



Release Configuration

Version 18.2.1



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1. Getting Started

1.1 Introduction

This document is the Release Configuration Sheet (RCS) for LORENZ eValidator 18.2.1.

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.

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`.

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.

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.

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). 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.



2. Release Notes

2.1 Distribution Methods / Media

LORENZ distributes LORENZ eValidator 18.2.1, 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 18.2.1 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 5.x found on the computer when you install LORENZ eValidator 18.2.1. Any version 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.

The setup will install the eValidator only. Since version 5.8.1, the LORENZ Automator is now a self-contained product, which needs to be installed separately.

2.5.1 LORENZ Foundation compatibility

This table shows the compatibility of the user management in eValidator webPanel to use the LORENZ Foundation system for user authentication and user authorization.

eValidator Release	Foundation Release	Compatibility
eValidator webPanel 18.2.1	1.0.0.0	Supported



eValidator Release	Foundation Release	Compatibility
eValidator webPanel 18.2.1	1.1	Supported
eValidator webPanel 18.2.1	1.2	Supported
eValidator webPanel 18.2.1	18.1	Certified
eValidator webPanel 18.2.1	18.1.1	Supported
eValidator webPanel 18.2.1	18.2	Certified

Table 2: eValidator-LORENZ Foundation 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 18.2.1. 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) 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:

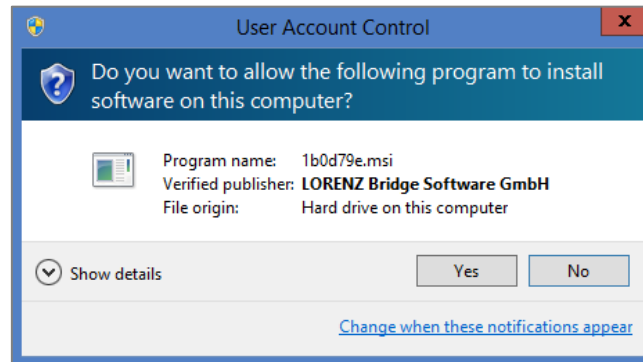
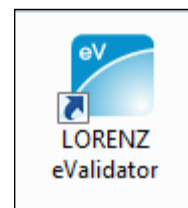


Image 1: Publisher's Identity Confirmation Dialog

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.



