BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC-2015-0075; NIOSH-288]

Request for Information on development of a Performance Test Protocol for Closed System Transfer Devices that incorporate air-cleaning technology to provide worker protection During Pharmacy Compounding and Administration of Hazardous Drugs

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 and comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) requests information for the development of a test protocol to evaluate the performance of closed system drug-transfer devices (CSTDs) that adopt air-cleaning technologies. CSTDs are generally available in

two design types: 1) one that uses a physical barrier to block the unintended release of drug into the surrounding environment or the intake of environmental contaminants into the sterile drug pathway and 2) one that uses air cleaning or filtration technologies to prevent the unintended release of drug into the surrounding environment or the intake of environmental contaminants into the sterile drug pathway. A draft protocol titled, "A Vapor Containment Performance Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs," was developed by NIOSH to evaluate how protective the physical barrier-type CSTD devices were as an indicator of how effective they would be at preventing hazardous drug escape from the closed system.

This RFI seeks information from the public regarding the feasibility of developing a protocol applicable to CSTDs using air cleaning or filtration technologies and to request information from stakeholders on this topic.

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- **BACKGROUND:**
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DATES: Electronic or written comments should be received on or before March 8, 2016.

ADDRESSES: You may submit comments identified by CDC-2015-0075 and Docket Number NIOSH-288 by any of the following methods:

- *Federal eRulemaking Portal: http://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, OH 45226-1998.

Instructions: All information received in response to this notice must include the agency name and docket number (CDC-2015-0075; NIOSH-288). All relevant comments 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 comments 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.

FOR FURTHER INFORMATION CONTACT: Gayle DeBord, NIOSH, Division of Applied Research and Technologies, Robert A. Taft Laboratories, 1090 Tusculum Avenue, MS–R2, Cincinnati, Ohio 45226, Phone: (513) 841-4256 [not a toll-free number], Email: hazardousdrugs@cdc.gov.

Background: The purpose of the RFI is to seek information relative to the development of a performance evaluation protocol for CSTDs using air cleaning or filtration technologies. The draft protocol released for public comment on September 8, 2015 [80 FR 53802] is applicable to barrier-type CSTDs only. This RFI expands the scope of the previous RFI to seek information to support development of a companion protocol that would apply to CSTDs using air cleaning or filtration technologies, thus covering the remainder of the currently known CSTD marketplace.

Information Needs: Additional data and information are needed to assist NIOSH to develop or adapt a test protocol for evaluating the efficiency of air cleaning or filtration

technologies CSTDs. In particular, NIOSH requests submission of existing test protocols developed for efficacy testing of air cleaning or filtration technologies CSTDs.

The National Institute for Occupational Safety and Health seeks public comments in response to the following questions. Please feel free to comment on any or all of the questions below:

1. Are there any other types of CSTDs available that would not fit into the two categories described, i.e., 1) barrier systems, and 2) air-cleaning or filtration technologies?

2. Is there an existing test protocol for evaluation of the protective efficacy of air-cleaning or filtration technologies CSTDs? Can this test protocol, and/or the details of the underlying procedures and test data be shared with NIOSH?

Please apply the following questions to a protocol you have developed, one you are aware of, or one you believe to be feasible to develop:

3. Are there any special restrictions, limiting assumptions or requirements for expertise required to conduct the protocol?

4. What are the performance criteria used with the protocol tests to determine acceptability and judge conformity?

4. Does the protocol apply to compounding operations, administration activities or both?

5. Does this protocol use a surrogate or does it require testing against the actual hazardous drugs?

6. If a surrogate is used,

    a. Does the surrogate represent all hazardous drugs or a subset?

    b. Which criteria are used in selection of the surrogate?

    c. Describe how the selection criteria address the degree to which the surrogate or surrogates are representative of the class of hazardous drugs to which they apply.

    d. Does the surrogate introduce any potential worker exposure hazards?

7. List the hazardous drugs for which this protocol has been used.

a. How were these hazardous drugs selected?

b. Were there any hazardous drugs for which the test protocol was not or would not be successful or compatible?

c. During protocol application, in what state were the hazardous drugs, e.g., full strength as delivered, full strength reconstituted, patient dose with diluent, or drug cocktail?

8. What procedure(s) can be used to verify that the protocol is applicable for new hazardous drugs as they are identified and brought to market?

9. Can the test protocol be used effectively for different formulations of the same active pharmaceutical ingredient?

10. If applicable, are you willing to share details of your test protocol with NIOSH? Would you be willing for the protocol details to be shared publicly or would you require the test protocol details to be protected as proprietary information?

11. If applicable, are you willing to share test results from the application of your air cleaning or filtration technologies CSTD test protocol with NIOSH?

12. Are you interested in being a collaborative partner with NIOSH on the development of an air cleaning or filtration technologies CSTD test protocol?

Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or to issue a grant. Information obtained as a result of this RFI may be used by the government for program planning on a non-attribution basis. Please do not include any information that might be considered proprietary, confidential, or personally identifying (such as home address or social security number).

Dated: January 12, 2016

John Howard,

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

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