



Ennov InSight Validator 5.1 User Guide

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Chapter 1. Validation

This topic provides an overview of the features and functions of Validator

The Validation tab of the Validator application is equipped with features that help you to validate electronic

Common Technical Document (eCTD) submissions and non-eCTD electronic submissions (NeeS) created by any software application. You can also verify the conformity of the CTD structure by performing a variety of validations to confirm that the submission is complete and accurate following ICH and regional requirements and specifications, prior to sending it to the agency.

The Validation tab includes the following features and functions:

- Intuitive graphical user interface
- Ability to copy applications from physical media to review area
- Ability to validate eCTD XML file(s) against eCTD DTD provided
- Validation of the regional XML files(s) against the corresponding regional DTD provided
- Validation of folders provided against XML references
- Validation that the files provided are all referenced in the regional and backbone XML files
- Validation that the relevant submission folder contains one and only one eCTD XML file
- Validation that the relevant submission folder contains only one XML file for a given region – Ability to Add/Remove validation criteria selection – Support for NeeS submissions

Validation Toolbar

Use the Validation toolbar to initiate eCTD validation actions and select criteria and preferences in Validator.

Op- tion	Description
Submission	
Sub- mis- sion	Use the Submission field to lookup for submission in your system for validation. Click the folder icon to browse your system folders and select a submission. You can also enter the full path to the submission, if known.
Ap- plica- tion	The Application field displays the root folder of the selected submission, and is only active after a Submission sequence has been selected. For subsequent sequences (e.g.: 0003), you must select the application root folder location that contains all previous sequences (e.g.: 0000 through 0002). If you selected this lo-

Op- tion	Description
	<p>caution when browsing to the submission, this value updates automatically and no action is required. Otherwise, the system prompts you to enter this value. Click the folder icon to browse your system folders and select an application.</p>
Validation	
Ver- sion	<p>Use the Version drop-down menu to select the validation version. Validation process is done on the validation criteria corresponding to the validation version you select.</p> <p>The drop-down menu values depend on the region that the selected Submission belongs.</p>
Vali- date	<p>Runs the validation checks based on the criteria selected in the Validation Criteria pane. This option is active after you have selected a submission. The status for each criteria will be updated in the Validation Results table at the completion of the validation process. The criteria which does not fulfill the requirements will be hyperlinked to the individual criteria report, providing further details about the failure.</p>
View Results	
Er- rors On- ly Re- port	<p>Produces a report that contains only validation items that has failed the validation process. This option is active after you have run the validation. A report in PDF format is generated. Each item includes a detailed failure description, severity and the status.</p>
Full Re- port	<p>Produces a full report that contains Pass/Fail status for each validation item. This option is active after you have run the validation. A report in PDF format is generated. Each item includes a detailed failure description, severity and the status</p>
Tools	
Me- dia	<p>Use the Media feature to create backup copies of selected submission files to compact disc (CD) or digital versatile disc (DVD) media.</p>
Settings	
Pref- er- ences	<p>Displays the various settings established for ICH and regional validation checks in a tabbed sequence. Optional action: As necessary, you can modify the values provided by ICH and regional authorities for specific validation checks.</p>
Validator	
Help	<p>Launches the Help system for Validator. For quick, summarized information, hover over each toolbar button to display the tool-tip Help. When using the online Help, you can navigate to a topic within the contents list or use the search feature to locate topics of interest.</p>
About	<p>Displays the Validator version and license information.</p>

Op- tion	Description
Exit	Exits the Validator application. The key combination Alt+F4 can also be used to close the application.

Settings and Preferences

The Preferences option in the *Validation* tab provides you the ability to edit the default values and settings to match the revised requirements of the ICH and regional specifications.

The default values and settings conform with the ICH and regional requirements specified at the time this version of Validator was released. It is recommended that these values and settings be altered only to complement any revision in the specifications, using the Preferences option.

ICH and STF Settings

Use the **Preferences** option to edit the **ICH eCTD** settings.

ICH settings

Use the **ICH settings** to edit the default values, such as the maximum length of the file name, folder name and file size version. You can also validate the file names against the naming convention specified by the ICH.

ICH DTD and STF DTD settings The **ICH DTD** and **STF DTD** sections in the *Preferences* window enable you to update the ICH provided MD5 values of the DTD files, which change whenever the DTD files are revised.

- For any DTD or schema file, if there are no published checksum values available, then Validator does not check for an MD5 value for that file.

In the **Preferences > ICH eCTD > STF DTD** section for **ich-stf-stylesheet.xml** (STF v2.2), the MD5 value is not updated and it will be blank.

- Any DTD or Schema file with a blank MD5 value on the *Preferences* window will be not verified. To prevent validating of older valid values, delete the corresponding MD5 value and save the changes by clicking **OK**.

Modify ICH or STF Settings

The **Preferences > ICH eCTD** feature under **Validation** tab enables you to modify the default settings for ICH or STF DTDs.

To modify default ICH eCTD or STF DTD settings:

1. On the Validator toolbar, click the **Preferences** icon.
2. Select the **ICH eCTD** tab and make the necessary changes. To change the length of leaf title, file name, folder name, or the size of the file, double-click on the text box corresponding to the options and enter the new value.

- To change the length of file name, double-click `Max. File Name Length` and enter a new value.
 - To change the file size, double-click `Max. File Size` and enter a new value.
 - To change the length of folder name, double-click `Max. Folder Name Length` and enter a new value.
3. To validate the file names against the naming convention specified by the ICH, select the option **Enforce ICH naming convention**.
 4. To change the **ICH DTD** or **STF DTD**, select a different option in the respective **Version** drop-down list.
 5. To modify MD5 values for ICH or STF DTDs, double-click on the **MD5 Value** corresponding to the DTD **File Name** and enter the new `MD5` value.
 6. When you finished all modifications, do one of the following:
 - To save your changes, click **OK**.
 - To undo your changes and return to the previous settings, click **Reset**.
 - To cancel your changes and close the *Preferences* window, click **Cancel**.

Modify the Leaf Title Length

Ennov InSight Validator provides you the ability to specify the leaf title length for validation by changing its value in the **filefoldersettings.xml** file.

Please note, the ability to specify the leaf title length is **not applicable** to US FDA submissions.

To specify the leaf title length in the **filefoldersettings.xml** file:

1. Exit the Ennov InSight Validator application. If any process is in progress, wait for the process to complete before exiting the application.
2. Locate the **filefoldersettings.xml** file. In a typical Windows installation, the **usersettings.xml** file is located in the following path: `<system drive>\users\<user name>\AppData\Roaming\Ennov\InSight Validator\`, where `<system drive>` is the installation drive and `<user name>` is the user profile folder. If you are unable to see the **AppData** folder, check the **Hidden Items** option under the **View** menu in the `<user name>` folder. **Note:** If you are unable to access the **filefoldersettings.xml** file, contact your IT administrator.
3. Open the **filefoldersettings.xml** file in a text or XML editor.
4. Locate the line: `<maxtitlelength>`
5. Enter a new value between `<maxtitlelength>` and `</maxtitlelength>`. By default, this value is set to 512.
6. Save and close the file.

