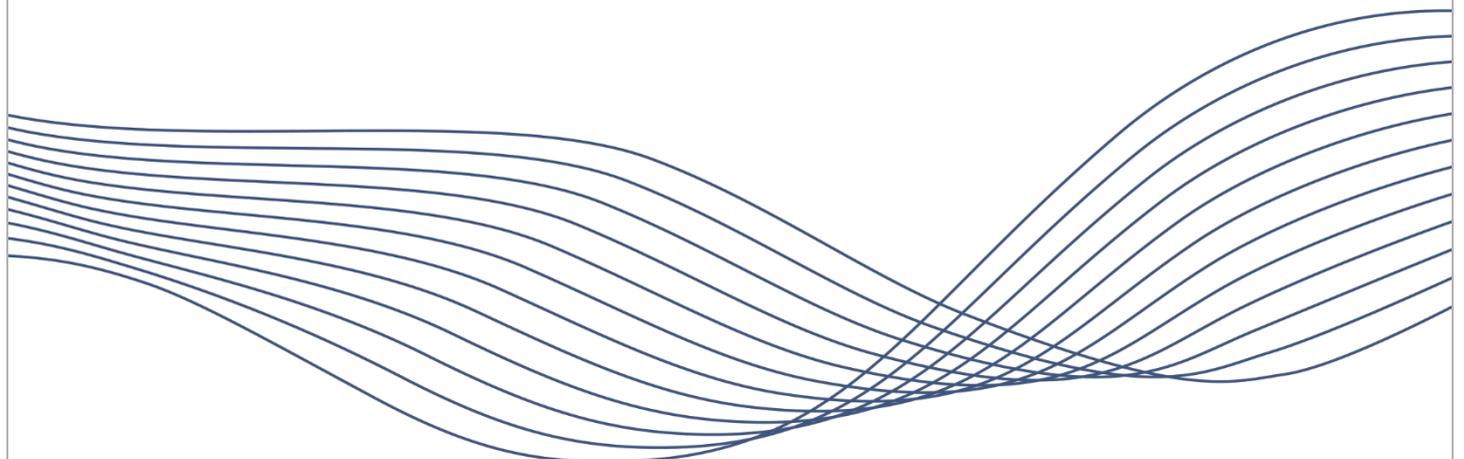




# Release Configuration

Version 19.1





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## Disclaimer

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# 1. Getting Started

## 1.1 Introduction

This document is the Release Configuration Sheet (RCS) for LORENZ eValidator 19.1<sup>1</sup>.

The main objective of the Release Configuration Sheet is to provide an overview of the scope and impact of this release and to provide a description of the issues addressed and/or features that have been added or modified in the new version, as well as its potential impact on existing systems.

## 1.2 How this guide is organized

This guide is organized in four Chapters:

**Chapter 1** contains general information about the release and the Release Configuration Sheet as well as an indication about expected target systems.

**Chapter 2** contains the actual Release Notes including Distribution Media, Product Documentation, Release Compatibility Information and Release Impact Information.

**Chapter 3** provides information about the installation process, as much as this information is of relevance to the Release Configuration Sheet.

**Chapter 4** contains a description of Release Highlights and a brief narrative description of enhancements and addressed issues. Each item provides a reference to the issues tracked under [LORENZ Help Desk](#) to allow every customer to identify items fixed on their behalf.

## 1.3 Where this software should be installed

This software release can be installed on both client and server computers. It may be used side by side with the docuBridge client, and also with the LORENZ Automator.

## 1.4 Installing into a validated environment

According to the implemented change control procedures, (re-)validation steps will be required when putting the application into operational use. This depends on the validation policy implemented at each customer site.

LORENZ strongly suggests performing Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) based on a Validation Plan (VP). In addition, a thorough risk analysis and risk controlling should be performed.

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<sup>1</sup> With the April 2018 releases, LORENZ has modified the product versioning. For further information. Please refer to <http://lorenz.cc/downloads/LORENZ-Changes-Release-Naming-2018.pdf>



The eValidator does not store or modify any electronic records for electronic submissions. However, due to the importance of correctness for the validation results, LORENZ recommends (re-)validating the product.

Note for validated environments: The software validation recommendations given in in this document only apply for customers upgrading from an existing version. All other customers should consider performing a full validation according to the policy defined in the organization.

#### 1.4.1 Installation Qualification (IQ)

Both the setup package and the software binaries have been signed electronically to comply with the new security guidelines on Windows Server 2008, Windows Server 2012, Windows Server 2016, and Windows 7, 8, or 10. The LORENZ certificate has been issued by GlobalSign ([www.globalsign.com](http://www.globalsign.com)). If you need additional details about the certificate used, please contact LORENZ Support.

Please only install LORENZ eValidator software that has a genuine electronic signature issued to LORENZ Bridge Software GmbH. The signature will be shown upon installation.

#### 1.5 Notes

Throughout this document:

- The phrase eValidator refers to the LORENZ eValidator product.
- The phrase installation folder refers to the folder where the eValidator has been or shall be installed to (this is usually the folder named `C:\Program Files\LORENZ Life Sciences\LORENZ eValidator`).
- The phrase configuration folder refers to the folder where the eValidator configuration files have been or shall be installed to (this is the sub-folder named `LORENZ Life Sciences\Automator` in the `CommonAppData` folder).
- The folder referred to by `CommonAppData` is `C:\ProgramData`.



