Government of Canada | Gouvernement du Canada

Canada.ca > Departments and agencies > Health Canada

> Drugs and health products > Drug products

> Applications and Submissions - Drug Products

> Guidance Documents – Applications and submissions – Drug products

> Filing submissions electronically

Validation rules for regulatory transactions provided to Health Canada in the non-eCTD format

May 13, 2022
Our file number: 22-105657-165

Health Canada has updated the validation rules for regulatory transactions submitted in the non-eCTD format. These rules are built in accordance with the information provided in the following documents:

- Guidance Document: Preparation of Regulatory Activities in Non-eCTD format
- Guidance Document: The Regulatory Enrolment Process (REP)

The purpose of the validation rules is to help ensure Sponsors provide a valid electronic transaction to Health Canada, and reduce errors and follow-up with Sponsors. Sponsors are encouraged to use a commercially available tool to validate their regulatory transactions in non-eCTD format, prior to filing them to Health Canada.

Health Canada validates each regulatory transaction as it is received. If the validation fails due to one or more errors detected, a Validation Report describing each error will be emailed to the sponsor as a .pdf file attachment.

Version of the non-eCTD validation rules: 5.1

Effective date: August 1, 2022

Should you have any questions regarding the content of this document, please email us at ereview@hc-sc.gc.ca.

Revision Table:

Date	Version	Summary of Changes
August 1, 2022	5.1	A08 – Added new valid file extensions I08 – Added lower case letter "f" followed by 7 digits

Health Canada non-eCTD format Validation Rules version 5.1

ID #	Rule Name	Rule Description	Severity
A – GENERAL			
A01	Empty Folders	This rule is configured to detect empty folders (folders without any files or subfolders) in the transaction structure.	Error
		TIP: All empty folders must be deleted before submitting the transaction to Health Canada.	
A03a	File Size	This rule is configured to verify the size of the files. A warning will be generated for PDF files between 150 MB and 200 MB. A warning will be generated for other file types (excluding SAS XPT) between 100 MB and 200MB.	Warning

ID #	Rule Name	Rule Description	Severity
		TIP: Check the size of each file before submitting to ensure it does not exceed the maximum limits.	
A03b	File Size	This rule is configured to verify the size of the transaction. An error will be generated for PDF files greater than 200 MB, SAS XPT files greater than 1GB and other files greater than 200MB.	Error
		TIP: Check the size of each file before submitting to ensure it does not exceed the maximum limits.	
A08	File types	This rule is configured to verify if the file extensions are valid. The acceptable file extensions are: Documents: .pdf, .doc, .docx, .xls, .xlsx, .wpd, .ppt, .pptx, Images: .png, .gif, .svg, .jpg, .jpeg, .tif, .tiff, .bmp Audio/Video: .wav, .mp3, .mp4, .wmv, .mov, .mpg, .mpeg Coding Language: .xml* Data: .dat, .inf, .txt, .sas, .xpt, .sdax, .edpdp, .wsp, .epr, .pnf, .psf *Applies only to regulatory transaction (rt-*.xml), product information (pi-*.xml) and application information (ai-*.xml) files provided as part of the Regulatory Enrolment Process (REP).	Error

ID #	Rule Name	Rule Description	Severity
		TIP: • Ensure that the file types for your documents are accepted before submitting. • File extensions written in uppercase letters are not accepted. • Do not change the file extension manually.	
A09	Corrupt and password protected WORD documents	Word document will be reported as corrupted or password protected if one or more of the following situations occur: 1. Document is corrupt or unreadable 2. Document has password protection 3. Document references an attached template located via http or https 4. Document is empty Note: This rule applies only to Word version 2007 or later (.docx).	Error
A10	Duplicate Transaction	This rule compares the content of the transaction received with the content of the previous transaction in the same dossier to ensure they are not the same.	Error
B - PDF ANALYSIS			

