



Washington, DC and Maryland Metro Section 509 ISO 9000 Users Group

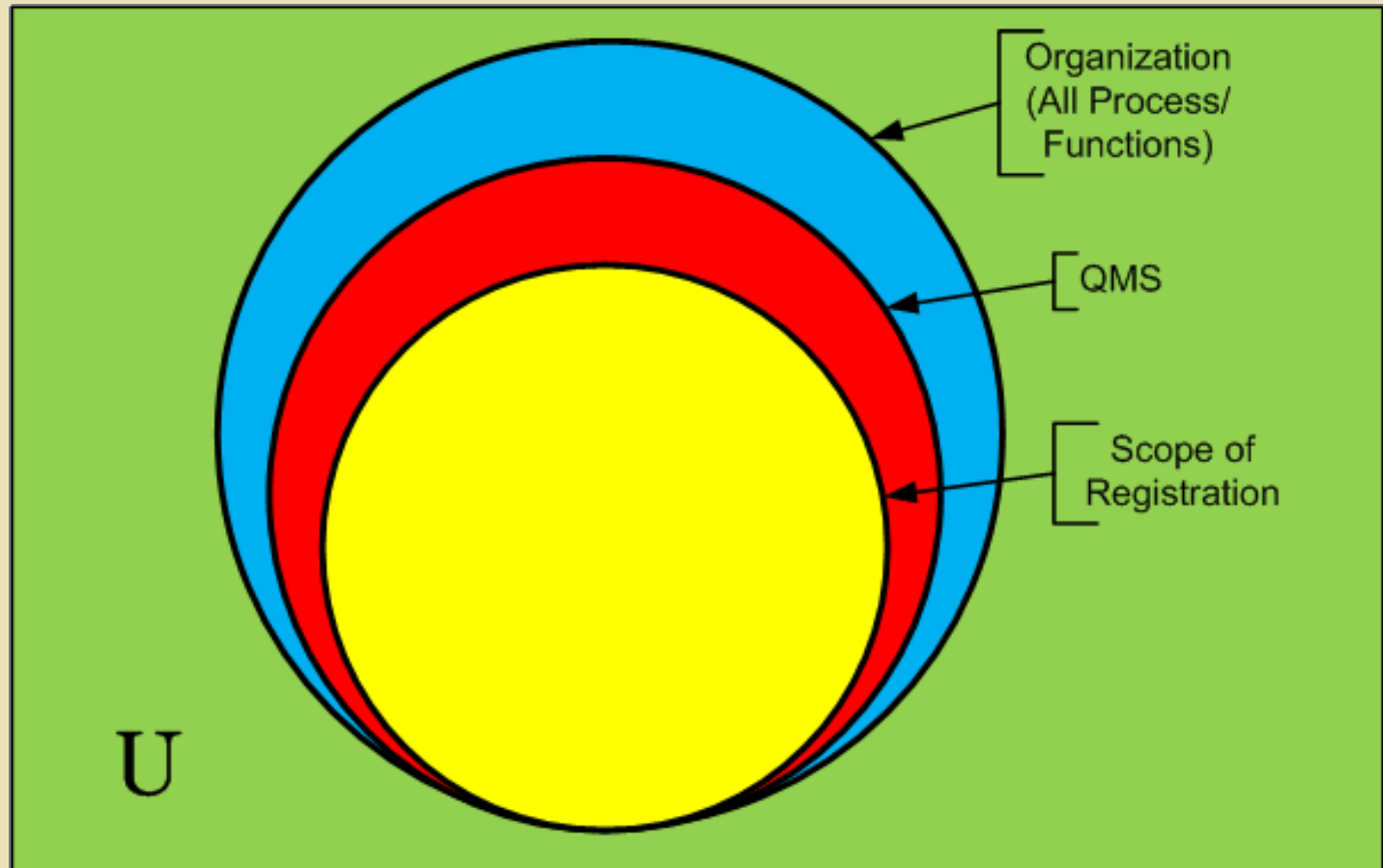
Holistic QMS Based on ISO 9001

April 18, 2012

Speaker: **Alan L. Lane**

Holistic QMS Based on ISO 9001 - In a Nut Shell

Defining the QMS. What is in? What is out?





Holistic QMS Based on ISO 9001

What Top Management says...

Our ISO9001-based QMS is how we do business

The reality...

The QMS is established for developing products to satisfy our customers. Parts of the organization that are perceived as not “contributing” to this purpose are often excluded from the QMS and scope of registration. External auditors and consultants often reinforce this belief.

The result...

- Lack of a “one-company” brand or image
- Inconsistencies in business operations and documentation
- Confused workforce and other stakeholders. What is expected?
- Inefficient processes and interfaces
- Fire-fighting or crisis management (reactive vs. proactive)

Question? Should the QMS include more business activities than just developing products to satisfy our customers?



