STEP 2010 APPLICATION REVISION: RATIONALE AND EXPLANATORY NOTES

April 2010

Introduction

The United States Coast Guard Shipboard Technology Evaluation Program (STEP) for onboard ballast water treatment systems provides incentive to ship owners and operators to install and operate experimental or prototype treatment systems with demonstrated potential for effective removal or destruction of organisms in ballast water. General program guidance is available both in the STEP Application Instructions and in the Coast Guard Navigation and Vessel Inspection Circular (NVIC) no. 01-04, "Shipboard Technology Evaluation Program (STEP): Experimental Ballast Water Treatment Systems".

The 2010 revision of the STEP application form takes into account recent research on ballast water treatment and performance experimentation and measurement methods. There have been two noteworthy developments:

- Technical guidance of the Environmental Technology Verification (ETV) program for land-based testing of ballast water treatment (BWT) systems, jointly administered by USCG and the Environmental Protection Agency (EPA). ETV includes thoroughly validated well-defined sampling and analysis protocols for biological experiments designed to measure performance of BWT systems. The Coast Guard has reviewed STEP guidance and decided that adaptation of the ETV methods to shipboard tests will yield the most reliable and meaningful results. The revised STEP application identifies ETV sampling and analytical protocols as the preferred approach to the development of a study plan.
- Analysis by the Naval Research Laboratory in Key West, Florida showing that sample volumes commonly used in past shipboard tests are insufficient to yield statistically significant numbers of live and dead organisms in the largest size category proposed in either domestic or international regulation (i.e., ≥ 50 μm dimension). The significant new development for STEP study plans is the requirement to demonstrate adequate statistical power in the sampling methods. That is, the water volumes must be large enough to have the potential to yield sufficient numbers of organisms for the live/dead counts in the assays to be meaningful. The revised STEP application includes guidance on sampling design derived from the NRL work and also allows for alternative approaches where the Applicant can show that the methods yield equivalent statistical power.

This revision also includes changes clarifying the technical requirements of the USCG and the Review Panel and other modifications intended to reduce the Applicant's burden. The latter include the elimination of several sub-sections in Section 3 "Ballast Water Treatment System Description" and consolidation of Section 4 "Proof of Performance" from seven sub-sections down to four.

A draft version of the STEP 2010 application was the subject of intensive review during a two-day workshop held at the Volpe Center (Cambridge, Massachusetts) during April 7-8, 2010, attended by Government, industry, and science community representatives.

This document aims to explain the substantive revisions in STEP 2010, by identifying the reason(s) for which each change was first proposed, the technical points considered (from literature and discussion), and the outcome. The organization of this document is parallel to that of the STEP 2010 application, that is, with the same numbering for sections and subsections.

Please note the following as you read this document:

- Deletions of numbered subsections, tables, etc. are referred to using identifying numbers from the previous STEP 2006 application.
- Additions of numbered subsections, tables, etc. are referred to using identifying numbers from the new STEP 2010 application.

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FRONT MATTER

- Modified Table of Contents to suit
- Added "Checklist", for use by the Applicant (optional)

SECTION 1.0: APPLICANT'S TEST ORGANIZATION AND MANAGEMENT PLAN

- Deleted subsection 1.6 "Public Funding Sources"
    - Reason. No further program need for this information.
    - Outcome. USCG decision to delete.

SECTION 2.0: VESSEL AND EXISTING BALLAST WATER SYSTEM SPECIFICATIONS

- Deleted Table 2-2 "Crew and Watchstanding Information"
    - Reason. No further program need for this information. Reduce Applicant's burden.
    - Outcome. USCG decision to delete.
- Deleted requests for several types of as-built drawings, leaving only BW and cross-connected piping diagrams
    - Reason. No further program need for this information. Reduce Applicant's burden.
    - Outcome. USCG decision to delete.

SECTION 3.0: BALLAST WATER TREATMENT SYSTEM DESCRIPTION

- Added Subsections 3.1 "Acceptability Criteria for BWT Systems" and 3.2 "Verification of Treatment Performance Claims"
    - Reason. Subsections 3.1 and 3.2 were added to the STEP application to ensure that the Applicant clearly understands the importance of and documents the relationship between prior experimentation (lab, pilot-scale, full-scale prototype studies) and development of treatment performance goals and design parameters for the BWT system.
    - Discussion. The Applicant will certify that the proposed BWT system meets several acceptance criteria:
        - Demonstrate that it can remove, kill or inactivate marine organisms, in accordance with stated treatment performance goals, for the ship's ballast water flows and volumes, for the anticipated range of operating conditions

        - Identify environmental and operational constraints for the BWT system, address disinfection residuals, by-products, and toxicity
        - Specify operational ranges and setpoints
        - All the foregoing must be supported by documented results of previous laboratory, pilot-scale (e.g., barge or shoreside) and/or full-scale testing, reported in Section 4.0 "Proof of Performance". The performance goals and BWT system operating parameters and setpoints (Sections 3.0 and 5.0) must be consistent with the experimental results presented in Section 4.0.
    - Outcome. The group agreed to adopt this clarified guidance.

