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### VIII. Other Information

#### A. Protection of Human Subjects Regulations

The applicant must comply with the DHHS Protection of Human Subjects regulations (which require obtaining Institutional Review Board approval), set out as 45 CFR Part 46, if applicable. General information about Human Subjects regulations can be obtained through the Office of Human Research Protections (OHRP) at <http://www.hhs.gov/ohrp>, or [ohrp@osophs.dhhs.gov](mailto:ohrp@osophs.dhhs.gov), or toll free at (866) 447-4777.

#### B. Objectives of Healthy People 2010

Emphasis will be placed on aligning OWH activities and programs with Healthy People 2010: Goal 2 to eliminate health disparities. More information on the Healthy People 2010 objectives may be found on the Healthy People 2010 Web site: <http://www.health.gov/healthypeople>.

#### C. Definitions

**Community-based organization:** Public and private, non-profit organizations that are representative of communities or significant segments of communities.

**Culturally competent:** Information and services provided at the educational level and in the language and cultural context that are most appropriate for the individuals for whom the information and services are intended. Additional information on cultural competency is available at the following Web site: <http://www.aoa.dhhs.gov/May2001/factsheets/Cultural-Competency.html>.

**Evidence-Based:** DHHS recognizes HIV/AIDS prevention education approaches for reaching minority populations, namely education/training, outreach (street, media), and care services. Additional information on evidence-based HIV/AIDS prevention programs is available at the following Web site: <http://www.cdc.gov/hiv/pubs/hivcompendium/organize.htm>.

**Gender-focused:** An approach which, in considering the social and environmental contexts impacting women's lives therefore structures information, activities, program priorities, and service delivery systems that compliment those factors.

**Healthy People 2010:** A set of national health objectives that outlines the prevention agenda for the Nation. Healthy People 2010 identifies the most significant preventable threats to health

and establishes national goals for the next ten years. Individuals, groups, and organizations are encouraged to integrate Healthy People 2010 into current programs, special events, publications, and meetings. Businesses can use the framework, for example, to guide worksite health promotion activities as well as community-based initiatives. Schools, colleges, and civic and faith-based organizations can undertake activities to further the health of all members of their community. Health care providers can encourage their patients to pursue healthier lifestyles and to participate in community-based programs. By selecting from among the national objectives, individuals and organizations can build an agenda for community health improvement and can monitor results over time. More information on the Healthy People 2010 objectives may be found on the Healthy People 2010 Web site: <http://www.health.gov/healthypeople>.

**Prevention education:** Accurate information to increase knowledge of methods and behaviors to keep individuals from becoming infected with HIV.

#### References

- (1) Centers for Disease Control and Prevention. HIV/AIDS Surveillance Report. 2002; 14/Addendum: 5. Table A3.
- (2) Centers for Disease Control and Prevention. HIV/AIDS Surveillance Report 2002, Vol. 14.

Dated: April 19, 2007.

**Wanda K. Jones,**

*Deputy Assistant Secretary for Health (Women's Health).*

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**BILLING CODE 4150-33-P**

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### National Toxicology Program (NTP); Liaison and Scientific Review Office; Meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM)

**AGENCY:** National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

**ACTION:** Meeting announcement and request for comment.

**SUMMARY:** Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of SACATM on June 12, 2007, at the Marriott Bethesda North Hotel and Conference Center, 5701 Marinelli Road,

Bethesda, Maryland. The meeting is scheduled from 8:30 a.m. to adjournment (5 p.m.) and is open to the public with attendance limited only the space available. SACATM advises the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), and the Director of the NIEHS and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM.

**DATES:** The SACATM meeting will be held on June 12, 2007. All individuals who plan to attend are encouraged to register online at the NTP Web site (<http://ntp.niehs.nih.gov/go/7441>) by June 8, 2007. In order to facilitate planning, persons wishing to make an oral presentation are asked to notify Dr. Mary S. Wolfe via online registration, phone, or email by June 4, 2007 (see **ADDRESSES** below). Written comments should also be received by June 4 to enable review by SACATM and NIEHS/NTP staff before the meeting.

**ADDRESSES:** The SACATM meeting will be held at the Marriott Bethesda North Hotel & Conference Center, 5701 Marinelli Road, Bethesda, Maryland 20852 [hotel: (301) 822-9200]. Public comments and other correspondence should be directed to Dr. Mary S. Wolfe (NIEHS, P.O. Box 12233, MD A3-01, Research Triangle Park, NC 27709; telephone: 919-541-7539 or e-mail: [wolfe@niehs.nih.gov](mailto:wolfe@niehs.nih.gov)). Persons needing special assistance, such as sign language interpretation or other reasonable accommodation in order to attend, should contact 919-541-2475 voice, 919-541-4644 TTY (text telephone), through the Federal TTY Relay System at 800-877-8339, or send e-mail to [niehs000@niehs.nih.gov](mailto:niehs000@niehs.nih.gov). Requests should be made at least 7 days in advance of the meeting.

#### SUPPLEMENTARY INFORMATION:

##### Preliminary Agenda and Availability of Meeting Materials

A preliminary agenda is provided below. Additional background materials will be posted on the NTP Web site (<http://ntp.niehs.nih.gov/go/7441>) or available upon request (see **ADDRESSES** above). One agenda topic is discussion of the draft NICEATM-ICCVAM 5-Year Plan, which will be available by May 7 and presented at a public Town Meeting at the William H. Natcher Center, NIH, 9000 Rockville Pike, Bethesda, Maryland on June 11 (<http://iccvam.niehs.nih.gov/meetings/5YPlanTM/townmtg.htm>). The Town Meeting will be announced in a separate

**Federal Register** notice. Following the SACATM meeting, summary minutes will be prepared and available on NTP Web site or upon request.

