















































































<b>Number:</b>	1765
<b>Group:</b>	STF
<b>Description:</b>	STF DTD version must match the XML file
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	Your STF DTD version listed in the leaf element does not match the DTD version in the STF XML file.
<b>Corrective Action:</b>	No corrective action is necessary unless FDA notifies you that it is unable to process your submission. Modify your SOPs to ensure that the DTD version specified in the leaf matches that specified in the STF XML file.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1
<b>Number:</b>	1782
<b>Group:</b>	STF
<b>Description:</b>	Unsupported STF DTD version in leaf element
<b>Severity Description:</b>	High
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You are using an unsupported STF DTD version in a leaf element.
<b>Corrective Action:</b>	Resubmit your submission using a version of the DTD that is supported. For STF Version 2.2 references, the version value should be indicated as "STF Version 2.2" exactly. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1

<b>Number:</b>	1786
<b>Group:</b>	STF
<b>Description:</b>	Unsupported STF DTD version in STF XML file
<b>Severity Description:</b>	High
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You are using an unsupported STF DTD version in a STF XML file.
<b>Corrective Action:</b>	Resubmit your submission using a version of the DTD that is supported. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1
<b>Number:</b>	1789
<b>Group:</b>	STF
<b>Description:</b>	A file has been submitted in a study section without providing an STF file
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	All files in a study section must be referenced by an STF file.
<b>Corrective Action:</b>	In a new submission include an STF and use the "Replace" operator to replace previously submitted documents which were not referenced in an STF.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1; FDA Presentations

<b>Number:</b>	1799
<b>Group:</b>	STF
<b>Description:</b>	STF cannot reference another STF
<b>Severity Description:</b>	High
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	The STF may not reference another STF.
<b>Corrective Action:</b>	Resubmit your submission ensuring that STFs do not reference other STFs. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	General good practice to ensure reviewability.
<b>Number:</b>	1816
<b>Group:</b>	STF
<b>Description:</b>	STF does not relate to any leaf elements
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	STF does not relate to any leaf elements.
<b>Corrective Action:</b>	In a future submission, you should include an STF that includes references to appropriate leaf elements. Modify your SOPs to ensure that all STFs submitted reference leaf elements.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1

<b>Number:</b>	1833
<b>Group:</b>	STF
<b>Description:</b>	STF relates to a non-existent leaf element
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	STF relates to a non-existent leaf element.
<b>Corrective Action:</b>	In a future submission, you should include an STF that includes references to existing leaf elements. Modify your SOPs to ensure that all STFs submitted reference leaf elements.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1
<b>Number:</b>	1850
<b>Group:</b>	STF
<b>Description:</b>	Study ID for STF must remain constant
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You have appended an STF with a second STF and the two Study IDs are different (not an exact match). The reviewer will see two studies instead of one.
<b>Corrective Action:</b>	"Delete" leaf references in the index.xml for the files with incorrect Study IDs and then add the leaf references as "New" to the index.xml and STF for the study that should remain. Modify your SOPs to ensure that a consistent Study ID (exact match) is used.
<b>Guidance Source:</b>	General good practice to ensure reviewability.

<b>Number:</b>	1867
<b>Group:</b>	STF
<b>Description:</b>	Invalid STF file extension
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You have included an invalid STF file extension.
<b>Corrective Action:</b>	Corrective action may be necessary. If corrective action is necessary, you will be contacted. Modify your SOPs to ensure that the name for the STF XML file starts with the term "stf-" followed by the alphanumeric code used by the sponsor to unambiguously identify the study (i.e., study-id) and followed by ".xml" to complete the file name.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1 Section I
<b>Number:</b>	1884
<b>Group:</b>	STF
<b>Description:</b>	Invalid STF file name
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You have included an invalid STF file name.
<b>Corrective Action:</b>	Modify your SOPs to ensure that the name for the STF XML file starts with the term "stf-" followed by the alphanumeric code used by the sponsor to unambiguously identify the study (i.e., study-id) and followed by ".xml" as the file extension to complete the file name.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1 Section I



<b>Number:</b>	1901
<b>Group:</b>	STF
<b>Description:</b>	Invalid STF TOC location
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	Your leaf that points to the STF is under an invalid heading area or invalid module. For example, STFs can only be associated with certain headings under Modules 4 or 5.
<b>Corrective Action:</b>	In a future submission, place the STF under the correct module and heading element. Modify your SOPs to ensure that STFs are included only in Modules 4 and 5.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1 Intro
<b>Number:</b>	1918
<b>Group:</b>	STF
<b>Description:</b>	Omitted STF doc-content file tag
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You have omitted the STF doc-content file tag which prevents the proper classification of the file within the submission.
<b>Corrective Action:</b>	In a future submission you should include an updated STF file that reflects the proper doc-content file tag using the "Replace" operator.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1 Intro

