A Proposal to Establish a Proficiency Testing System for Chemical Challenge Testing of Respirator Cartridges

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Proficiency Testing

(definition)

Stable, homogeneous Test Articles are identified or developed by a Coordinator and given Assigned Values.

Participants evaluate Test Articles and submit Test Values to a Coordinator who keeps results confidential and compares them to the Assigned Values.

The degree of agreement between Test Values and Assigned Values for a particular Participant determines “proficiency”. Each Participant is notified as to its level of “proficiency”.

Collaborative Testing

(round-robin)

Test Articles believed to be stable and homogeneous are identified or developed and distributed by a Coordinator.

Participants evaluate Test Articles and submit Test Values to a Coordinator who keeps results confidential and analyzes them.

Agreement or non-agreement among Test Values from multiple Participants is used to identify.

- Reference Labs capable of generating Assigned Values
- Difficulties with the Test Methods
- Difficulties with stability/homogeneity of Test Articles

Coordinator provides Participants with a summary report that may advance findings or conclusions, but does not judge Participants.

Inter-Laboratory Comparison
(ILC)

A term that can apply equally to:

Proficiency Testing

- ILC in which Participants are judged

Collaborative Testing

- ILC in which Participants are not judged

ISO/EC 17043

Conformity Assessment
General Requirements for Proficiency Testing

- Applies to Proficiency Testing
  - In which Participants are judged
- Does Not Apply to Collaborative Testing
  - In which Participants are not judged

Collaborative Testing vs Proficiency Testing

- Requirements for Proficiency Testing
  - Definitive Test Methods
  - Reference Lab(s)
  - Assigned values for Test Articles
- Requirements for Collaborative Testing
  - Test Methods
  - Homogeneous, Stable Test Articles
  - Desire for Collaboration
- Collaborative Testing can evolve toward Proficiency Testing

Evolution of Proficiency Testing

Collaborative Test Cycles
Inter-Laboratory Comparison

Analyze Discrepancies
Address Problems

Standardize Test Methods
Inter-Laboratory Meetings

Identify Reference Labs
Develop Assigned Values

Proficiency Testing Program

Survey of Interest in Collaborative Testing Program

(August 2014)

- 163 Respiratory Protection Professionals Queried
  - Mainly ISRP & AIHA Members
- 44 Participated in Survey
  - 27% response
- Demographics
  - Manufacturer (28) 64%
  - Testing Lab (3) 7%
  - Government (3) 7%
  - End User (3) 7%
  - Sorbent Mfr (3) 7%
  - Other (4) 8%

Survey Results
Collaborative Testing Program

- Test Labs Represented by Survey Respondents
  - 1 Test Lab (15) = 15
  - 2 Test Labs (5) = 10
  - 3+ Test Labs (9) = 27+

- **More than 52 Test Labs**
  - **Represented in Survey**

Survey Results
Collaborative Testing Program

- Do you believe a Collaborative Test scheme that could evolve into a proficiency testing program would be beneficial to the respirator community? (42 responses)
  - 93% - YES (39)
  - 7% - NO (3)
- Do you believe there would be general interest and/or support within your organization for a Collaborative Test scheme that could evolve into a proficiency testing system (40 responses)?
  - 30% - Very Likely (12)
  - 40% - Likely (16)
  - 10% - Unlikely (4)
  - 8% - Very Unlikely (3)
  - 12% - Don't Know (5)

Collaborative Testing Program

Suggested Benefits from Survey Participants

- Please summarize what you see as the benefits for your organization and/or the respirator community as a result of participation in a Collaborative Testing program
  - Identify & illuminate lab-to-lab differences (3)
  - Improved Understanding of Test Methods (3)
  - Address questions of equivalence (3)
  - Improved Confidence in Respirators (2)
  - Standardization is Always Good (4)

Collaborative Testing Program

Actual Comments from Survey Participants

- "Consistent differences in test results have been seen between private and government laboratories. Any initiatives that would reduce this would be a benefit."
- There is always the question of equivalence between test houses on gas capacity testing. Round –robin testing would allow differences to be evaluated."
- "It would identify differences between testing performance of participant labs – although not the reasons (initially). It might make labs realize the significance of their estimates for measurement uncertainties. My experience of ILCs so far indicates that the importance of this aspect (MUs) is widely under-rated – and in many cases misunderstood, or even ignored."

