



CALYX™

Maintaining Currency with Specifications

CALYX.AI

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All XML Definition files (.zip files including the DTDs, Schemas, stylesheets and publishing rules) should be managed in a central location in your repository.

When released, the latest specifications at the time of release will be included with the software. Upon release of new specifications, will conduct an analysis of the impact of the specification, whether compliance to the new specification simply requires pointing to the latest XML Definition file, a change to the assembly structure, or more detailed software changes. Once completed, an expected time frame to provide any updates necessary to comply with the new specifications will be announced via User Alert.

If a new XML Definition file is all that is required, these can be imported into the repository and the administrator can add the new files to the list of available XML Definition Files through Data Administration.

Users may then update their Assembly templates to use the latest XML Definition Files for any future Assemblies created using the templates. For any in-progress Assemblies, these may also be updated to use the latest XML Definition Files. However, users will need to make a decision whether they wish to use the latest XML Definition Files or continue with the older specification.

Regulatory Authorities have indicated that there is some flexibility in timing of adoption of new specifications, acknowledging the time frame necessary to update systems, so the decision to modify on-going assemblies to use the latest specification will depend on planned submission timing and the scope of changes in the new specification. will make its best effort to provide general recommendations for using the latest specifications, but emphasizes that it is always best for sponsors to consult with their Regulatory Authorities for specific questions and issues.