Conformity Assessment for Non-Respiratory Personal Protective Equipment in the U.S.

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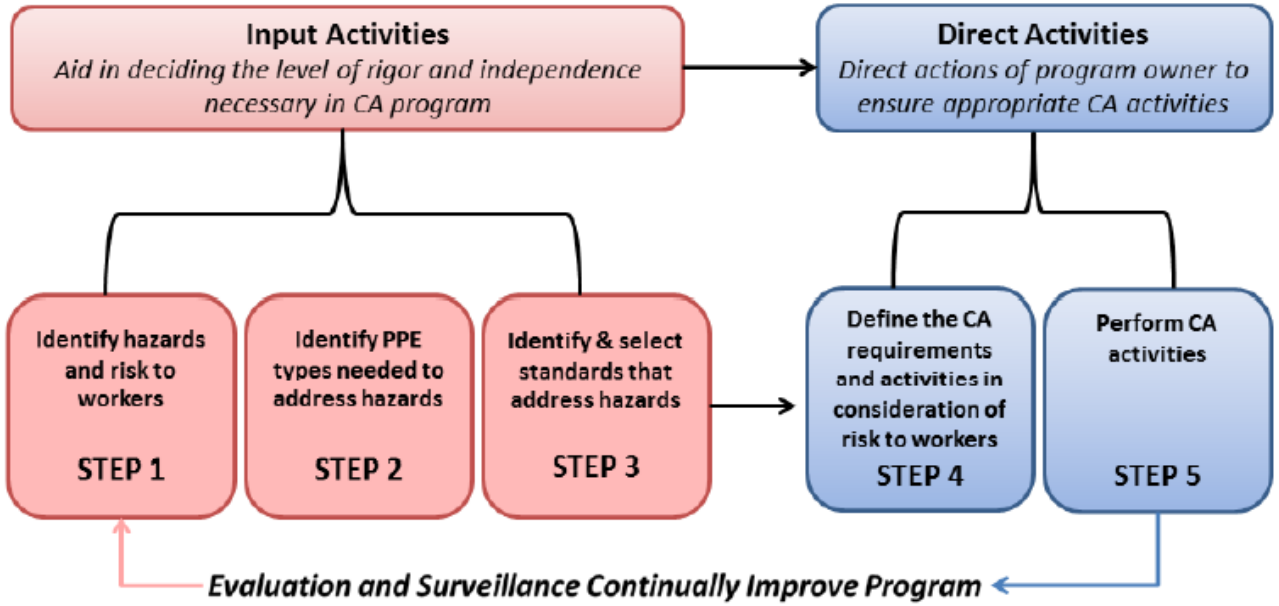
Ideal PPE Conformity Assessment Approach

