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PDA STANDARDS DEVELOPMENT PROGRAM Policies and Procedures

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PDA Standards Program National Procedures Manual

1.0 Program scope and objective

1.1 Program scope

The Parenteral Drug Association (PDA) is recognized as one of the foremost voluntary standards-setting organizations in the United States. The PDA procedures for documenting consensus on PDA-proposed or sponsored *American National Standards* are accredited by the American National Standards Institute (ANSI); the organization that coordinates the development and promotion of many U.S. voluntary standards and that officially represents the United States in international standards-setting. PDA's accredited scope is as follows:

“Standards for pharmaceutical and biopharmaceutical product manufacturing practices”

PDA's standards are developed by technical committees or working groups operating as consensus bodies with membership drawn from a variety of backgrounds— pharmaceutical manufacturers, manufacturing equipment suppliers, academicians, regulatory authorities, etc. Collectively, these interdisciplinary groups develop standards and other technical documents intended to advance medical technology and patient safety.

PDA also manages international technical committees that develop international standards and administers U.S. technical advisory groups (TAGs) that participate in the development of international standards on behalf of the U.S. The international aspects of the PDA standards program are governed by the policies and procedures of the International Organization for Standardization (ISO) and ANSI. PDA has developed a separate manual that sets forth policies for PDA's administration of U.S. TAGs.

Through its national and international technical committees and advisory groups, PDA plays a significant global role in the development of pharmaceutical manufacturing standards. Procedures and policies provided in this document—the *PDA Standards Program Policies and Procedures*¹—refer only to the PDA National Standards Program, unless otherwise specified.

1.2 Program objective

The PDA standards program works to assist the pharmaceutical community globally in the use, acceptance, and advancement of pharmaceutical manufacturing technology and practices.

1.3 Program benefits

PDA standards and other technical documents reflect the combined knowledge of pharmaceutical manufacturers, manufacturing equipment suppliers, academicians, regulatory authorities, and specific technology experts. They are intended to be voluntary and to be applied at the discretion and judgment of the reader. Consequently, the PDA standards program benefits the pharmaceutical industry without restricting technological advancement or freedom to operate.

1.4 Types of technical committee documents/publications

1.4.1 General

PDA technical publications are classified according to their objectives or the level of consensus they reflect. The types of technical publications described below are only examples—PDA committees may develop other types of documents in response to specific technical issues.

1.4.2 Standards

A standard may recommend to a manufacturer 1) the information that should be included with a product, 2) basic safety and performance criteria, and 3) conformance measures of a strictly technical or engineering nature that can be used to assess compliance. The inclusion of design specifications in a standard is

¹Hereafter “Policies and Procedures”.

permitted when circumstances warrant, but design specifications usually are avoided as they can hinder the advancement of technology.

A standard may provide pharmaceutical manufacturers with guidelines for the use, evaluation, or processing of pharmaceutical products, product packaging and handling, and manufacturing equipment.

PDA's standards require national consensus.

1.4.3 American National Standards

A PDA standard designated as an "American National Standard" (ANS) is developed in accordance with ANSI's requirements for consensus, due process, public review, and ANSI review.

PDA standards adhere to ANSI's planning and coordinating activities (ANSI Essential Requirements 4.3).

PDA may choose to develop consensus standards without submitting them for ANSI approval as American National Standards.

1.4.4 Other technical publications

The PDA also develops technical communications (e.g. technical reports, points to consider, surveys, etc.) tailored to the specific needs of its membership and the pharmaceutical manufacturing community at large. PDA committees are not limited to the categories of technical publications described in the foregoing may choose to devise innovative approaches to education and technology assessment. The work products from these efforts are not subject to ANSI review.

1.5 Metric Policy

The use of International System of Units (SI) is preferred in all PDA consensus documents. For situations where the SI unit is not commonly used or where the SI unit is not the term of art, the more commonly used measurement or term of art may be used. The value in SI units, however, also may be included parenthetically.

2.0 Due process

2.1 Due process in the development of standards

Due process means that any person (organization, company, government agency, individual, etc.) with a direct and material interest has a right to participate by expressing a position and its basis, having that position considered, and having the right to appeal. Due process allows for equity and fair play.

PDA standards are developed by consensus, in accordance with policies and procedures designed to ensure due process. PDA shall abide by all applicable requirements for due process provided in the *ANSI Essential Requirements: Due process requirements for American National Standards*.²

2.2 Consensus

Consensus means substantial agreement has been reached by directly and materially affected interests. This signifies the concurrence of more than a simple majority, but not necessarily unanimity. Consensus requires that all views and objections be considered, and that an effort be made toward their resolution. Consensus is achieved when individuals and organizations having a direct and material interest in a standard achieve substantial agreement according to the judgment of the PDA Advisory Board assigned to the standard development activity. Consensus does *not* require that all objections be withdrawn.

Establishing a consensus on a standard entails the following:

- a) substantial agreement³ by written ballot among the members of the responsible consensus body;

²Hererafter "ANSI Essential Requirements".

³"Substantial agreement" is defined as minimum approval of at least two-thirds of those voting (excluding abstentions), with at least two-thirds of eligible voters returning ballots (including abstentions). However the voting record of each interest category also may be considered.

- b) appropriate public review (for standards);
- c) good faith attempts at resolving any comments; and
- d) concurrence that consensus has been achieved in the judgment of the applicable PDA Advisory Board.

2.3 Openness

Participation shall be open to all persons who are directly and materially affected by the activity in question. There shall be no undue financial barriers to participation. Voting membership on the consensus body shall not be conditional upon membership in any organization, nor unreasonably restricted on the basis of technical qualifications or other such requirements.

PDA shall provide timely and adequate notice of any action to create, revise, reaffirm, or withdraw a standard, and the establishment of a new consensus body to all known directly and materially affected interests. PDA shall provide a clear and meaningful description of the purpose of the proposed activity and shall identify a readily available source for further information. In addition, the name (or if membership is by organization, the name of the organization with a point of contact), affiliation and interest category of each member of the consensus body shall be made available to interested parties upon request (ANSI Essential Requirements 2.1).

2.4 Lack of dominance

The standards development process shall not be dominated by any single interest category, individual, or organization. Dominance means a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints (ANSI Essential Requirements 1.2).

Unless it is claimed in writing (including electronic communications) by a directly and materially affected party that a single interest category, individual or organization dominated the standards development process, no test for dominance is required (ANSI Essential Requirements 2.2).

2.5 Balance

The standards development process should have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance. If a consensus body lacks balance, outreach to achieve balance shall be undertaken.

2.6 Coordination and harmonization

Good faith efforts shall be made to resolve potential conflicts between PDA standards and existing standards promulgated by other standards developers.

2.7 Notification of standards development

Notification of the development of PDA standards and TRs shall be announced in suitable media as appropriate to afford an opportunity for participation by directly and materially affected persons.

2.8 Consideration of views and objections

Prompt consideration shall be given to the written views and objections of all participants, including those commenting during public review.

