

NICEATM and ICCVAM are organizing the workshop in collaboration with partner organizations in the International Cooperation on Alternative Test Methods (ICATM): the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM), the Japanese Center for the Validation of Alternative Methods, the Korean Center for the Validation of Alternative Methods, and Health Canada. Cosponsors include EURL ECVAM, the Animal Health Institute, the International Alliance for Biological Standardization, and the USDA Center for Veterinary Biologics.

Preliminary Workshop Agenda and Registration

Registration information, draft agenda, and additional meeting information are available on the NICEATM–ICCVAM Web site (<http://iccvam.niehs.nih.gov/meetings/LeptoVaccWksp-2012/LeptoVaccWksp.htm>) and upon request from NICEATM (see **FOR FURTHER INFORMATION CONTACT**).

Call for Abstract Submissions

NICEATM and ICCVAM invite the submission of abstracts for scientific posters to be displayed during this workshop. Guidelines for the submission of abstracts are available at <http://iccvam.niehs.nih.gov/meetings/LeptoVaccWksp-2012/LeptoWksp-AbstractSubmit-508.pdf>. Abstracts must be submitted by email to niceatm@niehs.nih.gov. The deadline for abstract submission is August 13, 2012. The corresponding author will be notified regarding the abstract's acceptance within 7 working days of the submission deadline. Guidelines for poster presentations will be sent to the corresponding authors with notification of acceptances.

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. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability and promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine, or 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, 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 test methods and strategies applicable to the needs of U.S. Federal agencies. Additional information about ICCVAM and NICEATM can be found on the NICEATM–ICCVAM Web site (<http://iccvam.niehs.nih.gov>).

References

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Stokes WS, Kulpa-Eddy J, McFarland R. 2011. The International Workshop on Alternative Methods to Reduce, Refine, and Replace the Use of Animals in Vaccine Potency and Safety Testing: introduction and summary. In: 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 (Kulpa-Eddy J, McFarland R, Stokes WS, eds). *Procedia Vaccinol* 5: 1–15.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–12–0666]

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 S. Lane, CDC Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to 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

National Healthcare Safety Network (NHSN) (OMB No. 0920–0666), exp. 01/31/2015—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Healthcare Safety Network (NHSN) is a system designed to accumulate, exchange, and integrate relevant information and resources among private and public stakeholders to support local and national efforts to

protect patients and promote healthcare safety. Specifically, the data is used to determine the magnitude of various healthcare-associated adverse events and trends in the rates of these events among patients and healthcare workers with similar risks. The data will be used to detect changes in the epidemiology of adverse events resulting from new and current medical therapies and changing risks. The NHSN consists of four components: Patient Safety, Healthcare Personnel Safety, Biovigilance, and Long-Term Care Facility (LTCF). In general, the data reported under the Patient Safety Component protocols are used to (1) determine the magnitude of the healthcare-associated adverse events under study, trends in the rates of events, in the distribution of pathogens, and in the adherence to prevention practices, and (2) to detect changes in the epidemiology of adverse events resulting from new medical therapies and changing patient risks. Additionally, reported data will be used to describe the epidemiology of antimicrobial use and resistance and to understand the relationship of antimicrobial therapy to this growing problem. Under the Healthcare Personnel Safety Component protocols, data on events, both positive and adverse, are used to determine (1) the magnitude of adverse events in

healthcare personnel and (2) compliance with immunization and sharps injuries safety guidelines. Under the Biovigilance Component, data on adverse reactions and incidents associated with blood transfusions are used to provide national estimates of adverse reactions and incidents. The Long-Term Care Facility (LTCF) Component is used to more specifically and appropriately capture data from the residents of skilled nursing facilities. Surveillance methods and definitions for this component specifically address the nuances of LTCF residents.

This revision submission includes major revisions to the Patient Safety Component—Outpatient Dialysis Center Practices Survey (Form 57.104) in an effort to provide further clarification to those collecting the information. Additionally, some of the changes have been made to improve surveillance data available for the outpatient dialysis population. Due to the CMS End Stage Renal Disease (ESRD) Quality Improvement Program (QIP) reporting requirements, over 5,700 dialysis facilities have already enrolled or will enroll into NHSN to report data in 2012. Form 57.104 is completed by each facility upon enrollment into NHSN and then every January thereafter.

