



GUIDANCE NOTES
GD 21-2017

CHINA CLASSIFICATION SOCIETY

GUIDELINES FOR TYPE APPROVAL OF SHIP'S
BALLAST WATER MANAGEMENT SYSTEMS
2017

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CHAPTER 1 GENERAL

1.1 Objectives

1.1.1 The approval procedures and requirements for assessing whether ship's ballast water management systems meet the standards as set out in regulation D-2 of the Convention are given in the Guidelines. In addition, the Guidelines can be used as guidance for manufacturers and shipowners on the evaluation procedure that equipment will undergo and requirements placed on ballast water management systems.

1.1.2 The Guidelines include general requirements concerning design and construction, technical procedures for evaluation and the procedure for issuance of the Type Approval Certificate of the ballast water management system. The Guidelines also contain recommendations regarding the design, installation, performance, testing and approval of ballast water management systems. The purposes of the Guidelines are to:

- (1) provide interpretation of test and performance requirements for the approval of ballast water management systems;
- (2) assist in determining appropriate design, construction and operational parameters necessary for the approval of ballast water management systems;
- (3) provide a uniform interpretation and application of the requirements of regulation D-3 of the Convention;
- (4) provide guidance to equipment manufacturers and shipowners in determining the suitability of equipment to meet the requirements of the Convention;
- (5) assure that approved ballast water management systems are capable of achieving the standard of regulation D-2 of the Convention in land-based and shipboard evaluations and will not cause unacceptable harm to the ship, crew, the environment or public health;
- (6) provide guidance to Type Approval of ballast water management systems.

1.2 Scope of application

1.2.1 The Guidelines apply to the approval of ballast water management systems in accordance with the Convention.

1.2.2 Special requirements of the Administration (if any) are to be satisfied.

1.3 Basis of the Guidelines

The Guidelines are based on the following documents:

- (1) International Convention for the Control and Management of Ships' Ballast Water and Sediments, 2004 of IMO;

- (2) Resolution MEPC.279(70)— 2016 Guidelines for approval of ballast water management systems (G8);
- (3) Resolution MEPC.169(57)—Procedure for approval of ballast water management systems that make use of active substances (G9), as revised;
- (4) BWM.2-Circ.33— Guidance on scaling of ballast water management systems;
- (5) BWM.2-Circ.61—Guidance on methodologies that may be used for enumerating viable organisms for type approval of ballast water management systems;
- (6) CCS Rules for Classification of Sea-going Steel Ships.

1.4 Ballast water performance standard

Regulation D-2 of the Convention stipulates that the ballast water performance standard (D-2 Standard) meeting the requirements of the Convention is as follows:

- (1) less than 10 viable organisms per cubic metre greater than or equal to 50 micrometres in minimum dimension;
- (2) less than 10 viable organisms per millilitre less than 50 micrometres in minimum dimension and greater than or equal to 10 micrometres in minimum dimension; and
- (3) less than the following concentrations of indicator microbes, as a human health standard:
 - ① Toxicogenic *Vibrio cholerae* (serotypes O1 and O139) with less than 1 Colony Forming Unit (cfu) per 100 millilitres or less than 1 cfu per 1 gramme (wet weight) of zooplankton samples;
 - ② *Escherichia coli* less than 250 cfu per 100 millilitres; and
 - ③ Intestinal Enterococci less than 100 cfu per 100 millilitres.

1.5 Definitions

For the purpose of the Guidelines, the following definitions apply:

- (1) *Active Substance* means a substance or organism, including a virus or a fungus that has a general or specific action on or against harmful aquatic organisms and pathogens.
- (2) *Ballast Water Management System (BWMS)* means any system which processes ballast water such that it meets or exceeds the ballast water performance standard in regulation D-2. The BWMS includes ballast water treatment equipment, all associated control equipment, piping arrangements as specified by the manufacturer, control and monitoring equipment and sampling facilities. BWMS does not include the ship's ballast water fittings, which may include piping, valves, pumps, etc., that would be required if the BWMS was not fitted.
- (3) *The Ballast Water Management Plan* is the document referred to in regulation B-1 of the Convention describing the ballast water management process and procedures implemented on board individual ships.

(4) *Ballast Water Treatment Equipment* means equipment which mechanically, physically, chemically or biologically processes, either singularly or in combination, to remove, render harmless, or avoid the uptake or discharge of harmful aquatic organisms and pathogens within ballast water and sediments. Ballast water treatment equipment may operate at the uptake or discharge of ballast water, during the voyage, or at a combination of these events.

(5) *Control and Monitoring Equipment* means the equipment installed for the effective operation and control of the BWMS and the assessment of its effective operation.

(6) *The Convention* means the International Convention for the Control and Management of Ships' Ballast Water and Sediments, 2004.

(7) *Major Components* mean those components that directly affect the ability of the system to meet the ballast water performance standard described in regulation D-2.

(8) *Sampling Facilities* refer to the means provided for sampling treated or untreated ballast water as needed in the Guidelines and in the Guidelines for Ballast Water Sampling (G2) developed by IMO.

(9) *Shipboard Testing* is a full-scale test of a complete BWMS carried out on board a ship according to Chapter 9 of the Guidelines, to confirm that the system meets the standards set by regulation D-2 of the Convention.

(10) *Land-based Testing* is a test of the BWMS carried out in a laboratory, equipment factory or pilot plant including a moored test barge or test ship, according to the requirements of Chapter 7 of the Guidelines, to confirm that the BWMS meets the standards set by regulation D-2 of the Convention.

(11) *Treatment Rated Capacity (TRC)* means the maximum continuous capacity expressed in cubic metres per hour for which the BWMS is type approved. It states the amount of ballast water that can be treated per unit time by the BWMS to meet the standard in regulation D-2 of the Convention. The TRC is to be measured at the inlet of the BWMS.

(12) *Viable organisms* mean organisms that have the ability to successfully generate new individuals in order to reproduce the species.

(13) *Basic Approval* means the approval of Active Substances or Preparations used in prototype tests or Type Approval tests in accordance with their usage. Basic Approval is to confirm that the available information does not indicate possible unacceptable adverse effects or a potential for unreasonable risk to environment, human health, property or resources. This is to include consideration of potential risks during full-scale tests on commercial ships when possible.

(14) *Final Approval* means the approval of a ballast water management system using an Active Substance or Preparation to comply with the Convention and includes a review of the Type Approval tests in accordance with Guidelines for approval of ballast water management systems (G8). The Final Approval is to confirm that previous evaluations of risks to ship, crew and the environment including storage, handling and application of Active Substances or Preparations remain valid and the concerns expressed during the Basic Approval process have been addressed, as well as that the residual toxicity of the discharge conforms to the evaluation undertaken for Basic Approval. The risk evaluation at Final Approval is to take qualitatively into account cumulative effects that may occur due to the nature of shipping and port operations. The uncertainties involved in the application for approval is to be considered during the Final Approval process, and advice on how these uncertainties can be dealt with is to be provided as appropriate.

(15) *Representative sampling* means sampling that reflects the relative concentrations (chemicals) and numbers and composition of the populations (organisms) in the volume of interest. Samples are to be taken in a time-integrated manner and the sampling facility is to be installed in accordance with the annex, Part 1 of the Guidelines on Ballast Water Sampling (G2).

(16) *Test* means the set of required test cycles.

(17) *Test cycle* refers to one testing iteration (to include uptake, treatment, holding and discharge as appropriate) under a given set of requirements used to establish the ability of a BWMS to meet the set standards.

(18) *Valid test cycle* means a test cycle in which all the required test conditions and arrangements, including challenge conditions, test control and monitoring arrangements (including piping, mechanical and electrical provisions) and test analytical procedures were achieved by the testing organization.

(19) *Invalid test cycle* is a test cycle in which, due to circumstances outside the control of the BWMS, the requirements for a valid test cycle are not met. When a test cycle is invalid, it does not count as one of the required consecutive test cycles in a test and the test can be continued.

(20) *Failed test cycle* is a valid test cycle in which the performance of the BWMS resulted in treated water that is determined to be non-compliant with the standard set within regulation D-2. A failed test cycle interrupts the required consecutive test cycles and terminates the test.

(21) *Successful test cycle* means a valid test cycle where the BWMS functions to its specifications and treated water is determined to meet the performance standard described in regulation D-2.

(22) *System Design Limitations of a BWMS* means the water quality and operational parameters, determined in addition to the required type approval testing parameters, that are important to its operation, and, for each such parameter, a low and/or a high value for which the BWMS is designed to achieve the performance standard of regulation D-2. The System Design Limitations are to be specific to the processes being employed by the BWMS and are not to be limited to parameters otherwise assessed as part of the type approval process. The System Design Limitations are to be identified by the manufacturer and validated under the supervision of CCS in accordance with the Guidelines.

CHAPTER 2 REQUIREMENTS FOR THE APPROVAL OF BALLAST WATER MANAGEMENT SYSTEMS

2.1 Overview

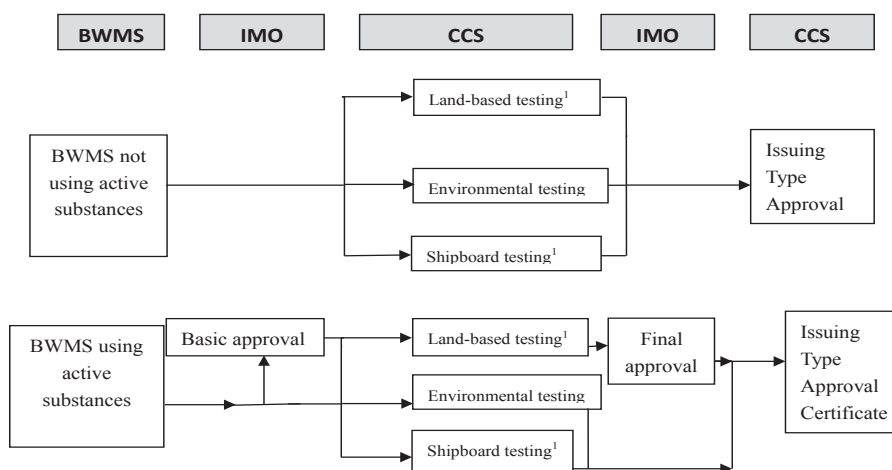
2.1.1 In addition to being type approved, a ballast water management system using and/or producing active substances defined in 1.5(1) is to be submitted to IMO in accordance with regulation D-3.2 of the Convention, and to be evaluated and approved by IMO in accordance with Procedure for Approval of Ballast Water Management Systems that make use of active substances (G9), in order to determine the application of active substances in the system is acceptable to ship safety, human health and the aquatic environment.

2.1.2 For the ballast water management system using and/or producing active substances, the Type Approval Certificate can only be issued after the system has obtained Final Approval of IMO and been type approved.

2.1.3 Special requirements of the Administration (if any) are to be satisfied.

2.2 Approval procedures for ship's ballast water management systems

2.2.1 Figures 1 is a flowchart for the approval of ship's ballast water management systems using and not using active substances. For ballast water management systems using active substances, applications submitted to IMO are subject to Basic Approval and Final Approval, and specific application and approval procedures are to be carried out in accordance with IMO G9 and provisions of the Administration concerned. For ballast water management systems not using and/or producing active substances as confirmed by evaluation, and having passed environmental acceptability assessment carried out by the Administration or the authorized organization, applications may not be submitted to IMO.



Note: 1 When there are provisions of the Administration, BWMS manufactures are to obtain written reply of the Administration on agreeing to type approval testing prior to requesting type approval service (including land-based testing and shipboard testing) by CCS.

Figure 1 Basic approval flow for ballast water management system

2.2.2 Manufacturers are to fully understand whether ship's ballast water management systems intended to apply for Type Approval belong to systems using and/or producing active substances as defined by 1.5(1). If there is any uncertainty, manufacturers are to consult the Administration concerned or CCS before applying for Type Approval so as to arrange various tests and the sequence and timetable of Type Approval and submission to IMO for approval (Basic Approval and Final Approval) in a reasonable manner.

2.2.3 Manufacturers may decide the sequence of applying for Type Approval and submitting to IMO proposals for Basic Approval/Final Approval taking into account the preparation. However, attention is to be given to the relation and correlation between IMO G8 and G9, in particular:

(1) generally, shipboard testing of Type Approval is to be carried out after obtaining Basic Approval from IMO. Where Type Approval is requested before obtaining Basic Approval from IMO, the results of land-based testing will be invalid in case the ballast water management system fails to obtain Basic Approval from IMO. Manufacturers are to be aware of the potential risks due to Type Approval carried out before obtaining Basic Approval from IMO and take the possible consequences;

(2) when applying for IMO's Final Approval, data of toxicity tests of discharged water after being treated by land-based testing equipment in Type Approval are to be submitted.

2.2.4 In the case of ballast water management systems that do not make use of Active Substances or Preparations, but which could reasonably be expected to result in changes to the chemical composition of the treated water such that adverse impacts to receiving waters might occur upon discharge, the documentation concerning results of toxicity tests of treated water as described in 7.4.9 of the Guidelines is to be submitted.

CHAPTER 3 PROCEDURES OF TYPE APPROVAL AND CERTIFICATION

3.1 Application for type approval

3.1.1 Manufacturers of ballast water management systems (the applicants for type approval service) are generally to submit application for CCS service in writing, including product specification and usage, acceptance standard, service time, inspection safety condition, payment arrangement contact information, etc. The applicants may also use Notification of Approval Service (see Appendix 2) recommended by CCS. CCS is to confirm the application in an appropriate way and notify relevant CCS requirements to the applicants after receiving the application for product approval service.

3.1.2 When submitting the application for approval service, the manufactures are also to submit following information:

- (1) technical characteristics of product;
- (2) drawings and technical documents of relevant products and manufacturing technology, including technological processes;
- (3) type approval test program;
- (4) suppliers' list of raw material and main components and parts for product;
- (5) quality assurance system files, including quality manual, procedures of quality control for relevant product, main manufacturing equipment, inspection and test device;
- (6) other valid documents, reports and certificates which could demonstrate the client's production capability of the product within the approval scope and its quality level;
- (7) enterprise registration certificate, business license, qualification certificate and/or production certificate (if any);
- (8) nameplate, identification card, operation instructions, quality certificate of marine product which has been inspected by CCS (including criteria, product property, quality assurance, responsibility, etc.) are to be compiled in the language stipulated by the ordering party. For ships engaged on international voyages, at least English is to be used;
- (9) other information deemed necessary by CCS;
- (10) written reply of the Administration on agreeing to carry out type approval (if required by the Administration).

