



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Coordinating Committee on the Validation of Alternative Methods:

Request for Comment on Draft Report on Validation, Qualification, and Acceptance of New Approach Methodologies

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) announces availability of the draft document, “Validation, Qualification, and Regulatory Acceptance of New Approach Methodologies.” ICCVAM will accept public comments on the document through September 5, 2023; 5:00 p.m.

EDT.

DATES:

Document Availability: The draft document is available at

<https://ntp.niehs.nih.gov/go/ICCVAM-submit>.

Written Public Comments Submissions: Submit comments to

amber.daniel@inotivco.com by September 5, 2023; 5:00 p.m. EDT.

FOR FURTHER INFORMATION CONTACT: Dr. Nicole Kleinstreuer, Director, National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), email: nicole.kleinstreuer@nih.gov, telephone: 984-287-3150.

SUPPLEMENTARY INFORMATION:

Background: ICCVAM, a congressionally mandated committee, promotes the scientific validation and regulatory acceptance or qualification of testing methods that accurately assess the chemical safety and hazards of relevant products in an effort to replace, reduce,

or refine (enhance animal well-being and lessen or avoid pain and distress) animal use.

Shortly after its establishment as a standing committee in 1997, ICCVAM published a report, “Validation and Regulatory Acceptance of Toxicological Test Methods,” which outlined criteria for the validation and regulatory acceptance for new and alternative test methods (62 FR 11901). This and subsequent related documents described a validation model that, while being initially useful, has lately demonstrated limitations such as being lengthy and resource-intensive and not being compatible with many modern approaches to toxicity testing. Furthermore, for some contexts of use, methods may not need to undergo every step of the validation process described by these documents to yield valuable data for a federal agency.

In 2021, ICCVAM established its Validation Workgroup to update the 1997 document and align it with the principles articulated in the 2018 ICCVAM publication, “A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States” (83 FR 7487). The Strategic Roadmap provides a conceptual framework promoting better communication between agencies and test method developers and more flexibility in how confidence is established, to help ensure the adoption of new methods by federal agencies and regulated industries once validated for a specific purpose or context of use.

A draft version of the new document, “Validation, Qualification, and Regulatory Acceptance of New Approach Methodologies.” is now available for public comment.

Requests for Comments: ICCVAM invites public comments from all ICCVAM stakeholders on the draft document. The document can be found on the NICEATM website at <https://ntp.niehs.nih.gov/go/ICCVAM-submit>.

Stakeholders may submit comments via email to Ms. Amber Daniel at amber.daniel@inotivco.com. Commenters should include their name, affiliation (if any),

mailing address, telephone, email, and sponsoring organization (if any) with their comments. Guidelines for public statements submitted to NTP are available at http://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.

All comments received will be posted on the NICEATM website and identified by the individual's name, affiliation, and sponsoring organization. Comments should be received by September 5, 2023; 5:00 p.m. EDT, to ensure consideration as the draft document is finalized.

Responses to this notice are voluntary. No proprietary, classified, confidential, or sensitive information should be included in statements submitted in response to this notice. This request for input is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information.

Background Information on ICCVAM and NICEATM: ICCVAM is an interagency committee composed of representatives from 17 federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability. ICCVAM also promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and replace, reduce, or refine animal use.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285I–3) establishes ICCVAM as a permanent interagency committee of NIEHS and provides the authority for ICCVAM involvement in activities relevant to the development of alternative test methods. Additional information about ICCVAM can be found at

<https://ntp.niehs.nih.gov/go/iccvam>.

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts and publishes analyses and evaluations of data from new, revised, and alternative testing approaches. NICEATM and ICCVAM work collaboratively to evaluate new and improved testing approaches applicable to the needs of U.S. federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about NICEATM can be found at <https://ntp.niehs.nih.gov/go/niceatm>.

Dated: August 4, 2023.

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Director,

National Institute of Environmental Health Sciences and National Toxicology Program,

National Institutes of Health.

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