Z80 Accredited Standards Committee for Ophthalmic Optics

ANSI Accredited Standards Developer

OFFICIAL OPERATING PROCEDURES
ACCREDITED STANDARDS COMMITTEE Z80

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Administrative Procedures for Accredited Standards Committee Z80, Ophthalmic Standards in the field of Instruments, Devices and Equipment

Contents

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A.1. General

These procedures for the Accredited Standards Committee Z80 meet the requirements for due process and development of consensus for the approval of American National Standards as given in *ANSI Essential Requirements: Due Process Requirements for American National Standards (hereafter the "ANSI Essential Requirements").*

A.2. Organization of the Accredited Standards Committee Z80

The Accredited Standards Committee Z80 — hereinafter referred to as the "Committee", the "Z80 Committee" or the "Parent Committee" — originally established in 1956, consists of its members and its secretariat. The membership shall be sufficiently diverse to ensure reasonable balance without dominance by a single interest category, individual or organization in accordance with Clause 2.2 and 2.3 of the *ANSI Essential Requirements.* Its title is "Ophthalmic Standards"; its current Scope and its interest classification system are tabulated below.

A.2.1. Scope

The establishment of standards that shall apply to ophthalmic lenses and to equipment, instruments and processes used in the final fabrication level which affect their performance; to ophthalmic frames, sunglasses, fashion eyewear and ready-to-wear near-vision spectacles; to contact lenses and accessories for their use; to intraocular implant lenses, refractive implants, refractive lasers, viscoelastic devices, glaucoma shunts and ophthalmic operating microscopes; to low vision devices and ophthalmic contact devices in addition to contact lenses; and to optical instrumentation used in ophthalmic procedures and vision evaluation.

Standards established by this Committee do not apply to industrial or sports safety devices

Clinical guidelines for professional practices, manufacturing practices, and laboratory practices are outside the scope of this Committee.

When clinical studies or investigations are required by regulatory bodies, examples may be included in informative annexes.

A.2.2. Classification of Members

1. Nationwide organizations of manufacturers (Classification Designator "P")

   Organizations whose members are primarily producers of products covered by ASC Z80 standards, and who may also produce products made to an individual prescription.

2. Nationwide professional organizations of ophthalmologists (Classification Designator "MD")

   Organizations whose primary members are ophthalmologists and who purchase or use the products covered by ASC Z80 standards.

3. Nationwide professional organizations of optometrists (Classification Designator "OD")

   Organizations whose primary members are optometrists and who purchase or use the products covered by ASC Z80 standards.

4. Nationwide professional organizations of opticians (Classification Designator "O")

   Organizations whose primary members are opticians and who purchase or use the products covered by ASC Z80 standards.

5. Nationwide organizations of ophthalmic laboratories (Classification Designator "L")

Organizations whose primary members process ophthalmic spectacles or contact lenses to individual prescriptions for products covered by ASC Z80 standards.

6. Nationwide scientific, public and general interest groups (Classification Designator "GI")

   Organizations whose primary members have a special interest in ASC Z80 standards due to safety, technical or other requirements covered by these standards, but neither produce or use them directly.

7. Federal agencies that are purchasers of ophthalmic materials (Classification Designator "G")

   A government agency or department that has an interest in the use of products covered by standards in ASC Z80.

8. Individual members, companies and experts (Classification Designator "I")

   Persons or companies that have a special interest in ASC Z80 standards due to safety, technical or other requirements, or with expert knowledge in the area.

A.2.3. Financial Support

The Committee may receive financial support from members or non-members, strictly in accordance with the standards for financial support attached hereto at Annex D.

A.3. Responsibilities

A.3.1. Committee

ASC Z80 shall be responsible for:

1. Selecting a responsible, willing and capable organization to serve as its administrative secretariat, to interact with ANSI and to oversee the Committee's compliance with its procedures and with ANSI rules;
2. Developing proposed American National Standards within the above scope and in conformity to the requirements for content indicated in Annex A;

   The Committee should take International Organization for Standardization (ISO) or International Electrotechnical Commission (IEC) standards into consideration and should, if appropriate, base their standards on or consider the adoption of an ISO or IEC standard as an American National Standard (ANS);

3. Developing proposed American National Standards within the above scope that parallel selected ISO standardization activities (this would serve to establish a US position on the ISO standard and possibly create a base working document for ISO use);
4. Adopting as ANSI standards those ISO standards within the scope of this Committee when appropriate. Adoption of ISO standards shall comply with the requirements set forth in the Procedures for the National Adoption of ISO or IEC Standards as American National Standards;
5. Developing ASC Z80 positions on the issues at ISO and submitting new ISO work items important to the US;
6. Voting on the approval of proposed American National Standards within the above scope;

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7. Maintaining the standards developed by the Committee in accordance with ANSI's five-year review cycle (Clause *4.7.1 of ANSI Essential Requirements*);
8. Responding to requests for interpretation of the standards developed by the Committee (see A.12.3);
9. Adopting Committee procedures and revisions thereof;
10. Appointment of subcommittees and ad hoc committees;
11. Providing technical experts to the U.S. Delegation representing ANSI at ISO and other international standardization meetings which pertain to ophthalmic products and processes*;*
12. Other matters requiring Committee action as provided in these procedures;
13. Considering and acting on proposals for termination of the Committee.

