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MCA QA (ISO) 1: Procedure for Assessments to ISO 9001:2015 and ISO 14001:2015 Standards

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1.0 Purpose

This Procedure describes how Maritime and Coastguard Agency Quality Assurance (MCAQA), conducts assessments in accordance with ISO 17021:2015 for clients seeking certification to ISO 14001:2015 and ISO 9001:2015. It also details how the results are reported, corrective and preventative actions verified and records maintained.

2.0 Scope

This Procedure applies to the MCAQA's assessments and all personnel involved in this activity.

3.0 References

ISO 9001:2015

ISO 14001:2015

ISO 17021:2015

ISO 19011:2011

IAF MD 5:2015

MCAQA Quality Manual

MCA QA2: Procedure for handling Complaints/Appeals and disputes

QAF 1: Auditor Audit Log

QAF 2: Lead Auditor Authorisation Certificate

QAF 7: Application review

QAF 9: Opening and Closing Meeting Attendance

QAF 10: Audit Report

QAF 11: ISO 9001/14001:2015 Aide Memoire

QAF 12: ISO 9001:2015/14001:2015 Audit Declaration

QAF 14: ISO 14001 Ship Based Questionnaire QAF 15: ISO 14001 Shore Based Questionnaire

QAF 16: Blank Audit Plan

QAF 24: Application form for Assessment to ISO standards

QAF 25: Contractual Agreement QAF 28: Client Audit Schedule

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QAF 29: Auditor Resource Assessment Form QAF 37: QMS Aide Memoire and Guidance QAF 38: EMS Company Aide Memoire QAF 41 Food and Hygiene aide memoire QAF 42 ISM/ISO audit file enclosure

QAF 49: MCAQA Interest and application decisions

4.0 Responsibilities

All Personnel	-	Act impartially and not allow commercial, financial or other pressures to influence certification activities
Head of Maritime Security & Safety Management Operations	-	Deciding if MCAQA is able to fulfil clients' requirements for certification (6.3)
	-	Approving certification quotation (6.3)
	-	Appointing Lead Auditors (6.4, 6.19 & 6.23)
	-	Deciding on appropriate action if non-conformities are
		not closed out (6.15)
	-	Making Certification decision (6.19)
	-	Approving audit schedule (6.19)
	-	Initiating appeal or dispute process (6.24)
	-	Defining MCAQA Resource requirements (6.2)
	-	Drawing up certification quotation (6.3)
	-	Carrying out Application Reviews with prospective clients (6.3 & 6.23)
	-	Creating audit schedule (6.19)
Lead Auditor	-	Appointing audit team (6.4)
	-	Undertaking document review (6.5)
	-	Making audit arrangements with client (6.6 & 6.19)
	-	Checking client files for 'Notes to Auditors' (6.6)
	-	Chairing opening (6.8) and closing (6.13) meetings
	-	Conduct of audit (6.8 to 6.11)
	-	Writing audit report (6.14)
	-	Closing out non-conformities (6.15)
	-	Completing declaration (6.16)
	-	Initial consideration of appeal or dispute (6.24)
	-	Updating Auditor Training logs (6.23)
Auditor	-	Undertaking audit activity (6.8 to 6.11)
	-	Recording non-conformities (6.12)
	-	Process Control Checks (6.23)
Administrator	-	Providing information pack to potential clients (6.1)
	-	Following up enquiries if no reply received (6.1)
	-	Organising logistical requirements (6.6)

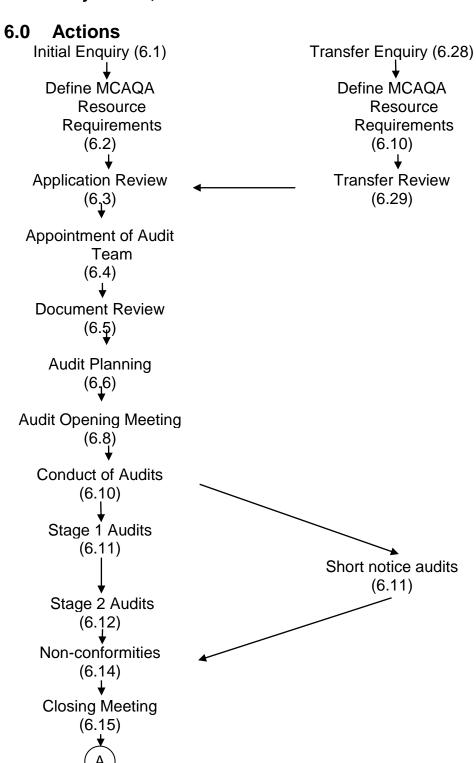
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-	Production of certificate (6.18)
-	Process control checks (6.23)

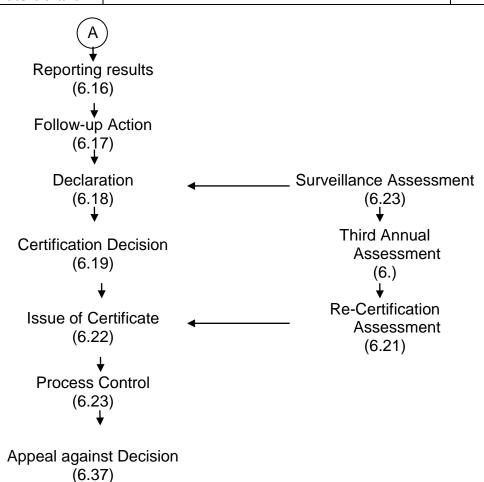
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5.0 **Definitions**

See Quality Manual, section 3.



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6.1 Initial Enquiries

Potential clients are provided with an Information Pack (see Quality Manual 5.5) on request by the Administrator. For enquiries about certifying environmental management systems, a ship-based questionnaire (QAF 14) and a shore-based questionnaire (QAF 15) are also sent to the client. Clients should be invited to complete the questionnaires, if applicable, and application form (QAF 24).

Copies of any correspondence are kept within the Client Queries file (MS166/01/0082) until such a time as the company completes the Application Form (QAF 24) and is allocated its own file (MS166/014/xxxx series for companies).

The Administrator should log who they have sent the Information pack out to using QAF 49. The Administrator should also follow up enquiries if the potential client does not make contact within one month of the information

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pack being sent out. The results of this follow up should be recorded in QAF 49.

