

# **Operating Procedures and Policies for the Microplate Standards Development Committee of the Society of Biomolecular Screening**

Approved June 5, 2002



## Table of Contents

Foreword .....	3
1 General .....	4
2 Organization of the Committee.....	4
3 Responsibilities.....	4
3.1 Working Group.....	4
3.2 Consensus Body.....	4
3.3 Chairs.....	5
4 Membership and Application.....	5
4.1 Application.....	5
4.1.1 Diverse interests.....	6
4.1.2 Combined interest.....	6
4.2 Review of membership.....	6
4.2.1 Suspension or Termination.....	6
4.3 Observers and individual experts.....	6
4.4 Interest categories.....	6
4.5 Membership roster.....	7
5 Meetings.....	7
5.1 Open meetings.....	7
5.2 Quorum.....	7
6 Voting.....	8
6.1 Vote.....	8
6.1.1 Single vote.....	8
6.2 Actions requiring approval by a majority.....	8
6.3 Actions requiring approval by two-thirds of those voting.....	8
6.4 Other review.....	9
6.5 Disposition of views and objections.....	9
6.6 Appeals Process.....	10
6.6.1 Complaint.....	10
6.6.2 Response.....	10
6.6.3 Hearing.....	10
6.6.4 Appeals panel.....	10
6.6.5 Conduct of the hearing.....	10
6.6.6 Decision.....	11
6.6.7 Further appeal.....	11
6.7 Report of final result.....	11
7 Submittal of standard.....	11
8 Termination of MSDC.....	12
9 Communications.....	12
9.1 Formal internal communication.....	12
9.2 External communication.....	12
9.3 Requests for interpretation of standards.....	12
9.4 Record Retention.....	12
10 Other Procedures and Policies.....	13
10.1 Procedures.....	13
10.2 Metrics.....	13
10.4 Patent Policy.....	13
10.5 Advertising and Marketing.....	13
10.6 Disclaimer of Liability.....	14
10.7 Confidentiality.....	14

## Foreword

This document outlining the operating procedures and policies of the Microplate Standards Development Committee (MSDC) was prepared and approved for submittal to ANSI as part of the process for becoming an ANSI accredited standards developer. Committee approval of this document does not necessarily imply that all committee members voted for its approval. At the time it approved this document, the MSDC had the following members:

Marc N. Feiglin, co-Chair  
Carol Ann Homon, co-Chair

<i>Organization Represented</i>	<i>Name of Representative</i>
Apogent Discoveries <sup>1,2</sup> .....	Neal Holtzman Bruce Jamieson Ron Ringleben Craig Weiss
BD Biosciences <sup>1</sup> .....	Mike Septak Michael Shanler
Beckman Coulter <sup>1,2</sup> .....	Doug Gard
Boehringer-Ingelheim <sup>3</sup> .....	Carol Ann Homon
Co Bio Engineering <sup>3</sup> .....	Clyde Grant Dan Grant
Corning <sup>1</sup> .....	Deborah Morton Mike Orzechowski Marty Popoloski
Greiner BioOne <sup>1</sup> .....	Gunther Knebel
Hamilton Co <sup>2</sup> .....	Dave Hansen
Hoffman La Roche <sup>3</sup> .....	TC Ramaraj
MatriCal <sup>1</sup> .....	Kevin Oldenburg
Merck & Co <sup>3</sup> .....	Collette DeChard
Millipore <sup>1</sup> .....	Ken Desilets Brian Foley Joe Lane
MJ Research <sup>1,2</sup> .....	David Titus
Molecular Devices <sup>1,2</sup> .....	Amer El-Hage
REMP <sup>2</sup> .....	Scott Reeves
Whatman <sup>1</sup> .....	Niran Shah

### Interest groups

1. Manufacturers of microplates (n=10)
2. Manufacturers of instrumentation that utilizes microplates (n=6)
3. Users of microplates that do not fit in either of the previous categories (n=4)

## **1 General**

The mission of the Microplate Standards Development Committee (MSDC) is to recommend, develop, and maintain standards to facilitate automated processing of microplates on behalf of and for acceptance by the American National Standards Institute (ANSI). Once such standards are approved by the MSDC, they are presented to the governing council of the Society of Biomolecular Screening (SBS) for approval for submission to the ANSI. Although sponsored by SBS, membership in the MSDC is open to all interested parties directly and materially affected by the MSDC's activities, including parties who are not members of SBS.

