Common Electronic Submissions Gateway (CESG)

Health Canada Reference Guide

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Glossary of Terms

AS2 – Applicability Statement 2 (Gateway-to-Gateway)
CESG – Common Electronic Submissions Gateway
eCTD – electronic Common Technical Document
ESG – Electronic Submissions Gateway
FDA – Food and Drug Administration
REP – Regulatory Enrollment Process
REP CO – REP Company template
REP PI – REP Product Information template
REP RT – REP Regulatory Transaction template
WebTrader – FDA ESG Web Interface

Overview

Health Canada has developed information to assist sponsors file regulatory transactions in eCTD and non-eCTD format that include REP files via the US Food and Drug Administration's (FDA) secure Electronic Submissions Gateway (ESG), also referred to as the Common Electronic Submissions Gateway (CESG) for Health Canada users.

Sponsors have two options available for CESG accounts:

Option 1: FDA ESG Web Interface (WebTrader) account
Option 2: Applicability Statement 2 (AS2) Gateway-to-Gateway account

To determine which option best fits your company's business requirements, regulatory activity types, and infrastructure capabilities, please visit Section 3.5 of the FDA's User Guide.

This document provides information on how to set up and use a WebTrader account. If your company is considering an AS2 account, please reach out to the FDA directly for setup instructions and guidance.

Step 1: Registering as a Trading Partner with Food and Drug Administration (FDA)

Registration with FDA

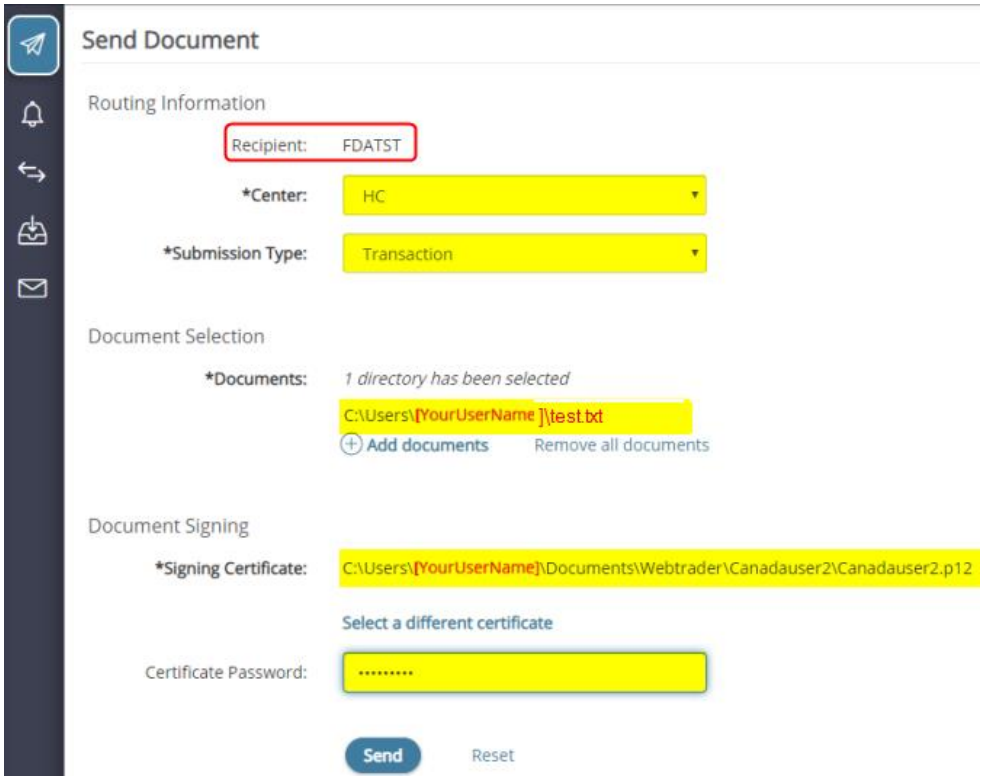
Registration is required for **each** WebTrader account within a company (e.g a company with an existing account is setting up an additional CESG account, or a company is setting their first CESG account). The account user will needs to complete the FDA Electronic Submissions Gateway (ESG) registration process. Information related to the ESG can be found in the FDA's User Guide. The FDA has also put together a convenient checklist, with the activities and requirements for companies preparing to setup a WebTrader account.

