

and in hardcopy from NICEATM (contact information provided below).

#### **Nominations and Submissions of Alternative Test Methods for Evaluation by ICCVAM**

Those persons nominating or submitting test methods are referred to the guidelines noted below for details on information required for an ICCVAM evaluation. Test methods for which adequate validation studies have been completed can be submitted to ICCVAM as test method submissions. Test method submissions should contain sufficient information to characterize the relevance and reliability of a test method for a specific, proposed regulatory testing application. Test methods for which complete submissions are not available may be nominated for further evaluation, including test methods that may require validation studies or a comprehensive review of their current validation status. Both nominations and submissions are prioritized for formal evaluation as described in the ICCVAM guidelines. Nominations should also be accompanied by as much information as possible as outlined in the ICCVAM guidelines. While there is no minimum requirement for information to provide with nominations, complete information will expedite ICCVAM's consideration of the proposed test method. All nominations and submissions should be sent to Dr. William S. Stokes, Director, NICEATM, P. O. Box 12233, MD EC-17, Research Triangle Park, NC 27709, phone: 919-541-2384, fax: 919-541-0947, or email: [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov).

#### **ICCVAM Guidelines**

The NICEATM announces the availability of the document, "ICCVAM Guidelines for Nomination and Submission of New, Revised, and Alternative Test Methods," September 2003, NIH Publication No. 03-4508. The updated guidelines replace the document previously published in 1999. The ICCVAM guidelines provide guidance for test method sponsors and nominators on the information needed by ICCVAM to evaluate the validation status of new, revised, and alternative test methods proposed for regulatory testing applications. A framework for organizing the information supporting the validity of a test method is provided. This framework can also be used to organize information to support test methods nominated for further evaluation, including validation study proposals. The updated ICCVAM nomination and submission guidelines are available electronically (PDF and HTML) on the NICEATM/ICCVAM Web

site at <http://iccvam.niehs.nih.gov>. A limited number of printed guidelines are available from the NICEATM at the address given above.

#### **Background Information on ICCVAM and NICEATM**

The NIEHS established the ICCVAM in 1997 to coordinate the interagency technical review of new, revised, and alternative test methods of interagency interest, and to coordinate cross-agency issues relating to the validation, acceptance, and national/international harmonization of toxicological testing methods. ICCVAM was established as a permanent interagency committee of the NIEHS under the NICEATM on December 19, 2000, by the ICCVAM Authorization Act of 2000 (Public Law 106-545, available at <http://iccvam.niehs.nih.gov/about/PL106545.pdf>). The committee is composed of representatives from 15 Federal regulatory and research agencies that use or generate toxicological information. ICCVAM seeks to promote the scientific validation and regulatory acceptance of toxicological test methods that will improve the agencies' ability to accurately assess the safety or hazards of chemicals and various types of products, while refining (less pain and distress), reducing, and replacing animal use wherever possible. NICEATM administers the ICCVAM and provides scientific and operational support for ICCVAM and ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of Federal agencies. Additional information about ICCVAM and NICEATM can be found at the following Web site: <http://iccvam.niehs.nih.gov>.

Dated: November 5, 2003.

**Samuel H. Wilson,**

*Deputy Director, National Institute of Environmental Health Sciences.*

[FR Doc. 03-28560 Filed 11-13-03; 8:45 am]

**BILLING CODE 4140-01-P**

---

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Public Health Service**

#### **National Institute of Environmental Health Sciences (NIEHS); National Toxicology Program (NTP); Request for Nominations and Submissions of Alternative Test Methods for Evaluation by ICCVAM; Notice of the Availability of the Updated Document, "ICCVAM Guidelines for Nomination and Submission of New, Revised, and Alternative Test Methods"**

#### **Summary**

The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests the nomination and submission of new, revised, and alternative test methods for potential evaluation by the Interagency Coordinating Committee on Alternative Toxicological Methods (ICCVAM). The nominations and submissions should be sent to Dr. William Stokes, NICEATM Director at the address provided below. Instructions for making nominations and submissions are described in the document, "ICCVAM Guidelines for Nomination and Submission of New, Revised, and Alternative Test Methods," September 2003, NIH Publication 03-4508. The guidelines are available electronically in PDF and HTML formats from the NICEATM/ICCVAM Web site (<http://iccvam.niehs.nih.gov>)