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Validation rules for regulatory transactions provided to Health Canada in the electronic Common Technical Document (eCTD) format

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Health Canada is pleased to announce the revised validation rules for regulatory transactions in the electronic Common Technical Document (eCTD) format. These revised validation rules (see table below) are being posted to provide further information to stakeholders to assist them in the preparation of regulatory transactions in eCTD format. The revised rules also build on the information provided in the Guidance Document:

Preparation of Drug Regulatory Activities in Electronic Common Technical Document (eCTD) Format as well as specifications for the regional administrative module (Module1) of the eCTD standard defined in Guidance for Industry: Creation of the Canadian Module 1 Backbone (eCTD) and the International Council for Harmonisation (ICH) Electronic Common Technical Document Specification (Version 3.2.2).

Since June 2016, Health Canada has been providing the Validation Reports **only** for regulatory transactions that failed validation. Sponsors are expected to validate their eCTD regulatory transactions and correct any warning(s) and error(s) before sending them to Health Canada.

Although the profile may be updated without further notice, as of March 30, 2019, Health Canada will be validating regulatory transactions in eCTD format using version 4.4 of the eCTD validation rules.

Should you have any questions regarding the content of the notice, please contact:

E-mail: hc.ereview.sc@canada.ca

Health Canada eCTD Validation Rules version 4.4

ID #	Rule Name	Rule Description	Severity
A - GENERAL			
A01	Empty Folders	Checks the sequence folder structure for any empty folders (folders without any files or subfolders).	Error
A02	File and Folder Security	Checks the sequence folder structure for any files or folders the user does not have access permission to.	Error
A03a	File Size	This rule's implementation checks for files that exceed the configured maximum size. Warning for PDF files between 150 MB and 200 MB. Warning for other file types larger than 100 MB (excluding SAS XPT).	Warning

ID #	Rule Name	Rule Description	Severity
A03b	File Size	This rule's implementation checks for files that exceed the configured maximum size (Max. size: 200 MB for PDF, 1 GB for SAS XPT).	Error
A05a	Sequence Folder Requirements	Checks the sequence folder name. Furthermore the rule will report a finding if the sequence seems to be the initial sequence for the application but its name is not 0000.	Error
A05b	Higher sequences found	Reports error if the validated sequence is not the highest in the application folder.	Error
A06a	XML Backbones Identification	Identifies all ICH and regional index files found in the sequence folder. Incorrect or invalid index files will be reported as errors.	Error
A06b	STF Identification	Identifies all STF files found in the sequence folder. Invalid STF files will be reported as errors. STF files with an incorrect name will be also reported as errors. Revised	Error

ID #	Rule Name	Rule Description	Severity
A07	Sequence numbering	<p>Each subsequent transaction provided in the lifecycle of a dossier, must have a sequence number that is consecutively incremented by 1 number (for example 0000, 0001, 0002, 0003, and so on).</p> <p>Skipping numbers is not acceptable for sequence numbers. Validating a transaction with sequence number 0004 will report an error if sequence number 0003 does not exist (even if sequence 0004 does not have any reference to it).</p>	Error
A09	Corrupt and password protected WORD documents	<p>Word document will be reported as corrupted or password protected if one or more of the following situations occur:</p> <ol style="list-style-type: none"> 1. Document is corrupt or unreadable 2. Document has password protection 3. Document references an attached template located via http or https <p>Note: This rule applies only to Word version 2007 or later (.docx). New</p>	Error
B - PDF ANALYSIS			

ID #	Rule Name	Rule Description	Severity
B01	Corrupt or unreadable PDF documents	<p>A PDF document will be reported as corrupt if one or more of the following situations occur:</p> <ol style="list-style-type: none"> 1. The document cannot be opened because it is damaged or the encryption is too strong. 2. The document appears to have 0 pages. 3. The document appears to be an application form, but the form content cannot be read. <p>An example of situation number (3) could be a document appearing to have 1 page only and the page contains the text phrase "Please wait... If this message is not eventually replaced by the proper contents of the document, your PDF viewer may not be able to display this type of document."</p> <p>Revised</p>	Error
B02	Bookmarks - Absolute (Rooted)	Retrieves all non-relative bookmarks in PDF documents and prints the total count, including the broken ones.	Error
B03a	Bookmark - External (www, e-mail)	Retrieves all web link bookmarks and e-mail bookmarks in PDF documents and prints the total count.	Error