The registration steps are:

1) Request a WebTrader account
    - Obtain a Digital Certificate. For more information on how to obtain Digital Certification, please see section: Digital Certificate.
2) Register your test account
3) Setup your machine/PC for ESG
4) Send "test transaction" (submission) – Test transaction is required when setting up all new user accounts. You are required to send a **TEXT** (*sample.txt*) file to the HC (Health Canada) center **using your WebTrader test account.** The content of the TEXT files are not reviewed. Once you send the TEXT file, you should receive the following two messages:
    - The first is the: *Message Disposition Notification (MDN)*
    - The second is the: Acknowledgement containing the *Message ID* and the *Core ID*.
5) After you received the two messages, please send an email to ESGHelpDesk@fda.hhs.gov with the Acknowledgement's *Core ID* from the second message. **Note:** The test transaction **must not** be sent via the production WebTrader account.

    The WebTrader "Routing Information" fields for a *sample.txt* test transaction should be as filled out as below:
    - Recipient: **FDATST**
    - Center: HC
    - Submission Type: Transaction

    Example 1: Screenshot outlining the WebTrader information when sending a *sample.txt* test transaction



The registration process is handled entirely by FDA; Health Canada is not involved in this step. Therefore, questions at this stage in the process should be directed to the FDA's Help Desk, at ESGHelpDesk@fda.hhs.gov.

After completing the registration steps with FDA, the test account will be migrated to Production, and you may begin using the CESG for sending regulatory transactions to Health Canada.

Digital Certificate

A digital certificate must be obtained. Digital certificates ensure private and secure transmission of electronic documents. The digital certificate binds together the owner's name and a pair of electronic keys (a public key and a private key) that can be used to encrypt and sign documents.
Digital certificates can be obtained from either a public or a private Certificate Authority (CA). It must be a X.509 version 3 certificate and all data fields in the "Issuer" and "Subject" fields must be completed. Few options are provide below, please refer to the FDA document *ESG Appendix C: Digital Certificates* for more information.

In-House
An in-house PKI makes it possible to achieve complete control of security policies and procedures. It also carries the burden of management and cost to set up and maintain the system.

Self-Signed
FDA has created a free tool to help WebTrader users create a self-signed certificates for use with ESG. Users can use this certificate for new accounts as well as for certificate renewals for existing accounts. **Note**: AS2 (Gateway-to-Gateway) users should not use these certificates, they must obtain their own encryption certificate.
Access the free tool from: https://esgcertificate.assyst.net/

Outsourced
Third-party certificate authorities can be leveraged to purchase X.509 certificates for general use. The CA manages the security policies and details such as certificate revocation.
If you plan to use an outsourced certificate, the following are just a few of the many companies that sell the X.509 certificates (Displayed in alphabetical order).

Note: References to commercial products are for illustrative purposes only and does not constitute an official FDA endorsement. If you are a CA and would like to list your URL here, please send the URL linking to your Class 1 Personal Identification certificate page to ESGHelpDesk@fda.hhs.gov.

- ComSignTrust: https://www.comsigntrust.com/digital-certificates/External Link Disclaimer
- Exostar: http://www.myexostar.com/Digital-Certificate-Service-OverviewExternal Link Disclaimer
- IdenTrust: https://www.identrust.com/partners/food-and-drug-administration-fda-electronic-submission-gateway-esgExternal Link Disclaimer

- Intesi Group: https://www.intesigroup.com/en/fda-esg-digital-certificate/External Link Disclaimer
- GlobalSign:http://www.globalsign.com/digital_certificate/personalsign/index.htm#2External Link Disclaimer
- SAFE Identity:https://makeidentitysafe.comExternal Link Disclaimer
- Sectigo: https://secure.instantssl.com/products/frontpage?area=SecureEmailCertificateExternal Link Disclaimer
- TAIWAN-CA (TWCA): https://www.twca.com.tw/External Link Disclaimer
- TRAN SPED: https://www.transsped.com/certifications

Step 2: Sending Transactions via the Production Account

After your company has been migrated to production, you may begin sending transactions to Health Canada. Refer to the below examples for guidance on the preparation, structuring and sending of transactions using the CESG WebTrader account.

Transaction for the REP draft CO XML file

This transaction is only used for the company enrolment/amendment process as described in the REP guidance document.

How to Send a REP Draft CO xml file to Health Canada via the CESG

1) Please consult the company enrolment/amendment section of the REP Guidance Document for details on when to submit a CO XML file.

2) Once you have generated your draft CO XML file, and created your top-level folder (e.g. rep<companyname>), you may login to the FDA Production Webtrader and navigate to the "Send Document" tab.

