Standardization of Procedures and Controls

in Chemical Challenge Testing of Respirator Cartridges and Canisters

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Service Life Testing

with Chemical Challenge Agents

- Conducted by a small community of expert labs who have developed esoteric test methods containing complex elements that are not well-understood or discussed out side a small circle of aficionados.
  - Could be considered by some as a “Cult”
- Perhaps, some aspects of practices in our cult could be improved by an increased dialogue leading to increased ...
  - Standardization of Procedures and Controls

Aspects of

Chemical Challenge Agent Testing

- Difficult & Highly Specialized
  - Methods are not taught in any Schools
- Small No. of Qualified Laboratories
  - Majority are Government Labs
- Small No. of Vendors of Test Equipment
  - Custom-made Equipment is Prevalent
- Few Forums for Idea-Sharing Between Labs
  - No Specialist Journals or Technical Meetings

Analytical Chemistry Testing

Food and Drug Testing, Blood Testing, Air Sampling

- Difficult & Highly Specialized
  - But Methods ARE taught in Schools
- Large No. of Qualified Laboratories
  - Accreditation of Labs is common
- Large No. of Vendors of Test Equipment
  - Example: Pittsburgh Conference (Pittcon)
- Many Forums for Idea-Sharing Between Labs
  - Many Journals and Technical Meetings

Technical Associations

who have more standardized methods (procedures & controls)

- College of American Pathologists (blood chemistry)
  - Proficiency Testing
- United States Pharmacopeia (drug chemistry)
  - Standard Methods & Proficiency Testing
- Association of Analytical Communities (food chemistry)
  - Standard Methods & Proficiency Testing
- American Industrial Hygiene Assn (air sampling)
  - Proficiency Testing

Aspects of Standardization

- Standardization of Procedures & Controls
  - Writing and Communicating Methods (Procedures & Controls) among many users
  - Round Robin Testing Protocols
  - Test Method Evaluation
  - General Improvement in Test Methods
- Round Robin (Proficiency) Testing
  - Uniform Test Articles distributed to Labs.
  - Compare Results from different Labs.

What Happens

When Standardization of Procedures & Controls is Implemented

- Standard Test Methods
  - Users evaluate methods more closely
  - Users argue about method details
  - Users publish articles about Methods
- Round Robin (Proficiency) Testing
  - Labs are supposed to be evaluated
  - Test Methods are actually evaluated

Need for Standardization

How do we know if Standardization and Proficiency Testing are necessary ?

- A Lab testing replicate articles (believed to be “identical”) obtains results that seem to be significantly different.
- Two different Labs testing seemingly “identical” articles obtain results that seem to be significantly different.

To Make a Case

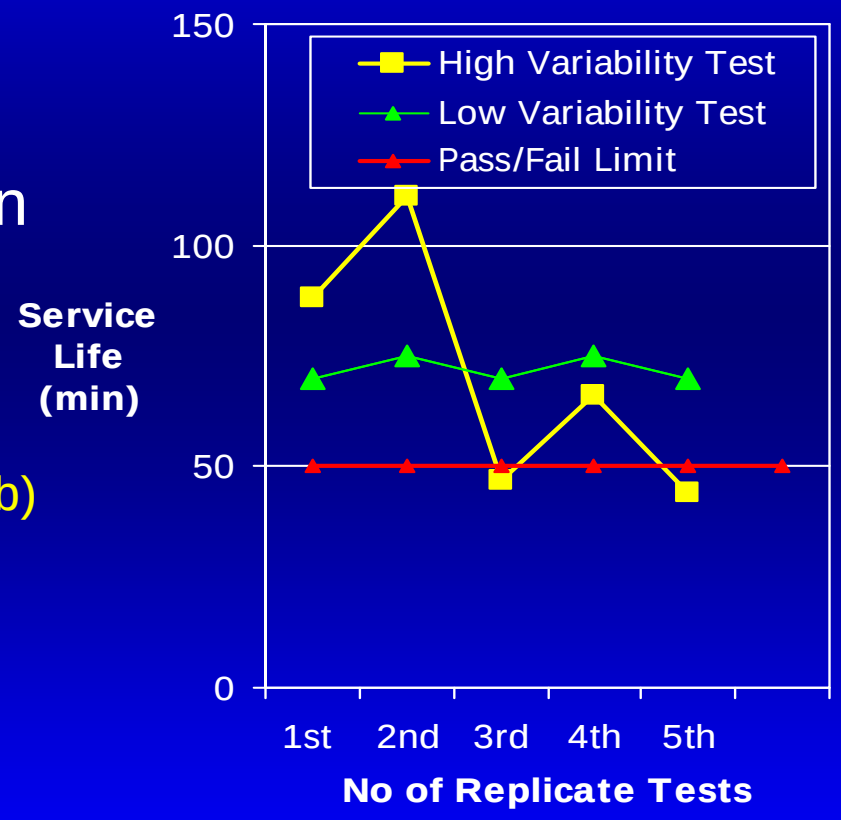
For Standardization of Procedures & Controls

