considered a high priority for interlaboratory studies based upon the lack of adequately validated test methods and the regulatory and public health need for such test methods. Based on this evaluation, ICCVAM recommended that:

- The BG1Luc ER TA test method should be considered a high priority for interlaboratory validation studies as an in vitro test method for the detection of test substances with ER agonist and antagonist activity.
- Validation studies should include coordination and collaboration with the European Centre for the Validation of Alternative Methods (ECVAM) and the Japanese Center for the Validation of Alternative Methods (JaCVAM) and include one laboratory in each of the three respective geographic regions (United States, Europe, and Japan).
- In preparation for the interlaboratory validation study, XDS should conduct protocol standardization studies with an emphasis on filling data gaps in the antagonist protocol for the BG1Luc ER TA.

The NIEHS subsequently agreed to support the validation study in light of its role as one of the three NTP agencies, whose mission includes the development and validation of improved testing methods. Based on the results of this study, ICCVAM is now reviewing the validation status of this test method for identification of substances with in vitro ER agonist or antagonist activity. NICEATM and the ICCVAM Interagency Endocrine Disruptors Working Group prepared a draft BRD that provides a comprehensive description and the data from the validation study used to assess the accuracy and reliability of the BG1Luc ER TA test method. ICCVAM also developed draft recommendations for its use.

Availability of the Peer Panel Report

The Panel’s conclusions and recommendations are detailed in the Independent Scientific Peer Review Panel Report: Evaluation of the Validation Status of the BG1Luc4E2 ER TA (LUMICELL), an In Vitro Transcriptional Activation Assay Used to Identify Chemicals That Can Interact with Human Estrogen Receptors which is available along with the draft documents reviewed by the Panel and the draft ICCVAM test method recommendations at http://iccvam.niehs.nih.gov/methods/endocrine/PeePanel11.htm.

Request for Public Comments

NICEATM invites the submission of written comments on the Panel report. When submitting written comments, please refer to this Federal Register notice and include appropriate contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, if applicable). All comments received will be made publicly available via the NICEATM–ICCVAM Web site at http://iccvam.niehs.nih.gov/methods/endocrine/PeerPanel11.htm. ICCVAM will consider the Panel report along with public comments and comments made by SACATM at their June 16–17, 2011 meeting (66 FR 23323) when finalizing test method recommendations. Final ICCVAM recommendations will be published in an ICCVAM test method evaluation report, which will be forwarded to relevant Federal agencies for their consideration. The evaluation report will also be available to the public on the NICEATM–ICCVAM Web site at http://iccvam.niehs.nih.gov/methods/endocrine/ERTA–TMRer.htm and by request from NICEATM (see ADDRESSES above).

Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 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 with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety testing methods that more accurately assess the safety and hazards of chemicals and products and that refine (decrease or eliminate pain and distress), reduce, and replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l–3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM and provides scientific and operational support for ICCVAM-related activities and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative toxicological test methods. Additional information about ICCVAM and NICEATM can be found on the NICEATM–ICCVAM Web site (http://iccvam.niehs.nih.gov).

SACATM was established in response to the ICCVAM Authorization Act [Section 2851-3(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.

References


ICCVAM. 2003b. ICCVAM Evaluation of In Vitro Test Methods For Detecting Potential Endocrine Disruptors: Estrogen Receptor and Androgen Receptor Binding and Transcriptional Activation Assays. (ONC). The meeting will be open to the public.

This notice announces a forthcoming meeting of a public advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). The meeting will be open to the public. The meeting will be open to the public.

Name of Committee: HIT Standards Committee.

General Function of the Committee: To provide recommendations to the National Coordinator on standards, implementation specifications, and
DEPARTMENT OF HEALTH AND HUMAN SERVICES

HIT Policy Committee Advisory Meeting: Notice of Meeting

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

ACTION: Notice of meeting.

This notice announces a forthcoming meeting of a public advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). The meeting will be open to the public.

General Function of the Committee: To provide recommendations to the National Coordinator on a policy framework for the development and adoption of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information as is consistent with the Federal Health IT Strategic Plan and that includes recommendations on the areas in which standards, implementation specifications, and certification criteria are needed.

Date and Time: The meeting will be held on June 8, 2011, from 10 a.m. to 4 p.m./Eastern Time.


Contact Person: Judy Sparrow, Office of the National Coordinator, HHS, 330 C Street, SW., Washington, DC 20201, 202–205–4528, Fax: 202–690–6079, e-mail: judy.sparrow@hhs.gov. Please call the contact person for up-to-date information on this meeting. A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App. 2). Dated: May 9, 2011. Judith Sparrow, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

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