the "Cross-Reference Text" from the link profile. ***Note:*** *Due to LinkText limitations in PDF, Calyx RIM does not support non-English characters when extracting linked text.*

Calyx RIM Link Types

Three types of links can be created in Calyx RIM: authoring, in-process, and post-publish.

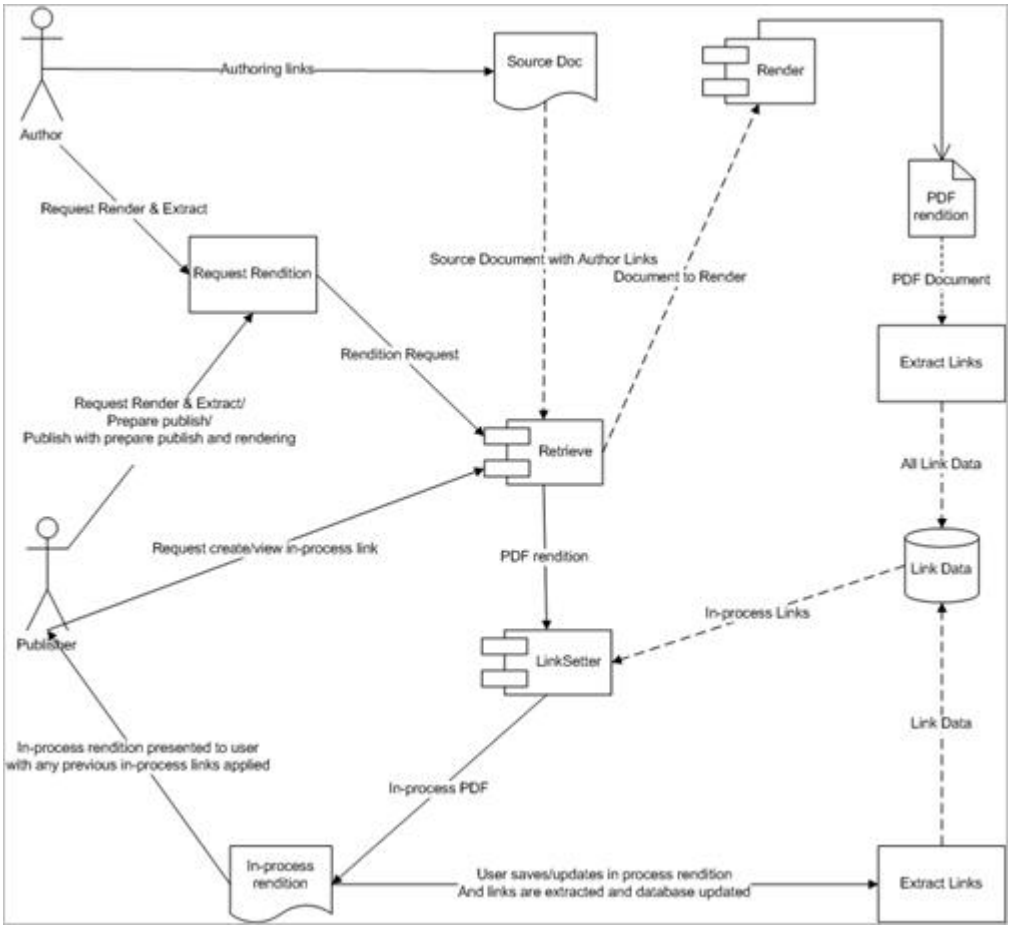
Three types of links can be created in Calyx RIM: authoring, in-process, and post-publish.

— Authoring Links – Links created by the authors in the source document
— In-Process Links – Links created by publishers (without modifying approved documents – because the data used to reconcile links is extracted and persisted and you can add/modify links without actually modifying the original rendition)
— Post-publish Links – Links created by publishers after the publish has been completed

Using the Calyx RIM database and service-based architecture, Calyx RIM can automatically reconcile lifecycle links and provide advanced queries.

Business Service Requests Sequence Example

The following diagram illustrates requests sent to business services to extract link information or apply existing links to an in-process rendition (used for publishers to create new links without modifying the existing approved rendition).



Copy Links Between Assemblies

Calyx RIM enables you to copy links from assembly to assembly, view to assembly, or just by reusing the same file again in a different assembly.

The following applies to this feature:

— The link applicability setting determines ultimately whether an in-process link is copied from one assembly to the other. Application only links remain in the source application. Global links show up in new applications.

— Link profiles are not copied to new assemblies. They are always reset to the System Profile.

— Link output channels are copied in certain cases only. If the link has been created using in-process linking and the applicability is set to Global, the output channel is always copied to the new assembly. For Calyx RIM Xrefs, the output channel is always copied to the new assembly.

When copying an assembly from another assembly, the following rules impact how links are copied:

— Link applicability determines exactly whether links are copied across assemblies. Any links with Global Applicability are copied, and any links with Application Applicability are not copied.

— While lifecycle links are updated to point to the correct replaced leaf during publishing, the original targets are retained for an assembly copy. This is also to insure the links are valid if sequences are removed from lifecycle.

Get Started with Linking add-in (Word)

Linking plug-in (PDF) and Linking add-in (Word) enable you to create hyperlinks in documents that target pages or bookmarks in the same document, in external documents, or in Calyx RIM assemblies.

When creating a hyperlink, you can specify attributes for the link, such as the text color and the line width and color of the bounding box. You can also open the target document for an external link to determine the destination page in the target document.

Linking plug-in (PDF)

Linking plug-in (PDF) enables you to create and modify hyperlinks during each stage of the publication process: authoring, in-process, and post-publishing. Each stage uses Linking plug-in (PDF) in its own way:

— In the authoring stage, the Linking plug-in (PDF) Acrobat plug-in enables you to create links in or between documents on file systems or DMS repositories. The Linking plug-in (PDF) Acrobat plug-in also supports comments, link quality control, keyword linking, and bookmark linking.

— In in-process linking, the Linking plug-in (PDF) Acrobat plug-in enables you to create or update links in a document in Calyx RIM by editing a temporary PDF rendition. Links are targeted directly to the assembly tree. The Linking plug-in (PDF) Acrobat plug-in also supports comments, keyword linking, and bookmark linking.

— In post-publishing linking, the Linking plug-in (PDF) Acrobat plug-in enables you to create or update bookmarks on a final published PDF. Import/export to Microsoft Excel and bookmark linking are supported. Starting with Calyx RIM Linking plug-in (PDF) 1.8, the create and update support for post-publishing links is discontinued.

Linking add-in (Word)

Linking add-in (Word) is a plug-in for Microsoft Word that enables you to create links in or between Word documents on file systems or DMS repositories. It also supports comments, keyword linking, version linking, and bookmark linking.

Note: *Linking plug-in (PDF) or Linking add-in (Word) must be installed on your local machine. A successful installation creates new toolbar icons in either Acrobat or Word.*

Modify In-Process Links

You can modify in-process links and retarget the links to new locations.

Beginning with Calyx RIM 7.0 CHF 3, you can modify the default link Applicability for new links from Global to Application in the Link Inspector only.

Note: *You cannot update the link Applicability for new links from Global to Application using Linking plug-in (PDF). To set up the necessary link Applicability, delete the link in Calyx RIM and create it again. See Link Applicability.*

When a link is in focus, meaning you have clicked the link and it is selected, you can change the destination and retarget the link by clicking the link icon. This is true for both normal and fast link modes. However, when you are in fast link mode you can draw a new link on top of the original link and the new link overwrites the original link. When you do this, only the new link remains.

The following is an example of an in-focus link:

When linking in-process, all links in a document will display with a red border. This is to indicate that only links may be modified from this interface. Any other changes made to the PDF will not be retained by Calyx RIM.

Link to Assembly Elements

After you log on, the SmartLink tool appears with the in-process mode turned on by default. Calyx RIM is selected and a window displaying the working view tree is open.

When the in-process mode is displayed, you can create links two ways: in fast link mode or normal link mode.

Targeting Assembly Elements in Fast Link Mode

With the fast link check box selected (the default), every time you draw a box in the rendition you create a link, so prior to creating a link you must select the destination. You can create a destination by highlighting a location in the assembly. You may also select a page number to target if you are highlighting a non-bookmark leaf (selecting a

bookmark nullifies the page number field). Once you select a destination, you can draw one or multiple links to the destination without ever clicking another button.

Targeting Assembly Elements in Normal Link Mode

When the fast link check box is not selected, you must click the link icon to execute creation of the link. When you are in the normal link mode, you can either draw the box or select the destination first. Once both are set you create the link by clicking the link icon. You can create a destination by highlighting a location in the assembly tree. You may also select a page number to target if you are highlighting a non-bookmark leaf (selecting a bookmark will nullify the page number field).

Creating a Comment Link

You can link comments to specific text in an Calyx RIM in-process rendition.

