

# **ISO 9001:2000 - A Quality Manual for the Transition Period and Beyond**

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## **Abstract**

This article shows a practical approach to converting an ISO 9001:1994 quality manual into the new ISO 9001:2000 format. It describes a method for creating a manual that meets the requirements of both the ISO 9001:1994 and the new ISO 9001:2000 revisions of the standard. This feature allows a business to maintain a common quality manual for the transition period. This paper will be of interest to the companies with established ISO 9001:1994 quality management systems that plan to transition to the new ISO 9001:2000 standard.

## **Quality manual for the transition period**

Not long ago in a discussion group, I met a colleague who worked for a major ISO 9000 registrar. During the group meeting, someone raised the following question for us professional assessors, "Would you consider it acceptable if you see a manual that is structured per the new ISO 9001:2000 [1] format while a company is still registered to the old ISO 9001:1994 [2] standard?" We both independently came to the same conclusion: standards, whether old or new, do not require a particular numeration or a sequence of elements in the quality manual. As long as all the requirements of a standard are addressed in the quality manual, it should meet the requirements of an applicable standard. In other words, we agreed that a quality manual that addressed all the requirements of the ISO 9001:2000 standard would meet the requirements of ISO 9001:1994 standard as well. This finding is very important, since it means that for the transition period a company will need to use only one quality manual.

Our conclusion was based on the fact that, while the new standard has quite a few new requirements and approaches, all the requirements of the old standard, except for a few minor details, are present in the new one. To prove this point, let's refer to a tested method of using checklists for verifying the completeness of a quality manual with a particular standard as described in [3]. Figure 1 shows a section of an ISO 9001:1994 Quality Manual Review Checklist. This figure indicates that all shown requirements are addressed in the new ISO 9001:2000 quality manual and designates locations of the responses to these requirements. By completing the entire checklist, we may prove that our new ISO 9001:2000 quality manual addresses the requirements of the old standard.

For example, new ISO 9001:2000 standard contains numerous significant changes from the previous revision. It focuses on the eight quality management principals and takes a more process-oriented and customer-focused approaches to quality management system than the previous edition. Eight quality management principals that can be used by

management to lead an organization toward improved business performance and quality of its products or services are:

1. Customer focus
2. Leadership
3. Involvement of people
4. Process approach
5. System approach to management
6. Continual improvement
7. Factual approach to decision making
8. Mutually beneficial supplier relations

For an organization to function effectively, it has to define and manage numerous processes. Often the output from one process forms the input into the next one. The systematic identification and management of the various processes within an organization, and particularly the interactions between them, is referred to as the 'process approach' to management in the new ISO 9001:2000 standard. Any activity or operation, which receives inputs and converts them to outputs, can be considered as a process.

Obviously, the new standard has a number of new requirements, and therefore needs new supporting procedures to address them. To identify which procedures can be used from our old ISO 9001:1994 quality system, and which need to be developed, let's create a "map" showing a list of the procedures required by the new standard. This listing is shown in Figure 2. Yellow highlights indicate new procedures.

Depending upon your particular industry, your company may already have some of those new processes in place. For example, if you are in medical device manufacturing, you most likely already have a Post-market Surveillance process to gather customer feedback, and a Validation procedure to evaluate the robustness of new and existing processes. There are also quite a few companies that have already started to address their business needs through the use of such processes as Human Resource Management, Balanced Scorecard [4] and others that nicely fit into the requirements of the new ISO 9001:2000 standard.

By now we have identified and documented new requirements in our ISO 9001:2000 quality manual. We have also referenced the procedures to support those new requirements. Identifying the new requirements is a good start. However, we still may not have all those procedures developed and implemented. Let's remember that the objective of this process is to develop a quality manual for the transition period. This means, that as long as a company is not claiming compliance with the new standard, it will not be expected to comply with it. So, for the time being, we may reference procedures that we still need to complete, and identify them as To Be Developed (TBD). For example, element 5.4.1 of our new quality manual may read:

*The top management of My Company, Inc. ensures that quality objectives, including those needed to meet product requirements are established at relevant functions and levels within the organization per the [Balanced Scorecard \(TBD\)](#). This method ensures that quality objectives are measurable and consistent with the [Quality Policy](#).*

This example shows that a Balanced Scorecard (TBD) still needs to be developed, while the Quality Policy has already been developed and implemented to support this element of our new quality manual.

