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Ships and marine technology — Aquatic nuisance species — Methods for evaluating the performance of compliance monitoring devices for ballast water discharges

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 8, *Ships and marine technology*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

A compliance monitoring device (CMD) is an instrument intended to analyse samples of ballast water, to estimate whether the concentration of living or viable organisms present in the sample exceeds, or is at risk of exceeding, the regulated limit [i.e. the discharge standard, (DS)]. Typically, CMDs are designed for use in shipboard and field locations to provide results rapidly and with less effort relative to complex analyses. CMDs are instruments that are relatively new to their application in ballast water testing. They can rely upon standard optical, chemical, or physical measurements, but these technologies are deployed in unique configurations. They can be packaged in a rugged, transportable housing, or installed as shipboard equipment. A CMD may operate along a spectrum of water types with diverse assemblages of organisms. As intended, CMDs provide critical information to vessel inspectors, ballast water management system (BWMS) commissioning test teams, Port State Control Officers, ship owners, among others.

This document was developed in response to the need for a standardized approach to evaluate the performance of CMDs. This evaluation includes:

— laboratory-based tests using prepared sample water amended with cultured organisms as well as dissolved and particulate materials;

— laboratory-based tests using samples of natural assemblages of organisms, experimentally manipulated to achieve target concentrations of living or viable organisms (but without manipulation of dissolved and particulate materials);

NOTE 1 It is recognized that the end user can require laboratory testing with ambient organisms instead of, or in addition to, cultured organisms. Additionally, the end user can require that both types of laboratory-based tests are conducted using water that is treated by a BWMS or has undergone a simulated ballast water treatment, instead of, or in addition to, un-treated water.

— field-based tests using samples of water treated with a BWMS collected aboard a ship.

This standardized approach defines a general test procedure and minimum set of trials to evaluate the performance of a CMD. The key evaluation metrics are accuracy (hereafter, “trueness” - the agreement to a reference method), precision, and reliability. While a CMD may report numerical values or estimates of organism concentrations, trueness and precision are determined based upon the agreement between the CMD and reference method on the sample disposition (i.e. whether the sample meets or exceeds the DS).

NOTE 2 This approach is not appropriate to evaluate methods or devices intended to be used as an alternate to the reference method, i.e. with precise, numerical measurements across a wide range of organism concentrations.

The test methods are adaptable, such that additional factors which are deemed important — e.g. interferences, organism types, or water characteristics — may be addressed experimentally and included in the set of performance metrics. This flexibility allows end-users to supplement these minimal test requirements to examine additional characteristics, such as CMD performance under different types of BWMS treatments.

Ships and marine technology — Aquatic nuisance species — Methods for evaluating the performance of compliance monitoring devices for ballast water discharges

1 Scope

This document specifies methods to evaluate the performance of a specific class of analytical instruments, known as compliance monitoring devices (CMDs). These instruments are designed and intended to examine ballast water to determine whether a sample meets or exceeds limits for the concentration of living or viable organisms. These limits include those specified by the International Maritime Organization (IMO) Regulation D-2 in the International Convention for the Control and Management of Ships' Ballast Water and Sediments[4] or other discharge standards (DS) adopted by national or regional authorities.

The test methods measure the agreement between the CMD and a reference method to calculate trueness and precision. Both trueness and precision consider only simple, categorical outcomes (e.g. "meets" or "exceeds" the DS). The performance metric reliability is quantified by the frequency of instances when the CMD is not available or is not operating as expected.

The set of tests and trials is based upon the CMD manufacturer claims, such as the DS group(s) targeted by the CMD, and known limitations, including those based upon the salinity of the sample water.

NOTE Additional tests and trials, if required by the end-user, can follow this general test method. Guidance on determining experimental power is found in 7.5. This document provides guidance for customizing the tests to evaluate the claims of the manufacturer or to address optional factors of interest to the end-users.

This document does not set or recommend success criteria of any performance metric, as these are appropriately defined by the end-users.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11711-1:2019, *Ships and marine technology — Aquatic nuisance species — Part 1: Ballast water discharge sample port*

ISO 11711-2:2022, *Ships and marine technology — Aquatic nuisance species — Part 2: Ballast water sample collection and handling*

ISO 21748, *Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty evaluation*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

ASTM D1141-98, *Standard Practice for Preparation of Substitute Ocean Water*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
accuracy
closeness of agreement between a test result and the accepted reference value

Note 1 to entry: The more specific term, *trueness* (3.24), is used as a metric throughout this standard.

[SOURCE: ISO 5725-1:1994, 3.6, modified — Note 1 to entry has been replaced.]

3.2
agreement
concurrence between two independent measurements on the outcome of analysis

Note 1 to entry: Analysis outcomes are qualitative or categorical descriptions of whether a sample meets or exceeds the *discharge standard* (3.13).

