

U.S. Department of
Homeland Security

United States
Coast Guard



U.S. COAST GUARD GUIDELINES FOR USING THIRD PARTY ORGANIZATIONS TO ENSURE REGULATORY COMPLIANCE



COMDTINST M5760.16

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Commandant
United States Coast Guard

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Subj: USING THIRD-PARTY ORGANIZATIONS TO ENSURE REGULATORY COMPLIANCE

- REF: (a) Office of Management and Budget Circular (OMB) A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities
 (b) International Organization for Standardization (ISO) 17000 series of standards
 (c) Memorandum of Understanding/Agreement, COMDTINST 5216.18 (series)

1. PURPOSE. In this Manual, the Commandant publishes guidelines for creating programs to leverage the expertise of third-party organizations (TPO) that conduct regulatory compliance activities on the Coast Guard’s behalf.
2. ACTION. Commandant (CG-5P) Directors and Office Chiefs, Commanding Officer Marine Safety Center, Commanding Officer National Maritime Center, and Director, National Vessel Documentation Center should implement the guidelines in this Manual. Internet release is authorized.
3. DIRECTIVES AFFECTED. None.
4. DISCLAIMER. This document is intended to provide operational requirements for USCG personnel and it is not intended to, nor does it, impose legally-binding requirements on any party outside the USCG.
5. ENVIRONMENTAL ASPECT AND IMPACT CONSIDERATIONS.
 - a. The development of this Manual and the general policies contained within it have been thoroughly reviewed by the originating office in conjunction with the Office of

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NON-STANDARD DISTRIBUTION:

Environmental Management, and are categorically excluded (CE) under current USCG CE # 33 from further environmental analysis, in accordance with Section 2.B.2. and Figure 2-1 of the National Environmental Policy Act Implementing Procedures and Policy for Considering Environmental Impacts, COMDTINST M16475.1 (series). Because this Manual contains guidance on, and provisions for, compliance with applicable environmental mandates, Coast Guard categorical exclusion #33 is appropriate.

- b. This directive will not have any of the following: significant cumulative impacts on the human environment; substantial controversy or substantial change to existing environmental conditions; or inconsistencies with any Federal, State, or local laws or administrative determinations relating to the environment. All future specific actions resulting from the general policies in this Manual must be individually evaluated for compliance with the National Environmental Policy Act (NEPA), DHS and Coast Guard NEPA policy, and compliance with all other environmental mandates. Due to the administrative and procedural nature of this Manual, and the environmental guidance provided within it for compliance with all applicable environmental laws prior to promulgating any directive, all applicable environmental considerations are addressed appropriately in this Manual.
6. DISTRIBUTION. No paper distribution will be made of this Manual. An electronic version will be located on the following Commandant (CG-612) web sites. Internet: <http://www.uscg.mil/directives/>, and CGPortal: <https://cg.portal.uscg.mil/library/directives/SitePages/Home.aspx>.

NOTE: If paper copies are required please complete Certificate of Need for Printing, DHS Form 500-07, which can be found at http://www.uscg.mil/directives/Printing_Graphics.asp.
 7. RECORDS MANAGEMENT CONSIDERATIONS. This Manual has been evaluated for potential records management impacts. The development of this Manual has been thoroughly reviewed during the directives clearance process, and it has been determined there are no further records scheduling requirements, in accordance with Federal Records Act, 44 U.S.C. 3101 et seq., National Archives and Records Administration (NARA) requirements, and the Information and Life Cycle Management Manual, COMDTINST M5212.12 (series). This policy does not have any significant or substantial change to existing records management requirements.
 8. GOALS AND OBJECTIVES: Through this Manual, the Coast Guard establishes a standardized process for creating third-party programs that are consistent with the direction and intent of references (a) and (b) in that they:

- a. Are effective in carrying out Coast Guard missions;
 - b. Minimize the cost of compliance to regulated entities;
 - c. Comply with statutory, regulatory, and international obligations;
 - d. Conserve and leverage Coast Guard resources; and
 - e. Increase acceptance of U.S. products in domestic and foreign markets.
9. **BACKGROUND:** The Coast Guard leverages the expertise and resources of third-party organizations (TPOs) in many ways and through diverse means. TPOs conduct inspections and examinations of commercial vessels, test and approve shipboard equipment, evaluate mariner training courses, and perform many other functions on the Coast Guard's behalf. Our third-party programs vary in their scope and originate from statutory mandates, regulations, memorandums, and other agreements. The use of TPOs aligns with federal mandates and programs for regulatory oversight, promotes risk-based allocation of our resources, creates important Government/industry partnerships, and fosters innovation. While leveraging the expertise of TPOs is a longstanding organizational philosophy, we seek a consistent approach for deciding on when to create and how to implement a third-party program. In this Manual, the Commandant standardizes the process that Coast Guard offices should use to develop and maintain third-party programs. The processes in this Manual rely heavily on recognized best practices from the National Institute for Standards and Technology (NIST), the International Organization for Standardization (ISO)/International Electrotechnical Committee (IEC), and other national and international bodies.
10. **DISCUSSION:**
- a. Leveraging TPOs is an effective approach to meet regulatory compliance goals while allowing an agency to reduce operating costs, gain resource flexibility, and ease the regulatory impact on stakeholders. For example, we routinely examine independent laboratories conducting equipment approval testing. Many of these laboratories meet internationally-recognized competency standards and are examined by other independent bodies. Thus, these laboratories must often satisfy two sets of similar requirements, creating additional costs without necessarily providing commensurate benefits. Coast Guard acceptance of the independent body's examination would benefit both the Coast Guard and the laboratory.
 - b. The international maritime community also recognizes the importance of third-party programs to help ensure compliance with international standards. The International Maritime Organization Instruments Implementation Code (III Code) and the Code for

Recognized Organizations (RO Code) rely on creation of programs with clear roles, responsibilities, and expectations validated by oversight and audits.

