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CG-OES Policy Letter
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To: Distribution

Subj: TYPE-APPROVAL TESTING METHODS FOR BALLAST WATER MANAGEMENT SYSTEMS THAT RENDER ORGANISMS NONVIABLE IN BALLAST WATER

Ref: (a) Title IX of the Frank LoBiondo Coast Guard Authorization Act of 2018 "Vessel Incidental Discharge Act of 2018 (VIDA)," Public Law 115-282
(b) Title 46 Code of Federal Regulations (CFR) Subpart 162.060
(c) EPA/600/R-10/146, Generic Protocol for the Verification of Ballast Water Treatment Technologies (ETV Protocol)

1. Purpose. This policy letter responds to the VIDA mandate requiring the Coast Guard to describe type-approval testing methods, if any, for ballast water management systems (BWMS) that render nonviable organisms in ballast water. Under VIDA at 33 U.S.C. § 1322(p)(1)(U) organisms are nonviable when they are permanently incapable of reproduction.

2. Accepted viability testing. At this time, the Coast Guard has not adopted any type-approval testing method for BWMS that render organisms in ballast water nonviable.

3. Action. The Coast Guard will follow this policy when implementing the BWMS type-approval program. Internet release is authorized.

4. Directives affected. None.

5. Disclaimer. This policy letter is 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. The regulatory requirements in 46 CFR Subpart 162.060 remain in effect and are unchanged by this policy letter.

6. Background. The Vessel Incidental Discharge Act of 2018 (VIDA)--found at Title IX of the Frank LoBiondo Coast Guard Authorization Act of 2018, Pub. L. 115-282--amended Section 312(p) of the Federal Water Pollution Control Act (33 U.S.C. § 1322), also known as the Clean Water Act (CWA). Pursuant to 33 U.S.C. § 1322(p)(6)(D)(iv), the Coast Guard issues this final policy letter. Congress directed the Coast Guard, in adopting a BWMS type-approval testing method, to base the evaluation of methods for measuring viability on the best available science. The Coast Guard is aware that methods exist which purport to

measure the concentration of viable organisms in ballast water, including those which use organism grow-out and most probable number statistical analysis. However, the Coast Guard does not presently have access to sufficiently detailed information or data pertaining to those methods to determine whether any of those methods are based on the best available science.

The Coast Guard has developed a best available science evaluation process to assess the acceptability of viability testing methods for use in BWMS type-approval. Following the process described in this letter, stakeholders may submit proposed methods based on viability, and the Coast Guard will make a decision whether any are acceptable after collecting and evaluating the available supporting science.

In accordance with 33 U.S.C. § 1322(p)(6)(D)(iv)(III), accepted viability testing methods which may be used in addition to the methods established under Subpart 162.060 of Title 46, Code of Federal Regulations (or successor regulations), will be announced, along with any necessary guidance on their use, in a revision of this letter. A Notice of Availability for the revised policy letter will be published in the Federal Register. The revised policy letter will be available through the Commandant (CG-OES) Office of Operating and Environmental Standards website: https://www.dco.uscg.mil/Our-Organization/Assistant-Commandant-for-Prevention-Policy-CG-5P/Commercial-Regulations-standards-CG-5PS/office-oes/

7. Definition of best available science. VIDA requires BWMS that render organisms nonviable to be evaluated for type-approval by measuring the concentration of organisms capable of reproduction based on the best available science. VIDA, which amends the CWA, does not define "best available science." However, the definition for "best available science" found in the immediately preceding section of the CWA, at 33 U.S.C. § 1321(a)(27), has reasonable applicability to ballast water viability testing methods. Consequently, the Coast Guard is adopting this definition which defines best available science as an evaluative process for assessing scientific information that:
   a. maximizes the quality, objectivity, and integrity of information, including statistical information;
   b. uses peer-reviewed and publically available data; and
   c. clearly documents and communicates risks and uncertainties in the scientific basis (for such projects).

8. Process for acceptance and use of new protocols.

   a. Information needed to assess available viability testing methods.

      1. Enclosure (1) describes information that the Coast Guard considers important in order to assess the acceptability of viability testing methods based on best available science. A lack of information will contribute to uncertainty in the testing method, which will, depending on the nature of the information lacking and the Coast Guard's ability to address informational gaps, affect the acceptability of that method. The Coast Guard may contact submitters to provide the opportunity to amend a submission to address identified gaps in the information provided.

2. The Coast Guard will need to review the potential environmental impact of any testing methods it considers accepting, to comply with the National Environmental Policy Act (NEPA) and other applicable environmental mandates. In order to make a valid determination, the Coast Guard anticipates a need to address the probability of non-viable organisms remaining non-viable for the remainder of their life and the overall accuracy of the discharge calculation. Therefore, the Coast Guard highly encourages submitters to include sufficient information in their submission to allow the Coast Guard to complete environmental documentation required by NEPA and other laws. The Coast Guard may contact submitters of specific methods to provide an opportunity to address information gaps preventing expeditious development of environmental review documentation. See Enclosure (1) section 4.