A.3.2. Secretariat

The secretariat shall:

1. Be responsible for the appropriate organization of the Committee and its accreditation in accordance with ANSI requirements, including submission of the Committee roster;
2. Oversee the Committee's compliance with these procedures;
3. Maintain a roster of the Committee and a list of standards for which the Committee is responsible;
4. Provide or obtain clerical assistance as necessary to perform administrative work, the distribution of meeting notices, the arrangement of meeting facilities, the preparation and distribution of agendas, minutes, ballots and draft standards, and the maintenance of adequate records;
5. Distribute meeting minutes of subcommittee and Committee meetings to all members promptly following each meeting;
6. Submit candidate standards as developed by subcommittees and approved by the Parent Committee for ANSI review and approval as American National Standards;
7. Arrange with ANSI for publication of Z80 Standards, revisions and addenda in the editorial format consistent with ANSI procedures;
8. Prepare and maintain evidence of compliance with ANSI procedures and the procedures of the Committee. Records concerning new, revised or reaffirmed American National Standards shall be retained for two complete standards cycles. Records of withdrawal of a standard will be kept for five (5) years from the date of withdrawal; and
9. Perform other administrative functions as required by these procedures.

A.3.3. Steering Committee

The Steering Committee shall be composed of the following voting members: Committee Chair, Vice-Chair, Secretary, Secretariat Administrator, Subcommittee Chairs and US Delegation Leader to ISO TC172/SC7. Legal Counsel shall be available to the Steering Committee as

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needed. The Steering Committee shall meet no less than once each calendar year with such meetings in general coinciding with Z80 Committee Meetings.

The Steering Committee shall:

1. Deal with the administrative functions of the Z80 Committee;
2. Develop budgets and dues assessments;
3. Share information and coordinate efforts of the subcommittees including relations to ISO;
4. Develop and initiate proposals for direction of the Committee that will be introduced to the Committee for approval with the understanding that proposals can always be brought to the Z80 Committee by any member of ASC Z80.

A.4. Officers

There shall be a Chair, a Vice-Chair and a Secretary, nominated by the secretariat from representatives of nationwide organizations or individual members. Additional nominations may be submitted to the Committee in writing from three or more Committee members. Election shall be by majority vote of the Committee. Each officer shall serve terms of three years, renewable until a successor is selected. The Vice-Chair shall carry out the Chair's duties if the Chair is temporarily unable to do so.

A.5. Membership

Members of the Committee shall consist of organizations (preferably national in scope), professional or trade associations, national public interest groups, government agencies, major standard-setting purchasers such as the military services and the Veteran's Administration, companies, and individuals having a direct and material interest in the activities of the Committee. The addition of a member shall be subject to approval by majority vote of the Committee after an application has been reviewed in accordance with A.5.1. The termination of a member shall be subject to approval by a majority vote of the Committee after a review of the membership in accordance with A.5.2.

A.5.1. Application

A request for membership shall be addressed to the secretariat and shall indicate the applicant's direct and material interest in the Committee's work, qualifications and willingness to participate actively. In addition, if the applicant is an organization, company or government agency, then a principal representative and up to four (4) alternates shall be named.

A.5.1.1. Recommendations

In recommending an action to the Committee on applications for membership, the secretariat shall consider the:

1. Need for active participation by each interest group;
2. Potential for dominance and imbalance by a single interest category;
3. Knowledge of the nominee's past involvement with the general subject area of standards;
4. Sufficient expertise in the broad and general work of the Committee;
5. Extent of interest expressed by the applicant and the applicant's willingness to participate actively;

6. The representative identified by the applicant organization, company or government agency;
7. Reasonable limits of Committee size to insure effective deliberation and interchange.

A.5.1.2. Diverse Interests

If distinct divisions of an organization demonstrate independent interests and authority to make independent decisions in the same area of activity of the Committee, each is permitted to apply for membership.

A.5.1.3. Combined Interests

When appropriate, the secretariat may recommend that the applicant seek representation through an organization that is already a member and represents the same or similar interest.

A.5.2. Review of Membership

The secretariat shall review the membership annually with respect to the criteria of Clause A5. Members are expected to fulfill the attendance, voting, correspondence, financial and other obligations of the Committee. If a member is found in frequent default of these obligations, the secretariat shall direct the matter to the Committee Chair for appropriate action that may include the termination of membership.

A.5.3. Observers and Individual Experts

Individuals and organizations having an interest in the Committee's work may request listing as observers.

The Committee, a subcommittee, working group or ad hoc committee may select individual experts to assist in technical work. An individual expert shall serve a renewable term of two years, subject to approval by a vote of the Committee.

Observers and technical experts shall be advised of Committee activities, be assigned to subcommittees, working groups and ad hoc committees, may attend meetings, and may submit comments for consideration, but shall be nonvoting.

A.5.4. Categories of Interest

All appropriate interests that may be directly or materially affected by the standards activity shall have the opportunity for fair and equitable participation without dominance by any single interest. Each member shall indicate its interest category as appropriate and in accordance with the Committee's established categories (see Clause 2.3 of *ANSI Essential Requirements*).

The categories of interest may be established or revised by a majority vote of the Committee. The rationale for the selection of categories shall be included in the Committee ballot and submitted to ANSI as part of the accreditation requirement.

A.5.5. Membership Roster

The secretariat shall maintain a current and accurate Committee Roster and shall distribute it to the member organizations and their representatives at least annually and otherwise on request. The roster shall include the following:

1. Title of the Committee and its numerical designation;
2. Scope of the Committee;
3. Name and address of the secretariat;
4. Names and addresses of the officers (chair, vice-chair and secretary) and subcommittee chairs;
5. Names of member organizations or agencies specifying principal and alternate representatives with their addresses and business affiliations. In the case of individual members or companies, the name, address and business or professional affiliation shall be given;
6. Listing of Observers and Individual Experts;
7. Interest classification of each member;
8. Tally of classifications, total voting organizational members and individual members with subtotals for each interest category;
9. For each subcommittee and working group, the title, chair, and names and addresses of all members;

A.6. Subcommittees Created by the Parent Committee

Within its scope, the Committee may form subcommittees to develop, draft and maintain specific standards. Upon the completion of their work, the Parent Committee may disband such subcommittees. The creation and disbanding of subcommittees shall be approved by a majority vote of the Parent Committee and appropriate public notice. The scope of the subcommittee shall be approved at the time it is formed and subsequent changes shall also require approval by the Committee. The charge to a subcommittee shall be:

The subcommittee is responsible for assisting the Parent Committee by actual drafting of all or a portion of a standard; responses to comments; positions on international standards, or other advisory functions.

