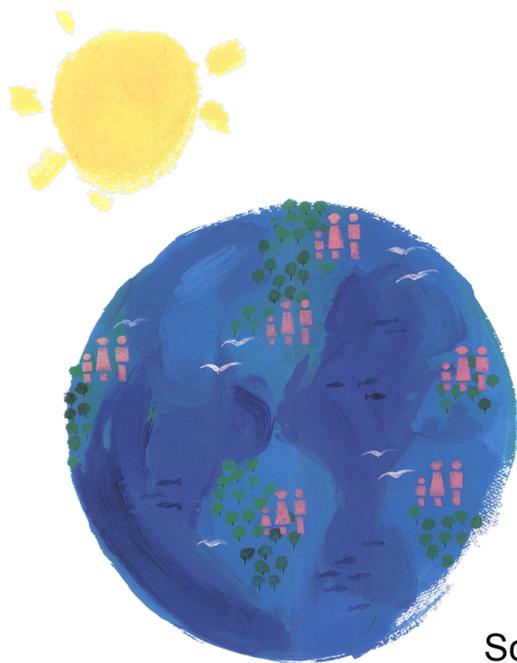


NICEATM

*National Toxicology Program Interagency
Center for the Evaluation of Alternative
Toxicological Methods*

ICCVAM

*Interagency Coordinating Committee on
the Validation of Alternative Methods*



Support Contract for the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods Project Concept Review

Dr. William Stokes, Director, NICEATM

Scientific Advisory Committee on Alternative Test Methods Meeting

September 6, 2012

National Institute of Environmental Health Sciences

Research Triangle Park, NC



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health



NIEHS
National Institute of
Environmental Health Sciences



NTP
National Toxicology Program



Outline

- Purpose
- Background
- Proposed Changes

Purpose of the Support Contract

- Provide administrative, logistical and scientific support for the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM).

- NICEATM:
 - Administers the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)
 - NICEATM provides administrative, operational and scientific support to ensure compliance with ICCVAM purposes and duties in the ICCVAM Authorization Act (42 USC 285ℓ-3)
 - Designs, coordinates, and conducts validation studies on alternative test methods

ICCVAM Duties (Public Law 106-545): Important Considerations

- ICCVAM is an Interagency **Committee**
 - The Committee does not have laboratories, dedicated staff, or budget
 - The Committee's duties do not conduct alternative test method R & D or validation studies
- Meeting the ICCVAM Authorization Act requirements
 - ICCVAM is an interagency committee of the NIEHS under NICEATM
 - NICEATM, as an NTP Center, provides the support to carry out the requisite activities required for ICCVAM to comply with its statutory duties
- Validation studies
 - Federal agencies and other stakeholders, including the NTP, conduct alternative test method R&D and validation studies
 - NICEATM, as part of the NTP, conducts validation studies
 - Agencies and stakeholders are encouraged to submit results to ICCVAM for technical evaluation



Background: History of the Contract

- 1998-2003
 - Initial contract awarded to ILS, Inc. at NIEHS
- 2003-2013
 - 2nd contract awarded to ILS Inc., at NIEHS
- Close and frequent coordination with NICEATM is essential

Background: NICEATM -1

- NICEATM comprised of three federal employees: Director, Deputy Director, and Special Assistant
 - Heavily rely on contract staff to carry out directed activities to assist NICEATM in administering and supporting ICCVAM, and to assist with coordinating and conducting validation studies

NICEATM Support activities

- Provide information to interested stakeholders
 - Validation criteria and processes
 - Nomination and submission guidance
 - Availability of accepted test methods
- Receive and process test method nominations and submissions
- Prepare comprehensive draft test method background review documents for test method evaluations

Background: NICEATM -2

NICEATM Support activities –continued

- Support test method evaluations by ICCVAM interagency working groups and ICCVAM
 - Identify usefulness and limitations of test methods for specific proposed uses
 - Assess extent that validation of test methods is adequate and appropriate
 - Evaluations provides agencies with information for decisions:
 - Has the test method been determined to be valid for its proposed use?
 - Will the test method provide data at least equivalent to existing methods for hazard identification, dose-response assessment, or risk assessment purposes?
- Assist with organizing international independent scientific peer review panels to review validation status of test methods

Background: NICEATM -3

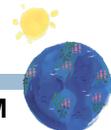
NICEATM Support activities–continued

- Assist with preparation of draft and final test method evaluation reports for consideration by Working Groups and ICCVAM
- Assist with preparation of ICCVAM report transmittal packages for clearance through HHS to agencies
- Assist with organizing state-of-the-science workshops
- Assist with other communications to stakeholders
 - Website
 - Listserv
 - News columns, FR notices
 - Biennial Reports
 - Other reports and publications

Background: NICEATM - 4

NICEATM Support activities

- Assist with meeting support for:
 - ICCVAM and 9 ICCVAM Interagency Working Groups
 - ICCVAM Subcommittees
 - Workshop Organizing Committees
 - ICATM Coordination and SACATM Meetings
 - Validation Study Management Teams
- Assist with international test method harmonization and adoption activities
 - Support for ICATM Study Management Teams
 - Assist with preparation of draft and updated international test guidelines, guidance documents, submission proposals
 - Support for international expert working group meetings, commenting rounds
- Assist with coordination of international independent validation study activities
 - Laboratory selection/qualification; reference chemical selection and distribution; protocol standardization/optimization; data collection and analysis; validation study reports; troubleshooting



Proposed Changes to Current Statement of Work

- Includes activities and expertise to support goals in the draft NICEATM-ICCVAM 2013-2017 Five Year Plan
 - Contribute to the transformation of safety testing by fostering and promoting the incorporation of scientific advances and innovative technologies into new improved test methods and integrated testing and decision strategies.

- Expanded expertise
 - Bioinformatics
 - Computational toxicology

Discussion

The SACATM members are asked to review the project concept for overall values and scientific relevance as well as for fulfilling the program goal of protecting public health. Specific areas should include:

- Scientific, technical or program significance of proposed activity
- Availability of the technology and other resources necessary to achieve required goals
- Extent to which there are identified, practical scientific or clinical uses for the anticipated results
- Where pertinent, adequacy of the methodology to be used in performing the activity.

- Is the proposed activity appropriate to address through the contract mechanism?
- Are the proposed activities appropriate to meet the support needs of NICEATM?

