



National Institute for
Occupational Safety and Health
Centers for Disease Control
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February 26, 2010

RADM William S. Stokes, D.V.M., DACLAM
Director, National Toxicology Program Interagency Center for the Evaluation of Alternative
Toxicological Methods
NIEHS
P.O. Box 12233, Mail Code K2-16
Research Triangle Park, NC 27709

Dear Dr. Stokes:

As requested by Dr. Linda Birnbaum, Director of the National Institute of Environmental Health Sciences (NIEHS), in her letter of September 18, 2009, the National Institute for Occupational Safety and Health (NIOSH) is herein responding to you regarding test method recommendations for the Local Lymph Node Assay (LLNA), a test method for potential allergic contact dermatitis (ACD). These methods were recommended by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM).

NIOSH agrees that the recommended alternative methods are valid for performing the LLNA, as described in the ICCVAM evaluation report and the performance standards report. NIOSH acknowledges the requirement that each agency review these recommended test methods and notify the ICCVAM regarding test methods for which these alternative methods may be substituted. NIOSH is a research agency and has no regulatory testing requirements; however, NIOSH does perform some testing for potential ACD using the LLNA. These methods are applicable to NIOSH studies using the LLNA; NIOSH scientists participated in the evaluation of the new recommendations, and they already apply the new performance standards. The recommended methods will be considered for use in those studies that might involve pre-screening of chemicals or identifying and confirming non-sensitizing compounds. However, most NIOSH studies using LLNA are applied to characterize chemicals already screened and identified as potential sensitizers, and these require data that cannot be obtained using the limited methods in these recommendations. NIOSH has informed scientists of these new recommendations and will continue to inform them via its Animal Care and Use Committee and training of laboratorians in use of the LLNA. The agency will continue to encourage use or consideration of alternative methods including these, in any animal-using tests that the agency may conduct. NIOSH will attempt to identify and support research programs that may contribute to future development of other alternative test methods.

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NIOSH commends the efforts and accomplishments of ICCVAM in reviewing and evaluating these alternative methods and other methods. We are proud of our participation on ICCVAM during its activity as an interagency committee.

Thank you for the opportunity to respond for NIOSH about this ICCVAM achievement.

Sincerely,

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~~John Howard, M.D~~
~~Director~~