



ASTM INTERNATIONAL
Helping our world work better

Disclaimer:

The information included in this presentation is provided by ASTM International. The views and/or opinions expressed in the presentation are those of the speaker(s) and do not necessarily represent the views of ASTM International. ASTM International is not endorsing, sponsoring, or recommending a particular company, product or application. ASTM International is not responsible for any damages arising out of a party's reliance upon or use of the content contained in this presentation.

www.astm.org

Preventative Measures to Prevent Counterfeiting of Personal Protective Equipment (PPE) – DHS Case Study



Science and
Technology

Philip Mattson
Office of Science & Engineering
Systems Engineering and Standards Division

June 9, 2022

Background

This material was originally presented September 2020 to the ASTM, International “*Workshop on Fast-Tracking Standards Development to Address Personal Protective Equipment (PPE) Shortages Due to the COVID-19 Pandemic.*” Much of the information reflects the conditions at that time.

- The growing, global **demand** for COVID-19 healthcare supplies (e.g., personal protective equipment (PPE), test kits, pharmaceuticals, etc.) **far exceeded the current supplies.**
- The ability for *testing and validating* imported supplies was limited and likely inadequate to ensure safety and effectiveness in protecting frontline workers in the COVID-19 response.
- The problem included sub-standard or illicit manufacturers, distributors, vendors, adulterated test reports, counterfeited certifications and websites advertising or transacting sales.

Background, continued

- Widespread supply chain issues caused by the COVID-19 pandemic provided an opportunity for criminal actors and organizations to target vulnerable populations for exploitation, and to defraud consumers via deceptive websites.
- Those illicit activities compromised legitimate trade and financial systems, threatened the integrity of the U.S. border, and endanger the safety and security of the American public.
- The end users were unaware that what they were ordering might be counterfeit or substandard and may not be able to acquire the supplies from reliable sources—it may be counterfeit knock-offs versus nothing at all.

Background, continued

- The growing global demand for COVID-19 PPE at that time far exceeded current supplies.
- This shortage resulted in the need to:
 - Accelerate procurement of large quantities of PPE
 - Decontaminate and reuse existing PPE
 - Rapidly identify, modify and/or develop relevant standards
- Standards and testing played a critical role.
- The Department of Homeland Security (DHS), in collaboration with several other agencies, employed multiple engagements to address these concerns.

DHS & Interagency Actions

- The ability to test and validate imported supplies was limited and likely inadequate to ensure safety and effectiveness for frontline workers in COVID-19 response.
- DHS Chief Medical Officer (CMO) chaired an Interagency working group on fraudulent PPE
- Participation in an Interagency working group on PPE decontamination and reuse
- DHS Component Activities
 - Customs & Border Protection (CBP)
 - Federal Emergency Management Agency (FEMA) activities
 - Immigration and Customs Enforcement (ICE) Operation Stolen Promise
 - Countering Weapons of Mass Destruction Office (CWMD) and CMO
 - Science & Technology (S&T) Directorate

DHS Activities

- Countering Weapons of Mass Destruction Office (CWMD)
 - Chief Medical Officer chartered interagency working group on counterfeit and fraudulent PPE
 - Working with Department of Defense (DoD) moderated working group focused on PPE decontamination issues
 - Coordinating with National Security Staff (NSC) and other Federal Agencies
- U.S. Customs and Border Protection (CBP)
 - CBP/FEMA joint statement on Defense Production Act for PPE
 - Guidance on Importing PPE
 - Mask and Respirator Information (viewed 3,626 times)*
 - Links and resources to other agencies

(* As of 10 September 2020)

DHS Activities

- Federal Emergency Management Agency (FEMA)
 - Respirators for Healthcare during COVID-19: Authorized Use and Avoiding Fraudulent Products
 - PPE Preservation Planning Toolkit
- U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI) launched Operation Stolen Promise to protect Homeland against threat posed by COVID-19-related fraud and criminal activity.
 - Initiated “Strategic Targeted Outreach Program” (S.T.O.P) COVID-19 Fraud campaign
 - Investigates financial fraud schemes, importation of prohibited pharmaceuticals and medical supplies, and other illicit activities
 - 969* COVID-19 related seizures of prohibited test kits, pharmaceuticals and counterfeit masks and more