Regional Settings

Ennov InSight Validator provides the ability to edit the default settings whenever it is necessary to revise the regulatory specifications of different regions such as the US, EU, UA, CA, JO, JP, TW, CH, CN, AU, TH, GCC, and, ZA. You can also update the settings specific to NeesS.

Settings you can edit include:

- A new file type to pass the validation process.
- PDF version.

- The length of the file or folder path.
- The option to select either the application number or the sequence number in the file path.
- The MD5 values of the regional DTD files.

Preferences - AU

The AU (Australia) region values section provides you the ability to search for applications based on the criteria specific to Australia.

Ennov InSight Validator enables you to modify the default regional settings. It is recommended that the changes made to the default settings adhere to the pertinent regulatory guidelines.

1. On the Ennov InSight Validator toolbar, click **Preferences**.
2. In the *Preferences* window, click the region tab, which is represented by the country code.
3. To include a new file type to pass the validation process, enter the file extension (e.g.: **xlsx** or **docx**) in the **Regional** and **ICH File Types** text box.
4. Make the necessary modifications:

Setting Name	Description
Maximum Folder/File Path Length	To change the length of the folder/file path, double-click on the Maximum Folder/File Path Length text box and enter the new value. The default value is 180 characters.
PDF Version	To include a new PDF version to pass the validation process, enter the PDF version (For example, 1.8) in the PDF Version text box. Note: If the text box is empty, the PDF document of any version will be valid.
Folder/file path starts from	If you want the file or folder path to include the Application Number or the Sequence Number against which the validation needs to be done, select the corresponding option.
Version	To change the Regional Schema , select the value in the Version drop-down list.
MD5 Value (table)	To modify MD5 values, double-click on the MD5 Value corresponding to the File Name and enter the new MD5 value.
Attributes Lists: <ul style="list-style-type: none"> ◦ MD 5 Value ◦ Ver-sion 	To modify MD5 values and corresponding version for the specific attributes in the Attribute Lists section, double-click on the MD5 Value/Version corresponding to the File Name and enter the new MD5/Version value.

5. For **NeeS submissions**, to include a new file type to pass the validation process, type the file extension (e.g.: **PDF, XML, SAS**) in the **NeeS File Extension(s)** text box.

- For **NeeS submissions**, to change the maximum values for the following settings, double-click on the text box corresponding to the option and enter the new value.

Setting Name	Default Value
Maximum Folder/File Path Length	180 (Chars.)
Maximum Folder Name Length	64 (Chars.)
Maximum File Name Length	64 (Chars.)
Maximum File Size	200 (MB)
PDF Version	1.4, 1.5, 1.6, 1.7

- To save your changes, click **OK**.
 - To undo your changes and return to the previous settings, click **Reset**.
 - To cancel your changes and close the *Preferences* window, click **Cancel**.

Preferences - CA

The CA region values section provides you the ability to search for applications based on the criteria specific to Canadian region.

Ennov InSight Validator enables you to modify the default regional settings. It is recommended that the changes made to the default settings adhere to the pertinent regulatory guidelines.

- On the Ennov InSight Validator toolbar, click **Preferences**.
- In the *Preferences* window, click the region tab, which is represented by the country code.
- To include a new file type to pass the validation process, enter the file extension (e.g.: **.xlsx** or **.docx**) in the **Regional** and **ICH File Types** text box.
 - Regional:** pdf, doc, docx, xls, xlsx, wpd, ppt, pptx, png, gif, svg, jpg, jpeg, tif, tiff, bmp, wav, mp3, mp4, wmv, mov, mpg, mpeg, xml, dat, inf, txt.
 - ICH:** pdf, doc, docx, xls, xlsx, wpd, ppt, pptx, png, gif, svg, jpg, jpeg, tif, tiff, bmp, wav, mp3, mp4, wmv, mov, mpg, mpeg, xml, xls, xsd, dtd, dat, inf, txt, sas, xpt, wks, wksx, wks, sdax, edpdp, wsp, epr, pnf, psf.

To exclude an existing file type from passing the validation process, highlight the file type and press **Delete**.

- Make the necessary modifications:

Setting Name	Description
Maximum Folder/File Path Length	To change the length of the folder/file path, double-click the Maximum Folder/File Path Length text box and enter the new value.

Setting Name	Description
PDF Version	To include a new PDF version to pass the validation process, enter the PDF version (For example, 1.8) in the PDF Version text box.
Folder/file path starts from	If you want the file or folder path to include the Application Number or the Sequence Number against which the validation needs to be done, select the corresponding option.
Version	To change the <small>Regional DTD</small> , select the value in the Version drop-down list.
<small>MD5 Value</small> (table)	To modify <small>MD5</small> values, double-click the MD5 Value corresponding to the File Name and enter the new <small>MD5</small> value.

- For NeeS submissions, to include a new file type to pass the validation process, enter the file extension (e.g.: PDF, XML, SAS) in the **NeeS File Extension(s)** text box. **NeeS File Extension(s): pdf, doc, docx, xls, xlsx, wpd, ppt, pptx, png, gif, svg, jpg, jpeg, tif, tiff, bmp, wav, mp3, mp4, wmv, mov, mpg, mpeg, xml, dat, inf, txt, sas, xpt, sdax, edpdp, wsp, epr, pnf, psf.**
- For NeeS submissions, to change the maximum values for the following settings, double-click the text box corresponding to the option and enter the new value.

Setting Name	Default Value
Maximum Folder/File Path Length	200 (Chars.)
Maximum Folder Name Length	64 (Chars.)
Maximum File Name Length	64 (Chars.)
Maximum File Size	200 (MB)
PDF Version	1.4, 1.5, 1.6, 1.7

- To save your changes, click **OK**.
 - To undo your changes and return to the previous settings, click **Reset**.
 - To cancel your changes and close the *Preferences* window, click **Cancel**.

Preferences - CH

The CH (Switzerland) region values section provides you the ability to search for applications based on the criteria specific to CH (Switzerland).

Ennov InSight Validator enables you to modify the default regional settings. It is recommended that the changes made to the default settings adhere to the pertinent regulatory guidelines.

- On the Ennov InSight Validator toolbar, click **Preferences**.
- In the *Preferences* window, click the region tab, which is represented by the country code.

3. To include a new file type to pass the validation process, enter the file extension (e.g.: **.xlsx** or **.docx**) in the **Regional** and **ICH File Types** text box. To exclude an existing file type from passing the validation process, highlight the file type and press **Delete**.
4. Make the necessary modifications:

Setting Name	Description
Maximum Folder/File Path Length	To change the length of the folder/file path, double-click on the Maximum Folder/File Path Length text box and enter the new value. The default value is 180 characters.
PDF Version	To include a new PDF version to pass the validation process, enter the PDF version (For example, 1.8) in the PDF Version text box. Note: If the text box is empty, the PDF document of any version will be valid.
Folder/file path starts from	If you want the file or folder path to include the Application Number or the Sequence Number against which the validation needs to be done, select the corresponding option.
Version	To change the Regional DTD , select the value in the Version drop-down list.
MD5 Value (table)	To modify MD5 values, double-click on the MD5 Value corresponding to the File Name and enter the new MD5 value.

