



Dental Standards Institute, Inc.

Standards Development Procedures Manual

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Mission statement

Dental Standards Institute, Inc. provides education, service and Standards through collaborative leadership to promote regulatory compliance, excellence in care and ease of electronic interoperability for healthcare professionals, patient safety and public protection.

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1.0 Overview

In conformity with guidance from the American National Standards Institute (ANSI) for organizations seeking accreditation as a Standards Development Organization (SDO), Dental Standards Institute, Inc. (DSI) has prepared the DSI Standards Development Procedures Manual (Procedures Manual) to provide the operational guidelines to be adhered to during the Standards development process. This manual is in compliance with the ANSI Essential Requirements (AER). The Procedures Manual is to be a resource and provide guidance to be followed for the Standards development activities of DSI and provide information on the process for all interested parties.

DSI agrees to update the Procedures Manual as required for continued SDO accreditation. Changes may occur as a result of new guidance from ANSI, the ANSI Executive Standards Council or published changes and updates to the AER. Substantial changes to this document will be provided to the ANSI Executive Standards Council for approval. All revisions shall be noted with a version number and approval date and shall be approved by the DSI Board of Directors.

Editorial changes or modifications to the procedures in the Procedures Manual as determined by DSI will be provided to ANSI for their approval, as required, and for their records. Revisions to the document and a record of the changes will be maintained by DSI.

The public may access this document and view the most updated version on the DSI website at dentalstandardsinstitute.com.

The DSI Board of Directors approved this DSI Standards Development Procedures Manual on August 1, 2019.

1.1 Scope and Rationale for DSI Standards Activities

DSI is an organization whose purpose is to provide an organization through which boards of dentistry act and counsel together on matters of common interest and concern affecting the public health, safety and welfare, including improving the transfer and storage of the Electronic Dental Record (EDR) containing electronic Personal Health Information (ePHI), as well as creating the opportunity for accelerating the development of technologies through shared platforms.

In support of DSI's mission, the purpose of creating a Standards Development Organization is to promote increased recognition and voluntary adoption of DSI's Standards of excellence in the regulation of dental practice through dental offices' collaboration throughout the United States and territories.

In cooperation with and support of its members, DSI continues to promote uniform high Standards in the regulation of dental practice communication through setting and maintaining electronic security requirements which are recognized throughout the United States and its territories. In addition, the Standards provided by DSI and implemented through its members, increase public protection and provide consumer confidence in the quality of dental practice, the communication process, and Standards for competency in the dental profession. DSI recognizes the important need to publish voluntary consensus Standards in the field of interoperability of ePHI.

Working with the broader partnership of regulatory boards, professional associations, and educational organizations, DSI is seeking to promote the voluntary adoption of electronic communication Standards to

demonstrate harmonization in the Standards development process.

It is the intention of DSI to propose Standards in the regulation of dental practice and interoperability requirements which:

- a. Document accepted security protocols;
- b. Establish fundamental definitions and terms; and
- c. Specify quality characteristics for performance.

These Standards will be representative of the perspectives of multiple Stakeholders—consumers, users, employers, government agencies, the regulatory community and healthcare providers. The Standards proposed by DSI will not favor, nor will they disadvantage, any participating Stakeholder.

The Standards proposed by DSI will be developed in such a way as to be easily adopted by the regulatory community for which DSI provides services and support. The Standards will represent the highest level of professional competency defined by the assessment development procedures of DSI which is recognized as the leader in interoperability competency and assessment.

The DSI proposed Standards will include the principles, design, development, implementation, model rules, policy statements, competence assessment, and continued maintenance requirements of interoperability regulation. The scope is further defined by DSI policies and procedures which govern the development and implementation of assessments and competency guidelines. The scope of Standards proposed by DSI will encompass the body of knowledge and direction of electronic record transference which is considered to be the highest Standard of entry-level practice as demonstrated by its adoption.

2.0 Organizational Structure

2.1 Organization and Sponsorship

The DSI Standards Development Committee (DSIDC) is a committee appointed by the DSI Board of Directors. The Board of Directors will appoint a Chair of the committee. The DSI Chief Executive Officer or designee (CEO) will staff the DSIDC. The DSIDC will be responsible for oversight, direction, strategy, implementation and maintenance of the DSI Standards development process. The DSIDC is responsible for adhering to the guidelines provided in the Procedural Manual, the AER, and the ANSI Executive Standards Council direction. Development of Standards will be consistent with the mission and direction of DSI for the benefit of public protection.

