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INTERNATIONAL CONVENTION FOR THE CONTROL AND MANAGEMENT OF SHIPS' BALLAST WATER AND SEDIMENTS, 2004

Protocol for the verification of ballast water compliance monitoring devices

1 The Marine Environment Protection Committee (MEPC), at its eightieth session (3 to 7 July 2023), approved the *Protocol for the verification of ballast water compliance monitoring devices* to provide a framework that can be used to verify the ability of a compliance monitoring device to assess non-compliance with the standard described in regulation D-2 of the BWM Convention, as set out in the annex.

2 Member Governments and international organizations are invited to bring this Protocol to the attention of all parties concerned.

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ANNEX

PROTOCOL FOR THE VERIFICATION OF BALLAST WATER COMPLIANCE MONITORING DEVICES

1 Purpose

1.1 The goal of this protocol is to provide a framework that can be used to verify the ability of a compliance monitoring device (CMD) to assess non-compliance with the standard described in regulation D-2 (the D-2 standard) of the *International Convention for the Control and Management of Ships' Ballast Water and Sediments*, 2004 (the BWM Convention), and its ability to operate, as claimed by the manufacturer, with regard to the degree or level of non-compliance that can be detected and with regard to the stated intended use of the device. This protocol is intended to support effective implementation of the BWM Convention by enabling the use of ballast water CMDs that satisfy a common level of quality.

2 Definitions

2.1 Compliance monitoring device (CMD): an instrument and its associated indicative analytical methodology typically used as a rapid assessment of the concentration of viable (or living) organisms in treated ballast water for the purpose of determining compliance or non-compliance with a discharge standard.

2.2 Ambient challenge water: ambient water that meets the challenge water criteria without augmentation or concentration.

2.3 Ambient water: water from a natural, local source.

2.4 Challenge water: water used to test a CMD which meets specific criteria for water quality and organism diversity as described in paragraphs 6.9 to 6.16 of this protocol.

2.5 False negative: a test result declared negative, where it is in fact positive.

2.6 False positive: a test result declared positive, where it is in fact negative.

2.7 Field test: a practicability test to assess the ability of the device to work under real-life conditions, including a demonstration of producing accurate and reliable results in an onboard environment or the location of the intended use of the device. It is designed around the intended use of the device. Parameters included within the field test are assessed within a shipboard environment and/or at locations appropriate to the stated intended use and application of the device.

2.8 Negative control: any well-characterized material or substance that, when tested by a specific procedure, demonstrates the suitability of the procedure to yield a reproducible, appropriately negative, non-reactive or minimal response in the test system.

2.9 Positive control: any well-characterized material or substance that, when tested by a specific procedure, demonstrates the suitability of the procedure to yield a reproducible, appropriately positive or reactive response in the test system.

2.10 Prepared challenge water: water (from any source) that is augmented to meet the challenge water criteria.

2.11 Calibration standard: sample containing the analyte of interest at a known concentration either purchased from an external source or prepared in-house from materials of known purity or concentration, or both, and used to calibrate the measurement system.

2.12 Treated water: water that has been processed by a type-approved ballast water management system (BWMS) or by a process that replicates, as close as possible, the processes undertaken by a type-approved BWMS.

3 Introduction

3.1 The objective of this protocol is to provide a framework for the verification of the performance of ballast water CMDs intended for use in the implementation of the BWM Convention. These devices may be used for a variety of purposes: during commissioning testing of ballast water management systems, during port State control inspections, and during ships' self-monitoring. The protocol relies on laboratory and field tests conducted in accordance with standard test procedures such as those under development or published by the International Organization for Standardization; additional tests (e.g. vibration, humidity) may be carried out when applicable.

3.2 This protocol is applicable to the two designated size classes prescribed by the D-2 standard (organisms ≥ 50 µm; organisms ≥ 10 µm and < 50 µm) and to the group of specified indicator microbes (toxicogenic *Vibrio cholerae* (O1 and O139), *Escherichia coli* and intestinal enterococci). For consistency and brevity, these three items (i.e. the two-size classes and indicator microbes) are hereinafter called "groups of organisms".

3.3 CMDs can include various sensors, instruments, kits, methods and assays designed to measure the concentrations of organisms in ballast water to determine compliance with regulation D-2. Following collection, samples can be analysed in the laboratory, in the field (e.g. dockside), on board ships (e.g. hand-held or mobile units brought on board or that reside on board), or by in-line units integrated directly into a ship's ballast system or BWMS.

