

Standards for Living Organisms in Ships' Ballast Water Discharged in U.S. Waters (33 CFR Part 151 and 46 CFR Part 162)

Frequently Asked Questions (Volume II), December 21, 2012

AMS Determination Questions

1. What is the process flow of an AMS application?

The process for review of an AMS application is as follows:

1. An application is submitted to the Coast Guard Marine Safety Center (MSC) in accordance with 33 CFR 151.2026.
2. Upon receipt of the application the MSC
 - a. Assigns the application a project number and enters the project into the MSC tracking system,
 - b. Sends an e-mail to the applicant confirming receipt, and
 - c. Delivers one application to the Coast Guard Environmental Standards Division (OES-3).
3. MSC and OES-3 review applications, evaluating for both engineering aspects and biological efficacy, including
 - a. Completeness of AMS application; specifically, all requirements under 33 CFR 151.2026 are present and understandable.
 - b. Potential issues that might arise during a review for type approval, to help:
 - i. Manufacturers understand issues related to their specific system, and
 - ii. Coast Guard understands current general state of ballast water management system (BWMS) conformity to Coast Guard engineering requirements.
4. Coast Guard engineering and biological reviews proceed independently
 - a. Offices interact with applicants separately regarding questions about submitted information, as necessary.
 - b. If review by one office is slowed, the other office continues.
 - c. In practice, several reviews may be underway at once, with some on hold pending response to questions.
 - d. Questions regarding status of application review should be directed to Ms. Regina Bergner of OES-3 at Regina.R.Bergner@uscg.mil or 202-372-1431.
5. Coast Guard identifies issues for both AMS and type approval as well as potential limitations regarding AMS designation based on the following:
 - a. Engineering aspects,
 - b. Missing elements or components of type approval requirements, and
 - c. Quality of information from prior testing.
6. OES-3 sends status e-mail to applicant that includes the following:
 - a. Notice that engineering and biological reviews are complete,
 - b. Notification of any missing components,
 - c. Questions regarding design treatment parameters and compliance assessment metrics, as necessary. Clarification may be needed for a variety of situations; for example, the design "dose" is not clearly described and explained, or it is not clear how an inspector would assess whether the BWMS had been operated and maintained as intended.
 - d. Invitation for applicant to respond and an offer to meet with Coast Guard either in person or via conference call to discuss,
 - e. Any additional issues regarding the acceptability of the BWMS for type approval, based on engineering requirements. These are provided for the manufacturer's information and future use when or if type approval is sought, and are not pertinent to the decision about

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AMS designation unless specifically identified as needing resolution prior to a decision regarding AMS designation.

7. Coast Guard suspends review of application pending receipt of any outstanding requirements and responses to questions.
8. Applicant responds to Coast Guard status e-mail with the requested information and a request for a meeting, if desired.
9. Coast Guard reviews any information submitted in response to Coast Guard status e-mail.
10. Coast Guard makes decision regarding designation of applicant's BWMS as an AMS.
11. Coast Guard sends applicant AMS designation letter, signed by the Chief, Office of Operating and Environmental Standards (CG-OES) informing applicant of decision
12. OES-3 posts the AMS decision on its web page:
<http://www.uscg.mil/hq/cg5/cg522/cg5224/bwm.asp>

2. Does the Coast Guard have a preferred AMS application submission model?

Other than completion of the AMS checklist that accompanies the AMS Policy Letter (available on the Environmental Standards Division web page), there is no generic format for organizing an AMS application.

3. What entities are reviewing AMS applications and when?

See the process flow outline above. The Coast Guard Marine Safety Center and the Environmental Standards Division are responsible for review of material regarding engineering issues and biological efficacy, respectively. Each office may make use of outside technical expertise as necessary.

4. What division (or who) is the primary point of contact for the applicant during the process?

Questions from the applicant regarding the status of the review should be directed to Ms. Regina Bergner of OES-3 at Regina.R.Bergner@uscg.mil or 202-372-1431. MSC and OES-3 may separately contact the applicant regarding issues arising during the review.