6.2 Defining MCAQA Resource Requirements

Upon receipt of a completed application form the Head of Maritime Security & Safety Management Operations reviews the assessment requirements for the client. There are two aspects to this; calculating the number of audits required and calculating the audit duration.

The Auditor Resource Assessment Form (QAF 29) is a spreadsheet used to quantify the number of audits required and audit duration in conjunction with ISO 17021:2015 and IAF MD 5:2015. Any deviation from the guidance provided is to be justified.

6.3 Application Review

Upon receipt of a completed application form, the Head of Maritime Security & Safety Management Operations or a Lead Auditor appointed by the Head of Maritime Security & Safety Management Operations, arranges for an Application Review.

The Application Review is undertaken to determine the requirements of the client and the ability of MCAQA to meet those requirements. A review need only be undertaken when the client is new to MCAQA or as deemed necessary by the Head of Maritime Security & Safety Management Operations if a change in certification or scope is required.

The following information should be collated during the Application Review, if it has not already been included on the application form:

- General details, including corporate identity, name, address and legal status;
- Desired scope of certification
- General information about the client organisation
- General information about the QMS and/or EMS, the activities it covers, physical locations, significant aspects of process or operations and legal obligations;
- Significant sites/premises/vessels of activities;
- Points of Contact:
- Details of human and technical resources;
- Status of EMS/QMS (it is necessary for the client to have completed one internal audit cycle and one management review cycle prior to assessment); and
- Details from the EMS questionnaires sent to the client if appropriate.

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The review should provide a deeper understanding of the client's operations. Any potential problems are to be discussed with the client, additional information obtained, and client queries addressed.

An Application Review Report (QAF 7) must be completed once a review has been undertaken.

Following the review, the Head of Maritime Security & Safety Management Operations decides if MCAQA can fulfil the client's requirements. If satisfied that MCAQA can do so, the Contractual Agreement signed on behalf of MCAQA is sent to the client for their review and signature. This may also be done electronically.

The covering letter will invite the client to return one copy of the completed contractual agreement duly signed and forward payment. It will also emphasise that signing the contract does not guarantee certification. The administrator should log details of a successful application and date of contract completion using QAF 49.

If the decision of the Head of Maritime Security & Safety Management Operations is to decline an application for certification, the reasons shall be recorded using QAF 49. The Head of Maritime Security & Safety Management Operations will need to make the decision clear to the client.

6.4 Appointment of Audit Team

The Head of Maritime Security & Safety Management Operations appoints a competent Lead Auditor for the assessment. The ISM/ISO Policy advisors are responsible for all financial dealings and must ensure that the fees have been received and an appropriate job number raised before work commences as far as practicable. The selection of the Lead Auditor is based upon the information gathered during the Application Review with regards to the requirements of the client and the competence, training, qualifications and experiences of the available Lead Auditors. Consideration is also given to the previous contact the Lead Auditor may have had with the client, e.g. ISM audits. The Head of Maritime Security & Safety Management Operations must consider the following when selecting the lead auditor:

- .1 Knowledge of applicable regulations;
- .2 Knowledge of assessment methods and MCAQA certification procedures and associated documents;
- .3 Technical/Environmental knowledge, including environmental aspects and impacts and their mitigation for ISO 14001 audits;

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- .4 Competencies as outlined above and required by the activity being assessed:
- .5 Any potential conflicts of interest; and

The Lead Auditor is responsible for selecting, leading and managing the audit team, taking account of the above. The number of auditors required will depend upon the size and nature of the client and the scope to be covered by the audit. The Lead Auditor must ensure that the team has the collective competence to perform an effective assessment of the client's management system against both the appropriate standard and the scope of certification. An auditor in training may be included in audit team as a participant but a Lead Auditor must also be present and be appointed as the overall evaluator and will have overall responsibility of the audit activities and findings

The Lead Auditor must also consider the need to include technical experts in the audit team and if considered necessary refer the matter to Head of Maritime Security & Safety Management Operations for a decision. Technical Experts shall not perform any independent auditing functions but will work at all times in close co-operation with, and under the supervision of, an MCAQA auditor.

6.5 **Document Review**

The document review is the first stage in the assessment process and must be undertaken prior to the Initial Assessment (1st stage audit). Once assigned to a client the Lead Auditor should make contact in order to make introductions and to arrange for appropriate documentation to be forwarded to MCA QA so a document review can be undertaken. If the client is not yet ready to undertake the document review the Lead Auditor should discuss time scales for when the client is likely to be ready. The Lead Auditor should keep in regular contact with the client.

The Document Review is undertaken by the Lead Auditor and consists of an examination of the client's policy documents, manuals, key procedures and any other necessary documents to ensure that these meet the requirements of ISO 14001:2015; and or ISO 9001:2015.

Following the document review, areas that do not meet the requirements of the standard should be brought to the attention of the client. Instances of good practice should also be pointed out. Non-conformances are not raised during this section of the certification process.

When the Head of Maritime Security & Safety Management Operations is satisfied that the documentation is adequate the Lead Auditor must then

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make arrangements for the Stage 1 on-site audit. The information gathered so far in the assessment process may be used in a confidential manner to prepare for the on-site visit.

An audit programme (QAF 28) must be established for the full three-year certification cycle. The audit programme must identify the audit activities required to demonstrate that the client's management system fulfils the requirements of the standard they are certificated to. The programme will include a two-stage initial audit, surveillance audits and a recertification audit in the third year prior to expiry of certificate. It is the responsibility of the Head of Maritime Security & Safety Management Operations and administrative staff to put the audit programme together and communicate to the client and auditors involved in the auditing process.

The audit programme developed will take into account issues raised at previous audits and are liable to change during the three-year certification period.

6.6 Audit Arrangements

The Lead Auditor is responsible for making the arrangements for the audit with the client. Logistical requirements (travel and accommodation etc.) are organised either by the client or by the Lead Auditor. Details of the audit including names of the auditors, times, dates and an audit plan (QAF 16) must be provided to the client in sufficient time to enable suitable arrangements to be made.

