SLOVENSKI STANDARD
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Potencialno eksplozivne atmosfere – Uporaba sistemov za kakovost

Potentially explosive atmospheres - Application of quality systems

Explosionsgefährdete Bereiche - Anwendung von Qualitätsmanagementsystemen

Atmospheres explosibles - Application des systemes qualité

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Potentially explosive atmospheres - Application of quality systems

Atmosphères explosibles - Application des systèmes qualité

Explosionsgefährdete Bereiche - Anwendung von Qualitätsmanagementsystemen

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Foreword

This document EN 13980:2002 has been prepared by Technical Committee CEN/TC 305 "Potentially explosive atmospheres - Explosion prevention and protection", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2003, and conflicting national standards shall be withdrawn at the latest by April 2003.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this document.

In this European Standard the annexes A and B are informative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard is complementary to EN ISO 9000 and EN ISO 9001 and is applicable to products intended for use in potentially explosive atmospheres. Its purpose is to embrace manufacturing practices that are appropriate to these products.

It does not preclude the use of other quality systems that are compatible with the objectives of EN ISO 9001.

1 Scope

1.1 General

This European Standard specifies particular requirements and information for establishing and maintaining a quality system in accordance with the requirements of Annex IV and Annex VII of Directive 94/9/EC.

It is intended for use by manufacturers, notified bodies and regulatory authorities.

Therefore, when notified bodies assess the quality systems of manufacturers this document is intended to be the basis of the initial assessment and subsequent visits.

1.2 Application

Only those requirements in clause 7 of this European Standard pertaining to the difference between Annex IV and VII of the Directive may be excluded, provided that conformity of the product can still be demonstrated.

Permissible exclusions with respect to Annex VII of Directive 94/9/EC are as follows:

7.1 Planning of product realisation;
7.2.3 Customer communication;
7.4 Purchasing;
7.5.1 Control of production and service provision;
7.5.2 Validation of processes for production and service provision;
7.5.3 Identification and traceability.

No explicit requirements in Annex IV and VII relate to the concept of “continuous improvement”. As a consequence, references in this European Standard to the requirements of EN ISO 9001:2000 exclude this concept.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

prEN 13237-1, *Potentially explosive atmospheres – Explosion prevention and protection — Part 1: Terms and definitions for equipment and protective systems intended for use in potentially explosive atmospheres.*

EN 45012, *General requirements for bodies operating assessment and certification/registration of quality systems (ISO/IEC Guide 62:1996).*

EN 45014, *General criteria for suppliers declaration of conformity (ISO/IEC Guide 22:1996).*

EN ISO 9000:2000, *Quality management system - Concepts and vocabulary (ISO 9000:2000).*

EN ISO 9001:2000, *Quality management system – Requirements (ISO 9001:2000).*

3 Terms and definitions

For the purposes of this European Standard the terms and definitions given in prEN 13237-1 and EN ISO 9000:2000 and following apply.

3.1
manufacturer
organisation, situated at a stated location or locations, that carries out or controls such stages in the manufacture, assessment, handling and storage of a product that enables it to accept responsibility for continued compliance of the product with the relevant requirements and undertakes all obligations in that connection

NOTE The term “manufacturer” is used instead of “organisation” as used in EN ISO 9001:2000. For the purposes of this standard they are interchangeable.

3.2
contract
requirements forming an agreement between a manufacturer and a customer and transmitted by any appropriate means

3.3
customer complaint
any reported written or verbal allegation made by a customer which concerns the identity, quality, durability, safety, security, conformity or performance of any equipment or protective system or component as defined in the EC type-examination certificate

3.4
product
equipment, protective systems, devices, components and their combinations, as well as software and service as defined in 3.4.2 of EN ISO 9000:2000

3.5
schedule drawing
drawing referenced in the EC type-examination certificate (e.g. in the schedule or the report)

3.6
related drawing
drawing not referenced in the EC type-examination certificate, but used for example, for detailed manufacture of component parts

3.7
equipment document
technical documentation as defined in Annex III of the Directive and product/production quality assurance notifications

3.8
manufacturers document
those documents required by a manufacturer but not subject to assessment by a notified body when making an application for either an EC type-examination certificate or product/production quality assurance notification. For example, instructions, related drawings, data sheets and sales literature

3.9
type of protection
specific measures applied to product to avoid ignition of a surrounding explosive atmosphere

4 Quality management system

4.1 General requirements

4.1 of EN ISO 9001:2000 applies.

The quality system shall ensure compliance of the product with the type described in the EC type-examination certificate.

4.2 Documentation requirements

4.2.1 General

4.2.1 of EN ISO 9001:2000 applies.

4.2.2 Quality manual

4.2.2 of EN ISO 9001:2000 applies.

