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Lead Paint Test Kits Workshop October 19 and 20, 2006 Summary Report

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Lead Paint Test Kits Workshop

October 19 and 20, 2006

Summary Report

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Table of Contents

List of Acronyms

ASTM	American Society for Testing and Materials
ASV	anodic stripping voltametry
CRADA	cooperative research and development agreement
EPA	U.S. Environmental Protection Agency
ETV	Environmental Technology Verification Program (EPA)
HEASD	Human Exposure and Atmospheric Sciences Division (EPA/ORD/NERL)
HUD	U.S. Department of Housing and Urban Development
NERL	National Exposure Research Laboratory (EPA)
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
OPPTS	Office of Prevention, Pesticides, and Toxic Substances (EPA)
ORD	Office of Research and Development (EPA)
RRP	Lead; Renovation, Repair, and Painting Program; Proposed Rule
SRM	standard reference material
TSCA	Toxic Substances Control Act
XRF	X-ray fluorescence

Executive Summary

The U.S. Environmental Protection Agency's (EPA's) Office of Research and Development (ORD) designed and conducted the Lead Paint Test Kits Workshop on October 19 and 20, 2006, at the EPA's Research Triangle Park, NC, campus. The workshop was conducted as part of ORD's support to EPA's Office of Pollution Prevention and Toxics (OPPT). OPPT has requested ORD's assistance in lead paint test kit technology development to support the proposed "Lead; Renovation, Repair, and Painting Program; Proposed Rule" (RRP rule) published in the January 10, 2006, *Federal Register* (pp.1587-1636). The proposed rule supports the attainment of the Federal government's goal of eliminating childhood lead poisoning by 2010. In the rule, EPA proposes new requirements to reduce exposures to lead hazards created by renovation, repair, and painting activities that disturb lead-based paint. EPA has proposed the use of EPA-recognized test kits to determine whether the components to be affected are free of regulated lead-based paint. The Federal regulated level is defined as paint containing lead at or above 1.0 mg/cm^2 or 0.5% by weight.

Research to date has shown that commercially available lead paint test kits suitable for use by remodelers, renovators, and painters are not an effective means of identifying homes that contain regulated lead levels in paint. In the proposed RRP rule, EPA has provided the following performance standards for a test kit to be recognized by EPA.

- Demonstrated probability (with 95% confidence) of a negative response less than 5% to lead levels above the regulated level
- Demonstrated probability of a false positive response of no more than 10% to lead levels below the regulated level

Additionally, in the proposed RRP rule, the stated goals for current EPA test kit research are to develop kits that meet the above performance standards and that

- can be used reliably by a person after minimal training (i.e., nonanalyst),
- inexpensive (under $2 per test),
- provide results within 1 h, and
- are available commercially within the next 3 years.

The workshop was a component of the first of a four-part approach developed by the Human Exposure and Atmospheric Sciences Division/ National Exposure Research Laboratory (HEASD/NERL/ORD) to facilitate the development and improvement of lead paint test kits to meet the performance specifications of the proposed RRP rule. The approach consisted of (1) evaluation of the state of the science of lead paint test kits as of 2006; (2) conducting research to address the identified sources of error; (3) development of synthetic lead paint test materials that are predictive or diagnostic of kits' performance with real-world paints; and (4) development of collaboration with vendors to refine, produce, and market lead paint test kits that meet the RRP requirements.

The first part of the HEASD approach, evaluation of the state of the science of lead paint test kits as of 2006, was supported by the preparation of an issue paper entitled "Draft Report on the State of Development, Availability, Evaluation, and Future Use of Test Kits for the Measurement of Lead in Paint." This report was sent to the participants as part of the preworkshop materials.

The Lead Paint Test Kits Workshop provided a forum for technical information exchange among experts from EPA, other government agencies, academia, private industry, and testing and standards organizations regarding the performance of lead test kits. The objectives and discussion areas of the workshop were to obtain information on (1) the accuracy, precision, and cost of lead test kits to determine the amount of lead present in paint in respect to the two Federal standards; (2) the specifications, availability, and costs of testing and reference materials to evaluate the performance of test kits for lead in paint in respect to the Federal standards; and (3) the specifications and availability of protocols to evaluate the performance of test kits for lead in paint in respect to the Federal standards, as well as the cost to perform these protocols.

The workshop began as a series of short presentations by EPA staff from ORD and OPPT, followed by general question and answer periods to elicit input from the workshop participants. The presentations outlined the technical and regulatory needs for lead paint test kit technology development to support the RRP rule, key items from the issue paper, and a procedure to delaminate the National Institute of Standards and Technology (NIST) standard reference material film for test kit use.

At the request of the workshop participants, discussions on the three objectives or discussion areas were held by the group as a whole, instead of in small breakout groups, as had been planned. Suggestions and comments from the participants were recorded on flip charts during the discussion periods. The highlights of the comments and action items from the first day were recapped at the beginning of day 2 before continuing discussions.

Among the wide range of input from the workshop participants, there were several key reoccurring comment areas.

Approaches to adjust test kit performance to support the proposed RRP rule

- Chemistries are available to detect the lead from paint, but there are constraints.
- Improvements may be made in precision and bias in kits used for in situ and ex situ testing by
  - increasing the exposure of the lead-containing paint layer to the extraction chemicals,
  - increasing the extraction efficiency of the lead from the paint, and
  - adjusting the kit sensitivity.

Verifying and ensuring the performance of test kits

- Few reference/characterized lead-in-paint films near the regulated lead levels in paint are commercially available for methods development and performance evaluation.
- Test kit performance evaluation needs and concerns included the procedures and protocols to be used for testing and interpreting the kits' responses in conjunction with the type of evaluation materials (real-world versus synthetic), their compositions, and availability over time.
- There were extensive discussions on real-world versus synthetic reference paint films and, if synthetic films are used, on which key variables (such as paint type, formulations, lead compounds, paint thickness or number of layers, substrates, and aging) should be considered to ensure that the use of the synthetic films predict the kits' performance on real-world paints.
- Ensure that the kits will perform in the field, not just in the laboratory, and that the performance is validated throughout the shelf life of the kit.
- Include a performance evaluation material or control material in the kit.
- Adequate hands-on training and clear instructions are needed to ensure testers properly use the kits and correctly interpret the kits' response.

At the end of the discussions, comments noted on the flip charts were reviewed, and a handout on designing the “dream” test kit was distributed. At the close of the workshop, highlights from the responses to the handout were read, and next steps were discussed. EPA invited the attendees to continue to interact with ORD and stated that research partnerships are needed to develop the next generation of lead test kits.

The discussions and recommendations from the workshop, along with the issue paper, will be used to inform the execution of the final three parts of the HEASD approach to facilitate the development and improvement of lead paint test kits to meet the performance specifications of the proposed RRP rule.

Lead Paint Test Kits Workshop

Introduction

The U.S. Environmental Protection Agency's (EPA) Office of Research and Development (ORD) hosted the Lead Paint Test Kits Workshop on October 19 and 20, 2006, at the EPA's Research Triangle Park, NC, campus. The objectives of the workshop were to obtain information on the accuracy, precision, and cost of lead test kits to determine the amount of lead present in paint in respect to the two Federal standards; the specifications, availability, and costs of testing and reference materials to evaluate the performance of test kits for lead in paint in respect to the Federal standards; and the specifications and availability of protocols to evaluate the performance of test kits for lead in paint in respect to the Federal standards, as well as the cost to perform these protocols. The workshop provided a forum for information exchange among experts from EPA, other government agencies, academia, private industry, and testing and standards organizations. This summary report is not a transcript of the meeting and is not meant to serve as a comprehensive record. It is, however, detailed and intended to document the breadth of discussions that took place. Appendix A of this report contains the recommendations and comments from the participants recorded on flip charts during the workshop. Appendix B contains comments submitted by the National Institute for Occupational Safety and Health (NIOSH) to EPA. Appendix C presents a summary of the responses to a handout distributed during the workshop. Appendix D and E contain a copy of the workshop agenda and a list of workshop participants, respectively.

Welcome, Introductions, and Meeting Overview

Dr. Myriam Medina-Vera with EPA's National Exposure Research Laboratory (NERL) welcomed all of the attendees to the workshop, thanked them for their participation, and discussed the format of the workshop.

Development of the Next Generation of Lead Paint Test Kits

Dr. Larry Reiter (Director, NERL) provided background on EPA's role in reducing lead-based paint health hazards and discussed the workshop goals.