Collaborative Testing Program

Suggested Benefits from Survey Participants

- “It would give us more confidence that required protocols are achieved, and that inter-laboratory variation is minimized.”
- “Confidence in quality and reliability of results.”
- Standardization, reliablility, confidence.”
- “Confidence in results, comparison between labs.”

Collaborative Testing Program

Suggested Benefits from Survey Participants

- “Better understanding of what works and how well it works.”
- “Confidence in quality and reliability of results.”
- “Standardization of test methods and correlation between laboratories is of high value for commodity testing of carbon and other adsorbents and product testig limits for filters. It is of potential large value for customers.”

Collaborative Testing Program

Suggested Drawbacks from Survey Participants

- Please summarize what you see as drawbacks or concerns about your organization's participation in a Collaborative Testing program.
- 26 of 44 Respondents did not voice concerns
- 18 of 44 Respondents voiced drawbacks or concerns
  - Cost - may be too expensive (7)
  - Protect proprietary information (4)
  - Protect anonymity of participant labs (4)
  - Other (3)

Collaborative Testing Program

Actual Comments from Survey Participants

- "The only concern would be dedicating resources to an effort not directly aligned with organizational goals."
- "Cost" (3)
- Two things: time and money. If it takes a considerable amount of time or there are substantial costs involved, then this would not be supported."
- "May not have the resources to participate."

Collaborative Testing Program

Actual Comments from Survey Participants

- "A concern would be around anonymity – we are happy to share results as part of a general pool, but would want to avoid identification as the originator of a particular set of results. In the Proqares studies, labs were identified by a letter in charts and suummaries. We were told which letter was our lab, and which was Proqares, all others were unknown to the participants."

- "Our company would require strict anonymity … "

Collaborative Testing Program

Actual Comments from Survey Participants

- “The program would need to overcome concerns about protecting proprietary information for most industrial companies.”
- “Loss of intellectual property, spending more company time educating other companies then we get in return.”
- “Coordination and non-disclosure of trade secrets.”

Conclusions from Survey

Actual Comments from Survey Participants

- High response rate (27%) indicates interest in the topic.
- A large majority of respondents (90%) is in favor of Collaborative Testing provided "drawbacks" are avoided.
  - Reasonable Cost
  - Confidentiality
  - Anonymity
  -
- Reasonable approach … Collaborative Testing
  - Evolve toward Proficiency Testing at some future time.

Evolution of Proficiency Testing

Collaborative Test Cycles
Inter-Laboratory Comparison

Analyze Discrepancies
Address Problems

Standardize Test Methods
Inter-Laboratory Meetings

Identify Reference Labs
Develop Assigned Values

Proficiency Testing Program

Proposal

- Begin with a Collaborative Testing Program
  - Inter-Laboratory Comparison
  - Results Anonymous & Confidential
  - No judging of Proficiency
- Identify or fabricate Test Articles
  - Homogeneous, Stable
- Select Tests to Perform
  - Easy Tests (stable agents)
  - Difficult Tests (reactive agents)

Selecting Test Methods

Type of Process	Challenge Agent
Stable, Non-Reactive Gas	Sulfur Dioxide, Ammonia
Stable Vapor	Cyclohexane
Reactive Gas	Cyanogen Chloride
Reactive Vapor	Acrolein
Catalytic Reactor	Phosphine

Selecting Test Methods

Degree of Difficulty	Challenge Agent
Straightforward Tests	Sulfur Dioxide, Ammonia, Cyclohexane, Hydrogen Sulfide, Chlorine
Test Methods that may have Problems	Formaldehyde, HCl, HF, HCN, NO2, Carbon Monoxide, Cyclic Tests
Test Methods that likely have Problems	Chlorine Dioxide, Tear Gas, CO2 Dead Space

Potential Test Method Problems

Challenge Agent	Difficulties in Test
isobutane, cyclohexane, sulfur dioxide, ammonia, hydrogen sulfide	Stable Agents are non-reactive or slightly reactive
acrolein, chlorine, phosgene, phosphine, hydrogen chloride, hydrogen fluoride	Unstable agents that are corrosive and/or reactive; HCl condense w/ moisture
Mercury Cyanogen Chloride Nitrogen Dioxide Carbon Monoxide CS & CN (Tear Gas)	Low Vapor Pressure Condenses near R.T. Two Breakthroughs Cyclic Vapor Pressure/Detection

