

**USP Guideline on Use of Accelerated Processes
for Revisions to the *USP-NF*¹
Version 1.0
December 1, 2008**

Background:

Sections 9.02 and 9.03 of the Rules and Procedures of the 2005-2010 Council of Experts (Rules)² specify various processes (Accelerated Revision Processes) that can be used to make revisions to the *USP-NF* official more quickly than through USP's standard process (Standard Revision Process). USP's Standard Revision Process calls for publication of a proposed revision in the *Pharmacopeial Forum (PF)* for a 90-day notice and comment period and, after the revision is approved by the relevant USP Expert Committee, publication in the next *USP-NF* or *Supplement*, as applicable. Accelerated Revision Processes, which include *Errata*, *Interim Revision Announcements* and *Revision Bulletins*, do not always require notice and comment and allow for a revision to become official prior to the next *USP-NF* or *Supplement*.

The purpose of this Guideline is to delineate the circumstances under which these Accelerated Revision Processes are utilized. The Decision Tree that follows specifies the criteria that are applied by USP in considering whether an Accelerated Revision Process is appropriate rather than USP's Standard Revision Process. The footnotes to the Decision Tree provide additional explanation for applying the criteria outlined in the Decision Tree, and further clarification as to when an Accelerated Revision Process rather than the Standard Revision Process should be utilized.³

This Guideline also addresses the use of delayed official dates for revisions made through the Standard Revision Process, where such revisions have broad industry impact and require additional time to implement.

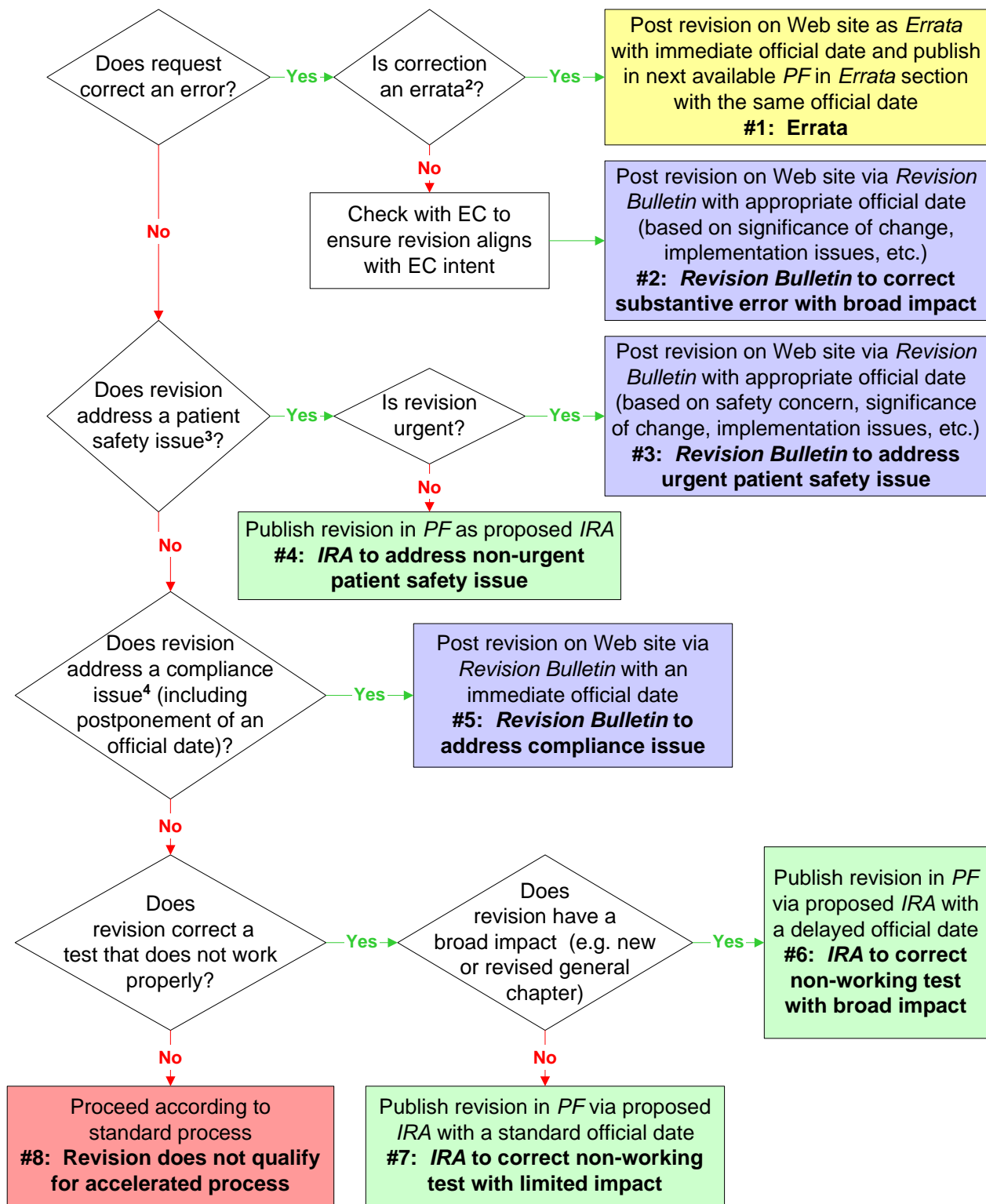
¹ "Revisions to the USP-NF" include new monographs and general chapters as well as changes to existing monographs and general chapters.