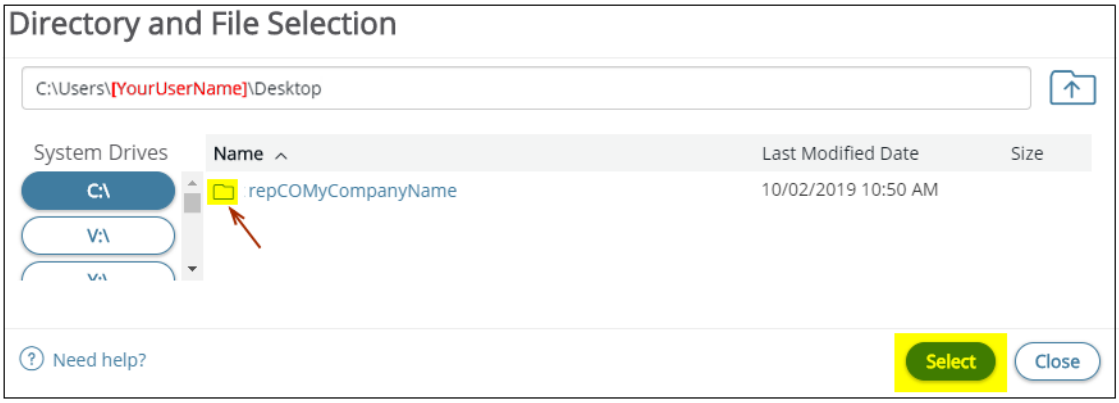
3) Fill out the "Routing Information" fields, as per below:
   - Recipient: **FDA***
   - Center: HC
   - Submission Type: Transaction

   ***Important:** once the test account has been migrated to production, the test account will also remain active and therefore each user can send transactions using the test gateway or production gateway. You will need to verify the Recipient information before sending your production transaction to ensure it is FDA. Health Canada is not checking the test environment, therefore any production transactions accidently sent via the test gateway (FDATST) will not be processed.

4) When selecting a document using the browsing tool, it is helpful to paste a copy of the entire folder to an easy-access location, such as your desktop.

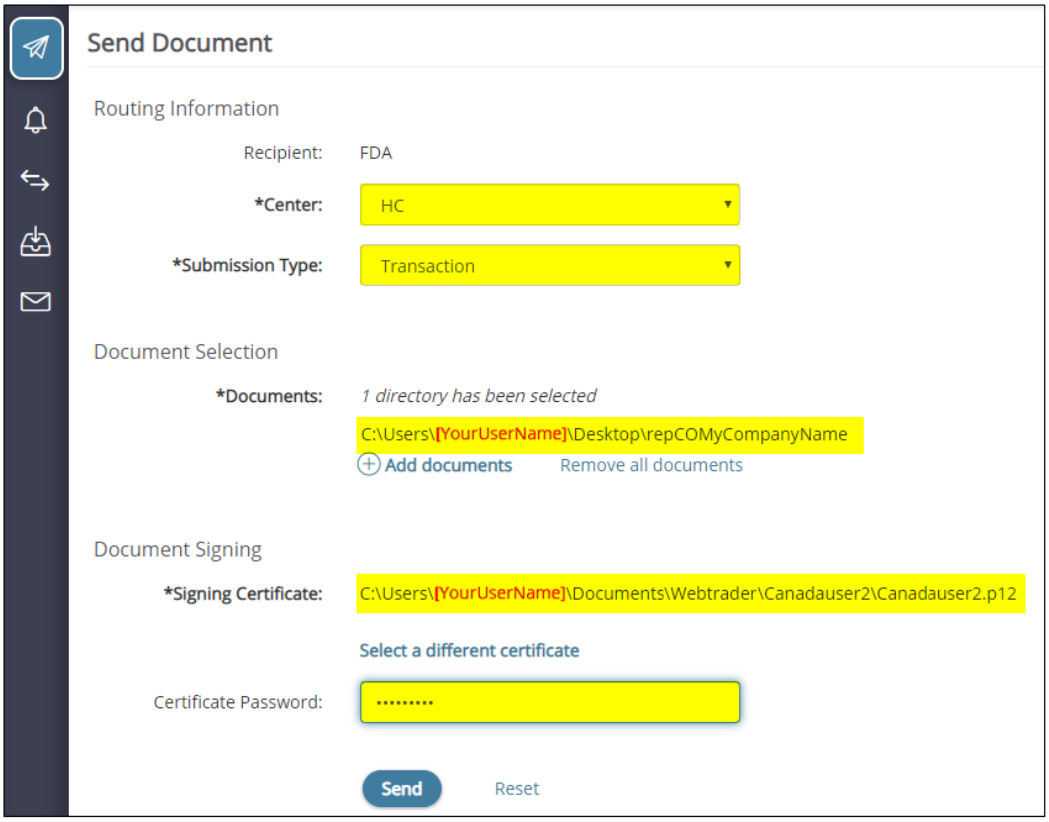
5) Once you have located the folder containing the CO XML file, click on the folder icon (), **not on the folder name** (*e.g. repCOMyCompanyName*); refer to the screenshot below.

