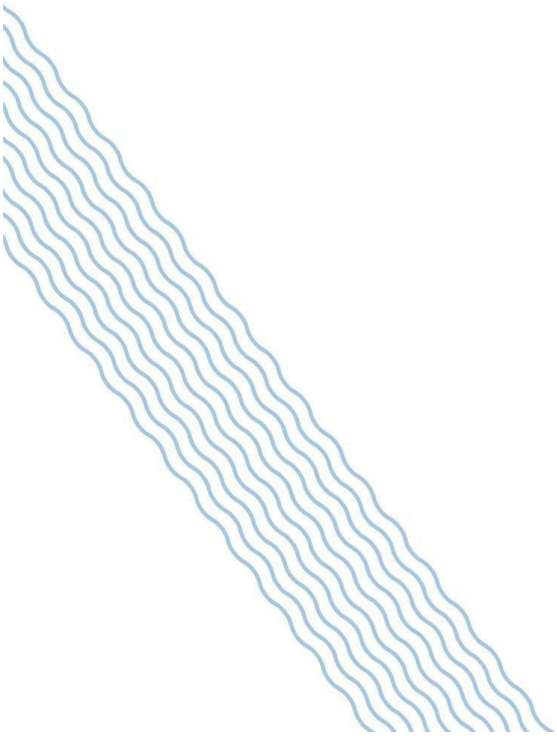
QACE - Entity for the Quality Assessment and Certification of ROs Recognised by the European Union (CIC)

QACE Interpretation of International Quality Standards (QIQS)



Independent, Transparent, Inclusive

INTRODUCTION

EU Regulation No. EC 391/2009 Article 11.2(c) requires:

The quality assessment and certification entity [QACE] shall carry out the following tasks:

> *(c) issue of interpretations of internationally recognized quality management standards, in particular, to take account of the specific features of the nature and obligations of recognized organizations.*

European Commission's periodic assessment of QACE in September 2017 concluded and confirmed that the two standards which QACE must interpret are:

- ISO 9001-2015 Quality management systems – Requirements
- ISO 17020 -2012 Conformity assessment – Requirements for the operation of various types of bodies performing inspection

Pursuant to the above requirement, QACE developed this scheme for interpreting the applicable international standards. The scheme is described in Part 1. The interpretation of the ISO 9001:2015 is contained in Part 2. The interpretation of the ISO 17020:2012 is contained in Part 3.

INTENT

The intents of 'interpretations' are:

- to clarify and unify the understanding of the requirements of the standards, amongst QACE, organizations and the accredited certification bodies,
- to facilitate consistency of application of the standards' requirements.

The intention of 'interpretations' is not to add to or extend the requirements of the standards, but merely to complement it.

Note: Requirements of QACE are detailed in other documents published by QACE.

DEVELOPMENT

The spirit of the standards augmented by good practices of the ship certification organizations form the basis of these interpretations. Relevant documentation of

other stakeholders of the maritime industry are also consulted in developing these interpretations to avoid contradictions and undesirable consequences thereof.

The interpretations have been developed in consultation with the industry. Towards this a QIQS Consultancy Group has been constituted comprising of selected representatives from the user group (classification societies, accredited certification bodies) and industry stakeholders.

CONSULTANCY GROUP

The QIQS Consultancy Group members are the EU ROs and the Accredited Certification Bodies (ACB's) involved with the development and maintenance of the QIQS. The Consultancy Group generally operates by email communication without the need for meetings, although these may be included if considered necessary. The Consultancy Group RO comments may be consolidated, or advised direct to the QACE Secretariat, as determined by the ROs' representative, the QACE President.

MAINTENANCE

These interpretations will be reviewed by the QACE Secretariat and Assessors based on experience gained in the use of these interpretations and considering the changing needs and requirements of the certification industry.

Any proposed changes to QIQS will be considered by the consultancy group and also by the QACE assessors. The Board has the final authority to accept or reject any changes.

POLICY

The interpretations are binding on all the QACE member organizations, considering that they have been developed in consultation with them and are a consequence of the requirements of the EU Regulation 391/2009.

The QIQS will be available on the QACE website.

Revision History

Version No.	Publish Date	Effective Date	Details
0.0	28/02/2020	01/01/2021	Initial issue

QACE

QACE - Entity for the Quality Assessment and Certification of ROs Recognised by the European Union (CIC)

PART 2 – INTERPRETATION OF ISO 9001 - 2015

Introduction

This part of the QIQS constitutes the QACE's interpretation of requirements of the ISO 9001:2015 standard as applicable to organizations which seek compliance to EU Regulation (EC) No 391/2009. These interpretations complement the requirements of the ISO 9001 standard, which itself constitutes the basic requirements of a certified quality management system.