A.6.1. Chairs and Members of Subcommittees

The chair of the Parent Committee shall appoint subcommittee chairs and may assist a subcommittee chair in selecting the members of a newly constituted subcommittee. A member organization shall be entitled to membership in any subcommittee and subgroup thereof, except an editorial committee, in which it has a germane interest.

The subcommittee chair shall appoint chairs and members of the technical working groups, editorial committees and ad hoc committees, where appropriate. The officers and members of such subgroups need not be members of the Committee. A person appointed to serve on a working group must be an expert in the subject under discussion and, without reference to affiliation with any organization, shall be entitled to vote on the reports submitted by the working group to its subcommittee.

A.6.2. Approval of Standards

Draft standards and any substantive change in the content of a standard proposed by a subcommittee shall be referred to the Committee for approval. A substantive change is one that directly and materially affects the use of the standard. Examples of substantive changes are:

a) “shall” to “should” or “should” to “shall”
b) addition, deletion or revision of requirements, regardless of the number of changes

c) addition of mandatory compliance with referenced standards

A.7. Meetings

The Parent Committee shall meet as scheduled by the Committee, the chair, the secretariat, or by a petition of five or more members, to conduct business, make assignments, receive reports, consider draft standards, resolve differences among subcommittees, and to consider views and objections from any source. Meetings of a subcommittee and its subgroups shall be held as decided upon by its members and its chair.

A.7.1. Open Meetings

Meetings of the Parent Committee and subcommittees shall be open to all members and others having direct and material interest. At least four weeks' notice of regularly scheduled meetings shall be given by the secretariat in ANSI's *Standards Action* or other media designed to reach directly and materially affected interests; or both. The notice shall describe the purpose of the meeting and identify a readily available source for further information. An agenda shall be constructed and distributed in advance of Committee and subcommittee meetings to members and others specifically requesting.

A.7.2. Quorum and Proxies

A majority of the members of the Committee or a subcommittee shall constitute a quorum for conducting business. If a quorum is not present, actions shall only be taken subject to subsequent confirmation by letter ballot or vote at a future meeting. The Parent Committee or subcommittees may use proxies on the form set out in Annex E to help develop a quorum. The proxy shall be valid only for a specific meeting, signed only by the delegate or alternative delegate for the member organization, and shall appoint a specific individual as designee for the member organization. The proxy allows an individual to represent the organization as if the delegate or alternative of that member organization was present at the meeting. If a member organization submits a proxy but is subsequently represented at the meeting by the delegate or alternate, then the proxy is voided.

A.8. Voting

The procedural goal in standards writing activities shall be to evolve acceptable consensus. Voting shall be conducted by the chair.

Consensus is demonstrated, in part, by a vote of the consensus body. Such a vote shall be conducted and reported in accordance with the rules set forth herein. Votes for the approval of a document or portion thereof as a candidate ANS may be obtained by letter, fax, recorded votes at a meeting or electronic means. All members of the consensus body shall have the opportunity to vote. When recorded votes are taken at meetings, members who are absent shall be given the opportunity to vote before or after the meeting.

A.8.1. Vote

Roll call vote may be authorized by the chair or a majority of the voting members present. Each member shall cast one vote in one of the following fashions:

1. Approve;
2. Approve with comment;
3. Disapprove, with reason (the reasons for a negative vote shall be given and shall include specific wording or actions that would resolve the objection);
4. Abstention, with reason.

For votes on membership and officer-related issues, the yes/no/abstain method of voting shall be followed.

A.8.1.1. Votes by Alternate Representatives

An alternate's vote is counted only if the principal representative fails to vote.

A.8.1.2. Voting Period

For letter ballots, the voting period shall end 30 calendar days from the day of issue or as soon as all ballots are returned, whichever is earlier. An extension of up to six weeks may be granted at the chair's option, or by a majority vote of the Committee, when warranted.

A follow-up communication requesting return of the ballot shall be sent as appropriate, to members and alternate members whose votes have not been received within ten calendar days before the ballot closes.

A.8.2. Actions Requiring Approval by a Majority

The following actions require approval by a majority of the membership of the Committee, either at a meeting or by letter ballot:

1. Election of officers;
2. Formation of a subcommittee, including its scope, procedures and duties;
3. Disbandment of subcommittees;
4. Addition of new Committee members and designation of their interest categories;
5. Approval of withdrawal of an existing standard.
6. Approval of a PINS submission to ANSI for a new standard or revision of an existing standard;
7. Abandonment of the processing of a proposed new or revised ANS or portion thereof. A written justification for such an action shall be made available upon receipt of any written request received by ASC Z80 within 60 days of the date of the final action.

   Appeals of such actions shall be made to the Executive Standards Council based on procedural noncompliance.

Other actions requiring a Committee vote may be approved by a majority of members present at a meeting, including:

1. Approval of minutes;
2. Authorization of letter ballot (A.8.4).

A.8.3. Actions Requiring Approval by Two Thirds of those Voting

The following actions require a letter ballot or an equivalent formal recorded vote with approval by at least a majority of the membership and at least two thirds of those voting, excluding abstentions:

1. Adoption of Committee procedures, categories of membership, or revision thereof;

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2. Approval of a new standard or reaffirmation of an existing standard;
3. Approval of revision or addendum to part or all of a standard;
4. Approval for submission to ANSI of change of Committee scope;
5. Approval of termination of the Committee;
6. Approval for change of the Secretariat;
7. Approval for financial support of ASC Z80.

