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January 14, 2022

Edmund C. Baird  
Associate Solicitor for Occupational Safety and Health  
Office of the Solicitor  
U.S. Department of Labor  
200 Constitution Ave. NW  
Washington, DC 20210

*Submitted electronically via [www.regulations.gov](http://www.regulations.gov)*

Re: ASTM International Comment on OSHA Docket No. OSHA-2021-0007, COVID-19  
Vaccination and Testing; Emergency Temporary Standard

Dear Mr. Baird:

On behalf of ASTM International's Committee F23 on Personal Protective Clothing and Equipment, the Executive Committee has approved the attached letter in response to the Occupational Safety and Health Administration's COVID-19 Vaccination and Testing; Emergency Temporary Standard.

Committee F23 is one of 147 ASTM technical committees composed of experts who represent producer, user, government, and academic stakeholder interests in the development of voluntary consensus standards for materials, products, systems, and services. Committee F23 adheres to well-regarded, industry-recognized, and time-tested principles for the development of consensus standards that reflect current technology and industry practice.

Thank you for the opportunity to submit these comments. Please feel free to contact Matthew Pezzella in the ASTM Washington Office at 202-223-8399 or [mpezzella@astm.org](mailto:mpezzella@astm.org) to discuss these comments or any issues related to this letter.

Sincerely,

A handwritten signature in black ink that reads 'Katharine E. Morgan'.

Katharine E. Morgan  
President



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Re: ASTM International Comment on OSHA Docket No. OSHA-2021-0007, COVID-19  
Vaccination and Testing; Emergency Temporary Standard

Dear Mr. Baird:

Thank you for the opportunity to provide the following comments in response to the U.S. Occupational Safety and Health Administration (OSHA), Department of Labor's COVID-19 Vaccination and Testing; Emergency Temporary Standard interim final rule and request for comments.

ASTM International is a leading, globally recognized, non-profit organization in the development and delivery of voluntary consensus standards. For more than 120 years, ASTM has served society by providing a global forum for the development and publication of voluntary consensus standards for materials, products, systems, and services. Today, over 12,800 ASTM standards are used by ninety industrial sectors in the United States and around the world to improve product quality, protect the environment, enhance health and safety, and strengthen market access and trade. Over 30,000 individuals from 149 countries, including manufacturers, retailers, consumers, regulators, academics, and researchers serve on ASTM's 147 technical committees.

ASTM has a long history of assisting federal agencies to meet evolving regulatory needs. According to the National Institute of Standards and Technology (NIST) Standards Incorporated by Reference Database, there are over 2,500 standards from ASTM International incorporated by reference in the U.S. Code of Federal Regulations. A strong and effective reliance on the non-governmental sector for development and maintenance of the standards in use across all sectors of our economy is supported by OMB Circular A-119 and codified by Congress through P.L. 104-113 – The National Technology Transfer and Advancement Act (NTTAA) of 1995.

Since July 2020, ASTM Committee F23 on Personal Protective Clothing and Equipment (F23) and Committee F04 on Medical Devices (F04) worked together to fast-track the development of PPE standards. An international workshop bringing together a broad range of participants was held to identify needs and promote collaboration around PPE standards. The workshop served to identify standardization needs across various categories of infection control PPE, including respirators and facemasks, protective clothing and face shields, reprocessing and reuse of PPE, conformity assessment and modelling and additive manufacturing, i.e. the use of 3D printing technology around PPE. Soon

after, Committees F23 and F04 began developing a new standard for barrier face coverings. The effort was co-chaired by a PPE-industry veteran and the deputy director of the National Personal Protective Technology Laboratory of the U.S. National Institute for Occupational Safety and Health (NIOSH) within the Centers for Disease Control and Prevention (CDC). For months, a task group met regularly to debate the qualifications necessary for a product worn on the face. Key points such as source control, particulate filtration, and airflow resistance were rigorously discussed based on emerging scientific data and studies. Substantial parts of the debate that went into the development of a face covering standard was its targeted population, its intended purpose, and the clarity of requirements would define product design, performance, and labeling information.

In February 2021, ASTM Committee F23 published a new voluntary standard, F3502-21, *Standard Specification for Barrier Face Coverings*. The standard brings value by specifying minimum design, performance, testing requirements, and allows comparison of products by end users where current guidelines have been limited. The committee ultimately created a broad specification that primarily focused on source control (protecting others) while also offering a level of inhalation protection from aerosols. The completed standard uniquely specifies the same test methodology as used for filtering facepiece respirators (e.g., N95 respirators). F3502-21 further establishes two permissible performance levels in the key metrics of filtration efficiency and airflow resistance which aid end users in selecting appropriate products. The standard further includes requirements for robust labeling, product user information, and a minimum conformity assessment approach that dictates having the key tests performed by accredited laboratories.

