Checklists – A Perfect Tool to Tune-up Your Manual

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Abstract

This paper offers practical methods to create and use checklists to verify compliance of a quality manual with the requirements of various international and national standards such as ISO 9001, EN 46001, ISO 9000: 2000, AS 9001 or any other. The author analyzes the advantages of using single- and multi-standard checklists. The various examples shown in the paper illustrate a practical approach to developing a simple yet very helpful tool to ensure that your quality manual addresses all the requirements of the applicable standards.

Introduction

Did you ever arrive at your camp site and realize that you forgot your fishing rod or charcoal for the grill? Did you ever arrive at a hotel on a business trip to find that your lap top power adapter is still on your desk in the office? Most likely at one time or another each of us found ourselves in situations where we were so busy preparing for an event that we forgot something important. The same thing happens when writing quality manuals – very often some of the requirements of the standards are forgotten and not addressed in the quality manual that per the requirement of ISO 9001: 1994, element 4.2.1 [1], shall cover "…the requirements of this International Standard."

The problem of forgetting to include some requirements in a quality manual is not just hypothetical. Through my work in the registration business with dozens of companies in the US, England, Mexico, the Pacific Rim and South East Asia, I have witnessed the implementation of numerous quality systems. I realize that what seemed to be a simple task of creating a quality manual and documenting a company's commitment to a particular standard can create significant difficulties for companies of various sizes, in diverse industries, in different countries. During my career in the registration business, I have not yet seen a quality manual that addressed all the requirements of an applicable standard on initial review.

There is a simple solution – using a checklist. Going back to the example of the forgotten fishing rod, most books for camping contain checklists of what you need to take on a fishing, climbing or camping trip. Not long ago I even saw a book that listed what business travelers need to take on a business trip. You may wonder what a checklist has to do with quality manuals. A quality manual for ISO 9001, EN 46001 [2], ISO 13485 [3], ISO Guide 25 [4] or any other standard or regulation, if we follow the rule to cover "…the requirements of this International Standard," may be a somewhat complicated document. Since we are human

beings, it is not unusual that some of these requirements may be missed and not addressed in the quality manual. Using a checklist will help you remember all the requirements. This is why many registrars use quality manual review checklists on initial assessments.

Creating a checklist

Checklists are widely used by companies in various industries for documenting test results, equipment maintenance procedures, internal audits and other tasks. Surprisingly, it is rare that companies use checklists for verification of quality manuals. If you are in the process of developing a quality system for registration, or reviewing your existing quality manual, you may ask your registrar for a checklist. If your registrar does not have one, creating a checklist for a standard is a relatively simple task. Based on the premise that a quality manual should cover all the requirements of a standard, we simply need to condense the standard into a set of requirements. For example, the simplest checklist for the ISO 9001: 1994 standard is a list of its 20 elements. A checklist in this format would look like the one shown in Figure 1.

Using the checklist, it is a good idea to not only note the requirement is included in your manual, but also its location. In Figure 1 the location of the responses in the quality manual is numbered synchronously with the elements of the standard. Whether you are creating your quality manual from scratch or tuning-up an existing manual, it may be a good idea to keep the numbers of the responses in your manual in sync with the elements of the standard. That's what we call user-friendly numeration. It is difficult for both a user and an assessor to work with a manual that, for example, addresses the requirements of element 4.4.1 of the standard in part 7.6.3.5 of the quality manual. I have seen a few examples of extremely creative numbering systems that quickly gave everyone a headache. It may be a very good idea to be gentle on yourself, your colleagues and your assessors – consider keeping the numeration simple and synchronized with the standard.

The simple checklist shown in Figure 1 may help you to verify if all elements of the standard are addressed in your quality manual. However, most likely it will not be sufficient to your quality system or your registrar, since there are many more requirements in this standard. To continue enhancing the checklist in Figure 1, you may consider including the requirements of sub-elements of the standard. In this case the checklist will be transformed into the list shown in Figure 2.

This expanded checklist includes requirements of both the elements and sub-elements of the standard and most likely will satisfy most quality systems and registrars. Depending on how detailed you want to be covering "the requirements of this International Standard," there are still ways to continue enhancing your

checklist. For example, element 4.1.3, Management review, makes reference to the element 4.16, Quality records; element 4.2.1, Organization, references ISO 10013 standard and so on. If you wish to include this level of detail in your manual, you can add them to your checklist. In this case the checklist would look like the one shown in Figure 3.