<b>Number:</b>	1935
<b>Group:</b>	STF
<b>Description:</b>	Multiple STF doc-content file tags
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You have multiple STF doc-content file tags; processor will process the first tag but will ignore any additional tags.
<b>Corrective Action:</b>	No corrective action is possible due to current STF limitations. Modify your SOPs to ensure that only a single doc-content file tag is used.
<b>Guidance Source:</b>	DTDs; General good practice to ensure reviewability.
<b>Number:</b>	1953
<b>Group:</b>	STF
<b>Description:</b>	STF XML title and leaf element title do not match
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	Your STF study title and leaf element title do not match; viewer will show the title in the stf.xml file only.
<b>Corrective Action:</b>	No corrective action is necessary. Modify your SOPs to ensure that STF titles match the provided leaf title.
<b>Guidance Source:</b>	General good practice to ensure reviewability.

<b>Number:</b>	1969
<b>Group:</b>	STF
<b>Description:</b>	Invalid STF XML file
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You have submitted an invalid stf-xxxxxxx.xml file. This error will occur when: no Study ID is defined, there are no child nodes in the XML document, or the XML document fails to load.
<b>Corrective Action:</b>	In a future submission, delete the leaves which were referenced in the previous invalid stf-xxxxxxx.xml file. Submit a new valid stf-xxxxxxx.xml files and use the "new" operator attribute to re-reference the previously submitted leaves in the STF files.
<b>Guidance Source:</b>	DTDs; The eCTD Backbone File Specification for Study Tagging Files V2.6.1
<b>Number:</b>	1981
<b>Group:</b>	STF
<b>Description:</b>	STF XML file is missing
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have referenced an STF XML file in the xlink:xref attribute of a leaf and the system is unable to locate the file.
<b>Corrective Action:</b>	Resubmit the missing STF XML file in a new submission sequence and re-reference the appropriate leaves using the operation attribute of "Replace."
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2 Appendix 6; The eCTD Backbone File Specification for Study Tagging Files V2.6.1

<b>Number:</b>	1985
<b>Group:</b>	STF
<b>Description:</b>	The study title for the STF is missing
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have omitted the title within the STF XML file. The title is required for STFs submitted using the version 2 specification.
<b>Corrective Action:</b>	In a new submission sequence, resubmit the STF file which includes the corrected study title (it is not necessary to resubmit files or regenerate leaves). Ensure that your Study ID is identical to what you previously submitted.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1
<b>Number:</b>	1990
<b>Group:</b>	STF
<b>Description:</b>	The same STF XML is referenced more than once.
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted one STF XML file and referenced that STF XML file in more than one section.
<b>Corrective Action:</b>	Only the first study will appear when an STF XML file is referenced more than once. Add a new study STF XML file and one PDF file that states the study is located in another section and provides a link to the study.
<b>Guidance Source:</b>	ICH Q&A 60

<b>Number:</b>	2001
<b>Group:</b>	M1
<b>Description:</b>	An older version of the DTD has been used after a submission to the application used a higher version.
<b>Severity Description:</b>	High
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You referenced a version of the DTD that can no longer be used for the application because a previous submission(s) to the same application referenced a higher, more recent version.
<b>Corrective Action:</b>	Resubmit your submission using the same or higher version of the DTD referenced in previous submissions. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	DTDs; The eCTD Backbone Files Specification for Module 1 V1.3 and V2.3
<b>Number:</b>	2002
<b>Group:</b>	Schema Error
<b>Description:</b>	XML didn't pass validation with the schema (DTD) and attribute files
<b>Severity Description:</b>	High
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You provided an index.xml, us-regional.xml or stf.xml file which does not conform to the schema (DTD) and/or attribute files.
<b>Corrective Action:</b>	Resubmit your submission ensuring that you use xml files valid with the schema (DTD) and attribute files as applicable. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2; The eCTD Backbone Files Specification for Module 1 V1.3 and V2.3; General good practice to ensure reviewability

<b>Number:</b>	2003
<b>Group:</b>	M1
<b>Description:</b>	us-regional.xml is not referencing the DTD and stylesheet at an approved valid location
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You submitted a submission with its us-regional.xml referencing incorrect DTD and stylesheet file locations.
<b>Corrective Action:</b>	Resubmit your submission that contains a us-regional.xml that references the valid, correct versions of the DTD and stylesheet. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3
<b>Number:</b>	2012
<b>Group:</b>	M1
<b>Description:</b>	A required attribute value in M1 is missing
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You have failed to provide a required attribute value for an M1 element.
<b>Corrective Action:</b>	Resubmit the submission and ensure all required attribute values are provided. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V1.3 and V2.3

<b>Number:</b>	2013
<b>Group:</b>	M1
<b>Description:</b>	Invalid M1 attribute value
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You submitted a submission that refers to an M1 attribute value that has a status of invalid or the value itself is not allowed according to the corresponding referenced attribute type list.
<b>Corrective Action:</b>	Resubmit the submission and ensure all provided M1 attributes are valid. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3
<b>Number:</b>	2021
<b>Group:</b>	M1
<b>Description:</b>	A submission sub-type error occurred because this particular submission sub-type is only allowed once for each regulatory activity.
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You used a submission sub-type that was provided in a previous submission to the same regulatory activity. Certain submission sub-types (application, original, report) can only be submitted once for each regulatory activity. (e.g., original-application should only have one submission with a sub-type value "application").
<b>Corrective Action:</b>	You will be contacted if corrective action is necessary. Modify your SOPs to ensure that the submission sub-types which should only be used once for each regulatory activity, are not used again for subsequent submissions to the same regulatory activity.
<b>Guidance Source:</b>	General good practice to ensure reviewability.