To create a comment link in an in-process rendition:

1. Open Link Stamper and then click and drag the pointer to create a bounding box around the text you want to be the hyperlink.
   The *SmartLink* dialog box opens.
2. Select Comment.
3. In the Link To drop-down box, enter an appropriate comment to remind publishers of the link that needs to be created once the target document exists.
4. Under Appearance, specify the attributes for the magnification, text color and bounding box.
5. Click Link.
   A comment hyperlink has been created with the attributes you defined.
6. Repeat steps 2-5 for as many comment links as you need to create.
   The *Link Stamper* dialog box preserves the previously defined settings so you can create multiple links with minimal or no changes.
7. To save your hyperlinks to the in-process rendition, click File > Save in Acrobat.
   Calyx RIM in-process rendition changes must be checked in to Calyx RIM.

Save Links to Calyx RIM

After you have finished creating links in the rendition, you can upload the links to Calyx RIM so they show in the published output.

To upload the links:

1. Select SmartLink > Save to Calyx RIM Publisher in the PDF editor.
2. Calyx RIM prompts you to upload the links when closing the *SmartDesk* dialog box and/or PDF editor.
3. In Acrobat, click Save.

Modify Bookmarks

The bookmark editor enables you to modify the existing bookmark structure of a document. Bookmarks modified in the editor impact all occurrences of the source document in Calyx RIM including TOCs, link targets, and final published bookmark structure.

Bookmarks are not affected by the output channel. When a document is assigned, its document structure is extracted according to rendering settings and bookmarks are created in the Calyx RIM database. These bookmarks are published for each file as-is unless you update them in the bookmark editor or they are overridden by a TOC. Bookmarks are applied only at publish time. They do not appear in in-process renditions.

If a link targets a bookmark and the document is updated with a new version, all bookmarks from the previous version are deleted and new bookmarks are created. Bookmark changes in the editor are not merged with a new version of the document. If a new version is checked-in and accepted by the publisher, its source bookmarks automatically overwrite any changes made with the bookmark editor.

Calyx RIM does not capture any actual bookmark information when extracting internal link information. Instead, it captures the page number for the document's bookmark. If the links are to external documents, information is captured because you are targeting to a bookmark of a PDF rendition.

After you have saved bookmark changes in the bookmark editor:

— Each item in the list is comprised of a page number and the bookmark name. You can edit both values.
— You can select individual or multiple bookmarks in the list and run any of the operations on all of them at once using the action buttons.
— You can move each bookmark up or down by dragging it to a different location and dropping it. Moving a bookmark changes its location in the source document association.
— You can move individual or multiple bookmarks up or down, promote or demote them, and increment or decrement their page numbers using action buttons on the toolbar.

Modify a Bookmark

You can modify bookmarks in a specific document in an assembly, including updating the location or deleting the bookmark.

To view and modify bookmarks:

1. Right-click a document in the assembly and select Edit Bookmarks.
   A comment hyperlink has been created with the attributes you defined.
2. Do one of the following:

Action	Procedure
To add a bookmark tied to the current source document	Click the Add Bookmark button.
To add the bookmark as a sibling of the bookmark you clicked	Click an existing bookmark then click Add Bookmark .

Note: *During the extraction of documents, blank levels are filled in if they are missing. If levels are missing in the bookmark editor, Calyx RIM compresses the tree and promotes the higher levels to fill in the missing gaps at publishing time.*

3. Select one bookmark in the list and click the Edit action button to edit fields not found on this page.
4. Select one or more bookmarks in the list and click to delete the specified bookmarks.

Note: *Deleting bookmarks that are targeted by links may not always invalidate the link. Calyx RIM still attempts to resolve these links at publishing time using a combination of page number, bookmark hierarchies, and bookmark neighbors. In most cases a warning results on the target document indicating the link was retargeted; in some cases however the bookmark represents a target page and no warning results.*

5. Click Save.
   Changes you make to bookmark values are saved once you click the Save button. Changes you make using the action buttons are saved immediately.

Note: *Changes you make in the bookmark editor are not merged with a new version of the document. If a new version is checked-in and accepted by the publisher, its source bookmarks automatically overwrite any changes you make using the bookmark editor.*

Link Inspector Query

The Link Inspector query enables you to view the status of all hyperlinks and cross references, and make any necessary changes prior to publishing.
The query shows the link status for links created with Linking plug-in (PDF) , Linking add-in (Word), native Word cross references, and internal (intra-document) native Adobe links.

You can run the Link Inspector query at the assembly, folder, leaf, volume, or document level. However, Link Inspector shows only the links within the selected element.

When a document has been modified, it must be saved as a different version in order for the changes to appear in the Link Inspector query.

Hyperlinks or cross references targeted to documents that do not exist in the current assembly, or that are targeted to versions of documents that do not exist in the current assembly, show as invalid links in the Link Inspector. They may be easily corrected by bulk retargeting them to the same destination document. This resets the target document to the current version assigned in the assembly.

To minimize confusion, unresolved links where the link source exists outside the current assembly do not appear in the Link Inspector query. The current assembly is based on how you last refreshed the query from Prepare for Publish:
— If you refreshed the current sequence view only, the query shows only links in the current sequence.

— If you refreshed the entire working assembly, stale links that target documents in the current assembly are also displayed.

In some cases, the link text does not come through from the PDF. This can occur when:
— The text under the link is an image that cannot be interpreted by the OCR.
— The text is not completely under the link.
— The text is Japanese or Eastern characters.

Refresh the Link Inspector Query

You can use the Link Inspector query to view updated links in the current sequence or the entire assembly.

When refreshing the Link Inspector query from Prepare for Publish, there are two options:

— Current Sequence View Only is recommended for lifecycle sequence assemblies. This refreshes only links in the current sequence/publishing view and not the entire working view. For standalone or non-lifecycle assemblies, this option does not refresh anything.
— Entire Working Assembly is recommended for standalone and non-lifecycle sequence assemblies. This refreshes the entire assembly for link changes. For lifecycle sequence assemblies, this is useful to allow an impact analysis to be made against older documents that link to current documents for possible inclusion of these documents in the latest sequence. However, this should be used sparingly within lifecycle sequence assemblies because it may take much longer to refresh this linking information during the Prepare for Publish process.

Note: *You must refresh link information using Prepare for Publish at least once before running the Link Inspector on an assembly.*

Run the Link Inspector Query

You can use the filters in the Link Inspector to view specific links, or specific types of links.

Warning: Always run a DMS synchronization before refreshing the Publishing Readiness query, Link Inspector query, and other queries. Calyx RIM uses the data available in the Calyx RIM database and relies on DMS synchronization to ensure this information matches what is in the DMS for each document.

To run a Link Inspector query:

1. Right-click a folder, leaf or document and select Run Link Inspector.
2. Select the filtering options.
3. Click Search. All the links that meet the search criteria are displayed.

Link Inspector Action Buttons

You can use the Link Inspector to edit or delete links in your assembly.

Button	Name	Description
	Retarget Links	You may change the location of the target document to a leaf or bookmark. To find an assembly, click the Search tab and use the *Search Assembly* wizard. See Searching for an Assembly.
	Edit Link Applicability	You may change where the link is applicable (for example, globally to each occurrence of the link pair in any assembly or for this application only).
	Edit Link Profile	You may modify the link properties to change the profile to change settings for each link either individually or through the multi-select checkbox.
	Edit Link Output Channel	You may modify the link properties to activate or deactivate output channels for each link either individually, or through the multi-select checkbox.
	Delete Link	Existing information about this link will be deleted.

Link Statuses

Calyx RIM uses flags in the results of the Link Inspector query to show the status of links.

Status Flag	Description	Details	Examples
OK	Link Targeted and Current	Link is targeted to resolvable location in the current or working assembly. Link is current with latest document rendition and the target document has not been updated since the link was established.	— Both documents exist in DMS. — Link points to valid page, leaf or bookmark in the target. — Source and target are both assigned in the same sequence.
OK	Link Suppressed	Link has output channel set to None.	Same as Link Targeted and Current but output channel set to none.

Status Flag	Description	Details	Examples
Warning	Link Lifecycle Auto-Update (Historical Link Scenario)	The link targets a document in an Calyx RIM assembly in the current Application, but not in the current sequence. In this scenario the target is linked to by a source that's been included in a prior sequence in the same Application. Calyx RIM lifecycle auto-updates this link to resolve correctly to the already-submitted document.	— Both documents exists in DMS. — Source document assigned in original sequence. — Target document not assigned in original sequence. — Target document assigned in current sequence. — Source document not included in current sequence. — Prepare for publish is run on the working or sequence view of the current sequence.
Warning	Link Lifecycle Auto-Update (Stale Link Scenario)	The source link (bound to current) targets a document in an Calyx RIM assembly, and the target document is bound to current and replaced in the second sequence with a new version of the target which is now bound to current. Calyx RIM will lifecycle auto-update this stale link because it considers this link to be following the latest replaced version of the document.	— Both documents exists in DMS. — Source and target document assigned in original sequence. — In current sequence an updated version of the target document is replaced with the "current" (label) document. — Source document not assigned in current sequence. — Prepare for publish is run on the working view of the current sequence.

