

Government Agencies. Meeting participants will learn, discuss, and collaborate on the current and emerging statistical methodologies and quantitative approaches used by sponsors to provide evidence for the approval of new therapies.

The goals of the program are to:

- Explore and implement innovative statistical solutions to issues associated with the regulatory review of therapeutic drugs and biologics.

- Describe the application of statistical methodologies and thinking to the development of new therapeutic biologics and drugs.

- Assess the impact of regulations and guidance on statistical practice.

- Discuss ideas for improving the communication between industry statisticians and FDA reviewers.

A description of the planned activities of the working groups can be found at <http://www.diahome.org/en/Meetings-and-Training/Find-Meetings-and-Training/Meeting-Details.aspx?ProductID=30457&EventType=Meeting>.

## II. Registration and Accommodations

### A. Registration

To register, please submit the registration form online at <http://www.diahome.org/en/Meetings-and-Training/Find-Meetings-and-Training/Meeting-Details.aspx?ProductID=30457&EventType=Meeting> (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) Registration fees cover the cost of facilities, materials, and food functions. Seats are limited, and conference space will be filled in the order in which registrations are received. Onsite registration will be available to the extent that space is available on the day of the conference. The costs of registration for different categories of attendee are as follows:

Category	Cost
Industry Representatives .....	\$1,400
Charitable Nonprofit/Academic (Full time) .....	700
Government (Full time) .....	420
Tutorial Fees .....	405

Government and nonprofit attendees and exhibitors will need an invitation code to register at the discounted rate. An invitation code can be obtained by sending an email to:

[Constance.Burnett@diahome.org](mailto:Constance.Burnett@diahome.org). All registrants will pay a fee with the exception of a limited number of speakers/organizers who will have a complimentary registration.

### B. Accommodations

Attendees are responsible for their own accommodations. Attendees making reservations at the Marriott Bethesda North Hotel and Conference Center, Bethesda, MD, are eligible for a reduced conference rate of \$209, not including applicable taxes. Those making reservations online should use the group code "13008" to receive the special rate. If you need special accommodations because of disability, please contact [Constance.Burnett@diahome.org](mailto:Constance.Burnett@diahome.org) at least 7 days before the meeting.

Dated: February 21, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-04331 Filed 2-25-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2012-1049]

#### Interim Guidance for Revised Implementation of the International Convention for the Prevention of Pollution From Ships (MARPOL), Annex V

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Coast Guard announces the availability of CG-CVC Policy Letter 13-01, "Interim Guidance for Revised MARPOL Annex V Implementation." On July 15, 2011, the International Maritime Organization's (IMO) Marine Environment Protection Committee (MEPC) formally adopted Resolution MEPC.201(62), which amends the International Convention for the Prevention of Pollution from Ships (MARPOL) Annex V, by establishing a general prohibition on discharges of garbage into the sea. The amendments in Resolution MEPC.201(62) entered into force on January 1, 2013. CG-CVC Policy Letter 13-01 provides interim guidance to assist U.S. flagged and foreign flagged oceangoing ships regarding compliance with the amendments in Resolution MEPC.201(62) until the Coast Guard updates the applicable regulations in 33 CFR part 151.

**DATES:** The effective date for the amendments in Resolution MEPC.201(62) was January 1, 2013. CG-CVC Policy Letter 13-01 is effective as of February 26, 2013.

**ADDRESSES:** This notice and the documents referenced within are

available in the docket and can be viewed by going to [www.regulations.gov](http://www.regulations.gov) and using "USCG-2012-1049" as your search term. CG-CVC Policy Letter 13-01 can also be viewed on the Coast Guard's Web site at <http://homeport.uscg.mil> by referring to the left side menu and following the links to "Domestic Vessels," "Domestic Vessel Policy," and "Office of Commercial Vessel Compliance (CG-CVC) Policy Letters."

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this notice or CG-CVC Policy Letter 13-01, call or email LT John Peterson, U.S. Coast Guard, Office of Commercial Vessel Compliance (CG-CVC-1), telephone (202) 372-1226, or email [CG-CVC-1@uscg.mil](mailto:CG-CVC-1@uscg.mil). If you have questions on viewing material in the docket, call Docket Operations, telephone (202) 366-9826.

### SUPPLEMENTARY INFORMATION:

#### Background and Purpose

The United States implements MARPOL Annex V through the Act to Prevent Pollution from Ships (33 U.S.C. 1901, *et. seq.*). On July 15, 2011, the IMO's MEPC formally adopted Resolution MEPC.201(62), which amends MARPOL Annex V by establishing a general prohibition on discharges of garbage into the sea. Under prescribed conditions, exceptions are provided for food wastes, cargo residues, cleaning agents or additives contained in cargo hold, deck, and external surface wash waters, and animal carcasses. The amendments in Resolution MEPC.201(62) entered into force on January 1, 2013.