Furthermore, minor revisions have been made to 28 other forms within the

package to clarify and/or update surveillance definitions. Six forms have been removed for the purposes of simplification from the Healthcare Personnel Safety Component of the package due to changes within NHSN reporting of healthcare personnel influenza vaccination. Old functionality of individual level vaccination reporting will be removed from NHSN. CMS Inpatient Quality Reporting (IQR) requirements designate that all acute care facilities will report healthcare personnel vaccination counts at the summary level for the 2012–2013 flu season.

The previously approved NSHN package included 54 individual collection forms; the current revision request removes six forms for a total of 48 forms. The reporting burden will decrease by 415,523 hours, for a total of 3,562,653 hours.

Healthcare institutions that participate in NHSN report their data to CDC using a web browser based technology for data entry and data management. Data are collected by trained surveillance personnel using written standardized protocols. Participating institutions must have a computer capable of supporting an Internet service provider (ISP) and access to an ISP. There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Form number and name	Type of respondents	Number of respondents	Number of responses per respondent	Avg. Burden per response (in hours)	Total burden (in hours)
57.100: NHSN Registration Form	Registered Nurse (Infection Preventionist).	2,000	1	5/60	167
57.101: Facility Contact Information	Registered Nurse (Infection Preventionist).	2,000	1	10/60	333
57.103: Patient Safety Component—Annual Hospital Survey.	Registered Nurse (Infection Preventionist).	6,000	1	30/60	3,000
57.104: Patient Safety Component—Outpatient Dialysis Center Practices Survey.	Registered Nurse (Infection Preventionist).	5,700	1	1.5	8,550
57.105: Group Contact Information ..	Registered Nurse (Infection Preventionist).	6,000	1	5/60	500
57.106: Patient Safety Monthly Reporting Plan.	Registered Nurse (Infection Preventionist).	10,000	12	35/60	70,000
57.108: Primary Bloodstream Infection (BSI).	Registered Nurse (Infection Preventionist).	6,000	36	35/60	126,000
57.109: Dialysis Event	Staff RN	5,700	60	16/60	91,200
57.111: Pneumonia (PNEU)	Registered Nurse (Infection Preventionist).	6,000	72	32/60	230,400
57.112: Ventilator-Associated Event	Registered Nurse (Infection Preventionist).	6,000	144	25/60	360,000
57.114: Urinary Tract Infection (UTI)	Infection Preventionist	6,000	27	32/60	86,400
57.116: Denominators for Neonatal Intensive Care Unit (NICU).	Staff RN	6,000	9	3	162,000
57.117: Denominators for Specialty Care Area (SCA)/Oncology (ONC).	Staff RN	6,000	9	5	270,000
57.118: Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA).	Staff RN	6,000	18	5	540,000
57.119: Denominator for Outpatient Dialysis.	Staff RN	5,700	12	6/60	6,840