<b>Number:</b>	2022
<b>Group:</b>	M1
<b>Description:</b>	Submission-sub-type is invalid for submission-type
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You have used a submission-sub-type which is not allowed for the submission-type and/or type of application.
<b>Corrective Action:</b>	Resubmit the submission using a valid submission-sub-type. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3
<b>Number:</b>	2023
<b>Group:</b>	M1
<b>Description:</b>	All grouped submission submission-sub-type values must be the same
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You have referenced more than one application and the submission sub-type values are not the same.
<b>Corrective Action:</b>	Resubmit the submission and provide the same submission sub-type for all applications referenced in the us-regional.xml. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3



<b>Number:</b>	2024
<b>Group:</b>	M1
<b>Description:</b>	For all sequences for a regulatory activity the submission type must be consistent, and the submission sub-type must be valid for the submission type.
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	TBD
<b>Problem:</b>	You have used a submission sub-type that is invalid for the submission type of the parent regulatory activity type or the submission type is different than the submission type of the parent regulatory activity.
<b>Corrective Action:</b>	Resubmit the submission with a valid submission sub-type that is allowed for the submission type of the parent regulatory activity and include the submission type that matches the parent regulatory activity type.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3.
<b>Number:</b>	2025
<b>Group:</b>	M1
<b>Description:</b>	The eCTD sequence number of the submission sub-type that starts a new regulatory activity and the submission id must match.
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	TBD
<b>Problem:</b>	You have used a submission sub-type where the eCTD sequence number does not match the Submission ID.
<b>Corrective Action:</b>	Resubmit the submission where the eCTD sequence number matches the Submission ID for the new regulatory activity.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3.

<b>Number:</b>	2031
<b>Group:</b>	M1
<b>Description:</b>	All grouped submission application-type values must be the same
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You have referenced more than one application and the application-type values are not the same.
<b>Corrective Action:</b>	Resubmit the submission and provide the same application-type for all applications referenced in the us-regional.xml. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3
<b>Number:</b>	2032
<b>Group:</b>	M1
<b>Description:</b>	All grouped submission submission-type values must be the same
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You have referenced more than one application and the submission-type values are not the same.
<b>Corrective Action:</b>	Resubmit the submission and provide the same submission-type for all applications referenced in the us-regional.xml. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3

<b>Number:</b>	2033
<b>Group:</b>	M1
<b>Description:</b>	Different sequence numbers are referenced for the same application number
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You referenced different sequence numbers to the same application in a grouped submission. When submitting to different regulatory activities in the same application, use the same sequence number for each submission.
<b>Corrective Action:</b>	Reference the same sequence number for all regulatory activities to the same application number.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3
<b>Number:</b>	2034
<b>Group:</b>	M1
<b>Description:</b>	Submission-type is invalid for application-type
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You have used a submission-type which is not allowed for the application type.
<b>Corrective Action:</b>	Resubmit the submission using a valid submission-type. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3

<b>Number:</b>	2035
<b>Group:</b>	M1
<b>Description:</b>	Submission description exceeds 128 characters
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You provided a submission description that exceeds the 128 character limit.
<b>Corrective Action:</b>	Ensure future submissions do not have a submission-description that exceeds 128 characters.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3
<b>Number:</b>	2036
<b>Group:</b>	M1
<b>Description:</b>	No application element with application-containing-files value of "true"
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You did not provide an application-containing-files value="true" for any applications referenced in the us-regional.xml.
<b>Corrective Action:</b>	Resubmit the submission indicating which application contains the files by ensuring the application's application-containing-files element has a value="true." You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3

<b>Number:</b>	2037
<b>Group:</b>	M1
<b>Description:</b>	More than one application-containing-files element has a value of "true"
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You have reference more than one application with an application-containing-files value= "true."
<b>Corrective Action:</b>	Resubmit the submission indicating which application contains the files by ensuring the application's application-containing-files element has a value="true." You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3
<b>Number:</b>	2038
<b>Group:</b>	M1
<b>Description:</b>	Cross-reference-application-number must contain 6 numeric digits only
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	Your cross-reference-application-number must be 6 numeric digits in length.
<b>Corrective Action:</b>	In a future submission, reference the correct six (6) digit application number.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3

