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Test and Certification Regulations

General terms and process guidelines for the certification of quality management systems by the TÜV Certification Office according to the Ex-Protection-Guideline and EX CB (Ex Certification body) in the IECEx-System issued by TÜV Rheinland Industrie Service GmbH

Inhalt

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0. Pre notice

The TÜV Certification Office for QA-Systems according to the guideline 2014/34/EU for Exprotection and EX CB (Ex certification body) in the IECEx-System issued by TÜV Rheinland Industrie Service GmbH (hereinafter called Certification Office) offers its services to interested companies, for the certification of QA-Systems for Ex-Protection- Products or Productions.

The obligation and securing of independence and objectiveness of the appointed auditors is guaranteed by TÜV. With the current organizational setup and routine at TÜV, the criteria specified in DIN EN ISO/IEC 17021 are met. The organization and the certification process are documented in appropriate Quality Management Handbooks.

1. Area of application

This test and certification ordinance regulates the certification and monitoring of QA-Systems based on the guideline 2014/34/EU respectively IECEx-System.

2. Certification process

2.1 Prerequisites

2.1.1 The ordering party instructs the TÜV Certification Office with the certification of its QA-system according to the Ex-Protection-Directive respectively IECEx-System.
The certification request is accompanied by a written declaration of the customer that no other certification office (notified body / EX CB) has been assigned to perform the same process.

2.1.2 When the order is placed initially with the certification office with the goal of obtaining a certification, it will enter into an „Agreement regarding the certification of its QA-system in accordance with guideline 2014/34/EU Ex-Protection-Guideline respectively IECEx-System“ with the ordering party.

With the signing of the above mentioned agreement, both contract partners consider the stipulate ons out of this test and certification ordinance as binding. The ordering party must be a properly registered corporation.

2.1.3 A multi-side sampling at several locations is not allowed. All sites with production and final testing of explosion protection products must be considered.

2.2 Procedure

The evaluation process of the QA-systems based on Guideline 2014/34/EU –Ex-Protection-Guideline respectively IECEx-System is divided into phases. The auditors are selected by the cer tification office according to its license for the branch of industry and qualification.

2.2.1 Optional pre-audit

In the pre-audit, the auditor assesses the extent to which your organization has implemented the requirements of the relevant standard. This assessment covers a document review plus an on-site visit with subsequent preparation of a pre-audit report including a statement on your system's basic readiness for certification.

2.2.2 Certification audit (stages 1 and 2)

Certification audits consist of two stages. Prior to the certification audit, you must take steps to en sure that:

- within the previous 12 months, all units of the organization to be certified have been assessed in internal audits carried out according to the relevant certification standard(s)

- non-conformities resulting from internal audits have been corrected
- a management review has been performed
- For each auditor, the customer must provide a supervisor for guidance and support in the audit

Stage 1
In stage 1 of the certification audit, your management system documentation (management manual, procedures and work instructions etc.) is reviewed to verify that your organization fulfils the key requirements for a stage 2 audit. Apart from the above, the organizational and process structure of the organization, the current information about the organization to review the contract details (e.g. number of employees, scope, etc.) and the points listed under 3.3 are reviewed.

The stage 1 audit is generally conducted on site at the earliest 6 months before the stage 2 audit. On a case-by-case basis, if certain criteria are fulfilled, the stage 1 audit may be carried out offsite or the stage 2 audit follow immediately on the stage 1 audit. For details please refer to your contact at TÜV Rheinland.

Stage 2
Completion of the stage 2 certification audit on site in your organization to verify the implementation and effectiveness of the established management system.
For this purpose, we will conduct interviews with individual employees of your organization as set forth in the audit plan. Additionally, the site and the relevant operational equipment will be inspected.

Stage 2 of the certification audit and the review result are documented in a report. If the overall result is positive, the auditor or audit team will recommend the issue of the certificate by the Certification Body of TÜV Rheinland.