The audit plan (QAF 16) will be put together on the basis of the audit programme (QAF 28) and shall include

- scope, (including identification of the organisational and functional processes to be audited)
- objectives
- criteria
- the dates and sites where the audit activities are to be conducted
- the expected time and duration of the on-site audit activities
- the roles and responsibilities of the audit team members and accompanying persons

Auditors are recommended to consult the guidance which is available in the following documents in drawing up the audit plan and any personal checklists needed:

- QAF37 QMS Aide Memoire
- QAF 38 EMS Company Aide Memoire
- QAF 41 Food and Hygiene aide memoire

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- QAF 28 Audit Schedule
- QAF 29 Frequency and duration of audits
- Previous Audit report and auditors notes

The audit objectives shall describe what is to be accomplished by the audit and will include:

- a) determination of the conformity of the clients' management system with the audit criteria;
- b) evaluation of the ability of the management system to ensure the clients organisation meets applicable statutory, regulatory and contractual requirements;
- c) evaluation of the effectiveness of the management system to ensure the client organisation is continually meeting its specified objectives;
- d) as applicable, identification of areas for potential improvement of the management system.

The audit scope shall describe the extent and boundaries of the audit, such as physical locations, organisational units, activities and processes to be audited.

The audit criteria shall be used as a reference against which conformity is determined and shall include:

- a) the requirements of a defined normative document on management systems e.g. ISO 9001 or ISO 14001
- b) the defined processes and documentation of the management system developed by the client

Prior to the audit taking place the Lead Auditor and members of the audit team must be provided with the appropriate documentation and background information to be able to successfully complete the audit. It is the responsibility of the lead auditor to ensure that appropriate data referring to the regulatory requirements of the client is updated by appropriate sources prior to the audit taking place, particularly in the case of vessels berthed at or calling in to foreign ports. Appropriate sources include other Maritime Authorities, internal MCA employees and Agents located at relevant ports.

Audits of vessels are completed using the same methodologies. Records are kept in Individual ship files (CMxxxxx/054/001 series).

6.7 <u>Combined ISO/ISM Audits</u>

ISO 9001:2015, ISO 14001:2015 and the International Safety Management (ISM) Code all contain common elements, which allow

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combined audits to take place. This may be carried out either where a combined system exists or two or more separate systems are in operation.

The ISO part of the audit follows the process detailed in this procedure. The procedures for ISM auditing can be found in MCA's Quality Management System

Combined audits require careful planning to ensure that the scope of the audit is adequately covered. It will be the responsibility of the Lead Auditor to ensure that the audit adequately covers all the requirements

Lead Auditors used on combined audits must possess the minimum qualifications as detailed in the Competency Analysis (QAF 27). A combined audit may be undertaken by a team consisting of two Lead Auditors if no single Lead Auditor has all the necessary competencies. In such cases the Lead Auditors will ensure that regular meetings occur between the audit team to ensure that all necessary sections are being audited adequately. Auditors must be competent to audit the tasks that are assigned to them.

During a stand-alone ISO audit the statutory forms msf 1602/1603 only need to be completed if deficiencies related to statutory certificates are identified. If statutory deficiencies are found, all the usual enforcement procedures (detention, prohibition, improvement) apply.

6.8 Audit Opening Meeting

An opening meeting must be held at the start of the first day of the audit. The Lead Auditor should chair the meeting and note those attending the meeting (QAF 9). The meeting should include suitable representatives of the client. During the opening meeting the following should be discussed:

- Introduction of participants, including outline of roles
- Confirmation of scope of audit
- Confirmation of audit plan (including type and scope of audit, objectives and criteria);
- Confirmation of formal communication channels between the audit team and client
- Confirmation that resources and facilities needed by the audit team are available
- Confirmation of matters relating to confidentiality
- Confirmation of relevant work safety, emergency and security procedures for the audit team
- Confirmation of the availability, roles, identities of any guides and observers

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- The method of reporting, including any grading and audit findings
- Information about the conditions under which the audit may be prematurely terminated
- Confirmation that the audit team leader and audit team representing the certification body is responsible for the audit
- Confirmation of the status of findings from previous review, if applicable
- Methods and procedures to be used to conduct the audit based on sampling
- Confirmation that the client will be kept informed during the audit of any concerns/progress
- Opportunity for the client to ask questions

6.9 Observers and Guides

An observer may attend during the audit activity, but agreement should be sought from the client and the auditor prior to the start of the audit. The audit team will ensure the observer does not in any way influence or interfere in the audit process. The auditor should be accompanied by a guide (unless otherwise agreed to) A guide should be assigned to the audit team to facilitate the audit. The audit team should ensure the guide does not influence or interfere in the audit process.

6.10 Conduct of Audits

The Lead Auditor is responsible for carrying out audits and should be available to the audit team should queries arise. The purpose of the audit is to obtain evidence of conformity (or non-conformity) regardless of familiarity with processes or persons involved.

The Lead Auditor must ensure that tasks are appropriately assigned to suitably qualified and competent team members, i.e. where an activity requires a particular specific competence, the auditor with that competency must be assigned to complete that part of the assessment.

During the audit each Auditor records details of the personnel who were the focus of each activity/process assessed and the specific details relating of the document/records examined. This information can be in the form of checklists and/or a copy of the notes made, or annotations to photocopies/records under audit. In the event that evidence obtained later in the audit clarifies or alters early evidence a suitable cross-reference is to be made in the auditor's notes or any aide memoirs used. These notes would need to be used for preparation of the audit report.

During the audit the audit team shall periodically review audit progress and exchange information. The team leader shall reassign work if needed

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between audit team members and continue to communicate progress or any concerns to the client.

Audits are a two-way process and their success depends on obtaining the facts. They are confidential between MCAQA and the client within the precepts of the Freedom of Information Act. The Quality Manual outlines the commitment to confidentiality and details what is expected of MCAQA personnel.

The audits will take into account the guidance given in ISO 19011:2011, ISO 17021:2015 and the MCAQA Quality Manual. The audit programme shall include stage 1 and 2 two-stage initial audits (see 6.11 and 6.12), surveillance audits in the first and second years and a recertification audit in the third year prior to the expiry of certification. The certificate commences from the certification or re-certification decision. The audit programme shall give due consideration to the size of the organisation, scope and complexity of its management system, products and processes, effectiveness of the management system and the results of previous audits, if any. However sufficient verifiable information needs to be collected to justify the audit programme and any adjustments made to the audit programme shall be recorded.