5. To save your changes, click **OK**.
 - To undo your changes and return to the previous settings, click **Reset**.
 - To cancel your changes and close the *Preferences* window, click **Cancel**.

Preferences - CN

The CN (China) region values section provides you the ability to search for applications based on the criteria specific to CN (China).

Ennov InSight Validator enables you to modify the default regional settings. It is recommended that the changes made to the default settings adhere to the pertinent regulatory guidelines.

1. On the Ennov InSight Validator toolbar, click **Preferences**.
2. In the *Preferences* window, click the region tab, which is represented by the country code.
3. To include a new file type to pass the validation process, enter the file extension (e.g.: **.xlsx** or **.docx**) in the **Regional** and **ICH File Types** text box. To exclude an existing file type from passing the validation process, highlight the file type and press **Delete**.
4. Make the necessary modifications:

Setting Name	Description
Maximum Folder/File Path Length	To change the length of the folder/file path, double-click on the Maximum Folder/File Path Length text box and enter the new value. The default value is 180 characters.
PDF Version	To include a new PDF version to pass the validation process, enter the PDF version (e.g.: 1.5) in the PDF Version text box. Note: If the text box is empty, the PDF document of any version will be valid.
PDF Standard	To include a PDF standard to pass the validation process, enter the PDF standard value (e.g.: PDF/A1, PDF/A2) in the PDF Standard text box. The default value: PDF/A1, PDF/A2.
Folder/file path starts from	If you want the file or folder path to include the Application Number or the Sequence Number against which the validation needs to be done, select the corresponding option.
Version	To change the Regional DTD , select the value in the Version drop-down list.
MD5 Value (table)	To modify MD5 values, double-click the MD5 Value that corresponds to the File Name and enter the new MD5 value.

5. To save your changes, click **OK**.
 - To undo your changes and return to the previous settings, click **Reset**.
 - To cancel your changes and close the *Preferences* window, click **Cancel**.

Preferences - GCC

The GCC (Gulf Cooperation Council) region values section provides you the ability to search for applications based on the criteria specific to Gulf Cooperation Council.

Ennov InSight Validator enables you to modify the default regional settings. It is recommended that the changes made to the default settings adhere to the pertinent regulatory guidelines.

1. On the Ennov InSight Validator toolbar, click **Preferences**.
2. In the *Preferences* window, click the region tab, which is represented by the country code.
3. To include a new file type to pass the validation process, enter the file extension (e.g.: **.xlsx** or **.docx**) in the **Regional** and **ICH File Types** text box. To exclude an existing file type from passing the validation process, highlight the file type and press **Delete**.
4. Make the necessary modifications:

Setting Name	Description
Maximum Folder/File Path Length	To change the length of the folder/file path, double-click the Maximum Folder/File Path Length text box and enter the new value. The default value is 180 characters.

Setting Name	Description
PDF Version	To include a new PDF version to pass the validation process, enter the PDF version (For example, 1.8) in the PDF Version text box. Note: If the text box is empty, the PDF document of any version will be valid.
Folder/file path starts from	If you want the file or folder path to include the Application Number or the Sequence Number against which the validation needs to be done, select the corresponding option.
Version	To change the Regional DTD , select the value in the Version drop-down list.
MD5 Value (table)	To modify MD5 values, double-click the MD5 Value corresponding to the File Name and enter the new MD5 value.

5. Make the necessary modifications:
6. For NeeS submissions, to include a new file type to pass the validation process, enter the file extension (e.g.: PDF, XML, SAS) in the **NeeS File Extension(s)** text box.
7. For NeeS submissions, to change the maximum values for the following settings, double-click the text box corresponding to the option and enter the new value.

Setting Name	Default Value
Maximum Folder/File Path Length	180 (Chars.)
Maximum Folder Name Length	64 (Chars.)
Maximum File Name Length	64 (Chars.)
Maximum File Size	100 (MB)
PDF Version	1.4, 1.5, 1.6, 1.7

8. To save your changes, click **OK**.
 - To undo your changes and return to the previous settings, click **Reset**.
 - To cancel your changes and close the *Preferences* window, click **Cancel**.

Preferences - EU

The EU (European Union) region values section provides you the ability to search for applications based on the criteria specific to European Union.

Ennov InSight Validator enables you to modify the default regional settings. It is recommended that the changes made to the default settings adhere to the pertinent regulatory guidelines.

1. On the Ennov InSight Validator toolbar, click **Preferences**.
2. In the *Preferences* window, click the region tab, which is represented by the country code.

3. To include a new file type to pass the validation process, enter the file extension (e.g.: **.xlsx** or **.docx**) in the **Regional** and **ICH File Types** text box. To exclude an existing file type from passing the validation process, highlight the file type and press **Delete**.
4. Make the necessary modifications:

Setting Name	Description
Maximum Folder/File Path Length	To change the length of the folder/file path, double-click on the Maximum Folder/File Path Length text box and enter the new value. The default value is 180 characters.
PDF Version	To include a new PDF version to pass the validation process, enter the PDF version (For example, 1.8) in the PDF Version text box. Note: If the text box is empty, the PDF document of any version will be valid.
Folder/file path starts from	If you want the file or folder path to include the Application Number or the Sequence Number against which the validation needs to be done, select the corresponding option
Version	To change the regional DTD version, select the required value from the Version drop-down list under Regional DTD .
MD5 Value (table)	To modify MD5 values, double-click on the MD5 Value corresponding to the File Name and enter the new MD5 value.

5. For NeeS submissions, to include a new file type to pass the validation process, type the file extension (e.g.: PDF, XML, SAS) in the **NeeS File Extension(s)** text box.
6. For NeeS submissions, to change the maximum values for the following settings, double-click on the text box corresponding to the option and enter the new value.

Setting Name	Default Value
Maximum Folder/File Path Length	180 (Chars.)
Maximum Folder Name Length	64 (Chars.)
Maximum File Name Length	64 (Chars.)
Maximum File Size	200 (MB)
PDF Version	1.4, 1.5, 1.6, 1.7

7. To save your changes, click **OK**.
 - To undo your changes and return to the previous settings, click **Reset**.
 - To cancel your changes and close the *Preferences* window, click **Cancel**.

Preferences - JO

The JO (Jordan) region values section provides you the ability to search for applications based on the criteria specific to Jordan.

Ennov InSight Validator enables you to modify the default regional settings. It is recommended that the changes made to the default settings adhere to the pertinent regulatory guidelines.

