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) official¹ and to the Food Chemicals Codex (FCC) effective² 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) or FCC Forum 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, FCC, or their Supplements, as applicable. Accelerated Revision Processes include Errata, Interim Revision Announcements, and Revision Bulletins for the USP–NF; and Errata, Expedited Standards, and Immediate Standards for the FCC. Also discussed in this Guideline are changes made via Compendial Notices, such as Reference Changes. Accelerated Revisions do not always require publication in PF and allow for a revision to become official or effective prior to the next USP–NF, FCC, or Supplement thereto.

The purpose of this Guideline is to delineate the circumstances under which these Accelerated Revision Processes and Compendial Notice Reference Changes 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 explanations 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.

Definitions

**Errata (USP–NF and FCC)**—An Erratum/Errata published in the errata table is erroneously published content in a USP compendium that does not accurately reflect the intended requirements of a standard as approved by the responsible Expert Committee. Errata published in the errata table are errors, clarifications, or missing information such as inaccuracies in chemical formulas, mathematical equations relevant to analyses and/or inaccurate descriptions of the apparatus, or materials used to perform analytical tests. Typically Errata are changes that do not have a broad impact on the standard. Errata are not subject to public notice and comment. Errata published on the USP website become official/effective on the first day of the month following publication. Errata are incorporated into the next available USP–NF, FCC, or Supplement thereto.

**Interim Revision Announcements (IRAs) (USP–NF)**—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 website, with the official date indicated. IRAs replace the entire published

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¹ Official: An official article is an article that is recognized in USP or NF. An article is deemed to be recognized and included in a compendium when a monograph for the article is published in the compendium and an official date is generally or specifically assigned to the monograph. (General Notices and Requirements Section 2.20)

² Effective: After approval by the Food Ingredients Expert Committee, an FCC proposal shall be published in the next edition of the FCC or Supplement thereto, as applicable, and shall become effective 90 days from the date of publication unless otherwise provided. Items published in the FCC are given effective dates and are not considered official USP–NF text.

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

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monograph including the specified change and are incorporated into the next available USP–NF or Supplement.

**Revision Bulletins (USP–NF)**—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 website with the official date indicated. Revision Bulletins replace the entire published standard including the specified change and are incorporated into the next available USP–NF or Supplement.

**Expedited Standards (FCC)**—If the Food Ingredients Expert Committee (FI EC) determines that for public health or other appropriate reasons, a new or revised standard should be made available prior to publication of the next edition of the FCC or Supplement, it may be posted as final on the USP website following notice and comment and approval by the FI EC. An Expedited Standard will be effective upon website publication after the 90-day comment period, unless a delayed effective date is specified therein. Upon publication of the next edition of the FCC or Supplement thereto, as applicable, any Expedited Standard that has become effective since publication of the last edition or Supplement will be included in such volume and removed from the USP website.

**Immediate Standards (FCC)**—In those rare cases where the FI EC determines that a new or revised standard should be made available immediately because of an urgent public health need, a standard may be approved by the FI EC and posted as final on the USP website without the notice and comment period specified above. An Immediate Standard will be effective upon website publication, unless a delayed effective date is specified therein. Upon publication of the next edition of the FCC or Supplement thereto, as applicable, any Immediate Standard that has become effective since the last edition or Supplement will be included in such volume and removed from the USP website.

**Compendial Notice (USP–NF)**—Reference Changes represent an example of changes made via Compendial Notice. Sometimes it is necessary for USP to modify general chapter titles, appendix titles, references to external resources, or similar text that may be referenced in standards throughout the USP–NF. Any reference changes that will have an impact on the interpretation or requirements of the standard are made using the routine revision process including publication for comment in PF. In cases in which an update appears to present no significant change in the affected standard, they are implemented through a direct update of the reference in that standard without providing an opportunity for notice and comment.

In these cases, USP will publish on its website a Compendial Notice (CN) indicating the source change and any resulting references. Updates made through direct publication in the USP–NF will be clearly identified by symbols and shading in the print and electronic publications.
Because some updates to references may be assigned delayed official dates to ensure that all related revisions become official together, the revision markup used to identify the reference updates will be dependent upon when the change will become official. Updates becoming official at the same time as the USP–NF in which they are published will be identified with the following revision markup, where CN denotes Compendial Notice:

▲

Changed text ▲ (CN 1-May-2019)

Updates becoming official/effective on a future date than the USP–NF in which they are published will be identified with the following revision markup:

▲

Changed text ▲ (Official 1-May-2019)
USP Guideline on Use of Accelerated Processes for Revisions to the USP-NF and FCC

Accelerated Revision Decision Tree

ACCELERATED PROCESSES FOR USP-NF AND FCC REVISIONS

Does request correct an error?

Yes → Is correction an erratum?

Yes → Post revision on Website as Errata official first day of month following posting Errata

No → Post revision on Website via Revision Bulletin (USP-NF) or Immediate Standard (FCC) with appropriate official/effective date Revision Bulletin / Immediate Standard to correct substantive error with broad impact

No → Check to ensure revision aligns with EC intent

Does revision address a patient/consumer safety issue?

Yes → Is revision urgent?

