Quality systems explanatory document

Contents

PED quality systems certification

Following a conformity assessment procedure demonstrates compliance with the Pressure Equipment Directive 2014/68/EU (PED). The PED offers several options for this. As a pressure equipment manufacturer, you can choose from different conformity assessment modules that best suit your products and your manufacturing process. Here, we can draw a rough distinction between product-related modules and quality system-related modules.
ECH is authorised to conduct assessments of all modules (RvA C621 and C675). The way we carry out the process leading to the certification of a PED quality system is explained below.

Step 1 Module choise

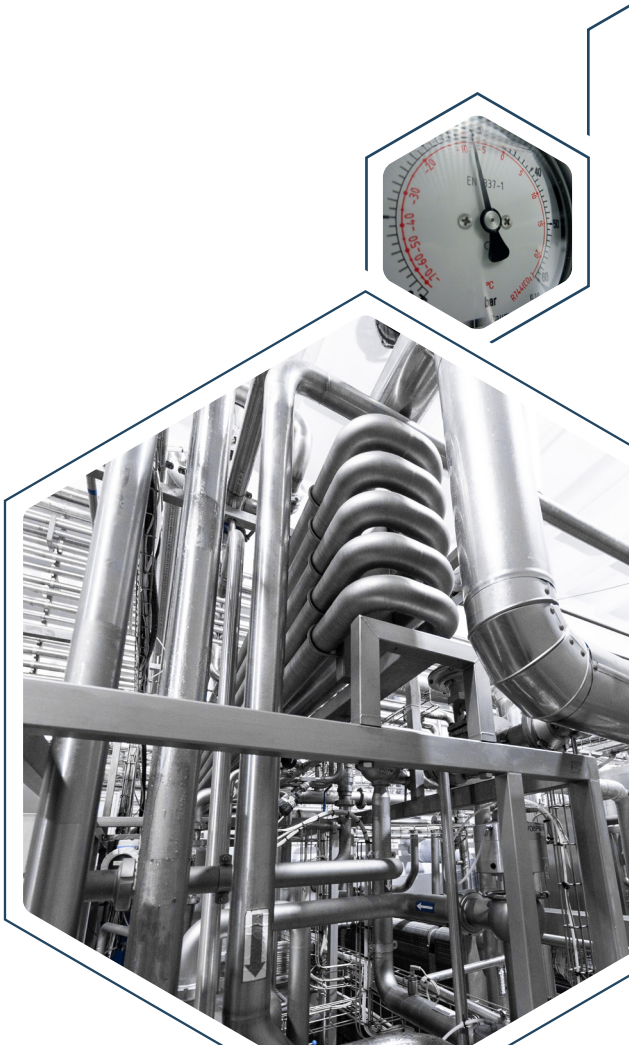
If you choose a quality module from the PED, you will have a choice of modules, D and D1, E and E1 and H and H1. These are all stand-alone modules that can be followed. For some, they can only be applied if you also have an EU-type examination. You make your choice according to the category classification in the PED (categories I to IV). The higher the category, the more extensive the monitoring. This has consequences for the options from which you can choose.
Various tools are available to help you choose the category classification and thus select the module. ECH has developed PED Select.nl for this purpose. This can also be installed as an application on a smartphone.
When you have selected a module, the PED also sets out the requirements for the quality system. It also outlines ECH's role as the certification body (EU-CAB) in the certification process.
ECH performs this work under accreditation. The certification of modules D, D1, E, E1 and H1 are carried out based on accreditation to EN ISO/IEC 17065.
The certification of module H, which relates to achieving conformity based on full quality assurance and is restricted to products in category III, is carried out based on accreditation to EN ISO/IEC 17021-1.

