SLOVENSKI STANDARD
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Navodilo za uporabo EN 29001 in EN 46001 ter EN 29002 in EN 46002 za ne-aktivne medicinske pripomočke

Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices

Anleitung zur Anwendung von EN 29001 und EN 46001 und von EN 29002 und EN 46002 für nicht-aktive Medizinprodukte

Guide d'application des EN 29001 et EN 46001 et des EN 29002 et EN 46002 pour les dispositifs médicaux non actifs

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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

Foreword

This European Standard prepared by the Technical Committee CEN TC 205 "Non-active medical devices", the Secretariat of which is held by BSI.

This European Standard has been prepared under a Mandate given to CEN by the European Commission and the Secretariat of the European Free Trade Association, and supports essential requirements of EC Directives(s).

This European Standard shall be given the status of a National Standard, either by publication of an identical text or by endorsement, at latest by April 1995, and conflicting national standards shall be withdrawn at the latest by April 1995.

Annexes designated informative are given only for information. In this standard annexes A, B and C are informative.

According to the 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, United Kingdom.

Introduction

This European Standard has been written to give guidance to organizations providing a non-active medical device who wish to ensure that they will comply with EN 29001/EN 29002 and the particular requirements given in EN 46001/EN 46002. It is also intended to provide guidance for certifying and regulatory bodies.The guidance in this standard for the fulfilment of requirements should always be in relation to the products being manufactured and interpreted accordingly.

This standard needs to be read in conjunction with the EN 29000 series of standards with which compliance is sought. This standard is not intended as a replacement for EN 29004 which has its own very distinct relationship with the EN 29000 series of standards.

The combination of EN 29001/EN 46001 and EN 29002/EN 46002 embraces the principles of Good Manufacturing Practices (GMP) which have been in operation in the manufacture of non-active medical devices for a number of years.

This document seeks to assist in the transition from GMP to quality systems by presenting familiar concepts under the relevant paragraphs of EN 29001/EN 46001 and EN 29002/EN 46002.

The references which have been made to EN 29004 are not necessarily exhaustive but seek to identify sections of EN 29004 with particular relevance to the guidance in this document. Consideration of this document alone is not an alternative to understanding EN 29004 and it is therefore recommended that EN 29004 is first read and understood in its entirety. For ease in the use of this standard, references to clauses in EN 29004 have been cited within the framework of EN 29001 and EN 29002.

Annex A to this European Standard provides additional guidance on those elements of quality systems to which particular emphasis should be placed for medical devices which are supplied either sterile or to a defined standard of microbial or particulate cleanliness. The guidance in annex A is intended to be considered in addition to that provided in the body of the standard.

1. Scope

This European Standard provides guidance on the establishment and maintenance of the quality systems specified in EN 29001/EN 46001 or EN 29002/EN 46002 for the manufacture of non-active medical devices. It does not add to, or otherwise change, the requirements of those standards and is not intended to be used for the assessment of a manufacturer's quality system.

This European Standard provides examples of how to meet the requirements, recognising that other methods which achieve the same ends are equally acceptable ; gives general advice on how to meet the requirements; and draws attention to aspects of requirements that may not be readily apparent to those unfamiliar with quality systems for non-active medical devices.

Annex A to this European Standard provides guidance on the elements of quality systems which are relevant to the manufacture of medical devices which are to be supplied either sterile or at a defined level of microbiological or particulate cleanliness.

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 specific 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 purpose of this standard the definitions given in EN 46001 and EN 46002 apply, together with the following :

3.1 contract

Any agreement between the supplier and the purchaser concerning the supply of product

NOTE : A contract may be in writing, verbal, or a combination of both.

3.2 design

Process of developing a product from concept to manufacture.

3.3 purchaser

Recipient of product and/or service delivered by the supplier.