3.4 Any acknowledged or suspected chemical or physical factors affecting the device's efficacy, including any interactions due to the treatment technologies used to treat the ballast water (e.g. flow, bubbles) should be assessed and addressed as appropriate.

3.5 This protocol primarily intends to validate the device's ability to measure groups of organisms in ballast water, including, when such claims are made by the manufacturer, the ability to distinguish between viable and non-viable organisms. CMDs may consist of their own components and apparatus for preparing the sample for measurement, including, but not limited to, sample collection, filtering, sieving, incubation. Additional validation may be required for those functions if they are not integral to the CMD and sold as part of the device.

3.6 Depending on the intended use of the device, the manufacturers' claims and specifications may vary; as such CMDs may not measure all groups of organisms as described in paragraph 3.2, and may use differing measurement approaches (i.e. direct measurement comparable to the D-2 standard, indirect measurement not directly comparable to the performance standard or a binary "pass/fail" designation). This protocol is designed to determine devices' data quality, as well as the ability of devices to operate effectively within the environment they have been designed for use in. A CMD should be verified following this protocol only for the group(s) of organisms it is intended to quantify, as per the manufacturer's specifications. Likewise, if the manufacturer of a CMD indicates there are restrictions on its use (for example, it is intended only for use in fresh water), the device should be tested under the stated limiting conditions. Otherwise, it should be tested in accordance with the full matrix of laboratory and field testing, as described in sections 4 to 6 and shown in tables 1 and 2.

3.7 The diverse biological communities and water quality conditions required for BWMS certification testing should also be used to verify the performance of these devices. However, if specific variables are known or suspected to affect the performance of a device (e.g. water temperature, the ship's electrical noise or residual chemicals in ballast water), they should also be included as test parameters in verification testing.

3.8 All verifications of ballast water CMDs should be conducted by an independent, third-party testing entity (having implemented a rigorous quality assurance/quality control programme, e.g. in accordance with ISO/IEC 17025 or equivalent, that is approved, certified and audited by an independent accreditation body) and include expert review of specific test plans. The expert should be independent of the team involved in the verification of the CMD and have documented competences and experiences with knowledge and understanding of the enumeration of biological parameters and of the quality assurance approval of detailed analysis procedures being used as referenced in this protocol. The specific test plans/protocols and final reports should be approved by the testing entity.

3.9 For a given make and model of CMD, one unit should be randomly selected for testing, and the same unit should be used in all verification testing (laboratory and field), which should take place over several weeks to months.

3.10 BWMS that make use of ultraviolet irradiation (UV) or Active Substances have been identified as the two dominant technology types. These technology types are referred to throughout this protocol as the basis for ensuring the suitability of the CMD for use against the range of BWMS that may be encountered. It is acknowledged that new and novel BWMS technology types may be developed and as such consideration should be given to these new technologies when verifying a CMD for use with water treated by BWMS. The principles outlined within this protocol should be applied and any methods utilized to assess water treated by a novel BWMS technology type should be consistent with the aims and purpose of this protocol.

3.11 When considering the verification of a novel CMD, benchmarking against standard reference methods (direct counts), similar to the approach detailed in the *Procedure for approving other methods of ballast water management in accordance with regulation B-3.7 of the BWM Convention* (resolution MEPC.206(62), as may be amended), should be adopted. Any deviation from this protocol should be described and an equivalent level of confidence in the verification of the CMD ensured based on the parameters outlined in section 4.

3.12 Where the protocol references a standard that is not directly related to the verification of compliance monitoring devices, those undertaking the verification should refer only to the sections of the referenced standard that are relevant to the process or methodology that is being referred to in this protocol. It should be noted that a range of standards may be relevant to the methods in this protocol and could be considered appropriate for use. Where this protocol references a standard, other equivalent standards may be used or referred to in place of the referenced document.

4 Verification testing parameters

4.1 This protocol is designed to evaluate the performance or capability of a CMD to detect non-compliance with the performance standard within the performance claims of the device manufacturer. The CMD is evaluated as suitable or appropriate for its final use (i.e. detection of non-compliance with the performance standard) if the verification criteria listed in paragraph 8.4 are fulfilled.

4.2 At a minimum, the performance of a given make and model of a CMD should be verified based on measures of the following parameters under varying conditions that represent the device's intended use. The minimum parameters are described in this section and in tables 1 and 2.

4.3 Trueness – A measure of the closeness of agreement between a value obtained from a series of test results and an agreed reference standard value under multiple salinities, communities and concentrations of organisms, and other water quality parameters that may influence device performance (e.g. temperature, optical clarity). For these verifications, the trueness of the CMD should be determined in controlled laboratory tests and field tests. Repeated comparisons between a device's measurements and a reference standard (described below) should be completed; a minimum of three replicate test measurements at each test condition type, or the appropriate level of replication to ensure statistical confidence, are needed.

