Good Testing Laboratory Practices

CONSIDERATIONS TO ENHANCE QUALITY AND RESULT VALIDITY IN THE CONFORMITY ASSESSMENT OF PERSONAL PROTECTIVE EQUIPMENT

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PRESENTER BACKGROUND

- 9 years working in/with the conformity assessment of PPE.
- Published on the topic of how testing and certification paradigms effectively create a variety of public and private regulatory frameworks for products the public relies on to protect against injury and preserve life. (*Cleveland-Marshall College of Law Journal of Law & Health Vol. 29 Issue 1*)
- Certified Quality Auditor since 2015. Licensed to practice law in OH since 2013.
- Active participation in multiple standards development organizations: ANSI, ASTM, CSA, NOCSAE, ISO). Member of ASTM Committees F08, F23, and E54. Chairman of ASTM Subcommittee F08.15 (Ice Hockey) from 2018 to present.
- Consult & advise clients on a variety of regulatory concerns regarding PPE performance and conformity assessment as it relates to QMS requirements, regulatory requirements, compliance solution and multiple legal considerations like importation, products/design liability, recall and labelling.

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ICS LABORATORIES, INC

- Independent Third-Party Testing Laboratory Accredited by the American Association for Laboratory Accreditation (A2LA)
- ICS Laboratories evaluates a wide variety of personal protective equipment (PPE) including eye and face protection, head protection, respiratory protective equipment, chemical protective clothing, athletic equipment, hand protection, hearing protection & more.
- ICS tests products according to a wide range of mandatory and voluntary standard test methods, standard performance requirements and standard material specifications.
- Conformity Assessment (testing and certification) of PPE and accompanying regulatory requirement of same is the primary means to verify conformity with regulatory requirements and/or market-determined-norms for product performance, which implicates the safety and often the livelihood of users and the public at large.

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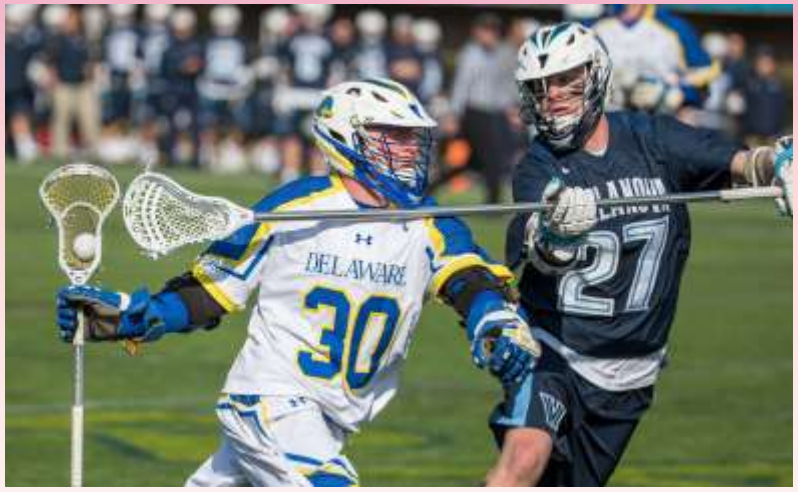

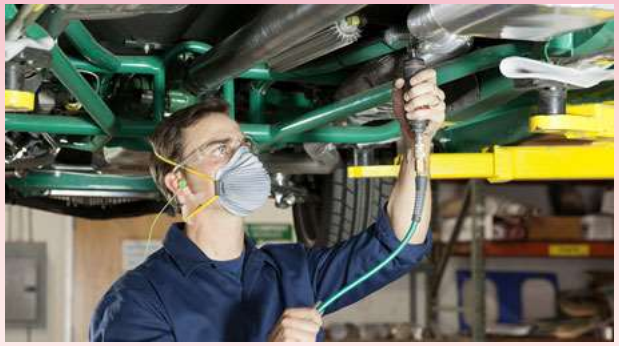

ACCREDITATION

- ICS Laboratories is ‘accredited’ on the basis of meeting the requirements of the ISO/IEC 17025:2017 “General Requirements for the competence of testing and calibration laboratories” document.

- Based on the quality precepts of ISO 9001 but adjusted to address measurement/assessment.
  - ”Accreditation” vs “Registration”
  - Product vs Reported Data/Results
  - Structural, Resource, Process and Management System requirements

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SCOPE OF ACCREDITATION

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BASIC PRINCIPLES/TENETS OF 17025's REQUIREMENTS FOR LAB COMPETENCE

- Data Validity and Transparency of Process
- Capacity/Capability
  - Resources (facilities, equipment, consumables, management system)
  - Human Resources (education, training, experience, knowledge, skill)
- Repeatability/Reproducibility
- Impartiality/Confidentiality
- Traceability of Measurement
- Traceability of Results
- Safety!