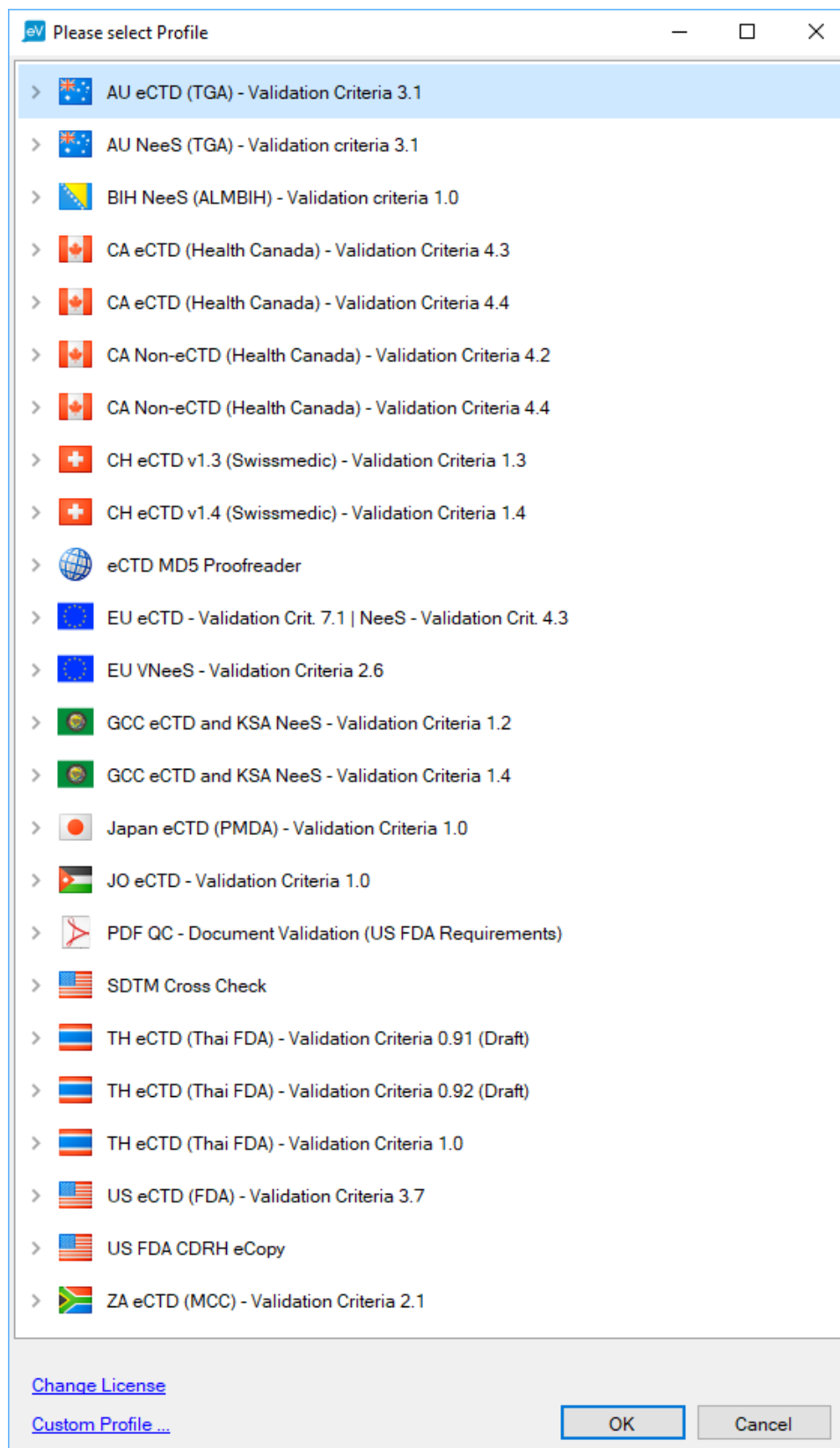


Image 2: Validation Profile Selection Dialog



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:

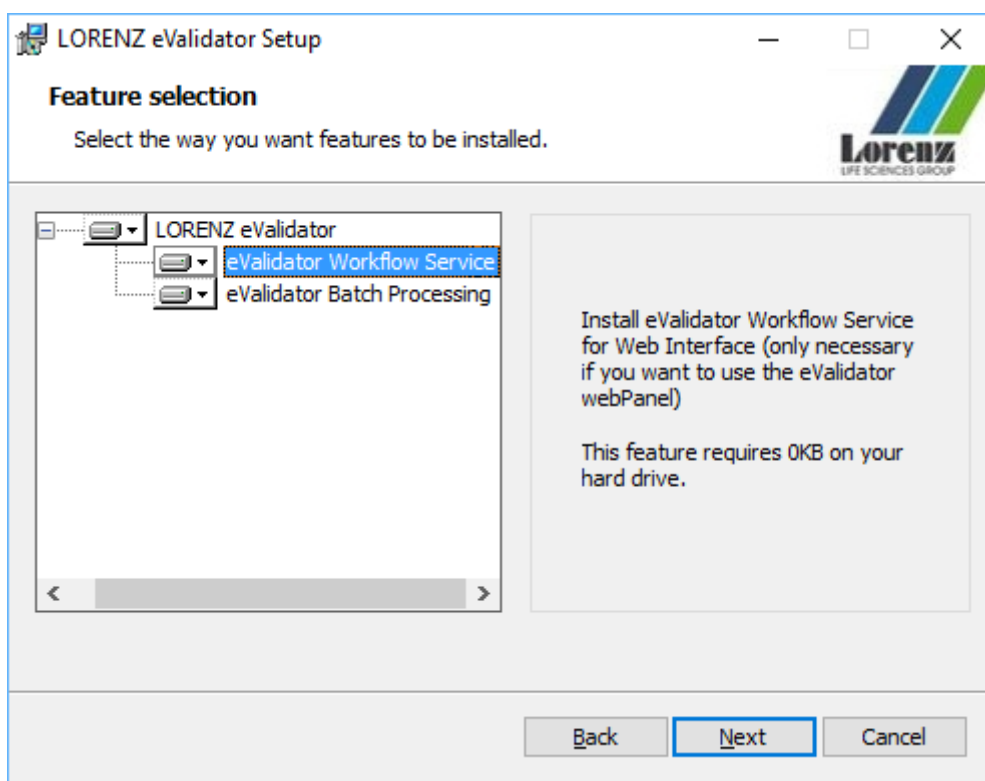


Image 3: eValidator Workflow Service Installation



4. Changes since eValidator Release 18.2

4.1 eValidator Workstation

4.1.1 Priority CRITICAL

4.1.1.1 EVA-2103 – AU NeeS: 4.1.29 and 4.1.30

Description

A missing p1-toc.pdf file in an AU NeeS submission caused an incorrect error message “too many files”. The error message text was incorrect, and there should not be an error being reported in such cases because the p1-toc.pdf file is not mandatory for AU NeeS.