The following procedures are set forth to meet the requirements for due process and development of consensus for approval of American National Standards as given in Clause 1 of the *ANSI Procedures for the Development and Coordination of American National Standards*.

## **2 Organization of the Committee**

The MSDC shall consist of its working group, consensus body, and chairs. Members of the MSDC shall define themselves as being in at least one of the following interest categories: Manufacturers of microplates, Manufacturers of instrumentation that utilizes microplates, and users of microplates that do not fit in either of the previous categories. MSDC shall use its best efforts to ensure that the membership is sufficiently diverse to ensure reasonable balance without dominance by a single interest category in accordance with Clause 1.2.2 and 1.2.3 of the ANSI Procedures.

## **3 Responsibilities**

### **3.1 Working Group**

The working group includes parties who have expressed an interest in participating in the work of the MSDC. Participation in the email ListServ and attendance at meetings are two methods of expressing such interest. The working group shall be responsible for:

- a. Proposing standards within the scope of the MSDC.

### **3.2 Consensus Body**

The consensus body is a dynamic membership. It includes those members of the working group who have attained the right to vote as defined in clause 4.1. The consensus body shall be responsible for:

- a. Proposing standards within the scope of the MSDC;
- b. Voting on approval of proposed standards within the scope of the MSDC;
- c. Maintaining the standards developed by the MSDC in accordance with Clause 4.4 of the ANSI Procedures;
- d. Adopting MSDC policy and procedures for interpretations of the standard(s) developed by the consensus body (see clause 9.3 herein);
- e. Responding to requests for interpretations of the standard(s) developed by the consensus body (see clause 9.3 herein);

- f. Adopting MSDC procedures and revisions thereof;
- g. Other matters requiring consensus body action as provided in these procedures.

### 3.3 Chairs

There shall be two co-chairs appointed by the governing council of the SBS from the individual members or representatives of the consensus body, subject to approval by majority vote of the consensus body. Each will serve until a successor is selected and ready to serve. The Chairs shall be responsible for:

- a. Applying for MSDC accreditation by ANSI and maintaining accreditation in accordance with ANSI requirements, including submission of the consensus body roster;
- b. Overseeing the consensus body's compliance with these procedures;
- c. Maintaining a roster of the consensus body and a list of standards for which the consensus body is responsible;
- d. Providing a secretary to perform administrative work, including secretarial services; preparation of meeting notices and the handling of meeting arrangements; preparation and distribution of meeting agendas, minutes, ballots, and draft standards; and maintenance of adequate records;
- e. Submitting candidate standards approved by the consensus body, with supporting documentation, for ANSI review and approval as American National Standards;
- f. Performing other administrative functions as required by these procedures.

## 4 Membership and Application

Members of the working group shall consist of organizations (preferably national in scope), companies, government agencies, individuals, etc., having a direct and material interest in the development of standards for microplates. The termination of members shall be subject to approval by majority vote of the consensus body after a review of the membership in accordance with clause 4.2.

### 4.1 Application

Membership in the Working Group is open to all interested parties and is implied by participation in the email ListServ and/or attendance at MSDC meetings. Membership in the Consensus Body, and its right to vote, shall be updated at each meeting. Membership is automatically given to those members who, in addition to attending the meeting at which the vote is occurring, have attended at least one of the last three MSDC meetings. For purposes of business conducted between meetings, membership in the Consensus Body is automatically given to those members who have attended at least two of the previous four MSDC meetings. Membership in the SBS is NOT required to participate in the MSDC.

#### 4.1.1 Diverse interests

If distinct divisions of an organization demonstrate independent interests and authority to make independent decisions in the area of the activity of the MSDC, each is permitted to request separate membership on the consensus body. Voting on the request shall be according to the procedures outlined in section 6 of these procedures for membership-related issues.

#### 4.1.2 Combined interest

When appropriate, the chairs may recommend that an applicant seek representation through an existing member of the consensus body that represents the same or similar interest. An example of such is multiple divisions of the same parent company shall be represented only once. Such recommendation or request shall be made to the consensus body for vote. Voting on the request shall be according to the procedures outlined in section 6 of these procedures for membership-related issues.

#### 4.2 Review of membership

The chairs shall review the consensus body membership list before each meeting with respect to the criteria of Clause 4 of these procedures.

An updated list of the Consensus Body membership list shall be made available at each meeting.

