



**RULES AND PROCEDURES OF THE
2005-2010 COUNCIL OF EXPERTS
Effective January 1, 2008**

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1. GENERAL

1.01 Governance

The Rules and Procedures of the Council of Experts govern the activities of the Council of Experts and those bodies related to the Council of Experts. These bodies include the Council of Experts, the Executive Committee, Division Executive Committees, Expert Committees, ad hoc Advisory Panels, Multidisciplinary Coordinating Groups, Stakeholder Forums and Project Teams.

1.02 Procedural Questions

On procedural questions, the current edition of *Robert's Rules of Order, Newly Revised* shall prevail where the Rules and Procedures of the Council of Experts are silent.

1.03 Amendments

These Rules and Procedures of the Council of Experts may be amended during the cycle in accordance with Chapter VII, Section 11 of the Bylaws.

2. STANDARDS OF CONDUCT

2.01 Code of Ethics

Members of the Council of Experts, Expert Committees and ad hoc Advisory Panels shall be required to adhere to the USP Code of Ethics and related USP Policies, copies of which are available on USP's website.

2.02 Representation

Members of the Council of Experts, Expert Committees, and ad hoc Advisory Panels serve USP as individual experts; they do not serve any outside interest. A member of the Council of Experts, an Expert Committee, or ad hoc Advisory Panel shall not use his or her membership in any way that is, or appears to be, motivated by private gain for himself, herself or any outside interest.

2.03 Performance Assessments

Members of the Council of Experts, Expert Committees, and ad hoc Advisory Panels are subject to performance assessments as needed to help evaluate their effectiveness as members of such bodies. The results of such assessments shall be shared with the member and with the chairperson of the body to which the member belongs.

2.04 Removal

Pursuant to Chapter VI, Section 11 and Chapter VII, Section 18 of the Bylaws, a member of the Council of Experts or an Expert Committee may be removed for cause by the Board of Trustees, upon recommendation of the Chairperson of the Council of Experts (referred to in these Rules and Procedures as the "CoE Chairperson") or the Executive Committee.

2.05 Conflict of Interest

(a) Prohibition on Voting. As set forth in Chapter VII, Section 7 of the Bylaws, no member of the Council of Experts, an Expert Committee or ad hoc Advisory Panel who has a financial or other interest that may conflict, or may appear to conflict, with his or her duties and responsibilities with respect to a particular matter, shall vote on such matter. An employee's interest shall be presumed to coincide with that of his or her employer. It is the responsibility of each member to inform the USP Executive Secretariat, the Scientific Liaison, and/or the chairperson of a particular Expert Committee or ad hoc Advisory Panel should a situation arise in which he or she has or may have a conflict of interest.

(b) Recusal. Where it appears that a conflict of interest may exist, or may be perceived to exist, any Council of Experts, Expert Committee, or ad hoc Advisory Panel member may excuse himself or herself from a Council of Experts, Expert Committee, or ad hoc Advisory Panel deliberation. Any member may be excused from such a deliberation by an affirmative vote of not less than two-thirds of the members of the deliberating body, other than himself or herself. The minutes of such meeting shall note that the member was excused from such deliberation.

(c) Assignment of Work. No member shall be assigned the primary responsibility to work on an issue or question in which he or she has a conflict of interest or the appearance of a conflict of interest. He or she may, however, provide relevant scientific information and may participate in discussions regarding such issue or question; providing, however, that final discussion, deliberation and vote on such issue or question shall be conducted without such member present.

(d) Conflict of Chair. In the case where the chairperson of an Expert Committee or ad hoc Advisory Panel has a conflict of interest or the appearance of a conflict of interest, the vice chairperson will serve or, if the vice chairperson is also conflicted, a designated non-conflicted member shall serve.

2.06 Conflict of Interest Statements

(a) Requirement. Each member of the Council of Experts, the Expert Committees, and ad hoc Advisory Panels shall submit to USP a statement of all employment, professional research, organizational memberships, and financial interests that relate either directly or indirectly to his or her duties and responsibilities. The conflict of interest statement shall be updated by the member as necessary to keep it current or as requested periodically by USP.

(b) Failure to Submit Statement. If a member of the Council of Experts, Expert Committee, or ad hoc Advisory Panel fails to submit a conflict of interest statement, that member will not be allowed to participate in Expert Committee or ad hoc Advisory Panel deliberations.

2.07 Identification and Resolution of Conflict Issues.

The chairperson of an Expert Committee or ad hoc Advisory Panel, together with appropriate USP staff, shall review conflict of interest statements on an ongoing basis to identify potential conflicts of interest. Where a potential conflict of interest arises, the chairperson and USP staff shall work with the individual, and if necessary, the USP Executive Secretariat and USP Secretary, to resolve the matter. If the matter cannot be resolved in this manner, the question shall be referred to the Executive Committee for resolution. Except as specified herein, the information provided in conflict of interest statements shall be kept confidential.

2.08 Confidentiality

(a) Obligation to Maintain Confidentiality. Each member of the Council of Experts, the Expert Committees, and ad hoc Advisory Panels shall maintain the confidentiality of all information gained in the course of his or her activities as a Council of Experts, Expert Committee or ad hoc Advisory Panel member, and shall not use or disclose such information for any purpose, unless such information is already publicly available. In case of doubt as to whether information is deemed confidential, the information shall be treated as confidential until otherwise indicated by the USP Executive Secretariat or USP Secretary.