This version of the checklist is much more detailed than the original example shown in Figure 1. However, just requiring the conduct of management reviews in response to the requirement 4.1.3 will not ensure that other requirements of this element are adequately covered in your manual. If you choose to go to yet the next level of detail in your quality manual review checklist, you may consider less obvious requirements. Most of the requirements in all standards are identified with the word *shall*. But there are also requirements that are subtly stated and can be identified through some other key words. Let's, for example, take a look at the requirement 4.1.3, Management review, of the ISO 9001: 1994.

*"The supplier's management with executive responsibility **shall** review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this International Standard and the supplier's stated quality goals and objectives (see 4.1.1). Records of such reviews **shall** be maintained (see 4.16)."*

This clause may be translated into the following requirements:

Shall: Review,
Defined intervals,
Ensure continuing suitability and effectiveness, and
Maintain records

Subtle: What constitutes "management with executive responsibility"?
Are quality goals and objectives defined?
Are they measurable to assess effectiveness?

Addressing subtle requirements, your checklist for the given sub-element may look similar to one shown in Figure 4. With this kind of a detailed checklist, you most likely will not miss any requirements of the standard in your quality manual. Using checklists during the initial release and subsequent revisions of the quality manual will ensure that all the requirements are addressed in your quality system.

So far in our examples we have discussed only one standard. Various industries use the ISO 9001 standard along with others. For example, EN 46001 and ISO 13485 for medical device manufacturers are not independent standards. They must be used in conjunction with the ISO 9001 standard. There are a couple of approaches that you may consider when creating a quality manual checklist for more than one standard. The first one is to use two standard-specific checklists.

For example, if you are in the medical device manufacturing industry and need to comply with ISO 9001 and EN 46001, you may use a checklist illustrated in Figures 3 or 4 for ISO 9001 standard along with a similar checklist developed for EN 46001. This checklist will address the requirements for various types of medical devices. An example of a checklist for EN 46001 is shown in Figure 5.

Another approach is to develop one checklist covering the requirements of all standards applicable to your quality system. If your quality manual addresses requirements of more than one standard, you can identify all the requirements in a common checklist. If, for example, you combine the requirements of ISO 9001 and EN 46001 standards into one checklist, you may have a checklist similar to the one shown in Figure 6. When working with checklists for more than one standard, it is a good idea to include identifiers denoting which requirements belong to what standard. The heart symbol in Figure 6 is used to identify requirements of the medical EN 46001 standard. The same approach may be used for standards that include text of the ISO 9001 standard, such as QS 9001: 1998 [5] for automotive and SAE AS 9001: 1998 [6] for aerospace industries. An example of a checklist for SAE AS 9001: 1998 is shown in Figure 7.

So far we have reviewed checklists for one standard, a set of related standards and combining requirements of a basic standard, such as ISO 9001, with industry specific standards. What if you also want to incorporate into your system the requirements of ISO 14001 [7]? An environmental system for ISO 14001 is independent from the ISO 9001 standard. Some companies choose to create a separate environmental management system rather than including ISO 14001 requirements in the existing system and documentation structure. Other companies choose to create one common quality and environmental system and manual. If you choose to document your quality and environmental systems in one manual, the checklist for the three standards, ISO 9001, EN 46001 and ISO 14001 may look like the one shown in Figure 8.

While it appears to be convenient to have one common checklist for multiple standards, there are practical limitations to this approach. If you think that things became complicated with two or three standards, as shown in Figure 8, wait until you get into the real world. What if, for example, you manufacture medical devices that you sell to the US and European markets, and your system is also certified to ISO 14001? The quality and environmental system of a company with this scope of activities will be expected to comply with the following standards and regulations:

1 ISO 9001, 2 or 3
2 EN 46001 or 2
3 ISO 13485 (if chosen or required),
4 The US FDA 21 CFR 820 [8],
5 The US FDA 21 CFR 803 and 804 [8],
6 European Council Directive 93/42/EEC [9], applicable Annexes, and

7 ISO 14001

Are there any volunteers to design a common checklist with the cross-reference structure for this type of quality and environmental system? No? I can't blame you. For complex quality and environmental systems, combined checklists may not be practical to create or use. A set of checklists covering the individual standards and regulations may be a more practical approach.

The approach I've described to designing quality and environmental manual review checklists is not limited to national and international standards. It can also be used to verify compliance with domestic and international regulations such as the US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), European Council Directive 93/42/EEC and others. An example of a checklist for FDA 21 CFR 820 that may be of interest to medical device manufacturers is shown in Figure 9.