2.9 Consensus vote

Evidence of consensus in accordance with these requirements and, where appropriate, the *ANSI Essential Requirements*, shall be documented.

2.10 Written procedures

These *Policies and Procedures* shall be available upon request to any interested party.

3.0 Program organization

3.1 General

PDA national standards and technical documents are developed by a consensus body (a technical committee or working group) assisted by staff and overseen by an assigned PDA Advisory Board.

3.2 Consensus bodies

Consensus bodies composed of volunteer technical experts are the heart of the PDA standards program. Each PDA consensus body has a defined scope of work and operates under established policies and procedures. A PDA Advisory Board evaluates the need for standards and other technical publications within its area of competency.

An Advisory Board may establish consensus bodies to address particular technological areas within the scope of the respective Advisory Board.

PDA standards are developed by a committee or working group acting as a consensus body. Consensus bodies provide the technical resources for developing, approving, and revising standards.

Some committees, working groups, or subgroups not only serve as consensus bodies but also may act in an advisory, organizational, or oversight capacity in the standards process. The provisions given in this document governing organization, membership, participation, and operations of consensus bodies do not apply to groups when not acting as consensus bodies.

3.3 PDA Advisory Boards

3.3.1 General

Advisory Boards (ABs) direct and supervise PDA consensus body activities relating to the national standards program. There are three ABs which cover certain subject matter areas:

- 1) Science Advisory Board - Provides guidance and sets strategic direction for PDA on technical topics associated with pharmaceutical manufacturing and quality.
- 2) Biotechnology Advisory Board - Establishes the strategic direction and provides oversight for PDA's biopharmaceutical scientific and technical activities.
- 3) Regulatory Affairs and Quality Advisory Board - Serves the PDA membership by influencing scientific-based regulations and providing interpretation on quality and regulatory issues affecting development, manufacturing and control of pharmaceutical products.

3.3.2 Membership

The AB leadership (Chair/Vice-Chair) is appointed by the Chair of the PDA Board of Directors (BoD) and approved by the BoD through a ballot. The leadership may be removed at any time by agreement of a simple majority voice or ballot vote of the BoD. The Chair/Vice-Chair assumes their positions for a three year period, which may be renewed once with the agreement of the BoD. In order to help ensure continuity, Vice-Chair will become next Chair.

Advisory Boards are comprised of individuals who have a demonstrated history of scientific and technical excellence within the scope of PDA's activities. ABs normally consist of approximately 18 – 25 members, representing scientific and technical disciplines within PDA's purview. AB members must be members of PDA and membership is open to qualified individuals, including those from regulatory agencies, compendia, and academia. AB members may be nominated by any PDA members or may self-suggest themselves as a nominee.

3.3.3 Terms

AB members are appointed (and reapproved) by the Chair/Vice-Chair of the AB and will serve a three-year term, which may be renewed once. Service by an AB member as Vice-Chair or Chair permits one additional three year term, however this extension must be approved by the BoD. Approximately one third of the

members should be renewed or replaced each year. All members must agree to and sign the PDA volunteer agreement form.

3.3.4 Responsibilities

The PDA Board of Directors, Advisory Boards, and staff adhere to and enforce the *PDA Standards Program Policies and Procedures*.

3.3.4.1 Advisory Boards

The AB's responsibilities include the following:

- a) authorizing the initiation and termination of consensus bodies and consensus body activities;
- b) advising the consensus body chairs in developing and directing the consensus body's program of work;
- c) reviewing the progress of consensus body work;
- d) advising the PDA Board of Directors on the appointment of consensus body chairs;
- e) endorsing new or revised policies for approval by the Board of Directors; and
- f) hearing appeals of consensus body decisions.

The PDA ABs serve as the final PDA appellate body for disputes concerning standards.

3.3.4.2 PDA Board of Directors

The Board of Directors (BoD) has general supervision, control, and direction of the affairs of the PDA. The BoD will be informed by the ABs and PDA Staff regarding the initiation of all standards development activities and authorizes the submission of proposed standards to ANSI for final approval as an American National Standard.

3.3.4.3 PDA Scientific and Regulatory Affairs staff

PDA Scientific and Regulatory Affairs (S&RA) staff manages the program on a day-to-day basis, advising consensus bodies on PDA policies and procedures, scheduling meetings, maintaining records, preparing documentation, editing technical documents, administering ballots, overseeing public review, and coordinating consensus body and AB activities.

The PDA S&RA staff reviews and confirms whether PDA policies and procedures have been followed in the development of standards and informs the BoD of this status during the final authorization for submission to ANSI process.

4.0 Consensus body membership and structure

4.1 Definition of consensus body

A consensus body is a "group that approves the content of a standard and whose vote demonstrates evidence of consensus" (*ANSI Essential Requirements*).

When a committee or working group is actively developing and approving PDA standards, that group is acting as a consensus body.

4.2 Consensus body leadership (chairs)

4.2.1 General

PDA consensus bodies have two chairs, preferably from different interest categories. If suitable candidates from disparate interests cannot be found, two chairs from the same interest category may serve or the consensus body may be chaired by a single member.

4.2.2 Selection of chairs

Advisory Boards appoint consensus body chairs with appropriate consultation with PDA staff.

In the event that a consensus body has no chair and there is pressing business before the group, the responsible AB may appoint an interim chair.

If a chair is not able to attend a meeting, an acting chair may be appointed by staff to lead the meeting.

4.2.3 Terms of chairs

The term of a consensus body chair appointment is for three years, renewable for a second three-year term. Additional terms may be approved following consultation with the responsible Advisory Board.

4.2.4 Qualifications of Consensus body Chairs

Consensus body chairs must be experts in the technology covered in the scope of the group.

4.2.5 Responsibilities of chairs

Specifically, chairs are responsible for:

- a) Conducting committee meetings;
- b) Implementing the policies, objectives, and priorities of the association;
- c) Efficiently managing consensus body activities to ensure timely completion of work;
- d) Advising staff, when requested, on membership matters;
- e) Appointing task group members or other consensus body officers;
- f) Advising staff on technical and administrative matters relevant to the consensus body's work;
- g) Documenting consensus body meetings in the absence of PDA staff; and
- h) Representing the consensus body at public meetings or hearings when requested by the PDA president or appropriate PDA staff.

Unless authorized by appropriate PDA staff or the PDA President, consensus body chairs may not speak officially for the Association.

4.2.6 Termination of chair appointments

A chair appointment may be terminated at any time by the responsible AB should it become evident that the chair has insufficient time or resources to fulfill the responsibilities of the position, is not properly executing PDA's policies and procedures, or is not abiding by PDA policies. In such a case, the chair will receive written notification that the appointment has been terminated and may appeal this dismissal.

4.3 Consensus body size

A consensus body shall consist of not more than 20 members, depending upon interest expressed by parties who are affected by the standard and the scope of the standard. In cases of exceptional expressions of interest by affected parties, the consensus body shall be permitted to exceed the limit of 20 members, while maintaining the balance requirements.