5. Are AMS applications date stamped upon receipt, and are applications reviewed in the order they are received?

Reviews of AMS applications are begun in the order received. However, if the Coast Guard has requested additional information from an applicant, other reviews are begun in the interim while the Coast Guard is awaiting the requested information. The Coast Guard returns to suspended applications upon receipt of requested information.

6. Will electronic submission of AMS application be permitted?

While the initial policy for AMS designations indicated that two paper copies should be submitted, experience with initial submissions has shown that electronic copies are sufficient in most cases. Therefore, paper copies or electronic copies are acceptable. In either case, two complete copies must be submitted. Electronic copies must be on compact discs (not DVDs), and files must be readable using Microsoft Office or Adobe Acrobat applications. If alternative file formats are involved, applicants

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should contact the Coast Guard to discuss, as inability to read files using Coast Guard standard workstations will prevent reviews.

7. The requirements for designation of a foreign type approved BWMS as an AMS under 33 CFR 151.2026(a) includes: “(5) A type approval application as described under 46 CFR 162.060-12.” When one reads 46 CFR 162.060-12, one learns that an application under this provision, in addition to the data and other information developed during approval testing and evaluation for another administration, must include (underlining added here for emphasis) a concise but thorough explanation of how the submission meets or exceeds the requirements of this subpart in respect to design, material and manufacture, and ability to meet the BWDS requirements. What, specifically does the Coast Guard want such an explanation to entail?

First, the required explanation is a critical component of the application for Coast Guard type approval when the applicant relies on data developed for type approval by a foreign administration in accordance with the IMO Ballast Water Management (BWM) Convention.

Second, for purposes of AMS determination, the type approval application under 46 CFR 162.060-12 would contain all of the other requirements in (a)(1)-(4), as well as a document, submitted by the applicant, in which the submitted foreign type approval data was evaluated to determine whether or not it meets the requirements for type approval described throughout 46 CFR 162.060. At a minimum, the required explanation should:

1. Compare the existing data and information with the specific requirements for USCG type approval, and
2. Provide a clear explanation of how the data and information meet the articulated requirements, including
 - a. Instances where requirements are clearly met,
 - b. Any clear deficiencies, and
 - c. Any instances where questions might exist regarding sufficiency of existing data and information.

For ease of presentation and review, the explanation could be built around a matrix, similar to the AMS application checklist, in which Coast Guard requirements for type approval under 46 CFR 162.060 were listed, and the applicant identified where in the submitted data and information the individual requirements were addressed and the degree to which the data and information met the requirements.

In developing the explanation required under 46 CFR 162.060-12(5) **for the purposes of an AMS application**, manufacturers:

1. Do not have to work through a test organization accepted as an Independent Laboratory (IL), as would be required if the type approval application using existing data were being submitted for a type approval determination;
2. May work with an IL if desired, or
3. May prepare the explanation themselves (using in-house or contracted technical resources).

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NOTE: Applications submitted for actual type approvals (not AMS designations) must be submitted under the auspices of an IL. See the FAQ regarding submission of type approval applications using existing data under 46 CFR 162.060-12 for further explanation of that process.

Submitting an application for type approval under 162.060-12 as part of the application for AMS designation **does not** begin the type approval application process. The purpose of submitting the application for type approval is to require the manufacturer to carefully assess the degree to which the foreign type approval information and data satisfy Coast Guard requirements for type approval.

Conducting this preliminary assessment has two objectives:

1. The manufacturer of an AMS will have a better understanding of the work needed with an IL when developing an actual application for type approval.
2. The Coast Guard will have a preliminary understanding, prior to receiving formal type approval applications, of the degree to which an AMS meets type approval requirements, and thereby the potential effort and time required for an AMS to transition to full type approval.