<b>Number:</b>	2041
<b>Group:</b>	M1
<b>Description:</b>	Supplement-effective-date-type attribute value is missing
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You did not provide the supplement-effective-date-type for this first submission to the supplement.
<b>Corrective Action:</b>	Include a supplement-effective-date-type in the first submission to a new supplement.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3
<b>Number:</b>	2042
<b>Group:</b>	M1
<b>Description:</b>	Email address exceeds 64 characters
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You provided an email address that exceeds the 64 character limitation.
<b>Corrective Action:</b>	Ensure email addresses are within character limitations in future submissions.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3
<b>Number:</b>	2043
<b>Group:</b>	M1
<b>Description:</b>	id element has changed
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You are using an company id element that is different than the id used in previous submissions to the application.
<b>Corrective Action:</b>	No corrective action is necessary since id can change from time to time. Modify your SOPs to ensure that same id is used consistently in future submissions to the application. The id should change only when there is a change in ownership of the application.
<b>Guidance Source:</b>	General good practice to ensure reviewability.

<b>Number:</b>	2044
<b>Group:</b>	M1
<b>Description:</b>	id element must contain 9 digits only
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You provided an id that is not 9 numeric digits.
<b>Corrective Action:</b>	Ensure future submissions include an id that is 9 numeric digits.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3
<b>Number:</b>	2045
<b>Group:</b>	M1
<b>Description:</b>	Invalid form type for eCTD location
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	You have included an invalid form-type attribute value in the submission-information section.
<b>Corrective Action:</b>	Reference the form in the m1-1-forms section and not in submission-information in the admin section of the us-regional.xml.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3
<b>Number:</b>	3001
<b>Group:</b>	STF
<b>Description:</b>	STF doc-content title used
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	You have included a STF doc-content title. This title is not visible to the reviewer and should not be used. The leaf title is visible to reviewers.
<b>Corrective Action:</b>	Corrective action may be necessary. In future submissions, ensure that doc-content titles for each document referenced in the STF XML are not included.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1 Page 14

<b>Number:</b>	3008
<b>Group:</b>	STF
<b>Description:</b>	Use of the property element is required in STF DTD V2.0; the xlink:href attribute of the doc-content element is not used
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	Use of the property element is required. The xlink:href attribute of the doc-content element is not used. Note: Only applies to the STF 2.0 specification.
<b>Corrective Action:</b>	Modify your SOPs to use the most current STF DTD indicated on the FDA eCTD Website.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V1.1 Section III
<b>Number:</b>	3015
<b>Group:</b>	STF
<b>Description:</b>	The element 'file-tag' preceded the element 'property'
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	In the STF XML the 'property' element should come before its sibling element 'file-tag'.
<b>Corrective Action:</b>	Modify your SOPs to ensure your STF is in conformance with the ordering as described in the specification and the DTD.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1 Section III



<b>Number:</b>	3029
<b>Group:</b>	STF
<b>Description:</b>	Use of content-block is not recommended
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	Although content block is in both DTD versions, the specification does not refer to it; it is recommended that you do not use it.
<b>Corrective Action:</b>	Remove the content block element in the identified stf-xxxxxxx.xml and resubmit at time of next planned submission.
<b>Guidance Source:</b>	The eCTD Backbone File Specification for Study Tagging Files V2.6.1
<b>Number:</b>	3036
<b>Group:</b>	M1
<b>Description:</b>	Application number must contain 6 numeric digits only
<b>Severity Description:</b>	High
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	The application number must be 6 numeric digits in length.
<b>Corrective Action:</b>	Resubmit your submission specifying a properly formatted application number. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V1.3 Section II

<b>Number:</b>	3050
<b>Group:</b>	M1
<b>Description:</b>	Submission sequence number must contain 4 numeric digits only
<b>Severity Description:</b>	High
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	Your submission's sequence number must be 4 numeric digits in length.
<b>Corrective Action:</b>	Resubmit your submission specifying a properly formatted sequence number.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V1.3 Section II
<b>Number:</b>	3064
<b>Group:</b>	M1
<b>Description:</b>	Related sequence number must contain 4 numeric digits only
<b>Severity Description:</b>	High
<b>US DTD Version</b>	2.01
<b>Effective Date:</b>	3/10/2008
<b>Problem:</b>	Your submission's related sequence number element must only contain 4 numeric digits or the element should not appear in the us-regional.xml file.
<b>Corrective Action:</b>	Resubmit your submission specifying a properly formatted related sequence number. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V1.3 Section II