DSI will sponsor and fund all costs of Standards development operations and provide support to the DSIDC to carry out the activities of the Standards development process on a continuing basis.

2.1.1 DSIDC Membership

The DSIDC membership will include, at a minimum, three members plus the Chair. All members will serve a term of four years and members may reapply for membership on the consensus body after the close of their second term. Criteria for membership shall include: willingness to serve, interest and knowledge of the ANSI SDO process, and appropriate technical and professional expertise or knowledge. The CEO, DSI Board of Directors, or the DSIDC may recommend the addition of technical experts, consultants, or others who may be hired or

contracted with to assist the DSIDC in the completion of their work. While technical experts may be recommended to DSIDC membership, no unreasonable restriction will be placed as a condition of voting membership on the consensus body. The appointment process will take into consideration the need for continuity of experience. New committee members will be trained and provided information on the SDO process.

2.1.2 DSIDC Chair

The Chair will be appointed by the Board of Directors. The Chair will serve a term of two years and may be appointed for no more than two terms.

2.1.3 Responsibilities of the Chair

The Chair will provide guidance to the DSIDC and coordinate the work of the DSIDC with ANSI. The Chair will be the point of contact for ANSI. The Chair may delegate to the CEO operational activities, including but not limited to, preparing all ANSI materials; updating all materials as required; maintaining records of the SDO process; sending all official notices and correspondence to ANSI; serving as the contact for audits and re-accreditation; providing response to audit reports; receiving information from ANSI during the SDO process; and preparing and maintaining a training plan and informational documents for all persons who serve on the DSIDC. The Chair and/or the CEO will be responsible for the training and orientation of DSIDC committee members on the SDO process; coordination and communication of all ANSI requirements to the DSIDC; and management of the project consistent with ANSI requirements.

2.1.4 Responsibilities of the DSIDC

The DSIDC will operate according to the guidelines of the Procedures Manual and under the direction of the DSI Board of Directors. The DSIDC will be responsible for the following:

- a. Providing continuity, oversight and administration of DSI's Standards activities.
- b. Reviewing and approving the Procedures Manual and revisions as required.
- c. Reviewing and approving the application for SDO status, changes or requirements as noted by the Executive Standards Committee (who have oversight and approval functions for the SDO process) and/or ANSI, and review of audit findings by ANSI upon reaching SDO status.
- d. Implementing the SDO process in conformity with ANSI guidelines, to include record keeping and maintenance of Standards.
- e. Considering all Standards to be proposed for the SDO process, including recommendations from outside the DSIDC.
- f. Reviewing existing Standards for the prevention of duplication of effort and the implementation of harmonization of the Standards process with interested parties prior to the implementation of proposed Standards. (See Section 6.4)
- g. Providing recommendations for balloting participants and definition of consensus groups appropriate to the Standard being proposed.
- h. Maintaining consensus body lists and rosters.
- i. Suspending non-participating consensus body members.
- j. Overseeing compliance of the voting process to conform to the AER.
- k. Submitting recommendations for any technical support, subcommittees or other additional

requirements needed for the successful implementation of the SDO process.

- l. Assisting the CEO and/or the DSI Board of Directors in the selection of Subject Matter Experts (SMEs) as needed for any technical committees required.
- m. Approving a nomenclature scheme for the organization of DSI Standards.
- n. Assisting in the contact of interested parties as requested to seek harmonization and coordination of Standards.
- o. Providing oversight to the balloting process to assure consensus is reached.
- p. Assisting in the written response to negative or opposing ballots and comments.
- q. Evaluating the potential of pursuing international recognition for Standards as requested.
- r. Determining if discontinuation of a Standards project is advisable.

2.1.5 Meetings of the DSIDC

Meetings of the DSIDC will be held at least annually at the DSI office or other location to be determined. Other required functions and contacts of the DSIDC may be accomplished through conference call or email correspondence from the Chair or the CEO. Announcements of the meetings will be published 45 days in advance on the DSI website. Non-DSIDC members and other interested parties may request in writing to either (a) attend the meeting in person or (b) provide materials for consideration at the meeting. Materials for consideration may include, but are not limited to proposals for Standards to be submitted for approval through the SDO process by DSI. All requests must include a rationale. Nonmember attendance at the meetings is at the discretion of the DSIDC based on review of the information provided in the request. Requests must be in writing and submitted to the Chair or the CEO a minimum of 30 days prior to the meeting. The Chair or CEO will respond in writing to all requests.