6.11 Stage 1 Audit

The Stage 1 Assessment of a client's management system is undertaken to gain an understanding of the management system and its implementation by the client. This enables any possible issues to be raised before the Stage 2 audit is undertaken.

The Stage 1 Audit should cover the following objectives:

- To audit the client's management system documentation;
- To evaluate the client's location and site-specific (includes remote offices and ships) conditions;
- To establish the readiness of the client for stage 2 audit;
- To review the client's status and understanding regarding requirements of the standard, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system;
- To collect necessary information regarding the scope of the management system, processes and locations of the client, and related statutory and regulatory aspects and compliance (e.g. quality, environmental. Legal aspects of client's operation, associated risks etc);

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- review the allocation of resources for the stage 2 audit and agree with the client on the details of the stage 2 audit;
- To provide a focus for planning the Stage 2 audit by gaining a sufficient understanding of the client's management system and site operations in the context of possible significant aspects;
- To evaluate if the internal audits and management review are being planned and performed, and that the level of implementation of the management system substantiates the client is ready for the stage 2 audit
- To allow the Lead Auditor to ascertain whether any further planning, resources or technical advice will be required to thoroughly assess the management system; and
- To provide feedback to the client prior to moving on to stage 2 audit, including any areas of concern that could be classed as a nonconformity during stage 2, and the interval before commencing stage 2.

If the management system documentation fails to meet the standard or its implementation is ineffective, non-conformity reports will be raised (see 6.14). Any issues, discrepancies or non-conformities raised following the stage 1 Audit must be closed out (see 6.17) prior to moving to the stage 2 Audit.

It is the Lead Auditor's responsibility to remain in contact with the client to ensure that the assessment moves onto stage 2.

6.12 Stage 2 Audit

The Stage 2 Audit consists of both a further audit of the client's head office and audits of a sample of other offices and ships included within the scope of certification. A final close-out audit may be held at the client's head office.

The audit team should draft an audit plan to cover the objectives of the Stage 2 Audit which are to test:

- Information and evidence about conformity to all requirements of the management system
- Performance monitoring, measuring, reporting and reviewing against key performance objectives and targets
- The client's management system and performance as regards legal compliance;
- Operational control of client's processes;
- Internal auditing and management review;
- Management responsibility for client's policies; and

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 Links between the standard's requirements, policy, performance objectives and targets, any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data and internal audit findings and conclusions.

Auditors are recommended to consult the guidance which is available in the following documents in drawing up the audit plan and any personal checklists needed:

•	QAF 11	ISO 9001/14001:2015 Aide Memoire
•	QAF 37	QMS Aide Memoire
•	QAF 38	EMS Company Aide Memoire
•	QAF 41	Food and Hygiene Aide Memoire

If major non-conformities are identified during the course of the audit, certification cannot be recommended until these are satisfactorily closed out. If these are not closed out within 6 months, the stage 2 audit would need to be repeated.

6.13 Short Notice Audits

It may be necessary to conduct short-notice audits:

- To investigate complaints, if there is insufficient response from the client to information requests, or the situation is so serious that only an audit will allow the provision of the necessary evidence of compliance
- As follow up to suspended clients
- If a client persistently or seriously fails to meet certification requirements; or
- If a client does not allow surveillance, or recertification, audits at the required frequency.

It is acknowledged that these audits will place a strain on the relationship with the particular client, but we have to assure ourselves that certification conditions remain sound. The Head of Maritime Security & Safety Management Operations is to exercise care when deciding the scope of the audit and in the selection of the audit team. MCA QA shall give advance notification to the client of such an audit, the details of the audit and the circumstances which lead to the same.

6.14 Audit Findings

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MCAQA operates a three-tier system of audit findings. Non-conformity is defined in Quality Manual, section 3.

- Observation No corrective action is required by the client
- Minor Non-conformity Corrective action required by the client, usually within three months.
- Major Non-conformity Corrective action required by the client, in most circumstances immediate action is required.

If during the course of the audit deficiencies within the system are found by an auditor, the findings should initially be discussed with the auditee to establish whether a non-conformity does exist. The auditee should be made aware that there is an intention to raise a non-conformity note against the area being audited, which will be presented to the management of the organisation during the audit closing meeting.

If objective (audit) evidence is found of non-compliance with requirements, it must be recorded as a non-conformity, rather than an "observation". If, however there is a lack of objective evidence, by definition, a non-conformity cannot exist. It should be remembered that when viewing the wider picture nobody benefits from use of lower categories as the priority assigned to corrective action will be inappropriate.

Non-conformity Note (NCN) Form MSF1902 must be used when raising non-conformities. The form must be filled out by the auditor, ensuring that the standards/code under which the non-conformity has been raised have been included.

The description of the deficiency on the NCN form should include:

• Identification of the problem:

"A Review of records of deck stores received revealed that no reports of compliance had been made for one year despite the 'ship XYZ' receiving stores every three months, and there has been no follow up from the company."

Identification of the requirement

"Procedure PR-08 requires ship staff to inspect 10% of deck stores received to verify compliance with specification and submit a report to the company."

Attribution

"Clause 7.4.3 of the ISO 9001:2015 requires the company to establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements." Although insertion of the clause reference in the required box will suffice.

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In this example the root cause of the deficiency has been identified rather than the shallower "control of records" (ISO 9001:2015, clause 4.2.4).

Deficiencies from similar clauses of the relevant standard should be grouped together under a single NCN.

All NCNs raised must be presented to the client at the closing meeting (see 6.15). This allows the client to discuss the findings with the audit team. If the client is in agreement with the findings of the audit a signature from a representative of the company is required on the NCNs.

Major non-conformities should be marked for immediate action. Corrective action should be agreed before leaving the premises.

Minor non-conformities may have a time scale of up to three months. If a client requests time to consider the appropriate corrective action the Lead Auditor has the discretion to grant the client one week to consider their options.

Observations do not require any corrective action. Observations may be raised to highlight information to both the client and to MCAQA personnel that may audit the client in the future.

Upon satisfactory completion of the NCN, including details of proposed corrective actions, the auditor signs and dates the NCN. The yellow copy is retained for MCA QA files. The client retains the white copy.

