From the Office of the Director:

It is with great regret that we say goodbye to Dr. Joe Perrone as our SDO Director. His efforts have been instrumental in the formation of the ATCC SDO and its subsequent accreditation by the American National Standards Institute, ANSI. Joe has left ATCC in pursuit of other challenges and we wish him all the best! Hopefully he will join us in the future as a member of the Consensus Standards Partnership.

Jeanne M. Riley will assume the duties of Acting Director of the ATCC SDO. Jeanne also serves as Senior Vice President and Chief Commercial Officer at ATCC.

Jeanne M. Riley, Acting Director, ATCC SDO

SDO/CSP Activities this Quarter:

- With an early March commencement of standard development activities, the workgroup is hoping to generate a draft standard for CSP review in the fall of 2008.

Next Steps:

- **ASN-0001 Workgroup Meeting:**  
  April 4, 2008, 1 – 2 PM Eastern Time

- **Call for References/Resources:**  
  Dr. Hughes and the ASN-0001 workgroup would like your help in identifying additional references and/or resources that might be valuable in their work in drafting the standard, Standardization of *In vitro* Assays to Determine Anthrax Toxin Activities. A summary of the tentative topics is outlined in Appendix B along with the draft scope.

- **Call for Proposals for Standard Development:**  
  Although CSP members may submit proposals for standard development at any time, the SDO would like to conduct another formal round of solicitation. Proposals may be new submissions or revisions of proposals previously reviewed by the ATCC SDO Steering Committee that have been modified in consideration of their recommendations and comments. Please use the SDR (Standard Development Recommendation) form to submit your proposal via email to thugunin@atcc.org by April 30, 2008. A copy of the SDR form is attached for your use.
ATCC SDO Web site: Coming soon!

Features will include:
- ATCC SDO news and information
- Policies, Procedures, Handbooks and Forms
- ANSI accreditation information and a link to the ANSI web site
- Online submission, review, comment and voting on proposals during development
- Meeting Announcements
- Contact information
- Member Tools – the how to get around “standard development”
- Specific Committee and Workgroup information
- A dedicated “Members Only” section

You will receive a special announcement when we go live…..watch for it!

Q & A:

Q. May a known expert on anthrax, who is not a member of the ATCC CSP, participate on the Workgroup ASN-0001, Standardization of In vitro Assays to Determine Anthrax Toxin Activities?

A. Certainly and we are actively soliciting such participation. Non-CSP members, however, may not be voting members of the workgroup though they are free to change their status at any time by joining the ATCC CSP. Joining the CSP would allow them to become voting members of the workgroup.

Please forward questions that you might have concerning the SDO and/or the CSP that might be answered for the entire membership to thugunin@atcc.org.

SDO Contact Information:
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Phone: 703-365-2746
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thugunin@atcc.org
Appendix A

Workgroup ASN-0001: Standardization of In vitro Assays to Determine Anthrax Toxin Activities

Molly A. Hughes, MD, PhD [Chair]  
Assistant Professor of Medicine  
Division of Infectious Diseases and International Health  
University of Virginia Health Sciences System  

Stephen A. Morse, PhD [Co-Chair]  
Associate Director for Science  
Science, Bioterrorism Preparedness and Response Program  
Center for Disease Control and Prevention  

Marian L. McKee, PhD [Recording Secretary]  
Director, Microbiology Collections  
Toxin Program Manager, Science Administration  
ATCC  

Drusilla Burns, PhD  
Chief, Laboratory of Respiratory and Special Pathogens Center  
Center for Biological Evaluation and Research (CBER)  
Food and Drug Administration  

Kristin Clement, PhD  
Senior Research Scientist, Molecular and Cellular Biology Group  
Battelle Memorial Institute  
Battelle Biomedical Research Center  

Linda J. Eaton, PhD  
Vice President, R&D  
List Biological Laboratories, Inc.  

Stephen J. Juris, PhD  
Central Michigan University  
Departments of Chemistry and Biology  

Cassandra D. Kelly  
Biodefense Laboratory  
Division of Infectious Disease  
Wadsworth Center  
State of NY Department of Health, David Axelrod Institute  

Bradford Scott Powell, PhD  
Principal Investigator, Bacteriology Division  
U.S. Army Institute of Infectious Diseases  

Wei-Jen Tang, PhD  
Professor, Ben May Department for Cancer Research  
Center for Integrative Science  
University of Chicago
Alternates:

Cindy Le [Alternate for L. Eaton]
List Biological Laboratories, Inc.

Thomas L. Rudge, Jr., PhD [Alternate for K. Clement]
Senior Research Scientist
Director, Molecular and Cellular Biology Group
Battelle Biomedical Research Center

Nancy Shine, PhD [Alternate for L. Eaton]
List Biological Laboratories, Inc.

Melissa Willis, PhD [Alternate for M. McKee]
Biodefense and Emerging Infections Resources (BEI) Collections Scientist/Toxins
ATCC
Appendix B

A summary of the tentative topics for ASN-0001: Standardization of In vitro Assays to Determine Anthrax Toxin Activities

1. Lethal toxin
   1.1 Cell lines and reagents (Materials)
   1.2 Toxin prep and use (including working stock prep, storage, ratios, etc.)
   1.3 Assay type (including type, performance, interpretation, etc.)

2. Edema toxin:
   2.1 Cell lines and reagents (Materials)
   2.2 Toxin prep and use (including working stock prep, storage, ratios, etc.)
   2.3 Assay type (including type, performance, interpretation, etc.)

Designation: ASN-0001
Standardization of in vitro Assays to Determine Anthrax Toxin Activities

1. Scope
   1.1. The standard addresses the following issues for each of the anthrax toxins, lethal toxin [protective antigen (PA) + lethal factor (LF)] and edema toxin [PA + edema factor (EF)]:
      1.1.1. Standardization of materials used, e.g. cell lines and reagents including cell confluence, description of serum and heat inactivation, etc., tissue culture incubation conditions such as temperature, %CO₂, etc.
      1.1.2. Description of the toxins including how the proteins were generated and purified (recombinant proteins purified from B. anthracis or E. coli), working stock preparation, and storage conditions
      1.1.3. Toxin ratios of PA:LF or PA:EF and specific procedures to be used handling the toxins in the respective toxin assays
      1.1.4. Standardization of assays for measuring cellular intoxication and activity each toxin, including which assay to use (e.g., LT cytotoxicity assay – specifically, which assay; ET adenylate cyclase (cyclic adenosine monophosphate (cAMP) production assay – specifically, which assay), methodology, output, and interpretation of results
   1.2. The overall objective of this standard is to provide researchers, vendors, and other stakeholders (henceforth, referred to as “stakeholders”) a standardized methodology for assaying anthrax toxin in vitro activity. In this way, stakeholders will have a means to compare toxin activities prepared within the same stakeholder group or between stakeholder groups.