Be careful: Clicking on the folder name, instead of the folder icon, will drill down an extra level and will send the transaction to Health Canada *without* the top-level folder. Transactions without a top-level folder will not be processed. The company will have to resend a corrected transaction again via the CESG.



6) After clicking the "Select" button, you will be brought back to the main "Send Document" tab. Here, you will be required to retrieve your "Signing Certificate" and enter your "Certificate Password".

7) The below screenshot is an example of how the "Send Document" should look when all the fields are populated.



8) When complete, click the “Send” button. You should then see a green bar that reads: “Your upload has been added to the queue. Completed uploads can be viewed in your "Sent Items" folder.”

9) From here, navigate to the “Inbox” tab. You must wait to see one Receipt and two Acknowledgements next to the *Delivered* indicator, as confirmation that your transaction has been received by Health Canada.

   Note: If you do not receive the Receipt confirmation or either of the two Acknowledgements, after a few hours, please email the Health Canada eReview team, at hc.ereview.sc@canada.ca.

10) Once the draft CO XML file has been processed, Health Canada will return the final CO XML file back to you via the same CESG account, using the *Core ID*. The xml file can be located in the WebTrader inbox in a zipped format. Please store the final CO XML file in a safe place for future references or amendments.

How to retrieve a final CO XML file sent from Health Canada

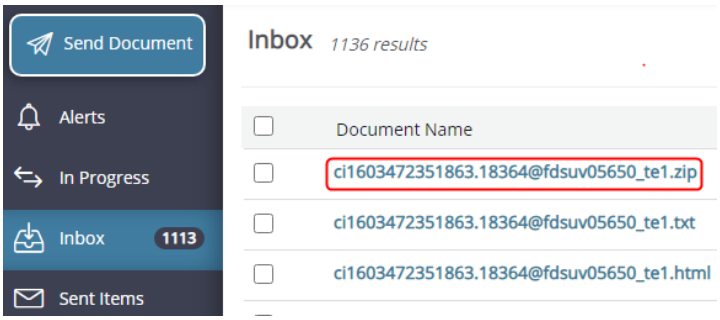
Once Health Canada finalized the CO file, it will be sent back to the sponsor via the CESG using the same *Core ID* that was created when the latest draft CO file was sent. The final xml file is provided as a .zip file

named using the *Core ID.zip* (e.g.: ci1603472351863.18364@fdsuv05650_te1.zip). The example below displays the interface for WebTrader accounts.

There are two ways to retrieve the final XML file:

1) In the Inbox

The *Core ID.zip* file will appear in the inbox as a stand-alone entry based on the "Document Name" being the *Core ID* with extension *.zip*. The zip file must first be downloaded to a location on your computer/pc before the final CO XML file is extracted.



2) In the Sent Items

The *.zip* file will appear in the "Sent Items" as the third (3rd) Acknowledgment based on the "Document Name" being the name of the top-level folder created when the latest draft CO file was sent. To retrieve the final CO file, click on the *.tar.gz* file and the very first entry will be the *Core ID.zip* file. The zip file must first be downloaded to a location on your computer/pc before the final CO XML files is extracted.

Regulatory Transactions in Non-eCTD Format

A regulatory transaction in non-eCTD format contains the content files for review as well as REP RT file, PI file when required.

How to Send a *Regulatory Transaction* in non-eCTD format to Health Canada, using FDA Production WebTrader account

1) Consult the Guidance Document: Preparation of Regulatory Activities in the "Non-eCTD Electronic-Only" Format when building regulatory transactions in non-eCTD format.

2) Login to FDA Production WebTrader and navigate to the "Send Document" tab.

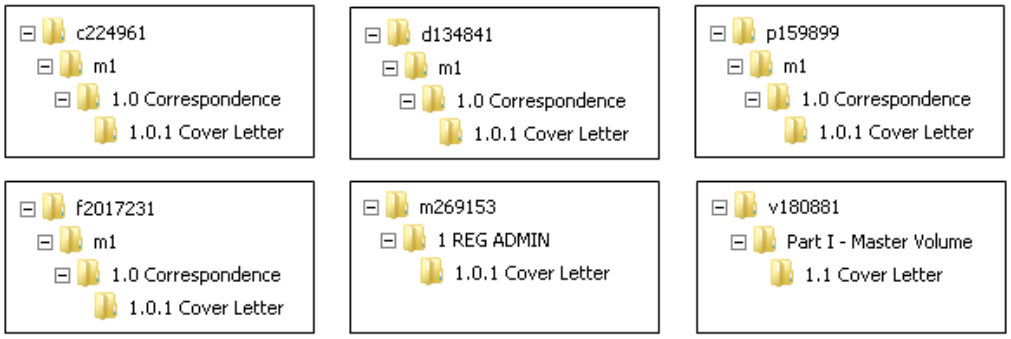
3) Fill out the "Routing Information" fields, as per below:
   - Recipient: **FDA***
   - Center: HC
   - Submission Type: Transaction

   ***Important:** once the test account has been migrated to production, the test account will also remain active and therefore each user can send transactions using the test gateway or production gateway. You will need to verify the Recipient information before sending your production transaction to ensure it is FDA. Health Canada is not checking the test environment, therefore any production transactions accidently sent via the test gateway (FDATST) will not be processed.