Type Approval Application Questions

1. Under 46 CFR 162.060-12, a manufacturer can seek type approval of a BWMS on the basis of existing data and information that were generated initially for type approval by another administration in accordance with the IMO BWM convention. What is the actual process for such an application – does the applicant submit the existing data package directly to the Coast Guard for a determination of acceptability, rather than work through an Independent Laboratory as required for type approval when no such existing data are used?

A: To apply for type approval on the basis of existing data, the manufacturer would prepare a dossier of all the testing and evaluation data and information from the foreign type approval.

Manufacturer's considering applications for type approval based on existing data may find it useful to discuss the acceptability of the original testing organization before proceeding with preparing and submitting a full application. Discussions on this issue can be initiated by contacting LCDR Ken Hettler of ENG-3 at Kenneth.A.Hettler@uscg.mil or 202-372-1367.

Once the acceptability of the test organization has been determined, the manufacturer should anticipate the following general sequence of events (note – this list is not detailed, and the steps below each contain numerous activities and requirements):

1. The manufacturer carefully compares the requirements for type approval contained throughout 46 CFR 162.060 with the existing data to understand where the existing data and information may or may not meet the Coast Guard requirements.
2. The manufacturer makes arrangements for an IL to evaluate and provide a detailed explanation of the degree to which the existing data and information satisfy the requirements for type approval in 162.060.

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- a. If the IL recommends that no further tests or evaluations are necessary, this detailed explanation will take the place of the Test Report required under 162.060-14(a)(9).
 - b. The IL will deliver a copy of the detailed explanation directly to the MSC.
3. If additional testing and evaluation **is not** necessary, the manufacturer will submit to the Coast Guard an application for type approval in accordance with 46 CFR 162.060-10. The following apply
 - a. The requirement for a letter of intent, under 162.060-10(a) is waived.
 - b. The evaluation of the existing data and information by the IL takes the place of the evaluation, inspection, and testing of the applicant's BWMS by an IL that is required under 162.060-10(b).
 - c. Under 162.060-10(c), the application must contain all of the information specified in 162.060-14, except that the IL's detailed explanation - see (2) above - will take the place of the Test Report required under 162.060-14(a)(9).
4. If additional testing and or evaluation **is** necessary, the following apply:
 - a. The manufacturer and the IL will make arrangements to complete required work.
 - b. A letter of intent must be submitted to the MSC prior to beginning the testing, in accordance with 162.060-10(a).
 - c. Testing and evaluation and the preparation of the application should proceed in accordance with 162.060-10 and 162.060-14.
5. After the testing and evaluation are completed,
 - a. The IL delivers to the MSC the explanation for the acceptability of any existing data and information as well as test reports for any additional tests or evaluations.
 - b. The manufacturer compiles the remaining component of the application, as detailed in 46 CFR 162.060-14, and submits the complete application to the MSC.
6. Upon receipt of the application, the MSC:
 - a. Assigns the application a project number and enters the project into the MSC tracking system
 - b. Sends an e-mail to the applicant confirming receipt.
7. Coast Guard reviews the submitted application; during the review, Coast Guard may enter into discussions with the IL and applicant, as necessary, regarding the content and clarity of the Test Report or any other required information.
8. Coast Guard completes any necessary documentation under other statutory requirements such as the National Environmental Policy Act, Endangered Species Act, or other relevant regulations.
9. MSC sends letter, informing applicant of decision. If type approval is granted,
 - a. An approval number is issued, and an approval certificate is included.
 - b. MSC adds BWMS to list of approved equipment posted at:
<http://cgmix.uscg.mil>

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Process for type approval without using existing data

2. In general, what is the process that a manufacturer can expect when applying for type approval of a BWMS *without* using existing data from a prior foreign type approval?

