

Operating Procedures and Policies for the Microplate Standards Advisory Committee of the Society for Laboratory Automation and Screening

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1. General

This document outlining the operating procedures and policies of the Microplate Standards Advisory Committee (referenced throughout this document as either MSAC, or “Consensus Body”) was prepared and approved for submittal to American National Standards Institute (ANSI) as part of the process for redirecting the Committee from being a standing committee to being an ad-hoc, working committee that assembles in a five-year cycle in accordance with ANSI requirements (Periodic Maintenance) to vote on the reaffirmation of the ANSI/SLAS Standards 1-4 and 6.

The overall role of the MSAC will therefore be to assist in the revision, reaffirmation or withdrawal of ANSI/SLAS Standards 1-4 & 6. The MSAC will retain its ability to oversee the creation of any new standards, should the directive arise.

SLAS Professional Staff, with the guidance of the Board of Directors, will oversee all Standards maintenance, and all records and processes will be retained and managed at SLAS Headquarters. There will be a call to re-convene the Consensus Body every three years to prepare for the re-affirmation process (see section 3.b.1 of these procedures). If action is taken to withdraw a Standard, ANSI shall be so notified. With the guidance of the Professional Staff, and keeping with ANSI requirements, SLAS Board of Directors will hold the responsibility for approving/dissolving this committee.

At any time of the process to either revise, reaffirm or withdraw OR if tasked with the development of a new standard, this committee will refer to these procedures along with the most current version of the *ANSI Essential Requirements: Due process requirements for American National Standards.*

2. Membership and Consensus Body Membership

In accordance with *ANSI Essential Requirements: Due process requirements for American National Standards, section 2.3; Balance,* the MSAC will act as a Consensus Body, ensuring that there is a balance of membership, most importantly showing that a) no single interest category (individual or organization) constitutes 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 other than safety-related standards. The Consensus Body can have up to 50% of its members from the interest group category for non-safety related standards and no more than one-third for safety related standards.

All appropriate interests that are directly and materially affected by the standards activity of the MSAC shall have the opportunity for fair and equitable participation without dominance by any single interest. Each member shall define themselves as being in at least one of proposed interest categories.

Membership in SLAS is not required to participate in the MSAC. Membership requests and rosters will be handled by the SLAS Professional Staff.

According to the SLAS Bylaws, it will be the responsibility of the MSAC Chair(s) to achieve balance of membership annually. The roster will be approved Board of Directors.

3. Interest Categories

The MSAC membership will be balanced between the following interest categories

- a) Manufacturers of microplates;
- b) Manufacturers of instruments that utilize microplates;
- c) Industrial and Academic Users of microplates
- d) Those with a general interest in the topic that do not fit in either of the previous categories.

Where appropriate, additional interest categories (individual or organization) should be considered. Membership in the group is open to all interested parties and will consist of organizations (preferably national in scope), companies, government agencies, individuals, etc., having a direct and material interest in the revision, reaffirmation or withdrawal of ANSI/SLAS Standards 1-4 and 6.

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

4. Process and Procedures

In order to comply with the *ANSI Essential Requirements: Due process requirements for American National Standards, section 4.7.1; Periodic maintenance of American National Standards*, the re-affirmation of the existing standards must take place every five years.

a) Notification of Activity (BSR-8 / PINS forms)

Whether to address an inquiry or to vote on any activity involving the ANSI/SLAS Standards, an appropriately timed call for participation will be sent via electronic communication. These channels include, but are not limited to, the SLAS Website, email and the MSAC LinkedIn Subgroup. Communications will be used to provide notification of new standards activity and/or discussion and to demonstrate the opportunity for participation by all directly and materially affected persons. Voting by the Consensus Body will comply with ANSI requirements and will allow the Consensus Body the opportunity to respond, reaffirm or change their votes.

Any proposal to revise, reaffirm or withdraw approval of the existing Standards must be communicated to ANSI using a BSR-8 form, or its equivalent, for listing in *Standards Action*, in order to provide an opportunity for public comment. The comment period shall be a minimum of forty-five days, and the document, in electronic format, shall be delivered within one day of a request. The document URL, along with email contact information from which it can be obtained by the public will be provided to ANSI for announcement in *Standards Action*.

Should there be initiation of a project to develop or revise an American National Standard; notification shall be transmitted to ANSI using the Project Initiation Notification System (PINS) form, or its equivalent, for announcement in *Standards Action*.

Comments received in connection with a PINS announcement shall be handled in accordance with these procedures, in compliance with *ANSI Essential Requirements: Due process requirements for American National Standards, section 2.5.1; Project Initiation Notification (PINS)*:

A statement shall be submitted and published as part of the PINS announcement that shall include:

- (a) an explanation of the need for the project, including, if it is the case, a statement of intent to submit the standard for consideration as an ISO, IEC or ISO/IEC JTC-1 standard;
- (b) identification of the stakeholders (e.g., telecom, consumer, medical, environmental, etc.) likely to be directly impacted by the standard.

