## EXECUTIVE SUMMARY

This report is a supplement to the EPA report "Risk Analysis to Support Standards for Lead in Paint, Dust, and Soil" (USEPA, 1998a), which presented the methods and findings of a risk analysis that supported efforts by the U.S. Environmental Protection Agency (EPA) to set regulatory standards for lead levels in dust and soil and to control lead-based paint hazards within most pre-1978 housing and child-occupied facilities. These regulatory standards were mandated through §403 of the Toxic Substances Control Act (TSCA), as specified within Title X, the Residential Lead-Based Paint Hazard Reduction Act of 1992 (42 U.S.C. 4851). The §403 risk analysis provided EPA with a scientific foundation for establishing the regulatory standards. On June 3, 1998, EPA proposed a regulation to establish these standards (40 CFR Part 745); this regulation is referred to as the "§403 proposed rule."

In 1998, the Environmental Health Committee of EPA's Science Advisory Board (SAB) conducted a technical review of the §403 risk analysis. In response to this review, EPA deemed that a supplement to USEPA (1998a), referred to as the "§403 risk analysis report," was necessary to provide additional technical analyses and to clarify certain key analyses and findings presented within the report. EPA used the summaries and analyses of data considered in the original §403 risk analysis to prepare responses to the public comments on the §403 proposed rule and to prepare the final rule. Although this supplement also presents summaries and analyses of data made available to EPA since the §403 proposed rule was released, such as interim data from the National Survey of Lead and Allergens in Housing (NSLAH), this type of information is meant only to provide an alternative to the findings presented in the §403 risk analysis report. EPA has not used these new data in efforts to select the hazard standards or levels of concern that are included within the final rule. Furthermore, this supplement does not replace any parts of the original §403 risk analysis, but rather supplements this risk analysis with more detailed analyses on selected topics.

The format of this supplement follows that of the §403 risk analysis report, with separate chapters for each phase of the risk assessment (hazard identification, exposure assessment, dose-response assessment, and risk characterization) and a final chapter on risk characterization under example options for standards. The remainder of this executive summary summarizes the key issues and findings presented within each chapter of this supplement.

#### Hazard Identification (Chapter 2)

Additional evidence that lead-based paint hazards pose a health risk to children and the magnitude of such risk was provided in the following four areas within this supplement:

• Adverse health effects of lead exposure, with a focus on neurological effects, as observed in animal studies (to address the point raised in the SAB review that animal data can support causality effects over and above the available data on humans).

- Evidence supporting causality between lead exposure and adverse health effects.
- The association between blood-lead concentration and reduction in intelligence quotient (IQ) score.
- The role that dust particle size and the chemical composition of lead compounds in lead-contaminated dust may play in determining the extent to which lead in residential dust is bioavailable to humans.

Adverse health effects, especially neurotoxicity, observed in animal studies. Lead has been observed to have widespread neurotoxic effects, as well as behavioral and cognitive symptoms, in humans. These observations are largely consistent with the findings that have been demonstrated in controlled, dose-response studies on animals (e.g., rodents, dogs, non-human primates). Animal studies are also congruent with observations of lead exposure in humans, suggesting an increased susceptibility of the young brain to lead poisoning (Banks et al., 1997). For example, lead-induced alteration of protein kinase C (PKC) activity in the brain has been shown to correlate with poor performance in several learning tasks in animal studies, and researchers have suggested that some of the learning and memory deficits observed in children are likely to be causally related to the types of PKC activity alterations exhibited in these studies (Chen et al., 1998). In addition, animal studies have provided physiological evidence that many of the effects of lead on the differentiation of the developing nervous system, such as synaptic and dendritic development, and myelin and other nerve structure formation, have the potential to be long-lived (USEPA, 1986). Although animal models do not duplicate the human response to lead exposure, they do serve to provide strong support for expecting certain health effects to occur when humans are exposed.

