Guideline for USP Staff Approval of Limited Documentary Standard Revisions and Omissions

Approved by Council of Experts: October 14, 2020

As set forth in Article VII, Section 1 of the Bylaws, the Council of Experts and its Expert Committees are responsible for determining and approving the content of the *United States Pharmacopeia* and *National Formulary* (*USP–NF*) and other compendia and information that may be published on behalf of the Council of Experts or an Expert Committee (including translations and line extensions of the *USP–NF*) and any associated reference standards.

According to section 9.06(a) of the Rules and Procedures of the 2020-2025 Council of Experts (Rules) prior to publication as final text, all new or revised documentary standards must be voted on and approved by the responsible Expert Committee (EC). However, under section 9.06(b), the Council of Experts may delegate to USP staff the authority to approve limited documentary standard revisions and omissions, in accordance with guidelines approved by the Council of Experts which provide for oversight by the Council.

This document was developed by the 2020-2025 Council of Experts to serve as a guideline to implement the USP staff delegation described in section 9.06(b) of the Rules. It details the specific types of revisions that may be implemented by USP staff without EC balloting. If a particular proposed revision meets the criteria below, it may be approved by USP staff. The guideline also describes the process by which USP staff review, evaluate, approve, and report such revisions and omissions to the ECs and Council of Experts.

This Guideline is subject to periodic re-evaluation and revision by the Council of Experts.

Part I: Criteria for USP Staff-Approved Revisions

1) FDA Compliance-Related Revisions

USP routinely processes monograph revisions necessary to address an FDA compliance issue. As these revisions essentially are non-discretionary, they do not require expert evaluation or judgment. Delegation of such revisions to USP staff will reduce the burden on ECs while permitting more expeditious approval and publication of clear-cut, necessary revisions and reduce compliance risk for manufacturers.

The only revisions that may be approved by USP staff without an EC ballot are those which:

- Are endorsed by FDA[1]
- Are required to align the USP monograph with an FDA-approved application
- Will not create a compliance issue for other stakeholders

The specific revision types that may be approved by USP staff are:

1) The addition of a dissolution test to a monograph
2) The addition of a strength to an existing dissolution test in a monograph
3) The widening of limits or acceptance criteria in a monograph

[1] USP obtains formal endorsement by FDA via email correspondence between USP Documentary Standard Scientist and FDA Compendial Operations Staff.

The revisions above may be implemented for final monographs or for monographs in the pending process, provided that the same criteria above are met.

2) Revisions to Effectuate Decisions on Requests for Postponement and Appeals

In sections 9.07 and 9.08 of the Rules, USP has codified processes to address requests for postponement and appeals of standards. Where these processes are followed, it is either unnecessary or redundant to require EC ballots to effectuate revisions consistent with the decisions rendered. Delegation of such revisions to USP staff will reduce the burden on ECs while permitting more expeditious approval and publication of revisions consistent with codified decision-making processes.

Revisions that may be approved by USP staff without an EC ballot are those essential to:

- Effectuate a decision by the CoE Chairperson to postpone the official date of the standard (or portion(s) thereof) subject to a request for postponement following consultation with the responsible EC, under section 9.07(c) of the Rules.
- Effectuate a decision by the CoE Chairperson upon initial assessment to grant the appeal (in whole or in part) and remand the standard (or portion(s) thereof) under appeal, following consultation with the Chair of the EC responsible for the standard under appeal, under section 9.08(d) of the Rules.
- Effectuate a decision rendered by the CoE on an appeal, under section 9.08(e) of the Rules, where appellants do not request further review by an Appointed Appeals Panel.
- Effectuate the final decision rendered by an Appointed Appeals Panel under section 9.08(f) of the Rules.

The specific types of revisions that may be approved by USP staff under this section include only: modifications to the official date of a standard; and textual modifications that result in reversion to previously official text (or portion(s) thereof) pending reconsideration by the EC. To be eligible for staff approval, the revision must be described with specificity in the written decision being effectuated.