With the revision of ISO 9000: 2000 standards coming out at the end of year 2000, you can get an early start preparing your checklist for the new standard now. Numerous sources say the current draft CD2 of ISO 9000: 2000 is not expected to change much. So, let's take a look at Figure 10 to see how your checklist for the new standard may look.

Afterword

I hope this review helped you realize that checklists can be a very useful tool in creating and maintaining a quality manual that aggresses the requirements of applicable standards and regulations. I also hope that I gave you enough ideas to create your own checklist for your specific needs. Now that you know how to make your own checklist with sufficient detail, but perhaps do not have time to put it together, check our web site at www.quality-works.com for examples of checklists for a number of standards. We would also appreciate your feedback – drop us an *e-line* at our site and let us know what you think about this paper. Thank you for your interest.

About the author

Mark Kaganov has nearly 20 years experience in R&D, Manufacturing and Quality Assurance of plastics, electronic equipment, aerospace and medical device manufacturing. Since 1996, he has been working for one of the world's leading registrars and Notified Bodies as an Account Manager and a lead auditor. The author's qualifications include ISO 9000, EN 46000, ISO 13485, AS 9001 and European Council Directive 93/42/EEC for CE marking. In 1998 the author led the first ISO 13483 assessment in North America. During his professional career, Mark Kaganov has published a number of technical articles in the areas of the research of plastic materials, the economics of manufacturing and the technology of ion-selective electrodes. He has also authored four international patents. Mark Kaganov has published 2 books on developing quality manuals for ISO 9001 and EN 46001 standards.

References

[1] ISO 9001: 1994, "Quality systems – Model for quality assurance in design, development, production, installation and servicing"

[2] EN 46001: 1997 "Application of EN ISO 9001 to the manufacture of medical devices"

[3] ISO 13485: 1996 "Quality systems – Medical devices – Particular requirements for the application of ISO 9001"

[4] ISO Guide 25: 1990 "General Requirements for the compliance of calibration and testing laboratories"

[5] QS 9000: 1998 "Quality System Requirements"

[6] SAE AS 9001: 1998 "Aerospace Basic Quality System Standard"

[7] ISO 14001: 1996 "Environmental management systems – Specification with guidance for use"

[8] Code of Federal Regulations, Food and Drugs, Title 21, Parts 800 to 1299, April 1, 1999

[9] Official Journal of the European Communities, Volume 36, Council Directive 93/42/EEC of 14 June 1993

[10] Mark Kaganov, "ISO 9000 - A Practical Guide to the Development and Implementation of a Quality Manual", www.quality-works.com

[11] Mark Kaganov, "EN 4600 - A Practical Guide to the Development and

Implementation of a Quality Manual", www.quality-works.com

Figure 1

Legend:

A	acceptable	**N**	not present or not acceptable
QM	Quality manual		

Elem.	Requirement	Response location	Y	N
4.1	Management responsibility	*QM, 4.1*	*Y*	
4.2	Quality system	*QM, 4.2*	*Y*	
4.3	Contract review	*QM, 4.3*	*Y*	
4.4	Design control	*QM, 4.4*	*Y*	
4.5	Document and data control	*QM, 4.5*	*Y*	
4.6	Purchasing	*QM, 4.6*	*Y*	
	…			

Figure 2

Elem.	Requirement	Response location	Y	N
4.1	**Management responsibility**	*QM, 4.1*	*Y*	
4.1.1	Management responsibility	*QM, 4.1.1*	*Y*	
4.1.2	Organization	*QM, 4.1.2*	*Y*	
4.1.2.1	Responsibility and authority	*QM, 4.1.2.1*	*Y*	
4.1.2.2	Resources	*QM, 4.1.2.2*	*Y*	
4.1.2.3	Management representative	*QM, 4.1.2.3*	*Y*	
4.1.3	Management review	*QM, 4.1.3*	*Y*	
4.2	**Quality system**	*QM, 4.2*	*Y*	
4.2.1	General, …procedures…	*QM, 4.2.1*	*Y*	
4.2.2	Quality system procedures	*QM, 4.2.2*	*Y*	
	…			

Figure 3

Elem.	Requirement	Response location	Y	N
4.1	**Management responsibility**	*QM, 4.1*	*Y*	
4.1.1	Management responsibility	*QM, 4.1.1*	*Y*	
4.1.2	Organization	*QM, 4.1.2*	*Y*	
4.1.2.1	Responsibility and authority	*QM, 4.1.2.1*	*Y*	
4.1.2.2	Resources	*QM, 4.1.2.2*	*Y*	
4.1.2.3	Management representative	*QM, 4.1.2.3*	*Y*	
4.1.3	Management review	*QM, 4.1.3*	*Y*	
	Records per 4.16	*QM, 4.1.3*	*Y*	
4.2	**Quality system**	*QM, 4.2*	*Y*	
4.2.1	General, …procedures…	*QM, 4.2.1*	*Y*	
	…			

