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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health

Partnership Opportunity on a Research Project to Evaluate the Performance of Isolation Gowns

Agency: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

Action: Notice of opportunity to support research

Summary: The NIOSH National Personal Protective Technology Laboratory is initiating a research study in support of American Society for Testing and Materials (ASTM) International standards development to establish minimum performance requirements for isolation gowns for health care workers. NIOSH is seeking to identify currently marketed isolation gown products. All manufacturers are requested to submit samples to NIOSH free of charge for testing. There will be no cost to the manufacturers for testing. Not all submitted products may be tested, depending on the response to this announcement and the results of screening tests. Each manufacturer that submits gowns that are tested will receive the test results from their gowns. Through submission of the gown samples, manufacturers will be making an

important contribution to ASTM, International's process to establish an important standard for evaluating the protection provided for health care workers by isolation gowns. Participating manufacturers will be recognized as contributing to the establishment of the performance standard. Manufacturers whose products are tested will also receive the results of all gowns tested in a blinded format.

Gown Criteria: Candidate gowns for inclusion in the research program must meet the following criteria: (1) The gowns must be identified (labeled) as "isolation gowns" and have full coverage in the back to provide protection for the health care worker and the patient; (2) A minimum of 100 units for each code (model) of disposable (single use) gown submitted; (3) A minimum of 200 "new" (unprocessed, unused, unwashed) reusable gowns for each model submitted. Reusable gown submissions must include a labeling recommendation for the maximum number of laundering cycles to be included in this study. Half of the gown samples will be tested after one laundering and drying cycle and half of the gown samples will be tested as laundered for the maximum number of cycles claimed by the manufacturer; and, (4) Samples should be provided in finished package format, with any claims that may not be noted on the packaging or labels provided by the manufacturer. NIOSH will not return any gowns submitted for this testing.

Dates: Submit letters of interest to provide gowns and participate in this research program prior to [insert date 30 days after the date of publication].

Addresses: Interested manufacturers should submit a letter of interest with information about their isolation gowns' capabilities to: NIOSH, National Personal Protective Technology Laboratory, Attn: Selcen Kilinc, PO Box 18070, Pittsburgh, PA 15236, E-mail address: jcq8@cdc.gov

Background: It has been reported by user groups (e.g. Association of Perioperative Registered Nurses and Association for Professionals in Infection Control and Epidemiology) as well as U.S. Food and Drug Administration (FDA), that performance properties and levels of protection for isolation gowns are poorly understood and defined. NIOSH and FDA are currently working with the ASTM International Committee on Personal Protective Clothing and Equipment – Biological Subcommittee, to establish a standard that defines criteria for measurement and minimum levels of performance for isolation gowns. Development of a standard is expected to improve users' understanding of levels of protection to be provided.

Product testing results will be provided to the ASTM Committee on Personal Protective Clothing and Equipment – Biological Subcommittee (a.k.a. ASTM Task Force), which will utilize the data as the scientific basis to develop a standard establishing minimum

performance criteria for single-use and reusable isolation gowns. The research objective is to evaluate performance properties, such as strength and barrier properties, of isolation gowns to be provided to the ASTM Task Force as scientific input for establishing minimum performances for conformance to this standard.

In this study, all testing will be conducted blind. Results will be shared with the ASTM Task Force only in a blinded format. Results will be shared with the individual manufacturers for their gowns only. The final summary of the testing will be shared in a blinded format only with all manufacturers that participated.

Randomized samples will be tested by both NIOSH and Nelson Labs. The ASTM Task Force will review and analyze all test results. Establishment of the minimum requirement for each property will be the responsibility of the ASTM Task Force. NIOSH plans to conduct testing to measure the following properties: fabric weight, breaking strength, tear strength, seam strength, water resistance (impact penetration and hydrostatic pressure), microbial/viral penetration resistance, air permeability, evaporative resistance, and thermal insulation.

Neither this announcement, nor product submittals in response to this announcement, obligates NIOSH to enter into a contractual agreement with any respondent. Inquiries should be sent to Selcen Kilinc at jcq8@cdc.gov. NIOSH reserves the right to establish a partnership based on scientific analysis and capabilities found by

way of this announcement or other searches, if determined to be in the best interest of the government.

_____**April 5, 2013**_

John Howard, Dated

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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