2.1.6 Minutes of the DSIDC Meetings

Minutes of the meetings of the DSIDC must be maintained by the CEO permanently and will be confidential to the DSIDC, Chair, DSI Board of Directors, and CEO. Any requests for review of minutes must be in writing and provide a rationale. The DSIDC will respond in writing to any requests, but is under no obligation to provide the minutes to anyone with the exception of requests from ANSI. Minutes of the DSIDC meetings will be supplied to ANSI in accordance to the AER.

2.2 Appeals Committee

The Board of Directors will appoint an ad hoc work group for appeals known as the Appeals Committee, during the SDO process in the event of appeals of action or inaction. The Board of Directors may appoint the Appeals Committee to serve as needed for the time period required to satisfy the appeals process. Appointments for membership of this ad hoc work group will be made on the basis of only procedure as related to the Standard under consideration or to the action or inaction appealed as determined by the Board of Directors. A minimum of three and a maximum of five independent persons will be appointed to adjudicate the appeals process. The committee will be populated by qualified, fair and impartial individuals. Appeals Committee members will be

required to sign an agreement regarding DSI copyright as noted in section 6.6.1 and a Standard DSI conflict of interest statement.

2.3 Technical Committees

Technical committees will be appointed by the DSI Board of Directors, based on advice and recommendations from the DSIDC. Appointments for membership of this work group will be made on the basis of technical and professional expertise related to the Standard under, as determined by the Board of Directors. A minimum of three and a maximum of five independent persons will be appointed to the Technical Committee. The committee will be populated by qualified, fair and impartial individuals.

Technical committees will assist the DSIDC in writing proposed Standards and providing interpretations as needed. Technical committee members will be required to sign an agreement regarding DSI copyright as noted in section 6.6.1 and a Standard DSI conflict of interest statement.

2.4 Consensus Bodies

Consensus bodies are groups chosen to participate in the approval process of American National Standards (ANSs) as required by the AER. These groups are chosen based on their expertise and/or interest in the Standards being proposed. The DSIDC will define consensus bodies and their membership for each Standard proposed. Membership will be determined based on requirements in the Standards Development Process outlined in section 3.0.

3.0 Standards Development Process

The following steps shall be followed by the DSIDC in compliance with the AER. The Chair or the CEO at the direction of the Chair will be directly responsible for all documents filed with ANSI; for confirmation of receipt of each; and for maintaining a record of all action items completed to record the due process required.

3.1 Proposed Standard

A Standard may be proposed for the SDO process by the Chair, the DSIDC, the DSI Board of Directors, a member of the DSI Executive staff, a Member Board representative, or an interested party who uses the process outlined in 2.1.5. All proposals for Standards must be reviewed and evaluated by the DSIDC for their appropriate nature to the scope of the Standards included in the DSI SDO description in 1.1 Scope and Rationale for DSI Standards Activities. Proposed Standards must also be evaluated for potential overlap or duplication (see 2.1.4.f) prior to approval for the SDO process.

3.2 Approval Process

The DSI Board of Directors will review all proposals submitted by the DSIDC and must approve the Standard prior to beginning the formal process of Standards approval.

3.3 Regulatory Adoption

To facilitate voluntary adoption by regulatory groups, the DSIDC will review each draft Standard for the following criteria:

- a. Written to be suitable for reference.
- b. Representative of best practice.
- c. Acceptable and endorsed by Stakeholders.
- d. Readily accessible to the public.
- e. Enforceable (in a regulatory context).

3.4 Submission Requirements

Each proposed Standard must contain the following elements as required by the AER:

- a. Title and proposed nomenclature.
- b. Statement of scope.
- c. Explanation of need.
- d. Identification of Stakeholders.
- e. Existing Standards—information that may have a bearing on this project which relate to existing Standards, if existing Standards are present.
- f. Supporting materials as required.
- g. Written interpretation of the Standard.

3.5 Preliminary Review

DSIDC will prepare a preliminary draft document for review of Stakeholders after filing of the ANSI Project Initiation Notification System (PINS) form and the formal and public review of no less than 30 days. This will aid in the development of the preliminary draft. DSIDC will use this step to gather preliminary comments or to make changes to the draft Standard prior to official filing with ANSI.

3.6 Project Initiation Notification System (PINS) Form and Public Review

ANSI requires that the initiation of a new Standard activity or revision to an existing Standard be noted by filing of the ANSI Project Initiation Notification System (PINS) form. The CEO will file this form electronically, upon approval by the DSIDC. This form will be used by ANSI to provide public notice in the ANSI Standards Action publication. This begins the formal process and public review of no less than 30 days.

