

(iv) Operates at the rated capacity, performance, and reliability as specified by the manufacturer;

(v) Contains control and monitoring equipment that operates correctly;

(vi) Was installed in accordance with the technical installation specification of the manufacturer for all tests; and

(vii) Was used to treat volumes and flow rates of ballast water during the shipboard tests consistent with the normal ballast operations of the vessel.

(b) Executive summary.

(c) Introduction and background.

(d) Description of the BWMS.

(e) For each test conducted, summary descriptions of—

(1) Test conditions;

(2) Experimental design;

(3) Methods and procedures; and

(4) Results and discussion.

(f) Appendices, including—

(1) Complete Test Plans for land-based, shipboard, and component tests, for which an EPA Environmental Technology Verification (ETV) Verification Report produced in accordance with the ETV Protocol can substitute for the land-based test plan;

(2) Manufacturer supplied Operation, Maintenance, and Safety Manual that meets the requirements of §162.060–38 of this subpart;

(3) Data generated during testing and evaluations;

(4) Quality Assurance and Quality Control records;

(5) Maintenance logs;

(6) Relevant records and tests results maintained or created during testing;

(7) Information on hazardous materials, active substances, relevant chemicals, and pesticides as detailed in paragraph (g) of this section; and

(8) Permits, registrations, restrictions, and regulatory limitations on use.

(g) The Test Report for a BWMS that may incorporate, use, produce, generate as a by-product and/or discharge hazardous materials, active substances, relevant chemicals and/or pesticides during its operation must include the following information in the appendix of the Test Report:

(1) A list of each active substance or preparation used in the BWMS. For each active substance or preparation that is a pesticide and is not generated

solely by the use of a device onboard the same vessel as the ballast water to be treated, the appendix must also include documentation that the sale or distribution of the pesticide is authorized under the Federal Insecticide, Fungicide, and Rodenticide Act for use for ballast water treatment. For all other active substances or preparations, the appendix must include documentation of the assessment specified in §162.060–32(b) of this subpart.

(2) A list of all hazardous materials, including the applicable hazard classes, proper shipping names, reportable quantities as designated by 40 CFR 117.1, and chemical names of all components.

§ 162.060–36 Quality Assurance Project Plan (QAPP) requirements.

The approval testing and evaluation process must contain a rigorous Quality Assurance and Quality Control program consisting of a QAPP developed in accordance with ISO/IEC 17025:2005(E), as amended ISO/IEC 17025:2005/Cor.1:2006(E) (incorporated by reference, *see* §162.060–5). The independent laboratory performing approval tests and evaluations is responsible for ensuring the appropriate Quality Assurance and Quality Control procedures are implemented.

§ 162.060–38 Operation, Maintenance, and Safety Manual (OMSM).

(a) Each OMSM must include the following sections:

(1) Table of contents.

(2) Manufacturer's information.

(3) Principles of ballast water management system (BWMS) operation, including—

(i) A complete description of the BWMS, methods and type(s) of technologies used in each treatment stage of the BWMS;

(ii) The theory of the BWMS' operation;

(iii) Any process or technology limitations of the BWMS;

(iv) Performance ranges and expectations of the system; and

(v) A description of the locations and conditions for which the BWMS is intended.

(4) Major system components and shipboard application, including—

(i) A general description of the materials used for construction and installation of the BWMS;

(ii) A list of each major component that may be fitted differently in different vessels with a general description of the different arrangements schemes;

(iii) Any vessel type(s), services, or locations where the BWMS is not intended to be used;

(iv) Maximum and minimum flow and volume capacities of the BWMS;

(v) The dimensions and weight of the complete BWMS and required connection and flange sizes for all major components;

(vi) A description of all actual or potential effects of the BWMS on the vessel's ballast water, ballast water tanks, and ballast water piping and pumping systems;

(vii) A list of all active substances, relevant chemicals, and pesticides generated or stored onboard the vessel to be used by the BWMS; and

(viii) Information on whether the BWMS is designed to be used in hazardous locations.

(5) System and major system component drawings as applicable, including—

(i) Process flow diagram(s) of the BWMS showing the main treatment processes, chemicals, and monitoring and control devices for the BWMS;

(ii) Footprint(s), drawings, and system schematics showing all major components and arrangements;

(iii) Drawings, containing a bill of materials, for the pumping and piping arrangements, and all related equipment provided with the BWMS;

(iv) All treatment application points, waste or recycling streams, and all sampling points integral to the BWMS;

(v) All locations and the sizes of all piping and utility connections for power, water, compressed air or other utilities as required by the BWMS;

(vi) Electrical wiring diagrams that include the location and electrical rating of power supply panels and BWMS control and monitoring equipment;

(vii) Unit(s), construction materials, standards, and labels on all drawings of equipment, piping, instruments, and appurtenances; and

(viii) An index of all drawings and diagrams.

