

Converting a ZA eCTD v1.0 to v2.1

The Conversion of the ZA eCTD from v1.0 to 2.1 may require some additional steps. There are two new features that have been released in the same timeline that affects how the South African eCTDs were compiled in v1.0. One of those features improves the user friendliness of compiling the South Africa 3.2.R Regional information which was specified in detail by the South African MCC Authority. The other feature introduces the ability to use manual file names on nodes where eSubmission Codes are assigned.

Removing Manual Filenames from the ZA eCTD Applications

Background

In the early days of the ZA CTD (2010-2013), LORENZ provided a template to be used for paper compilation of the CTD. Because there was not an electronic specification, there was no configuration for the ZA Module 1 in terms of docuBridge eSubmission Codes which manage the folder and file names. Without this definition, all files were published into an “m1” folder without further folder structures and the file names were adopted from the node title causing them to be listed in no logical order. As a response to customer requests, LORENZ provided a template with manual file names which integrated the section number into the file names so that content published electronically would provide a sense of organisation.

When the eCTD specifications were published in 2013, the same template was used to produce the eCTD template. When the eSubmission Codes were assigned to the nodes, the manual file name was deactivated because at the time manual file names were not allowed on nodes with eSubmission Codes.

The Current Issue

In docuBridge 5.9, as a response to a customer request, LORENZ enabled manual file names to be defined also for nodes with eSubmission Codes. The manual file names used in the early days of the template were then allowed to resurface and became active again. This led to issues with approximately 28 nodes in the ZA Module 1 where the manual file names must now be removed in order to revert back to the defined naming convention required by the MCC. The removal of the information requires 6 clicks per node (168 in total) and would be required for every submission created under the old template.

The Solution

LORENZ has provided VECTOR with a database script that will remove all manual file names from ZA submissions. This script will be performed together with the update. The script would not discriminate between file names originating from the template and those manually created by users. Therefore, if you have applied manual file names and wish to keep those setting you should not have the script run and manual updates to your submissions will be required.

The only locations that would have required manual file names are 1.4.2 and 3.2.R. The issues requiring manual file names in those locations has been resolved and is no longer necessary.

If you have run this script during you update, you will not have any issues with the Manual File names.

The Alternate Solution

Select the last sequence. If it is locked, Copy as New Sequence so that the changes will apply to the next sequence compiled.

Go through every node in module 1 including the structural nodes. If a document is assigned to the node, then check the Manual File Name field in the properties and remove any value if it exists. If there is no document assigned to the node, you will need to temporarily assign a document to the node (the Manual File Name field logically only appears if a file has been assigned to the node). If the node is configured to not allow content, these setting will have to be temporarily lifted so that a file can be assigned. Once the Manual File Name field has been emptied, the file can be removed and the settings can be put back.

Converting the Submission from v1.0 to v2.1

Select the last sequence. If it is locked, Copy as New Sequence so that the changes will apply to the next sequence compiled.

Select the South Africa node and change the eSubmission Code to South Africa 2.1.

Please note that under normal circumstances, this is all that would need to be done to convert a submission from one version to the next.

Converting the 3.2.R Regional Information

In version 1.0, the complex structure of the ZA Regional Information required the use of manual settings to create the required folder structures and file names as defined by the MCC. This has been simplified and made consistent with the way the rest of the submission content is managed in docuBridge. Since the file naming conventions have changed in the new validation criteria e.g. structure numbers have been added to the folder names, it is important that the 3.2.R section be updated to the new eSubmission Codes.

Select the 3.2.R node and change the eSubmission Code to Regional Information (South Africa). Now go through your entire 3.2.R section and assign the appropriate eSubmission Codes to the content.

DO NOT REMOVE THE CONTENT AND RECOMPILE IT IN A NEW MERGED SECTION!

All nodes in 3.2.R must have an eSubmission code assigned. If no eSubmission Code is available at a much lower level then content must be moved up to a level where and eSubmission Code can be assigned. The granularity prescribed in the previous templates is the same so this should not be necessary if the Best Practice templates were being used.

Ensure eSubmission Codes have been Assigned

Finally, review the content of modules 1-3 and ensure that **ALL** content has been assigned an eSubmission Code except the 3.3 Literature References. In particular, check sections where multiple files had been compiled e.g. the Analytical Procedures/Validation of Analytical Procedures at 3.2.S.4.2/3 and 3.2.P.5.2/3.

Your eSubmission Codes are what define the folder and file naming conventions for the content. Modules 1-3 have very defined naming conventions that must be adhered to. Modules 4-5 on the other hand, contain Study Reports and Literature References both of which should not have eSubmission Codes assigned. Only the structural nodes containing the content should have codes assigned, content nodes should be left without so that the it can take on the leaf title as file name.

Questions? Feel free to contact VECTOR at support@vectorls.co.za