Proposed Experimental Design Lead-in-Dust Verification Test

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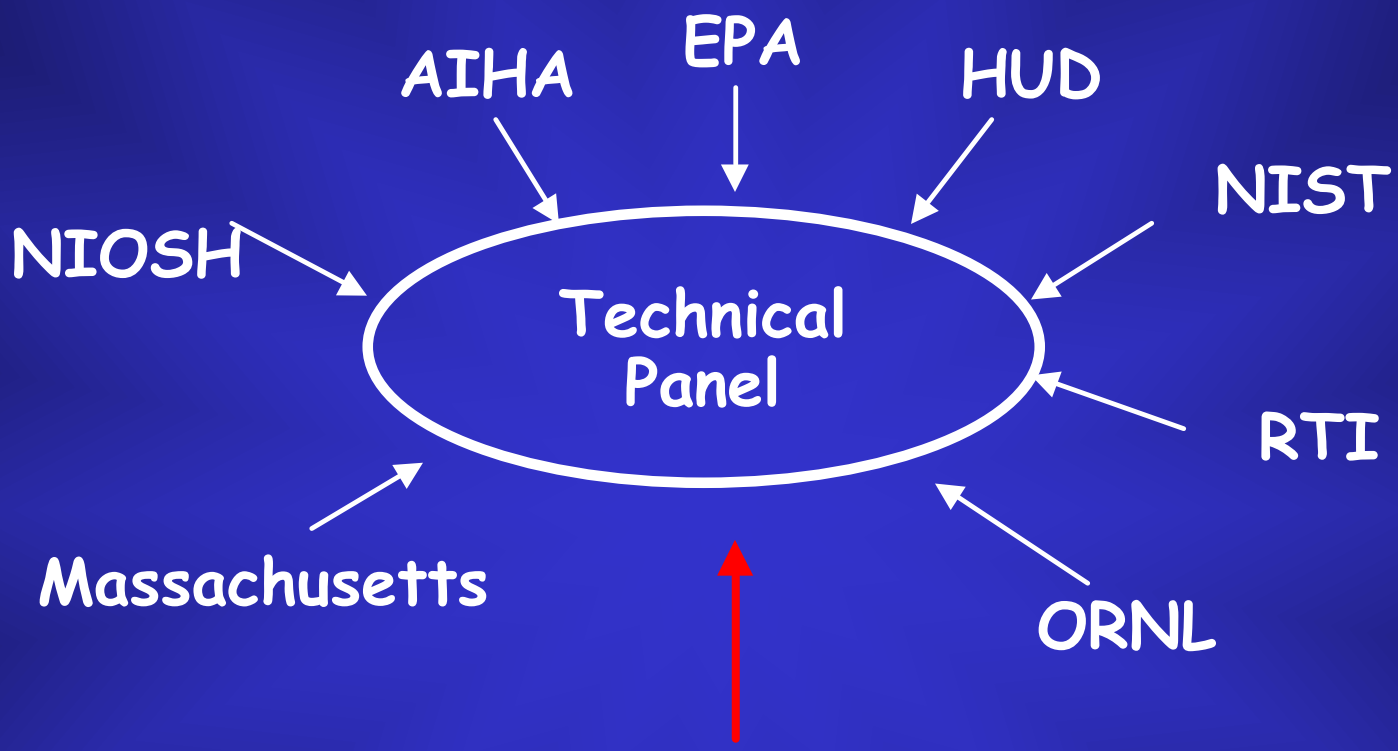
Acronym List

AA: Atomic Absorption
AIHA: American Industrial Hygiene Association
ELPAT: Environmental Lead Proficiency Analytical Testing Program
EPA: U.S. Environmental Protection Agency
ETV: Environmental Technology Verification Program
HUD: U.S. Department of Housing and Urban Development
ICP-AES: Inductively Coupled Plasma-Atomic Emission Spectrometry
NIOSH: National Institute for Occupational Safety and Health
NIST: National Institute of Standards and Technology
NLLAP: National Lead Laboratory Accreditation Program
ORNL: Oak Ridge National Laboratory
RTI: Research Triangle Institute

How did we arrive at this *preliminary* design?



