Certification process

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EUROPEAN MARITIME CERTIFICATION INSTITUTE

Contents

1. Definitions

1.1

The in this document mentioned terms are defined in the RD.004 (EMCI Register list of

terms and conditions).

2. Purpose

2.1

This document regulates how EMCI Register handles the certification of products
against the ISO 17065 criteria.

2.2

EMCI Register shall confine its requirements, evaluation, review, decision and
surveillance (if any) to those matters specifically related to the scope of certification.

2.3

The EMCI Register scope of certification is defined in ID.006 (Accreditation scope)

3. Certification process

3.1

Each certification issued by EMCI Register must have followed one or multiple certification processes.

3.2

A certification process is the culmination of the individual (sub) processes laid out in PD.001 (Certification process). A certification process can consist of the following:

- Application
- Application review
- Certification advice
- Certification plan
- Certification file
- Evaluation
- Certification decision
- Certificate
- Complaint

The above mentioned terms are explained in this document.

3.3

If the certification process is successful it must contain all the above (sub) processes/ documents.

3.4

A certification process results in:

- A product being certified against a norm for which EMCI Register is accredited/appointed to certify against
- The extension/modification of an existing certification
- The transferring of a certification from a different ISO 17065 accredited organization

3.5

If the client has requested the extension, modification or upgrade/downgrade of an existing certification, EMCI Register starts a new certification process.

3.6

EMCI Register may also invite external observers with or without consolation of the client. These observers will be given the right to view all documents relating the certification process. The EMCI Register accrediting body and the appointing government body are always external observers.

3.7

EMCI Register office ops officers are not authorized to meddle with the content based/norm specific matters of the certification process.

3.8

A product must meet the certification requirements and those set by the related norm.

3.9

At the end of the certification process, no matter the outcome/result, EMCI Register asks feedback of each client at the time of completion of the certification activities. It will do so using SurveyMonkey or Wufoo (in accordance with RD.002 (Quality manual)). The quality officer gets a copy of each filled in form and must respond to negative reviews.

3.10

EMCI Register shall inform the notifying authority of the following:

- Any refusal, restriction, suspension or withdrawal of certificates
- Any circumstances affecting the scope of and conditions for notification
- Any request for information on conformity assessment activities performed which they have received from market surveillance authorities
- On request, conformity assessment activities performed within the scope of their notification and, any other activity performed, including, cross-border activities and subcontracting

3.11

EMCI Register shall provide the other bodies notified under the same community harmonization legislation carrying out similar conformity assessment activities and covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

4. Application

4.1

Each product that EMCI Register certifies must have a valid application.

4.2

The application must be submitted to EMCI Register at the start of the certification process.

4.3

An application must contain at least:

- The product information
- The client information including company registration and contact details
- Desired start and end date for certification
- Information required to determine what norm is required for certification

4.4

The application may define specific documentation requirements for the client to submit.

5. Application review

5.1

Each application received by EMCI Register is subject to a review process.

5.2

EMCI Register is free to deny any application. However,

- Access to the certification process shall not be conditional upon the size of the client or membership of any association or group, nor shall certification be conditional upon the number of certifications already issued. There shall not be undue financial or other conditions.
- EMCI Register certification should be open to all clients and products if they fall within the scope of certification that EMCI Register operates.
- EMCI Register is free to refuse a client or product if there has been evidence of non-compliance with EMCI Register rules, national or international legislation or (suspected) participation in criminal activities.

5.3

EMCI Register will communicate the denial to the client. The client is allowed then to alter the application and submit it as a new application to be processed accordingly or file a complaint.

5.4

Each review must yield a certification advice. The certification advice will be presented to the client who must then decide whether to accept the advice and continue with the certification.

5.5

EMCI Register must determine at the application review process whether it is able to carry out the certification process requested by the client. This includes but is not limited to ensuring required testing equipment is available and the intellectual, experience and audit capacity/capability exists within EMCI Register to certify against the desired norm. If EMCI Register cannot executed a certification activity it shall document this and be reported to the quality officer.