Figure 4

	…			
4.1.2.3	Management representative	*QM, 4.1.2.3*	*Y*	
4.1.3	Management review	*QM, 4.1.3*	*Y*	
	"management with executive responsibility" defined	*QM, 4.1.3*	*Y*	
	Intervals defined	*QM, 4.1.3*	*Y*	
	Assessment of continuing suitability and effectiveness required	*QM, 4.1.3*	*Y*	
	Goals and objectives defined	*QM, 4.1.3*	*Y*	
	Goals are measurable	*QM, 4.1.3*	*Y*	
	Records per 4.16	*QM, 4.1.3*	*Y*	
4.2	**Quality system**	*QM, 4.2*	*Y*	
4.2.1	General, …procedures…	*QM, 4.2.1*	*Y*	
	…			

Figure 5

Legend:

AMD	all medical devices	**AIMD**	active implantable medical devices
IMD	implantable medical devices	**SMD**	sterile medical devices
A	acceptable	**N**	not present or not acceptable

Elem.	Requirement	Response location	Y	N
4.1	**Management responsibility**	ISO 9001 applies ----------		
4.2	**Quality system**	ISO 9001 applies ----------		
4.2.1	General, …procedures…	ISO 9001 applies ----------		
	AMD: …document specified requirements…	*QM, 4.2.1*	*Y*	
	…regulatory requirements…	*QM, 4.2.1*	*Y*	
4.2.2	Quality system procedures	ISO 9001 applies ----------		
4.2.2	**AMD:** …technical files…	*QM, 4.2.2*	*Y*	
	… …			
4.8	**Product id and traceability**	ISO 9001 applies ----------		
	…			
b)	Traceability	*QM, 4.8.b*	*Y*	
	AMD: … procedures for traceability	*QM, 4.8.b*	*Y*	
	…extent of traceability…	*QM, 4.8.b*	*Y*	
	…corrective actions…	*QM, 4.8.b*	*Y*	
	AIMD: … all materials and components…	*QM, 4.8.b*	*Y*	
	… records of environmental conditions…	*QM, 4.8.b*	*Y*	
	…			

Figure 6

Legend:
♥ Specific requirements of EN 46001: 1997 standard

♥	Elem.	Requirement	Response location	Y	N
	4.1	**Management responsibility**	*QM 4.1*	*Y*	
	4.1.1	Quality policy	*QM, 4.1.1*	*Y*	
	4.1.2	Organization	*QM, 4.1.2*	*Y*	
	4.1.2.1	Responsibility and authority	*QM, 4.1.2.1*	*Y*	
	4.1.2.2	Resources	*QM, 4.1.2..2*	*Y*	
	4.1.2.3	Management representative	*QM, 4.1.2.3*	*Y*	
	4.1.3	Management review	*QM, 4.1.3*	*Y*	
	4.1.3	Reference to 4.16	*QM, 4.1.3*	*Y*	
	4.2	**Quality system**	*QM, 4.2*	*Y*	
	4.2.1	General, …procedures…	*QM, 4.2.1*	*Y*	
♥		**AMD:** Specified requirements	*QM, 4.2.1*	*Y*	
♥	Note:	Regulatory requirements	*QM, 4.2.1*	*Y*	
	4.2.2	Quality system procedures	*QM, 4.2.2*	*Y*	
		…			

Figure 7

Legend:
✈ Specific requirement of SAE AS 9001 standard

✈	Elem.	Requirement	Response location	Y	N
	4.1	**Management responsibility**	*QM, 4.1*	*Y*	
	4.1.1	Quality policy	*QM, 4.1.1*	*Y*	
	4.1.2	Organization	*QM, 4.1.2*	*Y*	
	4.1.2.1	Responsibility and authority	*QM, 4.1.2.1*	*Y*	
	4.1.2.2	Resources	*QM, 4.1.2..2*	*Y*	
	4.1.2.3	Management representative	*QM, 4.1.2.3*	*Y*	
✈	4.1.2.4	Supplier's procedures	*QM, 4.1.2.4*	*Y*	
	4.1.3	Management review	*QM, 4.1.3*	*Y*	
	4.1.3	Reference to 4.16	*QM, 4.3*	*Y*	
	4.2	**Quality system**	*QM, 4.2*	*Y*	
	4.2.1	General, …procedures…	*QM, 4.2.1*	*Y*	
	4.2.2	Quality system procedures	*QM, 4.2.2*	*Y*	
	a.	Consistent with this document			
	b.	Effectively implemented			
✈	c.	Procedures available to .. agencies	*QM, 4.2.2.c*	*Y*	
		…and so on…			

