

Current Issues in the Assessment of Respiratory Protective Devices: non-Traditional Workers and Public Use

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Session 1

LESSONS LEARNED FROM THE LAST 100 YEARS OF RESPIRATORY PROTECTION

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Lessons learned from the last 100 years of Respiratory Protection and how these can be applied to the assessment of respiratory protective devices (RPD) moving forward

- ❑ Describe Conformity Assessment (CA)
- ❑ Describe the evolution of U.S. CA and respirator approval, and lessons learned that inform planning for future needs – occupational and public use of respirators



Conformity Assessment (CA)

Conformity Assessment is the demonstration that specified requirements relating to a product, process, system, person or body are fulfilled.

CA can include

- ☐ Supplier's declaration of conformity (SDoC)
- ☐ Certification
- ☐ Sampling and testing
- ☐ Inspection
- ☐ Management system assessment and certification (QA)
- ☐ Product quality control (QC)
- ☐ Accreditation of the competence of CA activities
- ☐ Recognition of an accreditation program's capability

<https://www.nist.gov/topics/conformity-assessment>

Conformity assessment activities form a vital link between standards and products, services, processes, systems, personnel qualifications and organizations.

https://www.standardsportal.org/usa_en/conformity_assessment/conformity_assessment.aspx

RPD requirements are typically defined in American National Standards developed by ANSI accredited standards development organizations (SDOs) or regulations.

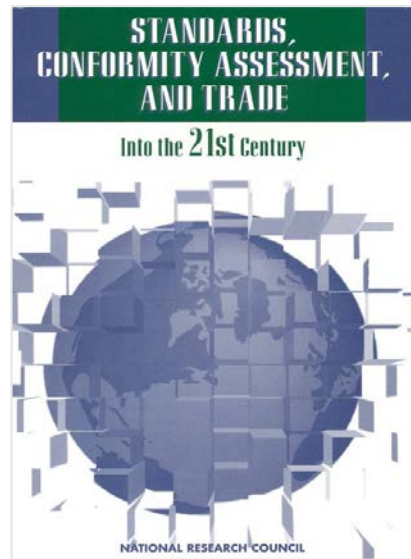
- ☐ Design
- ☐ Performance
- ☐ Quality Assurance & Control
- ☐ Reliability
- ☐ Labeling
- ☐ Cautions, Use and Limitations Instructions

Lesson 1 - Conformity Assessment

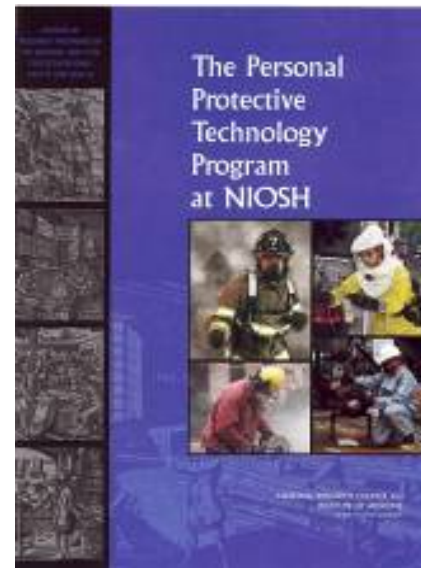
NAS has studied and made recommendations for effective conformity assessment including for PPE and RPD.

“NIOSH’s National Personal Protective Technology Laboratory (NPPTL) should serve in a leadership role....to implement a comprehensive, tiered risk-based framework for classification and conformity assessment of PPT for specific applications.