3.2 Plans and technical documents

3.2.1 Manufacturers are to submit plans and technical documents regarding the design, construction, operation and functioning of the BWMS in accordance with 5.1 of Chapter 5 of the Guidelines, including information regarding the water quality and operational parameters that are important to the operation of the system.

3.2.2 CCS approval of the submitted plans and technical documents as part of the approval process well in advance of the intended approval testing of a BWMS is to be a pre-requisite for carrying out independent approval tests. Plans revised in the process of prototype testing^① are to be re-submitted to CCS for approval.

3.2.3 Documentation is to be provided by the manufacturer/developer for two primary purposes: evaluating the readiness of the BWMS for undergoing approval testing, and evaluating the manufacturer's proposed System Design Limitations and validation procedures.

3.3 Approval testing

3.3.1 Approval testing of a BWMS includes land-based testing, shipboard testing and environmental testing.

3.3.2 Prior to land-based testing and shipboard testing, CCS will carry out pre-test evaluation in accordance with the requirements of Chapter 6 of the Guidelines to confirm the rationality of the manufacturer's proposed test requirements and procedures for the test and check the readiness of the system for testing.

3.3.3 Land-based testing and shipboard testing are to be carried out respectively in accordance with the relevant requirements of Chapters 7 and 9 of the Guidelines.

3.3.4 Temperature assessment is to be carried out during approval testing:

(1) The effective performance of BWMS through a ballast water temperature range of 0°C to 40°C (2°C to 40°C for fresh water) and a mid-range temperature of 10°C to 20°C is to be the subject of an assessment verified by CCS.

(2) This assessment may include:

- ① testing during land-based, shipboard, laboratory or bench-scale testing; and/or
- ② the use of existing data and/or models, provided that their source, suitability and reliability are reported.

(3) The report submitted to CCS is to contain all documentation (including procedures, methods, data, models, results, explanations and remarks) associated with the temperature assessment. The report is to include at least the information identified in 3.4.2 of this Chapter.

3.3.5 Regrowth evaluation is to be carried out during approval testing:

(1) The evaluation of the regrowth of organisms is to be undertaken to the satisfaction of the Administration in land-based and/or shipboard testing in at least two test cycles in each salinity.

(2) In the case of land-based testing being performed with a holding time of less than five days, a sufficient volume of treated uptake water is to be held under conditions similar to conditions in the relevant holding tank. In the case of shipboard testing, water is to be retained on board for the evaluation of regrowth during a shipboard test cycle. Additional bench-scale testing may be used to supplement the land-based and/or shipboard testing.

① It is the prototype testing defined in Chapter 3, PART ONE of CCS Rules for Classification of Sea-going Steel Ships.

- (3) In the case of a BWMS that includes mechanical, physical, chemical and/or biological processes intended to kill, render harmless or remove organisms within ballast water at the time of discharge or continuously between the time of uptake and discharge, regrowth is to be assessed in accordance with Chapters 7 and 9 of the Guidelines with a holding time of at least five days.
- (4) Otherwise, the enumeration of organisms to assess regrowth is to be undertaken at least five days after the completion of all of the mechanical, physical, chemical and/or biological processes intended to kill, render harmless or remove organisms within ballast water.
- (5) Any neutralization of ballast water required by the BWMS is to occur at the end of the holding time, and immediately before the enumeration of organisms.
- (6) The evaluation of regrowth is not intended to evaluate contamination in ballast tanks or piping, such as may arise from the presence of untreated water or residual sediments
- (7) A report is to be submitted to CCS containing all documentation (including procedures, methods, data, models, results, explanations and remarks) associated with the evaluation of regrowth. The report is to include at least the information identified in 3.4.2 of this Chapter.

3.4 Reporting of test results

3.4.1 After approval tests have been completed, a report is to be submitted to CCS. This report is to include information regarding the test design, methods of analysis and the results of these analyses for each test cycle (including invalid test cycles), BWMS maintenance logs and any observed effects of the BWMS on the ballast system of the ship (e.g. pumps, pipes, tanks, valves). Shipboard test reports are to include information on the total and continuous operating time of the BWMS.

3.4.2 The reports submitted are to contain at least the following information:

- (1) the name and address of the laboratory performing or supervising the inspections, tests or evaluations, and its national accreditation or quality management certification, if appropriate;
- (2) the name of the manufacturer;
- (3) the trade name, product designation (such as model numbers) and a detailed description of the equipment or material inspected, tested or evaluated;
- (4) the time, date and place of each approval inspection, test or evaluation;
- (5) the name and title of each person performing, supervising and witnessing the tests and evaluations;
- (6) executive summary;
- (7) introduction and background;
- (8) for each test cycle, inspection or evaluation conducted, summary descriptions of:
 - ① experimental design;

- ② methods and procedures;
 - ③ results and discussion, including a description of any invalid test cycle and a comparison to the expected performance; and
 - ④ in the case of land-based testing, test conditions including details on challenge water preparation in line with 7.5.2 of the Guidelines;
- (9) a description or photographs of the procedures and apparatus used in the inspections, tests or evaluation, or a reference to another document that contains an appropriate description or photographs;
- (10) at least one photograph that shows an overall view of the equipment or material tested, inspected or evaluated and other photographs that show:
- ① design details; and
 - ② each occurrence of damage or deformation to the equipment or material that occurred during the approval tests or evaluations;
- (11) the operational safety requirements of the BWMS and all safety related findings that have been made during the inspections, tests or evaluations;
- (12) an attestation that the inspections, tests or evaluations were conducted as required and that the report contains no known errors, omissions, or false statements. The attestation must be signed by:
- ① the manufacturer or manufacturer's representative, if the inspection, tests or evaluations are conducted by the manufacturer; or
 - ② the chief officer of the laboratory, or the chief officer's representative, if the Inspection or tests were conducted by an independent laboratory;
- (13) appendices, including:
- ① the complete test plan and the data generated during tests and evaluations reported under subparagraph (8) above, including at least:
 - a. for land-based tests, whether ambient, cultured or a mixture of test organisms have been used (including a species-level identification for cultured organisms, and an identification to the lowest possible taxonomic level for ambient organisms);
 - b. for shipboard tests, the operating parameters of the system during successful treatment operations (e.g. dosage rates, ultraviolet intensity and the energy consumption of the BWMS under normal or tested Treatment Rated Capacity, if available);
 - c. for System Design Limitations, details of all procedures, methods, data, models, results, explanations and remarks, leading to validation; and
 - d. invalid test information;

- ② the QMP, the QAPP, the TQAP and Quality Assurance and Quality Control records mentioned in 6.2.2 of the Guidelines;
- ③ maintenance logs including a record of any consumable components that were replaced; and
- ④ relevant records and tests results maintained or produced during testing.

3.4.3 The results of biological efficacy testing of the BWMS are to be accepted if during the land-based and shipboard testing conducted as specified in Chapters 7 and 9 of the Guidelines, it is shown that the system has met the standard in regulation D-2 and that the uptake water quality requirements were met in all individual test cycles as provided in 4.5.7 of the Guidelines.

3.4.4 The test report is to include all test runs during land-based and shipboard tests, including failed and invalid tests with the explanation required in 9.4.12(4) of the Guidelines for both shipboard and land-based tests.

3.4.5 In the case of a BWMS that was previously type-approved by CCS taking into account the resolution MEPC.174(58), the manufacturer, in seeking a new type approval under the Guidelines, is only to be requested to submit the additional test reports and documentation.

3.5 Issuance of certificate

3.5.1 A BWMS which in every respect fulfils the requirements of the Guidelines is approved by CCS by means of issuing a Type Approval Certificate of BWMS.

3.5.2 With reference to Chapter 2 of the Guidelines for the approval procedures for BWMS, for BWMS not using active substances, if land-based testing, shipboard testing and environmental testing are completed and they are found in compliance with the relevant requirements of the Guidelines, a Type Approval Certificate of BWMS is issued by CCS. For systems using active substances, in addition to completing land-based testing, shipboard testing and environmental testing and being compliant with the relevant requirements of the Guidelines, a Type Approval Certificate of BWMS is issued by CCS after the Final Approval is obtained from IMO.

3.5.3 A Type Approval Certificate of BWMS is issued for the specific application for which the BWMS is approved, e.g., for specific ballast water capacities, flow rates, salinity or temperature regimes, or other limiting conditions or circumstances as appropriate. The Approval Certificate will specify the main particulars of the apparatus and any limiting conditions on its usage necessary to ensure its proper performance. Refer to Appendix 1 for the format of the Certificate. A copy of the Type Approval Certificate of BWMS is to be carried on board ships fitted with such a system at all times.

3.5.4 The limitations of the BWMS, in addition to the required type approval testing parameters identified in 7.5.1 and 3.3.4(1) of the Guidelines, as submitted by its manufacturer and validated by CCS, are to be documented on the Type Approval Certificate. These design limitations do not determine if the equipment may be type approved or not, but provide information on the conditions beyond the type approval testing parameters under which proper functioning of the equipment can be expected.

3.5.5 The Type Approval Certificate of BWMS is to:

- (1) identify the type and model of the BWMS to which it applies and identify equipment assembly drawings, duly dated;
- (2) identify pertinent drawings bearing model specification numbers or equivalent identification details;
- (3) include a reference to the full performance test protocol on which it is based;
- (4) identify all conditions and limitations for the installation of BWMS on board the ship;
- (5) include the System Design Limitations, which are to be listed under the heading “This equipment has been designed for operation in the following conditions”;
- (6) include any restrictions imposed by CCS due to the minimum holding time or in accordance with 3.2.3(4) of the Guidelines; such restrictions are to include any applicable environmental conditions (e.g. UV transmittance, etc.) and/or system operational parameters (e.g. min/max pressure, pressure differentials, min/max Total Residual Oxidants (TRO) if applicable, etc.); and
- (7) an appendix containing test results of each land-based and shipboard test run. Such test results are to include at least the numerical salinity, temperature, flow rates, and where appropriate UV transmittance. In addition, these test results are to include all other relevant variables. The Type Approval Certificate is to list any identified system design limitation parameters.

3.5.6 The System Design Limitations are to be specified on the Type Approval Certificate in a table that identifies each water quality and operational parameter together with the validated low and/or high parameter values for which the BWMS is designed to achieve the ballast water performance standard described in regulation D-2.

3.5.7 The issued Type Approval Certificate is to include each and every basic unit and scaled system if the scaling is done according to Chapter 8 of the Guidelines.

3.5.8 In order to obtain the approval for the installation on board of approved BWMSs, the manufacturer is also to submit request for product inspection service as well as operations, maintenance and safety manuals of the BWMS to CCS. CCS is to carry out product inspection in accordance with the approved inspection scheme. Upon satisfactory completion of the inspection, a Certificate of marine products is to be issued.

3.6 Type approval report

3.6.1 According to the requirements of IMO, BWMS type approval report approved by or authorized by the Administration is to be submitted to IMO and made available to the public and Member States by an appropriate means.

3.6.2 BWMS manufacturers are to submit documents in accordance with the requirements of the Administration or the organization authorized by the Administration, and assist the Administration to complete type approval report. Type approval report is to contain at least:

- (1) information on the type approval of the BWMS, including:
 - ① the approval date;

- ② the name of the Administration;
 - ③ the name of the manufacturer;
 - ④ the trade name and product designation (such as model numbers) of the BWMS; and
 - ⑤ a copy of the Type Approval Certificate including its appendices, annexes or other attachments;
- (2) an executive summary;
- (3) a description of the BWMS, including, in the case of BWMS using Active Substances, the following information:
- ① the name of the Active Substance(s) or Preparation employed; and
 - ② identification of the specific MEPC report and paragraph number granting Final Approval in accordance with G9;
- (4) an overview of the process undertaken by the Administration to evaluate the BWMS, including the name and role of each test facility, subcontractor and test organization involved in testing and approving the BWMS, the role of each report in the type approval decision, and a summary of the Administration's approach to overall quality assurance and quality control;
- (5) the executive summary of each test report prepared in accordance with 3.3.4(3), 3.3.5(7), 3.4.1, 3.4.2, 10.3.2 and 3.2.3(6) of the Guidelines;
- (6) the operational safety requirements of the BWMS and all safety related findings that have been made during the type approval process;
- (7) a discussion section explaining the Administration's assessment that the BWMS:
- ① in every respect fulfilled the requirements of the Guidelines, including demonstrating under the procedures and conditions specified for both land-based and shipboard testing that it met the ballast water performance standard of described in regulation D-2;
 - ② is designed and manufactured according to requirements and standards;
 - ③ is in compliance with all applicable requirements;
 - ④ has been approved taking into account the recommendations provided by the MEPC in the Final Approval of the BWMS, if any;
 - ⑤ operates within the System Design Limitations at the rated capacity, performance, and reliability as specified by the manufacturer;
 - ⑥ contains control and monitoring equipment that operates correctly;
 - ⑦ was installed in accordance with the technical installation specification of the manufacturer for all tests; and

- ⑧ was used to treat volumes and flow rates of ballast water during the shipboard tests consistent with the normal ballast operations of the ship; and

(8) the following annexes:

- ① appropriate information on quality control and assurance; and
- ② each complete test report prepared in accordance with 3.3.4(3), 3.3.5(7), 3.4.1, 3.4.2, 10.3.2 and 3.2.3(6) of the Guidelines.

3.6.3 The Administration is to redact proprietary information of the manufacturer from the type approval report before submitting it to IMO.

3.6.4 The Type Approval Certificate and the type approval report (including their entire contents and all annexes, appendices or other attachments) are to be accompanied by a translation into English, French or Spanish if not written in one of those languages.

3.6.5 Documents are not to be incorporated by reference into the Type Approval Certificate. The Administration may incorporate an annex by reference into the type approval report if the reference (e.g. Internet URL) is expected to remain permanently valid. Upon any reference becoming invalid, the Administration is to promptly re-submit the type approval report to IMO and include the referenced document or an updated reference to it; IMO is to promptly make the revised report available to the public and Member States through an appropriate means.