Figure 8

9001	46001	14001	Requirement	Response
4.1	**4.1**	**---**	**Management responsibility**	*QM, 4.1*
4.1.1	4.1.1	---	Quality policy	*QM, 4.1.1*
---	---	4.2	Environmental policy	*QM, 4.1.1*
4.1.2	4.1.2	4.4.1	Organization	*QM, 4.1.2*
4.1.2.1	4.1.2.1	---	Responsibility and authority	*QM, 4.1.2.1*
4.1.2.2	4.1.2.2	---	Resources	*QM, 4.1.2.2*
4.1.2.3	4.1.2.3	---	Management representative	*QM, 4.1.2.3*
4.1.3	4.1.3	4.6	Management review	*QM, 4.1.3*
4.1.3	4.1.3	---	Reference to 4.16	*QM, 4.1.3*
4.2	**4.2**	**---**	**Quality system**	*QM, 4.2*
4.2.1	4.2.1	4.1	General, …procedures…	*QM, 4.2.1*
---	4.2.1	---	Specified requirements	*QM, 4.2.1*
---	Note	---	Regulatory requirements	*QM, 4.2.1*
4.2.2	4.2.2	4.4.6	Quality system procedures	*QM, 4.2.2*
			…	

Figure 9

Subpart B – Quality System Requirements

(*) Based on ISO/CD2 9001:2000

Part Section	9001 1994	9001 2000 (*)	Requirement	Response
820.20	**4.1**	**5.1,**	**Quality policy**	*QM, 4.1*
(a)	**4.1.1**	**5.4,**	**Quality policy**	*QM, 4.1.1*
		5.5.1	Management with executive responsibility defined	*QM, 4.1.1*
			Quality policy and objectives defined	*QM, 4.1.1*
			Policy understood and implemented at all levels	*QM, 4.1.1*
(b)	**4.1.2**	**4,**	**Organization**	*QM, 4.1.2*
		5.5.2	Adequate organizational structure	*QM, 4.1.2*
(1)	4.1.2.3	5.6.3	Responsibility and authority	*QM, 4.1.2.3*
			Authority and responsibility documented	*QM, 4.1.2.3*
			Interrelationship of personnel defined	*QM, 4.1.2.3*
(2)	4.1.2.2	5.1,	Resources.	*QM, 4.1.2.2*
		6.1.	Adequacy defined	*QM, 4.1.2.2*
		6.2 +	Assignment documented	*QM, 4.1.2.2*
(3)	4.1.2.3	5.6.3	Management representative	*QM, 4.1.2.3*
			Member of management	*QM, 4.1.2.3*
			Appointment documented	*QM, 4.1.2.3*
(i)	---	---	Ensures that quality system in accordance with this part.	*QM, 4.1.2.3*
			…	

Figure 10

Elem.	Requirement	Response location	Y	N
4	**QMS requirements**	*QM, 4*	*Y*	
4	System level procedures	*QM, 4*	*Y*	
4.b	Sequence procedures	*QM, 4.b*	*Y*	
4.c	Instructions	*QM, 4.c*	*Y*	
5	**Management responsibility**	*QM, 5*	*Y*	
5.1	General commitment	*QM, 5.1*	*Y*	
5.1.a	Importance of customer requirements	*QM, 5.1.a*	*Y*	
5.1.b	Quality policy and objectives	*QM, 5.1.b*	*Y*	
5.1.c	Quality management system	*QM, 5.1.c*	*Y*	
5.1.d	Management reviews	*QM, 5.1.d*	*Y*	
5.1.e	Resources	*QM, 5.1.e*	*Y*	
5.2	**Customer requirements**	*QM, 5.2*	*Y*	
5.2.a	Customer needs and expectations	*QM, 5.2.a*	*Y*	
5.2.b	Requirements understood and met	*QM, 5.2.b*	*Y*	
5.3	**Legal requirements**	*QM, 5.3*	*Y*	
5.3	Procedures	*QM, 5.3*	*Y*	
	…			