# BEST PRACTICE: PUBLISHING

# 1 Contents

# 2 Revision History

When Ennov releases a new version of Ennov InSight, they issue Release Notes which explain the new features and updates. The Ennov Business Consulting Team reviews the Release Notes against each Best Practice to determine any impact to the document:

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

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

| Software Version | Release/Revision Date | Summary of Change(s) (Refer to Release Notes for Full Description) |
|---|---|---|
| v7.3.1 | 28-Jun-2024 | Update Best Practice for Ennov rebranding & for v7.3.1 – No Impact |
| v7.2 | 20-Jun-2023 | Update Best Practice for v7.2 – No Impact |
| v7.1 | 13-Jan-2022 | Update Best Practice for v7.1 – No Impact |
| v7.0 | 25-May-2021 | Update Best Practice for v7.0 – Impact |

# 3 Publishing

Once the structure is complete and all of your content has been added to the assembly, or a section is ready, you can execute the Prepare to Publish function.
There are a number of options the user can select to have performed during the Prepare for Publishing. These include:

- Generating a preview of all paper finishing options (TOC, special sheets)
- Automatically creating paper volumes
- Ensuring all documents have renditions and extractions
- Removing empty portions of the assembly, those folders and leafs that have no content assigned (these are not removed by default due to the nature of iterative publishing, but once the assembly is believed complete, this is very useful in identifying and removing unwanted sections of the assembly)
- Updating information to be used in the Link Inspector Report
- Updating information to be used in the Publishing Readiness query

After running the **Prepare to Publish** function at least once, the Publishing Readiness query can help identify any potential issues by right clicking on the assembly root and choosing **Publishing Readiness Query**. This provides feedback about:

- Which assembly elements have special types applied
- Whether any attributes have been overridden
- Whether each leaf has at least one document under it
- Whether PDF renditions exist for the content

You can export the query results to Microsoft Excel™ where you can perform more detailed analysis, by sorting or filtering the information, particularly in support of iterative publishing needs.

## 3.1 Iterative Publishing Process

Users should publish iteratively if possible, as sections of the Assembly are completed and documents are available.

Simply select the branch of the assembly you wish to publish, select the Publish Request button and choose to publish the selected range only. Only the content in the selected branch of the Assembly will be published, greatly enhancing performance as only those selected files are processed. A recommended iterative approach might be the following:

- Using the Create eCTD wizard, create the eCTD assembly with all planned leaf elements and sections.
- Add planned documents and placeholders under the appropriate leaf elements.
- Remove empty sections and leaf elements through Prepare to Publish (those folders and leafs that have no content or placeholders assigned).
- Publish all eCTD XML by selecting publish request and indicating to publish XML only.

- As documents are completed, publish selected sections without XML, generating the final PDFs in the output folder (the Assembly documents will automatically indicate readiness for publishing through binding icon and status).
- Once all documents have been published, execute Ennov InSight Validator to update the checksums in the final eCTD XML. Optionally, you may choose to publish the XML Only as a final step.

When iteratively publishing, you may also choose to publish the selected files along with the XML files. In this case publishing may take somewhat longer as all XML files are built, but only the selected content will be generated. All publishing-created XML files (index.xml, regional XML, and STFs) are always rebuilt during XML publishing to ensure they have all the latest information, including updated checksum values for content published. This means, even if you are only publishing content in Module 3, for example, but are working on an assembly that includes STFs in Modules 4 and 5, the resulting output will include the m1 folder for the regional XML and m4 and m5 folders for the STF XML files. If an Assembly includes Reference Leaf elements that point to content outside of the current Assembly, these checksum values may not be available and the user should use Ennov InSight Validator to recalculate checksums for these elements.

## 3.2 Iterative Publishing and Checksums

Normally, when publishing an eCTD Sequence Assembly and XML files, all checksums are current and accurate. When doing iterative publishing, however, the checksums for Leaf elements may not be included in the specific publish job. Rather than being carried forward from the previously published values, they can appear as null.

This can happen if you create and publish a full eCTD Sequence Assembly and XML files that contains at least five Leaf elements and documents assigned, with some documents in M1 and some documents in another module, and then later publish a range from within this assembly that includes Module 1 and at least one Leaf in another module.

*Note: After validating the index.xml in Ennov InSight Validator without Update checksums turned on, only checksums for the Leaf in the Selected range are up-to-date, and all previously published Leaf elements in the regional and main index have a checksum that is blank.*

## 3.3 Paper Publishing Best Practices

### 3.3.1 Specifying Publishing Settings

Publishing Settings should be defined in the Publishing Settings Library after the creation of an Assembly. All templates shipped with Ennov InSight contain default Publishing Settings. It is recommended that each Template is reviewed and updated to meet the needs of your organization.