A.8.4. Authorization of Letter Ballots

A letter ballot shall be authorized by any of the following:

1. Majority vote of those present at a Committee meeting;
2. The chair;
3. The Steering Committee;
4. The secretariat;
5. Petition of five or more members of the Committee.

A.8.5. Other Review

In submitting a PINS, or approving, reaffirming, revising or withdrawing a standard, the Committee shall comply with Clause 2.5 of the *ANSI Essential Requirements*. Proposals for new American National Standards or reaffirmation, revision or withdrawal of existing American National Standards shall be transmitted to ANSI for listing in *Standards Action* for public comment.

The secretariat shall determine whether listings of proposed standards actions shall be concurrent with the final Committee letter ballot or whether announcements in other media are suitable.

Comments and objections resulting from the above shall be dealt with in accordance with A.8.6. Any substantive change made in the proposed ANS shall be relisted in ANSI Standards Action.

A.8.6. Disposition of Comments and Objections

When the balloting has been closed, the secretariat shall forward the ballot tally to the chair of the Committee and the concerned subcommittee. The chair shall determine whether the expressed comments and objections shall be considered by correspondence or at a subsequent Committee meeting. Evidence of consensus shall be documented in accordance with Clause 2.6 of the *ANSI Essential Requirements*.

In accordance with Clause 2.5 of the *ANSI Essential Requirements,* prompt consideration shall be given to the written views and objections of all participants, including those commenting on the PINS announcement or public comment listing in *Standards Action.* ASC Z80 will comply with clause 2.5 of the *ANSI Essential Requirements*.

In connection with an objection articulated during a public comment period, or submitted with a vote, an effort to resolve all expressed objections accompanied by comments related to the proposal under consideration shall be made, and each such objector shall be advised in writing (including electronic communications) of the disposition of the objection and the reasons therefore. If resolution is not achieved, each such objector shall be informed in writing that an appeals process exists within procedures used by the standards developer. In addition, except in the case of Audited Designators, each objection resulting from public review or submitted by a member of the consensus body, and which is not resolved, must be reported to the ANSI BSR.

When this process is completed in accordance with the written procedures of the standards developer, the standards developer may consider any comments received subsequent to the closing of the public review and comment period, or shall consider them in the same manner as a new proposal. Timely comments that are not related to the proposal under consideration shall be documented and considered in the same manner as submittal of a new proposal. The submitter of the comments shall be so notified.

Each unresolved objection and attempt at resolution, and any substantive change made in a proposed ANS, shall be reported to the consensus body in order to afford all members of the consensus body an opportunity to respond, reaffirm or change their vote. In all cases, the response on the recirculation vote will take precedence over the original ballot and, if a response on the recirculation ballot is not received, the response on the original vote will be used.

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A.9. Submittal of Standards

Upon completion of the procedures for voting, disposition of negative votes, objections and appeals, the proposed standard shall be submitted to ANSI by the secretariat. If the secretariat does not submit the proposal to ANSI within a reasonable period of time, any member of the Committee may make the submittal.

A.9.1. Information Submitted

ASC Z80 will reference clause 4.2.1.1h of the ANSI Essential Requirements when submitting the BSR-9 form, and any information that needs to be submitted along with the BSR-9 form to ANSI.

A.10. Technical Advisory Groups (TAG) for International Standards

The Z80 Committee supplies technically expert delegates to the International Organization for Standardization (ISO) Technical Committee 172, Subcommittee 7, and other international standardization meetings whose scope includes ophthalmic products and processes.

Expert delegates to international standards meetings are expected to participate regularly in Z80 Committee technical activities relating to their area of expertise and to attend Z80 Parent Committee meetings where unified U.S. positions are discussed and developed.

The Committee also provides liaison experts to other U.S. standards committees. Liaisons are nominated from Z80 member organizations and are subject to the approval of a majority of the Committee following the voting process described in section A.8.2.

A.11. Termination of the Committee

A proposal to terminate the Committee may be made by two or more directly and materially affected member organizations. The proposal shall be submitted in writing to the chair and secretariat, and shall include a full description of reasons, alternate organizations to assume responsibility for maintenance of existing standards, and the desired objectives that can be attained by termination.

If it appears, after review and discussion among the proponents of the action that the desired objectives can best be reached by termination, the proposal and supporting documentation shall be submitted to the Committee with a letter ballot to terminate the Committee and transfer responsibility, as appropriate, for the affected standards. Concurrently, the proposal shall be announced for comment in *Standards Action*.

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A.12. Communications

Correspondence of Committee officers should be on Committee letterhead. ANSI letterhead shall not be used.

A.12.1. Formal Internal Communications

If correspondence between subcommittees or working groups involves non-routine decisions affecting other subcommittees, copies shall be sent to all affected subcommittee chairs and to the Parent Committee officers.

A.12.2. External Communications

Inquiries relating to the Committee should be directed to the secretariat. All replies to inquiries shall be made through the secretariat.

A.12.3. Interpretation of Standards

Any response to verbal requests for interpretation shall be considered as informal and nonbinding.

Written requests for formal interpretation of a standard shall be directed to the secretariat and shall be acknowledged within 30 working days. A draft written response shall be prepared by impartial Committee members designated by the chair and shall be reviewed and approved by at least three other Committee members, including the chair, before being incorporated into a written reply to be transmitted by the secretariat to the requester. Copies of the reply shall be sent by the secretariat to all members of the Committee.

Interpretations which result in revisions to the standard shall be processed by the procedures established for formulating and revising these standards.

