The 9000 Advisers

ISO 9001:2000
Gap Analysis Report

Presented by

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This 9000 Advisers Gap Analysis Report represents a comprehensive list of requirements, considerations, and recommendations. Together with the examples provided in the Adviser model system, they provide the information needed to identify the changes you need to make in order to develop a system that meets the requirements of the ISO 9001 Standard and creates management practices that improve your business.

ISO9001:2000 Gap Analysis

1. **Establish a quality policy.**

   Read the requirements in the standard. The policy must meet specific qualifications. A note of caution: don't create policy conditions that are not measurable. (Becoming "world-class" is not a measurable goal.) Take a look at the policy in the manual of the Adviser model system, document 1-010.

2. **Establish objectives and develop leading indicators for measuring the progress toward achieving the objectives.**

   The objectives must to be in sync with the policy, which means that accomplishing the objectives should fulfill the goals of the policy. Also, the key indicators must be in sync with the objectives. These are the measurements that determine how well you're progressing toward meeting the objectives. Refer to the example in the model system manual, document 1-020.

3. **Select an ISO Representative.**

   The executive in charge of quality is not always the best choice. The ideal candidate is a systematic thinker with interpersonal skills and a broad understanding of all aspects of the business. He or she should have good writing skills and have an understanding of how database programs work. The position reports directly to the top person on all issues relating to the Quality Management System. The standard defines the responsibilities.

4. **Select an authorized registrar.**

   Check the resources page of the 9000 Adviser website. ANSI publishes a complete list of accredited registrars, including email addresses and some websites. The price can vary, and some are better than others. We don't recommend using the resister for QMS training purposes.

5. **Prepare a background report.**

   It should include:

   - Description of products
   - Operational conditions: service, production, job shop, distributor, etc.
   - Size of the business: sales volume and number of employees
   - Market profile; customers and competition
   - Direction of the business: growing, struggling, diversifying, etc.

   Also include those things you feel influence your management practices, e. g. outsourcing, product consignment, inventory control issues, etc.

   The Quality Management System processes should be designed around the needs of the business and not the ISO9000 standards. Refer to document 1-030 of the model system manual.

6. **Decide on the processes that best group the management activities of your operation.**

   Read the section in the Advisers Orientation Report discussing the "process approach" and the system structure.

Note that there is nothing in the ISO Requirements that suggests that the sections defining the ISO Standards represent recommended processes. The processes are derived from the conditions and needs of your operation, and are formulated based on the "process approach" definition described in the Orientation Report.. Remember ISO requirements don't change from company to company but the management processes can and should. Pick processes that are important to you and feel free to change them as you develop your system.

A good way of analyzing processes it to establish inputs and outputs. (Refer to the section cover pages in the model system Administrative Manual.)

7. Determine the interaction between the processes.

Start with an ultimate goal, i.e. continual improvement, growth and profitability, etc., and try not to make this exercise any more complicated than it has to be. The purpose is to ensure that all your processes have a common goal. (Refer to document 1-100 of the sample system Manual.)

8. Establish methods for monitoring and measuring the performance of your processes.

Some are easy to monitor and measure and others are not. Some monitoring and measuring possibilities include:

- Customer Relations: 1) Number of complaints, 2) Number of warranty claims, 3) Number of late deliveries
- Continual Improvement: Number of completed corrective and preventive actions
- Human Resources: 1) Number of successful training programs, 2) Number of internal promotions
- Quality System Integrity: Number of system improvements
- Purchasing: 1) Percent on-time deliveries, 2) Audit score
- Quality Control: 1) Percent non-conforming product, 2) Cost of Quality

It's essential that you come up with measurements for all of the processes, but too many for any given process may be counterproductive. (Refer to the examples in Administrative Instruction Manual, document 01-030.)

9. Decide on how to format and identify the QMS documentation.

The nomenclature and format used in the model system offers several advantages:

- The procedures are easy to read and write because explanations and policies are not mixed in with instructions.
- The nomenclature makes revising and adding documents easy because there's room within the numbering system to remove unwanted documents and add new ones.
- It is easy to relate forms to instructions because of the similar nomenclature and because the forms are filed immediately behind the related documents.
- Revised documents are easy to read because the changes are identified in the margins or with separate explanations as opposed to crossing out or underscoring the original verbiage.
- It is easy to kept track of the obsolete documents because the procedures are on separate pages, and because the revision level is part of the numbering system.
- The multiple sign-offs make enforcing accountability easier.

(Refer to the model system Manual, documents 1-110 and 1-130.)

10. Decide on how to control and protect the QMS documentation.

Follow the guidelines in the model system and you shouldn't go wrong. The rules are:

- Hold the ISO Representative responsible for all of the changes.
- Place every document on a separate file.
- Keep the forms together with the instructions.
- Rubber stamp every document including the reference documents.
- Use the QMS Audit database file to keep track of the documents.
- Make the procedure stakeholders sign off on every instruction.

- Use the Change Request form to make it easy for employees to recommend improvements.
- Use the QMS Revision procedure, 02-020, to legislate changes.

The 9000 Advisers Gap Analysis Report identifies the fifty-three primary compliance considerations that form the basis for establishing the implementation tasks.

Unlike some Gap Reports, it is not a long list of questions that make a project of establishing the tasks.