1. On the Ennov InSight Validator toolbar, click **Preferences**.
2. In the *Preferences* window, click the region tab, which is represented by the country code.
3. To include a new file type to pass the validation process, enter the file extension (e.g.: **.xlsx** or **.docx**) in the **Regional** and **ICH File Types** text box. To exclude an existing file type from passing the validation process, highlight the file type and press **Delete**.
4. Make the necessary modifications:

Setting Name	Description
Maximum Folder/File Path Length	To change the length of the folder/file path, double-click on the Maximum Folder/File Path Length text box and enter the new value. The default value is 180 characters.
PDF Version	To include a new PDF version to pass the validation process, enter the PDF version (For example, 1.5) in the PDF Version text box. Note: If the text box is empty, the PDF document of any version will be valid.
Folder/file path starts from	If you want the file or folder path to include the Application Number or the Sequence Number against which the validation needs to be done, select the corresponding option.
Version	To change the Regional DTD , select the value in the Version drop-down list.
MD5 Value (table)	To modify MD5 values, double-click on the MD5 Value corresponding to the File Name and enter the new MD5 value.

5. To save your changes, click **OK**.
 - To undo your changes and return to the previous settings, click **Reset**.
 - To cancel your changes and close the *Preferences* window, click **Cancel**.

Preferences - JP

The JP (Japan) region values section provides you the ability to search for applications based on the criteria specific to Japanese region.

Ennov InSight Validator enables you to modify the default regional settings. It is recommended that the changes made to the default settings adhere to the pertinent regulatory guidelines.

1. On the Ennov InSight Validator toolbar, click **Preferences**.
2. In the *Preferences* window, click the region tab, which is represented by the country code.
3. To include a new file type to pass the validation process, enter the file extension (e.g.: **.xlsx** or **.docx**) in the **Regional** and **ICH File Types** text box. To exclude an existing file type from passing the validation process, highlight the file type and press **Delete**.
4. Make the necessary modifications:

Setting Name	Description
Maximum Folder/File Path Length	To change the length of the folder/file path, double-click the Maximum Folder/File Path Length text box and enter the new value.
PDF Version	To include a new PDF version to pass the validation process, enter the PDF version (For example, 1.8) in the PDF Version text box. Note: If the text box is empty, the PDF document of any version will be valid.
Folder/file path starts from	If you want the file or folder path to include the Application Number or the Sequence Number against which the validation needs to be done, select the corresponding option.
Version	To change the Regional DTD , select the value in the Version drop-down list.
MD5 Value (table)	To modify MD5 values, double-click the MD5 Value corresponding to the File Name and enter the new MD5 value.

5. To save your changes, click **OK**.
 - To undo your changes and return to the previous settings, click **Reset**.
 - To cancel your changes and close the *Preferences* window, click **Cancel**.

Preferences - TH

Ennov InSight Validator enables you to modify the default regional settings. It is recommended that the changes made to the default settings adhere to the pertinent regulatory guidelines.

1. On the Ennov InSight Validator toolbar, click **Preferences**.
2. In the *Preferences* window, click the region tab, which is represented by the country code.
3. To include a new file type to pass the validation process, enter the file extension (e.g.: **.xlsx** or **.docx**) in the **Regional** and **ICH File Types** text box.
4. Make the necessary modifications:

Setting Name	Description
Maximum Folder/File Path Length	To change the length of the folder/file path, double-click on the Maximum Folder/File Path Length text box and enter the new value. The default value is 180 characters.

Setting Name	Description
PDF Version	To include a new PDF version to pass the validation process, enter the PDF version (For example, 1.8) in the PDF Version text box. Note: If the text box is empty, the PDF document of any version will be valid.
Folder/file path starts from	If you want the file or folder path to include the Application Number or the Sequence Number against which the validation needs to be done, select the corresponding option.
Version	To change the Regional Schema , select the value in the Version drop-down list.
MD5 Value (table)	To modify MD5 values, double-click on the MD5 Value corresponding to the File Name and enter the new MD5 value.

5. To save your changes, click **OK**.
 - To undo your changes and return to the previous settings, click **Reset**.
 - To cancel your changes and close the *Preferences* window, click **Cancel**.

Preferences - TW

The TW (Taiwan) region values section provides you the ability to search for applications based on the criteria specific to TW (Taiwan).

Ennov InSight Validator enables you to modify the default regional settings. It is recommended that the changes made to the default settings adhere to the pertinent regulatory guidelines.

1. On the Ennov InSight Validator toolbar, click **Preferences**.
2. In the *Preferences* window, click the region tab, which is represented by the country code.
3. To include a new file type to pass the validation process, enter the file extension (e.g.: **.xlsx** or **.docx**) in the **Regional** and **ICH File Types** text box. To exclude an existing file type from passing the validation process, highlight the file type and press **Delete**.
4. Make the necessary modifications:

Setting Name	Description
Maximum Folder/File Path Length	To change the length of the folder/file path, double-click on the Maximum Folder/File Path Length text box and enter the new value. The default value is 230 characters.
PDF Version	To include a new PDF version to pass the validation process, enter the PDF version (For example, 1.8) in the PDF Version text box. Note: If the text box is empty, the PDF document of any version will be valid.

Setting Name	Description
Folder/file path starts from	If you want the file or folder path to include the Application Number or the Sequence Number against which the validation needs to be done, select the corresponding option.
Version	To change the Regional DTD , select the value in the Version drop-down list.
MD5 Value (table)	To modify MD5 values, double-click on the MD5 Value corresponding to the File Name and enter the new MD5 value.

5. To save your changes, click **OK**.
 - To undo your changes and return to the previous settings, click **Reset**.
 - To cancel your changes and close the *Preferences* window, click **Cancel**.

Preferences - UA

The EU (European Union) region values section provides you the ability to search for applications based on the criteria specific to European Union.

Ennov InSight Validator enables you to modify the default regional settings. It is recommended that the changes made to the default settings adhere to the pertinent regulatory guidelines.

1. On the Ennov InSight Validator toolbar, click **Preferences**.
2. In the *Preferences* window, click the region tab, which is represented by the country code.
3. To include a new file type to pass the validation process, enter the file extension (e.g.: **.xlsx** or **.docx**) in the **Regional** and **ICH File Types** text box. To exclude an existing file type from passing the validation process, highlight the file type and press **Delete**.
4. Make the necessary modifications:

Setting Name	Description
Maximum Folder/File Path Length	To change the length of the folder/file path, double-click on the Maximum Folder/File Path Length text box and enter the new value. The default value is 180 characters.
PDF Version	To include a new PDF version to pass the validation process, enter the PDF version (For example, 1.8) in the PDF Version text box. Note: If the text box is empty, the PDF document of any version will be valid.
Folder/file path starts from	If you want the file or folder path to include the Application Number or the Sequence Number against which the validation needs to be done, select the corresponding option
Version	To change the regional DTD version, select the required value from the Version drop-down list under Regional DTD .

Setting Name	Description
MD5 Value (table)	To modify MD5 values, double-click on the MD5 Value corresponding to the File Name and enter the new MD5 value.

5. To save your changes, click **OK**.
 - To undo your changes and return to the previous settings, click **Reset**.
 - To cancel your changes and close the *Preferences* window, click **Cancel**.

Preferences - US

The US (United States) region values section provides you the ability to search for applications based on the criteria specific to the US (United States).

