CTO S.A.	**CENTRUM TECHNIKI OKRĘTOWEJ S.A.** Product Certification Division	Page/Pages: 1/12
I-05	**INSTRUCTION** **QUALITY ASSURANCE SYSTEM REQUIREMENTS** **FOR MARINE EQUIPMENT – MODULE D AND MODULE E**	
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1. Objective and scope

1.1 Objective

The purpose of this instruction is to define the requirements concerning the quality assurance system for manufacturers of marine equipment applying for:

- EC Production Quality Assurance Certificate (Module D), or
- EC Product Quality Assurance Certificate (Module E),

issued by the Product Certification Division of the Centrum Techniki Okrętowej S.A. (Maritime Advanced Research Centre), in accordance with the requirements of Directive 2014/90/EU.

1.2 Scope

The instruction is applied by the Division during the initial audit of the quality assurance system of the marine equipment manufacturer under Module D or Module E. It is also applied during scheduled surveillance audits, renewal audits, and special audits.

2. Referenced documents

Documents are normatively referenced in this document, in whole or in part, and are necessary for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

2.1 Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (Act of 2 December 2016 on marine equipment – implementing document – Journal of Laws 2017, item 32)

2.2 Act of December 2, 2016, on Marine Equipment.

2.3 Accreditation for Product Certification Bodies, Detailed Requirements.

2.4 DA-11 Accreditation of conformity assessment bodies for the purposes of notification.

2.5 PN-EN ISO/IEC 17067:2014-01 Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes.

2.6 Rules for using the identification number of the Notified body of Centrum Techniki Okrętowej S.A.

2.7 Resolution MSC.307(88) – International Code for Application of Fire Test Procedures (2010 FTP Code).

2.8 NC-08 Procedure for Conducting Certification and Surveillance.

2.9 DA-10 Accreditation in flexible scopes.

3. Definitions

QUALITY ASSURANCE SYSTEM (QAS) – a general term referring to the quality management system implemented by the manufacturer in order to meet the requirements of the applicable conformity assessment module (Module D – production quality assurance, or Module E – product quality assurance), in accordance with Directive 2014/90/EU. The term “QAS” may be used in documentation as a common designation for both the production quality assurance system and the product quality assurance system.

PRODUCTION QUALITY ASSURANCE SYSTEM (Module D) – a documented, permanent, and effectively implemented quality assurance system (QAS) applied by the manufacturer of marine equipment, covering surveillance of the entire production process, including control activities, inspections at various stages, as well as control and testing of the final product. The purpose of the QAS is to ensure that the final product complies with the approved type and meets the requirements of Module D, in accordance with the provisions of Directive 2014/90/EU.

FINAL PRODUCT QUALITY ASSURANCE SYSTEM (Module E) – a documented, permanent, and effectively implemented quality assurance system (QAS) applied by the manufacturer of marine equipment, covering exclusively the final control and testing of the finished product, aimed at confirming its conformity with the approved type and the requirements of Module E, in accordance with the provisions of Directive 2014/90/EU.

MANUFACTURER – a natural or legal person who manufactures marine equipment or has it designed and/or manufactured, and places it on the market under their own name or trade mark, assuming responsibility for its conformity with the requirements of Directive 2014/90/EU.

CERTIFICATION (CONFORMITY ASSESSMENT) – for the purpose of this procedure, the terms "certification" and "conformity assessment" are used interchangeably and refer to activities carried out under Modules B, D, and E, aimed at confirming the conformity of marine equipment with the requirements of Directive 2014/90/EU.

4. Responsibility

The Division is responsible for:

- conducting an initial audit of the manufacturer's quality assurance system within the scope of Module D or Module E,
- assessment and approval of the quality assurance system and issuance of the appropriate certificate of conformity,
- performing surveillance, renewal, and special audits to monitor the continued effectiveness of the quality assurance system,
- maintaining records and documentation related to certification and surveillance.