Part II: Implementation Process for USP Staff-Approved Revisions

A revision that meets the criteria described in Part I above will be reviewed, evaluated, and approved by a team of USP staff in accordance with current internal USP policies and processes.

Specifically, the USP Management Approval Team (MAT) is responsible for the review and discussion of proposed Accelerated Revisions to the *USP-NF*.[2] MAT meetings are held regularly. Members of the MAT include:

- the Chair of the Council of Experts (CoE Chair) (or designee)
- Chief Science Officer (if different from above) or designee

[2] See USP Guideline on Use of Accelerated Processes for Revisions to the *USP-NF*, available at: https://www.uspnf.com/official-text/accelerated-revision-process.

- Global Science and Standards Division (Senior) Vice Presidents/Directors
- Legal
- Quality Assurance
- Publications Vice Presidents/Directors and Production Coordinators
- Volunteer and Compendial Operations Staff
- Errata Content Review Team[3] members (as needed)

The CoE Chair (or designee) is responsible for approval of proposed Accelerated Revisions.

A pre-MAT meeting precedes each MAT meeting, with the pre-MAT team consisting of the CoE Chair's designee and a select group of representatives from Science (including Volunteer and Compendial Operations, and Compendial Policy) and Legal.

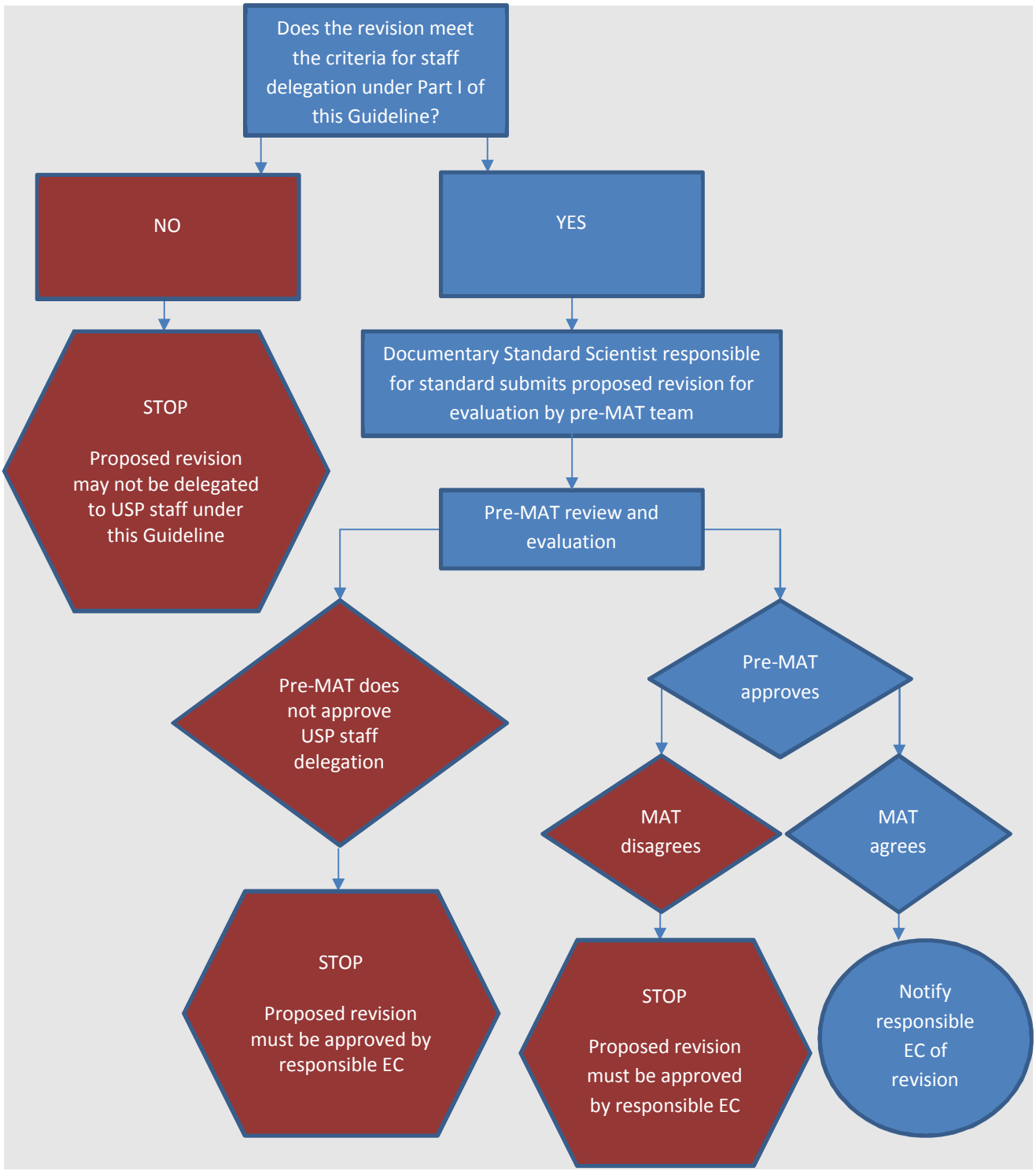
The pre-MAT team is responsible for review and evaluation of revisions described in Part I above, with the CoE Chair's designee responsible for approval of such proposed revisions.