## 2. Release Notes

### 2.1 Distribution Methods / Media

LORENZ distributes LORENZ eValidator 19.1, using the following distribution channels:

- HTTP download upon request

### 2.2 Product Documentation

This version of the LORENZ eValidator is created with the following documentation items:

Automator Documentation	Content
User Guide for LORENZ eValidator	This document describes how to use the LORENZ eValidator.
User Guide for LORENZ eValidator webPanel (contained in separate setup package)	This document describes how to use the eValidator webPanel, which provides a web browser user interface for the eValidator.
Configuration Guide for LORENZ eValidator webPanel (contained in separate setup package)	This document describes how to install and configure the eValidator webPanel.
Functional Specification (FSP)	This document outlines the desired features and behavior of the system.
Release Configuration Sheet (RCS)	This document is the RCS. The RCS outlines the changes in LORENZ eValidator in this release.

Table 1: Product Documentation

### 2.3 Target Platform Information

The application has been tested and certified for the following operating system platforms:

- Microsoft Windows 7 (32 and 64 Bit)
- Microsoft Windows 7 SP1 (32 and 64 Bit)
- Microsoft Windows 8 (32 and 64 Bit)
- Microsoft Windows 8.1 (32 and 64 Bit)
- Microsoft Windows 10
- Microsoft Windows Server 2008 R2 (incl. SP1)
- Microsoft Windows Server 2012
- Microsoft Windows Server 2012 R2
- Microsoft Windows Server 2016

**Please Note:**

The application setup requires Microsoft Windows Installer 3.1 or higher, which will not be installed automatically if not already installed on the target computer.

All components are native Microsoft .NET 4.6.2 assemblies. Therefore, the .NET 4.6.2 runtime is required to use the applications. The setup will not automatically install the .NET framework if not already present on the target computer. You need to do this manually before you start the installation of the eValidator.

**2.4 Hardware requirements information**

## Minimum system

- 1 GHz processor
- 1 GB RAM
- 100 GB HDD

## Recommended system

- 2 GHz processor with 2 or more cores or a multi-processor system
- 4 GB RAM
- 100 GB HDD

**2.5 Release compatibility information**

There are no compatibility issues for eValidator 19.1 related to previous versions. It can be used side by side with any version of the docuBridge client.

This version will automatically replace an existing previous version of LORENZ eValidator found on the computer when you install LORENZ eValidator 19.1. Versions before LORENZ eValidator 5.0 will not be removed or upgraded by the eValidator setup. If you want to remove such a previous version, you need to uninstall it manually via the Add/Remove Programs dialog in the Control Panel or by re-running the setup program that installed the version.



## 2.5.1 LORENZ Product Compatibility

Product	19.1	18.2	18.1	Release Version before 18.1
LORENZ Foundation	☑	☑	☒	☑
LORENZ Automator	☑	☑	☑	☑
LORENZ docuBridge	☑	☑	☑	☒
LORENZ drugTrack	n/a	n/a	n/a	n/a

### Legend:

- ☑ The product is compatible with LORENZ eValidator 19.1 (certified)
- ☒ The product is not compatible with LORENZ eValidator 19.1
- n/a Product or Interface is not available.

Table 2: LORENZ Product Compatibility



## 3. Installation Procedure Overview

### 3.1 Introduction

This section of the Release Configuration Sheet lists specific considerations for the installation of this release of the eValidator.

### 3.2 Software Installation Package

The distribution contains the software setup for eValidator 19.1. The setup can be used for both new and upgrade installations.

The setup is provided as a full setup. It does not require any previous installation. If a previous version of the LORENZ eValidator is found during installation, it will be updated.

#### 3.2.1 eValidator Workstation

This application allows verifying and validating electronic submissions purposely conforming to the ICH eCTD standard (see [www.ich.org](http://www.ich.org)) based on configured check options and dynamic verification rules. Validation results will be created as XML and as HTML reports; adequate XSL style sheets for viewing the report content in a web browser are also provided. LORENZ will periodically provide updates for the configuration base to keep the eValidator synchronized with the official specifications.

The eValidator also supports validating certain specified non-eCTD submissions (NeeS and VNeS). For details about the predefined validation rules for non-eCTD submissions, please refer to the User Guide or the Functional Specification (FSP).

#### 3.2.2 eValidator configPanel

This tool can be used by administrators to configure the LORENZ eValidator system. It will only be installed if the Workflow Service feature has been selected. The eValidator configPanel provides the following features and functions:

- Comprehensive configuration settings management
- License management
- Log file examination
- Start and stop the Workflow Service
- Detailed version information
- System configuration validation
- Importing and exporting system snapshots

### 3.3 Setup

Prior to installing eValidator, please unzip the distribution files to a temporary directory.



The setup is provided as a full setup. It does not require any previous installation. If a previous version of the LORENZ eValidator is found during installation, it will be updated.

### 3.4 License Types

For the LORENZ eValidator different license types are available:

#### 3.4.1 eValidator Basic license

This is a free of charge license which allows running validations for eCTD or non-eCTD submissions. Several features have been disabled for this license type:

- You cannot use customized profiles or change the report branding text and logo.
- The use of the LORENZ eValidator Batch Processing is not supported.
- Only English localization is available.
- You cannot create or use custom profiles.
- You cannot change any severity settings for the validation rules.
- You cannot change any rule parameters in a loaded profile.
- You cannot change the profile you have selected on first start of the software. Only reinstalling the software will allow re-selecting the profile.
- If you are using a “branded” version of the eValidator (such as BfArM eValidator or AGES eValidator), changing the profile is limited to the EU related profiles.
- You cannot validate submissions on a server operating system such as Microsoft Windows Server 2008 or 2012.
- The eValidator PowerShell host is not supported.
- You will not get the summary report in addition to the full validation report.
- You cannot use parallel execution of validation rules to improve the overall performance for large submissions.
- Profile content reports are not available.
- You cannot use “Baseline Optimized Validation”.
- You cannot use the automated profile update feature.