(b) Confidentiality Agreement. Prior to assuming office, each member of the Council of Experts, Expert Committee, or ad hoc Advisory Panel shall sign a confidentiality agreement with USP.

(c) Failure to Submit Confidentiality Agreement. If a member of the Council of Experts, Expert Committee, or ad hoc Advisory Panel fails to submit a confidentiality agreement, that member will not be allowed to receive any confidential information or participate in the Expert Committee or ad hoc Advisory Panel deliberations.

3. THE COUNCIL OF EXPERTS

3.01 Chairperson

In accordance with Chapter III, Sections 1 through 9 of the Bylaws of USP, the CoE Chairperson shall establish policies and work plans, assign responsibilities, and adjust tasks as needed for the Council of Experts and Expert Committees. The CoE Chairperson shall chair all meetings of the Council of Experts and the Executive Committee. In the event of the temporary absence of the CoE Chairperson, the Chief Science Officer or the CoE Chairperson's designee shall act in his or her stead.

3.02 Election of the Council of Experts

The Council of Experts shall be elected in accordance with Chapter VII, Section 1 of the Bylaws. In the event a member of the Council of Experts is unwilling or unable to serve, a new member shall be elected by the USP Convention membership in accordance with the Bylaws.

3.03 Function

The Council of Experts and its Expert Committees shall function to determine and approve content of the official compendia and other authorized publications, including but not limited to translations and line extensions of the *USP-NF*, journal articles as described in Section 11.02, and any other journal articles or information that may be published by or on behalf of the Council of Experts or an Expert Committee from time to time. The Council of Experts and its Expert Committees may be assigned additional tasks by the CoE Chairperson with the advice of the Executive Committee.

4. THE EXECUTIVE COMMITTEE

4.01 Composition

The Executive Committee shall be appointed by the CoE Chairperson pursuant to Chapter VII, Section 10 of the Bylaws. Unless sooner removed as provided herein, members of the Executive Committee shall serve a one year term and shall be eligible for re-appointment by the CoE Chairperson. Members of the Executive Committee may be removed by the CoE Chairperson at any time.

4.02 Function

The Executive Committee shall have those duties and responsibilities set forth in Chapter VII of the Bylaws, and shall perform such functions as are specified herein.

5. DIVISIONS OF THE COUNCIL OF EXPERTS

5.01 Divisions; Division Executive Committee

If the CoE Chairperson elects to organize the Council of Experts into divisions, a Division Executive Committee shall be appointed for each division in accordance with Chapter VII, Section 9 of the Bylaws. Such divisional organization may be modified during the period between elections by the CoE Chairperson with the approval of the Board of Trustees.

5.02 Chairperson; Absence of Chair

The chairperson of each Division Executive Committee shall be appointed by the CoE Chairperson, after consultation with the chairs of the Expert Committees in such Division, pursuant to Chapter VII, Section 9 of the Bylaws. A Division Executive Committee chairperson may be removed by the CoE Chairperson at any time. In the event of an absence of the chairperson of a Division Executive Committee, the CoE Chairperson or his or her designee shall act in his or her stead.

6. EXPERT COMMITTEES

6.01 Number of Members

The number of individuals to be elected to an Expert Committee shall be determined by the CoE Chairperson, after consultation with the chairperson of the Expert Committee. The Board of Trustees shall approve the number of persons to be elected to each Expert Committee, in accordance with Chapter VI, Section 29 of the Bylaws.

6.02 Election of Expert Committee Members

Members of each Expert Committee shall be elected by the chairpersons of the Expert Committees in the division in which the Expert Committee is placed. An individual may be elected to more than one Expert Committee. A chairperson of an Expert Committee may be elected to serve as a member of any other Expert Committee. In the event of a vacancy in an Expert Committee or if additional members are determined to be needed, such vacancy shall be filled or additional members added in accordance with this section.

6.03 Vice Chair

Each Expert Committee shall elect a vice chairperson to serve in the temporary absence of the chairperson. In the event of a permanent vacancy of the chairperson's office, the vice chairperson shall serve as chairperson until a new chairperson is elected by the Convention membership in accordance with the Bylaws.

6.04 Term and Scope of Service

An Expert Committee shall serve and act until its successor committee is installed or until dissolved by the CoE Chairperson. Each Expert Committee shall work within the areas determined by the CoE Chairperson, as provided in Section 3 above.

6.05 Expert Committee Assessment

Each Expert Committee chair, working with the CoE Chairperson, shall conduct periodic reviews of the Expert Committee's progress in fulfilling its work plan and the responsibilities and tasks assigned to it under Section 3 above.

6.06 Staff

The CoE Chairperson or his or her designee shall appoint a staff member to act as Scientific Liaison for each Expert Committee. Scientific Liaisons, in concert with the CoE Chairperson, shall be responsible for the assignment of tasks within the committees, subject to approval by the committee members to whom the tasks are assigned.

6.07 Subcommittees

Expert Committees may utilize subcommittees to advance their work. A subcommittee is a group of members of a single Expert Committee assigned to perform a certain task of the Expert Committee. A joint subcommittee is a group of members from two or more Expert Committees assigned to perform a certain task of interest to such Expert Committees. A subcommittee or joint subcommittee may make recommendations to an Expert Committee responsible for a particular task or issue, but all decision-making authority shall be retained and exercised by the Expert Committee as the scientific decision-making body of USP under Chapter VII, Section 12 of the Bylaws.