If the implementation of corrections of major nonconformities from the level 2 audit has not taken place within 6 months after the last day of level 2, a new level 2 must be carried out.

2.2.3 Certificate issue and use

Following positive evaluation of the certification audit, the certificate / QAR will be issued.
The original certificate will be prepared in German. The validity of the TÜV Certificate / QAR is three years, provided annual monitoring audits are performed at the company. Upon request, we also prepare further certificates in English, French, Spanish or Italian. For this purpose, please submit a translation of your certificate's scope of application into the relevant language.
Certificates in languages other than the above and/or certificates bearing your company logo are prepared upon request and against payment of an additional fee.

2.2.4 Certificate maintenance

To maintain certificate validity, annual surveillance audits must be carried out.
The objective of surveillance audits is to monitor the functioning and continuous improvement of the existing management system. Similarly to the certification audit, surveillance audits include interviews with individual employees carried out within the scope of an on-site visit. The result of each surveillance audit will be documented in an audit report.

Prior to the expiration of the certificate, a repeat audit to extend the certificate for an additional three years is performed at the company. During the repeat audit, the effectiveness of the QA sys tem is verified. The customer must file changes to the QA-system appropriate documents have to be sent to the certification office. The audit process will be the same as described in Certification audit without completion in two stages.

The repeat audit must be completed before expiry of the certificate validity. A new certificate will

be issued if the implementation of corrections of major nonconformities has been carried out. Once the certificate has expired, it is forbidden to place Ex-products on the market. Up to 6 months after the expiry date of the certificate, the certification can be restored. Afterwards at least a step 2 is required.

Short-notice audits
It may be necessary for the certification body to conduct audits of certified clients at short notice to investigate complaints, or in response to changes (new EC-Type Examination Certificate or type of protection), or as follow up on suspended clients.
An application for an extension of the scope of certification may also require an extra audit.
Short-notice audits can also be carried out within the framework of a surveillance audit.
The customer receives a separate offer. After the assignment, the certification office appoints the auditor or audit team. The procedure is the same as described in section 2.2.

3. Use of certificate

3.1 Because of the positive evaluation of audit reports, the certification office issues certificates Regarding the approval of QA-systems in accordance with Guideline 2014/34/EU respectively QAR in accordance with IECEx-System. After the certificate is issued, the customer is entitled to use the CE-identification in combination with the ID-number of the certification office according to the regulations of the Ex-Protection-Guideline.

3.2 The entitlement to use the certificate by the customer is limited only to the area of application listed in the certificate.

3.3 A certificate / QAR ceased to exist when

- the validity date listed in the certificate has expired
- the owner of a QA-certificate waives his right to use the certificate before its expiration date
- the „Agreement regarding the certification of a QA-system according to Guideline 2014/34/EU Ex-Protection-Guideline respectively IECEx-System “ is terminated by one of the contract partners before the end of the deadline
- the customer files for bankruptcy proceedings or a bankruptcy petition against the customer has been denied due to insufficiency of assets
- the stipulations on which the certificate is based on were changed or other stipulations, for example due to a change in utilization, are applicable

3.4 A certificate / QAR may be suspend by the certification office if

- the management system is seriously or permanently ineffective
- the client does not allow or hinders the agreed audits of its QA system by the certification body or its appointed auditing body
- the customer asks for suspension

A suspended certificate / QAR can be restored if the problem that caused the suspension is resoved.

3.5 A certificate / QAR may be withdrawn by the certification body or the scope of the certification, if

- the problem which led to a suspension was not solved within six months
- an inspection of the product reveals serious defects
- misleading or otherwise inadmissible advertising in connection with the certificate is published
- facts are found that were not detected at the time the certificate was issued

3.6 The certification office may publish the termination or withdrawal of the certificate at its own discretion.

3.7 The certification office is entitled to notify regulatory authorities, accreditation offices, the notified

bodies, the international commission on electronics and the licensing authorities of the termination or withdrawal of certificates.

