

of the approval or market authorization of the product. * * *

(b) Comments on the EIS may be submitted after the approval or market authorization of the drug, animal drug, biologic product, device, or tobacco product. Those comments can form the basis for the Agency to consider beginning an action to withdraw the approval or market authorization of applications for a drug, animal drug, biologic product, or tobacco product, or to withdraw premarket notifications or premarket approval applications for devices.

(c) In those cases where the existence of applications and premarket notifications for drugs, animal drugs, biologic products, devices, or tobacco products has already been disclosed before the Agency approves the action, the Agency will ensure appropriate public involvement consistent with 40 CFR 1506.6 and part 1503 in preparing and implementing the NEPA procedures related to preparing EISs while following its own disclosure requirements including those listed in part 20 and §§ 312.130(b), 314.430(d), 514.11(d), 514.12(b), 601.51(d), 807.95(e), 812.38(b), and 814.9(d) of this chapter.

* * * * *

Dated: September 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2015-0888]

Drawbridge Operation Regulation; Lake Washington Ship Canal, Seattle, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Montlake Bridge across the Lake Washington Ship Canal, mile 5.2, at Seattle, WA. The Montlake Bridge is a double leaf bascule bridge. The deviation is necessary to allow the bridge to operate in single leaf mode during day light hours, and a full closure (both bascule leaves in the closed-to-navigation position) during night time hours while work crews replace

bridge decking. This deviation allows a single leaf opening with a one hour advance notice during the day, and remains in the closed-to-navigation position at night.

DATES: This deviation is effective from 7 a.m. on October 3, 2015 to 7 a.m. on October 26, 2015.

ADDRESSES: The docket for this deviation, [USCG-2015-0888] is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206-220-7282, email d13-pf-d13bridges@uscg.mil.

SUPPLEMENTARY INFORMATION: Washington Department of Transportation has requested a temporary deviation from the operating schedule for the Montlake Bridge across the Lake Washington Ship Canal, at mile 5.2, at Seattle, WA. The deviation is necessary to accommodate work crews to conduct timely bridge deck repairs.

The Montlake Bridge in the closed position provides 30 feet of vertical clearance throughout the navigation channel, and 46 feet of vertical clearance throughout the center 60 feet of the bridge; vertical clearance references to the Mean Water Level of Lake Washington. When half the span is open, single leaf, 46 feet of vertical clearance will be reduced throughout the center to 30 feet of the bridge.

To facilitate this event, the south half of the bridge span, or single leaf, will open with at least a one hour advance notice provided to the bridge operator from 7 a.m. to 7 p.m. From 7 p.m. to 7 a.m., the Montlake Bridge span will remain in the closed-to-navigation position, or full closure.

The normal operating schedule for the Montlake Bridge operates in accordance with 33 CFR 117.1051(e) which requires the bridge to open on signal, except that the bridge need not open for vessels less than 1,000 gross tons between 7 a.m. and 9 a.m. and 3:30 p.m. and 6:30 p.m. Monday through Friday, except Federal Holidays from April 30 to September 1,

and from 7 a.m. to 10 a.m. and from 3:30 p.m. to 7 p.m. from September 1 to April 30. The draw need open only on the hour and half hour from 12:30 p.m. to 3:30 p.m. and from 6 p.m. to 6:30 p.m.

The deviation period is from 7 a.m. on October 3, 2015 until 7 p.m. on October 3, 2015 (south single leaf opening if a one hour notice is given); from 7 p.m. on October 3, 2015 until 7 a.m. on October 4, 2015 (remain in the closed-to-navigation position); from 7 a.m. on October 4, 2015 until 7 p.m. on October 4, 2015 (south single leaf opening if a one hour notice is given); from 7 p.m. on October 4, 2015 until 7 a.m. on October 5, 2015 (remain in the closed-to-navigation position); from 7 a.m. on October 24, 2015 until 7 p.m. on October 24, 2015 (south single leaf opening if a one hour notice is given); from 7 p.m. on October 24, 2015 until 7 a.m. on October 25, 2015 (remain in the closed-to-navigation position); from 7 a.m. on October 25, 2015 until 7 p.m. on October 25, 2015 (south single leaf opening if a one hour notice is given); from 7 p.m. on October 25, 2015 until 7 a.m. on October 26, 2015 (remain in the closed-to-navigation position).

Waterway usage on the Lake Washington Ship Canal ranges from commercial tug and barge to small pleasure craft. Vessels able to pass through the bridge in the closed-to-navigation position may do so at anytime. The bridge will be able to open for emergency vessels in route to a call when an hour notice is given to the bridge operator, and a single leaf opening will be provided. The Lake Washington Ship Canal has no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: September 18, 2015.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

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