The texts of all of ISO 9001 are applicable requirements, but not repeated in this document. The numbering used aligns with the ISO 9001 standard, clauses and sub clauses and therefore should be read in conjunction with the ISO 9001 text.

All the clauses are listed, even though some of them may not have / need interpretations by QACE. They will serve as place holders for inclusion of interpretations, if required, in the future. An interpretation, where required, is included under the clause number. Where no text is included under a clause number, the wording in ISO 9001 is considered sufficient and self-explanatory.

QACE's interpretations of the requirements of ISO 17020:2012 standard are included in Part 3 of this document.

Revision History

Version No.	Publish Date	Effective Date	Details
0.0	28/02/2020	01/01/2021	Initial issue

1 Scope

The intent of this part of the interpretations is to clarify and unify the understanding of the requirements of ISO 9001:2015 amongst QACE, organizations and the accredited certification bodies, as applicable to organizations (see definition in Sec. 3).

2 Normative references

The following documents have been referred to, in developing these interpretations:

- REGULATION (EC) No 391/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2009 on common rules and standards for ship inspection and survey organizations.
- ISO/IEC 17020-2012 "General Criteria for the Operation of Various Types of Bodies Performing Inspection".
- ISO/IEC 17021-1:2015 "Conformity Assessment Requirements for Bodies Providing Audit and Certification of Management Systems Part 1: Requirements.
- IMO Resolution MSC.349 (92): International Maritime Organization's Code for Recognised Organization (RO Code).
- IACS Quality System Certification Scheme – 11th. Edition (QSCS).
- IACS Quality Management System Requirements – 10th. Issue (QMSR).
- IACS Procedural Requirements.

3 Terms and definitions

For the purposes of the quality management system, the terms and definitions given in ISO 9000:2015 apply.

In the context of these interpretations, the following definitions apply:

Organization: is a legal entity, its subsidiaries and any other entities under its control, which jointly or separately carry out tasks falling under the scope of EU Regulation (EC) No. 391/2009 for the development and implementation of safety requirements for hull, machinery and electrical and control installations and the

inspection, survey and certification of ships for compliance with the international conventions on safety at sea and prevention of marine pollution.

Recognized Organization: a legally identifiable organization which has been assessed by a flag State and found to comply with the applicable requirements of the RO Code and is authorized by a flag State as defined in SOLAS Chapter XI-1, Regulation 1 and listed accordingly in the IMO database, Global Integrated Shipping Information System (GISIS).

EU Recognized Organization: an organization recognised in accordance with EU Regulation 391/2009 Art. 2.

Ship: a ship falling within the scope of the international conventions.

International conventions: the International Convention for the Safety of Life at Sea of 1 November 1974 (SOLAS 74) with the exception of chapter XI-2 of the Annex thereto; the International Convention on Load Lines of 5 April 1966 and the International Convention for the Prevention of Pollution from Ships of 2 November 1973 (MARPOL), together with the protocols and amendments thereto, and the related codes of mandatory status, in their up-to-date version.

QACE: Entity for the Quality Assessment and Certification of Organizations Recognised by the European Union (CIC).

QACE QIQS Consultancy Group: made up of selected interested parties, including the organizations and participating accredited certification bodies, to comment on the QIQS interpretations.

Interpretation: QACE interpretation of ISO 9001, ISO 17020.

Accredited Certification Body (ACB): An organization accredited to comply with ISO/IEC 17021-1:2015 standard by an Accreditation body who is a signatory to the International Accreditation Forum (IAF) Multinational Recognition Agreement (MLA).

International Maritime Organization (IMO): The United Nations' Organization dealing with aspects related to the safety of life at sea, security and protection of the marine environment.

International Organization for Standardization (ISO): the international organization dealing with the development of quality and industry standards.

IACS: International Association of Classification Societies.

Technical staff: includes plan approval engineers, surveyors, inspectors, auditors and other technical staff (whatever be their nomenclature in different organizations) who directly render the classification and statutory services of the organization.

Activity Monitoring: an assessment conducted by a monitor of the organization of its technical staff for plan approval or in the course of a survey, audit or inspection.

