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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-16-15BHH; Docket No. CDC-2016-0087]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the Personal Protective Equipment Information (PPE-Info) Database which is a compendium of

personal protective equipment (PPE) Federal regulations and consensus standards.

DATES: Written comments must be received on [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0087 by any of the following methods:

Federal eRulemaking Portal: [Regulation.gov](http://www.regulations.gov). Follow the instructions for submitting comments.

Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to [Regulations.gov](http://www.regulations.gov), including any personal information provided. For access to the docket to read background documents or comments received, go to [Regulations.gov](http://www.regulations.gov).

Please note: All public comment should be submitted through the Federal eRulemaking portal ([Regulations.gov](http://www.regulations.gov)) or by U.S. mail to

the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

PPE-Info Database - 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. Under P.L. 91-173 as amended by PL 95 -164 (Federal Mine Safety and Health Act of 1977), NIOSH is proposing a three-year study to conduct research to advance the health and safety of workers.

National Personal Protective Technology Laboratory (NPPTL) developed the NIOSH PPE-Info Database in response to recommendations from the Institute of Medicine (IOM) in its report, *Certifying Personal Protective Technologies (PPT): Improving Worker Safety*. The report recommended that NPPTL "expand its efforts to become a national clearinghouse for information on all types of PPT."

In its current application, the database provides standards developers, manufacturers, purchasers, and end users of PPE with a comprehensive tool which allows general or advanced criteria searches of relevant standards, target occupational groups,

basic conformity assessment specifications, accredited lab information, and standard connections.

The CDC is currently updating its PPE selection guidance related to the Ebola response. This guidance, *Guidance on Personal Protective Equipment To Be Used by Healthcare Workers During Management of Patients with Ebola Virus Disease in U.S. Hospitals, Including Procedures for Putting On (Donning) and Removing (Doffing)* (hereafter referred to as the "CDC Ebola Response PPE Guidance") will provide recommendations, in the form of protection standards, for PPE selection and use for the Ebola response.

The NIOSH PPE-Info Database is being expanded as a tool to connect the protection standards that already exist in the database, with relevant PPE information as identified through the updated CDC Ebola Response PPE Guidance. This new aspect of the NIOSH PPE-Info Database allows end users (e.g., healthcare workers) to find products (e.g., gowns and coveralls) that are compliant (as verified by manufacturer) with the protection standards outlined by the CDC Ebola Response PPE Guidance. The initial information in the NIOSH PPE-Info Database will only offer guidance on gowns and coveralls, but is intended to expand to all PPE types associated with the official CDC Ebola Response PPE Guidance in the future. Since there is no single source of

this information, NIOSH is requesting that Manufacturers provide it directly for input into the Ebola PPE selection guidance portion of the database.

NIOSH is requesting that a Memorandum of Understanding (MOU) be developed with Ebola response PPE manufacturers to facilitate cooperation and collaboration on the provision of product information. The primary focus of the collaboration will be the exchange of manufacturer product information to be aggregated and displayed in the NIOSH PPE-Info Database.

The nature and use of this information exchange includes the 1) provision of product information regarding compliance (as verified by manufacturers) with designated protection standards related to CDC guidance for personal protective equipment (PPE) used by healthcare workers during management of patients with confirmed or suspected Ebola Virus Disease ("Ebola") and 2) the verification, by manufacturers, of product information displayed in the NIOSH PPE-Info Database.

Once the MOU is signed, the manufacturer will be sent a product information sheet. Using the product information sheet, NIOSH collects manufacturer-specific product information such as; product category (e.g., gown or coverall), standards that the product claim complies with, product model number, product name, link to product specification sheet from manufacturer, and designation of whether third-party testing was performed. Once

this information is completed, the product information sheet is electronically signed and returned by email to NIOSH. The NIOSH project officer will then upload the information into a PPE-Info sub database, which acts as an interim point for review. The manufacturer is then sent a link to the sub database to review their products. The manufacturer has one week to make objections. If no objections are made, the information in the sub-database gets published to the live NIOSH PPE-Info database.

Quarterly, manufacturer products will be pulled from the database and sent through a pre generated product information sheet to the manufacturer POC. Manufacturers are required through the MOU to complete and return the PPE Information Sheet within two weeks of receipt along with the electronic verification form.

NIOSH will be soliciting information from manufacturers and manufacturer POCs. For products that comply with gown and coverall standards, we estimate that seven manufacturers will need to supply product information. The amount of time for manufacturers to complete the initial product information sheets and make quarterly updates will be no more than 3 hours for the initial product information and one hour for the quarterly updates. The total estimated burden hours are 42. There are no

costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Manufacturer	Initial Product Info Sheet	7	1	3	
Manufacturer POC	Quarterly product Info Sheet	7	3	1	21
Total					42

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Office of Scientific Integrity,
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