4.4 Precision – A measure of the repeatability of a measurement. The precision of an individual device should be determined under controlled laboratory tests. The standard deviation should be calculated from a minimum of 10 consecutive measurements of a reference solution under stable conditions (or the appropriate level of replication to ensure statistical confidence). This process should be repeated for multiple relevant conditions. For example, if the CMD claims to measure concentrations of organisms at the D-2 standard, then precision should be measured at a concentration similar to the performance standard.

4.5 Detection limits (also known as quantification limits) – The instrument or method detection limit of an individual device is the lowest (and, if applicable, the highest) value that can be detected with an acceptable level of confidence. Detection limits should be determined in controlled laboratory tests by quantifying the signal-to-noise ratio. Here, repeated (minimum of three, or the appropriate level of replication to ensure statistical confidence) measurements are made at low concentrations (at and below the D-2 standard) and of blanks (known zero), and the minimum concentration at which the known value can be quantified with a signal-to-noise ratio of 10:1 is determined.

4.6 Reliability – The ability to maintain integrity or stability of the CMD and data collection over time. Reliability of instruments should be determined in two ways from the data collected during all laboratory and field tests. First, comparisons should be made of the percentage of data points collected as a proportion of the data that the device was intended to have collected over a set period of time. Second, the percentage of time, and total number of times, that the device operated/functioned as designed without interruption or non-scheduled maintenance, calibration or repair should be reported. Comments on the physical condition of the device (e.g. physical damage, flooding, corrosion, battery failure, etc.) should also be recorded. Instruments should be tested and used in accordance with the manufacturers' instructions for calibration, operation and maintenance, and the reliability should be determined considering these time periods. When applicable, e.g. for in-line devices in continuous use, direct measures to assess drift over time should be collected.

4.7 Aspects of usability/vulnerability – the degree to which the CMD is fit for its intended use within the environments it is likely to encounter. Table 2 outlines the parameters that may form a part of the usability and vulnerability assessments which may be determined through field and laboratory testing. Unless the CMD is being verified against usability claims made by the manufacturer, the assessment is subjective in its nature and as such qualitative assessments of the CMD's performance can be used to provide an indication of the usability of the device.

5 Reference standard and verification protocol

5.1 While the true concentration of viable organisms in discharged ballast water is often unknown, accepted detailed analysis methods for quantifying viable organism concentrations are available. Methods used in type approving BWMS and identified in the *Code for Approval of Ballast Water Management Systems* (BWMS Code, resolution MEPC.300(72), as may be amended) and the *Guidance on methodologies that may be used for enumerating viable organisms* (BWM.2/Circ.61/Rev.1, as may be amended) should be used. When determining a suitable reference standard for use in verifying the performance of the CMD, consideration should be given to those identified within the BWMS Code. There is a range of available reference standards, each with associated uncertainties, and not all reference standards will be applicable to every device.

5.2 To maximize both the value and the harmonization of device testing, individual verification protocols should:

.1 be drafted separately for each specific type, or make and model, of CMD (e.g. to enumerate the group(s) of organisms the device is intended to quantify);

.2 be based on existing and accepted practices for instrument and method testing; and

.3 include independent expert review of test protocols.

6 Experimental design

6.1 Tests should be conducted in laboratory and field settings. All tests should be conducted (1) with sample volumes consistent with those required by the CMD and (2) with representative samples of the group(s) of organisms intended to be quantified by the device.

6.2 The range of tests undertaken should be designed to verify the ability of the CMD, taking into consideration the claims made by the manufacturer, including any limitations to the scope of the device's operation, to assess non-compliance with regulation D-2 of the BWM Convention. The experimental design should assess any claims made by the manufacturer with regard to interactions between the device and the treatment technologies being used to produce the treated water.

6.3 The laboratory tests should consist of tests using both treated and untreated water, such that the CMD is tested against samples with high and low organism concentrations, including a mixture of live and dead individuals in the same sample. The samples used for laboratory tests should be collected from a natural water source, containing a mix of ambient aquatic organisms (natural assemblages). The untreated test water should meet the salinity, dissolved organic carbon (DOC), particulate organic carbon (POC) and total suspended solid (TSS) thresholds for each of the three salinities (as prescribed in the BWMS Code) in which the device is to be verified (table 1). Where ambient water is unable to meet the set challenge criteria, the ambient water can be concentrated or augmented to achieve the minimum criteria, at which point the challenge water becomes "prepared challenge water"; therefore, ambient challenge water can only be used if it meets the set challenge criteria without concentration or augmentation. The organism concentrations may be adjusted to ensure a robust mix of species and an adequate range of organism concentrations to bracket the D-2 standard (described below).