VCA: a contract/order specific audit of production processes, including witnessing work at the workplace (for example, shipyards, plan approval offices, manufacturers' facilities, on-board ships, ship management offices) during attendance at a survey, audit, inspection or plan approval in progress and, as applicable, including relevant sub-processes, to verify the correct application of relevant requirements in service realization for the specific work in that contract/order, and their interactions.

4 Context of the organization

4.1 Understanding the organization and its context

Organizations are typically, but not limited to, classification societies.

The context of the organization is primarily the maritime world with all its stakeholders. The context also includes the geo-political and legal framework of the countries in which they deliver their services and the public in general.

4.2 Understanding the needs and expectations of interested parties

External interested parties are, *inter alia:*

a. Flag States;
b. Port States;
c. International regulators;
d. Industry bodies like IACS, relevant trade associations and insurance bodies;
e. National legal administrations, as applicable and relevant;

f. Customers;
g. Accredited certification bodies; their accreditation bodies and IAF, as relevant.

Internal interested parties are, *inter alia*:

a. Employees;
b. Owners/supervisory management of the organization.

4.3 Determining the scope of the quality management system

The scope shall, as a minimum, include the ships falling under the scope of international conventions, viz. ILLC, SOLAS, MARPOL, with their applicable annexes, protocols, codes and amendments.

The QMS shall not exclude any activity that is applicable to the process of certification of ships falling under the scope as interpreted above.

4.4 Quality management system and its processes

4.4.1

The processes shall include, *inter alia,* development and maintenance of Rules, procedures, instructions and guidelines, as relevant and applicable for:

a. the development of rules, guidelines, instructions, including associated research for the approval, inspection, survey and certification of ships;
b. adoption and implementation, as applicable, of the regulations and requirements of national, international and relevant industry bodies;
c. the design and construction, verification/approval thereof; survey during construction and in service of ship structures and essential machinery, as defined in the organizations' Rules;
d. the design, verification/ approval thereof and inspection of materials and components required for the ship structures and essential machinery as defined in the organizations' Rules;
e. the survey of ships during construction and in service on behalf of statutory authorities (nominating flag administrations) for the purposes of statutory certification, as defined in the relevant statutory regulations;

f. the recording, reporting, publication and maintenance of the survey/audit/inspection findings and conclusions;
g. auditing, reporting and follow-up of the safety and security management systems, both shore-based and on-board ships, in accordance with the relevant international regulations and guidelines;
h. issue, publication and maintenance of survey/audit/inspection reports and certificates;
i. publication of a database of ships certified and their current survey and audit status;
j. management of the approval, certification and maintenance of service suppliers and equipment manufacturers and sub-contracted services, if any;
k. the associated software and hardware to comply with the requirements of the above processes;
l. the recruitment, training, qualification and authorization of competent technical staff – plan approval engineers, surveyors, inspectors, auditors – for the execution of all the above processes.

4.4.2

5 Leadership

5.1 Leadership and commitment

5.1.1 General

Commitment is, *inter alia,* providing the right environment for continual improvement of the quality management system. One way for this, among others, is identifying – through internal or external findings or other relevant means – and accepting the deficiencies and opportunities for improvement / noteworthy points for working towards improvements.

The quality objectives established should focus on achieving the necessary improvements and not solely be related to minimizing the number of findings.

5.1.2 Customer focus

The focus on enhancing customer satisfaction should not undermine the organization's obligations to ensure the safety of life and property at sea, protection of the marine environment and prevention of pollution.

5.2 Policy

5.2.1 Establishing the quality policy

5.2.2 Communicating the quality policy

5.3 Organizational roles, responsibilities and authorities

Nomination of an individual as the 'management representative' is required to ensure conformity to the RO Code (even though it is not a requirement of ISO 9001:2015).

6 Planning

6.1 Actions to address risks and opportunities

6.1.1

6.1.2

In addition to business risks arising from analyses, the organization shall also consider, at appropriate levels and stages, those arising from changes to the organization & the quality management system, introduction of new services and products, changes in contractual agreements with customers, flag States, accreditation bodies and inadequacy of competent human and other resources.

Opportunities should not be limited to 'business' opportunities. They should include, *inter alia,* opportunities to improve the organization's technical capabilities, the quality, efficiency and effectiveness of the processes, the competence of the technical staff.

The organization's risk management process should define the levels and periodicity of review of their risks.

