SLOVENSKI STANDARD
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Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active

Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active (including active implantable) medical device industry

Anleitung f? r die Anwendung von EN 29001 und EN 46001 und von EN 29002 und EN 46002 f? r die aktive (einschlie? lich implantierbare aktive) Medizinprodukte herstellende Industrie

Guide pour l'application des EN 29001 et EN 46001 et des EN 29002 et EN 46002 ? l'industrie des dispositifs m? dicaux actifs (comprenant les dispositifs actifs implantables)

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Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active (including active implantable) medical device industry

Guide pour l'application des EN 29001 et EN 46001 et des EN 29002 et EN 46002 à l'industrie des dispositifs médicaux actifs (comprenant les dispositifs actifs implantables)

Anleitung für die Anwendung von EN 29001 und EN 46001 und von EN 29002 und EN 46002 für die aktive (einschließlich implantierbare aktive) Medizinprodukte herstellende Industrie

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CENELEC

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

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Foreword

This European Standard was prepared by the Working Groups "Quality systems for active implantable medical devices" and "GMP for active medical devices" of Technical Committee CENELEC TC 62, Electrical equipment in medical practice, with advice from the joint CEN/CENELEC "Coordinating Working Group on Quality Supplements".

The draft was submitted to the IEC-CENELEC parallel vote as prEN 61272 in October 1993. Although approved at IEC level, the IEC was not in a position to issue the document as an International Standard because the documents EN 46001 and EN 46002 referred to have not been approved on an international basis.
The draft was approved by CENELEC as EN 50103 on 1994-07-05.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1995-12-15
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1995-12-15

INTRODUCTION

This European Standard gives guidelines for SUPPLIERS of ACTIVE MEDICAL DEVICES (including ACTIVE IMPLANTABLE MEDICAL DEVICES) who wish to ensure that they comply with EN 46001 (Quality systems - Medical devices - Particular requirements for the application of EN 29001 for medical devices) or EN 46002 (Quality systems - Medical devices - Particular requirements for the application of EN 29002 for medical devices). Additionally this European Standard is intended to contribute to a common understanding between SUPPLIERS and third parties.

This European Standard is meaningful only if read in conjunction with EN 29000/ISO 9000 and EN 46000 series standards. The guidelines are not intended as a replacement or supplement to ISO 9004, which has its own very distinct relationship with the EN 29000/ISO 9000 series of standards.

NOTE 1 - The guidance given in this document has been arranged so that the numbers of the subclauses are the same as those of the requirements of EN 29001 and EN 46001, to which the guidance always refers. The respective subclause numbers of EN 29002 and EN 46002 are provided in parentheses.

NOTE 2 - Not all requirements of EN 29001 and EN 46001 and of EN 29002 and EN 46002 are addressed in this European Standard. It is, therefore, generally advisable to read these guidelines in parallel with ISO 9004.

NOTE 3 - This document provides guidelines both for manufacturers of ACTIVE MEDICAL DEVICES and ACTIVE IMPLANTABLE MEDICAL DEVICES. Most of the wording of this document is drafted to cover both PRODUCT groups: the class ACTIVE MEDICAL DEVICE includes ACTIVE IMPLANTABLE MEDICAL DEVICES by definition. In a few places the guidance applies specifically only to ACTICE IMPLANTABLE MEDICAL DEVICES or to non-implantable ACTIVE MEDICAL DEVICES: such exceptions are clearly indicated in the text.

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1 Scope

The guidelines contained in this European Standard are applicable to a QUALITY SYSTEM as specified by EN 29001 and EN 46001 or EN 29002 and EN 46002. This European Standard does not add to, or otherwise change the requirements of those standards, and is not intended to be used directly in the assessment of a SUPPLIER'S QUALITY SYSTEM.

The guidelines provide concepts and objectives which should be considered by a SUPPLIER of ACTIVE MEDICAL DEVICES while developing and maintaining his QUALITY SYSTEM.

This European Standard:

- provides examples of how to meet the requirements, while recognizing that other methods which achieve the same ends are equally acceptable;
- gives general advice on how to meet the requirements;
- draws attention to aspects of requirements that may not be readily apparent to those unfamiliar with QUALITY SYSTEMS used in the ACTIVE MEDICAL DEVICE industry.

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.

International registration :	Title:	European registration :
ISO 8402:1994	Quality management and quality assurance Vocabulary	---

ISO 9001:1987	Quality systems - model for quality assurance in design/development, production, installation and servicing	EN 29001:1987
ISO 9002:1988	Quality systems - model for quality assurance in production and installation	EN 29002:1988
----------	Quality systems - medical devices - particular requirements for the application of EN 29001	EN 46001:1993
----------	Quality systems - medical devices - particular requirements for the application of EN 29002	EN 46002:1993

3 Terminology and definitions

3.1 Terminology

3.1.1 *should*
This auxiliary verb indicates that a certain course of action is preferred but not necessarily required.

