SLOVENSKI STANDARD
SIST EN 928:2000

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Diagnostiļ ni sistemi in vitro - Navodila za uporabo EN 29001 in EN 46001 ter EN 29002 in EN 46002 za diagnostiļ ne medicinske pripomoļ ke

In vitro diagnostic systems - Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for in vitro diagnostic medical devices

In-vitro-Diagnostik/Diagnostika - Leitfaden für die Anwendung von EN 29001 und EN 46001 sowie EN 29002 und EN 46002 für Medizinprodukte für die In-vitro-Diagnose

Systemes d'analyses médicales in vitro - Guide d'application des EN 29001 et EN 46001, et EN 29002 et EN 46002 pour les dispositifs médicaux de diagnostic in vitro

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In vitro diagnostic systems - Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for in vitro diagnostic medical devices

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Contents list

Clause

Foreword

This European Standard has been prepared by the Technical Committee CEN/TC 140 "In vitro diagnostic systems" of which the secretarait is held by DIN.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

This European Standard needs to be considered in conjunction with both the EN 29000 series of standards and the EN 46000 series of standards. It is intended to provide guidance for industry, certifying bodies and regulatory bodies.

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of an identical text or by endorsement, at the latest by May 1996, and conflicting national standards shall be withdrawn at the latest by May 1996.

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

Introduction

This European Standard has been prepared to give guidance to organizations providing in vitro diagnostic medical devices (IVDs) and wishing to comply with EN 29001 and EN 29002 and the particular requirements for medical devices in EN 46001 and EN 46002. This European Standard needs to be read in conjunction with the relevant standards with which compliance is sought. This European Standard is not a substitute for, or a supplement to, EN 29004 which has its own very distinct relationship with the EN 29000 series of standards.

This European Standard does not add any requirements to those in the EN 29000 series. Care should be taken that the guidance, which may suggest various methods of providing assurance, is not used in place of, or as additional requirements to those given in the EN 29000 series.

The aim of this European Standard is primarily to assist suppliers, purchasers and certification bodies to achieve a uniform interpretation of EN 29001 and EN 29002 and of EN 46001 and EN 46002 by presenting familiar concepts under the relevant clauses from these standards. It attempts to explain what should be done to fulfil customer needs and is not only a guide for quality assessors.

The combination of EN 29001 and EN 46001 and of EN 29002 and EN 46002 embrace the principles of Good Manufacturing Practice (GMP) which have been used in the medical device industry for a number of years.

1 Scope

This European Standard provides guidance on the implementation of EN 29001 and EN 46001 and of EN 29002 and EN 46002 as applied to the manufacturer of IVDs. It is aimed at affording a better understanding of the standards themselves as well as assistance in their use, either in implementing or evaluating such a quality system. The guidance given is not intended to be exhaustive, but to highlight important aspects to which attention should be drawn.

The adoption of systems other than those described in this European Standard is not to be regarded as a non-compliance with EN 29001 and EN 29002 and/or the particular requirements in EN 46001 and EN 46002.

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.

EN 29001 : 1987	Quality systems – Model for quality assurance in design/development, production, installation and servicing
EN 29002 : 1987	Quality systems – Model for quality assurance in production and installation
EN 29004 : 1987	Quality management and quality system elements – Guidelines
EN 46001 : 1993	Quality systems – Medical devices – Particular requirements for the application of EN 29001
EN 46002 : 1993	Quality systems – Medical devices – Particular requirements for the application of EN 29002

3 Definitions

For the purposes of this standard, the definitions given in EN 46001 : 1993 and EN 46002 : 1993 apply.

4 Guidance on quality system requirements

[refers to clauses 4 of EN 29001 : 1987 and EN 46001 : 1993 and to clauses 4 of EN 29002 : 1987 and EN 46002 : 1993]

4.1 Management responsibility

[refers to clauses 4.1 of EN 29001 : 1987 and EN 46001 : 1993 and to clauses 4.1 of EN 29002 : 1987 and EN 46002 : 1993]

4.1.1 Quality policy

[refers to clauses 4.1.1 of EN 29001 : 1987 and EN 46001 : 1993 and to clauses 4.1.1 of EN 29002 : 1987 and EN 46002 : 1993]

When defining and documenting the supplier's quality policy, commitment and objectives, the management should express the policy in language that the staff can understand. The policy should be specific to the product supplied and to the staff employed.

