

QA/QC Issues for Lead Hazard Control and Healthy Homes Demonstration Grants

2008



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Session Objectives

- Review the Federal Guidelines on Information Quality (HH Demo Grants)
- Identify the Purposes and Elements of a Quality Assurance/Quality Control Plan (All Grants)
- Review Quality Assurance Measures for Lead Hazard Control Grants



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Background

- OMB Information Quality Guidelines
 - Published in Federal Register on February 22, 2002
 - Requires Federal agencies to:
 - Adopt specific standards for data quality (need to ensure objectivity, utility, and integrity of data)
 - Develop a process for reviewing information for quality before it is disseminated



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Background (cont.)

- **HUD's Information Quality Guidelines**
 - Published in Federal Register on November 18, 2002
 - Complements other Departmental objectives
 - Reaffirms existing approval procedures
 - Introduces new approval procedures where necessary to meet OMB requirements



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Background (cont.)

- **Relevance of HUD Information Quality Guidelines to Grantees**
 - Research performed under technical studies and demonstration grants may be used in the future to support new HUD rules and guidance
 - Producing and following a QA Plan helps to ensure the quality and validity of data



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Quality Assurance is...?

- A program for the systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met.



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QA Plan - Purpose

- **Ensures that project's technical and quality objectives are identified and agreed upon prior to the start of the project**
- **Identifies the measurements, data management protocols, and analytical methods that can be used to meet the project's objectives**



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QA Plan – Purpose (cont.)

- **Informs all project staff of the exact procedures that are to be followed throughout the study**
- **Helps to ensure that the results of the research or evaluation are “publishable”**



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QA Plan – HH and LTS vs. Demo Grantees

- Technical Studies Grantees – typically perform research involving collection of data and possible testing of hypotheses; requires a more comprehensive QA Plan
- Demonstration Grantees – typically collect data to assess hazards and evaluate interventions (e.g., allergen samples, asthma outcomes); simplified QA Plan focuses on data collection, analysis, and management issues



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QA Plan – Template

- **Intended to reduce grantee burden and streamline development of QA Plan**
- **Contains “boiler-plate” language for many sections**
- **Text for some sections can be extracted from work plan or grant proposal previously accepted by HUD**



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QA Plan – Template (cont.)

- Industry-accepted sample collection, analysis, and data management methods (ASTM, EPA) can be cited vs. describing methods in detail
- Quality programs and QC procedures (e.g., calibration details) used by accredited labs can be cited in lieu of describing the methods in detail
- Asterisked sections in next slides indicate sections included in HH Demo. template



QA Plan – Sections

- 1.0 Project Management
 - 1.1 Distribution List
 - 1.2 *Project Organization**
 - 1.3 Problem Definition/Background
 - 1.4 *Project Description and Schedule**
 - 1.5 Quality Objectives and Criteria for Measurement Data
 - 1.6 Special Training/Certification
 - 1.7 *Documentation and Records**
 - 1.8 *Human Subjects Research**



QA Plan – Sections (cont.)

- 2.0 Measurement/Data Acquisition
 - 2.1 Experimental Design
 - 2.2 *Sampling and Survey Methods**
 - 2.3 *Sample and Data Handling/Custody**
 - 2.4 *Analytical Methods**
 - 2.5 *Quality Control**
 - 2.6 Instrument/Equipment Testing, Inspection, and Maintenance



QA Plan – Sections (cont.)

- 2.0 Measurement/Data Acquisition (cont.)
 - 2.7 Instrument/Equipment Calibration and Frequency
 - 2.8 Inspection/Acceptance of Supplies and Consumables
 - 2.9 Use of Existing Data
 - 2.10 *Data Management**



QA Plan – Sections (cont.)

- 3.0 Assessment/Oversight
 - 3.1 *Assessments and Response Actions**
 - 3.2 *Reports to HUD**
- 4.0 Data Verification and Usability
 - 4.1 *Data Review and Verification**
 - 4.2 Verification Methods
 - 4.3 Reconciliation with User Objectives



QA Plan – Sections (cont.)

