U.S. Department of Homeland Security
United States Coast Guard

Commandant
United States Coast Guard

2703 Martin Luther King Jr. Ave. SE
Washington, DC 20593-7509
Staff Symbol: CG-OES
Phone: 202-372-1433
Fax: 202-372-8382
Email: environmental_standards@uscg.mil

16714
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Distribution to Coast Guard Accepted Independent Laboratories

Dear sir/ma'am,

The Coast Guard has received a number of formal and informal inquiries requesting clarification on how an Independent Laboratory (IL) should be assessing the system design limitations as stated by the manufacturer. This letter provides amplifying guidance for evaluating manufacturer-identified operational limitations during type approval testing of ballast water management systems (BWMS).

The process for evaluating and assessing operational limitations includes the following general steps:

1) The manufacturer identifies relevant limiting conditions or parameters in the required "technical data package" submitted to the IL that includes identification of all manufacturer-specific performance claims and relevant existing performance data. A format for the technical data package is located at Chapter 3, Section 3.10, p. 12 of the Environmental Technology Verification Program (ETV) Protocol . (Note – most, if not all, of the required information may be available in the BWMS manufacturer's Operation, Maintenance & Safety Manual (OMSM); however, submission of the technical documentation package is a standalone requirement that is not satisfied solely by the submission of the OMSM). The manufacturer should provide, as appropriate, the IL with all ancillary reference information used to justify operating limits which cannot be readily verified, through any combination of manuals, product literature, and electronic files;
2) In coordination with the BWMS manufacturer, the IL reviews, assesses, and as appropriate, identifies additional or missing limitations critical to the operation of the BWMS;
3) Based on the manufacturer supplied BWMS documentation, the IL develops comprehensive test plans for ship-board, land based, and component testing. The test plans must describe the procedures the IL intends to use for the required verification testing, as well as any indirect evaluation of the operational limitations for which verification tests were not conducted. Technical questions regarding the IL's assessment of operational limitations for the BWMS under evaluation must be resolved between the IL and the manufacturer prior to development of the IL's Test Plan;
4) At the completion of testing, the IL provides the Coast Guard with a "Test Report" as part of the manufacturer's Type Approval Application that presents all test results, including all data regarding manufacturer supplied operational limitations. The Test Report must include a statement by the IL in accordance with 46 CFR 162.060-34(a)(4) that validates its evaluation and assessment of the operational limitations of the BWMS (statement of assessment);
5) The Coast Guard accepts the IL statement of assessment as part of an approved application, and issues a Type Approval Certificate that reflects the manufacturer-

identified operating limits. The application will be returned for revision if it is incomplete or the assessment requires additional information.

Background

The Coast Guard published Ballast Water Management regulations in 2012 which required BWMS to meet U.S. Type Approval standards when used as a compliance method under 33 CFR 151.2025. To certify that these systems met the standard, the Coast Guard requires each system go through a rigorous testing regimen. Type Approval testing includes land-based, shipboard, and component testing conducted in accordance with test plans designed to examine the manufacturer's stated requirements and procedures for BWMS installation, calibration, maintenance, and operations that will be used by the BWMS during each test, as appropriate for the specified test (46 CFR 162.060-24).

The purpose of land-based type approval testing is to determine if a BWMS performs acceptably and meets the ballast water discharge standard in accordance with the regulatory requirements set forth in 33 CFR Part 151 Subparts C and D. The ETV Protocol, incorporated by reference into the Coast Guard's regulations that govern type approval of BWMS (see 46 CFR § 162.060-5(d)(1)), sets forth a three-step process for evaluating a BWMS that consists of "planning, verification, and data assessment/reporting" phases. Included in the planning phase is the development of the Test/Quality Assurance Plan (TQAP) which must include an examination of all of the manufacturer's stated requirements and operational limitations. However, the ETV Protocol was not designed to certify or validate the performance claims of the BWMS manufacturer under extreme or unusual conditions that might be encountered during the operation of a vessel. Nor was the ETV Protocol designed to identify the specific limits of a BWMS with respect to all possible limiting conditions. If manufacturer performance claims extend beyond the range of the ETV test conditions or are not appropriate for assessment during the verification test, it is the obligation of the IL to evaluate and assess those claims separately (46 CFR 162.060-26).

The purpose of shipboard testing is to verify that the BWMS, when installed and operated in a vessel in accordance with the OMSM, results in the discharge of ballast water that meets the ballast water discharge standard. Shipboard testing must be conducted on vessels with ballast water rates and volumes representative of the upper end of the BWMS treatment rated capacity, and the vessel's operation must provide a range of geographic and seasonal conditions. Shipboard testing provides an opportunity to test and evaluate the performance of the BWMS under operational circumstances that are not practicable to achieve during smaller-scale land-based testing – for example, shorter or longer hold times, more challenging water quality conditions, a broader range of organisms, and greater flow rates and volumes (46 CFR 162.060-28).