A.13. Appeals

Persons who have directly and materially affected interests and who have been or may be adversely affected by procedural action or inaction of the Committee or the secretariat shall have a right to appeal.

A.13.1. Complaint

The appellant shall file a written complaint with the secretariat within 30 days after the date of notification of action or at any time with respect to inaction. The complaint shall state the nature of the objections including any adverse effect, clauses of the procedures or the standard that is at issue, actions or inactions that are at issue, and the specific remedial actions that would satisfy the appellant's concerns. Previous efforts to resolve the objections and the outcome of each shall be tabulated.

A.13.2. Response

Within 30 working days after receipt of the complaint, the respondent (chair or secretariat representative) shall respond in writing to the appellant addressing each allegation of fact in the complaint to the extent of the respondent's knowledge.

A.13.3. Hearing

If the appellant and the respondent are unable to resolve the written complaint informally in a manner consistent with these procedures within 30 working days of respondent's response to appellant, the secretariat shall schedule a hearing by an appeals panel on a date which is

agreeable to all participants and which is within 60 working days of respondent's response to appellant, giving at least 14 working days' notice.

A.13.4. Appeals Panel

An appeals panel shall be appointed by the secretariat, consisting of three individuals who have not been directly involved in the matter in dispute and who will not be materially or directly affected by any decisions made or to be made. At least two members shall be acceptable to the appellant, and at least two members shall be acceptable to the respondent.

A.13.5. Conduct of the Hearing

The appellant has the burden of demonstrating adverse effects, improper actions or inactions, and the efficacy of the requested remedial action. The respondent has the burden of demonstrating that the Committee and the secretariat took actions in compliance with these procedures and that the requested remedial action would be ineffective or detrimental. Each party may adduce other pertinent arguments, and members of the Appeals Panel may address questions to individuals. *Robert's Rules of Order* (latest edition) shall apply to questions of parliamentary procedure for the hearing not covered herein.

A.13.6. Decision

The appeals panel shall render its decision in writing within 30 days, stating finding of fact and conclusions, with reasons thereof, based on a preponderance of evidence presented to the appeals panel. Consideration shall be given to the following positions, among others, in formulating the decision:

1. Finding for the appellant, remanding the action to the Parent Committee or the secretariat with a specific statement of the issues and facts in regard to which fair and equitable action was not taken;
2. Finding for the respondent, with a specific statement of the facts that demonstrate fair and equitable treatment of the appellant and the appellant's objections;
3. Finding that new, substantive evidence has been introduced, and remanding the entire action to the Parent Committee or the secretariat for appropriate reconsideration.

A.13.7. Appeals at ANSI

Persons who have directly and materially affected interests and who have been or will be adversely affected by any procedural action or inaction by ANSI or by any ANS-related process have the right to appeal. ANSI will not normally hear an appeal of an action or inaction by a standards developer relative to the development of an ANS until the appeals procedures provided by the standards developer have been completed. Appeals of actions shall be made within reasonable time limits; appeals of inactions may be made at any time. Such appeals shall be directed to ANSI in accordance with the procedures of the appropriate ANSI board or council (e.g., Board of Standards Review, Executive Standards Council).

A.14. Amendment

Written proposals to amend these procedures may be submitted to the secretariat by the representative of any member organization, or by an individual member of the Committee. The secretariat shall place the proposal on the agenda for the next scheduled meeting of the Committee. Voting on the proposal shall be governed by Clause A.8.3.

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A.15. Patent Policy

ASC Z80 adopts and will adhere to the ANSI Patent Policy as set forth in the *ANSI Essential Requirements.*

A.16. Commercial Terms and Conditions

ASC Z80 adopts and will adhere to the Commercial Terms and Conditions set forth in the *ANSI Essential Requirements.*

A.17. Antitrust Policy

ASC Z80 adopts and will adhere to the Antitrust Policy set forth in the *ANSI Essential Requirements*.

Administrative Procedures for the National Adoption of an ISO or IEC Document (NAIS)

General

The ASC Z80 Committee has an agreement with ANSI that allows for the National Adoption of an ISO or IEC Document (NAIS). The Committee will follow the “ANSI Procedures for the National Adoption of ISO and IEC Standards as American National Standards” in this process.

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Annex A

Requirements for the Content of ASC Z80 Standards

This document provides the required content for all ASC Z80 Standards. This content is patterned after ASTM and ISO requirements.

1. Title

The title shall be composed of:

- An *introductory element* indicating the general field (i.e. Ophthalmics);
- A *main element* indicating the principal subject treated within the field of use (e.g. Prescription Ophthalmic Lenses);
- (If necessary) a *complementary element* indicating the particular aspect of the principal subject or giving details which distinguish the document from other standards (e.g. Vocabulary).

2. Foreword

The foreword shall appear in every standard. It consists of a general part giving information relating to the organization responsible for creating the standard, and a specific part providing the following information:

- The subcommittee and the subcommittee members who prepared the standard;
- The organizational members of ASC Z80 and the names of each organizational representative and alternate;
- A statement that the standard cancels or replaces other documents in whole or in part, if appropriate;
- A statement of significant technical changes from the previous edition of the standard.

3. Designation and Year of Issue

(e.g. ANSI Z80.1-1999)

4. Scope and Purpose

The scope and purpose shall amplify the title, state the function of the standard, and note any materials, products, or systems that are excluded. It shall not contain requirements.

5. References

5.1.1. Normative References

- Normative references shall include the title, publication date and where the document may be obtained.
- Normative references are those documents that are referenced in the text and contain specifications or requirements.
- Normative references shall not include documents which are not publicly available, documents to which only informative reference is made or documents which have served merely as references for the preparation of the standard.

5.1.2. Informative References

- Informative references shall not include documents that are not publicly available or documents which have served merely as references for the preparation of the standard.

