Minutes of the September 12, 2001 Meeting of the SBS Microplate Standards Development Committee

Attendees:

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Agenda:

1. Committee Update
   - Working Group members (ListServ)
   - Current Consensus Body members
2. ANSI Update
   - Discussion on legal issues regarding plate standards, advertising, etc
   - Vote to accept modifications to the Policies and Procedures Document
   - Discussion on redraft of standards for ANSI
3. True position/Tolerances for 1536 well position (SBS 4 part 4.3)
4. Side Wall Rigidity (SBS 5)
   - Modification to apparatus
   - Cut off values for parts 4.1 and 4.2
5. Additional Plate Heights
   - “Deep well” (1.0 ml)- SBS 2 part 4.2
   - “Double Height” (0.5 ml)- create a SBS 2 part 4.3?

Committee Update

The current Working Group, as represented by the membership of the ListServ, contains almost 200 members representing over 100 organizations from over 15 nations. The current Consensus body had 27 eligible members (organizations that had been represented at one of the past three meetings). Of these, 15 were in attendance at the meeting.

Abgene [1,2]
BD Biosciences [1]
Beckman Coulter, Inc. [1,2]
Boehringer-Ingelheim [3]
Carl Zeiss [2]
Corning [1]
Greiner Bio-One [1]
MatriCal [1]
Matrix Technologies [1,2]
Merck & Co. [3]
Molecular Devices [1,2]
Nalge Nunc Int'l [1]
REMP [2]
Robbins Scientific [1,2]
Whatman [1]

Interest groups

1. Manufacturers of microplates (n=11)
2. Manufacturers of instrumentation that utilizes microplates (n=7)
3. Users of microplates that do not fit in either of the previous categories (n=2)

ANSI Update

The SBS is currently applying for accreditation as ANSI standards developer. The ANSI paperwork has recently been complete and is currently being submitted to SBS for legal review. The "Policies and Procedures" document, which was approved at the previous meeting, has been modified after review by the SBS legal counsel and comments from ANSI. The major changes include sections on…

- Suspension or termination (section 4.2.1)
- External communication (section 9.2)
- Records retention (section 9.4)
- Disclosure of conflict of interest (section 10.3)
- Patent policy (section 10.4)
- Advertising and marketing (section 10.5)
- Disclaimer of liability (section 10.6)
- Confidentiality (section 10.7)

The group discussed some important points brought up in these sections including the following:

- Conflicts of interest MUST be disclosed
- Member(s) of consensus body with COI may need to refrain from voting
- Members must disclose all relevant patent information known to them
- Owners of known existing or pending patents shall provide assurances that they would be willing to license their invention on reasonable terms or that the patent is not required for compliance with the standard(s)
- Members may accurately disclose their participation in MSDC
- 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

- Members may publicize its compliance with ANSI standards after such standards and 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. Marks or logos of the SBS or MSDC may not be used without the written permission of the SBS.

An updated version of the "Policies and Procedures" document was voted on and unanimously adopted by the consensus body. A copy of this document is enclosed.

The proposed standards are in the process of being rewritten to meet ANSI style guidelines. In addition to being distributed on the ListServ, copies of the rewritten standards were handed out at the meeting. The drawings in the current standards still need to be redrawn. Marty promises the drawings for SBS 1,2, and 3 within a month. SBS 4 will need a few more weeks beyond that, and SBS 5 will have to wait until the issues mentioned below are resolved. At this point, when values in the drawings differ from the text, the values in the text should be followed.

After the meeting, Deb Morton, of Corning, pointed out a number of errors in proposed standard 3. They have been corrected in the copies (dated September 20, 2001) being distributed with these minutes.

True position/Tolerances for 1536 well position (SBS 4 part 4.3)

After a year of debate on selecting a value for the positional tolerance of a well in a 1536 well plate, the group decided to use a value of 0.50 mm (0.0197 inches) in clause 4.3.4.1.
In addition, it was decided to round off the values used in clauses 4.1.4.1 and 4.2.4.1 for 96 and 384 well plates respectively to 0.70 mm (0.0276 inches).
Both suggestions were accepted by a unanimous vote.

Side Wall Rigidity (SBS 5)

Back on April 24, 2001, Marty Popoloski posted an email to the ListServ with a proposal from CoBio Engineering listing changes and possible improvements to the rigidity tester. The modified apparatus was displayed at the June meeting in East Brunswick, NJ. Since proposed standard 5 includes a description of the rigidity tester, an agenda item was included to discuss whether the Beckman design or CoBio design would be the one included in the standard.

