ISO 9001:2015... Are you ready?

ASQ Toronto Meeting

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PRESENTATION TOPICS

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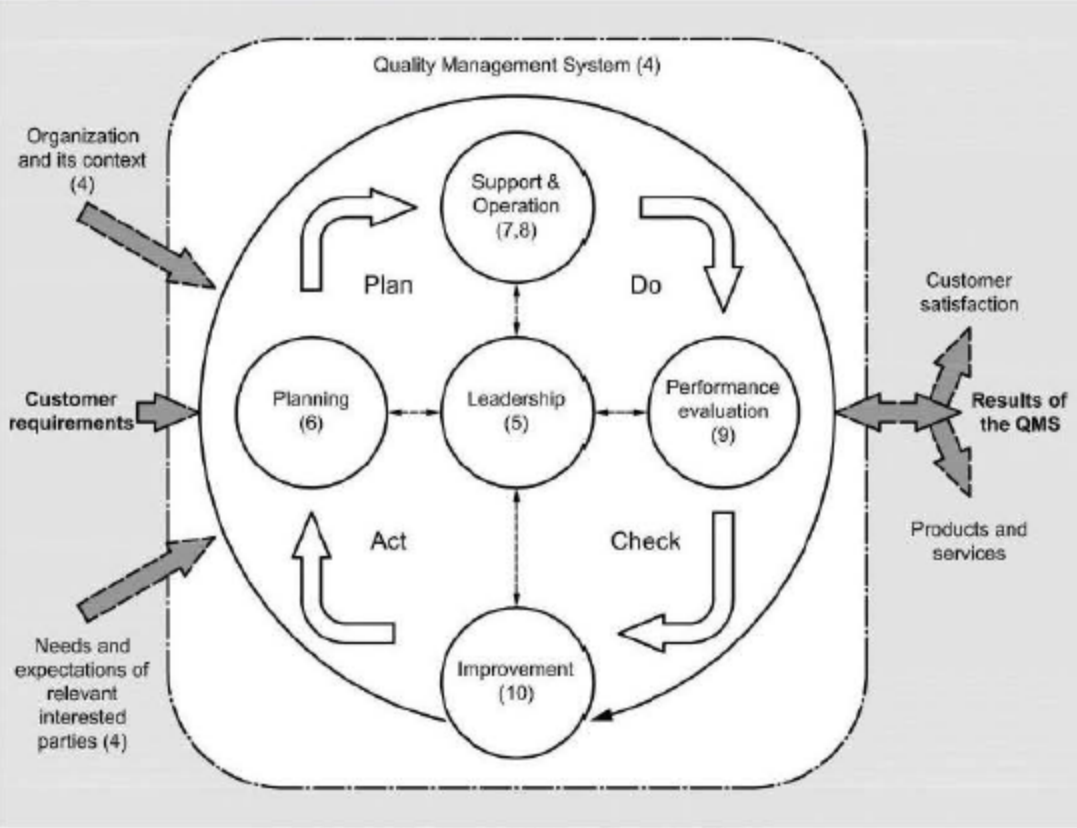
Q. Strategic Plng/Business Planning
R. SWOT Analysis / SWOT Matrix
S. Quality & Quality Objectives

… More???

OVERVIEW - ISO 9001:2015

(published on Sep 22/2015)

0. Introduction
1. Scope
2. Normative Reference
3. Terms and Definitions
4. **Context of the Organization**
5. **Leadership**
6. **Planning**
7. **Support**
8. **Operation**
9. **Performance Evaluation**
10. **Improvement**



Making the Transition / Upgrading

- There will be no ISO 9001:2008 Certificates issued past Sept/2018
- Determine when your re-registration date is… if it is in Sept/2017 then your ISO Registrar will only issue a one (1) year Certificate (as opposed to the normal 3 years) which means you will have to have another full re-registration audit a year later to the new Standard
- If you are not currently ISO 9001 Registered then use the 2015 version as your framework
- For those companies that are currently registered, conduct a gap assessment from where your QMS is at today versus what the 2015 requirements are asking for… then use those results to determine how much time and effort it will take to close the gaps… then build an action plan to do it!