This has now been resolved.

Ticket Evaluation	
Priority	Critical
Type	Bug

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	Customers with AU NeeS submissions who encountered the false error message described above should re-validate the affected submission to verify that the validation report is now correct.



4.1.1.2 EVA-2089 – FIPS Compliance

Description

The LORENZ eValidator can now be used on Windows systems where FIPS mode is enabled.

Ticket Evaluation	
Priority	Critical
Type	Feature

Item	Change Impact
Profiles	No changes
Configuration Files	Changed. New configuration files have been added to eValidator Program Files folder.
Program Code	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	Customers with FIPS mode enabled Windows systems should verify that the LORENZ eValidator can now be used on those systems. Please note that the LORENZ eValidator cannot actually comply with FIPS mode because eCTD requires non IPS-compliant algorithms such as MD5. That's why the eValidator now actively informs the Windows operating system that it ignores FIPS settings. For technical background information about FIPS mode in Windows, please refer to this link .



4.1.2 Priority MAJOR

4.1.2.1 EVA-2079 – Swissmedic eCTD Validation Criteria v1.4

Description

New profiles have been added to support the new validation criteria v1.4 for [eCTD](#) submissions to Swissmedic.

Ticket Evaluation	
Priority	Major
Type	Feature

Item	Change Impact
Profiles	CH eCTD 1.4 - Validation Criteria 1.4 CH eCTD 1.4 - Validation Criteria 1.4, EXTENDED
Configuration Files	Changed
Program Code	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	Customers with eCTD submissions to Swissmedic: Please verify that the new profiles are available in the profile selection window.
PQ	Customers with eCTD submissions to Swissmedic: The new validation criteria and the new M1 specification will become mandatory 01-Jul-2019. Please update the PQ documentation accordingly.



4.1.2.2 EVA-2088 – Health Canada Validation Rules v4.4 (eCTD and Non-eCTD)

Description

New profiles have been added to support the upcoming validation rules v4.4 for [eCTD](#) and [Non-eCTD](#) submissions to Health Canada.

Ticket Evaluation	
Priority	Major
Type	Feature

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	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	Customers with submissions to Health Canada: Please verify that the new profiles are available in the profile selection window.
PQ	Customers with submissions to Health Canada: The new validation criteria will become effective end of March 2019. Please update the PQ documentation accordingly.



4.1.2.3 EVA-2064 – Jordan eCTD Validation Criteria v1.0

Description

New profiles have been added to support the new validation criteria v1.0 for [eCTD](#) submissions in Jordan M1 specification v1.0.1).

Ticket Evaluation	
Priority	Major
Type	Feature

Item	Change Impact
Profiles	JO eCTD - Validation Criteria 1.0 JO eCTD - Validation Criteria 1.0, EXTENDED
Configuration Files	Changed
Program Code	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	Customers with eCTD submissions in Jordan: Please verify that the new profiles are available in the profile selection window.
PQ	Customers with eCTD submissions in Jordan: Please visit the web site of the Jordan FDA to check when the new validation criteria and the new M1 specification will become mandatory. Please update the PQ documentation accordingly. Please note: Currently there is an inconsistency in the file name definition for m1-9-responses between validation criteria document and M1 specification document. The current eValidator profile follows the M1 specification document (i.e. responses-var.pdf, in plural form, compared to response-var.pdf specified in the validation criteria).



4.1.2.4 EVA-2098 – XFA Forms reported as corrupted

Description

The LORENZ eValidator incorrectly reported PDF XFA forms as corrupt if the XFA data in the form was stored as a stream instead of a dictionary.

This has now been resolved.

Ticket Evaluation	
Priority	Major
Type	Bug

Item	Change Impact
Profiles	Affected are eCTD Profiles for all regions where application forms in XFA format are being used: CA, EU, US.
Configuration Files	No changes
Program Code	Changed
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	Customers with submission to EU, CA, or US, who had an XFA form reported as corrupt although it actually was not: Please validate the affected submission again (or use the PDF QC profile to validate the XFA form) and verify that the problem has been resolved.