Status Flag	Description	Details	Examples
Note: *When two or more sequences exist in a working assembly, and an authoring link in two different source documents point to the same target document, adding a new leaf with an updated version of the target document will cause the* ***Lifecycle Auto Update*** *status to display "auto updated" in the inspector report when Prepare to Publish is run. This is expected behavior, because: * Both documents exist in the DMS. - The target document was assigned in the original sequence. * In the current sequence, an updated version of the target document is replaced with the "current" (label) document. * The source document is assigned in the current sequence. (Even though this document has just been added to the sequence, it will still be auto-updated because the target has been replaced. It is updated to link to the new version that is in the sequence.) * Prepare to publish is run on the working view of the current sequence*			
Warning	Stale Link	The source link targets a document in an Calyx RIM assembly, but the target document is bound to a specific version in the first sequence and replaced in the second sequence with a new version of the target which is now bound to current. InSight cannot lifecycle auto-update this link because it considers this link to be bound to the old version.	— Both documents exists in DMS. — Source and target document assigned in original sequence. — In current sequence an updated version of the target document is replaced with the "current" (label) document. — Source document not assigned in current sequence. — Prepare for Publish is run on the working view of the current sequence.
Error	Incomplete Link	The link is of comment type, not a document.	Comment link type
Error	Incomplete Link	Target document cannot be found in the DMS.	Target document does not exist in DMS.
Error	Incomplete Link	The link targets a document that is not resolvable when published (not contained in any known assembly).	Target document does not exist in the application.

Status Flag	Description	Details	Examples
Error	Target Missing	The link must be retargeted because either (1) the targeted bookmark was deleted from the document or (2) the targeted page (last page in the document) was removed from the revised document.	Specific destination in document does not exist.
Unknown	Link Modified	The link has been modified in the Link Inspector since Prepare for Publish was run.	— Change of link from the Link Inspector query screen without prior to running a prepare for publish. — Link Modified status will be updated once prepare for publish is run.
Unknown	Undetermined Link	Gives a status to links we cannot determine.	Scenario where none of the other descriptions applies.

View the Link Inspector Query

When viewing the ***Link Inspector*** query, you can modify one or multiple links using the action buttons.
You can sort columns using standard Calyx RIM query functions. Please note that all columns do not appear by default.

Column Name	Description
Character Encoding Status	Indicates the status for each source or target link component: — Green - Character encoding appears to be correct. — Red - Character encoding update may be required. — White - Character encoding is not applicable. Either, the link is not an external link or the document contains no links.
Internal	Indicates if link source and destination documents are the same (intra-document link) or different (inter-document link).
Link Applicability	Displays whether the link pair and any modifications made through the Link Inspector are applicable globally to each occurrence of the link pair in any assembly or for this assembly only.
Link Code	A system-generated sequential number or alphanumeric equivalent unique to the link.

Column Name	Description
Output Channel	The output channels (paper/electronic) for each link. The user may modify the link properties to activate or deactivate output channels for each link either individually, or through the multi-select check box.
Source Assembly Name(s)	A system-interpreted, read-only field that displays the assembly names for the link source's assembly.
Source Description	A text message describing the link results based on the source flag and status.
Source File Path, Name and Version	The path, name and version of the bound document. ***Note:*** *If the source file name is too long to fit properly in the source column in the link inspector, go to the filter page and include* Source Path and File name and Version *as one of the selected columns for the query results.*
Source Filename	The name of the original document.
Source Flag	Displays a color indicating the link status of each link source: — Green = OK — Yellow = Warning — Red = Error
Source Link Status	System-generated text based on the source flag.
Source Link Text	The underlying text of the link in the document.
Source Page Number	A system-generated, read only numeric field that displays the source page number of the link.
Source Sequence Number(s)	A system-interpreted, read-only field that displays the sequence number(s) for the link source's assembly.
Target Assembly Name(s)	A system-interpreted, read-only field that displays the assembly name(s) for the link target's assembly.
Target Bookmark	The target bookmark, if applicable.
Target Comment	This is available if a planned destination or comment exists.
Target Description	A text message describing the link results based on the target flag and time stamp when the query was generated.
Target File Path, Name and Version	If the target is a document element, this column contains the path, name and version of the bound document. If the target is a leaf element, this column contains the file name attribute on the leaf (if defined).
Target Filename	Name of the file that contains the link target.

Column Name	Description
Target Flag	Displays a color indicating the link status of each link target: — Green = OK — Yellow = Warning — Red = Error
Target Link Status	System-generated text based on the target flag.
Target Page Number	The target page number (whether explicit or through a bookmark).
Target Sequence Number(s)	A system-interpreted, read-only field that displays the sequence numbers for the link target's assembly.
Time Stamp	The creation date of the record. This is displayed only once in the header of the query results.

Character Encoding Status

You need to verify and update external links in documents created with earlier versions of Acrobat 8.

For external links in PDF renditions that were created with Acrobat prior to Acrobat version 8, non-Unicode encoding of the links may not be correct in Calyx RIM. When assigning a document to an Calyx RIM assembly, Calyx RIM extracts linking information from the PDF. During the extraction, Calyx RIM applies the default character encoding of the Windows operating system that is used on the Calyx RIM Rendering server that processes the job. As a result, the character encoding that was used when creating the links in the existing PDF rendition of the document may be different than the character encoding applied by Calyx RIM when performing extractions.

The purpose of the ***Character Encoding Status*** column of the ***Link Inspector*** query is to identify external links affected by this scenario. When the encoding of the external links is flagged by this column, the following actions can be taken:

— You can re-render the source document.

— You can re-target the links using the re-targeting functionality built into the Link inspector query.

— For source PDF files, you can update the character encoding using Linking plug-in (PDF), and then perform a DMS Synchronization to re-extract the links.

Link Applicability

Applicability indicates whether the changes made to a link are Global or limited to the Application only. Applicability can be changed for a link in sequence assemblies only. If Applicability is defined when the link is created and set to Application, the link will not appear in assemblies that do not belong to the current Application and do not contain copy of source document. If Applicability is set to Global when the link is created, the link will appear in all assemblies that contain a copy of the source document.

Beginning with Calyx RIM7.0 CHF 3, you can specify the default link Applicability for new links to Global or Application. The link applicability functionality works with sequence assemblies, not standalone assemblies.

Before performing the following steps, verify that you have Adobe Acrobat and Linking plug-in (PDF) installed on your computer.

To set the default link Applicability to Global or Application:

1. In Calyx RIM, highlight any document with rendition assigned to the Assembly.
2. In Document Attributes, select More > Prepare Documents for Linking.

   If the document is already prepared for linking, click OK to overwrite it. Verify that other users are not working with the link before overwriting.

   The Prepare Documents for Linking Location field will be populated in the Document Attributes window.

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3. ***Note:*** *You cannot update the link Applicability for new links from Global to Application using Linking plug-in (PDF). To set up the necessary link Applicability, delete the link in Calyx RIM and create it again.*

   Select More > Edit Document Links.
4. Agree with the message about opening the file.
   The file will be opened in Adobe Acrobat.
5. Highlight the text in the document and select the target in the Assembly (example: leaf) where the link should be connected.
6. Select the Application or Global in the Applicability options list.

   The changes made to the links of the Application type are restricted by the Application.

   The changes made to the links of the Global type affect all the copies of the link.
7. Select LIQUENT SmartLink > Save to Calyx RIM.
8. Click OK to close the current in-process rendition.
9. Go back to the Calyx RIM Assembly and highlight the document (example: leaf), refresh link inspector data by selecting the Prepare to Publish option.
10. Highlight any node (example: leaf) and click Run Link Inspector.
11. In the Link Inspector Query window, go to the Display Columns menu.
12. In the filtering options, select Applicability.
13. Click Search.
    All the links that meet the search criteria will be displayed.
14. Verify that the Applicability type corresponds to the one you set up.
15. To edit the link Applicability in the previously existing way, select the necessary link from the list in the Search Results.
16. Click the Edit Link Applicability icon.
17. In the Applicability drop-down menu, change Global to Application and Save.
    The link modified flag changes its color to red and the Link Modified description appears.
18. To save the changes made, go back to the Calyx RIM Assembly and highlight the document (example: leaf), refresh link inspector data by selecting the Prepare to Publish option.

19. Verify that the Applicability value is saved.

Extension Types and Usage

You should provide attribute values in each assembly for the following elements that result in the creation of additional attributes for their corresponding XML elements.