ESTIMATE OF ANNUALIZED BURDEN HOURS—Continued

Form number and name	Type of respondents	Number of respondents	Number of responses per respondent	Avg. Burden per response (in hours)	Total burden (in hours)
57.120: Surgical Site Infection (SSI)	Registered Nurse (Infection Preventionist).	6,000	36	32/60	115,200
57.121: Denominator for Procedure	Staff RN	6,000	540	5/60	270,000
57.123: Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables.	Laboratory Technician	6,000	12	5/60	6,000
57.124: Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables.	Pharmacy Technician	6,000	12	5/60	6,000
57.125: Central Line Insertion Practices Adherence Monitoring.	Registered Nurse (Infection Preventionist).	1,000	100	5/60	8,333
57.126: MDRO or CDI Infection Form.	Registered Nurse (Infection Preventionist).	6,000	72	32/60	230,400
57.127: MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring.	Registered Nurse (Infection Preventionist).	6,000	24	10/60	24,000
57.128: Laboratory-identified MDRO or CDI Event.	Registered Nurse (Infection Preventionist).	6,000	240	15/60	360,000
57.130: Vaccination Monthly Monitoring Form—Summary Method.	Registered Nurse (Infection Preventionist).	6,000	5	14	420,000
57.131: Vaccination Monthly Monitoring Form—Patient-Level Method.	Registered Nurse (Infection Preventionist).	2,000	5	2	20,000
57.133: Patient Vaccination	Registered Nurse (Infection Preventionist).	2,000	250	10/60	83,333
57.137: Long-Term Care Facility Component—Annual Facility Survey.	Registered Nurse (Infection Preventionist).	250	1	45/60	188
57.138: Laboratory-identified MDRO or CDI Event for LTCF.	Registered Nurse (Infection Preventionist).	250	8	15/60	500
57.139: MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF.	Registered Nurse (Infection Preventionist).	250	12	5/60	250
57.140: Urinary Tract Infection (UTI) for LTCF.	Registered Nurse (Infection Preventionist).	250	9	30/60	1,125
57.141: Monthly Reporting Plan for LTCF.	Registered Nurse (Infection Preventionist).	250	12	5/60	250
57.142: Denominators for LTCF Locations.	Registered Nurse (Infection Preventionist).	250	12	3	9,000
57.143: Prevention Process Measures Monthly Monitoring for LTCF.	Registered Nurse (Infection Preventionist).	250	12	5/60	250
57.150: LTAC Annual Survey	Registered Nurse (Infection Preventionist).	400	1	30/60	200
57.151: Rehab Annual Survey	Registered Nurse (Infection Preventionist).	1,000	1	25/60	417
57.200: Healthcare Personnel Safety Component Annual Facility Survey.	Occupational Health RN/Specialist ..	100	1	8	800
57.203: Healthcare Personnel Safety Monthly Reporting Plan.	Occupational Health RN/Specialist ..	100	9	10/60	150
57.204: Healthcare Worker Demographic Data.	Occupational Health RN/Specialist ..	100	200	20/60	6,667
57.205: Exposure to Blood/Body Fluids.	Occupational Health RN/Specialist ..	100	50	1	5,000
57.206: Healthcare Worker Prophylaxis/Treatment.	Occupational Health RN/Specialist ..	100	30	15/60	750
57.207: Follow-Up Laboratory Testing.	Laboratory Technician	100	50	15/60	1,250
57.210: Healthcare Worker Prophylaxis/Treatment-Influenza.	Occupational Health RN/Specialist ..	600	50	10/60	5,000
57.300: Hemovigilance Module Annual Survey.	Medical/Clinical Laboratory Technologist.	500	1	2	1,000
57.301: Hemovigilance Module Monthly Reporting Plan.	Medical/Clinical Laboratory Technologist.	500	12	2/60	200
57.302: Hemovigilance Module Monthly Incident Summary.	Medical/Clinical Laboratory Technologist.	500	12	2	12,000
57.303: Hemovigilance Module Monthly Reporting Denominators.	Medical/Clinical Laboratory Technologist.	500	12	30/60	3,000
57.304: Hemovigilance Adverse Reaction.	Medical/Clinical Laboratory Technologist.	500	120	10/60	10,000

Form number and name	Type of respondents	Number of respondents	Number of responses per respondent	Avg. Burden per response (in hours)	Total burden (in hours)
57.305: Hemovigilance Incident	Medical/Clinical Laboratory Tech- nologist.	500	72	10/60	6,000
Total Est Annual Burden Hours					3,562,653

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Office of the Director (CAJQ1). (1) Provides leadership and overall direction for HCRMO; (2) develops goals and objectives, and provides leadership, policy formation, oversight, and guidance in program planning and development; (3) plans, coordinates, and develops strategic plans for HCRMO; (4) develops and administers human capital and human resource management policies and procedures; (5) coordinates all program reviews; (6) reviews, prepares, coordinates, and develops proposed legislation, Congressional testimony, and briefing materials; (7) establishes performance metrics and coordinates quarterly reviews to ascertain status on meeting of the metrics; (8) coordinates budget formulation, negotiation, and execution of financial resources; (9) identifies relevant scanning/benchmarking on workforce and career development processes, services and products; (10) provides leadership and guidance on new developments and national trends for public health workforce; (11) establishes and oversees policies governing human capital and human resources management, and works collaboratively within CDC and other components in planning, developing and implementing policies; (12) develops strategic plans for information technology and information systems required to support human capital and human resources management information requirements; (13) serves as