6.4 The device should be tested as per the manufacturer's claims; however, where no claims are stated with regard to treatment technology interactions or suitability to address potential interferences caused by the treatment technology, the device should be tested with UV-treated challenge water and with challenge water treated using the most commonly used active substance. The treated water used should reflect typical treatment dosages as used in type-approved, commercially available BWMS. If no manufacturer claims are made and the previously mentioned testing is completed, the use of UV and most common active substance should be clearly stated in the CMD test report.

6.5 The field tests are practicability tests undertaken to assess the ability of the device to work under real-life conditions, including a demonstration of producing true and reliable results in an onboard environment or at the location of the intended use of the device. They should be designed around the intended use of the device. The parameters against which the CMD is assessed should include, but not be limited to, those detailed in table 2, as is appropriate to the intended use of the device. Field tests are undertaken within a shipboard environment and/or at locations appropriate to the stated intended use and application of the device. During field tests, treated discharged water from a functioning BWMS (with no manipulation or augmentation) should be tested. Where the intended use of the CMD does not include a shipboard environment, treated water, appropriate to the environment associated with the intended use of the CMD, should be tested.

6.6 During both laboratory and field tests any treated water used should be produced by a type-approved BWMS and the provenance (type of treatment, holding times, dosages, etc.) of the treated water should be documented. If a type-approved BWMS is not used to produce the treated water used during testing, reasons for this should be explained and the treatment of the water should replicate, as close as possible, the processes undertaken by a BWMS.

Reference standards

6.7 In all tests (laboratory and field), the results of the CMD should be compared to an accepted reference method using direct counts for enumerating viable organisms that is relevant to the device being tested, as described in section 5.

6.8 For each analysis day or group of analyses, the results of the CMD should be validated by a positive control (ISO 10993-10:2010) or a calibration through a calibration standard (ASTM D1129), and a negative control (ISO 10993-10:2010).

Laboratory tests using prepared challenge water

6.9 The use of local ambient organisms is favoured but laboratory cultures of organisms of the appropriate size and species variety and diversity may be used in order to ensure the appropriate level of organism concentration and "challenge" or to improve the diversity of organisms present. The addition of cultured organisms is also considered acceptable when the number of organisms present, before and/or after the treatment of the prepared challenge water, is close to the detection limits or standard thresholds of the device. For consistency at a given laboratory, healthy ambient or cultures of organisms (e.g. phytoplankton cultures in exponential growth phase) should be used, and a minimum of three diverse species (e.g. from three higher taxa) should be tested together in a mixture.

6.10 In order to ensure a sufficient level of challenge, when using cultured organisms, the following should be considered: (i) diversity of species used (minimum three species), representing all groups of organisms that the CMD is designed for; (ii) the resistance of organisms to treatment; (iii) organism concentrations; and (iv) whether the ratio of organisms

should reflect natural/harbour waters. The BWMS Code requirements for challenge water should be referred to. If cultured test organisms are used, local applicable quarantine regulations should be taken into consideration during culturing and discharge.

6.11 It is appreciated that laboratory testing with cultures of toxicogenic strains of *Vibrio cholerae* is challenging and requires specific safety and handling conditions and procedures. However, if the CMD is designed to quantify toxicogenic *V. cholerae*, prepared challenge water laboratory testing is critical, since toxicogenic *V. cholerae* are rarely found in ambient waters or during shipboard type approval testing.

6.12 For each group of organisms, a dilution series should be created using filtered seawater or fresh water with the appropriate salinity. The dilution process should be completed following an internationally accepted standard. Each dilution series should have at least three, but preferably five, concentrations of organisms, with the concentrations created by diluting or concentrating the organism mix so that the dilution series brackets above and below the discharge standard. This step, and all other steps in preparing the challenge water, should be done carefully to minimize organism mortality and loss. The highest concentration of organisms should be at least 5x greater than the discharge standard (to ensure linearity measurements for devices that do not have pass/fail outputs). The verification report should state all organism concentrations tested.

6.13 The DOC, POC and TSS should be adjusted in the challenge water to meet the minimum thresholds in the BWMS Code for a given salinity. Temperature should not be manipulated, but it should be measured and reported.

