**PROCEDURE OP 04a**

**Accreditation of Certification Bodies, Inspection Bodies and Environmental Verifiers:**

**Processing applications – initial assessment – granting accreditation**

***Abbreviations:***

Cyprus Accreditation Body (CYS-CYSAB)

Assessor (AS)

Assessment Team (AT)

Certification Body (CB)

Conformity Assessment Bodies (CAB)

Director (DIR)

Environmental Verifiers (EV)

European co-operation for Accreditation (EA)

Inspection Body (IB)

Lead Assessor (LA)

Management System (MS)

Quality Manual (QM)

Review Committee (RC)

Technical Assessor (TA)

Technical Expert (TE)

**1. Scope**

This document describes the procedure for processing applications for accreditation of CABs.

The Procedure applies to new applications for accreditation.

The objective of this Procedure is to ensure that accreditation is granted in accordance with the relevant accreditation criteria applying at the time.

**2. Responsibilities**

The DIRis responsible forthe appointment of the LA.

The LA is responsible for:

* The appointment of a sufficient number of appropriately qualified ASs, TAs and/or TEs (F.04a.07) in order to cover the scope of accreditation.
* Creating records for the members of the AT or verifying that existing AT members’ records are adequate and updated according to OP 02. This is documented in Form F 04a.07.
* Informing the CAB on the composition of the AT and achieve the CAB´s acceptance well ahead.
* The communication with the applicant in all stages of this procedure.
* The review of documentation.
* Providing CABs’ documentation to the members of AT, prior to the assessment.
* Drafting the assessment plan in a way to ensure full coverage of the set task and seeks the CAB’s acceptance.
* Making sure that applicant CABs as well as ASs/ TAs/ TEs are informed of the pertinent accreditation criteria.
* Preparing and conducting assessment of applicant inspection and certification bodies in cooperation with appointed ASs/ TAs/ TEs and in accordance with CYS-CYSAB´s management system and the appropriate accreditation criteria.
* The AT overall, and all decisions taken by the ASs and TAs/ TEs.
* Monitoring the performance of ASs/ TAs/ TEs.
* Keeping records of all relevant correspondence related to application, assessment and granting accreditation.
* Providing information on the current status of the CABs’ accreditation to appear on the website.
* Reporting nonconformities with CYS-CYSAB´s management system to the Director.
* Informing the Director on any complaints and take part in the handling of them.

The LA is in charge of the AT and responsible for all decisions taken by the AT. The AS, TA and/or TE is/are responsible for assessing the specific part of the scope covered by their expertise. The AS, TA and/or TE refer to the LA for all matters relating to the assessment.

**3 Process**

**3.1 General**

After the receipt of the application (F.04a.01a, F.04a.01b, F.04a.02) a file is created for the CAB where all relevant records are kept.

Applicants are informed by CYS-CYSAB on relevant documents and procedures for accreditation. Records from all steps of the accreditation process shall be maintained in accordance with Procedure OP 07.

The assessment of CAB aims to:

* Determine whether the CAB is competent to perform its activities covered by its scope of accreditation in accordance with the requirements for CABs, as specified in the Standards CYS EN ISO/IEC 17020, CYS EN ISO/IEC 17021, CYS ΕΝ 17065, CYS ΕΝ ISO/IEC 17024, CYS EN ISO 14065, the relevant ILAC, IAF, EA guidelines, European legislation and national law requirements as (where applicable).
* Determine whether the documentation of the implementation of CABs’ MS conforms with the requirements of the above-mentioned standard, through the review of QM, the relevant procedures and its records.

CYS-CYSAB requires that a controlled copy of all relevant CABs’ MS documentation is kept at its head office.

In order to establish confidence in the CABs’ accreditation activities, CYS-CYSAB carries out an on-site assessment during an CABs’ on-site inspection/audit or certification, either during an initial inspection/audit or certifications, a re-inspection/audit or certification, or a surveillance inspection/audit or certification.

In case, any important issue appears, during an assessment which might inhibit its progress, LA in cooperation with the members of AT decide accordingly the actions to be taken. If there is an urgent need LA requests DIR’s opinion.

The CAB and/or the organization undergoing inspection/audit or certification (CABs’ client) has the overall responsibility to provide the means necessary and take the necessary actions in order to meet all relevant safety regulations for the members of CYS-CYSAB’s AT. It is the sole responsibility of the CAB undergoing assessment to inform in advance its client for this obligation.

In case that the CYS-CYSAB’s AT identify any situation or procedure that could implicate risks for the safety of its members and/or the premises and employees of the organization undergoing inspection/audit or certification, the LA reports the issue immediately (verbally) and later in writing, to the CAB undergoing assessment and the organization undergoing inspection/audit (CABs’ client) or certifications. A copy of the letter describing the above-mentioned statement shall be included in the Assessment Report of CYS-CYSAB.

**3.2 Application**

The CAB submits to CYS-CYSAB the application (F 04a.01a, F 04a.01b, F 04.02) fully completed. Main aspects addressed therein are the following:

* The Inspection/Certification Regulation or other relevant document.
* The procedures (optional).
* The documents stating its legal identification and the organization of which it forms a part (if applicable).
* The scope of accreditation.
* The liability insurance contract for Public Liability, Employer’s Liability and Professional Indemnity.
* Qualifications of key staff.
* Other location(s) where relevant activities are carried out.
* Equipment register complete with technical specifications.
* Internal calibrations carried out (where applicable).
* The application fees.
* Commitment to continuous compliance with the requirements for accreditation.
* Other relevant documents/records.
* CABs commitment through signature by CAB’s Manager or Authorized Person.

The DIR appoints the LA to be responsible for the accreditation process, for the particular application. The LA selects the other members of the AT. The AT consists of the LA and AS (if appropriate), TA and/or TE (not in the case of a pre-assessment). The AT must be consisted by a sufficient number of members with documented technical competency in accordance with the scope of accreditation. Form F 04a.07 is used for the appointment of the Assessment Team.

The CAB is informed in advance on the appointed members of the AT and the organization they belong to, to confirm acceptance or to object for justified reasons e.g. regarding impartiality or any possible conflict of interests.

In case a CAB raises doubt about the impartiality of a member of the assessment team, CYS-CYSAB investigates the issue and decides whether a replacement is required. The CAB can object to the decision; in such a case, the final decision is taken by the DIR.

When an assessment has been planned and the CAB decides not to proceed with it, CYS-CYSAB asks from the CAB to submit the reasons in writing. The assessment shall be carried out within six (6) months from the day of cancelling it. If the CAB cannot manage, the procedure is terminated and it could be reactivated only after a new application is submitted by the CAB. In such cases the applicant shall cover all the inheriting expenses.

Within three (3) months the LA reviews the CABs’ documentation to evaluate compliance with the requirements of the relevant standard. The form “Correlation of QM and the Standard” (F 04a.08, F 04a.12, F 04a.17) is used as appropriate to list all comments referring to the findings of this review (template used only as a part of the training of new employees). The CAB is informed on any deficiencies or lack of precision. The CAB may be asked to submit new or supplementary material before an assessment visit is agreed. Also, LA confirms the availability, by CYS-CYSAB, of the necessary standards relating to the assessment. In case there are not available LA takes the necessary actions to retrieve them. This is expected not to take more than three (3) months. The LA, based on the review of the documented information and in consultation with the DIR, may decide not to proceed with further assessment. In such cases, the results with their justification shall be reported in writing to the CAB.

Where the initial assessment cannot be conducted in a timely manner, this shall be communicated to the CAB.

**4. Preassessment**

Preassessment is advisable; however, it is upon the CAB to decide accordingly. After the confirmation that the CAB is ready for the next step, the preassessment or the initial assessment is carried out, depending on the preference of the CAB, is carried out within two (2) or three (3) months respectively. It is upon LA’s judgment to consider necessary or not, the participation of the AS/TA/TE.

During a preassessment:

* The documentation of the implementation of the CABs’ MS is being assessed.
* The LA confirms the scope of accreditation in order to appoint a competent AT.
* All forms used in initial assessment are being completed, except the one describing “Nonconformities”, the one referring to the Four-Year Period Surveillance Programme (F 04a.25) and the one referring to the handling of nonconformities (F 04a.06, F 04a.27).

Assessment techniques utilized during preassessment include the combination of on-site assessments and other assessment techniques such as document review, file review and interviewing techniques.

 It is noted that during preassessment:

* The aim is to document the implementation of MS.
* The technical competence issues are not thoroughly dealt with.
* The findings (without any classification) are presented to the CAB during the closing meeting.

A detailed report (F 04a.19, F 04a.14, F 04a.10) including the above-mentioned findings, follows within two (2) weeks

The CAB informs the LA on the handling of corrective actions taken and, depending on the case; it may be asked to submit relevant documentation.

After the completion of the preassessment the LA completes and keeps record of all relevant documents.

As soon as it is considered that the CAB is ready to undergo an initial assessment, the necessary planning is made by the LA.

