Understanding Third-Party Certification of Personal Protective Equipment

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Certification of Protective Equipment

Who is SEI?

- Non-profit 501 (c)(3) charitable organization established in 1981 & became a subsidiary of ASTM International in 2016
- Administer the first non-governmental, third-party certification program to test and certify over 3000 personal protective equipment (PPE) products
- SEI policies are developed by a Committee which represents interests from: PPE users, corporate safety, organized labor, insurance industry, and manufacturer interests
- Headquarters in McLean, VA
Certification of Protective Equipment

**SEI Mission**

- To assist government agencies, users, and manufacturers in meeting their mutual goals of protecting those who use safety and protective equipment to protect from potential hazards.

- To aid advancements in protective equipment technology, using recognized standards and state-of-the-art test facilities.

- To support protective equipment manufacturers and users by providing an easily recognized mark for certified products.
Compelling Factors for the SEI Program

- There was universal interest among users and manufacturers
- There was concern about the possibility of poor quality products being sold in North America
- There existed false claims of compliance and certification
- There was confusion among users concerning noncertified vs. certified products
- There were high injury rates
- Manufacturers were concerned about liability and competition with noncertified products
Certification of Eye, Head & Face Protection

Meeting Industry Needs

• To fill a void, certification programs were initiated in 1981 with seed money from National Safety Council, corporate users of PPE, and manufacturers
• This was used to start programs for the certification of head protection, eye & face protection, fire fighter helmets and bicycle helmets
• The ASTM equestrian helmet technical committee approached SEI because of SEI’s reputation in head protection certification
• The NFPA initiated a requirement for third-party certification in all PPE standards
Certification of Protective Equipment

**SEI Accreditation by ANSI**
ISO/IEC 17065 “General Requirements for Bodies Operating Product Certification Systems”

- Audited annually at SEI HQ
- SEI test labs are accredited to ISO/IEC 17025
  - ICS, Intertek & SIRC are approved labs
- SEI auditors are ISO 9001 lead auditors
Certification Organization - Procedures

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

ISO/IEC 17065, Conformity Assessment – Requirements for bodies certifying products, processes and services
Initial Certification for Manufacturer

- Application for product certification including submission of documentation, drawings, materials & components
- Signs contract agreeing to terms of certification
- Product samples submitted for testing in accordance with performance standard at ISO/IEC 17025 accredited laboratory
- Review of design requirements, labels and user information
- On site quality audit of entire Manufacturing Process
- Confirmation of appropriate Liability Insurance
- Approval of Product Recall Procedure
**Certification Process**

**SEI Surveillance and Follow-up**

- Following the initial product testing and an on-site quality audit of the manufacturing facility:
- SEI auditors return annually to evaluate significant organization, procedural or documentation changes
- The auditor also selects samples for annual certification testing
- These annual test samples are randomly selected during the manufacturer’s annual site audit.
Standards Used by SEI

- American Society for Testing and Materials
- American National Standards Institute
- National Fire Protection Association
- National Operating Committee on Standards for Athletic Equipment (NOCSAE®)
- National Institute of Justice (NIJ)
NFPA Standards & Conformity Assessment

Conformance and Risk

- Supplier's Declaration
  - 1st party conformity assessment
- Certification
  - 3rd party conformity assessment

Perceived Risk vs. Independence and Rigor of Conformity Assessment
The NFPA Certification Program Requirements
  - Contained in Chapter 4 of all PPE standards
- Used to demonstrate product conformity to Standard
- Referenced combination of time-tested accreditation and certification systems
- Federal Agencies, User Organizations
- Additional oversight by Accreditation Organization of Certification Process
Certification Program Requirements

Key Elements (Certification Organization):

- Must be independent
- Accredited to ISO/IEC 17065
- Accreditation organization must meet ISO 17011
- Testing performed by laboratories accredited to ISO 17025
- Performs quality assurance audits
- Provides follow-up program
Program Requirements

- Shall have ISO 9001 registered quality programs
- Must have safety alert and product recall procedure
- Audits of manufacturer’s facilities are performed by the certification organization twice a year
- Annual test specimens are randomly selected during the manufacturer’s site audit
Program Requirements

- Customer Complaints are reviewed
- Use of Certification Mark
- Testing on PPE is conducted annually or more often if required to ensure the user of continued compliance
- Web based Certified Product Listings are available to community to access
- The manufacturer submits to ongoing scrutiny of products and processes and agrees to recall non-conforming products
Initial Determination of Structural Glove Compliance to NFPA 1971

