



BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC-2017-0024, NIOSH-297]

Effect of stockpiling conditions on the performance of medical N95 respirators and high-level protective surgical 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: Request for information.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention announces the request for information about facilities that stockpile N95 respirators and high-level protective surgical gowns.

DATES: Electronic or written submissions must be received by [30 days from FRN posting].

ADDRESSES: You may submit responses, identified by CDC-2017-0024 and docket number NIOSH-297, by any of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. Follow the instructions for submitting comments.

- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, Ohio 45226-1998.

Instructions: All information received in response to this notice must include the agency name and docket number [CDC-2017-0024; NIOSH-297]. All relevant responses received will be posted without change to www.regulations.gov, including any personal information provided. For access to the docket to read background documents or information received, go to www.regulations.gov. All information received in response to this notice will also be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, OH 45226-1998.

FOR FURTHER INFORMATION CONTACT: Kerri Wizner, NIOSH, National Personal Protective Technology Laboratory, Research Branch, 626 Cochran Mill Road, Building 19A, Pittsburgh, PA, 15236, (412) 386-5225, (not a toll free number).

SUPPLEMENTARY INFORMATION: NIOSH seeks information about personal protective equipment (PPE) environmental storage conditions and inventory for federal, state, municipal, county, and hospital system stockpiles. Maintaining PPE stockpiles for public health emergencies is a significant cost and time investment for these various entities, which may include

purchasing new products, maintaining inventory records, and lease or purchase of environmentally controlled storage space away from contaminated areas, dust, sun light, extreme temperatures, excessive moisture, and damaging chemicals. The information provided by respondents to this Notice will be used to inform a research study design where N95 respirators and high-protection level surgical gowns are sampled from stockpiles and tested against established performance standards. The research study will be designed to obtain scientific data to assess 1) the potential to extend manufacturer-recommended shelf life and 2) the effect of common, albeit sometimes non-ideal, stockpile conditions on the protections provided by respirators and surgical gowns. NIOSH seeks to sample N95 respirators and high-protection level surgical gowns from a variety of stockpiles representing contemporary storage conditions from across the nation. To that end, the information sought in this Notice is aimed at ensuring that study findings are broadly applicable to U.S. stockpiles.

Background: Various entities stockpile personal protective equipment (PPE) in preparation for public health responses to outbreaks of high consequence infectious diseases such as SARS, influenza, and Ebola, where PPE demand may outpace supply. Stockpiling PPE is a costly endeavor that includes PPE purchase, storage space, product rotation over time, and environmental

controls for heat, humidity, dust, and sunlight. Resource limitations may lead facilities to stockpile PPE in environments that do not meet manufacturer storage recommendations or exceed shelf life, increasing the potential for PPE degradation. Even when resources exist to store PPE per manufacturer's environmental recommendations, the influence of long-term storage time alone on PPE performance has been questioned. Additionally, large quantities of stockpiled PPE obtained during previous nationwide responses may now be exceeding its shelf life and expected replacement costs will likely far exceed available budgets. Data is needed to better understand the potential impact upon worker health and safety.

Information Needs: Information is needed to assist NIOSH in identifying important factors to focus the research study design. Information is needed from facilities that stockpile N95 respirators and high-level protective surgical gowns for use during public health emergencies. Please ensure the type of stockpile you are affiliated with is included in the responses to any of the below questions.

1. Please describe the type of stockpile with which you are affiliated (e.g., federal, state, county). Please describe the end users of the stockpiled products (e.g., healthcare workers, public).

2. Please describe the extent to which environmental controls are implemented and maintained. For example, does the stockpile employ controls against humidity, temperature, sunlight, dust, or chemical exposure? Please describe how these controls are implemented, monitored, regularity of monitoring, and what optimal conditions are. Available guidance documents used for the stockpile would be welcome. What are the barriers to maintaining these controls? What factors are currently not being controlled that you feel are relevant to this effort?
3. How do you monitor for N95 respirator and high-level protective surgical gown deterioration? What are signs of deterioration you consider (e.g., cosmetic, box damage, expiration dates)? What are barriers in determining deterioration?
4. If applicable, please describe your process for PPE rotation. For example, please describe your process for ensuring new products are purchased upon expiration of shelf-life for currently stockpiled N95 respirators/high-level surgical gowns. Quantity estimates of the stockpiled N95 respirator/surgical gown inventory exceeding the recommended shelf life would be valuable to the design of this study.

5. If stockpiled N95 respirators/surgical gowns are purchased from a distributor (i.e. not directly from the manufacturer), please describe your process for obtaining information on storage practices from these distributors.
6. What types of controls are available in the shipping environment? Do they instruct points-of-use on storage requirements? Other use limitations/instructions?
7. Please provide information about the N95 respirator and high-level surgical gown inventory available in the stockpile, including brands, models, and related estimated numbers to help us better understand the type and quantities of PPE that may be affected by this research.

Frank Hearl,

Chief of Staff,

National Institute for Occupational Safety and Health,

Centers for Disease Control and Prevention.

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