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BEMA Position Statement on USCG Policy Letter CG-OES 02-22 Type approval testing methods for ballast water management systems that render organisms nonviable in ballast water

On Thursday, March 24, 2022, the United States Coast Guard (USCG) published Docket USCG-2019-0477 in the Federal Register indicating availability of the Final Policy Letter CG-OES 02-22, *Type-Approval Testing Methods for Ballast Water Management Systems (BWMS) That Render Organisms Nonviable in Ballast Water*. This policy letter was issued in response to the requirements of the Vessel Incidental Discharge Act (VIDA) of 2018 and 33 U.S.C. 1322(p)(6)(D)(iv) which requires the USCG to describe type approval testing methods for BWMS that render organisms nonviable in ballast water to be used in addition to those established in 46 Code of Federal Regulations (CFR) subpart 162.060.

Following review of the USCG's document, the Ballastwater Equipment Manufacturers' Association (BEMA), an independent trade association made up of BMWS manufacturers, BWMS testing facilities, industry experts, scientists, and stakeholders in the effective, efficient treatment of ballast water, presents this document with BEMA's position on the policy letter, as well as to provide guidance to any further rule-making processes.

Executive Summary

- In the Final Policy Letter, the USCG states that no known method of testing type-approved ballast water treatment systems exists that meets the definition of "best available science" as outlined in VIDA.
- Additionally, the USCG undertakes the responsibility to define what the standard for "best available science" is, using language from the Clean Water Act, in lieu of placing that responsibility with an agency with experience in assessing "best available science" and "best available technology" under the Clean Water Act, namely the U.S. Environmental Protection Agency (US EPA).
- The Final Policy Letter expands on the requirements of assessment for any new type of ballast water type-approval testing methods by including the need for a potential environmental impact assessment for any new methods accepted.
- As an industry group made up of scientists, ballast water treatment assessment specialists, and manufacturers, BEMA and our members have submitted documentation matching or exceeding the scientific rigor and requirements outlined in the Policy Letter without any progress being made in this matter.
- BWMS manufacturers, particularly those who use UV-light as part of their treatment system unanimously agree that failing to use a viability assessment requires much higher levels of power, UV-light, and filtration than are necessary to achieve the ballast water discharge standards of the BWM Convention, the USCG Final Rule in 33 CFR Part 151,

and VIDA which all aim to stop the spread of aquatic invasive species through the transfer of ballast water by ships.

- The inability to utilize testing methods approved by the US EPA for other disinfection applications (including drinking water) and approved by the USCG in ballast water for indicator organisms, causes a significant environmental impact due to increased carbon emissions, wasted fuel, and critically impacts the performance of BMWS in ports with challenging water conditions.
- BEMA believes that sufficient scientific data, together with assessments of reliability, trueness, uncertainty, and risks for false positives and/or false negatives exists and has been submitted to the USCG previously for the acceptance of the Most Probable Number (MPN) method to be accepted as an approved alternative to those established in 46 CFR subpart 162.060 and the Generic Protocol for the Verification of Ballast Water Treatment Technology (EPA/600/R-10/146).

Background

In 2004 the International Maritime Organization (IMO) issued the Convention for the Management of Ballast Water and Sediments (BWM Convention). This Convention includes related guidelines and guidance documents intended to facilitate implementation of the Convention, including Guideline G8 (now the BWMS Code) which outlines methods for assessing the performance of treatment systems.

In 2012, the USCG issued the Standards for Living Organisms in Ships' Ballast Water Discharged in U.S. Waters (herein, the USCG Final Rule) that created regulation 46 CFR 162.060, which contains the requirements for assessing the performance of treatment systems. This regulation incorporates the Generic Protocol for the Verification of Ballast Water Treatment Technology, EPA/600/R-10/146 (ETV Protocol) by reference, requiring that organisms in the 10-50 micron size class be tested using a vital stain. Through many comments received during the rulemaking process, the industry indicated that one particular type of treatment system, those based on the use of UV light, instead rely on viability assessment in order to correctly measure their performance.

The ETV Protocol contains allowances for the use of emerging testing methods in section 5.4.8 provided that they are validated by the Testing Organization (TO) to the satisfaction of the Verification Organization (VO). The TO is the organization responsible for preparing the Testing Quality Assurance Plan (TQAP) and for coordinating and conducting all testing of the BWMS. The VO is the organization responsible for overseeing the testing carried out by the TO and submitting the verification report and statement to the certifying authority.

In 2013, the US EPA issued the second Vessel General Permit for discharges incidental to the operation of vessels. This permit contains extensive language on the permitting of ballast water discharges and specifically indicated that the discharges from ballast water management systems

approved by IMO countries, which allows the use of MPN viability assays, was the best available technology and were acceptable for treatment in the Waters of the United States.

