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16714 CG-OES Policy Letter No. 01-20 September 16, 2020

From: S. T. BRADY, CAPT COMDT (CG-OES)

To: Distribution

Subj: USE OF MULTIPLE INDEPENDENT LABORATORIES (ILs) TO CONDUCT TYPE APPROVAL TESTING OF BALLAST WATER MANAGEMENT SYSTEMS (BWMS)

Ref: (a) "Standards for Living Organisms in Ships' Ballast Water Discharged in U.S. Waters," *Federal Register*, Vol. 77, No. 57, p. 17254, Friday, March 23, 2012, Final Rule

(b) Title 46 Code of Federal Regulations (CFR) Subpart 162.060

(c) Title 33 CFR Section 151.1511

(d) Title 33 CFR Section 151.2030

- 1. <u>PURPOSE</u>. To provide guidance when multiple ILs are used to conduct BWMS type approval testing in accordance with 46 CFR 162.060-10(b) and 46 CFR 162.060-16.
- 2. <u>ACTION</u>. The Coast Guard will follow this policy when implementing the BWMS type approval program. Internet release is authorized.
- 3. DIRECTIVES AFFECTED. None.
- 4. <u>DISCLAIMER</u>. This guidance is not a substitute for applicable legal requirements, nor is it itself a rule. It is not intended to, nor does it impose legally binding requirements on any party. It represents the Coast Guard's current view on this topic and may assist industry, mariners, the general public, and the Coast Guard—as well as other federal and state regulators—in applying existing statutory and regulatory requirements.
- 5. <u>APPLICABILITY</u>. This policy letter applies to the use of multiple ILs when conducting initial type approval testing of BWMS and amendments to those certificates.
- 6. <u>BACKGROUND</u>. The preamble of reference (a), at page 17273, states:

One commenter recommended that a manufacturer or vendor should be allowed to use multiple ILs as necessary and efficient during the different phases of approval testing.

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The Coast Guard agrees that a BWMS vendor may use the services of more than one entity to most effectively conduct the required tests, and there are provisions in this final rule that allow for this. However, in the interest of organizational and administrative efficiency, the Coast Guard requires that one IL coordinates and oversees all testing and reporting for each type-approval application.

Although the regulations do not specify criteria for the use of multiple ILs, 46 CFR 162.060-10(a)(2) requires the manufacturer to identify, in the Letter of Intent, any associated test facilities and subcontractors. Thus, it was anticipated that an IL may have multiple sub-labs, and those sub-labs may conduct testing for multiple ILs. For this reason, it is important that the application for initial type approval—as well as subsequent amendments—each have full oversight from a single IL with the ability to assess that the system was properly tested and meets all applicable requirements, as noted in reference (b).

- 7. INITIAL TYPE APPROVAL CERTIFICATE. The manufacturer of a BWMS may use multiple ILs, approved by the Coast Guard in accordance with 46 CFR 162.060-10(b), to conduct BWMS type approval testing. However, for the reasons stated in reference (a), a BWMS manufacturer must use one IL to coordinate and oversee all testing and reporting. This ensures consistency and provides a holistic understanding of the system's performance, as well as its limitations. It is the manufacturer's responsibility to select the coordinating IL. The coordinating IL must have access to the necessary material to ensure proper oversight of all testing and evaluations. If the manufacturer changes the coordinating IL during the testing or application process, the new IL must be able to verify the existing tests with the same level of oversight expected of the first IL. This verification includes access to all the test procedures, results, and sub-lab notes.
- 8. AMENDMENTS TO THE TYPE APPROVAL CERTIFICATE. The manufacturer of the BWMS will follow the requirements in 46 CFR 162.060-16 for any changes to an approved BWMS. This includes notifying the Coast Guard's Marine Safety Center (MSC). In cases where the MSC requires additional testing or evaluations, that work must be conducted and assessed by the IL to the criteria specified in the MSC's reply to the manufacturer's notification. To ensure a holistic view of the system and attest to the ability of the BWMS to meet the ballast water discharge standard per references (c) and (d), the coordinating IL is responsible for evaluating and verifying the overall certification, regardless of any changes made or any previous involvement by other ILs. This may be the case for proprietary information or where the information is lost.
- 9. <u>TYPE APPROVAL CERTIFICATE</u>. The coordinating IL, as determined by the manufacturer, will be the only IL listed on the most current type approval certificate.
- 10. <u>QUESTIONS</u>. If you have questions regarding the above, please contact the Chief of the Environmental Standards Division at <u>environmental standards@uscg.mil</u>.