ID #	Rule Name	Rule Description	Severity
B03b	Bookmarks - External (other)	Retrieves all external bookmarks other than web links and e-mail links from PDF documents and prints the total count.	Error
B04	Bookmarks - Inactive	Retrieves all inactive bookmarks in PDF documents and prints the total count.	Error
B06	Bookmarks - Inter Application, broken	Retrieves all broken inter-application bookmarks in PDF documents and prints the total count.	Error
B08	Bookmarks - Intra Application, broken	Retrieves all broken intra-application bookmarks in PDF documents and prints the total count.	Error
B10	Bookmarks - Intra Sequence, broken	Retrieves all broken intra-sequence bookmarks from PDF documents and prints the total count.	Error
B11	Bookmarks - Other	Retrieves all unknown bookmarks (links that could not be identified or contain JavaScript code) from PDF documents and prints the total count.	Warning
B12	Bookmarks - Count	Reports the number of bookmarks per document and the total number of bookmarks in the sequence.	Information
B13	Hyperlinks - Absolute (Rooted)	Retrieves all non-relative hyperlinks from PDF documents and prints the total count, including the broken ones.	Error

ID #	Rule Name	Rule Description	Severity
B14a	Hyperlinks - External (www, e-mail)	Retrieves all web links and e-mail links from PDF documents and prints the total count.	Error
B14b	Hyperlinks - External (other)	Retrieves all external hyperlinks other than web links and e-mail links from PDF documents and prints the total count.	Error
B15	Hyperlinks - Inactive	Retrieves all inactive hyperlinks from PDF documents and prints the total count.	Error
B17	Hyperlinks - Inter Application, broken	Retrieves all broken inter-application hyperlinks from PDF documents and prints the total count.	Error
B19	Hyperlinks - Intra Application, broken	Retrieves all broken intra-application hyperlinks from PDF documents and prints the total count.	Error
B21	Hyperlinks - Intra Sequence, broken	Retrieves all broken intra-sequence hyperlinks from PDF documents and prints the total count.	Error
B22	Hyperlinks - Other	Retrieves all unknown hyperlinks (links that could not be identified or contain JavaScript code) from PDF documents and prints the total count.	Warning
B23	Hyperlinks - Count	Reports the number of hyperlinks per document and the total number of hyperlinks in the sequence.	Information

ID #	Rule Name	Rule Description	Severity
B24	PDF Protection	Finds PDF documents with password protection.	Error
B25	PDF version checking	Checks all PDF document versions against the list of allowed versions.	Warning
B32	PDF Protection: Owner password	Finds all documents with an owner password set, excluding forms in m1-2-administrative-information subheading and literature references in subfolders: 33-lit-ref, 43-lit-ref, 54-lit-ref. Revised	Warning
B33	PDF Protection: Encrypted	Finds all encrypted documents.	Information
B35	Bookmarks - deep destination check	For all bookmarks, the named destination or destination page will be verified. Non existing destinations will be reported (i.e. the destination file exists but the page does not).	Error
B36	Bookmarks - multi action	Finds all bookmarks with multiple actions assigned.	Error
B37	Hyperlinks - deep destination check	For all hyperlinks, the named destination or destination page will be verified. Non existing destinations will be reported (i.e. the destination file exists but the page does not).	Error

ID #	Rule Name	Rule Description	Severity
B38	Hyperlinks - multi action	Finds all hyperlinks with multiple actions assigned.	Error
B40	PDF documents with attachments are not allowed	This rule is configured to detect attachments and portfolio documents found in PDF documents. Revised	Error
B41	Bookmark does not 'Inherit Zoom'	All bookmarks and hyperlinks should have a magnification setting of "Inherit Zoom". This rule performs the corresponding checks for bookmarks.	Warning
B42	Link does not 'Inherit Zoom'	All bookmarks and hyperlinks should have a magnification setting of "Inherit Zoom". This rule performs the corresponding checks for hyperlinks.	Warning
B43	PDF Initial View	Checks for PDF documents with an incorrect initial view. ICH eCTD Specification: Documents with bookmarks must show the bookmarks pane in their initial view. The Magnification and Page Layout should be set as "default".	Warning
B44	PDF documents with more than 10 pages must have bookmarks	PDF documents with more than 10 pages must have bookmarks. Excluded from this check are: literature references in sections 3.3, 4.3, and 5.4; the life cycle management table; and Health Canada application forms.	Warning