Questions being asked by Quality Professionals

From LinkedIn ISO9000 Group:

Q: As part of 9001 implementation, I could align HR, IT, Quality & Delivery and Admin-facilities to its different clauses, however not sure which clause of 9001 support or addresses finance. Please help.

A: Several diverse “answers” provided by LinkedIn participants

From ASQ “Ask the Expert”

Q: During an external audit, what records are we allowed to keep confidential – e.g. human resources records? Certain records pertaining to new business leads or accounting matters? Specifically, my question is related to audits to the ISO 9001:2008 Quality management systems-Requirements and ISO 13485:2003 Medical devices-Quality management systems- Requirements for regulatory purposes standards.

A: “The “scope” of any audit is the quality management system (QMS) as found in the ISO standard for quality management. Areas such as finance, marketing plans, sales goals, and other business related topics are not part of a QMS audit...”

“...Again, the scope of the audit, usually agreed to ahead of time, is the QMS — not any business related matters.”



Common Business Functions

- Business Management
 - Strategic Planning
 - Goals/Objectives
 - Risk Management
 - Measurements/Metrics
- Business Development
 - Customer Relationship Mgt.
 - Marketing/Publications
 - Bid & Proposal
- Contract Management
- Program/Project/Task Mgt.
 - Planning
 - Executing
 - Delivery
 - Close-out
- Product Engineering
 - Systems Development
 - Software Development
 - Hardware Development
 - Material Analysis & Testing
 - Fabrication
 - Integration & Testing
- Configuration Management
- Information Management
 - Standards/Regulations Management
 - Document/Drawing Control
 - Records Control
 - Archival Management
 - Publications
- Shipping & Receiving
 - Handling
 - Packaging
 - Transportation



Common Business Functions (Cont.)

- Facility Management
 - Plant Engineering
 - Environmental/Contamination Control
 - Test & Measurement Equipment (Calibration)
 - Electrostatic Discharge Control
 - Limited Shelf-Life Materials
 - Capital Equipment Commissioning
 - Pressure Vessel Certification
- Operations
 - Field Support
 - Consulting
 - Production Control
 - Logistics Support
 - Administrative Support
- Quality Assurance
 - Auditing/Inspections
 - Nonconformance Control
 - Corrective/Preventive Action
 - Data Analysis/Metrics
 - Supply Chain Management
- HR Management
 - Recruiting
 - Training & Development
 - Internships
 - Benefits Management
 - Compensation
 - Reward & Recognition
 - Recreation Services

– Maintenance



Common Business Functions (Cont.)

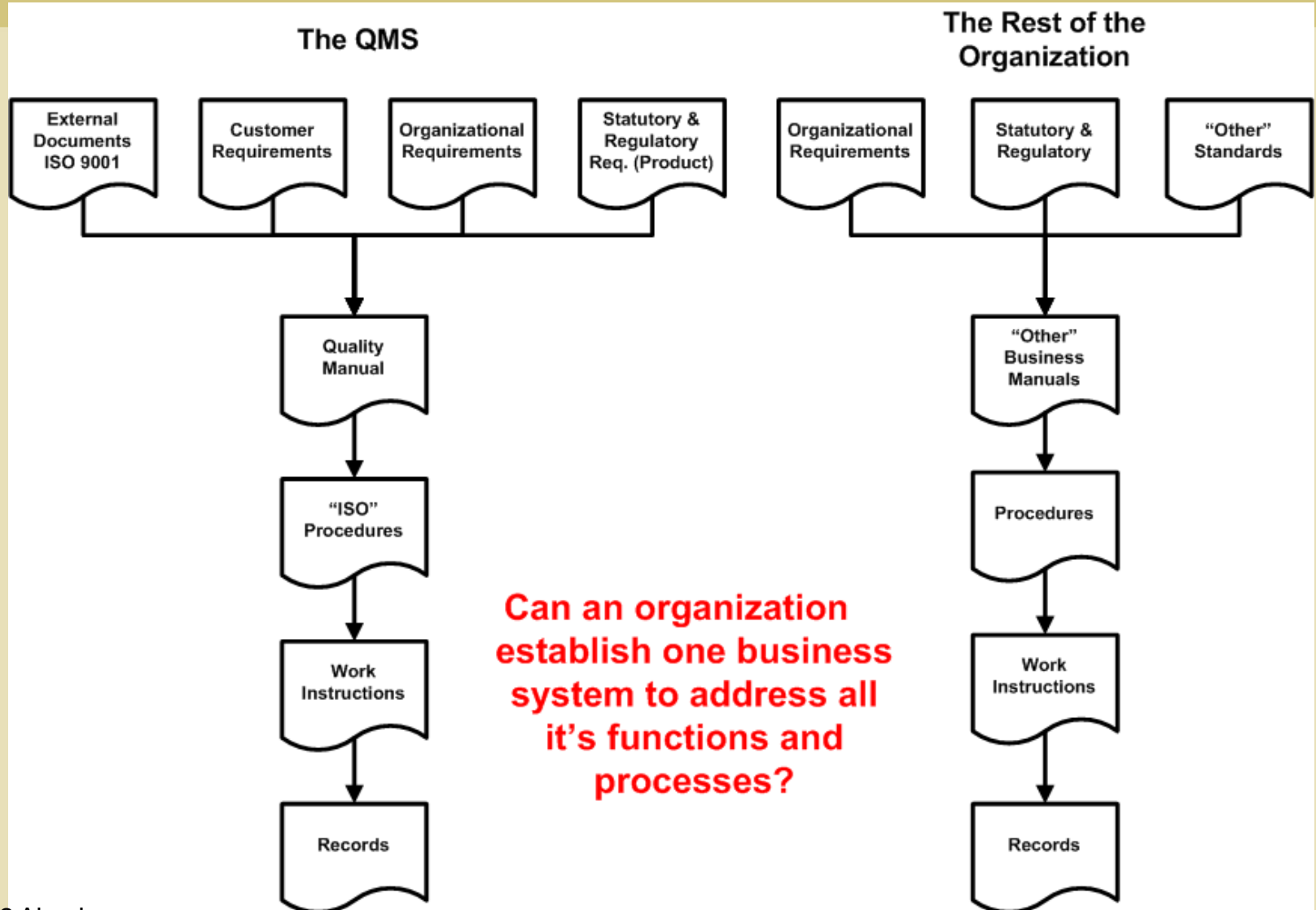
- Health, Environment & Safety
 - Bio-safety
 - Crane/Hoists Operations
 - Chemical Management
 - Hazard Communications
 - Energy Control
 - Laser Safety
 - Confined Spaces
 - Radiation Protection
- Security Management
 - Physical
 - Classified Information
- Procurement
 - Purchasing
 - Subcontracts
- Accounting & Financial Management
 - General Accounting
 - Planning/Budgeting
 - Billing/Accounts Receivable
 - Accounts Payable
 - Timekeeping
 - Payroll
 - Travel
- Asset Management
 - Customer Property
 - Company Property
 - Leased Property
 - Proprietary Information
 - Inventory/Stockroom Control
 - Surplus



