

**CROSS REFERENCE
BETWEEN THE
WORKING DRAFT OF THE FINAL QUALITY SYSTEM REGULATION
AND
ISO 9001:1994 & EN 46001:1994**

Working Draft of the Final Quality System Regulation 21 CFR § 820	ISO 9001:1994 & EN 46001:1994
§ 820.1 Scope	ISO - 1 Scope <i>EN - 1 Scope</i>
§ 820.3 Definitions	ISO - 3 Definitions <i>EN - 3 Definitions</i>
§ 820.5 Quality system	ISO - 4.2 Quality System ISO - 4.2.1 General ISO - 4.2.2 Quality-system procedures
§ 820.20 Management responsibility	ISO - 4.1 Management responsibility
§ 820.20(a) Quality policy	ISO - 4.1.1 Quality policy
§ 820.20(b) Organization	ISO - 4.1.2 Organization
§ 820.20(b)(i) Responsibility and authority	ISO - 4.1.2.1 Responsibility and authority <i>EN - 4.1.2.1 Responsibility and authority</i>
§ 820.20(b)(2) Resources	ISO - 4.1.2.2 Resources
§ 820.20(b)(3) Management representative	ISO - 4.1.2.3 Management representative
§ 820.20(c) Management review	ISO - 4.1.3 Management review
§ 820.22 Quality audit	ISO - 4.17 Internal Quality Audits
§ 820.25 Personnel	ISO - 4 Quality System Requirements
§ 820.25(a) General	ISO - 4.1.2.2 Resources
§ 820.25(b) Training	ISO - 4.18 Training
§ 820.30 Design Controls	ISO - 4.4 Design Control

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§ 820.30(a) General	ISO - 4.4.1 General
§ 820.30(b) Design and development planning	ISO - 4.4.2 Design and development planning ISO - 4.4.3 Organizational and technical interfaces
§ 820.30(c) Design input	ISO - 4.4.4 Design input <i>EN - 4.4.3 Design input</i>
§ 820.30(d) Design output	ISO - 4.4.5 Design output
§ 820.30(e) Design review	ISO - 4.4.6 Design review
§ 820.30(f) Design verification and validation	ISO - 4.4.7 Design verification ISO - 4.4.8 Design validation <i>EN - 4.4.5 Design verification</i>
§ 820.30(g) Design transfer	ISO - 4.2.3(c) Quality planning
§ 820.30(h) Design changes	ISO - 4.4.9 Design changes
§ 820.30(i) Design history file	ISO - 4.16 Control of Quality Records
§ 820.40 Document control	ISO - 4.5 Document and Data Control ISO - 4.5.1 General
§ 820.40(a) Document approval and distribution	ISO - 4.5.2 Document and data approval and issue
§ 820.40(b) Document changes	ISO - 4.5.3 Document and data changes
§ 820.50 Purchasing controls	ISO - 4.6 Purchasing ISO - 4.6.1 General
§ 820.50(a) Evaluation of suppliers, contractors, and consultants	ISO - 4.6.2 Evaluation of subcontractors
§ 820.50(b) Purchasing data	ISO - 4.6.3 Purchasing data <i>EN - 4.6.3 Purchasing data</i>
§ 820.60 Identification	ISO - 4.8 Product Identification and Traceability <i>EN - 4.8(a) Product identification and traceability</i>