<b>Number:</b>	3065
<b>Group:</b>	M1
<b>Description:</b>	Submission-id element must contain 4 numeric digits only
<b>Severity Description:</b>	High
<b>US DTD Version</b>	3.3
<b>Effective Date:</b>	6/15/2015
<b>Problem:</b>	Your submission-id must be 4 numeric digits in length.
<b>Corrective Action:</b>	Resubmit your submission specifying a properly formatted submission-id number. You may resubmit using the original sequence number of the submission.
<b>Guidance Source:</b>	The eCTD Backbone Files Specification for Module 1 V2.3
<b>Number:</b>	3078
<b>Group:</b>	General
<b>Description:</b>	eCTD element does not contain any leaf elements
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have included a lowest level element that does not contain any leaf elements.
<b>Corrective Action:</b>	No corrective action is necessary. Modify your SOPs to ensure lowest level elements contain leaf elements.
<b>Guidance Source:</b>	FDA Presentations
<b>Number:</b>	3102
<b>Group:</b>	PDF
<b>Description:</b>	Failed to process PDF contents
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document with contents that cannot be processed, e.g. a corrupted or invalid PDF document.
<b>Corrective Action:</b>	Resubmit a corrected leaf in a future submission with the operation attribute of "Replace" and an updated valid PDF file.
<b>Guidance Source:</b>	General good practice to ensure reviewability.

<b>Number:</b>	5005
<b>Group:</b>	PDF
<b>Description:</b>	Non standard font (not embedded)
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have used a non-standard font and failed to fully embed the font. You should limit fonts to standard fonts. If you use non-standard fonts you should fully embed them in the PDF file.
<b>Corrective Action:</b>	Resubmit a corrected leaf in a future submission with the operation attribute of "Replace" and an updated PDF file with all non standard fonts embedded.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2 Section 7; FDA Portable Document Format Specifications V3.1
<b>Number:</b>	5020
<b>Group:</b>	PDF
<b>Description:</b>	PDF security used
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a PDF file with security settings that limit the ability to select text or graphics, or make other changes. This prevents agencies from copying text and taking other actions with submitted documents. (Not applicable for FDA Forms)
<b>Corrective Action:</b>	Resubmit a corrected leaf in a future submission with the operation attribute of "Replace" and an updated PDF file without restrictions.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2 Section 7

<b>Number:</b>	5025
<b>Group:</b>	M1
<b>Description:</b>	US application form is not a fillable form
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted an application form (containing 356h or 1571 in its file name) that is not a fillable form.
<b>Corrective Action:</b>	Ensure that you submit an FDA fillable form in future submissions.
<b>Guidance Source:</b>	FDA Presentations
<b>Number:</b>	5029
<b>Group:</b>	M1
<b>Description:</b>	Misnamed form
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You may have submitted an application form that is not named correctly (a 1571 form missing 1571 in its filename or 356 form with missing 356h in its file name). If so, this will prevent automated processing of the form.
<b>Corrective Action:</b>	In the future, ensure that your application form is named 356h.pdf or 1571.pdf. It is also good practice to follow a similar approach when submitting other FDA forms (e.g., 2252, 3674, etc.).
<b>Guidance Source:</b>	FDA Presentations

<b>Number:</b>	5030
<b>Group:</b>	M1
<b>Description:</b>	Application number in form does not match application number in us-regional.xml
<b>Severity Description:</b>	High
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	The application number in your application form does not match the application number supplied in your us-regional.xml file. Note: This error can be ignored for trans BLAs.
<b>Corrective Action:</b>	In future submissions, ensure that these numbers match. You may need to resubmit with consistent information.
<b>Guidance Source:</b>	FDA Presentations
<b>Number:</b>	5031
<b>Group:</b>	M1
<b>Description:</b>	Submission date in form does not match submission date in us-regional.xml
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	2.01
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	The submission date in your application form does not match the submission date supplied in your us-regional.xml file.
<b>Corrective Action:</b>	In future submissions, ensure that these dates match. You may need to resubmit with consistent information.
<b>Guidance Source:</b>	FDA Presentations

<b>Number:</b>	5032
<b>Group:</b>	M1
<b>Description:</b>	Multiple application forms present for the same application
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted more than one application form for the same application. Note: This error can be ignored for trans-BLAs submitted with DTD version 2.01.
<b>Corrective Action:</b>	In future submissions, include only one file with the form number as part of the file name. For example, only include one file named 356h.pdf for an NDA, and do not include 356h in the file names of other ancillary documents.
<b>Guidance Source:</b>	FDA Presentations
<b>Number:</b>	5033
<b>Group:</b>	M1
<b>Description:</b>	Missing application form
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted an application without an application form. A lack of a valid, electronically readable form results in delays in processing your submission.
<b>Corrective Action:</b>	If corrective action is necessary, you will be contacted. You should provide a valid fillable form in future submissions. A form named 1571.pdf is expected for INDs. A form named 356h.pdf is expected for NDAs/ANDAs/BLAs.
<b>Guidance Source:</b>	FDA Presentations