Initial Scheme

Straightforward Tests

SO2, Cyclohexane, Formaldehyde

Simple Carbon Cartridges

Test in Triplicate

Analyze Results

Inter-Laboratory Meetings

Report Results

No Judgments

Summary Conclusions

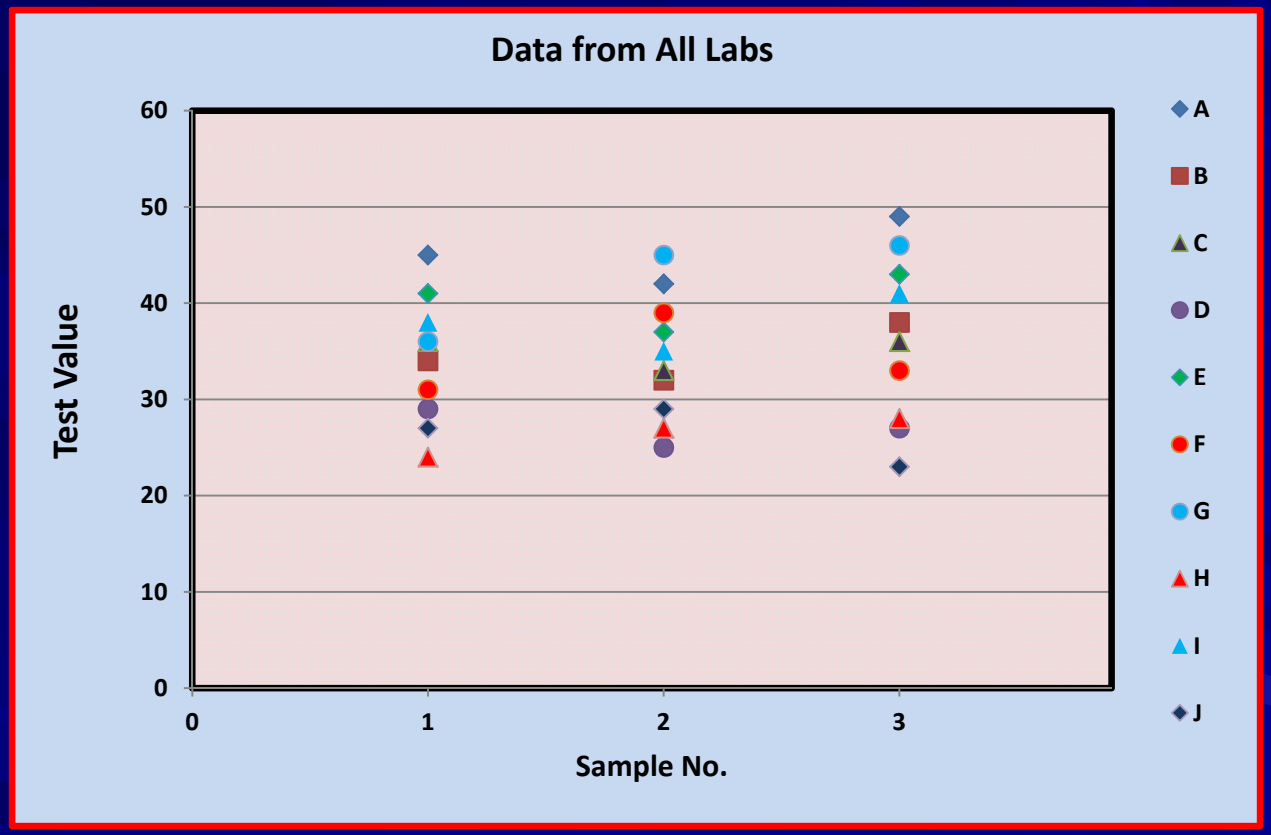
Details of Collaborative Testing Program

- Coordinator Distributes Samples to each Lab
  - Specify Challenge Conditions but not the Method
  - Provide Test Method Questionnaire
  -
- Labs Perform Report Tests
  - Breakthrough Time for each Test
  - Answers to Test Method Questionnaires
- Coordinator Report
  - Mean of all Results
  - Variation Statistics for all results
  - Mean of results from Reference Lab (if applicable)
  - Variation Statistics for Reference Lab(s) (if applicable)
  - Scatter Plot highlighting your lab results within “data cloud”