Although not segmented in the regulations by party responsibility, there are distinct roles and responsibilities that the manufacturer, IL, and Coast Guard play in the design, review, and approval of the systems.

Roles and Responsibilities

Manufacturer

Before testing begins, the manufacturer must identify the operating conditions of the specific BWMS. The technical data package and OMSM submitted to the IL in advance of testing must identify operational limitations of the BWMS, such as process or technology limitations, performance ranges and expectations, and descriptions of locations and conditions for which the BWMS is intended (46 CFR § 162.060-38).

The ETV Protocol identifies several primary operating conditions of interest for land-based type approval testing, based on a general understanding of treatment technologies under consideration when the ETV Protocol was developed. An illustrative list includes, but is not limited to:

Water Conditions:
- Temperature
- Salinity
- Total suspended solids
- Particulate organic carbon
- Dissolved organic carbon
- Biomass
- Nutrient concentrations (N, P, Si)
- Turbidity
- Dissolved oxygen
- pH
- ATP or other measures of metabolic activity

Organism Concentration:
- Size class >50µm
- Size class 10-50µm
- Size class <10µm

System Operating Conditions
- Pressure
- System Flow Rate
- Sampling Flow Rate
- Treatment Dose
- Holding or treatment time

Additional parameters may be pertinent for existing systems and as new approaches to BWMS design and operation are developed.

Independent Laboratory (IL)

After receiving the manufacturer's technical data package and OMSM, the IL must develop a Test Plan to examine manufacturer claims and stated requirements made for performance profiles. Performance considerations, which are appropriate for testing during the land based verification tests, should be addressed in the TQAP. The TQAP should include how the IL will evaluate demonstrated treatment efficacy under ETV Protocol conditions. A supplemental portion of the TQAP or a separate test plan should describe in detail how the IL will evaluate any manufacturer-identified operational limitations that fall outside the scope of the ETV Protocol's

testing criteria and cannot be directly tested. This plan may include a description of empirical and non-empirical evaluations that will be conducted.

For those operational limitations that are appropriate for testing within the standard ETV Protocol as noted in 46 CFR 162.060-24, the empirical tests conducted in accordance with the system-specific TQAP will provide key data relevant to the assessment of limiting conditions. For limits that are outside the range of physical, chemical, and biological water conditions required by the ETV Protocol, the IL will need to develop a plan for evaluation that draws on other sources of information and knowledge. Technical references and scientific literature may provide the basis for an assessment of the manufacturer-identified operational limits and requirements that are not appropriate for testing empirically under the ETV Protocol. Importantly, testing and data collection are done on a system specific basis. The findings for one system are not immediately applicable to another system without justification. For example, asserting that hold time during land-based testing on an Electro-Chlorination treatment system should be used as justification for similar limitations on an Ultra-Violet treatment system, is not acceptable without consideration for the specific design and function of the systems. In its Test Report, the IL must provide a data (empirical or non-empirical) driven statement that supports each conclusion related to an operational limitation whenever possible.

When assessing manufacturer-identified limiting conditions, the IL must ensure that all pertinent limits are included, and may use available empirical data or published information to evaluate the stated limits as an alternative when verification testing is not appropriate for the specific test. The IL must clearly identify the sources of data and information used as a basis to justify the assessment, and it must explain how the data and information support the manufacturer's claim that a BWMS is expected to be effective within specific operating limits. The IL assessment may be based on empirical data, indirect information, or a combination of the two. In some cases, a specific parameter may not be relevant to the operation and effectiveness of a specific BWMS. In these cases, the manufacturer should make a statement that the parameter is not relevant, and the IL should provide an assessment of the manufacturer's statement.

The report from the IL must include a statement containing the IL's assessment that the BWMS operates at the rated capacity, performance, and reliability as specified by the manufacturer, including the applicable, relevant, and appropriate operating conditions claimed by the manufacturer (46 CFR § 162.060-34). The IL should provide the scientific or technical basis for its assessment of operating conditions and performance claims. The statement from the IL should also identify those parameters or conditions for which sufficient data is not available and for which no assessment can be made. Based on the details in the IL's statement, those operating limits may require further explanation if questioned by the Coast Guard.

