

**Applicability**

The fees will apply to all passenger cruise vessels for which inspections are conducted as part of HHS/CDC's VSP.

Dated: August 14, 2012.

**Tanja Popovic,**  
Deputy Associate Director for Science,  
Centers for Disease Control and Prevention.

**Appendix A**

**SIZE/COST FACTOR**

Vessel size	GRT <sup>1</sup>	Approximate cost per GRT (in U.S. dollars)
Extra Small .....	<3,001	0.25
Small .....	3,001–15,000	0.50
Medium .....	15,001–30,000	1.00
Large .....	30,001–60,000	1.50
Extra Large .....	60,001–120,000	2.00
Mega .....	>120,001	3.00

**FEE SCHEDULE**

Vessel size	GRT <sup>1</sup>	Fee (in U.S. dollars)
Extra Small .....	<3,000	1,300
Small .....	3,001–15,000	2,600
Medium .....	15,001–30,000	5,200
Large .....	30,001–60,000	7,800
Extra Large .....	60,001–120,000	10,400
Mega .....	>120,001	15,600

<sup>1</sup> Gross register tonnage in cubic feet, as shown in Lloyd's Register of Shipping. Inspections and re-inspections involve the same procedures, require the same amount of time, and are therefore charged at the same rates.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Announcement of Requirements and Registration for Dare To Prepare (D2P) Challenge**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

*Award Approving Official:* Thomas R. Frieden, M.D., M.P.H., Director, Centers for Disease Control and Prevention, and Administrator, Agency for Toxic Substances and Disease Registry.

**ACTION:** Notice.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) announces challenge contests to improve nationwide preparedness awareness and readiness. HHS/CDC will use social media outlets (blog, Twitter, Facebook) to engage citizens with daily challenges during the month of September 2012. Participants will complete challenges by doing activities, assessing their preparedness needs, and creatively sharing solutions. The challenges will

be posted each weekday throughout the month of September. There will be a total of 20 challenges.

**DATES:** The contest will be held daily (Monday through Friday) September 3–October 1, 2012 with a different challenge each day. Interested persons should consult the contest Web site (<http://www.cdc.gov/phpr/daretoprepare.htm>) for specific submission deadlines.

**FOR FURTHER INFORMATION CONTACT:** Caitlin Shockley, Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention, 1600 Clifton Road, M.S. D–44, Atlanta, Georgia 30329. Phone (404) 639–7405; email [PHPRCommunications@cdc.gov](mailto:PHPRCommunications@cdc.gov).

**Eligibility Rules for Participating in the Competition**

- To be eligible to win a prize under this challenge, an individual or entity:
  - (1) Shall be at least 13 years old at the time of entry, and any individual under 18 years of age at the time of entry must have permission from a parent or guardian;
  - (2) Shall be a citizen or permanent resident of the United States;
  - (3) Shall comply with all rules set forth herein;
  - (4) You must use a consistent username throughout the challenge for your submissions to be counted;
  - (5) Must limit their entry to one per individual or entity per task;

(6) Must submit entries before each challenge submission time period closes;

(7) By submitting a challenge response, participants agree to participate in the competition under the rules developed by Centers for Disease Control and Prevention;

(8) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States; and

(9) May not be a Federal entity or Federal employee acting within the scope of their employment.

(10) Shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during a competition if the facilities and employees are made available to all individuals and entities participating in the competition on an equitable basis.

**Registration Process for Participants**

This challenge will be internet-based using a variety of social media platforms, including Facebook (<http://www.facebook.com/#!/cdcemergency>); Twitter (<https://twitter.com/#!/CDCReady/>), and the HHS/CDC Public Health Preparedness and Response Web site (<http://www.cdc.gov/phpr/daretoprepare.htm>). The challenge

period will begin September 3, 2012 and will close October 1, 2012.

On each weekday in September, CDC will post a daily challenge that must be completed within 24 hours. On Fridays, challenges will be tougher and the challenge period will be extended to 72 hours. There will be a total of 20 challenges in the month of September.

This contest does not require formal registration. Challenge answers will be submitted through a form on the challenge Web site (<http://www.cdc.gov/phpr/daretopprepare.htm>). The form will ask for basic participant information and will provide an answer text box or photo upload option, depending on the challenge. Participants will enter their name and email each day when submitting a challenge answer.