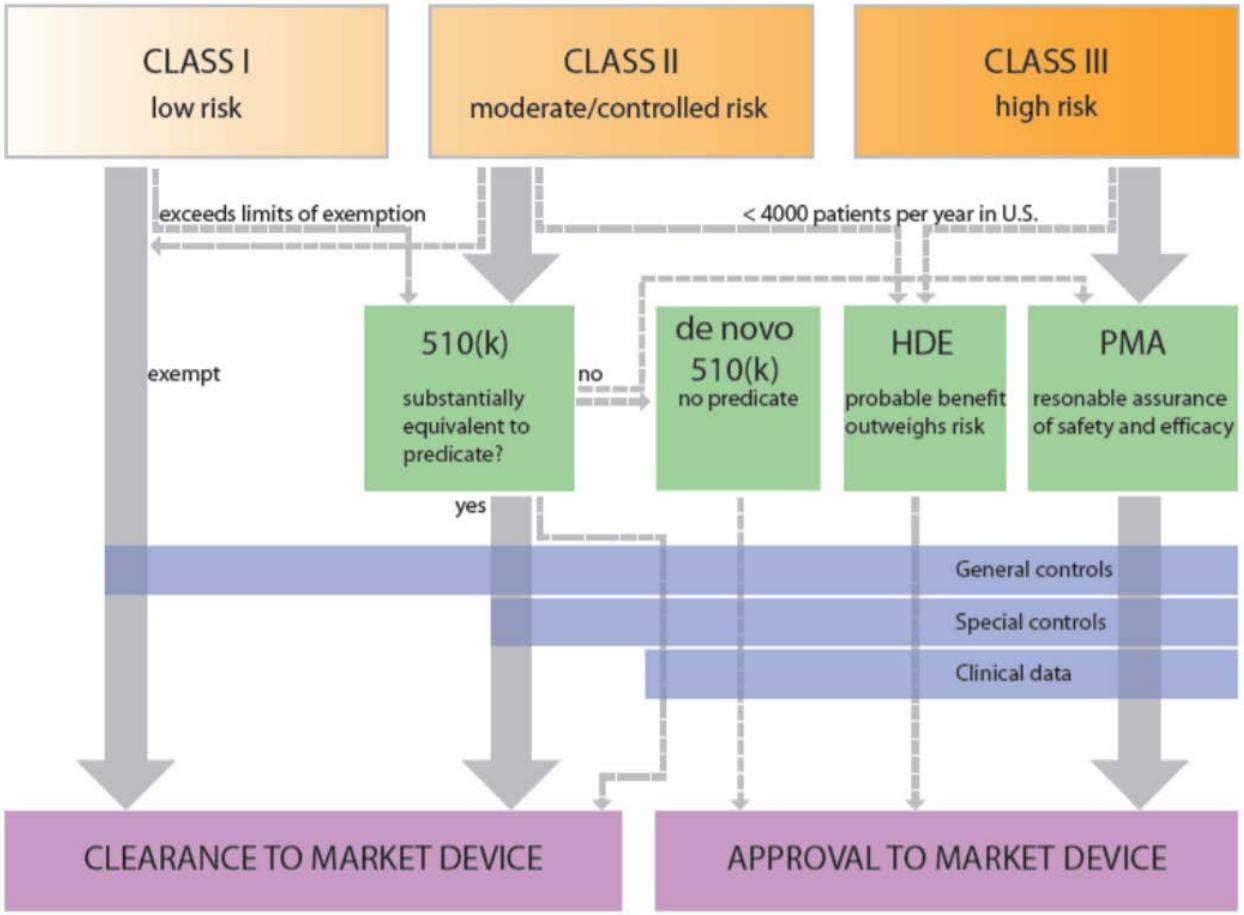
- PPE performance verification approach developed and reviewed in public forum with multiple stakeholders
- Steps for achieving balanced approach that mirror current proposed national strategy



Reviewed Conformity Assessment Approaches

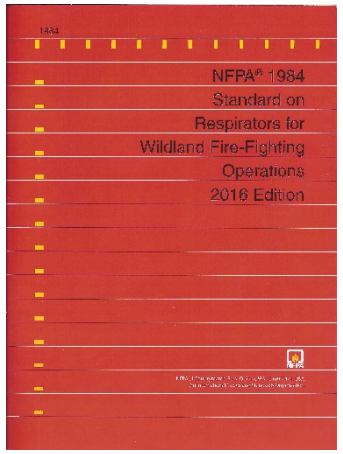
- Food and Drug Administration (FDA)
  - Process to clear “medical devices” under FD&C Act
  - 510(k) process for safety & efficacy of Class II devices
- National Fire Protection Association
  - Multiple PPE products and respirators for first responders
  - Mandatory 3rd party certification (part of each standard)
- ASTM International
  - F23 committee multiple committees (F23.65 new)
  - E54 standard on PPE including emergency escape devices
- International Safety Equipment Association
  - Multiple PPE product group
  - Separate conformity assessment standard