Normally, the initial assessment is carried out within five (5) months after the preassessment.

If the CAB decides not to proceed with a planned initial assessment the same rules as in 3.2 apply.

**5. Initial Assessment**

**5.1 Assessment Planning**

The initial assessment consists of the following stages:

* Assessment in head office.
* On-site assessment (where applicable).
* Extraordinary assessment (where applicable).
* Closing meeting / Assessment report.

The LA sets a date (where applicable) for each of the above-mentioned stages and elaborates a plan (F 04a.26, F 04a.27, F 04a.28) of the assessment in agreement with the other members of the AT and the CAB. The plan illustrates the allocation of responsibilities to the members of the AT. The plan shall also include the type and number of inspections or certifications carried out by the CAB. The number and frequency for assessing the performance of the inspectors is defined according to the type and area of activities of the CAB.

LA provides the plan to the CAB and the members of the AT at least one (1) week before the assessment. All relevant documents for conducting the assessment are provided by the LA to the AT.

In addition, the CAB must provide, on-time, its inspection/audit or certification schedule to its client and to CYS-CYSAB, to enable LA to elaborate the schedule of on-site assessment in collaboration among the CAB and the AT.

In case of any extension or reduction in the scope of accreditation, after the appointment of the AT and before the assessment at the head office, the composition of AT is re-evaluated for its competency.

It is the responsibility of the LA to make sure that members of the Assessment Team have received copies of the valid issue of the relevant Procedures and all relevant forms provided as well as copies of the inspection/certification procedures and/or checklists, if available prior to the assessment.

In case of an application for an extension of scope of a new standard, LA shall request a copy of the standard before the assessment and personally check if different methods are described in the relevant standard, so that they would be included in the four-year period surveillance program for witnessing.

It is the full responsibility of LAs to cooperate with TAs or TEs when preparing the assessment plan and especially the four-year period surveillance program for witnessing. All different inspections/ audits/ certifications described in the technical standards shall be assessed during onsite witnessing.

With regard to the duration of the assessment, CYS-CYSAB has set certain criteria to be considered by the LA when drafting the plan of the visit; these are based on the availability of TAs or TEs and their specific expertise in correlation with the detailed scope of accreditation in each particular case. The latter refers to the number of Inspection /Audit or certifications procedures within each type of technical field. In all cases the duration for carrying out each Inspection or Audit or certification is also taken into consideration. All these are also discussed with the TAs or TEs to be involved.

Assessment techniques utilized during surveillance assessment include the combination of on-site assessments and other assessment techniques such as, witnessing of methods as presented in the Program for witnessing Form (F 04a.25), document review, file review and interviewing techniques.

With regard to the risks relating to each initial assessment, the following risks are considered and documented in form F 04a.31 when drafting the plan of the visit:

* + Frequency/ reoccurrence of each inspection or certification contributing to the overall workload of the CAB,
* Risk factor magnitude/importance in case of non-conformities during the execution of specific inspections or certifications.
* Number of locations at which activities are performed,
* Number of sampling sites (e.g. organic certification),
* The detailed scope of accreditation in each particular case. This refers to the number of procedures within each type of inspection/audits or certification, critical procedures, procedures that are rare (and availability of the TE/ TA),
* The duration for carrying out each procedure,
* Whether the CAB has developed individual schemes,
* Whether the CAB performs internal calibration,
* Procedures (if available prior to the assessment),
* Minutes from the internal audit and management review (if available prior to the assessment),
* Any complaints regarding the CAB activities,
* Any other possible risks.

 When there are major changes as stated in R 01 (paragraph 5.2), the above-mentioned risks are documented in Form F 04a.31.

The above aspects are taken into account to fix the duration of the assessment (man-days) and, when needed, are also discussed with the TAs or TEs to be involved.

During the initial assessment the LA ensures an appropriate sampling with respect to staff performing inspection/audit based on risk considerations as well as procedures within different parts of the scope so that all parts are covered (F 04a.11, F 04a.15 or F 04a.20) as the case may be. During initial assessment, the inspection/audit procedures of all technical fields and premises from which key activities are performed shall be witnessed by the TA or TE. Exceptions may apply in cases regarding the accreditation for notification purposes. In addition, special requirements for the initial assessment's witnessing and sampling can be found in the relevant Guidance Documents issued by CYS-CYSAB in each technical field.

Regarding the organic production the lists of CAB’s customers will be obtained, detailed to:

• The product category.

• The number of customers per product category.

• The risk factor designated by the CAB for each customer.

These lists will form the base for CYSAB’s designing its sampling plan, taking also in account the findings so far, with regard the risk factors related to the CABs, such as impartiality, independence, work experience and training of inspectors, as well as risk of technical origin, such as the seasonal threats for deviation from the implementation of the organic rules.

In cases where a CAB submits an application for initial accreditation or extension of its existing scope, in a certain conformity assessment scheme, an evaluation of the scheme is carried out to determine the suitability of the scheme, in accordance with the requirements of EA 1/22.

Where a CAB submits an application for initial accreditation or extension of its existing scope for the purpose of demonstrating the required technical competence to become a Notified Body within the scope of the EU Harmonisation, the requirements of EA-2/17 are applied for the choice of the preferred Harmonised Standard and other requirements (Annex A and Annex B) - see Appendix I. The resolution TMB 2022(10)01 is also taken into account. The notification procedures in relation to the different directives have been agreed with the notifying authorities and the European Commission. These are uploaded to the NANDO Database - see Appendix II.

In relation to TMB Resolution 2022 (10) 02 when the witnessing is postponed, the accreditation is granted under the condition that the CAB makes sure that the NAB is able to witness its first customer (see EA-2/17 §Annex C):

1. The witnessing shall be carried out within a maximum of 18 months after receiving the

accreditation – if, during this period, the witnessing has not been carried out, then the

accreditation for that conformity assessment activity will be withdrawn (first suspended, if necessary), since the NAB is not able to fully assess the continuing competence of the CAB for all the applicable requirements;

2. Once the accreditation is withdrawn, the CAB may apply again, but the option of being

accredited with postponing of the witnessing for after the first clients’ requests have been

received, will not be available for a period of time of two years. The CAB can, however, apply again under the normal regime of accreditation after witnessing.

An initial assessment can be converted to a preassessment during process, if considered necessary and agreed on by the CAB and the LA. The plan for the assessment is as follows:

* Opening meeting (presentation of the plan for the assessment).
* Assessment of the CAB.
* Assessors’s meeting.
* Closing meeting (presentation of findings including confirmation of the accreditation scope between the CAB, the TA or TE and CYSAB).

All objective evidence must be recorded during the assessment on specified forms (see clause 7 - Forms).

**5.2. Assessment in head office**

**5.2.1 Opening meeting**

During the opening meeting the LA takes the following actions:

* Presenting the members of AT and explains the main aim of the assessment.
* Verifies the scope of accreditation.
* Requests from the head representative of CAB to present the rest of CABs’ representatives taking part in the meeting.
* Gives the opportunity to CABs’ representatives to present CABs’ main area of activities and give answers if any possible questions raised.
* Presents and explains the plan of the assessment, explaining in detail which part, each member of the AT, will assess. There shall not be a violation of the CABs’ working hours, if possible.
* Requests from the CABs’ to appoint an escort for each assessor. Any members of the staff that will have to be interviewed shall be available at any time.
* Confirms all the above arrangements with the CABs’ representative.
* Ensures verbally that all information and findings dealt by the AT will be treated with confidentiality.
* Explains the procedure until the completion and granting accreditation certificate.
* Requests from the CAB to appoint a representative to act as a contact point in case any matters arose.
* Requests from the CAB to provide a meeting place for the AT, where they can work and study the documentation and have regular meetings at their own.

**5.2.2 Main assessment**

In this stage a thoroughly assessment of the CABs’ MS and records is carried out.

An assessment is carried out to determine the CAB’s compliance with the relevant standard and its competence to perform its activities for which accreditation is sought. The assessment is carried out through the assessment of the records of MS, through the records of CAB’s clients as well as from in-person interviews with members of the staff (inspectors/auditors/supportive staff), in accordance with the relevant EA guidelines and/or European legislation and national law (where applicable).

If there is a need during this assessment, there is a possibility to revise the plan of on-site assessment accordingly.

An initial assessment can be converted to a preassessment during process, if considered necessary and agreed on by the CAB and the LA.

Nonconformities, if any found, are recorded in the form (F 04a.06).

In case where the CAB carries out its technical activities at its head office (in accordance with the European legislation and National law), on-site assessments can be carried out at the same time with the main assessment (e.g. Motor Vehicle Inspection Centers). Such an assessment is carried out in accordance with the clauses 5.3, 5.4 & 5.5 of this procedure.

**5.2.3 Intermediate meeting (where applicable)**

After the completion of the main assessment in the head office, an intermediate meeting is held, where all nonconformities (F 04a.06) are presented by the LA. LA asks the CAB’s management representative to accept them by signing them.