3.3
ambient water
natural water
water collected directly from the natural environment that 1) contains natural communities of organisms, dissolved and particulate constituents, and 2) has intrinsic characteristics, such as temperature and salinity

3.4
ballast water
water with its abiotic and biotic constituents taken on board a ship to control trim, list, stability or stresses of the ship

3.5
ballast water management system
BWMS
equipment that processes *ballast water* (3.4) such that the water discharged (the treated water) is intended to meet the specified performance requirements for eliminating, inactivating, or reducing aquatic organisms

3.6
calibration
analysis, in water, of standards to develop a relationship between raw output of an analytical system and analyte concentration

3.7
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

3.8
challenge water
water prepared or manipulated (e.g. by adding organisms and abiotic constituents) to achieve minimum test criteria when testing the performance of equipment, in this case *compliance monitoring devices* (3.11)

Note 1 to entry: This protocol shares some characteristics with the minimum water quality requirements for challenge water for *type approval testing* (3.25) of the International Maritime Organization and USA, such as salinity and temperature ranges and abiotic constituents. However, requirements for concentrations and diversity of organisms are unique to this application.

3.9
colonial organisms
collection of multiple, clonal individuals that are physically connected

Note 1 to entry: Clusters of connected, but non-clonal individuals are typically referred to as aggregated organisms.

3.10
compliance monitoring device
CMD
instrument and its associated analytical methodology typically used as a rapid assessment of the concentration of living or viable organisms in treated ballast water for the purpose of determining compliance or non-compliance with a *discharge standard* (3.13)

3.11
detection limit
method detection limit
lowermost quantity or concentration measurable by the *compliance monitoring device* (3.10)

Note 1 to entry: In the context of compliance monitoring device (CMD) evaluation, the detection limit is specified by the manufacturer. The CMD evaluation may include test samples with concentrations reflecting the stated detection limit to verify the *manufacturer claim* (3.16).

Note 2 to entry: In the context of *reference method* (3.21), the method detection limit is according to the definition in ISO/IEC Guide 99:2007.

3.12
dissolved organic matter
DOM
mass of organic compounds present in water that are not separated by particle (≤0,7 µm) filtration

Note 1 to entry: Dissolved organic carbon is a related quantity that is commonly measured directly. Although the two quantities are related, they are distinct and should be clearly identified.

3.13
discharge standard
DS
regulated limits of organism concentrations allowable in discharged ballast water

Note 1 to entry: Regulation D-2 of the International Maritime Organization's Ballast Water Management Convention.

Note 2 to entry: The term is generic unless a particular DS is specified.

Note 3 to entry: A DS is also known as a performance standard.

3.14
independent testing organization
testing organization that is free of any conflict of interest with the manufacturer of the *compliance monitoring device* (3.10)

3.15
living organism
organism that demonstrates characteristics of life (movement, membrane integrity, etc.)

Note 1 to entry: It is possible that living organisms are not *viable* (3.27).

3.16
manufacturer claims
specific characteristics of the *compliance monitoring device* (3.10) that are asserted by the manufacturer or vendor of the device

Note 1 to entry: Claims typically include the organisms size class(es) or indicator microbe(s) targeted by the device, limitations based upon organism characteristics (such as autotrophy), water temperature and salinity ranges, as well as the detection limits, accuracy, and precision of the compliance monitoring device.

3.17
mineral matter
MM
mass of inorganic compounds present in water and separated by particle (≤0,7 µm) filtration

Note 1 to entry: MM is estimated as the mass difference between *total suspended solids* (3.22) and *particulate organic matter* (3.18).

3.18
particulate organic matter
POM
mass of organic matter present in water and separated by particle (≤0,7 µm) filtration

Note 1 to entry: Particulate organic carbon is a related quantity and composes a portion of the mass of POM. Although the two quantities are related, they are distinct and should be clearly identified.

3.19
precision
agreement between replicate measurements of a sample measured under the same conditions

Note 1 to entry: The same conditions include the same sample, the same instrument unit, and the same analyst, if applicable.

3.20
reagent-grade, purified water
water meeting the characteristics of Type I or II water, used as the basis for preparing challenge water for laboratory testing

Note 1 to entry: The characteristics of Type I or II water are defined in ASTM D1193-06.

3.21
reference method
analytical method that produces a value used as a benchmark

Note 1 to entry: Reference methods produce direct measurements of numerical concentrations that are comparable to the *discharge standard* (3.13).

Note 2 to entry: Reference methods are typically methods used in *ballast water management system* (3.5) *type approval testing* (3.25).

3.22
total suspended solids
TSS
mass of organic and inorganic matter present in water and separated by particle (≤0,7 µm) filtration

Note 1 to entry: TSS is composed of mineral matter and particulate organic matter.