5.6

EMCI Register and the lead auditor must be able to select the applicable norm(s) for this product from the norm cache. EMCI Register may only process with the certification if the certification requirements are contained in specified standards and/or other normative documents as stored in the normative cache. If the norm is not found it must either be added, or the certification request cannot go ahead. If applicable the appropriate authority, government, committee or accrediting body will be consulted.

5.7

The lead auditor and an office ops officer must sign off on the certification advice to ensure that EMCI Register has the competence to carry out the desired certification activities.

6. Certification advice

6.1

A review of an application to certification will always yield a certification advice.

6.2

A certification advice must contain:

- Whether EMCI Register is capable of performing the actions requested in the application
- What norm the product in the application will be certified against
- What audit team will be responsible for the certification

6.3

A certification advice must always have a corresponding TD.001 (Certification agreement).

6.4

A certification advice must appoint a lead auditor who will be responsible for evaluating the product.

6.5

The certification advice must be accepted and approved by the lead auditor.

6.6

A certification advice must contain a certification plan which will detail how the certification be handles and what timetable it follows.

6.7

At the client's request the lead auditor will give explanation on how the certification process will proceed and what evaluations will be carried out as well as answering any other questions the client may have.

6.8

The certification advice will contain a review of the submitted technical file against the PD.008 (Requirements for a technical file). This review is conducted by the lead auditor.

7. Certification plan

7.1

Each certification advice will contain a certification plan.

7.2

The certification plan will contain the timetable for:

- What and when evaluations will take place
- When the certification will be submitted for a decision by the lead auditor

7.3

The certification plan is open to modification if additional evaluation activities are required.

8. Certification file

8.1

EMCI Register is responsible, through the legally enforceable commitment made in TD.001 (Certification agreement), for the management of all information obtained or created during the performance of certification activities and the execution of PD.001 (Certification process).

8.2

Every certified, currently being certified, or certified in the past product must have a corresponding certification file. The certification file will contain all information, documents, evidence, correspondence etc. related to the certification of the product.

8.3

The certification file will contain at least:

8.3.1 Always:

- Identification of the client.
- An application for certification & identification of the product
- The product technical information.

8.3.2. If certification advice was accepted:

- The certification agreement signed by EMCI Register and the client
- The certification plan

8.3.3. If certification was successful:

- As mentioned under 8.3.2 and additionally:
    - The standard(s) and other normative document(s) to which conformity has been certified
    - The evaluation audit report(s)
    - The certification decision
    - The certificate

8.3.4

The certification file must contain records to demonstrate that all certification process requirements are fulfilled. The documents as mentioned in 8.3.3 must demonstrate that all process requirements have been effectively fulfilled. Any relevant communication with the client may also be included.

8.4

The certification file is stored according to PD.007 (Document management).

9. Certification decision

9.1

After finalizing of all required evaluations without non-conformities, a certification decision is created.

9.2

The certification decision is issued by the head of certification upon receiving the recommendation of a certification file by the lead auditor and performing a review of that file.

9.3

The certification decision can lead to:

- Acceptance:
  - o This can only be done if the certification file is completed, including the presence of a technical file in accordance with PD.008 (Requirements for a technical file).
- Denial:
  - o In which case the product is denied. The client must then resubmit an application.
- Improvement required:
  - o The client/lead auditor will be given an X amount of days, at the discretion of the head of certification, to comply. Failure to do this will lead to automatic denial.

9.4

In case of acceptance, the board of EMCI Register retains the right to deny the certification on non-content-based grounds. If it does not exercise this, the product will be certified.

9.5

EMCI Register must inform the client of all certification decisions regardless of status and provide explanation hereto.

9.6

In case of acceptance, formal certification documentation shall only be issued after, or concurrent with, the following:

- The decision to grant or extend the scope of certification has been made (to be documented in a certification decision).
- Certification requirements have been fulfilled (to be documented in evaluation report(s))
- The certification agreement has been completed/signed (to be placed in the certification file)

9.7

The EMCI Register board must sign all issued certificates.

