ISO 9001:2015 Begins With Leadership

by Walter Tighe

As quality professionals, many of us have shared in the frustration regarding the lack of top management commitment, and specifically the lack of hands-on involvement with the company quality management system. What about management review meetings? Sure, the process of management review meetings does require top management involvement; however, too many times the company quality manager is the delegated source of data collection, measurement representation, and communication to all management review meeting attendees on the quality system effectiveness, or worse, the lack of process effectiveness.

Will the ISO 9001:2015 standard make a real difference in promoting leadership involvement? Yes, I certainly think so, but it will require increased discussion and integration of the quality group and the leadership team. Having accountability requires this. Meaningful involvement and learning from the quality group for top management will be required in the early stages of this transition—a top priority and an essential step.

Let's face reality. The ISO 9001 standard has not had any meaningful new requirements in 15 years! A mature, certified quality management system has most likely remained in the "been there, done that" stage for many years. Unless you're working for a technology juggernaut or a progressive auto manufacturer, such as Tesla Motors, radical change has not affected your documented operational management system in years. Consequently, your leadership team's involvement has been administered in a two- to four-hour management review meeting every quarter or, even more likely, once or twice a year.

Real involvement stems from top management when they realize the quality department is not a departmentalized function, but an integrated unit of established controls and monitoring methods. These methods are monitored against approved criteria, which are aligned with the company business objectives.

A quality truism: When your leaders are accountable, they will want to know what's required. They will need to know all of the new requirements that will require their attention, time, and necessary resources.

Let's take a look at the significant leadership differences in the new ISO 9001:2015 standard, and the changing role of the quality group with this new transition.

1. **Understand the needs, expectations, and the requirements of interested parties that are relevant to the QMS. Monitor and review information about these parties and their relevant requirements.**

This is a new requirement of the standard that is going to take some effort. Typical examples of interested parties from a leadership team would consist of customers, suppliers, and regulatory agencies. What should end up on your list of interested parties is dependent on the size of the organization, your market, the people who perform the work, and the complexity of your organizational processes.

Here's something to ponder: What are the needs, expectations, and requirements of the company quality group? Most likely, the quality group will be the body delivering information to the leadership team on the new requirement of "monitor and review information about these interested parties and their relevant requirements." ISO 9001:2015 Annex A.3 states, "It is for the organization to decide if a particular requirement of a relevant interested party is relevant to its quality management system." The quality group must have an active role with determining how this clause is applied so that it is workable, beneficial for the organization, and is not treated as a simplified task.

What methods will you use to identify and monitor this new requirement? Will you use the management review meeting so action plans can be developed with responsible, assigned personnel and the necessary resources allocated? What kind of objective evidence/records will you maintain, and how will they be monitored?

The degree to which the leadership team and the quality group execute these requirements will directly affect the extended requirements of risk, quality objectives, and planning to achieve them. To be successful, the quality group must ensure understanding of the requirements through effective training on the new standard and hands-on involvement with the leadership team.

2. **Ensure that the quality policy and quality objectives are established for the QMS and are compatible with the context of and strategic direction of the organization.**

Compatibility in this context requires integrating quality into business processes, as process objectives must now be more clearly aligned with your company's strategic direction, otherwise known as long-term business goals.

Define quality objectives that are compatible with the context and strategic direction of the organization. Can the quality group or a quality manager solely define organizational context and strategic direction to ensure the quality objectives' compatibility? Never. A much broader look at

the role of the management system is now required by leadership and its related processes.

The "how to" of achieving quality objectives is explicitly specific with the new requirements of (a) what will be done; (b) what resources will be required; (c) who will be responsible; (d) when will it be completed; and (e) how the results will be evaluated. If an organization continues to use management review meetings and the output of documented meeting minutes for this evidence requirement, this will clearly require increased analysis and detail within a project management framework. The level of involvement between leadership and the quality group will be increasing with quality objectives results evaluation and the need to ensure compatibility with the context of and strategic direction of the organization.

3. **Ensure the integration of the QMS requirements into the organization's business processes.**

An ongoing debate is that a wide gap of distinction exists between company quality processes and business processes. Experience tells us that wide gaps do exist in some organizations. How many times have we heard "that's an ISO requirement," or "the standard makes us do that"? This results in duplication of process measurement and increased labor. This can include separation of information on quality and business performance, measurement methods used, trends and indicators, and responsiveness to actions required.

An aggressive company business plan should include the integration of numerous business quality-related preparations and the controls required to expand operations and business opportunities, yet still maintain overall operational excellence. The impact quality has on a company's success is often well understood. However, companies have traditionally struggled to integrate requirements and establish metrics that can easily represent the effectiveness of quality in the organization.

Early leadership involvement will be critical for achieving an effective ISO 9001:2015 transition. The company quality group must take the lead. Establishing a solid foundation for required planning, assignment of responsibilities, authorities and related communication methodologies will require a continuous active role within the leadership team and the quality group. Moving quality out of the quality department is now expanding more than ever before.

About the author: **Walter Tighe** *is president/owner of Sustaining Edge Solutions, Inc. a management systems consulting and training firm in Phoenix and Tucson, AZ. Founded in 2002, the company is a full-service provider of design, development, and training of global management systems such as ISO 9001, AS9100 Aerospace, 14001 Environmental, 13485 Medical Devices, ISO/TS 16949 Automotive, 27001 Information Security, Lean and Six Sigma improvement. Tighe has more than 28 years' expertise in operational and quality management systems improvement. He has an MBA, is a member of the Institute of Management Consultants, an ASQ Senior member, an ASQ Certified Manager of Quality/Organizational Excellence (CMQ/OE), and an RABQSA Certified Quality Management Systems Auditor. Since 2004, Tighe has been a current member of the ASQ Phoenix Section Executive Committee, performing the role of newsletter editor.*

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