6.2 Quality objectives and planning to achieve them

6.2.1

Applicable requirements include those of the statutory and regulatory authorities, e.g., IMO, EU, flag and port States.

Some other relevant considerations in planning the quality objectives are results of past experience in service delivery, including accidents, failures and detentions, customer complaints and feedback, audit (internal & external) findings, and results of risk assessment.

6.2.2

The evaluation of the results of the measurements may be at multiple levels, including at organizational level Management Review. The evaluation should lead to actions to improve the processes, products, services and staff competence, as relevant and necessary.

6.3 Planning of changes

7 Support

7.1 Resources

7.1.1 General

7.1.2 People

The processes include those specified in Clause 4.4.1 above.

The human resources (technical staff) should be such as to enable the organization to provide world-wide coverage of its services through exclusive surveyors, in particular, while rendering the statutory certification services.

7.1.3 Infrastructure

7.1.4 Environment for the operation of processes

This includes, *inter alia*, the following:

- operational safety of surveyors, auditors and inspectors addressing such issues as their minimum personal protective equipment (PPE), instructions/guidelines on the selection and use of acceptable PPE, instructions/guidelines on acceptable operating conditions, safe work practices and related training thereof.
- social welfare (e.g. non-discriminatory, calm, non-confrontational work environment);
- psychological well being (e.g. stress-reducing, burnout prevention, emotionally protective).

These processes should be documented as necessary.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

7.1.5.2 Measurement traceability

This is applicable to any measuring and monitoring equipment used by the RO (for example, the multi-gas meter issued to the field surveyors, auditors and inspectors as part of their PPE).

With respect to equipment used by the manufacturers, builders, repairers and owners, as a part of the required survey/inspection, their validity shall be verified by the attending surveyor/auditor/inspector during their survey/audit/inspection activities, as appropriate. Records of such verification should be maintained in the internal records of the organization as deemed appropriate by the organization.

7.1.6 Organizational knowledge

This includes development and publication of internal technical circulars, conducting internal training seminars (in any mode), conducting experience exchange meetings, workshops and seminars.

7 .2 Competence

The requirements of relevant stakeholders (e.g. IMO, EU, Flag States, industry bodies) should be considered in determining the necessary competence in addition to the needs of processes/services.

The competence management system should, in determining and achieving the necessary competence, consider/include:

- the current qualifications, experience, training;
- induction, initial and continuous training;
- additional/follow-up training necessitated due to service and service delivery failures, errors found during monitoring and audits.

7 .3 Awareness

7.4 Communication

The relevant parties are the shareholders, members, employees, customers (shipyards, owners, manufacturers, service suppliers, sub-contractors), industry bodies, insurance bodies, flag and port States, national and international organizations (e.g. IMO & EU), international databases (e.g. EQUASIS, THETIS) and the public.

7.5 Documented information

7.5.1 General

This includes occupational health and safety processes.

7.5.2 Creating and updating

7.5.3 Control of documented information

7.5.3.1

7.5.3.2

Documents of external origin include those from, e.g.:

National and international standards;

National and international regulatory documents, codes;

Guidelines, instructions, requirements, interpretations, recommendations of industry bodies, as applicable.

8 Operation

8.1 Operational planning and control

8.2 Requirements for products and services

8.2.1 Customer communication

Customer communication should include the limitations, if any, imposed by national and international regulations, flag and port States and other relevant stakeholders in delivering the requested services. (e.g. in granting postponements, extensions of surveys, recommendations, final certification etc).

8.2.2 Determining the requirements for products and services

These may be in the form of specific or standard contracts, framework agreements, references (general or specific) to Rules and Regulations, internal requirements and interpretations but publicly available documentation, references to national and international standards, guidelines, instructions, flag & port State requirements embedded in specific agreements and their common circulars.

8.2.3 Review of the requirements for products and services

8.2.3.1

The review shall cover the availability (or appropriate access to) at the service delivery location, of:

- the competence requirements;
- authorized personnel;
- the reference documentation;
- inclusion of applicable limitations, if any.

The applicable review procedures for different sales situations should be defined in the relevant processes.

8.2.3.2

The evidence of review may be documented in a manner deemed appropriate by the organization.

8.2.4 Changes to requirements for products and services

8.3 Design and development of products and services

8.3.1 General

This applies to the development of:

- internal Rules, instructions, procedures for the classification and certification products and services of the organization;
- process for adoption of the requirements of national and international regulations;
- procedures for adoption and implementation of flag State agreements.