10. Certificate & certification documentation

10.1

An by the board of EMCI Register approved certification decision will always lead to the issuing of a certificate.

10.2

The certificate will be issued for the specific norm determined during the review phase and for the specific product submitted during the application phase.

10.3

Usage of the certificate and all issued marks, are subject to PD.004 (Rules for the use of marks and certificates).

10.4

Every certificate issued by EMCI Register can be revoked and suspended as described in PD.001 (Certification process).

10.5

EMCI Register will keep a public register of certificates, regardless of status, as described in PD.001 (Certification process).

10.6

Each certificate will have a unique identification number which must be visible in any distribution variant of the certificate. If the product certification norm defines a number format EMCI Register will follow this, in all other cases the following format will be followed:

- [type-certification]-[product name]-[issue date]-[expiry-date]-[unique alphanumeric sequence]

10.6

EMCI Register certificates contain at least the following:

- Name of the product
- Applied norm
- Period of validity
- Date of issuing
- Any comments left by EMCI Register. These will be binding.
- The EMCI Register certification number issued by the accrediting body (for example the RVA).
- The signature of the board

10.7

The board is responsible for signing the certificate.

10.8

All certificates must be sent with an accompanying TD.018 (Certificate backpage). The rules contained in this document apply.

11. Lead Auditor

11.1

EMCI Register will appoint a lead auditor for each certification process.

11.2

The lead auditor must meet the lead auditor competency profile described in RD.005 (Competency profiles).

11.3

The lead auditor will be responsible for guiding the audit process, ensuring that the product up for certification meets the desired standards in the norm, creating a recommendation for the certification decision and performing evaluations to support their claims.

11.4

The lead auditor must only be tasked with evaluating the product against the standards in the norm and may only recommend the certification file to the head of certification if the product conforms to the standards in the norm.

11.5

The lead auditor is responsible for submitting the certification file for review to the head of certification. The lead auditor is not involved in the decision of granting the certification of the product.

11.6

The lead auditor shall have a contract with EMCI Register and sign PD.006 (Code of conduct).

11.7

The lead auditor must determine the evaluation results without burden and consultation of EMCI Register. The lead auditor is independently authorized to the determine of the advice for the certification decision.

12. Head of certification

12.1

The head of certification is responsible for providing the certification decision and the review of the certification file in the certification process.

12.2

The task of the head of certification is to ensure:

- The correct protocol was followed when certifying a product.
- The management system performed effectively and if not, report to the quality officer and the board.
- Identifying (potential) nonconformities and if detected, report to the quality officer and the board
- Identifying (potential) impartiality issues and if detected, report to the quality officer, board and impartiality committee

Here to the head of certification has the obligation to sign off for the above-mentioned points on all certifications performed by EMCI Register.

12.3

The head of certification must meet the head of certification competency profile as described in RD.005 (Competency profiles).

12.4

The head of certification shall have a contract with EMCI Register and must sign PD.006 (Code of conduct).

12.5

The head of certification must make the certification decision without burden and consultation of EMCI Register.

12.6

The head of certification is independently authorized to create the certification decision.

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13. Evaluation and audits

13.1

As part of the certification process, EMCI Register must conduct one or multiple evaluations of the product against the relevant norm determined in the review process.

13.2

All evaluations must be carried out by the lead auditor assigned to the corresponding certification process.

13.3

All evaluations must be planned and accepted by both EMCI Register and the client.

13.4

All evaluations will be concluded with an audit report. This audit report will be placed in the certification file.

13.5

The lead auditor is responsible for creating the audit report. The audit report will be shared with the client.

13.6

The audit report will contain:

- Results of all evaluation activities both that were found during the evaluation and audit
- Clarification of non-conformities

13.7

 If one or more nonconformities have arisen, and if the client expresses interest in continuing the certification process, the certification body shall provide information regarding the additional evaluation tasks needed to verify that nonconformities have been corrected.