- Submit Glove Samples
- Review of Labels and Markings
  - Principle materials of construction, compliance information, manufacturer & model details
- Review User Information
  - Limitations, warranty, sizing, storage, cleaning, etc.
- Review of Design Requirements
  - Measurements, sizing, interface, etc.
- Quality Assurance audit conducted at Manufacturing Facility
- Confirmation of Manufacturer’s Overall Management System
Full testing on glove samples Submitted by Manufacturer

- Thermal Protective Property
- Heat and Thermal Shrinkage Resistance
- Heat & Flame Resistance
- Thread Melting
- Viral & Liquid Penetration Resistance
- Overall Liquid Integrity
- Cut & Puncture Resistance
- Burst & Seam Breaking Strength
- Glove Hand Function
- Glove Donning & Liner Retention
- Label Durability & Legibility
- Grip, Torque & Tool tests
## Where to look for certification labels

<table>
<thead>
<tr>
<th>Certification Label</th>
<th>NFPA Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fire Service Open-Circuit Self-Contained Breathing Apparatus</td>
<td>NFPA 1981</td>
</tr>
<tr>
<td>Personal Alert Safety Systems (PASS) for Fire Fighters</td>
<td>NFPA 1982</td>
</tr>
<tr>
<td>Fire Service Life Safety Rope, Harness, and Hardware</td>
<td>NFPA 1983</td>
</tr>
<tr>
<td>Liquid Splash-Protective Ensembles and Clothing for Haz Mat Emergencies</td>
<td>NFPA 1992</td>
</tr>
<tr>
<td>Protective Clothing for Emergency Medical Operations</td>
<td>NFPA 1999</td>
</tr>
<tr>
<td>Protective Ensemble for Structural Fire Fighting</td>
<td>NFPA 1971</td>
</tr>
</tbody>
</table>
## Other Certification Programs

### Law Enforcement & Industrial Programs

<table>
<thead>
<tr>
<th>Category</th>
<th>Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIJ Public Safety Bomb Suits</td>
<td>NIJ 0117.00</td>
</tr>
<tr>
<td>Fall Protection</td>
<td>CAN/CSA Z259 series</td>
</tr>
<tr>
<td></td>
<td>ANSI Z359 Series</td>
</tr>
<tr>
<td>Eye &amp; Face Protection</td>
<td>CAN/CSA Z94.3</td>
</tr>
<tr>
<td></td>
<td>ANSI Z87.1</td>
</tr>
<tr>
<td>Protective Headwear for Industrial Workers</td>
<td>CAN/CSA Z94.1</td>
</tr>
<tr>
<td></td>
<td>ANSI Z89.1</td>
</tr>
<tr>
<td>Criminal Justice Restraints</td>
<td>NIJ 1001.00</td>
</tr>
</tbody>
</table>

A Subsidiary of ASTM INTERNATIONAL
# NIJ Companion Document – Certification Requirements

## Public Safety Bomb Suit Certification Program Requirements

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Initial Determination of Compliance to NIJ Public Safety Bomb Suit Standard

- Full testing on Public Safety Bomb Suit Submitted by Manufacturer to NIJ Standard-0117.00
- Review of Form and Fit for Bomb Suit
- Review of Labels and Markings for Bomb Suit
- Review User Information and Technical Data Package
- Quality Assurance audit conducted at Manufacturing Facility
- Confirmation of Manufacturer’s Overall Management System
Performance requirements in NIJ Standard- 0117.00

- Ergonomics
  - Donning & doffing, field of view, completion of test course, gross mobility
- Optics
  - Distortion, refractive power, haze resistance
- Flammability
- Electrostatic Discharge
- Head Protection
  - Impact, perforation, retention system

And others..................
NIJ Certification Requirements

- Requirements for product liability insurance as recourse for users

- Web based Certified Product Listings are available to public
## Additional Certification Programs

### Sports & Athletic Programs

<table>
<thead>
<tr>
<th>Activity</th>
<th>Certification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equestrian Helmets</td>
<td>ASTM F1163</td>
</tr>
<tr>
<td>Baseball/Softball Batters Helmets</td>
<td>NOCSAE ND022</td>
</tr>
<tr>
<td>Football Helmets</td>
<td>NOCSAE ND002</td>
</tr>
<tr>
<td>Women’s Lacrosse Headgear</td>
<td>ASTM F3137</td>
</tr>
</tbody>
</table>
Certification Requirements – NOCSAE Sports & Athletic Equipment