#### 4.2.1 Suspension or Termination

Members of the consensus body may have their membership in the consensus body (but not the working group) suspended or terminated in cases where (1) a member is found to have been in habitual default of the obligations of active participation including attending meetings and engaging in active participation, or has otherwise shown a considerable neglect of the member's duties, (2) misrepresentation and fraud, or (3) other reasonable grounds brought to the attention of the MSDC. In all cases, prior to suspension or termination, the chair will contact the member and indicate that the MSDC is considering suspension or termination of the member and state the reasons for the proposed action. The member shall be provided with the opportunity to address the consensus body on the proposed action. The consensus body shall subsequently vote on the action proposed by the chair, with voting to follow the procedures outlined in section 6 for membership-related issues.

#### 4.3 Observers and individual experts

The chairs and/or consensus body may select individual experts to assist it. Such experts may include legal advice. Observers and individual experts shall be advised of the MSDC's activities, may attend meetings, and may submit comments for consideration, but shall have no vote.

#### 4.4 Interest categories

All appropriate interests that are directly and materially affected by the standards activity of the MSDC 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. (See clauses 1.2.2 and 1.2.3. of the ANSI Procedures.). The interest categories are as follows: Manufacturers of microplates, Manufacturers of instrumentation that utilizes microplates, and users of microplates that do not fit in either of the previous categories. Revision of the interest categories shall be by a majority vote of the consensus body.

#### 4.5 Membership roster

The chair shall maintain a current and accurate consensus body roster and shall distribute it to the members and their consensus body representatives at each meeting, and otherwise on request. The roster shall include the following:

- a. Title of the MSDC and its designation;
- b. Scope of the MSDC;
- c. Chair: name and addresses of chairs;
- d. Consensus Body Members: name of organization or agency, and business affiliations;
- e. Classification of each member in its interest category(ies);
- f. Tally of classifications: total of voting members and subtotals for each interest category.

## 5 Meetings

Consensus body meetings shall be held, as decided upon by the consensus body, the chair, or by petition of five or more members, to conduct business, such as making assignments, receiving reports of work, considering draft standards, resolving differences, and considering views and objections from any source.

### 5.1 Open meetings

Meetings of the consensus body shall be open to all members and others having a direct and material interest. At least four weeks' notice of regularly scheduled meetings of the consensus body shall be given by the Chair on the MSDC ListServ, in the publication ANSI Standards Action, or in other media designed to reach directly and materially affected interests; or in both. The notice shall describe the date, time, location, and purpose of the meeting and shall identify a readily available source for further information. An agenda shall be available and shall be distributed in advance of the meeting to members and to others expressing interest.

### 5.2 Quorum

A majority of the members eligible to be considered part of the consensus body (those members who are present at the current and have been present for at least one of the previous three meetings; and those members who have been present for at least two of the previous three meetings) shall constitute a quorum for conducting business at a meeting. If a quorum is not present, actions shall only be taken subject to a subsequent vote at a future meeting or by letter ballot.

## **6 Voting**

### **6.1 Vote**

Except in regard to votes on membership and officer-related issues, each Consensus Body member shall vote one of the following positions:

- a. Affirmative;
- b. Affirmative, with comment;
- c. 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);
- d. Abstain, with reasons.

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

#### **6.1.1 Single vote**

Generally, no representative organization, company, etc shall have more than one vote. However, if two or more individuals with different predispositions on the subject matter represent a single Consensus Body member, that member's vote may be fractionally divided into equal parts of the single vote between the representative individuals. Each member is given only a single vote to prevent domination by a single member.

Additionally, representation of more than one organization by the same individual (such as in the case of a hired consultant) shall require approval by a majority of the consensus body, excluding the votes of the organizations represented by that individual.

### **6.2 Actions requiring approval by a majority**

The following actions require approval by a majority of the current membership of the consensus body either at a meeting or by letter ballot:

- a. Confirmation of chairs appointed by the SBS governing council;
- b. Designation and adoption of interest categories;
- c. Termination of membership of a consensus body member;
- d. Approving the representation of more than one organization by the same individual, or taking other membership-related actions;
- e. Any other MSDC activities that do not involve standards development, revision, maintenance, or any related activity.

### **6.3 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 consensus body and at least two-thirds of those voting, excluding abstentions:

- a. Adoption of MSDC procedures, or revisions thereof;

- b. Approval of a new standard or reaffirmation of an existing one;
- c. Approval of revision or addendum to part or all of a standard;
- d. Approval for submission to ANSI of change of MSDC scope;
- e. Approval of withdrawal of an existing standard.