The Coast Guard intends to revise its regulations in 33 CFR part 151 to conform with the amendments in Resolution MEPC.201(62). These conforming regulatory provisions were not finalized prior to January 1, 2013. The lack of updated regulations does not exempt ships from meeting the requirements of the amended MARPOL Annex V. CG-CVC Policy Letter 13-01 provides interim guidance to assist U.S. flagged and foreign flagged oceangoing ships regarding compliance with the amendments in Resolution MEPC.201(62) until the Coast Guard updates the applicable regulations.

As of January 1, 2013, all U.S. flagged ships and fixed or floating platforms are expected to meet the requirements of the amended MARPOL Annex V. This is particularly important for U.S. flagged ships (including recreational and uninspected ships) on international voyages that want to avoid Port State control actions. For U.S. ships operating

strictly on domestic routes, Coast Guard Marine Inspectors should verify compliance with amended MARPOL Annex V during normally scheduled inspections, but inspectors are encouraged to use an educational outreach and awareness approach. Additionally, current enforcement options remain in place for willful and egregious violators or repeat offenders.

Additionally, all foreign flagged ships operating in the navigable waters of the U.S. or the Exclusive Economic Zone<sup>1</sup> of the U.S. are expected to meet the requirements of amended MARPOL Annex V.<sup>2</sup> Coast Guard Port State Control Officers should verify a foreign flag ships' compliance with MARPOL Annex V during normally scheduled Port State Control examinations.

The guidance in CG-CVC Policy Letter 13-01 is neither a substitute for applicable legal requirements, nor a rule. It is not intended nor does it impose legally-binding requirements on any party. It represents the Coast Guard's current policy on this topic and may assist industry, mariners, the general public, and the Coast Guard, as well as other Federal and state regulators, in applying statutory and regulatory requirements. An alternative approach may be used for complying with these requirements if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, you may contact the Coast Guard Office of Commercial Vessel Compliance (CG-CVC-1) using the methods provided in the **FOR FURTHER INFORMATION CONTACT** section above.

**Authority:** This notice is issued under authority of 5 U.S.C. 552(a) and 33 U.S.C. 1901 *et seq.*

Dated: February 19, 2013.

**P.F. Thomas,**

*Captain, U.S. Coast Guard, Director, Inspections and Compliance.*

[FR Doc. 2013-04319 Filed 2-25-13; 8:45 am]

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<sup>1</sup> With respect to the United States (including the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, Guam, American Samoa, the United States Virgin Islands, and any other territory or possession over which the United States exercises sovereignty), *exclusive economic zone* means the zone seaward of and adjacent to the territorial sea, including the contiguous zone, and extending 200 nautical miles from the territorial sea baseline (except where otherwise limited by treaty or other agreement recognized by the United States) in which the United States has the sovereign rights and jurisdiction and all nations have the high seas freedoms mentioned in Presidential Proclamation 5030 of March 10, 1983 (33 CFR 2.30(a)).

<sup>2</sup> See 33 U.S.C. 1902(a)(3).

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-3361-EM; Docket ID FEMA-2013-0001]

### Connecticut; Emergency and Related Determinations

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This is a notice of the Presidential declaration of an emergency for the State of Connecticut (FEMA-3361-EM), dated February 10, 2013, and related determinations.

**DATES:** *Effective Date:* February 10, 2013.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646-2833.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that, in a letter dated February 10, 2013, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in the State of Connecticut resulting from a severe winter storm beginning on February 8, 2013, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* ("the Stafford Act"). Therefore, I declare that such an emergency exists in the State of Connecticut.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program. This emergency assistance will be provided for a period of 48 hours.

Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved

assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Albert Lewis, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the State of Connecticut have been designated as adversely affected by this declared emergency:

All eight counties in the State of Connecticut for emergency protective measures (Category B), including direct federal assistance, under the Public Assistance program at 75 percent federal funding.

This emergency assistance will be provided for a period of 48 hours for all eight counties and the Tribal Nations of Mashantucket Pequot and Mohegan in the State of Connecticut.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2013-04324 Filed 2-25-13; 8:45 am]

**BILLING CODE 9111-23-P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4099-DR; Docket ID FEMA-2013-0001]

### Pennsylvania; Amendment No. 2 to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the Commonwealth of Pennsylvania