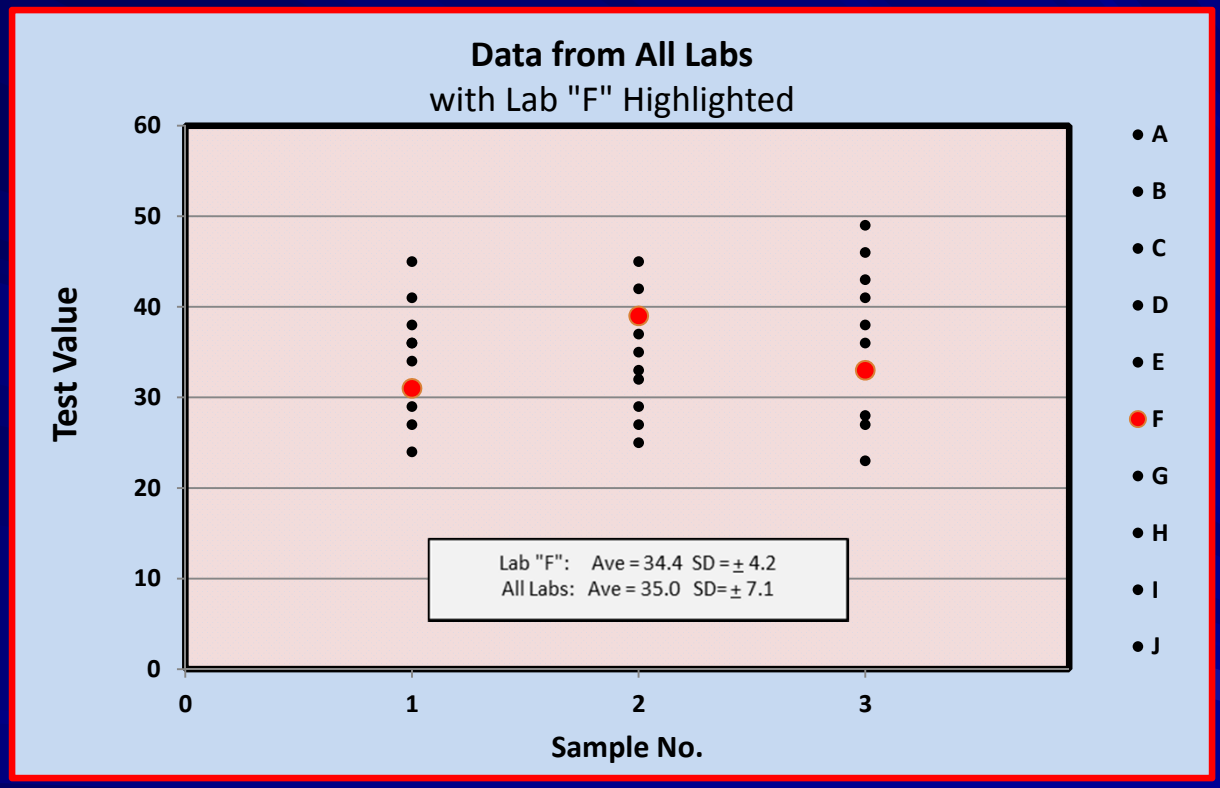
Test Method Questionnaire

- Atmosphere Generator (air)
  - How are Flow, Humidity, and Temperature Control maintained
- Generate & Verfy Challenge
  - Gas (Liquid) Concentration used
  - How is Flow Control maintained?
  - How is Challenge Concentration verified?
- Chamber & Apparatus
  - Material, Diameter, and Length of Delivery Tubing
  - Material & Size of Chamber (if applicable)
- Breakthrough Detection
  - Instrument or Principle Used to Detect Agent
  - Calibration Method & Frequency