The general process for obtaining type approval without using existing data is as follows:

1. The manufacturer follows the procedure in 46 CFR 162.060-10, including:
 - a. Arranging, independently of Coast Guard, for testing and evaluation by an IL; ILs are listed on the Coast Guard Maritime Information Exchange website at: <http://cgmix.uscg.mil>.
 - b. Submitting a letter of intent to the MSC at least 30 days prior to beginning testing (162.060-10(a)).
2. The manufacturer works with the IL, independently of the Coast Guard, to complete all required tests and evaluations. Depending on circumstances, the manufacturer and IL may discuss with the Coast Guard relevant issues arising during any stage of testing and evaluation.
3. Upon completion of all testing and evaluation,
 - a. The manufacturer assembles the information required under 46 CFR 162.060-14, except for the Test Report prepared by the IL, and the manufacturer submits the completed application under the manufacturer's signature, to the MSC.
 - b. The IL submits the completed Test Report directly to the MSC.
4. Coast Guard reviews the submitted application; during the review, Coast Guard may enter into discussions with the IL and applicant, as necessary, regarding the content and clarity of the Test Report or any other required information.
5. Coast Guard completes any necessary documentation under other statutory requirements such as the National Environmental Policy Act, Endangered Species Act, or other relevant regulations.
6. MSC sends a letter, informing applicant of decision. If type approval is granted,
 - a. An approval number is issued, and an approval certificate is included.
 - b. MSC adds BWMS to list of approved equipment posted at: <http://cgmix.uscg.mil>

3. If the applicant must submit a type approval application to the USCG along with the AMS application, and apparently must also submit a separate type approval application to an IL, what should the applicant expect from the USCG review of a type approval application? That is, what is the purpose and expected outcome of the type approval application/review by the USCG?

The application and review process for an AMS are separate and distinct from the application and review process for type approval.

As described in FAQ # 8 above, under the AMS process, Coast Guard requires the submission of a type approval application in accordance with 46 CFR 162.060-12. This submittal would consist of an application for Coast Guard type approval based on data developed during type approval by a foreign administration in accordance with the IMO BWM Convention.

The purpose of submitting this existing data application as part of the AMS process is not, as might first be assumed, to initiate the type approval process. In the context of the AMS application, the purpose of submitting the existing data application is two-fold.:

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1. It provides the Coast Guard an opportunity to examine the foreign type approved BWMS to identify, as early as possible, any issues that might exist for type approval by the Coast Guard regarding acceptability of the BWMS design and manufacturing. This information is transmitted to the manufacturer as part of the AMS review.
2. It provides the Coast Guard with an advance perspective on the degree to which testing for foreign type approval met Coast Guard requirements and the likely amount of effort and time required for foreign approved systems, both specifically and in general, to meet Coast Guard requirements. This information is necessary for the Coast Guard to be able to plan and implement ballast water management policies and regulations.

Further, it was not intended that submission of the type approval application with the AMS designation request would initiate a type approval review because, in the early stages of implementing the ballast water discharge standard final rule, it was not anticipated that independent laboratories would be established or available to work with applicants, as required for type approval. Hence, the requirement for the application was intended to provide useful information to both the potential type approval applicant and the Coast Guard on the nature of the foreign approved BWMS.

As stated above, in preparing an application in accordance with 46 CFR 162.060-12 *for the purpose of an AMS application*, the manufacturer:

1. Does not need to work with a Coast Guard-designated Independent Laboratory, as would be required for formal application for type approval.
2. May work with an IL to develop the analysis of whether or not the existing data and information meet Coast guard requirements under 46 CFR 162.060.
3. May work with a suitable technical consultant, or conduct the analysis using on-staff expertise.

4. What if a manufacturer intends to conduct testing in accordance with Coast Guard requirements under the auspices of an IL (in other words, does not intend to apply using existing data), but does want to apply for an AMS designation? Does the manufacturer still have to submit the type approval application in accordance with 46 CFR 162.060-12 as part of the AMS application?

Yes, the AMS application must contain the type approval application required under 46 CFR 162.060-12, as the purpose of this information as part of the AMS application is to assist both the applicant and the Coast Guard to understand how much effort is likely required to produce the necessary tests and evaluations required for type approval.