4.1.2.5 EVA-2101 – GCC eCTD: EU PDF Checks have been removed

Description

The additional PDF checks EU 16.x and EU 16.BPx have been removed from the GCC eCTD standard profile. These checks are now available in the extended profiles only.

The reason for this is have the standard profile as close as possible to the posted validation criteria.

Ticket Evaluation	
Priority	Major
Type	Feature

Item	Change Impact
Profiles	GCC eCTD - Validation Criteria 1.4
Configuration Files	No changes
Program Code	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	Customers with GCC eCTD submissions: If you have PQ documentation that refers to the results from the additional PDF checks listed above, please either switch to the GCC eCTD extended profile or remove the references from the PQ documentation.



4.1.2.6 EVA-2028, EVA-2104 – JP eCTD: Updates for PDF Checks

Description

For the Japan eCTD profile, a new check PDF-46 has been added to the profile to report PDF files that use JavaScript. Such documents are not conforming to ICH regulations and won't be accepted by the PMDA.

The check PDF-45, which reports an error if a document is a form, has been modified slightly: To omit false positives, documents will only be reported as AcroForm documents, if the document contains actual form fields. Documents that originally were AcroForm documents but have been cleared from any form fields will not be reported anymore.

Ticket Evaluation	
Priority	Major
Type	Feature

Item	Change Impact
Profiles	Japan eCTD (PMDA) PDF-45, PDF-46 Japan eCTD (PMDA), EXTENDED PDF-45, PDF-46
Configuration Files	Changed
Program Code	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	Customers with JP eCTD submissions should update the PQ documentation accordingly. PDF documents with any JavaScript code included will be reported as errors. The change to PDF-45 has been done to avoid error messages for documents that still have the "/AcroForm" tag inside but do not have any actual form fields. This can happen if an AcroForm document was modified in Adobe Acrobat by removing all form fields. When saving the document, it is no longer a form but some tagging remnants (such as "/AcroForm") might still be discoverable.



4.1.2.7 EVA-2108 – US FDA M1 Specification v2.4

Description

The LORENZ eValidator has been prepared to support the new submission type “REMS Supplement”.

Ticket Evaluation	
Priority	Major
Type	Feature

Item	Change Impact
Profiles	US eCTD - Val. Crit. 3.7 US eCTD - Val. Crit. 3.7, EXTENDED US eCTD - Val. Crit. 3.7 - Grouped Child Application US eCTD - Val. Crit. 3.7 - Grouped Child Application, EXTENDED
Configuration Files	Changed
Program Code	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	The new submission type is not active yet and will cause a validation error when being used in a submission. Please refer to the US FDA web site for information about the date when it will be accepted.



4.1.2.8 EVA-2111 – NeeS check number 1.8 incomplete

Description

In the NeeS validation criteria, the description text for number 1.8 mentions both hyperlinks and bookmarks. The eValidator only examined hyperlinks but ignored bookmarks for this check.

The problem has now been resolved.

Ticket Evaluation	
Priority	Major
Type	Bug

Item	Change Impact
Profiles	AU NeeS EU NeeS BIH NeeS
Configuration Files	No changes
Program Code	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	Customers with NeeS applications, please verify that bookmarks will be reported by rule number 1.8 if the bookmark destination path contains the sequence number.



4.1.2.9 EVA-2069 – ZA eCTD: 14.BP5 check for node-extension

Description

The LORENZ eValidator was only checking the folder granularity in 3.2.R but did not check for the required node-extensions.

The problem has now been added, node-extensions are expected as defined in the [ZA eCTD guidance](#).

Ticket Evaluation	
Priority	Major
Type	Bug

Item	Change Impact
Profiles	ZA eCTD - Val. Crit. 2.1
	ZA eCTD - Val. Crit. 2.1, EXTENDED
Configuration Files	No changes
Program Code	Changed
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	Although 14.BP5 is a B/P criterion only, should make sure that their submissions have the required granularity in section 3.2.R. This applies to having the correct folder structure and using node extensions with the correct titles.



4.1.2.10 EVA-2116 – ZA eCTD Profile could not be loaded

Description

On some Windows systems, the ZA eCTD profile could not be loaded. Instead, an error message was displayed, saying that the profile could not be loaded with the license in use. This affected Windows systems where the default list separator (a comma) for the “en-US” culture had been replaced with a different character (e.g. a colon).

The problem has now been resolved.

Ticket Evaluation	
Priority	Major
Type	Bug

Item	Change Impact
Profiles	ZA eCTD - Val. Crit. 2.1 ZA eCTD - Val. Crit. 2.1, EXTENDED
Configuration Files	No changes
Program Code	Changed
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	Customers who could not load the ZA eCTD profile(s), please verify that these profiles will now load as expected.