- c. The decision on whether to establish a third-party program is complex. An assortment of crucial factors should be considered, such as:
 - (1) The Coast Guard's goal for considering a third-party program to ensure regulatory compliance;
 - (2) A risk-based assessment of the tasks that a TPO could be authorized to perform;
 - (3) The statutory authority to use a TPO;
 - (4) Market forces that dictate whether a TPO exists or could be incentivized to conduct conformity assessment activities;
 - (5) The Coast Guard's capacity and qualifications to conduct oversight of TPO activities; and
 - (6) The net benefit to the stakeholders who would receive services from a TPO authorized by the Coast Guard.

- d. Similarly, the steps to create a relationship with a TPO can also be complicated and should accommodate, for example:
 - (1) The nature of the relationship, the scope of authorizations to the TPO, and existing industry standards for the TPO activities;
 - (2) The Coast Guard's role and the scope of Coast Guard activities to ensure regulatory compliance;
 - (3) How a program to leverage a TPO would be implemented and monitored;
 - (4) The qualifications of the TPO to perform authorized activities, the deliverables, and the measures of success;
 - (5) The need to maintain transparency of regulatory compliance activities;
 - (6) The procedures for documenting the relationship with the TPO including necessary regulatory changes;
 - (7) Whether authorizing a TPO to perform certain activities will meet the Coast Guard's overall goals; and
 - (8) The costs and benefits to the regulated entity and the public.

11. IMPLEMENTATION: Chapters 1 and 2 describe the processes and considerations for deciding whether to implement a third-party program and how to ensure regulatory compliance and adequate oversight. Offices considering using TPOs to ensure regulatory compliance should follow these principles to evaluate and establish programs, as applicable. While this Manual is not intended to compel review of existing programs, the concepts in this Manual could be applied to confirm the soundness and effectiveness of an existing program.
12. FORMS/REPORTS: The forms referenced in this Manual are available in USCG Electronic Forms on the Standard Workstation or on the Internet: <http://www.uscg.mil/forms/> and CG Portal <https://cg.portal.uscg.mil/library/forms/SitePages/Home.aspx>.
13. REQUEST FOR CHANGES. Units and individuals may recommend changes via the chain of command to: [HQS-DG-1st-CG-REG-SP](#).

PAUL F. THOMAS /s/
U.S. Coast Guard
Assistant Commandant for Prevention Policy

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CHAPTER 1. GUIDELINES FOR DECIDING WHETHER TO LEVERAGE A THIRD-PARTY ORGANIZATION TO ENSURE REGULATORY COMPLIANCE

- A. Definitions. These definitions apply to the guidelines in Chapters 1 and 2. They are based on the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17000 series of standards for conformity assessment activities listed in Enclosure (1). In some cases, the ISO definition has been modified for consistency with common Coast Guard terminology and to meet the goals of this Manual.
1. **accreditation** – means a statement or documentation that a third-party organization is competent to carry out specific activities related to demonstrating regulatory compliance.
 2. **accreditation body** – means an organization or individual that performs activities, such as audits, surveillance, and tests, to assess third-party competence.
 3. **attribute** – means a characteristic or part of the object that is the focus of compliance, including a physical property, a process, or a task, and is identified during deconstruction of the object for conducting a task analysis.
 4. **certification** – means a statement or documentation related to whether specified requirements have been demonstrated through a conformity assessment activity.
 5. **certification body** – means an organization or individual that performs activities to assess whether compliance with specified requirements has been demonstrated.
 6. **conditions** – means the constraints stipulated for the decision-making phase and program implementation and include items such as the program goal, industry standards or other specifications referenced in the program, metrics, desired level of oversight, or resources required.
 7. **conformity assessment** – means demonstrating that specified requirements relating to the regulatory compliance of a product, process, system, person, or body are fulfilled, and includes the following phases:
 - a. Gathering information through tests and inspections;
 - b. Determining whether the information demonstrates regulatory compliance; and
 - c. Assuring the competency of the bodies conducting conformity assessment activities.

8. **conformity assessment scheme** – means the standards, requirements, procedures, and processes that form the basis of conformity assessment for regulatory compliance.¹
9. **first-party** – means the person or organization that provides the object, such as a manufacturer or applicant.
10. **inspection** – means the process of gathering information by examining an object according to specified requirements or professional judgment.
11. **object** – means the product, process, system, person, or body that is the subject of conformity assessment.
12. **rules** – mean the stipulated procedures to implement the program and include topics such as the method of applying for the program, the Coast Guard oversight process, conformity assessment actions, information collection, and measurements.
13. **second-party** – means the person or organization that has a user interest in the object such as a consumer or product owner.
14. **self-declaration** – means a conformity assessment activity conducted by the first-party, such as the object manufacturer or provider.
15. **sponsor** – means the Coast Guard Headquarters office or other command responsible for initiating the program, managing the program, conducting oversight, and reporting the results.
16. **task analysis** – means the process of identifying and documenting the best body to conduct the activities necessary to demonstrate the object complies with specified requirements,
17. **test** – means the process of gathering information by determining one or more characteristics of an object according to a specified procedure.
18. **third-party** – means a person or body that is independent of the person or organization that provides the object (first-party) and of the interests of the object user (second-party).

¹ Coast Guard regulations and the roles and responsibilities of the participants form the conformity scheme and the Coast Guard is the scheme owner.

19. **third-party organization** – means, for the purposes of this Manual, an organization or individual authorized by the Coast Guard to perform specified activities related to demonstrating regulatory compliance.

B. Analysis. Sponsors considering whether to create a program that leverages the expertise of a third-party organization (TPO) should have a clear goal by which to judge the advantages and disadvantages of doing so. This goal should be clearly articulated, measurable, and should ultimately create a benefit for the public and the Coast Guard. The decision-making process to determine whether the Coast Guard can expect to meet the goal should be built around a task analysis and follow the path described in paragraphs B.1 through B.14 below. See example worksheets A through F in Appendix A to record the results of the task analysis.

