



QUALITY SYSTEMS STANDARDS

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Singapore 2002/05/17

BASIC STANDARDS

- ISO 9001 , 2 & 3:1994
 - ISO 9001:2000
 - EN 46001 , 2 :1993 Revised in 1996
 - ISO 13485 & 8:1996
 - DIS 13485:2002 =(ISO 13485:2003)
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ISO 9001

- ISO 9001:1987 >>> ISO 9001:1994
 - Quality systems- Model for quality assurance in design, development, production, installation and servicing
 - ISO 9002:1994=ISO 9001 without design and development
 - ISO 9001:2000
 - Quality management systems- Requirements
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EN 46001 & 2

EN 46001 & 2:1996 were developed by CEN & CENELEC to provide models for quality systems required by EU directives for medical devices – they are an editorial revision of versions published in 1993.

They require compliance with all of ISO 9001 & 2:1994 respectively, plus several requirements (in appropriate clauses in the standards) particular to medical devices.

ISO 13485 & 8

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ISO 13485 & 8:1996 were developed by ISO TC 210 – based on EN 46001 & 2 – to provide International Standards as models for quality systems for any countries outside Europe that wanted to use them

CEN & CENELEC have now also adopted ISO 13485 & 8:1996 as EN to replace EN 46001 & 2 in due course – (EN 46001 & 2 will be withdrawn in February 2004)

ISO 13485 & 8

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Like EN 46001 & 2 , ISO 13485 & 8:1996 require all of ISO 9001 & 2:1994 plus particular requirements for medical devices

Since ISO 9001 & 2:1994 have been revised and published as ISO 9001:2000 , ISO TC 210 are now in the process of revising ISO 13485 & 8:1996

ISO 9001:2000 / DIS 13485(2002)

ISO 9001:2000 – Title

Quality management systems – Requirements

DIS 13485 –Title

Quality systems – medical devices – System requirements for regulatory purposes

DIS 13485(2002)

SCOPE

This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices that consistently meet customer requirements and regulatory requirements applicable to medical devices.

DIS 13485(2002)

SCOPE 2

The primary objective of ISO 13485 is to facilitate harmonised medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the ISO 9001:2000 requirements that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001:2000 unless their quality management systems conform to the additional ISO 9001:2000 requirements

ISO 9001:2000 APPLICATION

Clause 1.2 (in part)

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organisation and its product, this can be considered for exclusion.

Where exclusions are made, ...these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organisation's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements

DIS 13485(2002) APPLICATION

Clause 1.2 (in part)

(Para 1) All requirements of this International standard are specific to the medical device industry, regardless of the type or size of the organisation.

(Para 4) In addition, regulatory requirements can permit exclusions for design and development controls. These regulations can provide alternative arrangements that must be addressed in the quality management system.

PRODUCT DESIGN

- As a result of the foregoing, it is therefore possible to tailor the quality system to cover medical devices in different risk classifications – provided the element of product design is covered in an appropriate way.
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QUALITY SYSTEM REGULATION

- Those of you considering setting up regulatory systems for medical devices should use ISO 13485:2003 as their model and not ISO 9001:2000
 - The EU Directive (93/42/EEC) allows 3 quality systems for various classes of devices. ISO 13485:2003 will cover all systems by simply allowing omission of certain sub-clauses in clause 7
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ISO 9001:2000

- Clause 4 Quality management system
 - Clause 5 Management responsibility
 - Clause 6 Resource management
 - Clause 7 Product realization
 - Clause 8 Measurement, analysis and improvement

 - The standard allows omission of parts or all of clause 7
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ISO 9001:2000 CLAUSE 7

- 7 Product realization
 - >7.1 Planning of product realization
 - >7.2 Customer-related processes
 - >7.3 Design and Development
 - >7.4 Purchasing
 - >7.5 Production and service provision
 - >7.6 Control of monitoring and measuring devices
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ISO 13485:2003 (DIS 13485)

- Will have the same format as ISO 9001:2000
- Will modify clauses in ISO 9001 that require “customer satisfaction” “continual improvement”
- Will incorporate particular requirements for medical devices that are in ISO 13485:1996
- Will retain documentation requirements
- Will be a “stand alone” standard
- Will allow omission of sub-clauses in clause 7 if they are not required for regulatory purposes

TYPE TESTING

As an alternative to design control within a quality system, the EU directive allows a procedure whereby the manufacturer submits a sample of the product with specifications and details of the manufacturing process to an approved test house for approval. The manufacturer then must declare that every product subsequently manufactured complies with the sample submitted – he will also have a quality system such as ISO 13488.

CONCLUSIONS

- Quality systems are the central plank of regulations covering medical devices
 - ISO 13485:1996 >>> ISO 13485:2003 provides an appropriate model for regulatory purposes
 - ISO 13485:2003 will be “stand alone” so no reference to ISO 9001 is required
 - Many countries (including regulators) have participated in the drafting and revision of ISO 13485
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