4.1.2.11 EVA-2060 – ALMBIH NeeS: Check PDF Link Path Case

Description

For ALMBIH NeeS submissions, the hyperlink paths in PDF documents must exactly match the destination file name, including its case.

The ALMBIH NeeS profile has been updated accordingly.

Ticket Evaluation	
Priority	Major
Type	Feature

Item	Change Impact
Profiles	BIH NeeS - Validation Criteria 1.0 1.5, 1.6, 1.7, 1.8
	BIH NeeS - Validation Criteria 1.0, EXTENDED 1.5, 1.6, 1.7, 1.8
Configuration Files	No changes
Program Code	Changed
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	The ALMBIH NeeS checker works in case-sensitive mode when checking if the bookmark or hyperlink destination exists. Customers should take this into account for their PQ documentation.



4.1.3 Priority MINOR

4.1.3.1 EVA-2080 – eCTD MD5 Proofreader Profiles for all Enterprise Customers

Description

The eCTD MD5 Proofreading and Correction profile is now available for all customers with an Enterprise license. The profile does not need to be licensed separately anymore.

Ticket Evaluation	
Priority	Minor
Type	Feature

Item	Change Impact
Profiles	eCTD MD5 Proofreading and Correction
Configuration Files	No changes
Program Code	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	n/a



4.1.3.2 EVA-2097 – EU eCTD: File Name in 1.3.1

Description

The check M1_013 has been update according to the [file name regulations](#) described by the EMA.

Ticket Evaluation	
Priority	Minor
Type	Bug

Item	Change Impact
Profiles	EU eCTD Validation Criteria 7.1, EXTENDED (M1_013)
Configuration Files	No changes
Program Code	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	This check is not included in the EU eCTD validation criteria. It has been added to the extended profile only, to help customers complying with the EMA regulations. Customers who recently had incorrect B/P warnings reported by M1_013, please verify that the rule now follows the name syntax as defined here .



4.1.3.3 EVA-2077 – US eCTD Grouped Submission Report

Description

When validating a US eCTD grouped submission that does not have the content, the validation report did not contain any sub-reports from PDF analysis.

This has now been corrected.

Ticket Evaluation	
Priority	Minor
Type	Bug

Item	Change Impact
Profiles	US eCTD - Val. Crit. 3.7 - Grouped Child Application US eCTD - Val. Crit. 3.7 - Grouped Child Application, EXTENDED
Configuration Files	No changes
Program Code	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	It is a minor priority issue only, because: - It affects US eCTD grouped child validations only - No high errors are using sub-reports - The report of the group “master” already has all the sub-reports



4.1.3.4 EVA-2112 – US eCTD: Rule 1314

Description

In the US eCTD validation profiles, the rule 1314 will now also report findings for files in additional folders in “util” (other than “dtd” and “style”).

Ticket Evaluation	
Priority	Minor
Type	Feature

Item	Change Impact
Profiles	US eCTD - Val. Crit. 3.7 1314
	US eCTD - Val. Crit. 3.7, EXTENDED 1314
	US eCTD - Val. Crit. 3.7 - Grouped Child Application 1314
	US eCTD - Val. Crit. 3.7 - Grouped Child Application, EXTENDED 1314
Configuration Files	No changes
Program Code	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	Normally, there are no further folders or sub-folders in “util”, other than “dtd” and “style”. Therefore, for most customers PQ update should not be necessary. The addition made to the implementation addresses scenarios where someone accidentally put additional folders inside the util folder.



4.1.3.5 EVA-2100 – GCC eCTD/NeeS: File Types in 1.3.5 and Labeling

Description

The GCC M1 specification does not list any picture file formats as accepted formats for section 1-3-5-samples.

The GCC M1 specification allows “.mathml” and “.tif” files in section 1-3-2-label.

For both sections, the corresponding file type configuration in the LORENZ eValidator has been corrected.

