



Category	Domestic Inspection Program				
	Request for Recognized Organization (RO) Internal Quality Management System				
Title	(QMS) Review – "Quality Case"				
Serial	CVC-WI-005(2)	Orig. Date	23MAY18	Rev. Date	31MAR20
Disclaimer:	This guidance is not a substitute for applicable legal requirements, nor is it itself a rule. It is not intended to nor does it impose legally-binding requirements on any party. It represents the Coast Guard's current thinking on this topic and may assist industry, mariners, the public, and the Coast Guard, as well as other federal and state regulators, in applying statutory and regulatory requirements. You can use an alternative approach for complying with these requirements if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach (you are not required to do so), you may contact the Coast Guard Flag State Control Division (CG-CVC-4) at <u>FlagStateControl@uscg.mil</u> who is responsible for implementing this guidance.				
References:	 (a) The International Code for Recognized Organizations (RO Code) (b) International Association of Classification Societies (IACS) Quality System and Certification Scheme (QSCS) (c) IACS Quality Management System Requirements (QMSR) (d) 46 USC 3316 - Classification Societies (e) 46 CFR Part 8 - Vessel Inspection Alternatives (f) 46 USC Part 32 - Management of Vessels (g) 46 CFR Part 139 - Third Party Organizations (h) 33 CFR Part 96 - Rules for the Safe Operation of Vessels and Safety Management Systems (i) IACS Recommendation No. 41 - Guidance for IACS Auditors to the ISM Code 				
Change Summary	 The following is a list of major changes found in revision 2. Expanded Section G - Procedures for Recommending a Quality Case Added Section H - Quality Case Actions Added Section I - Appeals. Added objective evidence enclosure. Removed memo template enclosure. 				

- A. <u>Purpose</u>. Coast Guard Marine Inspectors (MI) should use this guidance to evaluate situations where objective evidence indicates that a potential failure of a Recognized Organization (RO) or a Third Party Organization under 46 CFR Subchapter M (TPO) Quality Management System (QMS) resulted in the failure to adequately perform delegated functions¹ under mandatory IMO instruments or national legislation and regulations on behalf of the Coast Guard.
- B. <u>Action</u>. This work instruction applies to MIs performing inspections on U.S. flag vessels where ROs or TPOs also perform certain delegated functions

¹ "Delegated functions" is defined in 46 CFR 8.100. For the purpose of this work instruction, "delegated functions" is synonymous with "statutory certification and services" as described in the RO Code and "approved functions" described in 46 CFR 139.115 for towing vessels subject to inspection under 46 CFR Subchapter M.

