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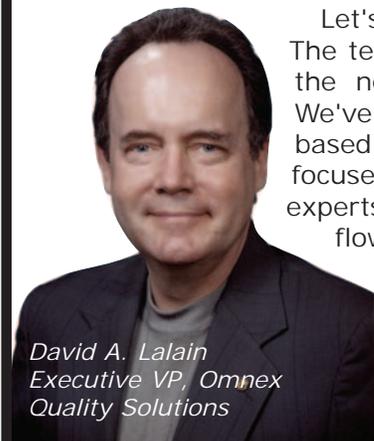
navigator

"I represent the future of quality"

by David A. Lalain - Executive VP, Omnex Quality Solutions

When asked recently what I do, I quipped that I represent the future of quality and an organization that will make it happen. Next question, "What is the future of quality?" Three things: quality culture to make everything you're doing more effective, quality outsourcing to reduce the cost of your quality management system and quality in healthcare where there are major opportunities. In this issue of the Navigator I'm going to touch on all three areas.

Quality Culture



David A. Lalain
Executive VP, Omnex
Quality Solutions

Let's start with quality culture. The term has been worn out, but the need is greater than ever. We've drifted back into a tool-based approach to quality that focuses on a few highly trained experts to make our processes flow better and reduce the variation that disturbs our customers. On the high end maybe 50 people in an organization of 5000

continued on page 5

integration, standardization and linkages

BETWEEN ISO/TS 16949:2002, ISO 14001:2004 AND OHSAS 18001:1999

by Chad Kymal - Chief Technical Officer and Founder, Omnex

"Integration, Standardization and Linkages" should be the mantra of quality practitioners for the next five years. Getting value and efficiency from all our different "standards" implementations should be the key. What these terms mean, how

continued on page 3

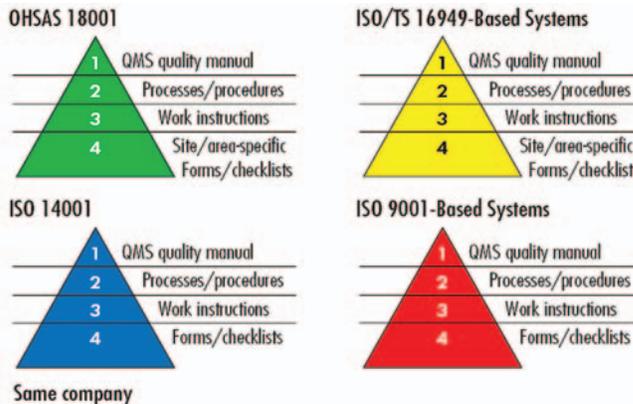


figure 1: stand alone implementations mean more work

integration, standardization and linkages

continued from page 1



Chad Kymal
CTO, Omnex

to save money and time, and how to start is the topic of this article.

Integration

Most organizations are juggling multiple standards. This not only includes ISO/TS 16949, ISO 9001, ISO 14001, OHSAS 18001, but also ISO 17025, MMOG, QOS, Q1, Six Sigma and Lean. Typically, these standards have been implemented by organizations at different time periods with different key players championing them. These factors and a lack of understanding of the similarities or relationships between initiatives have often led to implementations that are stand alone. (See figure 1)

Lack of integration leads to duplication of processes and confusion when a process is needlessly repeated multiple times. My favorite example of duplication is what top management endures in terms of

Management Review. Many times they are forced to do their business review, then management review for ISO/TS 16949, QOS, ISO 14001 and OHSAS 18001 each in turn. Simply said, lack of integration leads to duplication of processes, loss of efficiency, and confusion in the rank and file of the organization.

Integrating versus Not Integrating: A Case Study of ISO/TS 16949:2002 and ISO 14001

One can imagine the extra effort that would be required if an organization did not integrate its standards. In my estimate, the cost to maintain two standards will go up by at least 33%. How about the confusion factor of duplicate internal audits, document control, training, and management review? What is the cost of the confusion when it is multiplied by ISO 9001, ISO 14001, OHSAS 18001, Six Sigma or Lean?

For a complete example of the above situation, see the article "Juggling Multiple Standards", available on the resource center (a free service on omnex.com).