<u>Cause-effect relationship of lead exposure and adverse health effects</u>. The combined weight of human and animal studies provides evidence that lead may be assumed to cause adverse neurological effects in young children. For example, longitudinal studies in humans (e.g., Boston, Port Pirie) have shown that disturbances occur in neurobehavioral development early in life even at low lead exposure levels. These studies have observed effects of lead exposure even after accounting for other demographic factors (e.g., socioeconomic status, maternal IQ) that could affect neurological development. While these other demographic factors tend to be highly correlated with blood-lead levels early in life, the influence that lead exposure has on blood-lead tends to increase with a child's age. This is because over time, measures of a child's lead exposure tend to change at a faster rate than the child's demographic measures, and more recent lead exposures continue to be predictive of a child's current health consequences. The §403 risk analysis assessed these adverse neurological effects in children through measuring average IQ score decrements in the population due to lead exposure.

<u>Association between blood-lead concentration and IQ score decrement</u>. This supplement provides additional technical justification regarding the assumptions made in the §403 risk analysis on the association between blood-lead concentration and decrement in IQ score.

While prior investigations into this relationship have considered both linear and log-linear associations, a linear relationship (with positive slope) was used in the §403 risk analysis based on the evidence taken from these investigations and the desire not to unduly over-estimate the IQ decrement associated with children having low blood-lead concentrations.

Recent studies and meta-analyses investigating the presence of a threshold in the blood-lead/IQ relationship (e.g., Schwartz, 1994) have concluded either that no non-zero threshold exists, or if one does exist, if may be very low (e.g., less than  $1.0 \mu g/dL$ ; Schwartz, 1993). Researchers who disagree with this conclusion have not reached a clear consensus on a value for this threshold. Several older studies that have suggested high thresholds (e.g., over  $10 \mu g/dL$ ) involved few, if any, children at low blood-lead levels, thereby preventing their ability to provide information on potential health effects at low levels. Other researchers have used visual inspection of data summaries to conclude that thresholds exist at relatively high levels, rather than using statistical inference techniques that would yield more scientifically defensible conclusions. As it would have been necessary to have clear, scientifically defensible evidence of a particular non-zero threshold to justify its adoption within the §403 risk analysis, and based on the findings of recent meta-analyses, the approach taken in the §403 risk analysis was to assume that no threshold exists. Nevertheless, sensitivity analyses documented in this supplement have investigated the impact of assuming a positive threshold on the risk analysis estimates.

<u>Effect of residential dust characteristics on the bioavailability of lead in dust</u>. It has been suggested that lead speciation and particle size may affect the bioavailability of lead in dust through their influence on solubility. Therefore, this supplement included an investigation of current knowledge about bioavailability of lead in dust and how this knowledge may impact the rulemaking process.

There is relatively little in the literature which examines the relationship between bioavailability and chemical composition specifically for household dust. Animal studies have concluded that different lead compounds are associated with different rates of absorption (e.g., metallic-lead was associated with low absorption). Otherwise, most of the investigations into the effect of lead speciation on bioavailability primarily address lead in soil. However, soil can have a considerable influence on dustlead levels. Evidence exists that correlation between blood-lead and soil-lead levels can be influenced by both particle size and chemical composition. Generally, the smaller the particle size, the greater the absorption of lead due to more rapid dissolution in the gastrointestinal tract. Some researchers have also hypothesized that smaller particle sizes can contain higher lead concentrations.

While evidence does suggest that particle size and chemical composition can influence the level of bioavailability of lead in dust, the current information base may be inadequate to determine how such factors can reasonably be incorporated into the rulemaking effort. Furthermore, needing to characterize dust in this manner within a risk assessment would likely add to the expense of dust analyses, and dust standards that distinguish between these various characterizations could add considerable complexity to the rule.

## Exposure Assessment (Chapter 3)

When using model-based procedures to estimate health risks associated with lead-based paint hazards, the §403 risk analysis used data from the 1989-1990 HUD National Survey of Lead-Based Paint in Housing to characterize lead levels in dust and soil within the nation's housing stock. As mentioned above, more recent data have been made available to EPA since the §403 risk analysis report and the proposed rule were published, and some commenters on the proposed rule suggested that EPA should use these data when available. These data include interim data (collected in 1998 and 1999) for 706 housing units from the NSLAH, an on-going national survey of lead levels in dust and soil in the nation's housing. HUD assigned interim sampling weights to these 706 surveyed units in such a way as to allow interim results that properly incorporate these sampling weights to be nationally representative of occupied housing in which children can possibly reside. Other recently-acquired data that are summarized in Chapter 3 of this supplement include additional data from the Evaluation of the HUD Lead-Based Paint Hazard Control Grant Program ("HUD Grantees") and data from the 1997 American Housing Survey.