1. Identify the object of conformity assessment – The object is the product, process, system, person, or body to which conformity assessment is applied. The object might be as simple as a navigation light or as complex as an entire vessel.
2. Create a goal statement – State the desired outcome(s) of establishing a program to leverage a (TPO). This goal statement should be as short, concise, and specific as possible to avoid misconstruction. Some example goal statements are:
 - a. “The goal of this program is to reduce the Coast Guard’s costs to proctor mariner qualification tests by leveraging existing professional testing services.”
 - b. “The goal of this program is to reduce the cost burden of inspections to vessel owners by providing scheduling alternatives that minimize a vessel’s unavailability.”
3. Confirm statutory authority – Evaluate the Coast Guard’s authority related to the use of TPOs in this conformity assessment. Confirm whether statutes or regulations limit the Coast Guard’s authority to use a TPO or, conversely, direct the Coast Guard to use a TPO for a mission or task. Determine whether there are any other statutory or regulatory obstacles to establishing a relationship with a TPO and whether it requires a legislative or regulatory change to gain or revise authority.
4. Connect to strategic goals – Confirm the program goal stated in paragraph B.2 is consistent with high-level Coast Guard goals and objectives.
5. Identify the stakeholders – Consider which international and domestic industry, government, and private sectors might be affected by leveraging a TPO. This might include interest groups, trade associations, and tribal governments. A Federal Register notice could be used to solicit public comment on the concept of using a TPO for certain activities and might be a valuable means of identifying stakeholders to assess

support, opposition, advantages and disadvantages. Identifying stakeholders also helps put context to the task analysis that determines the scope of the potential program.

6. Identify the conditions – Note the conditions for conducting the decision-making analysis. Conditions help establish the scope of the program, justify decisions, and can lead to the rules used to implement and maintain a program. Some conditions might affect all of the other elements in the decision-making process. For example, a statutory mandate might have a deadline or other direction from Congress. Time and resources are usually critical considerations in any project. A commitment to harmonize with international standards might drive decisions about qualifications. Additionally, some conditions might be based on a desired level of confidence in avoiding risks. The nature of the object, such as a primary piece of lifesaving or firefighting equipment, might dictate the extent of Coast Guard reliance on a TPO and the necessary oversight to achieve the desired level of confidence.
7. Conduct a task analysis –
 - A. A task analysis is indispensable to setting the scope of a potential program and establishing the nature of the relationship with a TPO. Through a task analysis, the Coast Guard confirms the product (e.g. fire extinguisher or an entire ship), process (e.g. servicing an inflatable liferaft), system (e.g. a ship safety management system), or person (e.g. merchant mariner) that is the program object. The results of the task analysis reveal how much delegation the Coast Guard can afford within its authorities and responsibilities without degrading safety, security, and environmental stewardship standards, and public trust. The Coast Guard uses this information to create a model of the relationship with a potential TPO that includes the extent of authorizations, the required qualifications, and the Coast Guard and TPO roles and responsibilities. Appendix A contains sample worksheets to record the results of the task analysis.
 - B. To perform the task analysis, deconstruct the object into attributes that are amenable to analysis, depending on the scope of the goal and the technique employed. In many cases, such as with equipment or persons, the attributes might be inherently simple or obvious. In other cases, such as an entire inspection program, the product, process, or system could be complex and judgment could be used to divide the object into pieces large enough to be practical yet small enough to be analyzed.
 - (1) Scope of the analysis: Consider the attributes of the object and how they are discrete (e.g. component vs. system). Small conformity assessment activities are easier to analyze than large because the qualifications are easier to identify

and the relationships among components are simpler. However, analyzing too many attributes might be an inefficient and cumbersome approach.

- (2) Test/inspection activity: For each attribute of the deconstructed object, consider the tests and inspections that should be performed to gather the information needed to confirm regulatory compliance. These include visual examination, testing to a specified standard, verifying operation, following written guidance, and other forms of inspections normally conducted by the Coast Guard and other bodies. See worksheet Part A.
- (3) Compliance criteria: For each test or inspection activity, list the reference for the procedures to gather information. Also, list the reference used to determine regulatory compliance if it is different than the reference for conducting the test or inspection. These are often the same specified standard or regulation and should be listed in the conditions.
- (4) Recorded results: For each test or inspection activity, identify the information gathered that should be recorded to determine whether compliance has been demonstrated. This information will likely depend on the nature of the activity. While the result of a visual examination might be a “pass/fail” notation, the results of a test or inspection are likely to be the measurements taken during the information gathering activity.
- (5) Test/inspection qualifications: For each test or inspection activity, describe the qualifications required of the relevant body to perform the activity and record the information gathered competently. These qualifications might be specified in regulation, statute, or an industry standard used as a reference. For an inspection program, the qualifications might be certification through a training program.
- (6) Test/inspection type: For each test or inspection activity, decide which type of body is best suited to conduct the activity (e.g. first, second, or third-party testing) based on the qualifications required. In some cases, the manufacturer can perform the test or inspection activity. In other cases, the Coast Guard might want to specify that a third-party, such as a recognized laboratory, conduct the test or inspection. The decision on the type of test or inspection body often depends on the level of independence needed between the test or inspection body and the certification body.
- (7) Certification qualifications: For each test or inspection activity, determine the qualifications required of the certification body based on the compliance criteria reference. The certification body decides whether the object fulfills

the regulatory compliance criteria and usually issues the documentation. See worksheet part B.

