The 9000 Advisers

ISO 9001:2000

Implementation and Certification Manual

Presented by

The 9000 Advisers

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Implementation and Certification Manual

Implementation

The information in this manual identifies the activities involved in implementing an ISO 9000 quality management system and provides recommendations on how to manage these activities, starting with:

Conduct a Gap Analysis –

The 9000 Advisers Gap Analysis Report lists over fifty compliance requirements and provides considerations and suggestions for all of them. It's the basis for establishing the scope of the project and developing plans for achieving compliance.

We recommend you review this report with members of your administrative staff and evaluate the status of all the items on the list. It might take more than one meeting, and it may take some time to evaluate some of the items. It's our guess, however, that the status of most will be obvious, and you're probably already doing many of the things you need to do. Your findings, together with our recommendations should give you a pretty good idea of how much work is involved in implementing your system.

If you're like the majority of companies, most of the work will be related to developing of the documentation and managing system information.

Call if you're unsure of the meaning of any of the considerations. Avoid making a mountain out of a molehill but don't dismiss something that may be important. The goal is to develop a clear understanding of the project requirements.

We suggest holding off on making a formal announcements until you digest the findings and think about the impact they have on the business and the employees. Implementing a quality system isn't an operational issue, it's a strategic decision that requires an unwavering commitment.

Appoint a Project Manager –

The ideal candidate will know the nuances of the business, have interpersonal skills, writing skills, and understand data management. He or she will also be the main document writer and the full time ISO Representative; a position that reports directly to the person in charge of the operation on all matters relating to the quality system.

It's important that the project manager has top-level support. Projects of this nature normally are not crippled by the efforts of the implementation team but rather by the attitudes of mid-level management, and these managers need to know that the person managing this project has the support of top management.

Select a Registrar –

The registrar must be accredited by RAB or IRCA, which are the governing bodies that have the exclusive authority for accrediting registrars within the United States. (Our website can direct you to an extensive list of accredited registrars.)

There's lots to choose from. They're located across the country, some have different specialties and different capabilities, and prices will vary. Our only note of caution is that we don't recommend using your registrar for anything other than the certification process. RAB has ruled that the system auditors can't be the same people you use for consulting advice and training.

The registrars tend to focus mainly on conformity to ISO standards at the expense of the other system requirements

that may be essential to your particular business. They tend to favor standardizing systems because it simplifies the auditing process. They also tend to impose uniform interpretations of the standard in order to reduce variation. None of which is in your best interest from a system development standpoint.

Define the Processes –

The first responsibility of the project manager is to identify the processes that best describe the activities of your business, and then describe the inputs and outputs of those processes.   The processes form the outline of the administrative instructions manual and define the role of those activities not included in the ISO requirement but nevertheless important to the management of your business. Most importantly, they represent your approach to managing your business. All of the individual instructions used in the system are designed to satisfy the inputs and outputs of the processes.

Refer to the document in the model system manual that describes the processes of a typical manufacturing operation.

Examples on how to develop inputs and outputs can be found at the start of every section of the Administrative Instructions folder.

Develop an Implementation Plan –

The next step is to develop an implementation plan, including milestones and target dates. The plan doesn't need to be overly complex or extremely detailed, but it does need to identify the major events and establish deadlines. It's both a tool for measuring the progress of the project and a means of establishing accountability.

Typical milestones include:

1. Complete Manual
2. Complete Administrative Instructions
3. Complete Operational Instructions
4. Complete Operational Changes (List the major changes based on the Gap Analysis findings.)
5. Certification

The time line of the plan will vary depending on any number of considerations, but it's our feeling that anything over twelve months is too long. If it takes any longer that that, then you've either run into to roadblock, failed to provide adequate resources, made something more complex that it should be, don't have the proper support, or have lost focus.

> The Implementation Instruction Manual is a fourteen page document that offers a concise but complete guide to implementing an ISO 9000 system. It covers every aspect of the implementation process from beginning to end: from the Gap Analysis to the Compliance Audit and everything in between, and it includes concepts and implementation rules you won't find anywhere else.