



Conformity assessment of personal protective equipment used in industry

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NIST Public Workshop

Conformity Assessment – Approaches and Best Practices

April 11, 2012



ISEA is the association for personal protective equipment and technologies



Head protection

Eye and face protection

Hearing protection

Respirators

Protective clothing

Gloves

Fall protection

High visibility apparel

Gas detection instruments

First aid kits

Emergency eyewash and shower

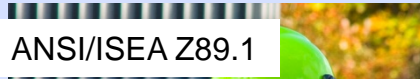
Testing services

- ANSI accredited standards developer
- Participant on national and international standards committees and boards
- Active partner with NIOSH, OSHA





ANSI/ISEA 103



ANSI/ISEA Z89.1

ANSI/ISEA Z87.1

42 CFR part 211

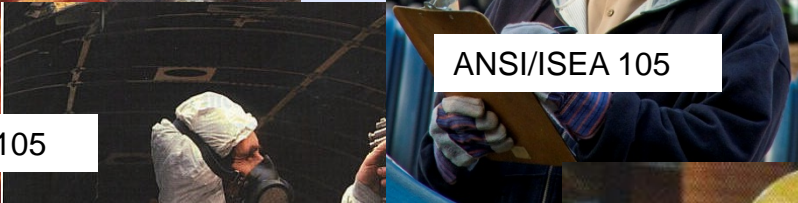


ANSI/ISEA Z89.1

ANSI/ISEA Z87.1

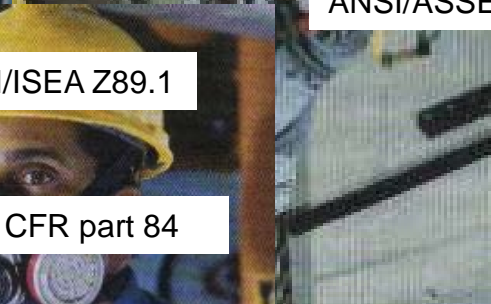


ANSI/ISEA 105



ANSI/ISEA 105

42 CFR part 84



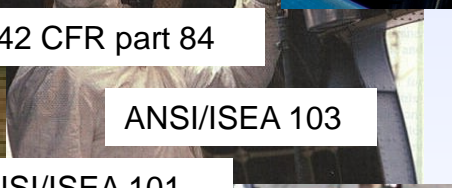
ANSI/ISEA Z89.1

42 CFR part 84

ANSI/ASSE Z359



ANSI/ISEA 113



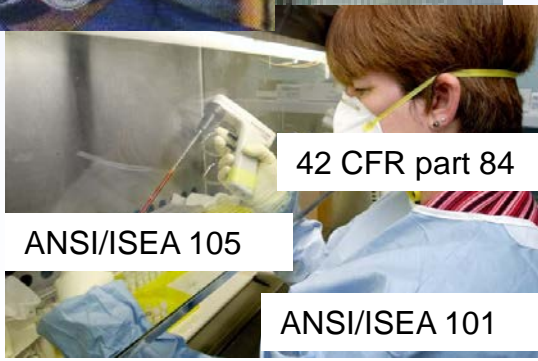
ANSI/ISEA 101

ANSI/ISEA 103

ANSI/ISEA Z89.1



ANSI/ISEA 107



42 CFR part 84

ANSI/ISEA 105

ANSI/ISEA 101



PPE is a standards-driven marketplace

- Specifications
 - What's the minimum performance?
 - How do you test?
 - Pass/fail criteria
- Classifications
 - Assist user to select the appropriate protection for the job/hazard
 - Types, classes, ratings etc.





OSHA rules the workplace

- OSHA regulations have an *expectation* of conformity to specified performance standards
 - ANSI, ASTM, NFPA consensus standards incorporated by reference in regulations.
- But there's no requirement for independent approval of non-respirator PPE
 - 1994 revision to 29 CFR 1019 Subpart I concluded that added benefits would be minimal: inherent safety of PPE would not be increased; selection, use and maintenance would not be enhanced; cost would burden employers; OSHA resources would be strained.



Conformity assessment isn't uniform

- Respirators are NIOSH tested and approved
 - NIOSH gets its regulatory punch through OSHA regulations
- Some PPE standards contain certification requirements
 - Firefighters demand independent certification in NFPA
 - Can be full third-party certification or some variant
- Third-party certification programs are voluntary and market-driven





The certification decision

- Risk
 - What is the risk to the user of noncompliant PPE?
 - What are the penalties for allowing non-conforming products into the marketplace?
- Regulatory requirements
 - What degree of certification does the government demand?
 - Does the standard require certification?
- Market factors
 - Does the customer expect independent certification?
 - Are competitors certifying their products? Are they bringing questionable products into the marketplace at lower prices?



It's a business decision

- Where do I want to sell my products?
 - What kind of certification is required?
 - Will the authorities accept another country's certification or mark?
- What level of certification do customers and users expect/demand?
- What's the cost?
- Do I test in-house or use an outside lab?
- Does my QA system meet requirements?
- What are my competitors doing?
- How do I ensure my OEM suppliers are conforming to standards and regulatory requirements?



Open questions

- How do responsible manufacturers compete against suppliers of substandard PPE?
 - Distributors importing and private labeling
 - Customer not looking beyond the product marking
 - No data to assess the extent of standards compliance
- Should NIOSH/NPPTL take a larger role?
 - IOM study recommended expansion of certification to all medium- or high-hazard PPE
 - But there's no infrastructure or legal basis to regulate
 - Enhanced worker protection or overkill?



ISEA manufacturers' approach

- Based on an assessment of user needs
 - Some users may need/want additional assurance of conformity
 - Independent certification may not be necessary in most cases
- Multi-level approach
 - Designed to allow the marketplace and regulators to specify appropriate level of conformity assessment
 - A consensus conformity assessment standard that is independent of any product standard, but applicable to all
 - Three levels to provide flexibility and choice



Conformity assessment standard

Level 1	Level 2	Level 3
Supplier testing	Supplier testing, ISO 17025-accredited lab	Independent third-party testing and certification
Quality management system	ISO 9001 registration	ISO 9001 registration
Supplier declaration of conformity	Supplier declaration of conformity	Third-party mark, certification
All levels require testing to a specified product standard, recordkeeping, verification of ongoing compliance, corrective action system, preventive action process, product recalls		



Conformity assessment standard

- Drafted by an ISEA task force
- Next step is an informal peer review
 - Are the purpose, definitions, requirement clear and unambiguous? Where does it need clarification?
 - Do levels provide valid confidence in desired product performance?
 - Does it harmonize with other recognized standards and norms for conformity assessment?
 - Are there shortcomings that could be exploited by a supplier to claim conformity without completing all the necessary procedures and steps?



Conformity assessment standard

- ISEA will conduct consensus/public review for approval as American National Standard
- Coordinate efforts with the NIOSH working group
- Contact Cristine Fargo to take part in the peer review or be on the consensus group

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