4.4 Members of consensus bodies

4.4.1 Member qualifications

A consensus body member should have a direct and material interest in the work of the consensus body, either as an individual or through association with an organization. Members who do not have a direct and material interest also may serve as voting members, subject to PDA approval, provided that they are knowledgeable about the subject of the consensus body's work or possess needed expertise. A consensus body member also must have sufficient time and resources to fulfill the responsibilities of membership and is required to review and vote on all balloted documents or proposals.

Consensus body members need not be individual members of PDA or represent institutional or corporate members of PDA; however, PDA may impose cost-reimbursement fees on consensus body members who are not individual members of PDA.

Consensus body members also must provide adequate contact information. Because consensus body communications and documents are normally distributed electronically, members must have access to the Internet and a functioning e-mail address.

4.4.2 Representative members and alternates

A representative member is anyone who meets the following criteria:

- a) The individual has a direct and material interest in the work of the consensus body. .
- b) The individual is expected to vote and speak as a technical expert with respect to standards under development by the consensus body, not as a representative of the views or practices of a particular company or organization.

A representative membership in a consensus body is held by the individual serving as a technical expert on the topic of the standard in development.

A representative can appoint a temporary alternate as a proxy representative to participate in specific meetings if the particular consensus body representative is unable to attend.

4.4.3 PDA Consensus body Member Code of Conduct

All participants in PDA consensus bodies shall comply with the PDA Consensus body Member Code of Conduct (Annex A).

4.5 Interest categories (stakeholders)

4.5.1 General

Every consensus body member (stakeholder) shall be classified by interest category. PDA recognizes four different interest categories: Producer, User, General Interest, and Regulator. Consensus bodies should strive for participation from all affected interest categories. Members are classified by their overall interest (or the overall interest of their affiliated organization) relative to the work of a specific consensus body or document.

4.5.2 Declaration of interest and disclosure of potential conflicts of interests

Consensus members must declare the interest they represent on PDA standards committees and must disclose all potential conflicts of interests. Consensus body members also must comply with any applicable conflict of interest policies set by the PDA.

4.5.3 Producer Interest members

A member of a consensus body who, as an individual or organizational representative, is involved in the commercial production, promotion, sale, use or distribution of materials, products, systems, or services covered in the scope of technical documents developed by PDA shall be classified as a Producer Interest stakeholder. Individuals in this interest category include manufacturers, those involved in supply chains, employees of test labs or commercial labs, etc.

4.5.4 User Interest members

A member of a consensus body who, as an individual or organizational representative, purchases, utilizes or receives the materials, products, systems, or services covered in the scope of technical documents developed by PDA in the delivery of pharmaceuticals shall be classified as a User Interest stakeholder. Individuals in this interest category include employees or representatives of pharmaceutical manufacturing organizations, patients, etc.

4.5.5 Regulatory Interest members

A member of a consensus body who, as an individual or organizational representative, is involved in the regulation of the materials, products, systems, or services covered in the scope of the technical documents developed by PDA shall be classified as a Regulatory Interest stakeholder. Individuals in this interest category would include those representing federal, state, local, foreign, or other government entities.

4.5.6 General Interest members

A member of a consensus body who, as an individual or organizational representative, has a general material interest in the materials, products, systems, or services covered in the scope of the technical documents developed by PDA and who does not fit into any of the preceding categories shall be classified as a General Interest stakeholder. Individuals in this category would include noncommercial academicians, noncommercial researchers, patient or consumer advocates, representatives of accrediting organizations, representatives of other organizations, etc.

4.5.7 Categorization of membership associations

A membership association (e.g., trade association, professional society) shall be categorized according to the appropriate interest category of its members.

4.6 Selection of consensus body members

4.6.1 General

Members of a consensus body are selected by application or by invitation.

4.6.2 Terms

There is no set term for consensus body membership.

4.6.3 Application process

Any person wishing to join a PDA consensus body must apply for consensus body membership. A completed application should be submitted to the PDA S&RA Department for review and approval by staff. Industry stakeholders shall disclose any corporate parent/subsidiary relationships and any financial relationships with concerned commercial entities. Producer, User, General, or Regulatory Interest stakeholders shall disclose any potential conflicts of interest (e.g., consulting arrangements with manufacturers, service on a corporate board).

A potential conflict of interest does not necessarily disqualify an applicant from independent voting status on a consensus body.

Applicants (or the organization represented by the applicant) deemed to be a stakeholder and clearly have a direct and material interest in the devices and/or processes covered in documents under development by the consensus body will be given preference toward consensus body membership. The application will be reviewed and approved or denied by authorized PDA S&RA staff.

4.6.4 Refusal of membership

Consensus body membership may be refused for one or more of the following reasons:

- a) The applicant (or organization represented) does not have a direct and material interest in the devices or processes covered by the consensus body.
- b) The work of the consensus body is nearing completion.
- c) The company or organization the applicant is associated with is fully represented on the consensus body (in order to avoid the appearance of undue influence by a particular company or organization).
- d) For Producer, User, General, or Regulatory Interest stakeholders, the applicant has a substantial relationship or conflict of interest that precludes granting independent voting status.

- e) The applicant refuses to complete the application fully or to disclose relevant financial relationships or possible conflicts of interest or provides incomplete or erroneous information in the application.
- f) The applicant is not in compliance with or has previously violated the terms of the PDA Consensus body Member Code of Conduct, the PDA Antitrust Policy, or the PDA Patent Policy.

An applicant has the right to appeal if membership is denied.

4.6.5 Responsibilities

Consensus body members shall actively participate in all consensus body business. In particular, they shall respond to all consensus body ballots in a timely manner. Regular attendance at meetings is desirable but is not required.

Consensus body members are responsible for notifying PDA of changes in e-mail address or affiliation. Departing consensus body members are responsible for recommending a replacement member of the same interest category of the departing member.

4.6.6 Change of interest category or representation

To ensure lack of dominance, balance, and due process, the membership of any individual on a consensus body terminates when that individual's interest category or representation changes. Such a change shall be disclosed, and continued participation in the consensus body by that individual requires that the individual reapply in his or her new capacity.

4.6.7 Temporary designation of alternate

A consensus body member who cannot attend a meeting may designate a proxy for that meeting by notifying PDA in writing in advance.

4.6.8 Organizational Liaisons

Organizational liaisons to technical committees are representatives of an organization who receive all committee documentation but who cannot vote.

Standards staff approves organizational liaisons and can deny or discontinue liaisons for cause.

4.7 Termination of consensus body membership for cause

PDA staff or the PDA Advisory Board may terminate an individual's consensus body membership for lack of participation or interest, especially for failure to record a vote or abstention on two consecutive letter ballots. An exception to this policy shall prevail in instances where a government member may be restricted by their respective agency from voting on a particular ballot. In these cases, the submission of abstention votes shall be allowed and the reason documented.

Substantive violation of PDA policies, including violation of the PDA Consensus body Member Code of Conduct, the PDA Antitrust Policy, or the ANSI Patent Policy, is also cause for termination of membership.

Failure to disclose a change in interest category or representation or to disclose a conflict of interest is grounds for termination of membership.