8.3.2 Design and development planning

The consideration shall also include the requirements to deliver the product/service in terms of competence, resources, training, contracts with the statutory authorities and the impact of the new services on existing services and resources.

Customer involvement could be through the formation of a competent technical committee whose composition should be documented. If in some specific projects, a need is identified for the involvement of other relevant customers outside the technical committee, this should be documented in the planning.

8.3.3 Design and development inputs

Inputs shall include, as relevant and appropriate, own service experience, experience of other similar bodies, lessons learnt from known failures within the organization and from other similar bodies, damage investigation reports available in the public domain.

8.3.4 Design and development controls

The control process should clarify the procedures of review, verification and validation as deemed applicable to their development activities, considering their different purposes and available options.

8.3.5 Design and development outputs

8.3.6 Design and development changes

8.4 Control of externally provided processes, products and services

8.4.1 General

External service providers whose output forms part of the organization's certification activity are, typically, thickness measurement firms, radio companies, underwater inspection companies and software developers.

This requirement shall also apply, as relevant, to equipment suppliers who are covered under special schemes such as 'type and batch approval', 'self-certification' and similar, whose internal process controls and inspection results form the basis for the organization's certification of products and services.

This requirement also applies to the use of the services of other organizations certifying ships as per their own Rules and or carrying out statutory certification.

8.4.2 Type and extent of control

The organization should define the procedures for initial certification, duration of certificates, maintenance thereof; renewal of certificates, suspension, withdrawal and subsequent follow-up, including testing, monitoring and documentation requirements. In defining this the organization shall consider the requirements and restrictions of other relevant stakeholders, e.g. flag States.

8.4.3 Information for external providers

8.5 Production and service provision

8.5.1 Control of production and service provision

The organization's process shall address the documentation requirements specifically in relation to the planning of the inspection/survey/audit (e.g. quality plan or inspection and test plan), progress of the inspection/survey/audit work, evidence of conformance to specified acceptance criteria, dealing with non-conformities found during inspections, audits and surveys (specifically for accepting of deviations) and final release/acceptance of the product/service.

The process shall also include provisions to address the requirements of statutory authorities and other relevant industry bodies regarding the scope of

inspection/survey/audit and acceptance criteria and procedures to deal with non-conformances found during inspections/surveys/audits.

The process shall also consider the need and procedures to inform other stakeholders (e.g., issuer of ship management certificate, flag State) of serious deficiencies found during inspections/surveys/audits on board ships.

8.5.2 Identification and traceability

The identification of documents and data (e.g. inspection/survey reports, test certificates and reports, calibration certificates, etc.) of intermediate stage inspection/testing should also be considered.

8.5.3 Property belonging to customers or external providers

8.5.4 Preservation

This includes the intermediate inspection & survey reports and test reports, etc. to ensure that their integrity is not compromised till the delivery of the final certificate.

The organization shall preserve the final inspection reports/certificates and related documentation (as deemed appropriate by the organization) for specified periods in conformance with applicable regulatory requirements. The organization should specify the retention periods for the documentation and records.

8.5.5 Post-delivery activities

This includes updating of information on applicable databases (e.g. EQUASIS and Thesis), provision of information to other relevant stakeholders as per agreements.

8.5.6 Control of changes

8.6 Release of products and services

8.7 Control of nonconforming outputs

8.7.1

This applies to the outputs of the organization, viz. certificates, reports and status data. Control is achieved through:

- review and monitoring of report and certificates;

- customer (or third party) feedback or complaints on errors in reports and certificates;
- following up on port and flag State inspections and detentions of ships;
- following up on the findings of vertical contract audits (internal & external).

8.7.2

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The organization shall define and document, as necessary, the processes to govern and implement the various monitoring identified below and others, if relevant.

The scope of this includes the following:

- Inspector, surveyor (including plan approval staff) and auditor performance through activity monitoring (AM) and vertical contract audits (VCA);
    - AM process shall be documented. The process shall address the planning, frequency, execution, qualification of the monitor, documentation, follow-up actions when the AM becomes overdue or results in a failure and other relevant aspects. The AM shall be repeated, as a minimum, once every two calendar years, covering the individual's regular activities of class and statutory services, plan approvals, surveys and audits, as applicable. The findings shall be documented and analyzed both individually and globally to identify improvements to the individual's performance and to the relevant process;
    - VCA process shall address the scope, methodology, frequency, selection criteria, auditor qualification, documentation, follow-up of findings. The scope of the program shall include new constructions (surveys and statutory certification), material and equipment certification, ships in service (surveys and statutory certification), management system (ISM, ISPS) audits – at least one of each of the above activities in a calendar year. VCAs are to be carried out covering the entire service network to the extent

practical. The audit cases should be selected to be representative of the complexity of the process and simple stages should be avoided (e.g. block inspection, survey kick-off meetings or similar). See the separate procedure on 'Audits' for more details;

