



Version 3.2.0.0002

Release Notes



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1. Release History

Release	Date	Version	Summary of Changes
Minor	08-Feb-2018	3.2.0.0002	This is minor release to address the enhancements and issues addressed in the 3.2.0.0002
<i>Hot Fix 8</i>	23-Aug-2017	2.3.3.0014	This is a Hot fix release that addresses the items identified in the 2.3.3.0014 Release Notes.
<i>Hot Fix 7</i>	09-Jun-2017	2.3.3.0013	This is a Hot fix release that addresses the items identified in the 2.3.3.0013 Release Notes.
<i>Hot Fix 6</i>	10-Apr-2017	2.3.3.0012	This is a Hot fix release to address the issues identified in the 2.3.3.0012 Release Notes.
<i>Hot Fix 5</i>	21-Dec-2016	2.3.3.0011	This is a Hot fix release to address the issues identified in the 2.3.3.0011 Release Notes.
<i>Hot Fix 4</i>	18-Nov-2016	2.3.3.0010	This is a Hot fix release to address the issues identified in the 2.3.3.0010 Release Notes.
<i>Hot Fix 3</i>	29-Sep-2016	2.3.3.0009	This is a Hot fix release to address the issues identified in the 2.3.3.0009 Release Notes.
<i>Hot Fix 2</i>	25-Aug-2016	2.3.3.0008	This is a Hot fix release to address the issues identified in the 2.3.3.0008 Release Notes.
<i>Hot Fix 1</i>	17-Jun-2016	2.3.3.0006	This is a Hot fix release to address the issues identified in the 2.3.3.0006 Release Notes.
Service Pack	04-May-2016	2.3.3.0001	This is Service Pack release to address the enhancements and issues in the 2.3.2.0007
Minor	02-Feb-2016	2.3.2.0007	This is minor release to address the enhancements and issues in the 2.3.2.0007
Minor	16-Sep-2015	2.3.0.0005	This is minor release to address the enhancements and issues in the 2.3.0.0005
Minor	21-Jul-2015	2.1.0.0013	This is minor release to address the enhancements and issues in the 2.1.0.0013
Major	23-Mar-2015	2.0.0.0008	This is major release to address the enhancements and issues in the 2.0.0.0008
<i>Hot Fix</i>	14-Jan-2014	1.2.1.0001	This is a Hot fix release to address the issues identified in the 1.2.1.0001 Release Notes.
Minor	06-Nov-2013	1.2.0.0015	Features enhancements for the new validation criteria for the Health Canada Validation Rules HC-SC-3.0, EU eCTD Validation Criteria – version 5.1, Swiss eCTD Validation Criteria – version 1.2, NeeS Validation Criteria – version 4.0 and bug fixes.
Minor	28-Mar-2013	1.1.0.0011	Production Release includes issues noted in the limited production release version 1.0.0.0010 were addressed.
Major	10-Jan-2013	1.0.0.0010	Limited Production Release.

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2. Definitions

ACRONYM	DEFINITION
ACTS	ACUTA Call Tracking System
ATTP	ACUTA Test Track Pro, system used to track issues and enhancements
eCTD	electronic Common Technical Document
FDA	Food and Drug Administration
HF	Hot Fix
XML	eXtensible Markup Language
EU	European Union
AU	Australia
GCC	Gulf Cooperation Countries
JP	Japan
US	United States (of America)
ZA	South Africa
STF	Study Tagging Files
NeeS	Non-eCTD electronic submission
	EU, AU, GC, JP, US, and ZA defined, plus STF, NeeS

3. Scope

This release notes provides an overview of regulatory enhancements and issues addressed in ACUTA Validator version 3.2.0 build 0002, referred to as version 3.2.0.0002. This version has been labeled a Minor Release per ACUTA software maintenance release procedures.

4. Enhancements

[Table 1](#), below includes the enhancements addressed in this release of ACUTA Validator

Table 1 – Enhancements

ATTP ID	Support ID	Summary
1759	N/A	ACUTA Validator now supports the South African eCTD validation Version 2.1.
2622	N/A	Validation ID 14.BP4 has been enhanced to ensure compliance with the validation guidance released in the EU M1 specification version 3.0.2.
3199	1704	A custom validation ID #Custom-03 has been added that will check that all fonts used are embedded into the document.
3200	N/A	HC: Additional sequence descriptions have been added for Health Canada eCTD. Following communication from Health Canada, the sequence description options have been updated with latest acceptable values.
3272	N/A	EU, AU, GCC, HC, JP and ZA submissions: Validator will now report as Warning if fonts used are not embedded in the document.
3490	N/A	Users no longer need to have Administrator access to activate the license key.
3498	N/A	Validator now supports the Australia v3.1 eCTD validation criteria.
3917	N/A	The validator profile version is now displayed in the export to Excel.