- C. <u>Background</u>. Pursuant to domestic regulations² and the RO Code, ROs and TPOs performing delegated functions on behalf of the Coast Guard must develop and implement a QMS.³ The purpose of a QMS is to define and document policy and objectives for, and commitment to, quality, safety, and pollution prevention. In addition, the QMS must contain provisions to ensure that national legislation and requirements of flag administrations, including U.S. Coast Guard requirements, are incorporated.
- D. <u>Discussion</u>. In its capacity as the Flag Administration, the Coast Guard is ultimately responsible to guarantee the effectiveness of delegated functions performed on its behalf. The Coast Guard executes third party oversight through a combination of verification and monitoring techniques executed at multiple levels of the organization. One of the most critical components of the oversight framework is MI "boots on deck." In addition to performing inspections, an MI must be able to evaluate whether any deficiencies noted constitute <u>objective evidence</u> of Safety Management System (SMS) failure for the company (see <u>CVC-WI-003 (series)</u>, *USCG Oversight of SMS on U.S. Flag Vessels*), as well as whether or not the substandard condition developed or was allowed to persist due to a potential failure, or lack of effectiveness, of a QMS. A "Quality Case" (QC) is a tool that the Coast Guard uses to request that the RO or TPO conduct an internal investigation or root cause analysis when objective evidence indicates a potential failure or lack of effectiveness of the QMS, related to unsatisfactory execution of delegated function(s). MIs that establish objective evidence of a QMS process failure shall initiate a QC recommendation to CG-CVC-4 in accordance with the provisions of this instruction.
- E. <u>Establishing Objective Evidence for a Potential QMS Failure</u>. Prior to recommending a QC, the MI must establish <u>objective evidence</u> that the RO or TPO failed to meet a <u>requirement</u> as it relates to *any* <u>delegated function</u> performed on behalf of the Coast Guard. A QC should NOT be recommended where the MI cannot *clearly identify and articulate* the objective evidence, requirement, and relationship to a delegated function performed on behalf of the Coast Guard.
 - 1. <u>Objective Evidence</u> means quantitative or qualitative information, records, or statements of fact.⁴ Examples include:
 - a. Survey/Audit Reports
 - b. Condition of vessel and/or equipment subject to survey
 - c. Surveyor/Auditor statements
 - d. Surveyor/Auditor checklists/procedures
 - e. Other correspondence (emails, notifications, letters, phone calls, etc.)
 - f. RO delegations (i.e. performing a delegated function that the RO did not have a delegation or authorization to perform)
 - 2. <u>Requirements</u> include the elements of the QMS as established by the RO Code or ANSI/ISO/ASQ Q9001-2000 (or equivalent), and by extension any national legislation and regulations of the flag administration that apply to ROs performing delegated functions on behalf of the Coast Guard. Examples of requirements include:
 - a. IACS QMSR/QSCS provisions

² See 46 CFR Part 8, 46 CFR Part 139 and 33 CFR Part 96.

³ Quality Management Systems are required to meet ANSI/ISO/ASQ Q9001-2000 or an equivalent standard (46 CFR 8.230). ROs that are members of International Association of Classification Societies (IACS) use the IACS Quality Management System Requirements (QMSR) and Quality System and Certification Scheme (QSCS) to fulfil this requirement. ⁴ See 33 CEP 96 120

⁴ See 33 CFR 96.120.

- b. IACS Procedural Requirements
- c. ACS Rules
- d. U.S. Supplemental Requirements (i.e. ACP U.S. Supplement)
- e. IMO Instruments
- f. TPO requirements (46 CFR Subchapter M)
- g. National legislation and other requirements or interpretations of the flag administration, including those specified in the Agreements⁵ between the RO and the Coast Guard.
- 3. <u>Delegated Function</u>⁶ means a function related to Coast Guard commercial vessel inspection that has been delegated to an RO or TPO. Delegated functions may include issuance of international convention certificates (e.g. Load Line Certificate, Cargo Ship Safety Construction Certificate), related surveys/audits, or participation in the Alternate Compliance Program, Maritime Security Program, or Towing Safety Management System (TSMS) option under 46 CFR Subchapter M. By extension, other services that eventually result in the issuance of international convention certificates, such as plan review, are delegated functions. A properly formed QC relates to a delegated function.
- F. Requirements Specific to Subchapter M TSMS Option.
 - 1. TPOs conduct independent verifications and surveys to assess whether towing vessels comply with the company's TSMS and if the TSMS complies with the applicable requirements contained in 46 CFR Subchapter M. TPOs are required to conduct such verifications and surveys in accordance with the applicable regulatory requirements and an internal QMS⁷ and may have their TPO approvals suspended or revoked⁸ if the Coast Guard determines that the TPO does not comply with the provisions of Subchapter M. TPOs perform the following delegated functions (not all functions are performed on all TSMS option vessels):
 - External Surveys⁹
 - External Audits¹⁰
 - Issuance of TSMS Certificates¹¹
 - Oversight of internal survey program¹²

For oversight of internal survey programs, as prescribed in 46 CFR 137.210, it is important to note that the procedures and elements of an internal survey program are to be included in the TSMS. To establish "objective evidence" that the TPO failed to adequately oversee an internal survey program, the QC recommendation should provide objective evidence that the TPO failed to adequately audit the required elements of an internal survey program. For example, an internal survey program requires that the TSMS include "procedures for surveying and testing described in 46 CFR 137.215." If, in fact, the TSMS does not include such procedures AND the TSMS was recently audited, it may be grounds for a QC for failure to perform oversight of the internal survey program.