Standardization

While "Integration" refers to duplication of processes between different standards, "Standardization" refers to duplication of processes within one standard's implementation. Standardization is the key to addressing the duplication of processes between plants, design centers, and sales centers when implementing one standard. See Figure 2. For example, a global organization that Omnex works with has multiple internal audit procedures, processes, software and websites in its multiple plants. Can you imagine the duplication of process maintenance, upkeep of processes and process management? Should they be managed globally in one place? Probably not. But it should not be duplicated thousands of times either.

Linkages

A linkage addresses the duplication of information between different tasks that makes a second task easier to do with more value added. This refers, for example, to the linkage between product family, product, characteristics, and manufacturing processes shown in Figure 3 (page 4).

On small example of Linkage is between the FMEA and Control Plan. If the FMEA and Control Plan are linked in columns 1, 2 and 3, there is consistency between improvement and control. If this linkage is not made, then the person performing the second task has to do extra work finding the Operation Number and describing the operation. Often, they will come up with two totally different descriptions. Second, if the recommended actions are

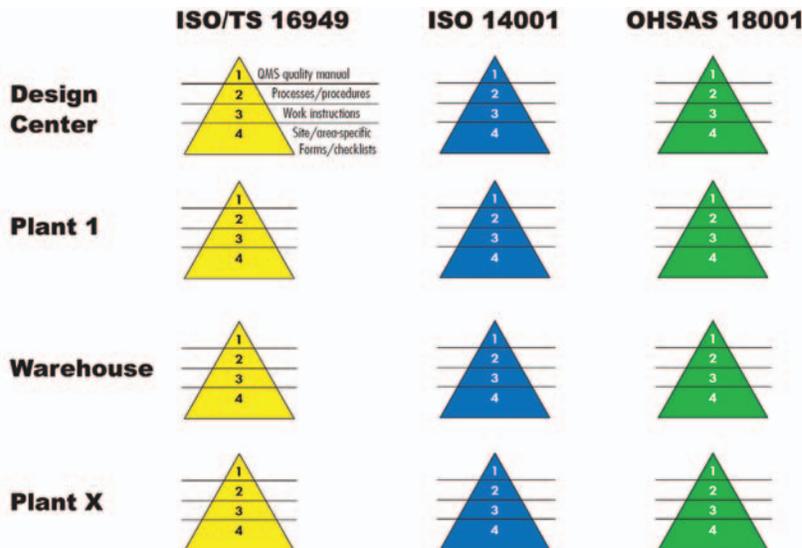


figure 2: lack of standardization in processes

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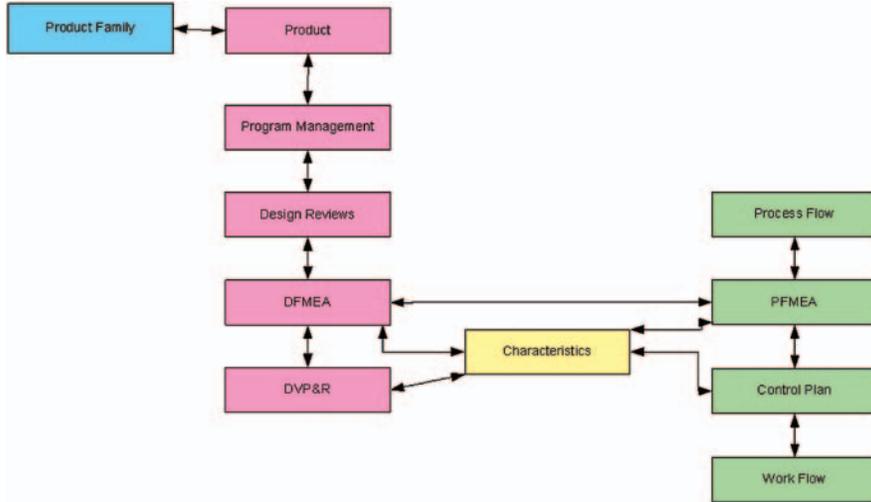


figure 3: product linkages

made without realizing that the control methods column of the Control Plan refers to current controls, the FMEA team will make assumptions on current controls and then make decisions on improved controls without studying the status quo. The value of linkages is huge for organizations.