The PINS Form shall also include a statement to be published as part of the PINS announcement:

- a. The statement of explanation of the need for the Standards project; and
- b. Identification of the Stakeholders who are likely to be impacted by the Standard.

3.6.1 Comments to PINS

Resulting comments shall be handled in accordance with AER section 2.5, subsections 2.5.1.2 and 2.5.1.3.

3.7 Deliberation Report

The documentation of the outcome of the deliberation (Deliberation Report) shall be conveyed in writing within 30 days after the conclusion of deliberation by the DSIDC to the commenter and shall be provided to ANSI. If more than one deliberation is required, a report from each shall be retained and sent to ANSI.

Upon submission of the Deliberation Report, the DSIDC will proceed with the submission of the draft Standard for public review, depending upon the outcome of the process and consensus. If additional deliberations take place, they should not delay the submission of the draft for public review, and an updated Deliberation Report shall be conveyed within 30 days after each deliberation. Any actions agreed upon from the deliberations shall be carried out in a reasonably timely manner, but normally should not exceed 90 days following the deliberation.

Deliberation reports are to be included with the BSR 9 to the ANSI Board of Standards Review (BSR) for consideration should DSIDC ultimately submit the subject Standard to ANSI for approval. Stakeholders who were involved in the PINS deliberation process may also file separate Deliberation Reports with ANSI and the DSIDC within 30 days of the conclusion of any deliberation for consideration by the BSR, if the Standard is submitted to ANSI for approval.

DSIDC will attempt to develop a consensus on whether and how the Standards development project should proceed.

3.8 Balance

The goal of the DSI is to achieve balance as defined in 2.3 of the AER. DSI will work diligently to achieve balance, recognizing that unless this goal is met, the Standards process cannot move forward. DSI is committed to the concept of balance and will include all Stakeholders and interested parties in the process to assure a balance of interests and that the process is not dominated by one group based upon size, position, leverage, strength, or representation to the exclusion of others.

No single interest category will constitute more than one third of the membership of the consensus body dealing with safety-related Standards.

3.9 Openness

The public review process and the formation of the consensus body are open to all interested parties, whether or not they are members of DSI or DSI associate members.

DSIDC will consider the views and objections of comments from the public review process as well as from the votes of the ballots from the consensus body. The public review process and comments may originate from responses to ANSI Standards Action, DSI publications and website notices, and related industry publications.

DSIDC will continuously direct outreach efforts to Stakeholders to achieve balance during all phases of the SDO process, including initiation, maintenance and renewal of Standards. Documentation of the outreach by DSIDC will be available to ANSI upon request and will be available for ANSI audit. Evidence will include documented efforts to reach all materially affected and interested groups. Such documentation will be retained in accordance

with section 6.2 Records Retention Policy.

3.10 Consensus Bodies Included

Consensus bodies are composed of persons who vote on approval of ANSs. In accordance with AER requirements for Openness (1.1) and Balance (1.3), participation will 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. DSI recognizes the need for including all Stakeholder groups materially affected by the proposed Standards in the consensus bodies. To this end, consideration for initial consensus bodies will include all Stakeholder groups listed and categorized below. Their relationship to DSI is defined in 3.9, consistent with the intent of the ANSI Standards process and the relationship of such entities to DSI as a not-for-profit organization in the regulatory field.

3.11 Stakeholder Lists

Stakeholder Lists shall comply with AER requirements for openness, lack of dominance and balance.

Stakeholders may be participants in the balloting process and shall be known as ballot participants. Each member will be assigned one interest group as indicated on their ballot. Each ballot participant must be a bona-fide representative of the defined category to assure they are representative of that interest group.

As per AER 2.3 (balance), the Stakeholders and interest categories appropriate to the development of consensus in any given Standards activity are a function of the nature of the Standard being developed. Accordingly, the DSIDC will be careful to define and include all Stakeholder lists specifically for each Standard that is to be balloted so as to assure appropriateness of Stakeholders/interest groups.

Voting rights are neither conditional upon membership in any organization nor restricted based on technical requirements. There will be no financial barriers to participation in the voting process.

Members from each group will be assigned to one of the following defined interest categories: professional association, employer, consumer, user, general interest, and producer, as appropriate. Professional associations include those organizations that represent the dental professionals in the arena of professional development, employment and membership services. Employers hire, train and manage dental professionals and include, but are not limited to dental systems, DSO's, dental schools, clinics, small practice settings, and individuals. Consumers include the general public. Users include dentists, dental professionals, regulators and others who implement the Standards. The general interest category includes educators. Producers include testing companies who produce Standards in assessment.

