ISO 9001: 2000 and ISO 14001 - An Up-to-Date Web Site Is A Great Communication Tool – A Case Study

By Mark Kaganov

Abstract

This paper presents a case study of applying a documentation management approach in order to control the web site of a small publishing company. Going beyond a simple case study model, this article explores alternative techniques for companies with different network structures. This article will be of interest to companies intending to comply with ISO 9001: 2000 and ISO 14001 Standards. The requirements for establishing a communication system in both standards may be effectively addressed by an up-to-date web site. This paper is especially timely, considering the fact that such regulatory agencies as the US Food and Drug Administration (FDA) have voiced particular concerns regarding the contents of web sites of companies in the pharmaceutical and medical device manufacturing industries.

Introduction

The author would like to express his gratitude to Ellen Cohig, Business Manager of Quality Works, for her willingness to conduct and document this case study.

Do you remember an ad with a farmer in blue overalls, wearing a straw hat, holding a pitchfork in one hand and a tin bucket in the other? The ad read: “He has a web site, have you?” A rhetorical question nowadays, it seems. Of course you have a web site! It seems that everybody has a web site, including children. Not long ago I was invited to a barbecue at a friend’s house, and found myself involved in a web site discussion with my friend’s 12 year-old daughter. “I made my own web site,” she proudly announced. I asked her what she had on her web site. “Pictures of my friends and me, jokes, recipes, invitations to parties and other stuff. I can change it anytime I want.”

And that is where the problem begins. Anyone and everyone, it seems, can create a web site, and anybody, including 12-year-olds, can easily change their contents. If my friend’s daughter happens to change her web site and forgets to include a new cake recipe or, overlooks some other information critical to the life and happiness of a 12 year old, nobody is likely to get hurt. On the other hand, what if your business did not update some pertinent information such as a price list or a quarterly financial report on its web site? This type of blunder may affect the company’s bottom line, as well as several people – including me, if I am a shareholder.

The need to effectively manage web sites is also recognized in regulated industries. For example, The FDA has expressed its concerns and expectations in regard to the promotion of medical devices on the Internet [1]. Even if your business is not subject to such regulations, it may be a good idea to more effectively manage your web site, since it is probably one of the most visible and important communication tools a business has. In addition to good business sense, effectively managing your web site will act as a very good start in establishing compliance with the requirements for communication as defined in ISO 14001 and the new ISO 9001: 2000 standards. While there are many great reasons to better manage a company web site, not many companies are taking advantage of this practice. Through my experience with dozens of companies around the world, on initial review, I found that only two (!) businesses I worked with had established documented systems for managing their web sites.

Actually, the idea to publish this case study stems from a customer's reaction to the fact that old versions of documents were located on the company's web site. Her frustration stemmed from the fact that IT department had not updated the manuals on the web site, and customers were downloading obsolete information. Realizing that many companies may face the same problem, I decided to present this case study to help companies establish mechanisms to effectively manage their web sites.

Initiation of the web site project

Quality Works, a small Internet-based publishing company, has set a goal to establish compliance with ISO 9001: 2000 and ISO 14001 standards. The Management Team assigned the company's Business Manager to develop and implement a web site in order to establish a presence on the Internet and address the requirements for communication processes. The Management Team documented this action item through the company's documented Corrective and Preventive Action (CAPA) program. The Web Site Story Team, consisting of the MIS, Design and Documentation Management functions, was created to develop and implement the web site and its management process.

Brainstorming

The Web Site Story team conducted a brainstorming session to identify and document the milestones of the project. The discussion resulted in the following outcome:

- Project objectives:
    - Design and publish a company web site to establish an Internet presence for the promotion of its products,

- Use the web site as **a** major communication tool to demonstrate compliance with the corresponding requirements of ISO 9001: 2000 and ISO 14001
- Considering the web site a document on electronic media, develop and implement an effective documentation management process to ensure the web site is kept current and up-to-date in accordance with established procedures

To achieve these objectives, the Web Site Story team identified the following milestones:

- Conduct research to gather methods for the management and documentation of web sites,
- Select an approach by which to develop documented procedures for the management of the web site,
- Develop and document a prototype site,
- Develop a validation protocol to ensure functionality of the prototype web site,
- Validate the prototype web site,
- Release the web site and corresponding procedures,
- Report to the Management Team upon closure of the project.