6. Definitions, Symbols and Abbreviations

Definitions shall be used when the term is not self-explanatory, not commonly used or understood, or not a common term in a dictionary or defined in an independent terminology standard.

7. Classification

7.1.1. When more than one material, product, or system is specified, they shall first be separated by types.

7.1.2. Further subdivisions by grades may be used.

7.1.3. If necessary, additional divisions into classes may be made.

8. Requirements

8.1.1. Requirements shall be quantified and shall include tolerances (when appropriate).

8.1.2. Requirements shall be referenced to a test method.

8.1.3. A clear distinction shall be made between normative requirements and statements included only for information or guidance.

8.1.4. Units of the International System of Units (SI), the modernized metric system, shall be used. Equivalent English system units may, optionally, be included.

8.1.5. The use of patented items may be included in the standard provided that the procedures in Annex B are followed.

8.1.6. Commercial terms and conditions:

Provisions involving business relations between a buyer and seller such as guarantees, warranties, and other commercial terms and conditions shall not be included in an ANS. 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.

9. Test Methods

9.1.1. For each requirement, a referee test method shall be given.

9.1.2. The test methods shall be identified to indicate whether they are type tests, sampling tests, or routine tests.

9.1.3. The referee test method shall include:

- the procedure for conducting the test
- necessary equipment or apparatus
- materials or reagents
- preparation and preservation of test samples and test pieces
- expression of the results including method of calculation
- test report

9.1.4. Examples of sources of supply for the equipment and material for a test method shall be given.

9.1.5. The test method shall indicate the accuracy and precision that is typically achieved, if known.

9.1.6. (Optional) If the accuracy and precision are not known for a particular test method, an inter-laboratory study shall be conducted to determine the precision and accuracy.

9.1.7. A note shall state “Other test methods may be used if it can be shown that the results are equivalent to the referee test method.”

10. Identification of product covered by standard

The identification of the product or component shall be specified on the product or on the package of the product or in an accompanying document.

11. Identification of the standard

Reference shall be made to ANSI Z80.X either on the product, the package or in available literature if the manufacturer or supplier claims compliance to this standard.

Z80 Accredited Standards Committee for Ophthalmic Optics
The Vision Council
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P: 703-548-4560 F: 703-548-4580

Annex B

Scope of Work for ASC Z80 Subcommittees

Scope of the Subcommittee on Prescription Ophthalmic Lenses

The scope of the Subcommittee on Prescription Ophthalmic Lenses shall be to establish standards for prescription ophthalmic spectacle lenses except those specifically excluded below. The lenses may be finished, semi-finished, uncut, edged or assembled into complete spectacle eyewear.

The standards shall cover the optical, geometric and mechanical attributes of prescription ophthalmic lenses including, but not limited to: power, prism, centration, impact resistance, thickness, transmittance, abrasion resistance and coating performance. These attributes result from manufacturing processes or subsequent processors. Standards will be based on the science of ophthalmic optics and accepted lens manufacturing practices.

The scope shall not include any clinical procedures or professional processes used to determine ophthalmic prescriptions or the dispensing of ophthalmic spectacle lenses.

The scope of the Subcommittee on Prescription Ophthalmic Lenses specifically excludes industrial safety eyewear covered by ANSI Z87.1, nonprescription sunglass lenses covered by ANSI Z80.3, sports eyewear covered by ASTM standards, and laser protective eyewear covered by ANSI Z136.

Scope of the Subcommittee on Nonprescription Sunglasses, Fashion, and Near-Vision Eyewear

The scope of the Subcommittee on Nonprescription Sunglasses, Fashion, and Near-Vision Eyewear shall be to establish and maintain national standards and requirements for all nonprescription sunglasses and fashion eyewear having lenses of substantially zero power, as well as for ready-to-wear near-vision spectacles (“ready readers”) available over the counter without prescription, except those specifically excluded below.

These standards and requirements are explicit expectations in product performance. They shall provide commonly accepted definitions, equations and test methods so that manufacturers can produce products to meet the requirements of the respective standards. These standards shall include, but not be limited to, impact-resistance characteristics of lenses; cosmetic, refractive, prismatic, and transmittance properties of lenses; and flammability and durability of frames and lenses.

The scope of the Subcommittee on Nonprescription Sunglasses, Fashion, and Near-Vision Eyewear specifically excludes products included in the current versions of other standards dedicated to specific types of products, except as such standards specifically reference ANSI Z80.3, Nonprescription Sunglasses and Fashion Eyewear – Requirements, and/or ANSI Z80.31, Specifications for Ready-to-Wear Near-Vision Spectacles. Such standards include, but may not be limited to, the following:
ANSI Z80.1 Recommendations for Prescription Ophthalmic Lenses
ANSI Z87.1 Practice for Occupational and Educational Eye and Face Protection
ANSI Z136.7 Testing and Labeling of Laser Protective Equipment

The Vision Council
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P: 703-548-4560 F: 703-548-4580

Scope of the Subcommittee on Spectacle Frames

The scope and purpose of the Subcommittee on Spectacle Frames is to prepare standards of quality and uniformity for the manufacture of all spectacle frames intended as ophthalmic eyewear with prescription lenses, excluding specialty and novelty products such as lorgnettes and monocles. Specifically excluded are products designed to be occupational eyewear, sports frames, and non-prescription sunglass frames. Furthermore, the Subcommittee will sustain the procedures which allow for the introduction of changes in technology and materials into the existing standard.

Scope of the Subcommittee on Low Vision

The Subcommittee on Low Vision deals with devices specified by the manufacturer to enhance the ability of visually impaired persons to perform visual task using their residual vision. It specifies optical, mechanical, and electrical requirements and test methods for optical low vision aids, optical devices with electrical components such as illuminators, electro-optical devices for low vision and electronic-optical devices for low vision.