7. AD HOC ADVISORY PANELS

7.01 Formation

The CoE Chairperson may form an ad hoc Advisory Panel in accordance with Chapter VII, Section 6 of the Bylaws to perform an assigned task for a particular Expert Committee or Expert Committees. The CoE Chairperson shall appoint the members of the ad hoc Advisory Panel, who may be removed by the CoE Chairperson at any time. Ad hoc Advisory Panels will continue until their assigned task has been completed or until dissolved by the CoE Chairperson.

7.02 Chairperson

The CoE Chairperson shall appoint the chairperson of an ad hoc Advisory Panel, who shall be a member of the Expert Committee to which the ad hoc Advisory Panel reports and who shall be responsible for communicating the panel's recommendations to the Expert Committee. The chairperson of an ad hoc Advisory Panel may be removed by the CoE Chairperson at any time.

7.03 Joint Advisory Panels

Joint Advisory Panels may be established in cooperation with other Expert Committees or organizations having interests in common with those of a particular Expert Committee. The CoE Chairperson shall appoint the chairperson of a Joint Advisory Panel. Such chairperson may be removed by the CoE Chairperson at any time.

8. MULTIDISCIPLINARY COORDINATING GROUPS

8.01 Formation

The CoE Chairperson may form a Multidisciplinary Coordinating Group in accordance with Chapter VII, Section 3 of the Bylaws.

8.02 Term; Coordination of Work

A Multidisciplinary Coordinating Group shall continue until the election of a new Council of Experts or until dissolved by the CoE Chairperson. The CoE Chairperson shall coordinate the work of the Expert Committees within the Multidisciplinary Coordinating Group.

9. STANDARDS EXPERT COMMITTEES; USP-NF STANDARDS

9.01 Official Publication of *United States Pharmacopeia* or *National Formulary Standards*

The final approved text of a revision to the *United States Pharmacopeia (USP)* or *National Formulary (NF)* shall be published and distributed to the public via print and/or electronic means through the following vehicles: annual editions of the *USP-NF*, *Supplements* to the annual edition, Interim Revision Announcements, and Revision Bulletins. Unless otherwise determined by USP, a revision that includes the use of a new USP Reference Standard shall not be published as final approved text until the required USP Reference Standard is available for purchase. All revisions shall become official six (6) months after publication, unless otherwise specified in the publication vehicle.

9.02 Interim Revision Announcements, Direct Interim Revision Announcements, and Revision Bulletins

(a) Use of Interim Revision Announcements and Revision Bulletins. Interim Revision Announcements (IRA) and Revision Bulletins shall be used for publication of official text only when there is a need for expedited publication as determined by the Scientific Liaison with the approval of the Director, the Department Vice President, the Chief Science Officer, and the appropriate Expert Committee. The use of a direct IRA or a Revision Bulletin, as described in Sections 9.02 (c) and (d) below, shall also require approval of the CoE Chairperson. Direct IRAs and Revision Bulletins also may be used for postponements, as described in Section 9.08 below.

(b) Proposed IRAs. A proposed IRA shall be published in *PF* as provided in Section 9.06 below; provided, however, that there shall be an expedited comment period as indicated in the *PF* publication. Following approval by the Expert Committee as set forth in Section 9.07 below, the IRA shall be published as final in the second edition of *PF* following the edition in which the proposal was published, and shall be official on the first day of the second month of such *PF*.

(c) Direct IRAs. If the circumstances require more expedited publication of a proposal or postponement, such proposal or postponement may be published in *PF* as final, without a comment period, as a direct IRA. Direct IRAs shall become official on the first day of the second month of the *PF* in which they are published.

(d) Revision Bulletins. If the circumstances require immediate publication of official text, a proposal or postponement may be published through a Revision Bulletin. Revision Bulletins shall be posted on the USP website, and published in the next USP-NF or Supplement, as applicable. Revision Bulletins shall be official immediately unless otherwise specified in the Revision Bulletin.

9.03 Errata

Errata are considered to be text erroneously published in the *USP-NF* or its *Supplements* that does not accurately reflect the intended official requirements as approved by the Council of Experts. A list of errata and corresponding corrections to an annual edition of the *USP-NF* or to a *Supplement* shall be published on USP's website, in each *PF* and in each following *Supplement* until the publication of the next annual edition of the *USP-NF*, which shall then reflect such corrections. Errata shall not be subject to notice and comment.

9.04 International Harmonization

With regard to the effort to harmonize the *USP-NF*, the *European Pharmacopeia*, and the *Japanese Pharmacopeia*, any harmonized standard that has been agreed to by a designated representative of USP

shall be approved by the relevant Expert Committee in order for such standard or information to be considered official or authorized or adopted by USP. If a matter has been agreed to by another recognized standard setting body and there has been an agreement not to modify such matter without mutual consent, such matter shall not be modified without first obtaining agreement of the other body, unless it is determined by the CoE Chairperson and the Expert Committee that such modification is necessary in the interest of public health. In such case, the CoE Chairperson shall notify the other body and provide the reasons for making such changes.

9.05 Requests for Revisions

(a) Submission of Requests for Revision. A Request for Revision is a proposal to revise the *USP-NF*. USP shall publish guidelines for the general content for submissions of Requests for Revision. Information and supporting data necessary to validate the accuracy and reliability of the submission must be provided to enable evaluation of the submission. A Request for Revision may be refused if the submission does not substantially conform to the guidelines.