Since the removal of lead from gasoline, exposure from paint and paint dust is regarded as the primary source of high-dose lead exposure in children. Title X was passed in 1992, creating "Title IV—Lead Exposure Reduction" of the Toxic Substances Control Act (TSCA) and giving EPA responsibilities to reduce lead-based paint hazards. Section 405(b) of TSCA Title IV directed EPA to establish protocols, criteria, and standards for the analysis of lead-in-paint films, soil, and dust. EPA issued a proposed rule in 2006 for renovation, repair, and painting activities that disturb lead-based paint in housing built before 1978 to support the goal of eliminating childhood lead poisoning by 2010. EPA's ORD and the Office of Prevention, Pesticides, and Toxic Substances (OPPTS) have taken the technical lead in developing improved lead paint test kits. The role of ORD is to perform research on test kits to support the proposed regulation and to seek technical collaborators to develop test kits that can be commercialized. The goals of the workshop were to solicit input on improvements in test kit technologies and to obtain comments on technical issues pertaining to the proposed rule to initiate a dialogue between EPA and manufacturers on the development of the next generation of test kits. Workshop discussions focused on two major challenges: (1) test kit performance characteristics, ease of use, quality control, and cost; and (2) test kit verification. NERL currently is engaged in research to examine test kit chemistry and modify the chemistry to improve test kit performance relative to the proposed rule, as well as to evaluate available film standards. This research and collaborations, facilitated through agreements such as cooperative research and development agreements (CRADAs), will result in commercially available products.

Lead-Based Paint; Renovation, Repair, and Painting Proposed Rule

Dr. Maria Doa (Director, OPPTS, National Program Chemicals Division) discussed the purpose, criteria, and phased implementation schedule of the Lead-Based Paint; Renovation, Repair, and Painting (RRP) proposed rule.

The purpose of the RRP proposed rule is to prevent the introduction of lead hazards during renovation, repair, and painting activities in homes containing lead-based paint by ensuring renovators are trained and certified properly, and that lead-safe work practices are followed. The proposed rule applies to housing built before 1978, where renovation is being done for compensation, and the renovation disturbs more than 2 ft^2 of painted surface. Each year, 10.7 million renovations are performed on pre-1978 housing. Only 24% of housing built between 1960 and 1978 contain lead-based paint. The figure is 69% for housing built between 1940 and 1959, and 87% for housing built before 1940. The exception to the rule is housing where no lead-based paint is being disturbed, as determined by a certified inspector or an EPA-recognized test kit used by a certified renovator. Currently, there are no test kits for lead-based paint detection recommended by EPA, but the rule proposes to introduce improved test kits to determine whether lead is present that are simple and inexpensive. The proposed rule includes criteria for the test kits to be recognized by EPA in prerenovation lead testing.

ORD has been asked to initiate research to ensure that test kits that meet the criteria will be available when the rule becomes effective. The criteria for the test kits are that the kit can be used reliably by a person with minimal training; the kit should be inexpensive ($2 per test); the kit should be fast, providing results within 1 h; the kit should have a false positive rate of no greater than 10% relative to the Federal regulated level; and the kit should have a false negative rate of no greater than 5% relative to the Federal regulated level. Phase I of the proposed rule's implementation will take effect 2 years after the final rule becomes effective and applies to owner-occupied housing built before 1960, where a child under the age of six resides; rental target housing built before 1960; and housing built before 1978, where a child under the age of six with an elevated blood level resides. By the time of Phase I implementation, the test kits should have no more than 5% false negative results. Phase 2 implementation of the proposed rule will occur 3 years after the final rule becomes effective and applies to all owner-occupied housing built before 1978, where a child under the age of six resides, and to rental housing built before 1978. At the time of Phase 2 implementation, the test kits need to meet all of the criteria of the proposed rule. The goal is that the test kits meet all of the criteria for Phase 2 implementation, be commercially available, and that the independent test kit evaluation results be available by December 2009.

Dr. Doa responded to questions from the workshop participants regarding the costs associated with blood level screening; the feasibility of a national laboratory system that could provide timely and inexpensive mail-out test results when renovator test results are questionable, the sensitivity of available test kits, and the potential for hazardous situations to arise resulting from a false sense of security on the part of the renovators. Dr. Doa stated that the purpose of the proposed rule is primarily prevention of exposure to lead from lead-based paint. The rule does not address directly the prevention of elevated blood lead levels. The point of the test kits is to obtain a quick and clear result. The universe of people using these test kits likely consists of renovators conducting 1- to 2-day jobs. Therefore, a mail-in laboratory would not meet the "quick" criterion. Dr. Doa clarified that the purpose of the proposed rule is to develop test kits that have a much lower false positive rate vis-à-vis the Federal regulatory level of lead-based paint, rather than to remove overly sensitive test kits that are currently on the market. The question of whether hazardous situations can arise when renovators think they are not dealing with lead-based paint (e.g., they could sand the paint and create a dust hazard) is really a question of whether EPA is using the right level for regulating lead-based paint. Dr. Doa explained that the proposed rule level criteria are what EPA has to work with at this time.

New Generation of Test Kits: Technical Approach

Dr. Linda Sheldon, Acting Director of NERL's Human Exposure and Atmospheric Sciences Division (HEASD), discussed the goals for the next generation of test kits and the challenges to their development and performance verification.

The technical goal of the workshop was to discuss innovative techniques that can be used to support the goals of the proposed rule. There are many challenges to meeting the goals of the proposed rule, but the main one is getting a test kit to perform to the specified criteria. ORD is seeking research partners, through CRADAs, to identify available test kits and develop approaches to optimize test kit chemistries. The problem is that commercially available test kits are too sensitive for rule requirements. The biggest challenge may be to reduce the sensitivity of the tests to reduce the rate of false-positive results.

Information is needed on kit technologies developed since 2000, including any unpublished evaluations of these technologies. Currently, there are 22 known available test kits. Some are in situ (test the paint on the wall) and some are ex situ (test a sample of paint removed from the wall). Two of the test kit challenges are the response and detection of lead. The goal is to obtain accurate and reproducible responses to lead, adjusted to the action level. Another challenge is extraction. Different paints behave differently, and it is harder to leach lead from some formulas. The eventual goal is to have a reproducible extraction for lead-based paint. Paint sample removal is another challenge. Many test kit evaluations are not using real-world scenarios such that if the lead is not evenly distributed throughout the paint, the test kits might not work properly with real-world paints. The test kits need to demonstrate performance with known film materials similar to, but not necessarily, real world materials. This challenge will be addressed more in test protocol development than in kit development.

The test kits will need to be verified, but there is a lack of known reference materials at appropriate lead concentrations. Appropriate protocols for validating test kits also are needed. The charge to the workshop attendees was to provide technical input and approaches that will modify test kits to meet the needs of the RRP rule and to identify potential roadblocks and constraints to developing and commercializing these test kits.

Key Items from the Issue Paper

Ms. Sharon Harper (NERL HEASD) discussed the issue paper *Draft Report on the State of Development, Availability, Evaluation, and Future Use of Test Kits for the Measurement of Lead in Paint*.

The purpose of the issue paper was to review the state of the science for lead paint test kits as of 2006 by identifying available test kits and summarizing their operational parameters and reviewing available literature on test kit evaluations. The paper was developed to advise the NERL test kit team on the key issues. The goal was to determine variables that can be modified to adjust kit performance to support the proposed rule and identify technical gaps in verifications of performance of kits developed to support the proposed RRP rule. The issue paper also identified technologies (kits) developed since the last formal kit evaluations performed from 1998 to 2000.

The commercially available lead test kits use chemistries such as chloranilic acid, dithizone, rhodizonate, and sodium sulfide, as well as mailers, anodic stripping voltametry, and colorimetry. There are three kits in development based on catalytic DNA-gold nanoparticle, immunoassay, or rhodizonate.

Literature reviewed for the issue paper included both field and laboratory studies that tested real-world paint chips and prepared films using professional and nontechnical users. Kits based on the same lead indicators had a wide range of performance. In the field studies, the variability of the paint on the tested surfaces impacted how well the test kits performed. Variables that influenced test kit performance included sample size collected, sample collection efficiency, exposure of lead layer to extraction chemicals, extraction rate and efficiency, interferences, strength of the response, chemical stability, and detection method (how the response was perceived: visual, use of a color wheel, or some other type of device).

Reference materials are needed to evaluate the kits to ensure they meet the proposed rule standards. Such materials can be real-world paint chips and powdered paints or laboratory-prepared films. EPA is seeking the input and insight of test kit manufacturers and researchers who have developed films to evaluate their test kits. There is a need to determine the paint film characteristics necessary to evaluate the kits' performance. Developing laboratory-prepared films present many challenges. Considerations for such films include the different paint bases, latex or oil; the number and thickness of lead paint layers and overcoats; the lead compounds that should be used in the formulations; interferences; the need for substrates; aging; and the similarity of the film to real-world materials.

The issue paper identified only two performance evaluation protocols that deal explicitly with onsite paint analysis. They are American Society for Testing and Materials (ASTM) E1828, which may require hundreds of films to evaluate a test kit, and ASTM E1775, which is a standard for electrochemical or spectrophotometric analysis.