#### 3.4.2 eValidator ONE license

This license provides the same features as the Basic version plus the option to switch between profiles (regions) without reinstalling the software. The other limitations of the Basic license are still effective.

The license can be purchased online at <http://www.lorenz.cc/eSolutions/eValidator>.

#### 3.4.3 eValidator Enterprise license

This license does not have the functional limitations of the eValidator Basic or eValidator ONE license.

**Please note:**

The available extended profiles may depend on the modules you purchased. Additional features (e.g. the webPanel) can be purchased separately for this license type. For detailed information please contact LORENZ Sales or speak with your LORENZ Account Manager.

**3.4.4 New/Update Installation**

There are two different setup packages available.

**3.4.4.1 Standard LORENZ setup, compressed**

This setup consists files: setup.msi. Start the setup.msi to install the software.

**3.4.4.2 Standard LORENZ setup, unpacked**

This setup consists of multiple files, including a setup.msi. Start the setup.msi to install the software. You can customize this package before deploying it on your site. For example, you can add the license serial number to the **system.config** file in the package before deploying the package.

**Note:** While it does not matter which setup (compressed or unpacked) you are using to update an existing previous product version or to install it for the first time, **you must use the same setup if you want to uninstall or modify it later**. Otherwise, uninstalling it will not work and when trying to modify an installation you would end up with two copies of the product installed.

Before installing LORENZ eValidator, please unzip the distribution file to a temporary directory.

Since the eValidator 18.1 release, new versions of "BfArM eValidator" or "AGES eValidator" are no longer made available. Please switch to the standard product "LORENZ eValidator" instead.

If you currently have "BfArM eValidator" or "AGES eValidator" installed and you want to upgrade to "LORENZ eValidator", you must uninstall the current version before you can start installing the other package.

Please follow these steps to perform the installation:

1. In case Windows Installer or Microsoft .NET 4.6.2 runtime cannot be found, these components will not be installed automatically. You need to do this manually before you start the installation of the eValidator.
2. Navigate to the setup folder **Setup LORENZ eValidator**.
3. Start the file **setup.msi**.
4. Acknowledge the confirmation dialogs and follow the instructions on the screen. Completing the installation of these components might require restarting the computer.



5. The eValidator installation wizard will be started. On Windows 7, Windows 8, Windows 10, Windows Server 2008, 2012, and 2016, you will get a confirmation message like the one in the following picture showing the publisher's identity:

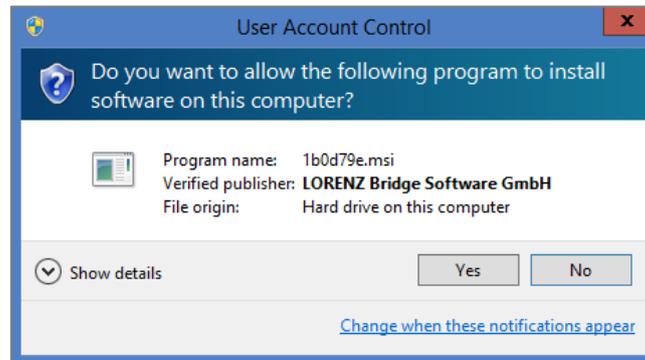


Image 1: Publisher's Identity Confirmation Dialog

6. To protect you from fraud through tampered software packages, please acknowledge this message only if the verified publisher is LORENZ Bridge Software GmbH. You can click on Show details to see additional information about the publisher's identity.
7. Follow the instructions displayed to complete the installation. For a quick and easy procedure, it is recommended to accept the default settings provided by the wizard.
8. A new desktop shortcut (LORENZ eValidator) and a new start menu item will be created (LORENZ Life Sciences\eValidator). Both shortcuts can be used to start the application.
9. Start the eValidator. You will now be asked to select a profile for validation.





Image 2: Validation Profile Selection Dialog



Profiles contain collections of validation rules and settings for a specific validation scope (e.g. submitting an application to the FDA or to Health Canada).

The LORENZ eValidator installs a set of different profiles you can choose from. However, with the Basic license, a profile once chosen cannot be changed without reinstalling the software. This applies to all users on a single computer (i.e. the profile chosen by the user who ran the application first will be applied to all other users as well and cannot be changed without reinstalling the software). The Enterprise version and the eValidator ONE versions do not have this limitation. To choose a profile, double-click the corresponding line or select the line and click the OK button. The profile will be loaded. The next time you start the LORENZ eValidator, you will not be prompted for the profile again; it will be loaded automatically.

### 3.4.4.3 LORENZ eValidator webPanel

If you consider using the eValidator webPanel, please note that the eValidator webPanel needs to be installed as a separate application after the LORENZ eValidator has been installed. For the eValidator webPanel setup, the same principal steps apply as described above (the folder with the setup is Setup LORENZ eValidator webPanel). Make sure to enable the eValidator Workflow Service feature:

