



**USP Guideline on Use of Accelerated Processes
for Revisions to the *USP-NF*¹
Version 2.1
Effective August 1, 2011**

Background

The Rules and Procedures of the Council of Experts (Rules) specify various processes (Accelerated Revision Processes) that can be used to make revisions to the *United States Pharmacopeia* and the *National Formulary (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 its *Supplements*, as applicable. Accelerated Revision Processes include *Errata*, *Interim Revision Announcements* and *Revision Bulletins*. *Accelerated Revisions* 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.²

Definitions

Errata—An *Erratum/Errata* is content erroneously published in a USP publication that does not accurately reflect the intended official requirements as approved by the Council of Experts. These typically are changes that do not have a broad impact on the standards. *Errata* are not subject to public notice and comment. *Errata* are published on the USP Web site and become official on the first day of the month following publication. *Errata* are incorporated into the next available *USP-NF* or *Supplement*.

Interim Revision Announcements (IRAs)—*IRAs* are an expedited mechanism for making revisions official. An *IRA* appears in *PF* first as a *Proposed Interim Revision Announcement* with a 90-day comment period.³ If there are no significant comments, the *IRA* becomes official in the "Official Text" section of the USP Web site, with the official date indicated. *IRAs* replace the entire published monograph including the specified change and are incorporated into the next available *USP-NF* or *Supplement*.

Revision Bulletins—If circumstances require rapid publication of official text, a revision or postponement may be published through a *Revision Bulletin*. *Revision Bulletins* are posted on the USP Web site with the official date indicated. *Revision Bulletins* replace the entire published monograph including the specified change and are incorporated into the next available *USP-NF* or *Supplement*.

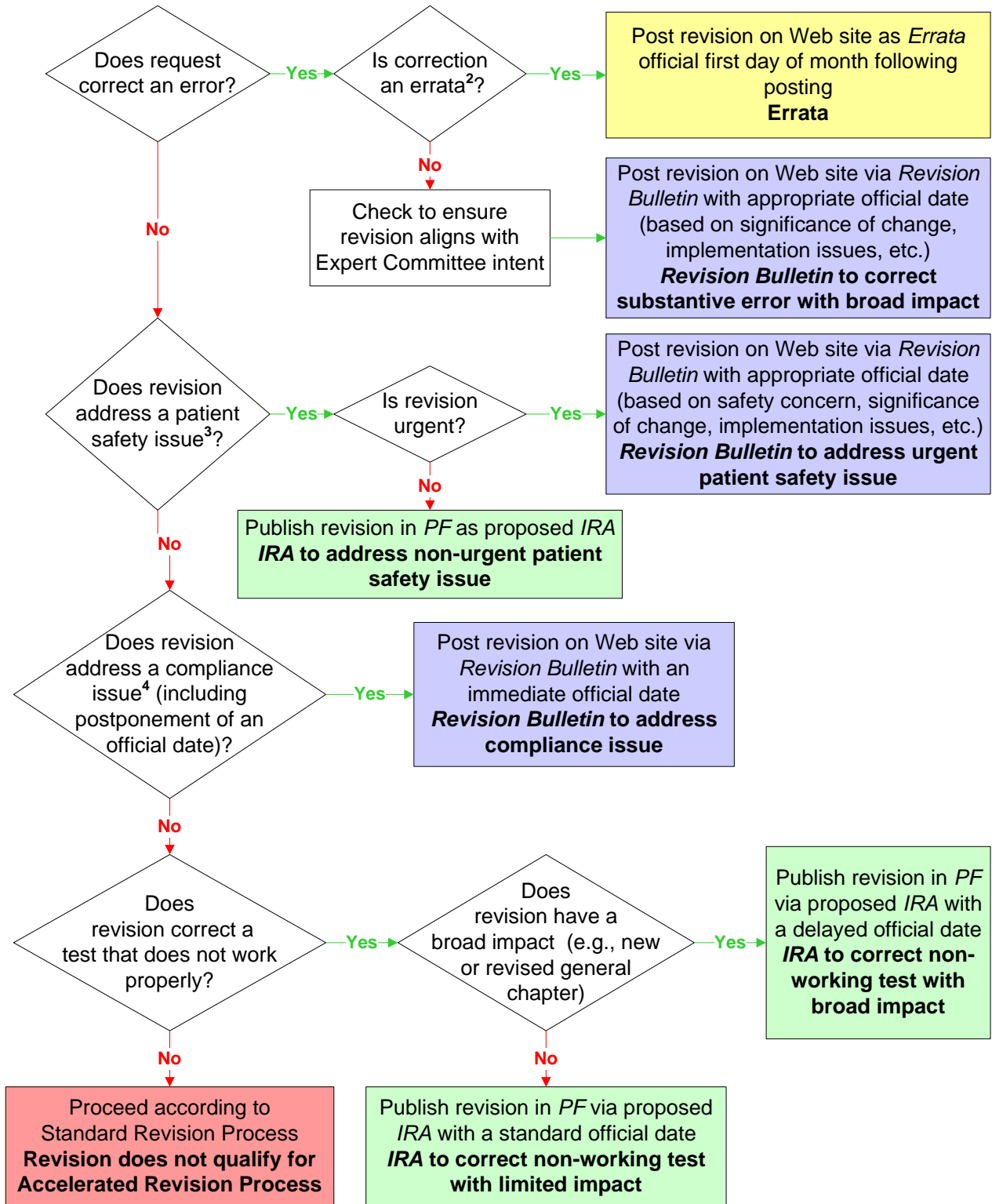
¹ "Revisions to the *USP-NF*" include new monographs and general chapters as well as changes to existing monographs and general chapters.