3.4 specified requirements

Any of the following apply :

a) requirements prescribed by the purchaser and agreed by the supplier in a contract for product;
b) requirements prescribed by the supplier which are perceived as satisfying a market need; or
c) regulatory requirements

3.5 validation

Exercise of carrying out a programme designed and documented to demonstrate that a process, operating within specified limits, will consistently produce product or services complying with predetermined requirements.

NOTE : Validation is considered as a total process which consists of :

a) obtaining and documenting evidence that the installation of equipment follows design intentions and that the equipment as installed will perform consistently within predetermined limits (commissioning), and ;

b) obtaining and documenting evidence that the equipment as installed and operated in accordance with process specifications will function reliably, produce acceptable product or services, and that key process variables are known (performance qualification).

4. Guidance on quality system requirements

4.1 Management responsibility

4.1.1 Quality policy

Guidance for clauses 4.1.1 of EN 29001 and EN 46001 and for clauses 4.1.1 of EN 29002 and 46002.

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 4.1, 4.2, 4.3 and 4.4.4. of EN 29004.

4.1.2 Organisation

4.1.2.1 Responsibility and authority

Guidance for clauses 4.1.2.1 of EN 29001 and EN 46001 and for clauses 4.1.2.1 of EN 29002 and EN 46002.

It is important that conformance with specified requirements is not compromised by considerations of increased production, economy or market pressure. Therefore, within an organization, levels of responsibility, authority and inter-relationships are established and typically illustrated in an organization chart. In particular, responsibilities for key elements of the quality system should be identified and be included in written job descriptions.

Responsibility for the effective operation of the quality system rests with the management representative (see 4.1.2.3) who should establish systems to ensure :

a) product meets specified requirements ;
b) documented quality systems, standards and specifications are maintained ; and
c) regular internal quality audits are performed.

The responsibility for quality assurance and production should be assigned to separate individuals. Annex B to this European Standard provides an example of the features of a job description for these individuals.

Particular guidance on responsibility and authority for the manufacture of sterile products, or other products for which the microbiological cleanliness is of significance, is provided in annex A.

Deputies for the key individuals identified above should be nominated and be capable of assuming the responsibilities when necessary.

For general guidance, see also 5.2.1, 5.2.2 and 5.2.3 of EN 29004

4.1.2.2 Verification resources and personnel

Guidance for clauses 4.1.2.2 of EN 46001 and for clauses 4.1.2.2 of EN 29002 and EN 46002.

The resources which need to be provided may include personnel trained in specific disciplines, for example materials science, microbiology or statistics.

For general guidance, see also 5.2.4 and 18.3 of EN 29004.

4.1.2.3 Management representative

Guidance for clauses 4.1.2.3 of EN 29001 and EN 46001 and for clauses 4.1.2.3 of EN 29002 and EN 46002.

If the management representative (see also 4.1.2.1) who has the responsibility for the quality system has other functions to perform, there should be no conflict of interest.

4.1.3 Management review

Guidance for clauses 4.1.3 of EN 29001 and EN 46001 and for clauses 4.1.3 of EN 29002 and EN 46002.

For general guidance, see 5.5 of EN 29004.

4.2 Quality system

Guidance for clauses 4.2 of EN 29001 and EN 46001 and for clauses 4.2 of EN 46002.

The main document in the quality system is usually a quality manual. This documents quality policy and describes the quality system. The quality manual is usually supported by detailed procedures, work instructions and specifications for product and processes. Such supporting documents themselves are generally not within the quality manual because of the frequency at which they may be subject to change.

EN 46001 and EN 46002 require that documentation supporting the quality manual is organized in a file for each product type. Such files may be referred to as "Device Master File" or "Device Master Record". This can contain, or give reference to the location of, documentation relevant to the manufacture of that product. Examples of such documentation may include :

- specifications for raw materials, labelling, packaging materials, intermediate and finished products;
- drawings ;
- work instructions, including equipment operation ;
- sterilization process details, if applicable ;
- inspection procedures and acceptance criteria.

Such files may also contain quality records (see 4.16) such as :

- design verification records ;
- process validation records.

All this documentation forms part of the quality system and should be subject to document control procedures (see 4.5).