4) When selecting a document using the browsing tool, it is helpful to first paste a temporary ready to be sent copy of the whole transaction to a folder in an easy-access location, such as your desktop. The top-level folder **must** be named with the "dossier ID" for the regulatory transaction.

   Below is a list of each dossier type and the lowercased letter associated with the specific regulatory activity type, along with six(6) numeric digits to form the dossier ID:

   Clinical Trials Dossier ID: Lowercase letter 'c' followed by a six-digit identifier (e.g. *c123456)*.
   Pharmaceutical / Biological Dossier ID: Lowercased letters 'd' (Div. 1) or 'p' (Div. 8) followed by a six-digit identifier (e.g. *d123456* or *p123456*).
   Master Files (MF) Dossier ID: Lowercased letter 'f' followed by a seven-digit identifier (*e.g. f1234567*). This seven-digit number is an adaptation of the MF Number (*e.g. MF 1234-567*).
   Medical Devices Dossier ID: Lowercased letter 'm' followed by a six-digit identifier (*e.g. m123456*).
   Veterinary Drugs Dossier ID: Lowercased letter 'v' followed by a six-digit identifier (*e.g. v123456*).



Important considerations:

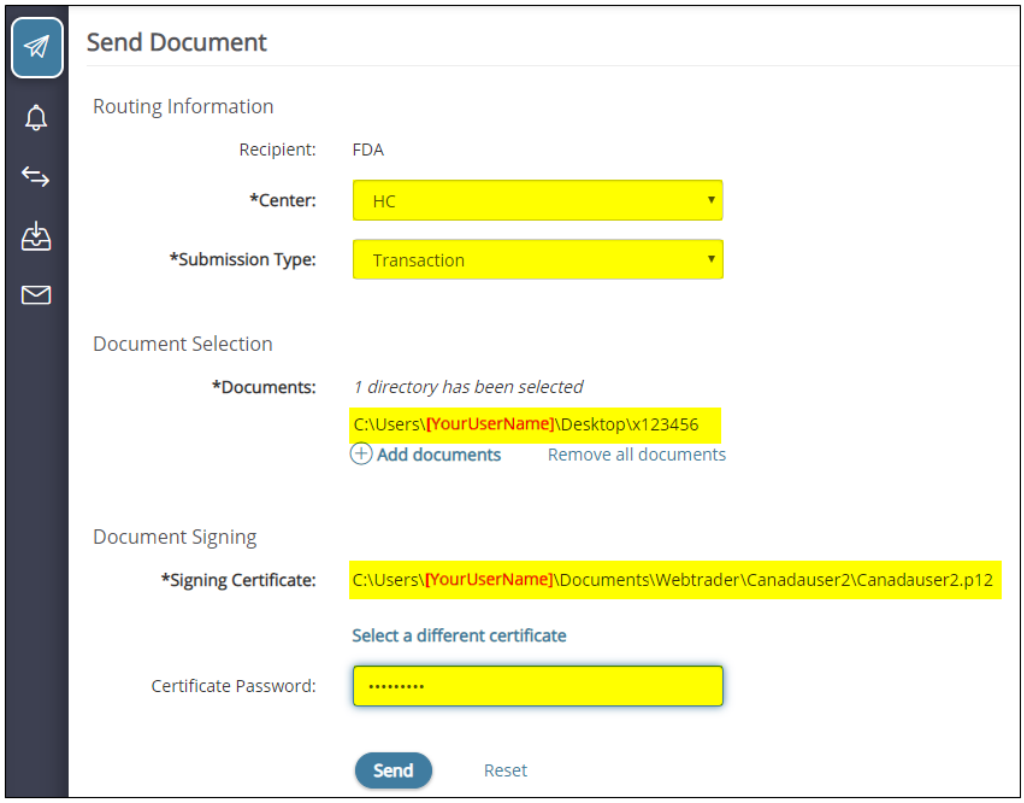
- This step applies to all regulatory transactions; be it the first, or the sixth, seventh, eighteenth, etc. It is important to always create a copy of the regulatory transaction you wish to file, and paste **just that one transaction** inside a folder named with the appropriate dossier ID. Attaching a transaction from a folder containing multiple transactions will result in you sending them all to Health Canada, which will result in a failed transaction. Please refer to the **Temporary Folder Structure** section of this document for more details.
- Information provided in previous transactions must **not** be provided again, unless it has been changed (i.e.: a MF update, MF letter of access, administrative change, response to NON, response to NOD, response to SDN, etc.).
- Health Canada must not be receiving loose files. Please refer to the guidance document applicable to your regulatory activity type for instructions on folder structure and file placement.