¹¹ See 46 CFR 138.305

⁵ See 46 CFR 8.420(e)

⁶ See 46 CFR Part 8, 33 CFR Part 96, 46 CFR Part 139

⁷ See 46 CFR 139.120

⁸ See 46 CFR 139.145 and 139.150, respectively

⁹ See 46 CFR 137.205

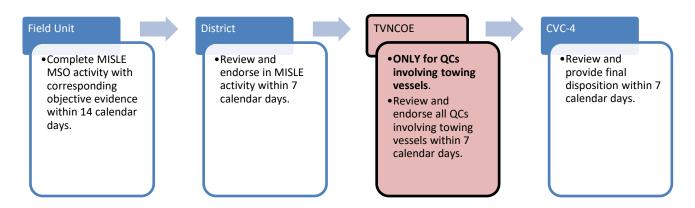
¹⁰ See 46 CFR 138.410

¹² See 46 CFR 137.130

- 2. A QC may be directed against a TPO where objective evidence indicates that the TPO failed to follow their required QMS and/or established "requirements" related to delegated functions performed on behalf of the Coast Guard. The Coast Guard may direct a QC when a valid TSMS Certificate has been issued by a TPO regardless of whether or not the vessel covered by that TSMS Certificate has been issued a Certificate of Inspection (COI). Where there are multiple TPOs that complete delegated functions (e.g., TPO#1 issues the TSMS certificate to the Company and TPO#2 completes the external surveys of a vessel), the OCMI must ensure that the objective evidence provided properly relates to the delegated function(s) performed by the relevant TPO. Generally, it is preferable to first assess whether or not the TPO that issued the TSMS certificate properly executed any delegated function prior to assessing any other TPO that may be involved.
- G. Procedure for Recommending a Quality Case.
 - 1. The OCMI establishes objective evidence that an RO or TPO failed to meet a requirement as it relates to a delegated function.
 - The OCMI documents the objective evidence in the MISLE inspection activity. Details of how to document objective evidence in the MISLE inspection activity can be found in <u>CVC-PR-001(series)</u> "Documenting Deficiencies on U.S. Flag Vessels and OCS Floating Offshore Installations" and <u>CVC-PR-004(series)</u> "Management Systems Oversight (MSO)." After documenting the objective evidence, the unit shall initiate an MSO activity referral with the "Quality Case" subtype.
 - The OCMI generates the QC MSO activity and routes the activity to CG-CVC through the District. *Field units shall forward the recommendation within 14 days of becoming aware of the potential QMS failure*. If field units need additional guidance for QC recommendations, it is strongly encouraged to engage CG-CVC-4 at <u>FlagStateControl@uscg.mil</u>.
 - 4. The District (dp) should review each QC recommendation to validate the sufficiency of the objective evidence against the cited requirement and delegated function. *The District (dp) shall review and complete the review and endorsement within 7 days upon receipt from the OCMI*. The District (dp) shall record the review and endorsement in the MSO activity narrative. If District (dp) determines that the objective evidence is insufficient, that the requirement is invalid, or that the objective evidence is unrelated to a delegated function performed by the RO, District (dp) shall non-concur with the QC recommendation. If District (dp) does not concur with the unit's recommendation for a QC, an explanation shall be provided in the MSO activity narrative. Regardless of District's (dp) determination, activity shall continue to be processed through the chain of command to CG-CVC-4.
 - In addition to the MISLE casework, after District (dp) review, the QC shall be forwarded to the Towing Vessel National Center of Expertise (TVNCOE) at <u>TVNCOE@uscg.mil</u> for QCs involving Subchapter M delegated functions and CG-CVC-4 for all other QCs at <u>FlagStateControl@uscg.mil</u>.
 - 6. For QCs involving Subchapter M delegated functions, *the TVNCOE shall complete review and endorsement within 7 days upon receipt from District then routed to CG-CVC-4.* If the TVNCOE does not concur with the recommendation, they shall provide an explanation within the MSO activity narrative and the activity shall continue to be processed to CG-CVC-4.
 - CG-CVC-4 will be the final reviewer for all QCs. CG-CVC-4 will review each QC. If affirmed, CG-CVC-4 will perform all QC actions as described in paragraph H. CG-CVC-4 will have 7 days to review and endorse the QC as valid or invalid. If the QC is not affirmed, CG-CVC-4