The pre-MAT team reviews the proposed revisions identified by Documentary Standard Scientist responsible for the affected monographs, pending monographs, or general chapters to: (a) determine whether any additional information is required to evaluate the proposal; and (b) evaluate each request against this Guideline to determine that the proposed revision qualifies as a staff-approved revision.

Determinations of the pre-MAT team regarding the appropriateness of staff approval are recorded and shared with the MAT for review prior to implementation. A USP staff-delegated approval will be implemented via *Revision Bulletin*. See Decision Tree below for a graphic representation of this process.

[3] The Errata Content Review Team includes USP scientific staff (and other staff as necessary) assigned by the appropriate department managers to evaluate and discuss the impact of each reported erratum in a USP compendium and to approve the recommended action to be taken in accordance with existing policies and processes.

Decision Tree for USP Staff-Approved Revisions



Part III: Reporting to ECs of USP Staff-Approved Revisions

On a monthly basis, the USP Executive Secretariat will notify each responsible EC of any USP staff-approved revisions related to standards under that Committee's purview. This notification will be provided prior to the *Revision Bulletin* being published.

SUMMARY OF CHANGES	RATIONALE FOR CHANGE
G01.18-00	
NA	New Guideline
G01.18-01	
Added section and updated Decision Tree to include delegation of revisions to effectuate decisions made on requests for postponement and appeals	Consistent with updates to the 2020-2025 CoE Rules
Rule citation and date range updates	To ensure accuracy and consistency with 2020-2025 CoE Rules
Replaced Scientific Liaison with Documentary Standard Scientist.	To reflect current position description.

Document Approval Certificate

This is an electronic record in the Livelink application that contains the manifestation of electronic signature(s)

UserName: Elena Gonikberg (EG)
Title: Principal Scientific Liaison
Date: Friday, 21 May 2021, 09:07 AM Eastern Daylight Time
Meaning: Document Owner Approval
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UserName: Karen Hammann (KRH)
Title: Coordinator of Board Relations
Date: Wednesday, 26 May 2021, 10:19 AM Eastern Daylight Time
Meaning: Technical Approval 1
==========

UserName: Jessica Simpson (JCS)
Title: Manager, Compendial Operations
Date: Thursday, 27 May 2021, 10:58 AM Eastern Daylight Time
Meaning: Department Supervisor Approval
==========

UserName: Jeanne Sun (JHS)
Title: Counsel
Date: Thursday, 27 May 2021, 03:36 PM Eastern Daylight Time
Meaning: Legal Approval
==========

UserName: Maira Adzema (MTA)
Title: Sr. Manager, Standards QA
Date: Wednesday, 02 June 2021, 10:05 AM Eastern Daylight Time
Meaning: QA Approval
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