Comparing dust-lead loadings in the HUD National Survey with those of other studies. Before dust-lead loadings measured in the HUD National Survey could be compared to dust-lead loadings from other studies, the loadings needed to be adjusted to reflect the fact that the HUD National Survey used a vacuum technique rather than a wipe technique to collect the dust samples. The §403 risk analysis included a procedure for performing this adjustment. The resulting dust-lead loadings, adjusted to represent dust samples collected using wipe techniques, tended to be lower than the wipe dust-lead loadings reported in other recent lead exposure studies (e.g., Rochester study, HUD Grantees evaluation), even when taking into account housing age category and Census region. One major exception, however, were data from the interim NSLAH, whose distribution of dust-lead loadings was lower than in the HUD National Survey for both floors and window sills. For example, household average floor dust-lead loadings based on the interim NSLAH data had a median of less than 2  $\mu$ g/ft<sup>2</sup>, compared to approximately 5.3  $\mu$ g/ft<sup>2</sup> as estimated in the §403 risk analysis based on the HUD National Survey data. The estimated percentage of housing units with average floor dust-lead loadings that exceed 50  $\mu$ g/ft<sup>2</sup> (i.e., the proposed floor dust-lead standard) was 6.4% based on HUD National Survey data used in the §403 risk analysis, and 0.9% based on interim the NSLAH.

<u>Comparing soil-lead concentrations in the HUD National Survey with those of other studies</u>. Data on yardwide average soil-lead concentrations from the HUD National Survey were compared with interim NSLAH data, as well as data for 22 other studies that characterized soil-lead concentrations in urban areas prior to any lead abatement. While geometric mean yardwide average soil-lead concentration was lower in the HUD National Survey relative to most of the other studies reviewed, the distributions of yardwide average soil-lead concentration were similar between the HUD National Survey and the interim NSLAH (although the estimated median was nearly 50% lower in the HUD National Survey versus the interim NSLAH for homes built prior to 1940). Regardless of which national survey is considered, the risk analysis supplement estimates that the yardwide average soil-lead concentration exceeds 2000 ppm in approximately 1.7% of housing, approximately 3.3% of housing exceeds an average soil-lead concentration of 1200 ppm, and between 11% and 12% of housing exceeds an average soil-lead concentration of 400 ppm.

Soil pica in children. Because the impact of paint pica (i.e., the purposeful ingestion of paint chips) on blood-lead concentration in the presence of deteriorated lead-based paint is not represented within other environmental exposures to lead, the §403 risk analysis accounted for paint pica as a separate factor when estimating risks. While the analysis did not consider the independent impact of soil pica (i.e., the purposeful ingestion of soil) over and above paint pica, it considered the impact of soil pica as part of the relation between soil-lead concentration and blood-lead concentration. While this supplement does not change the approach taken in the original risk analysis, it documents information obtained on the component of soil-lead exposure that may be attributable to soil pica.

Based on what has been found in the literature on studies in which paint pica and soil pica behaviors were characterized and could be separated, approximately 10% to 20% of study children appeared to exhibit soil pica behavior in the absence of paint pica. The frequency of soil pica episodes depends on many factors, including climate, access to bare soil, socioeconomic standing, age of child, and parental supervision. While estimates of the amount of soil ingested during pica episodes can vary widely among mass balance studies (i.e., from 500 to 13,000 mg/day), average daily ingestion over a year may be much lower. Because soil pica behavior tends to be episodic in nature, it is currently uncertain whether the amount of lead in soil ingested on an infrequent basis would be sufficient to elevate blood-lead concentration to unsafe levels. Again, it should be noted that the original §403 risk analysis did include an effect of soil pica in the relationship between soil-lead and blood-lead levels; the additional information presented in this supplement addresses how the effect of soil pica is separated from the effect of paint pica.

Dust-lead levels on surfaces other than floors and window sills. Comments were received on the §403 proposed rule recommending that EPA establish dust standards for surfaces other than floors and window sills. In response, EPA conducted further analysis on whether surfaces other than floors and window sills might provide significant additional information for risk assessments. EPA reviewed what has been published regarding dust-lead loadings from exterior locations, air ducts, window troughs (also known as window wells), and upholstery, with special attention given to studies that investigated the correlation between such dust-lead levels and blood-lead concentrations.