<b>Number:</b>	5034
<b>Group:</b>	M1
<b>Description:</b>	Application form placed in wrong TOC location
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted an application form that was not placed in the correct TOC location.
<b>Corrective Action:</b>	If corrective action is necessary, you will be contacted. You should provide forms in the correct Module 1 location as specified in the applicable eCTD Backbone Files Specification for Module 1.
<b>Guidance Source:</b>	FDA Presentations; The eCTD Backbone Files Specification for Module 1 V1.3 and V2.3
<b>Number:</b>	5035
<b>Group:</b>	PDF
<b>Description:</b>	PDF version of document is incorrect
<b>Severity Description:</b>	Low
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document using a PDF version that is not consistent with ICH / regional guidance.
<b>Corrective Action:</b>	No corrective action is necessary. Modify your SOPs to ensure that documents in future submissions conform to the published standards.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2 Section 7; FDA Portable Document Format Specifications V3.1



<b>Number:</b>	5038
<b>Group:</b>	M1
<b>Description:</b>	Wrong application form
<b>Severity Description:</b>	High
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted the wrong application form based on your application type, that is, you have submitted a form named 1571.pdf for an NDA/ANDA/BLA, a form named 356h.pdf for an IND or a form named 2252.pdf for a sequence that is not an annual report.
<b>Corrective Action:</b>	Resubmit your submission with the correct application form. You may resubmit using the original sequence number of the submission. Modify your SOPs to ensure that your submission has a the correct type of form correctly named 356h.pdf or 1571.pdf and referenced in the correct eCTD location.
<b>Guidance Source:</b>	FDA Presentations; FDA Form Instructions
<b>Number:</b>	5040
<b>Group:</b>	PDF
<b>Description:</b>	PDF does not have 'Fast Web Access' active
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a PDF that has been created without 'Fast Web Access' active.
<b>Corrective Action:</b>	Ensure that documents in future submissions are created with the 'Fast Web Access' option.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2 Section 7; ICH Q&A 36 #23

<b>Number:</b>	5045
<b>Group:</b>	PDF
<b>Description:</b>	PDF opening settings not optimal
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a PDF that does not open in the desired view.
<b>Corrective Action:</b>	Ensure that PDF Opening settings are correct for all future submissions. The initial view of the PDF files should be set as Bookmarks and Pages in the Navigation Panel. If there are no bookmarks, the initial view should be set to Pages only. PDFs should open in 'most recent view' (i.e. 'inherit zoom' for bookmarks and links, and 'default' in open dialogue box).
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2 Section 7; FDA Portable Document Format Specifications V3.1
<b>Number:</b>	5050
<b>Group:</b>	PDF
<b>Description:</b>	Document has password protection
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document that has password protection and cannot be opened. (Not applicable for FDA Forms)
<b>Corrective Action:</b>	Resubmit the protected file in a later submission referencing the original leaf using the operation attribute of "Replace."
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2 Section 7; ICH Q&A 36 #21

<b>Number:</b>	5055
<b>Group:</b>	PDF
<b>Description:</b>	Document has annotations, only PDFs in module 1, section 1.15 are permitted to have annotations.
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	9/14/2016
<b>Problem:</b>	You have submitted a document that has PDF annotations, only PDFs in module 1, section 1.15 are permitted to have annotations.
<b>Corrective Action:</b>	Ensure that documents in future submissions do not have annotations, only PDFs in module 1, section 1.15 are permitted to have annotations..
<b>Guidance Source:</b>	General good practice to ensure reviewability.
<b>Number:</b>	5057
<b>Group:</b>	PDF
<b>Description:</b>	Document contains no text
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document that is a scanned image only and is not text searchable.
<b>Corrective Action:</b>	Ensure that documents in future submissions are text searchable whenever possible (minimize the use of scanned documents).
<b>Guidance Source:</b>	FDA Portable Document Format Specifications V3.1

<b>Number:</b>	5100
<b>Group:</b>	PDF
<b>Description:</b>	Broken bookmark
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document with one or more bookmarks pointing to a file that does not exist.
<b>Corrective Action:</b>	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have broken bookmarks.
<b>Guidance Source:</b>	General good practice to ensure reviewability.
<b>Number:</b>	5101
<b>Group:</b>	PDF
<b>Description:</b>	Corrupt bookmark
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document with one or more bookmarks pointing to a file that cannot be opened.
<b>Corrective Action:</b>	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have corrupt bookmarks.
<b>Guidance Source:</b>	General good practice to ensure reviewability.

<b>Number:</b>	5102
<b>Group:</b>	PDF
<b>Description:</b>	Bookmark has non-existent named destination or page
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document with one or more bookmarks pointing to a named destination or page that does not exist.
<b>Corrective Action:</b>	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have bookmarks linking to non-existent pages or named destinations.
<b>Guidance Source:</b>	General good practice to ensure reviewability.
<b>Number:</b>	5103
<b>Group:</b>	PDF
<b>Description:</b>	Multiple action bookmark
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document with one or more bookmarks containing multiple actions.
<b>Corrective Action:</b>	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have bookmarks triggering multiple actions.
<b>Guidance Source:</b>	General good practice to ensure reviewability.