- (8) Certification type: For each test or inspection activity, determine the desired certification type, from self-declaration to third-party certification, based on the desired (or required) certification qualifications. The test or inspection body makes this determination in a self-declaration (or first-party declaration). Third-party certification is used when seeking greater independence between the test or inspection body and the certification body.
 - (9) Accreditation qualifications: For each certification type, determine the qualifications required of the accreditation body. The scheme owner uses accreditation to confirm the test or inspection body and certification body are competent to fulfill their responsibilities. Accreditation equates to oversight for the purposes of regulatory compliance and could be conducted by the Coast Guard or an independent accreditation body. See worksheet part C.
 - (10) Summary: Compile the results to list the desired level of conformity assessment, certification, and accreditation for each object attribute based on the decisions made for paragraphs 7.B.1 through 7.B.9. See worksheet part D.
 - (11) Program roles: Identify the proposed body responsible for each conformity assessment activity based on the decisions about the types of conformity assessment bodies. Examining the qualifications expected of Coast Guard personnel conducting the same activity, previous decisions made in regulations or policy documents, programs of other Government agencies, and the ISO/IEC 17000series of standards might reveal the best roles for the object owner, TPO, and Coast Guard. See worksheet part E.
 - (12) Identify what additional information should be recorded to facilitate planned oversight, meet record requirements, promote transparency, and ensure the program achieves the goal.
8. Consider risk and oversight – Evaluate the results of the task analysis and whether the risks are controlled. Leveraging a TPO adds another factor to managing risks because this approach changes the Coast Guard’s role in ensuring regulatory compliance. Therefore, the roles and responsibilities of the TPO and the Coast Guard in the conformity scheme should balance risks with oversight to achieve the desired level of confidence. Figure 1-1 shows the oversight hierarchy. Figure 1-2 illustrates that the need for confidence through oversight activity grows with increased risk and low expectations of compliance. Figure 1-3 illustrates the concept of increased confidence with increased independent review. As the public agency and the conformity scheme

owner, the Coast Guard is ultimately responsible for program success. The nature of the program, the diligence of the decision-making process, confidence, program management, the consequences of failure, and transparency of program information affect program success and the public's perception of responsibility.

Figure 1-1 – Third-party program oversight hierarchy

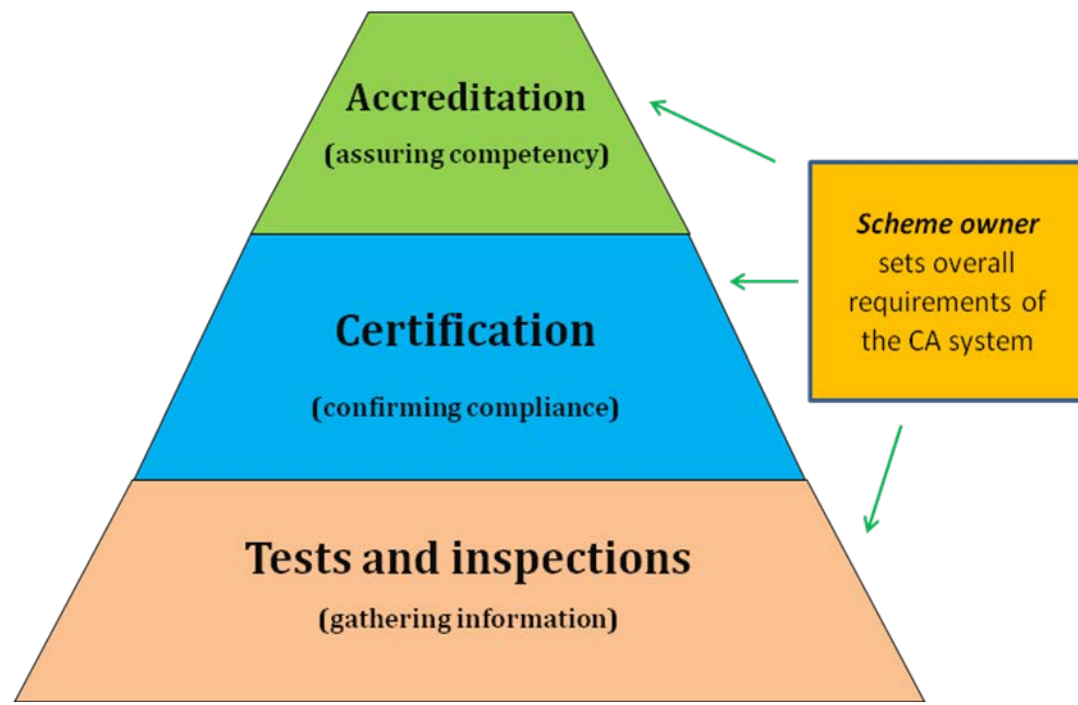
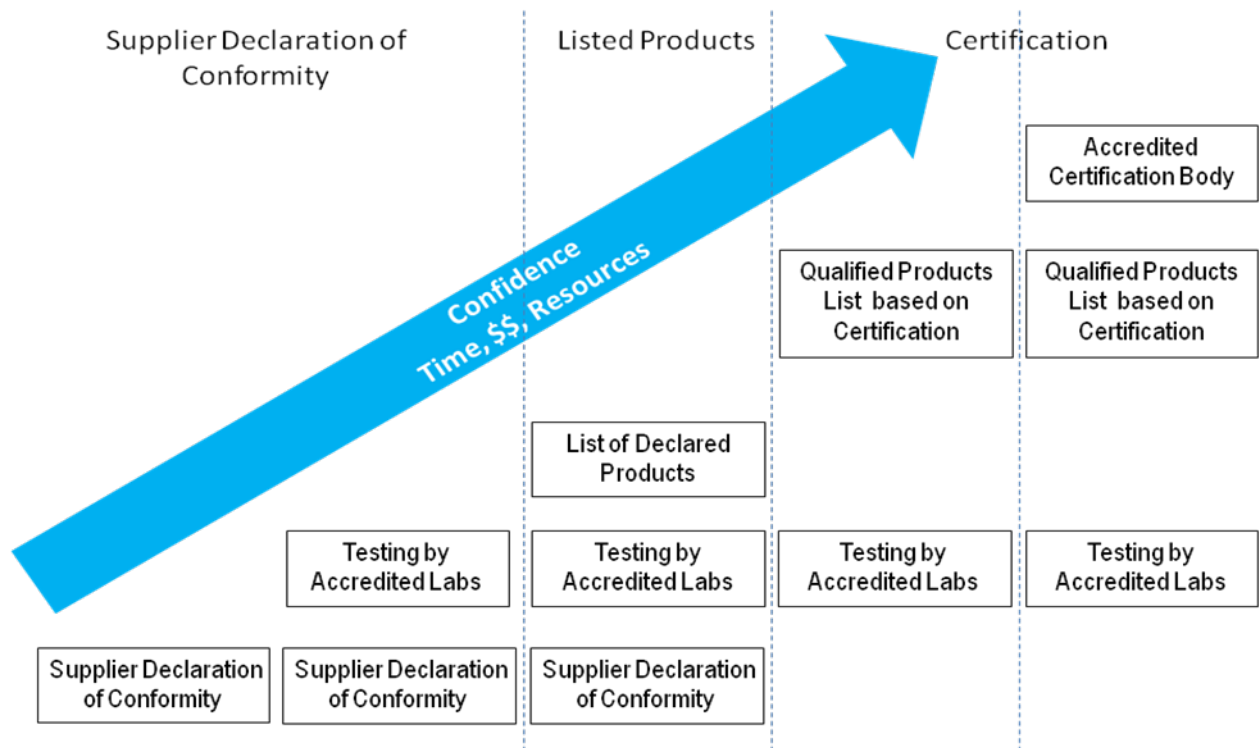


