

Service reference from DEKRA Certification for the mandatory certification of the quality management system applied by manufacturers of Ex equipment

Introduction

This document describes in the most general terms the procedure for certification of quality management systems according to the requirements in the ATEX Directive 2014/34/EU and the IECEx System.

DEKRA Certification – Business Line Explosion Safety

Concerning equipment intended for use in potentially explosive atmospheres DEKRA Certification participates in various standardization committees, the Ex Notified Bodies Group, the IECEx System and has a partnership with QPS and FM Approvals, which ensure mutual recognition of certificates in many parts of the world to ease the acceptance of products in different markets.

In addition to this DEKRA Certification evaluates and tests products upon manufacturer's specific requirements and performs quality management system assessments of Ex manufacturers and repair shops.

Services for certification of quality management systems are for instance:

- ATEX certification
- IECEx 02 certification
- IECEx 03 certification

Quotation

When requesting a quotation, please specify the requirements to which the quality management system must be certified, the desired scope of the certification, whether the company is in the possession of a valid ISO 9001 certificate, the size of the organization and the number of manufacturing sites. Additional information will be requested if considered necessary.

The quotation will include in detail what is expected during an audit as well as specification of the costs, the time spending and the necessary documentation.

Along with the quotation an application form for a 3-year certification agreement is added. This agreement defines your rights and obligations, and ours, in relation to continued certification.

Placing an order

To place an order the order confirmation and the certification agreement (application form) must be signed and returned to DEKRA Certification. Upon receipt of the order DEKRA Certification will contact to schedule the audit.

Pre-audit (optional)

On request a pre-audit can be conducted prior to the initial audit. The procedure of a pre-audit is identical to the procedure of an initial audit and has the following advantages:

- The subject of the pre-audit can be determined by yourself
- A quick overview is obtained of the status of the system and the degree to which it is ready for certification
- The first experience with an external audit stimulates employee involvement

Initial audit

During the audit it is assumed that the quality manager and the ATEX authorized person are fully available to the auditor. The audit process will first be explained and then the documented quality management system will be assessed against the applicable requirements. In the next step the implementation and effectiveness of the quality system will be assessed. Depending on the types of explosion protection applied, the routine tests, functionality tests, processing, material checks, etc. will be assessed in detail. The findings of the auditor will be discussed at the end of the audit. In case of nonconformities, these will be laid down in writing, signed by both parties for acceptance.

Certification and/or reporting

Following a positive verification by the certification manager, the audit report and/or certificate will be sent within a few days. As specified in the quotation, the certificate is issued for a period of three years.

Explanation

ATEX: Ex equipment that is produced in manufacturing locations covered by the required quality system certification and which are included in the audit process the CE-marking may be accompanied by DEKRA Certification's identification number 0344.

IECEX: All required product and quality system documents within the IECEx System are published on the IECEx website www.iecex.com.

Surveillance audit

After certification at least one surveillance audit will be carried out within three years. During the audit especially the implementation and effectiveness of the quality management system will be assessed. Also possible modifications in the quality management system will be verified. After approval by the certification manager the audit report will be issued.

Reassessment

A reassessment is carried out after three years. This audit once again involves a complete assessment and also includes an analysis of the implementation of the quality management system throughout the past three years and the results of the surveillance audit(s). Once the reassessment has been concluded successfully, certification can again be granted. DEKRA Certification must be contacted no later than four months before the contract expires to prolong the contract for another 3-year period and to schedule the reassessment. DEKRA Certification will then provide you with a new quotation, including the costs, the time schedule and the necessary documentation.

Non-conformities

A non-conformity is a deviation relative to a requirement in the standard and/or relative to the quality management system. DEKRA Certification reports non-conformities via a non-conformity report. When non-conformities are determined the manufacturer must resolve these non-conformities via a closed improvement loop. The cause of the non-conformity must be determined through analyses and it must be investigated whether the improvement has eliminated the cause and whether the improvement is also applicable for other parts of and processes within the organization. The corrective actions that are to be taken as a result of the determined non-conformity and the verification date are discussed with the lead auditor during the audit.

Conclusion

This service reference describes DEKRA Certification's general approach to the certification of quality management systems. On request this working procedure can be adapted to a specific situation as long as this working procedure complies with the rules DEKRA Certification has to follow as a certification body.

For any other questions, please get in touch with Randy Spivey, Business Development Manager at Randall.spivey@dekra.com or through +1 (936) 320 2485.