- Process performance measurements and performance indicators
- Organization's performance through external assessments – audits by ACBs (see tripartite agreement for more details), annual reports of MoUs of Paris, Tokyo & others, USCG, QACE Assessment, EMSA inspections and other similar;
- Ships' condition through port and flag State inspection and detention reports and data; reports from other certification organizations, accident and investigation reports;
- Internal system of monitoring the fleet quality;
    - The organization shall define and document their fleet quality monitoring process. The process shall address the scope, the procedure, criteria for inclusion (typically: age, type, survey results, PSC detention history, ISM audit findings and others, as deemed relevant by the organization) into the follow-up category, criteria for retention and withdrawal from the follow-up category, the follow-up actions, internal communication with the surveyors, external communication with the owners, managers, flag State, if and as necessary.

9.1.2 Customer satisfaction

The organization shall define the processes used to assess customer satisfaction, react to customer feedback (positive & negative) and customer complaints.

9.1.3 Analysis and evaluation

Appropriate data includes process performance indicators, audit findings, failure data (e.g. reporting errors, equipment and ship failures, ship detentions, errors of service suppliers and equipment manufacturers), results of report and activity monitoring, customer complaints and feedback and fleet quality status.

9.2 Internal audit

9.2.1

The program shall cover all the fundamental classification/certification processes and locations over a specified period (typically 3 years).

9.2.2

Consideration for the selection of the audit location shall also include service failure history, customer complaints and feedback, the nature and type of services delivered.

The scope of audits shall include the 'special interest areas' identified by QACE and other focus areas that may be identified by the ACBs, and other relevant industry bodies (e.g. IACS, EMSA, Port and flag States).

9.3 Management review

9.3.1 General

The planned frequency of the review shall not be less than once per calendar year.

9.3.2 Management review inputs

The input shall also include the status of occupational health and safety of the surveyors (typically, work-related accidents, near miss incidents and preferably sickness absence; and hazards encountered).

9.3.3 Management review outputs

The organization should establish a system to monitor, periodically during the implementation year, the implementation of the actions decided at management reviews.

10 Improvement

10.1 General

QACE's Individual and Collective Recommendations shall also be considered in identifying improvements to the processes and systems.

The improvement process shall also include improvements to process performance, competence enhancement, application of new technologies, the operational safety of employees.

10.2 Nonconformity and corrective action

10.2.1

10.2.2

10.3 Continual improvement

QACE

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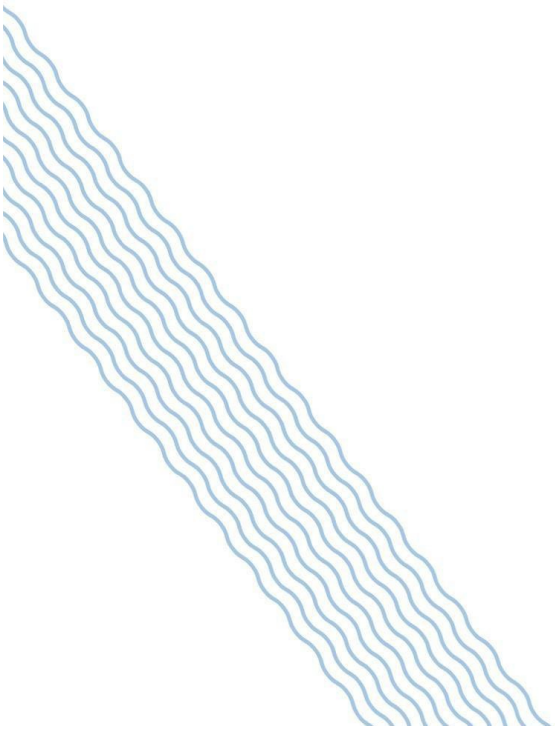
PART 3 – INTERPRETATION OF ISO 17020 – 2012



Introduction

This part of the QIQS constitutes the QACE's interpretation of requirements of the ISO 17020:2012 standard as applicable to organizations engaged in the activity of certifying materials and equipment for ships. These interpretations complement the requirements of the ISO 17020 standard, which itself constitutes the basic requirements for the operation of various types of bodies performing Inspection.