<b>Number:</b>	5105
<b>Group:</b>	PDF
<b>Description:</b>	External bookmark
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document that makes reference to one or more external bookmarks (e.g. web links, email links).
<b>Corrective Action:</b>	Ensure that documents in future submissions do not have bookmarks that are external to the application.
<b>Guidance Source:</b>	ICH Q&A 64
<b>Number:</b>	5110
<b>Group:</b>	PDF
<b>Description:</b>	Inactive bookmark
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document that has one or more inactive bookmarks.
<b>Corrective Action:</b>	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have inactive bookmarks.
<b>Guidance Source:</b>	General good practice to ensure reviewability.
<b>Number:</b>	5115
<b>Group:</b>	PDF
<b>Description:</b>	Non-relative bookmark
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document that has one or more non-relative (absolute) bookmarks.
<b>Corrective Action:</b>	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions have only relative bookmarks.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2 Section 6; FDA Portable Document Format Specifications V3.1; ICH Q&A 36 #23

<b>Number:</b>	5117
<b>Group:</b>	PDF
<b>Description:</b>	Bookmark does not 'Inherit Zoom'
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document with one or more bookmarks that are not set to 'Inherit Zoom'.
<b>Corrective Action:</b>	Ensure that all bookmarks are set to 'Inherit Zoom'.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2 Section 7; FDA PDF Specifications V2.0; Final Guidance for Industry: Providing Regulatory Submissions in Electronic Format--Human Pharmaceutical Applications and Related Submissions Using the eCTD Specifications
<b>Number:</b>	5200
<b>Group:</b>	PDF
<b>Description:</b>	Broken hyperlink
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document with one or more hyperlinks pointing to a file that does not exist.
<b>Corrective Action:</b>	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have broken hyperlinks.
<b>Guidance Source:</b>	General good practice to ensure reviewability.

<b>Number:</b>	5201
<b>Group:</b>	PDF
<b>Description:</b>	Corrupt link
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document with one or more links pointing to a file that cannot be opened.
<b>Corrective Action:</b>	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have corrupt links.
<b>Guidance Source:</b>	General good practice to ensure reviewability.
<b>Number:</b>	5202
<b>Group:</b>	PDF
<b>Description:</b>	Link has non-existent named destination or page
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document with one or more hyperlinks pointing to a named destination or page that does not exist.
<b>Corrective Action:</b>	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have links pointing to non-existent pages or named destinations.
<b>Guidance Source:</b>	General good practice to ensure reviewability.



<b>Number:</b>	5203
<b>Group:</b>	PDF
<b>Description:</b>	Multiple action hyperlink
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document with one or more hyperlinks containing multiple actions.
<b>Corrective Action:</b>	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have links triggering multiple actions.
<b>Guidance Source:</b>	General good practice to ensure reviewability.
<b>Number:</b>	5205
<b>Group:</b>	PDF
<b>Description:</b>	External hyperlink
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document that makes reference to one or more web references in a hyperlink (e.g. web links, email links).
<b>Corrective Action:</b>	Ensure that documents in future submissions do not have hyperlinks that are external to the application.
<b>Guidance Source:</b>	ICH Q&A 64
<b>Number:</b>	5210
<b>Group:</b>	PDF
<b>Description:</b>	Inactive hyperlink
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document that has one or more inactive hyperlinks.
<b>Corrective Action:</b>	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have inactive hyperlinks.
<b>Guidance Source:</b>	General good practice to ensure reviewability.

<b>Number:</b>	5215
<b>Group:</b>	PDF
<b>Description:</b>	Non-relative hyperlink
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document that has one or more non-relative (absolute) hyperlinks.
<b>Corrective Action:</b>	Corrective action may be necessary and you will be contacted if it is necessary. Ensure that documents in future submissions do not have non-relative hyperlinks.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2 Section 6; FDA Portable Document Format Specifications V3.1; ICH Q&A 36 #23
<b>Number:</b>	5217
<b>Group:</b>	PDF
<b>Description:</b>	Link does not 'Inherit Zoom'
<b>Severity Description:</b>	Medium
<b>US DTD Version</b>	2.01 and 3.3
<b>Effective Date:</b>	4/30/2013
<b>Problem:</b>	You have submitted a document with one or more links that are not set to 'Inherit Zoom'.
<b>Corrective Action:</b>	Ensure that all links in future submissions are set to 'Inherit Zoom'.
<b>Guidance Source:</b>	ICH eCTD Specification V3.2.2 Section 7; FDA PDF Specifications V2.0; Final Guidance for Industry: Providing Regulatory Submissions in Electronic Format--Human Pharmaceutical Applications and Related Submissions Using the eCTD Specifications

## Validation Error Codes (sorted by severity)

<b>Error Number</b>	<b>Severity Level</b>
1038	Low
1130	Low
1204	Low
1221	Low
1238	Low
1276	Low
1322	Low
1344	Low
1368	Low
1374	Low
1391	Low
1408	Low
1425	Low
1426	Low
1454	Low
1468	Low
1472	Low
1482	Low
1487	Low
1500	Low
1544	Low
1578	Low
1646	Low
1663	Low
1680	Low
1953	Low
2035	Low
2038	Low
2042	Low
2043	Low
3078	Low