The manufacturer is responsible for:

in Module D:

- implementation and maintenance of a production quality assurance system compliant with the requirements of Module D,
- ensuring that the production process, control, and testing are carried out in accordance with the approved quality system,
- conducting product sample testing during production according to the established test plan and requirements applicable under Module D,
- providing the certification body with documentation and facilities necessary to conduct audits and inspections.

in Module E:

- implementation and maintenance of a quality assurance system for final product control and testing compliant with the requirements of Module E,
- conducting testing and inspection of finished products in accordance with the approved test plan and the requirements of Directive 2014/90/EU,
- ensuring the conformity of the final product with the approved specifications and requirements,
- providing the certification body with documentation and products necessary to conduct audits and inspections.

5. Procedure

These procedural rules have been developed with reference to products covered by Directive 2014/90/EU (MED) and apply to conformity assessment systems under Module D (production quality assurance system) and Module E (final product quality assurance system).
For each point, it is specified whether it applies solely to Module D or to both Modules D and E, taking into account the differences arising from the scope of surveillance and the manufacturer's responsibilities as set out in Annex II of the Directive.

5.1 Preliminary arrangements (Modules D and E)

The manufacturer of marine equipment shall establish, implement, and maintain a documented quality assurance system (QAS) compliant with the requirements of either Module D or Module E, depending on the scope of certification applied.

This system must ensure that the product placed on the market meets the requirements specified in the technical specifications and applicable regulations.

The system shall include appropriate procedures, instructions, forms, as well as control and testing activities, including final product inspections and tests — regardless of whether the manufacturer applies Module D or Module E. Under Module D, the system additionally covers surveillance of the entire production process, whereas under Module E it focuses exclusively on the final control and testing of the finished product.

The results of control and testing activities — both during the production process (Module D) and concerning the finished product (Modules D and E) — shall be used to assess product conformity with the requirements. The manufacturer is obliged to ensure continuity of control activities and to document their results as records providing evidence of the effective operation of the quality assurance system.

In case of non-conformities, the system shall include requirements for taking corrective and preventive actions.

The quality assurance system shall be adapted to the specific nature of the product and the process, as well as to the requirements applicable to the relevant module. A manufacturer possessing a quality management system compliant with PN-EN ISO 9001 is considered to meet the quality assurance system requirements, provided that the system is appropriately applied to the requirements of Module D or E.

Where elements requiring certification are used in the product subject to the certification process due to their function, the Certification Body recognizes certificates for these elements issued by

notified or accredited certification bodies.

For the purposes of this Instruction, the terms “determine”, “establish”, and “define” have the same meaning as “document”.

5.2 Quality Assurance System (QAS) Documentation (Modules D and E)

The QAS documentation shall be controlled, updated, and supplemented in case of changes such as: extension of the system scope, modifications in product design, production process, control methods, or legal requirements.

A person with appropriate qualifications and authority shall be designated to control the documentation.

Contents of the Quality Assurance System (QAS) Documentation:

Procedures / instructions describing:

- surveillance of the production process (Module D),
- control and testing of the product at all stages of its manufacturing (Module D),
- final control and testing of the finished product before placing it on the market (Modules D and E),
- conformity assessment of the product against the technical specification based on conducted tests (Modules D and E),
- handling of non-conforming products and complaints (Modules D and E),
- surveillance and maintenance of control and testing equipment, including calibration and verification (Modules D and E),
- implementation of corrections, corrective and preventive actions to eliminate causes of identified and/or potential non-conformities (Modules D and E).

Where necessary for the proper functioning of the quality assurance system, other procedures shall also be documented.

Specifications

- technical specifications related to the product, including harmonised standards or other reference documents indicated in the implementing provisions of Directive 2014/90/EU (MED),
- technical documentation of finished products as well as materials, components, and/or raw materials used in production — compliant with the requirements set out in the reference documents applicable to the specific type of product and its intended use.

Informational documents

- organisational chart of the manufacturing facility,
- legal requirements and regulations concerning the product and its placing on the market in accordance with Directive 2014/90/EU (MED),
- technological description of the production or manufacturing process of the product.

