Pressure Equipment Directive 2014/68/UE assessment /certification process

CLIENT INFORMATION NOTE

Overview

This Client Information Note explains the main stages of our process for conformity assessment under the provisions of the Pressure Equipment Directive 2014/68/UE (PED).

Conformity Assessment quality modules (D, D1, E, E1, H, H1).

For quality modules, assessment process normally includes two visits to your site before we can recommend approval. We call these two visits:

- Stage 1 (document review and planning visit), and
- Stage 2 (initial assessment).

Once we have issued your approval certificate, we will carry out surveillance visits and un-expected visits to maintain your approval.

Before we visit, we will discuss and agree with you the visit dates, start and finish times, the assessment team members, how long the visit will last, and which parts of your business we will visit.

Visits will be carried out and reported in your national language unless otherwise agreed.

Stage 1 - Document review and planning visit

Purpose of the visit

We do this visit to:

- find out whether the management system processes and documents addressed the relevant essential safety requirements of PED and put into practice so that a meaningful Stage 2 assessment can take place.
- collect information about your company's organisation, processes and activities so that we can develop a plan for the Stage 2 assessment.
- confirm the scope, assessment team requirements and timing for the Stage 2 assessment
- answer any questions you may have about our service.

The visit will identify any weaknesses or omissions in your system that may need to be put right before the Stage 2 assessment.

Carrying out the visit

The visit (which usually lasts for two days), starts with an opening meeting.

The assessor will explain to your management team how we carry out assessments, and you will be able to introduce your company. The assessor will agree a plan for the visit with you.

The assessor will then:

- Assess the management system documentation to confirm that the relevant essential safety requirements of the PED have been addressed.
- Evaluate the client's location and specific conditions of the manufacturing premises.
- Assessment of the client's self-governance, internal audits and management review.
- Confirm that the manufacturer has established technical documentation relevant to the products being manufactured under the scope of the approval.
- Confirm that there is a procedure in place to communicate any change to us, the NoBo. In case of Modules E or D check that there are any design approved by a Notified Body.

- Confirm the contractual arrangements including any changes required as a result of the outcome of the Stage I assessment (including changes to the scope of assessment, duration of the Stage 2 visit, and duration of subsequent surveillance visits).
- Determine the planning, logistics, sampling regime that will be used during the Stage II visit.

The visit ends with a closing meeting to present the Stage 1 report and agree the next stage of the assessment process, including any health and safety, security and administrative issues.

The documentation reviewed during the Stage 1 visit will be used at future visits as a baseline. However, you should continue to amend system documents as a result of internal improvement activities. At each visit we will need to identify the changes between the latest issue and the baseline.

Stage 2 - Initial Assessment

Purpose of the visit

The aim of the Stage 2 assessment is to evaluate the implementation and effectiveness of the manufacturer's management system and verify compliance with the applicable requirements of the Regulations. Objective evidence must be obtained by means of interviews, review of documents and records, and observations of processes and activities.
The assessment shall take place at the key site(s) of the client including design, fabrication and testing facilities as necessary and at locations subcontracted by the manufacturer that have an impact on the quality of the products being produced (e.g. facilities used for forming, heat treatment, joining, etc.).

Carrying out the visit

The assessment follows the plan prepared during the Stage 1 visit. Members of the assessment team will visit areas with guides who can witness the findings and help the assessment.

The Stage 2 assessment usually includes a meeting with the representative of senior management with overall responsibility for the management system.

During the visit our assessor (s) will:
- Conduct a follow-up of findings from the Stage 1 visit
- Verify the organizational structure, and responsibilities concerning PED.
- Corrective actions: review of complaints, nonconformities, and concessions received.
- Operational control (including product checks / tests during and after the fabrication).
- Review technical files.
- Confirm the adequacy of quality records (such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests, etc.
- Verify product conformity and compliance with the essential requirements of the PED which require CE marking including the adequacy of the technical documentation.
- Application of the CE marking, labelling, user and operating instructions, and Declaration of Conformity.
- Witnessed a final assessment in order to check that there are in place adequate procedures, qualified personnel, installations and measurement and that final verification is carried out according to PED, annex I, section 3. 2 Final Assessment.