ID #	Rule Name	Rule Description	Severity
B45	PDF Protection – Printing	Finds all documents where printing is not allowed. New	Error
B46	PDF Protection – Content Copying	Finds all documents where copying the content is not allowed. New	Error
B47	PDF content restrictions	This rule checks for PDF files that contain JavaScript, dynamic content (e.g., audio, video or special effects), or 3D content. New	Error
C - REFERENCED FILES			
C01	HREFs to targets outside application	Checks for broken links in submission files.	Error
		Hyperlinks targeting files outside the application will be identified.	
C02	HREFs to targets outside sequence	Checks for broken links in submission files.	Information
		Hyperlinks targeting files outside sequence will be identified.	
C03	Life Cycle Management Semantics	This check option refers to the current sequence. It will perform a general verification of the leaf life cycle properties in this sequence only (no deep history scanning).	Error
		For leaf elements with operation "new", the eValidator verifies that: modified file must not exist / title is given / href must exist.	

ID #	Rule Name	Rule Description	Severity
		For leaf elements with operation "replace", the eValidator verifies that: modified file must exist / title is given / href must exist.	
		For leaf elements with operation "append", the eValidator verifies that: modified file must exist / title is given / href must exist.	
		For leaf elements with operation "delete", the eValidator verifies that: modified file must exist / title is not required / href must not exist.	
		The eValidator verifies that for initial submissions all leaf elements have the operation "new".	
		The eValidator checks modified files in LCM: leaf in previous sequence must exist. It also verifies that when the attribute "modified-file" has been used for a leaf document then the referenced document exists in the previous submission. It is recognized that this attribute is invalid when used for submission sequence number 0000.	
		The eValidator checks that all files referenced in the backbone exist.	

ID #	Rule Name	Rule Description	Severity
C04	MD5 Checksum	The eValidator regenerates the MD5 checksums for all referenced files and compares the checksums to the values provided in the backbone file.	Error
C05	Naming Syntax	Checks the syntax of all referenced file names (path length, illegal characters, etc.). The maximum path length is 200 characters.	Error
C06	Relative References	<p>The eValidator checks that only relative references (href and modified file) are used. Also, only forward slashes "/" are allowed (no backslashes).</p> <p>Do the file references in the index files (ICH, Regional, STF) use relative paths? Absolute (i.e. rooted) paths are not allowed.</p>	Error
C07	Unreferenced Files	Searches for files not referenced in an index file (ICH, Regional or STF).	Error
D - XML ANALYSIS			
D01	DTD/Schema Checksums	<p>Rule compares the checksums of the DTD and schema against the following checksums:</p> <p>ich-ectd-3-2.dtd: 1d6f631cc6b6357f0f4fe378e5f79a27</p> <p>ca-regional-2-2-.xsd: ff564d6e69adebd9a9b4f274e65cf5f1</p> <p>xml.xsd: 382b0a4f7529d2c5f7b0af0aa713b0a5</p>	Error

ID #	Rule Name	Rule Description	Severity
		xlink.xsd: 52d1a3b8596e4fb61d3ec1cde24be16a ich-stf-v2-2.dtd: 0972c10a4dadf3df5d2f41b2026a4a5c	
D02	Existence of Node extensions	The eValidator checks for "node-extension" elements being used and reports them for informational purposes.	Information
D03	MD5 for Index files	MD5 checksums for index files will be calculated and compared against the MD5 checksums provided in the MD5 text files.	Error
D04	Validate against delivered DTD	Performs XML validation for ICH Backbone and Regional backbones. Uses the DTD or Schema given in the sequence number folder (util/dtd).	Error
F - CA REGIONAL 2.2			
F01	All files should have one and only one file extension	Checks if referenced files have exactly one file extension.	Error
F03	Element must have leaf	Checks for elements not having any leaf child nodes. This only affects elements with a name that starts with 'm'.	Error
F04	The folder m1\ca must exist.	The sequence folder must have a subfolder m1 with a subfolder ca.	Error

ID #	Rule Name	Rule Description	Severity
F05	No subfolders in ca-subfolder	The folder m1\ca must not have any subfolders.	Warning
F06	Leaf title must not be empty	For operations other than 'delete', all leafs must have a 'title' child. The title must be present.	Error
F07	Module 1 (regional xml file) exists	The regional backbone ca-regional.xml file must exist in folder m1\ca.	Error
F08	Application folder name must match dossier-identifier	The element value for the dossier-identifier must match the name of the parent folder of the sequence folder. And the dossier-identifier must start with the letter e or s.	Error
F09	Element sequence-description	Refer to the CA M1 guidance document for the list of valid values for the sequence-description element.	Error
F10	Cover letter operation attribute	Cover letter should have 'new' operation attribute.	Warning
F11	Multiple operations on same document in same sequence	Checks for documents in the regional backbone, which are used as modified-file more than once.	Error
F12	File reuse	Checks for file reuse scenarios (Same values for xlink:href used multiple times in the regional backbone for this sequence).	Information