It is difficult to use data from lead exposure studies to characterize the effect of lead exposure from **exterior dust** on children's blood-lead levels, primarily because studies differ considerably in how they collect exterior dust and how they report the results of lead analysis. For example, some studies have collected both exterior dust and soil for lead analysis but report results that are combined across both media. Also, studies often differ in their sampling approaches (e.g., surface scrapings, vacuum sampling) and in the locations at which the samples are taken. Furthermore, studies frequently have not investigated the specific influence of exterior dust-lead on blood-lead level in the presence of

lead in other environmental media. For these reasons, along with the fact that lead in exterior dust can be highly correlated with soil-lead, a scientifically defensible standard for lead in exterior dust was not identified, nor was such a standard deemed essential over and above the planned standards for lead in soil and interior dust. This latter conclusion becomes more acceptable if risk assessors are made aware that lead in exterior dust can be associated with adverse health effects in children, and as a result, recommend corrective action in cases where lead is present in exterior dust and is suspected to be an important pathway of exposure (e.g., when children spend a considerable amount of time on hard surfaces immediately outside of the residence).

For **air ducts** and **upholstery**, there is insufficient data upon which to characterize the role that lead in dust from these surfaces plays in a child's total lead exposure, and therefore, to develop a hazard standard for lead on these surfaces.

Because dust from **window troughs** (i.e., window wells) has historically been sampled in lead exposure studies (along with floors and window sills), and because risk assessors sample dust from window troughs in determining clearance following a lead-based paint intervention, reports of window trough dust-lead levels are generally prevalent in the literature. However, several studies have reported that the association between window trough dust-lead and blood-lead is not statistically significant after taking into account the effects of dust-lead on floors and window sills (for which standards have been proposed under §403). For this reason, along with the likelihood that exceeding a window sill dust-lead standard will prompt a cleaning of leaded-dust from window troughs as well as sills, it does not appear that an additional standard for window troughs is necessary either to identify a home with a hazard or to guide corrective actions. Also, given the correlation in lead levels between window troughs and window sills, it is likely that if more sampling is to be done beyond a minimal risk assessment, more benefit would be obtained from sampling more windows at only the sill rather than fewer windows at both the sill and trough.

<u>Distribution of childhood blood-lead</u>. Information on the distribution of blood-lead concentrations in children based on data from the HUD Grantees evaluation was updated to reflect additional data collected through January, 1999. These data provided a means by which estimates based on data from Phase 2 of the Third National Health and Nutrition Examination Survey (NHANES III) (i.e., the data used in the §403 risk analysis to characterize blood-lead levels in the nation) could be evaluated. The HUD Grantees evaluation data (under venipuncture blood collection) had a geometric mean of 9.3  $\mu$ g/dL for children aged 1-2 years and 8.0  $\mu$ g/dL for children aged 3-5 years. In contrast, the geometric means based on data from Phase 2 of NHANES III were 3.1  $\mu$ g/dL for children aged 1-2 years and 2.5  $\mu$ g/dL for children aged 3-5 years. Also, 51 percent of children aged 1-2 years sampled via venipuncture methods had blood-lead concentrations at or above 10  $\mu$ g/dL, compared to the estimates of 5.9% for Phase 2 of NHANES III, 53.8% for the Baltimore R&M study (preintervention), and 23.4% for the Rochester Lead-In-Dust study. The trend toward high blood-lead levels in the HUD Grantees evaluation reflects, among other factors, the HUD Grantees program's procedure of selecting high-risk children for monitoring. While NHANES III provides the most nationally representative data on children's blood-lead concentration, it does not provide environmental-lead data that could be used to investigate the effect of environmental-lead exposure on blood-lead concentration. Therefore, other data sources such as the HUD Grantees evaluation must provide this information.

Regression modeling of the blood-lead concentration data suggests that the relationships between blood-lead concentration and household average dust-lead loading were relatively consistent across grantees. In particular, these relationships were similar to that observed for data from the Rochester study (i.e., the data used to develop the empirical model presented in Chapter 4 of the §403 risk analysis). This conclusion is important in that the data from the HUD Grantees evaluation reflect a much larger geographical area than the Rochester study and represent several types of exposure conditions.