Figure 1-2 – Degrees of oversight for program confidence



Figure 1-3 – Third-party relationships and level of confidence



9. Consider Coast Guard implications – Evaluate how leveraging a TPO to perform the tasks identified in the task analysis will affect the Coast Guard and whether or not the implications are consistent with the stated goals.
- a. Cost savings – Quantify whether the Coast Guard will save money and determine whether the savings can be exploited.
 - b. Resource savings – Quantify whether the Coast Guard will save resources other than money and determine whether the resources can be reprogrammed or re-used for higher priority tasks.
 - c. Cost to run the program – Calculate the costs in money and other resources to develop, implement, and maintain the program, including:
 - (1) Program life-cycle funding;
 - (2) Training Coast Guard personnel to fulfill their roles in the program based on the results of the task analysis;
 - (3) Ongoing oversight based on the results of the task analysis and the risks of establishing a program; and
 - (4) Capital costs (computer systems, software, publications, and contracts).
10. Determine incentives for stakeholder participation – Evaluate the incentives for the regulated entities and the TPO to participate in the program. Incentives might come in many forms and information can be gathered by reviewing industry data or publishing a notice to request information in the Federal Register.
- a. Market forces: Determine whether the market already provides this service (e.g. independent laboratory testing.) and whether existing qualifications, certifications, and accreditations can be leveraged in the program.
 - b. Comparison with user fees: Conduct a preliminary assessment of the likely costs borne by the regulated entity to use a TPO (e.g. inspection, certification, or accreditation body) and compare that estimate to any Coast Guard user fees, or other, associated costs such as inconvenience, vessel unavailability, or oversight activities.
 - c. Monetary: Evaluate whether the program is likely to be economically attractive to a TPO.
11. Evaluate rulemaking implications – Consult with Commandant CG-REG and Commandant CG-LRA to determine whether a regulatory or non-regulatory approach

can be used to implement the program and compare the rulemaking needs to other alternatives.

- a. Feasibility – Evaluate the complexity or difficulty of a rulemaking by:
 - (1) Conducting a preliminary cost/benefit assessment to estimate the regulatory affect; and
 - (2) Making a preliminary determination of significance after considering the cost/benefit.
- b. Timeline harmonization – Determine whether the regulatory development program can support a rulemaking project for the program in the desired implementation timeline.
- c. Collection of information (COI) implications – Determine whether the program would have COI consequences for the Coast Guard, the TPO, and the regulated public.
- d. Incorporation by reference (IBR) implications – Determine whether IBR is needed and if the material meets the IBR requirements of the Office of the Federal Register.

12. Determine information requirements – Determine what information should be collected to manage the program.

- a. Accessibility – Determine who would have access to program information, including the degree to which information would be made available to the public.
- b. Maintenance – Decide which headquarters offices should have responsibility for collecting, analyzing, maintaining, and reporting program information and whether the resources are available.
- c. Metrics – Identify the information that will be used to assess progress, the standards for establishing program metrics, key performance indicators for the TPO, and the measures of program success.

13. Consider political implications – Consult with the Coast Guard Congressional Affairs staff to assess whether Congress is likely to support or object to the Coast Guard leveraging a TPO for the particular conformity assessment activity.

14. Seek public feedback – Consider publishing a notice in the Federal Register to advise the public that the Coast Guard is evaluating a program and seeking public feedback. Reference (a) identifies public transparency as a key factor in assessing the

- effectiveness of using third-party organizations and determining the type of program to establish.
- C. Analysis outputs. The decision-making process in paragraphs B.1 through B.14 should result in the following outputs to develop program implementation and maintenance plans:
1. The object of conformity assessment activities;
 2. The program goal;
 3. A list of test, inspection, and process activities performed on the object to gather information of compliance;
 4. A list of standards and regulations used to determine regulatory compliance;
 5. The identity of the test, inspection, and process bodies and required qualifications;
 6. The identity of the certification bodies and required qualifications;
 7. The identity of the accreditation bodies and required qualifications;
 8. The Coast Guard resources, funding, and training needed to implement and manage the program;
 9. The information collection requirements for each test, inspection, and process;
 10. The metrics used to judge program performance; and
 11. The TPO deliverables.
- D. Final Decision and Recommendation. A final decision about establishing a program to leverage a TPO to ensure regulatory compliance should be based on all of the factors listed in paragraphs B.1 through B.14 and the outputs listed in paragraphs C.1 through C.11. A program proposal showing the results of the preceding analysis should be prepared for the Assistant Commandant for Prevention Policy Commandant (CG-5P) and submitted through the clearance process. The Assistant Commandant for Prevention Policy should approve the program proposal before proceeding to program implementation.