FDA Medical Device Clearance Process

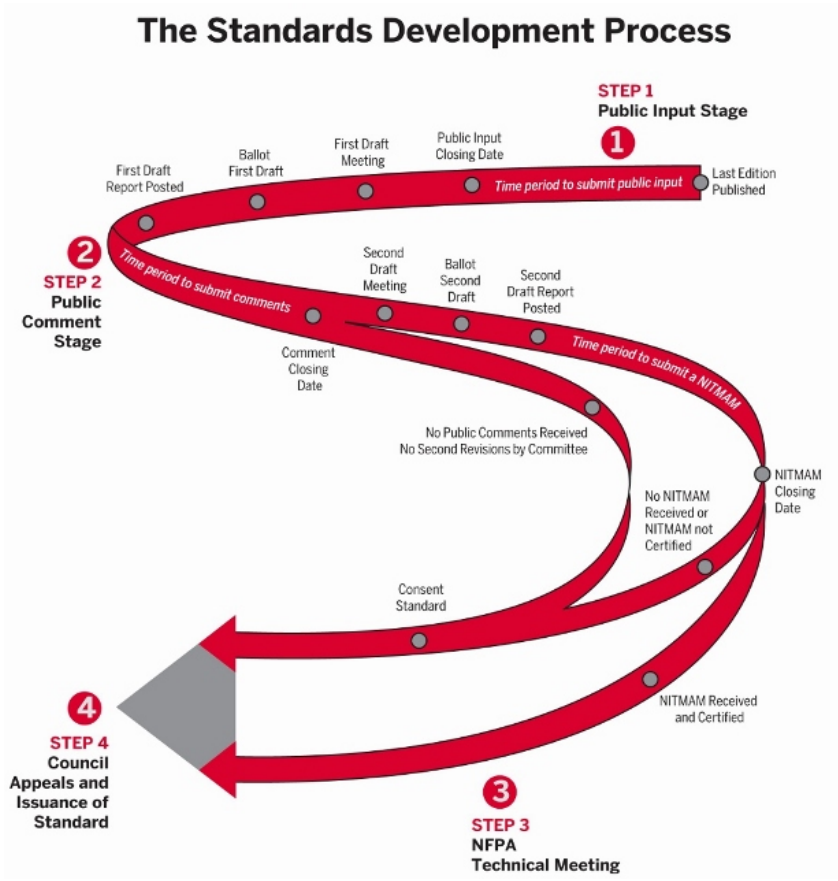


- Class I devices
  - Manufacturer meets general controls
- Class II devices (e.g., medical masks, gowns)
  - 510(k) submission
    - Demonstration of substantial equivalence to predicate product
    - Use of recognized standards
    - Manufacturer provision of safety and efficacy data
    - Good manufacturing practice

NFPA Conformity Assessment

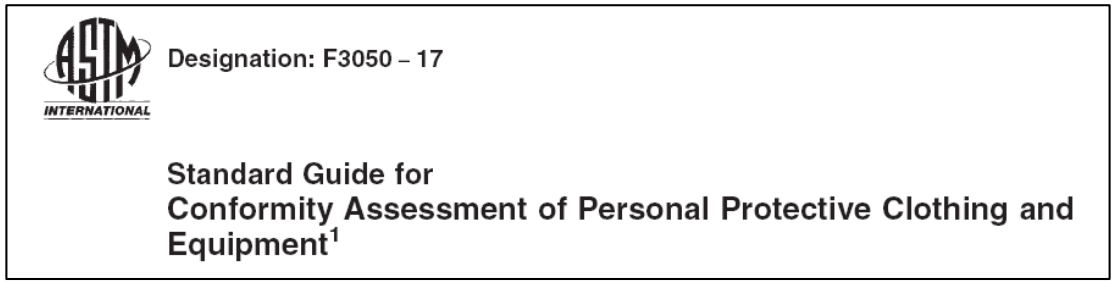


- Relevant Standards:
  - NFPA 1981 Fire Service SCBA
  - NFPA 1984 Wildland respirators
  - NFPA 1986 Tactical SCBA
  - NFPA 1987 Combination respirators
  - NFPA 1999 Hooded PAPRs
- 3rd party certification applied to products each standard
  - Cert. org./lab accreditation; quality requirements; initial/annual testing; some post-market surveillance



ASTM International Conformity Assessment

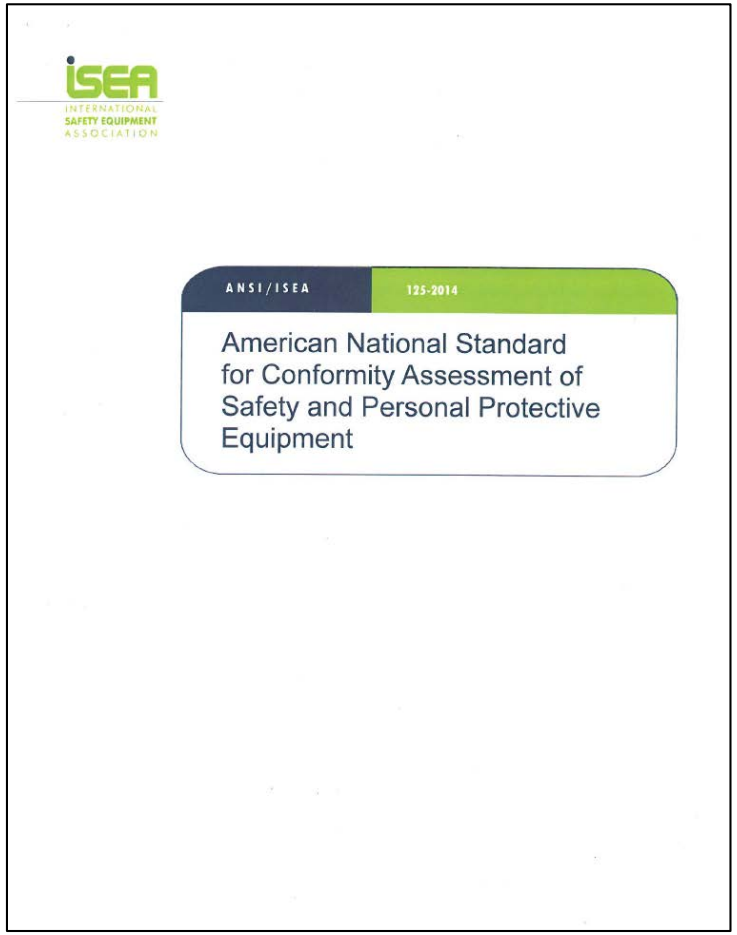
- Pertinent Standards
  - E2952-17 Specification for Air-Purifying Respiratory Protective Smoke Escape Devices (RPED)
  - F3407-20 Test Method for Respirator Fit Capability Conformance Test for Half-mask Air-purifying Particulate Respirators (*nearly adopted*)
  - FYYYY Specification for Barrier Face Coverings *(proposed)*
  - F3050 Guide for Conformity Assessment of Personal Protective Clothing and Equipment


Designation: F3050 – 17

Standard Guide for
Conformity Assessment of Personal Protective Clothing and Equipment[1]

- Provides 4 models of conformity assessment based on:
  - Attestation
  - Testing & inspection levels
  - Quality management system
  - Ongoing conformity
- Adjunct CA criteria being positioned for implementation within specific standards

ISEA Conformity Assessment



	Level 1	Level 2	Level 3
QMS	Initial and ongoing assurance of conformity	ISO 9001	Determined by cert body (ISO 17065)
Testing Laboratory	Supplier's Choice	ISO 17025 accredited lab (in or out of house)	Direction of cert body; 17025 accredited lab
Who determines retesting?	Supplier	Supplier	Cert body
Test Interval	At least every 5 years, determined by supplier		At least every 5 years, at direction of cert body
Corrective/ Preventative Action	Supplier to establish and maintain written program		
Recordkeeping			
Declaration of Conformity	Supplier	Supplier	Cert body issues cert, supplier applies mark to product

- Three levels of conformity established
- Currently, infrequently specified

Key Conformity Assessment Factors

- Determination of relative hazards and risks
  - Regulation or standards based (mandatory versus voluntary)
  - Overarching requirements in OSHA 29 CFR 1910 Subpart I
- Requirements and application of product testing/assessment
  - Laboratory qualification and relationship to supplier
  - Frequency of testing and decisions for conformance
- Implementation of quality systems
  - Specificity to products and level of monitoring
- Attestation of product conformance (supplier or 3rd party)
- Provisions for proper selection, care, and use; surveillance

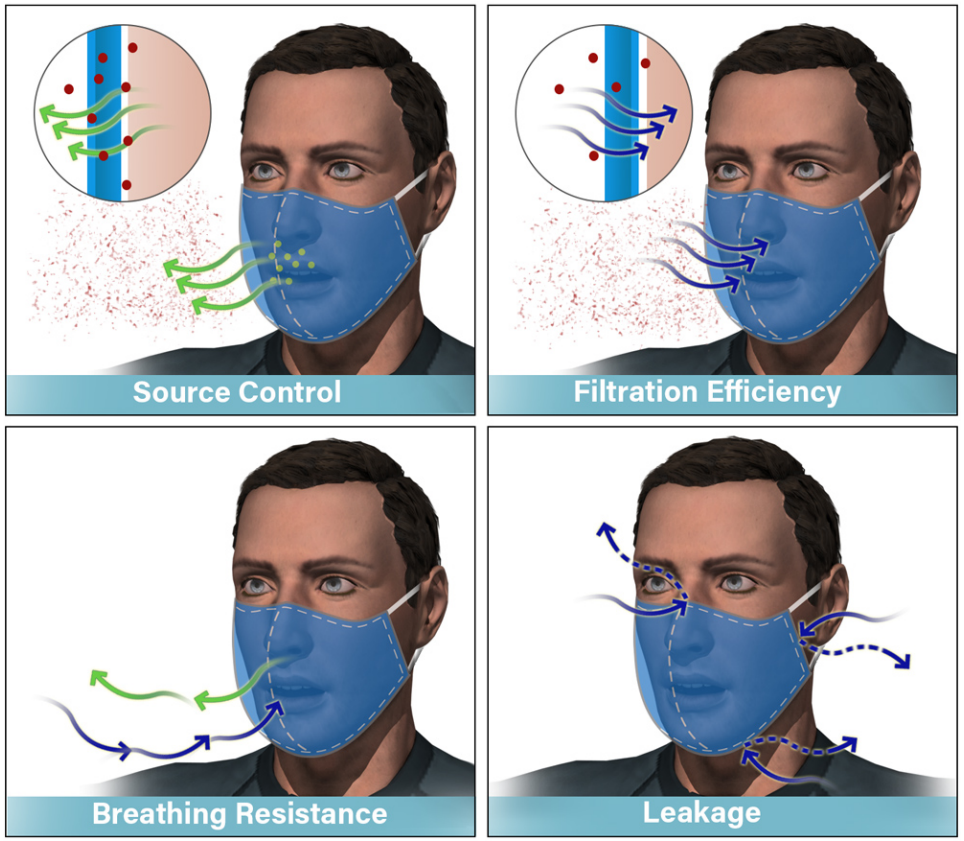
Comparison of Approaches

Organization	Identification of Hazards	Identification of PPE Types	Selection or Development of Standards	Define CA Approach	Perform Conformity Assessment
NIOSH NPPTL	Pre-market surveillance	US government	US government	US government	US government (3rd party)
FDA (510k)	US government	US government	Recognition of consensus stds. Guidance	Comparison to existing product	FDA review of manufacturer process
NFPA	By technical committee	By technical committee	By technical committee	By technical committee	Qualified 3rd party organization
ASTM Int'l*	By workgroup or subcommittee	By workgroup or subcommittee	By workgroup or subcommittee	Not yet implemented	Not yet defined
ISEA*	By internal product group	By internal product group	By internal product group	By internal product group	Qualified as per standard

* No defined process for post-market surveillance

Example for Barrier Face Covering Standard

- Proposed specification being developed
- Requirements for product design, performance, labeling, classification, user information
  - Use of NIOSH test methods
- Current conformity assessment
  - Minimum ASTM F3050 Model A approach
    - Attestation by self-declaration
    - Quality system recommended
  - Key tests to be performed by accredited laboratories
  - Minimum labeling/classification



Specific Recommendations

- Use U.S. Standards Development Organizations to allow expansion of product types and conformity assessment to address respiratory protection needs of other workers
  - Build on existing government regulations for additional criteria
  - Include appropriate conformity assessment approaches for both standards development and verification of product conformance
  - Create other standards to address selection, care, and maintenance
- Have a Federal Agency take centralized role for coordination of conformity assessment process
  - Recognize standards; conduct supportive research for requirements
  - Qualify conformity assessment bodies; provide surveillance support
  - Identify forums for listing conforming products