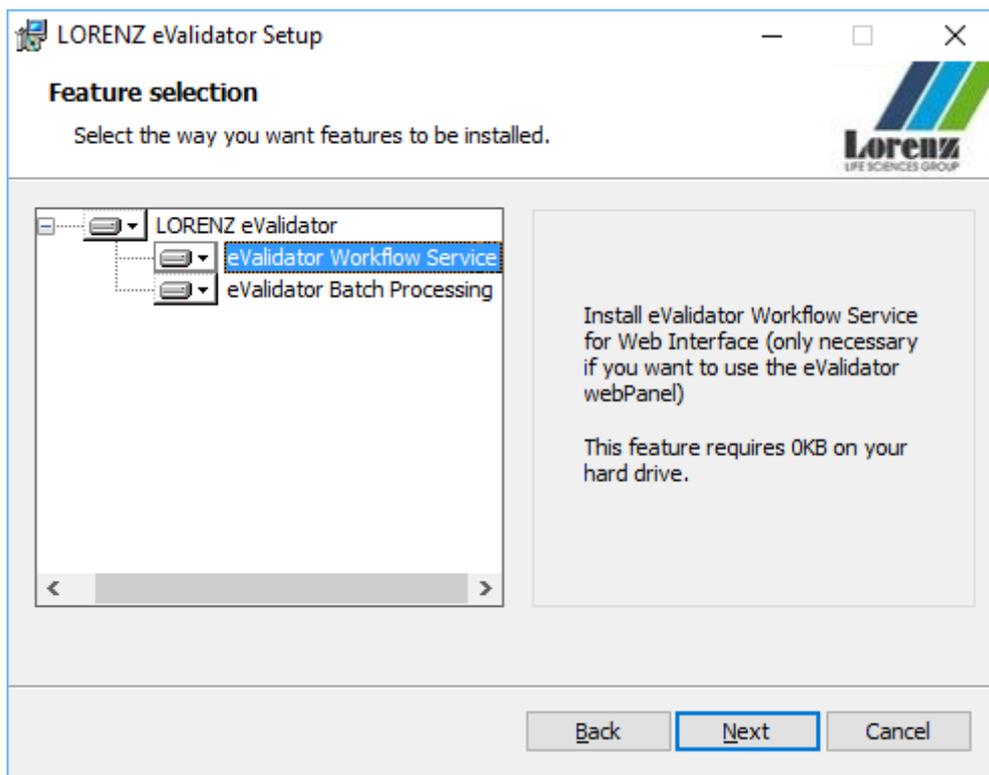


Image 3: eValidator Workflow Service Installation



## 4. Changes since eValidator Release 18.2.1

### 4.1 eValidator Profiles

#### 4.1.1 CA eCTD and Non-CTD Profile Updates

##### Description

The following updates and corrections have been made to the profiles for CA eCTD and CA Non-eCTD:

Ticket #	Description
<b>EVA-2226</b> Critical	<b>CA eCTD</b> <b>Criterion: G34</b>  When validating a CA eCTD submission, the eValidator reported G34 errors when a document was replaced or deleted in section 3.2.r and the original document was not inside of a node-extension. However, the criterion G34 only applies to new documents and should ignore leaf elements with replace, append, or delete operation. The problem has now been resolved.
<b>EVA-2145</b> Critical	<b>CA eCTD</b> <b>Criterion: G34</b>  Rule G34 had an incorrect severity level assigned (Information). This has now been resolved (correct level is "Error").  This correction was already available in the specific release LORENZ eValidator 18.2.1.01.
<b>EVA-2227</b> Major	<b>CA eCTD</b> <b>Criterion: G34</b>  The recommended node-extension title for 3.2.r.5 has been changed on the HC web site. It is now "3.2.R.5 Assessment of Similarity". The profile has been adjusted accordingly.
<b>EVA-2235</b> Major	<b>CA eCTD</b> <b>Criterion: B47</b>  When checking for JavaScript in PDF documents, XFA forms and AcroForms will now be excluded, regardless of their location in the TOC.



Ticket #	Description
<b>EVA-2185</b> Major	<b>CA eCTD</b> <b>Criterion F22</b>  Rule F22 incorrectly reported a Warning if an LCM document was not found in a sequence. Such documents are no longer mandatory though. The rule F22 has been updated accordingly and will now only report warnings if LCM documents were found with operation “new” in a sequence other than the initial one.  This correction was already available in the specific release LORENZ eValidator 18.2.1.01.
<b>EVA-2186</b> Major	<b>CA eCTD</b> <b>Criteria: C05, C07, G17, A09</b>  Previous versions of the LORENZ eValidator “tolerated” files like ~\$*.doc and ~\$*.docx in a submission and did not report any related findings for the rules C05, C07, and G17. Since the posted validation criteria on the Health Canada web site do not mention such files as being ignored by C05, C07, and G17, the rules in the profiles have been updated accordingly  This correction was already available in the specific release LORENZ eValidator 18.2.1.01.
<b>EVA-2166</b> Major	<b>CA eCTD</b> <b>Criterion F27</b>  Health Canada recently updated the posted validation criteria and added F27. The eCTD validation profile has been updated accordingly by adding this rule and removing the now obsolete EXT_F100 from the extended profile.  This correction was already available in the specific release LORENZ eValidator 18.2.1.01.
<b>EVA-2198</b> Major	<b>CA eCTD</b> <b>Criteria: G06, G08, G34</b>  The rules G34, G06, G08 sometimes reported findings with incorrect severity (warning in instead of error). This could happen if a submission was validated first that had one or more warning-level issues for those rules. A subsequent validation of another submission that actually had error-level issues for the same rules then reported the findings as Warnings only. The problem has now been resolved. Customers who observed warning-level results for G06, G08, or G34 where error-level results were expected: Please re-validate to verify that the problem has been resolved. Please note that the three rules dynamically adjust the severity level, based on the subject of the findings (described in the posted <a href="#">validation criteria</a> ).  This correction was already available in the specific release LORENZ eValidator 18.2.1.01.