Step 2
Request a quotation

Once you have selected the module, you can request a quotation from ECH for performing the corresponding assessment.
We will ask you for the information we need to provide you with a balanced quotation. If required, we can also provide you with a statement of costs covering an entire three-year certification cycle.
The information we need to prepare a quotation includes product-related details, whether and to what extent you already have a quality system, whether it is certified or not, and information about the nature and scope of your manufacturing capabilities. If, based on the information provided by you, ECH determines that it does not have sufficient competence to carry out the certification, ECH will inform you of this and will not submit a quotation.

Stap 3
Applying for certification

If you decide to take advantage of our proposal, then the next step is that you submit an application for certification. You can request offers from several EU-CABs. However, before applying, we will ask you to declare that you did not submit the same application to multiple EU-CABs.
Along with entering into the contract to attain certification, we will also ask you to enter into a certification agreement with ECH. In this agreement, we lay down the ground rules for obtaining and maintaining an ECH certificate.
With your application, you will need to send us the necessary information we need to prepare for our investigation. We will send you a list of the details we think we will need.
At this stage, we reserve the right to reject an application. This may be the case if the information you send us is not sufficient for ECH to embark on the certification process.
You will be informed in writing as to whether or not we can accept your application. In the event of a rejection, we will set out the reasons for our decision. At any time, you can use the options we offer for lodging objections and appeals against the decisions ECH takes.



Step 4
Preparing for certification

The contract is entered into. The application is accepted and the certification agreement is signed. The first thing we do for you is put together an audit team. You will be informed about the members of the audit team. Again, you are free to express any objections or reservations you may have about the team members. We will match the size of the team to the expected scope and depth of the audit.
It is also possible that a Lead Auditor will carry out the audit without further support from an Auditor or industry expert.
Everything concerning the planning and organisation of the audit will be looked after by ECH's Audit Coordinator. In terms of audit content, you will have the opportunity to communicate with the Lead Auditor.
Before the audit, we will send you details about the time we expect the audit will take, the audit plan and the audit programme. We will also inform you about who and what you want to mobilise during the

audit.

Stap 5
Initial audit

When you have your management system certified for the first time, it is referred to as the initial audit. The initial audit consists of two phases which are explained below. The audit plan specifies the days and times when the assessments will take place. The audit programme shows which elements of the standard are to be assessed. If a Phase 1 audit is planned, it is preferable to leave sufficient time between Phase 1 and Phase 2. This will allow you to process any experiences from Phase 1 prior to Phase 2.

Phase 1 - Pre-examination
In Phase 1, the audit team assesses the system documentation. This investigation can be conducted at your premises or in the ECH office. The audit plan specifies where this assessment will be carried out. Using the results of the pre-examination as a guide, the Lead Auditor will decide whether there is enough reason to be confident that Phase 2 could produce a positive outcome. You will be informed about this in writing. Deferring Phase 2 to a later date in order to give you more time to prepare is also possible.

Phase 2 - Implementation audit
During the Phase 2 audit, the deployment and effectiveness of the quality system are assessed. This assessment is always conducted at the client's premises. The audit team conducts audits to establish compliance with the Directive. Non-compliance is established if the evidence identified during the audit reveals a deviation from the normative element in the PED.
You will receive a report about this, and if there are any nonconformities, you will be given the opportunity to respond to them.
If no nonconformities are identified, or if they have been closed satisfactorily, then the Lead Auditor will formulate recommendations in the audit report. The audit report containing a full report of the audits conducted and the Lead Auditor's recommendations are then sent to the PED Certification descision maker.

Stap 6
Certification descision

The certification decision is a stand-alone process. The ECH's PED Certification Officer decides whether to proceed with certification. The audit report drawn up by the Lead Auditor and his/her recommendations form the input for the decision.
If the Certification Officer's decision is positive, then certification follows. We will send you a certificate and the audit report. The certificate remains valid for three years.
If the decision is negative, you will be informed and the reasons given. You will also be sent the audit report. Again, you will have the opportunity to lodge an objection and/or appeal in relation to the decision taken.