- 1 Administrative Information and Prescribing Information in US (DTD 2.01), CH, JP, ZA, AU, or TH template
- 1 Administrative and Product Information in CA template
- 1 Administrative Information folder in US (DTD 3.3) template
- EMA Envelope Information in EU template (The path to this is: 1 Administrative Information and Prescribing Information\Envelope Information folder\EU Envelope Information leaf\EMA Envelope Information.) EMA is used as an example. You can name any value you choose from the country list.
- GCC Envelope Information in GCC templates
- Galenic Form in CH template
- Elements under 1.1 Forms in US (DTD 3.3) template
- 1.15 Promotional Material Audience Type in US (DTD 3.3) template
- 1.15.2 Materials in US (DTD 3.3) template
- 1.15.2.1 Material in US (DTD 3.3) template
- 2.3.S Drug Substance (substance and manufacturer)
- 2.3.P Drug Product (product name, manufacturer, dosage form)
- 2.7.3 Summary of Clinical Efficacy (indication)
- 3.2.S Drug Substance (substance and manufacturer)
- 3.2.P Drug Product (product name, manufacturer, dosage form)
- 3.2.P.4 Excipients (excipient name)
- 3.2.A.1 Facilities and Equipment (manufacturer, substance, dosage form, and/or product name)
- 3.2.A.2 Adventitious Agents (manufacturer, substance, dosage form, and/or product name)
- 5.3.5 Reports of Efficacy and Safety Studies (indication)
- Study Report Folders (when creating STFs: Full Report Title, Report Number, Category information as applicable)

There are more extension types available, but the extension types listed here are needed for the XML headings that have additional attributes. The others are used to differentiate unnumbered sections and create other components in the XML that do not require additional information.

Extension Type: General Folders

Extension Type	Associated Attributes	Applied to Assembly Element	Result
Drug Substance folder	— Substance — Manufacturer	— 2.3.S Drug Substance folder — 3.2.S Drug Substance folder	Creates the appropriate `<m2-3-s-drug-substance> and <m3-2-s-drug-substance>` elements in the XML with applicable attributes. Also builds the directory structure for 32s to include substance and manufacturer information. If the combination of substance and manufacturer information result in a folder or overall path length that is too long, the automatic creation of these folders can be overridden by populating the Output Folder attribute on the 3.2.S folder with an abbreviated value. The Output folder should be populated as follows: `32s-drug-sub/sub-mfg`, where the italicized information is the abbreviated value for the folder.
Drug Product folder	— Product name — Manufacturer — Dosage form	— 2.3.P Drug Product folder — 3.2.P Drug Product folder	Creates the appropriate `<m2-3-p-drug-product> and <m3-2-p-drug-product>` elements in the XML with applicable attributes. Also builds the directory structure for 32p to include product and dosage form information. If the combination of product and dosage form information result in a folder or overall path length that is too long, the automatic creation of these folders can be overridden by populating the Output Folder attribute on the 3.2.P folder with an abbreviated value. The Output folder should be populated as follows: `32p-drug-prod/prod-form`, where the italicized information is the abbreviated value for the folder.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
Clinical Indication folder	Indication	— 2.7.3 Summary of Clinical Efficacy folder — 5.3.5 Reports of Efficacy and Safety Studies	Creates the appropriate `<m2-7-3-summary-of-clinical-efficacy>` and `<5-3-5-reports-of-efficacy-and-safety-studies>` in the XML with applicable attributes. Also builds the directory structure for m535 to include indication information. If the indication value results in a folder or overall path length that is too long, the automatic creation of this folders can be overridden by populating the Output Folder attribute on the 5.3.5 folder with an abbreviated value. The Output folder should be populated as follows: `535-rep-effic-safety-stud/indication`, where the italicized information is the abbreviated value for the folder.
Excipient folder	Excipient name	3.2.P.4 Excipients	Creates the appropriate `<m3-2-p-4-control-of-excipients>` in the XML with applicable attributes. Also builds the directory structure for m32p4 to include excipient information. If the excipient value results in a folder or overall path length that is too long, the automatic creation of these folders can be overridden by populating the Output Folder attribute on the 3.2.P.4 folder with an abbreviated value. The Output folder should be populated as follows: `32p4-contr-excip/excipient-1`, where the italicized information is the abbreviated value for the folder.
Quality Appendix folder	— Manufacturer — Substance — Dosage form — Product name	— 3.2.A.1 Facilities and Equipment — 3.2.A.2 Adventitious Agents	Creates the appropriate `<m3-2-a-1-facilities-and-equipment>` and `<m3-2-a-2-adventitious-agents-safety-evaluation>` with applicable attributes, and builds the directory structure to include manufacturer information.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
Quality Overall Summary folder	No additional attributes	2.3. Quality Overall Summary folder	Used during XML creation to differentiate between the two eCTD elements that are both numbered 2.3 (2.3 Quality Overall Summary resulting in XML element `<m2-3-quality-overall-summary>`, and 2.3 Introduction resulting in XML element `<m2-3-introduction>`).
Quality Introduction folder	No additional attributes	2.3 Introduction folder	Used during XML creation to differentiate between the two eCTD elements that are both numbered 2.3 (2.3 Quality Overall Summary resulting in XML element `<m2-3-quality-overall-summary>`, and 2.3 Introduction resulting in XML element `<m2-3-introduction>`).
Study Report folder	— Full Report Title — Report Number — Operation — Species — Route of Administration — Duration — Type of Control	In Assembly template for modules 2-5, applied to sample study report folders in sections 5.3.1.1 and 4.2.1.1. Should be applied to all study report folders as studies are added to the assembly.	When applied to study folders in an assembly that is using the `stf-2-2` XML definition file, triggers the creation of STF XML files for each study. The values provided as folder attributes are used to populate the `<study-information>` portion of the STF. All child leaf elements in the study report folder should have the leaf type of Study Report to capture their subject matter which is used to populate the `<study-document>` portion of the STF. The FDA has provided guidelines for which study types sponsors should provide information for species, route of administration, duration, and type of control. Studies under section 4.2.3.1 should include species and route of administration. Studies under section 4.2.3.2 should includes species, route of administration, and duration. Studies under section 4.2.3.4.1 should include species. Studies under 5.3.5.1 should include type of control. For all other study types, inclusion of this additional information in the study tagging files is optional.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
Study Data folder	— Dataset type — Subject Matter	Individual Patient Data Listings folder included in the sample study report under section 5.3.1.1. This folder type should be used as the parent folder for all datasets, and the value for Dataset type is datasets-and-associated-files. The subfolders of the Individual Patient Data Listings folder also have this type applied with different values for the Dataset type attribute.	Places the datasets in the location as specified by the FDA Study Data Specification (m5\datasets\study xx). This allows datasets to still be located in the assembly with the other study files, and referenced by the STF, but have them located in a different output location from the other study files. The value of the dataset type attribute dictates which subfolder the datasets should be placed in (analysis, tabulations, etc).
Study Patient Information folder	— Subject Matter — Site	Case Report Forms and Subject Profiles folders included in the sample study report under section 5.2.1.1. This folder type should be used as the parent folder for Case Report Form and Subject Profiles leaf elements to group them by site.	Creates the additional `<property>` element in the STF with the attribute name="site-identifier" and uses the value for the Site attribute to populate the value of the `<property>` element.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
Node Extension folder	No additional attributes	This folder type is not applied to any folders in the assembly templates, but may be applied to folders if needed to create additional subheadings in the XML using the node-extension concept.	Creates a `<node-extension>` element in the XML using the name of the folder as the value for the `<node-extension><title>` element. This should be used only after consulting with the reviewing agency as some have indicated they do not want node-extensions to be used. This folder type should only be applied to folders at the lowest level of the assembly as only the lowest level elements may be extended.

Extension Type: Regional Folders

Eurasian Economic Union

Extension Type	Associated Attributes	Applied to Assembly Element	Result
EAEU Module 1 Envelope Information	— EDoc Id — EDoc Reference Id — EDoc Date Time — Country — Registration Number Id — Application Id — Registration Kind Code — Submission Sequence	EAEU Module 1 Envelope Information folder in EAEU Template v1.0 assembly template	Attribute values provided for each folder with this type complete the envelope information within the `index-r-022.xml` file.
Quality Overall Summary	No additional attributes	Quality Overall Summary folder in EAEU Template v1.0 assembly template.	Creates the appropriate `<m2-3-quality-overall-summary>` element in the `index-r-022.xml` file.
Drug Substance	— Drug Product Name — Drug Substance Manufacturer	Drug Substance folder in EAEU Template v1.0 assembly template.	Creates the appropriate `<drug_substance>` element in the `index-r-022.xml` file.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
Solvent	— Solvent Name — Solvent Manufacturer	Solvent folder in EAEU Template v1.0 assembly template.	Attribute values provided for each folder of this type contain information about every solvent set within `index-r-022.xml` file and included under each leaf entry as additional attributes.

