It is with great sadness I come to the task of finishing this article alone instead of with Bob Politzer. Bob was a friend, colleague, and business partner. His death was sudden, unexpected and tragic. We worked together on this subject many times over the past two years. My hope is to present the topic in a manner of which Bob would approve. Vic Halpin

Bob Politzer presented A How to Achieve Registration to QS-9000 in Less Than a Year≅ at the Auto-Tech. 95. Of the many subjects we have discussed with our clients, this one is the most popular. Many companies have made the decision to achieve QS-9000 registration. That task is already assigned to staff members. Its time to do something. What, exactly, do we do now.

Step One: Education

It is quite common for management to commit to the QS-9000 process because it is a requirement of an important customer. Very practical, but this commitment, however sound as a business decision, often does not evaluate how the QS-9000 process will impact the company. The company=s management team must understand specifically what their commitment means. A thorough dissection of the major QS requirements (4.1, 4.2, 4.3, 4.4 [if applicable], 4.5, 4.6, 4.9, 4.11, 4.14, 4.17, 2-1, 2-2) may be an eye opener. When the requirements are translated into required actions by specific departments and staff, the QS-9000 registration process will be appreciated by management. This education is also necessary to guide the selection of the steering committee and the management representative.

Step Two: Evaluation

It has been said that even the best woodsman with the best maps and compass won=t be able to find their destination if they don=t know where they are. The current quality system; excellent, mediocre or missing; must be evaluated in relation to the QS-9000 requirements. This evaluation is called a Abaseline assessment≅ or Agap analysis≅.

Our company recommends a very detailed evaluation that is organized like the QS-9000 requirements. The report has three types of information per standard section, as follows;

1. the text of the standard
2. detailed observations
3. recommendations

This organization allows individuals to see the requirements, the observed state of the evaluated area, and recommendations about how to add new or modify existing activities to meet the QS-9000 requirements. This report is usually 85-115 pages. It is different from an initial or pre-assessment audit in that it is consultative in nature. Because it is consultive, it is important to assure that the individuals who perform the baseline assessment have extensive QS-9000 and relevant industrial experience.

Step Three: Quality System Design

QS-9000 specifically requires, AThe supplier shall establish, document and maintain a quality

system...≅ (4.2.1). This seems simple enough but it is useful to do some specific analyses of the words Aquality system≅ and Asystem≅.

ISO 8402 defines quality system as, AThe organizational structures, procedures, processes and resources needed to implement quality management. Webster defines system as, AA regularly interacting or interdependent group of items forming a unified whole.≅ Another popular definition from operations research, which is the study of systems, is; AA system is a whole which cannot be divided into independent parts.≅ This very precise analysis may seem to be a bit much, but it begins to identify why many of our Aquality systems≅ are not as effective as we might desire.

The benefits of systems are a result of the interactions of the interdependent parts, not of the characteristics of the individual parts. As such systems must be designed based on the interrelationship of the parts of the system. The most common problem in QS-9000 implementation is companies design a collection of quality related activities instead of designing a quality system. It is quite common for a company to separate the QS-9000 requirements into 23 sections (4.1 - 4.20 and 2.1 - 2.3) and assign those sections to various members of the staff. The creator of each section independently identifies a series of activities relative to their section of the standard. Then the staff meets in committee and glues these pieces together by way of the quality manual. If this collection of activities behaves as a system, it is the rarest of occurrences bordering on the miraculous.

