

The "cherry on the cake" on the QM system of manufacturers of explosion protected apparatus -

The EN 13980 adds the specific concerns of explosion protection in accordance with ATEX Directive 94/9/EG to ISO 9000

by Th. Arnhold and W. Moelard

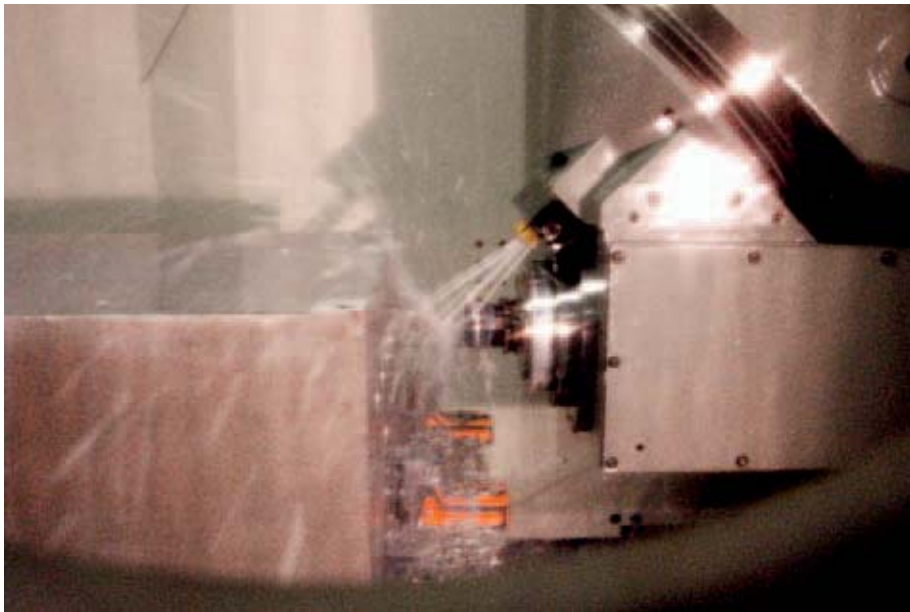


Figure 1: Thread cutting into flameproof enclosure

The transition period for conversion to the new European Explosion Protection Directive 94/9/EC within the European Union expired on 30 June 2003. For manufacturers of equipment and protective systems for use in hazardous areas and for the notified bodies (and testing authorities) in the EU, this means that the newly developed products must be assessed for compliance with the Directive 94/9/EC on the basis of specific conformity assessment modules, depending on their intended purpose. In addition to a type examination in which a notified body must determine and certify conformity of the design with the essential health and safety requirements (EHSR's) stipulated in Annex II, the quality assurance measures on the manufacturer's premises are now also monitored within the framework of the new Directive. This may be done in many ways. For example, a manufacturer may have each of his products to be delivered tested by a testing authority (Annexes V "Product verification" and IX "Unit verification" of the Directive). This will certainly be an exception which, however, may, by all means, make sense in certain cases, such as in special machine and plant construction sector. Manufacturers will chiefly have their quality management systems reviewed by a notified body in accordance with Modules IV "Production quality assurance" and VII "Product quality assurance".

The differences in the requirements between the two Modules for production of devices of Categories 1 and 2 are marginal and still originate from a period in which the ISO 9000 Series of Standards made graduated requirements of the company's quality management systems in the form of Standards 9001, 9002 and 9003. An end was put to this practice with the new ISO 9000:2000 – the requirements are equally stringent for all organisations but, depending on the type of company and purpose of the company, certain elements may be ignored.

Despite the high quality level defined with ISO 9000:2000, certain important aspects of Directive 94/9/EG were not taken into consideration or were given insufficient consideration. For this reason, EN 13980 was elaborated between 1998 and 2002 in a Working Group mandated by CEN, and this new Standard is to be the "cherry on the cake" on the QM system of manufacturers in the words of Prof. Wehinger of the Physikalisch Technische Bundesanstalt (PTB).

How the Standard originated

When the Working Group met for the first meeting in Brussels in the summer of 1998, there were still greatly differing ideas on form and content of the new Standard.

Representatives of manufactures simply wanted to adopt ISO 9000. By contrast, representatives of various testing authorities intended to adopt the extensive manufacturer monitoring practised for many years by BASEEFA in European practice.

However, it did not take long for the participants to agree on the joint requirements to be made of the new Standard, consisting of maintaining the already high safety level in Europe and consolidating it in regards to certain aspects without increasing the amount of red tape for manufacturers and testing authorities. In addition, it was agreed that the Draft of the new ISO 9000 which would be published in 2000 should be taken as the basis. The new Standard should, however, also provide manufacturers with adequate flexibility to be able to use a quality management system other than that of ISO 9000. As with the product characteristics, application of the Standard is not absolutely necessary, if the requirements stipulated in the annexes of the Directive are met.

Thanks to the good and constructive cooperation between participants in the Working Group, it was possible, within a relatively short time, to elaborate a draft of the Standard, which has been in force since February 2003 after approval was issued by the member states and which, together with ISO 9000:2000, forms the basis for regular auditing of the manufacturers by the notified bodies.

Special requirements applicable to the QM systems of the manufacturers of explosion protected apparatus

Documentation requirements

It will not have surprised any manufacturer that the requirements applicable to document control in the company exceed the normal extent. The documents describing the product for the type examination and the certification documents (elaborated for this type test by the notified body) document the compliance with the relevant essential health and safety requirements (EHSR's). They thus serve as "master documents" for all product-specific to production and sales documentation.