Research

The research stage turned out to be much easier and shorter than we had expected. We recorded 27 contacts with colleagues and customers from various industries around the world. Company size varied from 21 to 1,100 employees. Surveyed companies were located in the U.S., Singapore, Japan and Mexico. During the survey, we learned that almost all of the surveyed businesses had no documented processes for managing their web sites. We also found that in most cases, the process for web site management was very simple: “The MIS Department is responsible for it.” Remarkably, only one of the surveyed companies had established and maintained documented procedures for managing their web site. Their documentation contained numerous procedures, including:

- Alpha and Beta Release Test;
- Database Validation and Update;
- Sectional Revision and Update;
- Site Development and Expansion
- Email / Catalog / Drawing Request;
- Multiple Online Catalog Update for three languages and;
- New Product Release.

Another surveyed company indicated that their web site was formally released through their documentation change process about three years prior, but since that time there

was no history of any documented revision changes, despite the fact that the site had gone through numerous minor changes and major modifications.

Documentation structure

It did not take long for the Web Site Story Team to review and analyze the results of the survey. The team made a decision to start from scratch, electing to modify, where possible, the scopes and processes of existing procedures in order to cover web site development and management. As a result, the following procedures were modified and used in the process.

Documentation Management Procedure went through the most significant changes, as follows:

- Documents on electronic media were added to the scope to cover the web site and its components,
- The web site, its pages and component numbers followed established convention for document numbering as defined in the Documentation Management Procedure as outlined below:

    - The web site, as the "top level assembly," its pages and components were assigned unique three digit document numbers, such as 119, 120, 121, etc,
    - The document revision format was extended to add date formatting such as *August 25, 2000,* to be used to identify the web site's revision level. The site's revision level was required to be displayed on the Home page as the "Last Revised" field,
    - Page document numbers were identified within the page title and the html code on the bottom of each page formatted as a comment statement,
    - Document numbers of web site components such as images, external logos and others were identified within the component title.

- The web site and its components were added to the existing Documentation Master List. The document distribution section of the Master List was modified to include the web site as a possible location of documents.

All documents of external origin used within the site were included in the Documentation Master List. According to the Documentation Management Procedure, these documents became subject to periodic verification of their revisions. The following site components were considered documents of external origin:

- Better Business Bureau On-line (BBB On-line) logo,
- Thawte, security certificate provider, logo,
- Preview versions of publications; and,

- Staff summary of experience.

- The Review and Approval Matrix was modified to include requirements for web site changes,

    - Significant, strategic changes, including initial release of the site were required to be released through the Documentation Change Record (DCR) process;
    - The MIS manager had the authority to review and approve any dynamic, tactical changes. These changes were required to be recorded in the Change Record section of the Documentation Master List.

The Template Procedure used to specify the format of documents was modified to:

- Extend its scope to cover web site pages, and
- Include general specifications for web site pages.

The Network Management Procedure was modified to address periodic back up of the web site contents from the hosting server.

The Records Procedure was modified to identify periods for retention and location of documents on electronic and magnetic media, including back-up copies of the web site.

The Design Management Procedure and Validation Procedure were used in the process. They did not require any modifications, as they already covered development and validation of software.

The Management Review Record Template was modified to include the requirement for periodic review of the web site by the Management Team.

Modification of the documentation system to include **the** web site did not result in any additional procedures. We were able to use existing procedures with some modifications.