Sample Results



Sample Participant Report



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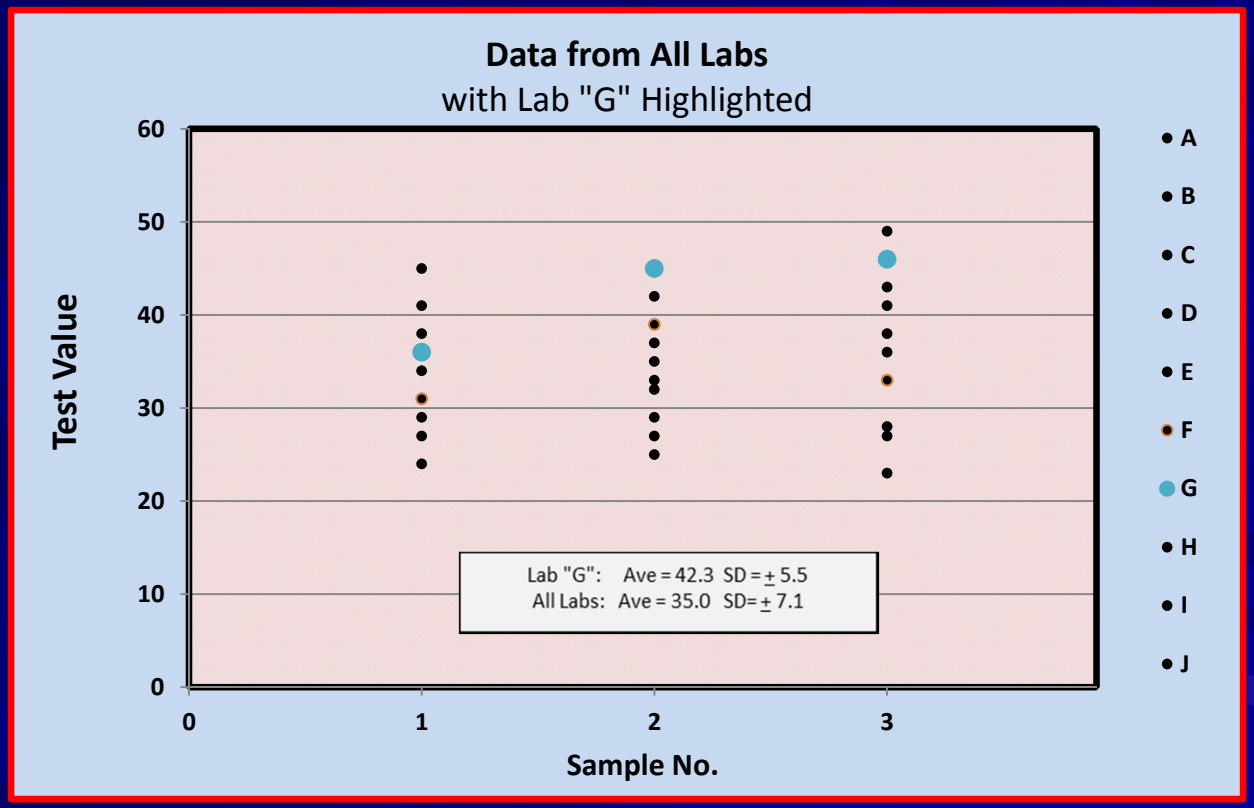

Completion of Collaborative Study

- Coordinator Analyze Results
  - Correlate Results with Test Method Questionnaire
    - Challenge Agent Generation
    - Chamber & Materials
    - Breakthrough Detection, etc.
- Generate Draft Report
  - Publish Results (anonymous)
  - Correlations with test Methods (if applicable)
- Participants Review report
  - Edits
  - Alternate Conclusions
- Final Report
  - Improvement Suggestions for Test Methods
  - Improvement Suggestions for Future Studies

Evolution Toward Proficiency Testing System

- Collaborative Test Cycles
  - Homogeneous, Stable Test Article
  - Inter-laboratory Comparison
- Analyze Discrepancies
  - Inter-Lab Variation
  - Variation among Replicate Tests
  - Identify Reference Labs
- Standardize Test Methods
  - Break Down into Parts
- Improve Individual Lab Conformance
  - Select Reference Labs

Next Steps (if successful)

- Future Collaborative Tests
  - Improved Test Articles
  - Improved Test Methods
  - Identify Reference Lab(s)
- Future Reports & Conferences
  - Suggestions for Further Improvements
  - Discussions of Results
  - Possibly a Conference!
- Evolution to Proficiency Testing
  - Definitive Test Methods
  - Reference Lab(s)
  - Assigned Values for Tests

Next Steps (alternate)

Or …. If good things are not happening

… just …

DROP the Whole Thing

Finis