Ticket Evaluation	
Priority	Minor
Type	Bug

Item	Change Impact	
Profiles	GCC eCTD - Validation Criteria 1.2	12.8, 13
	GCC eCTD - Validation Criteria 1.2, EXTENDED	12.8, 13
	GCC eCTD - Validation Criteria 1.4	12.8, 13
	GCC eCTD - Validation Criteria 1.4, EXTENDED	12.8, 13
	KSA NeeS - Validation Criteria 1.2	3.6, 3.8
	KSA NeeS - Validation Criteria 1.2, EXTENDED	3.6, 3.8
	KSA NeeS - Validation Criteria 1.4	3.6, 3.8
	KSA NeeS - Validation Criteria 1.4, EXTENDED	3.6, 3.8
Configuration Files	Changed	
Program Code	No changes	
Documentation	No changes	

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	Customers with GCC eCTD or KSA NeeS submission should verify that picture file types in section 1-3-5-samples will now be reported as errors. If applicable, customers with GCC eCTD or KSA NeeS submission should verify that tif and mathml files in section 1-3-2-label will no longer be reported as errors.



4.1.3.6 EVA-2087 – GCC eCTD: Content in “util” folder

Description

A new check (Files_006) has been added to the extended version of the GCC eCTD 1.4 profile. This check will report warnings if non-required files or folders exist in the “util” folder.

Ticket Evaluation	
Priority	Minor
Type	Feature

Item	Change Impact
Profiles	GCC eCTD - Validation Criteria 1.4, EXTENDED Files_006
Configuration Files	No changes
Program Code	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	There is currently no official validation criterion that forbids additional, non-required files the “util” folder in an eCTD submission. However, LORENZ was informed by customers that the folder content will nevertheless be checked by the GCC authorities and non-required files or sub-folders can lead to the submission being rejected.



4.1.3.7 EVA-2094 – PDF QC Page Size Verification

Description

In the PDF QC profiles, the page size verification (G10) did not work properly for letter size pages.

This has now been resolved.

Ticket Evaluation	
Priority	Minor
Type	Bug

Item	Change Impact
Profiles	PDF QC - US FDA (Single Document) G10
	PDF QC - US FDA (Multiple Documents) G10
Configuration Files	No changes
Program Code	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	Customers who are using the PDF QC profiles to check PDF for submission readiness, please verify that G10 will now detect and handle letter size pages correctly (i.e. all pages that are smaller or larger than letter format, with a tolerance of 7%, will be reported by rule number G10).



4.1.3.8 EVA-2038 – “Freeze” Profiles

Description

When a profile has been defined in the mappings file as a fixed profile for a specific region and format, and the profile has been marked as “frozen” to prevent overwriting it by subsequent software or configuration updates: The profile will still be discovered by the eValidator even if it was moved to the “Expired” folder later on.

Ticket Evaluation	
Priority	Minor
Type	Feature

Item	Change Impact
Profiles	No changes
Configuration Files	No changes
Program Code	Changed
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	Details about this feature can be found in the user guide, section 6.12.1.



4.1.3.9 EVA-2095 – Version Information in LORENZ eValidator

Description

The system version information in the LORENZ eValidator applications is now also showing the minor version number when it is 0 and a specific version number is included.

Example: 18.1.0.01 instead of 18.1.01

Ticket Evaluation	
Priority	Minor
Type	Feature

Item	Change Impact
Profiles	No changes
Configuration Files	No changes
Program Code	Changed
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	n/a



4.2 eValidator webPanel

4.2.1 Priority MAJOR

4.2.1.1 EVA-2036 – URL Issues with Load Balancers

Description

For environments with load balancers in use, the webPanel cannot return from the Foundation SSO web site. This has now been resolved by adding the webPanel URL to the system.config file (available as “Web Site Base URL” in the configPanel), which will be used when Foundation SSO has succeeded.

Ticket Evaluation	
Priority	Major
Type	Bug

Item	Change Impact
Profiles	No changes
Configuration Files	No changes
Program Code	Changed
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	Customers affected by the problem described above should contact their LORENZ representative to clarify how the new settings should be configured.
PQ	n/a



4.3 eValidator webPanel – Known Issues

4.3.1 EVA-2140 – US eCTD High Error Reports

When using the webPanel to validate a US eCTD submission through the profiles “US eCTD - Val. Crit. 3.7 - Controller Profile (Industry)” or “US eCTD - Val. Crit. 3.7 - Controller Profile (Agency)”, a High Error Report will be created in addition to the application sequence reports. The High Error Report will summarize all high-level findings from the application sequence reports. It will however always appear with green color and with the text “Passed” in the eValidator webPanel. Users need to open the High Error Report to see the actual findings.

This is a known issue with the current version of the eValidator, which will be resolved with the next release (since the High Error Reports are obsolete, they will be removed).

In the meantime, LORENZ recommends that the High Error Reports should be ignored. All relevant details are already listed in the application sequence reports. The additional summary is not needed.

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