Ennov InSight Validator enables you to modify the default regional settings. It is recommended that the changes made to the default settings adhere to the pertinent regulatory guidelines.

1. On the Ennov InSight Validator toolbar, click **Preferences**.
2. In the *Preferences* window, click the region tab, which is represented by the country code.
3. Make the necessary modifications for the following settings:

Setting Name	Description
Maximum Folder/File Path Length	To change the length of the folder/file path, double-click on the Maximum Folder/File Path Length text box and enter the new value. The default value is 230 characters.
PDF Version	To include a new PDF version to pass the validation process, enter the PDF version (For example, 1.8) in the PDF Version text box. Note: If the text box is empty, the PDF document of any version will be valid.
Folder/file path starts from	If you want the file or folder path to include the Application Number or the Sequence Number against which the validation needs to be done, select the corresponding option.
Version	To change the <small>Regional DTD</small> , select a different option in the Version drop-down list.
MD5 Value (table)	To modify MD5 values, double-click on the MD5 Value corresponding to the File Name and enter the new MD5 value.
Enable TBD criteria	To include the criteria 2024-2025 for validation, select Enable TBD criteria . By default, this option is selected.
CDER	To include the criteria 1551, 1553 and apply CDER validation rules for 1255, select CDER . By default, this option is selected. Extension types available for CDER only:

Setting Name	Description
	<ul style="list-style-type: none"> ◦ Extension location M5.3.3.5: .csv. ◦ Extension location M5: .cmp, .cmpx, .cmpz, .wks, .wksx, .wksz.lbr,.lbrx, .lbrz, .mdb, .pbk, .opd, .psd, .spd, .c, .cpp, .m, .mat, .rmd, .phxproj, .py, .jl, .cas, .dat, .lua, .ctl. ◦ Extension location M3-M5: .r.
CBER	To apply CBER validation rules for 1255, select CBER .

4. To save your changes, click **OK**.
 - To undo your changes and return to the previous settings, click **Reset**.
 - To cancel your changes and close the *Preferences* window, click **Cancel**.

Preferences - ZA

The ZA (South Africa) region values section provides you the ability to search for applications based on the criteria specific to ZA (South Africa).

Ennov InSight Validator enables you to modify the default regional settings. It is recommended that the changes made to the default settings adhere to the pertinent regulatory guidelines.

1. On the Ennov InSight Validator toolbar, click **Preferences**.
2. In the *Preferences* window, click the region tab, which is represented by the country code.
3. To include a new file type to pass the validation process, enter the file extension (e.g.: **.xlsx** or **.docx**) in the **Regional** and **ICH File Types** text box. To exclude an existing file type from passing the validation process, highlight the file type and press **Delete**.
4. Make the necessary modifications:

Setting Name	Description
Maximum Folder/File Path Length	To change the length of the folder/file path, double-click on the Maximum Folder/File Path Length text box and enter the new value. The default value is 180 characters.
PDF Version	To include a new PDF version to pass the validation process, enter the PDF version (For example, 1.8) in the PDF Version text box. Note: If the text box is empty, the PDF document of any version will be valid.
Folder/file path starts from	If you want the file or folder path to include the Application Number or the Sequence Number against which the validation needs to be done, select the corresponding option.
Version	To change the Regional DTD , select the value in the Version drop-down list.
MD5 Value (table)	To modify MD5 values, double-click on the MD5 Value corresponding to the File Name and enter the new MD5 value.

5. To save your changes, click **OK**.
 - To undo your changes and return to the previous settings, click **Reset**.
 - To cancel your changes and close the *Preferences* window, click **Cancel**.

User Preferences

The *User Preferences* tab in the *Preferences* window enables you to specify locations for the previously generated reports and the reports generated using the Silent Mode feature. You can also specify your preferences for the ErrorOnly Report.

Specify Reports Location

You can specify the location to store previously generated reports and the reports generated using Silent Mode feature.

1. In the Validator *Preference* window, select the **User Preferences** tab.
2. To specify the location to store the previously validated submissions report, click the browse button next to **Report Location** under **Previously Validated Submissions Settings**.
3. Browse to locate the folder on your computer or on your network.
4. To store a specific number of submissions in the location, enter the number under the option **Recently validated report**.
5. To specify the location to store the reports generated using Silent Mode feature, click the browse button next to **Report Location** under **Silent Mode Settings**
6. Click **OK**.

Specify Errors Only Report Preferences

The **Errors Only Report Preferences** can be customized to include specific criteria category, severity type and font type using the *User Preferences* tab.

To specify **Errors Only Report Preferences** values:

1. In the Validator *Preference* window, select the **User Preferences** tab.
2. Do the one of following:

Description	Action
To use legacy error reporting to generate <i>Fail</i> in the Errors Only Report for criteria that is flagged, irrespective of its severity:	Select Use legacy error reporting , and move to step 4.
To define which criteria category will generate an overall validation result of <i>Fail</i> in the Errors Only Report:	Select the validation category preferences for each region as appropriate using the Region drop-down menu. Note: To use the sec-

Description	Action
	ond option, the Use legacy error reporting check-box must not be selected.

3. Select the severity types under eCTD and NeeS sections. NeeS column appears for the following regions only:
 - AU (Australia)
 - CA (Canada)
 - EU (European Union)
 - GCC (Gulf Cooperation Council)
4. By default, Tahoma type font is used for reports. To use a different font, select a font from the **Font** drop-down list. These font settings apply to both **Full Report** and **Errors Only Report**. See: *Select Font for Reports*.
5. Click **OK**.

Silent Mode

The Silent Mode functionality in Validator enables you to generate an **Errors Only Report** or a **Full Report** on a sequence without the need to launch the Validator application from *Windows Explorer*.

Silent Mode invokes Validator (minimized in your system tray) and generates an **Errors Only Report** for the selected sequence. If the submission passes the validation process without any errors, a **Full Report** is generated. The reports are saved automatically as PDF files in the destination specified in the **ValidatorUser Preferences > Silent Mode Settings**.

The Silent Mode can be invoked only if no instances of Validator run at time the option is selected for a Sequence. If the Validator is already opened the error message is generated notifying that `Another instance of Validator is running`.

To perform a *Silent Mode* validation:

1. Open *Windows Explorer* and browse to a sequence folder.
2. On the selected sequence folder, right-click and choose **Validator**. Validator runs a full validation on the selected sequence as a background operation and saves the report (Errors Only or Full) in the folder specified in the **Validator > User Preferences > Silent Mode Settings**. The application remains minimized in your system tray -

When you restore the minimized Validator (from the system tray), the selected sequence is loaded, the status appears under *Validation Results*, and all features are active in the toolbar ribbon.

3. Go to the location specified in the **Validator User Preferences > Silent Mode Settings** to view the generated report. The default destination folder for Silent Mode validation report (Error Only or Full Report) is `..\My Documents\ Validator`. **Note:** By default, the **Errors Only Report** and **Full Report** are shown in Tahoma font. To use a different font, you must select it under *User Preferences*. See: *Select Font for Reports*.

