



USP Guideline on Use of Accelerated Processes for Revisions to the *USP-NF* and *FCC*

Background

The Rules and Procedures of the Council of Experts (Rules) state that Accelerated Revision Processes 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 Revision Process. Accelerated Revisions do not always require publication in the *Pharmacopeial Forum (PF)* or *FCC Forum*, and allow for a revision to become official or effective prior to the next scheduled compendial publication.³ 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.

The purpose of this Guideline is to delineate the circumstances under which these Accelerated Revision Processes and Compendial Notice 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)—*Errata* refer to an accelerated revision vehicle used to correct 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* are used to address changes that do not have a broad impact on the standard⁴ and are not subject to public notice and comment. *Errata* published on the USP webpage most often become official/effective on the first day of the month following publication; however, in some cases the official date of the *Errata* may be extended to align with previously published revisions that have not yet become official. The official or effective date will be noted in the revised version of these standards as well as in the revision tagging associated with the specific *Errata*.

Interim Revision Announcements (IRAs) (USP–NF)—*IRAs* are used: (1) to correct substantive errors (beyond the scope of *Errata*); (2) to address non-urgent patient safety or compliance issues where

¹ Official: After approval by the responsible Expert Committee, a revision to the *USP–NF* shall be published as official text and shall become official six (6) months after publication, unless otherwise specified in the publication vehicle.

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 USP's Standard Revision Process involves publication of proposed revisions for a minimum 90-day public comment period. The relevant Expert Committee evaluates comments received before voting to make revisions official or effective in a future scheduled publication of the *USP–NF* or *FCC*.

⁴ As described later in this Guideline, changes that have a broad impact on the standard are addressed using another appropriate revision vehicle (e.g., *IRA* or *Revision Bulletin*), depending on the factual circumstances.



USP Guideline on Use of Accelerated Processes for Revisions to the *USP-NF* and *FCC*

public comment on the revision is warranted; (3) to address time-sensitive reference standard (RS) issues, including but not limited to changes in a form or a presentation of an RS; and (4) to correct non-working tests in a standard. An *IRA* appears in *PF* first as a *Proposed Interim Revision Announcement* with a 90-day comment period.⁵ If there are no significant adverse comments, the *IRA* becomes official and is immediately incorporated into the *USP-NF* with the official date indicated.

Revision Bulletins (*USP-NF*)—*Revision Bulletins* are used to address issues that require rapid publication of official text, namely: (1) to correct substantive errors (beyond the scope of *Errata*); (2) to address urgent patient safety issues; (3) to address compliance issues where public comment is not warranted; (4) to issue postponements in response to Requests for Postponement (see *Rules*); (5) to remove postponed text from the official text of the compendium when the postponement has not been resolved within the normal revision lifecycle; and (6) to effectuate appeals-related revisions (see *Rules*). *Revision Bulletins* are immediately incorporated into the *USP-NF* with the official date indicated. *Revision Bulletins* are most often official on the first day of the month that follows the month in which they are published. However, in some cases the official date of the *Revision Bulletin* may be extended to align with previously published revisions that have not yet become official. The official date will be noted in the revised version of these standards as well as in the revision tagging associated with the specific *Revision Bulletin*.

Revision Bulletin Notice—Document posted along with the *Revision Bulletin* to identify the posting date of the *Revision Bulletin*, the official date of the *Revision Bulletin*, a description of the changes to the official text, and other information which may be useful such as the brand of column used during validation or typical retention times when chromatographic procedures are added to monographs.

Expedited Standards (*FCC*)—If the Food Ingredients Expert Committee (FI EC) determines that for non-urgent 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 *FCC* webpage following notice and comment and approval by the FI EC. An *Expedited Standard* will be effective upon webpage 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 archived on the *FCC* webpage.

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 webpage without the notice and comment period specified above. An *Immediate Standard* will be effective upon webpage 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 archived on the *FCC* webpage.

Compendial Notice (*USP-NF*)—Compendial Notice revisions are used sparingly to update, edit, or correct issues in compendial text that do not fit any of the categories described above, but where expeditious revision serves public health and quality needs and where public comment is not warranted. Any issues in compendial text that will have an impact on the interpretation or requirements

⁵ Prior to *PF* 37(1), IRAs were available for comment for 60 days.



USP Guideline on Use of Accelerated Processes for Revisions to the *USP-NF* and *FCC*

of the standard are addressed using the routine revision process including publication for comment in *PF*.

Reference Changes represent an example of changes made via Compendial Notice. Sometimes it is necessary for USP to modify general chapter titles, section titles, appendix titles, reference 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 webpage 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.