5) Once you have located the folder named with the dossier ID, click on the folder icon (), **not** on the folder name (e.g. *x123456*), before clicking the 'Select' button (refer to screenshot below).

Be careful: Clicking on the folder name (dossier ID), instead of the folder icon, will drill down an extra level and will send the transaction to Health Canada *without* the top-level folder. Transactions without a top-level folder will not be processed. The company will have to resend a corrected transaction again via the CESG. Please refer to the FDA's FAQs for more information on using the WebTrader client.

6) After clicking the “Select” button, you will be brought back to the main “Send Document” tab. Here, you will be required to retrieve your *Signing Certificate* and enter you *Certificate Password*.

7) The below screenshot is an example of how the “Send Document” should look when all the fields are populated.



8) When complete, click the “Send” button. You should then see a green bar that reads: “Your upload has been added to the queue. Completed uploads can be viewed in your "Sent Items" folder.”

9) From here, navigate to the "Inbox" tab. You must wait to see one Receipt and two Acknowledgements next to the *Delivered* indicator, as confirmation that your regulatory transaction has been received by Health Canada.

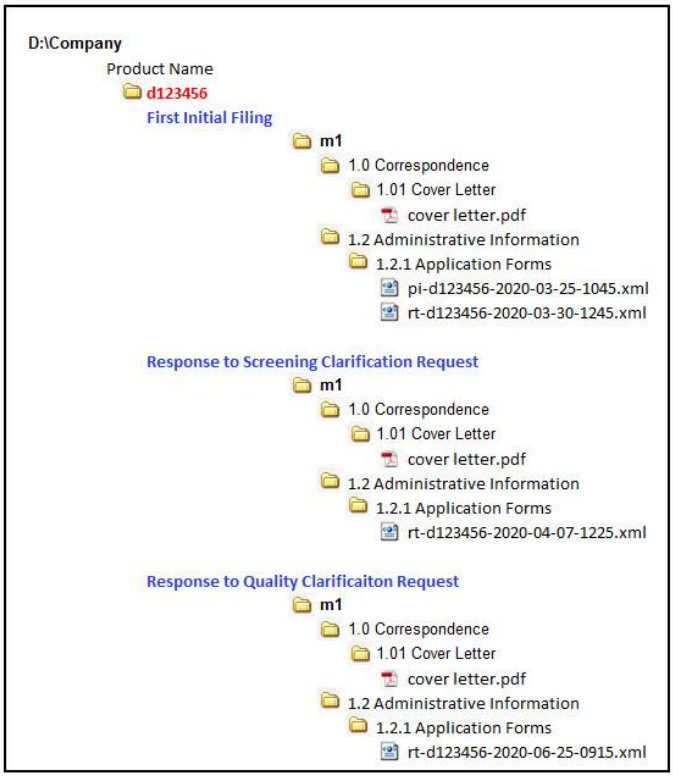
Note: If you do not receive the Receipt confirmation or either of the two Acknowledgements, after a few hours, please email the Health Canada eReview team, at hc.ereview.sc@canada.ca.

10) If you wish to see the progress of your transaction at any point after sending it to Health Canada, you can verify on the *Drug Submission Tracking System - Industry Access (DSTS-IA).* Please do not email eReview about the status of your submission, as eReview does not handle submission status inquiries.

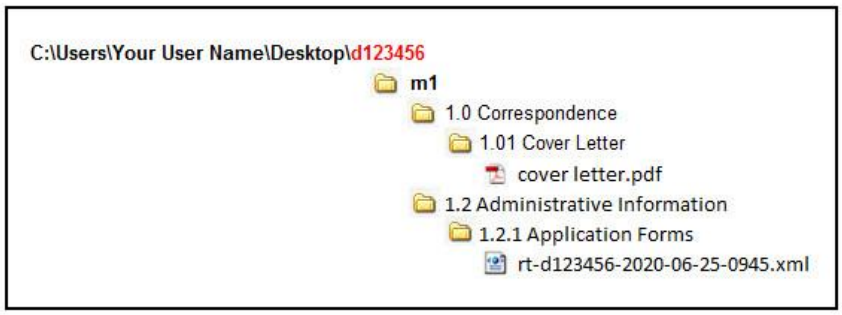
Temporary Folder Structure for regulatory transactions in non-eCTD format

Sponsor have many ways to set up their file system or document management system where they keep regulatory transactions based the licence names, medicinal ingredients, company, dossier, etc. How this is managed is left up to the sponsor.