ID #	Rule Name	Rule Description	Severity
F14	Replace or append should not provide identical content to the previous file	When replacing or appending content, the new content should be different from the previous content.	Error
F15	Invalid file extension	Valid file extensions include: pdf, .doc, .docx, .xls, .xlsx, .wpd, .ppt, .pptx, .xml, .dat, .inf, .txt, .png, .gif, .svg, .wav, .mp3, .mp4, .wmv, .jpg, .jpeg, .tif, .tiff, .bmp.	Warning
F16	Detect invalid life cycle: Append	Detect invalid life cycle pattern: Append operations causing branches.	Error
F17	Detect invalid life cycle: Delete	Detect invalid life cycle pattern: Delete operations causing branches.	Error
F18	Detect invalid life cycle: Replace	Detect invalid life cycle pattern: Replace operations causing branches.	Error
F19	Detect invalid life cycle: Delete	Detect invalid life cycle pattern: Operation on deleted leaf content.	Error
F20	Detect invalid life cycle: Append	Detect invalid life cycle pattern: Append on Append.	Warning
F21	Element sequence-number	The value of the sequence-number element must match the sequence folder name.	Error

ID #	Rule Name	Rule Description	Severity
F22	Operation for Life Cycle Management Table	The operation for this leaf when present must be 'replace' (or 'delete' if applicable) in sequences other than the initial one. Revised	Error
F23	Product Name and Applicant	Element values product-name and applicant must not be empty.	Error
F24	Cover letter	Cover letter should not have more than three pages. New	Error
F25	Node extensions in module 1	<p>Node extensions in module 1 backbone (ca-regional.xml) are not allowed, except in 1.2.6 Authorization for Sharing Information heading, 1.2.7 International Information heading, and 1.6.1 Comparative bioavailability Information heading.</p> <p>The validator checks all headings and subheadings in the Canadian regional backbone (ca-regional.xml). It generates an error when there is (are) node extension(s) found in any subheadings other than those mentioned above. Revised</p>	Error

ID #	Rule Name	Rule Description	Severity
F26	Node Extensions in 1.2.7 International Information	<p>Node extensions are expected in section 1.2.7 International Information heading.</p> <p>Note: There is a mixture of node extensions and leaves allowed in the 1.2.7 International Information heading. A warning is generated when there is a (are) leaf (leaves) added under this heading. The warning serves the purpose to notify the user to manually verify the leaves added under this heading. Requirements are outlined below and will result in failure of the transaction if not followed:</p> <p>When provided, the International Status document and the Foreign review attestation must be added as leaves directly under 1.2.7 subheading. Any other foreign agency (such as FDA, EMA) related documents must be provided using node extensions.</p> <p>Revised</p>	Warning
F27	Node Extension title must not be empty	For node extensions, the title child must be present (value must be present). New	Error
G - ICH BACKBONE 3.2			

ID #	Rule Name	Rule Description	Severity
G01	All files should have one and only one file extension	Checks if referenced files have exactly one file extension.	Error
G02	Attribute checksum-type	The checksum-type attribute must have the value md5 or MD5.	Error
G03	Attribute dosage form	Checks if the attribute value is present. Revised	Warning
G04	Attribute excipient	Checks if the attribute value is present. Revised	Warning
G05	Attribute Indication	Checks if the attribute value is present.	Error
G06	Attribute Manufacturer	Checks if the attribute value is present. Applicable only to sections where this attribute is mandatory, otherwise reported as warning. Revised	Error
G07	Attribute Product-Name	Checks if the attribute value is present. Revised	Warning
G08	Attribute Substance	Checks if the attribute value is present. Applicable only to sections where this attribute is mandatory, otherwise reported as warning. Revised	Error
G09	Element must have leaf	Checks for elements not having any leaf child nodes. This only affects elements with a name that starts with 'm'.	Error