7 Labels and Warnings

7.1 See Section 9, NOCSAE DOC.001.

7.2 Each helmet shall have permanently affixed to the exterior of the shell a clearly legible statement which can be easily read without removal of any decal tape, other temporary material or permanent part, which contains language which effectively communicates to the purchaser and user the following information, using the same or similar language:

WARNING
NO HELMET CAN PREVENT ALL HEAD OR ANY NECK INJURIES A PLAYER MIGHT RECEIVE WHILE PARTICIPATING IN FOOTBALL.
DO NOT USE THIS HELMET TO BUTT, RAM OR SPEAR AN OPPOSING PLAYER. THIS IS IN VIOLATION OF THE FOOTBALL RULES AND SUCH USE CAN RESULT IN SEVERE HEAD OR NECK INJURIES, PARALYSIS OR DEATH TO YOU AND POSSIBLE INJURY TO YOUR OPPONENT.

7.3 A permanent, exact replica of this seal must appear legibly on the exterior of the shell.

NOTE: You must have an executed, valid license agreement with NOCSAE to use any of the NOCSAE logos at any time. NOCSAE, the NOCSAE seallogos, and the National Operating Committee on Standards for Athletic Equipment are registered marks and the exclusive property of the Committee. Use of the marks in any manner is prohibited without prior written permission of the NOCSAE Board of Directors.

This standard is subject to revision at any time by the responsible technical authority and must be reviewed every five years and if not revised either reapproved or withdrawn. Your comments are invited either for revision, modification or creation of additional standards and should be addressed to NOCSAE's Executive Director. Check the web at www.nocsaee.org to obtain the latest version of a standard.

This standard is copyrighted by NOCSAE 11029 King St. Suite 213, Overland Park, Kansas 66210 USA. Copies may be obtained from the NOCSAE web site at www.nocsaee.org.
NOCSAE Certification Requirements

- Accreditation of Certification Organization to ISO 17065
- Quality Audits at manufacturer
- Specific QA/QC protocols
- Annual Product testing
- Surveillance Audits
- Recall Requirements
Benefits of third-party certification

- Product testing and quality assurance audits are repeated at annual intervals to ensure the user of continued compliance of product to standards.

- These annual audits provide oversight and ongoing scrutiny of products and processes and the manufacturer agrees to institute corrective actions.

- SEI evaluates any proposed changes to the certified product and determines if additional testing is required.
More Benefits…..

- Complaint logs are reviewed at quality audits to ensure proper handling
- Requirements for product liability insurance as recourse for users
- Timely adoption of new or revised standards
- Web based Certified Product Listings are available to public
Public Certification Information

Product Listings & Safety Alerts:

SEI Safety Alerts

The following list represents Product Safety Alerts Issued through the Safety Equipment Institute. If you are looking for a specific alert and do not see it listed below, please feel free to contact us.

<table>
<thead>
<tr>
<th>Date Issued</th>
<th>Alert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug. 2013</td>
<td>US Safety - Blaze 3.0 IR Frames - Safety Notice</td>
</tr>
<tr>
<td>Nov. 2012</td>
<td>Mine Safety Appliances (MSA) - Air Gauge for AirHawk® II, BlackHawk® &amp; FireHawk® M7 Air Masks - User Notice</td>
</tr>
<tr>
<td>Nov. 2012</td>
<td>Ansell Protective Solutions - VPS Flash Ensemble - Safety Notice</td>
</tr>
<tr>
<td>July 2012</td>
<td>NIOSH — SCBA Care &amp; Maintenance — User Notice</td>
</tr>
<tr>
<td></td>
<td>NFPA — SCBA Lenses — Alert Notice</td>
</tr>
<tr>
<td></td>
<td>Mine Safety Appliances (MSA) — V-Guard Cap — Labeling Error — User Advisory</td>
</tr>
<tr>
<td>June 2012</td>
<td>Mine Safety Appliances (MSA) — Cairns S501 — Lens Impact Resistance — User Notice</td>
</tr>
<tr>
<td>Aug. 2011</td>
<td>Honeywell - Sperian/Survivair SCBA - Air Klic Interface - Safety Notice</td>
</tr>
<tr>
<td>June 2011</td>
<td>Superior Glove Works - SURGE 670SG Glove - Safety Notice</td>
</tr>
</tbody>
</table>
Listing of Certified Products

WWW.SEINET.ORG

Questions?