Development and validation of the site

The MIS and the Design groups followed the Design Management Procedure to develop the web site. The milestones of the project were documented in the Web Site project plan, as shown in Figure 1. The plan also served as a record of allocation of human resources for the project. The Web Site Story Team met for its first design review to document the needs and expectations of all functions related to the project. Two associates at remote locations were present at the review via conference call. The design input developed and approved by this design review session was documented

using the Design Record Matrix. An example of the design input and output for the Index page is shown in Figure 2.

The MIS and the Design functions conducted verification of the site. As a result of the second design review, minor corrections were made to the site. Two associates of the company who were not part of the design project conducted validation. Records of verification and validation of the site were documented using the Design Record Matrix. An example of the validation record for the Index page is shown in Figure 3. While some insignificant variances in the plan were documented through the process, release of the site was completed on time. The Documentation Master List was updated to include the web site and its components, as shown in Figure 4. The Documentation Management Team released the first revision of the company's web site. The Business Manager reported completion of the action item to the Management Team.

Beyond the case study

The technique used in the case study for documenting the web site is by no means the only method that can be used. The company had an established documentation structure with numerous procedures. An existing Documentation Master List was the most convenient way to keep track of the new documents, such as web site pages and components. If your company's documentation is centered on your web site and you do not have too many other documents, you may choose to establish a master list within your web site. You may consider creating a *documentation* folder within your web site's root directory. A page called *Master list* or *Table of contents* may be used to include the information on your documents, similar to Figure 4.

As you may have noticed in Figure 4 - Documentation Master List, only certain entries contain hyperlinks to their corresponding documents. This is due to the fact that company's web site is located on a separate server, which limited our ability to establish an effective electronic reference structure, as we had to be constantly connected to the Internet Service Provider (ISP). If your company has a network configuration that allows access to the documentation system and the web site at all times, you may consider hyperlinking all your items in the list to their corresponding documents, including web pages and related components.

The web site used in the case study was considered to be a single entity, similar to a large document. All pages were assumed to be of the same revision level as the web site itself. Some companies choose to manage complex documents, such as quality manuals or lengthy procedures, by controlling the revisions of individual pages. For hard copy documents this approach, while often quite a headache, may be justified by saving paper for re-prints. There is no obvious advantage to using this approach for the management of a web site. However, if for any reason you do decide to use this technique, you will need to use separate revision history records for the individual

pages. Page revision history records may be located within your *documentation* folder, or on a page itself as a comment string. Remember HTML 101?

<!-- ISO Store.htm page revision history record -->
<!-- Revision 10/9/99, initial release, approved by Deb -->
<!-- Revision 12/30/00, released ISO 9001: 2000 manual, approved by MR -->

Afterword

As of this paper's publication date, Quality Works' web site had gone through a number of tactical and significant changes. Both change methods discussed in this article, the DCR process and the MIS approval method, proved to be effective in managing the web site. We also found that periodic reviews of the web site through the Management Review process helped the company to more effectively plan changes to its major communication tool. I hope this review helped you realize that documenting and managing your web site in accordance with established procedures will ensure that it is kept current and up-to-date. I also hope that this case study gave you enough hints on how to proceed with documenting your own company's web site. Visit our web site at http://www.quality-works.com/, for more details on documentation management procedures and techniques.

References

[1] AdvaMed Conference papers, Washington DC, July 11 – 12, 2000

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Project title: Web Site **Revision:** F

Project plan

Warning! Target dates are closer than they appear in the plan

No.	Task	Responsibility	6/30	7/7	7/14	7/21	7/28	8/4	8/11	8/18	8/25
1	Develop project plan	Web Site Story Team									
2	Conduct survey	Doc. Management									
3	Design input	MIS, Design Marketing									
4	Domain registration	MIS									
5	Security certificate	MIS									
6	Documentation	Doc. Management									
7	Prototype site	MIS, Design									
8	Design verification	MIS, Design									
9	Design review	Web Site Story Team									
10	Implement changes	MIS									
11	Design validation	Associate, Jerry									
		Associate, Alex									
12	Design review	Web Site Story Team									
13	DCR	Doc. Management									
14	Report completion	Business Manager									