5. What entities are reviewing the Type Approval applications submitted to the USCG and when?

Independent Labs (ILs) conduct the tests and evaluations required for Coast Guard type approval, and evaluate the degree to which existing data meet Coast Guard requirements for type approval. The MSC reviews type approval applications, which contain test reports from ILs, and may consult with the Environmental Standards Division, other Coast Guard offices, or other technical advisors, as circumstances warrant during the review.

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6. What is the mechanism by which the USCG communicates the status of the USCG type approval application? At what point(s) in the process will communications be provided to the applicant, and what division (or who) is the primary point of contact for the applicant during the process?

See FAQs on type approval process flow. In general, the Marine Safety Center (MSC) is the primary point of contact with the Coast Guard during review of a type approval application. Specifically, the MSC is responsible for the following:

1. Sending an e-mail informing the manufacturer that an application has been received,
2. As needed, communicating directly with applicants regarding the content of applications, identifying any outstanding information still required, or questions stemming from the review.
3. Sending a decision letter upon completion of the type approval review.

Questions regarding the acceptability of a test organization for purposes of submitting an application using existing data under 46 CFR 162.060-12 should be directed to the Systems Engineering Division (ENG-3), which oversees the acceptance of test organizations as Independent Laboratories. The point of contact is LCDR Ken Hettler in ENG-3 at Kenneth.A.Hettler@uscg.mil or 202-372-1367.

7. Who submits the IL final Test Report to USCG – the IL or the applicant?

The IL submits the Test Report, required under 46 CFR 162.060-14(a)(9) and in accordance with 162.060-34, directly to the Coast Guard. The manufacturer submits the remainder of the application required under 46 CFR 162.060-14 to the Coast Guard.

8. While it is understood that ILs and USCG are separate entities, what is the estimated cost to the applicant for IL review and testing?

The Coast Guard does not charge a fee for reviewing AMS and type approval applications. Fees charged by an IL are not under the purview of the Coast Guard.

9. Does the IL have a preferred application submission model?

The Coast Guard does not impose a specific application format for submissions to ILs, either for type approval testing or for evaluation of existing data. The applicant should work with the IL to ensure the IL receives the necessary information.

10. Does the USCG have a preferred application submission model?

The Coast Guard does not have a generic or model application format. Applications should be prepared in accordance with 46 CFR 162.060-14 and for each of the other sections of 162.060 referenced therein (for example, 162.060-34 Test Report requirements).

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Additional questions/thoughts regarding USCG and IL interactions

1. It seems that there will actually be two Type Approval application processes; one with USCG and one with the IL. Please clarify the distinction.

We are not clear what is meant by the reference to an “application with the IL”. Manufacturers must submit an application to the Coast Guard in accordance with 46 CFR 162.060-10 that meets the requirements of 46 CFR 162.060-14. This application will include the test report from an IL that either conducted the tests and evaluations, or assessed the acceptability of existing data in meeting the required tests and evaluations.

Individual ILs may have their own procedures for entering into a contractual arrangement with manufacturers, as well as procedures for exchanging information with the manufacturer. The Coast Guard has no role in determining these procedures.

2. While we don't expect the USCG to be able to speak much about the process an IL may have (process flow, who reviews, points of contact, cost, etc.) since they are separate entities, it would be helpful to have the links between the applicant, the IL and the USCG clarified. For instance, is the USCG primarily silent during the IL/applicant process, or do they anticipate ongoing cooperation / collaboration with the IL and /or the applicant during the process?

As BWMSs constitute a new series within the Coast Guard's type approval program, we anticipate there will be significant interaction between ILs and Coast Guard early in the process as ILs develop and then implement plans and procedures for the required testing and evaluation. Absent direction otherwise, contact between an IL and Coast Guard should be through the CG-ENG-3.

3. Although the process with the IL will be a separate process, the flow of the “big picture” process should be defined and clarified as much as possible. Who talks to whom, and when, to reach the ultimate goal of US Type Approval certificate?

The responses to the questions above provide additional clarity.