



Release Notes – EURSvalidator 2.0 SP2

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Table of Content

1	INTRODUCTION	3
2	VERSION 2.0 BUILD 07	3
2.1	NEW FEATURES	3
2.2	FIXED ISSUES	4
3	VERSION 2.0 SP1 BUILD 08	5
3.1	NEW FEATURES	5
3.2	FIXED ISSUES	5
4	VERSION 2.0 SP2 BUILD 11	7
4.1	NEW FEATURES	7
4.2	FIXED ISSUES	7
5	KNOWN ISSUES	8



1 Introduction

This document describes all features developed and bugs fixed in the EURSvalidator Version 2.0 development cycle, including service packs.

2 Version 2.0 Build 07

Status	Released		
Tested With	Operating Systems: Windows XP SP3, Windows 7		
Release Date	29.07.2011	Released By	
Build	07	Database version	n/a
Delivery	Setup Includes a full setup with all fixes and features mentioned below.		

2.1 New Features

Feature 17610: GUI Revision

The GUI is redesigned holding three main frames: **Submission Explorer**, **Result Explorer**, and **Information Explorer**.

Feature 17659: Create both PDF reports at the same time; allow 'send reports by mail'

The report functionality is enhanced by the 'send mail' option. The installed mail program is opened, a new email created and both validation reports are attached to it.

Feature 17973: Improve Paper Report

The PDF report is harmonized. Long and short report contain the same information. In addition, the long report contains results per file.

Feature 18230: Improve performance of validation

The validation performance is increased by several optimizations inside the EURSvalidator.

Feature 20153: Allow validation on CD

The validation can be run on a CD. In case of a validation of a submission with sequence higher than 0000, the absence of required sequences will be named. If a sequence is required and absent, the validation will be invalid.

Feature 21738: Support of new EU Validation Criteria - EU eCTD v3.1

There are 2 new validation sets (EU-eCTD Val.Crit 3.1 and EU-NEES Val.Crit 2.1) available for validation of EU submissions.

Feature 21746: Adapt report according to EMA Specification

The TIGes requires a list of sequences for the 'in context of other submissions' test. A respective comment is introduced into the PDF report.

**Feature 21805: Run validation and report only negative results**

Positive validation results are no more named in the electronic validation report (Result Explorer). Only warnings and fails are displayed.

Feature 21807: New User Guide and Online Help

The new online help gives a detailed view on the validation mechanism in EURSvalidator. It names positive tests and negative tests as well.

2.2 Fixed Issues

Issue 20822: CH – remove 'eu' from CC-List (Rule B02)

Former EURSvalidator versions allowed the use of 'eu' as valid CC attribute.
(Impact low, detect ability high) – Since version 1.5.00.15 of EURSValidator

Issue 20944: Verify common folder installation with CITRIX

EURSvalidator is now tested in a CITRIX environment.
(Impact low, detect ability high) – Since version 1.5.00.13 of EURSValidator

Issue 21267: Business validation should allow to export all details

With the harmonization of the short and long report, the export of all validation violation details is guaranteed.

(Impact low, detect ability high) – Since version 1.5.00.17 of EURSValidator

Issue 21775: A15 – replace should be checked in sequence 0000

Swissmedic requested to introduce this test to sequence 0000 - which was so far not performed. This issue is adapted for 'append' and 'delete' too.

(Impact low, detect ability high) – Since version 1.5.00.17 of EURSValidator

Issue 21928: Name of Validation Sets

The validation sets undergo a change in their name.

(Impact low, detect ability high) – Since version 1.5.00.17 of EURSValidator

Issue 22090: Change name of new validation set EU eCTD 3.1

The BETA entry is removed from the validation set.

(Impact low, detect ability high) – Since version 1.5.00.17 of EURSValidator

Issue 22111: Autoselector preset should be NEES 2.1

The pre-selection in this EURSvalidator version for not defined validation sets is set to EU Nees 2.1.

(Impact medium, detect ability medium) – Since version 2.0.00.04 of EURSValidator



3 Version 2.0 SP1 Build 08

Status	Released		
Tested With	Operating Systems: Windows XP SP3, Windows 7		
Release Date	17.08.2011	Released By	
Build	08	Database version	n/a
Delivery	Setup Includes a full setup with all fixes and features mentioned below.		

3.1 New Features

Issue 22158: Validation set Nees 2.1 - Introduce restricted mode

Restricted mode means that subfolders are not allowed, respectively the validation strictly follows the 'file&folder' naming convention for m1 to m4, m52, m536, and m54 with no additional subfolder, and in m531, m532, m533, m534, m535, and m537 no subfolder below 'study-report' level. The folder structure is implemented as described in the 'file&folder' tab of the Val. Crit. Specification.

3.2 Fixed Issues

Issue 22155: Cannot generate report with Ctrl + P

Generating a short report is possible by first selecting the concerning submission, then pressing **Ctrl + P** keys.

(Impact low, detect ability high) – Since version 2.0.00.07 of EURSValidator

Issue 21812: Increase validation speed of EU submission

Code reviews have been performed to decrease the validation time.