will send notification to the originating unit detailing why the QC was not accepted and close out the MSO activity.

8. General Procedure for routing QCs through the Chain of Command.



- H. Quality Case Actions.
 - 1. CG-CVC-4 staff will notify the RO or TPO that the Coast Guard is requesting a QC and send a business letter detailing the circumstances of the QC via email. The RO or TPO should acknowledge receipt of the QC by the next business day.
 - The RO or TPO should complete an internal review or root cause analysis and communicate any findings, to include any non-conformities and associated corrective actions, in writing to FlagStateControl@uscg.mil. The RO or TPO should provide this report within *30 calendar days* from receipt of CG-CVC-4's QC request.
 - 3. CG-CVC-4 will review the RO's or TPO's findings and proposed corrective actions. If accepted, the QC will be considered "closed" and relevant details related to the QC will be recorded within the MSO activity.
 - 4. The Coast Guard may address any non-conformities resulting from a QC at the next regularly scheduled Flag State Audit to ensure that the proposed corrective actions have been implemented and are effective.
 - 5. The Coast Guard will use the data and records derived from QCs to inform Key Performance Indicators (KPI) for ROs and TPOs, in accordance with the RO Code¹³ and as specified in the agreement between the RO/TPO and the Coast Guard.
- I. Appeals.
 - 1. Disputes may arise between the Coast Guard and ROs or TPOs on matters of QC interpretation (e.g. determining if the RO or TPO was performing a delegated function at the time of incident, if the requirement is applicable to the delegated function, or if the objective evidence supports the QC).
 - 2. The first level of dispute resolution is a request for reconsideration by the CG-CVC-4 Division Chief at <u>FlagStateControl@uscg.mil</u>. The next and final level of resolution is an appeal, in accordance with 33 C.F.R 1.03-15 to the Chief, Office of Commercial Vessel Compliance (CG-CVC). The decision by CG-CVC shall constitute final agency action.

¹³ RO Code 6.1.2 and 46 CFR 8.130(a)(22)-(24).

3. All appeals under review should be sent to CG-CVC for final disposition through CG-CVC-4 via email at <u>FlagStateControl@uscg.mil</u> or by mail at:

Office of Commercial Vessel Compliance (CG-CVC) U.S. Coast Guard, Stop 7501 2703 Martin Luther King Jr Ave., SE Washington, DC 20593-7501

> M. EDWARDS Captain, U.S. Coast Guard Chief, Office of Commercial Vessel Compliance By direction

Enclosure:

(1) Objective Evidence and Requirements Examples

Examples of Objective Evidence and Requirements

(These examples are not all-inclusive and are provided only as reference to give the MI a sense of the functions and structure of the objective evidence)

