

EXECUTIVE SUMMARY

Introduction

Protecting children from lead-based paint hazards in housing remains an urgent need. Despite significant improvement, the Centers for Disease Control and Prevention estimates that nearly half a million children in 1999-2000 still have excessive exposures to lead.

This study is the largest and most comprehensive of its kind ever. It examined over 3,000 houses located in over a dozen jurisdictions across the country where the U.S. Department of Housing and Urban Development (HUD) provided funding to address lead-based paint hazards in privately owned low-income housing where the risks are greatest. The study looked at virtually all of the modern ways of controlling lead-based paint hazards and their relative effectiveness.

The study provides evidence that the lead hazard control activities as practiced by the participating programs can substantially reduce dust lead levels on floors, window sills and troughs and in most cases, the lead-in-dust remains well below pre-treatment levels for at least three years. More importantly, the activities were also associated with substantial declines in children's blood lead levels (37% two years after treatment). The findings of this study should be disseminated so that all those engaged in lead hazard control work can benefit from them.

Background

In 1993 and 1994, HUD awarded funds to 30 grant recipients (grantees) under the HUD Lead-Based Paint Hazard Control Grant Program. HUD required all 11 grantees in 1993 to participate in an evaluation of the program. Three grantees that were awarded funds in 1994 agreed to join the evaluation. The participating grantees included State or local governmental agencies in the following locations: Alameda County, CA; Baltimore, MD; Boston, MA; California; Chicago, IL; Cleveland, OH; Massachusetts; Milwaukee, WI; Minnesota; New Jersey, New York, NY; Rhode Island; Vermont; and Wisconsin.

Each grantee in the Evaluation of the HUD Lead-Based Paint Hazard Control Grant Program collected comprehensive environmental data on all treated dwellings. Grantees also attempted to recruit families residing in the dwellings into the evaluation. Families that consented to participate agreed to be interviewed and allowed blood to be drawn from children between 6 months and 6 years of age at enrollment were eligible. Local Institutional Review Boards in the jurisdictions of the grantees reviewed and approved the study designs.

Information was gathered at four periods of time for all of the grantees: before the lead hazard control work, within 6 weeks after work, 6 months after work and 12 months after work. In order to assess the longevity of the treatments, HUD awarded funds to nine of the grantees to collect additional longitudinal data in approximately 40 percent of the dwellings two years and three years after work was completed.

Data collection began in January 1994. Data were collected from over 3,000 dwellings; of these units, 2,682 dwellings were treated and had final clearance results. The last dwelling unit was treated in October 1997 and the last 12-month data were collected in October 1998. The last dwelling eligible for the 3-year evaluation was treated in June 1996 and final data were collected for these units in June 1999.

The design of the HUD Lead Hazard Control Grant Program encouraged grantees to implement hazard control measures of their choice and did not include the use of control groups. The evaluation was designed to compare the effectiveness of the different classes of interventions that grantees used. The primary measures of effectiveness were dust lead loadings and blood lead concentrations; the methodology for collecting these measures is described at the end of this summary as well as in the body of the report.

Key Findings

Pre-Intervention Conditions:

- *Dwellings in the Evaluation tended to be older and have lower occupancy rates and much lower market values than those in the general US housing stock.* The majority of buildings were pre-1930, occupied rental units located in multi-unit buildings.
- *Paint lead and dust lead levels were higher than in average U.S. dwellings, as identified in the National Survey of Lead and Allergens in Housing.* This finding was expected since grantees targeted higher risk housing. However, before lead hazard control (pre-intervention), dust lead loadings were lower than expected, especially on floors. Contractors voiced concerns about passing the original floor clearance standard of 200 $\mu\text{g}/\text{ft}^2$, yet less than 25% of enrolled dwellings exceeded the standard *pre-intervention*.
- *Building components with higher paint lead levels were more likely to be deteriorated.* Exterior surfaces tended to have higher paint lead levels (Median of all dwellings: 2.2 mg/cm^2) than interior surfaces, and windows tended to have the highest paint lead levels (Median: 2.0 mg/cm^2) of all interior surfaces.
- *Occupancy status influenced floor and window sill dust lead, especially floor dust lead, with larger loadings observed in vacant dwellings.* For interior floors, the geometric mean dust lead loading in vacant dwellings was 132 $\mu\text{g}/\text{ft}^2$ compared to 17 $\mu\text{g}/\text{ft}^2$ in occupied dwellings. For window sills, the geometric mean dust lead loading in vacant dwellings was 1,001 $\mu\text{g}/\text{ft}^2$ compared to 278 $\mu\text{g}/\text{ft}^2$ in occupied dwellings. Anecdotally, grantees reported that vacant dwellings tended to be vacant for many months prior to enrollment.
- *Interior entry floors had significantly higher dust lead loadings than other interior floor surfaces.* In occupied dwellings, the geometric mean dust lead loading on entry floors was 23 $\mu\text{g}/\text{ft}^2$ compared to 17 $\mu\text{g}/\text{ft}^2$ on interior floors. Further analysis suggests that entry floors serve as a pathway of leaded dust from the building exterior to the interior.
- *Pre-intervention paint, dust and soil lead levels varied by grantee.* Some of these differences may be explained by differences in the recruitment strategies (i.e., targeting higher risk communities vs. targeting units where children were lead poisoned), but some appear to be the result of differences from city-to-city in the application of lead-based paint and the availability of other lead exposure sources. The results suggest that grantees should consider local conditions when developing their lead hazard control strategies.
- *The enrolled population had a lower level of education, lower income and a higher percentage of non-white individuals than the general US population.* This finding matches expectations for a population more at-risk of lead poisoning who predominantly lived in central city areas in the Northeast and Midwest.

- *Nearly half of the children in the Evaluation had an initial blood lead test that was at or above the CDC level of concern (10µg/dL). Pre-intervention, 46% of children tested had a blood lead level greater than or equal to 10 µg/dL and 15% of children had a blood lead level at or above 20 µg/dL.*
- *A high percentage of the children enrolled in the study were previously lead poisoned. Seventy-seven percent of children enrolled in the Evaluation had a blood test for lead prior to enrollment. Forty percent of these children were reported to have been lead poisoned. With 85% of all children living in the enrolled dwelling more than 6 months, the dwelling was a potential source of lead exposure for most of these children.*
- *The findings for blood lead were not based on a random sample of children in the communities studied, and reflect grantee enrollment strategies. Not only were the children in this study more at risk, but a number of them were selected because they were lead poisoned. Thus, it not surprising that 46% of children had blood lead levels above the CDC level of concern as compared with less than 5% of the US child population.*

Interventions and Costs:

- *Costs for interior lead hazard control work increased with the intensity of the interventions. Cost data reflect lead hazard control costs in the mid-1990s. Median costs were as follows:*

<u>Interior Strategy</u>	<u>Primary Activity</u>	<u>Median Cost</u>
02	Cleaning Only/Spot Painting	\$ 430
03	Full Paint Stabilization	\$ 4,930
04	Partial Window Treatments	\$ 6,120
05	Full Window Abatement	\$ 6,800
06	Full Lead Abatement	\$ 9,570
07	Full Lead Removal	\$ 4,110
All		\$ 5,960

Interior Strategy 07 did not follow the increasing trend in costs because it was most commonly conducted in homes with a limited number of leaded components. Note: Partial window treatments include window jamb liners, sash replacement or paint removal, as well as other treatments.

- *Grantees most often selected Interior Strategy 05 - full window abatement (window replacement or window paint removal) plus other interior treatments for their interior intervention. Fifty-five percent of dwellings were treated with Interior Strategy 05 as compared with: Strategy 02 (8%); Strategy 03 (13%); Strategy 04 (16%); and Strategies 06/07 (7%).*
- *Costs varied widely within Interior Strategies. Factors that influenced the variability of costs included the size and type (single-family/multi-family) of the dwelling; the percentage of leaded interior paint in poor condition; the number of dwellings treated by the contractor for the grantee; and whether hazardous waste requirements were placed on the contractor.*
- *Grantees treated the exterior of the buildings at 70% of the dwellings and conducted soil or site work at 13% of the dwellings. The most common combination of strategies was Interior Strategy 05 along with treatments to the exterior and no soil treatment (41%).*

- Exterior work most frequently included paint stabilization (84% of treated buildings), followed by component enclosure (29%), component replacement (26%) and paint removal (25%). The median cost of exterior work was \$1,870.
- Site work most frequently included mulch/seed/sod/plant (90% of treated buildings), followed by soil enclosure (22%), soil removal (10%), and structure removal (3%). The median cost of site work was \$1,080.
- The following individual treatments were used over 800 times by building component:

Component	Paint Stabilization	Paint Removal	Enclosure	Replacement
Wall/Ceiling	√		√	
Floor/Stair	√		√	
Doors	√			√
Trim	√	√		√
Windows	√		√ (jambs)	√
Exterior	√			

Effects of Interventions on Clearance Dust Lead:

- *Seventy-six percent of all 2,842 dwellings treated by grantees passed the initial clearance testing (using the local dust lead standards applicable at the time).* The findings offer strong evidence that clearance was achievable on the first attempt in the vast majority of interventions. During the period of the Evaluation, grantees generally used clearance standards of 200 µg/ft² on floors, 500 µg/ft² on window sills and 800 µg/ft² on window troughs.
- *Dwellings that initially failed clearance testing required an average of 1.13 recleanings and follow-up clearance tests to achieve final clearance.* Even when dwellings failed initial clearance, final clearance was generally successful after only one additional recleaning and retest.
- *Interior Strategy 05, the strategy that included window abatement, was associated with lower initial clearance dust lead loadings and lower failure rates on both window sills and window troughs, after controlling for other factors. Interior Strategy 02, the lowest intensity strategy that included cleaning and spot painting, performed as well or better than other strategies in similar models based on floor dust lead loadings and failures.* Initial clearance dust lead loadings and failure rates did not decline with treatment intensity. Interior Strategy 06, full lead abatement, was associated with higher clearance dust lead loadings on both floors and window troughs than most other strategies, after controlling for other factors. As reported above, Interior Strategy 02 had lower dust lead loadings on floors than other strategies. This same strategy had similar effects on window sill dust lead loadings, as long as pre-intervention dust lead levels were below 250 µg/ft².
- *Creating smooth and cleanable surfaces was an important determinant of lower clearance dust lead levels.* Surfaces in better condition at clearance had lower clearance dust lead loadings and lower failure rates, when controlling for other factors including Interior Strategy. In fact on *entry floors*, no elements of the interior lead hazard control interventions other than creating good floor conditions had a significant effect on entry floor clearance failure rates.

Occupant Protection:

- *Grantees generally followed HUD guidance on occupant protection and occupants were generally adequately protected.* 71% of households were relocated during the intervention, and when relocation did not occur, treatments tended to be of a more limited intensity. Twenty-two percent of relocated households reported that they returned to the dwellings during the intervention, although in most cases the return visits were less than one hour and did not include a child. Ninety-two percent of the households that did not relocate remained out of the work area and 80% reported that all dust and debris was cleaned up at the end of the day. Eighty-eight percent of relocated households and 85% of non-relocated households felt that they were adequately protected during the intervention.
- *Nine percent of the 869 children who had both pre-intervention and immediate post-intervention blood lead samples had blood lead increases equal to or greater than 5 $\mu\text{g}/\text{dL}$.* This can be compared to a study completed in the 1980s, in which over 50% of children in homes that had undergone the “traditional” form of lead abatement (without dust lead cleanup) exhibited a significant increase in blood lead (Farfel 1990). Analysis of children in the Evaluation with blood lead samples at pre-intervention and immediate post-intervention did not reveal any differential effects between interventions on the probability of a child experiencing a blood lead increase equal to or greater than 5 $\mu\text{g}/\text{dL}$, suggesting that the increase was probably not related to the intervention itself. Statistical analysis found that in a number of cases, the increases may simply have been a function of the child’s age or the season in which the blood sample was drawn (blood lead levels tend to increase during the summer).
- *When grantees felt that households did not need to be relocated or could be partially relocated, the children were as protected (when measured by change of blood lead increases) as when grantees felt that households had to be relocated.* The relocation status of the household did not have a significant effect on the probability that a child would experience a blood lead increase of 5 $\mu\text{g}/\text{dL}$ or more from pre-intervention to immediate post-intervention. However, grantees did report that nine of the 81 children whose blood lead levels “spiked” may have experienced increases because of breakdowns in the occupant protection system. This suggests that grantees must remain vigilant in enforcing occupant protection practices and offering households the necessary support and incentives to stay out of the work areas.