European Union

Extension Type	Associated Attributes	Applied to Assembly Element	Result
EU Module 1 folder	No additional attributes	1 Administrative Information and Prescribing Information folder in EU Module 1 assembly template	When applied to an Assembly folder that is using the eu-2-0 XML Definition file, triggers the creation of the `eu-regional.xml` file during publishing. The child folders of this folder complete the content included in the `eu-regional.xml` file.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
EU Module 1 Envelope Information folder (v3.0 and v3.0.1)	— Country — UUID — Submission Type — Submission Mode — High-Level/ Worksharing Submission Number — Application Tracking Number — Submission Unit Type — Applicant — Agency Name — Procedure Type — Invented Name — INN — Sequence — Related Sequence — Submission Description	Depending on the procedure type/ template selected, there will be appropriate CC Envelope Information folder(s) that is a child of the EU Envelope Information leaf in EU Module 1 assembly template. A folder for each country applicable in the sequence should be included to provide the appropriate envelope information.	Attribute values provided for each folder with this type complete the envelope information for the country specified within the `eu-regional.xml` file. You must create a separate folder for each country for which envelope information is provided. These folders should reside beneath the EU Envelope Information Leaf to ensure proper behavior during lifecycle updates. Multiple comma-separated values can be provided for: — Application Tracking number — Invented Name — INN — Related Sequence

Extension Type	Associated Attributes	Applied to Assembly Element	Result
EU Module 1 Envelope Information folder (v2.0)	— Country — Submission Type — Submission Mode — High-Level/ Worksharing Submission Number — Application Tracking Number — Applicant — Agency Name — Procedure Type — Invented Name — INN — Sequence — Related Sequence — Submission Description	Depending on the procedure type/ template selected, there will be appropriate CC Envelope Information folder(s) that is a child of the EU Envelope Information leaf in EU Module 1 assembly template. A folder for each country applicable in the sequence should be included to provide the appropriate envelope information.	Attribute values provided for each folder with this type complete the envelope information for the country specified within the `eu-regional.xml` file. You must create a separate folder for each country for which envelope information is provided. These folders should reside beneath the EU Envelope Information Leaf to ensure proper behavior during lifecycle updates. Multiple comma-separated values can be provided for: — Application Tracking number — Invented Name — INN — Related Sequence

Extension Type	Associated Attributes	Applied to Assembly Element	Result
EU Module 1 Country-specific Information folder	— Country — Language	— In EU Module 1 Assembly template, applied to the following folders: — 1.0 Cover Letter — 1.2 Application Forms — 1.3.2 Mock-up — 1.3.3 Specimen — 1.3.4 Readability Testing — 1.3.5 SPCs already approved in Member States	Creates the appropriate `<m1-0-cover>`, `<m1-2-form>`, `<m1-3-2-mockup>`, `<m1-3-4-readability>`, and `<m1-3-5-approved>` elements in `eu-regional.xml` with country values for the <specific> child element. Also includes the appropriate country values in the output directory structure. Each folder with this type can be duplicated for different countries and/or languages for which information is being provided.
EU Module 1 Labeling Information folder	— Country — Language — Labeling type	— 1.3.1 SPC, Labeling and Package Leaflet folder in EU Module 1 Assembly template	Creates the appropriate `<m1-3-1--spc-label-pl>` element with the `<pi-doc>` child element using attribute values to populate the attributes of the `<pi-doc>` element. Also includes appropriate country and language information in the output directory structure. Each folder with this type can be duplicated for different countries, languages, and/or labeling types for which information is being provided. The ***Create eCTD*** Wizard allows the user to indicate which sections should be included for all countries.
EU Responses folder	— Country — Language	Responses to Questions folder in the EU Module 1 Assembly template	Creates the appropriate `<m1-responses>` element in `eu-regional.xml` with country values for the <specific> child element. Also includes appropriate country information values in the output directory structure.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
EU Additional Information folder	— Country — Language	Additional Data folder in the EU Module 1 Assembly template	Creates the appropriate `<m1-additional>` element in `eu-regional.xml` with country values for the <specific> child element. Also includes appropriate country information values in the output directory structure.

Canada

Extension Type	Associated Attributes	Applied to Assembly Element	Result
Canadian Module 1 folder (v2.2)	— Applicant — Product Name — Dossier Identifier — Dossier Type — Regulatory Activity Type — Regulatory Activity Lead — Sequence Number — Submission Description — Related Sequence Number	1 Administrative and Product Information folder in Canadian Module 1 assembly template	When applied to a folder in an Assembly that is using the ca-2-2 XML Definition file, triggers the creation of the `ca-regional.xml` file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the `<ectd-regulatory-transaction-information>` element of the `ca-regional.xml` file. Multiple related sequence number values may be added by separating them with commas. The child folders of this folder complete the remainder of the `ca-regional.xml` file.

China

Extension Type	Associated Attributes	Applied to Assembly Element	Result
CN Module 1 v1.0 folder	— Application Number — Application Type — Product Type — Original Number — Related Sequence — Regulatory Activity Type — Sequence Number — Sequence Type — Sequence Description — Sequence Contact Name — Sequence Contact Telephone — Sequence Contact Email	CN Module 1 Administration Information folder in CN Module 1 assembly template	When applied to an Assembly folder that is using the cn-1-0 XML Definition file, triggers the creation of the `cn-regional.xml` file during publishing. The child folders of this folder complete the content included in the `cn-regional.xml` file.

United States

Extension Type	Associated Attributes	Applied to Assembly Element	Result
US Module 1 folder (v2.01)	— Company Name — Submission Date — Application Number — Product name and type — Application Type — Submission Type — Sequence Number — Related Sequence Number	1 Administrative Information and Prescribing Information folder in US Module 1 assembly template (v2.01)	When applied to folder in an Assembly that is using the us-2-0-1 XML Definition file, triggers the creation of the `us-regional.xml` file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <admin> element of the `us-regional.xml` file. Multiple related sequence number values may be added by separating them with commas. The child folder and leaf elements in this folder complete the remainder of the `us-regional.xml file`.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
US Module 1 folder (DTD v3.3)	— Applicant ID — Company Name — Submission Description — Applicant Contact — Application Number — Application Contains Files? — Application Type — Cross-Reference Application — Sequence Number — Submission ID — Submission Type — Submission Sub-Type — Supplement Effective Date Type	1 Administrative Information folder in US Module 1 assembly template (v3.3)	When applied to a folder in an Assembly that is using the us-3-3 XML Definition file, triggers the creation of the `us-regional.xml` file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <admin> element of the `us-regional.xml` file. The child folders of this folder complete the remainder of the `us-regional.xml` file.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
US Admin Forms folder	Application Form Type	The following folders in US Module 1 assembly template (v3.3): — 1.1.1 Form FDA 1571: Investigational New Drug Application (IND) — 1.1.2 Form FDA 356h: Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use folders in	Creates the appropriate `<form form-type="">` element within the `<submission-information>` element in `us-regional.xml`.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
US Forms folder	Application Form Type	The following folders in US Module 1 assembly template (v3.3): — 1.1.3 Form FDA 3397: User Fee Cover Sheet — 1.1.4 Form FDA 2252: Transmittal of Annual Reports for Drugs and Biologics for Human Use — 1.1.5 Form FDA 2253: Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use — 1.1.6 Form FDA 2567: Transmittal of Labels and Circulars — 1.1.7 Form FDA 3674: Certification of Compliance — 1.1.8 Form FDA 3792: Biosimilar User Fee Cover Sheet (BsUFA) — 1.1.9 Form FDA 3794: Generic Drug User Fee Cover Sheet (GDUFA)	Creates the appropriate `<form form-type="">` element within the `<m1-1-forms>` element in `us-regional.xml`.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
Promotional Material Audience Type folder	Promotional Material Audience Type	1.15 Promotional Material Audience Type folder in US Module 1 assembly template (v3.3)	Creates the appropriate `<m1-15-promotional-material>` element in `us-regional.xml`. The value of the attribute populated on this folder is used to complete the promotional-material-audience-type attribute of `<m1-15-promotional-material>` element.
Promotional Material Doc Type folder	Promotional Material Doc Type	1.15.2 Materials folder in US Module 1 assembly template (v3.3)	Creates the appropriate `<m1-15-2-materials>` element in `us-regional.xml`. The value of the attribute populated on this folder is used to complete the promotional-material-doc-type attribute of `<m1-15-2-materials>` element.
Promotional Material Type folder	— Promotional Material Type — Promotional Material ID — Issue Date	1.15.2.1 Material folder in US Module 1 assembly template (v3.3)	Creates the appropriate `<m1-15-2-1-material>` element in `us-regional.xml`. The values of the attributes populated on this folder are used to complete the attributes `<m1-15-2-1-material>` element.

Japan

Extension Type	Associated Attributes	Applied to Assembly Element	Result
JP Module 1 folder	— Submission Number — Brand Name — Sequence Number — Generic Name — Applicant — Submission Date — Submission Type — Operation	1 Administrative Information and Prescribing Information folder in JP Module 1 assembly template	When applied to a folder in an Assembly that is using the jp-1-0 XML Definition file, triggers the creation of the `jp-regional-index.xml` file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the `<content-block param="admin">` element of the `jp-regional-index.xml` file. Multiple generic and/or brand name values may be added by separating them with commas. The child folder and leaf elements of this folder complete the remainder of the `jp-regional-index.xml` file.