This risk analysis supplement includes evidence that housing age and condition play important roles in the likelihood of a resident child having an elevated blood-lead concentration. The association between older housing and the prevalence of lead hazards has been well-documented and is accepted by many experts in residential lead exposure. The level of deterioration is an important variable in the accessibility of lead-based paint hazards to children.

### Dose-Response Assessment (Chapter 4)

The objective of the dose-response assessment in the §403 risk analysis was to develop a statistical procedure to characterize the relationship between environmental-lead exposure and the resulting adverse health effects in young children. This characterization would then be used to estimate health risks at specified environmental-lead levels or over the entire population. The modeling tools used in this characterization were EPA's Integrated Exposure, Uptake, and Biokinetic (IEUBK) model and an empirical model developed especially for the §403 risk analysis from data collected in the Rochester Lead-in-Dust study. In this supplement, additional models were considered to quantify this characterization: a new model developed from epidemiological data collected from 12 lead exposure studies and made available to EPA after the §403 risk analysis was completed, and revisions to the multimedia model developed for the §403 risk analysis using the Rochester study data ("Rochester multimedia model"). In addition, this supplement provides additional detail on specific aspects of the model-based analysis employed within the §403 risk analysis, such as how post-intervention blood-lead concentration distributions are characterized and how measurement error was handled when fitting the empirical model.

<u>HUD Model</u>. An additional model for predicting blood-lead concentration as a function of environmental-lead levels became available after the §403 risk analysis report was published. Some commenters on the §403 proposed rule suggested that EPA use this new model. This new model is a log-linear regression model developed on behalf of the U.S. Department of Housing and Urban Development (HUD) from epidemiological data collected from 12 studies. Thus this model is referred to in this supplement as the "HUD Model." The goal of this model was to "estimate the contribution of lead-contaminated house dust and soil to children's blood-lead levels" (Lanphear et al., 1998).

When using the HUD model to predict blood-lead concentration as a function of lead levels in various environmental media, this risk analysis supplement has noted several caveats associated with interpreting the predicted blood-lead concentration:

- Risks associated with exposure to specific environmental-lead levels (as estimated from the HUD model) are generally not comparable to population-based risks (as estimated by the IEUBK and empirical models in the §403 risk analysis).
- The prediction parameters in the HUD model are not independent. Therefore, it is not appropriate to interpret the parameter estimates in the HUD model (or in the models developed for the \$403 risk analysis) in isolation.
- The HUD model has adjusted for measurement error in certain environmental-lead measures used as input. Therefore, the model assumes that these input values represent "actual" exposure levels. In contrast, the models developed for the §403 risk analysis use measured levels as input that would be reported from a risk assessment. Because the §403 standards will be compared to lead exposure measures that are subject to being measured with error, this latter approach is more relevant for rulemaking purposes.

Further discussion of the HUD model is provided in Chapters 4 and 5 of this supplement.

# Risk Characterization (Chapter 5)

Health risks associated with current (i.e., baseline) lead exposures for children aged 1 to 2 years were characterized in the §403 risk analysis. Both individual risk estimates (i.e., risks associated with specific environmental-lead levels) and population-based risk estimates (i.e., average risks over the entire nation) were presented. In this supplement, additional sensitivity and uncertainty analysis associated with the baseline risk characterization was performed, where possible alternatives to various approaches taken and assumptions made in the risk characterization were identified and incorporated into the analysis, and the resulting impact on the risk estimates was evaluated.

When predictions under the Rochester multimedia model (developed in the §403 risk analysis to characterize individual risks) were compared to predictions under the HUD model, the following general findings were observed:

• At very low floor dust-lead loadings (i.e.,  $1-5 \mu g/ft^2$ ), the HUD model and the Rochester multimedia model yield similar predictions for the geometric mean blood-lead

concentration, which also results in similar predictions for the health-effect endpoints that are calculated directly from this geometric mean (e.g., percentage of children with blood-lead concentration at or above a specified threshold; average IQ decrement resulting from lead exposure).