- Revised Subsection 3.5 "Physical Configuration and Shipboard Installation"
    - Reason. Get focus on what is essential for the Review Team to have, and reduce Applicant's submittal burden to the extent possible.
    - Discussion. The group considered what drawings should be requested from applicants, for the appropriate level of detail typically produced for shipboard BWT system designs, and what is essential for the USCG's review.
    - Outcome. The list of requested BWT system drawings, shipboard installation drawings, and electrical, process and instrumentation drawings has been reduced. The former subsection 3.4 "Shipboard Support System Requirements" was merged into subsection 3.5.

- Deleted 3.6.4 "BWT System Reliability"
    - Reason. No further program need for this information. Reduce Applicant's burden.
    - Discussion. This information will be captured through the quarterly and annual reports.
    - Outcome. USCG decision to delete.

- Deleted "Vessel Safety Matters" from Subsection 3.8 "Crew Health and Safety"
    - Reason. Implementation of the ISM code makes this section a duplication of information required under other laws and regulations.
    - Discussion. Ship safety matters relating to the installation of the BWT system are subject to review by the ship's flag administration, classification society or by the Coast Guard.
    - Outcome. USCG decision to delete this requirement and substitute statement that operator is responsible for vessel safety elements, with guidance as to the modification of the Ship's Safety Management System.

- Deleted Subsection 3.8 "Cost Estimates"
    - Reason. No further program need for this information. Reduce Applicant's burden.
    - Discussion. None.
    - Outcome. USCG decision to delete.

4.0 PROOF OF BALLAST WATER TREATMENT PERFORMANCE

- Added provision that the report of a successful ETV test is alone sufficient and may substitute for the entirety of Section 4.
    - Reason. Reduce Applicant's and STEP Review Team's burden.
    - Discussion. Successful completion of ETV shoreside tests more than exceeds STEP thresholds.
    - Outcome. Incorporated.
- Consolidated former subsections 4.1 through 4.6 to 4.1 through 4.3; the new subsections cover all general technical literature citations and prior BWT testing for the proposed system.
    - Reason. Reduce Applicant's and STEP Review Team's burden, and clarify the requirements for completing the tables provided.
    - Discussion. None.
    - Outcome. Section 4 is consolidated as proposed. Each subsection has two revised tables ("a" and "b"), which clearly demark general background literature from experimental work focused on BW treatment for the particular system proposed for STEP.

5.0 STEP STUDY PLAN

- Modified discussion of performance goals (Subsection 5.2) to clarify USCG's program goals and guidance as to the Applicant's shipboard treatment performance goals.
    - Reason. There has been confusion about the purposes of STEP testing and how applicants express BWT system performance goals: as concentrations of organisms or percentages/log reductions.
    - Discussion. Ideally the USCG's STEP purpose is to confirm shoreside testing of BWT systems and to learn about how the system configurations, maintenance, and reliability are affected by shipboard installation impacts. Because of the structural limitations to doing controlled experiments upon a working vessel, the program does NOT seek to independently determine absolute treatment efficacy.

      Outcome. Subsection 5.2 spells out the USCG's program goal and allows applicants to declare a variety of performance goals.
- Modified subsection 5.3 to offer more generalized and less prescriptive guidance on "challenge water".
    - Reason. It is often difficult for an operator to find challenge water up to specification and the expense/effort of sea testing may be for naught if it falls short.
    - Discussion. Shipowners need more practical guidance as to where the right water conditions can be found, thus removing the risk of failed tests and wasted resources due to challenge water issues. Available data showing global productivity by seasons and localities (e.g., coastal temperate Europe/North America/Asia) could be researched by prospective applicants.

      CG could be "selective" for operators in areas known to have very low

productivity and organism numbers. This would not prevent STEP entry by ships operating in such areas, but CG would avoid accepting multiple systems.

It would, however, be beneficial for Applicants to gather and preserve challenge water samples for analysis later.

- Outcome. Subsection 5.3 guidance language modified; includes data sources for productivity of ocean waters and requirement for sampling/preserving challenge water. Table 5-4 retained for guidance purposes only.