Jordan

Extension Type	Associated Attributes	Applied to Assembly Element	Result
JO Module 1 folder (v1.0, v1.1)	No additional attributes	JO Module 1 folder in JO Module 1 assembly template	When applied to an Assembly folder that is using the jo-1-0 or the jo-1.1 XML Definition file, triggers the creation of the `jo-regional.xml` file during publishing.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
JO Module 1 Envelope Information folder (v1.0, v1.1)	— Application Reference Number — UUID — Applicant — MAH — Agency — ATC — Submission Type — Submission Unit — Procedure — Invented Name — INN — Sequence — Related Sequence — Submission Description — Number	JO Envelope Information folder is a child of the JO Envelope Information leaf in JO Module 1 assembly template.	Attribute values provided for each folder with this type complete the envelope information within the `jo-regional.xml` file. Multiple comma-separated values can be provided for: — Application Reference Number — ATC — Invented Name — INN — Related Sequence

Extension Type	Associated Attributes	Applied to Assembly Element	Result
JO Product Information folder	— Language — Product Information Type	In JO Module 1 assembly template, applied to the product information subfolders of the following folders: — 1.3.1 Arabic SPC — 1.3.1 English SPC — 1.3.1 Arabic SPC-comp — 1.3.1 English SPC-comp — 1.3.2 Arabic — 1.3.2 English — 1.3.3 Arabic Patient Information Leaflet (PIL) — 1.3.3 Arabic Patient Information Leaflet (COMP) — 1.3.3 English Patient Information Leaflet (PIL) — 1.3.3 English Patient Information Leaflet (COMP)	Populates the labeling and language attribute of the `<pi-doc>` element within appropriate elements in the `jo-regional.xml` file. Also includes appropriate language values in the output directory structure.
JO Additional Information folder	No additional attributes	Additional Data folder in JO Module 1 assembly template	Creates the appropriate `<m1-additional-data>` element in the `jo-regional.xml` file.

Switzerland

Extension Type	Associated Attributes	Applied to Assembly Element	Result
CH Module 1 folder (v1.2 , v.1.3, and v1.4)	— Application Number — Submission Description — Invented Name — DMF Number — PMF Number — INN — Applicant — DMF Holder — PMF Holder — Agency — Submission Type — Paragraph 13 TPA — Sequence Number — Related Sequence	1 Administrative Information and Prescribing Information folder in CH Module 1 assembly template	When applied to a folder in an Assembly that is using the ch-1-2, ch-1-3, or ch-1-4 XML Definition file, triggers the creation of the `ch-regional.xml` file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the `<ch-envelope>` element of the `ch-regional.xml` file. Multiple comma-separated values can be provided for: — Application Number — Invented Name — INN — Related Sequence The child folders of this folder complete the remainder of the `ch-regional.xml` file.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
CH Module 1 folder (v1.5)	— Application Number — Submission Description — Invented Name — DMF Number — PMF Number — INN — Applicant — DMF Holder — PMF Holder — Agency — Submission Type — Article 13 TPA — Sequence Number — Related Sequence	1 Administrative Information and Prescribing Information folder in CH Module 1 assembly template	When applied to a folder in an Assembly that is using the ch-1-5 XML Definition file, triggers the creation of the `ch-regional.xml` file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the `<ch-envelope>` element of the `ch-regional.xml` file. Multiple comma-separated values can be provided for: — Application Number — Invented Name — INN — Related Sequence The child folders of this folder complete the remainder of the `ch-regional.xml` file.
CH Galenic Form folder	— Galenic Form Name — SwissMedic Number — Galenic Language Name — Galenic Language Text	Galenic Form folder in CH Module 1 assembly template	Creates the `<galenic-form>` element within the `<envelope country="ch">` element in the `ch-regional.xml`. If there are leafs submitted under the subfolders of the folder with this extension applied, creates the <m1-galenic-form> element in the `ch-regional.xml` file. The values of the attributes populated on this folder are used to complete the attributes of `<galenic-form>` and `<m1-galenic form>` elements.
CH Common Form folder	No additional attributes	Common folder in CH Module 1 assembly template	Creates the `<m1-galenic-form>` element in the `ch-regional.xml` file with the name="common" attribute populated.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
CH Swiss Responses folder	No additional attributes	Responses to Swissmedic LoQ folder in CH Module 1 assembly template	Creates the appropriate `<m1-swiss-responses>` element in the `ch-regional.xml` file.
CH Additional Data folder	No additional attributes	Additional Information in CH Module 1 assembly template	Creates the appropriate `<m1-additional-data>` element in the `ch-regional.xml` file.

Gulf Cooperation Council

Extension Type	Associated Attributes	Applied to Assembly Element	Result
GCC Module 1 folder (v1.5)	No additional attributes	GCC Module 1 folder in GCC Module 1 assembly template	When applied to an Assembly folder that is using the gc-1-5 XML Definition file, triggers the creation of the `gc-regional.xml` file during publishing. The child folders of this folder complete the content included in the `gc-regional.xml` file.
GCC Module 1 folder (v1.2)	No additional attributes	GCC Module 1 folder in GCC Module 1 assembly template	When applied to an Assembly folder that is using the gc-1-2 XML Definition file, triggers the creation of the `gc-regional.xml` file during publishing. The child folders of this folder complete the content included in the `gc-regional.xml` file.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
GCC Module 1 Envelope Information folder (v1.5)	— Country — Application Number — Applicant — Agency Name — ATC — Submission Type — Submission Unit Type — Procedure Type — Invented Name — INN — Sequence — Related Sequence — Submission Description	Depending on the procedure type/ template selected, there will be appropriate CC Envelope Information folder(s) that is a child of the CC Envelope Information leaf in GCC Module 1 assembly template. A folder for each country applicable in the sequence should be included to provide the appropriate envelope information.	Attribute values provided for each folder with this type complete the envelope information for the country specified within the `gc-regional.xml` file. You must create a separate folder for each country for which envelope information is being provided. These folders should reside beneath the GCC Envelope Information leaf. This is to ensure proper behavior during lifecycle updates. Multiple comma-separated values can be provided for: — Application Number — ATC — Invented Name — INN — Related Sequence

Extension Type	Associated Attributes	Applied to Assembly Element	Result
GCC Module 1 Envelope Information folder (v1.2)	— Country — Application Number — Applicant — Agency Name — ATC — Submission Type — Procedure Type — Invented Name — INN — Sequence — Related Sequence — Submission Description	Depending on the procedure type/ template selected, there will be appropriate CC Envelope Information folder(s) that is a child of the GCC Envelope Information leaf in GCC Module 1 assembly template. A folder for each country applicable in the sequence should be included to provide the appropriate envelope information.	Attribute values provided for each folder with this type complete the envelope information for the country specified within the `gc-regional.xml` file. You must create a separate folder for each country for which envelope information is being provided. These folders should reside beneath the GCC Envelope Information leaf. This is to ensure proper behavior during lifecycle updates. Multiple comma-separated values can be provided for: — Application Number — ATC — Invented Name — INN — Related Sequence

Extension Type	Associated Attributes	Applied to Assembly Element	Result
GCC Country-Specific Information folder	— Country — Language	In GCC Module 1 assembly template, applied to the country-specific subfolders of the following folders: — 1.0 Cover Letter Application Form Summary of Product Characteristics (SPC) — 1.3.2 Labeling — 1.3.3 Patient information leaflet — 1.3.4 Artwork (mock-ups) — 1.3.5 Samples — 1.7.4 Certificate of analysis - Excipients — 1.7.5 Alcohol-content declaration — 1.7.6 Pork-content declaration — 1.7.7 Certificate of suitability for TSE — 1.7.8 The diluents and coloring agents in product formula — 1.7.9 Patent Information — 1.7.10 Letter of access or acknowledgements to DMF — 1.8.1 Price list — 1.8.2 Other documents related	Populates the country attribute of the `<specific>` element within appropriate elements in the `gc-regional.xml` file. Also includes appropriate country information values in the output directory structure.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
GCC Label folder	— Country — Language — Labeling Type	In GCC Module 1 assembly template, applied to the language specific subfolders of the following folders: — 1.3.1 Summary of Product Characteristics (SPC) — 1.3.2 Labeling — 1.3.3 Patient information leaflet	Populates attributes for the `<pi-doc>` element within appropriate elements in the `gc-regional.xml` file. Also includes appropriate language values in the output directory structure.
GCC Responses folder	Country	1.9 Responses to Questions folder in GCC Module 1 assembly template	Creates the appropriate `<m1-9-responses>` element in the `gc-regional.xml` file with country values for the <specific> child element. Also includes appropriate country information values in the output directory structure.
GCC Additional Data folder	Country	Additional Data folder in GCC Module 1 assembly template	Creates the appropriate `<m1-additional-data>` element in the `gc-regional.xml` file with country values for the `<specific>` child element. Also includes appropriate country information values in the output directory structure.

