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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–44–03]

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) 498–1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

Antineoplastic Drug Exposure: Effectiveness of Guidelines—New—The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). Antineoplastic, chemotherapeutic, or cytostatic drugs are widely used in the treatment of cancer. These drugs possess mutagenic, teratogenic, and carcinogenic properties, cause organ damage, and affect reproductive function. Healthcare workers such as pharmacists and nurses who handle, prepare, and administer these drugs are at increased risk of adverse health effects from these agents, if exposed. The Occupational Safety and Health Administration (OSHA) developed guidelines for healthcare workers for the safe handling of antineoplastic drugs in 1986 and revised those guidelines again in 1995. However, recent studies suggest that the guidelines have not been effective in preventing exposure. A 1999 industrial hygiene evaluation of six cancer centers in the U.S. and Canada reported that 75% of the wipe test samples in the pharmacy were found to have detectable levels of antineoplastic drugs. Similar findings were reported in the Netherlands, which has similar guidelines. In addition, healthcare workers may assume that gloves designed for bloodborne pathogen protection will also prevent drug exposure which is often not the case. Since air concentrations of antineoplastic drugs in many of the studies have been low to non-detectable, it appears that the dermal route may be an important consideration for internal absorption.

Numerous studies, including those after the OSHA guidelines were revised in 1995, have demonstrated adverse health effects from healthcare workers' exposure to antineoplastic agents. The most common endpoints have been either markers of exposure, such as metabolites in the urine, or genotoxic markers, such as micronuclei, sister chromatid exchange, and chromosomal aberrations. Female reproductive adverse effects have also been shown to occur with healthcare workers' exposure to antineoplastic drugs. Not only have spontaneous abortion and miscarriage been reported, but changes in the menstrual cycle have been demonstrated as well. Based upon animal and human data, one study estimated that exposure to cyclophosphamide by healthcare workers increases the risk of leukemia cases by 17–100 new cases/million workers/10 years.

This project addresses the continuing concern of healthcare workers' exposure to antineoplastic agents. This is a multifaceted project that involves environmental sampling of the workplace and the collection of biological samples to determine how much of the agent is absorbed and if there are any early biological effects from that exposure. Biological measurements or biomarkers can detect effects of exposure long before a disease can be diagnosed. A questionnaire will be administered to determine confounders and other conditions that might affect exposure such as work history and work practices. This project will recruit oncology nurses, pharmacists, and pharmacy technicians and will be conducted in collaboration with the University of Maryland, the University of North Carolina, and the M.D. Anderson Cancer Center.

In the biological effects part of the study, the participant, after informed consent, will voluntarily provide blood and urine samples and respond to a questionnaire concerning medical history, work history, and work practices to identify study eligibility, past exposures, and confounders.

In the reproductive health part of the study and after informed consent, women will be asked to voluntarily give a daily urine sample for approximately 45 days and keep track of their menstrual cycle by entries into a diary. In addition, a short questionnaire will be given to each participant to determine eligibility for inclusion into the study and confounders of hormone analysis. By utilizing a battery of sensitive biomarkers, the effects of low-level chronic exposure to antineoplastic agents can be determined. Using the results of the proposed study, exposures can be minimized or eliminated before adverse health effects occur. Ultimately, the study will contribute to the prevention of occupational disease from antineoplastic drug exposure. The total annual burden for this data collection is 863 hours.

Survey	Number of respondents	Number of responses/ respondent	Average burden/ response (in hours)
Antineoplastic Handling Diary	75	1	10/60
Biological Effects Study Questionnaire	150	1	45/60
Reproductive Health Study Questionnaire	100	1	15/60
Reproductive Health Diary	100	42	5/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–43–03]

Agency Forms Undergoing Paperwork Reduction Act Review

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Proposed Project

Evaluation of Effectiveness of NIOSH Publications (OMB Control No. 0920–0544)—Reinstatement without change—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). Through the development, organization, and dissemination of information, NIOSH promotes awareness about occupational hazards and their control, and improves the quality of American working life. Although NIOSH uses a variety of media and delivery mechanisms to communicate with its constituents, one of the primary vehicles is through the distribution of NIOSH-numbered publications. The extent to which these publications successfully meet the information needs of their intended audience is not currently known. In a period of diminishing resources and increasing accountability, it is important that NIOSH be able to demonstrate that communications about its research and service programs are both effective and efficient in influencing workplace change. This requires a social marketing evaluation of NIOSH products to measure the degree of customer satisfaction and their adoption of recommended actions.

The present project proposes to do this by conducting a survey of a primary segment of NIOSH's customer base, the community of occupational safety and health professionals. In collaboration with the American Association of Occupational Health Nurses (13,000 members), the American Industrial Hygiene Association (12,400 members), the American College of Occupational and Environmental Medicine (6,500 members), and the American Society of Safety Engineers (33,000 members), NIOSH will survey a sample of their memberships to ascertain, among other things: (1) Their perceptions and attitudes toward NIOSH as a general information resource; (2) their perceptions and attitudes about specific types of NIOSH publications (*e.g.*, criteria documents, technical reports, alerts); (3) the frequency and nature of referral to NIOSH in affecting occupational safety and health practices and policies; (4) the extent to which they have implemented NIOSH recommendations; and (5) their recommendations for improving NIOSH products and delivery systems. The results of this survey will provide an empirical assessment of the impact of NIOSH publications on occupational safety and health practice and policy in the United States as well as provide direction for shaping future NIOSH communication efforts. Respondents will have the option of responding by mail or electronically through the NIOSH Web site. The annual burden for this data collection is 200 hours.

Respondents	No. of respondents	No. of responses/ respondent	Average burden/response (in hrs.)
Occupational Safety and Health Professionals	600	1	20/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–45–03]

Agency Forms Undergoing Paperwork Reduction Act Review

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Proposed Project

Performance Evaluation Program for Rapid HIV Testing—New—Public Health Practice Program Office (PHPPO), Centers for Disease Control and Prevention (CDC).

To support our mission of improving public health and preventing disease through continuously improving laboratory practices, the Model Performance Evaluation Program (MPEP), Division of Laboratory Systems, Public Health Practice Program Office, Centers for Disease Control and Prevention intends to provide a new HIV rapid testing performance evaluation program (HIV Rapid Testing MPEP). This program will offer external performance evaluation (PE) for rapid tests such as the OraQuick® Rapid HIV–1 Antibody Test, recently approved as a waived test by the U.S. Food and Drug Administration, and for other licensed tests such as the Abbott-Murex SUDS® HIV–1 Test. Participation in PE programs is expected to lead to improved HIV testing performance because participants have the opportunity to identify areas for improvement in testing practices. This program will help to ensure accurate testing as a basis for development of HIV prevention and intervention strategies.

This external quality assessment program will be made available at *no cost* (for receipt of sample panels) to