The texts of all of ISO 17020 are applicable requirements, but not repeated in this document. The numbering used aligns with the ISO 17020 standard, clauses and sub clauses and therefore should be read in conjunction with the ISO 17020 text.

All the clauses are listed, even though some of them may not have/need interpretations by QACE. They will serve as place holders for inclusion of interpretations, if required, in the future. The interpretation, where required, is included under the clause number. Where no text is included under a clause number, the wording in ISO 17020 is considered sufficient and self-explanatory.

QACE's interpretations of the requirements of ISO 9001-2015 standard are included in Part 2 of this document.

Revision History

Version No.	Publish Date	Effective Date	Details
0.0	28/02/2020	01/01/2021	Initial issue

1 Scope

The intent of this part of the interpretations is to clarify and unify the understanding of the requirements of ISO 17020:2012 amongst QACE, organizations and the accredited certification bodies, as applicable to organizations (see definition in Sec. 3 of Part 2).

The organizations (see definition in Part 2 of QIQS) are inspection/survey bodies of Type A.

2 Normative references

The following documents have been referred to, in developing these interpretations:

- EU Regulation (EC) No 391/2009 'common rules and standards for ship inspection and survey and organisations.
- IMO Resolution MSC.349 (92): International Maritime Organization's Code for Recognised Organisations (RO Code).
- IACS Quality System Certification Scheme – 11th. Edition (QSCS).
- IACS Quality Management System Requirements – 10th. Issue (QMSR).

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and the following apply.

In the context of these interpretations, the definitions in Part 2 of QIQS apply.

Further interpretations of the definitions of this standard are given below where considered necessary.

3.1 inspection

For the organization, this covers the inspection of material and equipment and survey of ships.

3.2 product

The product of the organization is one or more of the following:

- Approved design and drawing of ships/equipment
- Approved design calculations of ships/ equipment
- Final certificate and or report issued at the end of a satisfactory survey / inspection.

3.3 process

For the organization, the relevant processes are those related the inspection/survey and certification of material, equipment and ships.

3.4 service

3.5 inspection body

3.6 inspection system

This includes schemes such as:

- type and batch approval
- self-certification
- survey of ships

3.7 inspection scheme

3.8 impartiality

3.9 appeal

3.10 complaint

4 General requirements

4.1 Impartiality and independence

4.1.1.

The organization shall be governed by a *Code of Ethics / Conduct,* which shall address the policy of impartiality.

4.1.2

The personnel of the organization shall be free from any commercial, financial and other pressures which might affect their judgement. Procedures shall be implemented to ensure that persons or organizations external to the organization cannot influence the results of services carried out.

4.1.3

The organization's risk management process shall define the levels and periodicity of review of their risks.

4.1.4

4.1.5

4.1.6

The organizations are to meet the Type A requirements.

4.2 Confidentiality

4.2.1

The organization shall be governed by a *Code of Ethics / Conduct,* which shall address the policy of confidentiality.

Confidentiality requirements can be within specific or standard contracts, framework agreements; standard terms and conditions or a part of the organization's Rules which can be referenced in specific contracts.

4.2.2

4.2.3

5 Structural requirements

5.1 Administrative requirements

5.1.1

5.1.2

5.1.3

The organization's competencies should be documented in the quality management system as a part of the process description.

5.1.4

5.1.5

The contractual conditions documentation may not be required for every purchase order, provided the contractual conditions are still easily available to the customer.

5.2 Organization and management

5.2.1

5.2.2

Capability management is, normally, a part of the organization's competence management system. This should be either separate for inspection/survey activities or an integral part of the system for the rest of the activities of the organization.

The organization's management system should address the procedures for technical experience exchange with other inspection/survey bodies.

5.2.3

5.2.4

5.2.5

The documentation of the specific responsibilities of the technical manager(s) can be as functional descriptions for the specified roles.

5.2.6

5.2.7

6 Resource requirements

6.1 Personnel

6.1.1

The requirements of relevant stakeholders shall be considered in determining the necessary competence in addition to the needs of the inspection/survey requirements of products.

6.1.2

The human resources (technical staff) should be such as to enable the organization to provide world-wide coverage of its services through exclusive inspectors/surveyors, in particular, while rendering the statutory certification services. In implementing this, the regulatory requirements regarding the use of 'exclusive inspectors/surveyors' for statutory services should also be considered.