3. Viability testing methods with associated supportive information and data must be submitted 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 electronic copies sent by email to CG-OES@uscg.mil. In evaluating best available science, the Coast Guard may assess publically available information in addition to that submitted to ensure all aspects of the best available science definition above are fully and accurately evaluated.

b. Assessment of viability testing methods, supportive information, and data.
The Coast Guard will assess the scope and applicability of the submitted viability testing method to determine the specifics of how this testing method might be incorporated within the current testing protocol and if acceptance is within the authority granted by VIDA.

1. VIDA prohibits the Coast Guard from considering a testing method that relies on a staining method to measure the concentration of organisms greater than or equal to 10 micrometers and less than or equal to 50 micrometers. The term "stain" is undefined in VIDA and is not consistently used in science to describe a specific scientific procedure. A "stain" is defined by Merriam Webster's dictionary[1] in relevant part as "a dye or mixture of dyes used in microscopy to make visible minute and transparent structures, to differentiate tissue elements or to produce specific chemical reactions." According to this definition, a "stain" acts by "suffusing with color", "[coloring] by processes affecting chemically or otherwise the material itself." The Coast Guard will assess any submitted type-approval testing method information to determine if it utilizes a stain, using this definition.

2. The Coast Guard will assess whether the method description includes all of the necessary information in sufficient detail to allow use by test facilities.

3. The Coast Guard will evaluate supporting information and data on the basis of best available science to determine whether any viability testing methods are acceptable.

[1] Available at https://www.merriam-webster.com/dictionary/stain?src=search-dict-hed (last accessed 01/31/2022).

c. Acceptance of viability testing methods into BWMS type-approval testing. In addition to the assessment in section b. above, the Coast Guard will need to prepare a NEPA compliant analysis and documentation such as an Environmental Assessment or an Environmental Impact Statement before it is able to finally accept the viability testing method as part of the BWMS type-approval testing methods.

d. Acceptance of Independent Laboratories (ILs).

1. Test organizations seeking to use methods accepted under a revised final policy letter must submit an application for acceptance as an IL in accordance with 46 CFR Subpart 159.010 and 46 CFR § 162.060-40 that includes documentation of the ability to conduct such methods.

2. ILs accepted by the Coast Guard to conduct BWMS type-approval testing prior to the establishment of the final policy, must submit documentation and be accepted by the Coast Guard to conduct viability testing prior to conducting such tests for type approval. Documentation submitted to the Coast Guard that demonstrates the IL's ability to conduct viability testing must be in accordance with 46 CFR §§ 162.060-26 and 162.060-28, incorporating the accepted viability testing methods.

e. 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 to remove, and/or render nonviable, and/or kill organisms in ballast water, and/or to process ballast water to avoid the uptake or discharge of organisms;

b) When testing a BWMS designed to render organisms nonviable, ILs must use the accepted viability testing methods within the overall framework of testing and evaluation requirements described in 46 CFR Subpart 162.060. Unless otherwise specified in an accepted method identified in a revised version of this final policy letter, all other aspects of the testing requirements in 46 CFR Subpart 162.060 and the incorporated reference (c) must be met by the IL. The Coast Guard will confirm these requirements have been met when reviewing submitted applications for type-approval of a BWMS designed to render organisms nonviable.

2. The Coast Guard will identify on the BWMS type-approval certificate whether a system is approved on the basis of removing, and/or rendering nonviable, and/or killing organisms in ballast water, and/or processing ballast water to avoid the uptake or discharge of organisms.

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Encl (1): Coast Guard Viability Testing Methods Information Requirements.

Dist.: Public Distribution

ENCLOSURE (1): Coast Guard Viability Testing Methods Information Requirements.

The Coast Guard needs to take into consideration the following information to assess specific viability testing methods, including methods based on the use of grow-out and Most Probable Number (MPN) statistical analysis, for incorporation into accepted test methods established under 46 CFR Subpart 162.060. Submissions should be formatted in accordance with EPA standard methods (Guidelines and Format for Methods to be Proposed at 40 CFR Part 136 or Part 141, available at https://www.epa.gov/sites/production/files/2015-09/documents/guidelines-format-for-methods-parts-136141_1996.pdf). Use of this standard will facilitate efficient review of submitted methods (Note, Coast Guard has added uncertainty analysis, an element of best available science not contained in the referenced EPA standard method format.) Viability test methods must comprehensively describe the essential requirements for implementing the method within the BWMS type-approval procedures established in 46 CFR Subpart 162.060, including but not necessarily limited to:

1. Scope
   a) Staining Method
      i) A description of any testing procedure that relies on the use of a staining method, as described in section 8.b.1. in the body of this policy letter.
   b) Testing target:
      i) A description of the organism size class (i.e., "≥ 50 um" or "≥10 um and <50 um") and organism type(s) to be assessed by the method; and
   c) Sample Matrix
      i) A description of the sample matrix (eg, freshwater, marine water, brackish water) applicable to the method.
   d) Expected usage:
      i) A description of intended usage by testing facility, whether broadly as a standard method, or locally, as a testing site-specific method.
      ii) An explanation of how the proposed method would integrate into the existing testing regime, including which specific testing procedure(s) in the ETV Protocol (reference (c)) the proposed method would alter or replace.

