MATTERS TO BE CONSIDERED:


government performance and accountability. As more and more government processes move online, the amount of data that can be gathered and analyzed increases exponentially. This increased data collection, if not handled properly, can lead to privacy concerns and misuse of information. Therefore, it is crucial to ensure that there is no need for confidentiality with this collection of information.

The burden that respondents will have to face will be minimal. For instance, the burden for filing a petition to deny will be 17 hours, and the burden for filing a petition to dismiss or withdrawal will be 100 hours. The total annual cost for filing a petition to deny or an informal objection will be $63,750.

In conclusion, the OMB has approved the collection of information for the petition to deny or informal objection. The respondents will have to file their petitions within 5 days of the issue date, and the affected parties will have 5 days to respond. The Commission will then review the petition and make a decision within 30 days. The process is transparent and straightforward, with clear guidelines and requirements for all parties involved. There is no need for confidentiality with this collection of information.

Rachel E. Dickon, Assistant Secretary.

[FR Doc. 2016–22299 Filed 9–13–16; 4:15 pm]
BILLING CODE 6730–AA–P

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.”

FEDERAL MARITIME COMMISSION

Sunshine Act Meeting


TIME AND DATE: September 20, 2016; 10:00 a.m.

PLACE: 800 N. Capitol Street NW., First Floor Hearing Room, Washington, DC.

STATUS: The first portion of the meeting will be held in Open Session; the second in Closed Session.

MATTERS TO BE CONSIDERED:

Open Session

1. Briefing by Commissioner Maffei on U.S./Japan Bilateral Discussions
2. Staff Briefing on Foreign-based NVOCC Registration Renewal Process (Form FMC–65)

Closed Session

1. Staff Briefing on Hanjin Shipping Bankruptcy and Shipping Disruptions
2. Staff Briefing on the Maersk/MSC Vessel Sharing Agreement, FMC Agreement No. 012293

CONTACT PERSON FOR MORE INFORMATION:
Rachel E. Dickon, Assistant Secretary, (202) 523–5725.

Rachel E. Dickon, Assistant Secretary.

[FR Doc. 2016–22194 Filed 9–13–16; 8:45 am]
BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Sunshine Act Meeting
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I. Background
II. Protocol
III. Public Meeting

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:


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:

• Generated a list of surrogates to test both types of CSTDs.
• 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?
• 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.
• Is the 100 times the vapor pressure safety factor adequate?
• Should other chemical properties besides vapor pressure and water solubility be considered?
• Are there other surrogates NIOSH should consider for testing the performance of CSTDs?
• Will any of the NIOSH’s list of proposed surrogates cause damage to the CSTD plastic and/or parts (i.e., needles, septum, etc.)?
• Are there other aspects specific to air cleaning technologies that are not being adequately challenged with the proposed surrogate testing protocol?
• 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.
• 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?
• 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:
• 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?
• 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
must provide the following
information to Deborah V. Hirst.

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 emailed 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.
[FR Doc. 2016–22132 Filed 9–14–16; 8:45 am]
BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Health Resources and Services
Administration

Supplement to National Technical
Resource Center for the Newborn
Hearing Screening and Intervention
Program at the Utah State University

AGENCY: Health Resources and Services
Administration (HRSA), Department of
Health and Human Services (HHS).

ACTION: Notice of Supplement to
National Technical Resource Center for
the Newborn Hearing Screening and
Intervention Program at the Utah State
University—Grant Number
U52MC04391.

SUMMARY: HRSA announces the award of
a supplement in the amount of
$300,000 for the National Technical
Resource Center (NTRC) for the
Newborn Hearing Screening and
Intervention program cooperative
agreement. Funding in future years is
contingent upon satisfactory
performance of the recipient, need, and
availability of funds.

The purpose of the NTRC is to
address new research, approaches, and
practice advances in the fields of
family engagement, early language acquisition,
and early literacy. The supplement will
fund Utah State University, the
cooperative agreement recipient, during
the budget periods of the supplement
4/1/2016–3/31/2020, to respond to
changes in research, policy, technology,
and practice in the newborn hearing
screening field in the areas of family
engagement, early language acquisition,
and early literacy. Funding in FY 2017,
FY 2018, and FY 2019, is contingent
upon appropriations, satisfactory
performance of the recipient, need, and
availability of funds.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award:
Utah State University.

Amount of Non-Competitive Awards:
$300,000.

Period of Supplemental Funding:

CFDA Number: 93.251.

Authority: Public Health Service Act,
§ 399M, as added by § 702 of the
Children’s Health Act of 2000 (Pub. L.
106–310) and amended by § 2 of the
Early Hearing Detection and
Intervention Act of 2010 (Pub. L. 111–
337) (42 U.S.C. 280g–1)

JUSTIFICATION: In 2015, following an
objective review of its applications,
HRSA awarded the NTRC for the
Newborn Hearing Screening and
Intervention program cooperative
agreement to Utah State University, a
state institution of higher education.

Authorized by the Public Health
Service Act, § 399M, as added by the
Children’s Health Act of 2000, § 702
(Pub. L. 106–310) and further amended
by § 2 of the Early Hearing Detection
and Intervention Act of 2010 (Pub. L.
111–337) (42 U.S.C. 280g–1), the
purpose of the Universal Newborn
Hearing Screening (UNHS) program is to
utilize specifically targeted and
measurable interventions to increase the
number of infants that are followed up
for rescreening, referral, and
intervention after not passing a