The assessment team will hold review meetings with you each day to discuss any findings. Appropriate staff should be present to confirm that you accept these findings. Please see below in the 'Reporting' section for how we define findings. We finalise the grade of findings at the end of the visit.

The visit ends with a closing meeting to present a summary of the findings, and to agree the next stage of the assessment process. The assessor will give a complete report to your management representative. If we have not reported any Major Nonconformities, and you have informed the assessor of your proposed corrective action for any Minor Nonconformities, the assessor will recommend approval to the assessment standard (although this depends on an independent technical review by our office.) However, if any Major Nonconformities have been reported, we will delay approval and carry out a follow up assessment to review corrective actions. Our team leader will agree with you the arrangements for this.

Surveillance visits

Purpose of the visit

The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system and maintains and applies the quality system.

Surveillance audits shall be conducted at least once per calendar year, except in recertification years.

If the certified client does not allow surveillance or recertification audits to be conducted at the required frequencies, then the suspension or withdrawal of certification process will start.

Carrying out the visit

The scope of the surveillance visits will normally have been agreed with you at your previous visit. We will confirm the details with you at an opening meeting.

The assessment for each surveillance visit shall include:
- internal audit and management review processes
- Review of actions taken on nonconformities identified during the previous audit(s).
- corrective action processes including customer complaints.

- changes to your system and the effectiveness of their implementation, and
- Continuing operational control (manufacturing of the product within the approved scope).
- Review quality records as provided by the manufacturing part of the quality system such as inspection reports and test data, calibration data, qualification reports on the personnel concerned (Welders, NDT operators)

We will also review how you use LRQA mark, CE mark and our Notified Body number.

If we report any Minor Nonconformities during a visit the assessor will agree with you the deadlines for the issuance of a plan with corrective actions.

If we report a Major Nonconformity during a surveillance visit, we will arrange a special surveillance visit to follow up the necessary corrective action (normally within three months).

This is the first phase of our suspension and withdrawal of approval process.

At the closing meeting, our assessor will report on the current visit and agree with you the theme for the next visit. If any Major Nonconformities have been reported, the assessor will also agree arrangements for follow-up of actions you will take.

Certificate renewal

Planning for the certificate renewal

We conduct certificate renewals on a three-yearly basis, planned at the previous surveillance visit and agreed with you.

Purpose of the visit

The aim of the recertification audit is to confirm the continued conformity of the approved quality system with the requirements of the Regulations.

Conducting certificate renewal visits

We conduct the certificate renewal visit similarly to a Stage 2 assessment. In addition, we include a review of your system documentation to ensure that it:

- continues to suit your company, and
- complies with the certification requirements and the scope of certification.

If during the assessment, minor deviations are documented, you will inform and deadlines for the implementation of the corrective actions will be agreed with you.

Recommendation for certificate renewal can't be made till the assessor has evaluated the corrective actions proposed by you.

If major non-conformities are raised, the suspension process must be applied. The Certificate of Conformity shall not be re-issued until all major nonconformities have been closed out.

Changes to your approval

For any increase or decrease in your certificate of approval, please submit a formal request for the change. LRQA will review the request to consider:

- additions or changes to competency requirements for the visit team(s)
- additions or reductions in visit duration requirements
- and you will be notified of any changes by an amended contract.

If the change requested has meant a major change or addition to your documented system, we will undertake a separate document review visit (Stage 1).

We will conduct the change to approval visit in line with our process for Stage 2 assessment visits, although we do not normally produce a formal visit plan. If we did not need to conduct a document review (Stage 1), we will allow time during the visit for the team leader to review relevant documentation and to agree a plan for the visit.