Although specific Publishing Settings may exist, if they are not used within the Assembly they will be ignored at publish time. There is no harm in leaving an unused Overlay, for example, in the Publishing Settings Library.

Due to the ability to have multiple Overlay, TOC, Cover Page, Slip Sheet, and Tab Sheet settings, it is recommended that all names for these settings follow a defined naming convention. This will aid users when

selecting which of the settings to apply. If no settings are explicitly set, the publishing element will use the setting defined as the default.

### 3.3.2 Granularity and Tabs

Ennov InSight supports gutter and flush cut tabs for A4.

Flush cut tabs extend directly off the top of the page for the position one tab:

Gutter cut tabs are similar to the tabs on a manila folder; they dip down from the top of the page to the top of the tab:

If the tab type selected is different from what is used in the printer, the text on the first two tabs will shift up or down and the last two tabs will shift the opposite way.

The default templates ship with a tab on each leaf. The tab uses a TabText variable designed to pull the leaf element's parent folder number (minor division number which equates to the CTD section) and the leaf abbreviated name. The Abbreviated Name attribute enables you to use for longer, more descriptive leaf names in the eCTD XML and tables of contents while keeping a shorter name that will not exceed three lines on the tab.

Alternatively, with the exception of the module-level folder, which is a major division, you can modify the templates to make each folder a minor division so that the Minor Division Number – Minor Division Abbreviated Name attribute may be defined for the TabText variable (**$NN $NABBR**).

Folders must be minor divisions because the simple Element Name/Element Number variables indicate the name/number of the element, in this case the tab that does not have an exposed variable for name or number. Since minor divisions may be nested in the assembly, making each folder a minor division and using those variables on the tabs has no other impact. This will require an exception tab text variable to be

used on those sections where multiple leaf elements exist under a section, such as analytical methods and/or validation reports. A Tab setting must be created within the Publishing Settings Library, so you can then override the tab setting used on a case-by-case basis.

### 3.3.3 TOC Settings

Ennov InSight enables you to define different TOC settings to use at the root, folder (general module-level), volume, leaf and document levels using the Default TOC For attribute on the TOC settings. When you add a TOC to the assembly, Ennov InSight identifies the type of element on which the TOC is being added and assigns the TOC default settings for that element type. You may choose to select a different TOC type by selecting the desired TOC settings from the Mass Update Publishing Elements screen.

The default does not directly impact what will be included in the TOC range. The TOC range is determined by the combination of the following in the TOC settings:

- The TOC range start
- The setting for the tree elements to include
- The setting for Build TOC to Level (depth)

The definition enables you to select which element types should be included as TOC entries, regardless of depth. In the case of mixed granularity in a TOC range (some leaf elements at level 2, level 3 and level 4), you can choose a depth of 4 to get all the leaf elements. If you do not want to include the detail of documents and bookmarks, rather than omitting the documents and bookmarks at level 2, you can choose to not include documents and bookmarks in the TOC.

Using the combined depth and selected tree elements, Ennov InSight establishes the TOC range to include everything applicable in the branch of the assembly from the Range Start point. The TOC does not need to be placed on the parent element of the range in order to include all of it.

For example, if you are creating a NeeS submission, to create the ctd-toc.pdf that includes links to each module's TOC, the TOC can be added to the desired location in Module 1 and its Range Start set to the assembly root. You can then edit the TOC entries to deactivate any unwanted entries or perform any other desired manipulations.

TOC elements have a Title attribute, but not a Name attribute, so when defining the left column of the

TOC settings, the settings used for the ctd-toc.pdf should use the $TITLE variable in order to stamp correctly. When working with NeeS or paper CTD TOCs, it is recommended that you create the individual module TOCs first so they will be properly captured in the Overall TOC range. Ennov InSight can generate and render the TOCs as part of Prepare to Publish during a publish request, so you do not have to generate all TOCs prior to publishing.

### 3.3.4 Reference Leaf Elements in TOCs and Paper Output

It is best practice to include a document only once in a submission and link back to the document as needed.

According to the recommendation in Practical guidance for the paper submission of regulatory information in support of a marketing authorization application when using the Electronic Common Technical Document ("eCTD") as the source submission, this indicates the following:

"Where a document appears in several relevant locations in the eCTD backbone, it should only appear once in the paper output, in the most appropriate location. Consideration of the chosen location of the document is important."