Select Font for Reports

You can select fonts for **Full Report** and **Errors Only Report** using the *User Preferences* tab. By default, Tahoma font is used for reports of all regions.

To select font for reports:

1. In the *Preferences* window, select the **User Preferences** tab.
2. From the **Font** drop-down list, select one of the following fonts:
 - Arial
 - JhengHei ('Microsoft JhengHei')
 - Malgun Gothic.**Note:** When you use the Malgun Gothic font, the path separator symbol is used in report instead of the back slash as shown in the image below.
 - MS Gothic**Note:** When you use the MS Gothic font, the path separator symbol is used in the report instead of the back slash as shown in the image below.
 - SimSun
 - Tahoma
3. Click **OK**.

Add Font for Reports

You can add new fonts to use them for the **Full Report** and **Errors Only Report** By default, Tahoma font is used for reports of all regions.

Fonts that you want to add must be already be included as part of your Microsoft Windows or Office. To add fonts for reports:

1. Navigate to the **preferences.xml** file. By default, located here: **<drive>:\<folder name>\<folder name>\AppData\Roaming\Ennov\InSight Validator\preferences.xml**
2. Open the **preference.xml** file in a text editor such as a Notepad.
3. Locate the section below:

```
<FontSetting SelectedFont="Tahoma">
  <Fonts>
    <Font Name="Arial" />
    <Font Name="Microsoft JhengHei" ShortName="JhengHei" />
    <Font Name="Malgun Gothic" />
    <Font Name="MS Gothic" />
    <Font Name="SimSun" />
    <Font Name="Tahoma" />
  </Fonts>
</FontSetting>
```

4. Add `` to the list of fonts and replace "new font" with the font name.
5. Save and close the file. The new font is listed under **Preferences > User Preferences > Font** drop-down list.

Delete Font for Reports

You can delete fonts that are not required for **Full Report** and **Errors Only Report**.

1. Navigate to the **preferences.xml** file. By default, located here: **<drive>:\<folder name>\<folder name>\AppData\Roaming\Ennov\InSight Validator\preferences.xml**
2. Open the **preference.xml** file in a text editor such as a Notepad.
3. Locate the section below:

```
<FontSetting SelectedFont="Tahoma">
  <Fonts>
    <Font Name="Arial"/>
    <Font Name="Microsoft JhengHei" ShortName="JhengHei"/>
    <Font Name="Malgun Gothic"/>
    <Font Name="MS Gothic"/>
    <Font Name="SimSun"/>
    <Font Name="Tahoma"/>
  </Fonts>
</FontSetting>
```

4. Delete `` from the list of fonts. The font name is the name of the font that you want to delete.
5. Save and close the file. The updated fonts are listed under **Preferences > User Preferences > Font** drop-down list.

Modify User Interface Criteria

The changes you make to the default values in the *Preferences* window will not reflect in the application user interface.

For example, if you change the value of the maximum length of the folder/file path in the *Preferences* window, the changed value does not reflect in the *Criteria Description* under the *Validation Results* pane in the user interface, although the validation activity is carried out against the value specified in the *Preferences* window. Therefore, it is recommended that you make changes in the corresponding xml files to complement the changes in the *Preferences* window. This will avoid any discrepancy between the values displayed in the user interface and the values against which the validation process is carried out.

The following image illustrates that, although the default value of the folder/file path length is changed from 230 to 100 in the *Preferences* window, it does not reflect that change under the *Validation Results* pane in the user interface.

Submissions

Submissions must be validated against the different criteria specified by regional agencies and the ICH electronic Common Technical Document (eCTD) specification.

Use Validator to:

- select a submission in your system (using browse submission or drag-and-drop operations)
- view information and statistics about the submission
- validate the submission
- generate a report with submission validation results

Select a Submission

This topic includes a procedure on how to select submissions for validation using the browse submissions or drag-and-drop options.

Use Validator to select a submission in your system, to view information and statistics about the submission, and to validate the submission.

To select a submission for validation:

1. Click the browse folder icon next to the **Submission** field.
2. Browse your system and select a submission. You must specify the location of the submission at the sequence folder level only. For example: sequence folder 0000, 0001, 0002, and so on.
3. Click **OK**. The *Selected Submission Details* and *Selected Submission Statistics* pane displays information about the submission.

If you have selected a submission (For example, 0003) that includes a reference to a previous submission (For example, 0000 or 0001 or 0002), an error message appears. If this occurs, you must select the application root folder location that contains all previous sequences (For example, 0000 through 0002) using the browse folder icon next to the **Application** field.

1. After the submission is selected, you can select items in the *Validation Criteria* pane to validate all the items that appear in the *Validation Results* pane.

Validate Submissions

After you select a submission (using the browse function in the **Submission** option), you can select items listed in the *Validation Criteria* pane to validate them. The result of the validation is shown in the *Validation Results* pane.

Right-click on an item in the *Validation Criteria* list to select or clear all the listed criteria (**Select All/UnSelect All**).

The criteria and descriptions appear in the *Validation Results* pane.

Note: When you validate a submission that is not the initial sequence of an application, it is recommended that all previously submitted sequences that form the life cycle of the application in question are located in the root location of the sequence that is validated. This will ensure that the validation criteria are applied to the validated sequence as intended by the regulatory agency, and in accordance with the related specification.

Validation Reports

Validator provides several types of reports for viewing validation results for your submissions.

- **Summary Report** - The report provides a summary of the validation in the **Validation Results** table.
- **Individual Criteria Report** - The report provides details of the individual criteria which fail to meet the validation requirements.
- **Errors Only Report** - Use this report to view only the failed criteria. Unlike the Summary and the Individual Criteria reports, the Errors Only Report is opened as a **.pdf** file. Except of the criteria-related information, the PDF document also contains **Submission Information, Administrative Information, and Submission Statistics** data.

Note: When the nonconformity status of criteria is Medium, Low, Warning or Best Practice, the details of these will be provided in the **Full Report**.

- **Full Report** - Use this report to view all the information for the submission. Similarly to the **Errors Only Report**, the **Full Report** is opened as a **.pdf** file that contains **Submission Information, Administrative Information, and Submission Statistics** data in addition to the criteria-related information.

Summary Report

The Summary Report is the default report that appears in the *Validation Results* pane after the validation is completed.

The report itself is a table with the agency specified criteria number or ID, severity, criteria description, and the outcome of the process. The outcome of the process is the status that each specific criterion has after the validation is completed. The set of criteria presented in the table depend on the values selected in the **Validation Criteria** pane.

Individual Criteria Report

The Individual Criteria Report provides details specific to the criterion.

To view the details, you can click on the criterion that is displayed in the *Validation Results* pane.

You can view the details for the criteria that failed to meet the validation requirements, or are set to Best Practice. The details for the criteria that have status of Pass are not available.

Errors-Only Report

The Errors Only Report contains the agency specified criteria number, the description of the criteria, the path of all the files that have failed the criteria, and the severity of the criteria. This report also provides the submission and the envelope information.