Ticket #	Description
<b>EVA-2144</b> <b>EVA-2162</b> Major	<b>CA Non-eCTD</b> <b>Criterion A08</b>  For Non-eCTD submissions files with the extension “xml” are not allowed, with the following exceptions: REP RT files (Regulatory Transaction) REP PI files (Product Info) REP AI files (Application Info for Medical Device) Previously, the eValidator accepted REP RT files only. This has now been resolved.  This correction was already available in the specific release LORENZ eValidator 18.2.1.01.
<b>EVA-2187</b> Minor	<b>CA Non-eCTD</b> <b>Criterion A08</b>  The rule A08 for CA Non-eCTD profiles will now also report files as invalid that have names like ~\$*.doc or ~\$*.docx. This follows the <a href="#">regulations in the guidance document</a> posted by Health Canada. Even though you might have been informed that Health Canada normally tolerates files such as ~\$*.doc or ~\$*.docx, there is no guarantee that this will be true in the future. If your submission has one or more of such remnant files or “leftovers”, please verify that it will no longer pass A08.  This correction was already available in the specific release LORENZ eValidator 18.2.1.01.
<b>EVA-2205</b> Minor	<b>CA eCTD</b> <b>Criteria: F25, F26, G34, I02, I04</b>  The descriptions for these criteria have been updated on the HC web site. The profiles have been adjusted accordingly.  This correction was already available in the specific release LORENZ eValidator 18.2.1.01.
<b>EVA-2184</b> Minor	<b>CA eCTD</b> <b>Criteria F25, F26</b>  The messages reported for findings in F25 and F26 have been updated to better address the reason of the problem.  This correction was already available in the specific release LORENZ eValidator 18.2.1.01.



Ticket #	Description
<b>EVA-2146</b> Minor	<b>CA eCTD and Non-eCTD Locked Word Documents</b>  When validating a submission that contained Microsoft Word documents, one or more of the documents were still locked when the validation had finished. This applied to validations through the eValidator client application only (the program had to be closed to release the locks). The problem has now been resolved.  This correction was already available in the specific release LORENZ eValidator 18.2.1.01.
<b>EVA-2218</b> Minor	<b>CA eCTD Expired Profiles</b>  The CA eCTD validation profiles version 4.3 have been moved to the Expired folder.

Item	Change Impact
Profiles	CA eCTD - Validation Criteria 4.4 CA eCTD - Validation Criteria 4.4, EXTENDED CA Non-eCTD - Validation Criteria 4.4 CA Non-eCTD - Validation Criteria 4.4, EXTENDED
Configuration Files	Changed
Program Code	Changed
Documentation	FSP

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	LORENZ recommends to update the PQ scripts for the criteria listed above. There should be no need for a full profile validation.



## 4.1.2 US eCTD Validation Criteria 3.8

### Description

**EVA-2172:** New validation profiles have been added to support validation criteria v3.8.

The validation criteria with an effective date of “TBD” are activated in the extended profile only. The standard profile will not execute those checks. This applies to 1734, 1735, 1736, 1737, 2024, 2025. The criterion 1789 also has an effective date “TBD” but this criterion already existed before. Its severity has changed though. The new severity (“High”) has been set in both the standard and the extended profiles.

With the new v3.8 profile version, you will see separate profiles for FDA CDER and FDA CBER. This is because the scope differs for CDER and CBER in the validation of study data (see page 4 in this [document](#)). Currently, if you are using the standard profile for validation, it does not matter, which one you select (CDER or CBER). However, if you use the extended profile, where study data validation is already enabled, you should select the appropriate version. This will also become important for the standard profiles once the study data validation criteria have been enforced by the US FDA.

In addition to the changes in the new validation criteria as posted by the US FDA, the following changes and corrections have been made in the new profile(s) compared to the 3.7 profiles:

Ticket #	Description
<b>EVA-2139</b> Major	<b>Criterion 1782</b>  For criterion 1782, the profile will now check if the STF leaf version exactly matches “STF Version 2.2” or “STF version 2.2”. In previous versions, it was only checking for the presence of the version string “2.2”.
<b>EVA-2151</b> Major	<b>Criteria 2002, 1357,1362,1368, 2012, 2013</b>  The profile check for criterion 2002, which also included checks for 1357,1362,1368, 2012, 2013, has now been split into separate checks for each listed criterion. The check for 2002 has been moved to the new category “Schema Error”.
<b>EVA-2152</b> Major	The LORENZ specific checks <b>[I1]</b> and <b>[I2]</b> have been removed from the standard profile. The reason was: The standard profile however should follow the posted official criteria as close as possible. The checks are still available in the extended profile though because the output of these checks can provide relevant information for the user.
<b>EVA-2153</b> Major	<b>Criterion 1362</b>  For criterion 1362, the profile now reports multiple occurrences of the STF category element with a name “type-of-control”.



Ticket #	Description
<b>EVA-2154</b> Major	<b>Criterion 1442</b>  For criterion 1442, the profile now also reports a finding if the dtd-version attribute in the index.xml file is present but has a blank value (empty).
<b>EVA-2155</b> Major	<b>Criterion 1445</b>  For criterion 1445, the profile now also reports a finding if the dtd-version attribute in the us-regional.xml file is present but has a blank value (empty).
<b>EVA-2156</b> Major	<b>Criterion 1748</b>  For criterion 1748, the profile now also reports a finding if the version attribute in an STF leaf is present but has a blank value (empty). Please note that this will also be reported by 1782.
<b>EVA-2157</b> Minor	<b>Criterion 1765</b>  For criterion 1765, the eValidator did not report an error if the version number in the dtd-version attribute was blank. This has now been resolved.
<b>EVA-2158</b> Major	<b>Criterion 1969</b>  For criterion 1969, the eValidator now checks and reports the following: <ul style="list-style-type: none"> <li>• Missing study-id</li> <li>• Empty STF (no child elements)</li> <li>• Invalid. i.e. no well-formed STF files (stf-*.xml).</li> </ul>
<b>EVA-2159</b> Major	<b>Criterion 1981</b>  For criterion 1981, the profile now also reports missing STFs. Previously, missing STFs were reported by 1323 only (which will still happen).
<b>EVA-2160</b> Major	<b>Criterion 1663</b>  For criterion 1663, the profile was incorrectly checking the date value but not the format specifier attribute. This has now been corrected. An incorrect value for the format attribute will however also be reported by 2002.
<b>EVA-2164</b> Major	<b>Criterion 1752</b>  For criterion 1752, the profile now also reports a finding if the dtd-version attribute in an STF is present but has a blank value (empty).