Closing out non-conformities is covered in paragraph 6.15

6.15 Closing Meeting

At the end of the audit a closing meeting must be held, chaired by the Lead Auditor. Prior to the meeting with the client a private meeting must be held so the audit findings can be discussed among the team and any non-conformities written up, this must include;

- a) review of audit findings and any other appropriate information collected during the audit, against audit objectives
- b) agree upon audit conclusions
- c) identify necessary follow up actions
- d) confirm the appropriateness of audit programme and identify rectification/corrective action if required

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Records of those present at the closing meeting should be kept (QAF 9). The Lead Auditor should indicate that the meeting is an opportunity for the client to ask questions about the findings and their basis.

The findings, including non-conformities and areas of good practice should be discussed including the recommendation regarding certification. In particular, on completion of the audit, remedial action is discussed and NCN's signed by the Lead Auditor and relevant location management to agree appropriate action including timescale for completion.

At this point the Lead Auditor must provide the client with an indication of the conformity of the organisation's EMS and or QMS to the required standard. The client will be informed of the need for a full or partial reassessment or whether a written declaration, to be confirmed at a future surveillance visit will be considered adequate.

The closing meeting shall also include the following elements:

- a) advising the client that the audit evidence collected was based on a sample of the information; thereby introducing an element of uncertainty
- b) the method and the timeframe of reporting, including grading of findings
- c) the certification body's process for handling non-conformities including any consequences relating to the client's certification
- d) the timeframe for the client to present a plan for correction and corrective action for any nonconformities identified during the audit
- e) the certification body's post audit activities
- f) information about the complaint handling and appeal processes

The client must be given the opportunity to ask questions. Any conflicts of interest raised during the audit regarding findings between the client and audit team members shall be discussed and resolved where possible. Any issues that can not be resolved must be recorded and referred to the MCAQA.

6.16 Reporting Results

Following the assessment, the Lead Auditor is responsible for writing a report on the findings of the audit team (QAF 10). In writing reports to cover multiple standards (ISO 9001:2015, ISO 14001:2015 and ISM Code) it is necessary to group together comments under similar clauses from each standard. To aid this, the audit report section headings will identify the clauses of the standards that are applicable. A table at Annex A shows a simplified comparison, by reference to each requirement. There may be

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some differences in the specific requirements, but they have been considered equivalent for this comparison.

The Lead Auditor must endeavour to forward the report to the client within fifteen working days of completion of the audit. The Lead Auditor will need to liaise with team members and to ensure receipt of draft reports relating to activities and processes assessed. It is left to the Lead Auditor's discretion as to whether individual auditors should produce reports, which are then collated, or whether one report is produced by a combined effort of the audit team.

As a minimum the report must include:

- Identification of the certification body
- The name and address of the client and clients representative
- The type of audit (e.g.: initial, surveillance, recertification)
- The audit criteria
- The audit objectives
- The audit scope, identification of the organisational functions or processes audited
- Any deviation from the audit plan and their reasons
- Any significant issues impacting on the audit programme
- Name of audit team leader, audit team members and other accompanying persons
- Time, date and place of the audit
- Audit findings, evidence and conclusions, consistent with the requirement of the type of audit
- Significant changes, if any that affect the management system since the last audit
- Any unresolved issues, if identified
- Whether the audit is combined, joint or integrated
- A disclaimer statement indicating that auditing is based on sampling
- Comments on conformity of the system to the requirements of the standard;
- Clear statements of non-conformity when non-conformity was found;
- If appropriate, comparisons with previous assessments of the client; and
- A recommendation, if relevant regarding certification.
- Confirmation that the client is effectively controlling the use of the certification documents and marks
- A statement on the conformity and effectiveness of the management system
- A conclusion on the appropriateness of the certification scope

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Confirmation that the audit objectives have been fulfilled

The report may also include:

- Areas of good practice;
- · Areas of bad practice; and
- List of personnel audited.

The original report is then sent to the client, and a photocopy kept on the appropriate client file. The client's local management are invited to respond to this report highlighting any areas of ambiguity.

Following the dispatch of the audit report the client file is to be forwarded to the Administrator for process control (see 6.27) and to the Head of Maritime Security & Safety Management Operations for review and scope making on issuance of or maintaining of certification. The Head of Maritime Security & Safety Management Operations will inform the client in writing of the certification decision. Upon completion of the audit, the Administrator will send the Client a copy of QAF 44 (entitled MCAQA Customer Satisfaction Survey Form) for completion and return. If a response is not received within one month, the Administrator will write to the company requesting that it be completed and returned as part of MCAQA's commitment to continual improvement. Any "poor" rated markings will be examined in line with paragraphs 4.7, 9.8 and 10.3.5.2 (b) of ISO 17021:2015 and be treated as a complaint. All correspondence relating to this will be documented and placed upon MS 166/001/0015 (MCAQA Customer Satisfaction Survey) file.

6.17 Follow-up action

The Lead Auditor is responsible for ensuring that any NCN's raised during the assessment are closed out by the agreed dates. There should be three considerations when considering the close-out response to a NCN: correction of the deficiency identified; an analysis of the cause of the deficiency; and corrective action. When deciding to close-off a non-conformity the auditor needs to consider if objective evidence has been provided to demonstrate closure of all three considerations.

If it becomes clear that action cannot be completed within the timescale, the client should contact the lead auditor explaining the situation. If appropriate the Lead Auditor may then either:

- .1 close the existing non-conformity and raise a new non-conformity which is the same as the first but with an amended deadline; or
- .2 if the non-conformity is minor, upgrade it to a major. If the non-conformity is a major it may be necessary to suspend the

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certification process or any issued certificate following consultation with the Head of Maritime Security & Safety Management Operations.

When the close-out action is complete, the NCN with supporting evidence is returned to the Lead Auditor to demonstrate that required action has been taken. In the majority of cases, documentary evidence such as copies of revised records, instructions issued, or minutes/letters written will be accepted as proof and allow the Lead Auditor to effect close-out.

If the auditor is satisfied with the documentary evidence supplied the nonconformity may be closed out. If the auditor is not satisfied the client must be informed with an explanation of the requirements.

