

Standard operating procedure

Title: Translation workflow of EMA documents				
Status: PUBLIC		Document no.: SOP/PDM/1400		
Lead author	Approver	Effective date: 21-SEP-10		
Name: Carlotta Giordano	Name: Beatrice Fayl	Review date: 21-SEP-10		
Signature: On file	Signature: On file	Supersedes: SOP/T/1400 (20-DEC-05)		
Date: 21-SEP-10	Date: 21-SEP-10	TrackWise record no.: 2877		

1. Purpose

The purpose for this SOP is to define the procedure for managing correctly and consistently the translation workflow of EMA documents to and from the Translation Centre for the Bodies of the European Union (CdT) in Luxembourg.

2. Scope

This SOP applies to the European Medicines Agency's staff requiring translations of EMA documents and to the Document & Information Services (V-PD-DIS) Section.

3. Responsibilities

It is the responsibility of the V-PD-DIS Assistant-Translations to ensure that this procedure is adhered to. In case of absence of the Assistant-Translations, members of the V-PD-DIS assume the duties.

4. Changes since last revision

Procedure, responsibilities and flowchart have been revised.

5. Documents needed for this SOP

'CdT Worksheet' – the Web-Flosys electronic translation request.

'CdT Analysis' – Excel spreadsheet for invoices.

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom **Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<xxx xxxx> **E-mail** info@ema.europa.eu **Website** www.ema.europa.eu



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'CdT Client Satisfaction Form' (CSF) – form to be used for quality feedback to CdT on translated documents.

'Translation Log' – Excel spreadsheet for logging translation requests details.

WIN/PDM/1401 on the internal processing of translation requests of EMA documents with the CdT.

6. Related documents

'CdT Naming Convention for Documents' – E-mail (dated 27 Jan 2003).

'CdT Pricing rules for Translation Work' – Annual price list and types of services.

'CdT/EMA Translation Workplan' – Annual Workplan.

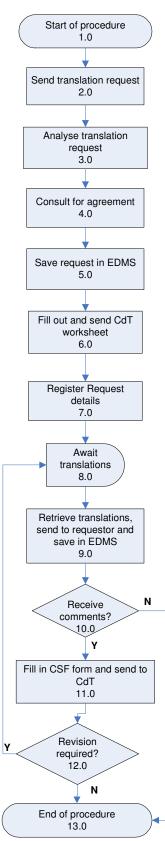
7. Definitions

CdT = Translation Centre for the Bodies of the European Union.

CdT Worksheet = the Web-Flosys electronic translation request.

EMA = European Medicines Agency.

Request = request for new translation job, including original document(s) and reference document(s). V-PD-DIS = Document & Information Services Section. 8. Process map(s)/ flow chart(s)



9. Procedure

Step	Action	Responsibility
1.0	Start of Procedure	
2.0	Send request for new translation job, including original document(s), reference document(s) and date of deadline, via e- mail to <u>translationsrequests@ema.europa.eu</u> (request to be submitted no later than 3 pm, if to be processed on the same day)	Author/Requesting person
3.0	Analyse request, determine number of document pages and select type of service/deadline/pricing according to latest `CdT Pricing rules for Translation Work' and EMA Workplan	V-PD-DIS
4.0	Consult with Author/Requesting Person for agreement	V-PD-DIS
5.0	Save Request in relevant DREAM folder according to CdT Naming convention (see also WIN/PDM/1401)	V-PD-DIS
6.0	Fill out and send CdT worksheet attaching any reference document(s) to the CdT	V-PD-DIS
7.0	Register details of each request in 'Translation Log' and 'CdT Analysis'	V-PD-DIS
8.0	Await return of translation(s) from CdT	V-PD-DIS
9.0	Retrieve translation(s) from e-mail(s), send to Author/Requesting person and save sent e-mail(s) in relevant DREAM folder	V-PD-DIS
10.0	Comments received on layout, formatting and/or quality from Author/Requesting Person?	V-PD-DIS
	If yes, go to 11.0	
	If no, go to 13.0	
11.0	Send CdT Client Satisfaction Form to Author/Requesting person to fill in section 4, 5 and 6. Once returned, e-mail it to CdT with relevant documentation	V-PD-DIS
12.0	Revision of translation required?	V-PD-DIS
	If yes, go to 8.0	
	If no, go to 13.0	
13.0	End of Procedure	V-PD-DIS

10. Records

All electronic correspondence and related documents are kept in the relevant folders in DREAM.

Hard copies of CdT worksheets for each job are filed in the office of the Assistant-Translations.