  (ISG's Newsletter Issue #1 Q&A section provides further information)
- Depending on how robust your current QMS is, you will have to decide to renovate or bulldoze and re-build… it's been 15 years since ISO 9001 has changed and your QMS likely needs a good overhaul…
- ISG's Newsletter Issue #2 provides further information on this topic

Annex A

- Informative

- Title: Clarification of new structure, terminology and concepts
  - A.1 Structure and terminology
  - A.2 Products and services
  - A.3 Understanding the needs and expectations of interested parties
  - A.4 Risk-based thinking
  - A.5 Applicability
  - A.6 Documented information
  - A.7 Organizational knowledge
  - A.8 Control of externally provided processes, products and services

Number of “shall” requirements?

- ISO 9001:2015 has more substance to it versus the 2008 version
- Almost all of 2008 requirements found their way into the 2015 version, with the primary exceptions being the terms “preventive action”, “documents”, and “records”
- Some have claimed this new version is less prescriptive then before… let’s look…
- The following are some comparisons with the 2008 version of ISO 9001:
  - the 2015 document has 19 pages containing “shall” requirements vs 2008 having only 13 pages;
  - there are 65 numbered sections containing “shall” requirements in the 2015 edition vs the 2008 version having only 51 of these; and
  - there are well over 400 “shall” requirements in the 2015 edition whereas in the 2008 version there are approximately 300. [NOTE - If you performed an actual count of the word “shall” in either of these documents you would find my numbers to be much higher… why is that?… keep in mind that one “shall” can represent many requirements due to the word “and”, as well as having multiple parts]
  - **How many “shalls” do you see below?:**

    From ISO 9001:2015, Clause 4.3

    When determining this scope, the organization shall consider:

    a) the external and internal issues referred to in 4.1;

    b) the requirements of relevant interested parties referred to in 4.2;

    c) the products and services of the organization.

