

**ATCC Standards Developing Organization (SDO)  
Consensus Standards Partnership (CSP)  
Newsletter  
June, 2007**

**CSP Orientation ----- Mark Your Calendars!**

The CSP Orientation will be held by teleconference:

**Thursday, July 26, 2007  
2:00-3:00 PM EST**

*(Relevant materials and dial-in instructions will be distributed via  
e-mail approximately one week prior to the teleconference.)*

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**SDO/CSP Update:**

The SDO Steering Committee held its inaugural meeting on May 30, 2007. Minutes from that meeting are appended to this newsletter.

ATCC's application for accreditation as an American National Standards Institute (ANSI) Standards Developing Organization (SDO) is proceeding. The ANSI "public review and comment" period ended May 21, 2007 with no comments submitted to Dr. Perrone.

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**Q & A:**

Q. Although the page for the Expert Panel on the Development of Standards for Biodefense exists at the site [www.biodefensestandards.org](http://www.biodefensestandards.org), the links to specific pages such as "Conference Advisors" and "Mission Statement" do not work.

*Our apologies – the web site is now blocked for construction. Upon request, we will gladly provide relevant SDO/CSP materials and/or information from the April 2006 conference "Expert Panel for Development of Standards for Biodefense". If you wish to review the proceedings of the panel's April 2006 work, please contact Trish Hugunin, [thugunin@atcc.org](mailto:thugunin@atcc.org).*

Q. Who are the 16 members of the Steering Committee for the ATCC Standards Developing Organization (SDO)?

*I have included the list of Steering Committee members as a separate attachment to this newsletter email.*

Q. When is this workgroup going to start working on something? My calendar is filling up for the summer and I want to make sure I can participate.

*The progression of major events is:*

- 1. Steering Committee initial meeting held May 30, 2007*
- 2. CSP Orientation meeting (virtual) – scheduled for July 26, 2007*
- 3. The Steering Committee will accept recommendations for specific standard development, prioritize the recommendations and organize individual workgroups at some interval following the CSP Orientation*

Please forward questions that you might have concerning the SDO and/or the CSP that might be answered for the entire membership to [thuginin@atcc.org](mailto:thuginin@atcc.org).

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### **We value your input!**

The value of a standard is increased by the size and diversity of the stakeholder community involved in its development and consensus body approving the final standard. We would appreciate recommendations from you or other individuals for general CSP membership, individuals who are concerned about standardization of biodefense materials and processes.

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### **SDO/CSP Contact Information:**

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ATCC Standards Development Organization (SDO) Steering Committee  
Conference Call Minutes  
May 30, 2007

**I. Welcome and Consolidated Remarks**

Joseph B. Perrone, ScD  
ATCC SDO Chair and Vice President Standards & Certification Program

Welcome to the inaugural meeting for the Steering Committee of the ATCC Standards Development Organization. Today is the kick-off meeting to acquaint everyone with each other, review our mission, the standard development process and your role as Steering Committee members. In accordance with the requirements of the American National Standards Institute (ANSI) to have broad stakeholder representation, this committee has been selected to fairly represent our industry, government, regulatory agency and academic stakeholders. Our intention is to develop and publish ANSI-accredited, voluntary consensus standards for biomaterials.

For many years our industry has been heavily regulated by the Food and Drug Administration. Many industries depend on consensus standards for self-regulation. Consensus standards serve as a benchmark for the purpose of comparison and reference. As many of you concluded from our conference last year on the development of standards for Biodefense, in our world of biomaterials and toxicology we particularly need the ability to accurately compare and contrast various instruments and tools and therefore have a pressing need for consensus standards.

As members of this steering committee you will provide oversight and guidance for the development of consensus standards for biomaterials. ATCC has applied for and is close to accreditation from ANSI for our SDO. Through ANSI accreditation, consensus standards published by our SDO will automatically be recognized as American National Standards and be eligible for consideration as international standards through the Organization for International Standardization, ISO.

**II. Roll-Call and Self Introductions**

*The following Steering Committee members were present:*

Joseph B. Perrone, ScD	Janet A. Warrington, PhD
Susan Berger, PhD	Kenneth D. Cole, PhD
Donald R. Callihan, PhD, ASCP	Peter Emanuel, PhD
Anna Johnson-Winegar, PhD	Colonel George W. Korch, Jr., PhD
Michael J. Langford, DVM, PhD	S. Elizabeth George, PhD
Marian L. McKee, PhD	Diane E. Griffin, MD, PhD
Dr. Clark Tibbetts for	Malak Kotb, PhD
Klaus O. Schafer, MD, MPH	Kimberly Schuenke, PhD

*Absent:*

Ernest T. Takafuji, MD, MPH and Captain Kenneth F. Martinez, MSEE, CIH

Steering Committee members introduced themselves and provided their reasons for joining the committee. Contact information and abbreviated biographies of SC members are found in section two of the *ATCC Standards Development Organization Handbook*.