Effects of Interventions on Dust Lead Loadings:

- *Lead hazard control activities undertaken by the grantees dramatically reduced the floor dust lead loadings and those levels were maintained for at least three years. The interventions were equally effective on window dust lead loadings.* Three years post-intervention geometric mean dust lead loadings on floors, window sills and window troughs were 9, 62 and 363 $\mu\text{g}/\text{ft}^2$, respectively. These levels represented declines of 78%, 89%, and 95%, respectively, from pre-intervention. Substantial declines were observed across all 14 grantee sites.
- *Although all interior strategies resulted in average floor dust lead loadings at one-year post-intervention that were well below the current hazard standard of 40 $\mu\text{g}/\text{ft}^2$, differential effects between Interior Strategies were identified.* Controlling for other factors, full interior lead abatement (Interior Strategy 06/07) was associated with the

largest relative reductions in floor dust lead loadings from pre-intervention to one-year post-intervention, while dwellings treated with window abatement (Interior Strategy 05) or full paint stabilization (Interior Strategy 03) had the smallest reductions.

- *Interior Strategy 05 was as effective at reducing floor dust lead loadings as most other strategies at clearance, but unlike homes treated with other interventions, something occurred in the Interior Strategy 05 homes between clearance and six months post-intervention that increased the geometric mean floor dust lead loadings.* Floor dust lead loadings in dwellings treated with Interior Strategy 03, 04, and 06/07 declined from clearance to six-months post-intervention, while loadings in dwellings treated with Interior Strategy 02 remained constant. The Evaluation was not able to identify the reason for the differences between interventions.
- *As with floors, Interior Strategies had different effects on post-intervention window dust lead loadings. The effects more closely matched original expectations that higher intensity interventions would result in larger relative reductions in window dust lead loadings.* Interventions where windows were abated (Interior Strategies 05 and 06/07) were associated with the largest reductions from pre-intervention to one-year post-intervention, while interventions where windows were only cleaned (Interior Strategy 02) had the smallest reductions.
- *Dust lead loadings on window sills and troughs all increased dramatically from clearance to six months post-intervention and then declined through three-years post-intervention, regardless of Interior Strategy.* Window dust lead loadings were higher at three years post-intervention than at clearance, but were substantially lower than pre-intervention. Because similar changes occurred in both dwellings where windows were abated and where they were unabated, it does not appear as though the windows themselves were a likely source of the immediate increase in dust lead.
- *While window abatement was demonstrated to be the most effective measure to reduce dust lead loadings on windows, this treatment must be performed in conjunction with other treatments that influence predictors of floor dust lead (e.g., floor surface type and condition, door and trim paint lead, and general interior building condition, as well as exterior dust/soil lead) in order to most effectively reduce floor dust lead levels.* Although pathway analysis suggests that window dust lead influences floor dust lead, only treating “up-stream” hazards would not result in substantial “down-stream” dust lead reductions. Furthermore, window dust lead loadings increased substantially shortly after clearance without influencing the floor dust lead loadings up to three years after treatment. These findings support the current requirement to address all interior, exterior and soil lead hazards in an integrated manner.
- *Both exterior and soil lead hazard control work influenced reductions in post-intervention floor dust lead loadings.* Interior floor dust lead loadings in dwellings not receiving exterior treatments were predicted to be 32 percent higher than the dwellings receiving exterior treatments, while floor dust lead loadings in dwellings not receiving soil work were predicted to be 45 percent higher than dwellings receiving soil treatments. For the average dwelling, the floor dust lead loading at one-year post-intervention was 3-4 $\mu\text{g}/\text{ft}^2$ higher if the dwelling did not receive one of the interventions to the outside of the building or its immediate surroundings.