**5.3 On-site Assessment/Witness visit**

The on-site assessment aims to determine whether the CAB’s inspectors/auditors have the competency to:

1. Apply documented procedures of the CAB’s MS to its clients.
2. Inspect, to a satisfying level, the activities of the body undergoing inspection/audit or certification (CAB’s client).
3. Inspect the implementation of the requirements of European legislation and National law.

The CAB shall inform its clients (where applicable), in advance, that the CYS-CYSAB assessors will be present. The CAB shall explain to the client the reasons of their presence and shall receive the client’s approval.

The on-site assessment takes place during the initial assessment of the CAB and also during the surveillance visit and it should include either assessment of initial inspection/audit or certifications or surveillance inspection/audit or certification, or re-inspection/audit or certification of the client.

The on-site assessment should be carried out by the LA or the LA/TE that in this case acts as an LA. It is an essential requirement that both of them have the technical competency of the scope of the body undergoing inspection/audit or certification,

The LA makes arrangements with the CAB’s inspector/auditor in advance that, the inspector/auditor will give him the opportunity to point out the following:

* To acknowledge the body undergoing inspection/audit or certification for permitting CYS-CYSAB to be present during the inspection/audit or certification and to explain the role of the AT.
* To assure about their confidentiality.
* To describe in brief the role of CYS-CYSAB.
* To inform that objective evidences will be recorded during the assessment by himself and/or by other members of the AT which is relevant to the activities of the CAB’s inspectors/auditors.

The members of the AT observe in silence all the steps of the inspection/audit or certification, (opening meeting, the main inspection/audit or certification, the meetings of the inspection/audit or certification team, the closing meeting) avoiding to influence in any way the process or to provide consultation. They observe the activities of the CAB inspectors/auditors and they record their findings (F 04a.03).

After the closing meeting, at premises of the body under assessment (where applicable), a meeting is conducted between the CYS-CYSAB’s AT and the inspection/audit team of the CAB. The CYS-CYSAB assessors present verbally their findings regarding the performance of each inspector/auditor.

CAB submits the Certificate/Report of Inspection/Audit as soon as it is drafted and, in any case, no later than one (1) month.

**5.4 Closing Meeting / Assessment Report**

After the completion of all the assessment steps (main offices and on site) the AT visits the CAB’s work place, where applicable, where all the findings from the assessment are discussed, agreed and classified. The time schedule for their implementation is also agreed with the LAB If the Assessment Report (F 04a.10, F 04a.14, F04a.19) of the CAB cannot be prepared and handled straight after the completion of the assessment then, it should be prepared and delivered to the CAB within four (4) weeks. In any case all the findings of the on-site and head office assessment are presented to the CAB and the LA asks from the CAB to accept the nonconformities, and to be signed by the management representative or lead inspector/auditor.

In case the LA cannot reach a conclusion about a finding, the LA refers back to CYS-CYSAB for clarification. The LA provides a copy of the nonconformities to the CAB. Observations are also presented to the CAB at the closing meeting.

The CAB has to provide adequate documentation for the implementation of corrective actions within five (5) weeks as from the date of the assessment. During this period, the CAB shall submit to CYS-CYSAB a form fully completed (F 04a.29) referring to nonconformities, extent and cause analysis and corrective actions taken and attach the relevant documentation. In the case where non-conformities are not resolved in an efficient way or the proposed extent and cause analysis is inadequate having a risk of recurrence of the non-conformity and the AT continually asks the CAB to submit new documentation, then at the third deposition/submission of corrective actions the LA stops the procedure and directly prepares a report to the RC which will decide accordingly.

In cases where more time is needed for the closing of nonconformities, the time schedule of resolution of nonconformities shall not exceed the three (3) months from the date of the assessment.

In case the CAB asks, in a justified way, for an extension, this could be given after an approval by the DIR, provided that the whole time for closing all nonconformities does not exceed five (5) months from the date of the assessment.

If nonconformities are not resolved in a satisfactory way, an extraordinary assessment can be arranged after the approval of the DIR.

If, even so, the CAB cannot manage, the LA informs the RC and the procedure might be terminated after the decision of the RC and could be reactivated only after a new application is submitted by the CAB.

The assessment checklist form (F 04a.30) is used to document that all steps of the assessment procedure are implemented. Form F 04a.30 is placed within the file pocket of the CAB concerned.

The LA confirms how the scope of accreditation will be described on the Accreditation Certificate (it should be agreed both in Greek and in English). The certificate is issued either in Greek or English according to the CAB's need. The CAB may request the certificate to be issued in both languages. The scope of accreditation should depend, mainly, on:

* The quality records which are assessed in the main offices.
* The competency of the inspectors/auditors as it is described in their curriculum vitas and records.
* On-site assessments.

Later, the LA informs the CAB that when all nonconformities are resolved and the corrective actions are implemented then a Report for the RC is prepared. The Report includes the proposed scope of accreditation which is described on the Accreditation Certificate.

**5.5 Extraordinary Assessment (where applicable)**

During the examination of the proposed corrective actions, if the LA and/or the AS/TA/TE find it necessary, there shall be conducted an extraordinary assessment to confirm that the proposed/implemented corrective actions are satisfactory. The extraordinary assessment is restricted only to the nonconformities reported during the assessment and there will not be recorded any other nonconformities concerning other activities/issues.

**5.6 Classification of findings**

The findings shall be classified as follows:

1. **Major Nonconformity**

The absence of or insufficient documentation or failure to implement one or more accreditation requirements in a way that compromises the confidence in the accredited activity and any certificates issued under this activity.

1. **Minor Nonconformity**

A single deviation of small extend from the accreditation requirements or other CAB’s rules or procedures, which does not compromise the confidence in the accredited activity and any issued certificates under this activity.

1. **Observation**

A finding that does not constitute nonconformity at the time of assessment but can, if no measures are taken, lead to nonconformity in the future.

**6. Granting Accreditation**

Within one week from the resolution of all nonconformities, the LA submits to the RC the Report with the CAB’s file in which the following documentation should be included:

* CAB’s application form.
* Type of IB (For Inspection Bodies).
* Assessment Report.
* The proposed scope of accreditation in both English and Greek.
* Other documentation and/or information relevant to the LA’s recommendation.
* Documentation that the accreditation costs (application form cost, assessment costs etc.) have been paid off.

Within five (5) weeks, the RC meets to discuss the issue and decides to grant or not to grant the accreditation. The LA informs the CAB about the decision and sends a Certificate of Accreditation to the CAB (F 04a.22, F 04a.23, F 04a.24). As soon as a CAB is accredited, CYS-CYSAB has to remind it of its rights and responsibilities.

In case an application for accreditation is not accepted,the CAB is informed about possibilities for appeals.

Relevant provisions of Procedure OP 05 are implemented.

The LA makes publicly available the scope of accreditation of the CAB.

In cases that a inspection/product certification body does not have clients as mentioned in the scope of the application (for the purpose of notification) the requirements of «EA-2/17 §Annex C» is applied.

Specifically, when accrediting a CAB / conformity assessment activity for the first time, CYS-CYSAB grants accreditation under the condition that the CAB once notified informs CYS-CYSAB as soon as it receives requests from its first clients. The CAB shall cooperate with CYS-CYSAB during organization of the first activities for its clients to ensure that the witnessing of that activity takes place within 1 year. The CAB shall not issue accredited certificates until appropriate witnessing has been satisfactorily performed.

It is noted that the non-active activities on the scope will be removed after 2 year of the date of granting accreditation.

It is the responsibility of LA (CYS-CYSAB) to inform the CABs and receive their agreement/confirmation before submitting any information (findings) of the assessment to third parties.