Membership in a consensus body also may be terminated if it is determined that the individual or company's continued membership or actions may be detrimental to the work of the consensus body, to the interests of PDA, or to the public good.

Persons, institutions, or corporations whose voting representation on a committee has been terminated for any of the above reasons will be notified in writing and will retain all other rights afforded them by due process.

If PDA is not able to contact a member or if a member cannot provide a working e-mail address, that individual's membership may be terminated without further notice.

5.0 Consensus body policies and operations

5.1 Patent policy

The consensus body and its members shall comply with the current ANSI patent policy (Annex B).

5.2 Commercial terms and conditions

The consensus body shall comply with the current ANSI policy for commercial terms and conditions (Annex B).

5.3 Antitrust policy

The consensus body and its members shall comply with PDA's Antitrust Policy (Annex C).

5.4 Transaction of consensus body business

Consensus body business is conducted via electronic correspondence, conference calls, webinars, and face-to-face meetings.

5.5 Announcement of meetings

All consensus body meetings will be announced as early as possible but at least 30 calendar days in advance for face-to-face meetings. Meetings held by teleconference or webinar also should be announced as early as possible but not less than 15 calendar days in advance, except in unusual and urgent circumstances. An agenda and any necessary agenda materials should be distributed in advance of the meeting.

5.6 Conduct of meetings

Consensus body meetings are conducted by the chairs, standards staff, or a designee. There is no quorum requirement to hold the meeting, but absent consensus body members shall be given the opportunity to vote regarding any final substantive actions relating to the disposition of a proposed document.

Meetings are conducted in accordance with general parliamentary principles and procedures, with some consensus body decisions made by motion and vote. Only voting members of the consensus body or a member's appointed alternate or proxy may vote at a meeting.

Formal votes on consensus body approval of a candidate document as a standard must take place via electronic or postal correspondence (not at meetings), and all consensus body members must be afforded the opportunity to vote.

5.7 Public participation in meetings

All PDA consensus body meetings are open to the public; however, at the discretion of the chairs, it is permissible to limit comments to members.

5.8 Closed meetings

Meetings of standing consensus bodies shall *not* be held in closed session on matters related to standards. Executive boards or task groups may, however, conduct meetings in closed session.

5.9 Documentation of meetings

All consensus body meetings, including substantive actions taken by the consensus body, shall be documented by minutes or a brief report.

5.10 Distribution of documents

Meeting minutes, documents in progress, and other consensus body materials are normally distributed by PDA staff. Only materials distributed by or with the explicit permission of PDA staff are part of the official record.

5.11 Task groups and project leaders

Task groups may be appointed by the consensus body chairs to address specific technical issues, research technical questions, organize work, or prepare early drafts. Assigning a project leader to write the first draft of a document or revise a working draft in response to consensus body input also is acceptable.

6.0 Development of consensus standards

6.1 New Work Proposal

6.1.1 Initiating new work

PDA shall make available a new work proposal form detailing information necessary to consider developing a new standard. To propose new work, a completed form shall be submitted to the PDA S&RA Department. Any individual or organization having a material interest may propose new work, but the work must be within the standards program's approved scope.

Whenever possible, a detailed outline or first draft of the proposed document should accompany the proposal.

PDA staff will review all new work item proposals for completeness, clarity, compliance with the Association's procedures and to ensure such work is not already in PDA's program of work or that of another standards developing organization. Where appropriate, staff may request that proposals be amended to correct deficiencies, provide clarity, or respond to questions.

6.1.2 Evaluation and approval of new work

Proposals may be sent to appropriate parties within PDA staff, Advisory Boards, the PDA Board of Directors, and PDA membership for review, and where appropriate, input may be sought from outside stakeholders with regard to the need and feasibility of the proposed work, as well as to whether PDA is the appropriate organization to develop the work. Such review may include distribution to appropriate PDA committees, working groups, or other experts for evaluation. A proposal under consideration should be announced via PDA publications, the PDA website, or press releases.

6.1.3 Approval and announcement of new work

After completion of the evaluation, new work items shall be publically announced in PDA publications, on the PDA website, or by other appropriate means. For documents proposed as American National Standards, announcements shall comply with 2.5 of the *ANSI Essential Requirements* with regard to the submission of PINS form and announcement in ANSI Standards Action. Announcements of new work on prospective standards shall comply with the requirements for openness. Any comments resulting from these announcements will be addressed in accordance with 2.5 of the *ANSI Essential Requirements*.

The PDA S&RA staff shall consider the need for the new work, the priority of the work for PDA, the feasibility of completing the work, whether the work is in PDA's scope, and whether PDA has sufficient resources—including stakeholder participation—to undertake the new work. In addition, the S&RA staff should consider whether a more appropriate technical organization should undertake the work.

The Advisory Board approves initiation of new work or the formation of a consensus body based upon S&RA staff recommendation at a meeting or by a ballot. At least two-thirds of those members submitting votes must support the proposal.

6.1.4 Creation and termination of consensus bodies

If the work does not fall under the scope of any existing PDA consensus body, the PDA Advisory Board may authorize the formation a new consensus body to develop the proposed standard.

The Advisory Board also may dissolve a consensus body and terminate its program of work, based on lack of progress, apparent lack of interest, or other cause.

The decision to dissolve a consensus body can be appealed.

6.1.5 Outreach

PDA S&RA staff shall perform and document outreach to materially affected parties to promote participation of affected stakeholders and a balance of interests on the consensus body.

6.2 Working Draft stage

The consensus body shall prepare the initial Working Draft in accordance with PDA practices, procedures, and editorial style.

After the initial Working Draft has been prepared, the document will be circulated to the responsible Advisory Board for informal review and comment. Written responses are required to AB comments submitted at the Working Draft stage.

Several iterations may be required at the Working Draft stage before advancing a proposed standard for concurrent ballot and public review.

6.3 Consensus body ballot and public review (Committee Draft)

This section describes the balloting and review procedures related to approving a new, revised, or reaffirmed *American National Standard*.

6.3.1 Decision to initiate ballot and public review

After a decision has been made that a document is ready for formal public review, it is designated a Committee Draft. The decision to issue a Committee Draft is approved by the consensus body via ballot.

6.3.2 Ballot period

The ballot period for a ballot is generally four weeks. Shorter ballot periods are discouraged. No ballot for approval of a Committee Draft for public review shall be less than three weeks.

6.3.3 Voting

Consensus body members may vote in the affirmative (e.g., “affirmative,” “yes,” or “approve”), in the negative (e.g., “negative,” “no,” or “disapprove”) or may abstain. A consensus body member should vote in the affirmative if the member endorses the document whether or not his or her comments are accepted. A consensus body member should vote in the negative if substantive technical changes are necessary to resolve one or more of the member’s comments.

Negative votes shall be accompanied by comments; otherwise, they shall be recorded as “negative without comments” without further notice to the voter. Affirmative votes may include comments; however a vote of approval cannot be contingent upon acceptance of those comments.

Abstentions should be accompanied by an explanation.

