Minutes of the May 13, 2002 Meeting of the SBS Microplate Standards Development Committee

Attendees:

* Lane Hallenbeck, ANSI, lhallenb@ansi.org
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Kevin Hughes, BD Biosciences, kevin_m_hughes@bd.com
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David Yang, Wyeth Vaccine Research (A division of Wyeth), yangd@wyeth.com

* Denotes attendees who only have observer status. They cannot vote (see paragraph 4.3 of MSDC Operating Procedures document)

Agenda:

Carol Homon chaired the meeting and presented the agenda for the day.

1. Committee Update
    - Working Group members (ListServ)
    - Current Consensus Body members
2. ANSI Update
    - Discussion and vote on updated Policies Document
    - Presentation by Lane Hallenbeck of ANSI
3. Update on existing draft versions of standards
    - Continue discussion on SBS-5
    - Discuss SBS-2
4. Miscellaneous Discussion

Membership Review

The current Working Group, as represented by the membership of the ListServ, now contains over 200 members representing over 100 organizations from over 15 nations.

The current Consensus body had 25 eligible members (organizations that had been represented at one of the past three meetings). Of these, 13 were in attendance at the meeting. A quorum was therefore present.

3M [1]
Apogent Discoveries [1,2]
BD Biosciences [1]
Beckman Coulter, Inc. [1,2]
Boehringer-Ingelheim [3]
Carl Zeiss [2]
Cellomics [2]
CoBio Engineering [3]
Corning [1]
Greiner BioOne [1]
Hamilton Co [2]
Hoffman La Roche [3]
Innovative Microplate [1]
MatriCal [1]
Merck & Co. [3]
Millipore [1,2]
MJ Research [1,2]
Molecular Devices [1,2]
Nalge Nunc Int'l [1]
Pfizer [3]
REMP [2]
Tecan [2]
TekCel Inc. [2]
Thermo Labsystems [1,2]
Whatman [1]

Interest groups
1. Manufacturers of microplates (n=14)
2. Manufacturers of instrumentation that utilizes microplates (n=12)
3. Users of microplates that do not fit in either of the previous categories (n=5)

no representative organization, company, etc shall have more than one vote." As an example, Apogent Discoveries includes the companies of Abgene, Matrix, and Robbins. It was not discovered until after the meeting that Nalge Nunc is also part of Apogent, so for future meetings, it will be included in the membership vote owned by Apogent. The chairs kindly remind the members to clarify the parent company especially if there are changes.

ANSI Update:

Carol then moved on to the status of the committee's application to ANSI. As part of our application to become accredited as an ANSI standards developer, we were required to prepare and submit an Operating Procedures and Policies document. During review of our application, the members of the executive committee of ANSI had raised questions regarding several areas of the document which required some clarification. The committee also pointed out a change in ANSI's voting policy. ANSI is now recommending that voting be allowed by paper ballot and not require attendance at a meeting. In order to clarify our policies document to answer ANSI's questions, Marc and Carol had made a few modifications to the document to address these issues. After a brief discussion, these changes were accepted unanimously by the attending MSDC consensus body members with no abstaining votes.

The changes in the MSDC Procedures document now allows for voting between meetings. These votes will occur online using a separate ListServ restricted to members of the MSDC. This ListServ will only be used for voting and all results will be published on the regular ListServ. Because of this change, the definition of a consensus body member had to be clarified too. It is still based on attending 2 out of 4 meetings, but it will now be worded as follows:

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.

Mr. Lane Hallenbeck, ANSI's Vice President of Conformity Assessment, did a short presentation on the procedures to become an ANSI approved standards developer and answered questions from the members of the MSDC.

- MSDC is considered to be on track to be approved by ANSI as a standards developer. Mr. Hallenbeck again clarified ANSI's role in approving standards developers. This means that ANSI does not enforce standards but insures that standards meet their guidelines. They also accredit laboratories as product certifiers. Product manufacturers to certify that their products meet specific standards often use these third parties. ANSI has accredited over 90 standards developers as well as 30 product certifiers. Accreditation bodies and product certifiers are evaluated according to guidelines of ISO/ IEC (specifically Guides 61 and 65).
- He pointed out that compliance with standards could either be by self-regulation based upon trust or by a compliance body. Compliance is not part of standards because it could create the potential for conflict of interest.
- MSDC plans to get ANSI accreditation and then consider moving on to ISO standards.
- During the questions, it was again pointed out that no product manufacturer is to use the SBS name or logo without the specific approval of the SBS.