- ISG’s Newsletter Issue #2 provides further information on this topic

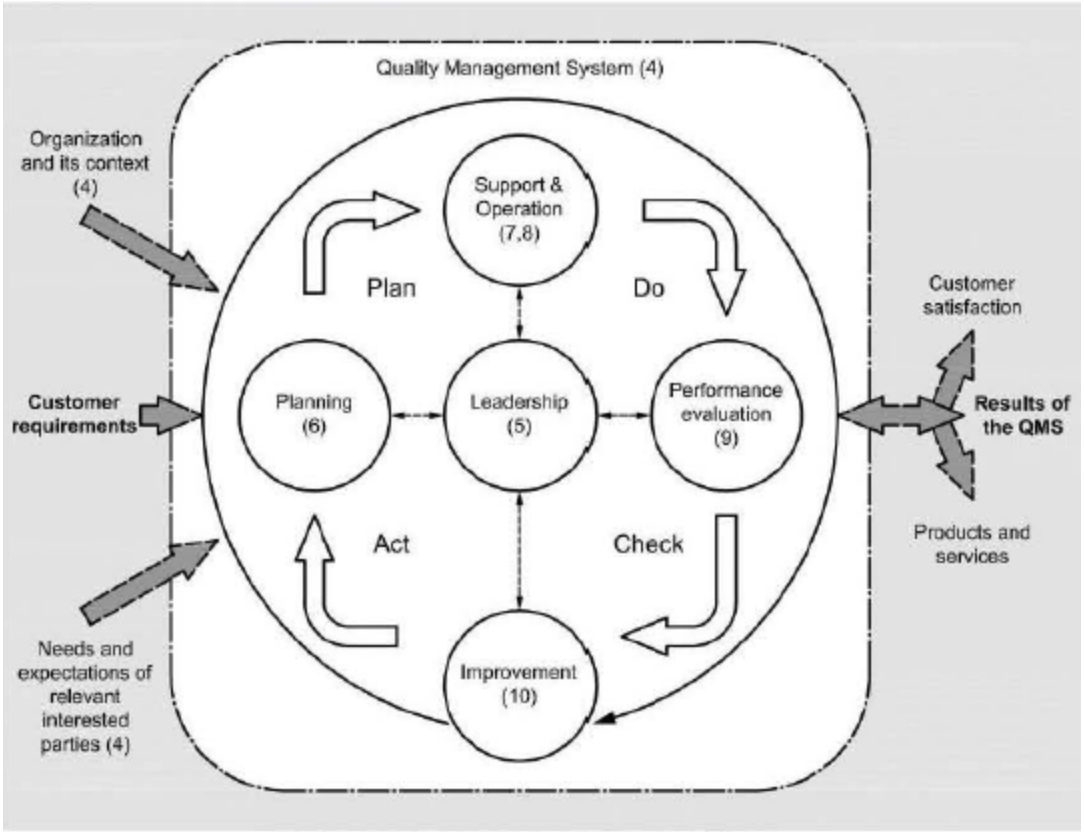
Not Applicables / Exclusions

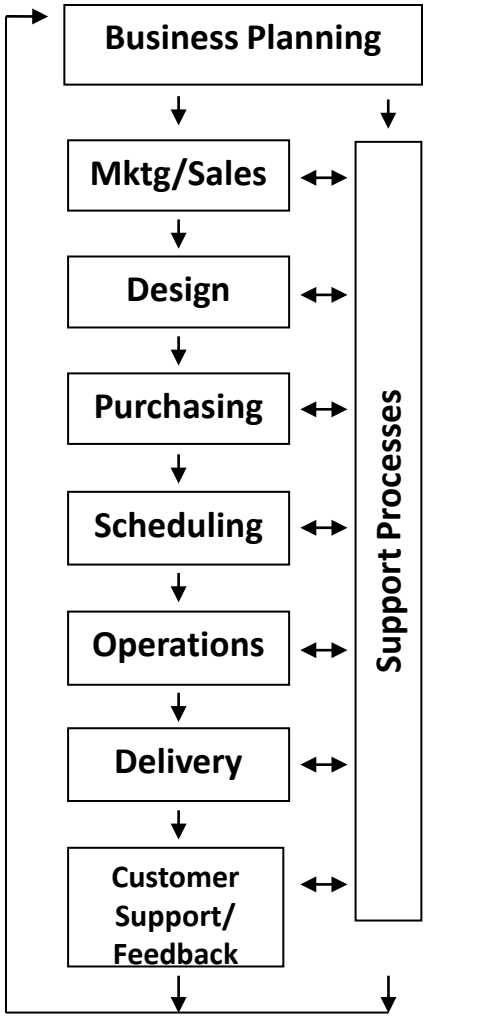
- ISO 9001:2015, Clause 4.3 - Determining the scope of the quality management system; plus Annex A.5
- In the 2008 version, you were allowed to take an “exclusion or not applicable” from only within the old Element 7.0 (Product Realization)
- In 2015, the term “exclusion” is no longer used and you are allowed to take a “not applicable” from anywhere within the ISO 9001 Standard
- *However, from Clause 4.3: “…Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction”*
- *From Annex A.5 - Applicability: “…The organization can only decide that a requirement is not applicable if its decision will not result in failure to achieve conformity of products and services”*
- ISG’s Newsletter Issue #3 provides further information on this topic

Products and Services (New?)

- ISO 9001:2015, Clause 1.0 - Scope (Note 1); plus Annex A.2
- *From Annex A.2 - The term "products and services" includes all output categories (hardware, services, software and processed materials)*
- In 2008 version, only the word “products” was used but it was defined as meaning “products and services”
- In 2015 version, the term “products and services” is used throughout so that there will be no confusion on this topic
- What “services” does your organization provide?
- Does your current QMS apply **all** of the ISO 9001 requirements to **each** of the “services” you provide?
- Can you still justify taking a “not applicable” on Design?... You may want to re-look at Clause 4.3 (Determining the scope of the quality management system), before you decide
- ISG’s Newsletter Issue #3 provides further information on this topic

P-D-C-A (Business Process Map)





Quality Manual

- No longer a requirement to have one
- The organization gets to decide what documentation is required *(from Clause 7.5 "… shall include …documented information determined by the organization as being necessary for the effectiveness of the QMS")*
- How many employees actually look at and read the Quality Manual?
- Does it take a lot of time to maintain this document?
- A Quality Manual should be a blueprint of how you've built your QMS
- Can also act as guidance document on your ISO interpretations
- Don't match the ISO numbering… The Quality Manual only needs a handful of pages with a couple of Appendices attached… make it "employee friendly"
- Your whole QMS structure has likely had many add-ins and deletions over the past 15 years… this is an opportunity to make it better!
- ISG's Newsletter Issue #3 provides further information on this topic

Context of the Organization (Int/Ext)

