

TENTATIVE TECHNICAL PROGRAM



WORKSHOP ON FAST-TRACKING STANDARDS DEVELOPMENT TO ADDRESS PERSONAL PROTECTIVE EQUIPMENT (PPE) SHORTAGES DUE TO THE COVID-19 PANDEMIC

Sponsored by ASTM Committee F04 on Medical and Surgical Materials and Devices and F23 on Personal Protective Clothing and Equipment.

September 9-10, 2020
Virtual Workshop

Workshop Chairs:	Ralph Basile Healthmark Ind Co., Inc. Fraser, MI, USA	Terry Woods US. Food & Drug Administration Silver Spring, MD, USA
	Hany Demian US. Food & Drug Administration Silver Spring, MD, USA	Karen Lehtonen Lion First Responder Products, Inc. Dayton, OH, USA
	Stephen Spiegelberg Cambridge Polymer Group, Inc. Boston, MA, USA	Brian Shiels ArcWear Louisville, KY, USA

About this Workshop

Many groups are working to address medical device shortages caused by the COVID-19 pandemic, including shortages of Personal Protective Equipment (PPE) like respirators, masks and gowns, as well as other devices like ventilators and nasal swabs. Approaches to alleviate the shortages include repurposing or reprocessing existing devices and materials and designing and producing new devices in a rapid fashion. The primary objective of the workshop is to leverage these efforts to identify subjects for new standards to address PPE shortages for the current pandemic and possible future outbreaks. The new standards will assist in managing future waves of infection as well as shortages that might occur due to decreased or disrupted supply chains. In vitro diagnostics for assessing infection are beyond the scope of this workshop.

WEDNESDAY, SEPTEMBER 9, 2020

10:00 AM **First Day Welcome**
Karen Lehtonen

SESSION 1

SETTING THE STAGE: RESPONSE TO THE PANDEMIC

Moderator: Brian Shiels

10:10 AM **COVID-19 Pandemic at the Frontline – Notes from an Infection Preventionist**
J. Daley, Infection Prevention Consultant, Mission Viejo, CA, USA

10:30 AM **0 to 60: Getting Up to Speed on PPE Manufacturing Standards**
K. Buscemi, Detroit Sewn, Pontiac, MI, USA

10:50 AM **Proposed Modifications to ASTM E1965**
S. Sullivan, USFDA, Silver Spring, MD, USA

SESSION 2

COVERING ALL THE BASES: PROTECTIVE CLOTHING AND FACE SHIELDS

Moderator: Brian Shiels

11:10 AM **Does Protective Clothing Provide Protection Against Droplet and Submicron Particle Penetrations?**
F. Selcen Kilinc-Balci, U.S. Centers for Disease Control and Prevention and National Institute for Occupational Safety and Health, Washington, DC, USA

11:30 AM **Face Shields**
J. Morgan, Emory Healthcare, Atlanta, GA, USA

11:50 AM **Face Shield Materials**
J. Hicks, Solvay Specialty Polymers, Alpharetta, GA, USA

12:10 PM **BREAK**

SESSION 3

ADAPTING TO THE NEW REALITY: REUSE OF SINGLE USE PPE

Moderator: Ralph Basile

- 12:30 PM **Decontamination of N95 Respirators – Vapor Hydrogen Peroxide, Electron Beam, Ethylene Oxide, Moist Heat**
E. Oral, Massachusetts General Hospital, Newtonville, MA, USA
- 1:00 PM **Decontamination of N95 Masks Using Chlorine Dioxide (CD)**
S. Barenberg, Northeastern University, Boston, MA, USA
- 1:20 PM **New Technique to Evaluate Decontamination Methods for Filtering Facepiece Respirators**
E. Vo, NIOSH, Pittsburgh, PA, USA
- 1:40 PM **None-Novel Approaches for Decontamination/Sterilization Processing of PPE**
A.Patel, Nelson Laboratories, Inc., Salt Lake City, UT, USA
- 2:00 PM **Effect of Various Decontamination Methods on 3M Filtering Facepiece Respirators**
E. Rexeisen, 3M, St. Paul, MN, USA
- 2:20 PM **Using Bacterial Filtration Efficiency to Assess Reprocessing Methods for Face Masks**
C. Stabler, Exponent, Philadelphia, PA, USA
- 2:40 PM **Leveraging UV Technology from the Weathering Testing Field**
S. Fowler, Q-Lab Corporation, Westlake, OH, USA
- 3:00 PM **Ensuring the Continued Performance of Protective Apparel and Drapes After Washing**
J. Decaens, Groupe CTT, Saint-Hyacinthe, Quebec, Canada
- 3:20 PM **First Day Wrap-Up**
Ralph Basile
- 3:30 PM **Workshop Adjourns for the Day**