CHAPTER 4 GENERAL TECHNICAL REQUIREMENTS

4.1 Overview

4.1.1 This Chapter details the general technical requirements which a BWMS is to meet in order to obtain Type Approval.

4.1.2 A BWMS is to meet the performance standard specified in 1.4 of the Guidelines.

4.1.3 A BWMS must be safe in terms of the ship, its equipment and the crew.

4.1.4 The Guidelines stipulate the common technical requirements for a BWMS. The manufacturer is to analyze the risks and potential technical requirements of a BWMS in terms of ship and personnel safety, environmental acceptability, feasibility, biological efficacy and economy according to the applied technology.

4.1.5 A BWMS is to be effective in meeting the D-2 standard on short voyages and long voyages (i.e. short and long intervals between treatment and discharge), regardless of temperature, unless the system is intentionally constructed for use in specific waters.

4.1.6 Ballast water discharged following treatment is to be safe for the environment on short voyages and long voyages (i.e. short and long intervals between treatment and discharge), regardless of temperature.

4.1.7 The design of the BWMS is to account for the fact that, regardless of the BWMS technology employed, viable organisms remaining after treatment may reproduce in the interval between treatment and discharge.

4.1.8 The BWMS tested for type approval is to be a final and complete product that meets the requirements of this Chapter and it is to be constructed using the same materials and procedures that will be used to construct production units.

4.2 Ballast water management systems

4.2.1 The BWMS is to be designed and constructed:

- (1) for robust and suitable operation in the shipboard environment;
- (2) for the service for which it is intended;
- (3) to mitigate any danger to persons on board when installed. Equipment that could emit dangerous gases/liquids is to have at least two independent means of detection and shutdown of the BWMS (i.e. hazardous gas level reaching lower explosive limits (LEL) or level of toxic concentrations that can result in severe effects on human health); and
- (4) with materials compatible for the substances used, purpose which it is intended, the working conditions to which it will be subjected and the environmental conditions on board.

4.2.2 The BWMS is not to contain or use any substance of a dangerous nature, unless adequate arrangements for storage, application, mitigation, and safe handling, acceptable to CCS, are provided to mitigate any hazards introduced thereby.

4.2.3 Where dangerous and corrosive substances are used on board ships, due regard is to be given to the possible consequences of the leakage or accumulation of dangerous substances in failure conditions.

4.2.4 In case of any failure compromising the proper operation of the BWMS, audible and visual alarm signals are to be given in all stations from which ballast water operations are controlled.

4.2.5 All working parts of the BWMS that are liable to wear or to be damaged are to be easily accessible for maintenance. The routine maintenance of the BWMS and troubleshooting procedures are to be clearly defined by the manufacturer in the operating and maintenance manual. All maintenance and repairs are to be recorded.

4.2.6 To avoid interference with the BWMS, attention is to be given to the following items:

(1) every access of the BWMS beyond the essential requirements of 4.2.5, is to require the breaking of a seal;

(2) if applicable, the BWMS is to be so constructed that a visual alarm is always activated whenever the BWMS is in operation for purposes of cleaning, calibration or repair, and these events are to be recorded by the control and monitoring equipment;

(3) the BWMS is to be provided with the necessary connections to ensure that any bypass of the BWMS will activate an alarm, and that the bypass event is recorded by the control and monitoring equipment.

4.2.7 Facilities are to be provided for checking, at the renewal surveys and according to the manufacturer's instructions, the performance of the BWMS components that take measurements. A calibration certificate certifying the date of the last calibration check is to be retained on board for inspection purposes. Only the manufacturer or persons authorized by the manufacturer are to perform the accuracy checks.

4.2.8 The BWMS is not to endanger the health and safety of the crew, interact negatively with the ship's systems and cargo or produce any adverse environmental effects. The BWMS is not to create long term impacts on the safety of the ship and crew through corrosive effects in the ballast system and other spaces.

4.2.9 Ship's general equipment of the BWMS, such as pipes, valves, pumps, pressure vessels, electrical equipment, etc., is to be designed, manufactured and surveyed in accordance with the relevant international conventions and applicable parts in the rules and Guidelines for survey of marine products of CCS.

4.2.10 The design of the BWMS is to be such as to prevent major hazards to the ship, personnel and environment due to a single failure, for example:

(1) Flammable and explosive gases are to be emitted to safe open spaces.

(2) The generation and storage equipment of smothering gases such as inert gases, strong oxidizing gases such as ozone, is to meet the rules of the Society and recognized standards and is to be installed in designated spaces in so far as practicable. Drain pipes such as safety valves are to be led to safe open spaces.

4.2.11 The ballast water treatment equipment is to be provided with simple and effective means for its operation and control. It is to be provided with a control system that is to be such that the services needed for the proper operation of the ballast water treatment equipment are ensured through the necessary automatic arrangements.

4.2.12 The ballast water treatment equipment is, if intended to be fitted in hazardous areas, to comply with the relevant safety regulations for such spaces. Any electrical equipment that is part of the BWMS is to be based in a non-hazardous area, or is to comply with the relevant requirements of CCS rules for use in a hazardous area. Any moving parts, which are fitted in hazardous areas, is to be arranged so as to avoid the formation of static electricity.

4.2.13 It is to be demonstrated by using mathematical modelling and/or calculations, that any up or down scaling of the BWMS will not affect the functioning and effectiveness on board a ship of the type and size for which the equipment will be certified. In doing so, the manufacturer of the equipment is to take into account the requirements of Chapter 8 of the Guidelines.

4.2.14 Scaling information is to allow CCS to verify that any scaled model is at least as robust as the land-based-tested model. It is the responsibility of CCS to verify that the scaling used is appropriate for the operational design of the BWMS.

4.2.15 At a minimum, the shipboard test unit is to be of a capacity that allows for further validation of the mathematical modelling and/or calculations for scaling, and preferably selected at the upper limit of the rated capacity of the BWMS, unless otherwise approved by CCS.

4.3 Control and monitoring equipment

4.3.1 Type approved BWMS is to have a suitable control and monitoring system that will automatically monitor and record sufficient data to verify correct operation of the system. The control and monitoring equipment is to record the proper functioning or failure of the BWMS. Where practical, system design limitation parameters are to be monitored and recorded by the BWMS to ensure proper operation.

4.3.2 The BWMS is to incorporate control equipment that automatically monitors and adjusts necessary treatment dosages or intensities or other aspects of the BWMS of the vessel, which while not directly effecting treatment, are nonetheless required for proper administration of the necessary treatment. Characteristic parameters affecting ballast water treatment performance are to be identified and recorded, and protective means, such as alarm or stop of the operation, are to be provided.

4.3.3 The equipment is to be able to produce (e.g. display, print or export) a report of the applicable self-monitoring parameters in accordance with 4.4 of this Chapter for official inspections or maintenance, as required.

4.3.4 To facilitate compliance with regulation B-2 of the Convention, the control equipment is also to be able to store data for at least 24 months. In the event the control and monitoring equipment is replaced, means are to be provided to ensure the data recorded prior to replacement remains available on board for 24 months.

4.3.5 For BWMS that could emit dangerous gases, a means of gas detection by redundant safety systems is to be fitted in the space of the BWMS, and an audible and visual alarm is to be activated at a local area and at a manned BWMS control station in case of leakage. The gas detection device is to be designed and tested in accordance with IEC 60079-29-1, or other recognized standards acceptable to CCS. Monitoring measures for dangerous gases with independent shutdown is to be provided on the BWMS.

4.3.6 All software changes introduced to the system after the pre-test evaluation are to be done according to a change handling procedure ensuring traceability.

4.4 Self-monitoring

4.4.1 BWMS is to monitor and store a minimum number of parameters for detailed evaluation. In addition, all system indications and alerts are to be stored and available for inspection. Data storage and retrieval are to follow common standards. This Part gives an overview of the minimum required self-monitoring parameters.

4.4.2 The applicable self-monitoring parameters listed below are to be recorded for every BWMS^①. Any additional parameters that are necessary to ascertain system performance and safety are to be determined by CCS and stored in the system. If a parameter is not applicable due to the particulars of the system, CCS may waive the requirement to record that parameter. Limiting operating conditions on the operation of the BWMS are to be determined by the manufacturer and approved by CCS.

4.4.3 The information and applicable self-monitoring parameters to be recorded for all systems are to include, inter alia:

(1) general information: ship name, IMO number, BWMS manufacturer and type designation, BWMS serial number, date of BWMS installation on ship, BWMS treatment rated capacity (TRC), principle of treatment (in - line/ in- tank);

(2) operational parameters: all recorded parameters are to be time tagged if applicable: BWMS operational modes and any transition modes, including bypass operations (e.g. uptake, discharge, warming-up, cleaning and start up), ballast water pump in operation (yes/no – if information is available from ship), flow-rate at system outlet, Indication of the ballast water tank that is involved in the ballast water operation when practicable;

(3) it is recommended that positional information on ballast water operations and on the holding time be recorded automatically. Otherwise it is to be entered manually in the ballast water record book as appropriate. CCS encourages to apply automatic position information recording to ships which install BWMS during ship's building to the greatest extent possible;

(4) system alerts and indications: all systems are to have an alert regime. Every alert is to be logged and time stamped. To assist the inspections, it would be helpful to record an alert summary after each ballast water operation automatically, if possible;

(5) general alerts include: shutdown of system while in operation, when maintenance is required, BWMS bypass valve status, status of BWMS valves representing system operational mode as appropriate;

① Associated guidance for a template on technical details of the monitoring parameters and record intervals intended to be developed by IMO is to be taken into consideration.

(6) operational alerts: whenever a relevant parameter exceeds the acceptable range approved by CCS, the system are to give an alert. In addition, an alert is to be logged and time stamped also when a combination of relevant parameters exceeds system specifications, even if each single parameter does not exceed its approved range. If a safety relevant parameter (safety for crew, cargo and/or the ship) related to the BWMS exceeds approved limits, an alert/alarm is to be mandatory (e.g. hydrogen level at appropriate measurement point(s));

(7) CCS may require additional alerts depending on the design of the system and for future developments; and

(8) the System Design Limitation parameters and their corresponding data such as e.g. range, alarm limit, alert delay, etc. be password protected on a level above what is required for normal operation and maintenance, i.e. on a system administrator level. Change of any data or parameters which are password protected and interruption of the measurement (wire break, signal out of range) is to be automatically logged and retrievable on a maintenance access level.

4.4.4 Data storage and retrieval

(1) Storage of data is to follow the requirements taking into account 4.3.1 to 4.3.5 of the Guidelines. The equipment is to be able to store a minimum number of self-monitoring parameters following common standards determined by IMO.

(2) The control and monitoring equipment is to automatically record the proper functioning or failure of a BWMS without user interaction and add a time stamp to every entry. Additionally, the system is to have a tool to produce summary text files for each ballast water operation on demand to support inspections work.

(3) The system is to store the required data in an acceptable format to be able to display, print or export the data for official inspections. An acceptable format could be:

- ① an internationally standardized readable format (e.g. text format, pdf, MS Excel); or
- ② the extensible mark-up language (xml).

(4) The equipment is to be so designed that, as far as is practical, it will not be possible to manipulate either the data being stored by the system or the data which has already been recorded. Any attempt to interfere with the integrity of the data is to be recorded.

(5) Permanent deletion of recordings is not to be possible. The system is to be capable of storing recorded data for at least 24 months to facilitate compliance with regulation B-2 of the BWM Convention. Where navigation equipment is connected to the monitoring system to provide data for recording, the interfaces are to comply with applicable parts of International Standard IEC 61162.

4.5 Sample analysis methods for the determination of constituents in ballast water

4.5.1 Samples taken during testing of BWMS are likely to contain a wide taxonomic diversity of organisms, varying greatly in size and susceptibilities to damage from sampling and analysis.

4.5.2 When available, widely accepted standard methods for the collection, handling (including concentration), storage, and analysis of samples are to be used. These methods are to be clearly cited and described in test plans and reports. This includes methods for detecting, enumerating, and determining minimum dimension of and identifying organisms and for determining viability (as defined in the Guidelines).

4.5.3 When standard methods are not available for particular organisms or taxonomic groups, methods that are developed for use are to be described in detail in test plans and reports. The descriptive documentation is to include any experiments needed to validate the use of the methods.

4.5.4 Given the complexity in samples of natural and treated water, the required rarity of organisms in treated samples under regulation D-2, and the expense and time requirements of current standard methods, it is likely that several new approaches will be developed for the analyses of the composition, concentration, and viability of organisms in samples of ballast water.

4.5.5 Sample analysis is meant to determine the species composition and the number of viable organisms in the sample. Different samples may be taken for determination of viability and for species composition.

4.5.6 The viability of organisms is to be determined using a method that has been accepted by IMO as appropriate to the ballast water treatment technology being tested. Acceptable methods are to provide assurance that organisms not removed from ballast water have been killed or rendered harmless to the environment, human health, property and resources. Viability may be established by assessing the presence of one or more essential characteristics of life, such as structural integrity, metabolism, reproduction, motility, or response to stimuli.

4.5.7 A treatment test cycle is to be deemed successful if:

- (1) it is valid in accordance with 9.4.6 (shipboard) or 7.5.1, 7.5.2, 7.5.5 and 7.6.10 (land-based testing) of the Guidelines, as appropriate;
- (2) the density of organisms greater than or equal to 50 micrometres in minimum diameter in the replicate samples is less than 10 viable organisms per cubic metre;
- (3) the density of organisms less than 50 micrometres and greater than or equal to 10 micrometres in minimum diameter in the replicate samples is less than 10 viable organisms per millilitre;
- (4) the density of *Vibrio cholerae* (serotypes O1 and O139) is less than 1 cfu per 100 millilitres, or less than 1 cfu per 1 gramme (wet weight) zooplankton samples;
- (5) the density of *E. coli* in the replicate samples is less than 250 cfu per 100 millilitres;
- (6) the density of intestinal Enterococci in the replicate samples is less than 100 cfu per 100 millilitres; and
- (7) no averaging of test runs, or the discounting of failed test runs has occurred.

4.5.8 It is recommended that a non-exhaustive list of standard methods and innovative research techniques be considered^①. For the determination of the number of viable organisms in the sample, refer to BWM.2/Circ.61 Guidelines for Method of Counting Viable Microbes in BWMS Type Approval. It is to be noted that this circular may be updated by IMO.

4.5.9 Toxicity tests of the treated water discharge are to be conducted in accordance with paragraphs 5.2.3 to 5.2.7 of G9. Eco-toxicological acceptability of discharge is determined by means of sample analysis.

