

**Minutes of the September 25, 2002 Meeting of the SBS Microplate Standards Development
Committee
SBS 8th Annual Conference
The Hague, The Netherlands**

Attendees:

David Duracher, APiBio
Roger Norwood, Astra Zeneca
Michael Shanler, BD Biosciences
Jim Barry, Beckman Coulter Inc.
Carol Ann Homon, Boehringer-Ingelheim
Jeri McMahon, Corning
Paul Conklin, Corning
James Buttarazzi, Corning
Rainer Heller, Greiner BioOne
Gunther Knebel, Greiner BioOne
Phil Okane, Heath Scientific
Marcy Engelstein, Millipore
Amer El-Hage, Molecular Devices
Ken Falkowitz, Nalge Nunc
Morten Suendsen, Nalge Nunc International
Richard Ellison, Picoliter
Resland Papen, Picoliter
Scott Reeves, REMP
* Terri Nackid, SBS
Marc Feiglin, Tecan
Daid Jerrie, The Automation Partnership
Arto Lahti, Thermo Electron
Steve Kabachus, Whatman
Daniel Paul, Whatman
Grahame Ledson, Whatman
Lynn Jordan, Zymark
* Denotes attendees who only have observer status. They cannot vote (see paragraph 4.3 of the Operating Procedures and Policies for the MSDC document)

Agenda:

Marc Feiglin and Carol Homon co-chaired the meeting and presented the agenda for the day.

1. Committee Update
 - Determine Current Consensus Body members in case of a possible vote
 - Review of the MSDC for new members and first time attendees
2. ANSI Update
 - Review of the Standards that were voted on and passed at August, 2002 meeting
 - Next steps for ANSI submission (PINS and BSR-8)
 - Review of Section 10.5 of the policy and procedures document
3. Update on existing draft versions of standard 5
 - Continue discussion on SBS-5
 - Miscellaneous Discussion

Membership Review

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

The current Consensus body as determined by clause 4.1 of The Operating Procedures and Policies (organizations that had been represented at one of the past three meetings) and at the present meeting. Of these, 11 were in attendance at the meeting. A quorum was therefore present.

Apogent Discoveries ^{1,2}	MatriCal ¹
BD Biosciences ¹	Merck & Co. ³
Beckman Coulter, Inc. ^{1,2}	Millipore ^{1,2}
Boehringer-Ingelheim ³	MJ Research ^{1,2}
CoBio Engineering ³	Molecular Devices ^{1,2}
Corning ¹	REMP ²
Greiner BioOne ¹	Tecan ²
Hamilton Co ²	Thermo Labsystems ^{1,2}
Hoffman La Roche ³	Whatman ¹

Interest groups

1. Manufacturers of microplates (n=11)
2. Manufacturers of instrumentation that utilizes microplates (n=9)
3. Users of microplates that do not fit in either of the previous categories (n=4)

“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.”

Marc did a brief review of the history of the MSDC and its mission:

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 for approval for submission to the ANSI. Although sponsored by SBS, membership in the MSDC is open to all interested parties affected by the MSDC's activities.

Marc also mentioned the current status of the committee with recognition by ANSI as a developer of standards for microplates in July of this year. He then reviewed section 10.5 of The Operating Procedures and Policies for the Microplate Standards Development Committee of the Society of Biomolecular Screening (full document can be found at:

<http://groups.yahoo.com/groups/microplatestandards/files>

This section deals with how to refer to the standards before and after final approval by ANSI.

“... in no case shall a member advertise, warrant, or imply that the member’s product, services, or processes meet any of the standards or policies proposed by the MSDC, SBS or ANSI prior to final adoption of the standards.” Then “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.” During the time period of review before the final approval, all members must understand that a change in wording of any standard may occur and so it is very important that any mention to the standards clearly indicate that they are “proposed” or draft standards. The likely title for the standard will be ANSI / SBS - # - date - verbal description of the standard. An example of a published standard from ISA (another ANSI approved standard developer) follows:



The chairs acknowledge that it is difficult for the plate manufacturers to word their product descriptions properly but hopefully, resolution of the first 4 proposed standards will come soon.

Draft Standards:

The draft standards were then reviewed. Standard #1 through #4 were finalized and voted on at the August meeting of the MSDC. All four were unanimously approved for submission to ANSI. Standard 5 continues to be in discussion for finalizing of the wording for submission.