- ***Appendices****
 - IRB Approval Form and updates
 - Sampling Protocols
 - Analytical Methods
 - Sample Custody Forms
 - Survey Instruments
 - ... other relevant appendices



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Survey and Assessment Tools

If possible, use surveys and assessment tools that have been carefully developed with some validation or extensive field use:

- Question development (questions understood by target population?)
- Variability between raters (e.g., visual assessment estimates)
- Predictive power of questions – how well do visual indicators predict hazards?



Surveys That Have Been Developed and Used by HH Grantees

Seattle-King County Public Health Dept.: Home Environmental Checklist (also in Spanish + Vietnamese: <http://www.metrokc.gov/health/asthma/healthyhomes/overview.htm>)

Environmental Health Watch: Home Moisture Audit, see: http://www.ehw.org/Healthy_House/HH_Moist_Audit.htm

Boston, Harvard University SPH: Environmental Health Assessment Survey (also training manual: www.hph.harvard.edu/hphi/)



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Allergen Sample Collection and Analysis

- No standardized protocols for dust sample collection, preparation, and analyses
- There is no external QC program for labs conducting ELISA analyses for allergens to ID problems/demonstrate proficiency
- OHHLHC has adopted measures to fill void:
 - providing guidance on sampling protocol
 - providing allergen QC samples (processed house dust)



Are QC Samples Really Needed?

(actual study results!)

Allergen	QC mean (ug/g)	Range (+/- 3 SD)	N	Lab X mean (ug/g)	N
Der p1	1.52	0.21- 2.8	15	0	26
Der f1	5.16	2.8 - 7.5	19	0.56	26
Mus m1	3.15	0.28 - 6.0	19	0.05	26
Fel d 1	6.89	2.4 - 11.3	19	1.11	26
Can f1	9.8	0 - 21.7	19	0.47	26



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HUD Allergen Studies

Objectives:

Characterize between- and within-laboratory variability in allergen analyses and investigate the utility of allergen QC samples for monitoring lab. performance

(2 studies: 2001 and 2004)



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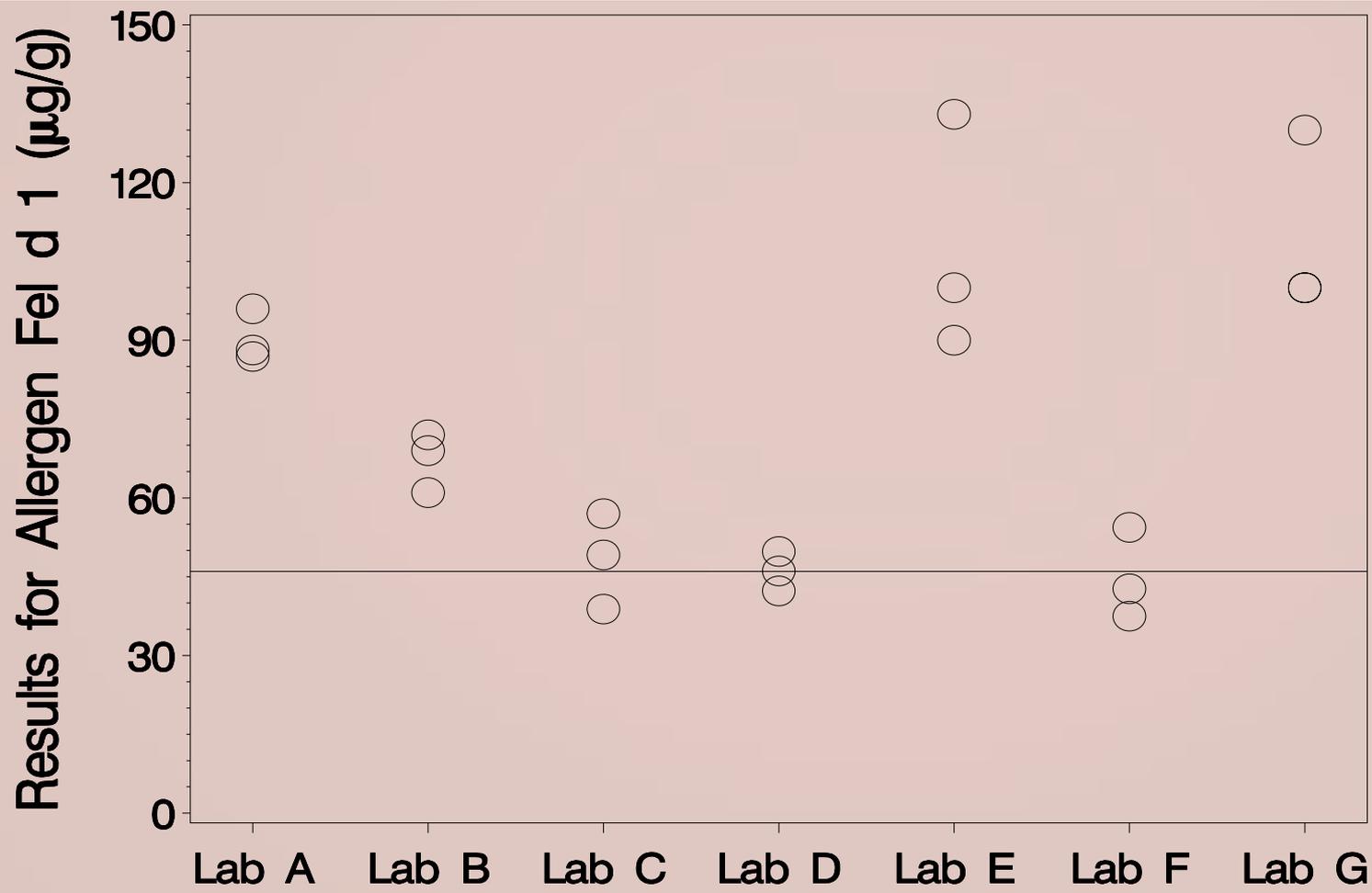
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Allergen Studies – Study Design