Following the publication of F3502-21, OSHA considered whether to incorporate the standard by reference in its June 21, 2021 Occupational Exposure to COVID-19; Emergency Temporary Standard; Interim Final Rule.<sup>1</sup> As noted in the document, OSHA determined that F3502-21 would not be feasible to implement for their timeframe, “due to time needed to manufacture and distribute such a new product.” In the November 2021 COVID-19 Vaccination and Testing; Emergency Temporary Standard, OSHA repeated its findings from June 2021 on F3502-21 that, “the agency has insufficient evidence to make a general finding of feasibility at this time.”

Within two weeks of its adoption and publication, the U.S. Food & Drug Administration (FDA) recognized F3502-21 and established a new product code specifically for products claiming compliance against this standard.<sup>2</sup> Later, in September 2021, the FDA included reference to ASTM F3502-21 as part of its “Enforcement Policy on Face Masks, Barrier Face Coverings, Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency,” newly retitled to include barrier face coverings.<sup>3</sup>

Beginning in May 2021, CDC began referencing F3502-21 as part of its guidance on masks. The CDC further established F3502-21 as the basis for the foundation for additional specifications for protection of workers as part of what it refers to as “workplace protection” and “workplace protection plus”

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<sup>1</sup> <https://www.osha.gov/laws-regs/federalregister/2021-06-21>

<sup>2</sup> [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard\\_\\_identification\\_no=42029](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=42029)

<sup>3</sup> <https://www.fda.gov/media/136449/download>

categories of face coverings.<sup>4</sup> These recommended categories build directly from the requirements of F3502-21 in terms of minimum acceptable filtration efficiencies, maximum breathability, and minimum levels of leakage, which are further combined with provisions from the standard for labeling and conformity assessment.

As of August 2021, NIOSH created a website dedicated to listing products that comply with F3502-21.<sup>5</sup> The product list is updated as new masks are evaluated and submitted. Currently, there are 15 manufacturers and 22 products listed on the site that comply with F3502-21. To be listed on the page, the supplier/manufacturer provides NIOSH with its quantitative test results for two purposes. First, to demonstrate the data was obtained by an accredited laboratory by the supplier/manufacturer and that the data is appropriate for making the claim of conformance. The supplier/manufacturer must also provide a checklist that they meet relevant individual requirements of F3502-21 and present a declaration of conformance. There are likely more barrier face coverings compliant with F3502-21 where the manufacturers have either not submitted their data to NIOSH or have undertaken the proper testing. NIOSH reports that there is still a steady interest in the website and that additional inquiries from manufacturers are being submitted.

Additionally, since F3502-21 was published early in 2021, the World Health Organization (WHO) has considered referencing the barrier face covering standard into their recommendations. ASTM International staff and technical experts have met with WHO Health Emergencies Programme specialists' multiple times since September 2021 to discuss F3502-21. As of December 22, 2021, the WHO formally included F3502-21 in their "COVID-19 infection prevention and control living guideline: mask use in community settings."<sup>6</sup> The WHO guidance states that "reusable, non-medical masks that comply with the ASTM F3502 standard" are a strong recommendation for settings where community or cluster spread of COVID-19 is possible, among other mask types.

ASTM technical committees have the flexibility to revise standards at any point in response to new information, materials, or technologies. Directly following F3502-21's publication in February 2021, Committee F23 immediately began work to revise, update, and strengthen the barrier face covering standard. Two ballots for potential revisions to the standard, principally to clarify existing requirements where one current ballot, will be concluded in January 2022.

Thank you for your consideration and the opportunity to submit these comments. If you have any questions regarding Committee F23 on Personal Protective Clothing and Equipment or ASTM F3502-21, please do not hesitate to contact Matthew Pezzella, Manager of Government and Industry Affairs at [mpezzella@astm.org](mailto:mpezzella@astm.org) or (202) 223-8399 or myself at [klehtonen@lionprotects.com](mailto:klehtonen@lionprotects.com) or (937-415-2932).

Sincerely,

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<sup>4</sup> <https://www.cdc.gov/niosh/topics/emres/pandemic/>

<sup>5</sup> <https://www.cdc.gov/PPEInfo/RG/FaceCoverings>

<sup>6</sup> <https://apps.who.int/iris/handle/10665/350927>

Karen Lehtonen

Karen Lehtonen  
Chair, ASTM Committee F23

cc: Mary Mikolajewski, Manager, Technical Committee Operations, ASTM Committee F23