**7. Forms**

**Forms for Certification / Inspection Bodies**

1,2 Notes on findings (F 04a.03)

Opening meeting - Attendance list (F 04a.04)

Final meeting - Attendance list (F 04a.05)

Nonconformity report (F 04a.06)

Appointment of LA/AT (F04a.07)

Four-year period surveillance program (F 04a.25)

Handling of nonconformities (F 04a.29)

3Assessment checklist (F 04a.30)

Risk Assessment-Initial assessment (Form F 04a.31)

**Forms for Inspection Bodies**

Application for Accreditation/ Extension of Scope of Inspection Body (F 04a.2)

Correlation of QM with the Clauses of CYS EN ISO 17020:2012 (F04a.17)

1Individual report of LA, AS, TA and TE (F 04a.18)

Report of the Assessment of Inspection Body (F04a.19)

2Table of the Clauses of the Standard being assessed (F 04a.20)

Report for Inspector Assessment (F04a.21)

Certificate of Accreditation (F 04a.22)

Assessment Plan for Inspection Body (F 04a.26)

**Forms for System Certification Bodies**

Application for Accreditation/ Extension of Scope of System Certification Body (F 04a.01b)

Evaluation of the documentation submitted (F04a.08)

1Individual report of LA, AS, TA and TE (F 04a.09)

Report of the Assessment of System Certification Body (F04a.10)

2Table of the Clauses of the Standard being assessed (F 04a.11)

Certificate of Accreditation (F 04a.23)

Assessment Plan for System Certification Body (F 04a.28)

**Forms for Product Certification Bodies**

Application for Accreditation/ Extension of Scope of Product Certification Body (F 04a.01a)

Evaluation of the documentation submitted (F04a.12)

1Individual report of LA, AS, TA and TE (F 04a.13)

Report of the Assessment of Product Certification Body (F04a.14)

2Table of the Clauses of the Standard being assessed (F 04a.15)

Report for Auditor Assessment (F04a.16)

Certificate of Accreditation (F 04a.24)

Assessment Plan for Product Certification Body (F 04a.27)

**8. References**

-Regulation for Accreditation (R 01)

-EA-2/17 M: 2020 EA Document on Accreditation for Notification Purposes

-IAF MD 4:2023 IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes

-IAF MD 5:2023 Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems

-IAF MD 7:2023 IAF Mandatory Document for the Harmonization of Sanctions and Dealing with Fraudulent Behaviour

-IAF MD12:2023 Accreditation Assessment of Conformity Assessment Bodies with Activities in Multiple Countries

-IAF MD20:2023 Generic Competence for AB Assessors: Application to ISO/IEC 17011

-IAF MD25:2023 Criteria for Evaluation of Conformity Assessment Schemes

1 In the case where clauses of the individual report are not sufficiently filled in, Form F 04a.03 shall be used with a clear reference to the appropriate clause of the individual report

2 Optional

3 Optional or when needed

**Appendix I**

***ANNEX A - PREFERRED STANDARDS (HS) PER LEGISLATION (MANDATORY)***Note: The column in table 1 entitled “other references equivalent to this module” covers nonaligned directives where there is a corresponding module covering the same process as the
NLF module. Table 2 covers non-aligned directives where there are specific attestation
modules that do not directly align with the standard NLF modules.
Where exceptions are identified, these are based on the expert opinion that the particular
module is used in a slightly different way to the other NLF directives.
**Table 1: Preferred Standards for Aligned Directives/Regulations and related Conformity
Assessment Activities:**

|  |  |  |  |
| --- | --- | --- | --- |
| Module  | Other references equivalentto this module | PreferredStandard | Exceptions |
| A1  | Internal productioncontrol plussupervised producttesting |  | ISO/IEC 17020 |  |
| A2  | Internal productioncontrol plussupervised productchecks at randomintervals |  | ISO/IEC 17020  | MeasuringInstrumentsDirective No2014/32/EU:ISO/IEC 17065 |
| B  | EU Type Examination | Machinery Directive No2006/42 EC- Annex IX;In vitro diagnostic medicaldevices (IVDMD) Directive No 98/79/EC Annex V;Active implantable medicaldevices (AIMD) Directive No90/385/EEC Annex III; |  ISO/IEC 17065 |  |
| C  | Conformity to EU-typebased on internalproduction control |  | ISO/IEC 17020(SPV)ISO/IEC 17065(HWB) | Module C doesnot require a NBwith theexception of:Simple PressureVessels DirectiveNo. 2014/29/EU(SPV)Hot-Water BoilersDirective No.92/42/EEC(HWB) |
| C1 | Conformity to EU-typebased on internalproduction control plussupervised producttesting |  | ISO/IEC 17065 | Recreationalcraft andpersonalwatercraft(RCD) Directiveno 2013/53/EU:ISO/IEC 17020 |
| C2  | Conformity to EU-typebased on internalproduction control plussupervised productchecks at randomintervals |  | ISO/IEC 17065 |  |
| D  | Conformity to EU-typebased on qualityassurance of theproduction process |  | ISO/IEC 17065 |  |
| D1  | Quality assurance ofthe productionprocess |  | ISO/IEC 17065 |  |
| E  | Conformity to EU-typebased on productquality assurance |  | ISO/IEC 17065 |  |
| E1  | Quality assurance offinal productinspection and testing |  | ISO/IEC 17065 |  |
| F  | Conformity to EU-typebased on productverification | Lifts and safety componentsfor lifts Directive No:2014/33/EC Annex V FinalInspection | ISO/IEC 17065 | Lifts and safetycomponents forlifts DirectiveNo: 2014/33/ECISO/IEC 17020 |
| F1  | Conformity based onproduct verification |  | ISO/IEC 17065 |  |
| G | Conformity based onunit verification | Noise emission in theenvironment by equipmentfor use outdoors Directive No2000/14/EC Annex VII | ISO/IEC 17065 |  |
| H  | Conformity based onfull quality assurance | Machinery Directive No2006/42/EC Annex X;Noise emission in theenvironment by equipmentfor use outdoors Directive No2000/14/EC Annex VIIIIn vitro diagnostic medicaldevices (IVDMD) DirectiveNo 98/79/EC Annex IV;Active implantable medicaldevices (AIMD) Directive No90/385/EEC Annex II; | ISO/IEC 17021-1 |  |
| H | Conformity based onfull quality assurance | 2014/68/EU Pressureequipment (PED) | ISO/IEC 17065 |  |
| H1  | Conformity based onfull quality assuranceplus designexamination |  | ISO/IEC 17065 |  |

**Table 2: Preferred Standards for Non-Aligned Directives/Regulations and Conformity
Assessment Activities, where there is no direct equivalent in the NLF Modules:**

|  |  |  |
| --- | --- | --- |
| Directive  | Conformity assessmentprocedure | Preferred Standard |
| 2014/68/EU Pressureequipment (PED) | Approval of NDT personnel  | ISO/IEC 17024 |
|  | Approval of PermanentJoining Personnel | ISO/IEC 17024 |
|  | Approval of PermanentJoining Procedures | ISO/IEC 17020 |
|  | European Approval ofMaterials | ISO/IEC 17065 |
| Construction ProductRegulation (EU) No305/2011 (CPR)(*see Annex E for details*) | System 1  | ISO/IEC 17065 |
|  |  |  |
|  |  |  |
|  |  |  |
|  | System 1+  | ISO/IEC 17065 |
|  | System 2+  | ISO/IEC 17065 |
|  | System 3  | ISO/IEC 17025 |
| 98/79/EC In vitro diagnosticmedical devices (IVDMD) | Annex III EC Declaration ofConformity | ISO/IEC 17065 |
|  | Annex VI EC Verification  | ISO/IEC 17065 |
|  |  |  |
|  | Annex VII EC Declaration ofConformity (Productionquality assurance) | ISO/IEC 17065 |

|  |  |  |
| --- | --- | --- |
| 90/385/EEC Activeimplantable medical devices(AIMD) modified by DirectiveNo 93/42/EEC, 93/68/EECand 2007/47/EC | Annex IV EC Verification  | ISO/IEC 17065 |
|  | Annex V EC Declaration ofConformity to Type(Assurance of productionquality) | ISO/IEC 17065 |
| 93/42/EEC Medical Devices  | Annex IV EC verification  | ISO/IEC 17065 |
|  | Annex V EC Declaration ofConformity - ProductionQuality Assurance | ISO/IEC 17065 |
|  | Annex VI EC Declaration ofConformity – ProductQuality Assurance | ISO/IEC 17065 |
| 2000/14/EC Noise emissionin the environment byequipment for use outdoors | Annex VI Internal control ofproduction with assessmentof technical documentationand periodical checking | ISO/IEC 17065 |
| 2010/35/EU Transportablepressure equipment (TPED) | Type Approval  | ISO/IEC 17020:2012(except clause 8.1.3) |
|  |  Supervision of manufactureand Initial Inspection andTests | ISO/IEC 17020:2012(except clause 8.1.3) |
|  | Periodic Inspections,Intermediate Inspectionsand Exceptional Inspection | ISO/IEC 17020:2012(except clause 8.1.3) |
|  | Surveillance of the inhouseinspection service | ISO/IEC 17020:2012(except clause 8.1.3) |
|  | Reassessment of conformity  | ISO/IEC 17020:2012(except clause 8.1.3) |

|  |  |  |
| --- | --- | --- |
| 2013/53/EU Recreationalcraft and personal watercraft(RCD) | PCA – Post constructionassessment | ISO/IEC 17065 |
| Railways InteroperabilityDirective (EU) 2016/797(IOD) | All modules in accordancewith Decision 2010/713/EUin conjunction with the ERAMandatory TechnicalDocument 000MRA1044. | ISO/IEC 17065 |