5025	Low
5029	Low
5031	Low
5032	Low
5034	Low
5035	Low
1034	Medium
1051	Medium
1068	Medium
1085	Medium
1102	Medium
1119	Medium
1136	Medium
1153	Medium
1154	Medium
1170	Medium
1255	Medium
1289	Medium
1298	Medium
1306	Medium
1314	Medium
1323	Medium
1357	Medium
1362	Medium
1442	Medium
1445	Medium
1451	Medium
1476	Medium
1478	Medium
1519	Medium
1545	Medium
1550	Medium
1561	Medium
1595	Medium

1612	Medium
1629	Medium
1635	Medium
1681	Medium
1735	Medium
1737	Medium
1748	Medium
1752	Medium
1765	Medium
1789	Medium
1816	Medium
1833	Medium
1850	Medium
1867	Medium
1884	Medium
1901	Medium
1918	Medium
1935	Medium
1969	Medium
1981	Medium
1985	Medium
1990	Medium
2021	Medium
2041	Medium
2044	Medium
2045	Medium
3001	Medium
3008	Medium
3015	Medium
3029	Medium
3102	Medium
5005	Medium
5020	Medium
5033	Medium

5040	Medium
5045	Medium
5050	Medium
5055	Medium
5057	Medium
5100	Medium
5101	Medium
5102	Medium
5103	Medium
5105	Medium
5110	Medium
5115	Medium
5117	Medium
5200	Medium
5201	Medium
5202	Medium
5203	Medium
5205	Medium
5210	Medium
5215	Medium
5217	Medium
1111	High
1459	High
1463	High
1496	High
1636	High
1697	High
1714	High
1731	High
1734	High
1736	High
1782	High
1786	High
1799	High

2001	High
2002	High
2003	High
2012	High
2013	High
2022	High
2023	High
2024	High
2025	High
2031	High
2032	High
2033	High
2034	High
2036	High
2037	High
3036	High
3050	High
3064	High
3065	High
5030	High
5038	High

## Validation Error Codes Removed

Number	1128
Severity	Low
In Version	2.0
Reason For Deletion	Error provided redundant functionality. Replaced by Error 1314.
Number	1161
Severity	Low
In Version	2.1
Reason For Deletion	A title may be provided, however, providing anything other than the original title may impact reviewability.
Number	1272
Severity	Low
In Version	2.0
Reason For Deletion	There are no invalid characters for leaf titles, only for file names.
Number	1340
Severity	Low
In Version	2.0
Reason For Deletion	There are no invalid characters for attributes.
Number	1480
Severity	Low
In Version	2.0
Reason For Deletion	There are no invalid characters for node extension titles.
Number	1952
Severity	Low
In Version	2.0
Reason For Deletion	Retired and replaced by Error 3001.



Number	5300
Severity	Low
In Version	2.1
Reason For Deletion	Error functionality removed by FDA eCTD tool vendor.
Number	1017
Severity	Medium
In Version	2.0
Reason For Deletion	Error provided redundant functionality. Replaced by Error 1153.
Number	1187
Severity	Medium
In Version	2.0
Reason For Deletion	Error provided redundant functionality. Replaced by Error 1153.
Number	1630
Severity	Medium
In Version	2.1
Reason For Deletion	Error provided redundant functionality. Replaced by Error 3064.
Number	3022
Severity	Medium
In Version	2.1
Reason For Deletion	Error provided redundant functionality. Replaced by Error 1362 and Error 1368.
Number	5000
Severity	Medium
In Version	2.1
Reason For Deletion	Non-standard fonts may be used if they are fully embedded in the PDF file (not just an embedded subset).

Number	5080
Severity	Medium
In Version	2.1
Reason For Deletion	Error provided redundant functionality. Replaced by Error 5040.
Number	1493
Severity	High
In Version	2.0
Reason For Deletion	Fatal XML errors will prevent the validation of the sequence. No validation report would be created.
Number	1510
Severity	High
In Version	2.0
Reason For Deletion	Fatal XML errors will prevent the validation of the sequence. No validation report would be created.
Number	1527
Severity	High
In Version	2.0
Reason For Deletion	This error would never occur. A change in application number would cause the sequence to be associated with a different application.
Number	1697
Severity	High
In Version	2.0
Reason For Deletion	This error would never occur. The duplicate sequence would be rejected by the FDA.
Number	3043
Severity	High
In Version	2.0
Reason For Deletion	Error provided redundant functionality. Replaced by Error 3036.

Number	3057
Severity	High
In Version	2.0
Reason For Deletion	Error provided redundant functionality. Replaced by Error 3050.

Number	3071
Severity	High
In Version	2.0
Reason For Deletion	Error provided redundant functionality. Replaced by Error 3064.