① Suggested sources may include but not be limited to:

- .1 The Handbook of Standard Methods for the Analysis of Water and Waste Water.
- .2 ISO standard methods.
- .3 UNESCO standard methods.
- .4 World Health Organization.
- .5 American Society of Testing and Materials (ASTM) standard methods.
- .6 United States EPA standard methods.
- .7 Research papers published in peer-reviewed scientific journals.
- .8 MEPC documents.

CHAPTER 5 DOCUMENTATION REQUIREMENTS FOR PRE-TEST EVALUATION

5.1 Drawings and technical documents to be submitted

5.1.1 The documentation may include specific information relevant to the test set-up to be used for land-based testing according to the Guidelines. Such information is to include the sampling needed to ensure proper functioning and any other relevant information needed to ensure proper evaluation of the efficacy and effects of the equipment. The information provided is also to address general compliance with applicable environment, health and safety standards during the type approval procedure.

5.1.2 The documentation to be submitted as a part of the readiness evaluation is to include at least the following drawings and technical documents in triplicate:

- (1) technical specification;
- (2) operation, maintenance and safety manuals;
- (3) information on hazard identification;
- (4) information regarding environmental and public health impacts;
- (5) information regarding System Design Limitations;
- (6) software change handling and revision control document;
- (7) functional description.

5.2 Detailed requirements for BWMS documentation

5.2.1 A BWMS technical specification, including at least:

- (1) a description of the BWMS and treatment processes it employs and details of any required permits;
- (2) adequate information including descriptions and diagrammatic drawings of the pumping and piping arrangements, electrical/electronic wiring, monitoring system, waste streams and sampling points. Such information is to enable fault finding;
- (3) details of major components and materials used (including certificates where appropriate);
- (4) an equipment list showing all components subject to testing including specifications, materials and serial numbers;
- (5) an installation specification in accordance with manufacturers installation criteria requirements for the location and mounting of components, arrangements for maintaining the integrity of the boundary between safe and hazardous spaces and the arrangement of the sample piping;

(6) information regarding the characteristics and arrangements in which the system is to be installed, including scope of the ships (sizes, types and operation) for which the system is intended. This information may form the link between the system and the ship's ballast water management plan; and

(7) a description of BWMS side streams (e.g. filtered material, centrifugal concentrate, waste or residual chemicals) including a description of the actions planned to properly manage and dispose of such wastes;

5.2.2 Operation, maintenance and safety manuals – These are to at least include:

(1) instructions for the correct operation of the BWMS, including procedures for the discharge of untreated water in the event of malfunction of the ballast water treatment equipment;

(2) instructions for the correct arrangement of the BWMS;

(3) maintenance and safety instructions and the need to keep records;

(4) trouble shooting procedures;

(5) emergency procedures necessary for securing the ship;

(6) any supplementary information considered necessary for the safe and efficient operation of the BWMS, e.g. documentation provided for approval under G9;

(7) calibration procedures;

5.2.3 Information on any hazard identification is to include:

(1) information on any hazard identification conducted to identify potential hazards and define appropriate control measures, if the BWMS or the storage tanks for processing chemicals could emit dangerous gases or liquids;

(2) appropriate risk assessment information on safe operation of BWMS required by 6.3.2(3) of the Guidelines.

5.2.4 Information regarding environmental and public health impacts, including:

(1) identification of potential hazards to the environment based on environmental studies performed to the extent necessary to assure that no harmful effects are to be expected;

(2) in the case of BWMS that make use of Active Substances or Preparations containing one or more Active Substances, the dosage of any Active Substances used and the maximum allowable discharge concentrations;

(3) in the case of BWMS that do not make use of Active Substances or Preparations, but which could reasonably be expected to result in changes to the chemical composition of the treated water such that adverse impacts to receiving waters might occur upon discharge, the documentation is to include results of toxicity tests of treated water as described in 7.4.9 of the Guidelines; and

(4) sufficient information to enable CCS to identify any potential health or environmental safety problems, unusual operating requirements (labor or materials), and any issues related to the disposal of treatment by products or waste streams.

5.2.5 Information regarding System Design Limitations, including:

- (1) the identification of all known parameters to which the design of the BWMS is sensitive;
- (2) for each parameter, the manufacturer is to claim a low and/or a high value for which the BWMS is capable of achieving the performance standard of regulation D-2; and
- (3) the proposed method for validating each claimed system design limitation is to be set out, together with information on the source, suitability and reliability of the method.

5.2.6 Software change handling and revision control document, including:

All software changes introduced to the system after the pre-test evaluation are to be done according to a change handling procedure ensuring traceability. Therefore, the manufacturer is to present a procedure describing how changes are to be handled and how revision control is maintained. As a minimum for a modification request, the following types of information are to be produced and logged:

- (1) reason for modification;
- (2) specification of the proposed change;
- (3) authorization of modification; and
- (4) test record.

5.2.7 Functional description including a textual description with necessary supporting drawings, diagrams and figures to cover:

- (1) system configuration and arrangement;
- (2) scope of supply;
- (3) system functionality covering control, monitoring, alarm and safety functions;
- (4) self-diagnostics and alarming functionalities; and
- (5) safe states for each function implemented.

CHAPTER 6 PRE-TEST EVALUATION

6.1 Testing program

6.1.1 Manufacturers are to develop approval testing programs in accordance with the Guidelines and submit the programs to CCS prior to approval testing. The testing program is to include at least the following:

- (1) rules and standards that the testing is based on;
- (2) selection of the prototype and verification of compliance;
- (3) the phyla/divisions intended to be added in the testing;
- (4) items of type approval testing and criteria for qualification;
- (5) testing methods and procedures;
- (6) diagram and specifications of sampling;
- (7) testing body, location and equipment;
- (8) qualification documentation of the laboratory.

6.1.2 The documentation is to include specific information relevant to the test set-up to be used for land-based testing according to 7.2 of Chapter 7 of the Guidelines. Such information is to include the sampling needed to ensure proper functioning and any other relevant information needed to ensure proper evaluation of the efficacy and effects of the equipment. The information provided is also to address general compliance with applicable environment, health and safety standards during the Type Approval procedure.

6.2 Quality Assurance and Quality Control Procedures

6.2.1 The testing facility is to demonstrate its competency in conducting valid type approval tests in two ways:

- (1) have implemented a rigorous quality control/quality assurance program, approved, certified and audited by an independent accreditation body, or to the satisfaction of CCS; and
- (2) be able to demonstrate its ability to conduct valid test cycles with appropriate challenge water, sample collection, sample analysis and method detection limits. It is the responsibility of CCS to determine the acceptability of the test facility.

6.2.2 The test facility's quality control/quality assurance program is to consist of:

- (1) a Quality Management Plan (QMP), which addresses the quality control management structure and policies of the testing body (including subcontractors and outside laboratories);

(2) a Quality Assurance Project Plan (QAPP), which defines the methods, procedures and quality assurance and quality control (QA/QC) protocols used by the test facility for testing BWMS in general. It identifies the test team members, and it includes all relevant standard operating procedures (SOPs), typically as appendices; and

(3) a Test/Quality Assurance Plan (TQAP), that provides specific details for conducting a test of a given BWMS at a given site and time. The TQAP includes detailed plans for commissioning the BWMS, the experimental plan, decommissioning, and reporting the results. The TQAP identifies all organizations involved in the test and includes the BWMS vendor's documentation and performance claims. The TQAP also identifies the data to be recorded, operational and challenge parameters that define a valid test cycle, data analyses to be presented in the verification report, and a schedule for testing. Appropriate statistical distributions are to be considered and used to analyze data.

6.2.3 The testing facility performing the BWMS tests is to be independent. It is not to be owned or affiliated with the manufacturer or vendor of any BWMS, by the manufacturer or supplier of the major components of that equipment.

6.3 Evaluation

6.3.1 CCS evaluates whether test requirements and procedures proposed by the manufacturer are reasonable and whether the BWMS is ready for the tests as well as System Design Limitations according to the documents submitted by the applicant for product approval service.

6.3.2 Readiness evaluation

(1) During the readiness evaluation, CCS is to ensure that each technical specification set out in 4.5 of the Guidelines has been met, other than those that will be assessed during later testing;

(2) The readiness evaluation is to examine the design and construction of the BWMS to determine whether there are any fundamental problems that might constrain the ability of the BWMS to manage ballast water as proposed by the manufacturer, or to operate safely, on board ships;

(3) CCS is to ensure adequate risk assessments including the implementation of preventative actions, have been undertaken relating to the safe operation of BWMS;

(4) As a first step, the manufacturer is to provide information regarding the requirements and procedures for installing, calibrating, and operating (including maintenance requirements) the BWMS during a test. This evaluation is to help the test organization to identify any potential health or environmental safety problems, unusual operating requirements (labor or materials) and any issues related to the disposal of treatment by-products or waste streams;

(5) The test facility is to have a procedure to deal with deviations that occur prior to testing and an evaluation process which includes an assessment and validation process to address any unforeseen deviations that may occur during testing. Deviations from the testing procedure are to be fully reported;

(6) During the readiness evaluation, the major components of the BWMS are to be identified. Major components are considered to be those components that directly affect the ability of the system to meet the performance standard described in regulation D-2. Upgrades or changes to major components are not to take place during type approval testing. A change to a major component is to require a new submission of the test proposal and involve a new evaluation and repeating of the land-based and shipboard tests;

(7) CCS may allow replacements of non-major components of equivalent specification (independently approved to a recognized and equal operational standard) during type approval. Replacements of non-major components during testing are to be reported;

(8) Upgrades of the BWMS that relate to the safe operation of that system may be allowed during and after type approval and are to be reported. If such safety upgrades directly affect the ability of the system to meet the standard described in regulation D-2, it is to be treated as a change of a major component, as per 6.3.1(1)⑥ above;

(9) The evaluation is to identify consumable components in the BWMS. CCS may allow replacement of like for like consumable components, during type approval testing and all replacements are to be reported.

6.3.3 System Design Limitation evaluation

(1) The System Design Limitation evaluation is to be undertaken by CCS. It is to assess the basis for the manufacturer's claim that the System Design Limitations include all known water quality and operational parameters to which the design of the BWMS is sensitive that are important to its ability to achieve the performance standard described in regulation D-2;

(2) CCS is also to evaluate the suitability and reliability of the methods proposed for validating the claimed low and/or high values for each System Design Limitation. These methods may include tests to be undertaken during land-based, shipboard or bench-scale testing and/or the use of appropriate existing data and/or models;

(3) The objective of the System Design Limitations approach is twofold. First, it ensures that the performance of the BWMS has been transparently assessed with respect to the known water quality and operational parameters that are important to its operation, including those that may not be specifically provided for in the Guidelines. Second, it provides transparent oversight of manufacturer BWMS performance claims that may go beyond specific criteria in the Guidelines. Although the validation of System Design Limitations yields transparent information that is reported on the Type Approval Certificate, this information does not affect the eligibility of a BWMS to receive type approval;

(4) The low and/or high parameter values for each system design limitation are to be validated to the satisfaction of CCS as follows:

- ① the validation is to be overseen by CCS and consist of a rigorous evidence-based assessment of a specific claim by the BWMS manufacturer that the equipment will operate as intended between pre-stated parameter values;
- ② tests to validate System Design Limitations are to be undertaken in accordance with 6.2 of the Guidelines. Such tests may be combined with land-based and/or shipboard testing if the QAPP establishes that the validation tests will not interfere with the specific procedures in Chapter 6 of the Guidelines. Laboratory or bench-scale testing may also be used in the validation of System Design Limitations;
- ③ methods other than testing, such as the use of existing data and/or models, may be used in the validation of System Design Limitations. The source, suitability and reliability of such methods are to be reported; and

- ④ validation is not intended as a stress-test of the BWMS or as a procedure for identifying equipment failure points. Validation is to be undertaken independently of the BWMS manufacturer and to be separate from BWMS research and development activities. Data and models may be supplied by manufacturer when appropriate but are to be independently assessed;
- (5) Claims of open-ended performance (expressed as the lack of either a low or a high parameter value for a system design limitation) are also to be validated.
- (6) BWMS manufacturers may include a margin of error in claiming System Design Limitations. For this reason, System Design Limitations are not to necessarily be interpreted as the exact parameter values beyond which the BWMS is incapable of operation. CCS is to take this into account in considering whether to include any additional restrictions on the Type Approval Certificate in connection with the validation of System Design Limitations;
- (7) System Design Limitations are to be established for all known parameters to which the design of the BWMS is sensitive that are important to the operation of the BWMS. In the case of system design limitation parameters that are also subject to specific criteria in Chapter 6 of the Guidelines, the procedure set out in Chapter 6 of the Guidelines is to be followed. For such parameters, the approach in (2) may be used only to the extent that the performance claim goes beyond the specific criteria in Chapter 6 of the Guideline;
- (8) A report is to be submitted to CCS containing all documentation (including procedures, methods, data, models, results, explanations and remarks) associated with the validation of System Design Limitations. The report is to include at least the information identified in 3.4.2 of the Guidelines;
- (9) For various ballast water treatment technology, potential SDL parameters are to include but not to be limited to following table^①:

Treatment technology	Potential SDL	
	Technical/operational parameters	Environment/water quality parameters
Filtration	Size threshold of filter mesh , filter capacity (flow rate), pressure, cleaning capability (back washing)	Suspended solid (size, flexibility, amount)
Hydrocyclone	Pressure	Suspended solid (weight)
UV lamp (light)	UV intensity, flow rate (exposure time)	UV light transmittance
Electro-chlorination	Decomposition/potential, active substance dosage (amount or concentration)	Salinity, temperature, suspended solid (TRO sensor)
	Neutralizing capability	
Chemical injection (e.g. ozone, sodium hypochlorite, chlorine dioxide, etc.)	Active substance dosage (amount or concentration), holding time	Salinity, temperature
	Neutralizing capability	
Heating	Temperature, contact/holding time	Temperature
Cavitation	Pressure at inlet and outlet	
Ultrasound	Ultrasonic frequency, power, flow rate (exposure time)	
Deoxygenation	Inert gas purity (%), injection rate, holding time	

6.3.4 Upon the completion of pre-test evaluation, land-based testing and shipboard testing are to be carried out in accordance with the requirements of Chapters 7 and 8 of the Guidelines.