***ANNEX B - APPLICABILITY OF STANDARDS (HS) (MANDATORY)*Table 3: Conformity Assessment Standards for Accreditation for Notification purposes
incl. Applicable Additional Requirements:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Module**  | **Description**  | **EN ISO/IEC17065** | **EN ISO/IEC 17020** | **ENISO/IEC17021-1** | **EN ISO/IEC 17025** |
| **A**  | **Internal productioncontrol** | **N/A**  | **N/A**  | **N/A**  | **N/A** |
| **A1**  | **Internal productioncontrol plussupervised producttesting** | **1 + t**  | **\* 1 + t + cd**  | **1 + cd** |  |
| **A2**  | **Internal productioncontrol plussupervised productchecks at randomintervals** | **1 + t**  | **\* 1 + t + cd**  | **1 + cd** |  |
| **B**  | **EC type examination**  | **\* 1 + t + pk**  | **1 + t + cd** |  |  |
| **C**  | **Conformity to typebased on internalproduction control** | **N/A**  | **N/A**  | **N/A**  | **N/A** |
| **C1**  | **Conformity to typebased on internalproduction controlplus supervisedproduct testing** | **\* 1 + t + pk**  | **1 + t + cd**  | **1 + cd + pk** |  |
| **C2**  | **Conformity to typebased on internalproduction controlplus supervisedproduct checks atrandomintervals** | **\* 1 + t + pk**  | **1 + t + cd**  | **1 + cd + pk** |  |
| **D**  | **Conformity to typebased on qualityassurance of theproduction process** | **\* 1 + qa**  | **1 + qa**  | **1 + pk** |  |
| **D1**  | **Quality assurance ofthe productionprocess** | **\* 1 + qa**  | **1 + qa**  | **1 + pk** |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Module**  | **Description**  | **EN ISO/IEC17065** | **EN ISO/IEC 17020** | **ENISO/IEC17021-1** | **EN ISO/IEC 17025** |
| **E**  | **Conformity to typebased on productquality assurance** | **\* 1 + qa**  | **1 + qa**  | **1 + pk** |  |
| **E1**  | **Quality assurance offinal productinspection andtesting** | **\* 1+ qa**  | **1 + qa**  | **1 + pk** |  |
| **F**  | **Conformity with typebased on productverification** | **\* 1 + t + pk**  | **1 + t + cd** |  |  |
| **F1**  | **Conformity based onproduct verification** | **\* 1 + t + pk**  | **1 + t + cd** |  |  |
| **G**  | **Conformity based onunit verification** | **\* 1 + t + pk**  | **1 + t + cd** |  |  |
| **H**  | **Conformity based onfull qualityassurance** | **1 + qa + cd\*\*** | **1 + qa**  | **\* 1 + pk** |  |
| **H1**  | **Conformity based onfull qualityassurance plusdesign examination** | **\* 1 + qa**  | **1 + qa**  | **1 + pk** |  |

\*\*This applies for the Machinery Directive, the Pressure Equipment Directive and the Lifts Directive.

**Key**

**\* Indicates for the corresponding module the preferred standard that shall be used**

**whenever possible (refer to annex A for details of specific legislation).**

**1 The possible Harmonised Standards used for accreditation.**

**+ Additional applicable requirements of the other pertaining Harmonised Standards used**

**for assessing the NB, as relevant to the situation.**

**t Additional applicable requirements of EN ISO/IEC 17025 if testing is required. To this**

**end fulfilment of the applicable requirements of clause 6 and 7 (except 7.9) in EN**

**ISO/IEC 17025:2017 shall be demonstrated.**

**cd Capability of and procedures for judging and deciding based on results of tests and/or**

**inspections, if the essential requirements are fulfilled and/or the Harmonised Standards**

**have been applied when required. To this end, fulfillment of clauses 4.1.2, 4.1.3, 7.5 and**

**7.6 in EN ISO/IEC 17065:2012 shall be demonstrated.**

**pk Ability – based on product knowledge - to make professional judgments related to**

**product requirements where required. To this end fulfilment of clauses 6.1.2, 6.1.3 and**

**6.1.6 to 6.1.10 in EN ISO/IEC 17020:2012 shall be demonstrated.**

**qa Ability to assess and approve manufacturer’s quality systems where required. To this**

**end, fulfillment of clauses 7.1.1, 7.1.2, 7.2.4, 7.2.5, 7.2.8, 7.2.10 and 9.1 to 9.4 and 9.6**

**in EN ISO/IEC 17021-1:2015 shall be demonstrated.**

**Appendix II**

**Notification procedure A**

|  |  |
| --- | --- |
| **Notifying Authority :** | Ministry of Energy, Commerce, Industry and Tourism-CY-1421 Lefkosia (Nicosia) |
| **EU legislation :** | 2014/33/EU |
| **Legal Act :** | The Essential Requirements to be fulfilled by Specific Product Categories Laws of 2002until 2013 (as amended) – Chapter IV (Notified Bodies), Articles 16 to 26. These articles incorporate the provisions of Chapter R4 of the Decision 768/2008/EC. |
| **Guidance Document(s) :** |  |
| **Notification process :** | Description of the notification process 1. Application for Notification The body interestedto be notified as a Cypriot Notified Body for particular or specific products submits an application to the Notifying Authority. The format of the application is established by means of a Notification issued by the Minister of Energy, Commerce, Industry and published in the Official Gazette of the Republic of Cyprus. The application should be accompanied by the following certificates and documents: (a) the technical specifications used for the procedure for assessing the conformity of the product with the essential safety requirements or a description of the body’s own methods where no such specifications are used, (b) the conformity assessment procedure/s provided for in the Regulations transposing the Directive for the specific product or products the body requests to be approved, (c) the accreditation certificate issued by the Cyprus Organization for the Promotion of Quality, unless otherwise provided in the Regulations transposing the Directive, whereby evidence is given that the body meets the following requirements: (i) Necessary infrastructure in facilities, tools and equipment. (ii) Necessary personnel that should be adequately and technically qualified in relation to the product or products for which the body seeks approval and on the relevant conformity assessment procedures. The personnel must be characterized for its professional integrity, especially in keeping professional confidentiality. (iii) Independence and objectivity in relation to the persons directly or indirectly related to the product, especially with the manufacturer, the designer, the authorized representative and the distributor in relation to the tests, the drafting of the reports, the issuance of certificates and the conduct of the surveillance, which is provided for in the Regulations transposing the Directive. (iv) Insurance with an insurance against civil liability of the body, which derives from and in relation to the safety of the products and their compliance with the essential safety requirements. Along with the application, the body pays to the Ministry a fee, as prescribed by Regulations, for the examination and evaluation of the application by the Notifying Authority. Only applications from legal entities established in the Republic of Cyprus are accepted. 2. Evaluation of the application The assessment of the application is carried out by the Notifying Authority, which examines the documents submitted and establishes compliance or non-compliance with the relevant requirements. The Notifying Authority is comprised of one member representative from each of the following: (a) The Ministry of Energy, Commerce, Industry (President), (b) The competent authority for the product/s for which approval is sought (Member), (c) The Cyprus Organization for the Promotion of Quality (Member).3. Notification Procedure of the Conformity Assessment Bodies (CAB) The Notifying Authority informs the Commission and the member states the approved CABs, using the electronic notification tool developed and managed by the Commission. For the notification, the Notifying Authority provides the Commission with the following information on the approved CABs: (a) Name and address of the approved CAB (b) Period for which the notification is valid (c) Mode of assessment of the approved body’s technical skills (d) The product categories and the conformity assessment procedures for which the approved CAB is entitled to follow. The Notifying Authority informs the Commission and the member states of any subsequent changes to the notification. Cypriot approved CABs fall under the surveillance of the Cyprus Organization for the Promotion of Quality to ensure that they maintain at any given time the ability to carry out the conformity assessment procedure for which they are notified and that they still meet the requirements on the basis of which they are approved and notified. Each Cypriot approved CAB submits to the Notifying Authority an annual surveillance report, through the Cyprus Organisation for the Promotion of Quality, which includes the latter’s assessment as to the extent to which the Cypriot CAB is still able to conduct the conformity assessment procedure for the products for which it has been notified, as to whether it still fulfils the approval requirements and to what extent it applies consistentlythe conformity assessment procedures for the relevant products. |
| **CAB complies :** | With the requirements related to (Article 24) |
| **Accreditation :** | Requirements of Table 1 and Table 2 of Appendix I of this Procedure do applyNote: It is a requirement that module H in the Lifts Directive is assessed and accredited according to EN ISO/IEC 17065 based on table 3 of Annex B and the 1+ approach of the EA – 2/17 M:2020 document |
| **Requirements not covered by****accreditation standards :** | CAB does participate in Horizontal Committee of Notified Bodies established under thelegislation (or national committee)CAB complies to the information obligation of NB (art 34) |

