

# DIN EN 15224:2012-12 (E)

## Health care services - Quality management systems - Requirements based on EN ISO 9001:2008

---

<b>Contents</b>		<b>Page</b>
Foreword .....		5
Introduction .....		6
0.1	Quality in health care .....	6
0.1.1	General .....	6
0.1.2	The concept of "health" .....	7
0.1.3	Health care .....	7
0.1.4	Quality in health care .....	7
0.1.5	The concept of "clinical" .....	8
0.1.6	Clinical risk .....	8
0.1.7	Health care specific preconditions .....	8
0.2	Process approach .....	10
0.2.1	General .....	10
0.2.2	Process approach and improvements .....	11
0.3	Compatibility with other standards .....	12
1	Scope .....	13
1.1	General .....	13
1.2	Application .....	13
2	Normative references .....	14
3	Terms and definitions .....	14
4	Quality management systems .....	18
4.1	General requirements .....	18
4.2	Documentation requirements .....	19
4.2.1	General .....	19
4.2.2	Quality manual .....	20
4.2.3	Control of documents .....	20
4.2.4	Control of records .....	21
5	Management responsibility .....	21
5.1	Management commitment .....	21
5.2	Customer focus .....	22
5.3	Quality policy .....	22
5.4	Planning .....	22
5.4.1	Quality objectives .....	22
5.4.2	Quality management system planning .....	23
5.5	Responsibility, authority and communication .....	23
5.5.1	Responsibility and authority .....	23
5.5.2	Management representative .....	23
5.5.3	Internal communication .....	24
5.6	Management review .....	24
5.6.1	General .....	24
5.6.2	Review input .....	25
5.6.3	Review output .....	25
6	Resource management .....	26
6.1	Provision of resources .....	26

6.2	Human resources .....	26
6.2.1	General .....	26
6.2.2	Competence, awareness and training .....	26
6.3	Infrastructure .....	27
6.4	Work environment .....	27
7	Product realization .....	27
7.1	Planning of product realization .....	27
7.2	Customer-related processes .....	28
7.2.1	Determination of requirements related to the product (health care service) .....	28
7.2.2	Review of requirements related to the product (health care service) .....	29
7.2.3	Customer communication .....	29
7.3	Design and development .....	30
7.3.1	Design and development planning .....	30
7.3.2	Design and development inputs .....	31
7.3.3	Design and development outputs .....	31
7.3.4	Design and development review .....	32
7.3.5	Design and development verification .....	32
7.3.6	Design and development validation .....	32
7.3.7	Control of design and development changes .....	32
7.4	Purchasing .....	32
7.4.1	Purchasing process .....	32
7.4.2	Purchasing information .....	33
7.4.3	Verification of purchased service/product .....	33
7.5	Production and service provision .....	33
7.5.1	Control of production and service provision .....	33
7.5.2	Validation of processes for production and service provision .....	34
7.5.3	Identification and traceability .....	34
7.5.4	Customer property .....	35
7.5.5	Preservation of product .....	35
7.6	Control of monitoring and measuring equipment .....	35
8	Measurement, analysis and improvement .....	36
8.1	General .....	36
8.2	Monitoring and measurement .....	36
8.2.1	Customer satisfaction .....	36
8.2.2	Internal audit .....	37
8.2.3	Monitoring and measurement of processes .....	37
8.2.4	Monitoring and measurement of product (health care service) .....	38
8.3	Control of non-conforming product (health care service) .....	38
8.4	Analysis of data .....	38
8.5	Improvement .....	39
8.5.1	Continual improvement .....	39
8.5.2	Corrective action .....	39
8.5.3	Preventive action .....	39
<b>Annex B (informative) Practical guide for the implementation of this standard in health care organizations .....</b>		<b>45</b>
B.1	General .....	45
B.2	Preparation and planning .....	45
B.2.1	General .....	45
B.2.2	Leadership in quality .....	46
B.2.3	Planning the quality management system set-up .....	46
B.2.4	Education and training in quality management .....	46
B.2.5	Customer focus .....	47
B.2.6	Planning the documentation .....	47
B.2.7	Provision of necessary resources .....	48
B.3	Implementing the quality management system .....	48
B.3.1	General .....	48
B.3.2	Quality policy .....	48
B.3.3	Quality characteristics and quality requirements in health care .....	49

<b>B.3.4</b>	<b>Quality objectives .....</b>	<b>50</b>
<b>B.3.5</b>	<b>Personnel working for and on behalf of the organization .....</b>	<b>50</b>
<b>B.3.6</b>	<b>Authority, responsibility and accountability .....</b>	<b>51</b>
<b>B.3.7</b>	<b>Communication and information management .....</b>	<b>51</b>
<b>B.3.8</b>	<b>Documenting the quality management system .....</b>	<b>51</b>
<b>B.3.9</b>	<b>Process-oriented quality management .....</b>	<b>53</b>
<b>B.4</b>	<b>Establishing the monitoring and evaluation system .....</b>	<b>55</b>
<b>B.4.1</b>	<b>General .....</b>	<b>55</b>
<b>B.4.2</b>	<b>Risk management .....</b>	<b>57</b>
<b>B.5</b>	<b>Continual improvement .....</b>	<b>58</b>
<b>B.5.1</b>	<b>General .....</b>	<b>58</b>
<b>B.5.2</b>	<b>Analysis of collected data .....</b>	<b>59</b>
<b>B.5.3</b>	<b>Management reviews .....</b>	<b>59</b>
<b>B.5.4</b>	<b>Corrective action .....</b>	<b>59</b>
<b>Bibliography .....</b>		<b>64</b>