THURSDAY, SEPTEMBER 10, 2020

10:00 AM **Second Day Welcome**
Terry Woods

SESSION 4

REMEMBER THE REGULATIONS: CONFORMITY ASSESSMENT

Moderator: Terry Woods

10:05 AM **Current and Future Approaches for Respirator Conformity Assessment
In Healthcare and Related Applications**
M. D'Alessandro, HHS/Centers for Disease Control and Prevention and NIOSH,
Pittsburgh, PA, USA

10:25 AM **Needed Development and Revision of Specific PPE Standards Addressing
COVID-19 that Incorporate Conformity Assessment Requirements**
J. Stull, International Personnel Protection, Austin, TX, USA

10:45 AM **Department of Homeland Security Personal Protective Equipment Standards
Engagements in Response to the COVID-19 Pandemic**
P. Mattson, U.S. Department of Homeland Security, Frederick, MD, USA

SESSION 5

**DEPLOYING ALL TECHNOLOGIES: MODELING AND ADDITIVE
MANUFACTURING**

Moderator: Terry Woods

11:05 AM **Flow Visualization of Masks and Face Coverings**
M. Staymates, National Institute of Standards and Technology, Gaithersburg, MD, USA

11:25 AM **Towards In-Silico Fit-Testing of 3D-Printed Facemasks**
P. Hariharan, USFDA, Silver Spring, MD, USA

11:45 AM **New Modeling and Simulation Standards to Accelerate Safety and
Performance Assessments of 3D-Printed PPE Produced at POC**
V. Carbone, InSilicoTrials Technologies, Milan, Italy

12:05 PM BREAK

SESSION 6

THE CRITICAL LINE OF DEFENSE: RESPIRATORS AND FACE MASKS

Moderator: Hany Demian

- 12:25 PM **Rapid Response to COVID-19 at the National Research Council of Canada: Filtration Efficiency Testing of N-95 Type Respirators**
R. Green, Metrology Research Center, National Research Council of Canada, Ottawa, Ontario, Canada
- 12:45 PM **Particle Filtration Efficiency Evaluation with Respect to the Performance Specifications in ASTM and NIOSH Standards**
J. Corbin, Metrology Research Centre, National Research Council of Canada Ottawa, Ontario, Canada
- 1:05 PM **Comparison and Evaluation of Particle Filtration Efficiency Measurements Using Mass and Number Based Approaches: A Metrological Perspective**
T. Koukoulas, Metrology Research Centre, National Research Council of Canada, Ottawa, Ontario, Canada
- 1:35 PM **Choosing Household Materials for Face Coverings During Airborne Pandemics: Potential Areas of Future Standards Development**
S. Guha, Center for Devices and Radiological Health, Silver Spring, MD, USA
- 1:55 PM **How Does Initial Bacterial Concentration Affect Bacterial Filtration Efficiency?**
E. Daley, Exponent, Philadelphia, PA, USA
- 2:15 PM **Adding Automated Colony Counting to Mask BFE Testing**
BD. Robertson, Exponent, Inc., Philadelphia, PA, USA
- 2:35 PM **Call to Action: Putting Your Experience to Work to Develop New Standards**
Stephen Spiegelberg
- 3:05 PM **Closing Remarks**
Stephen Spiegelberg
- 3:15 PM **Workshop Adjourns**