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§ 820.65 Traceability	ISO - 4.8 Product Identification and Traceability <i>EN - 4.8(b) Product identification and traceability</i>
§ 820.70 Production and process controls	ISO - 4.9 Process Control
§ 820.70(a) General	ISO - 4.9(a), (c), (d), (e), (f)
§ 820.70(b) Production and process changes	ISO - 4.4.9 Design changes
§ 820.70(c) Environmental control	<i>EN - 4.9.1(b) Environmental control in manufacture</i>
§ 820.70(d) Personnel	<i>EN - 4.9.1(a) Personnel</i> <i>EN - 4.18 Training</i>
§ 820.70(e) Contamination control	<i>EN - 4.9.1(c) Cleanliness of product</i>
§ 820.70(f) Buildings	ISO - 4.9(b)
§ 820.70(g) Equipment	ISO - 4.9(b), (g) <i>EN - 4.9.1(d) Maintenance</i>
§ 820.70(h) Manufacturing material	<i>EN - 4.9.1(c) Cleanliness of product</i>
§ 820.70(i) Automated processes	Recommended in Working Draft of ISO/DIS 13485
§ 820.75 Process validation	ISO - 4.9 Process Control <i>EN - 4.9.2 Special processes</i>
§ 820.80 Receiving, in-process, and finished device acceptance	ISO - 4.10 Inspection and Testing
§ 820.80(a) General	ISO - 4.10.1 General
§ 820.80(b) Receiving acceptance activities	ISO - 4.10.2 Receiving inspection and testing ISO - 4.7 Control of Customer-Supplied Product
§ 820.80(c) In-process acceptance activities	ISO - 4.10.3 In-process inspection and testing

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§ 820.80(d) Final acceptance activities	ISO - 4.10.4 Final inspection and testing
§ 820.80(e) Acceptance records	ISO - 4.10.5 Inspection and test records <i>EN - 4.10.4 Inspection and test records</i>
§ 820.84 Inspection, measuring, and test equipment	ISO - 4.11 Control of Inspection, Measuring, and Test Equipment
§ 820.86 Acceptance status	ISO - 4.12 Inspection and Test Status
§ 820.90 Nonconforming product	ISO - 4.13 Control of Nonconforming Product
§ 820.90(a) Control of nonconforming product	ISO - 4.13.1 General
§ 820.90(b) Nonconformity review and disposition	ISO - 4.13.2 Review and disposition of nonconforming product <i>EN - 4.13.1 Nonconformity review and disposition</i>
§ 820.100 Corrective and preventive action	ISO - 4.14 Corrective and Preventive Action <i>EN - 4.14 Corrective action</i>
§ 820.120 Handling	ISO - 4.15.1 General ISO - 4.15.2 Handling <i>EN - 4.15.1 General</i>
§ 820.122 Storage	ISO - 4.15.1 General ISO - 4.15.3 Storage ISO - 4.15.5 Preservation <i>EN - 4.15.1 General</i>
§ 820.124 Distribution	ISO - 4.15.1 General ISO - 4.15.6 Delivery <i>EN - 4.15.5 Delivery</i>
§ 820.126 Installation	ISO - 4.9 Process Control <i>EN - 4.9.1(e) Installation</i>

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§ 820.160 Device packaging	ISO - 4.15.1 General ISO - 4.15.4 Packaging <i>EN - 4.15.4 Packaging</i>
§ 820.162 Device labeling	<i>EN - 4.15.4 Packaging</i>
§ 820.180 General requirements	ISO - 4.16 Control of Quality Records ISO - 4.5 Document and Data Control ISO - 4.5.1 General <i>EN - 4.5.1 Document approval and issue</i> <i>EN - 4.16 Quality records</i>
§ 820.181 Device master record	ISO - 4.16 Control of Quality Records ISO - 4.2.2 Quality-system procedures <i>EN - 4.2 Quality system</i>
§ 820.184 Device history record	ISO - 4.16 Control of Quality Records <i>EN - 4.16 Quality records</i>
§ 820.186 Quality system records	ISO - 4.16 Control of Quality Records ISO - 4.2.1 General ISO - 4.2.2 Quality-system procedures ISO - 4.2.3 Quality planning <i>EN - 4.2 Quality system</i>
§ 820.198 Complaint files	ISO - 4.14.2 Corrective action ISO - 4.14.3 Preventive action <i>EN - 4.14 Corrective action</i>
§ 820.200 Servicing	ISO - 4.19 Servicing ISO - 4.9 Process Control
§ 820.250 Statistical techniques	ISO - 4.20 Statistical Techniques <i>EN - 4.20 Statistical techniques</i>
No equivalence	ISO - 4.3 Contract Review