- We will talk a little about Test Method Evaluation which looks into the variation of procedures we use in Chemical Challenge Testing.

- Listeners can reflect upon whether or not, in your experience, replicate tests of (seemingly) identical articles often lead to significantly different results.

Test Result Variations

- Test Variations can be observed in Round Robin Tests using
  - Different Labs
  - Different Analysts (Same Lab)
  - Different Procedures



Test Method Evaluation

Scientific approach ...

- Seeks to analyze methods rather than blame people or labs for differences in test results.
- Control of Test Parameters contained within each Test Methods lead to control of Test Results.

Terms in Test Method Evaluation

Meaning of "Error"...

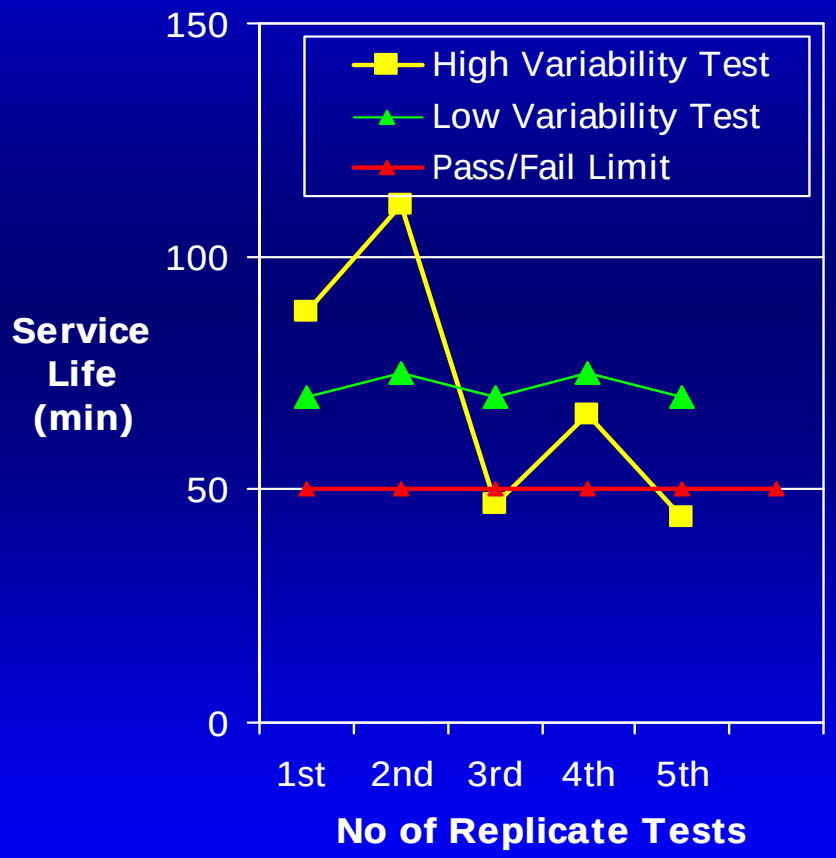
- ERROR = VARIABILITY Due to Extraneous Factors
  - Factors other than the TEST ITEM
  - Observed in REPLICATE TESTS

Significance ...