#### 6.4 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. If it is determined to make announcements to the media, announcements shall include the disclaimers set forth in clause 10.6 of these procedures. The chair shall arrange for a copy of the proposed new, revised, or reaffirmed standard to be published by the SBS at the same time.

Views and objections resulting from the above must be expressed at a meeting and recorded, or written and submitted to MSDC. Response to these views and objections shall be dealt with in accordance with clause 6.5. Any substantive change (see clause 1.2.9 of the ANSI Procedures) made in the proposed American National Standard shall be re-listed in accordance with clause 6.5.

#### 6.5 Disposition of views and objections

When the balloting related to a particular standard has been closed, there shall be a public review and comment period at least thirty days after publication in ANSI Standards Action. The chair shall determine whether the views and objections expressed by participants and by members of the public (including those commenting on the listing as published in Standards Action) shall be considered by correspondence or at a meeting.

In accordance with clause 1.2.7 of the ANSI Procedures, the consensus body shall make an effort to promptly consider and resolve such expressed views and objections of all participants, including those commenting on the listing in Standards Action. Each objector shall be advised in writing (including electronic communications) of the disposition of the objection and the reasons therefore. If resolution is not achieved, the chair shall advise the objector of the appeals process used by the MSDC (see clause 6.6 of these procedures).

Substantive changes (see clause 1.2.9 of the ANSI Procedures) required to resolve objections, and unresolved objections, shall be reported to the consensus body members in order to afford all members an opportunity to respond to them or to reaffirm or change their votes at the next meeting of the consensus body.

When the above process is completed, in accordance with these procedures, the MSDC may consider any comments received subsequent to the closing of the public review and comment period, or shall consider them at the next review.

## 6.6 Appeals Process

Persons who have directly and materially affected interests in the proposed standards as developed, revised, or reviewed by the MSDC or ANSI, and who have been or may be adversely affected by a substantive or 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 MSDC chair or the chair’s representative shall be the “respondent.” The appeal shall follow the procedures outlined below.

### 6.6.1 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.

### 6.6.2 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.

### 6.6.3 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.

### 6.6.4 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 ANSI Executive Standards Council or its designee, which shall appoint the members of the appeals panel.

### 6.6.5 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 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.

#### 6.6.6 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:

- a. 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
- b. 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
- c. Finding that new, substantive evidence has been introduced, and remanding the entire action to the consensus body or the chair for appropriate reconsideration.

#### 6.6.7 Further appeal

If the appellant gives notice that further appeal to ANSI is intended, the chair shall submit a full record of the complaint, response, hearing, and decision to ANSI, and ANSI shall conduct a final appeal according to ANSI's own internal procedures.

#### 6.7 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.

### **7 Submittal of standard**

Upon completion of the procedures for voting, disposition of views and objections, and appeals, the proposed standard shall be submitted to the governing council of the SBS by the chair.

If the proposed standard is approved by the SBS governing council, it shall be then submitted to ANSI by the chair. The information supplied to ANSI by the chair shall include all relevant material required by ANSI as outlined in clause 2.2 of the ANSI Procedures. If the chair does not submit the proposal to ANSI within a reasonable period of time, any member(s) of the consensus body may make the submittal.

The proposed standard may be returned by the SBS governing council to the consensus body for clarification.

## **8 Termination of MSDC**

A proposal to terminate the Microplate Standards Development committee may be made by a directly and materially affected interest. The proposal shall be submitted in writing to the MSDC and to ANSI and shall include at least the following:

- a. Reasons why the MSDC should be terminated
- b. The name(s) of the organization(s) that will assume responsibility for maintenance of any existing American National Standard(s) that is(are) the responsibility of the consensus body

If it appears, after review by ANSI and discussion among the proponent of the action, the chair, and the ANSI Executive Standards Council or its designee, that the desired objectives can best be reached by termination of the MSDC, the proposal and supporting documentation shall be submitted to the committee with a ballot to terminate the committee and transfer responsibility, as appropriate, for the affected standards. The proposal for termination of the MSDC shall be announced for comment in the *ANSI Standards Action*.

## **9 Communications**

### **9.1 Formal internal communication**

Any communication between members of the working group or consensus body involving issues or decisions (i.e., non-routine matters) affecting members or subcommittees, must be submitted to the email ListServ or other means to ensure dissemination to all affected members.