**Notification procedure B**

|  |  |
| --- | --- |
| **Notifying Authority :** | Ministry of Energy, Commerce, Industry and Tourism-CY-1421 Lefkosia (Nicosia) |
| **EU legislation :** | 2014/34/EU |
| **Legal Act :** | The Essential Requirements to be fulfilled by Specific Product Categories Laws (asamended) – Chapter IV |
| **Guidance Document(s) :** |  |
| **Notification process :** | 1. Application for Notification The body interested to be notified as a Cypriot NotifiedBody for particular or specific products submits an application to the Notifying Authority. The format of the application is established by means of a Notification issued by the Minister of Energy, Commerce, Industry and published in the Official Gazette of the Republic of Cyprus. The application should be accompanied by the following certificates and documents: (a) the technical specifications used for the procedure for assessing the conformity of the product with the essential safety requirements or a description of the body’s own methods where no such specifications are used, (b) the conformity assessment procedure/s provided for in the Regulations transposing the Directive for the specific product or products the body requests to be approved, (c) the accreditation certificate issued by the Cyprus Organization for the Promotion of Quality, unless otherwise provided in the Regulations transposing the Directive, whereby evidence is given that the body meets the following requirements: (i) Necessary infrastructure in facilities, tools and equipment. (ii) Necessary personnel that should be adequately and technically qualified in relation to the product or products for which the body seeks approval and on the relevant conformity assessment procedures. The personnel must be characterized for its professional integrity, especially in keeping professional confidentiality. (iii) Independence and objectivity in relation to the persons directly or indirectly related to the product, especially with the manufacturer, the designer, the authorized representative and the distributor in relation to the tests, the drafting of the reports, the issuance of certificates and the conduct of the surveillance, which is provided for in the Regulations transposing the Directive. (iv) Insurance with an insurance against civil liability of the body, which derives from and in relation to the safety of the products and their compliance with the essential safety requirements. Along with the application, the body pays to the Ministry a fee, as prescribed by Regulations, for the examination and evaluation of the application by the Notifying Authority. Only applications from legal entities established in the Republic of Cyprus are accepted. 2. Evaluation of the application The assessment of the application is carried out by the Notifying Authority, which examines the documents submitted and establishes compliance or non-compliance with the relevant requirements. The Notifying Authority is comprised of one member representative from each of the following: (a) The Ministry of Energy, Commerce, Industry (President), (b) The competent authority for the product/s for which approval is sought (Member), (c) The Cyprus Organization for the Promotion of Quality (Member).3. Notification Procedure of the Conformity Assessment Bodies (CAB) The Notifying Authority informs the Commission and the member states the approved CABs, using the electronic notification tool developed and managed by the Commission. For the notification, the Notifying Authority provides the Commission with the following information on the approved CABs: (a) Name and address of the approved CAB (b) Period for which the notification is valid (c) Mode of assessment of the approved body’s technical skills (d) The product categories and the conformity assessment procedures for which the approved CAB is entitled to follow. The Notifying Authority informs the Commission and the member states of any subsequent changes to the notification. Cypriot approved CABs fall under the surveillance of the Cyprus Organization for the Promotion of Quality to ensure that they maintain at any given time the ability to carry out the conformity assessment procedure for which they are notified and that they still meet the requirements on the basis of which they are approved and notified. Each Cypriot approved CAB submits to the Notifying Authority an annual surveillance report, through the Cyprus Organisation for the Promotion of Quality, which includes the latter’s assessment as to the extent to which the Cypriot CAB is still able to conduct the conformity assessment procedure for the products for which it has been notified, as to whether it still fulfils the approval requirements and to what extent it applies consistentlythe conformity assessment procedures for the relevant products. |
| **CAB complies :** | With the requirements related to (Article 21) |
| **Accreditation :** | Requirements of Table 1 and Table 2 of Appendix I of this Procedure do applyIf accreditation is not used, please describe the additional requirements and steps in theaudit process (please use as guide the document SOGS N640 REV1 EN of 11 January 2011):In case no accreditation is used, the Notifying Authority assesses if the Conformity Assessment Body (CAB) applying as a Notified Body (NB), fulfils the requirements ofArticle 21, 23, 29, 31 of the Directive 2014/34/EU. The assessment is carried out as adocument check and an on-site assessment according to the essential provisions of the standards EN ISO/IEC 17065, as well as the additional relevant requirements for Annex III, IV, V, VI, VII, VIII and IX of the Directive. |
| **Requirements not covered by****accreditation standards :** | CAB does participate in Horizontal Committee of Notified Bodies established under thelegislation (or national committee)CAB complies to the information obligation of NB (art 31) CAB complies to the operational obligations of NB (art 29) |

**Notification procedure C**

Procedures for the assessment and notification of conformity assessment bodies (CAB) and the monitoring of notified bodies

|  |  |
| --- | --- |
| Notifying authority: | Name: Ministry of Energy, Commerce and IndustryAddress: 1421 Nicosia, CyprusContact person: Mr. Savvas Savva |
| EU legislation: | Directive 2014/68/EU Pressure Equipment |
| Legal act: | The Market Surveillance Law of 2022 – Chapter III (Notified Bodies), Articles 16 to 26. These articles incorporate the provisions of Chapter R4 of the Decision 768/2008/EC, relating to notification of conformity assessment bodies. |
| Notification process: | Description of the notification process1. Application for NotificationThe body interested to be notified as a Cypriot Notified Body for particular or specific products submits an application to the Notifying Authority. The format of the application is established by means of a Notification issued by the Minister of Energy, Commerce and Industry and published in the Official Gazette of the Republic of Cyprus. The application should be accompanied by the following certificates and documents:(a) the technical specifications used for the procedure for assessing the conformity of the product with the essential safety requirements or a description of the body’s own methods where no such specifications are used,(b) the conformity assessment procedure/s provided for in the Regulations transposing the Directive for the specific product or products the body requests to be approved,(c) the accreditation certificate issued by the Cyprus Organization for the Promotion of Quality, unless otherwise provided in the Regulations transposing the Directive, whereby evidence is given that the body meets the following requirements:(i) Necessary infrastructure in facilities, tools and equipment.(ii) Necessary personnel that should be adequately and technically qualified in relation to the product or products for which the body seeks approval and on the relevant conformity assessment procedures. The personnel must be characterized for its professional integrity, especially in keeping professional confidentiality.(iii) Independence and objectivity in relation to the persons directly or indirectly related to the product, especially with the manufacturer, the designer, the authorized representative and the distributor in relation to the tests, the drafting of the reports, the issuance of certificates and the conduct of the surveillance, which is provided for in the Regulations transposing the Directive.(iv) Insurance with an insurance against civil liability of the body, which derives from and in relation to the safety of the products and their compliance with the essential safety requirements.Along with the application, the body pays to the Ministry a fee, as prescribed by Regulations, for the examination and evaluation of the application by the Notifying Authority. Only applications from legal entities established in the Republic of Cyprus are accepted.2. Evaluation of the applicationThe assessment of the application is carried out by the Notifying Authority, which examines the documents submitted and establishes compliance or non-compliance with the relevant requirements. The Notifying Authority is comprised of one member representative from each of the following:(a) The Ministry of Energy, Commerce, Industry (President),(b) The competent authority for the product/s for which approval is sought (Member),3. Notification Procedure of the Conformity Assessment Bodies (CAB)The Notifying Authority informs the Commission and the member states the approved CABs, using the electronic notification tool developed and managed by the Commission. For the notification, the Notifying Authority provides the Commission with the following information on the approved CABs:(a) Name and address of the approved CAB(b) Period for which the notification is valid(c) Mode of assessment of the approved body’s technical skills(d) The product categories and the conformity assessment procedures for which the approved CAB is entitled to follow.The Notifying Authority informs the Commission and the member states of any subsequent changes to the notification.Cypriot approved CABs fall under the surveillance of the Cyprus Organization for the Promotion of Quality to ensure that they maintain at any given time the ability to carry out the conformity assessment procedure for which they are notified and that they still meet the requirements on the basis of which they are approved and notified. Each Cypriot approved CAB submits to the Notifying Authority an annual surveillance report, through the Cyprus Organisation for the Promotion of Quality, which includes the latter’s assessment as to the extent to which the Cypriot CAB is still able to conduct the conformity assessment procedure for the products for which it has been notified, as to whether it still fulfils the approval requirements and to what extent it applies consistently the conformity assessment procedures for the relevant products. |
| CAB complies: | To the requirements of Articles 24 and 25 of the Directive (whatever is applicable). |
| Accreditation: | EN ISO/IEC 17065 and EN ISO/IEC 17020 where applicable according to table 2 of Annex A of this ProcedureAssessment Process not based on AccreditationIn the case the Notifying Authority carries out the assessment of a body interested to be notified without relevant accreditation, it provides detailed and comprehensive information describing how the approved CAB has been assessed as qualified to carry out the tasks for which it is notified and showing that it fulfils the relevant criteria. |
| Specific activities performed by CAB: | Modules* Module A: Internal production control
* Module A2: Internal production control plus supervised pressure equipment checks at random intervals
* Module B: EU-type examination
* Module C2: Conformity to type based on internal production control plus supervised pressure equipment checks at random intervals
* Module D: Conformity to type based on quality assurance of the production process
* Module D1: Quality assurance of the production process
* Module E: Conformity to type based on pressure equipment quality assurance
* Module E1: Quality assurance of final pressure equipment inspection and testing
* Module F: Conformity to type based on pressure equipment verification
* Module G: Conformity based on unit verification
* Module H: Conformity based on full quality assurance
* Module H1: Conformity based on full quality assurance plus design examination

