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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13-12RS]

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 (404) 639-7570 or send an email to 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

Exposure Assessment and Epidemiological Study of U.S. Workers Exposed to Carbon Nanotubes and Carbon Nanofibers – New – National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety and health at work for all people through research and prevention. The Occupational Safety and Health Act of 1970, Public Law 91-596 (Section 20[a][1] authorizes NIOSH to conduct research to advance the health and safety of workers. In this capacity, NIOSH will conduct an exposure assessment and epidemiological study of U.S. carbon nanotube (CNT) and carbon nanofiber (CNF) workers.

At present, because of the newness of the technology, much of the occupational exposure to engineered nanomaterials occurs at the research and development (R&D) or pilot scale. There have been few reliable surveys of the size of the workforce exposed to nanomaterials. Health effects from exposure to nanomaterials are uncertain, but may be more severe than from larger-sized particles of the same material. This is due to the small size, high surface area per unit mass (i.e., specific surface area) or (in some cases) high aspect ratio of nanomaterials. Carbon nanotubes and nanofibers are among the nanomaterials of greatest interest from a public health perspective because of their potentially asbestiform properties (e.g., high aspect ratio) and toxicological evidence of possible fibrogenic, inflammatory, and clastogenic damage resulting from exposures at occupationally relevant levels. In addition, the

useful properties of CNT and CNF have rendered them among the first nanomaterials to be commercially exploited in manufacturing settings. Thus, an epidemiologic study to determine whether early or late health effects occur from occupational exposure to CNT and CNF is warranted.

The proposed research is a cross-sectional study of the small current U.S. workforce involved with CNT and CNF in manufacturing and distribution, to be conducted in the following phases: 1) Industrywide exposure assessment study to evaluate worker exposure and further develop and refine measurement methods for CNT and CNF. This component will refine sampling and analysis protocols previously developed for the detection and quantification of CNT and CNF in US workplaces. 2) A cross-sectional study relating the best metrics of CNT and CNF exposure to markers of early pulmonary or cardiovascular health effects. After the sampling and analysis protocols have been established to measure CNT and CNF, an industrywide study of the association between exposure and health effects will be conducted. Medical examinations will be conducted and several biomarkers of early effect (for pulmonary fibrosis, cardiovascular disease, and genetic damage) will be measured in blood and sputum for workers exposed to a range of CNT and CNF levels.

The study will include a questionnaire with a three-fold purpose: (1) to determine whether study participants have any contraindications for certain medical procedures to be conducted (spirometry and sputum induction), (2) to assist in interpretation of the biomarker results, and (3) to inquire about current and past exposure to CNT, CNF, and other chemicals, dusts, and fumes. The questionnaire will be given by NIOSH personnel as a computer-assisted personal interview (CAPI). After administration of the CAPI, medical examinations will be conducted to evaluate pulmonary function (via spirometry) and blood pressure, and sputum and blood will be collected. Statistical analyses will be conducted to determine the nature of the relation between exposure to CNT and CNF and these biomarkers of early effect, considering potential confounding factors such as smoking, age, gender, and workplace co-exposures, including non-engineered ultrafine particles.

The proposed project supports the NIOSH legislatively mandated industrywide studies program that conducts epidemiological and exposure assessment research studies to identify the occupational causes of disease in the working population and their offspring and to effectively communicate study results to workers, scientists, industry, and the public.

The questionnaire will be administered one time only, at the worksite, to 100 workers involved in the production and use

of CNT or CNT, over a three-year period. The study will be carried out during the participants' regular work shift. There is no cost to respondents or their employers other than their time. We estimate that the average burden per response to be 22 minutes for the questionnaire and 20 minutes for the consent form. There are no costs to respondents other than their time. The total estimated annual burden hours are 23.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
Nanomaterials Workers	Questionnaire	33	1	22/60
Nanomaterials Workers	Informed Consent	33	1	20/60

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