Transition Checkup for ISO 13485:2003

BY MARK KAGANOV

While the ISO 9001:2000 transition is now behind us, medical device manufacturers are just beginning their transitions from the 1996 edition of ISO 13485 to the new 2003 edition.

The following is the story of a small US-based medical device manufacturer that completed the transition to the new standard while meeting the requirements of both the 2003 and 1996 editions of the ISO 9000-based quality requirement. This approach allowed the company to maintain a common quality manual for the transition period.

Why Meet Two Standards

The company's management team decided to upgrade its current quality management system (QMS) documentation to meet the requirements of the new standard soon after its release last summer. The management team appointed its director of quality assurance and its management representative to develop a system to meet the requirements of both editions. At the time of project conceptualization, the company's registrar was not yet accredited to the new standard, so this strategy would guarantee that there would be no break in accreditation.

The management representative reviewed drafts of the revised standard prior to its official publication. Based on the draft requirements, it was clear that of all of the previous requirements had been retained and quite a few new ones had been added.

The management representative prepared a draft of the quality manual to meet the requirements of the new ISO 13485:2003 standard. The management representative used checklists for verifying the completeness of the quality manual. By completing the entire checklist, the management representative confirmed that the new ISO 13485:2003-based quality manual addressed all the requirements of the old standard.

As mentioned earlier, the new standard has a number of new requirements, and therefore needed new supporting procedures to address them.

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Figure 1 - ISO 13485:1996 Quality Manual Review Checklist, Record

Document title:	Quality manual (QM)
Document number:	20089
Revision level:	01
Date of release:	11/27/03

Legend

A	Acceptable	N	Not present
QMS	Quality Management System	QM	Quality Manual
SMD	Sterile medical devices	AIMD	Active implantable
IMD	Implantable medical devices		

4 QUALITY SYSTEM REQUIREMENTS	LOCATION, COMMENTS	A	N
4.1 Management responsibility	of 9001 applies		
4.2 Quality system	of 9001 applies		
4.2.1 General	of 9001 applies		
AMDs:			
…document specified requirements…	QM, 4.2.2	Y	
…regulatory requirements…	QM, 4.2.2	Y	
4.2.3 Quality planning	of 9001 applies		
AMDs: …establish file for:			
- complete manufacturing	QM, 5.4.2	Y	
- installation and servicing	QM, 5.4.2	Y	
Reference to 4.5.2	QM, 5.4.2	Y	
Reference to 4.16	QM, 5.4.2	Y	
4.3 Contract review	of 9001 applies		
4.4 Design control	of 9001 applies		
4.4.1 General	of 9001 applies		
AMDs:			
…Throughout the design process … evaluate need for risk analysis…	QM, 7.3.2	Y	
4.4.8 Design validation	of 9001 applies		
AMDs:			
…records of clinical evaluation…	QM, 7.3.6	Y	
4.5 Document and data control	of 9001 applies		
4.5.2 Document & data approval & issue	of 9001 applies		
AMDs:			
…define lifetime of devices…	QM, 4.2.3	Y	
…one copy of obsolete documents…	QM, 4.2.3	Y	
4.6 Purchasing	of 9001 applies		
4.6.3 Purchasing data	of 9001 applies		
…	…		

Forum

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In identifying which procedures could be used from the old ISO 13485:1996 QMS, and which needed to be developed, the management representative created a "map" showing a list of the procedures that the company chose to use to support the new quality management system. (See Figure 1 on page 12.)

At this point, the company had successfully identified and documented new requirements in the ISO 13485:2003 quality manual. The objective of this process was not to immediately become certified to the new standard as mentioned earlier, but to develop a quality manual for the transition period.

Figure 2 - ISO 13485:2003 Second Level Procedure List

No	Procedure title, ISO 13485:2003*	96**
1	Audit Procedure	Y
2	Balanced Scorecard	No
3	Corrective and Preventive Action (CAPA) Procedure	Y
4	Communication Procedure	No
5	Contract Review Procedure	Y
6	Customer Property Procedure	Y
7	**Data Analysis Procedure**	**No**
8	Design Management Procedure	Y
9	Documentation Management Procedure	Y
10	Documentation Master List	Y
11	**Infrastructure Procedure**	**No**
12	Inspection Procedure	Y
13	Management Review Procedure	Y
14	Material Handling Procedure	Y
15	Measuring Equipment Procedure	Y
16	Medical Device Specific Procedures	Y
17	Nonconformity Procedure	Y
18	Organizational Chart	Y
19	Post Market Surveillance Procedure	Y
20	Product Identification Procedure	Y
21	Product Realization Procedure	Y
22	Purchasing Procedure	Y
23	Quality Policy	Y
24	Records Procedure	Y
25	**Resource Management Procedure**	**No**
26	Servicing Procedure	Y
27	Statistical Techniques Procedure	Y
28	Supplier Partnership Program	Y
29	Training Procedure	Y
30	Validation Procedure	Y

** While ISO 13485:2003 standard requires a limited number of documented procedures, the company chose to use the list above to support its QMS.*

*** 96 column indicates presence of a procedure in the quality manual for ISO 13485:1996 revision of the standard.*

This meant that as long as the company was not claiming compliance to the new standard, it would not be held accountable for meeting the new requirements. The management representative referenced new procedures that still needed to be completed, and identified them as To Be Developed (TBD). (See Figure 2.)

