



Weathering the Storm

An ISO 9001:2008 to ISO 9001:2015 Transitional Audit Tale

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October 2016, I was working in my office when ...


- The Corporate Quality Manager sort of quit, sort of got fired
- Switching me from CMMI-DEV to ISO 9001:2015, 20K and 27K audit preparations
- And, suddenly I am the Corporate Quality Manager
- I'd (not) been preparing for this moment all my life

Audits when?

April – May 2017




What is ISO 9001:2015?

- ▶ ISO standard for a Quality Management System that defines quality as Fulfillment of Customer Requirements
 - ▶ About 20 pages long
 - ▶ Plan-Do-Check-Act
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What is new in ISO 9001:2015?

- Context of the Organization
 - Assessment of risk and opportunities
 - Change management
 - Organizational knowledge
 - Communication
 - Some new, badly worded procurement requirements
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How did I prepare?

- ▶ Completed a detailed transition questionnaire provided by the auditing organizations
- ▶ Did the auditor look at it? No.
- ▶ How quickly did things go from bad to worse?
 - ▶ As soon as the auditor decided to do an **integrated** audit of all 3 of our ISO certifications.



What went right?

- ▶ Context of the organization
- ▶ Organizational knowledge

What went wrong?

- ▶ Change Management
 - ▶ The expectation was that all the issues would be logged in our Process Improvement Request database
- ▶ Communication
 - ▶ The expectation was that all types of corporate communications, along with reviewer and approver information be documented (Communication Matrix)
- ▶ Procurement requirements for “external process providers” – how is performance managed?
- ▶ Surprise! Payroll process not documented



In the end, we passed the audit ...

- ▶ With 17 nonconformities

Lessons Learned

- ▶ Manage the auditor
- ▶ Only do an integrated audit if you have prepared for it
 - ▶ Different auditor for each cert
- ▶ Insist on reviewing nonconformities prior to the final audit report
- ▶ Manage the auditor