Delamination and X-ray Fluorescence Analysis of National Institute of Standards and Technology Lead-in-Paint Film Standards

Dr. Kim Rogers (NERL, Las Vegas Laboratory) discussed delamination and X-ray fluorescence (XRF) analysis of the National Institute of Standards and Technology (NIST) lead-in-paint film standards.

The delamination protocol for the NIST Standard Reference Material (SRM) 2573 film standard (nominal 1.0 mg lead/cm^2) involved labeling the film, removing an archive strip (to measure in the future), running portable XRF analysis at five places on the film, heating and removing the polymer coating, and rerunning the XRF analysis. The purpose of measuring the concentration by XRF in four different places (quadrants) on the film plus the center was to determine whether the film was homogeneous after coating removal. Paint does wrinkle in places, but this did not make a difference in the XRF analysis. Dr. Rogers presented data for prepeeled and postpeeled SRM 2573 paint films, showing that the films had identical lead concentrations and reproducibility after delamination. This protocol for delaminating the NIST SRM 2573 film does not change the lead concentration and is relatively simple, reproducible, and applicable to all of the NIST film standards.

Dr. Rogers also discussed the results from the field and laboratory studies shown in Table 8 section 3.1.2 and Table 15 section 3.1.8 of the issue paper *Draft Report on the State of Development, Availability, Evaluation, and Future Use of Test Kits for the Measurement of Lead in Paint*. The percentage of false positives of various lead test kits versus the percentage of false negatives was charted. Plotting the data showed that the relationships are linear. The RRP rule goal of 10% false positives and 5% false negatives is far from the line, indicating that these are lofty goals.

Group Discussion

All of the workshop attendees participated in a group brainstorming session led by Ms. Sharon Harper on the precision, accuracy, and cost of the lead paint test kits, and the specifications and availability of testing and reference materials and protocols to evaluate the performance of test kits.

The first topic discussed was the test kits themselves. It was noted that instructions on the test kit needed to be followed. A question was raised, “How can we be sure the test kits will be able to perform outside of a laboratory?” Sometimes kits include a “tester,” which contains a small amount of lead to make sure the kit is working. An attendee commented that testers containing lead once were included in the kits that his company produced, which led to problems with the test kit being shipped overseas. The European Union has very strict regulations and will not allow the import of any product containing trace amounts of lead.

There was a discussion on how the results of the test kits were hard to interpret. In some kits, the color change was not obvious. A participant commented that to be able to correctly interpret the test, one needs to see examples of both a positive test and a negative test. Differences in lighting also can influence how the tests are interpreted. Sometimes, there can be a range of colors, which also makes the tests difficult to interpret.

There was a lengthy discussion regarding the amount of training necessary to use the test kits. Certification requirements for contractors should include 30 min of training on the test kits. The training should include examples of positive and negative test results. Dr. Medina-Vera suggested that lead test kits work like pregnancy tests that have a clear positive sign for a positive result and a clear negative sign for a negative result. Dr. Mark Geisberg of Silver Lake Research Corporation has a lead paint test kit in development that works like a pregnancy test. Their current water lead test kit is too sensitive.

Dr. Walter Rossiter discussed in detail the NIST study that he helped conduct. In this study, available test kits were given to lead inspectors. The inspectors participated in a 15- to 20-min training session that covered the manufacturers' instructions, as well as an extra set of instructions created after trial and error use of the kits. (The inspectors were given written copies of the instructions as well.) The extra instructions included details like "wear latex gloves." The participants in the study followed the instructions very closely, and the kits worked properly. Dr. Rossiter believes the instructions were followed properly because the participants were lead inspectors and, therefore, had a sense of responsibility. However, an average renovator might not follow the instructions as well as the lead inspectors did. Dr. Rossiter said the manufacturers were asked to review the extra instructions, but it is not known if the manufacturers made any changes to their original instructions as a result of reviewing the extra instructions created during the study.

Dr. Gary DeWalt, who worked on the aforementioned project with Dr. Rossiter, stressed the point that the instructions were critical to the proper operation of the test kits, and the people using the test kits need to see test result samples so they can distinguish a positive result from a negative result. Ms. Harper agreed that it is sometimes very difficult to distinguish between positive and negative results.

Ms. Sandra Cole, of Cole Environmental, mentioned that there are two different audiences for the test kit instructions: homeowners, who are not going to have much training, and industry professionals (renovators), who will have the benefit of training. Even with the use of a color chart, homeowners might not be familiar with the terms involved in testing. She suggested the tests for homeowners be extra sensitive so as to reduce the chance of a false negative. In addition, if a homeowner gets a positive result, he or she should be encouraged to conduct further testing. Ms. Harper clarified that the proposed rule is aimed specifically at renovators who have completed the training. Dr. Rogers later commented that having different test kits for homeowners and renovators might create problems; for example, if a homeowner's more sensitive test kit shows that there is lead present, but the contractor's test kit shows the lead is below the regulatory threshold, the homeowner might be upset if the contractor is not using lead-safe work practices.

Dr. Mark Geisberg, of Silver Lake Research Corporation, asked who would conduct evaluations of test kit instructions. Dr. Doa suggested that there be a focus group for evaluation of the test kit instructions prior to the test kits being made commercially available. Dr. Geisburg said that out of the tens of thousands of test kits his company sells to homeowners, they only receive a few calls per week regarding the instructions. A toll-free phone number should be provided in the test kit instructions for those that have questions on how to use the test kits.

Dr. Geng Lu of the University of Illinois asked about the false positive/false negative range EPA wanted to obtain. Dr. Doa said the preamble mandates 95% confidence. Dr. Rogers added to her statement by saying the 1991 RTI International report has a range of 0.1 to 0.7 mg/cm^2. Any positive tests below 0.1 mg/cm^2 were considered false positives. Any negative tests above 0.7 mg/cm^2 were considered false negatives. Using this range improved the accuracy and decreased the number of false positives and false negatives. Dr. Doa said the ultimate goal is for there to be zero false negatives, but ORD thinks this goal is unreasonable, hence the 95% false negative goal. Basically, EPA wants to minimize the false negatives and have a reasonable false positive rate. Dr. David Binstock of RTI International commented that the definitions of false positives and negatives are still not clear.

The discussion on false negatives and false positives led to a discussion of the standards. Dr. William Gutknecht of RTI International provided some background on the 1-mg/cm^2 number. In 1999, EPA visited Scitec, one of the first companies making an XRF machine to test for lead. 1

mg/cm^2 was the lowest concentration detected by the XRF machine, and that number became the standard. There has been a bit of confusion because there is another standard, 0.5% by weight, which also has been used. Dr. Albert Liabastre, USACHPPM-South, said there should only be one standard to which all kits can calibrate (or else there would be too much confusion, and contractors would have to go through a separate training for each kit). Dr. Lu asked which standard should be used in the event that the standards conflict. Mr. John Schwemberger, of EPA, said Title X defined the regulatory standard for lead-based paint as 1.0 mg/cm^2 or 0.5% by weight. Some of the history of the evolution of a regulatory standard for lead-based paint is documented in the U.S. Department of Housing and Urban Development (HUD) "Comprehensive and Workable Plan for the Abatement of Lead-Based Paint in Privately Owned Housing" dated December 7, 1990. EPA and NIST reports have noted that a rough rule of thumb is that 1.0 mg/cm^2 is about 1% by weight. However, the 1.0 mg/cm^2 and the 0.5%-by-weight standards are not interchangeable, and there is no universally recognized way to convert from one to the other. Manufacturers are free to choose which standard they wish to adhere to. The 0.5%-by-weight value is the stricter of the two standards.

Dr. Gutknecht added that one of the advantages of the 1.0-mg/cm^2 standard is that there are not many houses that have lead at the level of 1.0 mg/cm^2. There are many houses with higher levels and many with lower levels, so the 1.0 mg/cm^2-standard is a good break point. Ms. Harper qualified this assessment by mentioning a study in which hundreds of houses were examined; very few had lead-in-paint levels close to 1.0 mg/cm^2.

Mr. Brian Vargo, of EMD Chemicals, Inc., asked if there is a law that allows contractors to use lead-safe work practices in lieu of conducting a lead test. Dr. Doa said that there is nothing to that effect in the proposed rule, but that a contractor can assume that lead is present and use lead-safe work practices without testing. Using lead-safe work practices involves the use of extra plastic and duct tape, cleaning with dust collecting devices (such as Swiffers), and adds about $50 to $100 to the cost of a job. If lead-safe work practices are being used, a contractor does not have to buy a kit. However, most contractors do not want to assume that lead is present, especially in houses built after 1960. Regardless of whether a test is used or not, in cases where the proposed rule would apply, the contractor must test the work area with an electrostatic cloth at the end of a renovation to verify that the work area has been cleaned properly. Ms. Harper said (as an example of safe work practices) that, in houses built during a certain timeframe, renovators will not rip up flooring because the assumption is that the floor covering contains asbestos.

