National Institute of Standards and Technology
U.S. Department of Commerce

Voluntary Consensus Standards, Federal Standards Policy and Considerations for Success

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Federal Policy on Standards

National Technology Transfer and Advancement Act (NTTAA) (1996)

- Objective is for Federal agencies to use voluntary consensus standards, wherever possible, in lieu of creating government-unique standards
- Assigns NIST a standards coordination role across government

OMB Circular A-119 (2016)

- Establishes guidance for agency implementation and use of NTTAA

Our Standardization “system” in the U.S.

- Voluntary, decentralized and market-driven
- Led by private sector
- Public-private partnership
  - *Differs from centralized standards systems in other countries*
- Reflects U.S. culture and public-private sector dynamics
- Relies on cooperation, communication and parity among diverse stakeholder

What is a Voluntary Consensus Standard?

Development Process Attributes

- Openness
- Balance
- Due Process
- Appeals Process
- Consensus

Generally published by private sector organizations

Similar to the WTO Technical Barrier to Trade international standards attributes

Aligned with ANSI's *General Requirements for Due Process*

FDA U.S. FOOD & DRUG ADMINISTRATION

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Recognized Consensus Standards

FDA Home › Medical Devices › Databases

CDRH SuperSearch

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
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Part B: Supplementary Information Sheet (SIS)

FR Recognition List Number 053 **Date of Entry** 12/23/2019

FR Recognition Number 6-427

Standard

ASTM F2101-19
Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus

Scope/Abstract

1.1 This test method is used to measure the bacterial filtration efficiency (BFE) of medical face mask materials, employing a ratio of the upstream bacterial challenge to downstream residual concentration to determine filtration efficiency of medical face mask materials.

1.2 This test method is a quantitative method that allows filtration efficiency for medical face mask materials t… determined. The maximum filtration efficiency that can be determined by this method is 99.9%.

1.3 This test method does not apply to all forms or conditions of biological aerosol exposure. … method should review modes for worker exposure and assess the appropriateness of th… specific applications.

1.4 This test method evaluates medical face mask materials as an item o… …es not evaluate materials for regulatory approval as respirators. If respirat… …r is needed, a NIOSH-certified respirator should be used. Relatively high bac… …easurements for a particular medical face mask material does not ensure th… …ted from biological aerosols, since this test method primarily evaluates the perfor… …aterials used in the construction of the medical face mask and not its design, fit, o…

Extent of Recognition

Complete standard

Rationale for Recognition

This standard is relevant to medical devices and is recognized on its scientific and technical merit and/or because it supports existing regulatory policies.

Public Law, CFR Citation(s) and Procode(s)*

Regulation Number	Device Name	Device Class	Product Code
§878.4040	Mask, Surgical	Class 2	FXX
§878.4040	Respirator, Surgical	Class 2	MSH

Relevant FDA Guidance and/or Supportive Publications*

UNITED STATES DEPARTMENT OF LABOR

Occupational Safety and Health Administration

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By Standard Number / 1910.135 - Head protection.

- **Part Number:** 1910
- **Part Number Title:** Occupational Safety and Health Standards
- **Standard Number:** 1910.135
- **Title:** Head pr…
- **GPO Source:**

1910.135(…

…employer shall ensure that each affected employee wears a protective helmet when working in areas where there is a potential for injury to the head from falling objects.

1910.135(a)(2)
The employer shall ensure that a protective helmet designed to reduce electrical shock hazard is worn by each such affected employee when near exposed electrical conductors which could contact the head.

1910.135(b)
Criteria for head protection.

1910.135(b)(1)
Criteria for head protection. (1) Head protection must comply with any of the following consensus standards:

1910.135(b)(1)(i)
American National Standards Institute (ANSI) Z89.1-2009, "American National Standard for Industrial Head Protection," incorporated by reference in Sec. 1910.6;

1910.135(b)(1)(ii)
American National Standards Institute (ANSI) Z89.1-2003, "American National Standard for Industrial Head Protection," incorporated by reference in Sec. 1910.6; or

1910.135(b)(1)(iii)
American National Standards Institute (ANSI) Z89.1-1997, "American National Standard for Personnel Protection--Protective Headwear for Industrial Workers--Requirements," incorporated by reference in Sec. 1910.6.

Regulators incorporate standards by reference.

U.S. Standardization “system”

- Private sector membership organization
- Administrator/coordinator of U.S. standardization system
- Represents U.S. in many international standards development efforts
- Does not develop standards, but accredits standards developers
- Represents and serves more than 270K companies and organizations

U.S. Standardization “system”: NIST

- Coordinate Federal policy and activities in the development and use of standards
- Coordinate standards activities w/responsible government agencies and the private sector
- Provide foundation for development of standards (standard reference materials, calibrations, research in measurement science and technology)
- Enhance the competence of the federal government in standards

Standards Development Considerations

Factors in optimizing standards development processes:

- Stakeholders - Where do the “eagles” gather?
  - Is membership inclusive enough?
  - Will scientific research be tabled to inform development?
- Is there a reasonable development process including maintenance?
  - Can all the voices heard?
  - Will the users be represented?
- Is the published standard likely to be adopted?
  - Does the standards development organization have *cred*?
  - Are there barriers to global adoption?