ID #	Rule Name	Rule Description	Severity
G10	File index.xml exists	The index.xml file must be present.	Error
G11	File index-md5.txt exists	The MD5 checksum file index-md5.txt must be present.	Error
G12	Folder m1 exists	The m1 folder must be present.	Error
G13	Folder util exists	The util folder must be present.	Error
G14	Leaf title must not be empty	For operations other than 'delete', all leafs must have a 'title' child. The title must be present.	Error
G15	m1-administrative element must exist	The element m1-administrative-information-and-prescribing information must be present.	Error
G16	No other files in m1	The m1 folder must not have any other files in addition to the files explicitly allowed.	Error
G17	No other files in root	The root folder (sequence number folder) must not have any other files in addition to the files explicitly allowed.	Error
G18	Node Extension title must not be empty	For node extensions, the title child must be present (value must be present).	Error
G19	Regional backbone(s) referenced operations	Regional backbone(s) referenced (ca-regional.xml) should have 'new' operation attribute.	Warning

ID #	Rule Name	Rule Description	Severity
G20	Multiple operations on same document in same sequence	Checks for documents in the ICH backbone, which are used as modified-file more than once.	Error
G21	File reuse	Checks for file reuse scenarios (Same values for xlink:href used multiple times in the regional backbone for this sequence).	Information
G22	Invalid file extension	Valid file extensions include: .pdf, .doc, .docx, .xls, .xlsx, .wpd, .ppt, .pptx, .xml, .dat, .inf, .txt, .png, .gif, .svg, .sas, .xpt, .xsl, .dtd, .xsd, .wav, .mp3, .mp4, .wmv, .jpg, .jpeg, .tif, .tiff, .bmp.	Warning
G23	Replace or append should not provide identical content to the previous file	When replacing or appending content, the new content should be different from the previous content.	Error
G24	Leaf count under a node	The number of leaves directly under a single node must not exceed 1000. This rule applies only to module 5 when using node extensions and only to leaves with operation attribute "new".	Error
G25	Detect invalid life cycle: Append	Detect invalid life cycle pattern: Append operations causing branches.	Error

ID #	Rule Name	Rule Description	Severity
G26	Detect invalid life cycle: Append	Detect invalid life cycle pattern: Append operations not appending to most recent STF leaf.	Error
G27	Detect invalid life cycle: Delete	Detect invalid life cycle pattern: Delete operations causing branches.	Error
G28	Detect invalid life cycle: Replace	Detect invalid life cycle pattern: Replace operations causing branches.	Error
G29	Detect invalid life cycle: Delete	Detect invalid life cycle pattern: Operation on deleted leaf content.	Error
G30	Detect invalid life cycle: Append	Detect invalid life cycle pattern: Append on Append.	Warning
G31	Strength in dosage form attribute	Do not provide strength values in the dosage form attribute in sections 2.3.P, 3.2.P, 3.2.A.1, or 3.2.A.2. Any numeric value found in these attribute values will be reported as an error. If the strength value was already present in a previous sequence, the rule will not report an error for the current sequence.	Error

ID #	Rule Name	Rule Description	Severity
G32	Do not relocate content	<p>This applies to leaf elements in the ICH sections modules 2-5.</p> <p>When revisions are sent to a regulatory authority, the new leaf element should be submitted in the same location in the backbone as the leaf element being appended, replaced or deleted.</p>	Error
G33	SAS XPT dataset files (XPORT)	<p>This check will examine the SAS XPT dataset files (XPORT). Files that are corrupt or compressed will be reported as Error. For details about the technical specifications, please refer to the FDA study data technical conformance guide. New</p>	Error
G34	Node extensions in 3.2.R Regional Information	<p>Leaf elements in 3.2.R Regional Information heading must be provided using node extensions. PDF files are not allowed as leaf elements directly under 3.2.R Regional Information heading. Acceptable titles of the node extensions are:</p> <ul style="list-style-type: none"> 3.2.R.1 Production Documentation 3.2.R.2 Medical Devices 3.2.R.3 Lot Release Documentation 3.2.R.4 Yearly Biologic Product Report 3.2.R.5 Assessment of Similarity 3.2.R.6 On Site Evaluation <p>Warning will be reported if the naming of the title is not followed.</p>	Error

ID #	Rule Name	Rule Description	Severity
		<p>Notes:</p> <p>The requirements above apply only to leaves provided using operation attribute "New". They don't apply to leaves provided using operation attribute "Replace".</p> <p>The exact naming convention of the titles of node extensions must be used when the node extension(s) is (are) created for the first time under this heading.</p> <p>If new or replaced leaves are provided when there are already existing node extensions in the 3.2.R Regional information heading, the leaves must be provided under the existing node extensions, even if they don't follow the exact naming convention of the node extension title. Warning generated during the validation can be ignored. Revised</p>	
H - STF 2.2			
H01	Check Index Reference	Verifies that the href target exists and has the correct value.	Error
H02	Check Index Reference (title - match)	Verifies that the href target exists and matches the title value.	Warning
H03	Content Block are not accepted	Reports any used content-block element.	Warning