- The predicted geometric mean blood-lead concentration under the HUD model ranges from 20% to nearly 60% higher than the prediction under the Rochester multimedia model as floor dust-lead loadings increase from 15 to 100  $\mu$ g/ft<sup>2</sup> and as soil-lead concentrations decrease from 2000 ppm to 10 ppm (assuming, for the Rochester multimedia model, that window sill dust-lead loadings are at their estimated national median level). Note that for a fixed value of the geometric standard deviation (GSD) for the blood-lead distribution, the average IQ decrement in the population that is associated with lead exposure is a multiple of the geometric mean (as calculated in the §403 risk analysis). Therefore, similar differences in predictions between the two models would occur for <u>average IQ decrement</u>.
- If the geometric standard deviation (GSD) associated with the blood-lead distribution is fixed, then as floor dust-lead loadings increase beyond  $10 \mu g/ft^2$ , the predicted percentage of children with blood-lead levels at or above  $10 \mu g/dL$  increases at a much faster rate under the HUD model (at a constant soil-lead level). For example, if window sill dust-lead loading is at its estimated national median and soil-lead concentration is below 2000 ppm, the predicted percentage under the HUD model is at a minimum twice as large as the prediction under the Rochester multimedia model . This difference in predictions gets even greater as the assumed soil-lead concentration gets lower. For example, at a GSD of 1.6, a floor dust-lead loading of  $100 \mu g/ft^2$ , and a soil-lead concentration of 10 ppm, the prediction is over 7 times higher for the HUD model compared to the Rochester multimedia model (13.1% versus 1.76%).

Other findings within the additional sensitivity analyses performed to support the baseline risk characterization were as follows:

- If it is assumed that a 50% across-the-board decline in blood-lead concentration has occurred relative to the distribution portrayed by data from Phase 2 of NHANES III, the estimated number of children whose blood-lead concentration was at or above 20  $\mu$ g/dL declined by 95% (from 46,800 to 2,130), while the estimated number at or above 10  $\mu$ g/dL was reduced by nearly 90% (from 458,000 to 46,800). The estimated average IQ decrement in the population due to lead exposure is cut in half under this assumption (from 1.06 to 0.53 points).
- Model-based baseline risk estimates were calculated for various alternative assumptions on the percentage decline in dust-lead and soil-lead levels that may have

occurred in the housing stock since the HUD National Survey was conducted. Risk estimates under the empirical model seemed to be more sensitive to these changes than the estimates under the IEUBK model, and reductions in soil-lead concentration seemed to have more of an impact on reducing these risk estimates than reductions in dust-lead levels. Baseline estimates for the percentage of children with blood-lead concentrations at or above  $10 \mu g/dL$  were 45% lower under the empirical model when both dust-lead and soil-lead levels were decreased by 50%, with smaller declines occurring for less drastic total reductions in the environmental-lead levels.

In an effort to determine whether an assumption of no threshold made in the §403 risk analysis was particularly sensitive to the risk estimates, baseline estimates of the IQ-related health effect endpoints were calculated under the assumption that specified non-zero thresholds exist in the relationship between blood-lead concentration and IQ score decrement. While the §403 risk analysis estimated an average IQ decrement of 1.06 points occurs due to lead exposure across the population of children aged 1-2 years, this average declines by approximately 44% under a assumed threshold of 2 µg/dL (0.588 points) and by 90% under a threshold of 8 µg/dL (0.103 points).

## Analysis of Example Options for the §403 Standards (Chapter 6)

Prompted by public comments on the §403 proposed rule and risk analysis, this supplement included the following on methods used in the §403 rulemaking process to evaluate candidate hazard standards and levels of concern:

- Detailed information on performance characteristics analyses (also known as sensitivity/specificity analysis), used by EPA to help establish levels of concern within the \$403 rule.
- Characterizing the extent to which children with elevated blood-lead concentrations reside in homes where no candidate standard is met or exceeded (i.e., children who would be "missed" by a specified set of candidate standards), as part of the candidate standards evaluation process.
- An additional investigation into the assumptions made in the risk management study on post-intervention dust-lead loading (40  $\mu$ g/ft<sup>2</sup> on floors, 100  $\mu$ g/ft<sup>2</sup> on window sills).
- Additional sensitivity and uncertainty analyses for the analyses performed and documented within Chapter 6 of the §403 risk analysis, including alternative assumptions on baseline and post-intervention environmental-lead levels.