13.8

If the client agrees to completion of the additional evaluation tasks, the process specified in PD.001 (Certification process) shall be repeated to complete the additional evaluation tasks. The additional evaluation shall be documented in the certification file.

13.9

If EMCI Register relies on certifications it has already granted to the client, or has already granted to other clients, to omit any activities, then EMCI Register shall reference the existing certification(s) in the certification file and the advice to the head of certification. If requested by the client, EMCI Register shall provide justification for omission of activities.

13.10

EMCI Register shall only rely on evaluation results related to certification completed prior to the application for certification, where it takes responsibility for the results and satisfies itself that the body that performed the evaluation fulfils the requirements contained in PD.001 (Certification process, article 17) and those specified by the certification scheme.

13.11

EMCI Register shall carry out the evaluation activities that it undertakes with its internal resources and shall manage outsourced resources in accordance with the certification plan. The products shall be evaluated against the requirements covered by the scope of certification and other requirements specified in the certification scheme.

13.12

At the discretion of the lead auditor, if not all required technical files/documentation is present the evaluation will be postponed or cancelled.

14. Norm cache

14.1

EMCI Register will retain a cache of normative documents for as far as they relate to the (potential) certification activities that EMCI Register will carry out. These can be documents such as CE Module descriptions, relevant ISO norms etc.

14.2

The norm cache and its contents are stored according to the PD.007 (Document management).

14.3

The norm cache is a non-public document folder that may only be accessed by employees and EMCI Register appointed organizations.

14.4

Changes to the normative cache must be logged according to PD.007 (Document management).

15. Normative changes

15.1

In the lifespan of EMCI Register, norms that EMCI Register has, will, or may certify against can change.

15.2

EMCI Register will check once every six months whether changes have occurred to documents in the norm cache or whether the contents of the norm cache require addition/deletion. The quality officer will carry out these changes.

15.3

While checking for required change the quality officer must also check for announced changes and act accordingly.

15.4

Normative changes may lead to changes in the certification of products. PD.001 (Certification process) must be consulted to see how changes in certification norms that lead to non-conformity should be addressed.

15.5

15.5.1

When the certification scheme introduces new or revised requirements that affect the client, EMCI Register shall ensure these changes are communicated to all clients via email.

15.5.2

The client is requested to show proof of the implementation of the changes.

15.5.3

A EMCI Register appointed lead auditor shall verify the implementation of the changes by its clients and shall take actions required by the scheme.

15.6

EMCI Register shall consider other changes affecting certification, including changes initiated by the client, and shall decide upon the appropriate action.

15.7

The actions to implement changes affecting certification shall include, if required, the following:

- Evaluation
- Review
- Decision
- Issuance of revised formal certification documentation to extend or reduce the scope of certification
- Issuance of certification documentation of revised surveillance activities (if surveillance is part of the certification scheme)

And shall be done according to PD.001 (Certification process)

16. No use of harmonized standards

16.1

A client may request to have non-harmonized standards used in their audit.

16.2

EMCI Register will appoint a lead auditor and head of certification to review these standards and advice EMCI Register on whether this standard is allowed. Additional information may be asked of the client.

16.3

EMCI Register will add these standards to the normative cache if they are applicable.

16.4

The use of non-harmonized standards may be combined with additional costs for the review and application.

17. Resource management

17.1. Evaluation activities via internal resources or other resources under our direct control

17.1.1.

When EMCI Register performs evaluation activities, either:

- with its internal resources or
- with other resources under our direct control,

EMCI Register shall ensure to meet the applicable requirements of the relevant International Standards:

- For product certification:
  - It shall meet the applicable requirements of ISO/IEC 17065
  - In addition: if the product is to be certified under the EU directive 2013/53/EU, it must meet the applicable requirements of this directive
- For product certification evaluations:
  - The resource must always be ISO/IEC 17065 accredited, or part of an ISO/IEC 17065 accredited organization
  - In addition: if the product certification evaluation is performed under the RCD 2013/53/EU the resource must also be appointed hereto.
- For testing or product certification where testing is performed:
  - o it shall meet the applicable requirements of ISO/IEC 17025
  - o if evaluated by another resource under our direct control, it must be under ISO/IEC 17025 accreditation in accordance with the scope of the required work assignment or test.
- For inspection or product certification where inspection is performed:
  - o it shall meet the applicable requirements of ISO/IEC 17020
- For management system auditing:
  - o it shall meet the applicable requirements of ISO/IEC 17021.