- *Exterior entry dust lead loadings were found to contribute directly to interior entry floor, floor, and window sill dust lead loadings.* This finding suggests that treatments to control exterior entry dust lead may reduce interior dust lead loadings.
- *Site treatments (mainly interim soil controls) were associated with lower post-intervention exterior entry dust lead loadings.* Because of the impact of exterior entry dust lead levels on interior dust lead levels, these treatments also reduced dust lead loadings on window sills, interior entries and other interior floors.
- *Evidence of blow-in or track-in of lead from street dust was not observed.* The study shows that street dust does not serve as a significant source of lead in exterior entry dust because exterior entry dust lead concentrations were about four times as high as street dust lead concentrations. Therefore, street dust lead did not appear to be tracked into dwellings. Furthermore, street dust lead was not associated with window sill or trough dust lead loadings.
- *Window replacement was associated with lower window sill and window trough dust lead loadings one-year post-intervention compared to installation of window jamb liners, window paint stabilization or cleaning only.* At three years post-intervention, available data were more limited, but window sill and trough dust lead loadings were lower in dwellings with window replacement than those with cleaning only, after controlling for other factors.
- *Although rooms treated with paint removal are likely to have more dust lead at clearance, there did not appear to be a long-term detrimental effect of paint removal activities.* Rooms treated with paint removal had clearance dust lead loadings on bare floors that were 60% higher than loadings in rooms not treated with paint removal. However, at one and three years post-intervention, the geometric mean dust lead loadings were no longer significantly different for rooms treated with paint removal or not, after controlling for other factors.

Treatment Longevity:

- *Lead hazard control treatments tended to hold up for the three-year period for which they were observed.* The median dwelling in the Evaluation had only one physical failure two and three years post-intervention. Ten percent or less of the roughly 66,000 treatments analyzed were in a state of failure at any of the post-intervention phases (6 months: 4%, 1 year: 6%, 2 years: 9%, and 3 years: 10%).
- *Failures appeared to level off two years after clearance.* The percentage of failures rose quickly over the first year, then more slowly over the next two years. Since most if not all of the treatments were expected to last three years, the early rise in failure rates suggests that these failures were more attributable to poor installation or poor surface preparation than to product failure.
- *Components subject to abrasion, impact or weather were more likely to experience paint failure than other components.* During each post-intervention phase, paint stabilization of doors, windows and exterior components was more than twice as likely to fail than paint stabilization of interior trim and interior walls and ceilings.
- *Installation of window jamb liners was the treatment category that had the highest percentage of failures in each phase.* Six months after installation, 17 percent of rooms where jamb liners were installed had at least one jamb liner failure, while three years

after intervention, nearly half of the rooms with jamb liners failed (46%). This was twice the failure rate of the next most frequent failure (door paint stabilization). Over half of the jamb liner failures were attributed to inadequate installation and 29 percent failed because they were physically damaged.

- *Although further study is needed, the Evaluation suggests that encapsulation does not perform better than paint stabilization.* Strong conclusions are not possible because only 358 trim components and just over 100 wall/ceiling components were encapsulated (as compared with 10,025 trim and 7,949 wall/ceiling components that were paint stabilized). However, by two years after clearance, encapsulants had similar failure rates as paint stabilization on these components.

Effects of Interventions on Blood Lead Levels:

- *Interventions selected by grantees were quite successful in reducing blood lead levels.* Blood lead levels were significantly lower at each successive post-intervention phase until three-years post-intervention, at which time blood lead levels were not significantly different than at two-years post-intervention. At two-years post-intervention, geometric mean blood lead levels were 37 percent lower than at pre-intervention. Blood lead levels were 18 to 30 percent lower one-year post-intervention, which corresponds to declines in blood lead levels observed in previous studies of lead hazard control interventions (18-34%) (USEPA, 1995).
- *Children with pre-intervention blood lead levels as low as 10 µg/dL (the CDC level of concern) experienced substantial declines in blood lead level following interventions.* Previous studies had not observed substantial declines unless a child's pre-intervention blood lead level was above 20 µg/dL.
- *The results support the hypothesis that declines in residential dust lead loadings (as well as correction of deteriorated lead-based paint) resulted in lower blood lead levels.* Although the link between dust lead and blood lead that was observed pre-intervention was not significant one-year post-intervention, it is likely that the relationship could not be observed because the child's body burden of lead became a better predictor of post-intervention blood lead. The correlation between pre-intervention blood lead levels and floor dust lead loadings (0.29, $p < 0.01$) was very similar to the correlation one-year post-intervention (0.32, $p < 0.01$).
- *No differential interior strategy effect was noted for declines in blood lead.* The hypothesis that differences in lead hazard control intervention intensity would yield differences in blood lead levels was not demonstrated. For the four interior strategies that were examined in the one-year post-intervention blood lead models (Interior Strategies 02-05), *window sill and window trough dust lead* loadings were significantly lower in dwellings where windows were abated (Interior Strategy 05). However, *interior floor dust lead* loadings were not significantly lower in these same dwellings. Assuming interior floor dust lead is the primary exposure pathway of dust lead to a child, as established by the pre-intervention model and previous research, this finding may suggest a reason why Interior Strategy 05 did not prove to be more effective than the other interior strategies.
- *Exterior lead hazard control in the presence of high exterior paint lead loadings was related to differences in one-year post-intervention blood lead.* Children living in dwellings where the exterior paint lead levels were above 7 mg/cm² and the exteriors

were treated had lower post-intervention blood lead levels than children living in dwellings without these conditions.