Performance characteristics analysis. Performance characteristics analysis is a non-modeling approach (based on calculating conditional probabilities) to assessing how often a specified set of candidate hazard standards would "trigger" interventions in housing units within the studies in question and the extent to which these units contained a child with an elevated blood-lead concentration (\$10  $\mu$ g/dL). Data from the Rochester Lead-in-Dust study were used in these analyses. This supplement contains a detailed discussion of how to interpret performance characteristics analysis and provides additional information on analysis results that were cited in the \$403 proposed rule. Furthermore, this supplement presents the results of follow-on performance characteristics analyses which EPA considered when responding to public comments and in preparing the final rule. While the analysis presented in the proposed rule was based on data for 77 housing units in the Rochester study, additional assumptions made to the soil-lead data permitted up to 184 units to be represented among the data analyzed in the follow-on performance characteristics analyses. One goal of these analyses was to identify those sets of candidate dust-lead loading standards for which the analysis estimated that no more than 5% of children living in housing units with environmental-lead levels below the standards would have elevated blood-lead concentrations.

Investigating incidence of elevated blood-lead concentrations in homes where no candidate standard is met or exceeded. As an alternative to the performance characteristics analysis, a modelbased approach was developed to determine the likelihood of a child with elevated blood-lead concentration residing in a housing unit that exceeds none of a given set of candidate standards. This approach was designed to use data from the Rochester study and to yield results that would be directly comparable to those from the performance characteristics analysis.

<u>Review of published information on post-intervention dust-lead loadings</u>. To evaluate the performance of a given set of candidate standards in reducing population-based health risks to lead exposure, the 403 risk analysis needed to make assumptions on lead levels in dust and soil that would occur after performing interventions that would be prompted by exceeding the example standards. Assumptions made on post-intervention dust-lead loadings ( $40 \mu g/ft^2$  for floors,  $100 \mu g/ft^2$  for window sills) within the 403 risk analysis were evaluated in this supplement in a detailed review of results from studies that evaluated abatement effectiveness.

In the reviewed studies, geometric mean or median floor dust-lead loadings were generally at or below 41  $\mu$ g/ft<sup>2</sup> over periods ranging from 6 months to 6 years post-intervention, with several studies reporting levels below 21  $\mu$ g/ft<sup>2</sup> at follow-up periods ranging from 12 months to 2 years. Of the eight grantees participating in the HUD Grantees evaluation that had post-intervention floor dust-lead loadings available at 12 months post-intervention, four had median values for these loadings that were at or below 10  $\mu$ g/ft<sup>2</sup>. Median pre-intervention floor dust-lead loadings, geometric means or medians ranged from 9 to 26  $\mu$ g/ft<sup>2</sup>. For post-intervention window sill dust-lead loadings, geometric means or medians ranged from 24  $\mu$ g/ft<sup>2</sup> to 958  $\mu$ g/ft<sup>2</sup> in the reviewed studies. Most of the study groups had geometric mean or median post-intervention window sill dust-lead loadings below 100  $\mu$ g/ft<sup>2</sup>, while a few were at or below 51  $\mu$ g/ft<sup>2</sup>.

As a result of the post-intervention dust-lead loadings review, a sensitivity analysis documented in this supplement applied the methods developed in the risk analysis under alternative post-intervention floor dust-lead loadings of 10 and 25  $\mu$ g/ft<sup>2</sup> and post-intervention window sill dust-lead loadings of 50 and 75  $\mu$ g/ft<sup>2</sup>. Results of this sensitivity analyses indicated that while more housing units may be assumed to achieve reductions in average dust-lead loading as a result of lowering the post-intervention dust-lead loading assumptions, the corresponding reduction in the estimated blood-lead concentration and health effect endpoints appeared to be modest, especially compared to the reduction that occurs from pre-intervention conditions.

See page I-i of Appendix I for an executive summary of an investigation on the relationship between lead levels in carpet-dust and children's blood-lead concentration and on how extending the floor dust-lead loading standard in the §403 proposed rule to include carpeted floors might impact the performance of these proposed standards.