CHAPTER 2. GUIDELINES FOR IMPLEMENTING A PROGRAM TO LEVERAGE THIRD-PARTY ORGANIZATIONS

- A. Implementation. The analyses conducted during the decision-making phase described in Chapter 1 create a roadmap for implementation. These results inform the sponsor of the program scope and goal, the roles and responsibilities of the participants, the level of Coast Guard risk-based oversight, the resources and training needed to manage the program, and the vehicles used to inform the public. At this point, the sponsor has also gained the support and commitment of the collaborating program offices in Coast Guard Headquarters. The sponsor should consider creation of a project team comprising stakeholder representatives to develop an implementation plan for completing at least the following tasks, as needed:
1. Develop a strategy and schedule;
 2. Create program rules;
 3. Initiate the long-term actions;
 4. Create draft participant agreements;
 5. Develop a program maintenance plan;
 6. Make notifications; and
 7. Kick-off the program.
- B. Develop a strategy and schedule. The program scope and mandated deadlines drive the strategy and schedule. Developing the strategy entails identifying and prioritizing the implementation tasks, deciding on the degree and means of communicating with stakeholders and the public, and timing the important implementation events. The scope of the program usually determines the number of stakeholders, the degree of coordination required, and the amount of information managed. Required timelines could influence the resources applied to implement the program and the sequence of tasks. The sponsor, or project team, should create an implementation project plan to identify the steps needed to establish and maintain the program, meet the required and discretionary deadlines, and coordinate the parties responsible for completing tasks. Commandant (CG-REG) provides consultation on development and use of an implementation project plan.
- C. Create program rules. The sponsor should create the program rules from the outputs of the task analysis and the other strategic information developed during the decision-making process. The program rules should include:
1. Procedures for receiving and processing TPO applications;

2. Procedures for regulated entity participation;
3. Procedures for collecting conformity assessment information;
4. Procedures for documenting regulatory compliance;
5. Procedures for Coast Guard oversight;
6. Procedures for measuring performance;
7. Procedures for TPO appeals;
8. Procedures for ensuring public access to information; and
9. Procedures for suspending or terminating agreements.

D. Initiate long-term actions. The long-term actions could include rulemaking activities and addressing resource and training needs. These should be evaluated, confirmed, and initiated as soon as possible, as needed.

1. A rulemaking may be necessary to inform the public, establish the third-party qualifications, document program application procedures, and make certain aspects of the program legally enforceable. Rulemaking is an involved process built on demonstrating to the public that the benefits outweigh the costs. The rulemaking analyses help validate the program. The sponsor should consider meeting the transparency requirements of reference (a) and advising the public to solicit feedback by publishing a notice in the Federal Register. If a rulemaking is necessary, the sponsor should consult with Commandant (CG-REG) to submit a Request for Project Initiation (RPI) following the procedures in Preparation of Regulations, COMDTINST M16703.1 (series). Consequently, the sponsor should have the program conditions and rules complete before initiating a rulemaking through an RPI. The rulemaking process is the default vehicle to:
 - a. Announce the scope of the program to the public;
 - b. Publicize the required qualifications of a TPO;
 - c. Create the application and approval mechanisms;
 - d. Identify the collection of information requirements;
 - e. Describe conditions for suspending or terminating agreements; and
 - f. Make parts of the program legally enforceable.

2. While not usually as long a process as rulemaking, resource and training needs should be addressed early because they might also require detailed justification, intense internal scrutiny, and long-term planning according to Commandant (CG-1), (CG-741), (CG-8), and (CG-DCO-8) procedures. The sponsor should also consult with the Force Readiness Command on issues of techniques, training, metrics and measurements, and periodic quality assessments.
- E. Create draft participant agreements. A Memorandum of Agreement (MOA) is typically used to document agreements between the Coast Guard, TPO, and the regulated entity. Other means to document agreements might be used such as a contract or letter. In any case, the participant agreement is crucial to establishing roles, responsibilities, and authority. A program MOA should follow the direction and format in reference (c), Memoranda of Understanding/Agreement COMDTINST 5216.18 (series), and enclosure (2). MOAs used to establish an agreement with a TPO or regulated entity should follow the clearance and other specific requirements in reference (c) and should be signed by the appropriate authority under Delegation of Authority, HQINST M5402.3 (series). The MOA should:
1. Document the program agreements between the Coast Guard, regulated entity, and TPO, including any time constraints or scheduled periodic reviews.
 2. Establish the roles and responsibilities of the Coast Guard, the first-, second-, and third-parties, and other stakeholders involved in implementing and maintaining the program;
 3. Set the conditions and scope of Coast Guard oversight, including frequency of reporting, key performance indicators for the TPO, and audit authority, and describe who will fund oversight activities.
- F. Develop a maintenance plan. The sponsor should develop a program maintenance plan as the reference for sustaining the program after implementation. The program maintenance plan should include agreed milestones to confirm whether the assumptions made during the decision-making and implementation phases are valid and should address:
1. The roles and responsibilities for managing the program;
 2. The conditions and rules for reporting performance;
 3. The conditions and rules for conducting periodic reviews;
 4. The conditions and rules for processing applications for participation;
 5. The conditions and rules for processing suspensions, terminations, and appeals;

6. The circumstances under which the program would be revised;
 7. The circumstances under which the program would be terminated, and
 8. The need for periodic assessment of:
 - a. The level of industry and public interest;
 - b. The incentives for participation;
 - c. The costs to manage the program;
 - d. The benefits realized by the regulated entity and the public;
 - e. Public or political opinions of the program;
 - f. Continued validation of program conditions;
 - g. The feasibility of meeting the program goal; and
 - h. Changes in other factors that led to program implementation.
- G. Make Notifications. The sponsor or project team should ensure that stakeholders participating in program development are kept informed of progress through regular meetings or other communications, as needed for the scope of the project. The sponsor or project team should also ensure industry and public groups with an interest in the program, such as trade organizations, standards development organizations, and Federal Advisory Committees, have access to information about program implementation. Commandant (CG-092) should be consulted about notification and public affairs options, depending on the scope and impact of the program.
- H. Kick-off the program. The sponsor should confirm that all the program elements are in place prior to program kick-off because this event signifies the end of the implementation project and the beginning of program maintenance phase. The nature and scope of the program might dictate that a formal announcement be made to the public and primary stakeholders. The effective date of a rulemaking might also signify program kick-off. Appendix B shows a checklist of successful program features.