ID #	Rule Name	Rule Description	Severity
H04	No backslash in HREF	Verifies that href values do not contain backslashes.	Error
H05	Study Identifier category must not be empty	The value of the study-identifier/category element must not be empty.	Warning
H06	Study Identifier study-ID must not be empty	The value of the study-identifier/study-id element must not be empty.	Warning
H07	Study Identifier title must not be empty	The value of the study-identifier/title element must not be empty.	Warning
H08	Categories and file tags	Checks file tag values and category values against definitions in valid-values.xml file. Accepting values as defined in valid-values.xml v5. Revised	Error
H09	STF leaf element must reference other STF leaf upon append	STF leaf element must reference other STF leaf upon append.	Error
		Such leaf elements must not reference PDF files as modified files.	
H10	Category information must be provided for certain STFs	Category information must be provided for certain STFs.	Warning

ID #	Rule Name	Rule Description	Severity
H12	STF cannot reference another STF	Leaf references in STFs must always target content files, not STFs.	Warning
H13	STF does not relate to any leaf elements	STF files must reference at least one leaf.	Warning
H14	Study ID for STF must remain constant	The STF study IDs must not change in the application life cycle.	Warning
H15	Invalid STF TOC location	STFs should only be associated with certain headings under Modules 4 or 5.	Warning
H16	STF doc-content file tag count	There should be one and only one file tag for each doc-content.	Warning
H19	Case Report Form(s) structure in 5.3.7	If Study Tagging Files are used in the current sequence being validated, the node 5.3.7 must not be used. The Case Report Forms must be referenced from the Study Tagging Files. The previous sequences in the same dossier will not be checked.	Error

ID #	Rule Name	Rule Description	Severity
H20	Use Study Tagging Files or Node Extensions	<p>Leaf elements in module 4 (except those in subsection 4.3), with an operation attribute "new", can use either node extensions, STFs or may be placed directly under the TOC sections.</p> <p>Leaf elements in subsections 5.3.1, 5.3.2, 5.3.3, 5.3.4, 5.3.5, and 5.3.7, with an operation attribute "new", can use only node extensions or STFs.</p> <p>Although both node extensions and STFs are acceptable for study reports, only one or the other approach should be used consistently throughout the lifecycle of a leaf. Also, in a specific sequence all leaf elements should use the same approach.</p> <p>Note: Previous sequences in the same dossier will not be checked, and neither will leaf elements with operation attributes other than "new".</p>	Error
<p>I: Regulatory Enrolment Process* New</p> <p>*ONLY for users of the Regulatory Enrolment Process (REP)</p>			
I01	Corrupt xml file	An XML file will be reported as corrupt if the file cannot be opened because the file is damaged.	Error

ID #	Rule Name	Rule Description	Severity
I02	Missing Regulatory Transaction (RT) XML file	<p>Checks the 1.2.1 Application Forms node. Generates error if the RT file is missing from the current eCTD sequence and was provided in the previous eCTD sequence.</p> <p>Note: This rule is not based on the presence of the RT file in the current sequence. This rule is based on the existence of the RT XML file in the previous eCTD sequence. Error must not be generated if there is no RT xml file present in the previous eCTD sequence. Revised</p>	Error
I03	Placement of the Regulatory Transaction (RT) and Product Information (PI) xml files	Verifies the placement of the RT and PI xml files. Generates error if they are placed in a node other than 1.2.1 Application Forms.	Error
I04	Presence of the Submission Application form (3011)	Checks the 1.2.1 Application Forms node. Generates warning if, in addition to the RT xml file, there is a 3011 form named hc-sc-3011-en.pdf or hc-sc-3011-fr.pdf. Revised	Warning

ID #	Rule Name	Rule Description	Severity
I05	Presence of other xml files in the Application Forms node	Checks the 1.2.1 Application Forms node. Generates error if in addition to the RT xml and/or PI xml file there are other xml files.	Error
I06	Comparison of the RT file with the top level folder (Dossier ID folder)	Compares the value in the Dossier ID field in the RT file with the top level folder (eXXXXXX).	Error

Date modified:

2019-03-29