Note: It is a requirement that module H in the PED Directive is assessed and accredited according to EN ISO/IEC 17065 based on table 3 of Annex B and the 1+ approach of the EA – 2/17 M:2020 document. |
| Requirements not covered by accreditation: | * CAB does participate in Horizontal Committee of Notified Bodies established under the legislation (or national committee)
* CAB complies to the operational obligations (article 34)
* CAB complies to the information obligation (article 36)
 |

**Notification procedure D**

**D1: NOTIFICATION PROCEDURE ACCORDING TO REGULATION (EU) No 305/2011 CYPRUS**

|  |  |
| --- | --- |
| **Bodies/Procedures**  | **Remarks** |
| Notifying Authority  | Ministry of Interior1453 NicosiaCypruscp@moi.gov.cywww.moi.gov.cy |
| Accreditation Body  | Cyprus Organization for the Promotion of Quality1421 NicosiaCypruswww.cys.mcit.gov.cy |
| Certification of productsSystems 1, 1+ | Accreditation to EN ISO/IEC 17065:2012(or other standard amending or replacing this standard) |
| Certification of FPCSystem 2+ | Accreditation to EN ISO/IEC 17065:2012(or other standard amending or replacing this standard) |
| Testing laboratoriesSystem 3 | Accreditation to EN ISO/IEC 17025:2005(or other standard amending or replacing this standard) |
| Overview of the notificationprocedure | According to the National Legislation Construction ProductsLaw of 2013 Art. 11(1) and Art. 47(1) of CPR, applicationsfor the notification of a body authorised to carry out thirdparty tasks in the process of assessment and verification ofconstancy of performance are to be submitted to the Ministryof Interior.The accreditation is a mandatory requirement for organizationapplying for notification.Where the body concerned cannot provide an accreditationcertificate, it shall apply to the Cyprus Organization forPromotion of Quality for accreditation. |
|  | In the case where the Cyprus Organization for the Promotionof Quality is not an MLA signatory, then the body concernedcan choose to seek accreditation based on Art. 7 of Reg.765/2008.According to the above mentioned legislation Art. 8(1), theCyprus Organization for Promotion of Quality shall monitorthe notified bodies, including their compliance with Αrt. 43CPR. Also, based on Art. 8(2), every two years the CyprusOrganization for Promotion of Quality for accreditation shallprovide the Notifying Authority a report which includes theassessment of whether the Notified Bodies are still meet therequirements laid down in Art. 43 of Regulation (EU) No305/2011.Once the applicant’s ability to carry out third party tasks inthe process of assessment and verification of constancy isproved, the Ministry of Interior shall inform the EC (Art. 48(2) of CPR).If no objections are raised by the Commission or otherMember States in a period set in Art. 48(5) of CPR, theMinistry of Interior issues an official decision that approvesthe applicant to act as a Notified Body.According to the above mentioned legislation Art. 9(1) andArt. 50(1) of CPR, where the Ministry of Interior hasascertained or has been informed that a notified body nolonger meets the requirements laid down in Article 43, or thatit is failing to fulfill its obligations, it shall restrict, suspend orwithdraw the notification as appropriate, depending on theseriousness of the failure to meet those requirements or tofulfill those obligations. The Ministry of Interior based onArt. 9(2) shall immediately inform the Commission and theother Member States and shall publish the decision taken inthe Official Journal of the Republic of Cyprus. |

# Notification procedure D

|  |
| --- |
| **D2: Rules of Procedure of the Notifying Authority for Construction Products** |
|  | The following rules are hereby laid down for the purposes of establishing the operating procedure for the Notifying Authority with regard to the designation of Technical Assessment Bodies, the notification of Notified Bodies and the monitoring of the activities and responsibilities of those bodies. |
| Definitions | 1. For the purposes of these rules, the following definitions apply, unless the text specifically gives another meaning: |
|  | "competent authority" means the Ministry of the Interior for the implementation of the legislation on construction products and market surveillance; |
|  | "Regulation (EU) No 305/2011" means Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC; |
|  | "Law" means the 2013 Law on Construction Products as amended; |
|  | "Notifying Body" means the competent authority. |
|  | "national accreditation body" means the body referred to in Law 156 (Ι)/2002 (as amended); |
|  | "TAB" means the Technical Assessment Body; |
|  | "NB" means a Notified Body; |
|  | "member" means any member of the Notifying Body, including the president. |
| Composition of the Notifying Body | 2. The Notifying Body comprises the president and two members appointed by the competent authority. |
| Powers of the president | 3. The president heads the Notifying Body, convenes its meetings, signs the minutes and ensures that its decisions are implemented. |
| Convocation of meetings | 4. The president, by written letter, convenes meetings of the Notifying Body when he or she considers necessary or when requested to do so in writing by any of its other members. |
| Setting of the agenda | 5.-(1) The agenda shall be established by the president and communicated to the other members together with the convocation to the meeting and any other relevant documents.(2) Apart from the meeting convocation, the agenda and the minutes of each meeting, the documents sent to the Notifying Body by the applicant shall be treated as confidential. |
| Quorum and decision-making | 6.-(1) The Notifying Body shall be considered quorate if the president and at least one of the two other members are present.(2) Decisions of the Notifying Body are taken by a majority of members present. If a vote is tied, the president shall have the casting vote. |
| Notifying Body | 7. The president and the other members of the Notifying Body are not allowed to:1. have any financial or other interest which could influence their impartiality during the exercise of their statutory duties. Each member of the Notifying Body must sign a solemn declaration, as set out in Annex I, and submit it to the secretariat of the Notifying Body;
2. participate in the evaluation of the organisation;
3. offer or provide activities performed by NBs, or consultancy services on a commercial or competitive basis.
 |
| Third parties/ experts | 8. In the context of the exercise of its responsibilities, the Notifying Body is entitled to invite to its meetings any third persons, bodies, experts or government departments to provide any relevant information and/or additional elements relating to one or more items on the agenda. |
| Secretarial support | 9. The president ensures that secretarial support is provided to the Notifying Body. |
| Minutes of meetings | 10. Minutes are taken of every meeting of the Notifying Body. The president is responsible for taking the minutes. The minutes of each meeting of the Notifying Body are prepared by the president within fifteen days of the date of the meeting and are sent to the members for comment.Any comments on the minutes must be sent to the president in writing within one week of the date of the minutes being sent by email. |
| Approval of the minutes | 11. The minutes of each meeting are approved by the members and signed by the president. |
| Approval of Technical Assessment Bodies and notification of Notified Bodies | 12. The Notifying Authority is responsible for designating the Technical Assessment Bodies and for notification of the NBs. |
| Accreditation certificate and report on technical competence | 13.-(1) On request and on the basis of the results of relevant checks, the national accreditation body issues accreditation certificates for candidate NBs and reports on technical competence for technical assessment bodies. |
|  | (2) If the national accreditation body has been unsuccessful in its peer evaluation (MLA signatory) pursuant to Article 10 of Regulation (EC) No 765/2008), the candidate notified body may request accreditation pursuant to Article 7 of Regulation (EC) No 765/2008. |
| Technical accreditation assessment | 14. The technical assessment for the issue of an accreditation certification takes place as follows:(a) for the certification of products (systems 1 and 1+), certification is based on EN ISO/IEC 17065:2012, as amended or replaced in each case; |
|  |  |

|  |  |
| --- | --- |
|  | 1. for certificates of conformity of the factory production control (system 2+), certification is based on EN ISO/IEC 17065:2012, as amended or replaced in each case;
2. For a testing laboratory (system 3), certification is based on EN ΙSΟ/ΙΕC 17025:2005, as amended or replaced in each case.
 |
| Informing the Commission and other Member States | 15. The Notifying Authority shall announce to the other Member States and the Commission the name and address of the technical assessment body and the product fields for which it has been designated. The details of the notified body are also communicated to the Commission and the other Member States, chiefly by means of the electronic notification tool developed and managed by the Commission. |
| Monitoring of technical assessment bodies and notified bodies | 16.-(1) The national accreditation body monitors the activities and responsibilities of the technical assessment bodies and the activities and responsibilities of the NBs designated by the Notifying Authority and assesses them with respect to the conditions laid down in Articles 30 and 43 respectively of Regulation (ΕU) No 305/2011.(2) Every two years, the national accreditation body submits to the Authorising Authority a monitoring report on the technical assessment bodies and the NBs designated by the Notifying Authority, containing an evaluation of the extent to which the technical assessment bodies and NBs continue to meet the requirements laid down in Articles 30 and 43 respectively of Regulation (ΕU) No 305/2011. |
| Documentation | 17. The Ministry of the Interior forwards to the Notifying Authority and to the national accreditation body any EU documents relating to directives, regulations, guidelines, etc. pertaining to the approval/monitoring of technical assessment bodies and NBs. |
| Application form | 18. The Authorising Authority prepares/amends the application form, which it forwards to the Ministry for publication by announcement in theOfficial Gazette of the Republic pursuant to Article 11(1) of the Law. |
| Examination of applications | 19. The Authorising Authority examines applications and decides on whether or not the application is to be approved and, if so, under what conditions. |
| Notification of applicants | 20. Within three months of the date of submission of the application, the Authorising Authority must inform the applicant as to how far the application has been approved or rejected and for what reason(s).Regardless of the date of submission of the application, the time period of three months applies from the date on which the applicant has provided the Authorising Authority with all the required elements and information. |
| Additional information | 21. The Notifying Authority can ask the applicant for any additional information it considers useful for the assessment of the application. |
| Original documents | 22. The Notifying Authority may ask the applicant to produce the originals of certificates, attestations or other documents submitted to it in order to verify the accuracy of any elements and information. |
| Amendment of the rules | 23. These rules can be amended by decision of the Notifying Authority. |

**ANNEX Ι**

# Article 7 of the Rules of Procedure of the Notifying Authority

**Article 41 of Regulation (ΕU) No 305/2011**

# Solemn Declaration

I hereby declare that I shall exercise my duties as a member of the Notifying Authority conscientiously and impartially without fear or bias and shall maintain absolute discretion in the performance of my duties.