6.14 The treated water should be prepared from the challenge water, as described above. If testing with two treatment technology types, as opposed to testing against the claims made by the manufacturer, if it is not possible to test one of those two treatment types in the laboratory, the treatment type not tested in the laboratory should be tested during field tests.

Laboratory tests using ambient challenge water

6.15 Ambient challenge water should not be manipulated to dilute or concentrate organisms, or manipulate temperature, salinity, DOC, POC and TSS. While these parameters should be measured and reported, ambient challenge water should simply be natural concentrations of organisms and natural conditions of physical and chemical parameters.

6.16 To characterize the ambient challenge water, it should be analysed for the concentration and taxonomic composition of organisms. That is, species should be identified to the lowest possible taxonomic level, e.g. species, genus or family. Recognizing that devices may have species-specific biases, the purpose of this step is to demonstrate the diversity of organisms that are quantified by the CMD by using waters containing various organisms. This step should be done using an accepted method or microscopy; it is not intended to be performed with the CMD.

Field tests

6.17 When verifying trueness and reliability during field tests:

.1 at least three tests should be conducted with treated discharged water from a functioning and type-approved BWMS (the type of treatment should be reported) (see paragraph 2.7 for definition or paragraph 6.5 for field test criteria). The three tests should be conducted on separate ballast water

samples having variability in water quality parameters (e.g. different salinity or organism assemblages). In this type of testing, measurements of intake water are not required;

.2 the treated discharged water should be analysed for the concentration and taxonomic composition of organisms as in paragraph 6.16 and the reliability of the CMD should be evaluated for use under real-world conditions; and

.3 in the three field tests, only trueness (table 2) and reliability (paragraph 6.7) should be quantified, under conditions of the device's intended use.

6.18 To assess the practicability of the CMD, field tests should ensure that the device is able to operate in the static and dynamic conditions that may be experienced on board a ship or, as appropriate, the location of the intended use of the device. To assess the suitability of the device, the aspects of usability parameters that form the field test should be identified depending on whether the device is designed to be portable or to be a permanent installation. Parameters may be tested in situ on board a ship or, as appropriate, at the location of the intended use of the device, e.g. operability and readability of the device in a real-life situation, or within a laboratory, e.g. intrinsic safety, vibration testing, waterproof testing. The matrix of field test parameters (table 2) may be used as a basis for identifying parameters that should be assessed.

6.19 Where applicable, field test parameters should be assessed against any success criteria set and/or claims made by the manufacturer.

6.20 When assessing aspects of usability, it is acknowledged that some are subjective assessments of the device's practicability for use within its intended environment. These subjective assessments should only be used as an indicator for the practicability of the device's use as different users will have differing needs with regard to the usability aspects of a device, for example the need for two people to carry the equipment should not necessarily lead to a "fail".

6.21 When reporting on the outcome of these tests, the environmental conditions under which the tests were conducted should be recorded and commented on within the test report. The report should also include problems that occurred, along with any maintenance/repair information to help assess reliability and usability.

6.22 The results of this assessment should be used in order to provide an indication of the device's suitability within the location of the intended use of the device.

Ancillary data

6.23 At a minimum, water temperature, salinity (or conductance), pH and TSS should be measured in all laboratory and field tests. If possible, DOC and POC should be measured, as well as any other additional water quality parameters that are suspected to influence the performance of the CMD.

6.24 If the CMD performance claims are limited to monitoring treated water from specific BWMS technology types, this should be specified.

6.25 The evaluation of treated discharges should consider the effect of chemical/physical interferences, as applicable.

6.26 Verification testing should include evaluation of false positives and/or negatives.

Trueness, precision and detection limits

6.27 For these three parameters, the conditions for the laboratory tests and field tests are shown in tables 1 and 2 below. In all cases, the measurement/assessment of organism concentration that is collected by the CMD should be compared to the reference standard, and the appropriate statistical analysis should be conducted. Note that, if the manufacturer claims the CMD can measure concentrations well below the discharge standard, additional dilutions may be needed.

6.28 The measurements used to determine precision and detection limits (the last two rows of table 1) may be taken from the samples prepared for trueness testing, thereby reducing the total number of tests.

6.29 The applicable ISO standards should be used when determining trueness and precision.

Reliability tests

6.30 The reliability of the CMD should be determined as in paragraph 4.6 using data collected in all tests and specifically under the conditions of intended use (e.g. controlled laboratory bench top, field conditions on board a ship). First, reliability should be calculated as the percentage of data points collected as a proportion of the data that the device was intended to have collected over a given period of time. Second, reliability should also be calculated as the percentage of time, and total number of times, that the device operated as designed for each sample tested without interruption or requiring non-scheduled maintenance, calibration or repair. Third, the physical condition of the device (e.g. any physical damage, flooding, corrosion, battery failure) should be documented (e.g. with notes and photographs) and reported.