Quality system design is the process of defining goals for the system and its subsystems and designing the interrelationships for the subsystems. It is a difficult, thinking process that usually benefits from some experienced guidance. Consider the following questions;

- X What is the function of the quality system within the company?
- X Should our quality system be designed to accommodate a variety of goals?
- X Is our quality system a management system that is applied to quality or is it inherently a quality system? Which do we prefer?
- X Is achieving QS-9000 registration the goal of the quality system or is it a lower level requirement?
- X Should our quality system be self-correcting or self-identifying?
- X What is the purpose of documents within our quality system?
- X Should our corrective action activities be part of internal audits or are the results of internal audits just one input to a general corrective action system?
- X What subsystems are part of our quality system?
- X What are the purposes of and the goals for the identified subsystems?
- X What are the component parts of the subsystems?
- X Do any of the subsystems have subsystems?
- X Should the documentation system be designed for all company documents or is it only for quality related documentation?
- X Is training a subsystem or a separate system with common areas of application?
- X Which company function is responsible for the identified quality subsystems?
- X What is the relationship of our current records to our quality activities?

X How do we identify the records needed for quality activity verification?

The above questions are systemic in nature and are addressed through system design not through the identification of required activities.

Step Four: Document and Train the System

After you have done the hard work of identifying system questions, setting goals and designing the quality system you want to capture your efforts through appropriate documentation. This usually consists of a quality manual, requirements for the content of specific procedures, a document system design, and a records retention plan.

Many times companies struggle with the quality manual. It is usually very difficult to write a quality manual before you design the quality system. The struggle results from trying to create appropriate interfaces for independently developed pieces. Can you imagine how difficult it would be to frame a building if you cut all the lumber before you designed the structure? Conversely, it is easy to write a quality manual that describes your carefully designed quality system.

After you have documented your system train the staff that will implement your QS-9000 effort on the quality system structure. Make sure a common understanding of the goals and structures of the quality system results from the training.

Step Five: Develop a Project Plan

This step involves standard project management. Identify the activities required for implementation. Assign these activities to your staff. Develop target dates for completion of the tasks. Coordinate the sequences of the activities. You will require a variety of training on specific quality related tasks like documentation, calibration and internal auditing. You will want to start your selection of registrars and schedule their activities into your project plan. The entire QS-9000 implementation should be consider as an important project. It needs the same priority and importance as a model launch. It can not be relegated to a Awhen we get around to it≅ activity.

Step Six: Implement the New and Modified Procedures

QS-9000 systems are prescriptive; you write down what you are going to do and then you do it. To meet the QS-9000 requirements you will probably need to change several activities. The bulk of initial implementation of QS-9000 system usually involves documenting and implementing new or modified activities. If you intend to convert to all the changed activities on the same day you may want to reconsider. It is a good idea to implement these changed activities as they are completed over a period of three to four months. This reduces the feeling of chaos and converts it to an atmosphere of very rapid change. Both approaches are uncomfortable, but implementing all the changes on the same day will maximize the stress that accompanies change.

Step Seven: Begin the Cycle of Internal Auditing and Corrective Action

When an entire area or location has implemented all the new and modified processes start the auditing process. The first audit pass will likely produce a very large number of non-conformances. This is normal. Try as we will, we just can=t seem to think of everything. The first audit pass should be more informal, conversational and educational than future internal audits. Schedule significant management time to evaluate the first audit pass because you will discover areas that don=t work as expected and areas that were overlooked.

We recommend three complete audit passes before you submit the system for registrar preassessment or assessment. There should be a significant reduction in non-conformances between the first and second audit passes. When successive audit passes produce approximately the same number and severity of non-conformances the system is becoming stable. Be sure to evaluate any non-conformances and see if they indicate any systemic short-comings. When the number of non-conformances is few and the severity is minor in successive audit passes, your system is stable and effective.

Step Eight: Registration

The registration process should not be a time of high anxiety. When you have invested the time to properly design a system and you have implemented and audited faithfully, a successful registration audit is the natural result. The registrar will probably find some non-conformances no matter how well you prepare. You diligence throughout the entire process will assure that these are minor in nature. You will need to correct any non-conformances before the registrar can recommend you for registration.

Step Nine: Celebrate

Be sure to celebrate the significant accomplishment your company has achieved through concerted effort over a long period of time. You have assured yourself of favorable consideration from all existing and potential customers and should be well satisfied with a job well done.

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