- Modify Subsection 5.3 "Ballast Water Treatment Experimental Methods" to modify guidance on paired treatment and control tanks.
  - Reason. There have been difficulties in past STEP applications because of conflict between experiments requiring the use of multiple tanks and the ordinary operations of ships' BW systems. The USCG has pointed out that control water is not managed (per BWM regulations), and therefore should not be discharged unless treated after the experiment.
  - Discussion. Absent the problems mentioned above, the use of paired control and treated ballast tanks is the best approach for determining the effectiveness of a BWT system, both for replication and statistical power and for measurement of unaccounted variables in the control tanks. However, the requirement that STEP vessels treat all ballast water may result in contamination of control tanks with previously treated water that contains treatment residuals and byproducts. As a result it may be necessary in some cases to design a test program that focuses on challenge water and treated water measurements, although most likely this will require more test runs than if control data was available.

    The group discussed the merits of different designs relative to replication, that is, the variations of voyages, number of tanks sampled, and samples per tank. The suggestion that treating and sampling the entire ship would only be valid for the case where a ship ballasts all tanks at the same time. [3 x 3; it's not pseudo-replicating if you do it on different voyages for the 3 replications; if it's one voyage and you're taking 3 tanks and sampling them, it would be pseudo-replication; one tank per cruise, nine times;

    Figures 5-1 a and b "Schematic of required BWT Sampling" provide two possible experimental design scenarios for the Applicant's use. These diagrams, which may be modified to suit, provide boxes to check all relevant sampling locations, as a visual companion to Table 5.3 and Figure 5.2.

  - Outcome. Subsection 5.3 allows the design of a test program that focuses solely on challenge water (simplified sampling and preservation protocol) and treated water measurements. The Applicant has the option of using control tanks if design avoids contamination and they can properly address the control water prior to discharge. It also includes clear guidance on the minimal requirements for tank replication.

- Modify Subsection 5.3 "Ballast Water Treatment Experimental Methods" to clarify guidance on "holding times" in ballast tanks and provenance of ballast water to be used in experiments.
    - Reason. It is critical for performance testing experiments to know where ballast water originated and how long it has been held in the tank(s), these data composing the "provenance" of the water used in the experiments.
    - Discussion. It is essential that to know the provenance of the water to understand the treatment process, especially if there will not be control tanks. Holding time is important in particular to test for residuals and DBPs. Provenance of the water is not important for compliance testing, but is absolutely necessary for performance testing.

      This may pose difficulties for ships that move water between tanks during voyages, e.g., container ships that visit several ports and adjust trim/draft/heel during load/unload operations. Nonetheless, for voyages where BWT performance testing will occur, the study design needs to account for and ensure that the provenance of the water in the ballast tanks used for the experiments is known. This can include limiting testing to a sub set of the overall ballast tanks.
    - Outcome. Allows for arrangements to control provenance of the water in a limited number of tanks for the performance testing, although all the water is treated.
- Modify Subsection 5.3 "Ballast Water Treatment Experimental Methods" to include guidance on integrative sampling.
    - Reason. The use of time integrated sampling is important for the collection of valid ballast tank samples, so that representative sampling accounts for stratification effects in the ballast tanks.
    - Discussion. The requirement for integrated in-line sampling suggests that in-line sampling ports, properly designed and located in the ballast line, are required to sample treated water at discharge (no more grab sampling), with the intent of getting iso-kinetic samples. STEP 2010 can include citations of IMO G2 and NRL reports for guidance design, size, and location of sample port. It is essential to require applicants to show sample flow calculations for the tanks they intend to use in the experiments.

      Applicants will also have to show how they will process large volumes of sample water and deal with discharging afterwards. One suggestion is to put the water back into the ballast discharge line, possibly via closed loop piping provided for the purpose.
    - Outcome. The revised application includes guidance on integrative sampling, sample port designs and flows, and disposition of sample water.
- Modified Subsection 5.4 "Sampling and Analyses" to add QA/QC requirement and guidance.
    - Reason. STEP 2006 application lacked such guidance and applications lacked substantive QA/QC information. USCG notes that type approval procedures by some administrations have lacked sufficient QA/QC information in the relevant reports, e.g., no chain of custody documentation.

- Discussion. The Coast Guard stresses the importance of adequate QA/QC to assure that assay counts are done within required procedures to minimize errors. USCG is aware of the practicability issues of shipboard testing, but Applicants should nonetheless address these challenges in a QAPP, e.g., documenting holding time and mixing process for large volume samples and ensuring that numbers and skill sets of staff are sufficient for accuracy and precision in viability assays, within the time frame and work environment. It's not worth collecting a volume of water that will be meaningless when sampled, as shown by this research. Further it's critical to have data to show the lab can count what it thinks it can count.
- Outcome. The revision adds QA/QC guidance and requirements.

