



16714  
CG-OES Policy Letter  
No. 01-19  
26 July 2019

  
From: S. T. BRADY, CAPT  
COMDT (CG-OES)

To: Distribution

Subj: ACCEPTANCE OF TYPE APPROVAL TESTING PROTOCOLS FOR BALLAST  
WATER MANAGEMENT SYSTEMS (BWMS) THAT RENDER ORGANISMS IN  
BALLAST WATER NONVIABLE

Ref: (a) Title IX of the Frank LoBiondo Coast Guard Authorization Act of 2018 "Vessel  
Incident Discharge Act (VIDA)" 33 U.S.C. 1322(p)  
(b) Title 46 Code of Federal Regulations (CFR) Part 162.060  
(c) EPA/600/R-10/146, Generic Protocol for the Verification of Ballast Water Treatment  
Technologies (ETV Protocol)

1. Purpose. On December 4, 2018 reference (a) was signed into law and charged the Coast Guard with primary responsibility for prescribing, administering, and enforcing regulations, consistent with the standards established by the Environmental Protection Agency relating to the discharge of pollutants from vessels, for the design, construction, installation, and operation of the equipment and management practices required onboard vessels. Pursuant to Section 903 of reference (a), this policy letter establishes:
  - a. the accepted type-approval testing protocols for BWMS that render organisms in ballast water nonviable (meaning "permanently incapable of reproduction") and may be used in addition to the protocols established under reference (b);
  - b. the process for accepting type-approval testing protocols for BWMS, if any, that render organisms in ballast water nonviable and may be used in addition to the protocols established under reference (b), which includes:
    - (1) the process for incorporating accepted protocols into the type-approval procedures established under reference (b);
    - (2) the acceptance of laboratories to evaluate applicable treatment technologies; and
    - (3) the certification of BWMS that render nonviable organisms in ballast water.
2. Action. The Coast Guard will follow this policy when implementing the BWMS type-approval program. Internet release is authorized.

3. Directives Affected. None.
4. Disclaimer. This draft policy letter is issued pursuant to 33 U.S.C. 1322(p)(6)(D)(ii) and precedes the final policy letter that will be issued pursuant to 33 U.S.C. 1322(p)(6)(D)(iv). It is not intended to nor does it impose legally binding requirements on any party. If the regulated industry or any member of the public does not wish to follow the provisions set forth in the final policy letter, the regulatory requirements in 46 CFR 162.060 remain in effect and can be used in lieu of the final policy letter.
5. Applicability. This draft policy letter applies only to testing protocols for BWMS that render nonviable organisms in ballast water. Accepted testing protocols for BWMS that render organisms in ballast water nonviable may be substituted for methods identified in Section 5.4 of reference (c), as appropriate.
6. Background. The testing requirements for type-approval of BWMSs are described in reference (b), which incorporates by reference the technology verification protocol described in reference (c). The testing requirements in reference (b) remain in effect until new type-approval testing protocols are accepted under the final policy letter.

Reference (a) directed the Coast Guard, in coordination with the Environmental Protection Agency (EPA), to:

*publish a draft policy letter, based on the best available science, describing type-approval testing methods and protocols for BWMS, if any, that—*

*(I) render nonviable organisms in ballast water; and  
(II) may be used in addition to the methods established under subpart 162.060 of title 46, Code of Federal Regulations (or successor regulations)—*

*(aa) to measure the concentration of organisms in ballast water that are capable of reproduction;*

*(bb) to certify the performance of each BWMS system under this subsection; and*

*(cc) to certify laboratories to evaluate applicable treatment technologies.*

At the time of this publication, the Coast Guard does not know of any type-approval testing protocols for BWMS that render nonviable organisms in ballast water that are based on best available science. Therefore, this policy letter establishes the process developed by the Coast Guard for accepting type-approval testing protocols.

7. Accepted protocols. Type-approval testing protocols for BWMS accepted in accordance with the final policy letter will be posted to <http://www.dco.uscg.mil/OES/Type-approval-testing-methods-and-protocols/> and announced via “Maritime Commons” as they are identified.