Management should be seen to demonstrate commitment to their quality policy both actively and on a continuing basis.

For general guidance, see clause 4.3.2 of EN 29004 : 1987.

4.1.2 Organization

[refers to clauses 4.1.2 of EN 29001 : 1987 and EN 46001 : 1993 and to clauses 4.1.2 of EN 29002 : 1987 and EN 46002 : 1993]

4.1.2.1 Responsibility and authority

[refers to clauses 4.1.2.1 of EN 29001 : 1987 and EN 46001 : 1993 and to clauses 4.1.2.1 of EN 29002 : 1987 and EN 46002 : 1993]

Within an organization it is important that levels of responsibility, limits of authority and inter-relationships are established. Organizational charts often illustrate such structures. In particular, the responsibility and authority to control key elements of the quality system and process are typically defined in documented job descriptions. As appropriate, key personnel should have designated deputies capable of adequately assuming the responsibilities of the post.

4.1.2.2 Verification resources and personnel

[refers to clauses 4.1.2.2 of EN 29001 : 1987 and EN 46001 : 1993 and to clauses 4.1.2.2 of EN 29002 : 1987 and EN 46002 : 1993]

No specific guidance provided.

4.1.2.3 Management representative

[refers to clauses 4.1.2.3 of EN 29001 : 1987 and EN 46001 : 1993 and to clauses 4.1.2.3 of EN 29002 : 1987 and EN 46002 : 1993]

No specific guidance provided.

4.1.3 Management review

[refers to clauses 4.1.3 of EN 29001 : 1987 and EN 46001 : 1993 and to clauses 4.1.3 of EN 29002 : 1987 and EN 46002 : 1993]

No specific guidance provided.

4.2 Quality system

[refers to clauses 4.2 of EN 29001 : 1987 and EN 46001 : 1993 and to clauses 4.2 of EN 29002 : 1987 and EN 46002 : 1993]

A quality system comprises the organizational structure, responsibilities, procedures, processes and resources for implementing quality management. It typically applies to, and interacts with, all activities pertinent to the quality of a product. It involves all phases from initial identification to final satisfaction of requirements and customer expectations. These phases and activities may include the following:

- product design and development;
- validation of computer systems and software;
- procurement;
- process planning, development and validation;
- production;
- equipment qualification and validation;
- inspection, testing and examination;
- packaging and storage;
- sales and distribution;
- installation and operation;
- technical assistance and maintenance;

– corrective action.

It is important that the quality system is organized in such a way that adequate and continuous control is exercised over all activities affecting quality. Operational procedures coordinating different activities with respect to an effective quality system should be developed, issued and maintained to implement corporate quality policies and objectives. All written procedures should be stated simply, unambiguously and understandably and should indicate methods to be used and criteria to be satisfied.

The typical form of the main document used in drawing up and implementing a quality system is a quality manual. This manual should provide an adequate description of the quality management system and should serve as a permanent reference for the implementation and maintenance of that system. Methods should be established for making changes, modifications, revisions or additions to the contents of a quality manual.

4.3 Contract review

[refers to clauses 4.3 of EN 29001 : 1987 and EN 46001 : 1993 and to clauses 4.3 of EN 29002 : 1987 and EN 46002 : 1993]
The contract review is intended to cover the contractual relationship between the supplier and his customer.

NOTE: The relationship between the supplier and the sub-contractor is covered by clause 4.6 of EN 29001 : 1987.

Under normal circumstances IVDs are supplied to customers via one-off telephoned or written purchase orders, or on the receipt of a standing order. Such orders are often based on information supplied to the customer in the form of a sales catalogue.