All comments and objections, whether accompanying affirmative or negative ballots, must be specific and include the following information:

- a) the number of the paragraph containing the text in question;
- b) the rationale for the objection;
- c) alternative text that would resolve the objection; and
- d) an indication as to whether the comment is technical, editorial, or general in nature.

6.3.4 Ballot return and approval requirements

For a ballot to be valid, at least three-fourths of the consensus body members shall record a vote or an abstention. For a document to be considered as approved, at least two-thirds of those voting (excluding abstentions) must return an affirmative vote (with or without comments).

6.3.5 Public review

Public review is a process by which proposed standards are made available for review by interested parties.

Public comment is solicited by notice in appropriate PDA publications or on the PDA website and, for standards intended as American National Standards, by announcement in accordance with the requirements set forth in the *ANSI Essential Requirements*. This notice shall announce the proposed standard, state its availability for review and comment, explain how to obtain a copy of the document, and provide a deadline for submitting comments.

The public review period shall be in accordance with the provisions of the *ANSI Essential Requirements*.

PDA public review periods may be extended at the discretion of the staff.

6.4 Consideration and responding to comments

6.4.1 Return of comments

PDA reserves the right to return for resubmission any ballot or public review comments that are illegible or that reference a specific company, product, or product line other than the commenter's company or product, unless the comment refers to a section of a proposed draft that cites the specific company, product, or product line.

6.4.2 Response to ballot and public comments

6.4.2.1 Rationale for not accepting a comment

For any technical comment that is not accepted, the consensus body shall provide an explanation for the rejection in writing. If the comment is understandable, is specific, and offers a rationale, the explanation shall explain a technical basis for rejecting the comment. The response may refer to an explanation provided in response to another comment. The consensus body's explanation for rejecting other types of comments may be of a more general nature.

6.4.2.2 Withdrawn comments

The consensus body is not required to respond to comments that are withdrawn by the submitter. "Comment withdrawn" shall only be entered into the resolution column at the request of the commenting member or alternate.

6.4.2.3 Late comments

The consensus body is not required to consider or respond to late ballot or late public review comments in deciding whether to advance the document. If the document is reballoted, the late commenter shall be invited to resubmit comments during the subsequent ballot or public review. If the document advances to approval, the outstanding late comments shall be documented and can be held for consideration at the next revision, unless the commenter wishes the late comments to be treated as a proposal to begin an amendment or revision following publication.

6.4.2.4 Comments not related to the proposal undergoing ballot

The consensus body also is not required to consider comments that are not related to the proposal; however, such comments shall be documented and the commenter invited to submit a proposal for new work.

6.4.2.5 Negative votes without comment

Negative votes without comments or with comments not related to the proposal being balloted shall be treated in accordance with the provisions set forth in the *ANSI Essential Requirements*.

6.4.2.6 Unresolved objections

Unresolved objections exist when a negative vote is sustained by a member of the consensus body or when written comments submitted during public review have not been resolved in accordance with the provisions set forth in the *ANSI Essential Requirements*.

6.4.2.7 Distribution of responses

The compilation of comments and their resolutions shall be distributed in writing to all consensus body members and to any public review commenter.

6.5 Decision regarding further action

If disposition of comments results in substantive technical changes, public review shall be conducted of at least those changes and, unless there is a full reballot or a ballot of the substantive changes, consensus body members shall be given the opportunity to change their votes or raise objections before submission to the PDA Advisory Board.

If ballot results establish consensus, there are no outstanding objections, and only nonsubstantive changes have been made to the document, the document may be submitted to the PDA Advisory Board for approval.

The decision to approve submission to the Advisory Board may be decided by the consensus body chairs in consultation with PDA staff or by the consensus body at a meeting.

If there have been substantive changes or there are outstanding objections to approval, submission for final approval is subject to final consensus body review (recirculation).

6.6 Final consensus body review and notice to public reviewers (recirculation)

Members of the consensus body and any public reviewers with outstanding objections shall be informed of the decision to submit the document to the Advisory Board and, if applicable, to ANSI. All consensus body members and commenters shall be provided with documentation of the voting results, resolutions of all comments from or subsequent to the last full ballot and public review, and copies of any outstanding objections to the resolution of comments or final approval. Consensus body members shall have the option to vote on the recirculation of the ballot, even if they did not submit a vote on the original ballot.

Recipients shall be given a minimum of 15 calendar days in which to object to final approval of the document or (for members of the consensus body) to change their votes.

The voting results at the end of final consensus body review/recirculation still must support consensus for the proposed document to be submitted to the PDA Advisory Board.

6.7 Approval of final documents

6.7.1 General

The Board of Directors must approve publication of a consensus document as a final standard and, when appropriate, approve its submittal to ANSI for final approval as an American National Standard.

6.7.2 Procedural review

The Board of Directors decision to approve a standard or TR requires that the S&RA staff affirm that a consensus has been established in accordance with the *Policies and Procedures* and all ballot and public comments have received fair consideration and response. The Board does not conduct a technical review or technical evaluation of comments or objections.

6.7.3 Documentation

In its decision making, the Board of Directors reviews the following documentation:

- a) copies of all consensus body and public comments on the last full ballot/public review;
- b) the consensus body's responses to those comments;
- c) any further comments from persons objecting to the disposition of their comments; and
- d) objections to the finalization of the document and any other documentation that staff deems relevant.

The Board of Directors also reviews the consensus document itself to ensure that it conforms to PDA policies and practices.

6.7.4 Board of Directors action

The Board of Directors may take final action on a consensus document at a meeting or by correspondence (including electronic means). In the latter case, the following procedure applies:

- a) All relevant documentation shall be circulated to the members of the Board of Directors, along with a letter ballot. The initial voting period will be a minimum of 14 calendar days and subject to extension if insufficient response is received.
- b) The letter ballot offers each member the opportunity to vote for final approval, to abstain, or to vote, with an explanation, for holding the matter for deliberation via a meeting or conference call/web meeting. Any vote to hold the decision for deliberation is honored.
- c) Three-fourths of the voting membership of the Board of Directors must return ballots.

6.7.5 Denial of approval

If the Board of Directors denies approval, the document is returned to the responsible consensus body along with explanation for the disapproval.

6.7.6 Notification to objectors

Any consensus body member or public reviewer maintaining an objection to approval of the standard will be informed in writing of the Board of Directors' decision to approve and advance a document for ANSI approval. Those parties also shall be informed that appeal rights exist under these *Policies and Procedures* and that they may file an appeal in accordance with those procedures.

6.8 Publication

Consensus documents shall be published and made available as soon as possible upon final approval or reaffirmation. Publication of standards approved as American National Standards shall comply with the requirements given in the *ANSI Essential Requirements*.

6.9 Records

Substantive records of the development and approval of any consensus document shall be maintained for a minimum of five years or until approval of the subsequent revision or reaffirmation of the document, whichever is longer.

Substantive and relevant records concerning withdrawn consensus documents shall be retained for at least five years from the date of withdrawal.

Substantive records of any American National Standard shall be kept in accordance with the requirements of the *ANSI Essential Requirements*.