The manufacturer shall maintain an up-to-date list of the documentation, forms, and records

necessary for the proper functioning of the quality assurance system.

Technical documentation of the product, including test results, type conformity certificates, and declarations of conformity, shall be retained by the manufacturer for a period of at least 10 years from the date the product is placed on the market.

5.3 Organizational Structure (Modules D and E)

The manufacturer shall:

- define the organization of activities related to the quality assurance system (e.g., by means of an organizational chart),
- specify the scope of activities related to the production or manufacturing of the product carried out outside their organization (if applicable),
- establish and document the principles of surveillance over outsourced processes and services that affect the product's conformity with the requirements.

5.4 Personnel (Modules D and E)

Personnel Competence

The manufacturer shall:

- define the competence requirements for personnel performing, controlling, and managing activities within the quality assurance system and product control,
- document the required competencies for each employee whose activities affect product quality,
- provide personnel with access to documentation related to the quality assurance system and product control,
- organise training and competence development for personnel whose activities influence the product's conformity with requirements.

Responsibilities and Authorities

The manufacturer shall:

- appoint a person responsible for managing and overseeing the quality assurance system, as well as ensuring that system requirements are implemented and maintained,
- define, document, and update the scope of responsibilities and authorities of personnel performing, controlling, and managing activities within the quality assurance system.

5.5 Raw Materials and Production Materials (Module D)

The manufacturer shall:

- define the raw materials and production materials used,
- define and document the requirements for materials and raw materials as well as the criteria for approving their conformity,
- establish rules for storage of raw materials and materials in order to preserve their properties,
- verify compliance of deliveries with orders based on accepted criteria (supplier documentation confirming quality of deliveries, tests, and inspections),

- define properties, methods, and frequency of testing for raw materials accepted based on tests,
- designate persons responsible for releasing deliveries for production,
- establish purchasing procedures and maintain selection, listing, and evaluation of suppliers,
- keep records of the above activities.

5.6 Production Process (Module D)

Production Preparation

The manufacturer shall define the technical requirements for the product derived from the technical specification, depending on its intended use. These requirements shall be documented.

Surveillance of the Production Process

The manufacturer shall define:

- the stages of the production process subject to surveillance, the control parameters at these stages, the frequency of sampling, and the criteria for releasing semi-finished products for further operations,
- the requirements for products at each production stage,
- corrective actions to be taken in case of failure to meet established control values or evaluation criteria.

The manufacturer shall ensure:

- availability of current procedures/work instructions at workstations performing the respective technological operations,
- availability of specified product requirements (e.g., design drawing),
- proper safeguarding of the product during internal processing and delivery to the next stage of the process,
- conducting in-process controls and tests during production.

Records shall be kept of all activities related to the surveillance of the production process.

5.7 Production Machines and Equipment (Module D)

The manufacturer shall:

- ensure the use of production machines and equipment appropriate for manufacturing the product in compliance with requirements,
- develop a maintenance, inspection, and repair schedule for machines and equipment and supervise its implementation,
- define the method of inspecting machines and equipment after repair/maintenance,
- establish rules for daily inspection of the condition of machines and equipment,
- ensure the proper functioning of production equipment,
- keep records documenting the execution of the above activities.

5.8 Finished Product Testing (Module D and E)

The manufacturer shall define and document the method for conducting inspections and tests of the finished product concerning the essential properties specified in the reference document. This applies to both Module D and Module E—regardless of tests performed prior to placing the product on the market.

Inspections and tests shall be carried out according to a documented test plan, compliant with the requirements of the reference document.

The finished product test plan shall specify:

- properties to be tested relevant to the intended use,
- testing methods,
- frequency of testing,
- testing location (in-house/external laboratory).

The manufacturer must have the technical competence to conduct inspections and tests or use laboratories that possess such competence. The manufacturer shall maintain documentation confirming compliance with these requirements.