Ticket #	Description
<b>EVA-2165</b> Major	<b>Criterion 2002</b>  For criterion 2002, the profile will now perform the validation against the DTD files in the eValidator configuration folder but not against the DTD files provided with the submission. This applies to index.xml, us-regional.xml 2.01, and STFs. This way, missing DTD files will no longer generate High level errors. Exception: For us-regional using DTD v3.3, the DOCTYPE must still have the correct URL reference, which will be used to validate the regional backbone file.
<b>EVA-2168</b> Major	<b>Criterion 2012</b>  For criterion 2012, the profile will now check for and report empty attribute values in us-regional.xml where the attribute value is required.
<b>EVA-2169</b> Major	<b>Criterion 1368</b>  For criterion 1368, the profile will now check the following: <ul style="list-style-type: none"> <li>• STF valid values: The file-tag and the category values must be valid according to valid-values.xml</li> <li>• STF property: This should only be used with name="site-identifier" and info-type="us"</li> <li>• STF category: For a study in M5, a category with name="species" should not be used</li> <li>• ICH backbone: The attributes manufacturer, substance, product-name, dosageform, and indication should only be used where they are allowed by DTD. Please note that this is already covered by 2002.</li> </ul>
<b>EVA-2170</b> Major	<b>Criterion 1119</b>  For criterion 1119, the profile will now report findings for missing DTD files in the util folder. Previously, missing DTDs were not reported here but with 2002 only (and with the LORENZ specific check [1]).
<b>EVA-2171</b> Major	<b>Criterion 1357</b>  For criterion 1357, the profile will now report findings when: <ul style="list-style-type: none"> <li>• Attribute "indication" is present but empty (only where the attribute is required)</li> <li>• Attribute "substance" is present but empty (only where the attribute is required)</li> <li>• Attribute "manufacturer" is present but empty (only where the attribute is required)</li> <li>• For an STF, the "category" element is not present for a study in section m5-3-5-1, m4-2-3-2, or m4-2-3-4-1.</li> </ul>



Ticket #	Description
<b>EVA-2180</b> Minor	For ICH backbone, regional backbone (DTD v2.01), and STFs: An invalid or missing DOCTYPE declaration will no longer cause errors in the validation report if the dtd-version attribute value is provided and the required namespace declarations are provided in the root element.
<b>EVA-2189</b> Major	Compared to the v3.7 profile, the checks ICH_007, ICH_008, and ICH_009 have been removed from the extended profile. These checks are already covered by criterion 1357.
<b>EVA-2194</b> Minor	<b>Criterion 1314</b>  For criterion 1314, the eValidator no longer reports an error if the util\dtd or utilstyle folder is empty. The criterion only applies to non-required files, but not to missing files.
<b>EVA-2196</b> Major	<b>Criterion 2001</b>  For criterion 2001, the eValidator did not properly report version problems if the DOCTYPE was incorrect and validation was executed in offline mode. This has now been corrected.
<b>EVA-2197</b> Minor	<b>Criterion 1255</b>  For criterion 1255, incorrectly reported an error when running validation for a DTD 3.3 submission in offline mode and the DOCTYPE SYSTEM URL was invalid. This has now been corrected.
<b>EVA-2224</b> Major	<b>Criterion 2012</b>  For criterion 2012, the eValidator now focuses on empty attribute values in the admin section of the us-regional.xml (following the description of the criterion on the FDA web site). It no longer checks the applicant-info/id element and the telephone element.
<b>EVA-2206</b> Major	<b>Criterion 1519</b>  For criterion 1519, the eValidator now ignores case when comparing the application type prefix in the application folder name (if prefix is given) with the application type from the us-regional.xml. For example, both nda123456 and NDA123456 will be accepted.
<b>EVA-2246</b> Major	<b>Criterion 2021</b>  For criterion 2021, the eValidator now checks the current sequence and previous sequences in the context of the regulatory activity. It no longer checks sequences with higher numbers than the current one.



Ticket #	Description
<b>EVA-2253</b> Major	<b>Criterion 7</b>  For criterion 7, the eValidator will now only report an error, if no fillable forms could be found (356h, 1571, 22523, 2253). It will <b>not</b> be checked here if the correct form was submitted, if the form was properly named, or if the related sequence could be loaded to check if 2252 is required in case of an amendment to an annual report.
<b>EVA-2254</b> Major	<b>Criterion 5</b>  For criterion 5, the eValidator will now also check the application type in the form (356h, 1571, 2252, 2253) against the application type provided in the us-regional.xml file. Previously, only the application number was checked.
<b>EVA-2262</b> Major	<b>Criterion 5038</b>  For criterion 5038, the eValidator will now also check if the form 2253 is used in the correct context. In US 3.3 submissions, 2253 is valid for submission type fdast8 (“promotional”) only.
<b>EVA-2190</b> Minor	<b>Criterion: STF_008</b> (Extended profile only, not an official criterion)  The results from check STF_008 will now show the name and path of the corresponding STF: Previously, the user could not tell from the report, which file had caused the issue.

### Note for Study Data Validation (1734-1737) with Extended Profile:

To examine the life cycle data, a “current view” file will be created. This file will be stored in the application root folder. The name of this file will be APPNAME\_CurrentView.xml, for example 123457\_CurrentView.xml. The file location can be customized, please refer to the eValidator User Guide for details. Creating the current view file can take some time (up to several minutes) when the application already has a large number of sequences. But since the file will be re-used by subsequent validations, the time to create it is only needed once.