6.10 Discontinuation of a standards project

PDA may decide to abandon or discontinue the processing of a proposed new or revised standard or portion thereof at its own discretion and without a vote of the relevant consensus body.

For candidate American National Standards, PDA shall notify ANSI immediately of any such decision.

7.0 Additional procedures for development and maintenance

7.1 Interpretations of standards

The PDA standards program does not provide interpretations of its standards. Any verbal or written interpretations provided by committee members, chairs, or other authorities are their personal interpretations and not the official position of PDA or of the responsible consensus body.

If clarification of a standard is necessary, the consensus body shall revise or amend the standard to provide this clarification. Any amendment or revision will be developed following PDA's full consensus procedures.

This provision does not prohibit the publication of corrigenda (errata) to correct clear and unambiguous errors in PDA standards.

7.2 Amendments of standards

Amendments of published PDA standards may be proposed at any time. Requests for amendments shall be made in writing to the PDA S&RA Department, shall offer specific text changes, and shall include rationale for the recommended changes. A request for an amendment shall be approved or denied by ballot of the responsible committee and the committee's decision made available for public review and comment. The same balloting, public review, and final approval procedures for original documents apply to amendments. An approved amendment and information on how to obtain a copy shall be published by PDA.

7.3 Periodic maintenance of standards

Within five years of the last approval of a current PDA or American National Standard, the standard shall be balloted for reaffirmation to the responsible consensus body and be placed on concurrent review.

For identical adoptions of an ISO or IEC standard, the procedures in clause 4.0 of the ANSI Procedures for the National Adoption of ISO and IEC Standards as American National Standards apply

If a consensus body proposes to withdraw a document at any time, this proposal will be balloted and placed on public review.

Ballot forms for periodic maintenance shall include the following choices: reaffirm, withdraw, or abstain. Contingency votes (e.g., "reaffirm as long as the committee starts working on a revision") are not allowed, though a consensus body member may propose revision in response to periodic review. Comments shall be required only for a vote contrary to the proposed action (i.e., "reaffirm" or "withdraw").

The approval process for a reaffirmation or withdrawal of a standard follows that for the approval of a new standard except that reaffirmations without outstanding objections are not subject to Advisory Board approval.

7.4 Withdrawal for cause (administrative withdrawal)

The PDA President, the Advisory Board, or the Board of Directors can withdraw any PDA or American National Standard upon a sufficient showing that one or more of the following conditions applies:

- a) A significant conflict with another standard is identified and cannot be resolved.
- b) ANSI's requirements for designation, publication, and maintenance were violated.
- c) Supporting the document is contrary to the interests of the public or of the Association.
- d) The document contains unfair provisions or that due process requirements were violated in the document's development or maintenance.

Administrative withdrawal of any American National Standard shall comply with applicable provisions for administrative withdrawal set forth in the *ANSI Essential Requirements*.

7.5 Revisions

A proposal to revise a standard does not require a new work proposal form. The proposal to begin a revision of a standard shall be made to the consensus body that authored the document. Approval to begin a revision requires a majority vote at a meeting or by correspondence.

The initiation of a revision does not obviate the requirement for timely periodic review.

A revision of a standard otherwise follows the procedures detailed in section 6 of these *Policies and Procedures*.

The revision of any American National Standard shall comply with 2.5 of the *ANSI Essential Requirements* with regard to the submission of PINS form and announcement in ANSI Standards Action.

7.6 Continuous maintenance

Appropriate standards may be maintained on a continuous basis with approval of the Advisory Board. A consensus body proposing continuous maintenance for one of its documents shall prepare a documented program for periodic publication of revisions and timely consideration of each formally submitted request for change. Advisory Board approval of the proposal and the program is required.

Continuous maintenance shall comply with all the applicable provisions of these *Policies and Procedures* and, for any American National Standard, with the applicable provisions of the *ANSI Essential Requirements*.

7.7 Provisional standards

PDA may develop provisional American National Standards following the provisions set forth in Annex C of the *ANSI Essential Requirements*.

7.8 Adoption of international documents by PDA

7.8.1 Adoption of international standards

For adoptions of ISO or IEC standards, the requirements set forth in the *ANSI Procedures for the National Adoption of ISO or IEC Standards as American National Standards* and the applicable provisions from these *Policies and Procedures* apply with the following exceptions:

- a) A new work proposal form is not required to adopt an International Standard produced by an ISO or IEC Technical Committee or Subcommittee for which PDA holds the U.S. TAG, nor is Advisory Board approval required. The appropriate consensus body may propose and initiate adoption.
- b) Staff approval is required to adopt any document produced by an ISO or IEC Technical Committee or Subcommittee for which PDA does not hold the U.S. TAG. Any such adoption shall comply with the *ANSI Policy Regarding Rights to Nationally Adopt ISO Standards or Otherwise Use IEC and ISO Material*.
- c) For parallel adoption, the consideration of comments concerns only which comments to submit (either as written or with modification) or reject for submission as part of the U.S. consensus position; however, the consensus body can decide to accept a comment rejected internationally and publish the adoption with deviations.
- d) For parallel adoption, the responses of the U.S. consensus body shall be provided along with the ISO or IEC documentation indicating how all comments (U.S. and non-U.S. comments) were resolved.
- e) For parallel adoption of International Standards, the PDA Committee Draft ballot and public review occur at the international Enquiry stage (Draft International Standard for ISO and Committee Draft for Vote for IEC).
- f) The expedited procedures set forth in the *ANSI Procedures for the National Adoption of ISO or IEC standards as American National Standards* may be employed.
- g) Periodic maintenance shall follow the provisions for adoptions of International Standards set forth in the *ANSI Essential Requirements*.

PDA also may adopt ISO or IEC Technical Specifications as PDA TRs in accordance with the applicable procedures and provisions given above, but the adoptions shall be registered in accordance with the *Procedures for the Registration of Technical Reports with ANSI*.

The process for the adoption of ISO or IEC standards shall follow those set forth in Section 6.0 'Development of consensus standards.'

8.0 Appeals

8.1 General

This section sets forth formal appeal mechanisms for the impartial handling of complaints regarding substantive procedural actions or inactions related to PDA standards. Procedural appeals cannot be based on simple error or omission, but require substantive error, action, or inaction in the development process.

To appeal an action or inaction, an appellant shall demonstrate that his or her due process rights were compromised and shall have a direct and material interest that is or may be adversely affected.

8.2 Actions and inactions subject to appeal

The following actions may be appealed:

- a) approval or denial of a new work proposal;
- b) approval or disapproval of a document as a final or reaffirmed standard;
- c) authorization or refusal to submit a document to ANSI for approval as an American National Standard;
- d) withdrawal of a published PDA standard;
- e) establishment of a new consensus body or initiation of new work on a standard;
- f) termination of a consensus body or cessation of work on a standard;
- g) refusal or termination of membership on a consensus body;
- h) dismissal of a consensus body chair;
- i) other substantive uncorrected committee actions that deny due process rights;
- j) substantive procedural inactions, not covered above, that violate the due process rights of the adversely affected party.