- ISO 9001:2015, Clause 4.1
- *From ISO 9000:2015, 3.2.2 - Context of the Organization: combination of internal and external issues that can have an effect on an organization's approach to developing and achieving its objectives*
- *Online Searchable Definitions… https://www.iso.org/obp/ui#iso:std:iso:9000:ed-4:v1:en*
- Think of context in terms of the organization's internal environment/issues and external environment/issues
- Internal – Areas: Sales; Design; Purchasing; Operations; IT; HR; etc.
- External – Areas: Customers; Competitors; Industry; Vendors; etc.
- Keep in mind that it is explicitly stated within the Standard (Clause 4.1) that it is entirely up to you to decide what "context" means for your organization… not the Auditor!
- ISG's Newsletter Issue #3 provides further information on this topic

Documented Information

- ISO 9001:2015, Clause 7.5; also Annex A.6
- *From ISO 9000:2015, 3.8.6 - Documented Information: information required to be controlled and maintained by an organization and the medium on which it is contained*
- Replaces the words “documents” and “records” and eliminates the need for the previous Clauses called “control of documents” and “control of records”
- Some have claimed this new version reduces the need for documentation… really?:
  - In 2008 version: Quality Manual, 6 areas for a Procedure, and 19 Records
  - In 2015 version: 34 times the use of the words “documented information”
- The organization gets to decide what **additional** documentation is required *(from Clause 7.5 “… shall include …documented information determined by the organization as being necessary for the effectiveness of the QMS”)*
- ISG’s Newsletter Issue #2 provides further information on this topic

External Providers

- ISO 9001:2015, Clause 8.4 - Control of externally provided processes, products and services; plus Annex A.8
- *From ISO 9000:2015, 3.2.5 - Provider: organization that provides a product or a service; 3.2.6 - External Provider: provider that is not part of the organization; 3.2.1 - Organization: person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives*
- Includes more than just “Purchasing Dept” activities where money changes hands
- Need to consider satellite plants/facilities/divisions, under the same corporate umbrella, or joint ventures or associated companies, that are providing incoming products, or providing services, or providing processes that you’ve outsourced
- Think about “shared resources” such as HR, IT, etc…

Interested Parties (Int/Ext)

- ISO 9001:2015, Clause 4.2 - Understanding the needs and expectations of interested parties; plus Annex A.3
- *From ISO 9000:2015, 3.2.3 - Interested party, stakeholder: person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity*
- Think of “interested parties” in terms of being internal or external to the organization
- Internal: Employees; Owners; Other Divisions; Other Depts (i.e. Legal, Finance); etc.
- External: Customers; End Users; Vendors; Regulators; Unions, etc.
- Need to make the Quality Policy available to Interested Parties (Cl. 5.2.2)
- Keep in mind that this Clause (4.2) uses the word “relevant” as part of every “shall requirement… you decide who and what are relevant to your QMS!
- ISG’s Newsletter Issue #3 provides further information on this topic

Internal Audit

- ISO 9001:2015, Clause 9.2
- *From ISO 9000:2015, 3.13.1 - Audit: systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled*
- No change from 2008 version
- What **is** different is that the Internal Auditor will now need to address a number of “new” ISO 9001 “shall” requirements, which will also include more audit time with Top Management
- *From ISO 9000:2015,* 3.1.1 - Top management: person or group of people who directs and controls an organization at the highest level

Organizational Knowledge

- ISO 9001:2015, Clause 7.1.6; plus Annex A.7
- Intent is to safeguard the loss of knowledge due to factors such as employee turnover or retirement; or failure to keep good records; etc.
- Also to acquire new knowledge needed by the organization to move forward, from either internal sources (lessons learned database) or from external sources (benchmarking)
- Sometimes referred to as “corporate memory”… a very simple application of this concept is the creation of documented Procedures or Work Instructions which not only reduces the dependency on tribal knowledge (that might walk out the door) but also provides a structured approach for passing key information along when training employees