17.1.2.

EMCI Register excludes:

- inspection auditing
- management system auditing

17.1.3.

EMCI Register reserves the right to request permission from the Inspectorate for Human Environment and Transport for deviations on the before mentioned principles.

17.1.4.

Any deviation from these requirements must be documented in a board decision.

17.1.5.

The impartiality requirements of evaluation personnel must always meet ISO/IEC 17065:2012 requirements.

17.2 Outsourcing of evaluation activities

17.2.1

When EMCI Register outsources evaluation activities, it shall only be to bodies that meet the applicable requirements of the relevant International Standards:

- For product certification:
    - It shall meet the applicable requirements of ISO/IEC 17065
    - In addition: if the product is to be certified under the EU directive 2013/53/EU, it must meet the applicable requirements of this directive
- For product certification evaluations:
    - The resource must always be ISO/IEC 17065 accredited, or part of an ISO/IEC 17065 accredited organization
    - In addition: if the product certification evaluation is performed under the RCD 2013/53/EU the resource must also be appointed hereto.
- For testing or product certification where testing is performed:
    - o it shall meet the applicable requirements of ISO/IEC 17025
    - o if evaluated by another resource, it must be under ISO/IEC 17025 accreditation in accordance with the scope of the required work assignment or test.
- For inspection or product certification where inspection is performed:
    - o it shall meet the applicable requirements of ISO/IEC 17020
- For management system auditing:
    - o it shall meet the applicable requirements of ISO/IEC 17021.

17.2.2.

EMCI Register excludes:

- inspection auditing
- management system auditing

17.2.3.

EMCI Register reserves the right to request permission from the Inspectorate for Human Environment and Transport for deviations on the before mentioned principles.

17.2.4.

Any deviation from these requirements must be documented in a board decision.

17.2.5.

The impartiality requirements of evaluation personnel must always meet ISO/IEC 17065:2012 requirements.

17.2.6.

If evaluation activities are outsourced to non-independent bodies (e.g. client laboratories), EMCI Register shall ensure that the evaluation activities are managed in a manner which provides confidence in the results, and that records are available to justify the confidence. The lead auditor assures that the evaluation is executed in a verifiable manner and stores the proof in the certification file.

17.2.7.

Where EMCI Register subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in EU decision 768/2008, article R17, and shall inform our notifying authority accordingly.

17.2.8.

Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

17.3

EMCI Register ensures that required testing equipment is available. If non-available internal or external resources are required for certification a determination must be made during the application review stage and a request must be submitted to the board.

17.4

EMCI Register will keep a list of testing equipment (ID.005).

17.5

If testing equipment is required for a certification and this is not in ownership, or already leased by EMCI Register, the costs will be charged to the client.

17.6

EMCI Register may charge an administration fee to the client for the finding and renting of equipment.

17.7

If the client has testing equipment available EMCI Register may use that equipment to avoid costs. EMCI Register ensures this equipment is qualified according to PD.001 (Certification process), in order to avoid any breach of impartiality and to ensure the integrity of the certification process.

17.8

Testing equipment may be explicitly used by the lead auditor.

17.9

EMCI Register ensures testing equipment is correctly calibrated before use.

18. Monitoring

18.1

18.1.1

EMCI Register will continuously monitor the quality of certified products if this is a type certified product.

18.1.2

Once a year, in case of type certification, the client is hold to deliver a legal binding statement which declares that all products are built in accordance with the applicable norms and requirements.

18.1.3

EMCI Register clients must, without delay, inform EMCI Register of changes to the product and the client's ability to conform to the certification requirements.

