

Environmental and Sustainable Technology Evaluations (ESTE): Verification of Qualitative Spot Test Kits for Lead in Paint

Impact Statement

The ingestion of household dust containing lead from deteriorating or abraded lead paints is a common cause of lead poisoning in children. Although the use of lead-based paint has been banned by the U.S. Consumer Product Safety Commission since 1978, EPA estimates that 37.8 million pre-1978 housing units and child-occupied facilities are still in use. Since many of these housing units and facilities may have interior or exterior paint containing lead, quick, simple, and reliable test kits are needed to test or screen for the presence or absence of lead-based paint.

On April 22, 2008, EPA issued the final [Lead: Renovation, Repair, and Painting \(RRP\) Program Rule](#). The rule addresses lead-based paint hazards created by renovation, repair, and painting activities that disturb lead-based paint in target housing and child-occupied facilities. Under this rule, EPA must foster the development of improved test kits for lead-based paint surfaces that have false negative rates of no more than 5% and false positive rates of no more than 10%, as measured against the federal standards for lead-based paint. The rule also establishes a two phase process for evaluating and recognizing test kits that can be used to determine the presence or absence of regulated levels of lead in lead-based paint surfaces. For Phase 1, existing commercially available test kits will be evaluated by EPA Office of Pollution Prevention and Toxics (OPPT) via an equivalent process as described below.

Under this rule, EPA also determined that the Environmental Technology Verification Program (ETV) is a suitable vehicle for obtaining independent laboratory validation of test kit performance needed for this program. For Phase 2, EPA OPPT has arranged for ETV to verify the test kits and will provide data for the second phase of EPA's recognition program.

EPA OPPT Test Kit Evaluation and Recognition Program

Under the first phase of this program, EPA OPPT will evaluate and recognize existing commercially-available test kits that have a demonstrated probability (with 95% confidence) of a negative response less than or equal to 5% of the time at or above the lead regulated level of 1.0 mg/cm² or 0.5% by weight. OPPT will base their evaluation on data collected using the National Institute of Standards and Technology (NIST) protocol found in the NIST report entitled "Spot Test Kits for Detecting Lead in Household Paint: A Laboratory Evaluation." EPA OPPT has also arranged to test commercially available kits that were not tested under this study using the NIST protocol. EPA OPPT will start accepting applications for the first phase of the evaluation process on September 1, 2008. OPPT will also, on a first-come first-served basis, provide performance evaluation materials (PEMs) to vendors who have lead test kits that are commercial ready. Developers that are interested in obtaining PEM samples or in being evaluated for recognition by EPA OPPT should visit www.epa.gov/lead for more information.

During the second phase of this program, EPA OPPT will evaluate and recognize improved test kits that meet the criteria set for the first phase and a demonstrated probability (with 95% confidence) of a false positive response of no more than 10% of lead in paint at levels below the regulated level. EPA OPPT

ETV Program

The [ETV Program](#) is operated out of EPA's Office of Research and Development. ETV verifies the performance of innovative technologies using credible, quality-assured protocols developed using a stakeholder process. The goal of ETV is to provide credible performance data for commercial ready environmental technologies. Market input is conveyed by the active involvement of stakeholder groups consisting of technology buyers, sellers, permittees, consultants, financiers, exporters and others within each sector. ETV operates as a public-private partnership through cooperative agreements between EPA and private nonprofit testing and evaluation organizations. Agency priorities, which require the use of contracts rather than cooperative agreements, are verified under Environmental and Sustainable Technology Evaluations (ESTE) projects. See <http://www.epa.gov/etv/este.html> for more information.

will evaluate kit performance using data obtained by the ETV Program. ETV will start accepting applications for testing test kits in March 2009. After September 1, 2010 test kits must meet the above requirements to be recognized by EPA OPPT. Developers of commercially available kits that are interested in using verification results for the purpose of being recognized by EPA OPPT should visit www.epa.gov/lead for more information.

ESTE Spot Test Kits for Lead in Paint Project

ETV will verify the performance of the improved test kits for Phase 2 using an EPA-approved test/quality assurance plan (T/QAP) that is capable of demonstrating whether or not each test kit can achieve both the false negative and false positive criteria of 40 CFR 745.88(c) as published in the final lead RRP rule. ETV will base this T/QAP on ASTM International's E1828, Standard Practice for Evaluating the Performance Characteristics of Qualitative Chemical Spot Test Kits for Lead in Paint, as well as input provided by stakeholders (buyers, sellers, permittees, consultants, financiers, exporters, etc.), OPPT, and others. Cost, speed, and ease of use will also be considered.

The test kits will be tested using PEMs developed for the ETV project. PEMs are painted panels with known lead concentrations and made from different substrates. They will be similar in design to the PEMs developed by OPPT, but with different lead concentrations. The actual number and types of painted test surfaces shall be determined based on stakeholder and EPA input and shall be documented in the final T/QAP which will be posted on the ETV web site. Both synthetic painted film strips and real-world painted house components (containing lead-based paint) may be used. ETV will publish results in a verification report and statement, which will be posted on the ETV Web Site.

Time Line for Phase 2 Verification

September 2008 - ETV posted the vendor application process

March 2009 - T/QAP approved

May 2009 - Verification testing of test kits

September 1, 2010 - After this date test kits must meet both of the required probability criteria to be recognized by EPA

References

U.S. EPA, Lead; Renovation, Repair, and Painting Program; Lead Hazard Information Pamphlet; Notice of Availability; Final Rule. Federal Register. 40 CFR Part 745, April 22, 2008 <<http://www.epa.gov/fedrgstr/EPA-TOX/2008/April/Day-22/t8141.pdf>>.

U.S. EPA, ETV Case Studies: Demonstrating Program Outcomes. EPA/600/R-06/001. January 2006 <<http://www.epa.gov/nrmrl/std/etv/pubs/600r06001.pdf>>.

U.S. EPA, Lead in Paint, Dust, and Soil Web Site. Accessed August 2008, <<http://www.epa.gov/lead>>.

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OPPT Evaluation and Recognition Program

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