- In Evaluation of APR Service Life ... VARIABILITY due to Extraneous Factors needs to be minimized.

Test Method Error
(variation)

- Test Variations observed when identical Items are Tested multiple times
- To evaluate Items fairly, Test Variations must be minimized



Test Method Variability

Questions…

- Do variations that are allowed in the current Tests cause substantial variations in measured Service Lives independent of the Test Item?
- How much does each parameter contribute to overall measured variation in Service Life?
- Is there a way to control such variations?

How Test Variations Arise

Causes...

- The Test Result (Service Life, min) has a characteristic sensitivity to each Test Parameter
- Five (5) or more Test Parameters must be accurately and precisely applied during the Test
- Some Test Parameters are more difficult to Control than others
- The Test Result is more sensitive to the some Test Parameters than others

Chemical Challenge Tests

Basic Test Parameters …

- Challenge Agent Conc'n (ppm)
- Air Flow Rate (L/min)
- Time of Test (min)
- Break-Through Conc'n (ppm)
- Air Conditioning (Temp & RH)
- Pre-Conditioning (Temp, RH, and Flow Rate)

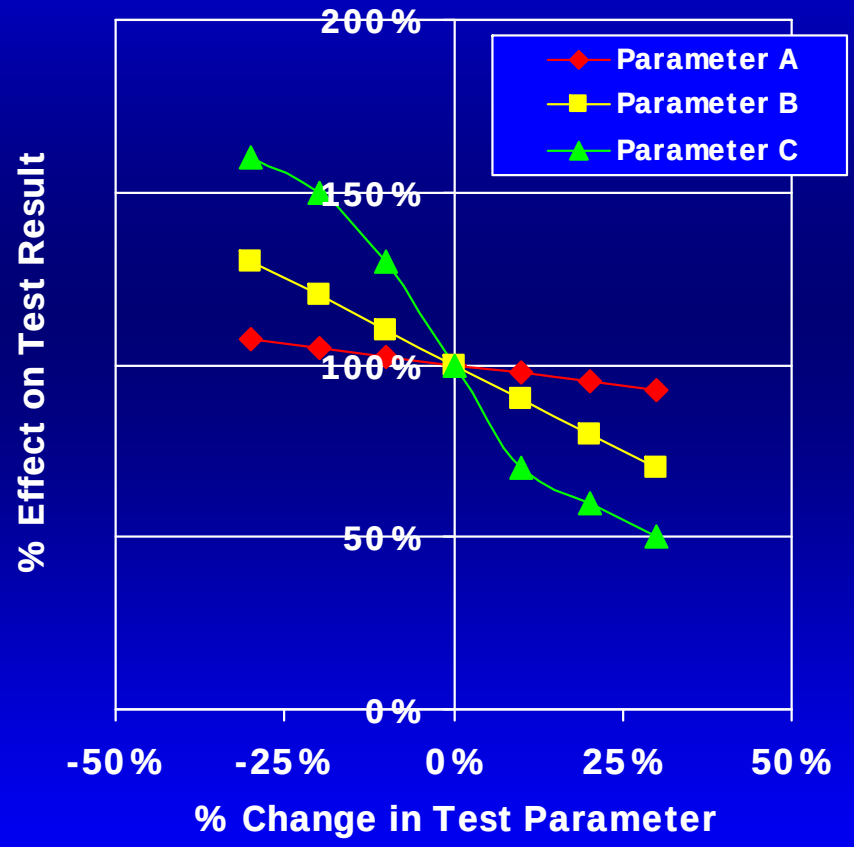
Chemical Challenge Tests

Secondary or "Hidden" Test Parameters …

- Temperature effect on Relative Humidity
  - an error in one propagates to the other
- Gas Concentrations (at various times)
- Accuracy of purchased Gas Standards
- Instrument Accuracy (at various times)
- Instrument Selectivity (interferences)
- The Written Test Method (itself) - Whether all Test Parameters are clearly specified