At the close of each daily challenge, the form will be disabled as the next challenge is posted. This will be a continual process for all 20 challenge prompts.

#### Amount of the Prize

Prizes for the Dare to Prepare Challenge have been donated. The following prize items are the anticipated prizes and may be subject to change. CDC's (and the Federal Government's) legal obligation extends only to the payment of any Federal share of the prize, and that the private source is therefore liable for the payment of its share of the prize.

Prizes will be as follows:

1st Prize: Zombie Experience Prize Pack (estimated value: \$500)

—Likeness in CDC's *Preparedness 101: Zombie Pandemic* animated novella

—Autographed copy of Max Brooks' *World War Z*

—*The Walking Dead*, Season 2

—Zombie prize pack (includes zombie task force shirt, novella, magnet, preparedness checklist, poster, zombie bag)

2nd Prize: Zombie Plus Prize Pack (Estimated Value \$100)

—Autographed copy of Max Brooks' *World War Z*

—*The Walking Dead*, Season 2

—Zombie prize pack (includes zombie task force shirt, novella, magnet, preparedness checklist, poster, zombie bag)

3rd Prize: Zombie Prize Pack (Estimated Value \$25)

—Zombie prize pack (includes zombie task force shirt, novella, magnet, preparedness checklist, poster, zombie bag)

#### Payment of the Prize

Prizes awarded under this competition will be mailed to winners and may be subject to Federal income taxes. HHS will comply with the Internal Revenue Service withholding and reporting requirements, where applicable. Winners who receive prizes are subject to any applicable Federal income taxes and to withholding.

#### Basis Upon Which Winner Will Be Selected

Winners will be selected according to a point-based system. Point value has been assigned to each challenge based on level of difficulty. Incorrect responses will not be awarded points. At the end of the month-long contest, the 3 Contestants who have accumulated the 1st, 2nd, and, 3rd most points will be awarded 1st, 2nd, and 3rd prize, respectively.

In the event multiple Contestants achieve the same high score, the winner will be chosen in a random drawing.

Winners will be announced on October 5, 2012 through the challenge Web site (<http://www.cdc.gov/phpr/daretopprepare.htm>) and Twitter/Facebook channels. Winners will be contacted via the email address provided on challenge submission forms.

#### Additional Information

Specific guidelines applicants/contestants must follow when submitting their contest entry.

(1) Challenge answers will be submitted through a form on the challenge blog. The form will ask for basic participant information and will provide an answer text box or photo upload option, depending on the challenge.

(2) Points will be awarded based on the correct completion of the task according to the daily challenge task.

(3) At the close of each daily challenge, the form will be disabled as the next challenge is posted. This will be a continual process for all 20 challenge prompts.

(4) Contestants must use a consistent username and email address throughout the challenge for submissions to be counted.

(5) Limited to one entry per person per task.

(6) All submissions must be in English.

(7) Entries must be submitted before each task closes.

(8) All photos must be original content created for this contest. Do not submit a photo that has been submitted elsewhere or previously displayed publicly through any means.

(9) Daily challenge answers must be submitted through the appropriate form available for that day's challenge at <http://www.cdc.gov/phpr/daretopprepare.htm>.

(10) Challenge responses (text or photos) should not include endorsements (names, logos, or slogans), direct or implied, of products, services, or enterprises.

(11) Answers (text or photos) containing profane language, violence or weapons, sexually explicit content, or personal attacks on people or named organizations will result in elimination of the Contestant from the challenge.

(12) Answers (text or photos) containing material that is obscene, offensive, or slanderous will result in elimination of the Contestant from the challenge.

(13) Answers (text or photos) containing material that promotes bigotry, racism, or harm against any group or individual or promotes discrimination based on race, sex, religion, nationality, disability, sexual orientation, or age will result in the elimination of the Contestant from the challenge.

(14) Upon submission, each Contestant warrants that he or she is the sole author and owner of the text/photo submitted; that the submission is wholly original with the Contestant; and that it does not infringe on any copyright or any other rights of any third party of which Contestant is aware.

(15) Contestant warrants and represents that its entry does not contain any viruses, spyware, malware, or other software that could cause harm or damage to government information systems.

(16) Winners who receive prizes are subject to any applicable Federal income taxes and to withholding.

#### Intellectual Property Rights

HHS/CDC will collect personal information from contestants when they submit each daily challenge. Name information will be requested for each challenge, but further information will not be requested unless the participant is declared a winner. None of the privately submitted information will be used in HHS/CDC or HHS/CDC-affiliated programs without the prior consent of the contestant.

