Why Is The Implementation Of API Spec. Q1, 7th Edition So Complex?
...The Quick Explanation…

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Companies have been previously certified to Q1, 6th Edition and have passed their audits on a regular basis. However, many companies are now experiencing problems with their renewal audits to the requirements of API Spec. Q1, 7th Edition.

There are several concurrent reasons for this; there have been significant changes:

- ✓ To the Q1 structure to parallel the changes of ISO 9001:2000
- ✓ Within the API
- ✓ In auditor certification, training and monitoring
- ✓ In the API Audit Checklist (Report)
- ✓ With a new API Purchasing of Monogrammed Equipment course being given to Production Companies

And, there are future changes expected in the API Audit Checklist (report) whereby, specialized product specification questions will be developed and implemented in the future. To add to this confusion, a few of the product specifications have been revised and have become effective within this same period of time.

The net results? A more thorough and sometimes painstaking audit. The new Q1 is more robust than ISO 9001:2000 and includes approximately thirty-three (33) more additional requirements than ISO 9001.

What are the basic requirements? While some of these requirements are new, many others have been revised.

Basic System
Based upon the API requirements (i.e., Q1 and the product specifications); each licensee is required to address:

- ✓ 7 procedures – a documented way to carry out an activity; and,

- ✓ 19 control features - a control feature is an "organization's documented method to perform an activity under controlled conditions to achieve conformity to specified requirements"

The procedures and control features are not typically included in the quality manual since the manual is required to be reviewed and approved by the API; keeping the requirements separate allow the licensee to better control "how" they implement their business activities as long as they do so to their quality manual requirements.

In addition to the procedures and control features further documentation is usually required by the product specifications. Such documentation normally consists of work instructions or a more detailed methodology as to "how" an activity is implemented.

The complexity of your quality management system will greatly depend upon the complexity of your processes, the number of products you produce and your product specification requirements. The complexity of the system will not traditionally have anything to do with the size of the organization.

Typical work instructions include, but are not limited to those shown below. The number of work instructions is going to greatly depend upon your processes and the specific requirements of the API product specifications to which you are licensed. Here are some examples:

- ✓ Material specifications
- ✓ Calibration instructions (for each inspection, measuring and testing device)
- ✓ Laboratory activities
- ✓ Nondestructive examination requirements:
  - o A Written Practices
  - o An instruction for each relevant method:
    - Visual examination
    - Liquid penetrant examination
    - Magnetic particle examination
    - Radiographic examination
    - Ultrasonic examination
- ✓ Special processes
  - o Welding
    - Electrode control
    - Welding procedure specifications
    - Procedure qualification records
  - o Heat treating
- ✓ Painting or coatings
- ✓ Plating
- ✓ Handling, shipping, packaging and storage instructions

Notes:

1. It is not enough to have the procedures, there needs to be a roadmap between the quality manual and the procedures, control features, work instructions and even the forms you use in your quality management system.

2. It doesn't matter whether some of these activities are subcontracted or not, it is incumbent upon the API licensee to verify whether or not these procedures are in place.

Interaction of Processes
Now that you have documented all of your procedures, control features and work instructions, you should be home free; right? Not so; API Spec. Q1 requires that you identify the interaction of ALL of your processes. A process is defined as a "set of interrelated or interacting activities which transforms inputs to outputs." This means the interaction of not just your production processes, but the interaction of all of your processes which includes the quality management system processes. The Plan, Do, Check, Act flow chart shown in Q1 will not suffice nor will a statement that your procedures describe the interaction of processes.

This requirement is generally met when the organization documents process flow charts which include both the manufacturing, production and/or fabrication processes interacting with the quality processes. Does this mean I need a flow chart for each process? Not necessarily, may organizations create an organizational overview of the basic Q1 requirements showing which departments within the organization are responsible for implementing that requirement with a process flow diagram that crosses the boundaries of the departments and Q1 requirements. Illustration 1, Process Interaction portrays a means of addressing this requirement.

Resource Management
The most significant change to this requirement is "determining competence", which basically means verifying that training was effective. While the other requirements for personnel are not new, there is a way to document your quality management system that will minimize any future problems with these requirements, for example:

- ✓ Cross-functionally, identify position qualification requirements – this means have a description (call it a position description or call it a job description) available for each Q1 responsibility

- ✓ Qualify and document personnel to the documented description – qualification is the act of comparing an individual to the stated requirement and documenting that an individual has met those requirements. In smaller organizations it may be necessary to cross-qualify a single individual to multiple position descriptions.