① Guidelines for System Design Limitations of Ballast Water Management System to be prepared by IMO and subsequent updating are to be taken into consideration.

CHAPTER 7 LAND-BASED TESTING

7.1 Land-based testing objectives

7.1.1 The land-based testing intends to determine the biological availability and environmental acceptability of the BWMS under consideration for Type Approval. The approval testing aims to ensure replicability and comparability to other treatment equipment.

7.1.2 Any limitations imposed by the ballast water management system on the testing procedure described are to be duly recorded and evaluated. Such limitations are not to affect the normal operation of the BWMS or cause constraints. Limitations that cause constraints in operation are to be indicated in the Certificate.

7.2 Requirements for land-based testing set-up

7.2.1 The test set-up for approval tests is to be representative of the characteristics and arrangements of the types of ships in which the equipment is intended to be installed. The test set-up is therefore to include at least the following:

- (1) the complete BWMS to be tested;
- (2) piping and pumping arrangements; and
- (3) the storage tank that simulates a ballast tank, constructed such that the water in the tank is to be completely shielded from light.

7.2.2 The control and treated simulated ballast tanks are each to include:

- (1) a minimum capacity of 200 m³;
- (2) normal internal structures, including lightening and drainage holes;
- (3) standard industry practices for design, construction and surface coatings for ships; Surface coatings are to be in accordance with Performance Standard for Protective Coatings of Dedicated Seawater Ballast Tanks on All New Ships and of Double-Sided Skin Spaces of Bulk Carriers (PSPC); and
- (4) the minimum modifications required for structural integrity on land.

7.2.3 The test set-up are to be pressure-washed with tap water, dried and swept to remove loose debris, organisms and other matter before starting testing procedures, and between test cycles.

7.2.4 The test set-up will include facilities to allow sampling as described in 7.6.5 and 7.6.6 of the Guidelines, and provisions to supply influents to the system as specified in 7.5 of the Guidelines. The installation arrangements are to conform in each case with the following requirements:

- (1) Sampling facilities are to be so arranged in order to collect representative samples of the ship's ballast water.

(2) Sampling facilities are in any case to be located on the BWMS intake, before the discharging points, and any other points necessary for sampling to ascertain the proper functioning of the equipment as may be determined by CCS.

(3) The installation arrangements are to conform in each case with those specified and approved under the procedure outlined in 11.1 of the Guidelines.

7.3 Scaling in land-based testing

7.3.1 Scaling of the BWMS is to be in accordance with the requirements of Chapter 8 of the Guidelines. CCS is to verify that the scaling used is appropriate for the operational design of the BWMS.

7.3.2 BWMS with at least one model with a TRC equal to or smaller than 200 m³/h is not to be downscaled.

7.3.3 For BWMS with at least one model that has a higher capacity than 200 m³/h or 1000 m³/h, the following must be observed for land-based testing. In-line treatment equipment may be downsized for land-based testing, but only when the following criteria are taken into account:

(1) BWMS with at least one model with a TRC larger than 200 m³/h but smaller than 1000 m³/h may be downscaled to a maximum of 1:5 scale, but may not be smaller than 200 m³/h; and

(2) BWMS with at least one model with a TRC equal to, or larger than, 1,000 m³/h may be downscaled to a maximum of 1:100 scale, but may not be smaller than 200 m³/h.

7.3.4 In-tank treatment equipment is to be tested on a scale that allows verification of full-scale effectiveness. The suitability of the test set-up is to be evaluated by the manufacturer and approved by CCS.

7.4 Test cycles

7.4.1 The test set-up including the BWMS is to operate as described in the provided operation, maintenance and safety manual during at least five consecutive successful test cycles in each salinity.

7.4.2 A test cycle is to include:

(1) the uptake of ballast water by pumping;

(2) the storage of ballast water;

(3) treatment of ballast water within the BWMS, except in control tanks; and

(4) the discharge of ballast water by pumping.

The order is to be dependent on the BWMS.

7.4.3 At least two test cycles in each salinity are to be conducted in order to evaluate compliance with the D-2 standard at the minimum holding time specified by the BWMS manufacturer.

7.4.4 In accordance with G9, test facilities carrying out identification of Relevant Chemicals and toxicity testing of the treated ballast water from test cycles with a storage time which is shorter or longer than five days, are to ensure that sufficient volumes of treated water are collected after five days or are reserved after the efficacy testing to permit the requirements of Procedure (G9) to be assessed for at least one test cycle per salinity.

7.4.5 Land-based testing of BWMS is to be independent of the system manufacturer.

7.4.6 Testing is to occur using different water conditions sequentially as provided for in 7.5.1 and 7.5.3 of this Chapter.

7.4.7 The BWMS is to be tested at its rated capacity or as given in 7.3 of this Chapter for each test cycle. The equipment is to function to specifications during this test.

7.4.8 The analysis of treated water discharge from each test cycle is to determine if the treated discharge meets regulation D-2 of the Convention.

7.4.9 The analysis of treated water discharge from the relevant test cycle(s) is also to be used to evaluate the formation of Relevant Chemicals as well as the toxicity of the discharged water for BWMS that make use of Active Substances. The same evaluation is to be conducted for those BWMS that do not make use of Active Substances or Preparations but which could reasonably be expected to result in changes to the chemical composition of the treated water such that adverse impacts to receiving waters might occur upon discharge. Toxicity tests of the treated water discharge are to be conducted in accordance with paragraphs 5.2.3 to 5.2.7 of G9, as revised.

7.5 Test water

7.5.1 For any given set of test cycles (five are considered a set), a salinity range is to be chosen for each cycle. Given the salinity of the test set up for a test cycle in fresh, brackish and marine water, each is to have dissolved and particulate content in one of the following combinations:

	Salinity		
	Marine 28-36 PSU	Brackish 10-20 PSU	Fresh < 1 PSU
Dissolved Organic Carbon (DOC)	> 1 mg/l	> 5 mg/l	> 5 mg/l
Particulate Organic Carbon (POC)	> 1 mg/l	> 5 mg/l	> 5 mg/l
Total Suspended Solids (TSS)	> 1 mg/l	> 50 mg/l	> 50 mg/l

7.5.2 Test water is to be natural water. Any augmentation of test water with dissolved organic carbon (DOC), particulate organic carbon (POC) or total suspended solids (TSS) to achieve the minimum required content is to be validated and approved by CCS. As natural DOC constituents are complex and primarily of aromatic character, the type of added DOC is particularly critical to the evaluation of BWMS performance. The validation is to ensure that relevant properties of the augmented water (such as the oxidant demand/TRO decay and UV absorption in the range of 200 to 280 nm, the production of disinfectant by-products and the particle size distribution of suspended solids) are equivalent, on a mg/L basis, to that of natural water that would quantitatively meet the challenge conditions. In addition, the validation is to ensure that augmentation does not bias a test for or against any specific treatment process. The test report is to include the basis for the selection, use and validation of augmentation.

7.5.3 The BWMS must be tested in conditions for which it will be approved. For a BWMS to achieve an unlimited Type Approval Certificate with respect to salinity, one set of test cycles is to be conducted within each of the three salinity ranges with the associated dissolved and particulate content as prescribed in 7.5.1 of this Chapter. Tests under adjacent salinity ranges in the above table are to be separated by at least 10 PSU.

7.5.4 Use of standard test organisms (STO):

(1) The use of standard test organisms (STO) is permissible if the challenge levels in naturally occurring water at the test facility require supplementation. The use of STO is not to be considered standard practice and CCS is to in every case review that the selection, number and use of supplementary STOs ensures that the challenge posed to the BWMS provides an adequately robust test. The use of STOs is not to bias a test for or against any specific treatment process. They are to be locally isolated to ensure that the risk to the local environment is minimized; Non indigenous organisms which have the potential to cause harm to the environment are not to be used;

(2) Procedures, processes and guidance for the use of STO are to be based on the most relevant and up to date available scientific data. Such procedures, processes and guidance are to form a part of the testing facilities quality assurance regimes; and

(3) The use of STO, including concentrations and species, is to be recorded within the test report. The test report is to include information pertaining to the evaluation and justification for the use of STO, an assessment of the impact of their use on other test parameters and potential impacts on the test being undertaken. The information contained within the report is to reflect both the positive and negative impacts of the use of STO.

7.5.5 Test organisms are to be naturally occurring in the source water as far as possible. The test water is to include:

(1) test organisms of greater than or equal to 50 micrometres or more in minimum dimension are to be present in a total density of preferably 10^6 but not less than 10^5 individuals per cubic metre, and are to consist of at least 5 species from at least 3 different phyla/divisions;

(2) test organisms greater than or equal to 10 micrometres and less than 50 micrometres in minimum dimension are to be present in a total density of preferably 10^4 but not less than 10^3 individuals per millilitre, and are to consist of at least 5 species from at least 3 different phyla/divisions;

(3) heterotrophic bacteria are to be present in a density of at least 10^4 living bacteria per millilitre; and

(4) the variety of organisms in the test water is to be documented according to the size classes mentioned above regardless if natural organism assemblages or cultured organisms were used to meet the density and organism variety requirements.

7.5.6 The following bacteria do not need to be added to the source water, but are to be measured at the influent and at the time of discharge:

(1) Coliform;

(2) Enterococcus group;

(3) *Vibrio cholerae*; and

(4) Heterotrophic bacteria.

7.5.7 If cultured test organisms are used, then it is to be ensured that relevant national law or applicable quarantine regulations are taken into account during culturing and discharge.

7.6 Monitoring and sampling

7.6.1 Species compositions and numbers of viable organisms in treated water and in the simulated ballast tank are to be determined using methods described in 7.7.2 of this Chapter.

7.6.2 It is to be verified that the treatment equipment performs within its specified parameters, such as power consumption and flow rate, during the test cycle.

7.6.3 The range of operational flow rates that a BWMS is expected to achieve in service, at the maximum and minimum operational flow rates (where it is appropriate for that technology), is to be verified after the filter on the discharge side of the pump. The range of flow rate may be derived from empirical testing or from computational modelling. Where appropriate for the technology, demonstration of system efficacy at low flow rates is to reflect the need for flow reduction during the final stages of ballast operations.

7.6.4 Environmental parameters such as pH, temperature, salinity, dissolved oxygen, total suspended solids (TSS), particulate organic carbon (POC), dissolved organic carbon (DOC) and turbidity (NTU) are to be measured at the same time that the samples described are taken.

7.6.5 Samples during the test for the purposes of determining biological efficacy are to be taken at the following times and locations: immediately before the treatment equipment, immediately after the treatment equipment and upon discharge after the appropriate holding time.

7.6.6 The control and treatment cycles may be run simultaneously or sequentially. Control samples are to be taken in the same manner as the equipment test as prescribed in 7.6.9 of this Chapter and upon influent and discharge.

7.6.7 Facilities or arrangements for sampling are to be provided to ensure representative samples of treated and control water can be taken that introduce as little adverse effects as possible on the organisms.

7.6.8 Samples described in 7.6.5 and 7.6.6 of this Chapter are to be collected with the following sampling regime and volumes for analysis:

(1) for the enumeration of viable organisms greater than or equal to 50 micrometres or more in minimum dimension:

- ① influent water is to be collected over the duration of uptake as one, time-integrated sample. The sample is to be collected as a single, continuous sample or a composite of sequential samples, e.g. collected at intervals during the beginning, middle and end of the operation. The total sample volume is to be at least one cubic metre. If smaller volume is validated to ensure representative sampling of organisms, it may be used;

- ② control and treated discharged water is to be collected as one time-integrated sample over the duration of discharge from the tank(s). The sample may be collected as a single, continuous sample or a composite of sequential samples, e.g. collected throughout the beginning, middle and end the operation. The total sample volume is to be at least three cubic metres;
 - ③ if samples are concentrated for enumeration, the organisms are to be concentrated using a mesh with holes no greater than 50 micrometres in the diagonal dimension. Only organisms greater than 50 micrometres in minimum dimension are to be enumerated; and
 - ④ the full volume of the sample is to be analyzed unless the total number of organisms is high, e.g. 100. In this case, the average density may be extrapolated based on a well-mixed subsample using a validated method;
- (2) for the enumeration of viable organisms greater than or equal to 10 micrometres and less than 50 micrometres in minimum dimension:
- ① influent water is to be collected over the duration of uptake as one time-integrated sample. The sample is to be collected as a single, continuous sample or a composite of sequential samples, e.g. collected at intervals during the beginning, middle and end of the operation. A sample of at least 10 litres is to be collected, and a fraction may be subsampled for transport to the laboratory, provided it is representative of the sample and is a minimum of 1 litre. A minimum of three, 1-millilitre sub-samples are to be analyzed in full to enumerate organisms;
 - ② control and treated discharged water is to be collected as one time-integrated sample over the duration of discharge from the tank(s). The sample may be collected as a single, continuous sample or a composite of sequential samples, e.g. collected throughout the beginning, middle and end the operation. A sample of at least 10 litres is to be collected, and a fraction may be subsampled for transport to the laboratory, provided it is representative of the sample and is a minimum of 1 litre. A minimum of six, 1-millilitre sub-samples are to be analyzed in full to enumerate organisms;
 - ③ the sample may not be concentrated for analysis unless the procedure is validated. Only organisms greater than 10 micrometres and less than 50 micrometres in minimum dimension are to be enumerated;
 - ④ the full volume of the sample is to be analyzed unless the total number of organisms is high, e.g. 100. In this case, the average density may be extrapolated based on a well-mixed subsample using a validated method;
- (3) for the evaluation of bacteria:
- ① for the influent and discharge samples, a minimum 10-litre sample referred to in 9.3.2(2) of the Guidelines, or another sample at least 10 litres in volume and collected in a similar manner, a sub-sample of minimum 1 litre may be transferred to a sterile container for analysis;
 - ② a minimum of three subsamples of appropriate volume taken from the 1 litre subsample described above are to be analyzed for colony forming units of bacteria listed in regulation D-2; and

- ③ the toxicogenic test requirements are to be conducted in an appropriately approved laboratory. If no approved laboratory is available, the analysis method may be validated to the satisfaction of CCS.

7.6.9 The samples are to be analyzed as soon as possible after sampling, and analyzed live within six hours or treated in such a way so as to ensure that proper analysis can be performed.

7.6.10 If in any test cycle the discharge results from the control water is a concentration less than or equal to 10 times the values in regulation D-2.1, the test cycle is invalid.