These linkages are there in many processes including:

- Customers, objectives, performance measurement and continual improvement
- Customer expectations, company objectives, personal objectives, teams and continual improvement
- Products, new product development, FMEAs, control plans and work instructions
- Products, gages, and calibration and measurement systems analysis
- Process maps, process flows, process measurables and improvement

These linkages exist in family, product and characteristics.

EwQMS and EwIMS

Enterprise management systems like Omnex Systems' EwQMS are a way to manage data and information flow in an Enterprise. It is difficult to make good decisions when information and data cannot be shared between people in the same facility or in different facilities within the same company. Furthermore, companies may duplicate information and recreate readily available information again and again. These problems lead to large losses within the enterprise. The best solution is the use of enterprise software.

In 2002 this author wrote about enterprise quality management software systems and heralded the arrival of this new genre of software. This type of software is becoming as important to how organizations function as a CRM or ERP. It helps organizations manage their business documentation, business metrics, internal audits (all kinds), corrective actions, continual improvement, policy deployment, new product development launches (including preventive tools), measurement systems analysis, total productive maintenance, statistical process control, and training.

Most enterprise quality management systems restrict the focus of the software and its functionalities to only "Quality Management". Today, most organizations are working with multiple standards or methodologies, including Environmental Management systems, Occupational Health and Safety systems, Malcolm Baldrige, Sarbanes-Oxley, etc. In this discussion, the enterprise quality management system of today will evolve into the enterprise integrated management system of the future.

Overarching Features of an Enterprise Integrated Management System

1) Each functionality (described below) should handle the multiple requirements of QMS, EMS, Sarbanes-Oxley or Malcolm Baldrige. For example, the documentation functionality should function with quality, environmental, health and safety and other documents irrespective of their origin or purposes.

2) Each functionality should recognize how the enterprise is organized (ie. Corporate,

The enterprise quality management system of today will evolve into the enterprise integrated management system of the future.

Business Units, Plants, Departments, Product Groups, etc.) and handle transactions in multiple languages. The software should reflect how enterprises share documentation between different entities. It must consider the concept of documentation,

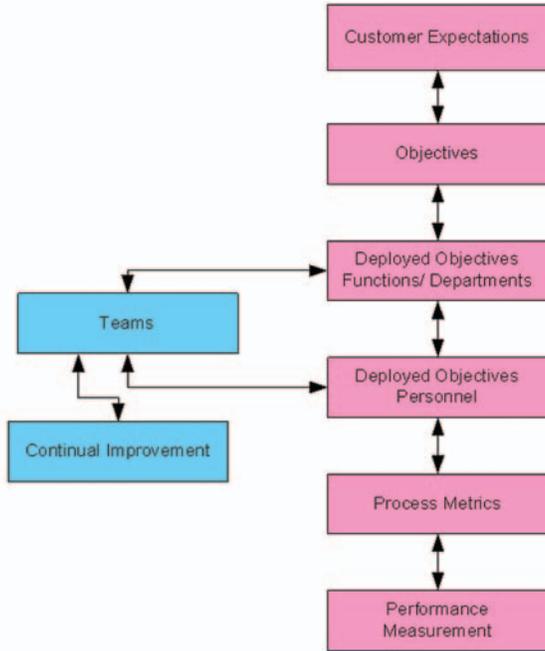


figure 4: objectives deployment and employee evaluations linkages

integration and flexibility from Rule 1 above; at the same time it must be able to handle the issue of standardization vs. inde-

pendence which is fundamental to how an enterprise works. To further the concept of the enterprise, we will use the term "entity" to describe the constituent parts of an enterprise.

3) There are linkage requirements in an enterprise integrated management system (between the common areas of a functionality across the entities of an enterprise). Here are a few:

a) Customers, objectives, performance measurement and continual improvement

b) Customer expectations, company objectives, personal objectives, teams and continual improvement. (See figure 4 on the next page for an example of this linkage.)

c) Products, new product development, Failure Mode Effect Analyses (FMEAs), control plans and work instructions

d) Products, gages, and calibration and measurement systems analysis

e) Process maps, process flows, process measurables and improvement

For an article called "Enterprise Quality Management Evolves", written for *Quality Magazine* in 2006, visit the omnex.com resource center. By the way, the architecture and features discussed in this article are found in Omnex Systems' Enterprise-wide Quality Management System (EwQMS). Call (734) 668-1000, ext 261 and speak to Don Cherry for a demo of the same.

continued on page 7

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