(* As of 10 September 2020)

DHS & Interagency Actions

- Interagency collaborations with:
 - National Institute of Standards and Technology (NIST)
 - U.S. Food and Drug Administration (FDA)
 - U.S. Department of Health and Human Services
 - Centers for Disease Control and Prevention (CDC)
 - National Institute of Occupational Safety and Health (NIOSH)
 - Environmental Protection Agency (EPA)
- Standards development body collaborations
 - U.S. Law stresses standards development through consensus standards bodies such as ASTM, International

Standards & Testing - Cross Cutting Issues

- Research to inform and validate standards, test methods and guidance
- Standards
 - Relevant standards setting organizations
 - Timelines for establishing standards for:
 - Cloth face coverings
 - Masks
 - Respirators
 - Decontamination and reuse
 - Publish guidance, best practices
- Testing / validation
 - Capacity/availability
 - Turnaround time, network and surge
 - Tracking
 - Reporting & Documenting

DHS S&T Research

- Inform and validate standards, test methods and guidance
- DHS Science and Technology Directorate (S&T) research
 - Master Question List and Current Research
 - SARS-CoV-2 Estimated Surface Decay Calculator
 - SARS-CoV-2 Estimated Airborne Particles Decay Calculator
- National Biodefense Analysis and Countermeasures Center (NBACC)
 - Research to understand the impact of environmental conditions on the virus—such as sunlight, temperature and humidity—to determine the virus' survivability in the air, in respiratory fluids, and on various surfaces.
 - Research on survivability of the virus in waste streams to inform guidance on preventing transmission in communities and homes.
 - Evaluation of decontamination methods to determine the most effective materials to clean and disinfect surfaces.
 - Answering operationally relevant questions related to personal protective equipment decontamination and reuse.

S&T Information Sharing

- [COVID-19 Resources for First Responders](#)
- [Innovative Partnerships to Address Personal Protective Equipment Challenges During COVID-19](#)
- [Disinfection and Reuse of Personal Protective Equipment Factsheet](#)
- [Reference Guide for Operating in Environments where SARS-CoV-2 may be Present](#)
- [Non-Medical Interventions: A Desk Reference to Help Planners Recover from COVID-19 and Prepare for Future Outbreaks and Pandemics](#)

Summary and Recommendations

- Integrated response:
 - Whole of government approach
 - Leveraged legal authorities and technical expertise of Federal Agencies
 - Law and customs enforcement
 - Logistical and supply chain expertise
 - Technical capabilities of existing medical, standards and testing infrastructure
 - Focused short term research for maximum impact
 - Standards bodies
 - Identified and made relevant standards freely available to users
 - Identified gaps in standards
 - Accelerated standards development
 - Partnered with other nations, industry and academia

Summary and Recommendations

- Support the need for accelerated standards, test methods and guidance development for:
 - PPE
 - Cloth face coverings
 - Face shields
 - Masks
 - Respirators
 - Decontamination
 - For reuse of PPE
 - Efficacy of different methods and impact on PPE performance
 - Publish guidance, best practices
 - Capabilities and limitations of products
 - Wear, donning, doffing, storage
 - Decontamination and reuse
 - Appropriate type of equipment
- Information and document sharing

Ongoing Engagements

- Federal interagency efforts in:
 - Continuing research in COVID-19/SARS CoV-2
 - Initiating effort related to building ventilation codes, standards and best practices
 - Continuing COVID-19 related PPE standards and testing
 - Exploring standards, reference materials and best practices to establish enduring capability for wastewater surveillance
- Continued collaboration with:
 - International partners
 - Standards development bodies
 - Private sector and industry
 - Academia

Questions?

Philip Mattson

DHS Standards Executive &
Senior Standards Advisor

Philip.Mattson@hq.dhs.gov

Office: 202-254-5861

Cell: 202-731-2833

standards@hq.dhs.gov

DIVERSE PERSPECTIVES + SHARED GOALS = POWERFUL SOLUTIONS

[SCIENCE AND TECHNOLOGY DIRECTORATE]

Engage with us:



scitech.dhs.gov



SandT.Innovation@hq.dhs.gov



[@dhsscitech](#)



Science and
Technology