To view only the criteria that failed validation:

1. On the **Validation** tab, click on the **Errors Only Report** icon.
2. The report opens in **.pdf** file format. **Note:** You can also generate an Errors Only Validation Report using Silent Mode in Ennov InSight Validator.

By default, the **Errors Only Report** and **Full Report** are shown in Tahoma font. To use a different font, you must select it under *User Preferences*. See *Select Font for Reports*.

Full Report

The Full report includes the agency specified criteria number, the description of the criteria, the path of all the files that have passed and failed the criteria and the severity of the criteria.

The Full report also contains submission information, envelope information, and submission statistics which include information such as the number of modules and the files included, their size, and their type.

For Canada region, the Full report also provides additional information for the criteria with the Info status. To view the full report, click on the **Full Report** icon on the **Validation** tab. The report opens as a PDF file. You can also generate a Full Report using **Silent Mode** feature in Validator.

Note: By default, the **Errors Only Report** and **Full Report** are shown in Tahoma font. To use a different font, you must select it under *User Preferences*. See

Select Font for Reports

Previously Validated Submissions

The **Previously Validated Submissions** option lets you view all the submissions that were validated previously.

You can also use this option to view the validation history of a submission. This option is available on the left side of the application interface.

To view the previously validated submissions:

1. On the left side of the application window, click **Previously Validated Submissions**. All previously validated submissions are listed. The number of submissions that are listed depends on the number specified in the **User Preferences** option.
2. To view the details of a submission and generate a PDF copy of the same, double-click that submission from the list.
3. To view the validation history of a submission:
 - a. Load the submission by using the browse button in the *Submission Selection* bar.
 - b. Click **Previously Validated Submissions** on the left side of the application window. The validation history of the submission is listed.

Criteria Severity and Corresponding Validation Status

The *Validation Results* window in the Validator application lists the criteria severity as well as their corresponding status upon the completion of the validation process. The criteria are region specific and therefore the terms used to label the severity and their statuses vary. The following table lists the criteria severity and their post-validation status.

Region	Criteria Severity	Status upon criteria conformity	Status upon criteria nonconformity
AU	Error	Pass	Error
	Warning	Pass	Warning
	Information	Pass	Information
US	High	Pass	High
	Medium	Pass	Medium
	Low	Pass	Low
<ul style="list-style-type: none"> • EU • GCC • CH • JO • TW • UA • NeeS 	P/F	Pass	Fail
	BP	Pass	Best Practice
CA	Error	Pass	Error
	Warning	Pass	Warning
	Info	Pass	Info
	Ignore	Pass	Ignore
CNNote: 1.3 criterion checks the actual folders structure.	Information	Information	Information
	Warning	Pass	Warning
	Error	Pass	Error
JP	Numbered Criteria	Pass	Fail
TH	P/F	Pass	Fail
	BP	Pass	Best Practice

Region	Criteria Severity	Status upon criteria conformity	Status upon criteria nonconformity
	Info	Pass	Information
ZA	P/F	Pass	Fail
	Error	Pass	Error
	Warning	Pass	Warning
	Information	Pass	Information
	BP	Pass	Best Practice

Note: When the nonconformity status of criteria is Medium, Low, Warning, or Best Practice, the submissions may still be accepted by the agency. However, it is recommended that submissions satisfy the validation requirements of these criteria. Please seek confirmation from the agency to which you are submitting.

To view the details of the criterion which fails to meet the validation requirement, click on the corresponding criteria status in the *Validation Results* pane. The validation status in the *Validation Results* window and the validation reports (Errors-only and Full) can be configured to display only the Pass/Fail status or the severity specific status.

Chapter 2. Review

The *Review* tab in the Validator application contains simple and intuitive features that allow you to view submissions that are validated as well as those that are in the development process. It enables you to review and approve submission content and structure before submitting it to a regulatory agency.

Note: Access to the *Reviewer* tab depends on your license type. For more information about licensing options of Validator, refer to the Validator licensing topic in the release notes.

Review Toolbar

Use the *Review* toolbar to initiate actions to view submissions in Validator tool as well in the web browser.

Op- tion	Description
Submission	
Sub- mis- sion	Displays the path of the submission selected using the Submission browse feature in the <i>Validation</i> tab. To view a submission in the <i>Review</i> tab, it must first be selected using the browse folder icon corresponding to submission in the <i>Validation</i> tab. The Submission field on the <i>Review</i> tab is read-only.
Ap- plica- tion	Displays the root folder of the selected submission. The field is read-only.
Save	
Save	Save any changes that are made to the document property values.
Checksum	
Re- cal- cu- late	Verifies all checksum attribute values in an XML instance.
XML	
Index	Open the index.xml file in a web browser. If the XML file editor is set up on the computer, the index.xml file is opened in the default XML editor.
Re- gion- al	Open the regional.xml file in a web browser. If the XML file editor is set up on the computer, the regional.xml file is opened in the default XML editor.

Option	Description
Re-load	Refresh the submission to incorporate the latest changes made on it.
Viewing Windows	
TOC	Show or hide the table of contents pane on the left.
Viewer	Show or hide a document (on the central pane) that is selected for viewing from the TOC.
Properties	Show or hide the properties of a document (on the bottom pane) that is selected for viewing from the TOC.
Settings	
Preferences	Personalize certain display options within the Reviewer tab and includes the following sections when selected: <ul style="list-style-type: none"> • TOC Settings • Document Display • User Interface Settings
Reviewer	
Help	Launches the Help system for Validator. For quick, summarized Help information, hover over each toolbar button to display the tool-tip Help . When using the online Help , you can navigate to a topic within the table of contents or use the search feature to locate topics of interest.
About	Displays the Validator version and license information.
Exit	Exits the Validator.

Review Preferences

The **Preferences** option in the *Review* tab enables you to personalize certain display options within the Review tab. The options you can customize include the TOC settings, document display, and the user interface settings.

To customize the options using **Preferences**:

1. In the *Review* tab, click **Preferences**.
2. In the **TOC Settings** section, select the following TOC display options as necessary:

Option	Description
Display operation icon in the TOC	Use this option to display the icons that represent the operations performed on the documents such as new, delete, replaced, etc.
Display Modules/Sections using Bold font in the TOC	Use this option to display the module/section titles in bold font in the TOC.
Display Document (Leaf) using Bold font in the TOC	Use this option to display the document (leaf) titles in bold font in the TOC.

3. To display a certain number of documents in the **Content** pane, specify the number in the text box corresponding to the option **Maximum number of documents open** in the **Document Display** section. For example, if you specify 3, the three recently viewed documents will show in the **Content** pane. If the fourth document is viewed, the oldest document open will be closed.
4. Select the option **Remember the settings before closing the application** in the **User Interface Settings** section to save the current user interface layout for subsequent use. The next time you open the application it will display the same layout.
5. When the settings are updated, do one of the following:
 - To restore the default settings, click **Reset**. To close the **Preferences** window, click **OK**.
 - To save changes and close the window, click **OK**.

Table of Contents

When a submission is loaded, the contents of that submission will appear in the *Table of Contents* (TOC) pane in the *Review* tab. The *TOC* pane includes the Sequence View and the Folder View.