Draft Standards:

The draft standards were then reviewed. Standard #1 and #3 have not been changed now for several meetings and are considered to be ready for submission to ANSI. Standard #4 needs some slight changes to the drawing as agreed to at the January meeting and then will be considered ready for submission.

The following points were discussed regarding the draft standards:

SBS-5 Side Wall Rigidity

- SBS-5 is not ready for submission to ANSI. More data is needed from manufacturers. The need for this including this standard was discussed once again. More discussion should be facilitated on the listserve. Amer will work with Brian (or his designee) and Marty (or his designee) to prepare a draft proposal before the next meeting. The device for measuring the rigidity may be removed from the standard itself.
- Instrument manufacturers will need to indicate what level of microplate rigidity will work in their instruments to help define the line between rigid and semi-rigid.

SBS-2 Height Dimensions

- SBS-2 continues to be controversial topic. The group recommended that a separate standard for flatness be considered which addresses the exact needs of the standard. During the discussion, it was not clear at what measurement the flatness needs to be

addressed. If the real issue is to define the bottom of the well then this is different than the flatness of the top of the plate for sealing purposes. "Profile" may be a better term.

- The members voted (13 yea's, no nays, no abstains) to eliminate the deep well height specifications for the height standard. Most deep well plates are created for specific uses and do not need standards because of specificity of application. One point of interest, this vote differed significantly than the current online poll regarding this issue. The current poll asks…

  How should the proposed standard for plate heights be written? (All options below would have separate sections for plates with and without the bottom clearance- See SBS-2 4.1 and 4.2)

Choices	Votes	%	Respondents
Have SBS-2 only specify typical plates of 14.35 mm high. Create completely new standards for other heights	0	0.00%	
Have SBS-2 specfiy three options: = 14.35 mm, <14.35 mm, and > 14.35 mm	4	36.36%	Ken_Desilets@millipore.com Michael_Shanler@bd.com britt@dtpax2.ncifcrf.gov Brian_Foley@millipore.com
Have SBS-2 specfiy two options: = 14.35 mm and other heights (with an identifying "height designation" required in the standard name (i.e. SBS-2 42.5)	6	54.55%	rdr@rochester.rr.com tim_hare@merck.com scott.reeves@remp.com Amer_Elhage@MolDev.com eric.matthews@bmglabtech.com andyk@genetix.co.uk
Create separate sections in part 4 of SBS-2 for each new height (We would start with sections for 14.35 mm, and 41-44 mm). Additional sections could be added as needed	1	9.09%	dhansen@hamiltoncompany.com

  There were eleven votes to date, none of which voted to remove the deep well section (option 1).

Miscellaneous Discussion

- Standards will not cover shrinkage in plates that undergo multiple uses such as heat and thawing cycles, re-sealing etc. Standards are for initial manufacture of plates only.
- Eventually, products may indicate that they are manufactured in accordance with ANSI specifications
- SBS will work together with ANSI to write a news release and develop other PR once the microplate standards are approved by ANSI.
- SBS should add a website link to ANSI (ansi.org) in the MSDC area
- Is there an easier way to poll members of MSDC? Polls need room for input—not just "yes" or "no."

Next Meetings

The next meeting is scheduled to be the one at which those draft standards considered ready for submission to ANSI will be voted on. This was announced prior to the May meeting giving any interested party an opportunity to attend two meetings and gain the right to vote even if they were unable to attend any meetings prior to May. The next meeting of the MDSC will be held to

coincide with the Drug Discovery Technology conference in Boston during the week of August 5-8.

The current consensus body (those members eligible to vote) includes the following organizations (with their identified interest group in superscript):

Apogent Discoveries [1,2]
BD Biosciences [1]
Beckman Coulter, Inc. [1,2]
Boehringer-Ingelheim [3]
CoBio Engineering [3]
Corning [1]
Greiner BioOne [1]
Hamilton Co [2]
Hoffman La Roche [3]
MatriCal [1]
Merck & Co. [3]
Millipore [1,2]
MJ Research [1,2]
Molecular Devices [1,2]
REMP [2]

Interest groups

1. Manufacturers of microplates (n=9)
2. Manufacturers of instrumentation that utilizes microplates (n=7)
3. Users of microplates that do not fit in either of the previous categories (n=4)

The following organizations will lose their membership on the consensus body if they are not in attendance at the next meeting:

- CoBio Engineering [3]
- MJ Research [1,2]

The following organizations will gain membership on the consensus body (and its right to vote) if they are in attendance at the next meeting:

- Carl Zeiss [2]
- Cellomics [2]
- Dupont [3]
- Innovative Microplate [2]
- Pfizer [3]
- Tecan [2]
- TechElan [2]
- Wyeth [3]