Requirements	Objective Evidence Example
46 CFR $8.230(a)(15) - RO$ is required to maintain	Following oversight exam on an ACP vessel, MI
a Quality Management System	noted that the last annual survey was completed by
	the RO just two weeks prior. Following a review of
ROs must comply with IACS Procedural	the survey report, it was noted that the lifeboats were
Requirements (IACS QMSR)	inoperable, the fuel oil purifiers were leaking and
	there was oil in the engine room's bilge. In aggregate,
	the combination of these deficiencies indicated that
	the safety management system was not effectively
	implemented. However, the surveyor did not notify
	the RO responsible for the SMS audit of the ship in
	accordance with IACS PR-17. The RO failed to
	follow IACS Procedural Requirements as required by
	their QMS.
46 CFR 8.420(e) and 46 CFR 8.430 – ROs have	During an ACP oversight exam, the MI was testing
to comply with their agreement with the Coast	the fire hoses and noted that none of the fire nozzles
Guard (MoA/MoU, as applicable), and the	were Coast Guard-approved. Following a discussion
requirements of a U.S. Supplement.	with the Chief Mate, it was discovered that the
	nozzles were recently replaced and the RO tested
	them during the annual safety equipment survey. The
(Cite the U.S. Supplement as appropriate to the	associated survey report indicated that the surveyor
RO)	examined the new nozzles and performed an
	operational test with satisfactory results. The
	surveyor did not ensure that the fire nozzles were
	Coast Guard-approved in accordance with the ACP
46 CFR 8.230(a)(15) – RO is required to maintain	supplement.
a Quality Management System	During an exam of a traditionally inspected cargo ship subject to SOLAS, the MI notes that the RO has
a Quanty Management System	issued a Cargo Ship Safety Equipment Certificate
(Note that the surveyor did not follow the internal	pursuant to their delegations. The certificate was
checklist)	properly endorsed within the last 30 days. During a
	test of the lifeboats, it is noted that the davit electric
	motor was inoperable and the falls should have been
	changed 6 months prior. Following a review of the
	RO's checklist for the Safety Equipment Annual
	Survey, the MI notes that there is a function to ensure
	that the lifeboat, liferaft, and rescue boat appliances
	(davits, falls, winches & brakes) are thoroughly
	examined and compliant. The surveyor failed to
	ensure that regulations requiring the performance of
	the function were complied with during the annual
	survey.
46 CFR 8.230(a)(15) – RO is required to maintain	CG-CVC received notification that a U.S. flag vessel
a Quality Management System	was detained in a foreign port after the Port State
	Control Officer had noted that the Company IMO
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	number was incorrect on the Document of Compliance. Objective evidence indicates that the RO's procedures related to the review of vessel certificates are inadequate.
46 CFR 139.135 – Addition and removal of auditors and surveyors	During a marine casualty investigation on a towing vessel inspected under the Subchapter M TSMS Option, the attending investigating officer is reviewing the TPO's survey and audit records for the vessel. The IO consults with the TVNCOE to determine, based on the TPO's records, whether or not ineffective surveys may have contributed to the casualty. Upon further review, it is noted that due to high demand, the TPO hired several new surveyors that were inexperienced. The TPO failed to notify the TVNCOE that new surveyors were hired and did not submit a record of the person's experience, background, and qualifications to the TVNCOE.
NVIC 01-13, Change (1), Enclosure (4), 1.20 – ACS Responsibilities under an agreement with the Coast Guard	During an annual oversight exam of an MSP Select vessel, the MI notes that the vessel has a short-term classification certificate and that the Unattended Machinery Space endorsement has been suspended due to a failure of the automated control system that cannot be fixed until an upcoming dry-dock (currently 6 months away). Following a review of the COI, it is noted that the vessel has reduced manning and is authorized for Periodically Unattended Machinery Spaces (PUMS). No notification was provided to the Coast Guard regarding a condition of equipment that was not in substantial compliance with the particulars of the COI.
IACS QMSR 4.1.2 Statutory Services The RO's QMS shall ensure that statutory regulations and related requirements are complied with through survey during service.	Following an ACP additional oversight exam for a vessel on the risk assessment list, the vessel was found to be in poor materiel condition. The emergency generator would not start, several on-deck gooseneck vents were severely corroded, and most of the fire dampers were inoperable or wasted. Based on
IACS QSCS 4.2 – Quality Management System Requirements ROs must comply with IACS Procedural Requirements	the fire dampers were inoperable of wasted. Based on the condition of the vessel, it is obvious that many of deficiencies developed over the course of several months or in some cases years. The MI notes that each of the deficiencies relates to an ACS survey checklist item that were signed off during the annual surveys, which occurred just two months prior. In addition, the surveyor failed to apply IACS PR-17 in accordance with the RO's QMS.