### **Navigating the new manual**

Using the technique described above, we can create a new manual for the transition period. However, we still need to navigate through it demonstrating compliance with the old standard. At first, it may be a difficult task for both users and assessors. Until we are used to the new numeration of requirements, it may be helpful to construct a conversion table showing where old requirements are addressed in the new manual. This conversion table may be a part of the new quality manual and structured as a set of hyperlinks directing to the appropriate location in the new manual as shown in Figure 3. For example, using this figure we can easily determine that the Management Representative requirement 4.1.2.3 of the old standard is addressed in the element 5.5.2 of our new quality manual. A similar approach may be used to assist in navigating our new manual for the requirements of ISO 14001 [5], if you use an integrated quality and environmental manual. ISO 14001 navigational table is shown in Figure 4.

### **Verification of the new manual**

By now we have completed our new quality manual and proved that it complies with the requirements of the old ISO 9001:1994 revision of the standard. Now we need to verify if it also meets the requirements of the new 2000 revision. As in the old revision, the best way to ensure that all elements of the standard are covered in a quality manual is to use a checklist. An example of a checklist for the new ISO 9001:2000 standard is shown in Figure 5.

### **Afterword**

I hope this paper has helped you to get started in drafting a new manual that can be used for the transition period. Start working on the areas that you initially identified as “TBD”. Preparation of the entire set of new procedures, while quite educational and fun, is also a very time consuming task. This is not rocket science and you definitely can do it yourself. However, if your schedule is busy with other projects, visit our site at [www.quality-works.com](http://www.quality-works.com) to find quality and environmental manuals, key second level procedures, and checklists that might be helpful. I also would appreciate your comments on this paper. Please drop me a line at [mark@quality-works.com](mailto:mark@quality-works.com) and let me know what you think about this article.

## About the author

Mark Kaganov is an IRCA certified QMS Lead Auditor, RAB certified EMS Auditor and a member of ASQ. He earned a master's degree in Design and Technology of Electronic Equipment from Moscow University of Radio-Electronics and Automation in Moscow, Russian Federation. For more information, go to [www.quality-works.com](http://www.quality-works.com).

## Acknowledgements

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## References

- [1] ISO 9001:2000, Quality management systems - Requirements
- [2] ISO 9001:1994, Quality systems, Model for quality assurance in design, development, production, installation and servicing.
- [3] "Checklists – A Perfect Tool to Tune-up Your Quality Manual", Mark Kaganov, Quality Progress, October 2000
- [4] "The Balanced Scorecard", Robert S. Kaplan, David P. Norton, Harvard Business School Press.
- [5] ISO 14001:1996, Environmental management systems – Specification with guidance for use

Figure 1 - ISO 9001:1994 Quality Manual Review Checklist, Record

|                                 |   |
|---------------------------------|---|
| Document title:                 | <i>QW Medical, LLP, Quality Manual</i>      |
| Document number:                | <i>20008</i>                                |
| Revision level:                 | <i>01</i>                                   |
| Date of release:                | <i>12/30/00</i>                             |
| Standard (circle or cross out): | <b>9001</b> <del>9002</del> <del>9003</del> |

**Legend:**

- A**        acceptable response
- N**        response is not present or not acceptable
- QM**      Quality manual

| Clause  | Requirements                                 | Location of response                                | A | N |
|---------|--|---|---|---|
| 4.1     | <b>Management responsibility</b>             | <i>Title only</i>                                   |   |   |
| 4.1.1   | <b>Quality policy</b>                        | <i>QM 5.1, 5.3</i>                                  | ✓ |   |
|         | ...“executive responsibility” defined        | <i>QM 3, Management Team</i>                        | ✓ |   |
|         | ...objectives for quality defined            | <i>QM 5.4.1, ref. to the<br/>Balanced Scorecard</i> | ✓ |   |
|         | ...commitment to quality defined             | <i>QM 5.1</i>                                       | ✓ |   |
|         | ...needs of the customers addressed          | <i>QM 5.2</i>                                       | ✓ |   |
|         | ...policy is implemented...                  | <i>QM 5.3</i>                                       | ✓ |   |
| 4.1.2   | <b>Organization</b>                          | <i>Title only</i>                                   |   |   |
| 4.1.2.1 | Responsibility and authority                 | <i>QM 5.5.1</i>                                     | ✓ |   |
|         | ...Interrelation and authority defined for:  |   |   |   |
| a)      | action to prevent NC's                       | <i>QM 8.3, a</i>                                    | ✓ |   |
| b)      | Identify and record problems                 |   |   |   |
| c)      | Initiate solutions                           | <i>QM 8.3, b</i>                                    | ✓ |   |
| d)      | verify implementation of solutions           | <i>QM 8.3</i>                                       | ✓ |   |
| e)      | control further processing                   | <i>QM 8.3, b</i>                                    | ✓ |   |
| 4.1.2.2 | Resources                                    | <i>Title only</i>                                   |   |   |
|         | identify resource requirements               | <i>QM 5.1.e</i>                                     | ✓ |   |
|         | provide adequate resources                   | <i>QM 6.1</i>                                       | ✓ |   |
|         | assignment of trained personnel for:         |   |   |   |
|         | management                                   |   |   |   |
|         | performance of work                          |   |   |   |
|         | verification activities                      |   |   |   |
|         | internal quality audits                      |   |   |   |
| 4.1.2.3 | Management representative                    | <i>QM 5.5.2</i>                                     | ✓ |   |
|         | Member of own management with authority for: |   |   |   |
| a)      | quality system is established                | <i>QM 5.5.2 a</i>                                   | ✓ |   |
| b)      | reporting on the performance                 | <i>QM 5.5.2 b</i>                                   | ✓ |   |
| Note 5  | liaison with external parties                | <i>QM 5.5.2</i>                                     | ✓ |   |
|         | ... and so on...                             |   |   |   |

