Practicability Review
Standards for Living Organisms in Ships' Ballast Water Discharged in U.S. Waters

Requirement

Pursuant to 33 Code of Federal Regulations (CFR) Subparts C (33 CFR § 151.1511(c) for The Great Lakes and Hudson River) and D (33 CFR § 151.2030(c) for waters of the United States), the Coast Guard is required to conduct a practicability review (Review) to determine:

> "Whether technology to comply with a performance standard more stringent than that required by paragraph (a) of this section can be practicably implemented, in whole or in part[;] *and* **(ii)** Whether testing protocols that can assure accurate measurement of compliance with a performance standard more stringent than that required by paragraph (a) of this section can be practicably implemented." 33 CFR §§ 151.1511(c)(1)/151.2030(c)(1).

If as a result of this Review, the Coast Guard determines that a more stringent standard could be practicably implemented, the regulations require the Coast Guard to "schedule a rulemaking to implement the more stringent standard." 33 CFR §§ 151.1511(c)(1)/151.2030(c)(1)

In conducting the Review, the Coast Guard considered the factors set forth at 33 CFR §§151.1511(c)(3)/151.2030(c)(3).

Scope of Review

The Coast Guard's legal authority applicable to regulation of non-recreational vessels, U.S. and foreign, that are equipped with ballast tanks and which operate in waters of the United States does not extend to onshore ballast water reception facilities, thus technology pertinent to this Review is limited to that which can be used on vessels.

Determination

The Coast Guard's Review is complete and determines that, at this time, technology to achieve a significant improvement in ballast water treatment efficacy onboard vessels cannot be practicably implemented. The reason for this determination is that, as of the date of this Review, there are no data demonstrating that ballast water management systems (BWMS) can meet a discharge standard more stringent than the existing performance standards in 33 CFR §§ 151.1511(a)/151.2030(a). In light of this determination, the Coast Guard has not evaluated whether testing protocols exist which can accurately measure efficacy of treatment against a performance standard more stringent than the existing performance standards.

Discussion

Criteria

During the Coast Guard's Review of whether technology to comply with a performance standard more stringent than the existing performance standard can be practicably implemented, all factors specified by regulation at 33 CFR §§151.1511(c)(3)/151.2030(c)(3) were considered. These factors are:

(i) The capability of any identified technology to achieve a more stringent ballast water discharge standard (BWDS), in whole or in part;
(ii) The effectiveness of any identified technology in the shipboard environment;
(iii) The compatibility of any identified technology with vessel design and operation;
(iv) The safety of any identified technology;
(v) Whether the use of any identified technology may have an adverse impact on the environment;
(vi) The cost of any identified technology;
(vii) The economic impact of any identified technology, including the impact on shipping, small businesses, and other uses of the aquatic environment;
(viii) The availability, accuracy, precision, and cost of methods and technologies for measuring the concentrations of organisms, treatment chemicals, or other pertinent parameters in treated ballast water as would be required under any alternative discharge standards;
(ix) Any requirements for the management of ballast water included in the most current version of the Environmental Protection Agency's Vessel General Permit and any documentation available from the EPA regarding the basis for these requirements; and
(x) Any other factor that the Coast Guard considers appropriate that is related to the determination of whether identified technology is performable, practicable, and/or may possibly prevent the introduction and spread of non-indigenous aquatic invasive species.

Information Sources for Ballast Water Management Systems

To make a determination on whether shipboard technology exists to achieve a more stringent BWDS, high quality credible data derived from comprehensive land-based and shipboard testing are required. At this time, the Coast Guard is not aware of any credible sources of data related to the evaluation of BWMS which apply equivalent standards of quality assurance and quality control as that required by the Coast Guard's current regulations at 46 CFR Part 162.060. Because of the lack of credible sources of data, it is not possible at this time to evaluate whether BWMS can achieve a more stringent standard than the existing United States standard.

In addition, as the Coast Guard explained in the preamble to the *Standards for Living Organisms in Ships' Ballast Water Discharged in U.S. Waters* (March 23, 2012) (Final Rule), in preparing the Review, the Coast Guard originally planned to draw "a significant component of its information from the type approved application packages that the Coast Guard expects to evaluate between [the] Final Rule's publication date and the initial implementation date." (77 FR 17254 at 17265). As of the date of this Review, the Coast Guard has not received an

application for type approval of a BWMS which has completed evaluation, inspection and testing by an independent laboratory, accepted by the Coast Guard, as required by Coast Guard regulations (46 CFR § 162.060-10(b)), and no BWMS has been type approved for installation on a vessel for the purpose of complying with the BWDS. Consequently, data conforming to the Coast Guard's required testing protocols in 46 CFR §162.060 are not available.

EPA Science Advisory Board Report

When the Coast Guard promulgated its Final Rule, it referenced a report prepared by the U.S. Environmental Protection Agency's (EPA) Science Advisory Board (SAB Report) titled "Efficiency of Ballast Water Treatment Systems: a Report by the EPA Science Advisory Board" (July 12, 2011, EPA-SAB-11-009). The SAB Report assessed the capability of certain existing shipboard treatment technologies to reach specified concentrations of organisms in vessel ballast water. The Coast Guard, citing to the SAB Report in the Final Rule, concluded that "[t]he numeric limitations in [the] final rule represent the most stringent standards that BWMS currently safely, effectively, credibly, and reliably meet." (77 FR 17254 at 17256).