South Africa

Extension Type	Associated Attributes	Applied to Assembly Element	Result
ZA Module 1 folder v2.1	— Application Number — Applicant — Submission Type/Proof of Efficacy — Proprietary Name — Dosage Form — INN — eCTD Sequence — Related Sequence — Duplicated Applications (Proprietary Names/ Application Numbers)	1 Administrative Information and Prescribing Information folder in ZA Module 1 assembly template	When applied to a folder in an Assembly that is using the za-2-1 Definition file, triggers the creation of the `za-regional.xml` file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <za-envelope> element of the `za-regional.xml` file. Multiple comma-separated values can be provided for: — Application Number — Proprietary Name — Dosage Form — INN — Related Sequence The child folders of this folder complete the remainder of the `za-regional.xml` file.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
ZA Module 1 folder v1.0	— Application Number — Applicant — Submission Type — Proof of Efficacy — Proprietary Name — Dosage Form — INN — eCTD Sequence — Related Sequence — Duplicated Applications (Proprietary Names/Dates of Application	1 Administrative Information and Prescribing Information folder in ZA Module 1 assembly template	When applied to folder in an Assembly that is using the za-1-0 Definition file, triggers the creation of the `za-regional.xml` file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <za-envelope> element of the `za-regional.xml` file. Multiple comma-separated values can be provided for: — Application Number — Proprietary Name — Dosage Form — INN — Related Sequence The child folders of this folder complete the remainder of the `za-regional.xml` file.

Australia

Extension Type	Associated Attributes	Applied to Assembly Element	Result
AU Module 1 folder (v3.1)	— e-Identifier — eBS Client ID — Approved Name(s) — Trade Name(s) — ARTG Number(s) — Submission or Application Number(s) — Sequence Number — Related Sequence Number — Regulatory Activity Lead — Submission Mode — Sequence Type — Sequence Description — Contact Email	1 Administrative Information and Prescribing Information folder of the AU eCTD template	When applied to a folder in an Assembly that is using the au-3-1 Definition file, triggers the creation of the `au-regional.xml` file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <au-envelope> element of the `au-regional.xml` file. Multiple, comma-separated values can be provided for: — Approved Name — Trade Name — ARTG Number — Submission or Application Number — Contact Email The child folders of this folder complete the remainder of the `au-regional.xml` file.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
AU Module 1 folder (v0.90 and v3.0)	— eSubmission Identifier — Applicant — Australian Approved Name(s) — Product Name — ARTG Number — Sequence Description — Sequence Number — Related Sequence Number — Regulatory Activity Lead — Sequence Type	1 Administrative Information and Prescribing Information folder of the AU eCTD template	When applied to a folder in an Assembly that is using the au-0-90 or au-3-0 Definition file, triggers the creation of the `au-regional.xml` file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <au-envelope> element of the `au-regional.xml` file. Multiple, comma-separated values can be provided for: — Australian Approved Name(s) — Product Name — ARTG Number The child folders of this folder complete the remainder of the `au-regional.xml` file.

Thailand

Extension Type	Associated Attributes	Applied to Assembly Element	Result
TH Module 1 folder (v1.0)	— eSubmission Identifier — Sequence Type — Regulatory Activity Lead — Licensee Number — Licensee Type — Licensee Name — INN/Generic Name — Product Name — Sequence Number — Related Sequence Number — Sequence Description — Contact Email	1 Administrative Information and Prescribing Information folder of the TH eCTD template	When applied to a folder in an Assembly that is using the th-1-0 Definition file, triggers the creation of the `th-regional.xml` file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <envelope> element of the `th-regional.xml` file. Multiple, comma-separated values can be provided for: — INN/Generic Name — Product Name The child folders of this folder complete the remainder of the `th-regional.xml` file.
TH Module 1 folder (v0.92)	— eSubmission Identifier — Sequence Type — Regulatory Activity Lead — Licensee — INN/Generic Name — Product Name — Sequence Number — Related Sequence Number — Sequence Description	1 Administrative Information and Prescribing Information folder of the TH eCTD template	When applied to a folder in an Assembly that is using the th-0-92 Definition file, triggers the creation of the `th-regional.xml` file during publishing. The values of the attributes populated on this folder are used to complete the values of the elements and attributes in the <envelope> element of the `th-regional.xml` file. Multiple, comma-separated values can be provided for: — INN/Generic Name — Product Name The child folders of this folder complete the remainder of the `th-regional.xml` file.

Extension Type:Leaf Types

Extension Type	Associated Attributes	Applied to Assembly Element	Result
Study Patient Information	— Subject Matter — Site	Can be applied directly to CRF and/or Subject Matter leaf elements in lieu of using the inheritance structure using the same folder type.	See *Study Patient Information Folder*.
EAEU Module 1 Envelope	No additional Attributes	Applied to a placeholder leaf element that holds envelope information.	Is automatically duplicated for each new working assembly to ensure that the appropriate envelope information is available and managed by the sequence.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
EAEU Leaf	— Registration File Indicator — Drug Registration Document Code — Drug Registration Document Name — Drug Registration File Section — Drug Registration File Code — Drug Registration File Name — Document Creation Date — Document Validity Date — Business Entity Name • Request Response Date • Reason Document Number • Requested Drug Registration File Section • Requested Drug Registration File Code • Requested Drug Registration Document Code • Other Information • General Information	Applied to each leaf in an EAEU submission.	Is applied to each leaf of EAEU submission to enable users to indicate additional attributes, if necessary.
EU Module 1 Envelope	No additional Attributes	Applied to a placeholder leaf element that holds envelope information.	Is automatically duplicated for each new working assembly to ensure that the appropriate envelope information is available and managed by the sequence.

Extension Type	Associated Attributes	Applied to Assembly Element	Result
GCC Module 1 Envelope	No additional Attributes	Applied to a placeholder leaf element that holds envelope information.	Is automatically duplicated for each new working assembly to ensure that the appropriate envelope information is available and managed by the sequence.
Japanese Module 1	Leaf Sequence	Applied to each leaf in the JP Module 1 assembly template.	Creates the appropriate <property> element with the attribute name="sequencenumber" using the value of the attribute to populate the value of the <property> element in the `jp-regional-index.xml` file.
JO Module 1 Envelope	No additional Attributes	Applied to a placeholder leaf element that holds envelope information.	Is automatically duplicated for each new working assembly to ensure that the appropriate envelope information is available and managed by the sequence.
Study Report	Subject Matter	Leafs in a Study Report.	See *Study Report folder*.

Extended Attributes Name, Type, and Version

The following table includes the list of extended attributes with name, type, and version.

Extended Attributes Name	Type	Version
AU Module 1	m1-au	0.9
AU Module 1	m1-au	3.0
Canadian Module 1	m1-ca	1.0
Canadian Module 1 v2.2	m1-ca	2.2
CH Module 1	m1-ch	1.0.
CH Module 1	m1-ch	1.1
CH Module 1	m1-ch	1.2
CH Module 1	m1-ch	1.3
CH Module 1	m1-ch	1.4
CH Module 1	m1-ch	1.5
CH Galenic Form	m1-ch-galenic-form	1.0
CH Galenic Form	m1-ch-galenic-form	1.1
CH Swiss Responses	m1-ch-responses	1.0
CH Additional Data	m1-ch-additional	1.0
CH Common Form	m1-ch-common-form	1.0
CN Module 1 v1.0	m1-cn	1.0
EAEU Module 1 Envelope Information	envelope-eaeu	1.0
EAEU Module 1 Envelope	eaeu-envelope	1.0
EAEU Leaf	eaeu_leaf	1.0
Quality Overall Summary	m2-3-quality-overall-summary	1.0
Drug Substance	drug_substance	1.0
Solvent	drug_solvent	1.0
EU Module 1	m1-eu	1.0
EU Module 1 Envelope Information	envelope	1.0
EU Module 1 Envelope	eu-envelope	1.0
EU Module 1 Envelope Information	envelope	1.2.1