3.1.2 *may*
This auxiliary verb indicates a course of action often followed by established SUPPLIERS of similar ACTIVE MEDICAL DEVICES.

3.1.3 *specific*
This adjective, when used with parameters or conditions, refers to a particular value or standardized arrangement, usually to those required in a European Standard or a legal requirement.

3.1.4 *specified*
This adjective, when used with parameters or conditions, refers to a value or arrangement to be chosen for the purpose under consideration and indicated usually in accompanying documents.

3.2 Definitions

NOTE - In this European Standard, terms printed in capital letters are used as defined in EN 46001 and ISO 8402 or as given in subclauses 3.2.1 to 3.2.4. Annex A provides an index of the terms used.
Where a defined term is used as a qualifier in another term it is not printed in capital letters, unless the concept thus qualified is also defined.

For the purposes of this European Standard, the definitions given in ISO 8402 and EN 46001 apply together with the following definitions.

3.2.1 *specified requirements*

Either

- requirements prescribed by the PURCHASER and agreed by the SUPPLIER in a contract for PRODUCT;

- requirements prescribed by the SUPPLIER which are perceived as satisfying a market need;

- regulatory requirements

3.2.2 *device history record*

A compilation of records containing the complete production history of a finished device

3.2.3 *device master record*

A compilation of records containing the design, SPECIFICATION, complete manufacturing PROCEDURES, QUALITY ASSURANCE requirements and labels and LABELLING of a finished device

3.2.4 *custom-made devices*

Any MEDICAL DEVICE specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his authority, specific design characteristics and is intended to be used only for an individual named patient

4 Guidance on quality system requirements

4.1 Management responsibility

4.1.1 QUALITY POLICY

[Also applies to 4.1.1 of EN 29002 and EN 46002; see note 1 in Introduction]

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.

4.1.2 Organization

4.1.2.1 Responsibility and authority

[Also applies to 4.1.2.1 of EN 29002 and EN 46002]

The SUPPLIER'S staff should be aware how the scope, responsibility and authority of their roles contribute to the achievement of corporate quality objectives. Staff should have a clear understanding of their freedom to take action to ensure quality objectives are met.

Additionally, for the manufacture of MEDICAL DEVICES, EN 46001 and EN 46002 require that management documents the organizational structure, to show the levels of responsibility, authority and staff inter-relationships. These inter-relationships are commonly shown on organization charts.

Staff having the authority to change the QUALITY SYSTEM or the processes controlled by the QUALITY SYSTEM should be identified and their job requirements defined.

Duties to be shared between the job specifications include

- the control and maintenance of the QUALITY SYSTEM, aimed at the prevention of quality deficiencies against the SPECIFIED REQUIREMENTS;

- the control of a CORRECTIVE ACTION system that prevents the recurrence of the quality deficiencies, by ensuring that changes to the QUALITY SYSTEM intended to prevent manufacture of non-conforming PRODUCT are effective;

- organising formal and systematic MANAGEMENT REVIEW of the QUALITY SYSTEM, to ensure that it remains appropriate to the quality objectives;

- the expert assessment of any PROCEDURES for microbiological control, and the validation protocols for all processes where microbiological control is of significance;

- managerial control of any sterilization processes, and ensuring these operate within VALIDATED parameters.

4.1.2.2 VERIFICATION resources and personnel

[Also applies to 4.1.2.2 of EN 29002 and EN 46002]

VERIFICATION resources include the provision of adequate time for the test and VERIFICATION PROCEDURES to be carried out.

Management may consider obtaining specialist professional control through a sub-contract to another organization, while employing their own staff to implement agreed PROCEDURES in a routine manner.

4.1.2.3 Management representative

[Also applies to 4.1.2.3 of EN 29002 and EN 46002]

A SUPPLIER of ACTIVE MEDICAL DEVICES should appoint a management representative within his organization whose function is to maintain and coordinate the implementation of the QUALITY SYSTEM. If the management representative has other functions to perform, these should not cause a conflict of interests.

To ensure that the management representative's duties remain clearly defined, they alone should be authorized to delegate their defined authority.

The management representative should have the responsibility and authority for ensuring that EN 29001 in combination with EN 46001 or EN 29002 in combination with EN 46002 are

complied with throughout the organization. This role implies responsibility for assigning the duties to

- approve documents defining the QUALITY SYSTEM;
- review SUB-CONTRACTOR'S QUALITY SYSTEM (see 4.6.2), to ensure that purchased PRODUCT fully complies with the SPECIFIED REQUIREMENTS;
- specify PROCEDURES for QUALITY CONTROL;
- review cleaning and maintenance instructions, to ensure the PROCEDURES do not hazard the quality of the PRODUCT, and approve and enforce PROCEDURES intended to prevent inadvertent contamination of any MEDICAL DEVICE;
- take and evaluate samples, sufficient to confirm that the SPECIFIED REQUIREMENTS are being met;
- segregate and control rejected items;
- authorize and document any CONCESSION that allows an item not meeting the original requirement to be released;
- analyze reports of DEFECTS;
- review the examination and documentation of returned ACTIVE MEDICAL DEVICES;
- publicize, within the SUPPLIER'S organization, the results of QUALITY CONTROL PROCEDURES, of analyses of reports of MEDICAL DEVICE defects, and of examinations of returned MEDICAL DEVICES, so that CORRECTIVE ACTION can be taken as necessary;
- ensure the preservation of copies of the DEVICE MASTER RECORD relating to released ACTIVE MEDICAL DEVICES (see 4.5);
- ensure the preservation of the DEVICE HISTORY RECORD (see 4.10.4 and 4.16).