Matrix Selection

Technical panel prioritized current industry needs for evaluation of field technologies for detection of lead as:

- DUST
- PAINT
- SOIL

Why are we doing this?

"Childhood lead poisoning remains a major preventable environmental health problem in the United States."

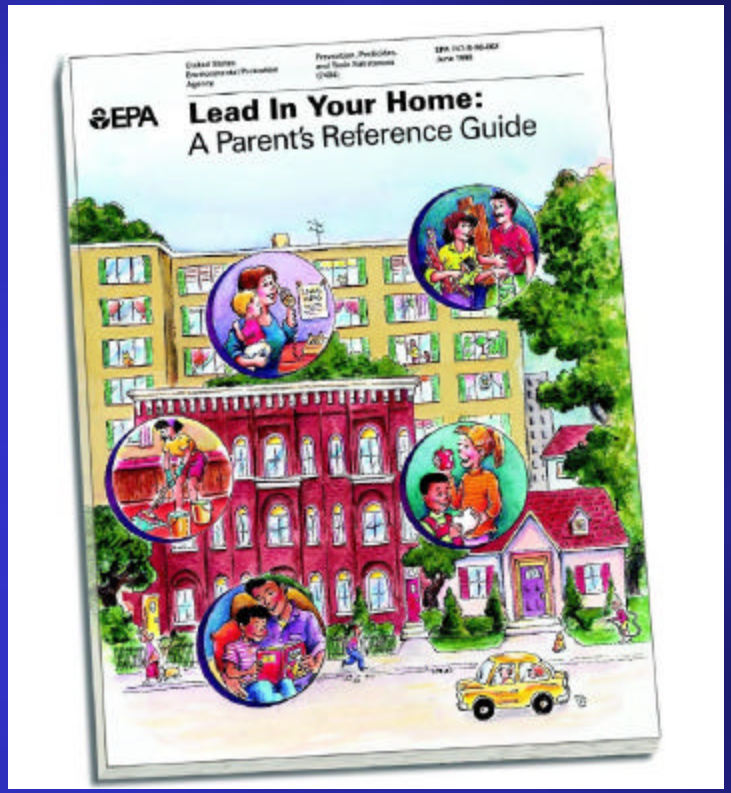
- *Centers for Disease Control and Prevention*

"Children are most frequently lead poisoned by household lead paint dust."

- *Massachusetts Dept of Public Health*

Why “dust wipes” versus “bulk dust”?

- Wipe sampling estimates surface lead loading
  - μg of lead per unit area
- Risk-based dust-lead loading standards established based on dust wipe sampling
- Testing under the NLLAP is restricted to dust wipes.
- Readily available ELPAT samples with certified concentrations
  - “Real-world” samples of known content



What are the current drivers for this dust wipe test?

- ETV test will provide information on potential applicability of field technologies for clearance testing.
- Relevancy to clearance levels†
  - 40 : g/ft^2 floors
  - 250 : g/ft^2 window sills
  - 400 : g/ft^2 window troughs
- Applications
  - Clearance testing
  - Risk assessment

† Identification of dangerous levels of lead, Final Rule, 1/5/01, 40 CFR 745.65

Outline of Proposed Experimental Design

136 dust wipe samples
- 80 archived ELPAT samples
- 36 newly-prepared samples
- 20 blanks (dust with no detectable lead)

Concentration Range
- 20 :g to 2000 :g per wipe
- Expected 5-6% variability per test level

