

July 9, 2021

Stephen Sanders
Technical Director

Safety Equipment
Institute

National Academies Meeting on Respiratory Protection



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Safety Equipment Institute Overview

- Non-profit charitable organization established in 1981
- Became an affiliate of ASTM International in 2016
- Administers voluntary PPE certification program open to all manufacturers
- Policies overseen by Committee on Certification Programs (CCP) under SEI Board of Directors –

Fire Service Rep, Insurance Rep,
Manufacturer, Organized Labor, Users,
Safety Consultants



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Certification Organization Accreditation

ISO/IEC 17065 “Conformity Assessment – Requirements for Bodies Certifying Products, Processes and Services”

Ensure fair & impartial treatment for all companies participating in the program that operates under a Controlled Policy & Procedures Manual.

SEI Board, Staff, Auditors, testing laboratories all agree to abide by.

- Accredited by both ANAB (U.S.) and SCC (Canada)
- Audits conducted annually of Certification Organization(s)
- Use of ISO/IEC 17025 accredited test labs
- Use of Qualified Auditors



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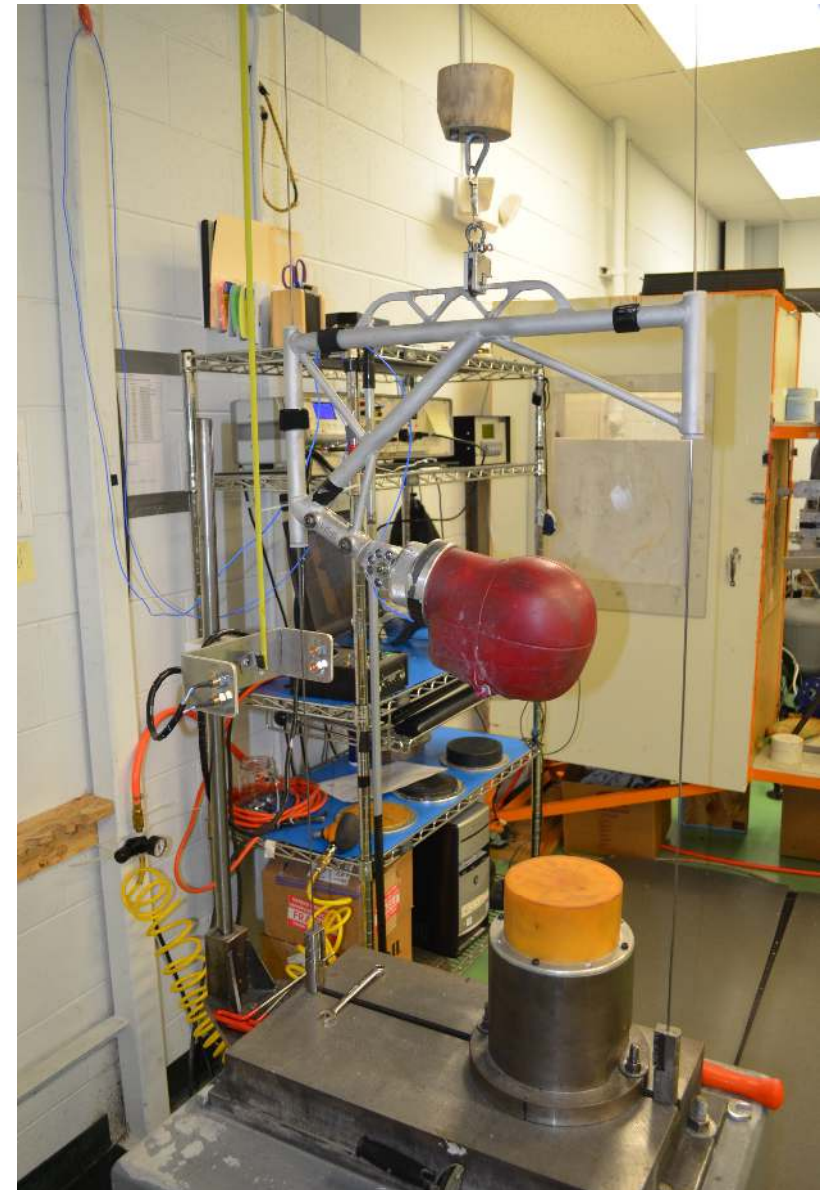
ISO/IEC 17065 Requirements

Requires Certification Organizations have Procedures for:

- Organization, Operations, Subcontracting, Quality System, etc.
- Certification Body Personnel – Competence
- Management of Impartiality, Confidentiality & Conflict of Interest
- Application for Certification
- Preparation for Evaluation – Testing & Auditing
- Evaluation Activities including Test Report and Quality Audit Report Evaluation
- Decision on Certification
- Use of Licenses and Certificates and Marks of Conformity
- Communicate Changes in Certification Program Requirements
- Appeals, Complaints and Disputes Procedure



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Program Types

Safety & Protective Equipment Programs

ASTM Standards:

- Safety eyewear, face protectors
- Recreational Helmets

Law Enforcement Standards:

- Law Enforcement Restraints
- Bomb Suits

NOCSAE Standards:

- Football, lacrosse & baseball helmets
- Football, lacrosse & baseball face protectors
- Shin guards
- Lacrosse balls, baseballs

NFPA Standards:

- Fire service SCBA
- Boots, helmets, gloves & garments for wildland, structural, hazmat & USAR responses
- Personal Alert Safety Systems (PASS) for firefighters
- Thermal Imaging Cameras (TIC's) for firefighters

ANSI & CSA Industrial PPE Standards:

- Emergency eyewash and safety shower equipment
- Fall-protection equipment
- Protective footwear



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Product Certification

Manufacturer Responsibility

- Manufacturer's Agreement
- Application for Product Certification with documentation, drawings, materials & components list
- Initial Testing Samples are sent to ISO/IEC 17025 accredited & SEI approved Testing Laboratory
- Quality Manual
- Procedures for Organization, Operations, Subcontracting, Quality System, Changes to Certified Product etc. presented during quality audit
- Customer Complaint Procedure
- Confirmation of appropriate product liability insurance
- Submit to annual testing and quality audits
- Recall Procedure approval



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Product Certification

Certification Organization Responsibility

- Following initial product testing and an on-site quality audit of the manufacturing facility, quality auditors return at least annually to evaluate significant organization or documentation changes
- Where possible, the auditor also selects samples for annual certification testing
- If needed, SEI evaluates any proposed changes to the certified product and determines if testing is required to maintain certification
- Proposed changes are classified as either “Class I” or “Class II changes. Class I changes require testing to confirm performance. Class II changes do not require testing (i.e., paperwork only)
- Maintain Web-based Certified Product Listings for user community access



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Product Certification

Compelling Factors for Certification

- Concerns about quality of products
- Substandard imports
- False claims of compliance
- Confusion among users
- Requirements for product liability insurance as recourse for users
- Manufacturers concerned about liability
- Product testing and quality assurance audits are repeated at regular intervals to ensure continued compliance
- Web based Certified Product Listings are available to public
- Certification staff involved in the standards process and work to support the organizing associations and governing bodies



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Product Certification

Factors against Certification

- Concerns about slow certification organization turn around times which could ultimately lead to time delays to market for newly developed or revised products
- Concerns about the additional cost(s) of testing and certification being passed on to users/consumers



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How Can SEI Help?

- SEI has a long history of cooperation with the National Institute for Occupational Safety and Health (NIOSH)
- Issuance of “joint certifications” with NIOSH for Fire Service SCBA
- Willing and able to initiate new, independent certification programs



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