If the response to sub-section (b) changes substantively as the standard is developed, a revised PINS shall be submitted and published.

b) Evidence of Consensus and Consensus Body Vote

Evidence of consensus in accordance with these procedures and the accredited procedures of the standards developer shall be documented. Consensus is demonstrated, in part, by a vote of the Consensus Body. (See *ANSI Essential Requirements: Due process requirements for American National Standards, section 2.7; Evidence of Consensus and Consensus Body Vote.*)

1) Voting Procedures and Timeline

A call for participation in the Consensus Body will be publicized on the SLAS website and sent to the membership via email in the November of the third year of the process (i.e. for reaccreditation in 2017, call for participation will be sent 2015). Balance of Consensus Body and roster approval by the Board of Directors will be finalized by June of the following year.

The ballot, along with an explanatory page outlining administrative matters of the vote, including ballot approval, resolution of ballot comments, handling of negative votes, and appeals will be sent in April of the following year so that the vote and all necessary forms can be submitted to ANSI early in the fifth year, if not sooner.

The time frame for voting shall be no shorter than two months, from the initial communication to the close of the ballot. Each Consensus Body member shall vote one of the following positions:

- Affirmative;
- Affirmative, with comment
- Negative, with reasons (the reasons for a negative vote shall be given and if possible should include specific wording or actions that would resolve the objection);
- Abstain, with reasons.

Voting will be handled electronically, but in the instance where a vote is taken at an in-person meeting, any person not present at this meeting will be given the appropriate means and time to cast their vote. A follow-up email to all participants will be sent 10 before the ballot closes.

2) Actions Requiring 2/3 Approval

The following actions require a letter ballot or an equivalent formal recorded vote with

approval by at least a majority of the consensus body and at least two-thirds of those voting, excluding abstentions:

- Adoption of MSAC procedures, or revisions thereof
- Approval of a new standard or reaffirmation of an existing one
- Approval of revision or addendum to part or all of a standard
- Approval for submission to ANSI of change of MSAC scope
- Approval of withdrawal of an existing standard.

c. Consideration of Views and Objections

All interested parties will be given 45 days after the vote takes place to make comments or objections regarding action of the Committee. The document(s) in question can be requested from SLAS Headquarters via email. The document, or the link to its location, will be delivered upon these requests within one day. The email address to request this documentation will be made available on the SLAS website, as well as provided to ANSI for announcement in *Standards Action*.

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 MSAC. In addition, 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 MSAC, all comments received subsequent to the closing of the public review and comment period shall be considered. Timely comments that are not related to the proposal to reaffirm shall be documented and considered. The submitter of the comments shall be so notified.

Each unresolved objection, along with attempts at resolution, and all substantive changes 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.

See *ANSI Essential Requirements: Due process requirements for American National Standards, section 2.5; Notification of Standards Development and Coordination and section 2.5.2 Public Review.*

d. Appeals Process

Persons who have directly and materially affected interests in the proposed standards or who have been or may be adversely affected by a procedural action or inaction of the

Consensus Body or the chair shall have the right to appeal by filing a complaint. A person filing a complaint shall be referred to as the “appellant,” and the MSAC chair or the chair’s representative shall be the “respondent.” The appeal shall follow the procedures outlined below.

i. Complaint

The appellant shall file a written complaint with the chair within thirty days after the date of notification of action or at any time with respect to inaction. The complaint shall state the nature of the objection(s) including any adverse effects caused the appellant, the clause(s) of these procedures or the standard that is at issue, actions or inactions that are at issue, and the specific remedial action(s) that would satisfy the appellant’s concerns. Previous efforts to resolve the objection(s) and the outcome of each shall be noted.

ii. Response

Within thirty days after receipt of the complaint, the chair shall respond in writing to the appellant, specifically addressing each allegation of fact in the complaint to the extent of the respondent’s knowledge.

iii. Hearing

If the appellant and the respondent are unable to resolve the written complaint informally in a manner consistent with these procedures, the chair shall schedule a hearing with an appeals panel on a date agreeable to all participants, giving at least ten working days’ notice.

iv. Appeals Panel

The appeals panel shall consist 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 decision made or to be made in the dispute. At least two members shall be acceptable to the appellant and at least two shall be acceptable to the respondent. If the parties to the appeal cannot agree on an appeals panel within six weeks of receipt of the hearing notification letter, the matter shall be referred to the Board of Directors, which shall appoint the members of the appeals panel who are impartial and not materially affected.

v. 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 Consensus Body and the chair took all 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.

vi. Decision

The appeals panel shall render its decision in writing within thirty days, stating findings of fact and conclusions, with reasons therefor, based on a preponderance of the evidence

presented to the appeals panel. Consideration shall be given to the following positions, among others, in formulating the decision:

- Finding for the appellant, remanding the action to the Consensus Body with a specific statement of the issues and facts in regard to which fair and equitable action was not taken
- Finding for the respondent, with a specific statement of the facts that demonstrate fair and equitable treatment of the appellant and the appellant's objection
- Finding that new, substantive evidence has been introduced, and remanding the entire action to the Consensus Body or the chair for appropriate reconsideration.

vii. Report of Final Result

The final result of the voting, including appeals and hearing decisions shall be reported, by interest categories, to the Consensus Body.