The SAB Report was based on evaluation of test reports produced during type approval by foreign administrations in anticipation of entry into force of the International Convention for the Control and Management of Ships' Ballast Water and Sediments (Ballast Water Management Convention), which was adopted by the International Maritime Organization (IMO) in February 2004. At the time of the SAB Report, all BWMS had been evaluated using the methods set forth in the IMO Guidelines for Approval of Ballast Water Management Systems (G8) and the Procedure for Approval of Ballast Water Systems that Make Use of Active Substances (G9) (IMO 2008 a,b).

The SAB Report identified several important conclusions from its analysis of the existing data regarding the ability of available technology to meet the proposed Coast Guard discharge standard (referred to in the SAB Report as the "IMO D-2/Phase 1 standard"). The SAB Report (pgs 3-4, in response to charge question 1) found that of 34 categories of BWMS assessed, "five different categories … achieved significant reductions in organism concentrations, and were able to comply with the Phase 1 standard," but that "detection limits for currently available test methods preclude a complete statistical assessment of whether BWMS can meet standards more stringent than IMO D-2/Phase 1." The SAB Report included recommendations to improve the quality of available data necessary to demonstrate the ability of systems to exceed the current discharge standard, including the use of the EPA's "Generic Protocol for the Verification of Ballast Water Treatment Technologies, version 5.1 (dated September 2010) (ETV protocol). The ETV protocol was incorporated by reference into the required testing protocols in 46 CFR §162.060. To date, no complete test data resulting from independent tests in accordance with the Coast Guard requirements in 46 CFR 162.060 are available.

While the SAB Report includes information which might appear to support a finding that specified technologies can achieve a more stringent standard than what is currently required for one or more organism sizes, these technologies were not tested using the ETV protocols and do not meet other data requirements stipulated in the Coast Guard's regulations. The SAB Report (pg. 3) concluded that "current methods (and associated detection limits) prevent testing of BWMS to any standard more stringent than D-2/Phase 1 (the USCG discharge standard) and

make it impracticable for verifying a standard 100 or 1000 times more stringent. New or improved methods will be required to increase detection limits sufficiently to statistically evaluate a standard 10x more stringent than IMO D-2/Phase 1." Furthermore, the SAB Report concluded that improved methods for testing and reporting are needed to ensure that high quality data are available with which to assess BWMS performance. At the time of the SAB Report, and to date, all BWMS have been evaluated using the basic approaches provided by the IMO Guidelines for Approval of Ballast Water Management Systems (G8) and the Procedure for Approval of Ballast Water Systems that Make Use of Active Substances (G9) (IMO 2008a,b). While G8 and G9 suggest a basic framework, the level of detail required for rigorous and comparable BWMS testing is lacking.

Foreign type approved BWMS

The Coast Guard's Alternate Management System (AMS) program, established by regulation, accepts the installation of foreign type-approved BWMS for use in U.S. waters, in lieu of ballast water exchange, for up to 5 years after an individual vessel's compliance date. (33 CFR § 151.2026). The AMS program was implemented as a temporary bridging strategy in recognition that a significant number of shipowners that operate in U.S. waters were, in the absence of Coast Guard type approved BWMS, installing non-Coast Guard approved systems in anticipation of the entry into force of the Ballast Water Management Convention.

A prerequisite to being accepted by the Coast Guard as an AMS, a BWMS must have been approved by a foreign administration pursuant to the standards set forth in the Ballast Water Management Convention. Foreign administration testing and evaluation of BWMS have used testing procedures which do not conform to the requirements of U.S. regulations. In its type approval regulations, the Coast Guard allows a manufacturer whose BWMS has completed approval testing for a foreign administration to use the data and information developed during such approval testing to support the submission of an application for type approval (46 CFR § 162.060-12). If a manufacturer intends to submit the foreign administration approved BWMS for type approval and rely on data generated during that testing, the applicant is required to provide to the Coast Guard the data and other information developed during the foreign administration approval testing and include a "concise but thorough explanation of how the submission meets or exceeds the requirements of the Coast Guard's type approval regulations." (46 CFR § 162.060-12(a)). To date, no BWMS manufacturer with foreign administration approval has submitted an application for consideration which has been deemed acceptable by the Coast Guard.[1] As such, it is not practical for the Coast Guard to unilaterally compare test results from evaluations conducted by foreign administrations and draw well-founded conclusions. For example: (1) the lack of a requirement to report test failures during testing for approval under the IMO convention precludes development of a conclusion on the consistency or reliability of a BWMS; (2) the absence of complete Quality Assurance/Quality Control documentation, which was the case for most data packages reviewed in the SAB Report, renders unknowable the level of rigor in following the protocols and methods described; and (3) the lack of a clear requirement for testing to be performed independently of the manufacturer raises the potential for conflicts of interest in conducting and reporting the tests.

