

Mid-Hudson APICS: Joint Professional Meeting with ASQ The Marriage of ISO and Lean Six-Sigma

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The revision of ISO 9001:2015 finally provides the missing balance between the ISO quality management system (QMS) requirements and your lean six-sigma process. The new version of ISO 9001 will force organizations to change their QMS, and this offers an excellent opportunity to integrate lean into your ISO-based QMS. The time to start is now!

When we look at lean and ISO the waste involved in having multiple systems serving the same purpose can be enormous. Both lean and the quality management systems intend to improve the process in which we work in. This is true in so many companies that are practicing lean and using an ISO 9001-based quality management system (QMS). The new revision to ISO 9001, released last September contains many major changes. It also provides your company with an opportunity to merge lean practices into your Quality Management System (QMS), thus making both systems more effective and driving out the system waste that is inherent in multiple systems with similar purposes. Is there a clear path that ISO 9001:2015 provides that will reduce redundancy and supports lean innovation and leadership? Do we see light at the end of the ISO tunnel with this major revision? Can it be possible no more stepping around the QMS system as you improve? Will the new standard truly improve its standing with our lean community and play the integral useful tool for waste elimination, process stability as well as continual improvement it should? I think I see the light. This PDM will review the key changes of the new ISO revision with an emphasis zeroing in on what this can mean for your organization and highlight the opportunity for a radical change your QMS/ISO system to a tool that truly enhances your lean practices while meeting the standard.

Let us look at the key revision areas:

- Strategic direction: *This is where the “lean” process of hoshin kanri, or “strategic process deployment” would fit magically.*
- An explicit requirement for risk-based thinking: *Process and systems wastes (e.g., in transportation or excessive inventory) are drivers of the many risks encountered and should be removed from the system.*
- Mistake Proofing: *A requirement in ISO 9001:2015 will be that organizations must address the “prevention of nonconformity due to human error, such as unintentional mistakes....”*
- Application of the process approach
- Fewer prescriptive requirements
- More flexibility regarding documentation
- Improved applicability for services
- A requirement to define the boundaries of the QMS
- Increased emphasis on organizational context
- Increased leadership requirements
- Greater emphasis on achieving desired process results to improve customer satisfaction

Then let us look at how the new revision provides the flexibility for solid lean quality-management system marriage:

- Lean tools and ISO process synchronization
- Value added auditing
- Value added documentation
- Formal recognition of the process based approach, P-D-C-A cycle, FEMA and risk based and other lean – six-sigma tools
- Leaning out your QMS system to improve its impact to the bottom line
- Case examples

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