Extraction of lead from paint was discussed as being a critical part of testing. Paints are made and age differently. Therefore, the extraction efficiency is variable. Extracting the lead in the paint and making sure the lead in the paint is exposed to the testing reagents is critical for the tests to work properly. It was suggested that a tool be constructed to generate the appropriate particle sizes for testing. The cost of such a tool would be about $500. Assuming the tool is used several hundred times, the cost per use would be approximately $1 to $2. However, most of the contractors and renovators affected by the proposed rule work for small firms, and a large up-front cost would be a burden. Such a tool would also necessitate additional training. It was suggested that there be a disposable tool developed to keep the costs of testing down.

Dr. Rossiter discussed an anodic stripping voltametry (ASV) study using some of the same paint panels and operators as his previous study. The expectations were that 80% of the known lead would be extracted. However, only 50% of the known lead in a sample was able to be extracted. Half of the samples had white lead and the other half had lead chromate, but the type of lead pigment was not a contributing factor to the poor results. The procedure used manual grinding of the paint and dry ice (the dry ice was not in the manufacturer's protocol but was based on an ASTM guideline). In one trial, vinegar was used to extract lead chromate. After an overnight extraction, vinegar still was unable to extract lead chromate. However, it was concluded that, even though the extraction is difficult, once the lead is in the solution, it will be detected. The ASV testing equipment cost approximately $4,000 at the time of the study (it is less expensive now) but can be used for thousands of tests. It should be able to generate a quantitative result within 1 h. It is estimated that, on average, a contractor completes approximately 100 renovation jobs in a year and likely bids (and, therefore, conducts tests) on more than 100 jobs.

Paint particle size is significant in testing. The feasibility of using a microwave or an ultrasonic cleaner to aid in the digestion was raised. A participant commented that this technique does not perform very well, and many contractors, especially those working in low-income housing, do not want to pay the associated up-front costs.

Dr. Doa stated that the $2 per test kit criterion is based on the cost of tests currently on the market. Home Depot sells Lead Check kits for less than $3.

There are many ways to remove the paint from the test surface. One way is a small propane soldering tool that will soften the paint. Small grinder-like tools with vacuums also exist and are effective if the paint is thick enough. However, if the paint is thin, the tool will pick up substrate as well as paint. The substrate, especially if it is a porous substance like wood, can contain high levels of lead.

If paint particles are ground in a mortar and pestle, the smaller particles (the particles that are left behind) contain higher concentrations of lead. When using a mortar and pestle, a finite amount of lead is left behind rather than a percentage, so the smaller the paint sample, the larger the percentage of the lead lost. By removing paint with vacuum extraction, a large amount of the sample can be lost.

Mr. Mike Wilson, of EPA, asked if there is a way to improve the accuracy of in situ testing because of the complicated nature of ex situ testing. Dr. DeWalt said that a standard V-cut will expose all layers of paint. However, exposure of the lead in the paint to the testing chemical depends on the thickness of the paint layer at the site of the cut. The thickness of lead-based paint layers will be different at different cut sites on the test surface, causing variability in the test results. Although most of the lead-based paint is in the bottom layers of paint, one cannot tell the thickness of the layers.

Questions were raised about validating test kits at various periods during their shelf lives. Test kit storage is important to the stability of the testing chemicals. For example, some acids are temperature and medium sensitive. If and when test kits are approved, EPA's Environmental Technology Verification (ETV) Program could be a mechanism to conduct the evaluations. The ETV program uses third-party evaluation centers to perform technology evaluations, then publishes the performance data. Currently, the ETV program is looking at test kits for other analyates to see how they operate using both technical and nontechnical operators.

The use of synthetic films versus real-world samples was discussed. Samples taken from the real world will have problems such as unknown concentrations and interferences. An advantage of synthetic films is that the desired concentration can be selected. Known interferences and thicknesses can be built into the films.

Test kit performance validation issues to be addressed include oil-based paint versus latex paint, interferences, the type of lead (lead chromate is the most difficult form of lead to remove from paint, but it is not very common), thickness, aging, and paints on substrates versus paints on stand-alone films. It was suggested that there be a limit on the variables tested. However, initial limiting of variables followed by the addition of complexities as the program continues can lead to problems. For example, it is possible that test kits would have to be reapproved and approvals could be stripped.

There may be lead oxide, lead chromate, white lead, driers, and titanium dioxide present in paint. Test specimens cannot incorporate every kind of lead and every component of paint that exists. A good experimental design will include at least one type of lead that is difficult to get into solution. It was suggested that elements in test samples be similar to elements found in paints manufactured between 1960 and 1978, the time period of most testing relevance.

Dr. Geisberg asked if comparing the results of the test kit validation studies with XRF for real-world sampling would be acceptable. Have there been any comparisons between test kits and XRF in real-world situations, where a test kit analyzed a sample then the XRF analyzed the same area? Dr. DeWalt said that synthetic test panels were made on substrates. These panels were compared to what is currently in the archive.[1] For flat, nonporous surfaces, the XRFs of synthetic panels matched the archive relatively well. The porous surfaces did not fare as well. Lead was absorbed into the substrate. Therefore, the substrate is an important parameter that needs to be included in validation tests.

In regard to the availability of a standard substrate, paints will penetrate different substrates differently. Variability is high on porous surfaces, which can affect the results of the test kit validation. One challenge is to create a consistent film that has variations, as in the real world.

One of the biggest challenges is to design the synthetic films to mimic the effect of aging on real-world paint layers. Humidity, drying, freezing, and aging techniques are not good enough to mimic the real world. Test kit responses are different for new and aged films. New films are difficult to handle. In the NIST ASV study, grinding the newer films did not yield the desired particle sizes. Older paint samples were very easy to grind. It is not difficult to age test films by heating them, but most of the test kit providers would not have the equipment to heat the films. Another variable the NIST ASV study tested was paint thickness. The study used a film with 15 layers (thick) and another film with 3 layers (thin). The films also had varying paint formulations. Creating samples is one way to control certain variables. One of the problems with using real-world samples is that few real-world samples of 1 mg/cm^2 exist, and, because this is the regulatory level, it is important that testing be conducted at this level. Therefore, synthetic samples are necessary.

Collecting an archive of real-world samples would be very expensive. EPA does not have a budget sufficient to support such an endeavor, but it is possible that collection could be achieved, as in an EPA study that tested XRF instruments and test kits in the 1990s. In this study, painted components were collected from study buildings to create a collection of real-world building components with a range of lead levels in the paint. This collection, called “the Archive,” was used to test new XRF instruments that became commercially available after the

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[1] The Archive is documented in the EPA reports “Methodology for XRF Performance Characteristic Sheets” (September 1997, EPA 747-R-95-008) and “Archive Operations and Protocols” (September 1997, EPA 747-R-97-004). Both of these documents are available at the Web site http://www.epa.gov/lead/pubs/leadtpbf.htm.

study ended. If a manufacturer goes through the trouble of making a set of paint standards, it is expecting to recoup the costs. If it does not recoup the cost, then more will not be made. A cost-effective reference material is needed. It was suggested that HUD cover some of the costs of the films.

Highlights of Group Discussion and "Dream" Test Kit Handout

Dr. Medina-Vera (NERL) recapped the highlights of the group discussion. She discussed the next generation of test kits. The workshop charge was to provide technical input for the next generation of test kits and provide technical input on potential constraints to development and commercialization. The constraints include making lead available to the extraction reagent, the particle size, aggressive versus safe extraction, and availability of reference materials. Other considerations are verifications of the test methods and protocols, training for users, and a clear definition of responsibilities. Action items are to clarify the target standard (percent of false positives and negatives, concentration response range, and concentration windows), identify who will develop the standards and protocols, and clarify varying points of views that may come from the homeowners and contractors.

The participants were asked to fill out a handout on a dream test kit based on their experiences. They also were asked to consider things that might not be possible. Some ideas for the dream test kit were that it be easy to use, provide a quick and clear result, employ mixed chemistries, work on a range of concentrations, use two steps (pulverize, then a chemical reaction), and two steps with a positive and negative control. The handout also asked about the perfect standard, the protocol for validating test kits, and what a reasonable cost would be.

Extraction is the key to getting the test kit to perform properly. Dr. Rogers proposed the idea of using a cylinder with a capsule containing strong acid in the cylinder. This likely would raise the cost of a kit and would require a special bag for disposal. Dr. Rossiter referred to the ASV study, in which trained lead inspectors were not willing to do a test if it required too many steps, but compliant if a spot test kit was used. Dr. Gutknecht mentioned a multistep kit made by Hach Company that students use, with reasonable but slow results.