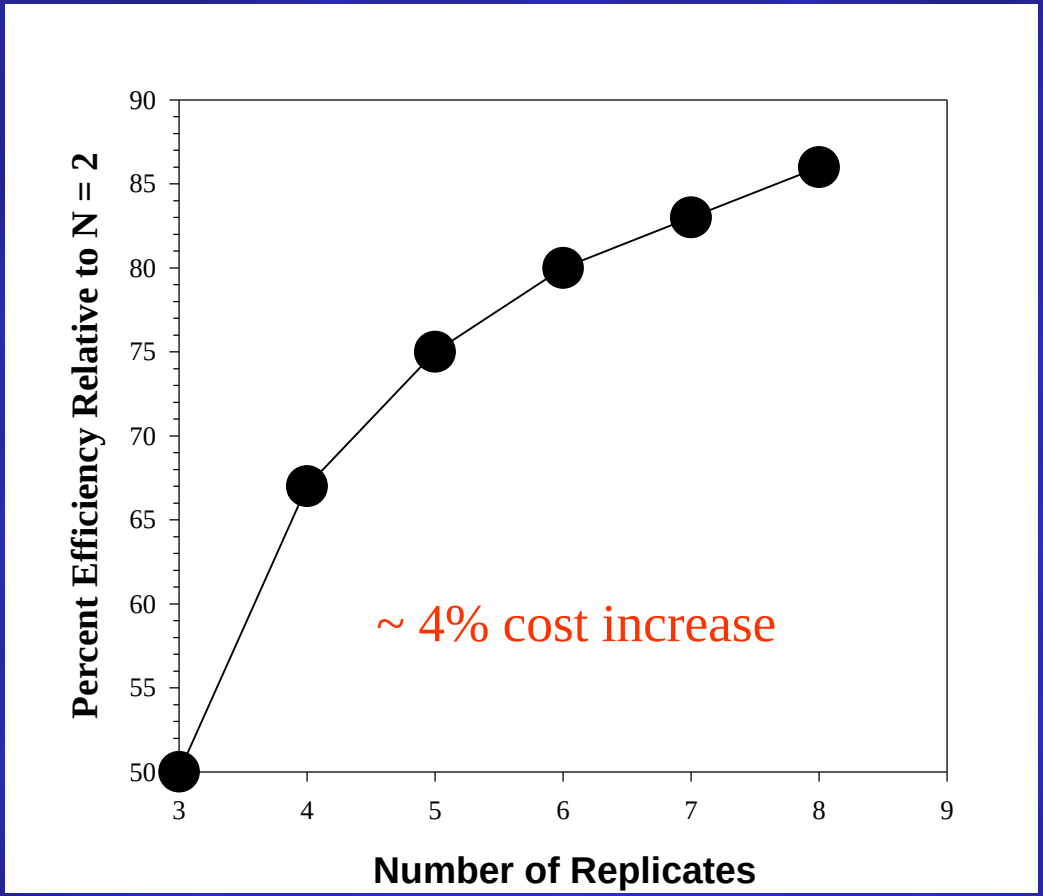
Loading
- 100 +/- 0.5 mg of dust in center of PaceWipe™

Dust Sources
- Wisconsin and North Carolina homes, sieved to 150 µm
- Other sources may be used in newly-prepared samples