I understand that if I have any financial or other interest, directly or indirectly, in any application to be examined by the Notifying Authority or I have any specific relationship or any blood relationship or relationship by marriage up to the fourth degree with any person who has a clear financial or other interest in a matter being examined by the Notifying Authority, I must reveal this interest or relationship to the Notifying Authority and withdraw from the examination of the application in question.

Signature:

Full name:

Position:

Ministry/Department:

Date:

**Notification Procedure E**

**Procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies**

|  |  |
| --- | --- |
| Notifying authority:  | Name: Ministry of Communication and Works, Department ofElectrical and Mechanical ServicesAddress: P.O. Box 29669, 1722 NicosiaContact person(s): Charalambos Charalambous |
| EU legislation:  | Directive 2010/35/EU |
| Legal act:  | The Transportable Pressure Equipment Law [N.17(I)/2012] |
| Guidancedocument(s): |  |
| Notification process:  | **1. Description of the notification process**The body interested to be notified as a Cypriot Notified Body fortransportable pressure equipment submits an application to theNotifying Authority. Only applications from legal entities establishedin the Republic of Cyprus are accepted.The application should be accompanied by the accreditation certificateissued by the Cyprus Organization for the Promotion of Quality(CYS-CYSAB), whereby evidence is given that the body meets thefollowing requirements:(i) Necessary infrastructure in facilities, tools and equipment.(ii) Necessary personnel that should be adequately andtechnically qualified in relation to the product or productsfor which the body seeks approval and on the relevantconformity assessment / inspection procedures. Thepersonnel must be characterized for its professionalintegrity, especially in keeping professional confidentiality.(iii) Independence and objectivity in relation to the personsdirectly or indirectly related to the product, especially withthe manufacturer, the designer, the authorizedrepresentative and the distributor in relation to the tests, thedrafting of the reports, the issuance of certificates and theconduct of the surveillance.(iv) Covered by employer’s liability, professional indemnityand public liability Insurance.**2. Evaluation of the application**The assessment of the application is carried out by the NotifyingAuthority, which examines the documents submitted and establishescompliance or non-compliance with the relevant requirements. If theNotifying Authority is satisfied, it informs the Commission and themember states of the approved CABs, using the electronic notification  |
|  | tool developed and managed by the Commission.The Notifying Authority informs the Commission and the memberstates of any subsequent changes to the notification. |
| CAB complies:  | □ With the requirements related to Article 20 |
| Accreditation:  | EN ISO/IEC 17020 **ACCREDITATION IS ALLWAYS USED**Requirements of Table 1 and Table 2 of Appendix I of this Procedure do apply. |
| Specific activitiesperformed by CAB: | □ Please specify (product categories or standards, TSI conformityassessment procedures, etc.)**Product Categories**1. Pressure receptacles, including gas cartridges, their valves and otheraccessories when appropriate.2. Tanks, battery vehicles/wagons, multiple-element gas containers(MEGCs), their valves and other accessories when appropriate.**Procedure**-Conformity assessment activities-Exceptional checks-Intermediate inspections-Periodic inspections-Reassessment of conformity□ For designations under the CPR (Council Reg 305/2011 onConstruction Products), please indicate which hENs |
| Requirements notcovered byaccreditationstandards: | □ CAB does participate in Horizontal Committee of Notified Bodiesestablished under the legislation (or national committee)□ CAB complies to the information obligation of NB (art 27)□ CAB complies to the operational obligations of NB (art 26)□ Other |

**Notification procedure F**

|  |  |
| --- | --- |
| **Notifying Authority :** | Ministry of Energy, Commerce and Industry -CY-1421 Lefkosia (Nicosia) |
| **EU legislation :** | Machinery Directive 2006/42/EC |
| **Legal Act :** | The Essential Requirements to be fulfilled by Specific Product Categories Laws of 2002until 2013 (as amended) – Chapter IV (Notified Bodies), Articles 16 to 26. These articles incorporate the provisions of Chapter R4 of the Decision 768/2008/EC. |
| **Guidance Document(s) :** |  |
| **Notification process :** | Description of the notification process 1. Application for Notification The body interestedto be notified as a Cypriot Notified Body for particular or specific products submits an application to the Notifying Authority. The format of the application is established by means of a Notification issued by the Minister of Energy, Commerce and Industry and published in the Official Gazette of the Republic of Cyprus. The application should be accompanied by the following certificates and documents: (a) the technical specifications used for the procedure for assessing the conformity of the product with the essential safety requirements or a description of the body’s own methods where no such specifications are used, (b) the conformity assessment procedure/s provided for in the Regulations transposing the Directive for the specific product or products the body requests to be approved, (c) the accreditation certificate issued by the Cyprus Organization for the Promotion of Quality, unless otherwise provided in the Regulations transposing the Directive, whereby evidence is given that the body meets the following requirements: (i) Necessary infrastructure in facilities, tools and equipment. (ii) Necessary personnel that should be adequately and technically qualified in relation to the product or products for which the body seeks approval and on the relevant conformity assessment procedures. The personnel must be characterized for its professional integrity, especially in keeping professional confidentiality. (iii) Independence and objectivity in relation to the persons directly or indirectly related to the product, especially with the manufacturer, the designer, the authorized representative and the distributor in relation to the tests, the drafting of the reports, the issuance of certificates and the conduct of the surveillance, which is provided for in the Regulations transposing the Directive. (iv) Insurance with an insurance against civil liability of the body, which derives from and in relation to the safety of the products and their compliance with the essential safety requirements. Along with the application, the body pays to the Ministry a fee, as prescribed by Regulations, for the examination and evaluation of the application by the Notifying Authority. Only applications from legal entities established in the Republic of Cyprus are accepted. 2. Evaluation of the application the assessment of the application is carried out by the Notifying Authority, which examines the documents submitted and establishes compliance or non-compliance with the relevant requirements. The Notifying Authority is comprised of one member representative from each of the following: (a) The Ministry of Energy, Commerce, Industry (President), (b) The competent authority for the product/s for which approval is sought (Member), (c) The Cyprus Organization for the Promotion of Quality (Member).3. Notification Procedure of the Conformity Assessment Bodies (CAB) The Notifying Authority informs the Commission and the member states the approved CABs, using the electronic notification tool developed and managed by the Commission. For the notification, the Notifying Authority provides the Commission with the following information on the approved CABs: (a) Name and address of the approved CAB (b) Period for which the notification is valid (c) Mode of assessment of the approved body’s technical skills (d) The product categories and the conformity assessment procedures for which the approved CAB is entitled to follow. The Notifying Authority informs the Commission and the member states of any subsequent changes to the notification. Cypriot approved CABs fall under the surveillance of the Cyprus Organization for the Promotion of Quality to ensure that they maintain at any given time the ability to carry out the conformity assessment procedure for which they are notified and that they still meet the requirements on the basis of which they are approved and notified. Each Cypriot approved CAB submits to the Notifying Authority an annual surveillance report, through the Cyprus Organisation for the Promotion of Quality, which includes the latter’s assessment as to the extent to which the Cypriot CAB is still able to conduct the conformity assessment procedure for the products for which it has been notified, as to whether it still fulfils the approval requirements and to what extent it applies consistentlythe conformity assessment procedures for the relevant products. |
| **CAB complies :** | With the requirements related to (Article 24) |
| **Accreditation :** | Requirements of Table 1 and Table 2 of Appendix I of this Procedure do applyNote: It is a requirement that module H in the Machinery Directive is assessed and accredited according to EN ISO/IEC 17065 based on table 3 of Annex B and the 1+ approach of the EA – 2/17 M:2020 document |
| **Requirements not covered by****accreditation standards :** | CAB does participate in Horizontal Committee of Notified Bodies established under thelegislation (or national committee)CAB complies to the information obligation of NB (art 34) |