- ✓ Specify what training each position requires – technical training will be required for each position as well as quality management system training. Training will have to be repeated anytime the quality management system (including applicable procedures, control features and work instructions) are revised and anytime an employee changes positions.

- ✓ Determine the competency of training – this will require the organization to develop a "documented" means of determining competency. Some of the larger companies have a Performance Evaluation which their Human Resources department uses to document that an employee has fulfilled the job requirements for a specified period of time. This methodology sometimes meets the competency requirement if competency is determined for all training performed. A test or an examination or proficiency demonstrations are other means of determining competence.

Quality Objectives
Q1 now addresses quality objectives in a more detailed manor and requires that these objectives to be

measurable. Objectives do not refer to the implementation of typical quality management system activities (e.g., training of all personnel by xx/xx/xx), but to those activities that would allow you to move toward continual improvement. Therefore, some of the following could serve as objectives:

- ✓ Reduce scrap
- ✓ Reduce rework
- ✓ Increase on time delivery
- ✓ Increase sales
- ✓ Increase throughput yield

However, just merely documenting these "wants" as an objective is not sufficient. A measurement must be associate with each objective such s reduce scrap by 5%. Once the measurement has been assigned, you have to have a means by which you track the performance of the measurement which means a data collection system and the ability to extract data and information and report it back to management. Many companies try to do this on an annual basis during their management review, but annually will not allow you to make any appreciable course corrections by which continual improvement will be realized. Optimally, objectives should be tracked on a monthly or at least quarterly basis.

Analysis of Data

Q1 has replaced the statistical techniques requirements with a requirement to analyze data related to (i) customer satisfaction, (ii) conformity to product requirements, (iii) characteristics and trends of processes and products including opportunities for preventive action; and (iii) suppliers.

To meet the requirements for analysis of data an organization needs to identify what it wants to track with regards to the specified requirements and needs to develop a data acquisition system. The data acquisition system could be something as simple as having forms which require the collection of specific data (e.g., a customer survey) and the subsequent input of the collected information onto a spreadsheet. After all the like data has been input (e.g., completed customer surveys), the data could be compared to determine if any necessary changes are required to the quality management system.

The requirement for Analysis of Data and Quality Objectives are parallel requirements in that the organization could track and analyze all of the information required by the Analysis of Data requirement and use this data to meet the Quality Objective requirement. However, experience has shown that this is only the starting place for those companies who really want to track continual improvement; many organizations address additional objectives and by tracking the data they specify, they learn the means by which to improve their processes and literally realize savings.

Management Review

The management review requirement is not new, but the requirements have been modified. The requirements address specific criteria that need to be included in the review process, including Quality Objectives and some of the topics from Analysis of Data information. The management review output requires that the following be determined as a result of the management review:

- ✓ Improvement of the effectiveness of the quality management system and its processes
- ✓ Improvement of product related to customer requirements, and
- ✓ Resource needs

The development and deployment of a comprehensive checklist would be useful to ensure that all management review criteria, including additional information from other aspects of the quality management system are periodically addressed. Although Q1 requires the management review to be conducted at least annually, it could be performed on a more frequent basis to ensure that the organization stays on track with its quality objectives.

Summary

While this article concentrated on some of Q1's major changes, there are many other subtle changes that require equal attention. Whether it is implicit or directly stated, the new Q1 is about continual improvement, customer satisfaction and about having a quality management system that allows an organization to define its processes and reduce nonconformities. Although the changes may not be welcomed by all, the user companies (the major petroleum producers) are the end customer of the products produced under the API Monogram Program requirements and they are involved with the API committee structure to ensure that they receive product that meets the requirements of the Monogram Program whether or not your direct customers (i.e., if you are not selling directly to a petroleum producer) show any interest in Q1 requirements or not.

As the petroleum producing companies experience more field failures, the more they influence API Monogram Program activities.

Welcome to the changes, they are here today and will be around for tomorrow… it's a new world in oilfield quality!

Illustration 1
Process Interaction (abbreviated)

DEPT vs. Q1	Quality	Mfg.	Eng.	Purchasing
Management responsibility	Flow between Q1 & DEPARTMENTAL RESPONSIBILITIES			
Resource management				
Product Realization				
Measurement, analysis, and improvement				

R.T. "Bud" Weightman is an:

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Bud also serves on various API committees including:

- ✓ SC18 – Subcommittee for Quality - member
- ✓ Task Group on Auditing Effectiveness – Chairman
- ✓ SC10 Audit Checklist Rewriter Work Group – member
- ✓ Q1, 7th Ed. Rewrite - member