- Modified Subsection 5.4 "Sampling and Analyses" to add guidance on water sample size, sub-sampling, and statistical power.

  - Reason. Recent research by NRL, SERC, and others has shown that sample volumes commonly used in past shipboard tests are insufficient to yield statistically significant numbers of live and dead organisms in the largest size category proposed in either domestic or international regulation (i.e., ≥ 50 µm dimension).
  - Discussion. Experimental designs and incorporating adequate ballast water sample numbers and sizes for the required statistical power

    To accurately quantify small numbers of organisms in large volumes (e.g. 10 organisms/m^3) it is necessary to either collect and concentrate moderately large volumes and count the entire sample or collect and concentrate very large volumes (15-60 m^3), and count a fraction of the concentrate. Both approaches can produce defensible results. The approach selected depends upon the time of processing the necessary volumes. The decision to concentrate to a 1 liter sample and count the whole thing versus to subsample and count 20 mL becomes one of processing quickly enough to avoid sample degradation..
  - Outcome. Explicit guidance is provided for acceptable sampling design. Other methods may be allowed but to be considered the applicant will need to provide thorough validation documentation.

- Modified Subsection 5.4 "Sampling and Analyses" to add guidance on fractionation of organisms and taxonomic sorting requirements.

  - Reason. There has been guidance requesting/mandating organism counts from five taxa within three phyla. It can be difficult to get this assemblage in samples for shipboard testing and there is also a considerable challenge making the identifications in field labs.
  - Discussion. USCG states that taxonomy won't be important in the future where size fractionation will drive type approvals; however, STEP's useful output should include sizes. Shipboard there are usually few live organisms in treated samples (e.g., 90% of organisms belong to just a few taxa, and the rest are rather rare). It is difficult for the microscopist to classify them.

    However, in the event that there is a spike of organisms in the discharge, it is important to know what those are, in order to characterize the treatment efficacy

(or limitations with regard to specific taxa.)

The group agreed that uptake samples ("challenge water", ref: 5.3) can be preserved for taxonomic analysis later, and discussed technological solutions for automated counts, especially of zooplankton.

- Outcome. Group agreed that Subsection 5.4 would include fractionation guidance.

6.0 Long-Term Performance Monitoring Plan

- This section was formerly Subsection 5.9 and has been moved into a section of its own to emphasize its importance.
  - Reason. USCG places a great deal of programmatic importance on the long term performance of STEP BWT systems, including discharge water quality, i.e., residual treatment agents and DBPs.
  - Discussion. The group did not discuss this matter.
  - Outcome. USCG decision to add Section 6.0.
- Section 6.0 adds the following guidance:
  - ➔ Applicant submits preliminary long-term monitoring plan for shipboard testing of BWT system as part of the conditions of entry into STEP, covering years 1 through 5
  - ➔ Applicant submits final plan following completion of the primary biological experiments in Year 1, reflecting any changes to the design or operation of the BWT system based on those results.
  - ➔ New Table 6-1 identifies long term performance reporting requirements, per NVIC 01-04, for the Applicant's information.
  - Reason. It is important for the STEP Review team to see how the Applicant intends: 1) to tie system performance to prior proofs and to Year 1 experimental results; and 2) to track and report said performance. It is also important for the Applicant to be able to adjust BWT system operation on the basis of Year 1 experimental results, as in any fielding of new equipment.
  - Discussion. The group did not discuss this matter.
  - Outcome. USCG decision to add Section 6.0.
- Guidance in Subsection 6.2 modified to specify engineering parameters only for routine BWT system monitoring in Years 2 through 5.
  - Reason. Shipboard biological performance measures for monitoring may be seen as burdensome by operators and may be a disincentive for some to ply to STEP.
  - Discussion. USCG states that discharge sampling (multiple samples) in year 5 would be reasonable, and that monitoring via engineering measures is appropriate for Years 2-5.
  - Outcome. USCG decision to modify this guidance.
- New guidance in Subsection 6.4, re: performance monitoring logs.
  - Reason. .
  - Discussion. .

- Outcome. USCG decision to modify this guidance.

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  - Reason. .
  - Discussion. .
  - Outcome. USCG decision to modify this guidance.
- Guidance in Subsection 6.2 .
  - Reason. .
  - Discussion. .
  - Outcome. USCG decision to modify this guidance.