- Used homogenized house dust; 4 – 6 common household allergens characterized by repeat monoclonal ELISA analyses
- 5 - 7 participating laboratories analyzed unblinded triplicate samples according to their standard ELISA methods
- Statistical analyses performed on results to evaluate within- and between-laboratory variability



2001 Study – Cat Allergen Results (Fel d1)

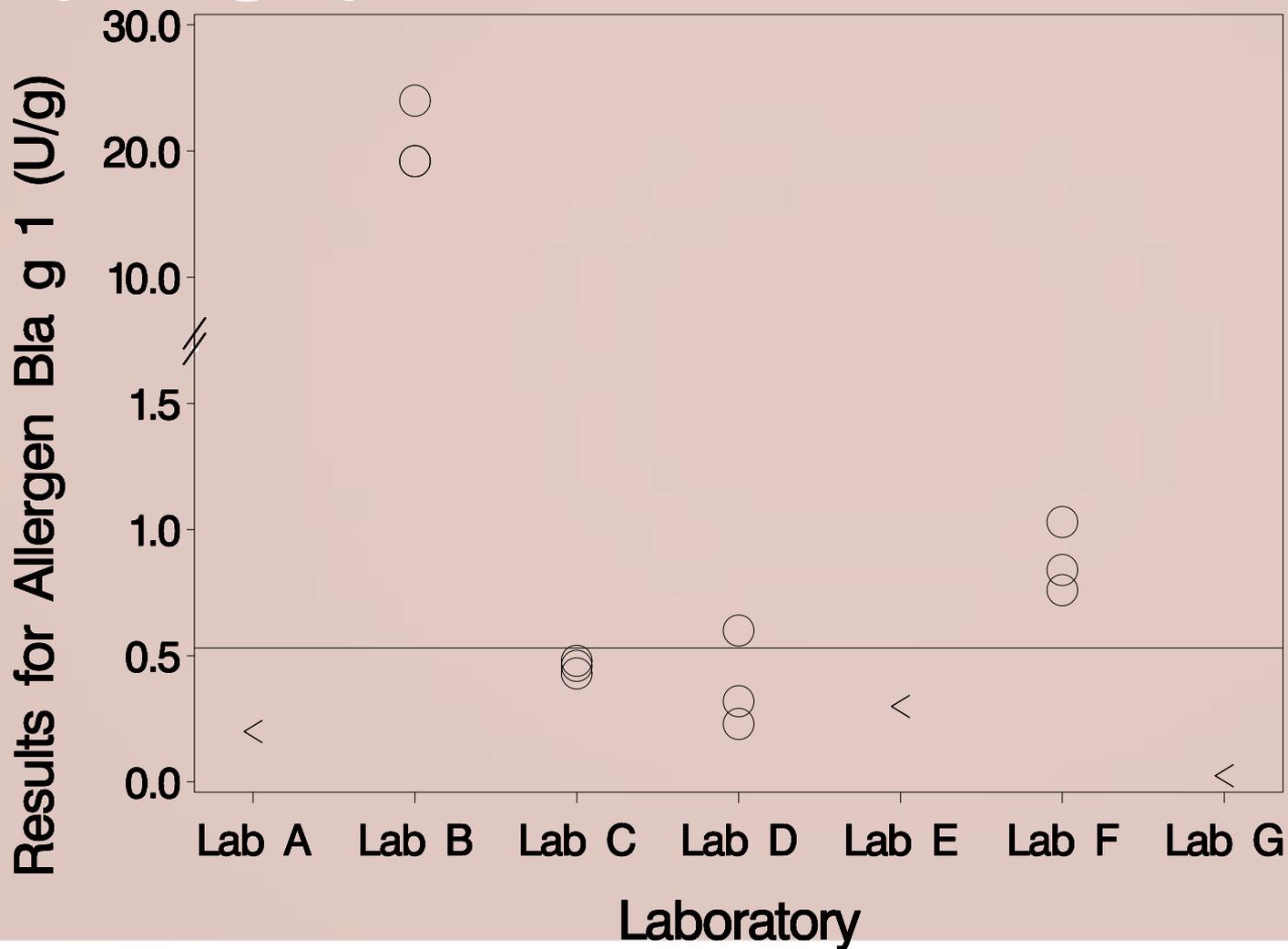


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Laboratory

2001 Study – Cockroach Results (Bla g 1)



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Note: < = Below laboratory detection limit

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Allergen Studies - Summary

- In general, between-lab variability was significantly greater than within-lab variability in both studies
- Use of QC samples useful in identifying outlier results and possible systematic error
- Development of SOPs for sample preparation and the performance of assays would likely reduce variability among labs.



OHHLHC QA Activities for Allergen Sampling and Analysis

- Recently revised dust sampling protocol
- Contract with QuanTech (QT) to provide QC samples to HH grantees
- QT has conducted round robin to compare results of QC sample analyses between labs
- Experiments to develop standard dust preparation protocol (sieve size/extraction time)



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Lead Grant QA Activities

- The NOFA requires the development of a written policy and procedures manual for “all phases of lead evaluation and control”
- This is the “QA/QC plan” for LHC program grantees.
- Experienced programs: Don’t become complacent!