The Coast Guard has received a number of inquires specific to required validation of shorter hold time as an operational limitation of the BWMS. A minimum of one day, or 24-hour, hold time following treatment is identified multiple times in the ETV Protocol but is most prominent in Section 5.4.5. Twenty-four hours was considered the minimum time that would generally be practicable for test facilities at the time the Protocol was developed. The Protocol does allow for longer hold times, and permits shorter hold times when justified. Under 46 CFR 162.060, empirically testing to hold-times shorter than 24 hours are not required, but may be used under some circumstances. In the event that a manufacturer elects to test at a hold time less than 24 hours, the manufacturer or the IL must submit a request for an alternative test in accordance with 46 CFR 162.060-10(b)(1). Such requests must clearly articulate why the shorter hold time is

appropriate given the manufacturer's stated operational and design claims, and why the selected hold time is practicable for the IL to implement. Although the regulations do not require empirical testing under the ETV Protocol to validate operational hold times shorter than 24 hours, a manufacturer may request to do so if the BWMS is specifically designed to be effective at a shorter hold time and they elect to validate it during land-based testing. If hold times longer than 24 hours are indicated by the manufacturer, longer times may be used in the test plan without prior approval, as the required hold time is a minimum of 24 hours. In the cases of both shorter and longer hold times, the IL must ensure that the sampling and analysis requirements of the ETV Protocol are met, and that tests meet all other requirements for valid test cycles.

At least five consecutive valid land-based tests are required under each salinity range for which approval is sought (46 CFR 162.060-26(b)). A manufacturer and IL may elect, but are not required by the Coast Guard, to conduct more than five test cycles, under one or more salinity regimes, to empirically test the BWMS efficacy at 24 hours as well as at greater or lesser hold times. Taking samples during empirical testing that mimic the operational hold time of the BWMS would provide the strongest support for a manufacturer identified hold time. In the event short duration tests are conducted under one or more of the three salinity ranges in addition to the required five tests at 24 hour hold time, a -10(b)(1) request would not be required, because the minimum number of tests specified in regulation would have been conducted.

Another source of empirical data to support shorter or longer hold times are the minimum of five shipboard tests. ILs may take advantage of real operating circumstances during the required shipboard testing to evaluate the ability of a BWMS to meet the discharge standard under hold times shorter or longer than 24 hours. In cases where empirical tests are not conducted at shorter or longer hold times, or for other manufacturer identified limiting conditions such as temperature, the IL will need to look to indirect evidence to assess the stated limits. Indirect evidence may include pertinent results from other type approval tests (such as available data from similar technologies with the same or similar dosages), information from widely accepted technical references, or other peer-reviewed scientific or technical publications.

Coast Guard

The Coast Guard will review and evaluate the IL's statements/supporting information that justifies the IL's conclusion regarding a manufacturer specified operational limitation. The Coast Guard will determine if the assessment of operating conditions and performance claims is justified by the information provided.

Test Reports with IL statements on operational limitations must be supported by appropriate scientific data and/or analysis. If Test Reports lack the appropriate scientific rigor and support, if a manufacturer-identified limiting condition or parameter is not assessed by the IL, or if a limiting condition or parameter pertinent to a particular type of BWMS is not identified by the manufacturer or the IL; the Coast Guard will request additional information and hold the application in abeyance pending a complete report/application. (Note – This last situation should be extremely rare, as procedures for evaluating all manufacturer–identified limiting conditions or parameters should be part of the IL's Test Plan.) Assessments based on non-empirical information must clearly explain why the information provided supports the assertion that the BWMS is likely to be effective under the specified conditions.

After approval of a BWMS application, the Coast Guard issues a Type Approval Certificate that references relevant manufacturer-identified operating conditions as assessed by the IL (46 CFR § 162.060-10(g)).

The manufacturer of a BWMS that is type approved by the Coast Guard must notify the Marine Safety Center of any changes in design or operational conditions (46 CFR § 162.060-16). As a general rule, existing Type Approval Certificates will not be amended unless requested by the manufacturer. After receipt of the manufacturer's notice, the Coast Guard will notify the manufacturer, in writing, of any tests or evaluations that must be conducted, and then determine if BWMS recertification and/or modification is required.

Coast Guard Type Approval Certificates are valid for a period of 5-years from the date set forth on the type approval certificate (46 CFR § 2.75-1). When renewal is required, the manufacturer may seek to change the limiting conditions identified in the OMSM and/or the Coast Guard may have new data indicating the previously identified limiting conditions need to be revised or amended. It is within the Coast Guard's discretion to amend a type approval certificate based on new data which was not available at the time the original type approval certificate was issued, or, the Coast Guard may require the manufacturer to submit additional information supporting a claim that the BWMS' limiting conditions should be revised and the Type Approval Certificate amended.

This letter is intended to provide guidance on existing regulatory standards. It does not mandate any additional requirements or alter the applicability of those standards. If you have additional questions or concerns, please contact me at (202) 372-1405 or sean.t.brady@uscg.mil.

Sincerely,

S. T. BRADY
Captain, U.S. Coast Guard
Chief, Office of Operating and Environmental Standards

Copy: NSF International
DNV GL AS Approval
Lloyd's Register EMEA
Control Union Certifications B.V.
Korean Register of Shipping
Commanding Officer, Coast Guard Marine Safety Center
Commandant, Office of Commercial Vessel Compliance