Dr. Kevin Ashley, of the Centers for Disease Control and Prevention/NIOSH, said he does not like the idea of painters or contractors performing the analyses because they have a monetary interest in the result of the test. He thinks an independent third party should perform the testing. He also worried about contractors cutting corners so a job can be done cheaply. Later during the discussion, Mr. Kenn White, of Consultive Services, commented that he has trained contractors and renovators. Many of them are not thinking about what they are doing when performing lead tests.

ASTM E1828 requires hundreds of samples to verify test kits. These verifications are very expensive, and materials are not readily available. EPA may not have the funding to validate the test kits and may have to partner with a manufacturer. The ETV program has the ability to develop an evaluation protocol and will evaluate commercially available products. Part of the function of the ETV program is to pool funding and resources.

A number of the participants suggested that the test kits be verified at various times during the kits' life cycles to determine the stability of the materials. This may depend on the resources available. The manufacturers should display information on the stability of the chemicals and the expiration date of the reagents on the outside of the test kit packaging.

A question was raised regarding who would be evaluating the kits in the validations (professionals or nonprofessionals), which sparked a discussion on training users to use the test kits. The training is still in development, but it will be 30-min long. Based on her experience with pesticides, Dr. Jeanette Van Emon, of EPA, felt that training will affect the outcome of test results, and suggested using videos to aid in training. Training needs to be simple. Many of the companies going through the training are small operations that have employees who would not understand highly technical terms. Many contractors do not speak English (there will be a training course available in Spanish). It was suggested that the vendor should provide training, but that could create a problem because only contractors who go through the training will be able to perform the test.

A participant said that there needs to be a simple yes/no test. If there is any lead present, even if it is below the regulatory level, then lead-safe practices should be used because the ultimate aim of the proposed rule is to protect children from lead poisoning. Definitions of a "false positive" and "false negative" are strictly from a regulatory standpoint. A "false positive" usually means that there is lead present in the paint, but below the regulatory levels. Ms. Jacqueline Mosby, of EPA, said the goal of the test kits in the proposed rule is to reduce the burden when lead in paint is below the regulatory standard. Dr. Ashley stated that the regulatory levels are inappropriate for protecting human health, and felt that using sensitive kits is acceptable. He does not think that the goal of the proposed rule should be to save money on the cost of renovations.

Dr. DeWalt said the extra costs of using lead-safe work practices are not excessive, and, if the extra costs are balanced against the increased liability, it is a good idea to use lead-safe work practices regardless of the outcome of a test. Dr. Liabastre agreed and said that lead-safe work practices are good work practices in general and using them adds only about 1% of the total cost of the job. Mr. White said there was a requirement at one time that lead-safe work practices be followed in all target housing.

Mr. White asked, if a spot test is positive, does the result have to be disclosed later to a potential buyer of the home? Mr. Schwemberger said that it does.

Mr. Schwemberger also pointed out that States may have lead programs that differ from the Federal government's lead program, and, in particular, Massachusetts and at least one other New England state currently allow the use of test kits for paint testing.

Information on research partnerships is available on the Environmental Technologies Opportunities Portal Web site www.epa.gov/etop/epa/. The Web site provides information on various programs, including development and verification programs, as well as partnership programs. The next steps include modifying technologies for responses and detection, improving extraction and reproducibility, assessing the sampling procedure, and applying the new approaches. Research partnerships are needed to develop the next generation of test kits.

Highlights of the Responses to Handout

Handout responses to the question about the dream test kit

- Simple
- Different principles of operation
- Work like a home pregnancy test
- All renovators use lead-safe practices.

- In situ-ex situ is complicated.
- Quantitative kits
- Exact change at the action level
- Minimal handling of paint and chemicals
- Fast

Comments about the perfect standards
- Multilayered standards
- On substrates
- Tailored to a spot test kit
- Available at little or no cost to the user
- Uniformly distributed
- Unknowns as well as knowns

Responses on what protocols should be used in validating the test kit
- Use ASTM methods
- Lab method in the field
- Number of standards in the protocols is driven by statistical differences.
- Real-world versus synthetic
- Performance parameters look at temperature, user information.

The handout included a question on how much the kits should cost. The answers included $5 to $15 for a spot test and $18 to $36 for a quantitative test. Many of the workshop participants felt that the creation of a dream kit is possible.

Mr. Schwemberger expressed his optimism about the future of the test kits. Dr. DeWalt thinks it is possible to desensitize the kits; it is possible that a pH adjustment would make the kits more controllable. However, this may cost more than $2 per kit. Ms. Harper said, if the goals of the proposed rule cannot be met entirely, they at least will be moving in the right direction. It may be the case that the manufacturers have to design two test kits: one to test whether lead is present and one to support the proposed rule. This may not be inexpensive, and most manufacturers do not have the research and development funds to make a test kit that fulfills the criteria within the next 2 years. However, this is still a *proposed* rule, and comments have been received and evaluated.

APPENDIX A

Workshop Flip Charts

Test Kits

(1) Instructions (problems), whose to follow?
(2) Functional reagents, lot testers, preuse validations, present lead standard problems (hazardous substances)
(3) Clarity of results
Yes/no
(Range) examples
Specificity for light conditions
(4) Training certification
-Experience, 30 min
-Test
(5) Zone rather than color alone (Immuno will do this.)
(6) NIST used 15- to 30-min training written instructions.
(7) Kits to include real test sample
(8) Two types of kits
-Homeowner—conflict?
-Industrial
(9) Rule to clarify instructions
(10) 95% confidence about false positive, false negative versus stated concentration window
(11) What about concentration range?
(12) Need clear definition of negative, positive
(13) Must train for all specified kits
-What if 1 mg/cm^2 and 0.5% contradict?
-Not equivalent
-People can choose.
-0.5% is lower.
(14) Suggestion of same standard for *all kits*
(15) Most house paint is above or below 1 mg/cm^2
(16) Can contractors use lead-safe all the time? Yes.
(17) Cost differential $50-$100 per job
Plastic, duct tape, Swiffers
(18) Color/ No color as one-sided test
(19) Leaching is a big problem.
-Particle size
-Extraction chemical
(20) Tool for collection/powdering $500-$600 (some added cost)
(21a) How many houses may be used in fixed cost evaluations?
(21b) $2 came from market survey.
(21c) Standard V-cut
(21d) Chemicals getting into cut
(21e) Paint thickness causes variability
(22) Best extraction gives only ±5% so performance evaluation may be a big challenge.
50% extraction
(23) What about quantitative methods? Getting lead into solution is the most difficult problem.
(24) What about ASV?

(25) How many surfaces are included in the rule?
(26) Representative
(27) Mechanical extraction
(28) Low upfront cost

Paint Films

Characteristics most critical aspects
Lab-prepared versus real-world issues—cost, availability

Crosswalk synthetic with Real World
Synthetic
  Variety
  Some chromate not used often.

Synthetic
  Variety of color, but mostly white lead
  Needs some research
Limit some variables
Ongoing certification

White lead will best approximate real world.
Also include titanium dioxide and other metals/pigments
Must consider carefully

Elements to consider
  matrix
  color
  metals, etc.
Real-world samples compared to XRF
Extraction is the issue.

Synthetic limitations
Aging (artificial heating)
Matrix
Other unknown composition

How many substrates?

Substrate is important
Synthetics
Advantages
  Concentration is known.
  Variability is known.
  Composition is known.

How do you make synthetic films act like real paint?
Combination of synthetic and real world

Reactions
Safe handling of reagents
ASV is too complex for field use (i.e., extraction).

Spot test kits are better for field.

What Will It Cost To Modify Test Kits To Meet Requirements?
Cost needs to be higher.
Labor/kit combination to determine overall cost

Concerns about qualifications of analyst
ASTM standards
ETV develops protocols and important issues.

ETV
Uses previously published procedure, then develops test protocol
Limited funding—so funding comes from companies as well.
Looks at commercially available technologies
Manufacturers need test materials and test protocols.

Need To Summarize Kit Attributes
- Shelf life
- Positive/negative results
- Kit standards

Can it be manufactured at a profit?

Kit user conflict of interest
Who is the user?
Training is an important issue.
EPA has not yet started on training.
Kits must be very simple.

What is the ultimate goal?
Protect kids

Reevaluate measurement detection limits

NIOSH-
Regulatory levels are not appropriate for protection of human health.

Lead penetrates substrate (i.e., wood)
Substrate is problem.

Lead-Safe Work Practices
Why not use the practices as routine?
There are other advantages to using lead-safe work practices.
Cost 1% of job

Specificity Is Issue
One-sided test is already here.