The quality management system must ensure that all documents used for production of the products are consistent with these papers and that no changes which have not been confirmed beforehand by the testing authority are made to the characteristics which are important in regard to explosion protection. For large manufacturers with a broad range of products in particular, it is important that the subassembly and part structure be linked to the manufacturer's document management system in a controlled manner. Subassemblies and individual parts may be incorporated in very many different final products. This means that, in the case of approved modifications to these components and subassemblies, the required amendments must be allowed for in the documents of all final products affected.

The authors made a minor formal mistake in relation to control of records for the quality management system: the per se normative requirements relating to the various records, e.g. concerning supplier review or employee training, have been incorrectly inserted in an informative note. Nevertheless, it goes without saying that one must systematically manage and retain all records documenting operation of the quality management system.

Management responsibility

The Standard clearly states that the Company Management itself bears responsibility for ensuring that there is an appropriate quality management system in order to ensure that each product delivered complies with the design described in the EC Type Examination Certificate. This quality management system must be adequately documented in writing.

The requirement that manufacturers must reach an agreement with their sub-suppliers allowing the testing authority to audit elements of the quality management system on the premises of suppliers themselves is certainly an important practical aspect.

Responsibility and authority

Even if it has been established beforehand that the Company Management is responsible for the quality management system, the Company Management is, after all, entitled to delegate responsibilities and authorities, as in other areas of business. Clear regulations stipulating responsibilities and authorities must be drawn up in particular for all activities relating to type examination, auditing and maintaining the quality management system, and compliance with these regulations must be verified by the notified body during the monitoring audit. Even though not explicitly stated in this chapter, it is important and practical to document the stipulations made in conjunction with this and to constantly update them.

In order to ensure compliance of the series product with the tested prototype, the Standard requires amendments to the production drawings and concessions, if they relate to explosion protection, to be authorised by specially competent staff.

Procurement process

During the course of globalisation and subject to the constantly more stringent rationalisation constraints, many companies →



Figure 2: Measurement of Ex-thread

→ have already, for some time now, switched to a policy of drastic reduction of the extent of manufacturing penetration and, during this process, have outsourced production steps freed up to sub-suppliers. The manufacturers of equipment and protective systems covered by the scope of validity of the Directive are no exception to this. For this reason, the present Standard gives broad scope to the topic of “supplier management and procurement”. The core statement is right at the start of the chapter: “While manufacture, test and final inspection may be sub-contracted, the responsibility for ensuring conformance with the EC Type-Examination certificate shall not be sub-contracted”. In brief, the manufacturer always bears overall responsibility for ensuring explosion protection.

Suppliers selected for explosion protection-related activities and/or products must be assessed beforehand thoroughly on the basis of specific procedures defined in the Standard. The following aspects should be allowed for in the case of initial review:

- The danger potential of the product, process or service
- The level of difficulty or complexity of the production process

- The location of the supplier and the associated difficulty in relation to reliably exchanging important information
- Other procurement sources on the part of the supplier.

If this initial review leads to a positive result and a supply partnership is established, the manufacturer must check, at least once per year, whether the sub-supplier is still able to comply with the stipulated quality requirements. The manner in which this is done is, to a certain extent, a matter of discretion. Thus, for instance, systematic review of the incoming inspection reports is mentioned as one possible way of doing this.

In the event of an interruption in business relationships lasting more than one year, a comprehensive review of the supplier must be conducted again, e.g. by means of an audit of the quality management system, before cooperation is resumed.

Special requirements are made of selection and monitoring of the service providers who calibrate measurement and test equipment.

This is understandable, if we consider the importance of the routine tests on the premises of the manufacturer of explosion protected apparatus.

The requirement for regular auditing of the suppliers, who supply products whose characteristics determining explosion protection cannot be tested subsequently and the routine test is delegated to the supplier should be just as understandable.

In this case, one is particularly reliant on the supplier performing the work carefully and one must personally ensure this at appropriate intervals. In addition, it is important to assist suppliers to set up the required organisational and technical competence by developing the appropriate quality management elements jointly and adequately training the supplier’s staff. Moreover, it is required that the organisational measures be stipulated in the procurement documents.

Overall, EN 13980 allows manufactures and their suppliers broad scope in organising mutual business relationships and allows virtually all forms of division of labour, but with the restriction that the required support and monitoring effort on the part of the manufacturer increase as the scope of work on supplier’s premises increases.

Tests and inspections

Monitoring, tests and inspections on the process and on the product are of major importance for ensuring explosion protection. The requirements of the Standard are thus just as comprehensive and precise.

The requirements from Chapter 7.6 of ISO 9000:2000 applicable to ensuring quality of the measuring and test equipment, which are very comprehensive and stringent anyway, are supplemented with requirements for comprehensive documentation of the calibration results.

Processes must be monitored in respect of the process parameters determining quality particularly if individual product features determining explosion protection cannot be tested subsequently.

The routine tests stipulated by the testing authority must be conducted and it is

not permitted to simply use random sample tests. The documentation function of the rating plates described in EN 50014 is taken into account by the requirement that the rating plate be attached only after successful conclusion of all routine tests.

In the event of nonconforming products being discovered, all required measures must be taken to withdraw products already delivered quickly and safely from circulation. The Standard defines corresponding targets for various cases and demands that the manufacturers affected cooperate closely and as quickly as possible with the notified bodies.

Summary

Now that certain audits have been conducted by notified bodies on the basis of EN 13980 or the Draft of this Standard during the past two years, it has been shown that this Standard is a practicable document allowing the requirements of Directive 94/9/EC in respect of quality management systems to be complied with without excessive additional red tape for the manufacturers of equipment and protective systems for hazardous areas. The leading manufacturers agree that it has been possible to codify operational practice in relation to manufacture of explosion protected electrical apparatus, operational practice, which has proven its worth over many decades, in the Standard and to unite it with elements of modern quality management.



Figure 3: Pressure test device for testing flameproof enclosures (routine test)