If documentary evidence does not provide enough evidence as to the effectiveness of the corrective action, the auditor may request that an additional visit to the client be made. This may be an additional full audit, and additional limited audit or a further request for documented evidence (to be confirmed during future surveillance audit). This may take place immediately or after an arranged time period to allow any new practices to be put in place. Such audits will be limited to assessing the effectiveness of corrective action.

If the Lead Auditor regards the client to be lacking in commitment when undertaking any follow up action, the Head of Maritime Security & Safety Management Operations must be informed so they can decide what action is to be taken.

6.18 **Declaration**

This must not be completed until all NCNs raised during the assessment have been closed out as certification can not be awarded if non-conformities remain open except in the case of transfer of certification from another certifying body and the Lead auditor is content to give the client the normal 3-month period allowed for closure of minor non-conformities.

Following the successful completion of stage 1 and stage 2 audits and the close out of all NCNs, the Lead Auditor must complete the Declaration Form (QAF 12) to indicate to the Head of Maritime Security & Safety Management Operations the level of compliance of the client's EMS to ISO 14001:2015 or QMS to ISO 9001:2015.

Section 4 is to record analysis of assessment information gathered during stage 1 and stage 2 audits on each clause of the standard. The comment

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section at the end of section 4 must be completed to include: comments on NCNs and where applicable their close-out; and provide either a 'positive' or 'negative' recommendation. The form must be signed by all members of the audit team to indicate agreement of the recommendation statement.

6.19 Certification Decision

The declaration is passed onto the Head of Maritime Security & Safety Management Operations, along with the associated client file(s), containing all relevant assessment information gathered during the assessment: application review; stage 1 audit(s) and stage 2 audits and the audits of the vessels. It is the responsibility of the Head of Maritime Security & Safety Management Operations to make the final unbiased and independent decision as to whether a client receives certification, recertification, or not.

The decision will be based on:

- Confirmation that audit report is sufficient with respect to certification requirements and scope;
- Correction and corrective actions for any major non-conformities have been accepted, reviewed and their effectiveness verified;
- Confirmation that client's plans for correction and corrective action for minor non-conformities have been reviewed and accepted;
- Confirmation that the audit objectives have been achieved;
- any other relevant information (public information, comments from client on audit report(s))
- confirmation that information provided to MCAQA was correct
- recommendation whether or not to grant certification together with any conditions or observations

6.20 Technical Review

The Head of Maritime Security & Safety Management Operations completes Section 6 of the Declaration Form (QAF 12) stating whether or not certification has been granted. If the Head of Maritime Security & Safety Management Operations disagrees with the recommendation of the Lead Auditor, the Head of Maritime Security & Safety Management Operations must state in the comments section the reasons for the decision.

However, if the Head of Maritime Security & Safety Management Operations has been part of the audit team (including being part of the document review or any other interaction with the client in relation to the

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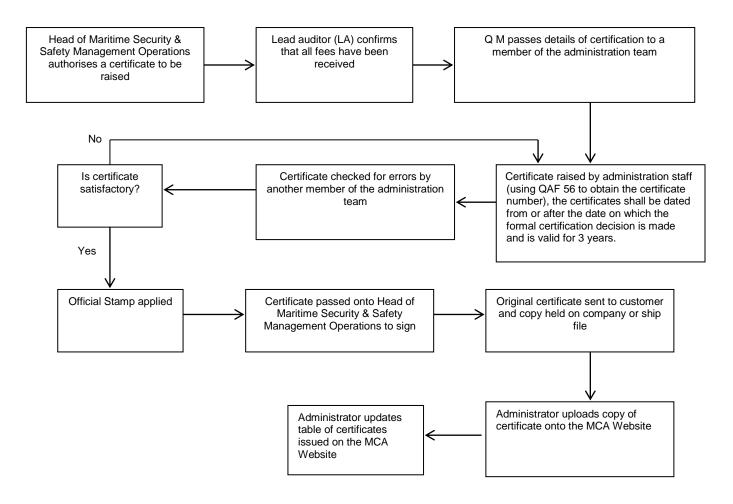
audit, which would be deemed to create a conflict of interest), he/she would delegate the decision making to another appropriate person who understands the applicable standard and demonstrates competence to evaluate the audit processes and recommendation of the audit team and who has not been involved in the audit activity.

6.21 Certification Period

The certification period is 3 years. MCAQA will harmonise the surveillance audits with those legally required by the five-year ISM certification period. The certification period cycle begins with the certification or re-certification decision.

6.22 Production of Certificates

After the certification decision has been made the declaration form and file are returned via the Lead Auditor to the Administrator for production of the certification document, in accordance with the following steps;



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6.23 Surveillance Assessments

Surveillance assessments are carried out according to the audit schedule. Changes to this schedule may occur if deemed necessary e.g. significant changes to the operations of the client take place or it is felt that the client is failing to meet the requirements of the standard. Surveillance audits are carried out as detailed in paragraphs 6.4 - 6.15.

It is the responsibility of the assigned Lead Auditor to contact the client to make the arrangements for the audit: Unless fundamental changes to the management system or organisation have been undertaken there is no need to undertake an Application or Document Review, although a copy of appropriate documentation may be requested prior to the audit being conducted.

EMS surveillance programmes will consider the environmental risks associated with a client's operations as well as environmental performance. Surveillance and re-certification assessment procedures shall be consistent with those concerning the initial certification of the client.

6.24 Surveillance Audits

Surveillance audits are to be conducted 'on-site'. The audits of the head office shall be conducted at least once a year. The date of the first surveillance audit following initial certification shall not be more than 12 months from the certification decision date. Those with remote sites and ships will be programmed over the certification cycle.

For EMS surveillance programmes the environmental risks associated with a client's operations as well as environmental performance will be considered. Surveillance and re-certification assessment procedures are consistent with those concerning the initial certification of the client.

The audit programme will include:

- Internal audits and management review
- Review of actions to close out previous NCNs
- Treatment of complaints
- Effectiveness of the management system regarding achieving the client's objectives

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- Progress of planned activities aimed at continual improvement
- Continuing operational control
- Review of any changes
- Use of marks and logos together with other references to certification.