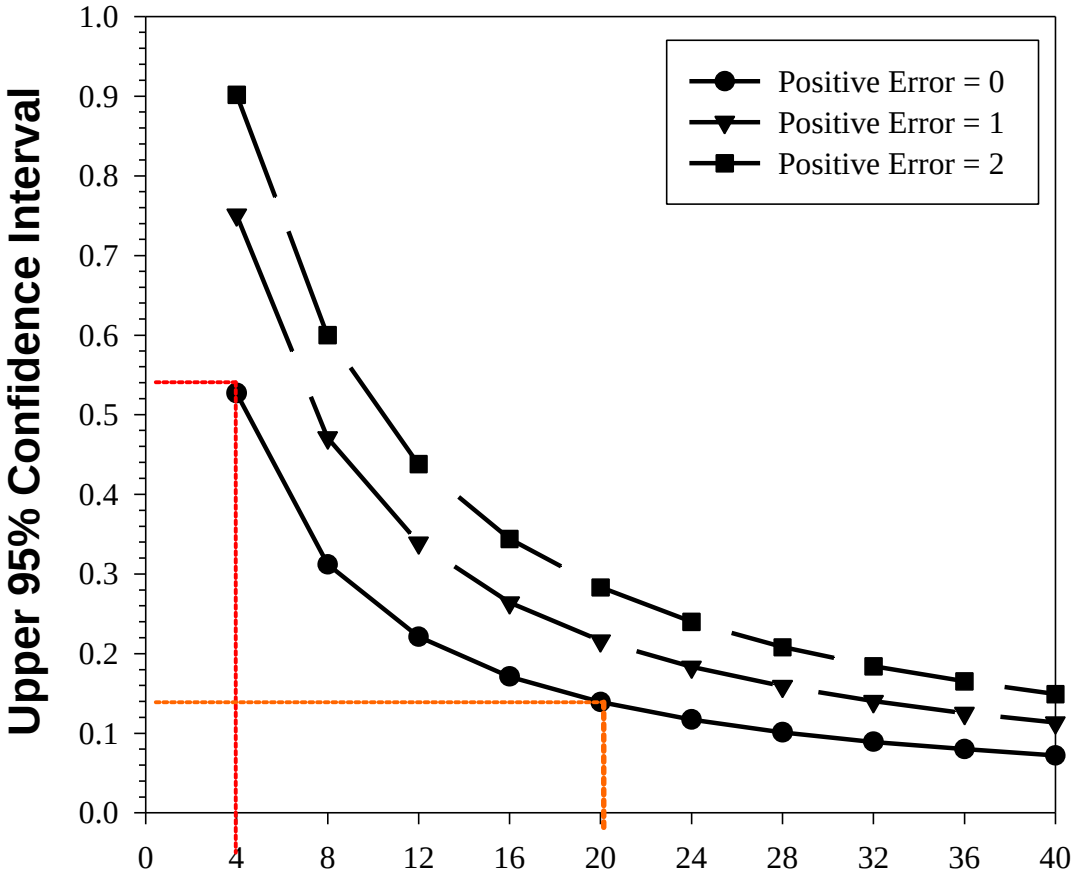
How did we arrive at 136 samples?

- Looked at all of the archived ELPAT samples; selections based on concentration and number of samples available
- Requested newly-prepared samples to fill concentration gaps, particularly at clearances levels (40, 250, 400 μg)
- Implemented statistically-balanced design of four replicates

Confidence in Precision Estimate Dramatically Increases With 4 Replicates versus 3 Replicates with Minimal Cost Increase