8.2.1 Fee

The fee for an appeal with the Advisory Board is \$1,500 (U.S.) payable by the appellant. The fee for a subsequent appeal with the Board of Directors is an additional \$1,500 (U.S.).

Fees are payable by the appellant within seven calendar days of notification of the decision by the appeal body (the Advisory Board or the PDA Board of Directors) to hear an appeal.

An appellant may request that PDA reduce, waive, or refund these fees and must provide a rationale for this request (e.g., demonstrable financial hardship). The decision to reduce, waive or refund any appeal fee will be made by the PDA President after review of the request and rationale.

8.3 Appeal procedure

8.3.1 Appeal to a PDA Advisory Board

8.3.1.1 Filing of an appeal

An appeal of a covered action shall be filed within 15 calendar days of notification of the action.

There is no deadline for appealing a procedural inaction.

The appeal shall state the nature of the objection, including the details of the denial of due process rights, the real or potential adverse effects upon the appellant, the actions or inactions at issue, and the specific remedial action that would satisfy the appellant's concerns. Previous efforts to resolve the objection and the outcome shall be reported. Upon the filing of a properly executed appeal, the responsible consensus body and Advisory Board are notified and the original action is suspended until the appeal can be resolved or considered.

8.3.1.2 Initial staff review of the appeal (informal resolution phase)

Within 30 calendar days of the filing of an appeal, PDA staff shall make a preliminary determination as to whether a substantive error or omission occurred that violated the appellant's due process rights. If staff determines that a procedural error or omission appears to have occurred but is correctable by further consideration or action of the consensus body, staff will consult with the associated Advisory Board and chairs of the consensus body to determine what action can be taken to cure any real or potential adverse effect.

If, in staff's estimation, a cure cannot be agreed upon by the parties or if staff cannot establish that a procedural omission or error occurred, the appeal shall be submitted to the Advisory Board with all relevant documentation.

8.3.2 Advisory Board consideration of the appeal

The Advisory Board will be asked to review the appeal to determine if significant evidence exists of a substantive procedural error or omission that violated the due process rights of the appellant and that created potential or actual harm to the appellant. A decision by the Advisory Board to hear an appeal requires approval by a majority of the Advisory Board by ballot or at a meeting. When the Advisory Board reaches a decision, the appellant and the responsible committee are notified in writing within 60 calendar days of the filing of the appeal.

If the Advisory Board decides not to hear the appeal, the appellant may submit his or her appeal to the PDA Board of Directors as detailed below.

If the Advisory Board agrees to hear the appeal, a hearing will be scheduled in accordance with the following provisions.

8.3.2.1 Advisory Board Hearing

The Advisory Board shall set a time to hear the appeal via a face-to-face meeting, web meeting, or conference call within six months of the date on which the appeal was filed (or on a date mutually agreeable to all parties). The appellant and the responsible committee shall be invited to be represented at the hearing with at least 30 calendar days' notice. Any committee member or other materially interested party may attend the public portion of the appeal hearing, provided advance notice of attendance is given. Upon hearing all arguments, the Advisory Board will decide the matter in closed session immediately following the appeal hearing. A two-thirds vote of eligible Advisory Board members is required to modify an original action or position.

8.3.3 Notification of Advisory Board decision

Advisory Board decisions on appeals are rendered *only* in writing. The appellant and the responsible committee shall receive written notification of the Advisory Board decision and reason(s) thereof within 15 calendar days of the decision.

8.4 Appeal to the PDA Board of Directors

8.4.1 Filing of an appeal to the Board of Directors

An appeal to the PDA Board of Directors shall be filed in writing within 15 calendar days of notification of the results of an appeal to the Advisory Board and must explain why the Advisory Board decision should be modified.

A decision by the Board of Directors to hear an appeal requires approval by a majority of the Board of Director by ballot or at an electronic or in-person meeting. The complete Advisory Board case file shall be made available to the Board of Directors for consideration in reaching a decision on whether to hear the appeal. When the Board of Directors reaches a decision, the appellant and the responsible committee shall be notified in writing.

8.4.2 Board of Directors Hearing

If the Board of Directors agrees to hear an appeal, the appellant and the responsible committee are invited, with at least 15 calendar days' notice, to be represented at the hearing. The hearing may be held in person or via a web meeting or conference call. The chairs of the Advisory Board participate in the Board's deliberations without vote. Any consensus body member or other interested party may attend the public portion of the appeal hearing with advance notice to the Vice President of Standards Policy and Programs. Upon hearing all arguments, the Board of Directors will decide the matter in closed session. To reverse an Advisory Board decision, a majority vote of all eligible voting members of the Board of Directors is required.

8.4.3 Notification of Board decision

Board decisions on appeals are rendered *only* in writing. The appellant, the responsible committee, and the Advisory Board shall receive written notification of the Board of Directors' decision within 30 calendar days of the appeal hearing.

8.5 Appeal of ANSI decisions on American National Standards

Persons who maintain negative votes on and/or unresolved objections to proposed American National Standards also may have rights of appeal under ANSI's procedures.

Annex A – PDA Consensus body Member Code of Conduct

This PDA Consensus body Member Code of Conduct (Code) is adapted from the ISO Code of Conduct for the technical work.

The goal of this Code is to facilitate PDA’s standards development work—work that is carried out in a multi-stakeholder environment. The Code also is intended to ensure that consensus body deliberations are conducted in a respectful and professional manner by all parties.

It applies to anyone who chooses to participate on a PDA consensus body. The Code is an obligation for participation.

As participants in PDA’s standards program, we acknowledge the responsibility and value of participating in the development of standards and TRs. We therefore adhere to this Code in accordance with the terms below.

Work for the net benefit of the pharmaceutical community	We recognize that the development of standards is for the net benefit of the pharmaceutical community, over and above the interests of any individual or organization. We are committed to advancing standards within their agreed scope, and we will not hinder their development. We support PDA’s goal of advancing patient safety and medical technology.
Uphold consensus and governance	We will uphold the key principles of PDA’s standardization: consensus, due process, honesty, openness, transparency, fairness, effectiveness, relevance, and coherence.
Agree to a clear purpose and scope	We are committed to having a clear purpose, scope, objectives, and will work to ensure the timely development of standards and technical documents.
Participate actively and manage effective representation	We agree to actively participate in standards development projects. We will make our contributions to the work according to the PDA Policies and Procedures.
Escalate and resolve disputes	We will identify and escalate disputes in a timely manner to ensure rapid resolution. We will uphold the agreed dispute resolution processes.
Behave ethically	We will act in good faith and with due care and diligence. We will avoid collusive or anticompetitive behavior. We will promote a culture of fair and ethical behavior.
Respect others in meetings	We are committed to respecting others and the professional culture of standards development. In meetings we are committed to: conducting ourselves in a professional manner; respecting others and their opinions; accepting group decisions; and ensuring that the views of all are heard and understood.

Annex B – ANSI Patent Policy and Commercial Terms

3.1 ANSI patent policy - Inclusion of Patents in American National Standards

There is no objection in principle to drafting an American National Standard (ANS) in terms that include the use of an essential patent claim (one whose use would be required for compliance with that standard) if it is considered that technical reasons justify this approach.