(b) Review of Request for Revision. All Requests for Revision shall be forwarded to the appropriate Scientific Liaison. The Scientific Liaison and his or her immediate supervisor shall evaluate the relevancy, supportability, and urgency of the Request for Revision in accordance with established policies and procedures. The Scientific Liaison may provide the Request for Revision to the relevant Expert Committee or ad hoc Advisory Panel for its recommendations.

(c) Notice of Intent to Revise. If it is determined that revisions to a monograph or general chapter should be made, and upon request of any party, a Notice of Intent to Revise will be posted on USP’s website indicating the changes to be made upon approval by the relevant Expert Committee(s). Such changes shall be made through a Request for Revision in accordance with the procedures described herein.

(d) Approved for Inclusion. Upon the written commitment from a party to submit a Request for Revision, adequate supporting data, and the bulk material required for any accompanying reference standard, USP may notify the Centers for Medicare and Medicaid Services (CMS) that such article has been “approved for inclusion” in the *USP-NF*. Such “approved for inclusion” status may be revoked at USP’s discretion upon the party’s failure to fulfill such commitment in a timely fashion.

9.06 Publication in the *Pharmacopeial Forum*

(a) Approval for Publication in *Pharmacopeial Forum*. Except as provided in Sections 9.02 and 9.03 above, all proposals for revisions to articles in or the addition of new articles to the *USP-NF* shall be published in the *Pharmacopeial Forum (PF)* for public review and comment. Approval for publication in *PF* shall be in accordance with the Revision Approval Process table set forth below. Unless otherwise determined by USP, a proposal that includes the use of a new USP Reference Standard shall not be scheduled for publication in *PF* until a suitable reference standard bulk candidate has been received by USP.

Revision Approval Process

Level of Impact*	Publication in <i>PF</i>		
	Approval	Notification	
		Staff	Committee
Low (less than 5 monographs; editorial changes)	Scientific Liaison	Director	Entire Committee
Medium (5-100 monographs)	Scientific Liaison and Director	Department Vice President	Entire Committee
High (>100 monographs)	Scientific Liaison and Director	Department Vice President and Chief Science Officer	Entire Committee

*The Level of Impact is determined by the level of impact that the revision has upon the users of the *USP-NF*. Low is defined as having an impact on up to five monographs or editorial in nature. Medium is defined as affecting more than 5 and up to 100 monographs. High is defined as affecting over 100 monographs or potentially having a significant impact on the users of the *USP-NF*. For those proposed revisions that have no direct association to monographs or where the level of impact cannot easily be determined by the Scientific Liaison, his or her immediate supervisor and the Expert Committee Chair or member will determine the impact level.

(b) Public Notice; Comments. Except as provided in Section 9.02 above, a period of at least ninety (90) days from the date of publication will be allowed for public review and comment. The time allowed for public comments shall be noted in the publication in the *PF*. For good cause shown, the CoE Chairperson may alter the time specified. The Scientific Liaison will compile the comments received and forward them to any individuals who were involved in the decision to publish the proposal for publication in *PF* under Section 9.06(a) above and to the appropriate Expert Committee or Committees, who shall review the comments and accept or reject them, make any additional changes to the text it deems appropriate, and determine whether to proceed with the proposal. If the determination is made to proceed, the proposal must be approved by formal vote of the Expert Committee prior to publication in the *USP* or *NF* pursuant to Section 9.07 below.

(c) Republication in *PF*. A proposal published in *PF* for comment shall not be reprinted in *PF* for additional comment prior to publication in the *USP* or the *NF* unless the Expert Committee, the Division Executive Committee or the CoE Chairperson determines that reprinting is necessary due to the nature or significance of the comments received or changes made to the proposal.

(d) Comment Summary. Where a proposal is published in the *USP* or the *NF* without reprinting in *PF*, such a summary or abstract of each type of comment received and a response to the comment from the Expert Committee, Division Executive Committee, or CoE Chairperson shall be posted on USP's website.

(e) Additional Notice and Comment. In addition to publication in *PF* as provided herein, other means such as the USP website may be used to provide notice of and an opportunity to comment on proposals, if determined appropriate by the Expert Committee, the Division Executive Committee, or the CoE Chairperson.

9.07 Approval by Expert Committee

(a) Voting. Prior to publication as final text, proposals must be voted on and approved by the appropriate Expert Committee. Voting may occur at a meeting of the Expert Committee held in accordance with Section 13 below or by written ballot. A specific section or sections of a proposal may be voted on and approved separately by the appropriate Expert Committee. Voting on a proposal or any aspect thereof may not occur prior to the end of the public comment period specified in Section 9.06(b) above. A record of the proposal, the evaluation and approvals for the item, all public comments, and the initial Request for Revision will be made available to the Expert Committee not less than twenty (20) business days prior to the end of the voting period.

(b) Ballots. If voting is by ballot, such ballot may be issued or returned electronically, by mail, facsimile transmission or any other method. Such ballot shall state a reasonable period of time by which ballots must be received. Ballots must be returned by a majority of the members of the Expert Committee for the vote to be valid. Members who are abstaining from voting due to conflict of interest or other reasons shall indicate such abstention on their ballots and be counted towards this majority requirement. The results of voting shall be reported back to the Expert Committee.

(c) Resolution of Issues. The Executive Secretariat shall bring to the attention of the Scientific Liaison and chairperson of the Expert Committee any issues or questions arising with the approval process for resolution.