Sequence View

The Sequence view displays the contents and structure of the submission as compiled in the submission building tool.

The *TOC* pane also includes module buttons that can be used for filtering the TOC in the Sequence view. Clicking on a module button when that module is displayed in the TOC will hide that module in the TOC. Clicking on that module button again will show the module in the TOC.

Folder View

The Folder shows the contents of the submission folder.

Double-clicking on a document node in the TOC displays the document in the *Content* pane.

Expand and Collapse

You can use the **Expand All** and **Collapse All** buttons to expand or collapse the entire submission. To expand or collapse the entire submission, select the sequence number and then use the expand or collapse buttons. Similarly,

to expand or collapse a specific section or folder of a submission, select that section in the TOC and then use the **Expand All** or **Collapse All** buttons.

You can also expand or collapse a specific section or folders of the submission, use the expand (+) and collapse (-) icons for that section or folder.

The expand and collapse icons, as well as **Expand All** and **Collapse All** buttons, can be used in both the Sequence View and Folder View.

Note: When switching between Sequence and Folder views, the root (module or sequence or section) in the TOC must be selected for using expand/collapse functionality.

View Documents

The *Content* pane in the *Review* tab displays the document that is selected from the TOC. When you double-click a document (leaf) in the TOC, the file associated with that document shows in the *Content* pane. The total number of documents displayed at any time is dependent on the settings established in the Review **Preferences**.

Along with the document content, the regional administrative information and the STF details can also be viewed in the *Content* pane. While the regional administrative information of a submission is displayed by default, the STF details can be viewed by clicking on the study in the TOC.

Also, when a document shows in the *Content* pane, the document properties appear in the *Properties* pane.

Modify Submission Metadata

Validator enables you to edit submission metadata to include envelope information and STF leaf details, save any updates made to their backbone and regional XML, and recalculate checksums accordingly. This allows for minor changes to be made without the need to republish an entire submission or any individual elements.

To modify the submission metadata:

1. In the *Properties* pane, click on the **Value** text box of the attribute value you want to modify.
2. Modify the attribute value as needed.
3. Click **Save**.
4. Do one of the following:
 - To update the changes in the existing backbone xml files, retain the default path under **Target Folder**. Select the options **regional.xml**, **index.xml** and/or **stf.xml** to update the respective files.
 - To make a copy of the backbone xml files with the changes, use the **Browse** button and select a new location. When a copy of the backbone xml files are created, no changes will affect the existing backbone xml files. Select the options **regional.xml**, **index.xml** and/or **stf.xml** to update the respective files.
5. Do one of the following:

- To save the **index-md5.txt** file with the backbone xml file, select the option **Save index-md5.txt file with Backbone XML file** option.
 - To save the **index-md5.txt** file in a different location, clear the option **Save index.md5.txt file with Backbone XML file option** and using the **Browse** button, select a location.
6. Click **OK**.
 7. In the confirmation message window, click **OK**.

View Index and Regional XML Files in a Web Browser

The **Index** and **Regional** buttons on the *Review* tab enable you to view the **index** and **regional** XML files in a web browser. You can also view the index and **regional** XML files from the TOC.

To view the **index** and **regional** XML files:

1. To open the **index.xml** or **regional.xml** files, on the toolbar click **Index** or **Regional**.
2. To view the **index.xml** or **regional.xml** files from the TOC, right-click on the TOC sections and select **View ICH XML** or **View Regional XML**.
 - The **index.xml** file includes hyperlinks to the files in the submission.
 - The **regional.xml** file displays details of the regional files along with hyperlinks to the documents.
3. To view the documents from the **index.xml** or **regional.xml** files, click the corresponding hyperlinks. The documents appear in a web browser.

Recalculate Checksum Attribute Values

The **Recalculate** feature enables you to recalculate checksums for any number of leafs as required, as well as for the entire sequence, when changes have been made to the submission metadata and/or for verification purposes. You have the option of saving the **index-md5** checksum file to an alternative location from within the application. Changes can therefore be made and checksums updated from within Validator.

To recalculate the checksum attribute values of a submission in an XML instance:

1. Click the **Recalculate** option in the toolbar. A message appears, indicating that the recalculating process takes a few minutes to complete.
2. Click **Yes**.
3. In the confirmation message, click **OK**.
4. To recalculate the checksum attribute value of a document, in the *TOC*, right-click on the document and select **Calculate Checksum**. The new checksum will be updated in the *Properties* window.

Edit STF Properties

This topic includes instructions to edit the STF properties

Validator enables you to edit Study Tagging File (STF) properties and save the changes to the backbone, STF and index xml files, and recalculate checksums accordingly. This allows for minor changes to be made without the need to republish an entire submission or any individual element.

To edit STF properties:

1. Right-click on a STF in the *TOC*.
2. Click **Edit STF Properties**.
3. Click on the **Value** text box of the attribute value you want to edit.
4. Edit the attribute value as needed.
5. Click **Save**. In the confirmation message window, click **OK**. **Note:** Clicking **Save** in the *Edit STF Properties* window does not save the changes to the backbone XML file. To save the changes to the backbone XML file and to save the **index-md5.txt** file with backbone XML file, continue with the next step.
6. Click **Save** on the toolbar.
7. Do one of the following:
 - To update the changes in the existing backbone xml files, retain the default path under **Target Folder**. Select the options **regional.xml**, **index.xml** and/or **stf.xml** to update the respective files.
 - To make a copy of the backbone xml files with the changes, use the **Browse** button and select a new location. When a copy of the backbone xml files are created, no changes will affect the existing backbone xml files. Select the options **regional.xml**, **index.xml** and/or **stf.xml** to update the respective files.
8. Do one of the following:
 - To save the **index-md5.txt** file with the backbone xml file, select the option **Save index.md5.txt file with Backbone XML file** option.
 - To save the index-md5.txt file in a different location, clear the option **Save index.md5.txt file with Backbone XML file** option and using the **Browse** button, select a location.
9. Click **OK**. In the confirmation message window, click **OK**.

Customize the Viewing Windows

The major portion of the *Review* tab is, by default, occupied by the viewing windows. These viewing windows include: the *TOC* that displays the TOC structure of a submission, the *Viewer* that displays the document content, and the *Properties* window that displays the properties of a document. You may choose to hide or display these windows for appropriate viewing in the interface.

To hide or display the viewing windows:

1. To hide any of these windows, click on the corresponding option on the toolbar. You can also hide these windows by clicking on the **X** option available at the top right hand corner of these windows.
2. To display the *Viewing Windows*, click any of the options available in the Viewing Windows section in the toolbar again. You can also restore these windows using the **Restore default settings** option available in the *Review* tab.
 - a. **Review > Preferences > Apply > OK**

Chapter 3. Best Practice

The publishing best practice topics provide recommendations to enable you to take advantage of built-in efficiencies in Ennov InSight Validator.

The following topics are intended to be used in conjunction with the Ennov InSight Validator user documentation.

Name
AU v3.2 validation warning.xml