

2010 Shipboard Technology Evaluation Program General Guidance for the Applicant

1.0 Information for the Applicant

1.1 Program overview and objectives

The United States Coast Guard Shipboard Technology Evaluation Program (STEP) for assessment of onboard treatment of ballast water is designed to provide incentive to ship owners and operators to install experimental or prototype ballast water management (BWM) systems with demonstrated potential for effective removal or destruction of unwanted organisms in ballast water. This document summarizes the policy, implementation, and general guidance for STEP, found in the Coast Guard [Navigation and Vessel Inspection Circular no. 01-04](#), "Shipboard Technology Evaluation Program (STEP): Experimental Ballast Water Treatment Systems", and the STEP 2010 application process.

Acceptance into STEP results in a designation of equivalency to current and future ballast water discharge standard regulations, for up to the life of the vessel or the system, while the prototype system operates satisfactorily. The U. S. Coast Guard (Coast Guard) and the successful Applicant enter into an agreement whereby valuable experimental data accrues to the Government and the public at large and the Applicant's vessel is accepted into the STEP for a specific period of time, during which operation of the experimental system is considered equivalent to meeting applicable regulatory requirements for ballast water management. The terms of the equivalency require that the application meet a detailed set of specifications to enable a thorough evaluation prior to acceptance.

Since this is a prototype technology evaluation program, the general expectations for STEP study plans are for well-conceived and statistically defensible experimental designs and proper testing protocols. This makes a STEP study plan substantially different from the dossier one would develop to demonstrate compliance with an existing regulatory standard. The updated application provides a detailed framework for applicants to frame their study design. A successful application completes this template and addresses the testing and monitoring provisions outlined in NVIC 01-04, including:

A. Treatment Efficacy Study Plan

- The applicant needs to present a cogent argument in support of their proposed study plan that addresses statistical sufficiency and appropriateness. The methodology should be chosen to address:

- Replicates, including repeated experimental runs or cruises and replicated ballast tanks, samples of treated and untreated ballast water. Analytical replicates, within each experimental run, need to support valid statistical analysis as well as capture natural and analytical variability related to enumerating ballast water organisms.
- Sample volumes must be large enough to account for the non-uniformity of organisms and to permit a statistical resolution that can detect viable numbers over and above counting error.
- It is important that the experimental design selected by the applicant yield results with clear detection limits and pre-determined accuracy and precision of results.
- Finally the test plan should clearly show how you ***know*** you have enough replicates/sample volume to accurately assess treatment effectiveness.

Testing with appropriate challenge waters.

- Applicants should self select ships with applicable routes.
- Successful applicants will be able to conduct testing in organically active natural waters- those with sufficient numbers of organisms. These waters typically occur in harbors, estuaries, near-shore shelf waters. They typically do not include open-ocean or tropical offshore waters.
- Ships with “liner” routes offer the greatest ease of study design and for getting numerous samples to make the statistically valid conclusions sought by STEP.

B. BWM system performance

- The application should provide evidence of the system’s performance based on smaller scale experiments. Laboratory studies must demonstrate that the Coast Guard’s treatment criteria as specified in the NVIC can be met. Including:
 - 98% removal of organisms ≥ 50 microns, and testing the efficacy of the treatment system for inactivation, removal or killing of eukaryotic organisms < 50 microns and bacteria.
 - Results of experiments specifically addressing the mortality and/or viability of the wide variety of organisms present in ballast water. This requires that the test program capture differences in mortality and/or viability by taxa. Since it is not expected that an applicant test across a wide variety of source waters, this information allows for the discrimination of potentially rare but highly resistant organisms.

- Viability determinations of the upper 5 most abundant taxonomic groups of the ≥ 50 micron size class of organisms; upper 3 most abundant taxonomic groups of phytoplankton (or the < 50 μm & ≥ 10 μm size class).