(d) Responsibility for Approvals. When more than one Expert Committee collaborates on a particular proposal, one Expert Committee shall be designated by the CoE Chairperson as the lead Expert Committee and will be responsible for approvals. The other collaborating Expert Committee(s) shall be notified of the approval.

9.08 Postponement

(a) Request for Postponement. A request for postponement shall be accompanied by a statement of the grounds upon which the postponement is requested and appropriate supporting data. A request for postponement submitted under this section shall be clearly distinguished from a Request for Revision. A request for postponement may originate from a *USP-NF* user, an Expert Committee or other USP volunteer body, or staff.

(b) Untimely Requests. A request for postponement received within thirty (30) days of the official date may be refused for consideration by the CoE Chairperson if, solely within his or her discretion, he or she considers the request untimely or lacking adequate supporting data. Such decision shall not be subject to appeal, and the matter instead will be considered as a Request for Revision.

(c) Granting of Postponement. The Expert Committee responsible for approving the standard for which postponement is sought shall have the authority to postpone the official date of any requirement or textual material in such standards; provided, however, that all decisions to postpone shall require review and approval by the CoE Chairperson, who may at his or her option refer the matter to the Executive Committee for its consideration.

(d) Postponement Due to Unavailability of Reference Standards. Where a new reference standard is required in a new monograph or in a revision of an existing monograph but is not yet available, the official date of any portion of the monograph or monograph revision utilizing such reference standard shall be postponed until such reference standard is available. The postponement and the name of such unavailable reference standards shall be published. At such time as such reference standards become available, their availability and the official date of the postponed portion(s) of the monograph shall be announced.

9.09 Lifting a Postponement

(a) Evaluation of Issues. In the event that a postponement is granted, the Expert Committee shall take reasonable action to evaluate the issues involved and determine as promptly as practicable whether the postponement should be lifted and the standards should become official as scheduled, or whether the standards should be revised based on the issues presented.

(b) Decision to Lift Postponement. In making the determination to lift a postponement, the Expert Committee shall consider all information reasonably relevant and material to the matter. To gather this information, the Expert Committee may invite other parties it deems to have an interest in the matter to submit information. When a postponement is lifted, this decision, along with the postponed standard shall be published as quickly as possible in *PF* and on USP's website with an official date assigned to it. Parties that are deemed to be affected by this decision may also be notified.

9.10 Appeals

(a) Process. All appeals shall be received and considered as provided in Chapter VII, Section 16 of the Bylaws and this section.

(b) Timing of Appeals. A matter may properly be appealed only prior to its official date or, in the case of a reference standard, prior to its issuance. Once official or issued, the matter is not subject to appeal, however, any interested party may request that the matter be considered as a Request for Revision.

(c) Submission of Appeals. All appeals must be submitted in writing and be accompanied by supporting data and evidence. Electronic submission is preferred but not required. An appeal submitted under this section shall be clearly distinguished from a Request for Revision. The appellant shall indicate whether an oral hearing is requested or if the appeal should be decided solely based on the submitted documents.

(d) Determination to Grant or Deny. All appeals of decisions made by an Expert Committee shall be submitted to the CoE Chairperson who will make the initial determination whether or not to grant the appeal. This determination may be based upon whether or not the appeal is accompanied by sufficient data or evidence, is frivolous, or is untimely. For appeals of a decision made by the Executive Committee, the initial determination whether or not to grant the appeal shall be reviewed by the Board of Trustees. The determination to not grant an appeal is not subject to appeal. Where an appeal is not granted, the appeal will be treated as a Request for Revision.

(e) Adjudication by Executive Committee. If an appeal of a decision made by an Expert Committee is granted, the CoE Chairperson shall submit it to the Executive Committee for adjudication. For an appeal via oral hearing, the Executive Committee shall determine the time and place of the hearing and the CoE Chairperson or his or her designee shall be the presiding officer. The oral hearing may be held by conference call or similar communication by means of which all persons participating in the meeting shall hear one another in the same period of time. The Executive Committee may invite other parties that it deems to have a substantial interest in the matter being appealed to participate in the appeal, including the Expert Committee whose decision is being appealed. At an oral hearing any party may offer such additional evidence deemed necessary to an understanding and determination of the issues. In an oral hearing, witnesses may be called, and a witness presented by one party may be questioned by any other party with regard to the evidence the witness has offered. The Executive Committee shall be the judge of the relevancy and materiality of the evidence offered and conformance to legal rules of evidence shall not be necessary.

(f) Referral to Board of Trustees. A decision of the Executive Committee on an appeal shall be referred to the Board of Trustees. Where an appeal is determined by the Board to be primarily on a procedural matter, the Board may uphold the decision or remand the decision to the appropriate Expert Committee for reconsideration under proper procedures. Where a decision is determined by the Board to be primarily on a scientific issue, the Board may request the Council of Experts to review the decision. After such review, which shall be given as promptly as practicable, the Council of Experts may uphold or reverse the decision of the Executive Committee.

(g) Review by Council of Experts. Where there is an appeal of a decision originally made by the Executive Committee, the appeal will be adjudicated by the Board of Trustees, which upon consideration of the facts may request the Council of Experts to review the decision. After such review, which shall be given as promptly as practicable, the members of the Council of Experts may uphold or reverse the decision of the Executive Committee.