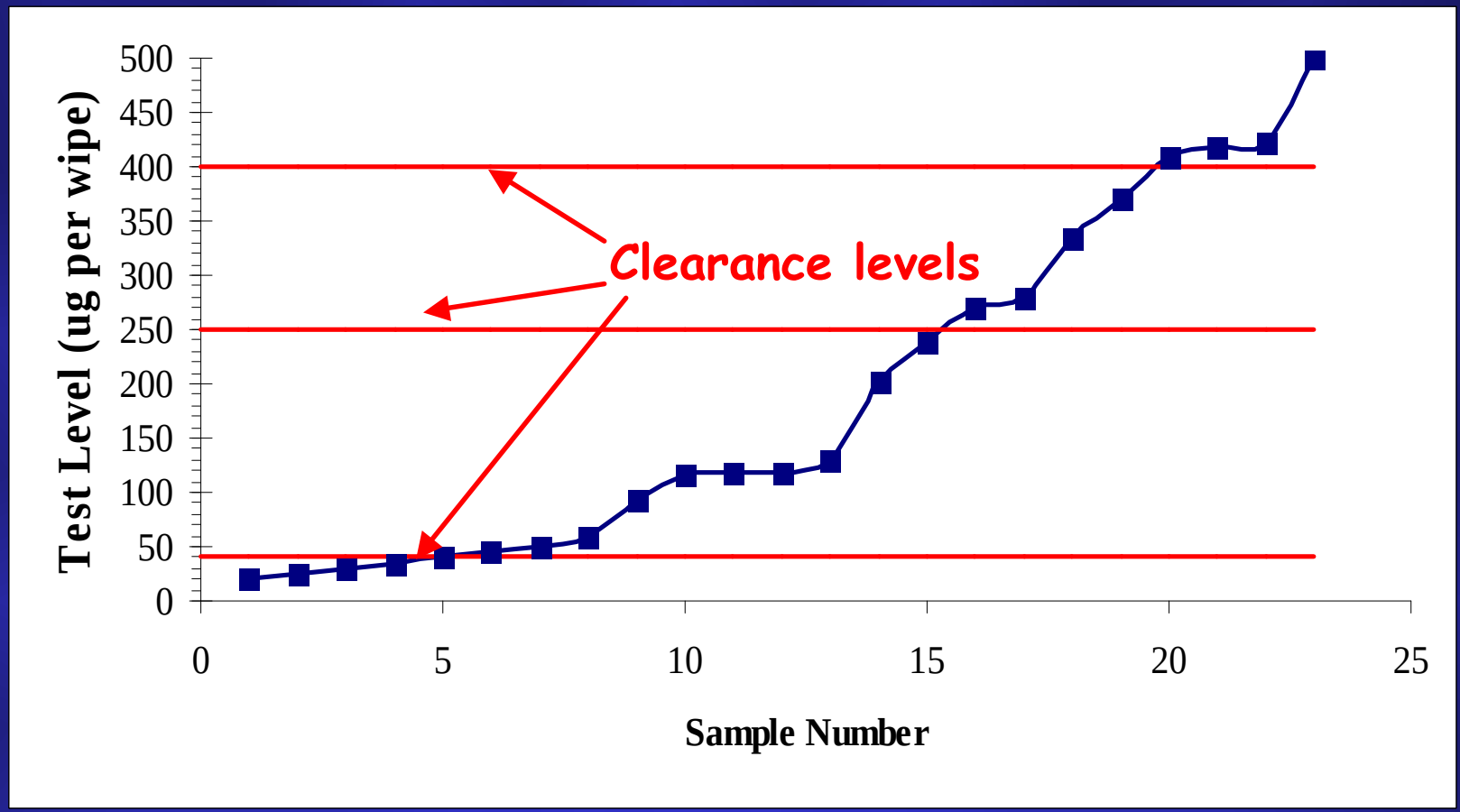


Determining the Number of Blank Samples to Evaluate False Positive Error Rate