6.31 An applicable internationally recognized standard should be used when determining reliability.

Testing for viable/non-viable organisms

6.32 If a manufacturer claims that the CMD is able to distinguish between viable and non-viable organisms, this should be assessed using the appropriate methodology for the device being tested. Methods that may be employed to quantify viable organism concentrations have been provided within the BWMS Code.

Additional tests

6.33 The research and development stage of the device design should have ensured the suitability of the equipment for the environment in which its use is intended. Assessment or verification of product design considerations, including standard principles when considering the use of a piece of equipment for the shipboard environment, i.e. intrinsic safety, waterproofing, temperature tolerance, vibration, humidity, power supply consistency, robustness/durability of the CMD, etc., is required.

Parameter	Test type	Salinity	Minimum replicate measurements per group of organisms								
			Microbes			≥ 10 and < 50 µm			≥ 50 µm		
Trueness	Untreated prepared challenge water	Fresh	<DS n≥3	≈DS n≥3	>DS n≥3	<DS n≥3	≈DS n≥3	>DS n≥3	<DS n≥3	≈DS n≥3	>DS n≥3
		Brackish	<DS n≥3	≈DS n≥3	>DS n≥3	<DS n≥3	≈DS n≥3	>DS n≥3	<DS n≥3	≈DS n≥3	>DS n≥3
		Marine	<DS n≥3	≈DS n≥3	>DS n≥3	<DS n≥3	≈DS n≥3	>DS n≥3	<DS n≥3	≈DS n≥3	>DS n≥3
	Untreated ambient challenge water	Fresh	n≥3			n≥3			n≥3		
		Brackish	n≥3			n≥3			n≥3		
		Marine	n≥3			n≥3			n≥3		
	Treated water (for each tested technology type)	Fresh	n≥3			n≥3			n≥3		
		Brackish	n≥3			n≥3			n≥3		
		Marine	n≥3			n≥3			n≥3		
Precision	Prepared challenge water (treated and untreated)	1 salinity (different from the detection limits test)	Against the manufacturer's claims n≥10								
Detection limits	Prepared challenge water (treated and untreated)	1 salinity (different from the precision test)	Against the manufacturer's minimum and maximum claims n≥3								

Table 1: Matrix of verification tests for ballast water compliance monitoring devices

Note 1: The range of tests undertaken should reflect any claims made by the manufacturer; the full suite of tests represented by this table is only needed for a device that claims to (1) quantify all groups of organisms in the D-2 performance standard and (2) operate in all three salinities.

Note 2: Trueness testing is only needed for either prepared or ambient challenge water (as applicable) and treated water.

Note 3: The table indicates the minimum recommended level of replication that is needed for a statistically robust analysis.

Note 4: For the tests to calculate trueness and detection limits, the bracketing of the performance (discharge) standard is represented by <DS, ≈DS, and >DS to indicate below, approximately equal to, and above the discharge standard, respectively.

Note 5: Salinity ranges are to be as follows: fresh (<1 PSU), brackish (10-20 PSU), marine (28-36 PSU).

Table 2: Field test parameter matrix

Location of intended use / **Parameter**	On board a ship		Other
	Portable	Permanently installed	
Trueness according to the claim of the manufacturer, ≥3 replicates	✓	✓	✓
Reliability according to the claim of the manufacturer, ≥3 replicates	✓	✓	✓
Aspects of usability			
Is the device easy to set up for taking a measurement?	✓	-	(✓)
Can the display be easily read (with respect to light conditions, contrast, brightness, reflections, vibrations and temperature)?	✓	(✓)	✓
Is the device easy to transport to the location of use (weight, size, shape, volume)?	✓	-	(✓)
Is the device easy to operate (buttons, menu dialogues, command dialogues, user guidance)?	✓	✓	✓
Does the device have adequate power supply for taking measurements at the location of use (battery conditions, power consumption, battery life)?	✓	✓	✓
Other usability aspects	(✓)	(✓)	(✓)
Are the measurement outputs tamper-proof?	✓	✓	✓
Is the device easy to maintain?	✓	✓	✓
Vulnerability with respect to environmental aspects			
Humidity (display failure, electrical fault, etc.)	✓*	✓	(✓)
Vibrations (electrical fault, etc.)	✓*	✓	(✓)
Air temperature (result drift, display failure, battery life, etc.)	✓*	✓	(✓)

✓ = General requirement (✓) = If applicable - = Not applicable
* = Required but results from the research and development stage of the device design (paragraph 6.33) may be substituted

7 Data and quality management

7.1 The independent testing entity should follow standard/accepted data management and analysis procedures. For example, data logs should be recorded throughout testing, copied, or duplicated and archived daily. The datasheets should be signed by the analyst upon completion, verified by a quality officer and stored until the data are manually logged into a

digital file. Data reported by the CMD should be manually transcribed on formatted data sheets and, if applicable, logged by the device itself. Additionally, data from other analyses should be recorded in standard formats, such as data-collection forms, bound and paginated laboratory and field notebooks, spreadsheets and electronic data files.