7.6.11 For details of sample analysis methods for the determination of constituents in ballast water, refer to 4.5 of the Guidelines.

7.7 Reporting of land-based test results

7.7.1 After land-based tests have been completed, a report is to be submitted to CCS according to 3.4 of the Guidelines.

7.7.2 The results of biological efficacy testing of the BWMS are to be accepted if during the land-based testing, it is shown that the system has met the performance standard in regulation D-2 mentioned in 1.4 of the Guidelines and that the uptake water quality requirements were met in all individual test cycles as provided in 4.5.7 of the Guidelines.

CHAPTER 8 SCALING OF PRODUCT SERIES^①

8.1 Definitions

- (1) Base unit is a ballast water management equipment as defined in the Guidelines.
- (2) Scaled unit is the ballast water treatment equipment that is based on the base unit but has been modified to accommodate a higher or lower management rated capacity (TRC).

8.2 Requirements for scaled systems

Scaled systems are to comply with the following requirements:

- (1) mathematical modelling and/or calculations demonstrating that any parameters that would affect system performance are equivalent between base and scaled units; and
- (2) environmental tests for each configuration of scaled units are to be carried out in accordance with the requirements of Chapter 10 of the Guidelines.

8.3 The assumptions made for the scaling of the base unit are to be verified for each scaled unit by testing to the requirements of Chapter 9 for shipboard tests of the Guidelines. The time required in 9.4.8 of the Guidelines may be reduced from 6 to 3 months.

8.4 The same consideration is to be given for scaled systems that are tested according to the requirements for land-based tests.

8.5 In the case where all discrete models are tested according to the requirements for land-based tests, the most vulnerable model is to be tested according to the requirements for shipboard tests, to demonstrate the ability of the model to operate in normal ships' conditions.

8.6 Combinations of base units and scaled units which have been verified in their performance according to 8.2 to 8.5 are to be regarded as multiple units mounted in parallel and do not fall within the scope of this Chapter.

8.7 Failing to meet the provisions of 8.2 to 8.5, each scaled system is to be tested according to the requirements for land-based tests and shipboard tests.

8.8 If scaling and shipboard testing are intended to be utilized to type-approve a system beyond its currently approved TRC without land-based testing then the following process applies:

- (1) The documentation is to identify the key internal and external performance parameters (e.g., dosage concentration, UV intensity, filter flux density, etc.) required to achieve the system's efficacy, and also specify the physical/environmental conditions and design parameters that affect these.

① The requirements of this Chapter refer to IMO Guidance on Scaling of Ballast Water Management Systems (BWM.2-Circ.33), attention is to be paid to any renewal or revision of BWM.2-Circ.33 while this Chapter is applied.

(2) Validated mathematical model and/or calculations are to be used to predict that the key performance parameters will be achieved in the scaled unit design and that the fundamental mechanism of operation is not modified.

(3) It is to be verified through shipboard testing that the scaled unit achieves the critical values of the key performance parameters utilizing the design determined by the model and or calculations identified in 8.8.2.

(4) Modelling is to address the efficacy and environmental impact of the system. The actual chemical analysis for by-products is to be performed during shipboard testing, if necessary.

8.9 Notwithstanding the requirements of 8.3, a representative number of scaled systems capacities, taking into account the treatment technology used for BWMS, is to be tested according to the requirements for shipboard tests.

8.10 When scaling from systems that have received Basic Approval and Final Approval by IMO according to the Procedure (G9), the manufacturer is to ensure that any conditions on Final Approval of the base unit are still met for the scaled system or systems.

CHAPTER 9 SHIPBOARD TESTING

9.1 Evaluation prior to shipboard testing

9.1.1 Prior to shipboard testing, the manufacturer is to submit the shipboard testing program, quality assurance plan and quality control procedures in accordance with relevant requirements of Chapter 6 of the Guidelines.

9.1.2 CCS will carry out evaluation in accordance with 6.3 of Chapter 6 in the Guidelines.

9.1.3 Prior to shipboard testing, the installation of the BWMS has been completed and complies with relevant requirements of Chapter 11 in the Guidelines upon satisfactory completion of survey by CCS.

9.2 Shipboard testing

9.2.1 A shipboard test cycle includes:

- (1) the uptake of ballast water of the ship;
- (2) treatment of the ballast water in accordance with paragraph 9.4.4 of this chapter by the BWMS;
- (3) the storage of ballast water on the ship during a voyage; and
- (4) the discharge of ballast water from the ship.

9.2.2 Shipboard testing of the BWMS is to be conducted by the test facility, independent of the BWMS manufacturer, with the system being operated and maintained by the ships' crew as per the operational manual.

9.3 Samples and sample volumes

9.3.1 for the enumeration of viable organisms greater than or equal to 50 micrometres or more in minimum dimension:

- (1) influent water is to be collected over the duration of uptake as one, time-integrated sample. The sample is to be collected as a single, continuous sample or a composite of sequential samples, e.g. collected at intervals during the beginning, middle and end of the operation. The total sample volume is to be at least one cubic metre. If smaller volume is validated to ensure representative sampling of organisms, it may be used;
- (2) treated discharged water is to be collected as one time-integrated sample over the duration of discharge from the tank(s). The sample may be collected as a single, continuous sample or a composite of sequential samples, e.g. collected throughout the beginning, middle and end the operation. The total sample volume is to be at least three cubic metres;

(3) if samples are concentrated for enumeration, the organisms are to be concentrated using a mesh with holes no greater than 50 micrometres in the diagonal dimension. Only organisms greater than 50 micrometres in minimum dimension are to be enumerated; and

(4) the full volume of the sample is to be analysed unless the total number of organisms is high, e.g. 100. In this case, the average density may be extrapolated based on a well-mixed subsample using a validated method.

9.3.2 for the enumeration of viable organisms greater than or equal to 10 micrometres and less than 50 micrometres in minimum dimension:

(1) influent water is to be collected over the duration of uptake as one, time-integrated sample. The sample is to be collected as a single, continuous sample or a composite of sequential samples, e.g. collected at intervals during the beginning, middle and end of the operation. A sample of at least 10 litres is to be collected, and a fraction may be subsampled for transport to the laboratory, provided it is representative of the sample and is a minimum of 1 litre. A minimum of three, 1-millilitre sub-samples are to be analysed in full to enumerate organisms;

(2) treated discharged water is to be collected as one time-integrated sample over the duration of discharge from the tank(s). The sample may be collected as a single, continuous sample or a composite of sequential samples, e.g. collected throughout the beginning, middle and end the operation. A sample of at least 10 litres is to be collected, and a fraction may be subsampled for transport to the laboratory, provided it is representative of the sample and is a minimum of 1 litre. A minimum of six, 1-millilitre sub-samples is to be analysed in full to enumerate organisms;

(3) the sample may not be concentrated for analysis unless the procedure is validated. Only organisms greater than 10 micrometres and less than 50 micrometres in minimum dimension is to be enumerated; and

(4) the full volume of the sample is to be analysed unless the total number of organisms is high, e.g. 100. In this case, the average density may be extrapolated based on a well-mixed subsample using a validated method.

9.3.3 for the evaluation of bacteria:

(1) for the influent and discharge samples, the minimum 10-litre sample referred to in paragraph 9.3.2(2) of this chapter, or another sample at least 10 litres in volume and collected in a similar manner, a sub-sample of minimum 1 litre may be transferred to a sterile container for analysis;

(2) a minimum of three, subsamples of appropriate volume taken from the 1 litre subsample described above are to be analysed for colony forming units of bacteria listed in regulation D-2; and

(3) the toxicogenic test is to be conducted in an appropriately approved laboratory. If no approved laboratory is available, the analysis method may be validated to the satisfaction of CCS.

9.3.4 The samples are to be analysed as soon as possible after sampling, and analysed within six hours or treated in such a way so as to ensure that proper analysis can be performed.

9.4 Test evaluation (Success criteria for shipboard testing)

In evaluating the performance of BWMS installation(s) on a ship or ships, the following information and results are to be supplied to the satisfaction of CCS:

9.4.1 test plan to be provided prior to testing;

9.4.2 documentation that an inline BWMS is of a capacity to reflect the flow rate of the ballast water pump for the full rated capacity range of the BWMS;

9.4.3 documentation that an in-tank BWMS is of a capacity to reflect the ballast water volume that it is intended to treat within a specified period of time;

9.4.4 the amount of ballast water tested in the test cycle on board is to be consistent with the normal ballast operations of the ship and the BWMS is to be operated at the treatment rated capacity for which it is intended to be approved;

9.4.5 documentation showing that the discharge of each valid test cycle was in compliance with regulation D-2;

9.4.6 for a test to be valid, the uptake water for the ballast water to be treated is to contain a density of viable organisms exceeding 10 times the maximum permitted values in regulation D-2.1;

9.4.7 sampling regime and volumes for analysis are conducted in accordance with paragraph 9.3 of this chapter.

9.4.8 the test cycles including invalid test cycles are to span a period of not less than six months;

9.4.9 the applicant is requested to perform three consecutive test cycles in compliance with regulation D-2. Any invalid test cycle does not affect the consecutive sequence;

9.4.10 the six-month shipboard test period starts and ends with the completion of a successful test cycle or invalid test cycle that meets the D-2 standard. The three consecutive and valid test cycles that are required in paragraph 9.4.9 of this chapter must be suitably separated across the six-month period;

9.4.11 the source water for test cycles is to be characterized by measurement of salinity, temperature, particulate organic carbon, total suspended solids and dissolved organic carbon;

9.4.12 for system operation throughout the test period, the following information is also to be provided:

(1) documentation of all ballast water operations including volumes and locations of uptake and discharge, and if heavy weather was encountered and where;

(2) documentation that the BWMS was operated continuously throughout the test period for all ballasting and deballasting of the ship;

(3) documentation detailing water quality parameters identified by the testing organization, is to be measured as appropriate and practicable;

- (4) the possible reasons for an unsuccessful test cycle, or a test cycle discharge failing the D-2 standard are to be investigated and reported to CCS;
- (5) documentation of scheduled maintenance performed on the system during the test period;
- (6) documentation of unscheduled maintenance and repair performed on the system during the test period;
- (7) documentation of engineering parameters monitored as appropriate to the specific system; and
- (8) a report detailing the functioning of the control and monitoring equipment.

9.5 Reporting of shipboard test results

9.5.1 After tests have been completed, a report is to be submitted to CCS in accordance with 3.4 of the Guidelines.

9.5.2 The results of biological efficacy testing of the BWMS are to be accepted if during the shipboard testing conducted as specified in 1.5 of the Guidelines it is shown that the system has met the standard in regulation D-2 and that the uptake water quality requirements were met in all individual test cycles as provided in 4.5.7 of the Guidelines.

CHAPTER 10 ENVIRONMENTAL TESTING

10.1 General

10.1.1 The electrical and electronic parts of the BWMS in the standard production configuration are to be subject to the environmental tests specified in 10.3 of this Chapter at a laboratory recognized by CCS or the competent authority of the country where the manufacturer is located, and the scope of the accreditation is to cover the ISO/IEC 17025 and the relevant test standards.

10.1.2 Evidence of successful compliance with the environmental tests of this Chapter (if any) is to be submitted to CCS by the manufacturer together with the application for type approval.

10.2 Basic requirements

Equipment is to be maintained in a normal order upon the completion of each operating environment tests listed below.

10.3 Test items and specifications

10.3.1 Equipment is to be carried out in accordance with CCS Guidelines for type approval test of electrical and electronic products or the relevant requirements of other equivalent standards.

10.3.2 The report of environmental test is to be submitted to CCS.

CHAPTER 11 INSTALLATION SURVEY AND COMMISSIONING PROCEDURES FOLLOWING TYPE APPROVAL

11.1 Installation requirements

11.1.1 The BWMS is to be accompanied by sampling facilities as described in Guidelines on ballast water sampling (G2), so arranged in order to collect representative samples of the ship's ballast water discharge.

11.1.2 Suitable bypasses or overrides to protect the safety of the ship and personnel are to be installed and used in the event of an emergency and these are to be connected to the BWMS so that any bypass of the BWMS is to activate an alarm. The bypass event is to be recorded by the control and monitoring equipment and within the ballast water record book.

11.1.3 The requirement in above 11.1.2 does not apply to internal transfer of ballast water within the ship (e.g. anti-heeling operations). For the BWMS that transfers water internally which may affect compliance by the ship with the standard described in regulation D-2 (i.e. circulation or in-tank treatment) the recording in above 11.1.2 is to identify such internal transfer operations.

11.2 Verification of documentation

When the approved BWMS is allowed for installation on board, the CCS surveyor is to verify that the following documentation is on board in a suitable format:

- (1) a copy of the Type Approval Certificate of the BWMS and the Marine Product Certificate of the BWMS;
- (2) the operation, maintenance and safety manual of the BWMS;
- (3) the ballast water management plan of the ship;
- (4) installation specifications, e.g. installation drawing, piping and instrumentation diagrams, etc.; and
- (5) installation and commissioning procedures.

11.3 Installation survey

The surveyor is to confirm that:

- (1) the BWMS installation has been carried out in accordance with the technical installation specification referred to in paragraph 11.2(4) of this Chapter and the manufacturer's equipment specification;
- (2) the BWMS is in conformity with the Type Approval Certificate of BWMS issued by CCS;
- (3) any operational inlets and outlets of the BWMS are located in the positions indicated on the drawing of the pumping and piping arrangements;

(4) the workmanship of the installation is satisfactory and, in particular, that any bulkhead penetrations or penetrations of the ballast system piping are to meet the relevant requirements of rules of CCS; and

(5) the installation and commissioning procedures have been completed.

11.4 Running tests

The BWMS is subject to running tests upon the completion of installation onboard according to the commissioning procedures. The tests are to include:

- (1) function tests of control and monitoring equipment;
- (2) safety alarms tests;
- (3) running tests; and
- (4) other related tests.