10. STANDARDS EXPERT COMMITTEES; OTHER STANDARDS

10.01 Food Chemicals Codex.

(a) Requests for Revision. Proposals to create new standards or to revise standards in the *Food Chemicals Codex (FCC)* shall be submitted in accordance with any applicable guidelines developed by USP. The Scientific Liaison and his or her immediate supervisor, shall evaluate the relevancy, supportability, and urgency of the request in accordance with the established policies and procedures and determine whether to proceed with the requested revision. The Scientific Liaison shall notify the Food Ingredients Expert Committee (FIEC) of a pending *FCC* request for revision. The Scientific Liaison may provide the request to other relevant Expert Committees or ad hoc Advisory Panels.

(b) Notice and Comment Period. Except as provided in subsections (e) and (f) below, all proposals to revise the *FCC* shall be published in the *FCC Forum* on the USP website for public review and comment. Unless otherwise determined by USP, a proposal that includes the use of a new USP Reference Standard shall not be scheduled for publication in the *FCC Forum* until a suitable reference standard bulk candidate has been received by USP. A period of ninety (90) days from the date of publication in *FCC Forum* will be allowed for public review and comment. For good cause shown, the CoE Chairperson may alter the time specified. The Scientific Liaison will review the comments and, together with his or her supervisor, shall determine whether to proceed with committee approval as set forth in subsection (c) below.

(c) Approval by Expert Committee and Publication. Following the notice and comment period, the FIEC shall review all comments, accept or reject them, and make any final changes to the proposal it deems appropriate. Prior to publication in final form, the proposal must be approved by the FIEC using the voting procedures provided in Section 9.07 above. After approval by the FIEC, the *FCC* proposal shall be published as final in the next edition of the *FCC* or *Supplement* thereto, as applicable, and shall be effective as of the date of publication. Unless otherwise determined by USP, a revision to the *FCC* that includes the use of a new USP Reference Standard shall not be published as final approved text until the required USP Reference Standard is available for purchase.

(d) Expedited Standards. If the FIEC 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 under subsection (b) and approval by the FIEC under subsection (c). Such a standard (Expedited 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 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.

(e) Immediate Standards. In those rare cases where the FIEC 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 FIEC and posted as final on the USP website without the notice and comment period specified in subsection (b) above. Such a standard (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.

(f) Errata. Errata are considered to be text erroneously published in the *FCC* or its *Supplements* that does not accurately reflect the intended requirements as approved by the FIEC. A list of errata and corresponding corrections to an edition of the *FCC* or to a *Supplement* shall be published on USP's website, until the publication of the next edition of the *FCC* or *Supplement*, which shall then reflect such corrections. Errata shall not be subject to notice and comment

10.02 Standards for Articles Legally Marketed Outside the U.S. (SALMOUS)

(a) Requests for Revision. Proposals to create new monographs or to revise monographs for articles legally marketed outside of the U.S. (SALMOUS proposals) shall be developed in accordance with the USP Guidelines on Standards for Articles Legally Marked Outside the U.S., available at <http://www.usp.org/standards/international/guidelines.html>. The Scientific Liaison and his or her immediate supervisor shall evaluate the relevancy, supportability, and urgency of the SALMOUS proposal in accordance with the established policies and procedures, and determine whether to proceed with the proposal. The Scientific Liaison shall notify the relevant Expert Committee of a pending SALMOUS proposal.

(b) Notice and Comment Period. All SALMOUS proposals shall be published on USP's website for public review and comment. A period of at least ninety (90) days from the date of publication will be allowed for public review and comment. For good cause shown, the CoE Chairperson may alter the time specified. The Scientific Liaison will review the comments and, together with his or her supervisor, shall determine whether to proceed with committee approval as set forth in subsection (c) below.

(c) Approval by Expert Committee. Following the notice and comment period, the International Health Expert Committee shall review all comments, accept or reject them, and make any final changes to the proposal it deems appropriate. Prior to publication in final form, the SALMOUS proposal must be approved by the relevant Expert Committee using the voting procedures provided in Section 9.07 above.

(d) Publication. After approval by the relevant Expert Committee, a SALMOUS proposal shall be published and maintained on the USP website as a final SALMOUS monograph and shall be considered authorized text. Any subsequent comments received shall be treated as proposed revisions of a SALMOUS monograph in accordance with subsections (a), (b) and (c) above.

10.03 Pending Standards (PS)

(a) Request for Revision. Proposals to create new monographs for articles pending FDA approval shall be submitted in accordance with the USP Pending Standards Guideline, available at <http://www.usp.org/standards/pending/guidelines.html>. The Scientific Liaison and his or her immediate supervisor shall evaluate the relevancy, supportability and urgency of the PS proposal in accordance with the established policies and procedures, and determine whether to proceed with the proposal. The Scientific Liaison shall notify the relevant Expert Committee of a pending PS proposal.

(b) Notice and Comment Period. All PS proposals shall be published on USP's website for public review and comment. A period of at least ninety (90) days from the date of publication will be allowed for public review and comment. For good cause shown, the CoE Chairperson may alter the time specified. The Scientific Liaison will review the comments and, together with his or her supervisor, shall determine whether to proceed with committee approval as set forth in subsection (c) below.

(c) Approval by Expert Committee. Following the notice and comment period, the relevant Expert Committee shall review all comments, accept or reject them, and make any final changes to the proposal it deems appropriate. Prior to publication in final form, the PS proposal must be approved by the relevant Expert Committee using the voting procedures provided in Section 9.07 above.

(d) Publication. After approval by the relevant Expert Committee, a PS proposal shall be published and maintained on the USP website as a final PS monograph and shall be considered authorized text. After FDA approves the article to be marketed in the U.S., the standard will become official and be moved to *USP-NF* as provided in the Pending Standards Guideline.