Yes → Post revision on Website via Revision Bulletin (USP-NF) or Immediate Standard (FCC) with appropriate official/effective date Revision Bulletin / Immediate Standard to address urgent patient/consumer safety issue

No → Publish revision in PF as proposed IRA or FCC Forum as proposed Expedited Standard (ES) IRA/ES to address non-urgent patient/consumer safety issue

No → Does revision address a compliance issue (including postponements & revisions from PMP)?

Yes → Does revision have a broad impact (e.g., new or revised general chapter)?

Yes → Publish revision in PF as proposed IRA or in FCC Forum as proposed ES IRA/ES to correct non-working test with broad impact with delayed official/effective date

No → Proceed according to Standard Revision Process Revision does not qualify for Accelerated Revision Process

No → Does revision correct a test that does not work properly?

Yes → Publish revision in PF as proposed IRA or in FCC Forum as proposed ES IRA/ES to correct non-working test with limited impact with standard official / effective date

No → Post revision on Website via Revision Bulletin (USP-NF) or Immediate Revision (FCC) with appropriate official/effective date Revision Bulletin / Immediate Standard to address compliance issue

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Notes and References on Decision Tree

1. General
   a. Revisions to the USP–NF or FCC (whether new monographs or general chapters/tests or changes to existing monographs or general chapters/tests) generally are made through the Standard Revision Process unless the revision falls into one of the categories listed in the Accelerated Revision Process 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 and Immediate Standards generally are posted on the USP website on the last Friday of every month with an appropriate official/effective date. Revision Bulletins and Immediate Standards that address an urgent patient/consumer safety issue as described in Paragraph 3 below may be posted at any time. These Revision Bulletins or Immediate Standards, or those that address a compliance issue as described in Paragraph 4 below may become official/effective immediately.
   d. Notices of Intent to Revise: USP may issue a Notice of Intent to Revise (NITR) to alert manufacturers to the upcoming revision to a proposed or official standard. The NITR will be posted on the Compendial Notices section of the USP–NF or FCC website. NITR can be utilized for revisions made via an Accelerated Revision or through the Standard Revision Process.

2. Correction of Errors
   a. Errata are corrections to items erroneously published that do not accurately reflect the intended official/effective requirements as approved by the responsible 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 or Immediate Standards with appropriate official/effective dates.

3. Safety-related Revisions
   a. Urgent safety-related revisions are handled as Revision Bulletins or Immediate Standards, with an appropriate official/effective date, which can sometimes be immediate. The official/effective date should be determined based on level of safety concerns, significance of change, and/or potential implementation issues, etc. Interim Revision Announcements and Expedited Standards are used to effectuate non-urgent safety-related revisions.
   b. Prior to posting a Revision Bulletin or Immediate Standard for an urgent 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/effective date after publication.

4. **Compliance-related Revisions**
   a. In order to qualify for a Revision Bulletin or Immediate Standard, a compliance-related revision cannot create a compliance issue for other stakeholder.
   b. **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.
   c. **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 the compendial requirement is in conflict with the application requirement, then a revision or retraction of the compendial requirement via a Revision Bulletin with an immediate official/effective date can be used to ensure the company is not out of compliance. Additional compliance-related revisions for products without an approved application with FDA (e.g., OTCs monograph drugs, Food Ingredients, and Dietary Supplements) can be considered on case-by-case basis.
   d. **Flexible Monographs:** USP can utilize a flexible monograph approach using a Revision Bulletin or Immediate Standard to resolve a compliance issue for a company. These Revision Bulletins or Immediate Standards 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 or adding a new hydrate/polymorphic form and associated specifications. Interim Revision Announcements are typically used for inclusion of an additional procedure for impurities in a monograph, to provide an opportunity for public comments.

5. **Pending Revisions (USP–NF):** Revisions proposed under the Pending Monograph Program (PMP) become official via Revision Bulletin. For more information and details on the Pending Monograph Program please see Pending Monograph Guideline and FAQs on this topic.

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**Revision History**

**Version G01.01-01**

**Section:** Various

**Changes:**
- Incorporated description of Reference Changes in the Guideline. Included note that changes made to accommodate external reference changes may also use the Compendial Notices Reference Change process.
• Added a note that compliance-related revisions can be made to accommodate sponsors of non-FDA approved products on a case-by-case basis.
• Combined discussion of USP-NF and FCC Accelerated Revisions into one guideline. Previously, there was a separate guideline for FCC Accelerated Revisions, G1.02-00. The contents of this document were added to G1.01-00. G2.01.00 will be retired once G1.02 is effective.
• Added footnote and information in decision tree regarding handling of Revision Bulletins from the Pending Monograph Program.
• Revised description of Errata to match current USP definition in the Errata SOP and remove specification the Errata can only be made on official text.
• Indicated that the Revision Bulletins/Immediate Standards are typically posted on the last Friday of the month, previously Revision Bulletins were scheduled to be posted every other month.
• Updated decision tree diagram to reflect incorporation of FCC revisions and reference to note about Pending Monograph Program.
• Deleted the footnote pertaining to the Authorized Pending Monographs.

Version G1.01-00 August 1, 2015
Document number added and document routed through document control. No changes to Guideline content.

Version 3.1, Effective March 6, 2014
Section: Various
Change: Updated template and made minor editorial corrections.

Version 3.0, Effective August 31, 2012
Section: Footnotes for Decision Tree
Change: Specify that Revision Bulletins typically are posted every other month, but may be posted at any time to address an urgent need.

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.”

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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.

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