In some situations a documented contract may be agreed between the parties concerned. This contract review should be conducted against prescribed steps which should include the following as appropriate:

– ensuring that the requirements are clearly understood and agreed by both parties and that they are properly recorded and kept;

– clear and timely communication by both parties of any difference or non-conformity to the specified requirements and the recording as a part of the contract documentation of the conclusions reached together with how the differences are to be resolved;

– both parties going through a defined process to ensure that they have the necessary resources, organization and facilities to conform to all the requirements in the contract;

– further review of the contract when a change to the terms of the original contract is required by either party.

The extent of the contract review procedure and the necessary documentation should be determined taking into account the nature of the contract.

4.4 Design control

[refers only to clauses 4.4 of EN 29001 : 1987 and EN 46001 : 1993]

4.4.1 General

[refers only to clauses 4.4.1 of EN 29001 : 1987 and EN 46001 : 1993]

The design phase takes a product from concept to production and is an important phase in the life cycle of an IVD. The essential quality aspects of safety, performance and reliability of a device are established during this phase. Therefore, adequate design controls should be established and implemented to ensure these aspects are met prior to production.

IVDs for self-testing should be designed to ensure their suitability for use by lay persons including appropriately worded instructions for use in a non-laboratory environment.

For general guidance, see clause 8.1 of EN 29004 : 1987.

4.4.2 Design and development planning

[refers only to clauses 4.4.2 of EN 29001 : 1987 and EN 46001 : 1993]

For general guidance, see also clauses 8.2.1, 8.2.2 and 8.2.3 of EN 29004 : 1987.

4.4.2.1 Activity assignment

[refers only to clauses 4.4.2.1 of EN 29001 : 1987 and EN 46001 : 1993]

For general guidance, see clauses 8.2.1 and 8.2.2 of EN 29004 : 1987.

4.4.2.2 Organizational and technical interfaces

[refers only to clauses 4.4.2.2 of EN 29001 : 1987 and EN 46001 : 1993]

For general guidance, see clause 7 of EN 29004 : 1987.

4.4.3 Design input

[refers only to clauses 4.4.3 of EN 29001 : 1987 and EN 46001 : 1993]

Key design input information should be documented in the form of a product definition. The specified requirements should be based on "harmonized" European Standards where applicable. If no "harmonized" European Standards exist national or International Standards should be considered. Alternative published methods or in-house standards or procedures can also be considered.

For general guidance, see also clauses 8.2.4, 8.2.5 and 8.3 of EN 29004 : 1987.

4.4.4 Design output

[refers only to clauses 4.4.4 of EN 29001 : 1987 and EN 46001 : 1993]

It is important that the supplier establishes and maintains master documentation for each type of product. This documentation is a key element of the design output and should be prepared, dated and signed by the designated individual(s). The master documentation should either refer to the location of or include the following information:

- specifications, including appropriate drawings, raw materials, compositions, formulations and component specifications;
- manufacturing procedures and work instructions;
- quality assurance procedures and specifications including quality control checks applied and the test equipment to be used;
- packaging and labelling specifications, including copies of approved labels, methods and processes used.

Ensuring that the design output meets design input requirements can be monitored by timely application of the design review process. Documentation of design reviews can constitute an important part of design output.

For general guidance, see also clauses 8.5.1, 8.5.2 and 8.6 of EN 29004 : 1987.

4.4.5 Design verification

[refers only to clauses 4.4.5 of EN 29001 : 1987 and EN 46001 : 1993]

The results of all tests and evaluations should be documented regularly throughout the qualification test cycle. Review of test results should include defect and failure analysis.

The testing, e.g. by model or prototype tests, should include the following activities:

- evaluation of performance, durability, safety, reliability and ease of maintenance under expected storage and operational conditions;

- inspections to verify that all design features are as intended and that all authorized design changes have been accomplished and recorded;

- validation of computer systems and software.

The design verification may also be undertaken by either evaluation using samples or assessing the design against user experience with similar designs.