² Available at <http://www.usp.org/aboutUSP/governance/policies/rulesAndProcedures/section09.html>

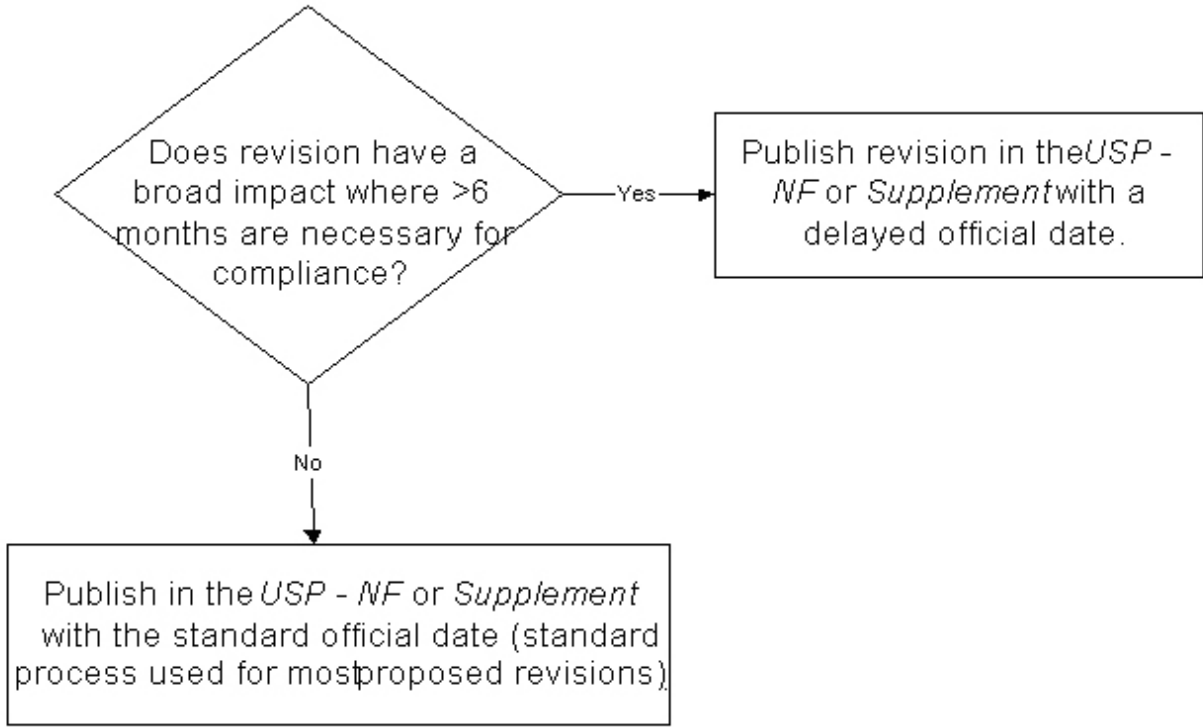
³ This Guideline does not address the use of *Revision Bulletins* to move Authorized Pending Monographs to the *USP-NF* upon FDA approval of the relevant drug product application, which is provided for separately in the Pending Monographs Guideline available at <http://www.usp.org/standards/pending/guidelines.html>.