Figure 1 - Project Plan

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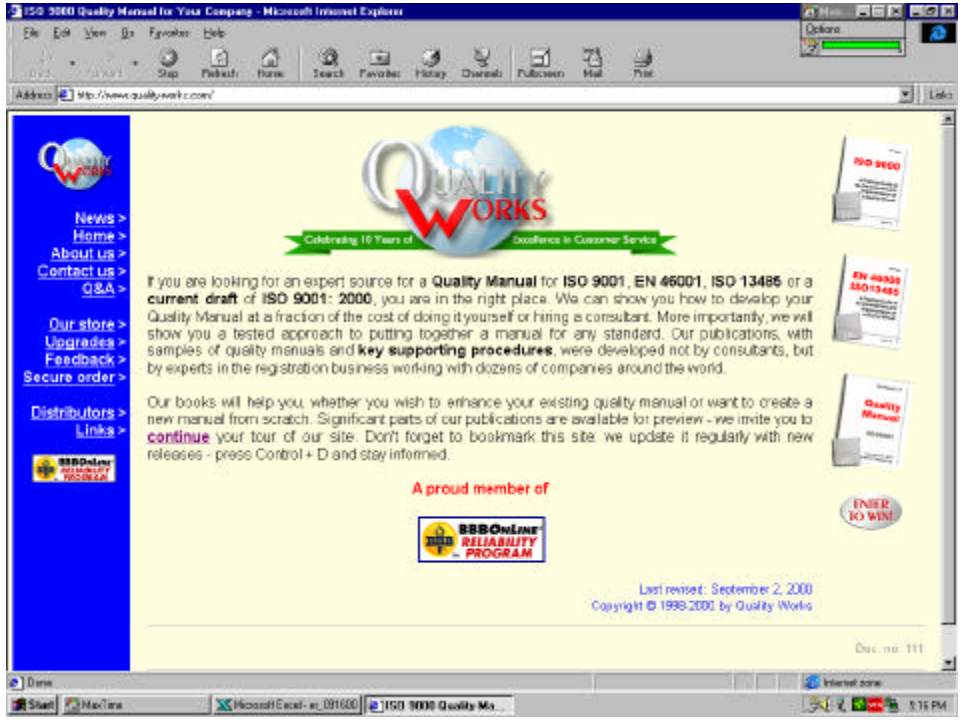
Project title: Web Site **Revision:** F

Design input / output record

No.	Input	UOM	A/C	Output
1	Index page			
1.1	Generator: MS Front Page 2000	Y/N	Visual	
1.2	Page format: no frames, table structure	Y/N	Visual	
1.3	Navigation bar, left, hyperlinks to:	Y/N	Visual	
1.3.1	News	Y/N	Visual	
1.3.2	Home	Y/N	Visual	
	Etc.			
1.4	Brief summary of services	Y/N	Visual	
1.5	Company logo	Y/N	Visual	
1.6	BBB On-line logo	Y/N	Visual	
1.7	Images of main products	Y/N	Visual	
1.8	Enter to Win link to the Store page	Y/N	Visual	
1.9	Last updated field	Y/N	Visual	
1.10	Copyright statement	Y/N	Visual	
1.11	Index page document number, html	Y/N	Visual	
1.12	Background color: light yellow spectrum		Visual	
1.13	Load time @ 28.8 Kb	sec	Max 8	
1.14	Load time @ 56 Kb	sec	Max 5	

UOM - unit of measure A/C - Acceptance criteria

Figure 2 - Design Input / Output

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Project title: Web Site **Revision; H**