8. Standard for acceptance of new protocols. References (b) and (c) set the standard for rigor, documentation and transparency required of any BWMS type-approval testing protocol submitted to the Coast Guard for acceptance. BWMS type-approval testing for systems that render organisms nonviable will incorporate protocols based on viability and will be subject to the same level of rigor currently used for type-approval laid out in references (b) and (c). It is expected that BWMS type-approval testing protocols for systems that render organisms nonviable will primarily replace the biological efficacy testing requirements in chapter 5.4 of reference (c) with protocols applicable to measurement of viability. However, the Coast Guard recognizes that other relevant sections of reference (c) may require amendment, in whole or in part, depending on the specifics of accepted viability methods. Any such additional changes will be identified in the accepted methods.

The content and technical requirements for proposals of new type-approval testing protocols for BWMS that render organisms in ballast water nonviable are described in the "Enclosure: Instructions for submitting testing protocols." Any associated criteria affected by the incorporation of a viability protocol should be addressed as well. Any accepted type-approval testing protocols based on viability, and any associated protocols required for specific viability assessment methods, may only be used as an alternative to specific protocols identified in reference (c). All other aspects of the test protocols in reference (c) must still be met.

9. Process for acceptance and use of new protocols.
- a. Acceptance of proposed type-approval testing protocols for BWMS that render organisms in ballast water nonviable.
- (1) Proposals for type-approval testing protocols must be submitted to the Coast Guard in writing to Commandant (CG-OES), Office of Operating and Environmental Standards, U.S. Coast Guard STOP 7509; 2703 Martin Luther King Jr. Ave SE; Washington DC 20593-7509, or by email to [environmental\\_standards@uscg.mil](mailto:environmental_standards@uscg.mil).
  - (2) The Coast Guard will review complete proposals emphasizing peer-reviewed supporting documentation and validation of proposed protocols to meet the statutory requirement to base decisions on the best available science.
  - (3) Following review of proposed protocols, if any are accepted, the Coast Guard will post to <http://www.dco.uscg.mil/OES/Type-approval-testing-methods-and-protocols/> any type-approval testing protocols accepted for use in addition to the protocols detailed in reference (b) as described in paragraph 6.
- b. Acceptance of Independent Laboratories (ILs)
- (1) ILs that use protocols accepted under the final policy letter must include in the application for acceptance as an IL documentation of the ability to conduct such protocols, in accordance with 46 CFR 159.010. Note: applications for acceptance as an IL for testing BWMS must be submitted in writing to Commandant (CG-OES), Office of Operating and Environmental Standards, U.S. Coast Guard STOP 7509;

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2703 Martin Luther King Jr. Ave SE; Washington DC 20593-7509, or by email to  
environmental\_standards@uscg.mil.

- (2) For existing ILs accepted before establishment of the final policy, documentation of the ability to conduct such protocols must be submitted to the Coast Guard as above, and accepted, prior to submission of test reports required under 46 CFR 162.060-42.
- (3) For any accepted IL seeking to submit test reports required under 46 CFR 162.060-42 from testing conducted prior to acceptance as an IL, the IL must include in the application for acceptance all information necessary to demonstrate that at the time the testing was conducted the IL met all relevant acceptance criteria.
- (4) The Coast Guard will verify that ILs have standard operating procedures to evaluate viable organisms in accordance with any accepted viability protocols used in land-based and shipboard testing, as appropriate.
- (5) The Coast Guard will notify ILs in writing of the Coast Guard's decision regarding their application to evaluate BWMS.

c. Certification of BWMS

- (1) The Coast Guard will verify that:
  - (a) Manufacturers of BWMS identify in the Operation, Maintenance and Safety Manual required in an application for type-approval per 46 CFR 162.060-38(a)(3) whether the BWMS is designed and intended to render nonviable organisms in ballast water, or the BWMS is designed and intended to kill organisms in ballast water .
  - (b) ILs use accepted protocols when testing BWMS designed and intended to render nonviable organisms in ballast water; and
  - (c) ILs use the accepted protocols within the over-all framework of testing and evaluation requirements described in 46 CFR 162.060. Unless specified in an accepted protocol, all aspects of the testing requirements in 46 CFR 162.060 and the incorporated reference (c) must be met by the IL.
- (2) The Coast Guard will identify on the type-approval certificate whether an approved BWMS is designed to render nonviable organisms in ballast water or to kill organisms in ballast water.