C. STEP Equivalency period, and experimental and monitoring phases

The equivalency is granted for the lesser of the life of the vessel or the service life of the BWM system. The equivalency determination applies to 33CFR151.2035(b) requirements. The operator remains responsible for compliance with other applicable portions of BWM regulations currently found in 33CFR151 Subparts C & D.

o Experimental phase

- Year 1 system installation and testing, including primary biological experiment(s)
- Year 1-5 collection of operational readiness and system performance data
- Year 5 repeat primary experiment
- Quarterly and annual reports

o Monitoring Phase. Requires that the system performance parameters be tracked to ensure that it continues to function within the manufacturers' performance parameters.

- During the monitoring phase the operator must continue to use the system for all BWM activities and file annual reports of system performance.

Applicants should note that there is an important operational difference between BWM system testing for removal or inactivation of biological organisms versus routine ballasting operations once accepted into STEP. System testing may include treatment of the water in a subset of the ship's tanks, while routine operations during the equivalency period must include treatment of all ballast water in all tanks as the ship's method of ballast water management.

D. Environmental compliance requirements

o Requirement that Coast Guard ensure compliance through the National Environmental Policy Act (NEPA) process.

- Due diligence by Applicant in providing requested biological and ecological information, and obtaining the applicable permits (e.g.- FIFRA registration for biocidal treatment systems) from regulatory agencies (Federal, state, local).
- Systems found to have potential for adverse impact on the environment or presenting a risk to the vessel or human health will require redesign, mitigation or likely will not be enrolled or if already enrolled may be withdrawn from the program.

E. Safe design and operation

- Foreign vessel owners must provide documentation that indicates that the proposed installation satisfies their classification society and flag Administration.
- U.S. vessel owners must submit drawings and other information on the interface between the proposed BWM system and the vessel's vital systems to their classification society and the USCG Marine Safety Center, showing that the interface does not degrade existing systems or create dangerous conditions.

F. Significant BWM System Modifications

- Since these are prototype systems, it is expected that changes, adjustments and modifications may be identified and the need for such changes is not viewed negatively. System manufacturers' must report plans for system or operational modifications. These reports should include documentation/support for module upgrades and revised functionality expectations.

1.2 Who may apply

STEP applicants must be ship owners or operators, that is, the entity that receives the regulatory equivalence offered by the Coast Guard with respect to ballast water management. The Applicant must:

- Propose a particular ship or ships for the BWM system installation
- Have BWM system installed on the ship or have detailed design drawings for the installation
- Have a BWM system that is ready for shipboard installation
- Have test information (bench, pilot, or full scale, the latter including shoreside or shipboard trials) providing clear evidence that the BWM system can treat ballast water to the NVIC specification;
- Have sufficient technical and operational data to complete the data tables in the STEP 2010 Application Form. Prospective applicants should review the Form carefully to ensure that their test program is sufficiently mature for consideration for acceptance into STEP by the Coast Guard.

1.3 Role of the Review Panel

The Volpe National Transportation Systems Center (Volpe Center) is an agency of the U.S. Department of Transportation. The Volpe Center acts as the Coast Guard's technical agent in this matter and manages the STEP Review Panel. The Review Panel consists of marine biologists and marine and civil engineers, with multiple persons in each relevant subject matter area. For each STEP application, the Volpe Center STEP

project manager will designate a Review Team (four to six people) from the Review Panel. The Review Panel's work includes:

- Technical evaluation of STEP applications;
- Observation and evaluation of the experimental test program, including shipboard visits, in Years 1 and 5 of the equivalency period;
- Review of the Applicants' reports on the monitoring of the treatment system's operation and performance throughout the equivalency period. Neither the Volpe Center nor the Review Panel has any enforcement authority. The Panel's findings and recommendations will, in part, be the basis of the Coast Guard's decisions on acceptance into the STEP and of compliance with STEP's terms during the period of equivalency.