In the meantime, either apparatus is certainly adequate for collecting rigidity data. Since none of the microplate vendors had not provided the promised data to the ListServ, each manufacturer identified a contact person responsible for making sure the data was posted to the ListServ at least one month before the next meeting. The chairs will contact these contact people to remind them. The following companies identified the contact people listed below:

- Abgene - Neal Holtzman
- BD Biosciences - Michael Shanler
- Corning - Deb Morton
- Greiner Bio-One - Gunther Knebel
- Innovative Microplate - Jon Lipsky
- Matrix Technologies - Craig Weiss
- Molecular Devices - Amer El-Hage
- REMP - Scott Reeves

Other manufacturers of microplates not listed above are encourage to submit a contact person to the chairs and the provide side-wall rigidity data to the ListSerrv. This will assist in selecting appropriate values for the standard. "Double-Height" plates will be addresses after this.

Additional Plate Heights for SBS-2

Once again, data was presented summarizing the heights of various deep well plates that had been submitted to the ListServ. This data is in the table below:

Plate	Volume (ul)	Wells	Material	Height (mm)
AbGene AB-0859	600	96	PP	31.1
AbGene AB-0564	1000	96		42.5
BD 353964	1000	96	PP	44.06
Corning	2000	96		43.815
Corning	1000	96		42.164
Corning 3957	500	96	PP	27.178
Corning		384		27.813
Greiner	500	96	PP	22.6
Greiner	1000	96	PP	41.5
Greiner	2000	96	PP	44.0
Greiner	240	384	PP	22.0
Greiner	20	1536	PP	10.4
Nunc 278605	1000	96	PS	41
Nunc 278607	1000	96	PP	41
Nunc 260251	1000	96	PP	31.5

Although there are a wide variety of plate heights, many of the plate heights in the 1-2 ml volume range are between 41 – 44 mm high. Three possible scenarios were posed:

- Create a plate standard that is more inclusive with loose tolerance to include all the plates in the above range (i.e. 42.50 mm +/- 1.50 mm). Although most plates will meet this, is it really useful?
- Create a more useful standard with tighter tolerance like 2a (i.e. 42.50 mm +/- 0.25 mm). Currently only two plates meet this
- Can choose new standard that is 3X of 2a height (43.05 mm +/- 0.25 mm). No plates meet it, no advantage to anyone today. However, would new plates be changed to meet it? This could be advantageous to storage instruments since it is a multiple of 2a

After some discussion, the following resolution for creating a clause for "deep-well" plates in SBS-2 was agreed upon:

- Plates can be between 41 – 44 mm high. This allows most of today's "deep-well" plates to be able to meet the standard.
- The requirements for flatness should be similar to part 4.1.

A question was posed as to whether the clauses specifying "External Clearance to the Plate Bottom" should be a part of the height standard. Some felt that it really had nothing to do with height and should be removed as keeping it would exclude some new plates that were being designed without this clearance for optical purposes. A number of instrument vendors mentioned that they utilize this clearance for placement of plates in their instruments. The

agreed upon solution was to create additional parts in the standard that did not have the external clearance clause.

Based on these requirements, section 4 of SBS-2 would be written as follows:

4 Microplate height

Microplates that meet this standard may either comply with those standards specified in parts 4.1, 4.2, 4.3, or 4.4. Microplates, or instruments that use them, that advertise compliance with this standard must clearly state which of these four parts they meet.

4.1 Normal height with clearance

4.1.1 Plate height

4.1.1.1 The plate height, measured from Datum A (the resting plane) to the maximum protrusion of the perimeter wells, shall be 14.35 mm ± 0.25 mm (0.5650 inches ± 0.0098 inches)

4.1.1.2 The overall plate height, measured from Datum A (the resting plane) to the maximum protrusion of the plate, shall be 14.35 mm ± 0.76 mm (0.5650 inches ± 0.0299 inches)

4.1.2 Top Surface

4.1.2.1 The maximum allowable projection above the top-stacking surface is 0.76 mm (0.0299 inches). The top-stacking surface is defined as that surface on which another plate would rest when stacked one on another.

4.1.2.2 When resting on a flat surface, the top surface of the plate must be parallel to the resting surface within 0.76 mm (0.0299 inches)

4.1.3 External Clearance to the Plate Bottom

The minimum clearance from Datum A (the resting plane) to the plane of the bottom external surface of the wells shall be 1 mm (0.0394 inches). This clearance is limited to the area of the wells.