Change to approval visits may be carried out as separate visits or may be combined with a scheduled (Surveillance or Certificate Renewal) visit.

LRQA will issue a new revision of certificate, using the same expiry date as on the current certificate.

Unexpected visit

As part of the surveillance process, we will conduct, in addition to the annual surveillance visit, unexpected visits.

The number of unexpected visits shall equal 2 in the first year of production for Category III & IV equipment and a minimum of 1 for Category II equipment.

For subsequent years the number of unannounced visits can be calculated bearing in mind: No. Of equipment to be manufactured, outcomes from previous visits demand for follow up of corrective actions, significant changes in the organization of the manufacturer, quality system, productive means, new technics, etc

The visit shall confirm the number of items covered by the approval being manufactured, the outcome from previous audits / visits which require follow-up of corrective actions, significant changes in the quality system and production / testing methods.

The following elements will be checked / confirmed during this visit to verify that the manufacturer's quality system functions correctly:

- Verify fully implementation and efficiency of any corrective action proposed by client to close any minor non conformity open during the previous unexpected visit of during the last initial/surveillance /renewal visit.
- Conformity of the selected product(s) with the technical documentation.
- Traceability of all critical components and materials.
- Fabrication / manufacturing activities ongoing at the time of the visit.
- Manufacturer's documentation relevant for the fabrication / manufacturing / testing activities.

At the time of the visit and where possible, product tests will be carried

out and / or witnessed in order to check the operational control.

Special surveillance of the final assessment

For module H1 special surveillance of the final assessment visit need to be conducted, so the manufacturer will inform on the items for final assessment. During the final inspection points in paragraph 3.2.2 of the Annex I of the Directive will be witnessed.

Reporting

The reporting process for all our visits is similar. We fill in visit reports to record assessment findings, progress against the assessment plan, positive comments, and also points of clarification or interpretation. We record assessment and identify them as Major Nonconformity or Minor Nonconformity. We define these gradings as follows:

Major nonconformity

The absence of, or the failure to implement and maintain, one or more quality system elements, or a situation which would, on the basis of the available objective evidence, raise significant doubt of the management to achieve:

- The policy, objectives or public commitments of the organization.
- Compliance with the applicable regulatory requirements.
- Conformance to applicable customer requirements.
- Conformance with the audit criteria deliverables.

Typically, fundamental issues with the quality system, the risk of products not complying with requirements of the Regulations or noncompliance of the essential safety requirements (ESRs), changes to the product or in the approved Quality System invalidating the results of the tests previously carried out.

Minor nonconformity

A finding indicative of a weakness in the implemented and maintained system, which has not significantly impacted on the capability of the management system or put at risk the system deliverables but needs to be addressed to assure the future capability of the system.

Typically, minor errors in the system documentation (typographical), errors in data records, results, etc., should not be regarded as non-compliances as they do not indicate a weakness in the quality system.

Our team leader will make arrangements with you for follow up.

According to Pressure Equipment you have to, for a period ending 10 years after the pressure equipment has been placed on the market, keep at the disposal of the national authorities the decisions and reports of the notified body.

Sampling

It is important to remember that even though a problem may not have been identified in an area of activity, it does not necessarily mean that there are no problems. As assessment work is based on sampling techniques, statistically there is always a possibility that issues will not be identified during an assessment. Please consider this when you audit your own management system.

Conformity Assessment module C2.

In order to verity the quality of the final assessment and the internal checks conducted by you, we carry out visits at random intervals. The number of visits to be conducted is defined in our annual quote.

In order to schedule those visits you have to submit to LRQA, on monthly basis, your production plan.

During those visits we:

- Review the EU Type Examination Certificate (s) provided by the client.
- Review the manufacturing records including, but not limited to, procedures and personnel qualifications, materials certificates and examination and test records in order to verify that the final evaluation has been performed appropriately by the client.
- Conduct visits (which could be unannounced) to perform tests over manufacturing production samples in order to verify conformity with the type.