Scope of the Subcommittee for Ophthalmic Instruments

The Subcommittee for Ophthalmic Instruments is responsible for the development, review and revision of standards for ophthalmic diagnostics and measuring instrumentation. This includes but is not limited to, consideration of health hazard, accuracy, test methods, and unit of measure. This subcommittee will not address electronic information interchange.

Scope of the Subcommittee for Contact Lenses

The scope of the Subcommittee for Contact Lenses consists of preparation, participation and periodic review of national and international standards that encompass contact lenses and contact lens care products which contain requirements so that these products have the necessary characteristics for these products to achieve an acceptable level of performance. These standards shall include or provide commonly accepted terminology, tolerances, methods of measurement of physical parameters, appropriate material physical, chemical and biological properties and methods for measuring material physical, chemical and biological properties for products that have been approved for marketing by authorized regulatory agencies in the United States.

Scope of the Subcommittee on Medical/Surgical Ophthalmic Devices

The scope and purpose of the Subcommittee for Medical/Surgical Ophthalmic Devices is to prepare standards for ophthalmic medical/surgical devices including ophthalmic refractive devices designed to alter the optical and/or focusing function of the eye. Such devices include those which are to permanently alter the structure or function of the eye, whether implanted or not. Examples of these devices include but are not limited to, excimer lasers and refractive implants (intraocular lenses including multifocals, foldable lenses and delivery systems, intracorneal implants, intracameral contact lenses, phakic IOLs, etc.). Additionally, the Subcommittee develops standards for glaucoma shunts, viscoelastics, endotamponades, and operating microscopes.

The Vision Council
225 Reinekers Lane, Suite 700
Alexandria, VA 22314
P: 703-548-4560 F: 703-548-4580

The standards and specifications shall cover the optical, geometrical, biological and mechanical attributes as applicable including, but not limited to, power, thickness, transmittance, coating, biocompatibility, chemical stability and light hazards.

Manual surgical instruments not linked to implant devices are excluded from the scope of the Subcommittee.

When appropriate, the Subcommittee works in conjunction with similar international committees, such as ISO, to develop joint standards.

Scope of the Subcommittee on Information Interchange for Ophthalmic Instruments and Equipment

The scope of the Subcommittee on Information Interchange for Ophthalmic Instruments and Equipment is limited to transmission protocol and file content and format for the electronic transmission of data between computers and ophthalmic instruments (such as perimeters, phoropters, corneal topography mappers, etc.), between computers and laboratory equipment (such as generators, blockers, edgers, etc.) and between prescription orders entry computers and computers and equipment used for lens processing.

Z80 Accredited Standards Committee for Ophthalmic Optics
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Annex C

ASC Z80 Standards for Financial Support

WHEREAS, the *ANSI Essential Requirements* for due process and the ASC Z80 operating procedures require that ASC Z80 operate in accordance with principles of (i) openness for all persons who are directly and materially affected by the standard-making activity, (ii) lack of dominance of any single interest category, individual or organization, and (iii) balance of interests of the various affected parties in the standards-making process; and

WHEREAS, in order to achieve the most broad-based participation possible it is important to keep member dues below that level which could deter some affected parties from becoming members and participating in the standard-making process; and

WHEREAS, one way to keep ASC Z80 dues to the lowest possible level is to obtain financial support in the form of unrestricted grants to the operating funds of Z80, or designated contributions as allowed herein; and

WHEREAS, those providing such financial support may not be given any opportunity to influence the standards-making process by such support (other than by increasing the broad-base of participating members by maintaining dues at an affordable level);

NOW THEREFORE, in order to achieve the broadest representation of membership possible, and to maintain adherence to principles of openness, lack of dominance, and balance of interests, ASC Z80 hereby adopts the following standards for financial support:

1. ASC Z80 will encourage those who are interested in a fair and open standards-making process involving participation by all potentially affected parties, to provide financial support to ASC Z80 in the form of unrestricted grants to the operating funds of ASC Z80, or to the extent allowed below in the form of designated contributions.

2. Any such contributions will be accepted in accordance with the following rules:

   a. The Parent Committee has determined that the contribution meets all of the requirements of Subsections 2(b-g) below. The Parent Committee shall make such determination by the affirmative vote of a majority of the voting membership, provided that at least two thirds of those voting vote in the affirmative, excluding abstentions.

   b. Cash contributions shall be placed in the general operating funds of ASC Z80, thereby enabling ASC Z80 to set its dues at a lower level than would otherwise be possible. In kind contributions may also be made.

   c. A financial supporter may designate use of its contribution to support a particular Z80 or ISO meeting(s) or event(s); in which case the Secretariat shall provide a written report to the financial supporter within 12 months of receipt of the support, evidencing the use of the support as designated.

The Vision Council
225 Reinekers Lane, Suite 700
Alexandria, VA 22314
P: 703-548-4560 F: 703-548-4580

d. No contribution of such financial support shall entitle the contributor to any Committee position, access or any other type of influence over any aspect of ASC Z80 standards-making, including without limitation any decision to develop, renew, not develop, or not renew any standard, or any decision concerning the text of any standard, or any decision concerning the agenda for any ASC Z80 Committee, subcommittee or working group meetings.

e. The sole opportunity to influence any ASC Z80 standards-making activities shall continue to be provided through participation as a member, observer, individual expert or through public comment, and not whatsoever through status as a financial supporter of ASC Z80.

f. ASC Z80 shall at least once a year provide public acknowledgement and thanks to financial supporters for their unrestricted grants to the ASC Z80 operating fund; and a financial supporter may be given an acknowledgement of their support for a meeting or event; but no financial supporter shall be described as a sponsor of the Committee itself or of any subcommittee or standard.

g. The ASC Z80 Steering Committee may place limits on the amount of contribution received from any single financial supporter in any year, where the Steering Committee deems it necessary to do so in order to avoid undue influence, or the appearance of undue influence, by any single financial supporter. Any such limitation imposed by the Steering Committee shall be subject to approval by the Parent Committee.

h. Any member of the public is entitled upon request to disclosure of the identity of each financial contributor to ASC Z80 and the amount given by each.