5. Items Addressed

Table 2, below includes the issues addressed in this release of ACUTA Validator

Table 2 – Issues

ATTP ID	Support ID	Summary
1064	N/A	Changed values in validation settings were not retained when we validator was reinstalled. This issue has been resolved.
1899	N/A	Validator now verifies only the required element metadata and ignores optional metadata such as 'xml:lang'
2376	1427	Validator Profile Version was not being retained in the validation settings. This issue has been resolved.
2617	N/A	Validation criteria ETICS-01 was reporting a fail even though the required STF category was present under the section 4.2.3.2. This issue has been resolved.
2621	N/A	The FDA Validation-ID:1519 failed if the application folder was prefixed with 'bla'. This issue has been resolved.
2623	1401	It was not possible to enter a brief description for the sequence description 'Unsolicited Data'. This caused validation errors. This issue has been resolved.
2625	N/A	Validator: AU and EU: The overall validation result displayed in the file exported to Excel was incorrect. This issue has been resolved.
2781	N/A	US: Validation ID 1544 was incorrectly reporting as a fail because ARIM checked against all lower sequences and failed the criteria if there was a mismatch between any company name when compared to the current sequence. This issue has been resolved and Validator will now only compare the current sequence "Company name" with the previous sequence "Company name", and report a warning if there is a mismatch. The order is determined by the modified date in the xml files.
2839	N/A	US: for DMF Applications with no application form, the validation criteria 1038 was reporting as a fail. This issue has been resolved.
3195	N/A	HC: Criteria F09 reported as Fail, when the submission contained Sequence Description "Pre-Submission Meeting Request". This issue has been resolved.
3248	N/A	The user was able to edit the values of the 'Results' column for validated submission. This issue has been resolved.
3264	N/A	US: Validation ID 5032 was giving a fail when validating grouped submissions with more than one application form. This issue has been resolved.
3300	N/A	US v3.3: Criteria 2044 was not reporting as a Fail when a submission contained a DUNS number with special characters. This issue has been resolved.

ATTP ID	Support ID	Summary
3302	N/A	US v3.3: Criteria 1636 was not reporting as Fail, when a user had selected an incorrect submission ID. This issue has been resolved.
3324	N/A	EU: Version “2.0” has been removed from the error details.
3915	N/A	GCC: When exporting the validation results to Excel Member States were duplicated. This issue has been resolved.
3918	N/A	US: When validation failed for Criteria ID 1038, the error details were not displaying the xlink:href, Leaf ID and Title for the replaced document Cover Letter and Application Form. This issue has been resolved.
3920, 2869	1721	US: Validation criteria 1038 was reporting as fail for application types that do not require an application form. This issue has been resolved.
3921	1783	FDA criteria 5030 was incorrectly being reported as a fail as ACUTA Validator was unable to extract the submission number from the 356h form. This issue has been resolved.
3922	N/A	When attribute value was missing for the Supplement Effective Date Type in, Criteria ID 2012 was not reporting as Fail. This issue has been resolved.
3925	N/A	The US Criteria ID 1636 was reporting incorrectly as Fail for mixed DTD (3.3 & 2.01). This issue has been resolved.
3926	N/A	US: For Promotional Labeling submissions criteria ID 5033 was reporting as a Fail if the submission did not contain Forms. This issue has been resolved.
3928	N/A	US v3.3: Criteria ID 2025 was not reporting a Fail if the Submission Sub type contained Report, Correspondence or Original in subsequent submissions within the same Regulatory Activity. This issue has been resolved.
3929	N/A	EU NeeS: Criteria IDs 2.8 and 2.11 were not reporting a Fail, when file name contained invalid characters. This issue has been resolved.

6. Assumptions / Dependencies

This document assumes that the minimum Hardware and Software have been pre-installed as specified in the ACUTA Validator System Requirements Specifications.

7. User Instructions

For user instructions, refer to the steps included in the *User Manual* provided with the Release package.

8. Installation

This release has 2 installation options:

8.1 New Installation

For a new installation of the software, refer to the installation steps as per the Installation Guide document provided in the ACUTA Validator Release Setup Kit.

8.2 Upgrade from v2.3.3.0014

Those who are currently using version 2.3.3.0014 should uninstall that version and install this new version 3.2.0.0002. This re-installation does not require new registration/activation.

9. Deliverables

9.1 List of Documents

The following are the list of documents provided as part of the ACUTA Validator 3.2.0.0002.

- User Manual
- Install Guide
- System Requirements Specifications
- Release Notes (this document)