4.2.3 Control of documents

4.2.3 of EN ISO 9001:2000 applies.

a) Equipment documents and manufacturer's documents shall be controlled;

b) Documented procedures shall ensure that information contained within manufacturer's documents is compatible with equipment documents. The manufacturer shall not initially approve or subsequently amend related drawings unless they are in compliance with the schedule drawings;

c) The quality system shall ensure that no factor (type, characteristic, position etc.) defined within the EC type-examination certificate and technical documentation (e.g. schedule drawings) is modified;

d) There shall be a documented system that refers all related drawings to the relevant schedule drawings,

e) Where there are common schedule drawings associated with more than one EC type-examination certificate, there shall be a documented system to ensure simultaneous supplementary action in the event of an amendment to such drawings;

NOTE Some manufacturers use common components with common drawing numbers on more than one product. Some of these products can have different persons responsible for them. Therefore, if one product with a common component and drawing number is revised to meet a need and the necessary supplementary certificate obtained, there needs to be a system for ensuring that any other certificates that call up such components are also subject to supplementary certification in order to avoid those products not being in compliance with their equipment documents.

f) Where a manufacturer also has drawings for products not intended for use in potentially explosive atmospheres then the manufacturer shall have a system that enables both the related drawings and schedule drawings to be clearly identified

NOTE The following examples indicate some methods of achieving this:

- the use of visual markers;
- the use of a unique series of drawing numbers, e.g. all drawings concerning a certified product have an Ex prefix to the drawing number.

g) The manufacturer shall document which notified body is responsible for the quality system notification for each EC type-examination certificate;

h) Where equipment documents or manufacturer's documents are passed to a third party, they shall be provided in a way that is not misleading.

4.2.4 Control of quality records

4.2.4 of EN ISO 9001:2000 applies.

NOTE It is in the manufacturer's interests to retain adequate quality records to demonstrate conformity of the product. Examples of documents requiring control and retention are:

— those arising from regulatory requirements;

— customer order;

— contract review;

— training records;

— inspection and test data (per batch);

— calibration data;

— sub-contractor evaluation;

— delivery data (customer, delivery date and quantity, including serial numbers where available).

5 Management responsibility

5.1 Management commitment

5.1 of EN ISO 9001:2000 applies.

5.2 Customer focus

5.2 of EN ISO 9001:2000 applies.

5.3 Quality policy

5.3 of EN ISO 9001:2000 applies.

5.4 Planning

5.4.1 Quality objectives

5.4.1 of EN ISO 9001:2000 applies.

5.4.2 Quality management system planning

5.4.2 of EN ISO 9001:2000 applies.

The quality system shall ensure that the product conforms to the type described in the EC type-examination certificate. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of quality programmes, plans, manuals and records.

The manufacturer shall facilitate an arrangement whereby the notified body may audit aspects of the suppliers operations that affect the type of protection.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

5.5.1 of EN ISO 9001:2000 applies.

Responsibilities and authority for the following shall be defined:

a) the effective co-ordination of activities with respect to products intended for use in potentially explosive atmospheres;

b) the need to liase with the notified body responsible for the issue of the EC type-examination certificate with respect to any proposed change to the design defined in the EC type-examination certificate and the technical documentation;

c) the need to liase with the notified body responsible for the assessment of the quality system with respect to intended updating of the quality system;

NOTE It is not practicable for the manufacturer to inform the notified body each time the quality system is updated. It is only practicable to inform the notified body of “substantial” updating of the quality system relevant to the type of protection. Similarly, it is not practicable to specify in general terms what types of updating are or are not “substantial”. It is therefore recommended that the manufacturer establishes and maintains a system for categorising updates as “substantial” or not and informing the notified body as appropriate.

d) the authorising of initial approval and changes to related drawings, where appropriate;

e) the authorising of concessions (see 8.3 f));

f) informing its customer of any applicable special conditions for safe use and any schedules of limitations;

NOTE 1 Certificates with a suffix X can contain special conditions for safe use. Component certificates, with a suffix U can contain schedules of limitations.

NOTE 2 For each EC type-examination certificate it is recommended that an authorised person is appointed who should have responsibility and authority for the above activities so providing an unambiguous focal point within the organization.

5.5.2 Management representative

5.5.2 of EN ISO 9001:2000 applies.

5.5.3 Internal communication

5.5.3 of EN ISO 9001:2000 applies.

5.6 Management review

5.6.1 General

5.6.1 of EN ISO 9001:2000 applies.

a) the maximum intervals between reviews should normally be 12 months and shall not exceed 14 months;

b) top management shall chair the review;

c) the person(s) responsible for the activities as detailed in 5.5.1 shall participate in the review.