(Impact low, detect ability high) – Since version 1.5.00.17 of EURSValidator

Issue 22171: Online help accessible in Result Explorer for EU 3.1 Validation Criteria Set only

The online help is accessible in the new EU 3.1 Validation Set only. Calling the online help within results of other validation sets reports a warning message.

(Impact medium, detect ability high) – Since version 2.0.00.07 of EURSValidator

Issue 22193: General Information tab not updated

The General Information tab is not updated after single submission validation. You have to click in the Result Explorer and then in the Submission Explorer again to refresh the General Information tab.

(Impact medium, detect ability high) – Since version 2.0.00.07 of EURSValidator

Issue 22202: Croatian eCTD envelope not shown

Croatian eCTD envelopes can be displayed.

(Impact medium, detect ability high) – Since version 2.0.00.07 of EURSValidator

Issue 22205: Technical error when running a validation of a submission located on a network drive

Issue 22239: A validation does not work if a network submission is added of which the path is too long

A validation works smoothly either it is located on a local or a network drive.

(Impact low, detect ability high) – Since version 2.0.00.07 of EURSValidator



Issue 22221: In case validation gets reexecuted statistics do not reset

Each validation starts after the statistic has been reset. If a submission will be validated more than once, the statistic is not cumulative.

(Impact medium, detect ability medium) – Since version 2.0.00.07 of EURSValidator

Issue 22224: Automatic scrollbar missing within the Information Explorer if a rule has many details

If a text does not fit into the pane, a scrollbar ensures that all rule details can be viewed.

(Impact low, detect ability high) – Since version 2.0.00.07 of EURSValidator

Issue 22225: Missing details for the eCTD validation rule 02.07

The Test-Result-Explorer displays details in the respective window section if an error or warning of the validation rule 02.07 occurs.

(Impact medium, detect ability high) – Since version 2.0.00.07 of EURSValidator

Issue 22227: Report date missing in cell Date/Sign of report

The report date for long and short reports is displayed in the Date/Sign cell of the report form.

(Impact low, detect ability medium) – Since version 2.0.00.07 of EURSValidator

Issue 22241: List of validation sets is not sorted

The list of validation sets is displayed in alphabetical order within the Validation Set pull down list of the Submission Explorer.

(Impact low, detect ability high) – Since version 2.0.00.07 of EURSValidator

Issue 22242: Progress bar is not accurately working with multiple submissions

When validating one of multiple submissions, the progress bar is inaccurate.

(Impact low, detect ability medium) – Since version 2.0.00.07 of EURSValidator

Issue 22269: Long indication folder and file names are not considered by validation criteria rules of NeeS 2.6 and eCTD 15.05

Long folder and file names are considered on every node level of the eCTD tree. If names are too long (more than 64 characters including a file name's suffix), an error message occurs.

(Impact medium, detect ability high) – Since version 2.0.00.07 of EURSValidator



4 Version 2.0 SP2 Build 11

Status	Released		
Tested With	Operating Systems: Windows XP SP3, Windows 7		
Release Date	09.11.2011	Released By	
Build	11	Database version	n/a
Delivery	Setup Includes a full setup with all fixes and features mentioned below.		

4.1 New Features

Issue 22434: Integrate new HR Validation Set (eCTD)

Croatian validation set HR eCTD v3.1 is included.

Issue 22435: Integrate new HR Validation Set (NEES)

Croatian validation set HR NeeS v2.1 is included.

4.2 Fixed Issues

Issue 22063: EV should recognize hyperlinks with indirect references

EURSvalidator did not recognize hyperlinks in a PDF file if the associated GotoR action inside of the PDF file contains an indirect reference. EV reported unreferenced files in this case.
(Impact high, detectability high) – Since first version of EURSvalidator

Issue 22143: Setup without automatic uninstall of the old version

During installation, EURSvalidator did not uninstall its former version. This issue is now fixed.
(Impact high, detectability medium) – Since version 1.5 of EURSvalidator

Issue 22236: NeeS index.xml and index-md5.txt are not rejected

Index.xml and index-md5.txt were not identified as invalid files during NeeS validation.
(Impact low, detectability high) – Since first version of EURSvalidator

Issue 22265: Insert a line break after each finding in the Details part of the Information Explorer section

The formatting of the details has been improved to show each finding in a new line.
(Impact low, detectability high) – Since version 2.0.00.07 of EURSvalidator

Issue 22271: Starting a 2nd validation, the validation bar disappears

In some situations the progress bar for a submission showed “Waiting” although the validation was still running.
(Impact low, detectability low) – Since version 2.0.00.07 of EURSvalidator

Issue 22278: Swiss validation set - The Extedo Validator v2.0 Build 7 does not appear to validate rule A19 “The sequence number is 4 digits”

The issue is fixed in a way that in CH 1.1 the validation rule A19 checks the sequence number in the envelope instead of the folder name.
(Impact medium, detectability medium) – Since version 1.4.00.03 of EURSvalidator

Issue 22385: Error in new NeeS v2.1 validation from server path

NeeS v2.1 validation could not resolve hyperlinks in ToCs when they are stored in a UNC (Uniform Naming Convention) path.
(Impact high, detectability high) – Since version 1.5.00.18 of EURSvalidator

Issue 22411: EURSvalidator terminates when open button is pressed

Under some circumstances pressing the “open” button after the installation caused EURSvalidator termi-



nation. This issue is fixed.