Except where prohibited, participation in the Contest constitutes the winner's consent to use of the winner's name, likeness, photograph, voice, opinions, and/or hometown and state information by the contest's sponsors and/or agents for promotional public health purposes in any media,

worldwide, without further payment or consideration.

HHS/CDC claims an irrevocable, royalty-free, non-exclusive worldwide license to use, copy for use, distribute, display publicly, create derivative works, and license others to do so for the purpose of the Dare to Prepare challenge and/or for the purpose of raising awareness for preparedness.

### Compliance With Rules and Contacting Contest Winners

Finalists and the Contest Winners must comply with all terms and conditions of these Official Rules. Winning is contingent upon fulfilling all requirements herein. The finalists will be notified by email after points have been totaled and winners determined. Awards may be subject to Federal income taxes, and the Department of Health and Human Services will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

### Privacy

When Contestants provide HHS/CDC with personal information by registering or filling out the submission form through the Challenge.gov Web site, that information is used to respond to Contestants in matters regarding their submission, announcements of entrants, finalists, and winners of the Contest. Information is not collected for commercial marketing. Winners are permitted to cite that they won this contest.

### Liability

The Contestant/Submitter agrees to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property (including any damage that may result from a virus, malware, etc. to HHS/CDC systems utilized to upload photos), revenue, or profits, whether direct, indirect, or consequential, arising from their participation in the competition, whether the injury, death, damage, or loss arises through negligence or otherwise. The Contestant/Submitter shall be liable for, and shall indemnify and hold harmless the Government against, all actions or claims for any claim, demand, judgment, or other allegation arising from alleged violation of an individual's trademark, copyright, or other legally protected interest in videos submitted to CDC.

### Insurance

Contestants must obtain liability insurance or demonstrate financial responsibility in the amount of \$0 for claims by: (1) A third party for death, bodily injury, or property damage, or loss resulting from an activity carried out in connection with participation in a competition, with the Federal Government named as an additional insured under the registered contestant's insurance policy and registered contestants agreeing to indemnify the Federal Government against third party claims for damages arising from or related to competition activities; and (2) the Federal Government for damage or loss to Government property resulting from such an activity. Contestants who are a group must obtain insurance or demonstrate financial responsibility for all members of the group.

### General Conditions

HHS/CDC reserves the right to cancel, suspend, and/or modify the Contest, or any part of it, for any reason, at HHS/CDC's sole discretion.

Participation in this Contest constitutes a contestants' full and unconditional agreement to abide by the Contest's Official Rules found at [www.Challenge.gov](http://www.Challenge.gov).

**Authority:** 15 U.S.C. 3719.

Dated: August 14, 2012.

### Tanja Popovic,

*Deputy Associate Director for Science, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0891]

#### Post-Approval Studies 2012 Workshop: Design, Methodology, and Role in Evidence Appraisal Throughout the Total Product Life Cycle; Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the following public workshop entitled "Post-Approval Studies 2012 Workshop: Design, Methodology, and Role in Evidence Appraisal Throughout the Total Product Life Cycle." The topics of

discussion will include lessons learned from previous experiences with post-approval studies, improvement of implementation strategies for post-approval studies, best practices, and innovative methodologies for evidence appraisal.

**Date and Time:** The public workshop will be held on August 30, 2012, from 8 a.m. to 5 p.m.

**Location:** The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

**Contact Persons:** Nilsa Loyo-Berrios, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3214, Silver Spring, MD 20993, 301-796-8528, email: [Nilsa.Loyo-Berrios@fda.hhs.gov](mailto:Nilsa.Loyo-Berrios@fda.hhs.gov) or Danica Marinac-Dabic, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4110, Silver Spring, MD 20993, 301-796-6689, email: [Danica.Marinac-Dabic@fda.hhs.gov](mailto:Danica.Marinac-Dabic@fda.hhs.gov).

**Registration:** Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m. on August 23, 2012. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. Onsite registration will not be available on the day of the public workshop.

If you need special accommodations due to a disability, please contact Cindy Garris, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg., 66, Rm. 4321, Silver Spring, MD 20993, 301-796-5861, email: [Cynthia.garris@fda.hhs.gov](mailto:Cynthia.garris@fda.hhs.gov).

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email,