Results and details of all checks conducted during those visits are recorded in a visit report.

The EU certificate of conformity is valid for 1 years is renewable.

If during the visits it is found that the samples do not meet the accepted quality levels, or do not conform to the type described in the EU-type examination or do not meet the requirements of the directive, additional visits will be necessary to verify the implementation of the measures in place to solve the non-conformities detected.

When such non-conformities are considered very significant and could be prejudicial to the manufacturer capacity to comply with the existing authorization to use LRQA Inspection Iberia, S.A.. Notified Body number 0094, then the authorization could be:

- Suspended and a corrective action will be required in a given period of time. During this suspension period, the products cannot be CE marked.
- Withdrawal if the corrective action is not executed in the defined period.

Conformity Assessment module F

Suitable examinations are carried out to verify the conformity of the pressure equipment with the type described in the approved Type Examination certificate and satisfies the requirements of the Directive that apply to it.

To carry out those examinations some visits are conducted during the manufacturing process

During those visits we:

- Review the EU Type Examination Certificates provided by the client.

- Verify that permanent joining of components are carried out by suitably qualified personnel according to suitable operating procedures and that those operating procedures and personnel are approved by a notified body or a third-party organisation recognised for PED.
- Verify that non-destructive tests of permanent joints are carried out by suitable qualified personnel approved by a notified body or a third-party organisation recognised for PED.
- Evaluate the materials and verify the certificates issued by the materials manufacturer in accordance with PED point 4.3 of Annex I
- Carry out the final inspection and proof test and examine the safety devices, if applicable.
- Detail and Results of all examinations conducted are recorded in a visit report.

Where non-conformities have been identified these shall be rectified before the certificate (s) can be issued.

Conformity Assessment inspection module B – Type examination

For Production Type – the adequacy of the technical design of the pressure equipment is carried out by examination of the technical documentation and supporting evidence, plus examination of a specimen (complete pressure equipment), representative of the envisaged production.

Details and Results of the design review are recorded in a design appraisal document. Details and Results of all examinations conducted in the prototype are recorded in a visit report.

Design Type – The adequacy of the technical design of the vessel is carried out by examination of the technical documentation and supporting evidence without examination of a specimen.

Details and Results of the design review are recorded in a design appraisal document.

Where non-conformities have been identified these shall be rectified before the certificate (s) can be issued.

The Type Examination certificate is valid for 10 years and is renewable.

Conformity Assessment module G

In order to check the conformity of the pressure equipment with the applicable requirements of the Directive. We conduct or check that examinations and tests, set out in the relevant harmonised standard(s) and/or equivalent tests have been carried out.

As part of the certification process we:

- Review all the technical documentation regarding the design and the manufacturing procedures.
- Evaluate the materials and verify the certificates issued by the materials manufacturer in accordance with PED point 4.3 of Annex I.
- Verify that permanent joining of components are carried out by suitably qualified personnel according to suitable operating procedures and that those operating procedures and personnel are approved by a notified body or a third-party organisation recognised for PED.
- Verify that non-destructive tests of permanent joints are carried out by suitable qualified personnel approved by a notified body or a third-party organisation recognised for PED.
- Conduct visits during the manufacturing process in order to perform inspections and tests as required by the applicable harmonised or reference standards.
- Perform the final inspection and the proof test of all the equipment.
- Examine the safety devices, if applicable, of all the equipment.

Confidentiality

We will not pass on any of the information we gather about your organisation (including the contents of reports) to any other person or organisation without your permission (except as required by the accreditation body or National Authorities).

Further information

You can get additional information about the conformity assessment process by sending an email to madrid-aroc@lrqa.com.

Get in touch

Visit www.lrqa.com/es-es for more information

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YOUR FUTURE. OUR FOCUS.