[1] As of the date of this Review, three BWMS manufacturers have systems which are the subject of administrative appeals before the Coast Guard's Deputy Commandant for Operations Policy & Capabilities (CG-DCO-D).

The Coast Guard continues to evaluate the quality of the data submitted in association with AMS applications, but strongly believes an assessment of the capabilities of systems to exceed the current standard will only be credible when the following are available: 1) data derived from testing in accordance with Coast Guard requirements in 46 CFR §162.060, 2) and evaluation of BWMS' long term operational performance onboard vessels, and 3) new test procedures with the capability of measuring to specific lower concentrations of organisms than are currently tested for during type approval evaluation.

Coast Guard's Shipboard Technology Evaluation Program (STEP)

The Coast Guard's STEP provides an incentive for shipowners to participate in the effort to develop and refine effective BWMS. During the development of a BWMS, a manufacturer may need to install a full-scale prototype BWMS on a ship to better investigate the performance of the system under realistic operating conditions. Such installations may entail significant efforts by the shipowner, and once the ship is required to comply with the Coast Guard's ballast water management regulations (other than ballast water exchange), the installation of a BWMS that is not an AMS or type approved by the Coast Guard may be viewed as not worth the effort. Under STEP, a vessel owner participating in a testing program deemed acceptable by the Coast Guard may use the prototype system to meet the ship's ballast water management requirements for a specific period of time. This allowance may provide some owners with sufficient incentive to participate in testing efforts, and so facilitate the development of more effective technology. Such testing efforts result in credible data, but are not specifically directed at quantifying the performance of the systems in the same manner as does testing for type approval. Key differences are that testing under STEP is performed by the developer of the system, not by a Coast Guard approved Independent Laboratory, and the testing is designed to answer questions identified by the developer, not to evaluate the system against the Coast Guard's type approval requirements. For these reasons, data from testing under STEP are not viewed as being applicable to the question of whether technology is available to meet more stringent discharge standards.

Independent Laboratories (IL)

In order to make any determination on a more stringent standard, the Coast Guard considers it appropriate and efficient to defer consideration until such time as test data from Coast Guard certified ILs that employ the type approval testing procedures prescribed in 46 CFR § 162.060 are received. These data are expected to be of sufficient quality on which to assess BWMS performance and ascertain whether a more stringent BWDS can be practicably implemented. During development of the ballast water regulations, the Coast Guard estimated type approval applications would be submitted as early as 2015; however, as of the date of this Review, no complete applications have been received. We are expecting type approval application submittals to occur in 2016.

BWMS type approval evaluation, inspection and testing at Coast Guard certified ILs is complicated and time consuming. The Coast Guard acknowledges that, as a foundational issue, the process to accept the ILs needed to test BWMS for type approval has been lengthy. However, the Coast Guard has currently accepted 5 ILs worldwide (see http://cgmix.uscg.mil for more information), and ILs are conducting BWMS testing for a number of systems. In sum, the

delays in testing which have been caused by the IL certification and approval process should now be significantly reduced.

Conclusion

The Coast Guard considered the extent to which the factors set forth at 33 CFR §§ 151.1511(c)(3)/151.2030(c)(3) are applicable given the current limitations in available data and standard test methods which would inform a decision that BWMS technology exists to achieve a significant improvement in ballast water treatment efficacy.

To best understand the capabilities of technology, the Coast Guard requires credible data from standardized testing performed independently of the developer/manufacturer and under rigorous quality assurance and quality control procedures. Such testing is now in progress under the Coast Guard's type approval program as described in 46 CFR 162.060. To date, no systems have completed the testing and submitted the requisite data to the Coast Guard. The Coast Guard believes it is more effective and efficient to await the availability of data from the type approval program, rather than enter into a parallel effort to evaluate data from disparate sources over which the Coast Guard has little or no control, or which are not designed to explicitly evaluate the performance of systems against the Coast Guard's discharge standard. Furthermore, only after experience with the existing test procedures would it make sense for Coast Guard and others to begin the effort of developing and validating procedures expressly designed to evaluate systems against more stringent standards. Important lessons will be drawn from the experience of implementing the existing procedures and methods that will greatly facilitate the development of procedures for evaluating systems against more stringent standards.

When credible data are available, i.e., from IL type approval testing and confirmation of reliable onboard operation of BWMS, the Coast Guard will re-evaluate the feasibility of implementing a more stringent BWDS as part of its requirement under the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990, as amended by the National Invasive Species Act of 1996 *(*16 U.S.C. §§ 4701 *et seq*) for ongoing review and revision of ballast water management guidelines and regulations. However, until such time as type approved BWMS are applied for, tested, approved, and installed, and the capability of available technology to exceed the current performance requirements can be quantitatively assessed, it is not currently practicable for the Coast Guard to implement a more stringent BWDS.

Therefore, until such time as: 1) BWMS applications are received and fully evaluated at ILs using Coast Guard approved test methods, 2) post-installation operational reliability is analyzed, and 3) more sensitive test methods are developed to allow an evaluation of performance in achieving even greater reductions in organism concentration, the Coast Guard concludes it is not possible to determine whether technology exists to practicably implement a more stringent BWDS.