1.4 STEP Program contact information

- LCDR Brian Moore, STEP project manager (202-372-1434)
- Website: <http://www.uscg.mil/hq/cg5/cg522/cg5224/step.asp>

2.0 STEP Application Submittal, Review and Approval Process

2.1 Application Format and Quality

STEP is a significant change in the way Coast Guard requests information from applicants. The STEP Application Form emphasizes presentation of technical information in pre-formatted figures and tables with brief textual descriptions, with primary references organized in appendices. To be accepted by the Coast Guard, a STEP application must follow the format and information requests listed in Table 1 of the STEP Application Form. The Applicant must provide all requested data, but may add or omit information provided as applies to their particular system if there is satisfactory explanation for the change. The Coast Guard and the Review Panel expect applications of high quality, which must include, specifically:

- Completion of all tables in application form
- Succinct, clear language
- Inclusion of all technical data requested in the Application Form, avoiding reference to appendices or cited materials for such data
- Proper referencing of appended materials

- Primary references (required for review) included as appendices
- Submission of the application in electronic format
- Submission of five hard copies of the application

2.2 Milestones:

The major milestones in the STEP program are the following:

- Initial completeness review by the Review Team to ensure that all required elements of the application are in place;
- Revision/augmentation of the application, as determined by the initial completeness review.
- Detailed technical review of the application and supporting documentation by the Review Team. This phase has typically required multiple communications between the panel and the applicants scientific and vendor team.
- Submission of panel's Technical Report to the Coast Guard
- Coast Guard NEPA documentation publication
- Coast Guard decision, re: acceptance into STEP

The Applicant is not responsible for the development of ecological data or environmental analysis, but must provide sufficient information about the BWM system operation, in particular residual chemicals in discharged ballast water and other waste streams, and the ship's operation, in particular volumes of water loaded and discharged and the range of existing and potential geographic locations for those operations.

2.3 Communications between Applicant and the Government

It is important that clearly defined lines of communication, particularly during the review of STEP applications, be established between the Applicant and Government, since review and approval of the application is an intensive, short term process involving the Review Panel, the Coast Guard, and, sometimes, other Federal agencies. The important lines of communication are between:

- A. Applicant and Coast Guard: Applicant's STEP project manager and the Coast Guard STEP program manager (LCDR Moore).
- B. Applicant and Volpe Center:

- For project management, scheduling matters, set-up of meetings and teleconferences: Applicant's STEP project manager and Volpe Center's designated Review Team leader (Contact information to be provided upon receipt of application)
- For technical matters: Applicant's and Review Team's respective subject matter experts, via telephone and E-mail, as determined by the Applicant's STEP project manager and Volpe Center's designated Review Team Leader.

3.0 Post-Approval Process and Activities

3.1 Experimental Period – Years 1 - 5

The Review Panel's work continues following the decision of the Coast Guard to accept the vessel into STEP. The Panel's evaluation of compliance with the study plan and system operation will continue throughout the experimental phase (Years 1 - 5) of the equivalency period, through review of reports submitted by the Applicant. The Panel will function similarly in tracking the system's engineering and treatment performance during the monitoring phase (Years 6 and onward). Onboard inspections may be carried out by the Coast Guard as part of routine and non-routine vessel inspections throughout the equivalency period.

The Review Panel will request one or more site visits:

- Scoping visit to the ship following installation and engineering testing of the treatment system and before the start of the experimental program.
- One visit to the ship during the primary experimental test program.
- One or more follow up visits in subsequent years for monitoring of operational and environmental performance of the system, including the Year 5 repetition of the primary experiment(s).

Applicants may request additional visits should they determine a need.

3.2 Monitoring Period – Years 5 – End

During the monitoring phase (post Year 5), the Applicant is required to provide annual reports only, for review by the Review Team and the Coast Guard. The Coast Guard does not anticipate the need for detailed inquiry or ship visits by the Review Team during this period, unless the Applicant makes significant modifications to the design or operation of the BWM system, or if system performance degrades significantly or fails in terms of engineering, treatment efficacy, or environmental compliance. As part of the ships overall machinery, the BWM system is subject to inspection by U.S. Coast Guard and other nations Port State Control officers conducting routine port entry inspections.