APPENDIX 1 TYPE APPROVAL CERTIFICATE OF BALLAST WATER MANAGEMENT SYSTEM

The certificate is issued under the authority of the Government of the _____
by China Classification Society. (*delete as appropriate*)
本证书经_____授权, 由中国船级社颁发。(如合适, 删除)



(Limiting Operating Conditions Apply)

(操作条件限制)
(*delete as appropriate*)
(如合适, 删除)

格式
Form CPXX

中国船级社
CHINA CLASSIFICATION SOCIETY

编号
No. _____

船舶压载水管理系统型式认可证书 TYPE APPROVAL CERTIFICATE OF BALLAST WATER MANAGEMENT SYSTEM

This is to certify that the Ballast Water Management System listed below has been examined and tested in accordance with the requirements of the specifications contained in the Guidelines contained in IMO resolution MEPC.279(70). This certificate is valid only for the Ballast Water Management System referred to below.

兹证明, 已按IMO MEPC.279(70) 决议中的指南要求和规定, 对下列压载水管理系统进行了检查和试验。本证书仅对下列压载水管理系统有效。

Ballast Water Management System supplied by
压载水管理系统供应方

Under type and model designationand incorporating:
指定类型和型号_____并包括

Ballast Water Management System manufactured by
压载水管理系统制造厂

To equipment/assembly drawing No. date
设备/组件图号 日期

Other equipment manufactured by
其他设备制造厂

To equipment/assembly drawing No. date
设备/组件图号_____日期_____

Treatment Rated Capacity m³/h
额定处理能力

A copy of this Type Approval Certificate, should be carried on board a vessel fitted with this Ballast Water Management System at all times. A reference to the test protocol and a copy of the test results should be available for inspection on board the vessel. If the Type Approval Certificate is issued based on approval by another Administration, reference to that Type Approval Certificate shall be made.

任何时候，安装了压载水管理系统的船上应备有一份型式认可证书的副本。船上检查时，应提供试验协议参考和一份试验结果副本。如果型式认可证书的签发是基于另一国主管机关的认可，则应参照该型式认可证书。

Limiting Operating Conditions imposed are described in this document.

规定的限制条件见本文件的附录。

(Temperature / Salinity)

(温度/盐度)

Other restrictions imposed include the following:

其他的限制包括：

This equipment has been designed for operation in the following conditions:

本设备设计用于以下运行条件：

(insert System Design Limitations)

(插入系统设计限制)

Signed/签署

Official stamp ()

检验标志

China Classification Society/中国船级社

Dated this/发证日期 day of

Enc. Copy of the original test results.

试验结果正文副本。

APPENDIX 2 NOTIFICATION OF APPROVAL SERVICE

Form: RPIMP801-B1



CHINA CLASSIFICATION SOCIETY

Notification of Approval Service

Approval Work Control No. : _____
(Completed by CCS)

The Notifier acknowledges: Once this Notification with the Notifier's signature and stamp is processed by China Classification Society, this Notification shall be deemed the evidence of contract between the Notifier and China Classification Society. Unless otherwise agreed by CCS, the relevant terms in the latest edition of Rules for Classification of Sea-going Steel Ships of CCS, including, but not limited to, the General Part of the Rules, constitute the contract between the Notifier and CCS, which governs all services provided in relation to this Notification.

The Notifier guarantees that the drawings and technical documents submitted are legally owned, and is responsible for the completeness and truthfulness of all contents declared in this Notification and all materials submitted by the Notifier. If any false data are found, the Notifier shall assume legal responsibility, and hold responsibility for all the serious consequences arising therefore. The Notifier agrees to provide the sufficient and safe conditions of approval and pay the fee for the specified service and, in addition, any traveling and other expenses incurred by the surveyor related to the services. In the event of this project not being completed under CCS' services due to the Notifier's cause, the Notifier also agrees to pay the relevant fee and expenses for the services provided.

Name of Products		Intended for	International voyage ☐ Domestic voyage ☐ Others ☐
Model			
Technical specification: (In details) CCS Rules: International conventions or national regulations: International or national standards: Industry standards: Others:			
Titles of submitted plans/documents:			

Types of approval services and items:

Design approval	☐ B model of type approval	☐ A model of type approval	☐ Works approval
Initial approval	☐ Periodical review	☐ Renewal of approval certificate	☐ Modification of approval certificate

Approval of class notations ☐

Last approval certificate No. (if approved before):

Expiration date of certificate:

Original drawing approval No. (if approved before by CCS):

Note: In "□": "X" means "yes" or "applicable", "-" means "not" or "not applicable".

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Rev. 1 20171201

CHINA CLASSIFICATION SOCIETY
Notification of Approval Service

(continued)

Name of notifier			Liaison person	
Address of notifier:				
	Post code			
	Telephone No.:		Fax No.:	
Name of manufacturer:			Liaison person	
Address of manufacturer:				
	Post code			
	Telephone No.:		Fax No.:	

Signed by the representative of notifier /stamped by:

Date:

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**APPENDIX 3 PROCEDURE FOR APPROVAL OF BALLAST WATER
MANAGEMENT SYSTEMS THAT MAKE USE OF ACTIVE SUBSTANCES
(G9)(MEPC.169(57))**

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- Notification of approval
- Modification
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**Appendix Approval Scheme for Active Substances or Preparations and ballast water
management systems that make use of Active Substances**

PROCEDURE FOR APPROVAL OF BALLAST WATER MANAGEMENT SYSTEMS THAT MAKE USE OF ACTIVE SUBSTANCES (G9)

1 INTRODUCTION

1.1 This procedure describes the approval and withdrawal of approval of ballast water management systems that make use of Active Substances to comply with the Convention and their manner of application as set out in regulation D-3 of the “International Convention for the Control and Management of Ships’ Ballast Water and Sediments, 2004”. The Convention requires that at withdrawal of approval, the use of the relevant Active Substance or Substances shall be prohibited within 1 year after the date of such withdrawal.

1.2 To comply with the Convention, ballast water management systems that make use of Active Substances or Preparations containing one or more Active Substances shall be approved by the Organization^①, based on a procedure developed by the Organization.

1.3 The objective of this procedure is to determine the acceptability of Active Substances and Preparations containing one or more Active Substances and their application in ballast water management systems concerning ship safety, human health and the aquatic environment. This procedure is provided as a safeguard for the sustainable use of Active Substances and Preparations.

1.4 This procedure is not intended for the evaluation of the efficacy of Active Substances. The efficacy of ballast water management systems that make use of Active Substances should be evaluated in accordance with the Guidelines for approval of ballast water management systems (G8).

1.5 The goal of the procedure is to ensure proper application of the provisions contained in the Convention and the safeguards required by it. As such the procedure is to be updated as the state of knowledge and technology may require. New versions of the procedure will be circulated by the Organization following their approval.

2 DEFINITIONS

2.1 For the purposes of this procedure, the definitions in the Convention apply and:

- .1 “Active Substance” means a substance or organism, including a virus or a fungus that has a general or specific action on or against harmful aquatic organisms and pathogens.
- .2 “Ballast Water Discharge” means the ballast water as would be discharged overboard.
- .3 “Preparation” means any commercial formulation containing one or more Active Substances including any additives. This term also includes any Active Substances generated onboard for purposes of ballast water management and any relevant chemicals formed in the ballast water management system that make use of Active Substances to comply with the Convention.
- .4 “Relevant Chemicals” means transformation or reaction products that are produced during and after employment of the ballast water management system in the ballast water or in the receiving environment and that may be of concern to the ship’s safety, aquatic environment and/or human health.

① The Organization means the International Maritime Organization(IMO).

3 PRINCIPLES

3.1 Active Substances and Preparations may be added to the ballast water or be generated on board ships by technology within the ballast water management system using an Active Substance to comply with the Convention.

3.2 Active Substances and Preparations accomplish their intended purpose through action on harmful aquatic organisms and pathogens in ships' ballast water and sediments. However, if the ballast water is still toxic at the time of discharge into the environment, the organisms in the receiving water may suffer unacceptable harm. Both the Active Substance or Preparation as well as the ballast water discharge should be subjected to toxicity testing in order to protect the receiving environment or human health from toxic effects due to the discharges. Toxicity testing is needed to determine if an Active Substance or Preparation can be used and under which conditions the potential of harming the receiving environment or human health is acceptably low.

3.3 Any system which makes use of, or generates, Active Substances, Relevant Chemicals or free radicals during the treatment process to eliminate organisms in order to comply with the Convention should be subject to this Procedure.

3.4 Ballast water management systems that make use of Active Substances and Preparations must be safe in terms of the ship, its equipment and the personnel to comply with the Convention.

3.5 The approval of Active Substances and Preparations using viruses or fungi for use in ballast water management systems is not addressed in this procedure. The approval of such substances for ballast water management should require an additional consideration by the Organization in compliance with regulation D-3 of the Convention if the use of such substances is proposed.

3.6 Administrations should check the quality and completeness of any Basic Approval or Final Approval submission, against the latest version of the Methodology for information gathering and the conduct work of the Technical Group agreed by the Organization, prior to its submission to the MEPC.

4 GENERAL REQUIREMENTS

4.1 Identification

4.1.1 The proposal for approval of an Active Substance or a Preparation should include a chemical identification and description of the chemical components even if generated on board. A chemical identification should be provided for any Relevant Chemicals.

4.2 Data-set for Active Substances and Preparations

4.2.1 A proposal for approval should include information on the properties or actions of the Preparation including any of its components as follows:

- .1 Data on effects on aquatic plants, invertebrates, fish, and other biota, including sensitive and representative organisms:
 - acute aquatic toxicity;

- chronic aquatic toxicity;
- endocrine disruption;
- sediment toxicity;
- bioavailability/biomagnification/bioconcentration; and
- food web/population effects.

.2 Data on mammalian toxicity:

- acute toxicity;
- effects on skin and eye;
- chronic and long-term toxicity;
- developmental and reproductive toxicity;
- carcinogenicity; and
- mutagenicity.

.3 Data on environmental fate and effect under aerobic and anaerobic conditions:

- modes of degradation (biotic; abiotic);
- bioaccumulation, partition coefficient, octanol/water coefficient;
- persistence and identification of the main metabolites in the relevant media (ballast water, marine and fresh waters);
- reaction with organic matter;
- potential physical effects on wildlife & benthic habitats;
- potential residues in seafood; and
- any known interactive effects.

.4 Physical and chemical properties for the Active Substances and Preparations and the treated ballast water, if applicable:

- melting point;
- boiling point;
- flammability;
- density (relative density);
- vapour pressure, vapour density;
- water solubility / dissociation constant (pKa);
- oxidation/reduction potential;
- corrosivity to the materials or equipment of normal ship construction;
- autoignition temperature; and
- other known relevant physical or chemical hazards.

.5 Analytical methods at environmentally relevant concentrations.

4.2.2 A proposal for approval should include the above data set either for the Preparation or for each component separately, and a list of the name and relative quantities (in volumetric percentages) of the components should be also attached. As described in section 8.1, all proprietary data should be treated as confidential.

4.2.3 The tests for Active Substances and Preparations should be carried out in accordance with internationally recognized guidelines^①.

4.2.4 The testing process should contain a rigorous quality control/quality assurance programme consisting of:

- .1 Both a Quality Management Plan (QMP) and a Quality Assurance Project Plan (QAPP). Guidance on preparation of these plans, along with other guidance documents and other general quality control information are available for download from the International Organization for Standardization (ISO) (www.iso.org).
- .2 The QMP addresses the quality control management structure and policies of the Test Organization (including subcontractors and outside laboratories).
- .3 The QAPP is a project specific technical document reflecting the specifics of the system to be tested, the test facility, and other conditions affecting the actual design and implementation of the required experiments.

4.2.5 Dossiers already used for registration of chemicals can be submitted by the applicant to satisfy the required data needed for the evaluation of Active Substances and Preparations according to this procedure.

4.2.6 The proposal should describe the manner of application of the Preparation for ballast water management, including required dosage and retention time.

4.2.7 A proposal for approval should include (Material) Safety Data Sheets ((M)SDS).

4.3 Assessment report

4.3.1 A proposal for approval should include an assessment report. The assessment report should address the quality of the test reports, the risk characterization and a consideration of the uncertainty associated with the assessment.

5 RISK CHARACTERIZATION

5.1 Screening for persistency, bioaccumulation and toxicity

5.1.1 An assessment on the intrinsic properties of the Active Substance and/or Preparation such as persistency, bioaccumulation and toxicity should be conducted (see Table 1 in section 6).

① Preferably Organization for Economic Co-operation and Development (OECD) Guidelines for Testing of Chemicals (1993) or other equivalent tests.

.1 Persistence tests:

Persistence should preferably be assessed in simulation test systems that determine the half-life under relevant conditions. Biodegradation screening tests may be used to show that the substances are readily biodegradable. The determination of the half-life should include assessment of relevant chemicals.

.2 Bioaccumulation tests:

The assessment of the (potential for) bioaccumulation should use measured bioconcentration factors in marine (or freshwater) organisms. Where these tests are not applicable, or if $\log P_{ow} < 3$, Bio Concentration Factor (BCF) values may be estimated using (Quantitative) Structure-Activity Relationship ((Q)SAR) models.

.3 Toxicity tests:

Acute and/or chronic ecotoxicity data, ideally covering the sensitive life stages, should in principle be used for the assessment of the toxicity criterion.

5.2 Toxicity testing of the treated ballast water

5.2.1 Toxicity testing is necessary for the Active Substance, or Preparations (see sections 4.2.1 and 5.3) and the treated ballast water discharge as covered in this section. The advantage of conducting toxicity testing on the ballast water discharge is that it integrates and addresses the potential for interactions of the Active Substances and Preparations with the possible by-products:

- .1 For the Basic Approval process, the discharge testing should be performed in a laboratory using techniques and equipment to simulate ballast water discharge following treatment by the Preparation.
- .2 For Final Approval, the discharge testing should be performed as part of the land-based type approval process using the treated ballast water discharge.

5.2.2 The applicant should provide both acute and chronic toxicity test data using standardized test procedures to determine the toxicity of the Preparation and Relevant Chemicals as used in conjunction with the ballast water management system. This testing approach should be performed on the treated ballast water discharge, as the ballast water management system could either mitigate or enhance the adverse effects of the Preparation or Relevant Chemicals.

5.2.3 The discharge toxicity tests should be conducted on samples drawn from the land-based test set-up, which would be representative of the discharge from the ballast water management system.

5.2.4 These toxicity tests should include chronic test methods with multiple test species (a fish, an invertebrate and a plant) that address the sensitive life-stage. The preference is to include both a sub-lethal endpoint (growth) and a survival endpoint. Either freshwater or marine test methods should be tested^①.