In compiling the consensus body, consideration will be made that a) no single interest category will constitute more than one-third of the membership of the consensus body dealing with safety related Standards or b) no single interest category constitutes a majority of the membership of a consensus body dealing with any other Standards, not relating to safety.

3.12 Consensus Body Notice

Notice will be provided to each person by electronic means inviting them to participate by commenting on the proposed Standard. The written notice will be based on recommendations by the DSIDC, the interest of each

person and the category they represent. Each person will be provided a minimum of 30 days from the date of the letter, to respond whether they are willing to participate by commenting on the proposed Standard.

The defined interest categories will be monitored throughout the notice process to attain balance in agreement with section 3.8. Additional notices will be sent out as needed to achieve balance of representation. The CEO will maintain a record of all notices sent, responses and a final total of representation for each group.

3.13 BSR-8

The BSR-8, the Standards Action Public Review Request, is a required ANSI form used to record the Standard and is provided to the public for review via ANSI publications. The DSIDC will review and approve the filing of form BSR-8 by the CEO. The CEO will file BSR-8 with ANSI electronically and confirm its receipt. Copies of the date of filing and receipt and acknowledgment by ANSI are to be retained in the DSIDC Standards records. DSI will publish announcements of the draft Standard for public review on its website (www.dentalstandardsinstitute.com). The DSI website will include a description of the ANSI process, how to participate, and how the public may respond to the draft Standard.

3.14 Ballot Instructions

Ballots will be sent to all members of the consensus body electronically with complete copies retained at DSI by the CEO.

Ballots will include the following:

- a. Recipient demographic information, defined category of interest and consensus body representation. A copy of the proposed draft Standard and all required information.
- b. A written interpretation of the Standard for clarification (if requested).
- c. Notice that all ballot procedures will be completed by electronic format.
- d. The draft Standard marked "COPYRIGHT DSI."
- e. Requirement to acknowledge the DSI copyright information and agreement.
- f. Instructions that copying the draft Standard is not permitted for other purposes.
- g. Date and location of publication of the Standard and due date for written responses to comment.
- h. Indication that non-agreement to these terms will result in non-participation in the balloting process.
- i. Deadline for response and how and to whom to respond,
- j. Indication of requirement for written responses.
- k. Instructions on how to respond to record ballot properly. (Sections 3.17 and 3.18).
- l. Instructions on the appeals process.

3.15 Reminders

After a period of 14 days, DSI will send electronic reminder notices to all ballot participants alerting them of the

deadline for response.

3.16 Due Process

The DSIDC will seek consensus through the consensus body balloting. The DSIDC will respond to all written comments whether positive or negative from both public review and votes of the consensus body balloting and will publish the comments and the responses on the DSI website for public review. In addition, all comments and responses will be sent to all ballot participants. The CEO will maintain a record of all responses in the DSIDC records and will make these available to ANSI and/or ANSI auditors as required. The CEO will maintain consensus body records that include, but are not limited to the ballot participant's name, the consensus body they represent, and their defined category.

3.17 Participation

As part of due process, DSI will make every effort to obtain ballots from participants. If needed, a second electronic reminder will be sent to participants urging them to complete the process. The DSIDC will carefully review the responses to make certain that all affected parties are represented.

3.18 Ballot Categories

Ballots may be filed as follows:

- a. Approve without comment;
- b. Approve with comment;
- c. Negative with comment providing written rationale and explanation; or
- d. Abstain (may or may not provide rationale).

3.19 Negative Ballots

Views and objections of consensus bodies will be considered as required under section 2.6 of the AER regarding Consideration of Views and Objections.

Ballots may be filed as a negative vote and ballot participants are required to file a written rationale with the negative vote. By filing a comment with the negative ballot, these comments will assist the DSIDC in understanding the vote and in responding to the comment. Instructions will be included in the initial ballot to provide every opportunity to the ballot participants to record both their negative vote and the rationale. It is the responsibility of the ballot participant to provide the written rationale. No attempt can be made to resolve the objection unless the participant provides a rationale for the objection.

The DSIDC will respond to all negative ballots in writing, including those resulting from the public comment review and ballot participants. In the response, the DSIDC will explain in detail why the negative comment was accepted and if the Standard is modified accordingly. If it is the consensus of the DSIDC not to accept the negative comment for use in modifying the Standard, the DSIDC shall explain their rationale for this decision.