10.04 Information Monographs Developed by Standards Expert Committees

Information monographs may be developed by Standards Expert Committees including the Veterinary Medicine Expert Committee and Radiopharmaceutical Information Expert Committee. Such monographs shall be posted on the USP website for public comment for a period of thirty (30) days. The relevant Expert Committee shall review all comments, alter the text as appropriate, and approve the monograph using the voting procedures described in Section 9.07 above.

11. INFORMATION EXPERT COMMITTEE PROCEDURES

11.01 Medicare Model Guidelines

The Information Expert Committee chairs shall serve as members of the Model Guidelines Expert Committee, which shall be responsible for developing and approving revisions to the Model Guidelines and related information and documents that pertain to formularies and plan designs that may be used by prescription drug plans under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The Model Guidelines Expert Committee shall adopt appropriate rules and procedures to govern its work, consistent with the provisions of the Bylaws relating to rules and procedures of the Council of Experts.

11.02 Journal Articles

Articles to be submitted to the *Annals of Internal Medicine* or other journals on behalf of USP's Information Expert Committees shall be assigned to the Information Expert Committee with expertise in the subject matter of the article, who shall work with USP staff to develop the proposed article. The final content of the article shall be approved by the Information Expert Committee to which it is assigned prior to submission to the *Annals of Internal Medicine* or other journal.

11.03 Additional Functions

Information Expert Committees shall perform such additional functions and tasks as may be assigned to them from time to time under Section 3 above.

12. Stakeholder Forums and Project Teams

12.01 Formation

Stakeholder Forums and Project Teams may be formed by the CoE Chairperson in accordance with Chapter III, Section 9 of the Bylaws. The CoE Chairperson shall appoint the members of all Stakeholder Forums and Project Teams and shall have the right to remove any member at any time.

12.02 Membership and Representation

Stakeholder Forum and Project Team members serve as representatives of a particular interest, group and/or company and not as representatives of USP. Members of the Board of Trustees, Council of Experts, Expert Committees and ad hoc Advisory Panels may participate in Stakeholder Forum and Project Team discussions, but only as representatives of USP.

12.03 Role

Stakeholder Forum and Project Team deliberations are advisory and are not binding in any way on the Council of Experts, its Expert Committees, or USP staff.

12.04 Responsibility

When attending a meeting, Stakeholder Forum and Project Team members' travel and accommodation arrangements and costs are the responsibility of the individual Stakeholder Forum or Project Team member, unless otherwise indicated by USP.

12.05 Stakeholder Forums

(a) Purpose. Stakeholder Forums shall be formed to enable an exchange of information and perspectives between USP and the affected public, with the ultimate goal of improving USP standards and information.

(b) Formation. The decision to form a Stakeholder Forum will be made by the CoE Chairperson, with input from the Council of Experts. When establishing a Stakeholder Forum, the CoE Chairperson shall develop a specific charge for the Stakeholder Forum, including goals and expected outcomes. Stakeholder Forums will continue until dissolved by the CoE Chairperson.

(c) Membership. Membership of Stakeholder Forums will consist of organizations that may be affected by USP actions and who, in turn, might affect USP activities. Member organizations may be drawn from the USP Convention membership and elsewhere depending on the topic being considered. Each member organization may appoint up to six representatives to attend a Stakeholder Forum meeting.

(d) Chair. The Stakeholder Forum members, with the advice and consent of the CoE Chairperson, will select the chairperson(s) of such Stakeholder Forum. Subsequent rotation of chairperson(s) of a Stakeholder Forum is at the Stakeholder Forum's discretion. The chairperson(s) of a Stakeholder Forum leadership shall

work with USP staff to create agendas for each meeting. The Stakeholder Forum may elect to create a planning committee to manage that activity. The chairperson(s) will preside over the Stakeholder Forum meetings.

(e) Meetings. Stakeholder Forum meeting dates and times will be posted on the USP website and are open to attendance by other interested individuals who may attend as observers. Meeting notes will be prepared by USP staff, endorsed by the Stakeholder Forum chairperson, and distributed and posted on the USP website. Recommended action items will be considered by USP after each Stakeholder Forum. Those accepted by USP will be tracked and progress reported at each Stakeholder Forum meeting.

(f) Reports. Summary reports of a Stakeholder Forum will be prepared periodically as agreed upon by the Stakeholder Forum and USP.

12.06 Project Teams

(a) Purpose. Project Teams will be formed to enable stakeholders with a specific technical or scientific expertise to provide information, perspectives, advice, and assistance to the Council of Experts, its Expert Committees, and USP staff on a particular topic or set of topics, with the goal of improving USP standards and information. Project Teams will function under a particular Stakeholder Forum and generally will be advisory to a particular Expert Committee.

(b) Formation. Project Teams generally shall be formed to address a specific compendial topic. The formation of a Project Team may be recommended by the members of a Stakeholder Forum or by the CoE Chairperson. When forming a Project Team, the CoE Chairperson shall develop a specific charge for the Project Team, including goals and expected outcomes, with input from the related Stakeholder Forum. Project Teams will continue until completion of their charge or until dissolved by the Chairperson.

(c) Membership. Members of Project Teams shall be appointed by the CoE Chairperson, based on recommendations from the related Stakeholder Forum, based on their scientific or technical expertise. The membership shall be primarily organization-based, reflecting the composition of the related Stakeholder Forum. The CoE Chairperson shall determine the appropriate number and type of representatives on the Project Team, with input from the Stakeholder Forum.