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Encl: Instructions for submitting testing protocols.

Dist: Public Distribution

ENCLOSURE: Instructions for submitting testing protocols.

Requirements for proposed type-approval testing protocols for BWMS that render nonviable organisms in ballast water, for use in addition to the protocols established under subpart 162.060 of Title 46, Code of Federal Regulations or successor regulations.

A submission must include the following:

- 1) A description of the proposed protocol.
  - a) Although not required, the Coast Guard recommends structuring submissions to utilize an easily understood progression of documents. There is no required format, but documentation in the format of EPA standard methods (e.g., EPA 821-R-14-011, Sept. 2014; Method 1600) will facilitate efficient review of proposed methods.
  - b) An explanation of the scientific and technical basis for the protocol, including references to supporting information.
  - c) Explanation of why the proposed protocol is based on the best available science. Independently peer-reviewed scientific reports and publications that address the issue of evaluating the total concentration of mixed assemblages of viable organisms in samples of treated ballast water will present the strongest case.
- 2) Documentation to allow a determination that the following criteria are met:
  - a) Independent Laboratory or sub-laboratory personnel can implement the protocol in a replicable manner, including:
    - i) in different locations and salinity conditions; and
    - ii) during land-based and shipboard tests conducted in accordance with 46 CFR 162.060.
  - b) The precision and accuracy of the proposed protocol, including across locations, is at least equivalent to the precision and accuracy of the relevant method in 46 CFR 162.060. At a minimum, a quantitative evaluation will include:
    - i) the accuracy of the proposed protocol using a spike-and-recovery approach or a comparison to other assays, as appropriate;
    - ii) the precision of the proposed protocol as quantified by the variation among multiple readings of the same sample; and
    - iii) the comparative accuracy and precision of the proposed protocol with the accuracy and precision of the required protocol.
- 3) Descriptions of the following laboratory specifications:
  - a) Required equipment, including performance specifications;
  - b) Reagents, chemicals, solutions, and media, including working concentrations;
  - c) Reference standards and standard test organisms, if required;
  - d) Procedural steps required to employ the protocol; and
  - e) Known interferences, cautions, and health and safety warnings, if applicable.
- 4) A description of the organism type and size class to be assessed.
  - a) If a subset of organisms in the size class is targeted by the protocol, the protocol must:
    - i) describe the basis for estimating the concentration of the entire community based upon the concentration of a targeted subpopulation;
    - ii) demonstrate the feasibility of the method through empirical studies;
    - iii) clarify the requirements and limitations of using a subpopulation to represent the concentration of the entire assemblage; and
  - b) for methods employing either direct or non-direct measurements, or both to obtain final organism counts, documentation must be provided supporting the statistical approach for



combining results for methods employing direct and/or non-direct measurements.

Regardless of method used, the point estimate (organism count) must be accompanied by the 95% confidence interval and, when applicable, the standard error of the test result.

- 5) Validation data of the proposed protocol, developed pursuant to "Method Validation of U.S. Environmental Protection Agency (EPA) Microbiological Methods of Analysis" Rev. 12/21/2016. A report of validation data must be included to address the following:
  - a) Laboratory tests using at least 5 unique taxa amenable to laboratory culture and representative of taxa found in natural plankton assemblages;
  - b) Field tests conducted in at least 4 different locations, encompassing locations on the Pacific Coast, Atlantic Coast, and the Great Lakes of North America (other additional locations outside of the United States may be included as well), and entailing assessment of the concentrations of total, naturally occurring organisms in ambient water samples, including a range of salinity conditions from marine (salinity > 28 PSU), estuarine (salinity 1-28 PSU) and freshwater (salinity < 1 PSU); and
  - c) Data demonstrating the method can be used to distinguish between organisms that are temporarily rendered nonviable and organisms that have been rendered permanently nonviable, per the definition of "render nonviable" in reference (a);