Stap 7
Surveillance audits

Within the three-year cycle, two surveillance audits take place and the recertification audit is conducted. These audits are held annually. The purpose of the surveillance audits is to verify, in accordance with the Audit Programme, whether the quality system is still operational and meets the applicable requirements. Control audits are reported in writing.
Some modules of the Directive also include random checks of the product itself. These random checks are performed by an inspector. You will be sent inspection reports on the random checks.

Stap 8
Recertification

Recertification comes at the end of the three-year cycle. The timing of the recertification audit is chosen to allow enough time to rectify any shortcomings that may have been identified without causing a break in the certification process. Recertification is also combined with the recommendations that the Lead Auditor makes to the PED Certification Officer about the continuation of certification.
If the PED Certification Officer's decision is positive, then you will receive a new certificate with a new validity period.

Additonal information

Suspending, revoking, restricting and restoring a certificate
ECH remains the owner of the certificate at all times, even after its issue. ECH will issue a request for the certificate to be returned after a decision to revoke it has been taken or if a restriction in the scope of certification means the certificate needs to be amended. The PED Certification Officer is authorised to take the unilateral decision to suspend, revoke or restrict the certificate. In all cases, the board and/or management of the certificate holder will be notified in writing.
As a certificate holder, you may voluntarily indicate at any time that you wish to waive the certification.

Suspending the certificate
Failure to respond adequately to observed nonconformities is grounds for suspension. Improper use and/or misuse of certification may also be grounds for suspension. Failure to comply with financial agreements with ECH is also grounds for suspension. Suspension of the certificate is used as a first resort before proceeding to revocation. Suspension always has a time limit and can last up to three months.
Restoration of Certificate Holder status following suspension is possible without additional audits. After a decision to revoke certification has been taken, the recertification process always starts with a new audit.

Revoking or restricting the certificate
The decision to revoke or restrict the certificate is taken if suspension fails to result in a resolution. Another reason for revocation may be the products covered by certification are not manufactured for more than one year, or if problems meeting financial obligations persist. Misuse of certification, deceptive practices related to certification, bringing ECH into disrepute, or misuse of certification-related visual marks can also produce grounds for a decision to revoke or restrict a certificate.
There could be other grounds for revoking or restricting a certificate. Such grounds can always be traced back to a specific regulatory basis in the PED and/or the Dutch accreditation scheme for EU CABs.

Extending the scope of certification
If you wish to extend the scope of certification, for example, because you wish to add a new EU-Type Examination to the manufacturing process, you may submit a request at any time. You can contact the Lead Auditor or our Audit Coordinator for this purpose. They will check with you whether we need to start the process of issuing a quotation or whether you can start applying right away. You should assume that each extension of the scope will involve audit activities. The Lead Auditor will assess whether these audits can be combined with the audits that are already scheduled.

The use of visual marks and logos

Our Certification Marks Style Guide on this website contains all the information you need to use our quality label responsibly once you are certified. We also set out rules about this issue in our certification agreement.

You may only use our visual marks and logos after we have entered into the agreement and certification is a given. If you have any doubts or questions about this, please contact us. We will help you further.

Complaints, objections and/or appeals

The Rules on submitting a complaint, objection or appeal as well as your opportunity to share a view with us are available on our website. If you feel this way of providing us with your client feedback is too much effort, we would still invite you to share your experience with us. We greatly appreciate receiving positive client feedback as it lets us know what we are doing well. We always analyse and follow up on negative client responses so we can make improvements where possible.

Independent and Impartial

ECH is committed to performing all its activities as an independent service provider. This commitment is embodied in our mission statement .

Independence is the foundation of impartiality and being free from conflicts of interest. It is an integral part of our way of working and thinking so we are always willing and able to be accountable for it.

Authorised
Involved
Flexible

ECH provides a social service by delivering highquality professional services covering energy, the environment and safety.

Would you like to request more information, or make an appointment?
Please contact us by phone on 0318 - 55 11 06 or visit www.ech-groep.nl

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