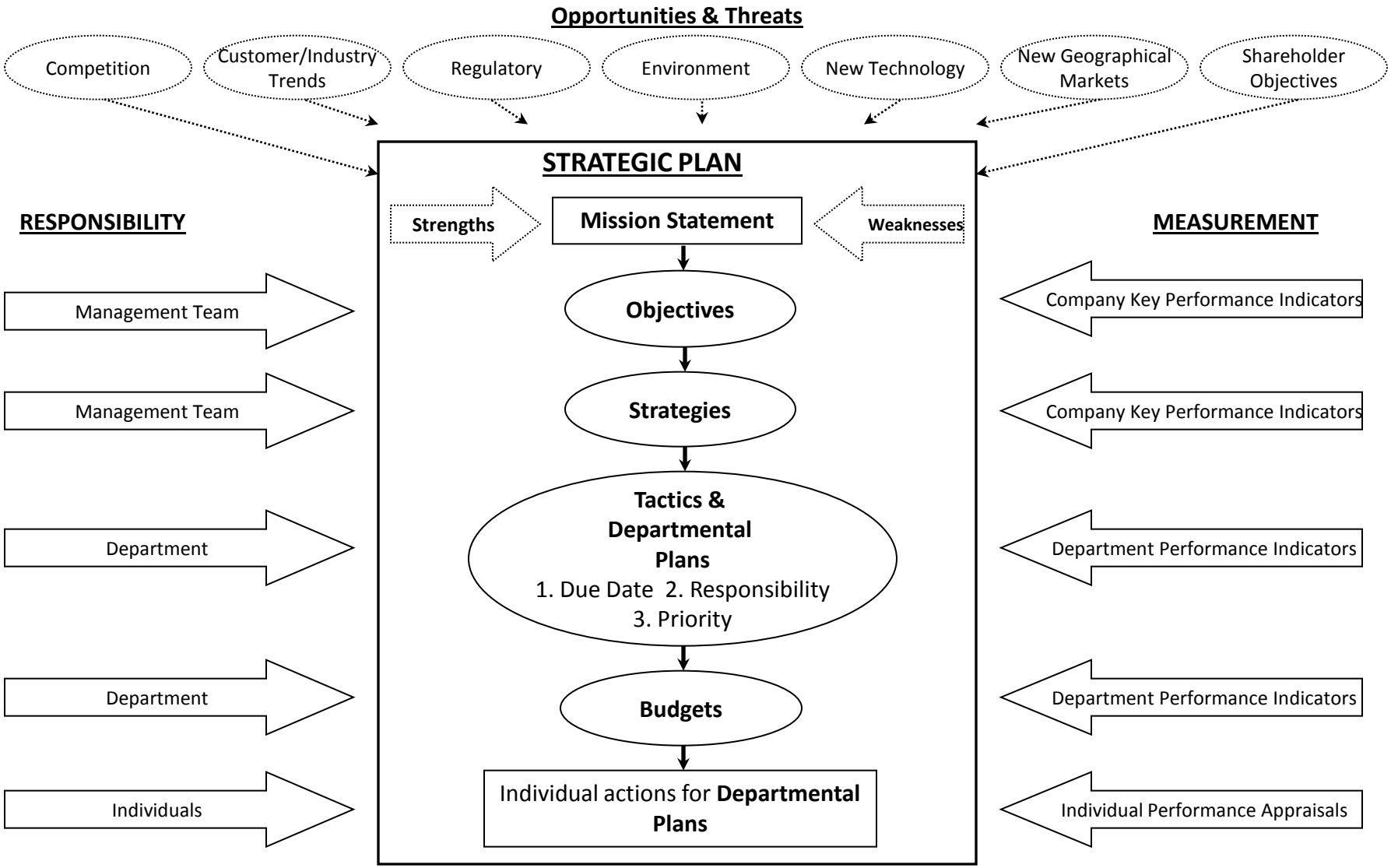
QMS Representative

- No longer a requirement to have one
- ISO 9001:2015, Clause 5.3 - Organizational roles, responsibilities and authorities
- The organization gets to distribute QMS responsibilities, deciding who does what *(from Clause 5.3 "Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization…")*
- If Top Management is truly committed to "Quality" then no real impact
- In many organizations, the QMS Representative, along with Internal Audits, are two key mechanisms for ensuring that the QMS doesn't fade away or erode over time… so be careful about eliminating this role
- Another approach is to rotate this role every 2 years to a different member of Top Management each time
- ISG's Newsletter Issue #5 provides further information on this topic

