Information Document for Lead Test Kit Stakeholder Meeting & Webinar June 4, 2015

I. Lead Test Kit Background

On April 22, 2008, the U.S. Environmental Protection Agency published the Lead-Based Paint Renovation, Repair and Painting rule, which requires contractors to use lead-safe work practices during renovation, repair, and painting activities that disturb lead-based paint in target housing and child-occupied facilities built before 1978 unless a determination can be made that no lead-based paint would be disturbed during the renovation or repair. The use of an EPA-recognized lead test kit, when used by a trained professional, can reliably determine that regulated lead-based paint is not present by virtue of a negative result. The federal standards for lead-based paint in target housing and child-occupied facilities is a lead content in paint that equals or exceeds a level of 1.0 milligram per square centimeter (mg/cm²) or 0.5 percent by weight. If regulated lead-based paint is not present, there is no requirement to employ lead-safe work practices under the RRP rule.

The RRP rule established negative-response and positive-response criteria outlined in 40 CFR 745.88(c) for lead test kits recognized by the EPA. Lead test kits recognized before September 1, 2010 must meet only the negative-response criterion outlined in 40 CFR 745.88(c)(1). The negative-response criterion states that for paint containing lead at or above the regulated level, 1.0 mg/cm² or 0.5% by weight, a demonstrated probability (with 95% confidence) of a negative response less than or equal to 5% of the time must be met. The recognition of kits that meet only this criterion will last until the EPA publicizes its recognition of the first test kit that meets both of the criteria outlined in the rule. To date, there are two EPA-recognized test kits commercially available nationwide that meet the false-negative criterion and continue to be recognized by the EPA.

Lead test kits recognized after September 1, 2010 must meet both the negative-response and positive-response criteria outlined in 40 CFR 745.88(c)(1)-(2). The positive-response criterion states that for paint containing lead below the regulated level, 1.0 mg/cm² or 0.5% by weight, a demonstrated probability (with 95% confidence) of a positive response less than or equal to 10% of the time must be met. Qualitatively speaking, lead test kits recognized by the EPA should also serve as a quick, inexpensive, reliable, and easy to perform option for lead-based paint testing in the field.

The EPA put forth significant effort and resources to foster the development of a test kit that would meet both the false negative and false positive criteria outlined in the 2008 RRP rule. As stated in the preamble to that rule, the EPA determined that the EPA's Environmental Technology Verification Program was a suitable vehicle for obtaining independent laboratory validation of test kit performance and that the EPA intended to use ETV or an equivalent testing program to evaluate test kits.

On September 1, 2008, the ETV program began accepting applications for testing from test kit manufacturers. For more than two years, the EPA supported test kit research and development efforts by several private companies by funding not only the manufacture of testing reference materials, but also the technical evaluation of test kits through the ETV program. After a test kit went through the ETV or other EPA-approved testing process, the EPA reviewed the test report to determine whether the kit had demonstrated it could achieve the criteria set forth in the rule. In addition to the two test kits that were recognized by the EPA in 2008, the EPA recognized an additional test kit in 2010 as a result of these efforts. In 2012, the EPA expanded its recognition for an existing test kit to include its use on two additional substrates. Test data were provided by the manufacturer of the test kit and generated by an independent third-party laboratory using an EPA-approved test protocol. The ETV program concluded operations in early 2014.

At this time, the agency is aware of a lead test kit research grant awarded by the U.S. Department of Housing and Urban Development's Office of Lead Hazard Control and Healthy Homes under its Lead Technical Studies grant program. The grantee, QuanTech, Inc., has initiated research, and the EPA will monitor progress. Once available, the agency will review results of this research and assess its impact on the capabilities of existing lead test kit technology. Although the EPA is unaware of any other test kit currently available or under development that would also meet the positive criterion, any commercial entity that wishes to receive the EPA recognition of their test kit may have an ETV-equivalent evaluation performed and present evaluation results to the EPA for consideration and potential recognition.

Despite the EPA's commitment of resources to this effort, to date no test kit has met both of the performance criteria outlined in the RRP rule.

II. Stakeholder Dialogue

The report accompanying the EPA's FY 2015 Appropriations included a policy rider that "directs the agency to prioritize efforts with stakeholders in fiscal year 2015 to identity solutions that would allow for a test kit to meet the criteria within the 2008 rule to reduce costs for consumers, remodelers and families to comply with the rule and, if no solution is reached by the end of the fiscal year, to revisit the test kit criteria in the 2008 rule and solicit public comment on alternatives." Therefore, in an effort to understand the current state of the science for lead test kits and lead-based paint field testing alternatives, as well as the existing market and potential availability of additional test kits, the EPA is soliciting input from relevant stakeholders. The EPA is seeking information related to: 1) the existing market for lead test kits as referenced in the 2008 RRP rule; 2) the development or modification of lead test kit(s) that may meet the EPA's positive-response criterion (in addition to the negative-response criterion); and 3) other alternatives for lead-based paint field testing.

To help the EPA understand the current situation, the agency is engaging stakeholders that develop, manufacture and/or sell lead test kits or other lead-based paint field testing instruments, as well as those who use lead test kits to determine if lead-safe work practices are required under the RRP rule to perform renovations for compensation in target housing or child-occupied facilities. Examples of child-occupied facilities are day-care centers, preschools, and kindergarten classrooms.

Following this meeting, a transcript will be made available in the public docket. The EPA welcomes additional dialogue with stakeholders as well as any information interested parties may wish to provide the agency in order to improve its understanding of the current situation and identify possible solutions.

III. Lead Test Kit Questions

Key questions the EPA wishes stakeholders to answer in the public meeting are:

Lead Test Kit Market

- a. Do you use lead test kits?
 - i. If so, approximately how often do you use lead test kits per year?
 - ii. If not, what prevents you from using lead test kits?
 - iii. If not, what would cause you to use lead test kits?
- b. How does your use of lead test kits compare with assuming lead-based paint is present?
- c. How does your use of lead test kits compare with X-ray fluorescence testing for lead-based paint?
- d. How does your use of lead test kits compare with sending paint samples to a National Lead Laboratory Accreditation Program lab for testing?

State of the Science

- e. Besides what has been presented here today, are you aware of any lead test kits in development?
- f. Are you aware of challenges that have been encountered in developing new lead test kits?

Lead Test Kit Alternatives

- g. Are you aware of other field technologies that could be used in lieu of lead test kits?
 - i. Specifically, are you aware of portable atomic stripping voltammetry?
 - ii. Are you aware of other colorimetric methods?

IV. Additional Information

Additional information regarding this meeting, including contacts and instructions regarding participation in the meeting, may be found at <u>http://www2.epa.gov/lead/lead-test-kit-stakeholder-meeting</u>.