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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC-2016-0090, Docket Number NIOSH 288-A]

**A Performance Test Protocol for Closed System Transfer Devices
Used 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: Notice of public meeting and request for public comment on a draft testing protocol.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces a public meeting concerning a universal closed system drug-transfer device (CSTD) testing protocol entitled, *A Performance Test Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs*, <http://www.cdc.gov/niosh/topics/hazdrug/default.html/>.

This is an opportunity for public comment on the protocol, the proposed list of surrogates, and to respond to NIOSH questions regarding the protocol.

To view the protocol and related materials, visit www.regulations.gov and enter CDC-2016-0090 in the search field and click "Search."

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DATES: The public meeting will be held on November 7, 2016, 9:00 a.m. - 3:00 p.m. Eastern Time, or until after the last public commenter has spoken, whichever occurs first. Electronic or written comments must be received by December 7, 2016.

ADDRESSES: The public meeting will be held at the Alice Hamilton Laboratories, Conference Room C, 5555 Ridge Avenue, Cincinnati, OH 45213. Virtual attendance using LiveMeeting and audio conference will be available.

You may submit written comments, identified by CDC-2016-0090 and Docket Number NIOSH 288-A, by either of the following two 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-2016-0090; NIOSH 288-A]. All relevant comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. 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: Deborah V. Hirst, NIOSH, Division of Applied Research and Technology, Alice Hamilton Laboratories, 1090 Tusculum Ave, MS R-5, Cincinnati, OH 45226. (513) 841-4141 (not a toll free number) or email DHirst@cdc.gov.

SUPPLEMENTARY INFORMATION:

I. Background: Closed system drug-transfer devices (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. On September 8, 2015, NIOSH released the draft test protocol, *A Vapor Containment Performance Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs*, for public review. The draft protocol was developed by NIOSH to evaluate how containment effective the physical barrier-type CSTDs were as an indicator of how protective they would be at preventing hazardous drug escape from the closed system. After significant public comment and several inquiries, on January 19, 2016, NIOSH published a Request for Information for the development of a test protocol to evaluate the performance of CSTDs that adopt air-cleaning or filtration technologies. Since the Federal Register docket for both the draft protocol and

the request for information closed on March 8, 2016,
NIOSH has done the following:

- a. Generated a list of surrogates to test both types of
CSTDs.
- b. Met individually with CSTD manufacturers who requested
informal meetings to discuss the current draft
protocol and/or items NIOSH should consider in
developing a new performance test protocol for air-
cleaning CSTDs. This was in answer to NIOSH's Request
for Information question #12, Are you interested in
being a collaborative partner with NIOSH on the
development of an air cleaning or filtration
technologies CSTD test protocol?
- c. Drafted a new universal performance test protocol
applicable to both barrier and air-cleaning types of
CSTDs.

II. Protocol: The proposed protocol will apply to both
barrier and air-cleaning types of CSTDs, NIOSH will host
a public meeting to give an update of new protocol
developments. The update will include discussions
covering proposed drug surrogates, benefits, and
challenges with developing a new universal test protocol,

and to allow the public to comment. Special emphasis will be placed upon the following:

- **Proposed surrogates:** Surrogates were identified based on vapor pressure and water solubility. Drug surrogates were chosen with vapor pressures up to 100 times that of the most volatile drug vapor pressure known to exist on the NIOSH hazardous drug list. The increased surrogate vapor pressure should offer a safety factor to the test protocol.
 - o Is the 100 times the vapor pressure safety factor adequate?
 - o Should other chemical properties besides vapor pressure and water solubility be considered?
 - o Are there other surrogates NIOSH should consider for testing the performance of CSTDs?
 - o Will any of the NIOSH's list of proposed surrogates cause damage to the CSTD plastic and/or parts (i.e., needles, septum, etc.)?
 - o Are there other aspects specific to air cleaning technologies that are not being challenged with the proposed surrogate testing protocol?
 - o Are there other aspects specific to the barrier CSTD technologies that are not being adequately

challenged with the proposed surrogate testing protocol?