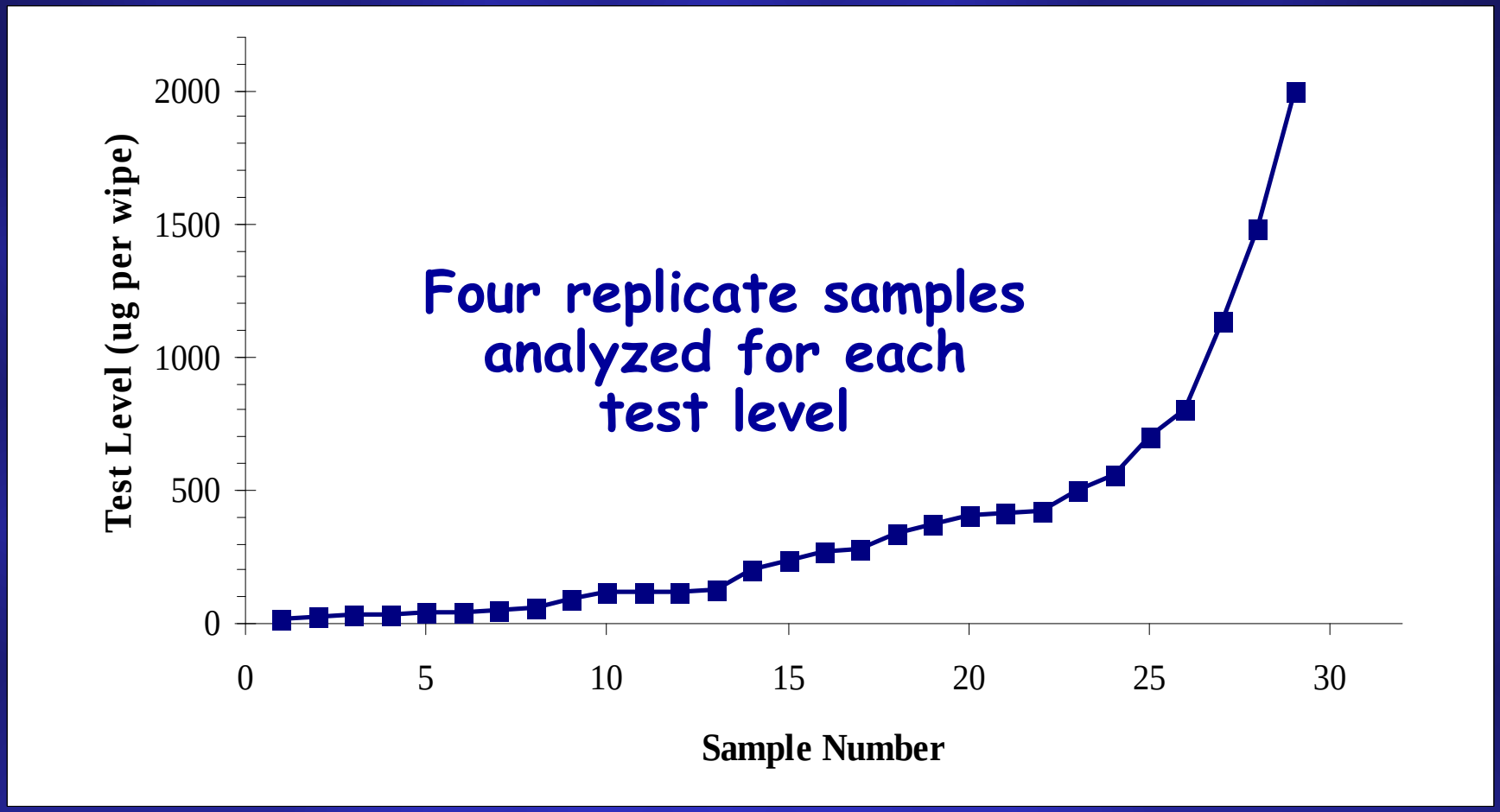
Confidence in estimate of FP error rate increases as more blank samples are evaluated.