The following points were discussed regarding draft standard 5:

SBS-5 Side Wall Rigidity

CoBio is willing to write an article on the device that was developed to measure the side wall rigidity. However, it still needs to be determined who will be the first author of this paper. James Barry of Beckman will contact the people from Beckman that originally worked on the device and get them to work with CoBio on this publication. CoBio does not want to release their drawings of the modified device but Beckman has released their drawings of the original device. Since the standard cannot refer to a commercial device, the device will be considered a generic testing device and will be referred to in such terms. The testing procedure would also be written in a generic manner.

Rigid Plate Definition:

Recent testing by MJ Research has resulted in a proposal to change the differential displacement between the applied minor load and the applied major load of a rigid plate from 0.5mm or less to 0.6mm or less. MJ Research had testing done by CoBio to determine the deflection value and then had testing in many devices from several companies to support their claim that a plate with a deflection of 0.6mm works with robots and various other automated

devices. The group was polled for opinion on this proposed change. No company present appeared to consider this change to present a problem so it was recommended to make the amendment.

Semi Rigid Plate

A second change to the standard was also discussed. This would be to change the differential displacement for a semi rigid plate from no greater than 3.00 down to 2.50mm. Testing done with the Beckman equipment of plates with a 3.00mm deflection seemed to work in their devices. Since there was still little data to support a change, it was proposed to leave this part of the standard the same.

Once again, plate manufacturers were asked to test their plates and to post the results to the listserv. This is a continuous request for information to help to finalize this standard. 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 as well. This standard continues to be of interest to the committee to finalize but with little new data, it is very difficult to know what should be the cut off points to define rigid and non-rigid plates.

Ideas for New Standards:

Any proposals for a new standard for microplates should be written up as a proposed standard and posted on the listserv. Members tend to throw out a topic for a possible standard rather than a true proposal for a standard which would define what is needed and with some proposed measurements or tolerances. Some of the topics mentioned have been:

Minimum opening of the well

Lids for microplates

Flatness

Defining the bottom of the well.

Members are asked to please start the ball rolling on the listserv so that all members can come to the next meeting prepared to discuss.

Miscellaneous Discussion:

Nalge Nunc International (NNI) has officially requested in writing an appeal to the vote by the committee that combined their vote with their parent company, Apogent. According to the Operating Procedures and Policies for the MSDC section 6.1.1;

“Generally, no representative organization, company, etc. shall have more than one vote.”

According to their letter requesting the appeal, Nalge Nunc International (NNI) is a stand-alone operating business entity separated from other Apogent operating divisions. The NNI business unit is run as its own company...

Section 6.6.4 states:

“The appeals panel shall consist of three individuals who have not been directly involved in the matter in the dispute. At least two members shall be acceptable to the appellant (Nalge Nunc) and at least two shall be acceptable to the respondent (MSDC).

Marc and Carol will contact people to participate in this panel before the next meeting of the MSDC or before the next vote of the MSDC.

Next Meetings

Future meetings will be on an as needed basis except for an annual meeting that will occur at the SBS annual meeting. If there is sufficient activity on the listserv on either standard 5 or on a new proposal for a standard, a meeting can be arranged for the Lab Automation meeting in Palm Springs in February of 2003.

Based on the attendance at the meeting, the current consensus body (those members eligible to vote) now includes the following organizations (with their identified interest group in superscript):

Apogent Discoveries ^{1,2}	MatriCal ¹
BD Biosciences ¹	Merck & Co. ³
Beckman Coulter, Inc. ^{1,2}	Millipore ^{1,2}
Boehringer-Ingelheim ³	MJ Research ^{1,2}
CoBio Engineering ³	Molecular Devices ^{1,2}
Corning ¹	REMP ²
Greiner BioOne ¹	Tecan ²
Hamilton Co ²	Thermo ¹
Hoffman La Roche ³	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=4)

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

- Beckman Coulter, Inc.^{1,2}
- Hamilton Co²
- Hoffman La Roche³
- Merck & Co.³

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

- ApiBio
- AstraZeneca³
- Dupont³
- Heath Scientific
- Picoliter²
- TechElan²
- The Automation Partnership²
- Waters²
- Wyeth³
- Zymark²