① Currently there is no compelling physiological or empirical proof that marine organisms are more sensitive than freshwater organisms or vice versa. Should this however be demonstrated for the substance under consideration, this should be taken into account.

5.2.5 The test results to be provided include: acute 24-hour, 48-hour, 72-hour, and 96-hour Lethal Concentration at which x % of the test organisms die (LCx), No Observed Adverse Effect Concentrations (NOAECs), chronic No Observed Effect Concentration (NOEC) and/or Effect Concentration at which x % of test organisms show effect (ECx), as appropriate based on the experimental design.

5.2.6 A dilution series including a 100% ballast water discharge would be tested to determine the no adverse effect level using the statistical endpoints (NOEC or ECx). An initial analysis could use a conservative approach where the dilution capacity would not be taken into consideration (no modelling or plumes analysis would be used). The rationale for taking a conservative approach is that there could be multiple discharges into one location (even though this is not necessarily the case).

5.2.7 The acute and chronic toxicity test data in conjunction with the information in section 4.2.1 should be used to determine the holding time necessary to achieve the no adverse effect concentration upon discharge. Knowing the half-life (days), decay rate, dosage rate, volume of system and toxicity tests with time series, then a computational model can be used to determine the amount of time needed to hold the treated ballast water before discharge.

5.2.8 Information on Total Residual Oxidants (TRO) and Total Residual Chlorine (TRC) should be provided as part of the application for evaluation, for both the ballast water treatment process and the ballast water discharge.

5.3 Risk characterization and analysis

5.3.1 For the Basic Approval process, fate and effect testing should be performed in the laboratory with Active Substances and Preparations. This section lists information that could be useful for a preliminary risk characterization.

5.3.2 Both the Active Substance or Preparation as well as the treated ballast water discharge should be subject to toxicity testing in order to protect the receiving environment from toxic effects due to discharges.

5.3.3 The reaction with organic matter of Active Substances and Preparations that produce free radicals, should be addressed qualitatively so as to identify products of concern to the environment.

5.3.4 The rate and route of abiotic and biotic degradation of the Active Substances and Preparations under aerobic and anaerobic conditions should be assessed, resulting in the identification of relevant metabolites in the relevant media (ballast water, marine and fresh waters).

5.3.5 The rate of abiotic and biotic degradation of the Active Substances and Preparations under aerobic and anaerobic conditions should be assessed, resulting in the characterization of the persistence of the Active Substances, Preparations and Relevant Chemicals in terms of degradation rates under specified conditions (e.g., pH, redox, temperature).

5.3.6 The partition coefficients (solids-water partition coefficient (Kd) and/or organic carbon normalized distribution coefficient (Koc)) of the Active Substances, Preparations and Relevant Chemicals should be determined.

5.3.7 For Active Substances and Preparations, the potential for bioaccumulation should be assessed in marine or freshwater organisms (fish or bivalves) if the logarithm octanol/water partition coefficient (logPow) is >3.

5.3.8 Based on the information on fate and behaviour of Active Substances and Preparations, the discharge concentrations at selected time intervals should be predicted.

5.3.9 The effect assessment of the Active Substances, Preparations and Relevant Chemicals is initially based on a dataset of acute and/or chronic ecotoxicity data for aquatic organisms, being primary producers (algae or sea grasses), consumers (crustaceans), predators (fish), and should include secondary poisoning to mammalian and avian top-predators, as well as data for sediment species.

5.3.10 An assessment of secondary poisoning is redundant if the substance of concern demonstrates a lack of bioaccumulation potential (e.g., BCF <500 L/kg wet weight for the whole organism at 6% fat).

5.3.11 An assessment of sediment species is redundant if the potential of the substance of concern to partition into the sediment is low (e.g., K_{oc} <500 L/kg).

5.3.12 The effect assessment of the Active Substances, Preparations and Relevant Chemicals should include a screening on carcinogenic, mutagenic and endocrine disruptive properties. If the screening results give rise to concerns, this should give rise to a further effect assessment.

5.3.13 The effect assessment of the Active Substances, Preparations and Relevant Chemicals, taking the indicated information into account, should be based on internationally recognized guidance^①.

5.3.14 The results of the effect assessment are compared to the results of the discharge toxicity testing. Any unpredicted results (e.g., lack of toxicity or unexpected toxicity in the discharge assessment) should give rise to a further elaboration on the effect assessment.

5.3.15 An analytical method suitable for monitoring Active Substances and Preparations in ballast water discharges should be available.

6 EVALUATION CRITERIA

The Organization should evaluate the application for approval based on the criteria in this section.

6.1 The information that has been provided should be complete, of sufficient quality and in accordance with this Procedure.

6.2 That this information does not indicate possible unacceptable adverse effects to environment, human health, property or resources.

6.3 Ship and personnel safety

① Such as relevant OECD guidelines or equivalent.

6.3.1 In order to protect the ship and personnel safety the Technical Group should evaluate the physical and chemical hazards (see paragraph 4.2.1.4) to ensure that potential hazardous properties of the Active Substances, Preparations or Relevant Chemicals formed in the treated ballast water should not create any unreasonable risk to the ship and personnel. Proposed procedures for the use and technical equipment introduced needs to be taken into account.

6.3.2 For the protection of personnel involved in the handling and storage of the Active Substances and Preparations, the proposal should include relevant ((M)SDS). The Organization should evaluate (M)SDS, mammalian toxicity data and chemical properties hazards (see paragraphs 4.2.1.2 and 4.2.1.4) and ensure that potential hazardous properties of the Active Substances, Preparations or Relevant Chemicals should not create any unreasonable risk to the ship or personnel. This evaluation should take into account the different circumstances that a ship or personnel may face in its trade (e.g., ice, tropical, humidity, etc.).

6.3.3 A Human Exposure Scenario (HES) should be provided by the applicant as part of the Risk Assessment procedure for ballast water management systems.

6.4 Environmental protection

6.4.1 In order to approve the application, the Organization should determine that the Active Substances, Preparations or Relevant Chemicals are not Persistent, Bioaccumulative and Toxic (PBT). Preparations that exceed all these criteria (Persistence, Bioaccumulation and Toxicity) in the table below are considered PBT.

Criteria for identification of PBT substances

Table 1

Criterion	PBT criteria
Persistence	Half-life: > 60 days in marine water, or > 40 days in freshwater*, or > 180 days in marine sediment, or > 120 days in freshwater sediment*
Bioaccumulation	BCF > 2,000 or $\text{Log}P_{\text{octanol/water}} \geq 3$
Toxicity	Chronic NOEC < 0.01 mg/l

* For the purpose of marine environmental risk assessment half-life data in freshwater and freshwater sediment can be overruled by data obtained under marine conditions.

6.4.2 The Organization should determine the overall acceptability of the risk the Preparation may pose in its use for ballast water management. It should do so by comparing the information provided and the undertaken assessment of PBT and the discharge with scientific knowledge of the Active Substances, Preparations and Relevant Chemicals concerned. The risk evaluation should qualitatively take into account cumulative effects that may occur due to the nature of shipping and port operations.

6.4.3 The risk evaluation should consider the uncertainties involved in the application for approval, and as appropriate, provide advice on how these uncertainties can be dealt with.

6.4.4 An Emission Scenario Document (ESD) should be provided by the applicant as part of the Risk Assessment procedure for ballast water management systems. The ESD should be based on the worst-case discharge scenario and should be regarded as the first stage of a stepped approach to the development of a full ESD, when more data on potential discharges and technologies becomes available.

7 REGULATION OF THE USE OF ACTIVE SUBSTANCES AND PREPARATIONS

7.1 Handling of Active Substances and Preparations

7.1.1 The proposal for approval of Active Substances and Preparations should include information on their intended use and application. The quantity of Active Substances and Preparations to be added to the ballast water and the maximum allowable concentration of the Active Substances therein should be described in the instructions provided by the manufacturer. The system should ensure that the maximum dosage and maximum allowable discharge concentration are not exceeded at any time.

7.1.2 An assessment should be undertaken to ensure the safe on-board handling and storage of chemicals used to treat ballast water, using the existing IMO Conventions, Codes and guidance as a basis.

7.2 Hazard documentation and labelling

7.2.1 The proposal should include ((M)SDS) as required. The (M)SDS should describe appropriate storage and handling together with the effects of degradation and chemical reactivity during storage and should be included in the instructions provided by the manufacturer.

7.2.2 Documentation of hazards or the (M)SDS should conform to the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and the relevant IMO regulations (e.g., the IMDG Code) and guidelines (e.g., the GESAMP Hazard Evaluation Procedure). Where these regimes are not applicable, relevant national or regional regimes should be followed.

7.3 Procedures and use

7.3.1 Detailed procedures and information for safe application of Active Substances and Preparations on board should be developed and supplied, taking into consideration existing IMO Conventions, Codes and guidance. The procedures should comply with the approval conditions such as maximum allowable concentration and maximum discharge concentration, if any.

8 APPROVAL

8.1 Basic Approval

8.1.1 All proprietary data should be treated as confidential by the Organization and its Technical Group, the Competent Authorities involved, and the evaluating regulatory scientists, if any. However, all information related to safety and environmental protection, including physical/chemical properties, environmental fate and toxicity, should be treated as non-confidential.

8.1.2 Procedure to be followed:

- .1 The manufacturer should evaluate the Active Substances or Preparations and the potential discharge in accordance with the approval criteria specified in this procedure.
- .2 Upon completion, the manufacturer should prepare an Application on the Active Substances and Preparations and submit it to the Member of the Organization concerned. An application should only be made once the ballast water management system, Active Substance or Preparation has been sufficiently designed, progressed and tested to provide the full data necessary for a Basic Approval.

- .3 The Administration having received a satisfactory application should as soon as possible propose an approval to the Organization.
- .4 Members of the Organization may propose an approval.
- .5 The Organization should announce and set the time frame for the evaluation of Active Substances and Preparations.
- .6 Parties, Members of the Organization, the United Nations and its Specialized Agencies, intergovernmental organizations having agreements with the Organization and nongovernmental organizations in consultative status with the Organization may submit information that is relevant to the evaluation.
- .7 The Organization should establish a Technical Group in accordance with its rules of procedure ensuring that proprietary data should be treated as confidential.
- .8 The Technical Group should review the comprehensive proposal along with any additional data submitted and report to the Organization whether the proposal has demonstrated a potential for unreasonable risk for environment, human health, property or resources in accordance with the criteria specified in this procedure.
- .9 The Technical Group's report should be in written form and circulated to the Parties, Members of the Organization, the United Nations and its Specialized Agencies, intergovernmental organizations having agreements with the Organization and nongovernmental organizations in consultative status with the Organization, prior to its consideration by the competent Committee.
- .10 The Committee of the Organization should decide whether to approve any proposal, introduce any modifications thereto, if appropriate, taking into account the Technical Group's report.
- .11 The Member of the Organization that submitted the application to the Organization should inform in writing the applicant about the decision made with regard to the respective Active Substance or Preparation and their manner of application.
- .12 Active Substances or Preparations receiving Basic Approval by the Organization may be used for prototype or type approval testing based on the guidelines developed by the Organization^①. Subject to evaluation against the criteria developed by the Organization, an Active Substance or Preparation may be used for Prototype or Type Approval testing for the approval of different BWMS.
- .13 An applicant seeking to take advantage of an Active Substance or Preparation's Basic Approval should provide in its application a written agreement from the applicant whose Active Substance or Preparation has been granted the initial Basic Approval.

8.2 Final Approval

^① Guidelines for approval and oversight of prototype ballast water treatment technologies (G10) and Guidelines for approval of Ballast Water Management Systems (G8).

8.2.1 In accordance with regulation D-3.2, a ballast water management system using an Active Substance or Preparation to comply with the Convention (which received Basic Approval) must be approved by the Organization. For this purpose, the Member of the Organization submitting an application should conduct the Type Approval tests in accordance with Guidelines for approval of ballast water management systems (G8). The results should be conveyed to the Organization for confirmation that the residual toxicity of the discharge conforms to the evaluation undertaken for Basic Approval. This would result in Final Approval of the ballast water management system in accordance with regulation D-3.2. Active Substances or Preparations that have received Basic Approval by the Organization may be used for evaluation of ballast water management systems using Active Substances or Preparations for Final Approval.

8.2.2 It is to be noted that from the Guidelines (G8) land-based testing only the results of the residual toxicity tests should be included in the proposal for Final Approval in accordance with Procedure (G9). All other Guidelines (G8) testing remains for the assessment and attention of the Administration. Although Basic Approval under Procedure (G9) should not be a pre-requisite of Type Approval testing, as an Administration can regulate discharges from its own ships in its own jurisdiction. Basic Approval would still be required, and the specific technology could not be used in vessels in another jurisdiction without Basic Approval.

8.2.3 It should be noted that once a system has received Final Approval under this Procedure, then the respective applicant should not have to retrospectively submit new data if there is a change in the Methodology agreed by the Organization.

8.3 Notification of approval

8.3.1 The Organization will record the Basic and Final Approval of Active Substances and Preparations and ballast water management systems that make use of Active Substances and circulate the list once a year including the following information:

- Name of ballast water management system that make use of Active Substances and Preparations;
- Date of approval;
- Name of manufacturer; and
- Any other specifications, if necessary.

8.4 Modification

8.4.1 Manufacturers should report any modifications in names, including trade and technical name, composition or use of the Active Substances and Preparations in the ballast water management systems approved by the Organization, to the Member of the Organization. The Member of the Organization should inform the Organization accordingly.

8.4.2 Manufacturers intending to significantly change any part of a ballast water management System that has been approved by the Organization or the Active Substances and Preparations used in it should submit a new application.

8.5 Withdrawal of approval

8.5.1 The Organization may withdraw any approval in the following circumstances:

- .1 If the Active Substances and Preparations or ballast water management system that make use of Active Substances no longer conforms to requirements due to amendments of the Convention.
- .2 If any data or test records differ materially from data relied upon at the time of approval and are deemed not to satisfy the approval condition.
- .3 If a request for withdrawal of approval is made by the Member of the Organization on behalf of the manufacturer.
- .4 If unreasonable harm to environment, human health, property or resources is demonstrated by any Member of the Organization or observer to have been caused by the approved ballast water management system that make use of Active Substances or Preparations.

Appendix

Approval Scheme for Active Substance or Preparation and Ballast Water Management systems that make use of Active Substances

