

office staff. The annual reporting burden is as follows:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
OS Participants	82,044	.96876	.4557	36,219
Next-of-kin	2,741	1	.0835	229
Physician's Office Staff	226	1	.0835	19
Total				36,467

The annualized cost burden is \$365,428.

There are no annual Capital Costs, Operating Costs and/or Maintenance Costs to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Linda Pottern, Project Officer, Women's Health Initiative Program Office, 6705 Rockledge Drive, 1 Rockledge Centre, Suite 300, MSC 7966, Bethesda, MD 20892-7966, or call (301) 402-2900 or E-mail you request, including your address to: Linda_Pottern@nih.gov.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before November 8, 1999.

Dated: August 27, 1999.

Donald P. Christoferson,

Executive Officer, National Heart, Lung, and Blood Institute.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institute of Environmental Health Sciences, National Toxicology Program, Request for Data and Suggested Expert Panelists for Evaluation of the Current Status of the Frog Embryo Teratogenesis Assay—Xenopus (FETAX)

Background

The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), with participation by 14 Federal regulatory and research agencies and programs, was established in 1997 to facilitate cross-agency communication and coordination on issues relating to validation, acceptance, and national/international harmonization of toxicological test methods. The Committee seeks to promote the scientific validation and regulatory acceptance of toxicological test methods that will enhance agencies' ability to assess risks and make decisions, and that will refine, reduce, and replace animal use whenever possible. The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), provides administrative and technical support for ICCVAM, and serves as a communication and information resource. NICEATM and ICCVAM collaborate to carry out related activities needed to develop, validate, and achieve regulatory acceptance of new and improved test methods applicable to Federal agencies. These activities may include:

Test Method Workshops, which are convened as needed to evaluate the adequacy of current methods for assessing specific toxicities, to identify areas in need of improved or new testing methods, and to identify research efforts that may be needed to develop a new test method.

Expert Panel Meetings, which are typically convened to evaluate the

validation status of a method following the completion of initial development and pre-validation studies. An Expert Panel is asked to recommend additional validation studies that might be helpful in further characterizing the usefulness of a method, and to identify any additional research and development efforts that might enhance the effectiveness of a method.

Independent Peer Review Panel Meetings, which are typically convened following the completion of comprehensive validation studies on a test method. Peer review panels are asked to develop scientific consensus on the usefulness and limitations of test methods to generate information for specific human health and/or ecological risk assessment purposes. Following the independent peer review of a test method, ICCVAM forwards recommendations on their usefulness to agencies for their consideration. Federal agencies then determine the regulatory acceptability of a method according to their mandates.

Evaluation of FETAX

ICCVAM and NICEATM are currently planning an Expert Panel Meeting to assess the current validation status of the Frog Embryo Teratogenesis Assay—Xenopus (FETAX), a method proposed for evaluating the developmental toxicity potential of chemicals (Bantle JA, 1995, FETAX—A Developmental Toxicity Assay Using Frog Embryos, *Fundamentals of Aquatic Toxicology*, 2nd ed., G.M. Rand, ed, Taylor and Francis, USA, pp. 207-230). Possible applications of FETAX to human health and environmental assessments may include screening and prioritizing compounds for further testing, evaluating complex mixtures and environmental samples, and as supplemental information in a weight-of-evidence evaluation of toxicity hazards. NICEATM is preparing a background document summarizing the initial studies and the performance characteristics of FETAX. The Expert Panel will evaluate the conclusions presented in the background document

and address the potential uses of FETAX. The Expert Panel will address additional test method development and validation efforts that should be considered that might further enhance and characterize the usefulness of FETAX for various applications and other relevant aspects of the Xenopus model.

Request for Data and Expert Names

The Center would welcome receiving data and information from completed, ongoing, or planned studies using or evaluating FETAX. Information should address the criteria for validation and regulatory acceptance provided in NIH publication 97-3981, "Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods" (<http://ntp-server.niehs.nih.gov/htdocs/ICCVAM/iccvm.html>). Where possible, data and information should adhere to the guidance provided in the document, "Evaluation of the Validation Status of Toxicological Methods: General Guidelines for Submissions to ICCVAM" (<http://iccvm.niehs.nih.gov/doc1.htm>), which is available on request from the NTP Center at the address provided below. Information submitted in response to this request will be incorporated into the background material provided to the Expert Panel. Meeting information, including date, location, and availability of the background document, will be announced in a future notice.

The ICCVAM also welcomes suggestions of scientists with relevant knowledge and experience who might be considered for the Expert Panel. For each person suggested, their name, address, and a brief summary of relevant experience and qualifications should be provided. Where possible, telephone, fax number, and/or e-mail addresses should also be provided. Information should be sent by mail, fax, or e-mail to the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods by October 7, 1999. Correspondence should be directed to: Dr. William S. Stokes, NTP Interagency Center for the Evaluation of Alternative Toxicological Methods, Environmental Toxicology Program, NIEHS/NTP, MD EC-17, PO Box 12233, Research Triangle Park, NC 27709; 919-541-3398 (phone); 919-541-0947 (fax); iccvm@niehs.nih.gov (e-mail).

Dated: August 27, 1999.

Kenneth Olden,

Director, National Institute of Environmental Health Sciences.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies, and Laboratories That Have Withdrawn From the Program

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be identified as such at the end of the current list of certified laboratories, and will be omitted from the monthly listing thereafter.

This Notice is now available on the internet at the following website: <http://www.health.org/workpl.htm>.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, 5600 Fishers Lane, Rockwall 2 Building, Room 815, Rockville, Maryland 20857; Tel.: (301) 443-6014.

Special Note: Please use the above address for all surface mail and correspondence. For all overnight mail service use the following address: Division of Workplace Programs, 5515 Security Lane, Room 815, Rockville, Maryland 20852.

SUPPLEMENTARY INFORMATION: Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order

12564 and section 503 of Pub. L. 100-71. Subpart C of the Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414-328-7840/800-877-7016 (Formerly: Bayshore Clinical Laboratory)
Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901-794-5770/888-290-1150
Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615-255-2400
Alabama Reference Laboratories, Inc., 543 South Hull St., Montgomery, AL 36103, 800-541-4931/334-263-5745
Alliance Laboratory Services, 3200 Burnet Ave., Cincinnati, OH 45229, 513-585-9000 (Formerly: Jewish Hospital of Cincinnati, Inc.)
American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 20151, 703-802-6900
Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119-5412, 702-733-7866/800-433-2750
Baptist Medical Center—Toxicology Laboratory, 9601 I-630, Exit 7, Little Rock, AR 72205-7299, 501-202-2783 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center)
Clinical Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215-2802, 800-445-6917
Cox Health Systems, Department of Toxicology, 1423 North Jefferson Ave., Springfield, MO 65802, 800-876-3652/417-269-3093 (Formerly: Cox Medical Centers)
Dept. of the Navy, Navy Drug Screening Laboratory, Great Lakes, IL, P.O. Box