4.2 Normal height

4.2.1 Plate height

4.2.1.1 The plate height, measured from Datum A (the resting plane) to the maximum protrusion of the perimeter wells, shall be 14.35 mm ± 0.25 mm (0.5650 inches ± 0.0098 inches)

4.2.1.2 The overall plate height, measured from Datum A (the resting plane) to the maximum protrusion of the plate, shall be 14.35 mm ± 0.76 mm (0.5650 inches ± 0.0299 inches)

4.2.2 Top Surface

4.2.2.1 The maximum allowable projection above the top-stacking surface is 0.76 mm (0.0299 inches). The top-stacking surface is defined as that surface on which another plate would rest when stacked one on another.

4.2.2.2 When resting on a flat surface, the top surface of the plate must be parallel to the resting surface within 0.76 mm (0.0299 inches)

4.3 Deep-well height with clearance

4.3.1 Plate height

4.3.1.1 The plate height, measured from Datum A (the resting plane) to the maximum protrusion of the plate, shall be between 41 mm (1.614 inches) and 44 mm (1.732 inches).

4.3.1.2 The variation of the height, measured from Datum A (the resting plane) to the maximum protrusion of the perimeter wells, shall be no more ± 0.25 mm (± 0.0098 inches)

4.3.1.3 The variation of the height, measured from Datum A (the resting plane) to the maximum protrusion of the plate, shall be no more than ± 0.76 mm (± 0.0299 inches)

4.3.2 Top Surface

4.3.2.1 The maximum allowable projection above the top-stacking surface is 0.76 mm (0.0299 inches). The top-stacking surface is defined as that surface on which another plate would rest when stacked one on another.

4.3.2.2 When resting on a flat surface, the top surface of the plate must be parallel to the resting surface within 0.76 mm (0.0299 inches)

4.3.3 External Clearance to the Plate Bottom
The minimum clearance from Datum A (the resting plane) to the plane of the bottom external surface of the wells shall be 1 mm (0.0394 inches). This clearance is limited to the area of the wells.

4.4 Deep-well height

4.4.1 Plate height

4.4.1.1 The plate height, measured from Datum A (the resting plane) to the maximum protrusion of the plate, shall be between 41 mm (1.614 inches) and 44 mm (1.732 inches).

4.4.1.2 The variation of the height, measured from Datum A (the resting plane) to the maximum protrusion of the perimeter wells, shall be no more ± 0.25 mm (± 0.0098 inches)

4.4.1.3 The variation of the height, measured from Datum A (the resting plane) to the maximum protrusion of the plate, shall be no more than ± 0.76 mm (± 0.0299 inches)

4.4.2 Top Surface

4.4.2.1 The maximum allowable projection above the top-stacking surface is 0.76 mm (0.0299 inches). The top-stacking surface is defined as that surface on which another plate would rest when stacked one on another.

4.4.2.2 When resting on a flat surface, the top surface of the plate must be parallel to the resting surface within 0.76 mm (0.0299 inches)

The majority of the group present felt that the next height that should be included should be one used in 1536 well plates. This will be shorter than the standard height plate. **Members are encouraged to submit suggested heights to the ListServ.**

Other Issues

A number of attendees questioned whether a standard for well depth would be useful. This will be addressed on the ListServ.

Next Meeting

The next meeting will be held to coincide with the LabAutomation 2002 conference held January 26 – 30, 2002 in Palm Springs, CA. The exact time and room are still to be determined. The

consensus body (those members eligible to vote) at the next meeting will include those of the following companies (with their identified interest group in subscript) who are in attendance:

3M [1]
Abgene [1,2]
BD Biosciences [1]
Beckman Coulter, Inc. [1,2]
Boehringer-Ingelheim [3]
Carl Zeiss [2]
Cellomics [2]
CoBio Engineering [3]
Corning [1]
Edge Biosystems [?]
Greiner BioOne [1]
Hamilton Co [2]
Innovative Microplate [1]
MatriCal [1]
Matrix Technologies [1,2]
Merck & Co. [3]
Millipore [1,2]
MJ Research [1,2]
Molecular Devices [1,2]
Nalge Nunc Int'l [1]
REMP [2]
Robbins Scientific [1,2]
Roche [3]
SBS [3]
TekCel Inc. [2]
Thermo Labsystems [1,2]
Thomson Smith [?]
TPP Techno Plastic Products [1]
Whatman [1]

Interest groups

1. Manufacturers of microplates (n=17)
2. Manufacturers of instrumentation that utilizes microplates (n=13)
3. Users of microplates that do not fit in either of the previous categories (n=5)

So far, the proposed agenda will include:

- Votes on the completed standards ready for ANSI submission (SBS-1, SBS-3, SBS-4)
- Possible vote on SBS-2 for submission to ANSI
- Discussion on SBS-5: Side Wall Rigidity

Additional items of business for the agenda should be submitted to the chairs prior to the meeting.