For example, element 5.5.2 c of the quality manual read: "The top management has appointed Director of QA/RA who, irrespective of other responsibilities, has responsibility and authority to ensure the promotion of awareness of regulatory and customer requirements throughout the organization per the Communication Procedure (TBD)."

This example shows that a communication procedure still would need

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Figure 3 - ISO 13485:1996 vs. ISO 13485:2003 Manual, Reference Matrix

Requirement	ISO 13485	
	1996	This manual, 2000
Scope	1	1
Application (exclusions)	---	1.2 Application
Normative references	2	2
Definitions	3	3
Quality system requirements	4	---
MANAGEMENT RESPONSIBILITY	4.1	---
Quality policy	4.1.1	5.1 Mgmt. commitment 5.3 Quality policy 5.4.1 Quality objectives
Organization	4.1.2	---
Responsibility and authority	4.1.2.1	5.5.1 Responsibility and authority
Resources	4.1.2.2	5.1 Mgmt. commitment 6.1 Provision of resources 6.2.1 General, HR 6.3 Infrastructure
Management rep.	4.1.2.3	5.5.2 Management rep.
Management review	4.1.3	5.6.1 General, MR 5.6.2 Review input, MR 5.6.3 Review output, MR 8.5.1 Continual improv.
QUALITY SYSTEM	4.2	---
General	4.2.1	4.1 General requirements 4.2.1 General, Documentation 4.4.2 Quality manual 5.1 Mgmt. commitment 5.4.1 Quality objectives
Quality system procedures	4.2.2	4.2.1 General, Documentation
Quality planning	4.2.3	5.4.2 QMS planning 6.2.1 General, HR 7.1 Planning of product realization
...	...	...

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to be developed and implemented to support this element of the new quality manual.

Navigating the New Manual

Using the technique described above, the company created a new manual for the transition period. However, it was determined that both the company's personnel and its assessors needed to navigate through the manual to locate corresponding clauses of the old standard. To resolve this issue, the management representative added to the manual a cross-reference table showing where old requirements are addressed in the new manual. This table was designed as a set of hyperlinks to the appropriate locations in the new manual as shown in Figure 3 (see page 13). For example, using this figure one can easily determine that the management representative requirement 4.1.2.3 of the old standard is addressed in element 5.5.2 of our new quality manual.

Verification of the new manual

Once the new quality manual was completed and verified to be in compliance with the requirements of the ISO 13485:1996 standard, the management representative verified its compliance with the new revision of the standard.

The management representative employed an ISO 13485:2003 quality manual review checklist (see Figure 4), similar to the one used for verification of compliance to the old standard.

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Figure 4 - ISO 13485:2003 Quality Manual Review Checklist

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Clause	Requirements	Response location	A	N
1.2	Application	QM, 1.2	Y	
	exclusions are limited to Clause 7	QM, 1.2, no exclusions	Y	
4	QMS	QM, 4, Title only		
4.1	General requirements	QM, 4.1	Y	
	QMS per this standard	QM, 4.1	Y	
	maintain QMS effectiveness	QM, 4.1	Y	
a	identify the processes needed for QMS	QM, 4.1 a	Y	
b	sequence and interaction of processes	QM, 4.1.b	Y	
c	criteria and methods for the operation and control of processes are effective	QM, 4.1 c	Y	
d	availability of resources and information	QM, 4.1 d	Y	
e	monitor, measure and analyze processes	QM, 4.1 e	Y	
f	actions to achieve planned results and maintain the effectiveness of these processes	QM, 4.1 f	Y	
	management of processes in accordance with this standard	QM, 4.1 f	Y	
	management of outsourced processes	QM, 4.1 f	Y	
Note	processes for management activities…	QM, 4.1	Y	
	provision of resources…	QM, 4.1	Y	
	product realization and measurement…	QM, 4.1	Y	
4.2	Documentation requirements	QM, 4.2, Title only		
4.2.1	General	QM, 4.2.1	Y	
a	documented statements of a quality policy and quality objectives	QM, 4.2.1 a	Y	