6.25 Maintaining Certification

MCAQA shall maintain certification based on the demonstration that the clients continue to satisfy the requirements of the management system standard. Client's certification to be maintained on a positive conclusion by the Lead Auditor without any further independent review provided:

- 1) In the case of any Non-conformity or similar situation occurring which may lead to suspension or withdrawal of certification then the Lead Auditor shall report to the Head of Maritime Security & Safety Management Operations the need to initiate a review. Such a review would need to be conducted by personnel who have not conducted the audit. This review would determine whether the certification can be maintained and
- 2) Competent personnel of MCAQA monitor its surveillance activities, including monitoring the reporting by its auditors, to confirm that the certification activity is operating effectively.

6.26 Re-certification Assessments

A recertification audit shall be planned and conducted for all clients to evaluate continued fulfilment of all the requirements of the management system standards. The purpose of the recertification audit is to confirm continued conformity and effectiveness of the management system as a whole and its continued relevance and applicability for the scope of certification.

Re-certification assessments are completed as scheduled in the certification cycle plan. They may require a stage 1 audit in addition to a stage 2 audit in circumstances where there have been significant changes to the management system or the operating context. Assessments are completed as the initial assessment as detailed in paragraphs 6.4 to 6.15. MCA QA clients with multiple certifications (9001 & 14001) and / or multiple sites should have audit plans to cover on-site audit coverage to provide confidence in the certification over the certification period (QAF 28)

During recertification audits the time limit for corrective action to be implemented shall normally be before the expiry of current certification. The recertification audit should consider the performance of the management system over the period of certification and should include review of previous surveillance audit reports.

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The recertification audit must include an on-site audit which should address

- 1) the effectiveness of the management system in the light of internal and external changes for continued relevance and applicability to the scope.
- 2) demonstrate commitment to maintain effectiveness and continual improvement of the management system to enhance performance.
- 3) whether the operation of the certified management system contributes to the achievement of the organisation's policy and objectives.

A declaration is completed by the Lead Auditor (see paragraph 6.18) for a certification decision by the Head of Maritime Security & Safety Management Operations (see paragraph 6.19) which will also include consideration of a performance review over the certification cycle and any complaints received. After a positive decision the new certificate will be issued (see paragraph 6.22). The Head of Maritime Security & Safety Management Operations shall review the results of the recertification audit over the period of certification and the complaints received from users of certification prior to confirming renewal of certification.

Re-certification may be awarded prior to the close out of minor non-conformities, provided corrective action and deadlines for closure have been agreed by the Lead Auditor. However, for any major non-conformity, corrective actions would need to be implemented and verified prior to the expiry of certification.

If the recertification audit or verification of corrective actions for any major non-conformity has not been completed prior to the expiry of the certificate, the validity of the certification cannot be extended. Certification can be restored within 6 months once the outstanding recertification activities have been completed, otherwise at least a stage 2 audit shall be conducted. The effective date of the certificate shall be on or after the recertification decision and the expiry date shall be based on the previous certification cycle.

6.27 During stand-alone ISO audits on board ships, it is necessary to have a look around the ship (deck, engine room, bridge & galley) to verify operational activities in addition to looking at the documentation on board and speaking to personnel. This is not a statutory inspection (GI). However, if any statutory deficiencies are found during the course of this, these need to be recorded as usual on the MSF 1603. The MSF 1602/1603 forms need to be completed only if statutory deficiencies are found. If no deficiencies are found these forms need not be completed.

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Following the audit and completion of the documentation required the auditor shall number each document required for ease of reference, the Administrator is then responsible for undertaking checks to ensure all the appropriate information is held within the client file (see QAF 19).

After completion of the process review the file is to be passed to the Head of Maritime Security & Safety Management Operations for review (see 6.14).

6.29 Transfer of Certification

Transfer is defined as the recognition of an existing and valid EMS or QMS certificate granted by another certification body accredited by an accreditation body, which is IAF-MLA recognised, for the purpose of issuing its own certification.

IAF MLA accredited certificates may be considered for transfer and the process detailed in paragraph 6.1 will be followed.

In cases of non-IAF MLA accredited certificates the transfer will be dealt with as a new application for certification. Certificates that have been suspended or are under threat of suspension should not be accepted for transfer.

6.30 Transfer Review

A review of the system will be undertaken by a lead auditor appointed by the Head of Maritime Security & Safety Management Operations. The transfer review will normally take the form of an application review (paragraph 6.3) including a document review (paragraph 6.5). The remaining steps of the certification assessment (paragraphs 6.5 to 6.15) will be determined on a case by case basis, based upon the size of the client, number of remote sites and ships, scope of certification and other relevant information including information regarding the current status of the ISM and / or ISO certificates held.

The transfer review should cover the following points in addition to those covered in paragraph 6.3:

- Reasons for seeking transfer;
- Ensure that a valid certificate, in terms of authenticity, duration and scope is held for the sites or sites that wish to transfer;
- Consideration of the last assessment reports and non-conformities;
- Complaints received, and action taken; and
- The stage in the current certification cycle.

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Before certification is granted, the issuing certification body must close out all outstanding non-conformities. If this is not possible, it is acceptable for MCAQA to close out the non-conformities.

Following the review of the system a Declaration (see 6.18) is to be completed before a certification decision (see 6.19) is made.

All assessment reports and non-conformities will be taken into consideration from the previous certification cycle.

6.30 Suspending, Withdrawing or Reducing Certification

In the event that a situation arises that could suspend, reduce or withdraw certification the Head of Maritime Security & Safety Management Operations should be notified in writing together with supporting documentation. The Head of Maritime Security & Safety Management Operations will request Administrative staff to keep records of the situation and inform the Assistant Director, Technical Performance.

If notification of the situation came from an external source the Head of Maritime Security & Safety Management Operations will appoint an EMS or QMS Auditor, as appropriate, to investigate and review evidence. The Client will be notified of situation, appointment of investigator, and invited to reply. A review will be conducted, and a recommendation made.

Once a recommendation has been made the Head of Maritime Security & Safety Management Operations will consider the documentation and make a decision. If the decision is that the scope will be reduced, then a new certificate will need to be issued.

If the Head of Maritime Security & Safety Management Operations decides Certification should be withdrawn or suspended the Client will be informed in writing stating the decision and reasons behind making it. The contractual requirements of returning certification and conditions for displaying marks and logs will be pointed out as well as right of appeal (MCAQA 2).