### Preliminary Agenda

*Scientific Advisory Committee on Alternative Toxicological Methods*

June 12, 2007

Marriott Bethesda North Hotel & Conference Center, 5701 Marinelli Road, Bethesda, Maryland 20852

8:30 a.m.

<bullet> Call to Order and

Introductions

<bullet> NICEATM–ICCVAM Update

<bullet> Draft NICEATM–ICCVAM 5-Year Plan

[cir] Public Comment

Noon LUNCH

1 p.m.

<bullet> ICCVAM Evaluation of *In*

*Vitro* Pyrogenicity Test Methods

[cir] Public Comment

<bullet> Nominations to ICCVAM

[cir] Public Comment

<bullet> NTP High Throughput

Screening Initiative

[cir] Public Comment

<bullet> Update from the European

Center for the Evaluation of

Alternative Methods

<bullet> Update from the Japanese

Center for the Validation of

Alternative Methods

<bullet> Other Business

5 p.m. ADJOURN

### Request for Comments

Public input is invited and time is set aside at the meeting for presentation of oral comments. Each organization is allowed one time slot per public comment period. At least 7 minutes will be allotted for each speaker, and if time permits, may be extended up to 10 minutes at the discretion of the chair. Registration for oral comments will also be available on-site, although time allowed for presentation by on-site registrants may be less than for pre-registered speakers and will be determined by the number of persons who register at the meeting.

Persons registering to make oral comments are asked to do so through the online registration form (<http://ntp.niehs.nih.gov/go/7441>) and to send a copy of their statement to Dr. Wolfe (see **ADDRESSES** above) by June 4 to enable review by SACATM and NIEHS/NTP staff prior to the meeting. Written statements can supplement and may expand the oral presentation. If registering on-site and reading from written text, please bring 40 copies of the statement for distribution and to supplement the record. Written comments received in response to this notice will be posted on the NTP Web

site. Persons submitting written comments should include their name, affiliation (if applicable), and sponsoring organization (if any) with the document.

### Background Information on SACATM

SACATM was established in response to the ICCVAM Authorization Act [42 U.S.C. 285l–3(d)] and is composed of scientists from the public and private sectors. SACATM advises ICCVAM, NICEATM, and the Director of the NIEHS and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. SACATM provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, implementation, and national and international harmonization of new, revised, and alternative toxicological test methods. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at <http://ntp.niehs.nih.gov/go/167>. Information about NICEATM and ICCVAM is available at <http://iccvam.niehs.nih.gov> or by contacting the NICEATM Director, Dr. William Stokes (telephone: 919–541–2384 or e-mail: [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov)).

Dated: April 17, 2007.

**Samuel H. Wilson,**

*Deputy Director, National Institute of Environmental Health Sciences and National Toxicology Program.*

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**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institute of Environmental Health Sciences (NIEHS); National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Availability of Draft NICEATM–ICCVAM 5-Year Plan and Request for Public Comments; Announcement of a Town Meeting on the Draft NICEATM–ICCVAM 5-Year Plan

**AGENCY:** National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

**ACTION:** Meeting announcement and request for comments.

**SUMMARY:** The NIEHS and NICEATM request public comments that can be considered by NICEATM, the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), and relevant program offices

on the draft NICEATM–ICCVAM 5-Year Plan. The draft plan addresses: (a) Research, development, translation, and validation of new and revised non-animal and other alternatives assays for integration of relevant and reliable methods into federal agency testing programs and (b) identification of areas of high priority for new and revised non-animal and alternative assays for the replacement, reduction, and refinement (less pain and distress) of animal tests. The draft plan will be available on or before May 7, 2007, at the NICEATM–ICCVAM 5-Year Plan Web site (<http://iccvam.niehs.nih.gov/docs/5yearplan.htm>). Copies of the draft plan may also be obtained by contacting NICEATM (see **ADDRESSES** below). NICEATM and ICCVAM will hold a public Town Meeting at the National Institutes of Health, Bethesda, Maryland on June 11, 2007, beginning at 1 p.m. to adjournment (5 p.m.) to receive oral comments on the draft NICEATM–ICCVAM 5-Year Plan.

**DATES:** The draft NICEATM–ICCVAM 5-Year Plan will be available by May 7, 2007. Registration to attend the meeting and written comments on the draft NICEATM–ICCVAM 5-Year Plan should be received by June 7, 2007. The Town Meeting will be held June 11, 2007.

**ADDRESSES:** The Town Meeting will be held at the William H. Natcher Conference Center, Room E, NIH, 9000 Rockville Pike, Bethesda, Maryland. Persons needing special assistance, such as sign language interpretation or other reasonable accommodation in order to attend, should contact 919–541–2475 voice, 919–541–4644 TTY (text telephone), through the Federal TTY Relay System at 800–877–8339, or send e-mail to [niehsoeeo@niehs.nih.gov](mailto:niehsoeeo@niehs.nih.gov). Requests should be made at least 7 days in advance of the meeting. Written comments should be submitted preferably electronically at the NICEATM–ICCVAM 5-Year Plan Web site: <http://iccvam.niehs.nih.gov/docs/5yearplan.htm>. Comments can also be submitted by e-mail to [5yearplan@niehs.nih.gov](mailto:5yearplan@niehs.nih.gov).

### FOR FURTHER INFORMATION CONTACT:

Other correspondence should be directed to Dr. William S. Stokes, NICEATM Director (NIH/NIEHS, P.O. Box 12233, MD EC–17, Research Triangle Park, NC 27709; telephone: 919–541–2384, fax: 919–541–0947 or e-mail: [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov). Courier address: NICEATM, 79 T.W. Alexander Drive, Building 4401, Room 3128, Research Triangle Park, NC 27709).