(6) A description of the BWMS's control and monitoring equipment and how it will be integrated with the existing shipboard ballast system, including—

(i) Power demand;

(ii) Main and local control panels;

(iii) Power distribution system;

(iv) Power quality equipment;

(v) Instrumentation and control system architecture;

(vi) Process control description;

(vii) Operational set points, control loops, control algorithms, and alarm settings for routine maintenance, and emergency operations; and

(viii) All devices required for measuring appropriate parameters, such as pressure, temperature, flow rate, water quality, power, and chemical residuals.

(7) A description of all relevant standard operating procedures including, but not limited to—

(i) BWMS start-up and shutdown procedures and times;

(ii) Emergency shutdown and system by-pass procedures;

(iii) Requirements to achieve treatment objectives (e. g., time following initial treatment, critical dosages, residual concentrations, etc);

(iv) Operating, safety, and emergency procedures;

(v) BWMS limitations, precautions, and set points;

(vi) Detailed instructions on operation, calibration and zeroing of each monitoring device used with the BWMS; and

(vii) Personnel requirements for the BWMS, including number and types of personnel needed, labor burden, and operator training or specialty certification requirements.

(8) A description of the preventive and corrective maintenance requirements of the BWMS, including—

(i) Inspection and adjustment procedures;

(ii) Troubleshooting procedures;

(iii) An illustrated list of parts and spare parts;

(iv) A list of recommended spare parts to have during installation and operation of the BWMS;

(v) Use of tools and test equipment in accordance with the maintenance procedures; and

(vi) Point(s) of contact for technical assistance.

(9) A description of the health and safety risks to the personnel associated with the installation, operation, and maintenance of the BWMS including, but not limited to—

(i) The storage, handling, and disposal of any hazardous wastes;

(ii) Any health and safety certification/training requirements for personnel operating the BWMS; and

(iii) All material safety data sheets for hazardous or relevant chemicals used, stored, or generated by or for the system.

(b) If any information in the OMSM changes as a result of approval testing and evaluations, a new OMSM must be submitted.

§ 162.060-40 Requirements for Independent Laboratories (ILs).

(a) For designation by the Coast Guard as an independent laboratory for the evaluation, inspection, and testing of BWMS, an independent laboratory must demonstrate compliance with 46 CFR 159.010-3, 46 CFR 159.010-5, and 46 CFR 159.010-11 through 159.010-19.

(b) Each request for designation as an independent laboratory authorized under paragraph (a) of this section must be delivered to the Commandant (CG-ENG), Office of Design and Engineering Standards, U.S. Coast Guard, 2nd St. SW., Stop 7126, Washington, DC 20593-7126, in a written or electronic format.

(c) A list of independent laboratories designated by the Coast Guard under paragraph (b) of this section may be found at <http://cgmix.uscg.mil/>, or may be obtained by contacting the Commandant (CG-ENG), Office of Design and Engineering Standards, U.S. Coast Guard, 2100 2nd St. SW., Stop 7126, Washington, DC 20593-7126.

§ 162.060-42 Responsibilities for Independent Laboratories (ILs).

(a) Upon receipt of a request from a manufacturer for approval testing of a ballast water management system (BWMS), the independent laboratory will conduct a readiness evaluation and

determine the acceptability of the BWMS for testing.

(1) The readiness evaluation will 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 it safely onboard vessels. This evaluation must determine that the BWMS—

(i) Is designed and constructed according to the requirements of § 162.060-20 of this subpart;

(ii) Meets all existing safety and environmental regulatory requirements for all locations and conditions where the system will be operated during the testing and evaluation period; and

(iii) Meets the definition of a complete BWMS, as defined in this subpart, to include both ballast water treatment equipment and control and monitoring equipment. Only complete systems in the configurations in which they are intended for sale and use will be accepted for type-approval testing.

(2) The independent laboratory has the right to reject a proposed BWMS for type-approval testing if it does not satisfy the requirements in paragraph (b) of this section, is not deemed ready for approval testing or if, for technical or logistical reasons, that independent laboratory does not have the capability to accommodate the BWMS for testing or evaluation.

(3) Upon determination that the BWMS is ready for testing, the independent laboratory will notify the Commanding Officer, U.S. Coast Guard Marine Safety Center, 2100 2nd St. SW., Stop 7102, Washington, DC 20593-7102, and provide the estimated date for commencement of type-approval testing.

(b) The independent laboratory must prepare a written Test Plan for each approval test to be completed, in accordance with § 162.060-24 of this subpart.

(c) Prior to land-based testing, the independent laboratory must ensure that the BWMS supplied by the manufacturer is set up in accordance with the BWMS' Operation, Maintenance, and Safety Manual (OMSM).