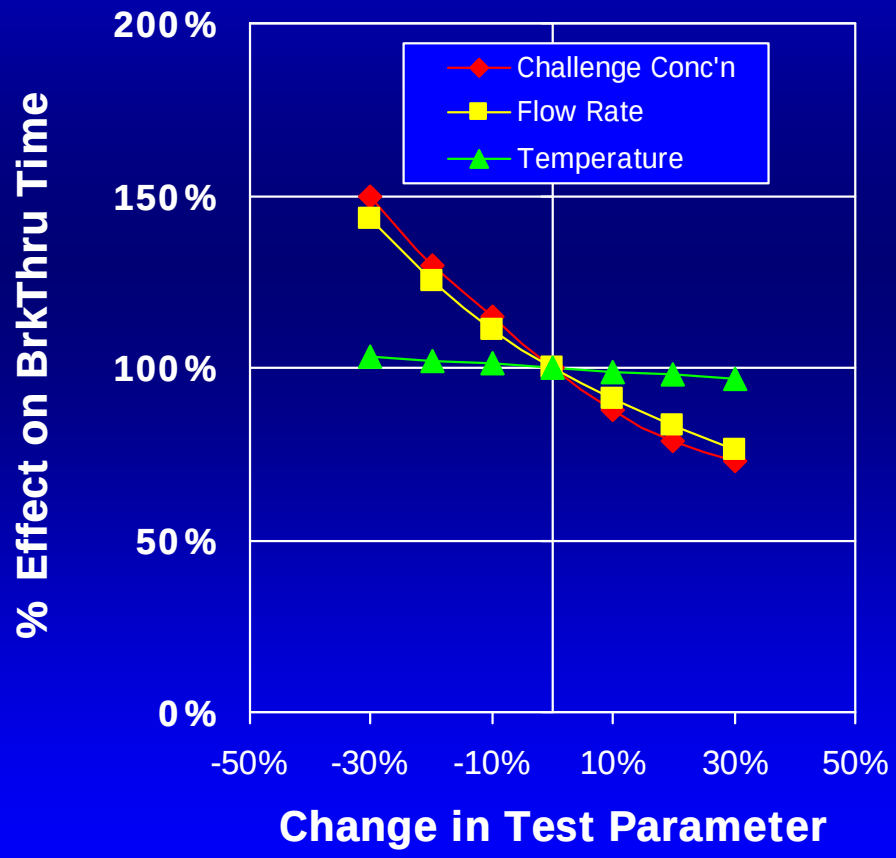
Sensitivity of Test Result to Test Parameters

- The Test Result is more sensitive to variations in some Test Parameters than in others
  - A – Not Very Sensitive
  - B – Proportional
  - C – Very Sensitive