2. Method Details
   a) Summary of method, including known assumptions.
   b) Definitions, including any limitation of the method in enumerating target organisms.
   c) Interferences, if any.
   d) Health and safety warnings, if any.
   e) Equipment and supplies, including any required equipment and associated performance specifications.
   f) Reagents and standards, including:
      i) Reagents, chemicals, solutions, and media, including working concentrations; and,
      ii) Reference standards and standard test organisms, if required.
   g) Sample collection, handling, and storage requirements, if any.
   h) Quality control, including sampling spiking procedures, if any.
   i) Calibration and standardization of the method.

j) Procedure, including any procedural steps required to employ the method, including any changes in any aspects of the test requirements under 46 CFR Subpart 162.060 necessary for use of the method.
k) Verification procedure, including for false positives and false negatives.
l) Data analysis and calculations, including:
   i) If direct or non-direct measurements or both are used 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.
   ii) If a subset of organisms in the size class is targeted by the method, the method should:
      (1) describe the basis for estimating the concentration of the entire assemblage of the size class in the sample based upon the concentration of a targeted subset; and,
      (2) clarify the requirements and limitations of using a subset to represent the concentration of the entire size class.
m) Pollution prevention, if any.
n) Waste management, if any.

3. Method validation
   a) An explanation of the scientific and technical basis for the method, including references to supporting information.
   b) Evaluation of method performance and uncertainty, including:
      i) The ability of Independent Laboratory or sub-laboratory personnel to implement the protocol in a replicable manner under land-based or shipboard circumstances regardless of location.
      ii) Demonstration of method feasibility through empirical studies.
      iii) Statistical analysis of the precision and accuracy of the proposed method, including across locations, method specificity and false positive and negative rates.
      iv) For site-specific methods, explanation should describe how the performance of BWMS can be evaluated when tested in multiple locations utilizing site-specific testing methods. This information should address a viability testing method's risks or uncertainties when used in a facility or site-specific manner, within the global context of type-approval testing. Such risks and uncertainties may be mitigated through facility or site-specific validations during use and adjustment of method details based on facility or site-specific conditions.
      v) For tests utilizing standard laboratory-cultured organisms, explanation of the basis for equating effect on tested organisms to BWMS treatment efficacy on mixed assemblages in naturally occurring ballast.
      vi) Explanation of how validation of the proposed method addressed method utilization in a wide variety of environmental conditions and geographic locations. Ideally, this would include field tests assessing the concentrations of total viable, naturally occurring organisms in ambient water samples, including a range of organisms concentrations and salinity conditions from marine (salinity > 28 PSU), estuarine (salinity 1-28 PSU) and freshwater (salinity < 1 PSU).

vii) Explanation of how the proposed method ensures that organisms deemed to be non-viable are permanently unable to reproduce, as required under VIDA. Ideally, this would include 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).

viii) Analysis of random and systemic uncertainties. Uncertainty analysis should follow standard approaches, such as the Guide to the Expression of Uncertainty in Measurement (ISO, 2008, Geneva ISBN, 50, 134, doi:10.1373/clinchem.2003.030528)

4. Environmental impact documentation
   a) The Coast Guard must provide a detailed statement that includes, but is not limited to: (i) analysis of the direct, indirect and cumulative environmental impact of the proposed action, (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented, (iii) analysis of a reasonable range of alternatives to the proposed action, (iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and (v) any irreversible and irretrievable commitments of resources which would result from implementation of the proposed action. The Coast Guard will need to develop a thorough description of the "proposed action" before the NEPA review can begin. As indicated in the Final Policy Letter, this evaluation will address, among many factors, the effectiveness of a non-viability treatment and the overall accuracy of a discharge assessment.
   b) Submitters may choose to include any information that would assist in the Coast Guard's NEPA review. Detailed information on the requirements for an Environmental Impact Statement is found in the Council on Environmental Quality (CEQ) regulations and guidance, such as CEQ's Memorandum for Heads of Federal Departments and Agencies: Improving the Process for Preparing Efficient and Timely Environmental Reviews under the Environmental Policy Act, 6 March, 2012 (http://ceq.hss.doe.gov/ceq_regulations/guidance.html). Specific issues that will need to be analyzed under NEPA include, but are not limited to the potential for acceptance of a testing method with systemic risks and uncertainties in the scientific basis of that method. Systemic risks and uncertainties in a testing method, including but not confined to the scope of the method or the degree to which non-viability may be non-permanent, may result in type-approval of BWMS that do not meet the discharge standard. Such BWMS could introduce more invasive organisms than determined to be acceptable in the 2012 Ballast Water Discharge Standard rulemaking and associated Final Programmatic Environmental Impact Statement. The resulting impacts to aquatic ecosystems must be reexamined in detail, should the Coast Guard accept a testing method with systemic risks and uncertainties in the scientific basis for that method. Coast Guard will provide further guidance upon request.

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