- **Sampling Strategy:** The new draft protocol relies upon analytical chemistry analysis of at least two simultaneously-collected sorbent tube air samples to detect drug surrogate escape from the CSTD.
 - Should less or more sampling tubes be used inside the environmental test chamber?
 - How should the sampling tubes be positioned inside the environmental test chamber?
 - Since contaminant levels will no longer be immediately known, background concentrations will not be realized until after test completion and sample analysis. What metrics should be applied to the background concentrations and how should they impact the reported concentrations observed during conduct of the protocol tasks?
- **Design of environmental test chamber:** NIOSH proposes to keep the same environmental test chamber as that proposed for the original vapor containment test protocol, however airflow through the chamber will cease during the actual test procedures and air sampling.

- o Should NIOSH keep the current design of the environmental test chamber?
 - If not, what other designs should be considered and what validation requirements should be placed upon them?
- o Sampling for escaped surrogate will be performed by a sampling pump and air sampling tubes.
 - Are there concerns that the sample pump discharge air plus task-associated hand movements will be insufficient to provide adequate air mixing?
- **Compounding and Administration tasks:**
 - o NIOSH has updated Task 1 and Task 2 in Appendix A of the performance test protocol to incorporate the adoption of CSTD manufacturers' Instructions for Use (IFU).
 - Should other manipulations be added or deleted from the current tasks listed in order to comply with a manufacturer's IFU?
 - o For purposes of challenging a CSTD's containment performance, should the number of repetitions for each CSTD:Task pairing be less than or greater than 4?

- What special considerations has NIOSH not considered in developing the new draft performance test protocol?

III. Public Meeting: NIOSH will hold a public meeting to discuss a universal closed system drug-transfer device (CSTD) testing (draft) protocol entitled, *A Performance Test Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs*. The meeting will allow commenters the opportunity to address the new draft protocol, the proposed list of hazardous drug test surrogates, and to discuss NIOSH questions regarding the new protocol.

The meeting is open to the public, limited only by the capacity (80 attendees) of the conference room. Confirm your attendance to this meeting by sending an email to DHirst@cdc.gov by October 21, 2016. An email confirming registration will be sent from NIOSH and will include details needed to participate.

Registration is required for both in-person and LiveMeeting participation. An email confirming registration will be sent from NIOSH for both in-person participation and audio conferencing participation.

Details required to participate via the audio conferencing will be provided by NIOSH in a separate email. This option will be available to participants on a first come, first served basis and is limited to the first 100 participants.

Non-U.S. Citizens: Because of CDC Security Regulations, any non-U.S. citizen wishing to attend this meeting in-person must provide the following information to Deborah V. Hirst. Requests may be submitted by facsimile (513) 841-4506, or e-mailed to DHirst@cdc.gov, no later than September 28, 2016. The information required includes:

Name:

Gender:

Date of Birth:

Place of Birth (city, province, state, country):

Citizenship:

Passport Number:

Date of Passport Issue:

Date of Passport Expiration:

Type of Visa:

U.S. Naturalization Number (if a naturalized citizen):

U.S. Naturalization Date (if a naturalized citizen):

Visitor's Organization:

Organization Address:

Organization Telephone Number:

Visitor's Position/Title within the Organization:

This information will be transmitted to the CDC Security Office for approval. Visitors will be notified as soon as approval has been obtained. If access approval is not granted to a non-U.S. Citizen, the individual may participate by LiveMeeting and audio conference.

Requests to provide oral comments at the public meeting should be submitted by telephone (513) 841-4141, facsimile (513) 841-4506, or e-mailed to DHirst@cdc.gov with "**Request to Speak**" in the subject line. Requests can also be mailed to Deborah V. Hirst, 1090 Tusculum Ave, MS R-5, Cincinnati, OH 45226. All requests to speak should contain the name, address, telephone number, and relevant business affiliations of the speaker, and the approximate time requested for oral comments. Requests must be received by October 21, 2016.

Oral comments from each speaker will be limited to 10 minutes. After reviewing the requests to make oral comments, NIOSH will notify the speaker when his/her oral comments are scheduled. If a participant is not in attendance when he/she is scheduled to speak, the

remaining participants will be heard in order. After the last scheduled speaker is heard, participants who missed their assigned times may be allowed to speak, limited by time available.

Attendees who wish to speak but did not submit a request for the opportunity to make oral comments may be given this opportunity after the scheduled speakers are heard, at the discretion of the presiding officer and limited by time available.

Oral comments will be transcribed and included in the docket.

John Howard,

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

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