5. Other Review

Proposals for new American National Standards or reaffirmation, revision, or withdrawal of existing American National Standards shall be transmitted to ANSI for listing in the publication ANSI Standards Action for comment.

The chair shall determine whether listing of proposed standards actions shall be concurrent with the final consensus body ballot and whether announcement in other suitable media is appropriate. The chair shall arrange for a copy of the proposed new, revised, or reaffirmed standard to be published by SLAS at the same time.

Views and objections resulting from the above must be written and submitted to MSAC. Response to these views and objections shall be dealt with in accordance with clause 4.c. Consideration of Views and Objections of these procedures. Any substantive change (see clause 2.5 of the ANSI Essential Requirements) made in the proposed American National Standard shall be re-listed, also in accordance with clause 4.c.

6. Discontinuation of a Standards Project

The MSAC holds the right to abandon the processing of a proposed new or revised Standard or portion thereof at its own discretion and without a vote of the relevant consensus body. ANSI will be notified immediately of such actions which will be announced in Standards Action.

7. Submittal to ANSI

Upon completion of the procedures for voting, disposition of views and objections, and appeals, the results shall be submitted to ANSI by the Professional Staff. All information supplied to ANSI shall include all relevant material required by ANSI as outlined in the ANSI Essential Requirements.

8. Policies

a) Records Retention Policy

The SLAS Professional Staff will retain records to demonstrate compliance with all aspects of ANSI Essential Requirements Due Process Requirements for American National Standards, section 3.4.1 Evidence of Compliance (periodic maintenance) as well compliance with these procedures.

Records for new, revised or reaffirmed Standards shall be retained for one complete standards cycle, or until the standard is revised.

Such records shall be available for audit as directed by the ANSI Executive Standards Council (ExSC).

Records concerning withdrawals of all American National Standards shall be retained for at least five years from the date of withdrawal or for a duration consistent with the audit schedule.

b) Patent Policy

If the MSAC receives a notice that a proposed standard or an approved standard may require the use of a patent claim, The committee will adhere to the ANSI Essential Requirements Due Process Requirements for American National Standards, section 3.1, ANSI patent policy - Inclusion of Patents in American National Standards as follows:

I. Statement from patent holder

The MSAC shall receive from the patent holder or a party authorized to make assurances on its behalf, in written or electronic form, either:
assurance in the form of a general disclaimer to the effect that such party does not hold and does not currently intend holding any essential patent claim(s); or
assurance that a license to such essential patent claim(s) will be made available to applicants desiring to utilize the license for the purpose of implementing the standard either:

- a. under reasonable terms and conditions that are demonstrably free of any unfair discrimination; or
- b. without compensation and under reasonable terms and conditions that are demonstrably free of any unfair discrimination.

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

transfer documents.

II. Record of Statement

A record of the patent holder's statement shall be retained in the files of both the MSAC and ANSI.

III. Notice

When the MSAC receives from a patent holder the assurance set forth in 6.2.2 above, the standard shall include a note substantially as follows:

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

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

I. Responsibility for Identifying Patents

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

c) Interpretation Policy

Written inquiries requesting interpretation of any SLAS approved American National Standards shall be forwarded to the Consensus body for interpretation and clarification. It will be the responsibility of the MSAC Chair to respond.

The Chair shall only respond to written requests for interpretation. All requests shall be summarized on a form to include: the requester's name, address, and contact information; the date of the request; the specific section of the standard to be interpreted; the requester's understanding of the section; and any questions or other specific information relevant to the request. The form and a copy of the original request shall be forwarded to the Consensus Body for review and interpretation within 10 days of receipt.

Upon review and interpretation by the Consensus Body and approval by the Chair, a written response will be forwarded to the person requesting the interpretation. SLAS may also include a listing of the interpretation on its website.

d) Commercial Terms and Conditions Policy

The Commercial Terms and Conditions Policy of the MSAC will comply with *ANSI Essential Requirements Due Process Requirements for American National Standards, section 3.2 Commercial Terms and Conditions:*

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

e) Anti-Trust Policy

The Anti-Trust Policy of the MSAC will comply with *ANSI Essential Requirements Due Process Requirements for American National Standards, section 3.3 Anti-Trust Policy:*

Any standards developed by the MSAC shall be developed in accordance with applicable antitrust and competition laws and meetings amongst competitors to develop American National Standards are to be conducted in accordance with these laws.

f) Metric Policy

The Metric Policy of the MSAC will comply with *ANSI Essential Requirements Due Process Requirements for American National Standards, section 3.5 Metric Policy:* Units of the International System of Units (SI), the modernized metric system, are the preferred units of measurement in American National Standards.