7.2 Specific data analyses should be conducted as prescribed in individual device test plans. For example, trueness should be measured relative to the reference method using a standard approach (e.g. per cent difference), and precision should be measured as the variation among replicate readings and subsamples.

7.3 All testing should occur at facilities with a rigorous quality assurance/quality control programme for laboratory activities (such as ISO/IEC 17025) that has been approved, certified and audited by an independent accreditation body. A test plan and standard operating procedures should be followed while conducting all tests.

7.4 The test plan should include procedures to ensure quality results, as appropriate.

7.5 For at least one randomly chosen subsample per test, two analysts should aliquot, distribute, process and analyse the same sample using the CMD. Readings differing by ≤ 25% are considered within typical variation. Likewise, the variation of the reference method used should be quantified and reported in this manner.

8 Reporting

Test report

8.1 The test report should:

.1 include the following elements:

.1 a statement of verification;

.2 an executive summary;

.3 a description of the technology undergoing verification;

.4 details of the test design for laboratory and field tests (as applicable); and

.5 annexes to provide additional information or data;

.2 include the specific information, where applicable, outlined in the example verification reporting format in the annex to this protocol;

.3 follow the format provided in the annex to this protocol; and

.4 be made available to the public.

8.2 A list of CMDs that have been verified in accordance with this protocol can be found at https://bwema.org. Any CMD manufacturers who wish their verified equipment to be included in this list should provide the relevant information via the URL above.

Verification criteria

8.3 A CMD being verified as a valid CMD by this testing protocol should assure the end users that the CMD is able to function as claimed. If performance is poor, troubleshooting may be required.

8.4 For this purpose, a list of verification success criteria should be provided by the manufacturer and agreed as appropriate by the testing facility. This list should include, as a minimum, the criteria below, which the CMD should, as a minimum, be able to meet:

.1 precision (repeatability): it might be assessed as the coefficient of variance (CV). A CV of less than 25% is considered as acceptable, while a CV of less than 10% indicates excellent repeatability;

.2 reliability: it might be assessed as the percentage of data recovered compared to the data that the device was intended to have collected over a set period of time. A per cent value >90% is considered as acceptable. Comments on the physical condition of the device (e.g. physical damage, flooding, corrosion, battery failure) should also be recorded. Instruments should be tested and used in accordance with the manufacturers' instructions for calibration, operation and maintenance; and

.3 agreement between CMD results and detailed analysis results: at least 80% of the CMD results should be in agreement with the conclusion given by the corresponding detailed analysis results regarding the results being in compliance or not with the D-2 discharge standard.

8.5 The measurement uncertainty (ISO TS 21748:2010) for both detailed and indicative analysis should be quantified, reported and taken into consideration for the comparison.

9 References

ASTM D1129 Standard Terminology Relating to Water

BWM.2/Circ.61/Rev.1 *2022 Guidance on methodologies that may be used for enumerating viable organisms*

International Convention for the Control and Management of Ships' Ballast Water and Sediments, 2004

ISO/IEC 17025 Testing and calibration laboratories

ISO 10993-10:2010 Tests for irritation and skin sensitization

ISO 21748:2010 Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation

MEPC.206(62) *Procedure for approving other methods of ballast water management in accordance with regulation B-3.7 of the BWM Convention*

MEPC.300(72) *Code for Approval of Ballast Water Management Systems*

ANNEX

VERIFICATION REPORT

The verification report should include, as applicable, the following information:

1 Statement of verification

A clear statement declaring whether or not the device passed (or failed) all verification tests to the agreed standard, including the type of evaluation(s) undertaken (laboratory, field testing or both) and any limitations of the device and its operation.

This section should also include:

- the name of the organization or individual making the statement of verification;
- the date and location at which verification was confirmed;
- the name of the organization providing testing facilities (if different than the organization making the statement);
- a description (manufacturer name, make and model) of the device that has been verified;
- details of any limitations of the verification (BWMS technology, organism sizes, deviations from verification criteria in paragraph 8.4); and
- a statement that the report is freely available to the public.

