



BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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

A Vapor Containment Performance Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs; Request for Comment

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 draft document available for public comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the availability of the following draft document for public comment entitled *A Vapor Containment Performance Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs*. The document and instructions for submitting comments can be found at www.regulations.gov.

This guidance document does not have the force and effect of law.

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DATES: Electronic or written comments must be received by
[Insert date, 60 days after publication date].

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

- *Federal eRulemaking Portal:* www.regulations.gov Follow the instructions for submitting comments.
- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, 1090 Tusculum Avenue, MS-C34, Cincinnati, Ohio 45226.

Instructions: All information received in response to this notice must include the agency name and the 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. All electronic comments should

be formatted as Microsoft Word. Please make reference to CDC-2015-0075 and Docket Number NIOSH-288. 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 Avenue, MS R-5, Cincinnati, Ohio 45226, (513) 841-4141 (not a toll free number), E-mail: hazardousdrugs@cdc.gov.

SUPPLEMENTARY INFORMATION: The purpose of the protocol is to test a closed system transfer device's (CSTD) capability to perform as a closed system. During an evaluation of the protocol, registered pharmacists, familiar with the use of CSTDs, tested the protocol's prescribed compounding and administration tasks using five commercially available CSTDs. They also performed the assigned tasks using a negative control condition without a CSTD. Prescribed tasks were performed in a NIOSH-developed environmental test chamber with 70% isopropyl alcohol (IPA) as the challenge agent. A highly specific gas analyzer, with measurement capabilities specific to IPA and with a low limit of detection (LOD), was used to detect vapor

concentrations of escaped IPA during the tasks. The protocol is not intended for CSTDs designed to operate using air-cleaning technologies. This protocol has multiple applications and can be used by manufacturers to evaluate prototype CSTDs, by consumers to compare CSTD products, or by jurisdictions wishing to adopt the protocol for a CSTD performance certification procedure.

A panel consisting of peer reviewers and stakeholders was asked to review and comment on the draft guidance document and protocol. NIOSH reviewed the recommendations of the peer reviewers and stakeholders then made the final determination regarding document content as well as the decision not to propose a specific pass/fail performance threshold. The protocol is being published for comment in CDC-2015-0075 and Docket Number NIOSH-288 and can be found at www.regulations.gov.

Dated: September 1, 2015

John Howard,

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

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