EDQM roadmap for electronic submissions

Cornelia Bigler Weber
scientific assistant
Certification Department, EDQM
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Agenda

- eSubmissions Roadmap for CEP applications with its major changes to current practices and key deadlines
- How to submit CEP applications in electronic format
- Baseline submissions
- EU module 1 specifications version 3.0.1/3.0.2 for eCTD
- Common European Submission Portal (CESP) for CEP applications

Current situation

Submission format	New CEP applications	Revisions /Renewals
PDF	41%	47%
NeeS	17%	20%
eCTD	42%	33%

Blocking at reception for format reasons: 7%

Single and secure entry point for submission of data:

HMA Common European Submission Portal **CESP**

EDQM eSubmissions Roadmap - Goals

- Efficient and secure electronic handling of data related to CEP applications (submission, reception, validation, processing)
- Automation of data transfer and storage
- Standard and consistent electronic format for dossiers
- Alignment with practice in place in regulatory agencies for eSubmission of marketing authorisation applications

eSubmission Roadmap

Topic	Objectives	Time-frames
Submission format and content	Single format for submission of data: **eCTD** (except for TSE only submissions and for submissions for substances for veterinary use only)	2020
Receipt and validation of data	Automation of data transfer and storage, reduction of manual handling and checks	2018
Application form	Implement e-Application form	2018

Submission format and content

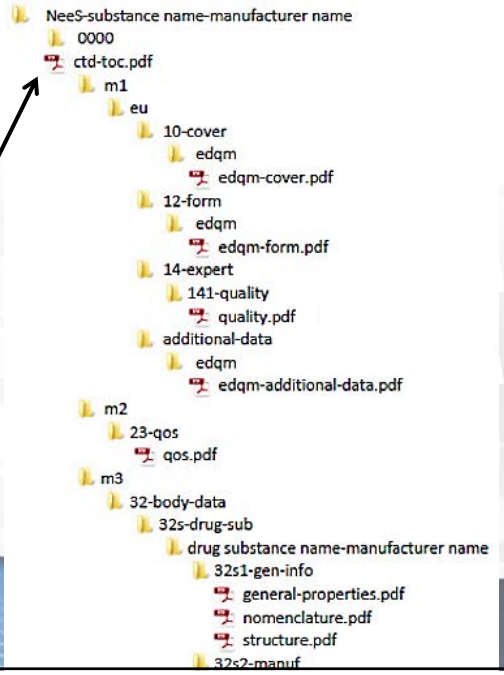
PDF submissions

eCTD

Timeframe	Actions
January 2018	Require eCTD submissions for new applications
January 2018	Stop accepting PDF submissions for revisions and renewals. Therefore, all such submissions need to be in NeeS or eCTD format
January 2020	Require eCTD submissions for all applications

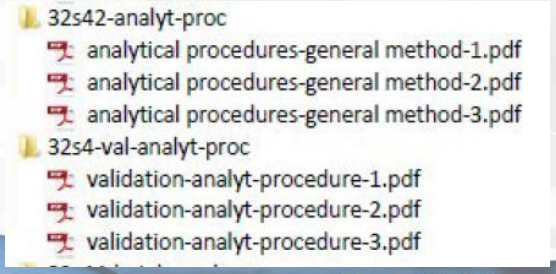
How to send a NeeS submission

- Structure according to Annex 2 and 4 of esubmission guidance
- A table of content with hyperlinks towards each file should be placed within the sequence



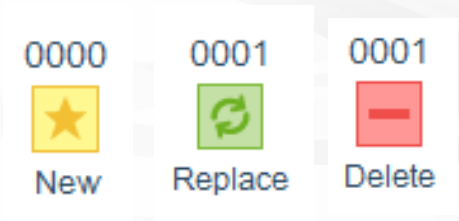
How to send an eCTD submission

- Once eCTD – always eCTD: coming back to a previous submission format is not allowed
- For each update a new sequence 000(X+1) should be provided
- For some sections, a multiple file approach can be used, but there are limitations to the number of files included in one section



How to send an eCTD submission

- Before submitting to EDQM, the submission should be technically validated with an appropriate validation tool
- The operation attributes chosen should be appropriate



How to avoid common format errors

- Use the CESP, do **not** send documentation via email
- Annexes/attachments are not allowed in module 3, they should be integrated into the relevant CTD sections
- Coming back to a previous submission format is not allowed
- All files should be in PDF format

Baseline Module 3

- Consolidated picture of all the CTD sections already assessed and approved
- Facilitates the management of the lifecycle for the applicant and EDQM
- Highly recommended when switching from PDF/NeeS to eCTD
- Baseline should be submitted at the start of a procedure
  - either as a separate sequence (preferred option)
  - Or including a revision/renewal application

EU Module 1 eCTD specifications

Version 3.0.1 /3.0.2 as of April 2017

- Country code (cc): **edqm**
- EU-envelope:
  - Country: **edqm**
  - Submission type: **cep** (for all applications regarding CEPs)
  - Submission number: **cep application number if known**
  - Agency code: **EU-EDQM**

- eCTD Validation criteria v6.1

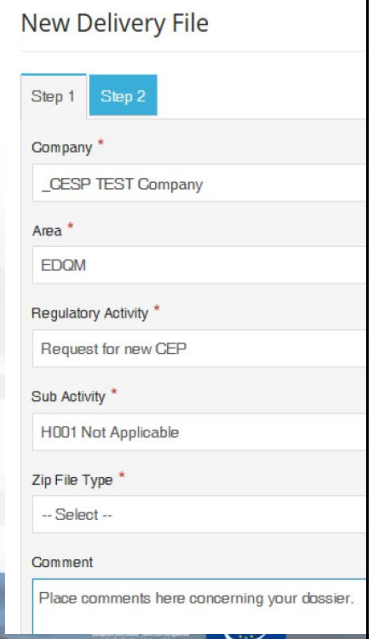
CESP version 2.0

Delivery file information:

Area: EDQM

Regulatory activities:

- Request for new CEP
- Notification/revision/renewal
- Response to request for additional information
- EDQM inspection
- Other
- **Comment:** CEP number, substance name



Useful links

- **Guidance for electronic submissions for Certificates of Suitability (CEP) applications**

https://www.edqm.eu/sites/default/files/guidance_for_esubmissions_foe_cep_applications-november2016.pdf

- **EDQM helpdesk**

https://www.edqm.eu/en/faq-helpdesk-certification-and-ceps

- **EU esubmission**

http://esubmission.ema.europa.eu

- **EU Module 1 eCTD Specifications**

http://esubmission.ema.europa.eu/eumodule1/index.htm

- **TIGes/CMB harmonised NeeS guidance:**

http://esubmission.ema.europa.eu/tiges/docs/NeeS%20eGuidance%20Document%20v4%200_final%20for%20publication%20Nov%202013.pdf

Useful links

- **ICH website**

http://www.ich.org/home.html

- **CESP**

http://cespportal.hma.eu/

- **Use of CESP for CEP applications**

https://www.edqm.eu/sites/default/files/pa_ph_cep_13_67_2r.pdf

If you have further questions, please do not hesitate: cep@edqm.eu

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