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* vehicle 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 with a greater than 6-month implementation period will be identified with the following revision markup:

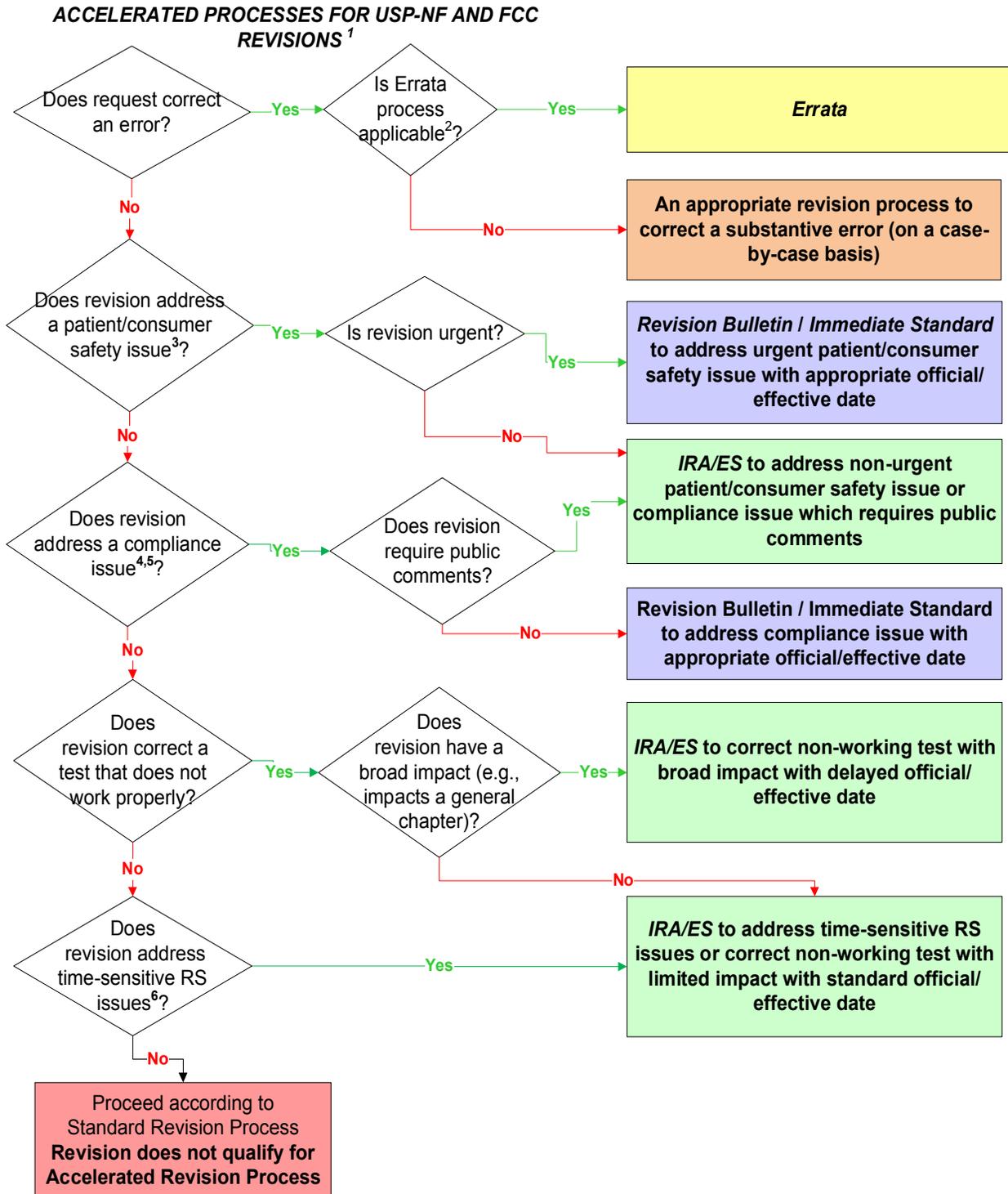
▲
 Changed text ▲ (Official 1-May-2019)

Notices of Intent to Revise—USP may issue a Notice of Intent to Revise (NITR) to alert stakeholders to an upcoming revision to a proposed or official or effective standard. The NITR will be posted on the Compendial Notices section of the *USP-NF* or *FCC* webpage. NITRs can be utilized to alert stakeholders to upcoming revisions made via an Accelerated Revision or through the Standard Revision Process.



USP Guideline on Use of Accelerated Processes for Revisions to the USP-NF and FCC

Accelerated Revision Decision Tree





USP Guideline on Use of Accelerated Processes for Revisions to the *USP-NF* and *FCC*

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 yellow, blue, orange, or green boxes within the Accelerated Revision Process Decision Tree. “Standard Revision Process” is listed in the red box within 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 applicable webpage on the last working 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.

2. Correction of Errors

- a. The *Errata* process is used to address errors, clarifications, or missing information such as inaccuracies in chemical formulas, mathematical equations relevant to analyses and/or inaccurate descriptions of the apparatus, materials used to perform analytical tests, or non-substantive typographical mistakes. 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 corrected using other appropriate revision processes as determined on a case-by-case basis.