18.1.4

If changes are reported EMCI Register will appoint a lead auditor to evaluate the changes and see if they violate the standards set by the applied norms.

18.1.5

If the changes violate the standards set by the applied norms EMCI Register will create a certification advice that contain the required changes.

18.1.6

The client must accept this advice, or the certification will be revoked.

18.2

18.2.1

As part of the monitoring process the client must setup a register of complaints regarding the product in any way. The client must provide EMCI Register with access to this register and the supporting documentation of how each complaint has been dealt

with. If this is denied, or this information is not available, EMCI Register is authorized to revoke the certification.

18.2.2

EMCI Register will keep a publicly accessible complaints system of its own in which the product end users can leave complaint, for as far as they relate to the compliance with the norm. EMCI Register will pass these complaints and appoint a lead auditor to investigate. These complaints are to be handled according to PD.002 (Complaint procedure) .

18.2.3

If a complaint is filed, the client must inform EMCI Register within 10 working days or the client is in violation TD.001 (Certification agreement)

18.3

EMCI Register may, at any time and if for good reason, perform a (partial) re-certification and corresponding evaluation. If the client does not consent to this, EMCI Register has the right to suspend the certification.

18.4

EMCI Register will periodically monitor the usage of certificates, marks and company public material.

18.5

In the event of a change, to a certified product or its production, that violates the norm, any applicable regulation, applied standard or certification requirment the corresponding certification is automatically invalid.

19. Non-conformity, Suspension and Revocation

19.1

Every certificate, and corresponding certification can be revoked, suspended or changed by EMCI Register.

19.2

The client is always allowed to request revocation of the certificate for any possible grounds.

19.3

EMCI Register may decide to continue the certification under pre-conditions if a minor non-conformity was determined and this is allowed by the norm. What these conditions are and what is considered a minor non-conformity is up to the individual lead auditor. This continuation must be agreed upon with EMCI Register's appointing body.

19.4

19.4.1

If certification is suspended, EMCI Register shall assign a lead auditor to formulate and communicate the following to the client:

- Actions needed to end suspension and restore certification for the product(s) in accordance with the certification scheme
- A defined timeframe to resolve the issues
- Any other actions required by the certification scheme

19.4.2

These persons shall be competent in their knowledge and understanding of all aspects of the handling of suspended certifications.

19.4.3

If successful, the certification will be reactivated.

19.4.4

If the client does not correct the non-conformities within the aforementioned timeframe, EMCI Register will revoke the certification.

19.5

If certification is suspended, EMCI Register shall a lead auditor to formulate and communicate the following to the client:

- Actions needed to end suspension and restore certification for the product(s) in accordance with the certification scheme;
- Any other actions required by the certification scheme.

19.6

If the client wants to reactivate the certification after a suspension (resolve the suspension) a new certification process will be started according to PD.001 (Certification process).

19.7

If certification is reinstated after suspension, EMCI Register shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure all appropriate indications exist that the product continues to be certified. If a decision to reduce the scope of certification is made as a condition of reinstatement, EMCI Register shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.

19.8

Once a certification is revoked it cannot be renewed. To achieve the same/comparable certification status a new certification application must be submitted.

19.9

19.9.1

If certification is terminated (by request of the client), suspended or revoked, EMCI Register shall take actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure it provides no indication that the product continues to be certified.

19.9.2

If a scope of certification is reduced, the certification body shall take actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.

19.9.3

Any change in the certification status must be reflected in the public register.

20. Public register

20.1

EMCI Register will maintain a public register of certified products and the norm(s) under which they are certified.

20.2

The public register must be leading in the validity of certificates. EMCI Register is bound to keep the online register up-to-date and update its contents as soon as relevant changes present themselves.

20.3

The public register will contain:

- The unique certificate number
- The product name and image
- The applied norm(s) and standard(s)
- The status of the certification
- The client name and address

20.4

The public register must be searchable by the unique certificate number.

21. Complaints

21.1.

It is possible to make complaints against EMCI Register. Complaints will be handled according to PD.002 (Complaints procedure).