**Figure 2 - ISO 9001:2000 Second Level Procedure List**

| <b>No</b> | <b>Process title, ISO 9001:2000</b> | <b>94</b> |
|-----------|-------------------------------------|-----------|
| 1         | Audit Process                       | Y         |
| 2         | Balanced Scorecard                  | No        |
| 3         | CAPA Process                        | Y         |
| 4         | Communication Process               | No        |
| 5         | Contract Review Process             | Y         |
| 6         | Customer Property Process           | Y         |
| 7         | Data Analysis Process               | Y         |
| 8         | Design Management Process           | Y         |
| 9         | Documentation Management Process    | Y         |
| 10        | Documentation Master List           | Y         |
| 11        | Infrastructure Process              | No        |
| 12        | Inspection Process                  | Y         |
| 13        | Management Review Process           | Y         |
| 14        | Material Handling Process           | Y         |
| 15        | Measuring Equipment Process         | Y         |
| 16        | Non-conformity Process              | Y         |
| 17        | Organizational Chart                | Y         |
| 18        | Post Market Surveillance Process    | No        |
| 19        | Product Identification Process      | Y         |
| 20        | Product Realization Process         | Y         |
| 21        | Purchasing Process                  | Y         |
| 22        | Quality Policy                      | Y         |
| 23        | Records Process                     | Y         |
| 24        | Resource Management Process         | No        |
| 25        | Servicing Process                   | Y         |
| 26        | Statistical Techniques Process      | Y         |
| 27        | Supplier Partnership Program        | Y         |
| 28        | Training Process                    | Y         |
| 29        | Validation Process                  | No        |
|           |                                     |           |

94 – indication of presence of a procedure in the quality manual for ISO 9001:1994 revision of the standard.

**Figure 3 - ISO 9001:1994 v ISO 9001:2000 Manual, Reference Matrix**

| Requirement                        | ISO 9001   |   |
|------------------------------------|------------|---|
|                                    | 1994       | This manual, 2000   |
| <b>Scope</b>                       | 1          | 1   |
| <b>Application (exclusions)</b>    | ---        | <a href="#">1.2 Application</a>   |
| <b>Normative references</b>        | 2          | 2   |
| <b>Definitions</b>                 | 3          | 3   |
| <b>Quality system requirements</b> | <b>4</b>   | ---   |
| <b>Management responsibility</b>   | <b>4.1</b> | ---   |
| Quality policy                     | 4.1.1      | <a href="#">5.1 Management commitment</a><br><a href="#">5.3 Quality policy</a><br><a href="#">5.4.1 Quality objectives</a>   |
| Organization                       | 4.1.2      | ---   |
| Responsibility and authority       | 4.1.2.1    | <a href="#">5.5.1 Responsibility and authority</a>  |
| Resources                          | 4.1.2.2    | <a href="#">5.1 Management commitment</a><br><a href="#">6.1 Provision of resources</a><br><a href="#">6.2.1 General, HR</a><br><a href="#">6.3 Infrastructure</a>  |
| Management representative          | 4.1.2.3    | <a href="#">5.5.2 Management rep.</a>   |
| Management review                  | 4.1.3      | <a href="#">5.6.1 General, MR</a><br><a href="#">5.6.2 Review input, MR</a><br><a href="#">5.6.3 Review output, MR</a><br><a href="#">8.5.1 Continual improvement</a>   |
| <b>Quality system</b>              | <b>4.2</b> | ---   |
| General                            | 4.2.1      | <a href="#">4.1 General requirements</a><br><a href="#">4.2.1 General, Documentation</a><br><a href="#">4.4.2 Quality manual</a><br><a href="#">5.1 Management commitment</a><br><a href="#">5.4.1 Quality objectives</a> |
| Quality system procedures          | 4.2.2      | <a href="#">4.2.1 General, Documentation</a>  |
| Quality planning                   | 4.2.3      | <a href="#">5.4.2 QMS planning</a><br><a href="#">6.2.1 General, HR</a><br><a href="#">7.1 Planning of product realization</a>  |
| <b>Contract review</b>             | <b>4.3</b> | ---   |
| General                            | 4.3.1      | ---   |
| Review                             | 4.3.2      | <a href="#">5.2 Customer focus</a><br><a href="#">7.2.1 Req's for product</a><br><a href="#">7.2.2 Req's for product</a><br><a href="#">7.2.3 Cust. communication</a>   |
| ... and so on ...                  |            |   |