The MCAQA administrator will amend QAF 31 with the current information and certification status

Completed documentation will be reviewed by the MCAQA Management Team and the Impartiality Committee.

MCAQA will not delegate the authority for granting, maintaining, extending, reducing, suspending or withdrawing certification to an outside

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person or body. All certification decisions are made by the Head of Maritime Security & Safety Management Operations or someone specifically delegated.

6.31 Suspension of Certificates

A certificate may be suspended (usually for a maximum of six months) due to:

- .1 The client's management system persistently or seriously failing to meet certification requirements, including requirements for effectiveness of the management system such as;
 - .1 unauthorised change of scope, activity, or ownership of the company,
 - .2 failure to pay fees,
 - .3 failure to comply with the certification process,
 - .4 misuse of logos and marks or a breach of contract;
- .2 Client not allowing surveillance or recertification audits at the required frequency
- .3 At the request of the client.

The partial or complete suspension of a certificate is the responsibility of the Head of Maritime Security & Safety Management Operations on the basis of a recommendation made by a Lead Auditor. Under suspension the management system certification is temporarily invalid, and the client is to refrain from further promotion of its certification.

The client may appeal against the suspension of certification through the appeals process (Procedure MCAQA 2).

Failure to resolve the suspension issues in the established timescale will result in withdrawal or reduction in scope of the certification.

6.32 Reducing Scope of Certification

Certification may be reduced in line with the management system standard if:

- .1 if MCAQA determines that the client is unable to fulfil any part of the scope that the client holds, e.g. through failure to close non-conformities, significant changes to the activities and operation of the organisation or failure to comply with the requirements of the standard; or
- .2 at the request of the client.

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MCAQA will inform the client, in writing, of any decision regarding a reduction in certification, outlining the justifications for the action being taken

The client may appeal against the reduction in scope through the appeals process (Procedure MCAQA 2).

6.33 Extending Scope of Certification

If a client wishes to extend certification MCAQA must be informed in writing. The Head of Maritime Security & Safety Management Operations will then make a decision based either on existing information regarding the client or following an additional assessment of the client, carried out to establish the ability of the client to comply with the requirements of the scope.

The additional assessment will take the form of a surveillance assessment and will focus on sections of the client's organisation that will be affected by the change in scope.

A completed declaration of audit (QAF 12) will provide the Head of Maritime Security & Safety Management Operations with the recommendations of the lead auditor appointed for the purpose of reviewing the system.

6.34 Withdrawal of Certificates

A certificate may be withdrawn due to continuing failure to comply with the certification process, or a breach of contract.

Decisions to withdraw a certificate, either partially or in total, will be made by the Head of Maritime Security & Safety Management Operations on the basis of a recommendation made by a Lead Auditor. The client may appeal against the withdrawal of certification through the appeals process (Procedure MCAQA 2).

If, following withdrawal of a certificate and subsequent removal from the certified Clients lists, the client continues to use the marks in literature, MCAQA may take appropriate legal action.

Following a reduction or extension in certification or a change in the clients' activity or operation the audit schedule for the client will be reviewed, and if appropriate, revised (see QAF 28).

6.35 Re-instatement of Certificates

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Re-instatement, following withdrawal or reduction of the certification, will require reassessment of the company's systems. A review will be necessary to determine/verify the scope of assessment required.

Re-instatement, following suspension of certification, will be made by the Head of Maritime Security & Safety Management Operations on the basis of a recommendation prepared by a Lead Auditor once corrective action has been taken by the client and verified by MCAQA; or following a successful appeal process.

6.36 Use of Logos and Marks

Once certification has been confirmed and issued the certified organisation may display marks to reflect the level of certification achieved. The certification marks terms and conditions form part of the contractual agreement (QAF 25) and can be found in QAF 26. These terms and conditions are available upon request.

6.37 Appeals and Disputes

In the event of audit findings or a certification decision not being accepted by the client, reasons for rejection must be provided and the NCN returned to the Lead Auditor. If satisfied by the evidence supplied, the Lead Auditor will close out the NCN and sign accordingly. However, where the Lead Auditor is not satisfied with the response, the Head of Maritime Security & Safety Management Operations will be informed and with a view to resolving outstanding issue. In cases where agreement cannot be reached, the Lead Auditor will make a report to the Head of Maritime Security & Safety Management Operations to initiate the appeals or disputes procedure (MCAQA 2).

7.0 **Documentation**

7.1 Client File storage locations

MS 166/001/082 – Client Enquiries (before receipt of application form)
MS 166/014/..... – Office file (one per office)
CM/054/001 – Ship file (one per ship)

7.2 Assessment Documentation

The following document is required in the appropriate client file.

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Application Form (OAF 24)	(Head office file only)		
Application Form (QAF 24)	(Head office file only)		
Ship Based Questionnaire (QAF 14)	(EMS Head office file only)		
Shore Based Questionnaire (QAF 15)	(EMS Head office file only)		
Application Review Report (QAF 7)	(Head office file only)		
Contractual Agreement (QAF 25 + QAF	(Head office file only)		
26)	,		
Audit Declaration (QAF 12)	(Head office file only)		
Client Audit Schedule (QAF 28)	(Head office file only)		
MCAQA Resource Requirements (QAF	(Head office file only)		
29)			
Auditor Authorisations (QAF 21)	NCN Form (MSF 1902), if applicable		
Opening/Closing meeting form (QAF 9)	Audit Report Form (QAF 10)		
Audit Plan (QAF 16)	Certificate of compliance (QAF 13)		
ISM/ISO Audit File Enclosure (QAF 42)			
Notes to Auditors, if applicable			
Correspondence relevant to certification			

Food and Hygiene Aide Memoire (QAF 41)
To be completed for Stena & Red Funnel.
The following documentation is optional for use during assessments.

EMS Audit aide-memoire (QAF 38) QMS Audit aide-memoire (QAF 37) ISO 9001/14001:2015 Aide Memoire (QAF 11) Application Review aide-memoire

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Document Review Checklist

The aide memoire for food and hygiene (QAF 41) must be completed for all ships audits where it is included in the scope. The form is not designed to cover all areas but to sample an area of each section. The auditor may choose to cover all areas but to be used at own discretion.