In 2015, three ballast water treatment system manufacturers made the first applications for USCG Type Approval under 46 CFR 162.060 using the alternate methods outlined in the ETV Protocol. The USCG rejected these applications because they relied on the Most Probable Number (MPN) viability assay to measure system performance, despite this method being accepted by both the TO and the VO (DHI and DNV-GL, respectively, in the case of these applications) in accordance with the requirements of section 5.4.8 of the ETV Protocol. During review of these applications significant verification studies were conducted and submitted to the USCG.

In 2018, responding to industry requests for a harmonization of the EPA and USCG discharge standards together with the patchwork of individual state requirements under the Clean Water Act for ballast water discharges, the US Congress passed the Vessel Incidental Discharge Act (VIDA) in order to place the requirement for setting a discharge standard under the US EPA and setting the requirements for enforcing the discharge standard under the USCG. As part of VIDA, the USCG is mandated to "…take into consideration a testing method that uses organism grow-out and most probable number statistical analysis to determine the concentration of organisms in ballast water that are capable of reproduction;…" rather than simply relying upon a "living/dead" assessment used by staining methods. It was also specifically indicated that the Policy Letter could not take into consideration a testing method that relies on a staining method. The Final Policy Letter was to be issued in 2019, within 1 year after enactment of VIDA.

Following the enactment of VIDA, numerous BWMS manufacturers, including many BEMA members, submitted hundreds of documents to the USCG proving the scientific rigor of the MPN viability assay for the assessment of BWMS performance.

In 2019, the USCG published their Draft Policy Letter CG-OES 01-19, *Acceptance of Type Approval Testing Protocols for Ballast Water Management Systems (BWMS) that Render Organisms in Ballast Water Nonviable* on using viability assessments, which indicated that the USCG did not know of type approval testing protocols based on best available science. During a listening session following the issuance of the Draft Policy Letter, numerous industry groups, including BEMA, provided input to the USCG and EPA regarding the MPN viability assay and its use in other disinfection applications. Some of these applications are regulated by the Clean Water Act, and include use of the MPN viability assay to assess EPA-regulated Potable Water Facilities. BEMA notes that using water from a US public water supply meeting certain EPA drinking water standards is an option for ballast water management that the USCG included in the Final Rule.

In 2022, the USCG published their Final Policy Letter CG-OES 02-22, *Type-Approval Testing Methods for Ballast Water Management Systems That Render Organisms Nonviable in Ballast Water*, which retains the position that the USCG is not aware of viability testing methods that are based on best available science. Further, the USCG indicated that it "…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 best available science." The USCG outlined a method for submitting the relevant data to get such a method approved which included a new requirement that any assessment of a new method must include extensive environmental impact studies.

In 2022, during the 9th session of IMO's Pollution Prevention and Response Subcommittee (PPR 9), the IMO ballast water review group recommended a revision to BWM Circular 61 (to be published as BWM.2/Circ.61/Rev.1), which was approved during the 78th session of the Marine Environment Protection Committee (MEPC 78). This revision approved an updated description of the analysis method using MPN culture plus motility as presented in document PPR 7/INF.10 as an acceptable method of verifying the performance of ballast water management systems. This action was a result of IMO's invitation for submissions on analysis methods and confirmed the prior acceptance of the MPN plus motility method for assessing the performance of all BWMS treatment technologies, including UV-based systems.

Industry Need for Viability Assessment Methods

It may seem tempting to state that based on the current status of the industry, viability assessments are not needed for BWMS approvals. As of 15 June 2022, there are forty-eight (48) BWMS which are type approved under the USCG Final Rule and twenty-three (23) of these use UV light as their disinfection stage. UV systems make up a significant portion of the BWMS installation market and they are critical systems for smaller vessels and those vessels which trade exclusively in fresh water.

The restriction on the use of viability testing methods and limiting to staining methods only has had two very significant impacts on the UV industry:

1. Systems which relied on low-pressure UV lamps have been forced out of the market because the targeted UV-C light is not sufficient to achieve the rupture of the cellular wall that is required by the CMFDA/FDA stain to identify mortality; and
2. UV systems using medium pressure UV lamps (broad spectrum UV) have had to increase their power demand by a factor of 3 – 5 times, making the systems much harder for smaller vessels to implement and consuming much more fuel than would be required for viability assessments.

BEMA recognizes that each of these issues is critically important both for the industry and for shipowners looking to implement effective ballast water treatment in the current environment where carbon emissions need to be reduced to a minimal level and there is an increasing focus on the Energy Efficiency Design Index (EEDI) of vessels and vessel designs. Arbitrarily eliminating a very efficient type of UV lamps and forcing systems and ships to use more power than is required to achieve the ballast water discharge standard without providing any additional treatment benefit is contrary to the overall sustainability goals of the IMO, the United Nations, and the United States.