Design verification and validation record

No.	Input	UOM	A/C	Output	Verification	Validation
1.1	Generator: MS Front Page 2000	Y/N	Visual		Deb, 8/10/00	Jerry, 8/17/00
1.2	Page structure: no frames, table format	Y/N	Visual		Deb, 8/10/00	Jerry, 8/17/00
1.3	Navigation bar, left, hyperlinks to:	Y/N	Visual		Deb, 8/10/00	Jerry, 8/17/00
1.3.1	News	Y/N	Visual		Deb, 8/10/00	Jerry, 8/17/00
1.3.2	Home	Y/N	Visual		Deb, 8/10/00	Jerry, 8/17/00
	Etc.				Deb, 8/10/00	Jerry, 8/17/00
1.4	Brief summary of services	Y/N	Visual		Deb, 8/10/00	Jerry, 8/17/00
1.5	Company logo	Y/N	Visual		Deb, 8/10/00	Jerry, 8/17/00
1.6	BBB On-line logo	Y/N	Visual		Deb, 8/10/00	Jerry, 8/17/00
1.7	Images of main products	Y/N	Visual		Deb, 8/10/00 Deb, 8/10/00	Jerry, 8/17/00
1.8	Enter to Win link to the Store page	Y/N	Visual		Deb, 8/10/00	Jerry, 8/17/00
1.9	Last updated field	Y/N	Visual		Deb, 8/10/00	Jerry, 8/17/00
1.10	Copyright statement	Y/N	Visual		Deb, 8/10/00	Jerry, 8/17/00
1.11	Index page document number, html	Y/N	Visual		Deb, 8/10/00	Jerry, 8/17/00
1.12	Background color: light yellow spectrum		Visual		Deb, 8/10/00	Jerry, 8/17/00
1.13	Load time @ 28.8 Kb	sec	Max 8		Deb, 8/10/00, 7 sec	Jerry, 8/17/00, 8 sec
1.14	Load time @ 56 Kb	sec	Max 5		Deb, 8/10/00, 4 sec	Jerry, 8/17/00, 5 sec

UOM - unit of measure A/C - Acceptance criteria

Figure 3 - Design Verification and Validation

Quality Works Documentation Master list

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Part number	Document title	I(internal), E(external	Media	Documentation level	Revision level	Issue date	Obsolescence date	DCR number	Internal documents: Change record External documents: verification record	Distr. Master file	Distr. Web site Quality Works
101	ISO 9000: 1994 Manual Book	I	e	3	06	6/30/00		101	See release	1	1
102	EN 46000 Book	I	e	3	01	2/3/00		124	Initial release	1	1
103	ISO/FXDIS 9000: 2000 Manual	I	e	3	01	3/10/00		124	Initial release	1	1
104	Custom Manual Service	I	e	3	01	3/10/00		124	Initial release	1	1
105	Documentation Master List	I	e	2	01	5/30/00	7/30/00	>	Replaced with rev. 2	1	0
105	Documentation Master List	I	e	2	02	7/30/00		128	Added distribution matrix	1	0
106	Privacy policy.htm	I	w	2	01	5/1/99		126	Initial release	1	0
107	Custom Manual Checklist-Cust	I	e	3	01	7/30/00		128	Initial release	1	1
108	Custom Manual Checklist-QW	I	e	3	01	7/30/00		128	Initial release	1	0
109	QW Web Site	I	w	3	>	4/22/99		127	Initial release	0	1
110	News.htm	I	w	3	>	4/22/99		127	Initial release	0	1
111	Index.htm (home)	I	w	3	>	4/22/99		127	Initial release	0	1
112	About us.htm	I	w	3	>	4/22/99		127	Initial release	0	1
113	Contact us.htm	I	w	3	>	4/22/99		127	Initial release	0	1
114	BBB On Line Logo	E	w	-	>	N/A		N/A	Verified 4/22/99, Ellen Verified 10/15/99, Ellen Verified 4/21//00, Ellen	0	1
115	Thawte certificate logo	E	w	-	>	N/A		N/A	Verified 4/22/99, Ellen Verified 10/15/99, Ellen Verified 4/21//00, Ellen	0	1

Obsolete document or revision, can not be referenced

Documents of external origin

Media: e - electronic
w - Web site

Figure 4 - Documentation Master List