For general guidance, see also 5.1.1, 5.1.2, 5.2.5, 5.3.2 and 5.3.3 of EN 29004.

4.3 Contract review

Guidance for clauses 4.3 of EN 29001 and EN 46001 and for clauses 4.3 of EN 29002 and EN 46002.

It is important that the supplier obtains a thorough understanding of the purchaser's needs. This is established during contract review. Contract review should cover factors such as :

- product description, quantity and price ;
- delivery details ;
- any special packaging, storage and transport requirements ;
- service ;
- spare parts.

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

4.4 Design control

4.4.1 General

Guidance for clauses 4.4.1 of EN 29001 and EN 46001 ; not applicable to EN 29002 and EN 46002.

The design phase takes a product from concept to production and is an important phase in the life cycle of a medical device. 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. One of the major causes of quality problems leading to device recalls and failures is deficient design.

For general guidance see also 8.1 and 19 of EN 29004.

4.4.2 Design and development planning

Guidance for clauses 4.4.2.1 of EN 29001 and EN 46001 ; not applicable to EN 29002 and EN 46002.

The planning, operation and management of the design phase may be documented in a design manual.

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

4.4.2.1 Activity assignment

Guidance for clauses 4.4.2.1 of EN 29001 and EN 46001 ; not applicable to EN 29002 and EN 46002.

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

4.4.2.2 Organizational and technical interfaces

Guidance for clauses 4.4.2.2 of EN 29001 and EN 46001 ; not applicable to EN 29002 and EN 46002.

When input to the design is from a variety of sources, such as from personnel from different functions and/or disciplines within or external to the supplier's organization or from individuals with specialist expertise, the inter-relationship or interfaces should be clearly understood and controlled.

For general guidance see also clause 7 of EN 29004.

4.4.3 Design input

Guidance for clauses 4.4.3 of EN 29001 and EN 46001 ; not applicable to EN 29002 and EN 46002.

Design input is typically in the form of a performance specification and/or a product description. Design input should be specified to the level of detail necessary to permit the design activity to be carried out effectively, and to provide a consistent basis for design decisions, design verification and design changes.

Design input data may include a product brief and performance requirements, together with requirements of regulations, harmonized European Standards and other published technical standards.

Design input data may also include advice from an appropriately qualified practitioner. For example, consideration may need to be given to anatomical and physiological implications of the intended use of the product.

For general guidance, see also clauses 7, 8.2.4 and 8.2.5 of EN 29004.

4.4.4 Design output

Guidance for clauses 4.4.4 of EN 29001 and EN 46001 ; not applicable to EN 29002 and EN 46002.

The design output documents include typically :

- product specifications and drawings ;
- manufacturing specifications and drawings.

They should :

- be able to be related to the design input and permit design verification ;
- identify aspects which affect safety, performance and reliability ;
- be maintained as quality records (see also 4.16).

4.4.5 Design verification

Guidance for clauses 4.4.5 of EN 29001 and EN 46001 ; not applicable to EN 29002 and EN 46002.

Design verification should be a formal procedure. A detailed, documented description of the design verification programme should be established, including organizational functions involved, procedures and methods to be used, documentation required, and variables to be considered and evaluated.

The extent of design verification required is a function of the safety, performance and the reliability requirements for the item under consideration, the complexity of the design, the existence of published technical standards, the state of the art and the similarity with previously proven designs. Should the person(s) responsible for design verification decide that certain aspects or parameters related to safety, performance and reliability do not need to be verified, the decision should be properly reasoned and recorded.

Upon completion of design verification activities, the final design configuration is documented and manufacturing specifications established prior to release to production. For any subsequent design changes see 4.4.6.

Design verification commonly consists of design reviews supported by other design control measures as described in a) to d) below.

a) Design reviews

Design reviews involve critical analysis of the design activities and are carried out at the conclusion of each design phase. Records of design review meetings are retained (see 4.16) and usually identify those present and decisions reached.