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Annex D

ANTITRUST COMPLIANCE GUIDELINES FOR ANSI ASC Z80

This Annex is provided as a convenience to the members of ASC Z80; to any extent its terms conflicts with the Antitrust Policy set out in the *ANSI Essential Guidelines* the terms of the latter document shall control the actions of ASC Z80 members.

ANTITRUST COMPLIANCE STATEMENT

A primary goal of Accredited Standards Committee Z80 ("Z80") is to create a secure environment where members can meet and share information with the understanding that their activities will be conducted in legal compliance with the US antitrust laws. Z80 recognizes that the antitrust laws preserve and foster competition and is committed to a policy that requires strict antitrust compliance. The Z80 Committee has adopted the following Antitrust Compliance Guidelines to be used by members and staff in conducting Z80 activities.

Application of the Antitrust Laws to Standards Writing Activities:

Antitrust compliance is important for all members because violations of the law could result in civil fines and penalties, or even criminal prosecution. Violations of the antitrust laws can result in costly investigations and litigation involving a great loss of time and payment of legal fees. It is Z80's goal to make members aware of these laws and be proactive in insuring compliance.

Z80 Antitrust Compliance Operating Procedures:

1. The Z80 Committee has adopted a formal antitrust compliance policy and is pro-actively taking steps to insure compliance.

2. The Z80 antitrust compliance statement will be provided to all attendees at Z80 meetings.

3. If topics that could be antitrust sensitive will be discussed at the Committee or subcommittee meetings, then those topic, in outline form, must be provided for review by staff and legal counsel prior to their presentation.

4. All Z80 membership meetings will be regularly scheduled and members will not be permitted to hold informal unscheduled meetings.

5. Agendas will be prepared in advance for all meetings. Agendas will be reviewed by staff, and when appropriate, by legal counsel.

6. Meeting discussions will follow the approved agendas.

7. Minutes will be kept at all meetings with the attendees at the beginning of each meeting.

8. Staff shall review meeting minutes, and if appropriate ask for a review by legal counsel, prior to distribution to ensure that antitrust sensitive discussions are properly documented.

The Vision Council
225 Reinekers Lane, Suite 700
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P: 703-548-4560 F: 703-548-4580

9. The Z80 subcommittee chairs and staff will seek legal advice when needed to insure Z80 projects and programs are compliant with relevant antitrust laws.

10. The Z80 members and staff will receive periodic briefings by legal counsel concerning antitrust compliance and will seek legal advice when necessary.

11. Z80 has adopted a formal record retention program.

12. Any action by Z80 or its Steering Committee that has the effect of rejecting a membership application, or removing a party from membership, shall be sent to legal counsel for review before becoming final.

The following Antitrust Guidelines for Discussions at Z80 Meetings should be provided to attendees of Z80 meetings.

Antitrust Guidelines for Discussions at Z80 Meetings

It is extremely important that members, meeting attendees, and speakers understand that the provisions of the antitrust laws regulate their conduct at Z80 meetings.

Guidelines for Discussions Between Competitors at Z80 Meetings

What You Cannot Do

1. Do not draft standards that favor one product over another unless there is a scientific or technical reason for doing so and the development of the standard was transparent and parties negatively impacted are given the opportunity to participate and comment.

2. Do not enter into any agreements with competitors regarding or affecting prices.

3. Do not discuss your company's current pricing strategy with competitors.

4. Do not agree with competitors on pricing or profit levels.

5. Do not agree with competitors to give or deny cash discounts or promotional allowances.

6. Do not agree with competitors to give or deny credit to a specific customer, or to establish uniform credit terms.

7. Do not agree with competitors to deal or not to deal with any customer or agree on the prices to be charged to a specific customer.

8. Do not discuss allocation of markets.

9. Do not enter into agreements with competitor's regarding price quotation or bids.

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What You Can Do

1. Discuss better ways to educate and provide meaningful information useful for standards writing activities.

2. Discuss economic trends, business forecasts and materials availability, emphasizing that each member company is free to use this information in the way it sees fit and should make their own business decisions.

3. Discuss Federal and State governmental actions and, the actions of other Standards Writing Association, and their impact on standards writing lobbying efforts'.

4. Discuss technological advances and better ways to utilize them.

5. Discuss ways to promote the use of standards to the interested public.

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Annex E

PROXY STATEMENT

TO THE SECRETARY OF THE ACCREDITED STANDARDS COMMITTEE Z80

I, the undersigned, as authorized delegate/alternative delegate (circle one choice) for _____[insert member organization name] hereby appoint and empower _____ as proxy authorized to represent _____[insert member organization name], and to cast votes, make proposals and sign any necessary documentation in its name in accordance with my instructions set forth below at the Fall/Spring [circle one choice] meeting of ASC Z80 and its subcommittees that will be held at _____[insert site of meeting] on _____[insert meeting date(s)].

SCOPE OF POWER OF REPRESENTATION (Circle one choice)

a) The proxy is authorized to vote on all agenda items at his/her discretion.

b) The proxy is authorized to vote on all agenda items in accordance with instructions given below.

Instructions: (Special instructions must be in writing)

PRINT NAME:

SIGNATURE: _____

NAME OF ASC Z80 MEMBER: