

Alternative Conformity Assessment Approaches, Factors, and Implementation



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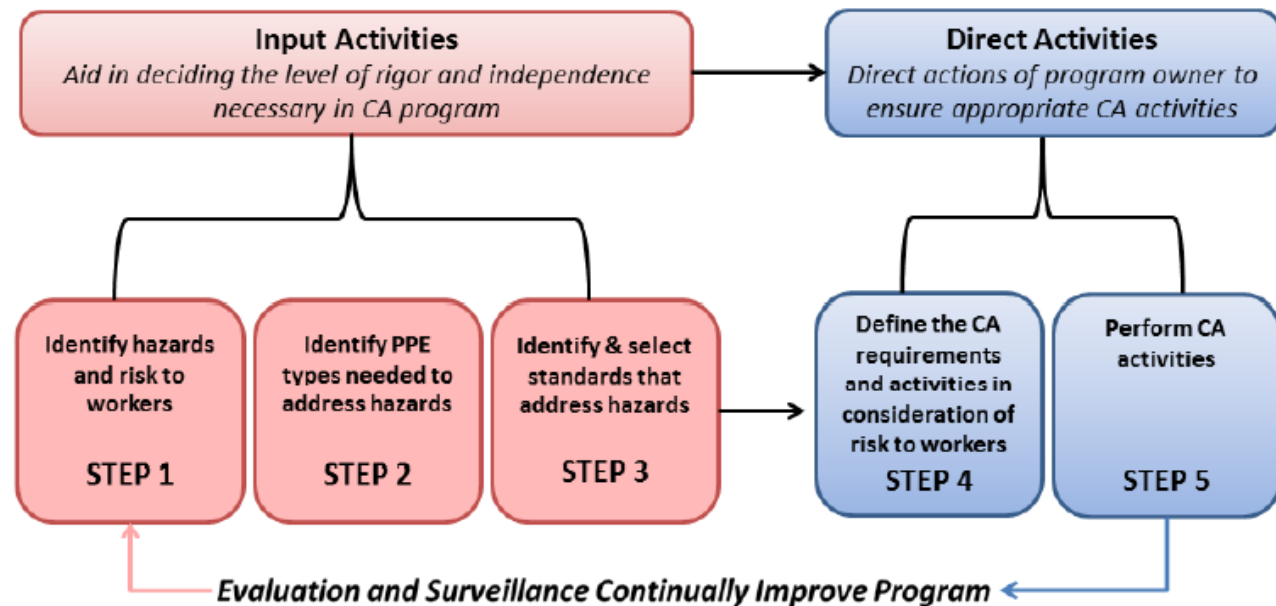
International Personnel Protection, Inc.

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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



- Committee on European Standardization (CEN)
 - PPE Directive/Regulations establish basic requirements
 - CE Type Examination for multiple types of respirators



- National Fire Protection Association
 - Multiple respirators for first responders
 - Mandatory 3rd party certification



- ASTM International
 - Newly formed F23 subcommittee on respiratory protection
 - E54 standard on emergency escape devices

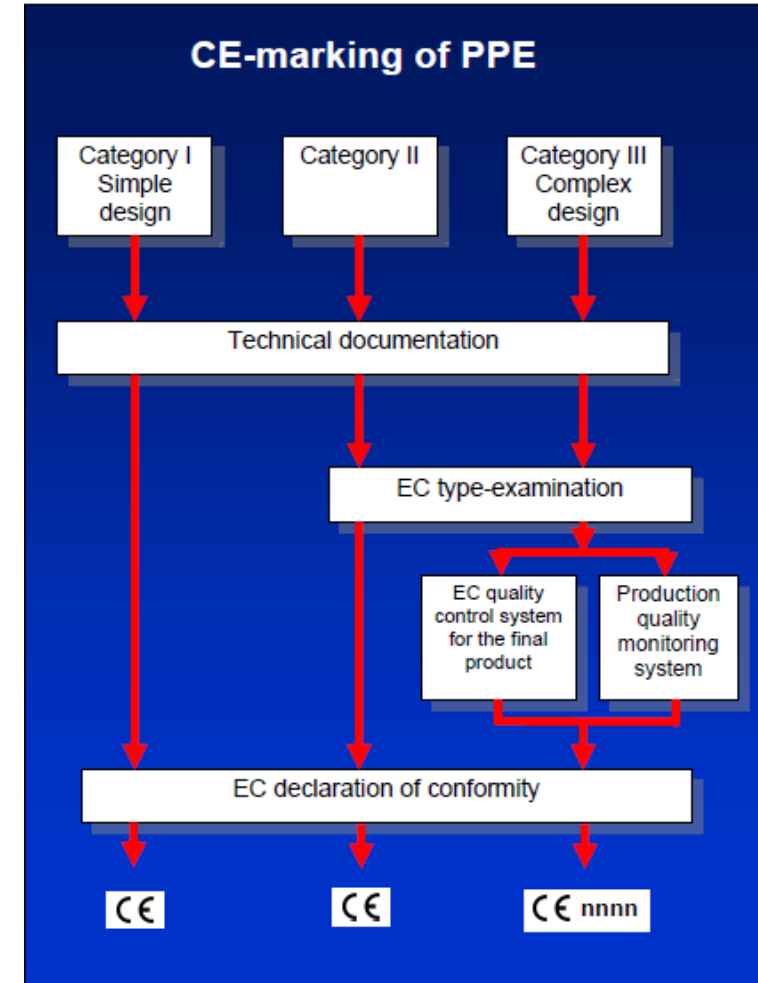


- International Safety Equipment Association
 - Respirator product group
 - Separate conformity assessment standard

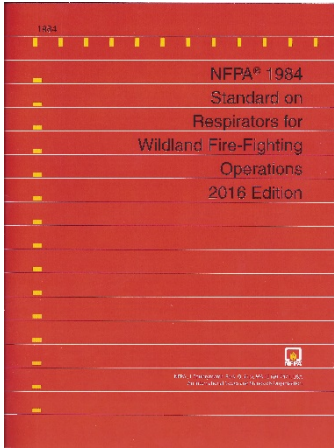


CEN Conformity Assessment

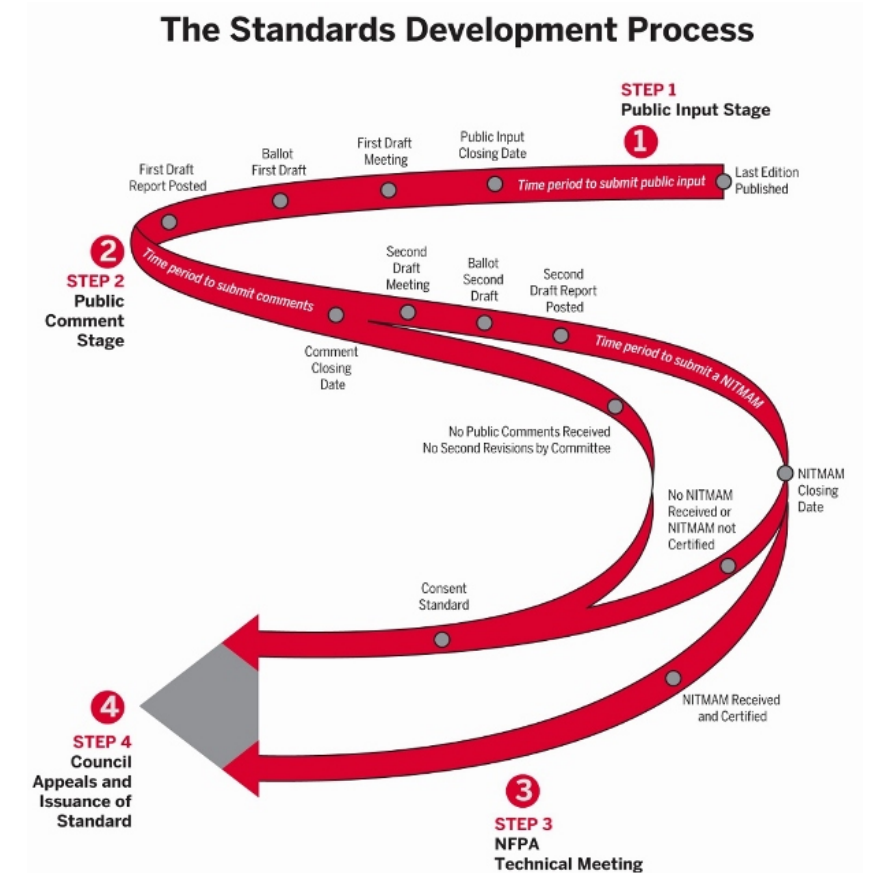
- Key EU Directives/Regulations
 - 2016/425 (PPE CE Marking)
 - 2019/1832 (use of PPE)
- Example European Norms
 - EN 136 Full facepieces
 - EN 140 Half and quarter masks
 - EN 143 Particulate filters
 - EN 149 Filtering facepiece respirators
 - EN 12941 powered hood/helmet respirators
- Separate but parallel effort by ISO TC94/SC15 on respiratory protective devices