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National Lead Laboratory Accreditation Program (NLLAP) Requirement

- You must use a lab that is recognized under EPA's National Lead Laboratory Accreditation Program (NLLAP)
- This means that the lab has shown proficiency in the analysis of lead samples (dust, paint, soil)
- BUT, it is still recommended that you include QC samples in your sample stream (blanks and dust-wipes)



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Recommended QA Activities

- **QA of Contracted Activities**
 - Qualified staff should randomly observe risk assessments, LBP inspections, clearance (use check list based on policy/procedures manual)
 - Monitor intervention work in progress to ensure proper set up of work site (containment, end of day clean-up if no relocation) (check list)
 - Final inspection of completed units (confirm all work completed and **acceptable quality**)



Long Term Monitoring?

- HUD's National Evaluation
 - enrolled units from 14 grantees ('93 and '94)
 - 3 yrs post-intervention (n = 278)
 - geometric mean floor- and sill-dust Pb loadings were 78% and 89% < pre-intervention levels
 - 9% treatment failure at 2 years and 10% at 3 years



How About Your Program?

- Consider: monitoring a random sample (5-10%) of units 1-3 years post-intervention (visual inspection for treatment integrity, and dust wipes)
- Create database with RA findings, treatments, and monitoring results
- Assess: long term treatment efficacy, patterns of treatment failures



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Thank You!

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