Ennov InSight understands that there is still a need to recognize those Reference Leaf elements in paper output. The original recommendation involved creating a supporting assembly from the existing assembly and converting those reference leaf elements to default leafs and re-assigning the content to them. Ennov InSight is aware that this method is still valid to duplicate the file in the output, but we also include the functionality to show navigation back to the original referenced location in the paper output.

There are two methods of displaying the navigation in the output:

- Overlays
- Cover Pages

When using either of these methods on a Reference Leaf there are a specific set of variables that can be used to navigate the reviewer to the original referenced location. The paper Reference Leaf specific variables (below) are created from already existing variables but by appending RL to the beginning of each we have made them specific to paper reference leafs.

- Application code <RLAC>
- Sequence code <RLSC>
- Volume Number <RLVN>
- Major Division Name <RLMNAME>
- Major Division Number <RLMN>
- Minor Division Name <RLNNAME>
- Minor Division Number <RLNN>
- Leaf Name <RLLNAME>

**Note:** These variables are specific to paper Reference Leafs and therefore will only resolve when included in a cover page or overlay that is assigned to a Reference Leaf. It is recommended that the user creates a separate cover page specifically for Reference Leafs. See the section in this guide about cover pages and overlays for more information about how they can be utilized.

When a TOC range covers a paper Reference Leaf you will see the location in the left column (as typical of all other Leafs in the TOC range). The right column stamp of the TOC displays the location of the Reference Leaf, directing the reviewer to the Cover Page which can be used to navigate to the original referenced location.

### 3.3.5 Volumization

The iterative process of submission compilation is common.

To make the most of the Volumization capabilities in Ennov InSight, you can perform Volumization on a branch of the tree, generally module by module. To ensure that volumes do not extend beyond intended

boundaries, you can create a single volume at the start of each module. If you are Volumizing an earlier module, you can lock the first volume in the next module to prevent cross-module Volumization.

You can perform Volumization at any point. You can also apply special sheets to elements after Volumization. However, since many of those special sheets can be included in the assembly templates, they may already exist. When a significant number of special sheets will be included, it may be better to add them prior to Volumization to ensure they are included in the overall page count of the Volume. Even though they do not impact pagination, they do impact the overall size of the Volume.

To manipulate special sheets (TOCs, Cover Pages, Slip Sheets, and Tabs) that you are adding to a Volume, you must access the Volume attributes and then modify the order of the special sheets. If any special sheet needs to be removed from a Volume, you must open the special sheet from the Volume attributes, and then delete it.

### 3.3.6 Working with Page Markers

You can manually create, modify, and delete Page Markers in the assembly.

The Page Marker is intended only to indicate to Ennov InSight where to start a new Volume. It does not isolate
(and therefore break away) pages if it is modified or removed from the Assembly. When a Volume is anchored to a Page Marker or any other element in the assembly, that element cannot be removed. The volume must first be removed or moved to have another anchor point and then the Page Marker can be removed.

When moving Volumes manually, you must drag them onto the element in the Assembly where you want them to be located; you cannot drag them to the left of the Assembly. The icon will change once you drag the Volume over an available element and will be moved so that the highlighted element is its anchor point.

## 3.4Reviewing Published Output

Ennov InSight Validator and Ennov InSight Viewing are available for viewing the structure, contents, and life cycle of submissions, and to enable your collaborative eCTD and NeeS review processes.

### 3.4.1 Ennov InSight Validator

Ennov InSight Validator is a comprehensive software tool that enables you to both validate and review submissions using a single application.

Its logical interface simplifies the validation and reviewing processes, enhances the user experience, and helps you manage time efficiently.

The functions related to submission validation and reviewing processes can be performed using the features and options available under the **Validation** and **Review** tabs in the tool.

Ennov InSight Validator is licensed at no additional cost to Ennov InSight customers.

### 3.4.2 Ennov InSight Viewing

Ennov InSight Viewing is a web-based application that supports the access and viewing of submission information. With appropriate permissions, you are able to view and interact with electronic information, including eCTD and NeeS applications and associated submissions, while consistently accessing information in the same place through a secure, thin client application.

You may view the structure (TOC), contents (documents/data) and life cycle of submissions, creating a thorough and quick review process. Using the various search features, you can search for keywords or metadata (that is stored in the XML backbone) within your submission content.
The interactive element of Calyx RIM for Viewing makes the review process a collaborative experience. Reviewers may add comments directly to submissions and Authors (Publishers and/or Submission Managers) may view, track, and respond to comments.

Ennov InSight Viewing is available by separate license.