

can reduce, refine, or replace the use of animals for vaccine potency and safety testing is one of the four highest priorities of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), an interagency committee of the Federal government administered by NICEATM.

To address this priority, NICEATM and ICCVAM, along with international partners organized an "International Workshop on Alternative Methods To Reduce, Refine, and Replace the Use of Animals in Vaccine Potency and Safety Testing: State of the Science and Future Directions," which took place on September 14–16, 2010 at NIH in Bethesda, Maryland. The report of the workshop is now available.

#### Workshop Goals and Outcomes

The goals of the workshop were to (1) review the state of the science of alternative methods currently available and/or accepted for use that can reduce, refine (enhance animal well-being and lessen or avoid pain and distress), and replace animal use in vaccine potency and safety testing, and discuss ways to promote their implementation; (2) identify knowledge and data gaps that should be addressed to develop alternative methods that can further reduce, refine, and/or replace the use of animals in vaccine potency and safety testing; and (3) identify and prioritize research, development, and validation efforts needed to address these knowledge and data gaps in order to advance alternative methods for vaccine potency and safety testing while ensuring the protection of human and animal health.

The workshop report is comprised of 27 papers that summarize the plenary session presentations and the conclusions and recommendations developed by the workshop participants during six breakout group sessions. The report recommends vaccines that should have the highest priority for future reduction, refinement, and replacement efforts. Other key recommendations include:

- Procedures such as earlier humane endpoints should be developed and implemented immediately to reduce or avoid the pain and distress experienced by animals for vaccines that still require live-agent challenge testing. Until non-animal tests are available, development of serological assays should also be considered as a way to avoid challenge testing.

- Specific non-animal approaches that have successfully replaced animals for some vaccine potency testing should be developed for vaccines currently

requiring animals through identification, purification, and characterization of vaccine protective antigens.

- International harmonization and cooperation efforts and closer collaborations between human and veterinary vaccine researchers should be enhanced in order to support more rapid progress towards reduction, refinement, and replacement of animal use for vaccine testing.

The workshop was organized by NICEATM and ICCVAM in partnership with the European Centre for the Validation of Alternative Methods, the Japanese Center for the Validation of Alternative Methods, and Health Canada. The workshop was co-sponsored by the Society of Toxicology.

#### Background Information on NICEATM and ICCVAM

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. The ICCVAM Authorization Act of 2000 (42 U.S.C. 2851-3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. ICCVAM conducts technical evaluations of new, revised, and alternative 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 reduce, refine, or replace animal use.

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM technical evaluations and 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 test methods and strategies applicable to the needs of Federal agencies. Additional information about NICEATM and ICCVAM can be found on the NICEATM–ICCVAM Web site (<http://iccvam.niehs.nih.gov>).

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30Day–12–0530]

#### Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

#### Proposed Project

EEOICPA Dose Reconstruction Interviews and Forms (0920–0530, Expiration 03/30/2012)—Extension—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

On October 30, 2000, the Energy Employees Occupational Illness Compensation Program Act of 2000 (42 U.S.C. 7384–7385) was enacted. This Act established a federal compensation program for employees of the Department of Energy (DOE) and certain of its contractors, subcontractors and vendors, who have suffered cancers and other designated illnesses as a result of exposures sustained in the production and testing of nuclear weapons.

Executive Order 13179, issued on December 7, 2000, delegated authorities assigned to "the President" under the Act to the Departments of Labor, Health and Human Services, Energy and Justice. The Department of Health and Human Services (DHHS) was delegated the responsibility of establishing methods for estimating radiation doses received by eligible claimants with cancer applying for compensation. NIOSH is applying the following methods to estimate the radiation doses of individuals applying for compensation.

In performance of its dose reconstruction responsibilities, under the Act, NIOSH is providing voluntary interview opportunities to claimants (or their survivors) individually and providing them with the opportunity to

assist NIOSH in documenting the work history of the employee by characterizing the actual work tasks performed. In addition, NIOSH and the claimant may identify incidents that may have resulted in undocumented radiation exposures, characterizing radiological protection and monitoring practices, and identify co-workers and other witnesses as may be necessary to confirm undocumented information. In this process, NIOSH uses a computer assisted telephone interview (CATI) system, which allows interviews to be conducted more efficiently and quickly as opposed to a paper-based interview instrument. Both interviews are voluntary and failure to participate in either or both interviews will not have a negative effect on the claim, although voluntary participation may assist the

claimant by adding important information that may not be otherwise available.

NIOSH uses the data collected in this process to complete an individual dose reconstruction that accounts, as fully as possible, for the radiation dose incurred by the employee in the line of duty for DOE nuclear weapons production programs. After dose reconstruction, NIOSH also performs a brief, voluntary final interview with the claimant to explain the results and to allow the claimant to confirm or question the records NIOSH has compiled. This will also be the final opportunity for the claimant to supplement the dose reconstruction record.

At the conclusion of the dose reconstruction process, the claimant submits a form to confirm that the

claimant has no further information to provide to NIOSH about the claim at this time. The form notifies the claimant that signing the form allows NIOSH to forward a dose reconstruction report to DOL and to the claimant, and closes the record on data used for the dose reconstruction. Signing this form does not indicate that the claimant agrees with the outcome of the dose reconstruction. The dose reconstruction results will be supplied to the claimant and to the DOL, the agency that will utilize them as one part of its determination of whether the claimant is eligible for compensation under the Act.

There is no cost to respondents other than their time. The total estimated annual burden hours are 4,900.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondent	Number of respondents	Responses per respondent	Average burden per response (in hours)
Initial interview .....	4,200	1	1
Conclusion form .....	8,400	1	5/60

**Kimberly Lane,**  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-12-0740]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects.

To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call (404) 639-7570 and send comments to Kimberly Lane, CDC Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance

of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

**Proposed Project**

Medical Monitoring Project (MMP)—(OMB No. 0920-0740 Exp: 5/31/2012)—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

This proposed data collection supplements the HIV/AIDS surveillance programs in 23 selected state and local health departments, which collect information on persons diagnosed with, living with, and dying from HIV infection and AIDS and will incorporate data elements from two data collections: Supplement to HIV/AIDS Surveillance (SHAS) project (0920-0262) and the Adult/Adolescent Spectrum of HIV Disease (ASD). Both projects stopped

data collection in 2004. Although CDC receives surveillance data from all U.S. states, these supplemental surveillance data are needed to make population-based national estimates of key indicators, related to the quality of HIV-related ambulatory care, the severity of need for HIV-related care and services, and HIV-related behaviors and clinical outcomes.

This project collects data on behaviors and clinical outcomes from a probability sample of HIV-infected adults receiving care in the U.S. through in-person or telephone interviews and abstraction of medical records. Information is also extracted from HIV case surveillance records for a dataset, referred to as the minimum dataset, which is used to assess non-response bias, for quality control, to improve the ability of MMP to monitor ongoing care and treatment of HIV-infected persons, and to make inferences from the MMP sample to HIV-infected persons in care nationally. No other Federal agency collects nationally representative population-based behavioral and clinical information from HIV-infected adults in care. The data are expected to have significant implications for policy, program development, and resource allocation at the state/local and national levels.

The Centers for Disease Control and Prevention request approval for a