APPENDIX A. SAMPLE TASK ANALYSIS WORKSHEET

Determination for use of Third Party Organizations	
Program Object	
Program Goal	
Statement of authority or limitations	
Strategic goals	
Stakeholders	
First party	
Conditions	

Task Analysis Part A – Testing and inspection

No¹	Object attribute (What attribute of the object is being tested or inspected?)	Test/inspection activity (What test or inspection must be conducted for this attribute?)	Compliance criteria (What standards must be met to demonstrate compliance?)	Recorded results (What results from the test or inspection must be recorded?)	Test qualifications (What qualifications are required of the person conducting the test or inspection?)

¹ Numbering helps identify and track entries through the task analysis.

Task Analysis Part B - Certification

No.	Object attribute (What attribute of the object is being tested or inspected?)	Test/inspection activity (What test or inspection must be conducted for this attribute?)	Test/inspection type (Is this a 1 st , 2 nd , or 3 rd party test?)	Certification qualifications (What qualifications are required of the person confirming compliance?)	Certification type (Is this 1 st , 2 nd , or 3 rd party certification?)

Task Analysis Part C - Accreditation

No.	Object attribute (What attribute of the object is being tested or inspected?)	Test/inspection activity (What test or inspection must be conducted for this attribute?)	Certification type (Is this a 1 st , 2 nd , or 3 rd party certification?)	Accreditation qualifications (What qualifications are required of the person confirming the competence of the person conducting the test or inspection?)	Accreditation type (Is this 1 st or 3 rd party accreditation?)

Task Analysis Part D - Summary

No.	Object attribute (What attribute of the object is being tested or inspected?)	Test/inspection activity (What test or inspection must be conducted for this attribute?)	Test type (Is this a 1 st , 2 nd , or 3 rd party test?)	Certification type (Is this a 1 st , 2 nd , or 3 rd party certification?)	Accreditation type (Is this 1 st or 3 rd party accreditation?)

Task Analysis Part E – Program roles

No.	Object attribute (What attribute of the object is being tested or inspected?)	Identify Test/inspection Body (Who will perform the test or inspection?)	Identify Certification Body (Who will determine regulatory compliance?)	Identify Accreditation Body (Who will verify the competency of the test/inspection and certification bodies?)	What program information must be recorded? (What information is required for metrics, oversight, and transparency?)

Task Analysis Part F – Other strategic considerations	
Factors to consider	Explanation
Public perception of responsibility for failures	
Coast Guard implications	
Incentives for stakeholder participation	
Rulemaking implications	
Information requirements	
Political considerations	
Other factors	

Recommendation and justification

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APPENDIX B. CHECKLIST OF PROGRAM FEATURES

Checklist of Program Features	Check
The program identifies the object of regulatory compliance <i>see</i> Chapter 1.B.1	<input type="checkbox"/>
Coast Guard has statutory authority to create the program <i>see</i> Chapter 1.B.3.	<input type="checkbox"/>
The program meets the Coast Guard's goal for leveraging third-party organizations <i>see</i> 1.B.4	<input type="checkbox"/>
Connects to Coast Guard strategic goals <i>see</i> Chapter 1.B.4	<input type="checkbox"/>
The program conditions reference the relevant industry standards <i>see</i> Chapter 1.B.6	<input type="checkbox"/>
The standards for regulatory compliance have been established <i>see</i> Chapter 1.B.6	<input type="checkbox"/>
The program identifies the test and inspection, certification, and accreditation bodies <i>see</i> Chapter 1.B.7	<input type="checkbox"/>
The qualifications for each role are identified <i>see</i> Chapter 1.B.7	<input type="checkbox"/>
The roles and responsibilities of the regulated entity, third party, and Coast Guard are clearly described and based on the task and risk analyses <i>see</i> Chapter 1.B.7	<input type="checkbox"/>
The program is consistent with other agencies' approaches <i>see</i> Chapter 1.B.8	<input type="checkbox"/>
The purpose and degree of Coast Guard oversight have been established <i>see</i> Chapter 1.B.9	<input type="checkbox"/>
A third-party organization exists to participate in the program; or, the program provides incentives for the market to produce a third-party program <i>see</i> Chapter 1.B.11	<input type="checkbox"/>

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<p>The program provides incentives for the regulated entity to participate in the program <i>see</i> Chapter 1.B.11</p>	<input type="checkbox"/>
<p>The program provides net benefits for the public <i>see</i> Chapter 1.B.12</p>	<input type="checkbox"/>
<p>The program recordkeeping requirements support the intended level of oversight and performance monitoring by the regulated entity, third-party organization, and Coast Guard <i>see</i> Chapter 1.B.13</p>	<input type="checkbox"/>
<p>The program is politically palatable and has the likely support of Congress, industry, and the public <i>see</i> Chapter 1.B.14</p>	<input type="checkbox"/>
<p>The program resource needs have been evaluated and procured. <i>see</i> Chapter 2.D.2</p>	<input type="checkbox"/>
<p>The program describes the procedures for the regulated entity and the third-party organization to participate <i>see</i> Chapter 2.B</p>	<input type="checkbox"/>
<p>Means of communication and conflict resolution among the regulated entity, third party, and Coast Guard have been established <i>see</i> Chapter 2.B</p>	<input type="checkbox"/>
<p>The program rules include performance standards and measurements of success <i>see</i> Chapter 2.B.5</p>	<input type="checkbox"/>
<p>The program contains provisions for public transparency to the same degree as if the Coast Guard is ensuring compliance <i>see</i> Chapter 2.B.8</p>	<input type="checkbox"/>
<p>The program rules include the circumstances and processes for termination <i>see</i> Chapter 2.B.9</p>	<input type="checkbox"/>
<p>The program procedures and processes are consistent with existing statutes, regulations, and policy (e.g. rules for classification society approval and the IMO RO Code) <i>see</i> Chapter 2.C.4</p>	<input type="checkbox"/>
<p>The program implementation and maintenance plans have been developed <i>see</i> Chapter 2.F</p>	<input type="checkbox"/>
<p>The program rules include provisions for program review, revision, and termination <i>see</i> Chapter 2.F.8</p>	<input type="checkbox"/>