<https://www.nap.edu/catalog/12962/certifying-personal-protective-technologies-improving-worker-safety>



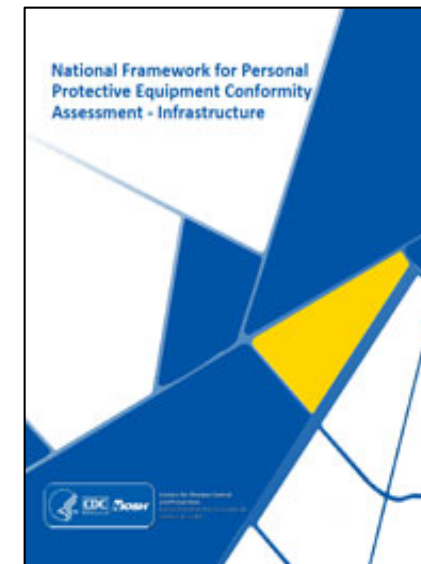
1996



2008



2011

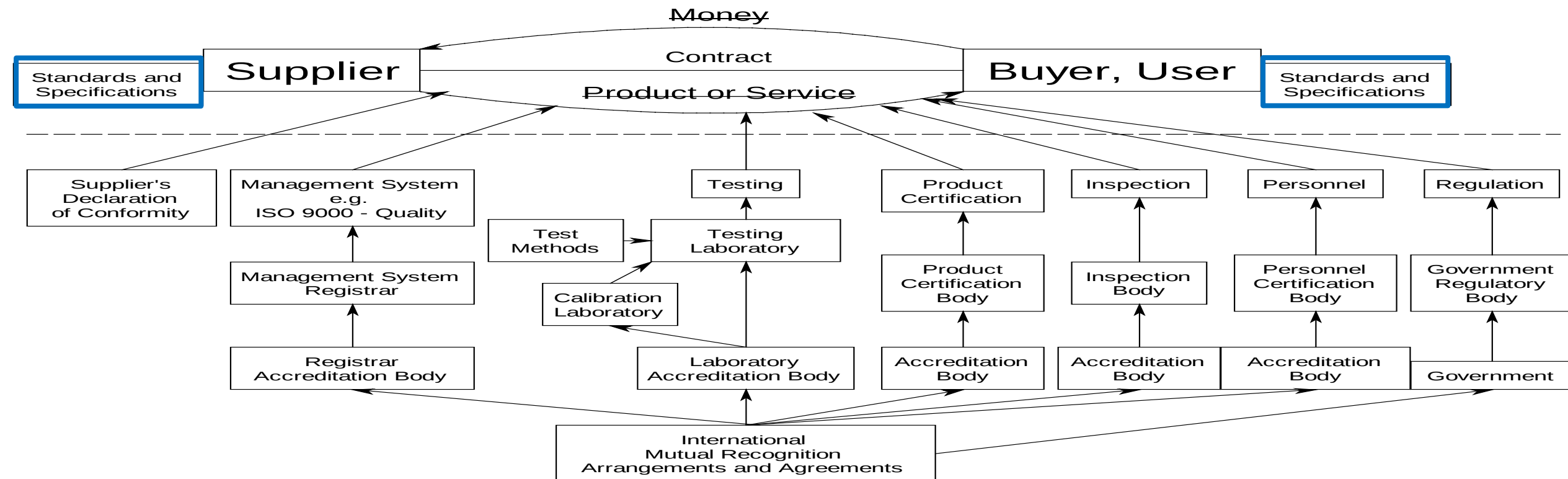


2018

Lesson 2 - Conformity Assessment

U.S. CA Infrastructure is robust and can support risk-based PPE CA using private-sector CA programs with centralized oversight applying NIOSH PPE CA Framework to ensure CA Program effectiveness.

DOMESTIC AND INTERNATIONAL TRADE



CONFORMITY ASSESSMENT

Respiratory Protective Device (RPD) Approval

Certificate of Approval is based on – *Permissibility* – “safe for intended use”

USBM basic health and safety requirements for all Approved RPD:

- ☐ Give adequate protection for intended use
- ☐ Reasonably comfortable and convenient to wear
- ☐ Provide an acceptable period of protection
- ☐ Be constructed of durable materials

Citation examples:

I.C. 7086, September 1939, H.H. Schrenk

Page 2, First Paragraph (*purpose of certificate of approval*)

Page 7, Second Paragraph (*adequate protection, reasonable comfort, satisfactory period of protection*)

Page 8, Third Paragraph (*filtering efficiency based on safe, permissible limits*)

Page 9, Second Paragraph (*particle size equal to or less than size found in mining*)

I.C. 7792, June 1957, S.J. Pearce

Page 1, First Paragraph (*standards to be safe for use under specified conditions*)

Page 2, Second Paragraph (*based field of use...*)



1919 –1972

Lesson 3 – Respiratory Protective Device Approval

CA is necessary to safeguard personal protection but not sufficient to ensure intended protection.