Extended Attributes Name	Type	Version
EU Module 1 Envelope Information	envelope	1.3
EU Module 1 Envelope Information	envelope	1.4
EU Module 1 Envelope Information	envelope	2.0
EU Module 1 Envelope Information	envelope	3.0
EU Module 1 Envelope Information	envelope	3.0.1
EU Module 1 Country-Specific Information	eu_module_1_country_specific_information	1.0
EU Module 1 Country-Specific Information	eu_module_1_country_specific_information	1.2.1
EU Module 1 Country-Specific Information	eu_module_1_country_specific_information	2.0
EU Responses to Questions	m1-responses	1.0
EU XML Application Form	eu_xml_application_form	1.0
EU XML Application Form	eu_xml_application_form	2.0
EU Additional Information	m1-additional	1.0
EU Additional Information	m1-additional	1.2.1
EU Additional Information	m1-additional	2.0
EU Additional Information	m1-additional	3.0
EU Responses	m1-responses	1.2.1
EU Responses	m1-responses	2.0
EU Responses	m1-responses	3.0
EU Module 1 Labelling Information	m1-3-1-spc-label-pl	1.0
EU Module 1 Labelling Information	eu_module_1_labeling_information	1.0
EU Module 1 Labelling Information	m1-3-1-spc-label-pl	1.1
EU Module 1 Labelling Information	eu_module_1_labeling_information	1.1
EU Module 1 Labelling Information	m1-3-1-spc-label-pl	1.2.1
EU Module 1 Labelling Information	m1-3-1-spc-label-pl	2.0
EU Module 1 Labelling Information	m1-3-1-spc-label-pl	3.0
EU Module 1 Labelling Information	eu_module_1_labeling_information	1.2.1
EU PIM Labelling	m1-3-1-pim	1.0
EU PIM Labelling	eu_pim_labeling	1.0
EU PIM Additional Documents	eu_pim_additional_documents	1.0
EU Responses to Questions	eu_responses_to_questions	1.0

Extended Attributes Name	Type	Version
GCC Module 1	m1-gc	1.2
GCC Module 1 Envelope	gc-envelope	1.2
GCC Module 1 Envelope Information	envelope-gc	1.2
GCC Module 1 Envelope Information	envelope-gc	1.5
GCC Responses	gc-m1-responses	1.2
GCC Additional Data	gc-m1-additional	1.2
GCC Country-Specific Information	gc_module_1_country_specific_information	1.2
GCC Label	gc_module_1_label	1.2
JO Module 1	m1-jo	1.0
JO Module 1 JO Envelope Leaf	jo-envelope	1.0
JO Module 1 Envelope Information	envelope-jo	1.0
JO Product Information	jo_pi_doc	1.0
JO Additional Information	jo-additional	1.0
JP Module 1	m1-jp	1.1
Japanese Leaf	japanese_leaf	1.0
TH Module 1	m1-th	0.92
TH Module 1	m1-th	1.0
TH Responses	m1-th-responses	1.0
TH Additional Data	m1-th-additional	1.0
US Module 1 v2.01	m1-us	1.0
US Module 1 v3.3	m1-us	3.3
US Module 1 Application	m1-us-meta-data-application	3.3
US Admin Forms	m1-us-admin-form	3.3
US Forms	m1-us-form	3.3
Promotional Material Audience Type	m1-15-promotional-material	3.3
Promotional Material Doc Type	m1-15-2-materials	3.3
Promotional Material Type	m1-15-2-1-material	3.3
ZA Module 1	m1-za	1.0
ZA Module 1	m1-za	2.1
Clinical Indication	clinical_indication	1.0

Extended Attributes Name	Type	Version
Clinical Indication	clinical_indication	1.1
Drug Substance	drug_substance	1.0
Drug Product	drug_product	1.0
Drug Product	drug_product	1.1
Excipient	excipient	1.0
Excipient	excipient	1.1
ICH Study Report	study_report_leaf	1.0
Study Report	study_report_leaf	1.1
Study Report	study_report_leaf	3.0
Module 4 Studies	module_4_studies	1.1
Module 4 Studies	module_4_studies	1.2
Module 5 Studies	module_5_studies	1.1
Module 5 Studies	module_5_studies	1.2
Module 5 Studies	module_5_studies	1.3
Module Studies	module_studies	1.0
Module Studies	module_studies	3.0
Node Extension	node-extension	1.0
Quality Appendix	quality_appendix	1.0
Quality Appendix	quality_appendix	1.1
Quality Introduction	m2-3-introduction	1.0
Quality Overall Summary	m2-3-quality-overall-summary	1.0
Study Data	study_data_folder	1.0
Study Data	study_data_folder	3.0
Study Patient Information	study_patient_information_folder	1.0
Study Patient Information	study_patient_information_folder	3.0
Study Patient Information	study_patient_information_leaf	1.0
Study Report	stf	1.0
Study Report	stf	1.1
Study Report	stf	3.0
Study Report	stf	5.0

Assembly Node Creation by API Request

Use API request to populate the default values of the assembly node automatically.
When an assembly node is created by an API request but with a value missing for a field, the default value of the field (if it exists) is automatically populated by the system for that field. For example, the Abbreviated Name is automatically taken as a value from the Name Field.

Note: *When a field does not have a default value, no value is assigned to a field.*

Calyx RIM Publishing Best Practices

The publishing best practice topics provide recommendations to enable you to take advantage of built-in efficiencies in Calyx RIM .

The following topics are intended to be used in conjunction with the Calyx RIM user documentation. They provide best practices and process recommendations for using the Calyx RIM suite to create and manage eCTD submissions to regulatory authorities. It provides general best practice usage guidelines as well as module-by-module tips and tricks to best leverage the lifecycle management aspects and assembly features of the Calyx RIM suite. It is not intended to replace the user documentation. Specific details on how to perform individual functions are included in the online help, not in these Best Practice guides. For Registration Best Practice guides, see Registration Best Practices.

Name
Assembly_Template_Structures_Best_Practice_Calyx_RIM_Publishing
BREXIT-Data Admin Management for UK Departure from the EU - Calyx_RIM_Publishing
BREXIT-Managing the UK Withdrawal from CPs registration - Calyx_RIM_Publishing
BREXIT-Managing UK Northern Ireland and GB for MRP-DCP - Calyx_RIM_Publishing
Complying_with_the_Study_Data_Technical_Conformance_Guide_v4.1
Configuring_Templates_Best_Practice_Calyx_RIM_Publishing
Creating_Assemblies_Best_Practice_Calyx_RIM_Publishing
Creating_IMDRF_Assembly_Templates_for_Health_Canada_Best_Practice_Calyx_RIM_Publishing
Creating_US_Grouped_Submissions_Best_Practice_Calyx_RIM_Publishing
CTD_Based_Assembly_Best_Practice_Calyx_RIM_Publishing
Data_Management_Best_Practice_Calyx_RIM_Publishing
EAEU_Submissions_Best_Practice_Calyx_RIM_Publishing
FDA eCTD Submission Standards v3.9 - Calyx_RIM_Publishing
Guide_to_Managing_BREXIT_Related_Regulatory_Activities_Best_Practice_Calyx_RIM_Publishing
Hyperlinking_Best_Practice_Calyx_RIM_Publishing
Importing_Existing_eCTDs_Best_Practice_Calyx_RIM_Publishing
Maintaining_Currency_with_Specifications_Best_Practice_Calyx_RIM_Publishing
Pre-Submission Activities - Calyx_RIM_Publishing
Publishing_Best_Practice_Calyx_RIM_Publishing
Publishing_Guidelines_Best_Practice_Calyx_RIM_Publishing

Name
Relate_Sequence_to_Multiple_Supplements_Same_Application_Best_Practice_Calyx_RIM_Publishing
Table of Contents and Bookmark Handling - Calyx_RIM_Publishing
Troubleshooting_Publishing_Best_Practice_Calyx_RIM_Publishing
UUID for an EU eCTD Assembly - Calyx_RIM_Publishing
Working_in_the_Assembly_Best_Practice_Calyx_RIM_Publishing

Index

A

Applications 16, 326, 327
Assemblies 15–18, 109–114, 116–127, 129, 136–145, 147, 148, 150–152, 155–158, 160–169, 172–174, 177–183, 185–196, 198, 200–205, 207, 209, 213, 216–222, 224–229, 247, 260, 261, 263, 264, 268–270, 273, 275, 277, 281, 283, 284, 286, 287, 325, 326, 330, 332
Assembly 209, 212, 213, 406

D

D2 176
Data Admin 105, 367, 368, 372, 399

E

Events 329, 330
Extended Attributes 402

I

Installation 2

L

Lifecycle 230, 231, 233–236, 238, 240–244, 246
Linking 87–89, 295, 296, 346–350, 352–359, 362, 364

P

Publishing 1, 19, 21, 22, 30–32, 34–37, 41, 49, 50, 53, 55, 82, 85, 86, 88, 96, 103, 289–296, 298–301, 304–306, 308–316, 334, 336, 339, 341–344
Publishing Elements 19, 23–26, 28–30, 33, 36, 38, 39, 41, 43–46, 48, 49, 51–54, 56, 58–60, 62–68, 70–73, 76, 82, 83, 85, 86, 90, 91, 93, 94, 99–102, 104, 108, 208

Q

Querying 183, 184

R

Repository 107, 188
Reviewing 317

S

Sequences 328, 329
Submissions 248, 249, 251, 254, 256, 257, 259, 314, 319, 320, 322–324

T

Templates 2, 10

V

Veeva 175
Volumes 47

W

Wizards 247, 287