### **9.2 External communication**

Inquiries relating to the MSDC should be directed to the chair, and members should so inform individuals who raise such questions. All replies to inquiries shall be made through the chair, and shall include the disclaimers set forth in clause 10.6 of these procedures.

### **9.3 Requests for interpretation of standards**

Written inquiries requesting interpretation of the MSDC's approved American National Standards shall be forwarded to the Consensus body for interpretation and clarification. Responses to the written inquiries shall follow the guidelines for external communication set forth in clause 9.3 of these procedures.

Revisions to the standard resulting from requests for interpretations shall be processed in accordance with these procedures.

### **9.4 Record Retention**

The SBS office shall retain records of all official communication, decisions, etc. Such records shall be made available in a manner accessible to any interested public party. The primary means of communication may include an archive of the email ListServ, web site postings, and/or publication in relevant journals.

## **10 Other Procedures and Policies**

### **10.1 Procedures**

The MSDC shall operate in accordance with the ANSI Procedures, and in cases of uncertainty members shall refer to the ANSI Procedures for clarification on policy and procedures. On questions of parliamentary procedure not covered in these procedures or the ANSI Procedures, Robert's Rules of Order (latest edition) may be used to expedite due process.

### **10.2 Metrics**

Units of the International System of Units (SI), the modernized metric system, are the preferred units of measurement in standards developed by the MSDC.

### **10.3 Disclosure and Conflict of Interest**

Any member of the consensus body with an actual or perceived conflict of interest must disclose such conflict to the consensus body. A conflict of interest would include any other commercial, personal, or financial interest of the member or the member's family in the development, adoption, or implementation of the proposed standards discussed by MSDC. For purposes of these procedures, the member's general status as a manufacturer or user of microplates shall not constitute a conflict of interest; further, conflicts related to patents shall be treated as described in clause 10.4 of these procedures. A member with a conflict must disclose the conflict to the consensus body, and the consensus body may by majority vote require the member to refrain from discussion and/or voting on those matters related to the member's conflict of interest.

### **10.4 Patent Policy**

MSDC shall follow the procedures set forth in the *ANSI Patent Policy* (Sections 1.2.11 through 1.2.11.4 of the ANSI Procedures) and the ANSI Guidelines therefor. In general, this policy encourages standards developers to disclose and identify as soon as possible any existing or pending patents held by the member that may relate to the standards under development. In accordance with the *ANSI Patent Policy* MSDC shall (1) request that members and other participants in the standards development process disclose known patent information at certain specified times, and members and participants shall provide all such information known to them; (2) request, and owners shall provide, assurances that owners of known existing or pending patents would be willing to license their invention on reasonable terms or that the patent is not required for compliance with the standard(s), and (3) take such actions as may be appropriate or necessary to effectuate such license or make assurances to the patent holder. This policy shall also apply to subsequently discovered patents that may or may not have been in the member's portfolio when the standards were developed.

### **10.5 Advertising and Marketing**

All standards shall be developed in accordance with section 1.2.10 of the ANSI Procedures, which generally prohibit the use of proper names or trademarks in the text of standards. While members of the MSDC may accurately disclose their status and/or participation in the MSDC, its working group, or consensus body, in no case shall a member advertise, warrant, or imply that the member's products, services, or processes meet any standards or policies proposed by the MSDC, SBS, or ANSI prior to final adoption of the standards. A member may publicize its compliance with ANSI standards after such standards are finalized and approved by ANSI for

publication and provided that the member does in fact meet such standards. Members may not use the SBS or MSDC names, marks or logos in any misleading manner or without the written permission of the SBS.

#### 10.6 Disclaimer of Liability

Members understand that the MSDC is a voluntary, public forum for the exchange of information and ideas regarding the development of ANSI standards in the area of microplate construction and use, and that these standards are to be approved and promulgated by ANSI. No member shall represent that SBS or the MSDC is developing or enforcing standards for use or microplates for the SBS or MSDC members, or that SBS or MSDC is responsible for application of the standards. SBS and MSDC disclaim all liability related to development or implementation of the standards as approved by ANSI.

#### 10.7 Confidentiality

Members acknowledge that MSDC meetings and ListServ communications may expose them to confidential or proprietary information or trade secrets of other participants, and agree to maintain such information as confidential, except as may otherwise be provided in these procedures or ANSI Procedures and Guidelines.