**III. Steering Committee Handbook Orientation**

Please refer to your handbook Table of Contents for an outline of this presentation and a summary of its contents.

#### IV. Voluntary Consensus Standards Development

This presentation is found in *Section Five* of your handbook. An additional slide referenced by Dr. Perrone in the committee meeting that summarizes the ATCC voluntary consensus standards development process will be sent to you under separate cover.

#### V. Discussion

We have summarized the questions and answers. The complete dialogue is available upon request.

Q. How will the initial list of standards be generated?

A. *The Consensus Standard Partnership (including the Steering Committee) will make recommendations for standards to be developed.*

Q. Are you asking for a multi-year commitment from Steering Committee members?

A. *Yes, we would like to have at least to two year commitment. We will be developing some very groundbreaking standards, but the process could take some time and continuity is preferable.*

Q. Are there organizations who you feel are not represented on the Steering Committee and yet have a major stake in standards/consensus standard setting?

A. *The Steering Committee is comprised of members from academia (3), government (6-7) and industry (6-7). Although every stakeholder organization cannot be represented on the Steering Committee, we strive to do just that for the CSP membership, where the standards are actually developed. We feel that the current CSP membership represents a well-balanced stakeholder community, which is an ANSI requirement. However, if anyone on the Steering Committee feels that there are other organizations that should be represented, we would welcome those names and invite them to become Consensus Standard Partnership members.*

*The Steering Committee will be responsible for selecting working groups to deal with specific issues and develop specific standards, so it would be your decision in terms of who should be represented on any particular working group. If a deficiency exists, it will need to be filled.*

Q. Aren't there some guidelines as to the size and the make up of the working group? Don't you want a balance of people from public and private industry and other organizations who are experts in those areas so that you make sure that all interests are represented?

A. *Not only do we want that but we are actually required by ANSI guidelines to have balance, or a resulting standard will be rejected by ANSI. This requirement is included in our policy and procedures manual and is also part of the consensus process.*

Q. Will some of these standards turn out to be recommendations for further research due to gaps in the current knowledge or guidance documents that are going to point out where additional research is needed?

A. *When the standard is reviewed, we will make changes as required from comments relating to most current knowledge. The standard may stimulate research, but initially and essentially, these standards are guidance documents for industry that are living documents, modified as advances in technology dictate.*

*The timing element for determining which standards to develop is a very important one. During the prioritization discussion, we will survey what's happening in industry, what's being published, what we actually know and where we can make some recommendations for the guideline. A lot will have to do with how mature a specific area is. In some areas, it will be too soon to develop a*

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*standard because technology is moving so rapidly. We can revisit those areas at some time interval.*

*There are areas with immediate needs for standards, particularly in the biodefense arena. This is where the consensus standard really helps facilitate interoperability and commerce.*

- Q. How would ATCC and the organization support bringing in outside expertise to present perspectives on issues different from the representative industry, government and academic arenas? And will a mechanism be provided to facilitate travel?
- A. *Yes, we will bring in expertise as needed. Some subsidies may be available but we will try to do as much as possible by teleconference, email, Web-casts and other mechanisms.*
- Q. Could the outcome of the symposium last April be put in a form that would allow us to pick some low-hanging fruit and actually get started on some standards?
- A. *Yes. Actually, that's some of the first materials we would like to present to the CSP for consideration.*
- Q. How quickly do you think that will happen?
- A. *A few months at the most. The kick-off will be the CSP orientation in about a month.*
- Q. Will the Steering Committee be invited to the orientation meeting of the CSP?
- A. *Yes, the Steering Committee is part of the Consensus Standard Partnership and will be invited.*

**VI. Date and Time for Next Meeting**

The next meeting of the ATCC SDO Steering Committee will take place after orientation of the Consensus Standards Partnership. The CSP orientation will be scheduled for mid-summer, provided by web cast and recommended for all SDO members.

**VII. Adjourn**

Future meetings will be conducted along the lines of abbreviated Robert's Rules of Order. A motion to adjourn was made and seconded.