ISO/IEC CONFORMITY ASSESSMENT STANDARDS

Topic	Standard	Title
Requirements for Third-party Bodies		
Impartiality	ISO/PAS 17001:2005	Conformity assessment — Impartiality — Principles and requirements
Code of good practice	ISO/IEC Guide 60:2004	Conformity assessment — Code of good practice
Accreditation bodies	ISO/IEC 17011:2004	Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies
Inspection bodies	ISO/IEC 17020:2012	Conformity assessment — Requirements for the operation of various types of bodies performing inspection
Audit and certification bodies	ISO/IEC 17021: 2011	Conformity assessment — Requirements for bodies providing audit and certification of management systems
Audit and certification bodies	ISO/IEC TS 17021-3:2013	Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 3: Competence requirements for auditing and certification of quality management systems
Testing and calibration laboratories	ISO/IEC 17025:2005	General requirements for the competence of testing and calibration laboratories
Peer assessment	ISO/IEC 17040:2005	Conformity assessment — General requirements for peer assessment of conformity assessment bodies and accreditation bodies
Proficiency testing	ISO/IEC 17043:2010	Conformity assessment — General requirements for proficiency testing
Certification bodies	ISO/IEC 17065: 2012	Conformity assessment — Requirements for bodies certifying products, processes and services
Certification bodies	ISO/IEC 17024: 2012	Conformity assessment — General requirements for bodies operating certification of persons
Conformity assessment systems		
Product certification	ISO/IEC 17067: 2013	Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes
Conformity assessment procedures		
Vocabulary	ISO/IEC 17000:2004	Conformity assessment — Vocabulary and general principles
Management systems	ISO/PAS 17005: 2008	Conformity assessment — Use of management systems — Principles and requirements
Audit reports	ISO/IEC TS 17022:2012	Conformity assessment — Requirements and recommendations for content of a third-party audit report on management systems
Indications of conformity	ISO/IEC Guide 23:1982	Methods of indicating conformity with standards for third-party certification systems

Topic	Standard	Title
Marks of conformity	ISO/IEC 17030:2003	Conformity assessment — General requirements for third-party marks of conformity
Declaration of conformity	ISO/IEC 17050-1:2004	Conformity assessment — Supplier's declaration of conformity — Part 1: General requirements
Supporting documentation	ISO/IEC 17050-2:2004	Conformity assessment — Supplier's declaration of conformity — Part 2: Supporting documentation
Mutual recognition of results	ISO/IEC Guide 68:2002	Arrangements for the recognition and acceptance of conformity assessment results
Information disclosure	ISO/PAS 17004:2005	Conformity assessment — Disclosure of information — Principles and requirements
Complaints and appeals	ISO/PAS 17003:2004	Conformity assessment — Complaints and appeals — Principles and requirements
Enforcement		
Corrective actions	ISO Guide 27:1983	Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity
Conformity assessment standards		
Conformity assessment standards	ISO/IEC 17007:2009	Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment

SAMPLE MEMORANDUM OF AGREEMENT FORMAT¹

MEMORANDUM OF AGREEMENT

Between The United States Coast Guard and **[Third-party organization (or Regulated Entity)]**

Regarding **[Explain the action to demonstrate regulatory compliance]**

I. Statement of Purpose: Explain the purpose of the MOA. For example –

Through this Memorandum of Agreement (MOA), the U.S. Coast Guard and [TPO] agree to the procedures, processes, roles, and responsibilities for Coast Guard acceptance of [TPO] [conformity assessment activity] of [object] as meeting the requirements of [insert regulation or statute].

II. Authority: Describe the Coast Guard's authority to regulate the object and to establish a partnership with the TPO through an MOA. Include a statement that the MOA is non-exclusive and does not prevent the Coast Guard entering into similar agreements with other TPOs.

III. Involved parties: Describe the involved parties by name and list the representative and title, mailing address, telephone number, and email address, as appropriate.

IV. References: List the references cited in the MOA including any industry standards used for testing and inspection, certification, accreditation, measuring results, and reporting performance.

V. Roles and Responsibilities:

A. For the purposes of this MOA, the Coast Guard will –

List Coast Guard responsibilities according to the results of phase I, including

- (a) Tests and inspections, certification, and accreditation activities
- (b) Oversight activities
- (c) Communications between the regulated entity and the TPO
- (d) Documenting compliance
- (e) Reporting procedures
- (f) Recordkeeping

¹ Based on Memoranda of Understanding/Agreement, COMDTINST 5216.18 (series)

(g) Periodic program review dates and procedures

B. For the purposes of this MOA, the [third-party organization] will –

List the TPO responsibilities, according to the results of phase I, including

- (a) Testing and inspection, certification, and accreditation activities
- (b) Communications between the regulated entity and the Coast Guard
- (c) Reporting
- (d) Recordkeeping
- (e) Periodic program review

VI. Costs: Describe which party is responsible for the costs of meeting each of the responsibilities listed in paragraph V, particularly user fees for Coast Guard oversight or accreditation activities if the TPO receives a benefit from these. (See OMB Circular A-25, User Charges)

VII. Amendments: Describe the procedures for amending the MOA.

VIII. Conflict resolution and appeals: Describe how conflicts will be identified and resolved and the process for appealing Coast Guard decisions.

IX. Conditions for suspending or withdrawing the agreement: Describe the conditions under which either the Coast Guard or the TPO can suspend the agreement for an agreed period or withdraw from the agreement.

X. Effective dates: State the dates the MOA becomes effective and ends.

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Signature	Date	Signature	Date
[Name,]		[Name,]	
[Title]		[Title]	
U. S. Coast Guard		[Third-party organization]	