- ❑ RPD Program is vital to assure proper selection, use, and maintenance
- ❑ Certification **≠ Approval**
- ❑ U.S. Law requires new standards do not reduce protection
- ❑ Centralized CA Program oversight can assure effectiveness
 - New or evolving hazards
 - Technology advancements
 - Updated requirements or revised standards
 - Transitions or “Grandfather periods”
 - Resolutions of non-conforming products
 - CA process evaluations



National Strategy

RPD CA is a component of a broader U.S. integrated system of requirements to ensure protections.

- ☐ US laws and regulations
- ☐ Industrial hygiene infrastructure – AIHA ACGIH
- ☐ US standardization infrastructure – ANSI accreditation of standards development organizations (ASTM, NFPA, AIHA, ISEA)
- ☐ US CA infrastructure – Accreditation bodies, testing & calibration laboratories, certification bodies, etc.
- ☐ Federal and private research

Lesson 4 – National Strategy

A public protection system with recognized administrative authority (ies) can integrate safety and health and CA risk-based requirements to ensure PPE wearers are and remain properly protected.

A nationally recognized authority can

- **Establish and maintain protection requirements based on hazards and risks**
- **Investigate non-conformance and fraudulent CA declarations; remove non-conforming products**
- **Inform and provide public guidance**
- **Update processes and requirements to address new or evolving hazards, advancements in technologies, and revised or new national consensus standards**

The absence of a centralized authority or failure to perform these oversight functions weakens protection and reduces confidence in PPE conformance declarations.

Summary

4 Key Lessons

Lesson 1 – Conformity Assessment – NAS has studied and made recommendations for effective conformity assessment of personal protective technologies (PPT).

- ❑ *“NIOSH’s National Personal Protective Technology Laboratory (NPPTL) should serve in a leadership role and convene other relevant governmental agencies, certifying and accrediting organizations, manufacturers, and end users to develop and implement a comprehensive, tiered risk-based framework for the classification and conformity assessment of PPT products for specific applications.”*

Summary

4 Key Lessons

Lesson 2 – Conformity Assessment – U.S. CA Infrastructure is robust and can support risk-based PPE CA using private-sector programs applying NIOSH PPE CA Framework and with centralized oversight.

- ❑ CA programs must integrate hazard assessment, product selection, standards or requirements, CA activities and conformance declarations, program and product evaluation, and on-going surveillance administered by a recognized authority.
- ❑ Can be applied by NIOSH to update its approval program.
- ❑ For public applications a centralized authority is required.

Summary

4 Key Lessons

Lesson 3 – Respiratory Protective Device Approval – CA is necessary to safeguard personal protection but not sufficient to ensure intended protection.

- ☐ RPD Program is vital to assure proper selection, use, and maintenance
- ☐ Certification **≠ Approval**
- ☐ U.S. Law requires new standards do not reduce protection
- ☐ Centralized CA Program oversight can assure effectiveness
 - New or evolving hazards
 - Technology advancements
 - Updated requirements or revised standards
 - Transitions or Legacy Periods
 - Resolutions of non-conforming

Summary

4 Key Lessons

Lesson 4 – National Strategy – A public protection system with recognized administrative authority(ies) can integrate safety and health and CA risk-based requirements to ensure PPE wearers are and remain properly protected.

A nationally recognized authority can

- ☐ Establish and maintain protection requirements based on hazards and risk
- ☐ Investigate non-conformance and fraudulent CA declarations; remove non-conforming products
- ☐ Inform and provide public guidance
- ☐ Update processes and requirements to address new or evolving hazards, advancements in technologies, and revised or new national consensus standards

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Planning Committee Discussion

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