

Quality management system - Requirements

Context of the organisation	4.1	Understand the organization and its context	
	4.2	Understanding the needs and expectations of interested parties	
	4.3	Determining the scope of the quality management system	
	4.5	Quality management system and its processes	
Leadership	5.1	Leadership and commitment	General Customer focus
	5.2	Policy	Establishing the quality policy Communicating the quality policy
	5.3	Organizational roles, responsibilities and authorities	
Planning	6.1	Actions to address risks and opportunities	
	6.2	Quality objectives and planning to achieve them	
	6.3	Planning of change	
Support	7.1	Resources	General
			People
			Infrastructure
			Environment for the operation of processes
			Monitoring and measuring resources
	Organizational knowledge		
7.2	Competence		
7.3	Awareness		
7.4	Communication		
7.5	Documented information	General	

			Creating and updating Control of documented information
Operation	8.1	Operational planning and control	
	8.2	Requirements for products and services	Customer communication
			Determining the requirements for products and services
			Review of the requirements for products and services
	8.3	Design and development of products and services	Changes to requirements for products and services
			General
			Design and development planning
			Design and development inputs
			Design and development controls
	8.4	Control of externally provided processes, products and services	Design and development outputs
Design and development changes			
General			
8.5	Production and service provision	Type and extent of control	
		Information for external providers	
		Control of production and service provision	
		Identification and traceability	
		Property belonging to customers or external providers	
		Preservation	
8.6	Release of products and services	Post-delivery activities	
8.7	Control of nonconforming outputs	Control of change	
Performance	9.1	Monitoring, measurement, analysis and evaluation	General
			Customer satisfaction
			Analysis and evaluation

evaluation	9.2	Internal audit	
	9.3	Management review	General
Management review inputs			
Management review outputs			
Improvement	10.1	General	
	10.2	Nonconformity and corrective action	
	10.3	Continual improvement	

Note 1. The improvement section above, Section 10, refers, predominantly, to the improvement of the work process and not the specification of the Service.

Note 2. The Sections highlighted in red are the Sections identified as the most suitable starting point for the design and implementation of a QMS for the NHS from the top down (Senior Management).

Note 3. The Sections highlighted in blue are the Sections identified as the most suitable starting point for the design and implementation of a QMS for the NHS from the bottom up (Front Line Staff).