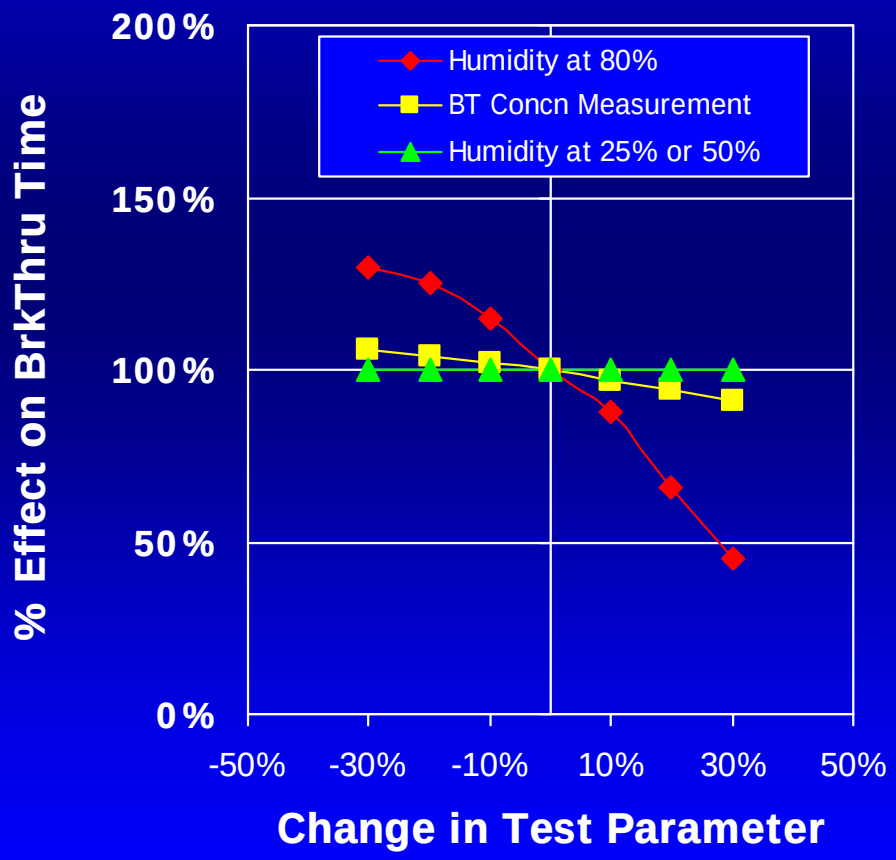
Sensitivity of Test Result to Test Parameters

- The Test Result is more sensitive to some Test Parameters
  - Control of Challenge Agent Concentration
  - Control of Flow Rate
- Not so sensitive to
  - Temperature
    - (Measured as ^{o}C)



Sensitivity of Test Result to Test Parameters

- The Test Result is more sensitive to some Test Parameters
  - Humidity Variation above 80%
- Not so sensitive to
  - Measurement of Break Through Concentration
  - Variation in control of RH at 25-50%



Estimated Variation
in Generating Challenge Agents

Type of Challenge Agent	***Estimated Variation***
Agent Concentration Control & Measurement	± 5 - 50 %
Stable, Compressed Gas	± 5 %
Stable, Volatile Liquid	± 10 %
Reactive Liquid	± 10-50 %
Non-Volatile Liquid or Solid	± 10-50 %

Error Budgeting in Test Methods

Estimates ...