In responding to negative ballots, the DSIDC will provide instructions to the objectors on how to appeal the process. Written interpretation of the Standard will also be provided by the DSIDC to prevent misunderstanding of the draft Standard, upon request.

Unresolved negative ballots will be reported to ANSI as part of the records of the process. Negative ballots received from public comments will also be recorded. Responses shall be provided to public comments if contact information is provided.

In the case of negative ballots involving technical issues, the DSIDC may request the advice of a technical committee (section 2.3) or consultant(s) (section 2.1.1) to assist in reviewing the objections and developing the response. All attempts at resolution of negative ballots should be published. Names and demographics of the negative comments are not to be included in these publications unless permission is granted by the participant.

3.20 Recirculation and Procedural Appeal

Comments received which are not related to the proposed Standard under review will be documented but considered a new proposal and not appropriate to the draft Standard.

3.20.1 Circulation and Recirculation

The DSIDC will circulate all comments received during a ballot to all ballot participants to provide more information to participants.

In addition, the DSIDC will recirculate all unresolved public review comments and unresolved votes from consensus members, along with attempts at resolution and any substantive changes. This recirculation will be sent directly to all unresolved objectors and to all ballot participants in order to provide them an opportunity to respond, reaffirm, or change their vote. Notice of instructions and timeframe for response (30 days from the date of recirculation) will be included in the recirculation. Record of recirculation will be maintained with the DSIDC records by the CEO as well as any resulting changes in votes. Objections which are not resolved shall be reported to the ANSI Board of Standards Review and maintained as evidence for review by ANSI. Each unresolved objection and attempt at resolution, and any substantive change made in a proposed American National Standard 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.

3.20.2 Procedural Appeal

The DSIDC will publish a notice of the right to appeal in writing in DSI publications and directly to all unresolved objectors, including those comments from the public and from ballot participants that they may appeal on procedural grounds. (See also 4.0 and 4.1)

3.21 Change of Negative Ballots

The DSIDC will inform the ballot participants of their options in the written response to negative ballots. If the negative ballot remains unresolved, the ballot participants have the following options:

- a. Negative votes may only be changed at the option of the ballot participant by written request; or
- b. For unresolved objectors, the right to appeal is available, see procedural appeal above.

The CEO will record all responses to the notice including any change of negative votes with the DSIDC records. Evidence of any change of voting will be documented and provided in writing as requested by ANSI and retained for ANSI audit.

3.22 Substantive Change to the Standard or Discontinuance

If substantive changes result to the Standard based on negative or positive comments from ballot participants or public comment, the Standard is to be republished and ballot participants and the public will be alerted to the changes. At this time, all ballot participants are to be apprised of their options to respond, reaffirm their original vote, or change their original vote.

If substantive changes occur during this process, the DSIDC is responsible for revision of the interpretation of the Standard for publication.

Such changes to the Standard require notice to ANSI for republication for public notice and review and comment in Standards Action for an additional period of 30 days; or 45 days if the changes are substantive and result in more than five pages in length.

3.22.1 Discontinuance

At this time, if significant negative comments have been received to indicate the discontinuance of the proposed draft Standard is a potential procedure, the DSIDC will discuss this option and determine whether or not to proceed with the process of approval or file a process of discontinuance with ANSI. Public notice will be made if discontinuance is determined.

3.22.2 Minor Changes

Minor changes to the Standard, including typographical, editorial or grammatical changes do not require public notice and republication of the Standard.

3.23 Consensus

After all necessary re-circulations are completed, the Appeals Process is concluded (if necessary), and the filing deadline for appeals has expired, the CEO will tabulate the votes from balloting, record whether or not consensus was reached, and provide the information to the Chair.

Consensus will be determined by:

- a. Receipt of a majority of ballots returned, including all abstentions (50% +2 of all sent); and
- b. Two thirds of those votes received (minus abstentions) represent positive votes.

3.24 BSR-9 Report

The DSIDC is responsible for reviewing a report to ANSI which records the results of the balloting and achieving consensus. The report will verify the use of due process, including confirmation that a balance of interest was

achieved, and certify the results. The form BSR-9 will be provided with this report and will be filed electronically by the CEO upon approval by the Chair. The CEO will record the filing and response from ANSI and dates of filing. Ballot information must accompany this form. If requested, the Chair or the CEO will provide any additional information requested by ANSI. Deliberation report(s), if appropriate, will be included with the BSR 9. See also 3.6 Project Initiation Notification system (PINS) Form and Public Review.