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 risk, 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



USP Guideline on Use of Accelerated Processes for Revisions to the *USP-NF* and *FCC*

- c. USP will consider the impact of the safety-related revision in determining the approach used to address the issue (speed of method development, ease of implementation in industry) and the timing of the official/effective date after publication.
- d. Safety-related revisions may address access issues, such as the prevention of drug shortages.

4. Compliance-related Revisions

- a. Regulatory alignment: 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 date is used to ensure the company is not out of compliance. In order to qualify for a *Revision Bulletin*, a compliance-related revision cannot create a compliance issue for other stakeholders. If a compliance-related revision may affect other stakeholders, it is processed via an *Interim Revision Announcement* to provide an opportunity for public comments. Additional compliance-related revisions for products without an approved application with FDA (e.g., OTC monograph drugs, Food Ingredients, and Dietary Supplements) can be considered on a case-by-case basis and addressed in a *Revision Bulletin* or *Immediate Standard*, as appropriate.
- b. Postponement-related revisions: In the event that a request for postponement is granted, USP will issue a *Revision Bulletin* postponing the official date of the standard (see *Rules* for details on Postponement). This *Revision Bulletin* may have an immediate official date and may be posted outside of the normal *Revision Bulletin* posting schedule. Postponement may be granted until compliance can reasonably be achieved or until the proper next steps could be determined. If an official documentary standard contains postponed text that is not resolved within the normal revision lifecycle, the postponed text may be removed from the standard via *Revision Bulletin*. In such cases USP will post a *Notice of Intent to Revise* to alert stakeholders of the upcoming deletion of the postponed text.
- c. Appeals-related revisions: In the event a decision on an appeal warrants an accelerated revision to compendial text, USP will issue a *Revision Bulletin* to effectuate the decision (see *Rules* for details on Appeals).
- d. Flexible Monographs: USP can utilize a flexible monograph approach to resolve a compliance issue for a company. 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. These revisions are typically processed via *Revision Bulletins* or *Immediate Standards*. *Interim Revision Announcements* are typically used for inclusion of an additional procedure for impurities in a monograph, to provide an opportunity for public comment.

- 5. **Pending Revisions (*USP-NF*)**: Revisions proposed under the Pending Monograph Program (PMP) are a subset of compliance-related revisions and 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.



**USP Guideline on Use of Accelerated Processes
for Revisions to the *USP-NF* and *FCC***

6. Revisions to Address Time-Sensitive Reference Standard (RS) Issues: This category covers revisions needed to address time-sensitive changes needed to support the availability of necessary RSs, including but not limited to changes in the form or presentation of an RS. Depending on the timing and the impact on stakeholders, these revisions may be processed via *Interim Revision Announcement* and may need an extended implementation timeframe.

Revision History

SUMMARY OF CHANGES	RATIONALE FOR CHANGE
G01.01-02	
Revised definitions and conditions of use for specific Accelerated Revision vehicles throughout document	Aligned with current USP policies, practices, and associated SOPs
Accelerated Revision Decision Tree	Reorganized and streamlined for clarity
Revisions throughout document, including express references to use of Accelerated Revision vehicles to address postponements and appeals	Align with the Rules and Procedures of the 2020-2025 Council of Experts
Added Section 6	Added to address Time-Sensitive Reference Standard Issues

Version G01.01-01, Effective May 14, 2019

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.



USP Guideline on Use of Accelerated Processes for Revisions to the *USP-NF and FCC*

- 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."

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.

G01.01-02
Compendial Affairs & Executive Secretariat



USP Guideline on Use of Accelerated Processes for Revisions to the *USP-NF* and *FCC*

- 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



Document Approval Certificate

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

UserName: Amber Day (AMBER.DAY)
Title:
Date: Monday, 01 February 2021, 09:59 AM Eastern Daylight Time
Meaning: Document Owner Approval

=====

UserName: Elena Gonikberg (EG)
Title: Principal Scientific Liaison
Date: Monday, 01 February 2021, 10:10 AM Eastern Daylight Time
Meaning: Technical Approval 1

=====

UserName: Karen Hammann (KRH)
Title: Coordinator of Board Relations
Date: Monday, 01 February 2021, 10:23 AM Eastern Daylight Time
Meaning: Technical Approval 2

=====

UserName: Domenick Vicchio (DWV)
Title: Senior Scientist
Date: Tuesday, 02 February 2021, 05:45 PM Eastern Daylight Time
Meaning: Technical Approval 3

=====

UserName: Jessica Simpson (JCS)
Title: Manager, Compendial Operations
Date: Friday, 05 February 2021, 05:37 PM Eastern Daylight Time
Meaning: Department Supervisor Approval

=====



Document Approval Certificate

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

UserName: Jeanne Sun (JHS)
Title: Counsel
Date: Tuesday, 09 February 2021, 10:05 AM Eastern Daylight Time
Meaning: Legal Approval

=====

UserName: Maira Adzema (MTA)
Title: Sr. Manager, Standards QA
Date: Wednesday, 10 February 2021, 10:20 AM Eastern Daylight Time
Meaning: QA Approval

=====