RBT / Risks and Opportunities

- RBT = Risk-based Thinking
- ISO 9001:2015, Clause 6.1 - Actions to address risks and opportunities; also 0.3.3 (Risk-based Thinking); plus Annex A.4 (Risk-based Thinking)
- *From ISO 9000:2015, 3.7.9 - Risk: effect of uncertainty; Note 1 to entry: An effect is a deviation from the expected - positive or negative.*
- Most view "risk" as a negative consequence
- Somewhat confusing - Clause 0.3.3 and Annex A.4 both have the same title but the former mentions "risks and opportunities" but the latter only deals with "risks" and not once is "opportunities" mentioned
- *From Annex A.4 - …Although 6.1 specifies that the organization shall plan actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process …Under the requirements of 6.1, the organization is responsible for its application of risk-based thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence of its determination of risks*
- *Also from Annex A.4 - …The concept of risk-based thinking has been implicit in previous editions of this International Standard …One of the key purposes of a quality management system is to act as a preventive tool. Consequently, this International Standard does not have a separate clause or subclause on preventive action.*
- All of the above implies lots of ways to comply: If you do formal strategic (or business) planning, then refer to it; OR If you only do SWOT Analysis then just add a resulting action plan to it; OR Address all these RBT requirements in a separate QMS Procedure that Top Management follows each year; OR Handle it in a new section of your Quality Manual
- ISG's Newsletter Issue #3 provides further information on this topic

Strategic Planning / Business Planning



SWOT Analysis / SWOT Matrix

SWOT MATRIX (DEC/2014)	**TOP STRENGTHS (internal)** ▪ Operations personnel very technically skilled ▪ Majority of sales are repeat orders ▪ Strong/stable purchasing process ▪ … ▪ …	**TOP WEAKNESSES (internal)** ▪ New Customer Accounts less than 5% ▪ Long lead times for existing prods/srvcs ▪ Lengthy development cycle for new offerings ▪ Overdue for software/hardware upgrades ▪ Employee morale is at a low
TOP OPPORTUNITIES (external) ▪ New geographies opening up ▪ Marketplace asking for tech help ▪ Possible exclusivity w/ Suppliers ▪ Trend towards using accredited companies ▪ Customers want faster delivery	**S – O Strategies (offensive):** (Capitalize on an opportunity that is available today) **Strategy #1**: Establish a "tech" helpline using experienced Operations staff **Strategy #8**: Obtain industry recognized accreditation in primary market	**W – O Strategies (offensive):** (Overcome a weakness in order to pursue an opportunity) **Strategy #2:** Identify most promising new territory and re-assign 1 salesperson to it **Strategy #5:** Implement Lean tools/ methods to streamline existing product cycle times
TOP THREATS (external) ▪ Customers see us as old/stale ▪ Competitors pricing aggressively ▪ Not a player in new geographies ▪ Customers want latest technology ▪ Suppliers raising costs	**S – T Strategies (defensive):** (Enhance and strengthen a competitive advantage) **Strategy #3:** Develop long-term contracts with top 2 Suppliers **Strategy #7:** Use experienced Operations staff to reach out to long-term Customers and identify new products/services wanted	**W – T Strategies (defensive):** (Develop a defensive plan to prevent a weakness from becoming more susceptible to an external threat) **Strategy #4:** Develop a 3 yr technology upgrade plan and begin Phase 1 this year **Strategy #6:** From existing hopper, select 1 new product and 1 new service and launch by the end of the year

Quality & Quality Objectives

- ISO 9001:2015, Clause 6.2 - Quality objectives and planning to achieve them
- *From ISO 9000:2015, 3.7.2 - **Quality Objective**: objective related to quality; 3.6.2 - **Quality**: degree to which a set of inherent characteristics of an object fulfils requirements; 3.6.1 - **Object, Entity, Item**: anything perceivable or conceivable, Examples – product, service, process, person, organization, system, resource… Note 1 to entry: Objects can be material (e.g. an engine, a sheet of paper, a diamond), non-material (e.g. conversion ratio, a project plan) or imagined (e.g. the future state of the organization).*
- **Quality Objectives flow from your Quality Policy!**… in order to achieve the Quality Policy you need to set specific quality objectives each year to get there
- Some alternative definitions for Quality…
- **Quality:** the standard of something as measured against other things of a similar kind; the degree of excellence of something…
- **Quality:** The word "Quality" represents the properties of products and/or services that are valued by the consumer…
- **Quality:** Quality starts from when the Customer says they want something until the organization satisfactorily provides it (and includes every step in between)…
- **Quality:** The degree to which something meets or exceeds the expectations of its consumers…
- **How do you define "Quality"?**

Thank you!

Still have questions?…

Contact me at trenaud@isosupport.com

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… in USA call: 262-872-0707

Interested in reading a science fiction thriller on how to combine ISO 9001 with Lean manufacturing?...

“Lean 9001”, Co-Authors: John Guderian and Tim Renaud

Go to www.sme.org or www.amazon.com