The manufacturer shall define:

- criteria for evaluating the results of finished product inspections and tests, including acceptance limits of the obtained results,
- product batch,
- size and number of samples for inspection and testing,
- sample collection procedures and related records,
- rules for releasing the finished product to storage.

Test and inspection results of finished products shall be recorded and include:

- product type,
- production date,
- sample collection date, sample size, and place of sampling,
- date of inspection and/or testing,
- applied measurement and/or testing methods,
- test and inspection results,
- evaluation of conformity of the results with declared levels/classes/descriptions of performance properties,
- identification of personnel collecting the sample and performing the test/inspection.

Testing shall be conducted according to methods specified in the reference document. The use of indirect testing methods is acceptable when:

- a correlation can be established between the property to be tested and another property that is safer or easier to measure,

- the manufacturer provides evidence that the indirect method used produces appropriate results.

5.9 Non-conforming Product (Module D and E)

The manufacturer shall establish and implement procedures for identifying and controlling products that do not conform to requirements, clearly defining responsibilities and authorities for decision-making in such cases. The procedure should also include the possibility of reclassification of the product.

Non-conforming products shall be clearly marked and physically segregated to prevent unintended use or shipment to the customer.

In case a non-conforming product is produced, the manufacturer shall take immediate actions, including:

- correction of identified non-conformities,
- reclassification of the product to another category (if feasible),
- prevention of the product's use,
- corrective actions.

If the product is repaired or reclassified, the manufacturer shall re-perform inspections and/or tests to confirm conformity with the requirements.

Appropriate records shall be maintained for all actions related to non-conforming products.

5.10 Identification and Traceability (Module D and E)

The manufacturer shall ensure the possibility of identifying products, components, or batches at every stage — starting from the production process, through storage, up to shipment to the customer (for Module E — identification applies only to the finished product, storage, and shipment).

Where possible, the manufacturer shall ensure product traceability, i.e., the ability to reconstruct its production history (in Module E — limited to data obtainable from the finished product inspection stage).

For each manufactured product or batch, appropriate records shall be maintained, including information on the production process and test results (in Module E — only records related to finished product inspection).

Based on these records, it shall be possible to reconstruct key information about the product and its manufacturing process, such as production date, materials used, batch number, product type, intended use, marking method, date of release from storage, and product recipient (in Module E — limited to data obtained during finished product evaluation).

5.11 Equipment for Inspection and Testing (Module D and E)

<u>The manufacturer is obliged to:</u>

- ensure measurements are performed with the required accuracy and maintaining measurement consistency,
- define inspection and measuring equipment with the appropriate accuracy level necessary for performing specific measurements (including standards used for internal verifications),

- ensure availability and adequacy of the inspection and testing equipment used,
- maintain a register of inspection and measuring equipment containing data uniquely identifying the equipment,
- develop a calibration/verification plan for the inspection and measuring equipment, specifying the required frequency and supervise its implementation,
- define acceptance criteria for the results of equipment verification,
- label equipment with calibration/verification status,
- ensure and monitor environmental conditions for measurements and tests where required,
- define procedures for handling damaged equipment,
- designate personnel responsible for overseeing the inspection and measuring equipment, maintain and keep records concerning the technical condition of the equipment as well as calibrations/verifications,
- supervise equipment used for inspection and testing even if the equipment is not owned by the manufacturer.

Inspection and measuring equipment should have operating instructions available to employees. The equipment should be used according to its intended purpose and operating instructions.

Records from calibrations/verifications should include:

- identification of applied standards,
- measurement results and their comparison with the standard,
- evaluation of calibration/verification results,
- date of calibration/verification,
- identification of personnel performing the calibration/verification.

5.12 Declaration of Conformity and Marking (Module D and E)

Finished products covered by Directive 2014/90/EU may be marked with the Wheelmark only if the manufacturer:

- has fulfilled the requirements of the appropriate conformity assessment procedure (e.g., Module B combined with D or E),
- holds an EU type-examination certificate (Module B) for the given product,
- has implemented and maintains a suitable quality assurance system (Module D or E) that has been approved and is under the supervision of a notified body,
- has drawn up the EU declaration of conformity in accordance with the guidelines of Article 16 of Directive 2014/90/EU.