2 Executive summary

A high-level overview of the verification criteria tests undertaken, the objectives of the tests, the results gained and conclusions drawn.

3 Description of technology

Details of the device undergoing verification. This should include:

- manufacturer;
- model, including serial number and software version number (as applicable);
- operational claims made by the manufacturer; and
- limitations declared by the manufacturer.

4 Test design

This section should outline the objectives of the tests undertaken and include details of the criteria, including any claims made by the manufacturer, against which the device was tested. The experimental design and methodologies used should be described and relevant information provided as required to indicate adherence to this protocol. The following information is required:

- **Laboratory testing**

  - Name of testing organization(s) and any lead or primary personnel
  - Test facility accreditation status and standards, quality assurance and quality control programme(s) as a list and/or table of contents
  - Details of the calibration status of equipment used during testing, including details of certificates and calibration intervals
  - Location and dates of tests
  - Details of the tests undertaken, including descriptions of all verification criteria used and levels of replication
  - Information regarding challenge and ambient water used for testing, including:
    - Source and location of ambient water
    - Volumes used for testing
    - Water quality parameters analysed (including water temperature, salinity, DOC, POC, TSS and any other additional water quality parameters identified in the experimental design)
    - Description of biological community in the test water (organism size, diversity and relative abundances)
    - Details of any augmentation or concentration methods, including any natural organism assemblages (i.e. ≥50 µm or ≥10 to <50 µm) or cultured organisms added (i.e. species used)

  - Details of treated water
    - BWMS make and model or process used to produce treated water (as applicable)
    - Treatment type, including details of active substance type, as applicable
    - Water quality parameters analysed (including water temperature, salinity, DOC, POC, TSS and any other additional water quality parameters identified in the experimental design)
    - Applied treatment doses

  - Sample collection and processing methods in line with paragraph 6.1 of this protocol, including volumes collected, handling prior to analysis (i.e. condition of transportation and holding times) and volumes of samples used for analysis
  - Details of reference methods used
  - References to any applied standards
  - Details of failures or unexpected results or scenarios and actions taken
  - Results / outcomes for parameters as required by the protocol or claimed by the manufacturer
  - Discussion, including any implications of any findings
  - Conclusions

- **Field testing**

  - Name of testing organization(s) and any lead or primary personnel
  - Details of facility accreditation status and standards, quality assurance and quality control programme(s) as a list and/or table of contents
  - Details of the calibration status of equipment used during testing
  - Location(s), date(s) and ship(s) from which samples were taken
  - Location, date and time that tests were undertaken
  - Details of ballast water origin, including
    - Source location

        - Details of the BWMS type and model
        - Whether or not ballast water exchange has taken place
        - Description of biological community in the sample(s) (organism size, diversity and relative abundances)
        - Water quality parameters analysed (including water temperature, salinity, DOC, POC, TSS and any other additional water quality parameters identified in the experimental design)
    - Sample collection and processing methods, in line with paragraph 6.1 of this protocol, including volumes collected, handling prior to analysis (i.e. condition of transportation, storage conditions such as temperature and light shielding property and holding times) and volumes of samples used for analysis
    - Details of the tests undertaken, including descriptions of all verification criteria used and levels of replication
    - Details of reference methods used
    - References to any applied standards
    - Treated water quality parameters (e.g. temperature, salinity, DOC, POC, TSS, organisms present)
    - Environmental conditions including air temperature, water temperature, humidity, vibration, salinity, pH, TSS and any other additional water quality parameters that are suspected to influence the performance of the CMD
    - An assessment of the aspects of usability and vulnerability of the device, including any operational or technological factors as detailed in the protocol, including photographs
    - Details of failures, unexpected results or scenarios, or deviations from standard operating procedures and actions taken
    - Condition of the device, including any damage, wear and tear, battery status, software failures or any notable observations resulting from use of the device during field tests (including photographic evidence)
    - Results/outcomes for parameters as required by the protocol or claimed by the manufacturer
    - Discussion, including any implications of any findings
    - Conclusions

Annexes

Additional information to support the detail provided within the body of the verification report should include:

- Quality assurance/quality control documentation as a list and including details of how documentation can be accessed; this should include a URL that provides direct access to the documentation
- Standard operating procedures, either in full or as a list of documents that can be provided upon request
- Details of the calibration of the CMD
- Raw data
- Data logged by the device (as applicable)
- Any sample and sample handling guidelines
- Instructions/operating manual for device use, as provided by the manufacturer