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SYSTEM REQUIREMENTS FOR LABORATORY COMPETENCE

- Document Control
- Records Control
- Control of Suppliers (Technical (EQ, Consumable), Testing SubK)
- Contract Review (Communication & Consensus)
- Systems for Monitoring Conformity Internally
  - Internal Audits and Management Reviews
- Systems for Evaluating and Resolving Non-Conforming Conditions
  - Tracking Feedback, Root Cause Analysis and Corrective Actions
- Systems for Identifying and Addressing Risk
  - Preventive Actions & Continuous Improvement

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RECORDMAKING CONSISTENCY AND COMPLETENESS

- Essential for result traceability: Complete and accurate records facilitate tracing back the steps/inputs of testing when necessary to investigate results
- Documentation is the backbone of proper laboratory operation. Records:
  - create definition of the process and their controls
  - constitute primary evidentiary function to demonstrate comformity
  - are the basis for the analysis and evidence-based decision-making designs to come out of systems.
- Immediacy of recordmaking
- Controls on ”automated” aspects of measurement:
  - Operator interaction with data collection interface = process is monitored and increases chances that OOT conditions will be caught
  - “Clinging to the Analog” vs LIMS (Convenient/Seamless or “Mindless”)

Review mechanisms and processes that require evaluating at least the existence-of (but ideally involve interacting with the contents-of) records helps ensure that records will be made. (Expectations / Accountability)

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“STANDARDS” AS THE BASIS OF TESTING/CERTIFYING PPE

- What are “Standards”
  - Developed by Standard Development Organizations (SDO’s)
  - Variety of affiliations, regional relevance, membership criteria, degrees of ‘consensus’ integrated into development processes
  - Standard Test Methods, Standard Performance Requirements, Standard Material Characteristics, etc.

ASTM INTERNATIONAL

JIS

NFPA®

National Institute for Occupational Safety and Health NIOSH

CSA®

SOLDIER

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STANDARDS-BASED CONFORMITY ASSESSMENT OF PPE

- Method/Document Fidelity
- Standards must be “integrated” into the laboratory’s management system and on record as such
  - Review by subject matter experts, notice of contents
  - Monitor for revisions/changes

How to Connecting Lab Reality/Processes to the Document(s)

What is the Context of the Text ?

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STANDARDS-BASED CONFORMITY ASSESSMENT OF PPE

- USING DOCUMENTATION TO IMPLEMENT STANDARDS
  - ISO 17025 - Quality Manual and Standard Operation Procedures
  - Technical Standards/Methods – Use of Work Instructions and Informative Data Sheets
    - Work Instructions provide granular detail on test set up, equipment use, step-by-step procedures, quality considerations to be attended to during testing (record-making, verifications of set-up, response, conditions, etc)
    - Policies and Datasheets are additional systemic reinforcements of how testing and other technical processes should be carried out

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STANDARDS-BASED CONFORMITY ASSESSMENT OF PPE

- USING STANDARDS – WHAT IS THE CONTEXT OF THEIR TEXT
  - Challenges endemic to all documents apply to test methods : translation, lack of detail, ambiguity, etc – (and can affect results)
  - What sources of information are authoritative / valid?
    - Officially published/promoted clarifications and technical guidance
    - SDO meeting minutes and technical notes
    - Correspondence?

Interpretations Deviations Clarifications

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STANDARDS-BASED CONFORMITY ASSESSMENT OF PPE

- Active Participation In/With Standards Development Organizations (where/when possible) – input opportunities, improvement of standards, access to valuable information related to context (minutes, drafts, discussions)
- Awareness of Legal and Regulatory Compliance Realities Relevant to the Laboratory's Technical Competencies and Client Markets
- Monitoring Standards–Related Activities, Undertakings and Developments

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MECHANISMS/PRACTICES TO PROMOTE TEST VALIDITY

- Process Transparency
  - Document everything, from initial quote request to report issuance.
- Comparative Testing
  - Internal: Repeatability and Reproducibility Studies, Internal Audits, Verifications & Set Up Checks
  - External: Accredited Proficiency Tests, Interlaboratory Comparisons, Round Robin Testing
- Eliminate Conflicts of Interest & Threats to Impartiality – Preserve Confidentiality
- Develop and Maintain Subject-Matter Expertise
  - Meaningful Engagement With Methods/Requirements (translation into internal docs)
  - Well-defined and documented training procedures and practices
  - Recruit technical personnel with special training and skills

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MECHANISMS/PRACTICES TO PROMOTE TEST VALIDITY

- Measurement Traceability
  - Calibrate measurement equipment or equipment that is otherwise specified/defined and can/may influence test results using a traceable calibration resource, preferable one that is accredited.
- Result Traceability
  - Document all variables, inputs, etc that could influence test results
    - Operator, Area, Equipment Used, Environmental Conditions
    - Where testing implicates visual inspection, take photographs as appropriate.
  - Create and preserve records of performed & reported testing to facilitate recall

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MECHANISMS/PRACTICES TO PROMOTE TEST LAB SAFETY

- TRAINING

- Written (documented, implemented and regularly reviewed) safety programs
  - Respiratory Protection Program
  - Chemical Hygiene Program
  - Hazcomm , Fire Safety, Evacuation Procedures, Emergency Contacts, basic GLP
- Signage, Provision of Proper PPE, Verify Observation of Safety Protocols

- Continually build-on & refresh knowledge of requirements and best practices relevant to laboratory (and workplace, generally) safety

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BEST PRACTICES FOR OVERCOMING RECENT PPE TEST LAB CHALLENGES

- COMPLETE RECORDS AND THOROUGH DOCUMENTATION
- EVIDENCE OF PROCESS/METHOD CONTROL
- OPERATION OF ACCOUNTABLE AND EFFECTIVE SYSTEMS
- ACTIVE STANDARDS-DEVELOPMENT PARTICIPATION & MAINTAINED AWARENESS OF REGULATORY LANDSCAPE

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THANK YOU!

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