Note: the examples below **do not** display complete content files required for a regulatory transaction. Please ensure to add **all folders and content files** as required for the particular regulatory activity or regulatory transaction. For the structure and the document placement, refer to the *Organisation and Document Placement for Canadian Module 1*, available on the Filing Submissions Electronically page.



When a transaction is validated and ready to be sent via the CESG (e.g. A *Response to Quality Clarification Request)*, please ensure that a temporary dossier ID folder is created outside of the document system, somewhere in the desktop or in a different location. The transaction that has to be sent to Health Canada is placed in this folder. Additional subfolders or files that have been submitted in a previous transaction **must not** be added in this temporary folder.



In the document selection in the WebTrader, you will need to verify the path of the document. It must end with the dossier ID (*i.e.* ***C:\Users\Your User Name\Desktop\d123456***).

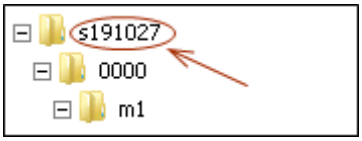
This will ensure that Health Canada will receive only the desired transaction, contained in the top-level folder.

Regulatory Transactions in eCTD Format

A regulatory transaction in eCTD format contains the content files for review as well as REP RT file, PI file when required.

How to send an *Sample Transaction* in eCTD format to Health Canada, using FDA Production WebTrader account

1) Consult section 4.1 of the Guidance Document: Preparation of Regulatory Activities in eCTD Format when building regulatory transactions in eCTD format and other eCTD format related guidance documents outlined on website Filling Submissions electronically.
2) Send an email to the Health Canada eReview team, at hc.ereview.sc@canada.ca, with the information below. Doing so will allow the eReview team to send out any additional information, pertaining to your specific situation.
    - Type of submission you are planning on filing (MF Type I, II, III, or IV; NDS; etc.).
    - The name of any third party consultant (if you are not building your own sequences).
    - The name of the eCTD software you are using to build your transactions/sequences.
3) The sample transaction in eCTD format must have a top-level folder, named with a sample dossier ID. The sample dossier identifier start with 's' followed by six digits representing the current date in yymmdd format (e.g. on October 27th, 2019, the sample dossier ID would be s191027.)



4) Login to your FDA production WebTrader and navigate to the "Send Document" tab.
5) Fill out the "Routing Information" fields, as per below:
    - Recipient: **FDA***
    - Center: HC
    - Submission Type: Transaction

    ***Important:** once the test account has been migrated to production, the test account will also remain active and therefore each user can send transactions using test gateway or production gateway. You will need to verify the Recipient information before sending your production transaction to ensure it is FDA. Health Canada is not checking the test environment, therefore any production transactions accidently sent via the test gateway (FDATST) will not be processed.

6) When selecting a document using the browsing tool, it is helpful to paste a copy of the entire folder to an easy-access location such as your desktop. Be sure to that you copy the entire test transaction, from the dossier ID level, onward (e.g. **s191027**/0000/m1/…).

7) Once you have located the folder named with the dossier ID, click on the folder icon ( ) **not**

on the folder name (*e.g. s191027*); refer to the screenshot below.

Be careful: Clicking on the folder name instead of the folder icon will drill down one extra level and will send the transaction to Health Canada *without* the top-level folder. Transactions without a top-level folder will not be processed.

8) After pressing the "Select" button, you will be brought back to the main "Send Document" tab. Here, you will be required to retrieve your *Signing Certificate* and enter your *Certificate Password*.

9) When complete, click the "Send" button. You should then see a green bar that reads: "Your upload has been added to the queue. Completed uploads can be viewed in your "Sent Items" folder."

10) From here, navigate to the "Inbox" tab. You must wait to see one Receipt and two Acknowledgements next to the *Delivered* indicator, for confirmation that your regulatory transaction has been received by Health Canada.

Note: If you do not receive the Receipt confirmation or either of the two Acknowledgements, after a few hours, please send an email to Health Canada at hc.ereview.sc@canada.ca.

11) Once your test sample has been sent, please advise the Health Canada eReview team, via email, at hc.ereview.sc@canada.ca.

12) The sample will be validated and evaluated and written feedback will be provided via email.