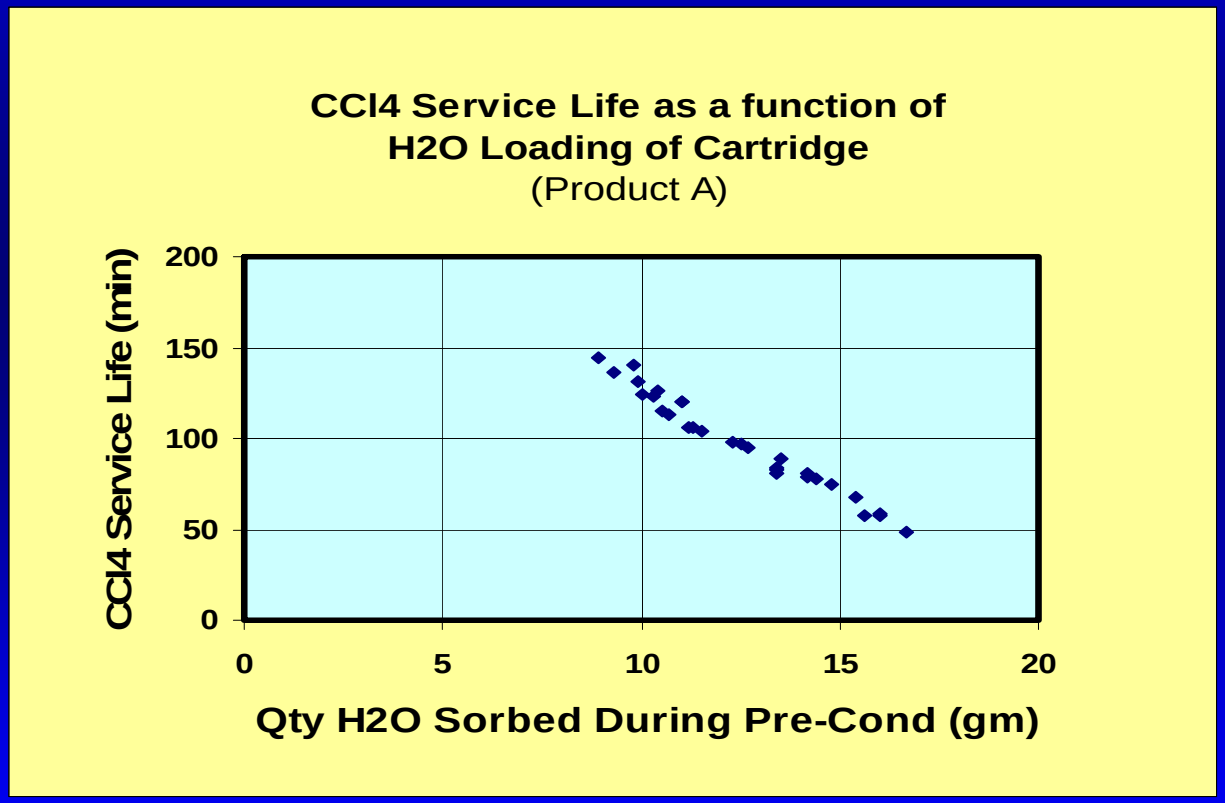
Test Parameter	*Allowed Parameter Variation*	→ *Induced Test Result Variation*
Agent Conc'n	± 10 %	± 10 %
Flow Rate	± 3 %	± 3 %
Temp	± 5 %	± 1 %
RH	± 5 %	± 1 %
Break-Through Measurement	± 5 %	± 1 %

TOTAL Test Variation (estimated) = **± 16 %**

Example...

Effect of Moisture Load

on Measured Service Life



Example...