**Please note:** Since the current view file will possibly be re-used for all validations of a given application, please make sure that there is not more than one validation running for an application at the same time. Otherwise the current view file may be corrupted. If you cannot or do not want to re-use the current view file, you can configure a different location for the file (e.g. in the report folder). Please follow the instructions in the User Guide.



Item	Change Impact
Profiles	US eCTD - Val. Crit. 3.8 (CDER) US eCTD - Val. Crit. 3.8 (CDER), EXTENDED US eCTD - Val. Crit. 3.8 (CBER) US eCTD - Val. Crit. 3.8 (CBER), EXTENDED  US eCTD - Val. Crit. 3.8 (CDER) - Grouped Child Application US eCTD - Val. Crit. 3.8 (CDER) - Grouped Child Application, EXTENDED US eCTD - Val. Crit. 3.8 (CBER) - Grouped Child Application US eCTD - Val. Crit. 3.8 (CBER) - Grouped Child Application, EXTENDED
Configuration Files	Changed
Program Code	Changed
Documentation	FSP

Validation Impact	Description
IQ	n/a
OQ	Verify that the new profiles are available in the select dialog. The previous version (3.7) of the profiles has been moved to the Expired folder.
PQ	LORENZ recommends a full validation of the new v3.8 profiles because, compared to the v3.7 profiles, many changes have been made.



### 4.1.3 AU NeeS

#### Description

The following updates and corrections have been made to the profiles for AU TGA AU NeeS:

Ticket #	Description
<b>EVA-2247</b> Critical	<b>AU NeeS</b> <b>Criteria: 4.3.1, 4.3.2, 4.3.3</b>  When validating an AU NeeS submission, the rules 4.3.1, 4.3.2, and 4.3.3 did not work properly due to a misnamed folder in the eValidator configuration file. This could lead to the following problems: A missing document in 10323-cmi-approved was incorrectly reported as an error (Pass/Fail) while it actually should have been reported as a B/P warning only. Missing documents in 10331-mockup-clean, 10332-mockup-annotated, 10333-mockup-approved were not reported.  This has now been resolved.

Item	Change Impact
Profiles	AU NeeS - Validation Criteria 3.1 AU NeeS - Validation Criteria 3.1, EXTENDED
Configuration Files	No changes
Program Code	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	Users wo encountered issues related to the ticket description given above: Please validate again to verify that the described problems no longer occur.



#### 4.1.4 ZA eCTD

##### Description

The following updates and corrections have been made to the profiles for ZA SAHPRA eCTD:

Ticket #	Description
EVA-2236 Major	<p><b>ZA eCTD</b> <b>Criterion: 14.BP5</b></p> <p>The node-extension titles in section “3.2.R Regional Information” will no longer be checked by the validation profile. Only existence of node-extensions will be verified (and the files and folders, by 14.BP2 and 14.BP3). The node extension titles shown in the ZA guidance document 2.23 are examples only but not binding regulations.</p>

Item	Change Impact
Profiles	ZA eCTD – Val. Cri. 2.1 ZA eCTD – Val. Cri. 2.1, EXTENDED
Configuration Files	No changes
Program Code	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	LORENZ recommends updating the PQ script to reflect the changes described above (that node-extension titles will not be checked anymore).



#### 4.1.5 EU eCTD

##### Description

The following updates and corrections have been made to the profiles for EU eCTD:

Ticket #	Description
<b>EVA-2217</b> Major	<p><b>EU eCTD</b> <b>Criterion: M1_013 (Extended profile only, not an official criterion)</b></p> <p>When checking the name of product information files in m1-3-1-spc-label-pl, leaf elements with operation "delete" should be excluded from the check. This has now been resolved.</p>
<b>EVA-2228</b> Minor	<p><b>EU eCTD</b> <b>Criteria: 9.8. 9.9</b></p> <p>The comparison of the UUID in the EU envelope should not be done in case-sensitive mode. This has now be resolved (i.e. two UUIDs are considered identical if they differ in case only).</p>

Item	Change Impact
Profiles	EU eCTD Validation Criteria 7.1 EU eCTD Validation Criteria 7.1, EXTENDED
Configuration Files	No changes
Program Code	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	LORENZ recommends updating the PQ script to reflect the changes described above.



#### 4.1.6 CN eCTD

##### Description

A preview version of the Chinese eCTD validation profiles has been added to the eValidator.

Ticket #	Description
<b>EVA-2147</b> Major	<b>CN eCTD Validation Criteria 0.2</b>  The validation profiles are for testing and preview purposes only. The validation criteria have not been finalized by the Chinese authorities (CDE) yet.

Item	Change Impact
Profiles	China eCTD Val. Crit. 0.2 (Preview) China eCTD Val. Crit. 0.2, Extended (Preview)
Configuration Files	Changed
Program Code	No changes
Documentation	FSP

Validation Impact	Description
IQ	n/a
OQ	Please verify that the new profiles are available in the select dialog.
PQ	The profiles are for testing purposes only (preview version). The validation criteria have not been finalized yet by the CDE.



#### 4.1.7 JO eCTD

##### Description

A preview version of the Chinese eCTD validation profiles has been added to the eValidator.

Ticket #	Description
<b>EVA-2174</b> Minor	<p><b>JO eCTD</b> <b>Criteria 12.9, 13</b></p> <p>The Jordan authority has updated the M1 specification document (1.0.2): Files in <code>m1\jo\13-pi\131-spc</code> must be placed in a language specific subfolder <code>m1\jo\13-pi\131-spc\ar</code> or <code>m1\jo\13-pi\131-spc\en</code>. The validation profile has been adjusted accordingly.</p> <p>This correction was already available in the specific release LORENZ eValidator 18.2.1.01.</p>

Item	Change Impact
Profiles	JO eCTD - Validation Criteria 1.0 12.9, 13 JO eCTD - Validation Criteria 1.0, EXTENDED 12.9, 13
Configuration Files	C:\ProgramData\LORENZ Life Sciences\eValidator\Naming\naming_ectd_jo_1-0-1.xml
Program Code	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	Customers with Jordan eCTD submissions: Please verify that files placed directly under <code>m1\jo\13-pi\131-spc</code> will not pass validation anymore.