How to Send a *Regulatory Transaction* in eCTD format to Health Canada, using FDA Production Webtrader account

1) Consult the guidance documents below when building your transaction:
   - Guidance Document: Preparation of Drug Regulatory Activities in the eCTD Format
   - Guidance Document: Creation of the Canadian Module 1 Backbone
   - Other eCTD related guidance documents posted on the Filing Submissions Electronically and Regulatory Enrolment Process pages.

2) Login to your FDA Production webtrader and navigate to the "Send Document" tab.

3) Fill out the "Routing Information" fields, as per below:
   - Recipient: **FDA***
   - Center: HC
   - Submission Type: Transaction

   ***Important:** once the test account has been migrated to production, the test account will also remain active and therefore each user can send transactions using test gateway or production gateway. You will need to verify the Recipient information before sending your production transaction to ensure it is FDA. Health Canada is not checking the test environment, therefore any production transactions accidently sent via the test gateway (FDATST) will not be processed.

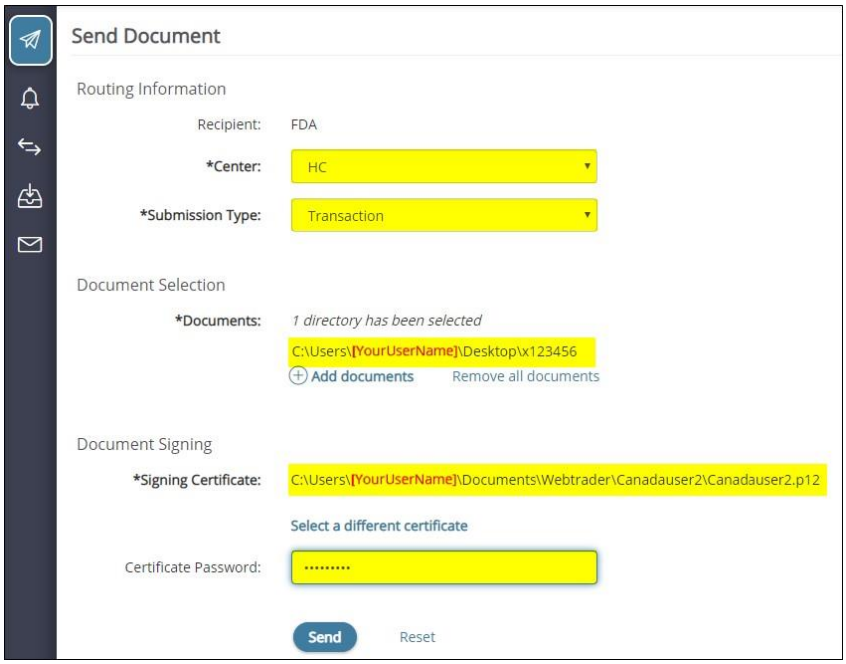
4) When selecting a document using the browsing tool, it is helpful to first paste a temporary copy of the transaction/sequence to a top-level folder in an easy-access location, such as your desktop. The top-level folder must be named with the transaction's dossier ID issued to you by Health Canada (*e.g. e123456*). **Please note:** This step applies to all sequences, be it the first transaction (Seq. 0000), or the sixth, seventh, eighth, etc. It is important to *always* create a copy of the transaction you wish to send, and paste **just that one** transaction/sequence inside a folder named with the appropriate dossier ID. Attaching the sequence from a folder containing multiple sequences will result in you sending them all to Health Canada, which will result in a failed transaction.

5) Once you have located the folder named with the dossier ID, click on the folder icon ( ) **not on the folder name** (*e123456*), before clicking the 'Select' button, refer to the screenshot below.

   Be careful: Clicking on the dossier ID, instead of the little folder icon, will drill down an extra level and will send the transaction to Health Canada *without* the top-level folder. Transactions without a top-level folder will not be processed.

6) After clicking the "Select" button, you will be brought back to the main "Send Document" tab. Here, you will be required to retrieve your *Signing Certificate* and enter your *Certificate Password*.

7) The below screenshot is an example of how the "Send Document" tab should look when all the fields are populated



8) When ready, press Send. You should now see a green bar that reads "Your upload has been added to the queue. Completed uploads can be viewed in your 'Sent Items' folder."

9) From here, navigate to the Inbox tab. You must wait to see one Receipt and two Acknowledgements next to the Delivered indicator, as confirmation that your regulatory transaction has been received by Health Canada.

Note: If you do not receive the Receipt confirmation or either of the two Acknowledgements, after a few hours, please email the HC eReview team, at hc.ereview.sc@canada.ca.

10) If you wish to see the progress of your transaction, at any point after sending it to Health Canada, you can verify on the *Drug Submission Tracking System - Industry Access (DSTS-IA).* Please do not email eReview about the status of your submission, as eReview does not handle submission status inquiries.