3.23
trial
complete set of samples and sample analyses associated with a single test condition, such as water salinity

3.24
trueness
closeness of agreement between the average value obtained from a large series of test results and an accepted reference value

[SOURCE: ISO 5725-1:1994, 3.7, modified — Notes 1 and 2 to entry have been deleted.]

3.25
type approval testing
testing performed as part of a formal certification of a *ballast water management system* (3.5) for use aboard ships

3.26
uncertainty
measurement uncertainty
parameter, associated with the result of a measurement, which characterizes the dispersion of the values that can reasonably be attributed to the measurand

[SOURCE: ISO 21748:2017, 3.14, modified — "measurement uncertainty" has been added as a preferred term; Notes 1, 2 and 3 to entry have been deleted.]

3.27
viable
living and capable of reproduction

Note 1 to entry: Manufacturers shall indicate whether their *compliance monitoring device* (3.10) quantifies living or viable organisms, and the test should be designed to evaluate their claims using the appropriate *reference method* (3.21) for living or viable organisms.

4 General

4.1 Compliance with the discharge standard

A compliance monitoring device (CMD) determines whether a sample is likely to comply with or exceed the discharge standard (DS), such as the IMO Regulation D-2[4] which sets limits on the concentration of viable organisms in the following size or taxonomic groups:

— organisms ≥50 µm in minimum dimension;

— organisms ≥10 µm and <50 µm in minimum dimension;

— toxicogenic *Vibrio cholerae* (serotypes O1 and O139);

— *Escherichia coli;*

— intestinal enterococci.

NOTE National or regional authorities can define the same or similar categories and concentration limits.

The test methods described in this document are generic: the methods apply to any of the groups defined in the DS and the corresponding reference method used for each of those defined groups. This performance evaluation considers the claims of a CMD manufacturer, such as those defining the targeted group(s), the relevant DS e.g. References [4] and [5], and the stated limitations, such as limits on the salinity of the sample water.

4.2 Reference method

A reference method is an analytical approach used to quantify living or viable organisms in one of the categories of a DS (see 4.1). Typically, the reference method is used during type approval (TA) tests, such as those prescribed in the test protocols of the IMO[6] or the United States.[7] In general, a reference

method estimates numerical concentrations of living or viable organisms in a single category of DS. Consequently, each category examined requires a unique set of measurements using the appropriate reference method.

The numerical results from the reference method shall be reported with estimates of measurement uncertainty, which shall be determined in accordance with the approaches described in ISO 21748. Numerical values shall also be converted to one of three categorical values: "meets the DS", "exceeds the DS", or "indeterminant", which considers the ranges of values with a 95 % confidence interval of the measurement (see 5.1). This conversion permits a direct comparison between the CMD and the reference method.

4.3 Challenge water

Challenge water — as defined in this document — is similar to the "challenge water" used for TA testing.[6][7] Challenge water for CMD testing is only used in the subset of laboratory trials designed to evaluate the CMD performance under standardized and simplified conditions. The salinity of challenge water is either fresh (<1 g kg^{-1}),[1)] brackish (10 g kg^{-1} to 20 g kg^{-1}), or marine (28 g kg^{-1} to 36 g kg^{-1}), and it may be prepared from natural waters or with purified water amended with sea salts according to ASTM D1141-98.

Challenge water consists of abiotic characteristics, defined as minimum concentrations of dissolved organic matter (DOM), particulate organic matter (POM), and mineral matter (MM) and total suspended solids (TSS), as defined in TA test protocols.[6][7]

NOTE For other trials, including laboratory tests using ambient water, the salinity, DOM, POM, MM, and TSS are measured but not manipulated.

For the purpose evaluating the performance of CMD, abiotic challenge water components are as defined in TA test protocols,[6][7] but requirements for organism concentrations and diversity are specific to this test protocol and are defined in 4.4 and 6.2.

4.4 Test concentrations of organisms

The concentrations of living or viable organisms are defined relative to the DS. Concentrations below, approximately equal to, and above the DS are most relevant to this performance evaluation, and the target ranges ensure that samples meeting and exceeding the DS are included in the evaluation.

Target ranges are at a minimum defined below:

— below: >0 % and <50 % the DS;

— approximately equal to: ±50 % the DS;

— above: >150 % and <1 000 % the DS.

Concentrations below the DS shall be non-zero and measurable by the reference method (i.e. > limit of quantification).

NOTE 1 At concentrations 50 % of the DS (e.g. ≤4 organisms ml^{-1}), the probability that a random sample will have ≤9 organisms ml^{-1} is > 99 %. Likewise, at concentrations >150 % of DS, e.g. ≥16 organisms ml^{-1}, the probability that a random sample will have ≥ 11 organisms ml^{-1} is >95 %.

NOTE 2 Additional concentrations can be added, provided that both concentrations above and below the DS are included in the evaluation.

1) Salinity is reported here as g kg^{-1}, which for the purposes of this test protocol is approximately equivalent to Practical Salinity Units (PSU)[5].