ID #	Rule Name	Rule Description	Severity
B01	Corrupt or unreadable PDF documents	This rule is configured to detect corrupt or unreadable PDF files within the transaction. An Error will be generated if the document: 1. Cannot be opened because it is damaged. 2. Appears to have zero number of pages. 3. Appears to be an application form, but the form content cannot be read. 4. The document contains additional data (more than 1024 characters) after the last %%EOF (End Of File). An example of situation number (3) could be a document appearing to have one 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."	Error
B24	PDF Protection	This rule is configured to detect if the PDF documents are password protected. An error will be generated if there is a password. **TIP**: Before submitting to Health Canada, ensure PDF documents are not password protected.	Error

ID #	Rule Name	Rule Description	Severity
B25	PDF version checking	This rule is configured to verify that if the PDF document versions are valid. The acceptable PDF versions are 1.4, 1.5, 1.6, and 1.7. **TIP:** Ensure the PDF documents are created using the acceptable PDF versions.	Warning
B32	PDF Protection: Owner password	Finds all documents with an owner password set, excluding Health Canada application forms regardless of their location in the folder structure. **TIP**: Ensure that "No Security" is selected for the "Security Method" displayed in "File", "Properties" and then, "Security".	Warning
B36	Bookmarks - multi action	This rule is configured to detect all bookmarks with multiple actions assigned to them. **TIP**: Ensure that all bookmarks have only one action assigned to it. This action should open the destination page. These settings should be verified in the bookmark properties.	Error
B40	PDF documents with attachments are not allowed	This rule is configured to detect attachments and portfolio documents found in PDF documents. **TIP**: Ensure that the PDF document does not include attachments or portfolio documents.	Error

ID #	Rule Name	Rule Description	Severity
B44	PDF documents with more than 10 pages must have bookmarks	This rule is configured to verify if PDF documents greater than 10 pages have bookmarks. Excluded from this check are: literature references in sections 3.3, 4.3, and 5.4; and Health Canada application e-forms.	Warning
B45	PDF Protection – Printing	Finds all documents where printing is not allowed.	Error
B46	PDF Protection – Content Copying	Finds all documents where copying is not allowed.	Error
B47	PDF Content restrictions	This rule checks for pdf files that contain dynamic content (e.g., audio, video or special effects), or 3D content. Health Canada application forms are excluded from this check regardless of their location.	Error
B48	PDF Content restrictions	This rule checks for PDF files that contain JavaScript. Health Canada application forms are excluded from this check regardless of their location.	Error
C - REFERENCED FILES			

ID #	Rule Name	Rule Description	Severity
C05	Naming Syntax	This rule is configured to verify that the maximum path length including the first level folder of the regulatory transaction must not exceed 200 characters. The file names must not exceed a maximum of 64 characters, including the file extension. Since non-eCTD transactions do not have sequence numbers, the second level folder must not be a sequence folder named nnnn (four digits).	Error
		TIP: File path length character count starts at the application folder and includes the file name. The correct structure path for non-eCTD transaction is x123456\m1.	
I: Regulatory Enrolment Process* ***ONLY for users of the Regulatory Enrolment Process (REP)**			
I01	Corrupt xml file	An XML file will be reported as corrupt if the file cannot be opened because the file is damaged.	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.	Error

ID #	Rule Name	Rule Description	Severity
I08	Dossier ID naming convention	Checks the Dossier ID field in the RT XML file. It must be one of the lower case letters "p", "d", "m", "v", "c" followed by 6 digits, or lower case letter "f" followed by 7 digits.	Error
I09	Product Name and company ID in the RT XML file	Element values for "product-name" and "company_id" must not be empty.	Error
I10	Presence of the RT file	Checks that the transaction has a valid RT XML file based on the root elements TRANSACTION_ENROL or DEVICE_TRANSACTION_ENROL. Error will also be reported if more than one RT is found in the transaction.	Error

Date modified:

2022-05-16