**Figure 4 - ISO 14001:1996 v ISO 9001:2000 Manual, Reference Matrix**

| <b>Requirement</b>                  | <b>ISO 14001</b> | <b>This manual</b>   |
|-------------------------------------|------------------|--|
| <b>EMS requirements</b>             | <b>4</b>         | ---  |
| <b>General requirements</b>         | <b>4.1</b>       | <a href="#">4.1 General requirements</a>   |
| <b>Environmental policy</b>         | <b>4.2</b>       | <a href="#">5.3.2 Environmental policy</a>   |
| <b>Planning</b>                     | <b>4.3</b>       | <a href="#">5.4 Planning</a>   |
| Environmental aspects               | 4.3.1            | <a href="#">5.4.3 Environmental aspects</a>  |
| Legal and other requirements        | 4.3.2            | <a href="#">7.2.1.2 Legal requirements</a>   |
| Objectives and targets              | 4.3.3            | <a href="#">5.4.1.2 EMS objectives</a>   |
| Environmental programs              | 4.3.4            | <a href="#">5.4.2.2 EMS programs</a>   |
| <b>Implementation and operation</b> | <b>4.4</b>       | ---  |
| Structure and responsibility        | 4.4.1            | <a href="#">5.5.1 Responsibility...</a>  |
| Management representative           | 4.4.1            | <a href="#">5.5.2 Management rep.</a>  |
| Training, awareness and competence  | 4.4.2            | <a href="#">6.2.2 Competence</a>   |
| Communication, internal             | 4.4.3            | <a href="#">5.5.3 Internal communication</a><br><a href="#">7.2.3 Customer comm.</a> |
| EMS documentation                   | 4.4.4            | <a href="#">4.2.1 General</a>  |
| Document control                    | 4.4.5            | <a href="#">4.2.3 Management of documents</a>  |
| Operational control                 | 4.4.6            | <a href="#">7.1 Planning of product real.</a>  |
| Emergency preparedness and response | 4.4.7            | <a href="#">8.3 Management of NCs</a>  |
| ... and so on ...                   |                  |  |

Figure 5 - ISO 9001:2000 Quality Manual Review Checklist

|                         |  |
|-------------------------|--|
| <b>Document title:</b>  |  |
| <b>Document number:</b> |  |
| <b>Revision level:</b>  |  |
| <b>Date of release:</b> |  |

**Legend:**

- A** acceptable response
- N** response is not present or not acceptable
- QM** Quality manual

| Clause     | Requirements  | Location of response | A | N |
|------------|---|----------------------|---|---|
| 1.2        | <b>Application</b>  |                      |   |   |
|            | exclusions limited to the clause 7  |                      |   |   |
| <b>4</b>   | <b>Quality management System</b>  |                      |   |   |
| 4.1        | <b>General requirements</b>   |                      |   |   |
|            | QMS per this standard   |                      |   |   |
|            | continually improve its effectiveness   |                      |   |   |
| a          | ID of the processes needed for QMS  |                      |   |   |
| b          | sequence and interaction of processes   |                      |   |   |
| c          | criteria and methods to ensure the operation and control of processes are effective |                      |   |   |
| d          | availability of resources and information   |                      |   |   |
| e          | monitor, measure and analyze processes  |                      |   |   |
| f          | Implement actions to achieve planned results and continual improvement              |                      |   |   |
|            | management of processes in accordance with this standard                            |                      |   |   |
|            | management of outsourced processes  |                      |   |   |
| Note       | processes for management activities...  |                      |   |   |
|            | provision of resources...   |                      |   |   |
|            | product realization and measurement...  |                      |   |   |
| <b>4.2</b> | <b>Documentation requirements</b>   |                      |   |   |
| 4.2.1      | General   |                      |   |   |
| a          | documented statements of a quality policy and quality objectives                    |                      |   |   |
| b          | a quality manual  |                      |   |   |
| c          | documented procedures   |                      |   |   |
| d          | documents needed by the organization  |                      |   |   |
| e          | required records by this standard   |                      |   |   |
| Note 1     | definition of documented procedure  |                      |   |   |