Effect of Humidity
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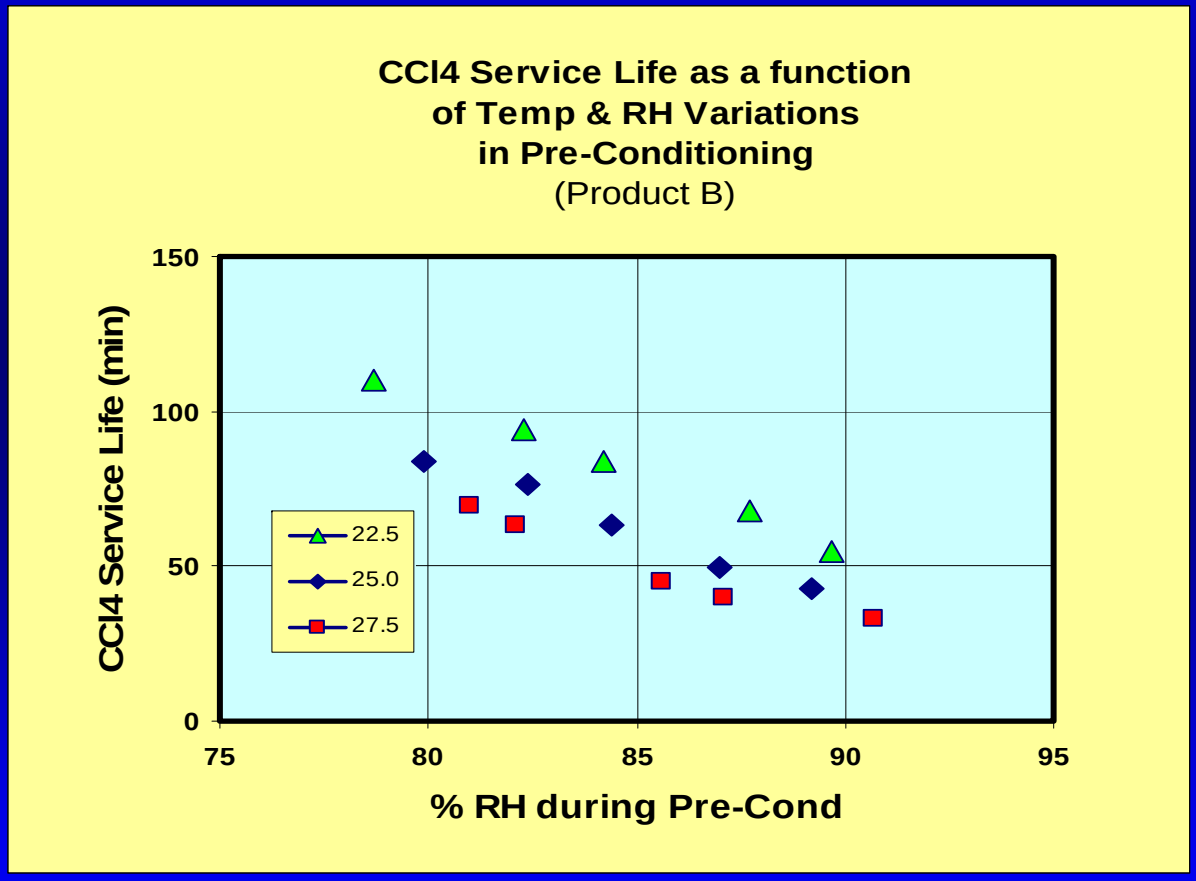

Making a Case

For Standardization of Procedures & Controls

- We have now looked into the variation of some of the processes and procedures we use in APR Cartridge and Canister Testing.

- Listeners have had time to reflect on whether, in your experience, replicate tests of (seemingly) identical articles often have led to significantly different results.

Aspects of Standardization

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How Would We Do
Proficiency (Round Robin) Testing?

- Acquire a significant quantity of APR Cartridges believed to be uniform in content and character (i.e. a “good lot”).
  - Document SOP for Cartridge Preparation.
- Submit samples to different labs for the same type of test.
  - Specific, Control, or at least Document the Test Methodology that is actually used
- Record test results in a format that facilitates comparison among the different labs performing the tests.
  - Specify how data is to be reported and analyzed.

Possible Round-Robin Tests

Agent	***Possible Method Issues***	***Possible Lab-to-Lab Variation***
SO2	No significant problem	± 7%
HCN	Must Detect Breakthrough of 2 gases	± 10%
Acrolein	Reactive, Very Volatile Liquid	± 25%
ClO2	Must generate with Reactor using Cl2	± 25%
CN (Tear Gas)	Hugh boiling, difficult to volatilize	± 25%

Evolution

Toward future improvement ...

- Conduct Round Robin Testing.
- Publish more details of Test Methods.
- Publish discussions of Procedures & Controls and their effect on Test Results.
- Refine Test Methods.

Final Comments

- Standardization Procedures and Controls is required in order for Laboratories to comply with ISO 17025 (general standard for “testing and calibration labs”).
- ISO 17025 is incorporated into the AIHA’s current LQAP program for accreditation of Laboratories engaged in in Air Sampling and analysis.
- Extension of this approach to Chemical Challenge Testing for Respirator Service Life is feasible.