Lead-safe processes are required for HUD.
Problem of differing State regulations under Title X

Was the cost of liability insurance for the contractor considered?

Errors and omissions insurance is ~$12K.
This will be taken back to EPA rulemakers.

Does contractor need to be prequalified?

Kits
Simple
Color changes
Immunoassay/format
Safe practices for all renovations
Very fast
Minimal handling of reagents
Standards
Multilayer lead
Substrates—wood, plaster

Standards
Available at little or no cost

Protocols
Similar to ASTM
Lab method in field
Number of standards/statistical

Cost Ranges
$5 to $15 spot test

Quantitative
$22 to $36

Last Comments
Rule calls for test kits in Phase 1.
Only requires the 5% false negative
Phase 2 requires 10% false positive.

Do not give up—improvement is possible.
How to desensitize kits?
What about two kits?
Public and professionals have different sensitivity levels.

Questions about health concerns when kits are misused

Parking Lot

1. Homeowner requests due to differences/results of more sensitive kit versus what is suggested in the proposed rule. How do we address the issue?
2. White glove test (electrostatic cleaning)
3. Damaged paint
4. Cr^{+6}
5. Bioavailable

APPENDIX B

NIOSH Comments on EPA Proposed Rule (Faxed)

National Institute for Occupational Safety and Health

NIOSH **Comments to EPA**

Comments of the
National Institute for Occupational Safety and Health
on the
Environmental Protection Agency
Proposed Rule on
Lead; Renovation, Repair, and Painting Program

40 CFR Part 745

Department of Health and Human Services
Public Health Service
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

4/7/06

The National Institute for Occupational Safety and Health (NIOSH) has reviewed the Environmental Protection Agency (EPA) proposed rule (PR) *Lead; Renovation, Repair, and Painting Program* published in the Federal Register on January 10, 2006 [71 FR 1588]. NIOSH supports EPA's effort to require reduction of exposure to lead hazards created by renovation, repair, and painting activities that disturb lead-based paint in support of the attainment of the Federal government's goal of eliminating childhood lead poisoning by 2010. NIOSH comments follow the italicized text from the preamble of the FR notice.

I. General Information
A. Does this Action Apply to Me?

Page 1589 – *Potentially affected entities may include, but are not limited to: ...*

EPA may wish to include NAICS code 562910 (SIC code 1799), the code for specialty trade contractors for lead paint and asbestos removal, in the list of potentially affected entities. It is also the code for abatement and lead paint removal workers in NIOSH's Adult Blood Lead Epidemiology and Surveillance (ABLES) program. Inclusion of NAICS 562910 in this section of the preamble would enhance NIOSH's ability to help EPA protect lead renovation, repair and painting workers from over-exposure to lead by the efficient surveillance of blood lead levels among these workers. NIOSH Health Hazard Evaluations (HHEs) cited in these comments have reported lead abatement workers also performing lead renovation activities.

III. Introduction
B. The Federal lead-based Paint Program
2. EPA's lead-based paint program.

Page 1592 - *An individual who wishes to become certified must take an accredited training course in at least one of the certified disciplines: Inspector, risk assessor, project designer, abatement worker, and abatement supervisor.*

and

Page 1595 – *C. EPA Activities Related to This Rulemaking. ... EPA identified the following 11 categories of renovation and remodeling activities with the potential for resulting in exposure to lead:*

- *Paint removal.*
- *Surface preparation.*
- *Removal of large structures (demolition).*
- *Window replacement.*
- *Enclosure of exterior painted surfaces (i.e., siding).*
- *Carpet or other floor covering removal.*
- *Wallpaper removal.*
- *HVAC (central heating system) repair or replacement, including duct work.*

- *Repairs or additions resulting in isolated small surface disruptions.*
- *Exterior soil disruption.*

Inclusion of the six-digit NAICS codes for the certified disciplines described on page 1592 and the eleven categories of renovation activities on page 1595 would be very helpful to the state ABLES programs for accurately coding workers in surveillance reports [http://www.census.gov/epcd/naics02/naicod02.htm]. It would also be useful to the State ABLES programs to provide the occupational codes within industry, using either the 2000 Census Occupation Codes [http://www.census.gov/hhes/www/ioindex/indcswk2k.pdf] or the 2000 Standard Occupational Classification [http://www.bls.gov/soc/], systems that are used by some State programs. NIOSH suggests that EPA collect NAICS codes for the certified disciplines, categories of renovation activities conducted, and worker occupation codes when firms apply for certification or re-certification.

IV. Proposed Requirements for Renovation Activities

Page 1597 - *A. TSCA Section 402(c)(3) Determination*

... the following renovation and remodeling activities, when conducted where lead-based paint is present, generated lead loadings on floors that exceeded the TSCA section 403 dust-lead hazard standard:
Paint removal by abrasive sanding.
Window replacement.
HVAC duct work.
Demolition of interior plaster walls.
Drilling into wood.
Sawing into wood.
Sawing into plaster.

Residential abatement and renovation work use similar tasks and methods resulting in similar health risks [NIOSH 1998]. In addition to the seven renovation and remodeling activities listed in the preamble, other activities common in residential renovation and lead hazard reduction work create lead-based paint hazards due to emissions of airborne lead dust which result in high lead concentrations on floors and other surfaces. NIOSH has concluded that the following activities also create lead-based paint hazards [HETA 99-0113-2853, HETA 93-0818-2646, HETA 96-0200-2799, HETA 98-0285-2989; HETA 92-095-2317]:

Dry manual sanding,
Dry manual scraping,
Power finish sanding, and
Wet manual scraping.

B. Scope of Proposed Regulation
1. Housing units that would be covered.

Page 1599 - *EPA believes that during this phase in period it will be possible to develop test kits that are able to identify more accurately those homes that do not contain lead-based paint at regulated levels.*

One example of a test kit that is able to identify those homes that do not contain lead-based paint at regulated levels is portable ultrasonic extraction and anodic stripping voltammetry (UE/ASV) [Sussell and Ashley 2002; Ashley et al. 1998].

Page 1599 - *EPA is proposing to exempt renovations that affect only components that have been determined to be free of paint or other surface coatings that contain lead equal to or in excess of 1.0 mg/cm² or 0.5% by weight.*

NIOSH field studies indicate that EPA's proposal to exempt renovations with components that have painted surface lead concentrations below those action levels will not adequately protect workers, occupants and young children from lead-based paint hazards in homes undergoing renovation. In several field studies, NIOSH found that hazardous levels of airborne and surface lead in residences undergoing lead hazard abatement or renovation activities can occur even when the lead concentration in the paint surface coating does not exceed 1.0 mg/cm^2 or 0.5% lead by weight [Sussell et al. 1995; 1999; NIOSH 1998]. NIOSH found only a very weak correlation between mean paint lead concentration and airborne lead concentration during these activities, due to the influence of several variables, including abatement method or strategy, pre-cleaning surface lead concentration, mean pre-abatement soil lead concentration, and the contractor's work practices [HETA 90-070-2181]. A study of cleaning activities also found a very weak correlation between mean paint lead and airborne lead during work activities: the mean worker exposure to airborne lead was greater than 50 $\mu g/m^3$ in four of nine rooms with mean paint lead concentrations below 0.5% lead [HETA 92-095-2317].

Page 1599 - *Research on the use of these kits for testing lead in paint has been published by NIST.*

Additional relevant research which EPA may wish to cite here includes the 1993 EPA chemical spot test kit report *Investigation of Test Kits for Detection of Lead in Paint, Soil and Dust* (EPA 600R-93/085) and Ashley et al. [1998] *Field investigation of on-site techniques for the measurement of lead in paint films*. Ashley et al. comparatively evaluated three field-portable lead measurement techniques: chemical spot test kits, portable x-ray fluorescence (XRF), and anodic stripping voltammetry (ASV) following ultrasonic extraction. This study found that in situ testing of lead in paint by portable XRF and chemical spot test kits can be used for screening. Ex situ on-site testing with portable XRF and ultrasonic extraction/portable ASV met the analytical performance guidelines of EPA [1992] and ASTM [1996].

Page 1599 - *These false positive rates mean that the currently-available test kits are not an effective means of identifying the 76% of homes built between 1960 and 1978 that do not contain regulated lead-based paint. EPA believes that the sensitivity of test kits could be adjusted for paint testing so that the results from the kits reliably correspond to one of the two Federal standards for lead-based paint, 1.0 mg/cm^2 and 0.5% by weight.*

Available chemical spot test kits may be effective for identifying lead in paint at lower levels that may still be potentially hazardous to workers and children [Ashley et al. 1998]. Relevant American Society for Testing and Materials (ASTM) standards that describe the use of UE/ASV for extracting and measuring lead in paint chips and other environmental samples should be cited [ASTM 1998; ASTM 1997].

