

Certification of Substances Department

HB/CB

PUBLIC DOCUMENT

(LEVEL 1)

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Certification of suitability to the Monographs of the European Pharmacopoeia

Management of CEP guidelines and operational documents for the CEP procedure

Implementation date	December 2022
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1. Scope and background

This document describes the process for elaboration of various documents issued by the EDQM and supporting the Certification of Suitability (CEP) procedure.

It covers the following categories of documents:

- governance documents for the CEP procedure, intended to lay down the procedural aspects linked to the practical implementation of the CEP procedure (such as *Rules of Procedure*, *Code of Practice*, etc.);
- technical guidelines, intended to communicate the requirements in place for the submission or evaluation of CEP applications (such as “Content of the dossier for chemical purity”, “Guideline for revisions of CEP applications” etc.);
- administrative or operational documents, intended to clarify specific aspects of the procedure or to facilitate the submission of CEP applications by companies (such as complaints management, applications forms for CEPs etc.).

The elaboration process is intended to ensure that the development, stakeholders’ consultation, final adoption, publication and implementation of CEP documents are both efficient and transparent. The steps involved depend on the category of the document, as described in the sections below.

The process for CEP documents is placed under the responsibility of the CEP Steering Committee (SC) as described in the EDQM document *CEP Terms of Reference and Rules of Procedure* (PA/PH/CEP (01) 1).

Whenever possible, the documents covered by this process are intended for release to the public; however some of them, depending on their content, may be for restricted use by the bodies involved in the CEP procedure. The ultimate destination (public or restricted) of a document, as well as the details of the consultation process, are decided by the CEP Steering Committee.

The Resolution on the Certification procedure is outside the scope of this document as it follows the specific process for resolutions established by the Council of Europe. Any proposed revision of the Resolution should be approved by the CEP Steering Committee before being submitted to the adopting body.

2. Numbering system and language

Governance documents and technical guidelines carry a unique reference code in the format **PA/PH/CEP (XX) YY**. When these documents are revised, a revision number (“ZR”) is added to the end of this initial code number. The revision history of a document is provided within it.

All CEP documents are available in English.

3. Elaboration process for CEP documents

This chapter describes the elaboration process of the different categories of documents. There may be exceptional and justified cases where certain steps can be skipped (e.g. for a minor revision/a correction of a document) and these exceptions, together with their justification, should be clearly documented. The process is the same for new documents and for revision of existing documents.

3.1. Governance documents

Governance documents are elaborated as described below.

- initiation and preparation of the initial draft by the EDQM;
- review of the draft and agreement by the CEP SC to enter the consultation phase (see Section 4); this may be done either during a meeting of the CEP SC or by correspondence; if the CEP SC considers that further work is needed before consultation the EDQM is in charge of updating the draft accordingly and re-submitting it to the CEP SC;
- consultation phase (see Section 4);
- consolidation of comments and preparation of the final version;
- if critical comments that prevent finalisation of the document are received during the consultation phase, an additional round of consultation or specific discussions may be foreseen before finalisation;
- adoption by the CEP SC; if the CEP SC considers that further work is needed, the draft is updated accordingly and re-submitted to the CEP SC for adoption;
- publication and implementation.

3.2. Technical guidelines

Technical guidelines are elaborated as described below.

- initiation and preparation of the initial draft by the EDQM and/or by members of the relevant Technical Advisory Board (TAB);
- review of the draft and agreement by the relevant TAB; if the TAB considers that further work is needed, the draft is updated accordingly and re-submitted to the TAB;
- review of the draft and agreement by the CEP SC to enter the consultation phase (see Section 4); this may be done either during a meeting of the CEP SC or by correspondence; if the CEP SC considers that further work is needed, the draft is updated accordingly and re-submitted to the TAB and then to the SC;
- consultation phase (see Section 4);
- consolidation of comments, finalisation of the document and agreement by the relevant TAB;
- if critical comments that prevent finalisation of the document are received during the consultation phase, an additional round of consultation or specific discussions may be foreseen before finalisation;

- adoption by the CEP SC; if the CEP SC considers that further work is needed, the draft is returned to the TAB for update and approval by the TAB and then it is re-submitted to the CEP SC;
- publication and implementation.

3.3. Operational documents

Operational documents are prepared by the EDQM. If considered necessary by the EDQM, the CEP SC and/or interested parties may be consulted (see Section 4).

4. Consultation phase

The consultation phase is intended to ensure that the process is transparent with regard to relevant stakeholders, to inform them of upcoming proposed changes and to give them the opportunity to provide input or comments.

For governance documents and technical guidelines, the CEP SC is in charge of deciding on the consultation process, i.e. kind of consultation and associated steps, as well as the time allocated.

- Public consultation:

The main channel for public consultation is via publication of draft documents on the EDQM website www.edqm.eu (specific page). In addition, it could also be decided to raise awareness of any on-going consultations, by sending the draft document to the chairs/secretariats of identified relevant stakeholder organisations.

- Targeted consultation:

Targeted consultation involves specific types of stakeholders in order to gather feedback from experts in the relevant area. For targeted consultation, a draft document is sent to identified interested parties, for example the relevant EMA Working Parties/Groups, EU CMDh, CMDv, Industry associations or any other group/organisation.

The time allocated to a consultation depends on the type of document and/or the topic, and is usually between 3 weeks and 3 months depending on the changes proposed. The time allocated is clearly indicated when the draft document is released for consultation.

To facilitate compilation and review of comments, templates for submission of comments are made available, and interested parties will be encouraged to use them.

Comments should be appropriately justified and should contain a substantial proposal or action to be undertaken. Comments that are incomplete and/or unclear are taken into account but may be rejected on these grounds.

Compilations of comments received, including justifications for any decisions made, are prepared and are made available to the groups in charge of approving and adopting the documents.

5. Publication and implementation of final documents

The EDQM publishes the valid versions of CEP documents on its website www.edqm.eu

The implementation date defined for a document is such that interested parties have sufficient time to apply any new or revised requirements.