3.8 The certification body shall not be liable for any disadvantages which the customer may incur as a result of the refusal, the suspension, restriction of the scope, withdrawal or extinction of a certifcate.

3.9 If a certificate / QAR is not renewed, not restored or withdrawn, the customer is obligated to re move the CE-identification and the ID-number of the certification office from all products of the type affected by the certificate that he has access to and to allow the certification office or one of its authorized offices to perform an appropriate inspection. Any resulting expenses will be borne by the customer alone.

3.10 After a certificate / QAR expired, the circulation of inventory on hand at the time of expiration is permitted for a reasonable period of time, but not more than two years.
Inventory of products that carry the ID number of the certification office must be reported to the certification office, if so requested.
For the duration of the circulation of the products in question, the contractual stipulations between the parties remain in effect.
A permission to sell is not given if the certificate was declared invalid.

3.11 Use of the TÜV Rheinland certificate according to the ATEX directive and if the use of the Registered TÜV Rheinland mark has been agreed upon, it can be used exclusively

- on business papers and in presentations
- on flags and Roll-ups
- on exhibition stands
- in e-mails
- on websites and webbanners
- on vehicles

It cannot be used on products or product packaging, laboratory test reports, calibration certificates, inspection reports or certificates, nor in any other manner, and which could be interpreted as an indication of product conformity.

4. Obligations on the part of TÜV certification office

4.1 The TÜV-Certification association is obliged to keep strictly confidential all information on the company of the customer that they have gained access to and to evaluate these solely for the agreed purposes. Any documentation that they have given access to will not be handed over to third parties. Excluded is the detailed reporting to the arbitration board in case of disputes. The customer may release the certification office of its professional discretion for specific reasons.

4.2 The TÜV certification office is only liable towards the customer or third parties as prescribed by law due to intent or gross negligence. Any additional claims are excluded.

4.3 The manager of the certification office is obligated, if feasible, to observe the correct representa tion of the certification by the customer in his advertising schemes. .

5. Participation of customer

5.1 The customer notifies the certification office immediately of any planned respectively implemented changes to the certified QA-system. The additional approval depends on the verification by the customer regarding compliance with the guideline requirements or an additional audit.

5.2 The customer notifies the certification office ahead of time of any intended relocations of audited

production facilities or the intended transfer of his company to another company or another com pany owner.

5.3 The customer must record and archive all complaints related to his certified product. If requested, he must present these documents to the certification office immediately and free of charge and inform the certification office of any measures taken to rectify justified complaints.

5.4 The customer is obligated to immediately rectify any later detected severe safety defects on pro ducts that carry the CE-identification, and to take immediate and suitable measures to minimize the damages on the market. In each case, he must notify the certification office of such circum stance and immediately stop the circulation of the identified products.

5.5 The customer is obligated to archive the product documents prepared within the framework of the QA-system, regardless of the validity of the certificates, for a minimum period of 10 years after the product was placed on the market. Any additional requirements from other rules and regulations remain untouched.

5.6 The customer is obligated to inform the certification office of newly attained or acquired EU-Type Examination Certificates / Ex-TR´s before they are placed on the market.

6. Appeal

6.1 The customer may file an appeal with the certification office against any decisions made by the certification office within the framework of the completed certification process. The certification office will then have to provide detailed reasons to the complaining party for their decision.

6.2 If the certification body receives complaints against the customer, it shall pass these on to the Certified customers for opinion. The certification body shall provide the complainant progress re ports and the outcome of the complaints.
If the reasoning given by the certification body is not acceptable to the complainant, it shall be open to the steering committee of the certification body.
The steering committee has to make a definitive decision.

7. Effective date and change

7.1 The test and certification ordinance becomes effective on 2022/07/01.

7.2 It always applies to Certificates / QAR´s that are issued during the period of its validity.

7.3 Any future changes to the test and certification ordinance may be applied to existing certificates if the owners agreed on that in writing.