- *Important factors that modified the effects of strategies on blood lead levels included pre-intervention blood lead levels, parental report of previous lead poisoning, child's age, and season.* When controlling for all other factors, children who were reported to be lead poisoned prior to enrollment and/or had higher pre-intervention blood lead levels also had higher post-intervention blood lead levels. Even after intervention, children's blood lead levels tended to peak for children 24 months of age and when children were tested in the summer. This supports the finding that body burden is significantly related to blood lead level.

Measures of Effectiveness

Dust Lead Loading

Inspectors trained in the Evaluation's standard single-surface dust wipe collection protocol collected floor samples from the interior entry to the dwelling, and doorways in the youngest child's playroom (or living room), that child's bedroom, a second child's bedroom and the kitchen. Interior window sill samples were collected from the youngest child's bedroom and kitchen. Window trough samples were collected from the child's playroom and second child's bedroom. The inspector determined the exact sampling locations based on the availability and operability of windows and the presence of a second child's bedroom. Inspectors returned to the same sampling locations in each phase of the evaluation. Inspectors alternated the exact location of the sampling from one side to the other of the doorway or window in each phase, to reduce the possible influence of the previous sampling.

Each grantee selected its own laboratory (or laboratories) to analyze the dust samples. Each laboratory provided evidence that it was proficient under the American Industrial Hygiene Association's Environmental Lead Proficiency Analytical Testing Program. Laboratories were not required to be accredited under the EPA National Lead Laboratory Accreditation Program because the study began early in that program's existence and few laboratories were as yet recognized. Lead was measured by flame atomic absorption, graphite furnace atomic absorption, or inductively coupled plasma-atomic emission spectrometry.

Grantees submitted both blank wipe samples and double-blind quality control samples to the laboratories on a regular basis. The quality control samples were prepared by the Wisconsin State Occupational Health Laboratory by applying set quantities of NIST Standard Lead Paint Dust (Standard 1578) to a wipe. Dust samples analyzed during a period when a laboratory's values exhibited a pattern of deviation by more than 20 percent from the target values are excluded from this report.

The method detection limits of the laboratories varied from 1 to 25 $\mu\text{g}/\text{ft}^2$. Midway through the evaluation, it was determined that many dust lead results (e.g., about one-half of the post-intervention floor dust lead values) were falling below the limits of detection. Because the values would restrict the observations of changes in dust lead levels, the evaluators asked the laboratories to provide the instrument reported value for future samples and previously reported samples. The instrument value, when available, is used in this report. Where the instrument value was not available, values below detection limits were assigned a value using imputation.

Blood Lead Concentration

Trained phlebotomists obtained blood specimens from participating children, primarily by venipuncture. On a case-by-case basis, a phlebotomist could make a determination that a venous sample was unattainable and collect a capillary sample instead. Three grantees received approval to use capillary sampling (fingerstick) as their primary blood collection method. Phlebotomists at these sites received training in proper fingerstick techniques.

Each grantee selected its own laboratory (or laboratories) to analyze the blood specimens. Each laboratory was required to meet the proficiency standards set under the Clinical Laboratory Improvement Act of 1988. Lead was measured by either graphite furnace atomic absorption spectrophotometry or anodic stripping voltammetry. The limits of detection varied by laboratory from 1 to 5 $\mu\text{g}/\text{dl}$. Undetectable levels were assigned a value using imputation.

Grantees submitted blinded quality control samples to the laboratories on a regular basis. CDC prepared the quality control samples from whole bovine blood pools. The evaluation quality control officer worked with any laboratory whose performance fell outside of the quality control standards set in the study protocols (more than 3 $\mu\text{g}/\text{dl}$ different from the target value). Blood samples analyzed during a period when a laboratory fell outside of the standards are excluded from this report.