The marking of the product with the Wheelmark shall comply with the requirements specified in Chapter 2 of Directive 2014/90/EU, including the identification number of the notified body supervising the manufacturer's quality assurance system and the year the mark was affixed.

The EU declaration of conformity is a document for which the manufacturer holds sole responsibility. The notified body **does not approve, certify, or assess the EU declaration of conformity or the**

Wheelmark. However, as part of the supervision of the quality assurance system (Module D or E), the notified body should be familiar with the content of the declaration, as it serves as a reference for the scope of the product and technical requirements and may—if such a situation arises—inform the manufacturer about any observed irregularities or deficiencies.

5.13 Packaging, Storage, and Transport (Module D and E)

The manufacturer should define the procedures for handling the finished product — including its packaging, storage, protection, and transport — in a manner that prevents any damage or changes in properties during storage and transport to the customer. These processes should be controlled.

In justified cases, the manufacturer should perform periodic inspections of stored products to detect any possible damage or changes in properties.

Records should be kept for the acceptance and release of the product.

5.14 Complaints (Module D and E)

The manufacturer should define and document the procedure for handling complaints:

- submitted by customers and/or users,
- submitted by the manufacturer itself to producers of raw materials, materials, and components used in the manufacturing process (Module D only)

The manufacturer is obliged to:

- document and archive records related to all complaints/warranties,
- take appropriate actions concerning each submitted complaint/warranty,
- analyze the causes of product nonconformities and take appropriate corrective actions to eliminate them, then analyze the effectiveness of these actions and keep records of this process,
- use the complaints submitted by itself for the periodic evaluation of suppliers of raw materials, materials, and components (Module D only).

5.15 Corrective and Preventive Actions (Module D and E)

In the event of nonconformities, the manufacturer should:

- take corrective actions to eliminate the causes of nonconformities in order to prevent their recurrence,
- take actions to eliminate the causes of potential nonconformities to prevent their occurrence.

The analysis of nonconformities should be documented and include: cause analysis, actions taken, and evaluation of their effectiveness.

Records should be maintained for all corrections, corrective actions, and preventive actions taken.

5.16 Use of Certificates (applies only to audit supervision – Modules D and E)

The manufacturer shall:

- use the certificate of conformity exclusively for products that meet the requirements and are consistent with the type covered by the EU type-examination certificate (Module B),

- refer to the certificate in accordance with the established rules and regulations arising from Directive 2014/90/EU and the relevant module (D or E),
- use the identification number and the name of the notified body in a non-misleading manner and only in connection with the wheelmark, in accordance with regulations concerning the marking of marine equipment.

5.17 Corrective Actions Following Previous Audit (if applicable – Modules D and E)

In the event that observations and non-conformities were identified during the previous surveillance audit, the manufacturer shall take appropriate and effective corrective actions addressing all observations and non-conformities.

Records/evidence of the corrective actions taken shall be available.

6 Forms

Form number	Title
FI-05/01	PLAN OF INITIAL[1)] QUALITY ASSURANCE SYSTEM AUDIT (MODULE D / MODULE E)
FI-05/02	LIST OF NONCONFORMITIES (N) FROM INITIAL [1)] / AUDIT OF QUALITY ASSURANCE SYSTEM (MODUL D / MODUL E)
FI-05/03	ASSESSMENT REPORT ON THE QUALITY ASSURANCE SYSTEM DOCUMENTATION (MODUL D / MODUL E)
FI-05/04	REPORT OF INITIAL[1)] QUALITY ASSURANCE SYSTEM AUDIT (MODUL D / MODUL E)
FI-05/05	QUALITY ASSURANCE SYSTEM AUDIT (MODUL D / MODUL E)

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