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)
 - FXXXX 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



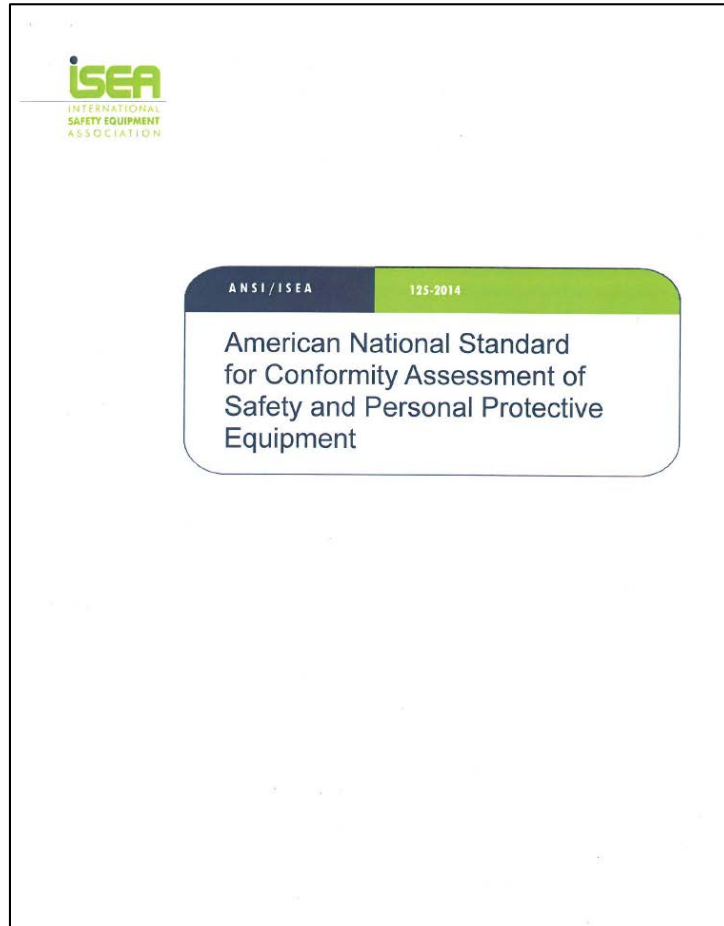
Designation: F3050 – 17

Standard Guide for
Conformity Assessment of Personal Protective Clothing and
Equipment¹

- 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

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 (3 rd party)
CEN	Basic health & safety req'ts in EU PPE regulations	By technical committee	By technical committee	By EU PPE regulations	Member recognized notified bodies
NFPA	By technical committee	By technical committee	By technical committee	By technical committee	Qualified 3 rd 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 product group	By product group	By product group	By product group	Qualified as per standard

* No defined process for post-market surveillance



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 NIOSH take centralized role for coordination of conformity assessment process
 - Recognize standards; conduct supportive research for requirements
 - Qualify conformity assessment bodies; provide surveillance support