Participants in the ASD/ANSI standards development process are encouraged to bring patents with claims believed to be essential to the attention of the ANSI-Accredited Standards Developer (ASD).

If an ANSI-Accredited Standards Developer (ASD) receives a notice that a proposed, revised, or approved ANS may require the use of such a patent claim that is not already covered by an existing assurance, the procedures in this clause shall be followed.

3.1.1 Statement from patent holder

The ASD shall receive from the patent holder or a party authorized to make assurances on its behalf, in written or electronic form, either:

- a) assurance in the form of a general disclaimer to the effect that such party does not hold and does not currently intend holding any essential patent claim(s); or
- b) assurance that a license to such essential patent claim(s) will be made available to applicants desiring to utilize the license for the purpose of implementing the standard either:
 - i. under reasonable terms and conditions that are demonstrably free of any unfair discrimination; or
 - ii. without compensation and under reasonable terms and conditions that are demonstrably free of any unfair discrimination.

Such assurance shall indicate that the patent holder (or third party authorized to make assurances on its behalf) will include in any documents transferring ownership of patents subject to the assurance, provisions sufficient to ensure that the commitments in the assurance are binding on the transferee, and that the transferee will similarly include appropriate provisions in the event of future transfers with the goal of binding each successor-in-interest.

The assurance shall also indicate that it is intended to be binding on successors-in-interest regardless of whether such provisions are included in the relevant transfer documents.

3.1.2 Record of statement

A record of the patent holder's statement shall be retained in the files of the ASD and shall be made publicly available (at the ASD's election, either on the ASD's website or ANSI's LOA repository).

3.1.3 Notice

When the ASD receives from a patent holder the assurance set forth in 3.1.1.b above, the standard shall include a note substantially as follows:

NOTE - The user's attention is called to the possibility that compliance with this standard may require use of an invention covered by patent rights.

By publication of this standard, no position is taken with respect to the validity of any such claim(s) or of any patent rights in connection therewith. If a patent holder has filed a statement of willingness to grant a license under these rights on reasonable and nondiscriminatory terms and conditions to applicants desiring to obtain such a license, then details may be obtained from the standards developer.

3.1.4 Responsibility for identifying patents

Neither the ASD nor ANSI is responsible for identifying patents for which a license may be required by an American National Standard or for conducting inquiries into the legal validity or scope of those patents that are brought to their attention.

3.2 Commercial terms and conditions

Provisions involving business relations between buyer and seller such as guarantees, warranties, and other commercial terms and conditions shall not be included in an American National Standard. The appearance that a standard endorses any particular products, services or companies must be avoided. Therefore, it generally is not acceptable to include manufacturer lists, service provider lists, or similar material in the text of a standard or in an annex (or the equivalent). Where a sole source exists for essential equipment, materials or services necessary to comply with or to determine compliance with the standard, it is permissible to supply the name and address of the source in a footnote or informative annex as long as the words "or the equivalent" are added to the reference. In connection with standards that relate to the determination of whether products or services conform to one or more standards, the process or criteria for determining conformity can be standardized as long as the description of the process or criteria is limited to technical and engineering concerns and does not include what would otherwise be a commercial term.

Annex C – PDA Antitrust Policy

PDA Antitrust Guide for Industry Functions

Trade associations are subject to close scrutiny under both federal and state antitrust laws. Trade associations are particularly vulnerable to allegations of antitrust violations because a trade association, by its very nature, is a group of competitors joined together for a common business purpose. Therefore, participants in association activity must maintain the highest standards of conduct and proceed with caution in certain areas that have antitrust implications. Below are descriptions of conduct that must be avoided. If a member is present at a meeting where prices or other prohibited topics are discussed, he or she should inform PDA staff or counsel immediately and the PDA representative will give the group a warning. If the discussions do not terminate following such a warning, the meeting will be adjourned.

Price-Fixing and Other Collective Action on Terms of Sale

Price-fixing among competitors is illegal *per se*. The law prohibits both direct price-fixing and indirect price-fixing. Thus, competitors need not agree on price as such to violate the law. Also prohibited are agreements or understandings about sales or credit terms, promotional allowances, discount practices, or any other terms that may affect price.

Agreements to limit or increase supply of products are also prohibited. Agreements among competitors to fix maximum prices are generally viewed the same as agreements to fix minimum prices. Both are illegal. It does not matter if the goal is a "worthy" one to provide "reasonably" priced products to consumers. The agreement is still illegal.

Moreover, price-fixing and other collective action on sales terms does not have to be proven by written or verbal agreement, and seldom is. Discussions among companies, with subsequent parallel conduct, can be strong circumstantial evidence that there was an illegal agreement, even if none in fact existed. It is not even necessary that the plan be carried out. The fact of the agreement or understanding, tacit or otherwise, constitutes a violation.

Group Boycotts and Other Joint Pressure

Concerted, collective action by competitors to refuse to deal with other traders is considered a "group boycott" and is illegal *per se*. This means that there are no circumstances that can justify the action. Boycott activity aimed at customers is also legally suspect and can pose a serious antitrust risk in many cases. In addition to outright boycotts, you should know that agreements or understandings with your competitors to pressure, threaten or coerce traders are also illegal. An individual business is generally free to buy from or sell to whomever it wants, so long as the seller makes that decision unilaterally. To prove illegal collective action, the government or a private plaintiff does not have to prove an actual illegal agreement through direct evidence. As noted, a showing of parallel, i.e., similar, actions among competitors against another trader or customer can be strong circumstantial evidence of a Sherman Act violation. Indeed, many if not most Sherman Act price-fixing, boycott or other violations are established in this manner.

General Guidance

Business practices other than those discussed above and below may be discussed generically, without identifying traders by name or specifying terms of sale. For example, procedures to expedite collection of invoices could be reviewed generally, based on trends experienced by members, but names of customers and details of the sales agreements, such as particular percentage discounts, should never be discussed.

Examples of topics to avoid:

1. Prices or pricing policies, including costs, discounts, rebates, what is a fair or reasonable profit level, possible increases or decreases in prices, standardization or stabilization of prices, pricing procedures, methods, or formulas, etc..
2. Controlling sales, including production or sales quotas, territories, allocations, or market shares.
3. Specific credit or billing terms, such as percentage discounts or invoice remittance times, and other specific terms or conditions of sale.
4. Complaints that a competitor's prices are unfair or unethical or constitute an unfair trade practice.
5. Collective refusals to deal with a company, including boycotts or joint pressure on a company, because of its pricing or distribution practices, terms of purchase, or other suppliers with whom it deals.

Hallway Discussions or Rump Sessions

There should be no informal "hallway" sessions about these topics before, during, or after an association meeting. Quips or joking remarks about prohibited topics should also be avoided. Anti-competitive practices that could be linked to informal discussions, even in a social setting, could have serious consequences both for the individual members and the association.

Approved 01 November 2010 By the PDA Board of Directors