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.
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
SCOPE OF ACCREDITATION
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!

ICS INC. LABORATORIES
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
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 conformity
  - 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)
“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.
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?
STANDARDS-BASED CONFORMITY ASSESSMENT OF PPE

- USING DOCUMENTATION TO IMPLEMENT STANDARDS
  - 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
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
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
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
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
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
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
THANK YOU!