(Impact high, detectability high) – Since version 2.0.00.07 of EURSvalidator

Issue 22437: PDF protection error for unprotected file

PDF files without a trailer could not be opened and were reported as protected.

(Impact high, detectability medium) – Since first version of EURSvalidator

Issue 22449: FDA validation set – submission date from envelope is displayed incorrectly

The Envelope pane showed an incorrect date for FDA submissions.

(Impact low, detectability medium) – Since version 2.0.00.07 of EURSvalidator

Issue 22462: Wrong email address in different dialogs

The correct email address is hotline@extedo.com.

(Impact low, detectability low) – Since first version of EURSvalidator

Issue 22511: No message when opening invalid folder

When the selected folder does not contain any submissions or the folder name is not a valid sequence number an appropriate message is shown now.

(Impact low, detectability medium) – Since version 2.0.00.07 of EURSvalidator

Issue 22514: Exception on resize column "File"

Sometimes an exception message showed up when using the mouse to resize the "File" column in the Results Explorer.

(Impact low, detectability high) – Since version 2.0.00.07 of EURSvalidator

Issue 22551: Autodetect does not select eCTD-HR-3.1 Validation Set

For Croatian eCTD submissions the old validation rules (HR-eCTD v2.1 (DTD 1.4)) were selected automatically instead of the new ones (HR-eCTD v3.1 (DTD 1.4)).

(Impact medium, detectability high) – Since version 2.0.00.09 of EURSvalidator

5 Known Issues

Issue 20718: Referenced files result in severity C error (EU eCTD 2.1)

From the guidance: Referenced Files = Files should be submitted only once. If a file (identical MD5) is presented inside an eCTD, the second time, only a reference should be introduced into the XML backbone.

In EURSvalidator, if the same file is presented in the eu-regional.xml as well as in e.g. the 3.2.R section (= eu-regional.xml) and the index.xml contains a reference to the files in m1, EURSvalidator reports a severity C violation.

(Impact low, detectability high) – Since version 1.5.00.07 of EURSvalidator

Issue 20991: Deleted files are not verified in submission (eCTD) context (EU eCTD 2.1)

There is a limitation of displayed error messages per validation. The number of e.g. 67 detected errors is correct, but there are only the first 50 error details displayed in the GUI and PDF reports. It should be named if not all details are displayed.

If 'append', 'replace' or 'delete' errors occur in the same XML and the same rule, after detection of a single error of e.g. 'replace', the other two LC checks ('append' and 'delete') are not performed. Reason: Increase pace of validation. Problem: Other validation tools name all errors.

(Impact low, detectability high) – Since version 1.5.00.13 of EURSvalidator

Issue 22051: EU eCTD v3.1 Rule 13.03 error (EU eCTD 3.1)

If the path to regional xml contains uppercase letters like 'm1/EU', the rule 13.03 reports a mismatch between sequence folder name and sequence stored in the envelope.

(Impact low, detectability high) – Since version 2.0.00.01 of EURSvalidator

Issue 22825: eCTD v3.1 criterion 16.BP08 / NeeS v2.1 Criterion 03.BP06

The eCTD v3.1 rule 16.BP08 and the NeeS v2.1 rule 03.BP06 should detect an incorrect initial view setting of a PDF file. Instead they detect an incorrect inherit zoom setting for bookmarks and hyperlinks in the PDF file.

(Impact medium, detectability high) – Since version 2.0.00.00 of EURSvalidator



Issue 22949: Validation engine does not show error regarding fast web access

For some PDF files EURSvalidator does not recognize that the "Fast Web View" option is missing. This happens when the PDF file has been linearized but modified after linearization.
(Impact medium, detectability low) – Since version 2.0.00.00 of EURSvalidator

Issue 23083: EU eCTD v3.1 Rule 16.03 does not consider exceptions

According to EU eCTD v3.1 Rule 16.03 PDF files must not have any security restrictions. However, the sections m3/33-lit-ref, m4/43-lit-ref and m5/54-lit-ref are exempt from this rule. EURSvalidator does not consider this exception. The same applies to EU NeeS v2.1 rule 03.03 and the HR counterparts.
(Impact medium, detectability high) – Since version 2.0.00.00 of EURSvalidator

Issue 22942: NeeS v2.1 PDF tests are skipped

EURSvalidator reports skipped PDF rule tests when a NeeS v2.1 validation set is used. EU and HR are affected.

Workaround: Start EURSvalidator and run an eCTD v3.1 validation for an arbitrary submission once. Subsequent NeeS v2.1 validations will work correctly.

(Impact high, detectability high) – Since version 2.0.00.11 of EURSvalidator