Page 1599 - *EPA's goals...are to develop a kit that can be reliably used by a person with minimal training, is inexpensive (under $2 per test), provides results within an hour, and is demonstrated to have a false positive rate of no more than 10% and a false negative rate...of less than 5%.*

NIOSH estimates the cost of UE/ASV to be between $7 and $10 per analysis [www.palintestusa.com]. EPA may also wish to cite ASTM E1775 [2001] as a standard on performance criteria for on-site lead analysis instrumentation.

Page 1599 - *EPA requests comment on whether EPA should wait to finalize the proposed second stage of this regulation until the new kits are commercially available nationwide.*

NIOSH suggests not waiting to finalize because applicable field-portable technologies for on-site determination of lead in paint are commercially available at this time, as discussed above.

Page 1603 - *These performance parameters would have to be validated by a laboratory independent of the kit manufacturer, using ASTM International's E1828, Standard Practice for Evaluating the Performance Characteristics of Qualitative Chemical Spot Test Kits for Lead in Paint (Ref. 50) or an equivalent validation method.*

NIOSH is not aware of an equivalent validation method to ASTM E1828.

C. Training, Certification, and Accreditation.
2. Individuals

Page 1607 – *b. Dust sampling technicians. ... As discussed in Unit IV.E., some renovators or homeowners may choose to perform dust clearance testing at the completion of renovation activities instead of the post-renovation cleaning process that EPA is proposing.*

Clearance testing should be conducted following post-renovation cleaning. NIOSH research has demonstrated that significant lead contamination on surfaces may still be present despite a visual inspection for cleanliness [Esswein et al. 1996] and that floors which have undergone a single cleaning and wet mopping can remain contaminated with lead after lead-based paint removal activities [HETA 92-095-2317]. Decisions regarding whether to perform dust clearance testing instead of post-renovation cleaning, as well as the clearance testing itself, should be conducted by an independent third party to avoid the appearance of a conflict of interest. A chemical spot test method for lead screening in surface dust samples has been patented by NIOSH researchers [Esswein et al. 2001] and marketed commercially. The procedure has been published as a NIOSH analytical method [Esswein and Ashley 2003] and is useful as a screening tool for clearance purposes.

Page 1608 – *c. Initial certification. ... To become a certified dust sampling technician, a person would have to successfully complete a dust sampling technician training course that has been accredited either by EPA or by a State, Territorial, or Tribal program authorized by EPA under 40 CFR part 745, subpart Q. The dust sampling technician course primarily covers dust sampling methodologies and clearance standards and testing.*

The use of relevant ASTM standards in a lead hazard assessment curriculum should be considered. ASTM International Subcommittee E06.23 on Mitigation and Management of Lead Hazards has promulgated standards that are potentially applicable [www.astm.org].

D. Renovation Activities
2. Proposed work practice standards – a. Occupant protection.

Page 1612 - *iii. Prohibited practices. ... These practices are open flame burning or torching of lead-based paint; machine sanding, grinding, abrasive blasting, or sandblasting of lead-based paint except when done with HEPA exhaust control; dry scraping of lead based-paint except around electrical outlets or for any area no more than 2 ft^2 in any one room, hallway, or stairwell, or for any area no more than 20 ft^2 on exterior surfaces; and operating a heat gun at 1100 degrees Fahrenheit or higher. Unlike with abatement, EPA is proposing to allow the use of these practices during renovation activities.*

EPA should not remove the prohibition on hazardous lead-based paint activities as proposed, with the exception of flame burning on millwork or scroll work on old historic buildings, where no feasible alternative exists for surface preparation. NIOSH has documented in health hazard evaluations of residential lead renovation work that these activities produce hazardous worker exposures [HETA 99-0113-2853, HETA 93-0818-2646, HETA 96-0200-2799, HETA 98-0285-2989], and generate large amounts of lead in settled dust [HETA 98-0285-2989, 99-0113-2853]. NIOSH evaluations have found that technically feasible and effective alternatives to these hazardous activities exist, including power sanding with HEPA exhaust control [HETA 99-0113-2853, HETA 93-0818-2646, HETA 96-0200-2799, HETA 98-0285-2989, HETA 92-095-2317]. The most hazardous renovation activities are power sanding without exhaust control, dry manual scraping, and dry manual sanding [HETA 99-0113-2853].

Page 1613 – *E. Cleaning Verification*
1. Background. ... Dust clearance sampling, which is required after abatements, may be very expensive. ... Laboratory results may not be available for several days, during which time the work area cannot be re-occupied.

Laboratories currently offer lead analyses for as little as $5 per sample, and overnight service can be obtained for less than $10. On-site analysis can be performed for about $10 or less per sample.

Page 1614 – *2. Disposable Cleaning Cloth/White Glove Study.*

and

3. Steps for cleaning verification.

The use of the NIOSH chemical spot test method for lead screening in surface dust samples, discussed above, should also be considered for confirmatory screening [Esswein et al. 2001; Esswein and Ashley 2003].

VIII. Statutory and Executive Order Reviews
C. Regulatory Flexibility Act
6. Small Business Advocacy Review Panel

Page 1625 – *h. Interior clearance. ... The SBA introduced a new option to the Panel, consisting of a specific cleanup methodology followed by a visual clearance requirement, as an alternative to dust clearance testing. The Panel recommended that EPA include this new option in the proposal and take comment on the merits of all the interior clearance options in the proposal. The Panel also recommended that EPA take comment on options for clearance that are less costly and less burdensome and yet still demonstrate the absence of lead hazards. As discussed in Unit IV.E., EPA followed the Panel report with research into alternatives to laboratory dust clearance and is proposing an option based on this research. EPA is also requesting comment on other methods of ensuring that leaded dust and debris created during renovations have been cleaned up properly.*

Consideration for interior clearance should also be given to the use of currently available field-portable lead measurement methods such as UE/ASV discussed above, as well as the numerous relevant ASTM standards describing sampling, sample preparation, and analysis. See www.astm.org/cgi-bin/SoftCart.exe/COMMIT/SUBCOMMIT/E0623.htm?L+memberstore+xxto5604+1140195873 for a listing of ASTM standards.

Page 1626-7 – *I. Technology Standards.*
Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (``NTTAA"), Public Law No. 104-113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. ... EPA is proposing to adopt a number of work practice requirements that could be considered technical standards for performing renovation projects in residences that contain lead-based paint. EPA has identified 2 voluntary consensus documents that address aspects of the proper performance of renovation projects where lead-based paint is present. ... Each of these ASTM documents represents state-of-the-art knowledge regarding the performance of these particular aspects of lead-based paint hazard evaluation and control practices and EPA recommends the use of these documents where appropriate. However, because each of these documents is extremely detailed and encompasses many circumstances beyond the scope of this rulemaking, EPA does not believe that it is practical to incorporate these voluntary consensus standards into this proposal.

The ASTM standards discussed in this section – ASTM 2052 and 2271 -- are directly applicable to the scope of the PR, including renovation and abatement. NIOSH recommends that these voluntary consensus standards be used by EPA consistent with NTTAA in this regulatory activity.

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APPENDIX C

Workshop Handout Summary

At the lead test kit workshop, a handout, "Technical Exchange Workshop: Next Generation of Test Kits," was distributed to the participants. The handout asked four questions: (1) My "dream" test kit looks like: ? (2) What would the perfect standard look like? (3) If you had the standards, what would the protocol look like? and (4) What would be a reasonable price? There were 10 respondents. The responses were anonymous, and the respondents are numbered 1 through 10. [Note: Not every respondent answered every question.]

Responses to the question "My 'dream' test kit looks like: ?"

(1) The respondent drew a schematic of the test kit. It is a complicated device that looks a bit like a drill. It has a "Specialized Grinding Bit Assembly." There is a "tape seal" around the wall surrounding the paint being extracted, so that the paint would be collected inside the instrument. The pieces of paint would fall into a vial on the bottom of the machine. There is an "extraction chemical capsule" (probably a strong acid to digest the paint). The capsule would be broken and the paint powder would fall to the bottom causing a color change when the powder mixes with solution. The vial containing the reaction would slide off and is disposable.

(2) A simple piece of paper; place in a solution 1 (solution 1 contains paints). Place the paper in a second solution. If the "+" sign is shown; then the result indicated the concentration is greater than 1 mg/cm^2. Place all solutions, paper into solution 2. Principle of operation is the papers act as an immunoaffinity column; solution 1 acts as a loading process; solution 2 acts as an eluting/reacting solution. Solution 3 is a magic solution that can destroy lead and/or other pollutants.