3.25 Approval of an American National Standard (ANS)

After approval of all forms and accompanying information, and with clarification that due process was completed; ANSI will notify the Chair of the approval of the Standard as an ANS. Upon receipt of this notice, DSI may publish this declaration of an ANS in newsletters, trade journals, websites and other sources of information as it deems appropriate.

3.26 Publication of Standard

It is the responsibility of DSI to publish the Standard for use by the public. This publication must be completed within six months of the declaration of an ANS by ANSI. DSI will provide publication of the Standards to interested parties. The Standard will be made available on the following website for downloading as a PDF document: dentalstandardsinstitute.com.

3.27 Maintenance of Standards

The DSIDC is responsible for the maintenance and review of Standards in accordance with section 5.1 and 5.2.

3.28 Interpretation

As a requirement of the AER, the DSIDC will provide interpretations to the Standards as requested by any interested party, including participants in the balloting process, through public review and comment at any time during the Standards development process, including after the Standard has been published. Interpretation of the Standard is to prevent misunderstanding of the Standard or improper interpretations that might result in harm or misuse. Interpretations of the Standard will be included in its publication for clarification. Any revisions to the Standard will be accompanied by written interpretation.

4.0 Pre-Appeals and Appeals Process

The DSI appeals policy governs both appeals of action and inaction of DSI in regard to its American National Standards activities.

4.1 Pre-Appeals

Prior to the formal appeals process, the DSIDC will attempt to resolve complaints informally during a Pre-Appeals process by the DSIDC Chair or the CEO contacting the ballot participant to discuss the objection and present options to attempt resolution prior to an appeal. These results and the contacts, both written and oral, will be documented in the minutes of the DSIDC.

If the complaint is not resolved during the Pre-Appeals process, the Appeals Committee (See Section 2.2) will

review the complaint.

4.2 Terms for Appeal

It is the responsibility of the person filing the appeal to provide a written description of the objection, a description of any adverse effects attributed to the Standards, and recommendations of what action(s) would satisfy the person filing the appeal. Procedural grounds may include whether or not a technical issue was afforded due process.

4.3 Procedural Appeals

Appeals filed on procedural grounds will be reviewed by the Appeals Committee which will make a recommendation on how to proceed. A single member will be appointed to be responsible for responding to the issues raised by the appellant before the Committee. Recommendations will be conveyed in writing to the person filing the appeal within 30 days of receipt of the appeal by the Appeals Committee.

4.4 Deadlines Appeals

Filing

Appeals must be filed in writing, and include all related documents and filed within 30 calendar days of publication of response to negative comments and notice of appeal or within 30 calendar days of the action to be appealed. An appeal may be submitted at any time with regard to an inaction.

4.5 Appeals Committee Notice

Notice of the appeals committee members will be provided to the appellants within 14 calendar days after receipt of the appeal.

4.6 Conflict of Interest Notice

The appellant has 14 calendar days from the receipt of the appeals panel notice to file a conflict of interest notice to the DSIDC regarding members of the appeals committee.

4.7 Appeals Decision Notice

A written notice of the appeals decision will be provided to the appellant no later than 45 calendar days after receipt of the appeal. The appeals decision notice will include the rationale for the decision and include all pertinent dates and facts regarding the appeal. The decision must represent a two-thirds majority vote of the appeals panel.

4.8 Delays in Process

If a conflict of interest notice is filed and DSIDC determines that new appeals committee member(s) are appropriate based on the filing by the appellant, the appeals decision notice will be delayed by a mutually agreeable schedule between the DSIDC and the appellant.

4.9 Process

The appeals process and deliberation of the committee may be accomplished by teleconference and other means but does not require an in-person hearing.

4.10 Records

Records of all appeals will be maintained by the Appeals Committee, filed by the DSIDC and made available to ANSI for audits or upon request.

If the written response and Pre-Appeals Process and potential actions do not satisfy the person filing the appeal, and the appeal is denied, the person filing the appeal has the option to further contest the action by filing a procedural appeal with ANSI. It is the responsibility of the Appeals Committee to inform the person filing the appeal of the opportunity to take this action within 30 days. The person filing the appeal must file the appeal with ANSI in writing. Further appeals of approval of the standard can be made to ANSI only after it has been approved as an ANS. The DSI must provide all appeal documentation to ANSI prior to the appeal being filed with ANSI.

4.11 Notice

The Appeals Committee will provide written information on the appeals process to the consensus groups during the balloting process.