6.1.3

6.1.4

6.1.5

6.1.6

6.1.7

The competence management system should consider/include additional/follow-up training necessitated due to service and service delivery failures, errors found during monitoring and audits.

6.1.8

Monitoring of the inspectors/surveyors may be a part of report monitoring and activity monitoring processes of the organization.

6.1.9

Observation is applicable in the initial stages of authorization. Subsequently, monitoring will apply.

6.1.10

6.1.11

6.1.12

Impartiality requirements shall be conveyed to the inspectors/surveyors in a manner deemed appropriate and effective by the organization. (e.g. online training, part of induction/refresher training).

6.1.13

Confidentiality requirements shall be conveyed to the inspectors/surveyors in a manner deemed appropriate and effective by the organization. (e.g. online training, part of induction/refresher training).

6.2 Facilities and equipment

6.2.1

6.2.2

6.2.3

6.2.4

6.2.5

6.2.6

With respect to equipment used by the manufacturers, builders, repairers and owners, as a part of the required inspection/survey, the traceability shall be verified by the attending surveyor/inspector during their survey/inspection activities. Records of such verification are to be maintained in the internal records of the organization as deemed appropriate by the organization.

6.2.7

6.2.8

6.2.9

6.2.10

6.2.11

The requirement for the approval of suppliers shall also apply, as relevant, to external software developers, if any, who services are engaged to develop the reporting software.

6.2.12

6.2.13

6.2.14

6.2.15

6.3 Subcontracting

6.3.1

The organization shall consider the requirements, restrictions, if any, imposed by statutory regulations e.g. use of exclusive inspectors/surveyors, in particular, while rendering the statutory certification services.

If sub-contractors are used for inspection/survey services, then the organization shall ensure that they – depending on the complexity of the inspection/survey being sub-contracted – are also subject to training on the organization's policies on impartiality, confidentiality and procedures for inspection/survey and reporting.

6.3.2

The information to clients should be embedded either in the specific contract or in framework agreements or in standard contracts, which, as applicable are made available to the client.

6.3.3

The organization's monitoring system shall address the monitoring of the subcontractors' reports by a competent person of the organization, prior to final acceptance of the inspected item.

6.3.4

7 Process requirements

7.1 Inspection methods and procedures

7.1.1

7.1.2

This inspection/survey requirements may be in the form of a 'quality plan', 'inspection & test plan'.

7.1.3

The non-standard methods could be documented in the form of a 'quality plan', 'inspection & test plan'.

7.1.4

7.1.5

7.1.6

7.1.7

7.1.8

7.1.9

7.2 Handling inspection items and samples

7.2.1

7.2.2

7.2.3

7.2.4

7.3 Inspection records

7.3.1

The inspection/test/survey recording system should include procedures to document the conclusions of intermediate/stage inspections/surveys, in cases of multi-stage inspections/surveys.

7.3.2

7.4 Inspection reports and inspection certificates

7.4.1

7.4.2

7.4.3

7.4.4

7.4.5

7.5 Complaints and appeals

7.5.1

7.5.2

7.5.3

7.5.4

7.5.5

7.6 Complaints and appeals process

7.6.1

7.6.2

7.6.3

7.6.4

7.6.5

8 Management system requirements

8.1 Options

8.1.1 General

8.1.2 Option A

8.1.3 Option B

Refer to QIQS Part 2 – QACE Interpretations of ISO 9001-2015

8.2 Management system documentation (Option A)

8.2.1

8.2.2

8.2.3

8.2.4

8.2.5

8.3 Control of documents (Option A)

8.3.1

8.3.2

8.4 Control of records (Option A)

8.4.1

8.4.2

8.5 Management review (Option A)

8.5.1 General

8.5.1.1

8.5.1.2

8.5.1.3

8.5.2 Review inputs

8.5.3 Review outputs

8.6 Internal audits (Option A)

8.6.1

8.6.2

8.6.3

8.6.4

8.6.5

8.7 Corrective actions (Option A)

8.7.1

8.7.2

8.7.3

8.7.4

8.8 Preventive actions (Option A)

8.8.1

8.8.2

8.8.3

Annex A

(normative)

Independence requirements for inspection bodies

A.1 Requirements for inspection bodies (Type A)

A.2 Requirements for inspection bodies (Type B)

A.3 Requirements for inspection bodies (Type C)