



**ATCC® Standards Development Organization
Newsletter
January – March, 2008**

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:

- This first quarter of 2008 welcomed the initiation of work on the inaugural standard for development by the ATCC SDO: **ASN-0001, Standardization of *In vitro* Assays to Determine Anthrax Toxin Activities**. Dr. Molly Hughes is leading the Standards Development Workgroup, with Dr. Stephen Morse acting as Co-chair and Dr. Marian McKee as the Recording Secretary.
- The ASN-0001 Workgroup Members were selected and confirmed by the Steering Committee and the kick-off meeting was held on March 7, 2008. Workgroup Committee members and alternates are listed in Appendix A.

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

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

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

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

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

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

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

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

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

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

Wei-Jen Tang, PhD *Academia*
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

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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.)

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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.