4.1.3 MANAGEMENT REVIEW

[Also applies to 4.1.3 of EN 29002 and EN 46002]

Management can fulfil its duty to monitor the continuing suitability and effectiveness of the QUALITY SYSTEM by conducting periodic, systematic reviews. Such MANAGEMENT REVIEWS are additional to, and use the findings of, internal QUALITY AUDITS (see 4.17) conducted to ensure continued adherence to the system. Both MANAGEMENT REVIEWS and QUALITY AUDITS should be performed regularly, and not be conducted as a reaction after quality problems have been identified.

EN 46001 and EN 46002 require that the MANAGEMENT REVIEW process and the reasons behind are known and understood by staff responsible for the day to day operation of the QUALITY SYSTEM.

MANAGEMENT REVIEW should include

- review of the actual QUALITY of the MEDICAL DEVICES being placed on the market, as indicated by information based on external feedback, internal feedback, and statistics on process or PRODUCT performance;

- review of internal audit results, to confirm that the current working methods reflect the defined QUALITY SYSTEM;

- review the suitability of documented policy and PROCEDURES that define the quality system, to ensure that the quality objectives of the organization are met;

- considerations for up-dating the QUALITY MANAGEMENT in relation to changes brought about by new technologies, quality concepts, market strategies, and social or environmental conditions.

EN 46001 and EN 46002 require that the MANAGEMENT REVIEW is performed in accordance with documented PROCEDURES, and that records should be kept of the review and the changes initiated. Timetables should be established for implementing changes which cannot be implemented immediately. The effectiveness of decisions should be reviewed at subsequent meetings.

4.2 Quality system

[Also applies to 4.2 of EN 29002 and EN 46002]

Typically, the quality system is defined by a QUALITY MANUAL. This may be a single document or file, or a hierarchy of documents, or even legible output from an information storage system.

At the highest level, the QUALITY MANUAL will set out the QUALITY POLICY of the SUPPLIER and his operational PROCEDURES for the design, manufacture, and release of MEDICAL DEVICES.

The QUALITY MANUAL is usually supported by documents that define PROCEDURES in detail, work instructions, and requirements for product and processes.

The SPECIFIED REQUIREMENTS for ACTIVE MEDICAL DEVICES placed on the market are set by the SUPPLIER, usually based on his perception of clinical need and the potential market. Within the SUPPLIER'S organization, for each specific model of MEDICAL DEVICE, documentation should identify the requirements for the device that ensure its fitness for use, and the means by which the requirements are met.

4.3 Contract review

[Also applies to 4.3 of EN 29002 and EN 46002]

These requirements are 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 4.6 of EN 29001.

The SUPPLIER of a MEDICAL DEVICE may need to review the CUSTOMER'S order in a systematic and defined manner to ensure understanding and agreement of a delivery schedule that allows adequate time for all quality related aspects.

The key steps to be taken should include:

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

- discussion by all relevant parties involved of any difference or NON-CONFORMITY to the originally SPECIFIED REQUIREMENTS, required as a consequence of the agreed changes (for example PRODUCT lifetime, packaging, default settings) and recording, as part of the contract documentation, the conclusions reached together with how the differences are to be resolved;

- that the parties involved follow a defined PROCEDURE to ensure that they have the necessary resources, organization and facilities to conform to all the requirements in the contract.

For custom-made devices, a more extensive review may be required. This review should be conducted against prescribed stages or steps.

4.4 Design control

4.4.1 General

The design PROCEDURE for a MEDICAL DEVICE should be fully specified in the SUPPLIER'S QUALITY SYSTEM.

The design PROCEDURE should be capable of taking the SPECIFIED REQUIREMENTS and translating them, in a systematic and controlled way, into a SPECIFICATION that defines the MEDICAL DEVICE.

Specific guidelines on the application of EN 29001 to the development of software are provided by EN 29000-3.

4.4.2 Design and development planning

Design planning should include the preparation of a time-phase design programme, with checkpoints appropriate to the nature of the PRODUCT, to ensure that all QUALITY SYSTEMS' requirements are met.

If any clinical evaluation is necessary, the SUPPLIER should consider whether any special documentation is required to comply with regulatory PROCEDURES (see EN 540).

4.4.2.1 Activity assignment

The responsibilities for specific design functions should be clearly assigned to designated personnel. Design activities should be specified to a level of detail that permits subsequent VERIFICATION of the actual design process.