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DIVISION OF PUBLIC HEALTH

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Laurie Altman, Vice President
3M Construction and Home
Improvement Markets Division
3M Center, Building 0223-04-S-02
St Paul MN 55144-1000

Dear Ms. Altman:

We have received your request for recognition of the 3M LeadCheck® Lead Test Kit in Wisconsin along with your formal request for approval of an alternative to an administrative requirement. Wisconsin administrative code under s. DHS 163.16 (2) requires a recognized test kit to meet or exceed both the negative and the positive response criteria. Your request is for recognition of the LeadCheck test kit under the Negative Response Criteria only. The standard for approving an alternative to an administrative requirement under Wisconsin administrative code at s. DHS 163.02 (2) requires that the alternative be as protective of human health and the environment as the original requirement.

Decision

The Department reviewed the regulatory requirements and test kit performance measures and has concluded that the 3M LeadCheck test kit can reliably determine that lead-based paint is *not* present on wood, ferrous metal (alloys that contain iron), drywall and plaster substrates. Therefore, effective immediately, the Department recognizes the 3M LeadCheck paint test kit for use in Wisconsin limited to the negative response criteria under s. DHS 163.16 (2) (a) when performed by certified lead-safe renovators following the manufacturer's instructions. This recognition will remain in effect until such time that a test kit that meets both the negative and positive response criteria is recognized by the Department.

Basis

The Department of Health Services (the Department) requested the Wisconsin State Laboratory of Hygiene (WOHL) to review the studies used in the U.S. EPA Environmental Technology Verification (ETV) process to determine if the 3M LeadCheck test kit reliably detects lead at Wisconsin lead loading standards. The original studies evaluated the suitability of the LeadCheck kit to detect lead in paint at or above the EPA threshold value of 1.0 mg/cm^2, but the studies contained data that also allowed interpretation at the corresponding Wisconsin standard of 0.7 mg/cm^2. The Federal and Wisconsin standards for lead concentration measurements of lead by weight, at 0.5% and 0.06% respectively, were *not* evaluated in these or other EPA studies and were not considered in WOHL's review.

Currently, EPA recognizes a lead test kit if it meets the negative response criterion of no more than 5% false negatives, with 95% confidence for paint containing lead at or above the regulated level or 1.0 mg/cm^2. This recognition will remain in effect until such time that EPA publicizes

recognition of a test kit that meets both the negative and positive response criteria outlined in the EPA Renovation, Repair and Painting rule.

Under Administrative Code at s. DHS 163.16 (2), Wisconsin requires a test kit to meet or exceed *both* the negative and positive response criteria for paint containing lead at or above the regulated level of 0.7 mg/cm^2, or .06% by weight. For the negative response criteria, the test kit must give less than 5% false negative results, with 95% confidence, for paint containing lead at or above the regulated level. For the positive response criteria, the test kit must give less than 10% false positive results, with 95% confidence, for paint containing lead below the regulated level.

EPA has recognized three lead test kits under its pre-September 1, 2008 requirement to meet only the negative response criterion, with the 3M LeadCheck being one of the three recognized kits. EPA recognizes that "when used by a certified renovator, the 3M LeadCheck lead test kit can reliably determine that regulated lead-based paint is not present on wood, ferrous metal (alloys that contain iron), or drywall and plaster surfaces."

The WOHL reviewed the same NIST and Battelle Labs studies used to determine EPA recognition. Based on its review of the data, WOHL has concluded that the 3M Lead Check test kit meets the criteria for use as a negative screen at the Wisconsin threshold value of 0.7 mg/cm^2.

The Department reviewed the formal conclusions provided by WOHL along with the rules for approving an alternative to an administrative requirement that require the alternative to be as protective as the original requirement. This involved analyzing the protective characteristics of using the negative response criterion alone versus using both the negative and positive response criterion as required under s. DHS 163.16 (2) to determine recognition of a paint test kit. The Department has determined that using the negative response criterion alone is as protective of human health and the environment as the original administrative requirement given that a false positive result under the positive response criterion would require a renovator to follow the lead-safe renovation requirements when they would not have been necessary and would therefore be overly protective rather than less protective of human health and the environment.

The Department will place information about its recognition of the 3M LeadCheck paint test kit on the lead program website at www.dhs.wisconsin.gov/lead and will provide information about the recognition of the test kit to all Wisconsin training providers offering accredited lead-safe renovation training courses.

Sincerely,

Shelley Bruce
Supervisor, Asbestos and Lead Section
Bureau of Environmental and Occupational Health

cc. Bob Golledge
Chuck Warzecha, Director, Bureau of Env & Occ Hlth