It is therefore critical that the industry continues to evolve and seeks to optimize ballast water treatment as a part of the overall energy load that vessels are now required to track, report, and improve upon. As major equipment that is required to be installed onboard, shipowners are correctly looking to BWMS manufacturers to help them meet their carbon emission goals. To support this, the associated BWMS regulations must evolve as well. The ability to use viability-based testing methods, and therefore, reduce excessive power consumption, would allow BWMS manufacturers to better support shipowners in reaching these targets.

Assessing "Best Available Science"

As described in OES-CG 02-22, the USCG seeks to review and rule upon the validation of methods that may be submitted under this new protocol. As part of this assessment, the USCG requires significant documentation, testing, validations, and verifications across multiple types of organisms, water sources, and geographic regions.

Enclosure (1) of the document contains the following submittals required for validation of a method:

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)

BEMA agrees that these validation parameters and submittals are a thorough means of validating a new method of assessment; however, there are two primary concerns:

1. The MPN method is already established and is recognized globally by the scientific community as having strong reliability and rigor; and
2. The standard of rigor for assessing a new type of BWMS assessment should not be significantly greater than that used for the currently approved CMDFA/FDA vital stain method.

The MPN viability assay is not a new method which has been developed for the testing of BWMS. MPN assessments are used in numerous US EPA disinfection standards, including those used for potable water. The US EPA also has a specific standard for using MPN assays (USEPA Method 1680/1, 1682, SM 9221B, SM 9221F, and others). MPN assays are acceptable under the IMO BWMS Code (MEPC.300(72)) and viability assessment is a part of the USCG Final Rule when assessing indicator organisms that cannot be individually counted through microscopy.

BEMA believes that while it is important to fully assess the validity of a newly created assessment method, the application of such a high standard of rigor for a test method which has an established history in science and is widely used throughout the world as the best available method for assessing disinfection efficacy is not needed and creates an undue burden on industry.

BEMA members have submitted hundreds of documents, peer reviewed papers and studies, articles published in scientific journals, and opinions by leading marine scientists, all with a uniform recognition of the scientific rigor and validity of the MPN viability assay to the USCG.

Additionally, BEMA is aware that its members have undertaken a validation study as outlined in Enclosure 1 of OES-CG 02-22 and submitted this study to the USCG. An independent website was set up as a repository of the information about and validations of the MPN method. It is the opinion of BEMA that if the amount of documentation, studies, research, and global acceptance of the MPN method that has been submitted to the USCG by this date is still insufficient for the validation of this method, then it is unlikely that any other method would be validated.

Risks of Denying Viability Assessment Methods

Enclosure 1 of OES-CG 02-22 requires that an Environmental Assessment be submitted as a critical part of the submittal. This should include details on:

(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.

BEMA has identified a number of risks to not allowing the swift implementation of the MPN or other similar method for assessment of viability for BWMS approved under 46 CFR 162.060:

1. Assessing the vitality of organisms immediately following discharge has the potential to allow dormant organisms, non-staining organisms, or organisms in an oocyst or embryonic state which do not process the stain to be indicated as a false negative (EPA/600/R-10/146, 5.4.6.5);
2. Failing to assess the grow-out potential of organisms does not account for the potential of repair or return to vitality of organisms which may be impacted by the treatment but still able to return to vitality once the disinfectant is removed;
3. Eliminating the potential for future development of higher efficiency UV technology into the BWMS market will significantly reduce the ability of UV-based BWMS to improve efficiency and reduce power demand through the use of emergent, optimizing technologies;
4. Inability of UV-A and UV-B wavelength light to break down the cellular wall structure of complex organisms has led to the implementation of increasingly fine-mesh filters in the BWMS market which has had negative impacts on BWMS performance on vessels. For vessels with 20 micron filters that encounter high TSS, contingency measures including system bypass may happen more frequently due to filter clogging when compared to a 40- or 50-micron filter mesh; and
5. The significant power increases needed for UV-A and UV-B light to break down cellular walls precludes UV use on large flow vessels due to the significant power demand.

Summary

BEMA feels strongly that the MPN viability assessment method is an internationally recognized, science-based, rigorous, validated, peer-reviewed procedure that meets the standard of "best available science" under any reasonable definition. BEMA further emphasizes that the risks of not implementing this test procedure are significant and this matter remains both relevant to the industry and important to the overall protection of our global environment.

BEMA welcomes any opportunities to provide input to the USCG, the US EPA, or any other regulatory agency in support of developing an assessment method for BWMS which takes the viability of organisms into account. As an industry association made up of manufacturers, BWMS component manufacturers, scientists, ballast water equipment testing facilities, and concerned industry stakeholders, we are uniquely positioned to provide technical information related to the ballast water treatment industry and we welcome the earnest opportunity to contribute toward the USCG's acceptance of viability methods.

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