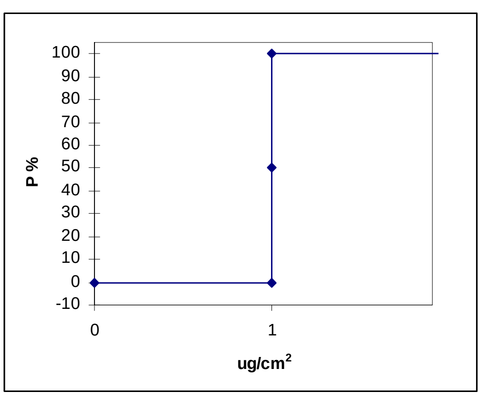
(3) In situ test. Fast. Yes/no answer (visual). Minimal handling of paint. Minimal handling of chemicals.

(4) 1. An all-inclusive kit in one package
2. An all-or-none, yes-or-no result, similar to the widely used home pregnancy test

(5) Colorimetric kit with a quantitative measurement methodology, possibly modification of reflectance spectrometry. If standards are lowered, this technology could continue to be relevant.

(6) No response

(7) (*only* options)
Colorimetric: in situ

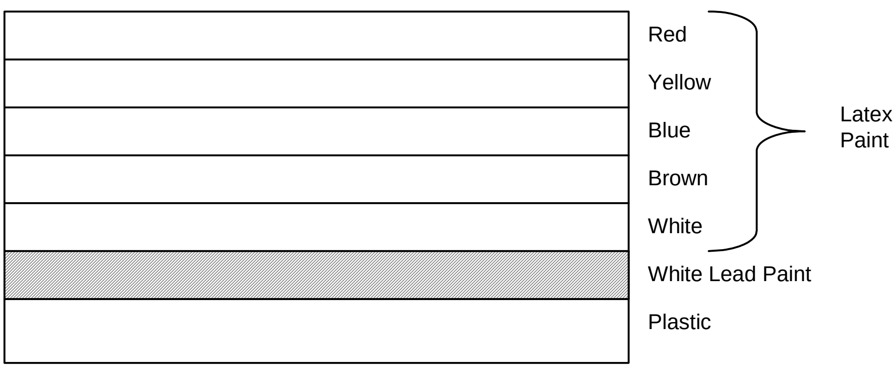


Quantitative: ex situ
Meets International Organization for Standardization 17025 and National Lead Laboratory Accreditation Program accreditation as a field operations laboratory
Both: no/low hazardous waste

(8) A spot test that is based on application of a solution on the paint surface that will penetrate all layers of paint and will provide a well-defined color change at the 1.0-mg/cm^2 concentration.
(9) I would suggest that all renovators assume that lead is present and practice lead-safe work practices at all times.
(10) A variation of an easy-to-use kit such as Lead Check, Silver Lake Research paint kit, or the Abottex kit, which has a consistent spike at a known lead level, and the kit can be adjusted to spike at different lead levels. (The respondent drew a simple diagram very similar to the one drawn by respondent 7.)

Responses to the question, "What would the perfect standard look like?"

(1) Standard concentration set.
a. 0, 0.1, 0.5, 1.0, 2.0, 5.0



(2) Standards should have two to three concentration levels (<1, 1, >1, mg/cm^2).
Standards can be coated on at least three matrixes.
Selection of matrix should be based on the existing information.
And choose three most commonly found matrixes.
(3) For standards used for evaluations, real world is best. Manufactured films shown to behave close to real world would be second best.
a. For standards used to verify kit function, any lead film would be okay.
(4) It would have a negative control and a positive control. The positive control would have what was determined by consensus to be an average number of overlayers of paint.
(5) Uniformly painted substrates (characterized by XRF and inductively coupled plasma-atomic emission spectroscopy) at five concentrations (e.g., 0, 0.5, 0.8, 1.0, 1.6 mg/cm^2). Standards should be characterized for multielements.
(6) No response
(7)

- Available at little/ no cost
- Replenishable and disposable
- Multiple lead concentrations, certified reference material
- Uniformly distributed on various substrates
- Includes a population of unknowns for conduct of blind performance-based examination of users in the field (also for use in XRF performance analytical testing)

(8) It would be “tailored” to the test kit. If spot test above is used, the standard would be comprised of a segment of a layered substrate that would provide a range of concentrations.
(9) No response
(10) A sandwich of the four major lead pigments ([1] lead carbonate, [2] lead silicate, [3] lead sulfide, and [4] lead oxide); lead levels at a variety of levels above and below regulatory standards.

Responses to the question, “If you had the standards, what would the protocol look like?”

(1) No response
(2) The protocol should follow similar formats as other EPA methods and/or ASTM methods.
(3) There are many pieces to such a protocol. The number of standards needed to do evaluations is essentially a statistical question. There exists enough variability data on existing kits to come to a sound decision as to the number of lead levels needed to properly define the response curve (which is needed to really characterize the kits). The number of different characteristics these standards would have to have to cover real-world (commonly encountered) paint surfaces is somewhat debatable but likely could be established with reasonable confidence.
(4) Use pulverized paint chips (microwaved, sonicated, etc.) from 1 cm^2 would be dumped into a tube of liquid extractant (provided as part of the kit). After a set period of time (relatively short), the chemistry portion of the protocol would be initiated by mixing chemicals provided to the kit and guided to the reactant.
(5) Protocol would require testing? (n=3) at 0 mg/cm^2 and the action level. In addition, procedures to dispose of waste will be simple (disposed into solid packaging?). Recommend testing like substrates to be disturbed.
(6) ETV would develop protocol based on performance parameters of interest to buyers and users of test kits (accuracy, precision, false positive, temperature effects, waste disposal, etc.).
(7) Colorimetric: *Very* simple as an ASTM standard method(s), mostly/based on pictograms/pictures/illustrations
Quantitative: ASTM standard method(s) for sample prep *and* analysis
(8) Follow the ASTM protocol and modify as needed
(9) No response
(10) Round robin test with 10 renovators, trained as will be done under the rule, testing of 7 lead levels, 3 tests per renovator, so about 210 tests per substrate.

Responses to the question, “What would be a reasonable price?”

(1) No response
(2) $5 and/or below. In order to meet the criteria as required. No, it is unlikely a $2 kit can perform the job properly. I would suggest that the criteria should be changed to *NO* (0%) false negative rate at 1 mg/cm^2 and no requirement for false positive.
(3) Any kit >$10 per test would likely *not* be used by any R&R contractor. Add the cost of lab plus shipping (even waiting overnight for an answer) would be *less*!
(4) Realistically, up to $10 per kit
(5) $5 to $10 per sample
(6) No response
(7) (Using the “dream” test kit, cost of materials *only*)
Colorimetric: $2 per test

Quantitative: $18 to $36 per test

(8) $10 to $15

(9) No response

(10) Assuming five tests per renovation, cost needs to be less than $10 per test, or might as well use lead-safe work practices.

APPENDIX D

Workshop Agenda

LEAD PAINT TEST KITS WORKSHOP

U.S. EPA/Office of Research and Development (ORD)/
National Exposure Research Laboratory (NERL)

Research Triangle Park, NC
October 19-20, 2006

AGENDA

THURSDAY, OCTOBER 19, 2006

8:00 a.m. **Registration** - EPA Auditorium

9:00 a.m. **Logistics**
Dr. Myriam Medina-Vera, EPA/NERL

9:10 a.m. **Development of the Next Generation of Lead Paint Test Kits**
Dr. Larry Reiter, EPA/NERL

9:40 a.m. **Overview of EPA Lead R&R Rule and Role of Lead Paint Test Kits**
Dr. Maria Doa, EPA/OPPT

10:10 a.m. **Break**

10:30 a.m. **HEASD's Technical Approach**
Dr. Linda Sheldon, EPA/NERL

11:00 a.m. **Key Items from Issue Paper**
Sharon Harper, EPA/NERL

11:15 a.m. **HEASD Technical Update**

11:30 a.m. **Lunch** (on your own, EPA Cafeteria is available)

1:00 p.m. **Breakout Groups Discussions**

1. Accuracy, precision and cost of lead (Pb) test kits to determine Pb in paint at the federal action level (chemistry and approaches) - C111A

2. Specifications, and availability of testing/reference materials and protocols to evaluate the performance of test kits for Pb in paint at the federal action level and cost to perform the protocols – C111C

2:15 p.m. Break

2:30 p.m. Continuation of Breakout Group Discussions

5:00 p.m. End of Day 1

FRIDAY, OCTOBER 20, 2006

9:00 a.m. Highlights of Discussions from Breakout Groups
Breakout group participants

10:15 a.m. Break

10:30 a.m. Summary of Discussions
Full group

11:00 a.m. Workshop Wrap-up and List of Key Points
Myriam Medina-Vera and Sharon Harper, EPA/NERL

12:00 p.m. Workshop Adjourns

APPENDIX E

List of Attendees

Lead Paint Test Kits Workshop
October 19 and 20, 2006
Research Triangle Park, NC

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