(d) Chair. Each Project Team shall elect a chairperson. Subsequent rotation of chairpersons of a Project Team is at the Project Team's discretion. The chairperson shall preside over the Project Team's meeting(s).

(e) Meetings. Upon formation of a Project Team, an initial kick-off meeting shall be held with the Project Team and appropriate USP staff and Council of Experts or Expert Committee members. Subsequent meetings of the Project Team will occur as determined necessary by the Project Team, and may be face-to-face or via teleconference or webcast. USP staff and Council of Experts or Expert Committee members shall attend such subsequent meetings only as reasonably necessary, upon request of the Project Team.

(f) Reports. Project Teams shall report progress to the appropriate Stakeholder Forum. The Project Team, on its conclusion, shall prepare a final report with conclusions and recommendations based on its findings. The final report together with any written response will be posted on USP's website. The relevant Expert Committee, with the assistance of USP staff, will respond to the issues, in writing, as appropriate and necessary.

13. MEETINGS

13.01 Expert Committee and ad hoc Advisory Panel Meetings

(a) Open Meetings. In accordance with USP's Open Meeting Policy, a meeting of an Expert Committee or ad hoc Advisory Panel shall be open to the public, except that a meeting or a portion of a meeting may be closed if the chairperson of the Expert Committee or ad hoc Advisory Panel or the CoE Chairperson determines that there is good and sufficient reason for closure. Such reasons may include, without limitation: review or discussion of trade secret or confidential, commercial information; or review or discussion of matters the premature disclosure of which could be detrimental to the USP. If the determination is made to close a meeting, such determination and the reason for closure shall be noted in the minutes of such meeting, and any non-member participants attending such meeting (other than Government Liaisons, as described in Section 13.04(c) below) shall be excused from the meeting.

(b) Teleconferences. An Expert Committee or ad hoc Advisory Panel may hold a meeting by means of a conference telephone call, computer technology, or other communications equipment by means of which all persons participating in the meeting shall hear one another or perceive each other's comments in the same period of time. Participation by such means shall constitute presence in person at a meeting. A meeting held by means of a telephone conference call, computer technology, or other communications equipment shall provide an opportunity for public listening, viewing, and comment unless the meeting is closed as provided above.

13.02 Division Executive Committee, Executive Committee, and Council of Experts Meetings

Meetings of the Division Executive Committee, Executive Committee, and Council of Experts shall be closed unless otherwise indicated.

13.03 Announcement of Public Meetings; Minutes

To the extent possible, all USP open meetings shall be announced beforehand by appropriate means, which shall include the USP website. To the extent possible, minutes of Expert Committee meetings shall be posted on the USP website, excluding minutes from any closed portion thereof.

13.04 Non-member Participants in Expert Committee or ad hoc Advisory Panel Meetings

When a USP meeting is open to the public, a non-member may participate in one of three ways:

(a) Invited Guest. Invited guests are non-members who are invited specifically to share a particular expertise or express their particular point of view. This shall be carried out under the control of the chairperson of the Expert Committee or ad hoc Advisory Panel and shall be subject to the Rules and Procedures of the Council of Experts. These non-members shall be provided with appropriate briefing materials, excluding confidential information. The Expert Committee or ad hoc Advisory Panel chairperson shall ask the invited guest to be excused during a confidential discussion or deliberation.

(b) Observer. Observers are non-members who themselves choose to attend the Expert Committee or ad hoc Advisory Panel meeting. Observers must notify the Scientific Liaison **at least five business days** in advance of the meeting (or as soon as possible after posting of the meeting notice and agenda) of their proposed attendance, and provide necessary background information about themselves. Observers may or may not receive briefing materials. USP retains the right to refuse permission for an observer to attend a meeting. The Expert Committee or ad hoc Advisory Panel chairperson shall ask the observer to excuse himself or herself during a confidential discussion or deliberation. Observers will be permitted to make presentations or otherwise speak at the meeting only if approved in advance by the Scientific Liaison or chair of the Expert Committee or ad hoc Advisory Panel.

(c) Government Liaison. Government Liaisons are representatives from the FDA or other domestic or foreign government agencies who desire to participate in an Expert Committee or ad hoc Advisory Panel in their capacity as government employees. Government Liaisons generally shall receive briefing materials and be allowed to participate in confidential discussions occurring at a meeting, provided that they have signed confidentiality agreements for such meeting requiring them to keep all such information confidential except to the extent limited disclosure within the respective agency is required in the performance of their governmental duties. The Expert Committee or ad hoc Advisory Panel chairperson may ask a Government Liaison to excuse himself or herself during any discussion or deliberation in which the chairperson believes such Government Liaison's participation would not be appropriate due to confidentiality, conflict or other reasons.

13.05 Working Sessions and Status Conferences

Two or more members of an Expert Committee or ad hoc Advisory Panel may engage in informal dialogue and working sessions as part of their work, and an Expert Committee or ad hoc Advisory panel may hold informal teleconferences and online discussions to review the status of work being performed by members, without the need to call or conduct a formal meeting of the Expert Committee or ad hoc Advisory Panel as provided herein. Except as provided in Section 9.07 above, any decision on any substantive issue shall be made by an Expert Committee or ad hoc Advisory Panel only at a meeting called and conducted in accordance with the provisions of Sections 13.01 through 13.04 above.