Title: US Regulatory Requirement on Masks and Barrier Face Coverings and Proposed Revisions to ASTM F3502-21

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Presenter: Jeffrey Stull, President, International Personnel Protection, Inc.

Synopsis: This presentation will provide an overview of the United States standards and regulatory requirements for respirators, medical face masks, and barrier face coverings that are being used to minimize the spread of COVID-19. The use of these products will be described in the context for how they address the spread of airborne infectious diseases for source control as well as protection of the individual wearer; this information will be related to how various end user groups have specified the use of conforming products. Background information will be provided to describe the individual qualifications for products in terms of required test results, selection of laboratories, and expectations for product quality control. These will be contrasted with those from other selected global regions.

Information on how the subject standards and regulatory requirements can be effectively implemented as part of a national strategy to govern the manufacture, export, and import of these products with specific information on conformity assessment. This will involve a discussion of the essential elements of initial verification of product conformity, an on-going product quality control program, and audits.

Finally, the presentation will briefly explain the new ASTM F3502 specification on barrier face coverings as well as proposed changes being made through ASTM's balloting process. The changes are being undertaken to further evolve the standard to provide corrections, clarifications, and other short-term actions on specific areas of the standard.

Intended Audience: This presentation is being directed towards:

- Manufacturers of respirators, medical face masks, or face coverings
- Testing laboratories involved in the evaluation of medical device products.
- Individuals involved the development of standards for manufacture of medical device products or their use
- Government authorities that regulate public health and the provision of protective products for both healthcare and the general public
- Government officials involved in the approval or clearance of medical devices
- Members of organizations representing healthcare end users and other workers
- Professionals involved in research for disease transmission or individual protection

Learning Objectives: As a result of this presentation, attendees will understand:

- How different products work to capture expelled particulate and droplets
- The degree to which face covering products provide protection to the wearer for the inhalation of potentially infectious particulates
- The principal similarities and contrasts between respirators, medical masks, and face coverings

- The general types of testing and requirements that are applied to respirators, medical masks, and face coverings in the United States
- Different options for how products can be manufactured to meet U.S. standards and requirements and how related requirements can be applied locally for end users including healthcare and the general population

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