5.0 Maintenance of Standards

5.1 Maintenance of ANSs

The period for an ANS is five years unless ANSI grants an extension based on a written request and rationale from the DSIDC. DSI will support and fund all activities of the DSIDC required for the continued maintenance and administrative support of ANSs submitted. This support includes the publication of the ANSs, providing interpretations if requested, and processing revisions. After the period of five years from the date of approval, each ANS must be reaffirmed, revised or withdrawn.

5.2 Review Procedures

No later than the fourth year after being approved as an ANS, each Standard must be reviewed by the DSIDC and the consensus body for updates and revisions. After this process, the DSI may submit the appropriate forms for re-approval of the ANS by ANSI. At this review period, the DSIDC has the following options:

- a. Revise the approved Standard by providing updated language which might change the technical content or interpretation.
- b. Reaffirm that the review of the Standard resulted in the decision to make no changes.
- c. Withdraw the Standard if it is deemed of no current value to Stakeholders.

Any of the above actions require approval by the DSIDC, consensus body approval and require filing the appropriate documents with ANSI. A record of the review and these decisions should be reflected in the minutes of the DSIDC.

DSI acknowledges that the ANSI Executive Standards Council (ExSC) may remand an American National Standard (ANS) for reconsideration as a result of an audit or an appeal and be considered by the ANSI Board of Standards Review.

6.0 Documentation and Administrative Elements

6.1 Metric

Any reference to measurement in the Standards will be consistent. However, it is not anticipated that the Standards will include units of measure.

6.2 Records Retention Policy

DSI will maintain all DSIDC records permanently, as specified in the DSI records retention policy.

6.3 ANSI Request for Documents

The DSIDC, Chair, and CEO will comply with all ANSI document policies and requests for documents.

6.4 Harmonization

DSI supports the concept of harmonization. Harmonization is an ANSI essential requirement for conflict resolution. It applies to the process of resolving potential conflicts between existing and proposed ANSs. Harmonization defines an additional process beyond reviewing existing Standards for duplication. The DSIDC, Chair, and CEO will work with all Stakeholders to assure that harmonization is reached in the Standards development process. The DSIDC will be responsible for review of any Standards that may present duplication and will make every effort to prevent duplication or conflict.

6.5 Patents

It is the intention of DSI to comply with ANSI's current patent policy.

6.6 Copyright

DSI and the DSIDC will comply with all U.S. Copyright Law requirements.

6.6.1 Copyright Assignment

The CEO, DSI staff, and each person agreeing to serve on the DSIDC, or as the Chair, technical committee members, consultants, ad hoc committee members and consensus group members, will be required to sign an agreement to relinquish their right to all materials developed by DSI during the Standards development process. All products will be the sole ownership of DSI. The CEO will keep the agreement forms stipulating this assignment on file with the DSIDC documents.

6.6.2 Documentation

All versions of draft Standards, materials, and ballots shall be marked "Copyright: DSI." DSI will register all ANSs with the US Copyright office.

6.7 Commercial Terms and Conditions

It is the intention of DSI to comply with ANSI's current terms and conditions for Commercial Terms and Conditions as provided in the AER.

6.8 Liability and Warrantees

Although DSI intends to develop Standards in electronic transmission of information regulation, it cannot be held accountable for individual practitioners or for the improper implementation of its Standards.

6.9 Conflict of Interest

Members of the DSIDC, the Chair, consultants and technical committee members shall sign a conflict of interest statement to assure that they agree with the conflict of interest policies of DSI and will adhere to those policies during the Standards development processes in which they participate.

6.10 Logo

DSI will grant the use of the DSI logo to identify Standards approved and developed by the DSIDC and subsequently approved as an ANS. DSI will use the ANS logo for use on a published American National Standard only as directed and approved.

6.11 Evidence of Compliance and Audit Process

The CEO is responsible for the compliance of all AER procedures and for the maintenance of documents to show evidence of compliance with the procedures. The CEO or Chair will provide any material requested by ANSI, including all documents required for audits. The DSIDC will provide all documentation and provide support and information to the ANSI audit team and welcome recommendations for continuous improvement of the DSI Standards process.

6.12 Indemnity

DSI agrees to hold ANSI harmless from any suit or claim filed against ANSI which might arise from a Standard that is a product of the DSI's Standards process and submitted as an American Standard.

6.13 Antitrust Policy

It is the intention of DSI to comply with ANSI's current antitrust policy and to develop Standards in accordance with applicable antitrust and competition laws. Meetings amongst competitors to develop ANSs will be conducted in accordance with these laws.

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