USP ACCELERATED AND STANDARD PROCESSES FOR REVISIONS TO THE *USP-NF* DECISION TREES

ACCELERATED PROCESSES FOR *USP-NF* REVISIONS ¹



**STANDARD PROCESS FOR
USP-NF REVISIONS**



Footnotes for Decision Tree

1. General

- a. Revisions to the *USP-NF* (whether new monographs or general chapters or changes to existing monographs or general chapters) generally are made through the Standard Revision Process unless the revision falls into one of the categories listed in the Accelerated Revision Processes Decision Tree.
- b. To the extent possible, changes resulting from the Pharmacopeial Discussion Group (PDG) harmonization process are made through the Standard Revision Process.
- c. *Revision Bulletins* generally are posted on the USP Web site at the end of each month, and will be official on the first day of the second month following the posting, unless otherwise specified. However, *Revision Bulletins* that address a compliance issue, as described in Paragraph 4 below, and *Revision Bulletins* that address an urgent patient safety issue, as described in Paragraph 3 below, may be official immediately.

2. Correction of errors

- a. *Errata* are corrections to items erroneously published that do not accurately reflect the intended official requirements as approved by the Council of Experts. These typically are minor changes that are fairly obvious and do not have a broad impact.
- b. Errors that are more substantive and do have a broad impact (such as those that impact test method instructions, solution preparations, etc. and require change control to implement) are not considered *Errata*. These errors are corrected using *Revision Bulletins* with appropriate official dates.

3. Safety-related revisions

- a. Urgent safety-related revisions are handled as *Revision Bulletins*. *Interim Revision Announcements* are used to effectuate non-urgent safety-related revisions.
- b. Prior to posting a *Revision Bulletin* for a safety-related revision, USP will, as feasible and appropriate given the safety issue involved and impact of the proposed revision, obtain stakeholder input through expedited and informal processes.
- c. USP will consider the impact of the safety-related revision in determining the approach used to address the safety issue (speed of method development, ease of implementation in industry) and the timing of the official date after publication.

4. Compliance related revisions

- a. Postponement of official date: If a *USP-NF* requirement has been published that will have the effect of putting all or a substantial part of the pharmaceutical industry out of compliance, then the use of a *Revision Bulletin* that postpones the official date of such requirement until compliance can reasonably be achieved is appropriate. This *Revision Bulletin* will have an immediate official date.
- b. Retraction of a requirement: If a *USP-NF* requirement has been published for a specific article for which a company has an approved application with FDA but that company cannot meet the requirement, then a retraction of that requirement via a *Revision Bulletin* with an immediate official date is appropriate to ensure the company is not out of compliance. Alternatively, USP may post a Notice of Intent to Revise pursuant to the Rules indicating its intent to revise the requirement to address the compliance issue, and subsequently complete such revision via a *Revision Bulletin*, *IRA*, or through the Standard Revision Process.

- c. Creation of a flexible monograph (inclusion of tests and procedures in a monograph that are not applicable to all manufacturers of that article): The creation of the flexible monograph must be necessary to address a compliance issue in at least one company, and the revision must not change the current monograph requirements in a way that would cause a compliance issue for another company, in order to qualify for publication as a *Revision Bulletin* with an immediate official date. Examples of such revisions are the inclusion of an additional dissolution test or related compound test in a monograph.