## 4.1.8 Reports

### Description

The following updates and corrections have been made to the general validation report content:

Ticket #	Description
<b>EVA-2210</b> Minor	Alongside with the program version, the report will now also show the configuration version. This will help LORENZ support to identify the exact version used by customers. The version appears either at the bottom of the report (US eCTD and PDF QC) or at the top (any other profile).
<b>EVA-2199</b> Minor	The section "Modified Profile Settings" has been removed from the reports. Previously the section appeared in the validation reports (for profiles other than US eCTD and PDF QC) if the user had modified one or more settings before starting a validation.



## 4.1.9 PDF Analysis

### Description

The following updates and corrections have been made to the PDF Analysis module:

Ticket #	Description
<b>EVA-2010</b> Major	The eValidator sometimes reported PDF documents as password-protected although there was no password set. This has now been resolved.  <b>Profiles affected: All</b>
<b>EVA-2204</b> Major	The eValidator profiles now support text extraction and analysis in PDF documents. Currently, no profile contains such checks. LORENZ is currently in discussion with several agencies and industry clients about when and where text analysis could be helpful to simplify submission processing and/or improve content quality.
<b>EVA-2083</b> Major	The PDF QC profiles have been modified and redesigned. They are now using the pdfium library internally. Several improvements have been made to the PDF QC profile to identify multimedia content and 3D content. The profiles will now perform about 50% faster than before.



## 4.2 Changes to eValidator Application

### Description

The following changes have been made to the eValidator client application (including the Batch Processing client):

Ticket #	Description
<b>EVA-2231</b> Minor	<p>To prevent malicious XPath injection, several portions in the eValidator client application code have been updated by escaping XPath strings.</p> <p>This has no effect on the validation results. It merely provides a higher security standard for the eValidator client application. For the previously existing option to inject malicious XPath expressions when loading a profile, no known exploits are known.</p>
<b>EVA-2215</b> <b>EVA-2102</b> Minor	<p>In the eValidator Batch Processing client application, the setting “Prefer Extended Profiles” was not preserved when closing and re-opening the application. This has now been resolved. Furthermore, when the user changes the profile for one or more listed items, the extended version of the selected profile will automatically be picked.</p> <p>This has no effect on the validation results. Customers working with the Batch Processing client application should verify that the setting will now be preserved when restarting the program.</p>
<b>EVA-2201</b> Minor	<p>In the eValidator client application, the check for software and/or regulatory updates has been improved. It will now also show a link in the status bar whenever an update is available. By clicking the link, additional information about the update will be displayed. It is now possible to directly install a software update from here (provided that an Internet connection is available).</p> <p>The configuration update packages are now called “Regulatory Update Packages”.</p> <p>Please refer to the user guide for further information about the available options to configure the check for updates.</p>
<b>EVA-2173</b> Major	<p>The eValidator client application now supports high resolution displays. Previously, several portions of the user interface were misaligned or distorted when the application was used on a display with magnification settings above 150%.</p>
<b>EVA-2085</b> Major	<p>All LORENZ eValidator executables are now digitally signed. To avoid startup delays when no Internet connection is available, signature verification upon program start is disabled by default.</p>



### 4.3 Changes to eValidatorConsole

#### Description

The following changes and improvements have been made to the eValidatorConsole application:

Ticket #	Description
<b>EVA-2200</b> Major	<p>In the eValidatorConsole application, additional command line switches are now supported:</p> <pre data-bbox="488 607 1321 678" style="border: 1px solid #ccc; padding: 5px;">/extended_results</pre> <p>When this is specified in the command line, the eValidatorConsole will provide additional result summary information in the standard output (i.e. the console window) when the validation has finished. This information contains a list of all findings and severities, by rule number. Third-party applications can use this information to evaluate the validation results without opening the report files.</p> <pre data-bbox="488 913 1321 985" style="border: 1px solid #ccc; padding: 5px;">/p_copy_profile_to_report</pre> <p>By setting this to false (default is true), no profile copy will be created in the report folder when the validation has finished.</p>
<b>EVA-2141</b> Major	<p>In the eValidatorConsole application, additional command line switches are now available for multi-client scenarios:</p> <pre data-bbox="488 1234 1321 1305" style="border: 1px solid #ccc; padding: 5px;">/clients_file</pre> <p>Through this command line parameter, the name and location of a client definition file can be specified. An example is available in the folder Repositories\OEM. Please refer to the user guide for further information.</p> <pre data-bbox="488 1473 1321 1545" style="border: 1px solid #ccc; padding: 5px;">/client_id</pre> <p>The ID of a client from the clients definition file. The name of the client will then be shown in the validation report (instead of the name of the license holder). Furthermore, the validation report will be placed in the folder that has been specified for this client in the client definition file. Please refer to the user guide for further information.</p>
<b>EVA-2085</b> Major	<p>All LORENZ eValidator executables are now digitally signed. To avoid startup delays when no Internet connection is available, signature verification upon program start is disabled by default.</p>



#### 4.4 Changes to eValidator webPanel

##### Description

The following changes and improvements have been made to the eValidator webPanel:

Ticket #	Description
<b>EVA-2212</b> Minor	The text and layout of the logout message dialog have been updated to align with LORENZ adminPanel.

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