Attention to Clearance Levels

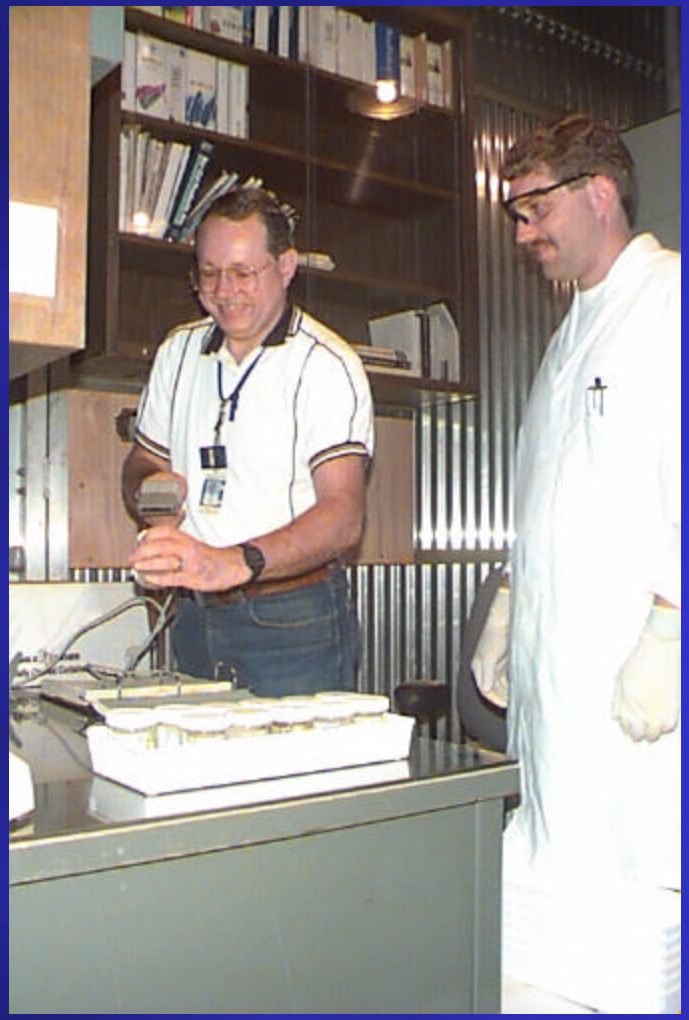


Four replicate samples analyzed for each test level.

Proposed Distribution of Test Levels



Distribution of Samples During Testing



- Vendor runs own equipment.
- Samples distributed in batches of 12.
- Quantitative and semi-quantitative technologies will receive same suite of samples.

Strong Emphasis on QA Enhances Acceptance of Results by User Community

- Blind, random analyses
- Each vendor's sample suite will be a unique randomization of the sample order.
- One-to-one matching with fixed-lab analysis
- 4 replicates analyzed for each concentration
  - 29 conc levels x 4 reps = total 116 samples (+ 20 blanks)
- Test will include only prepared samples (rather than collecting samples at actual housing unit due to the influence of sampling errors)

Performance Characteristics on Which Technology Will be Assessed

- ✓ **Accuracy (80 ELPAT archived samples)**: percent recovery (quantitative results) or % in agreement (interval results) with ELPAT certified result
- ✓ **Precision (all samples)**: relative standard deviation (quantitative results) or % sample sets where number of replicates reported consistently (interval results)
- ✓ **Comparability (all samples)**: relative to **fixed-laboratory** results (one-to-one)

Selection of Laboratory/Method

- "Typical" results if you sent the samples off-site for analysis (NOT necessarily the "right" or "true" answer)
- Technical panel suggestions:
  - Sonication/AA or ICP-AES
  - Hot plate-acid digestion/AA or ICP-AES
- Will utilize ELPAT process in selection
- Looking for vendor input; probably no final decision today

Performance Characteristics cont'd

- ✓ **Detectable Blanks**: number of blanks where lead is detected
- ✓ **False positive/negative results**: relative to all three clearance levels (e.g., number of samples where field technology reports concentration as < 40 μg but laboratory reports concentration as ≥ 40 μg).
- ✓ **Logistical operation**: sample throughput; power requirements; set-up time; ruggedness; hazardous waste generation

Ease of Use

- Always a component of the verification process, but of particular interest to this technical panel
- In typical ETV test, vendors operate technology so that errors/bias is mostly related to the technology and not the operator.

Propose Demonstration Day:

- No statistical evaluation of ease of use, but users report back on user-friendliness.
  - Typical users (e.g., risk assessors) do hands-on work with technologies

Summary Features of the Experimental Design

- Broad range of sample concentrations
- Attention to relevant clearance levels
- High level of QA to enhance acceptance
- Each vendor analyzes same sample set, but in randomized fashion to insure “blind” nature of tests.
- Effort made to assess “user-friendliness” of technology.