² 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>.

³ Prior to PF 37(1), *IRAs* were available for comment for 60 days.

Accelerated Revision Decision Tree

ACCELERATED PROCESSES FOR *USP-NF* REVISIONS ¹



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 on the last Friday of each month, and will be official on the first day of the second month following the posting, unless otherwise specified. *Revision Bulletins* that address an urgent patient safety issue as described in Paragraph 3 below or a compliance issue as described in Paragraph 4 below may become official immediately.
- d. *Notices of Intent to Revise*: When a standard with a broad impact is revised using the IRA process to correct a test, USP may issue a “Notice of Intent to Revise” to alert manufacturers to the upcoming proposal. The Notice of Intent to Revise will be posted on the “Compendial Notices” section of the USP Web site.

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 particular Expert Committee. 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*, with an appropriate official date (which can sometimes be immediate). *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, and may be posted outside of the normal *Revision Bulletin* posting schedule.
- b. Compliance Issues: 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 revision or retraction of that requirement via a

Revision Bulletin with an immediate official date can be used 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. Flexible Monographs: USP can utilize a flexible monograph approach using a *Revision Bulletin* to solve a compliance issue for a company, but only if the revision does not create a compliance issue for anyone else. The *Revision Bulletin* will have an immediate official date. Examples of such revisions are the inclusion of multiple procedures (e.g., Test 2) for dissolution or impurities in a monograph.

Revision History

Version 2.1, Effective August 1, 2011

Section: Definitions and Decision Tree

Change: Revised definition of Errata and changed official date of Errata from immediately when published to the first day of the month following publication.

Version 2.0, Effective September 1, 2010

Section: Background

Change: Removed the reference to the obsolete document *The Rules and Procedures of the 2005-2010 Council of Experts*

Removed sentence: "this Guideline 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."

Section: Definitions

Change: Created section.

Section: Decision Tree

Change: Removed numbers from each scenario, removed reference to *Errata* appearing in *Pharmacopeial Forum (PF)* due to the change to the all-online *PF* in January 2011, and made minor editorial changes.

Section: Decision Tree

Change: Removed Standard Revision Process Decision Tree because delayed implementation for Standard Revisions is not related to the Accelerated Revision Process.

Section: Footnotes for Decision Tree, General, Paragraph 1c

Change: Clarified that generally *Revision Bulletins* will be posted on the last Friday of the month and that *Revision Bulletins* intended to address urgent safety-related revisions or compliance issues may become official immediately

Section: Footnotes for Decision Tree, General, Paragraph 1d (new)

Change: Added a provision that USP may issue a "Notice of Intent to Revise" to alert manufacturers to the upcoming proposal

Section: Footnotes for Decision Tree, Correction of Errors, Paragraph 2a

Change: Changed “Council of Experts” to “particular Expert Committee” to be consistent with the Decision Tree.

Section: Footnotes for Decision Tree, Safety-related revisions, Paragraph 3a

Change: Clarified that *Revision Bulletins* for urgent safety-related revisions will have an appropriate official date which can be immediate

Section: Footnotes for Decision Tree, Compliance-related revisions, Paragraph 4a

Change: Added a provision that a *Revision Bulletin* created to address a postponement of an official date may be posted outside of the normal *Revision Bulletin* posting schedule

Section: Footnotes for Decision Tree, Compliance-related revisions, Paragraph 4b

Change: Clarified that 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 revision of that requirement via a *Revision Bulletin* with an immediate official date can be used to ensure the company is not out of compliance. Added the term “retraction” to the above sentence after the word “revision” because at times revisions are retracted by USP.

Section: Footnotes for Decision Tree, Compliance-related revisions, Paragraph 4c

Changes: Added a provision that a *Revision Bulletin* created to solve a compliance issues will have an immediate official date; replaced the term “related compounds” with “impurities” in the final sentence to indicate the inclusion of “multiple procedures” for dissolution or impurities in a monograph.

Version 1.0, Effective December 1, 2008

Initial version