Common Business Functions (Cont.)

- Information Technology
 - Computer Builds & Upgrades
 - Network/Server Maintenance
 - Application Development & Maintenance
 - Help Desk Services
 - Information Security
- Legal

Documentation Hierarchy





Why do we “create” a separate system?

- Definition of a “Quality Management System?”
 - Interpretation of Standard (See examples)
 - Emphasis is on “Product-related” activities and not “business-related”
 - Focus on external customer requirements/satisfaction only
- Other parts of organization are governed by other requirements or regulations (OSHA, EEO, ADA, NISPOM, GAP, FAR, etc.)
- ISO 9001 is not a regulatory requirement
- Keeps QMS auditors away from “business-related” activities
- Culture-related causes – Facilitates “silos.”



Interpretation of the ISO 9001 Standard

Interpretation of the ISO 9001 Standard - QMS Implementation is often focused on ISO 9001's "conformity to product requirements" and not the support functions of the organization. Examples of ISO clauses for discussion:

- "0.2 Process Approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements."

- "1.1 General

This International Standard specifies requirements for a quality management system where an organization

- a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and
- b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

NOTE 1 In this International Standard, the term "product" only applies to

- a) product intended for, or required by, a customer,

- b) any intended output resulting from the product realization processes."

Interpretation of the ISO 9001 Standard (Cont.)

- “4.1 General Requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

- a) determine the processes needed for the quality management system and their application throughout the organization (see 1.2),
- b) determine the sequence and interaction of these processes,
- c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitor, measure where applicable, and analyse these processes, and
- f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard...”

Interpretation of the ISO 9001 Standard (Cont.)

- “4.2.4 Control of Records

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.”

- “5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives...”

- “6.2.1 General

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

NOTE Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.”

Interpretation of the ISO 9001 Standard (Cont.)

- “7.5.4 Customer Property

The organization shall exercise care with customer property while it is under the organization’s control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4).

NOTE Customer property can include intellectual property and personal data.”



Does the term “Quality” confuse matters?

- Management System vs. Quality Management System
- Business Objectives vs. Quality Objectives
- Business Policies vs. Quality policy
- “ISO” Procedures vs. Organizational procedures for doing business
- Quality Manual vs. Operations Manual, Hardware Manual, Maintenance Manual, HR Manual, Safety Manual, Security Manual, Procurement Manual, etc.
- Control of Records (ISO 9001-2000/8) vs. Control of Quality Records (ISO 9001-1994)
- Internal Audits vs. Internal Quality Audits



8 “Quality” Management Principles

- **Customer focus** - Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.
- **Leadership** - Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.
- **Involvement of people** - People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.
- **Process approach** - A desired result is achieved more efficiently when activities and related resources are managed as a process.
- **System approach to management** - Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.
- **Continual improvement** - Continual improvement of the organization's overall performance should be a permanent objective of the organization.
- **Factual approach to decision making** - Effective decisions are based on the analysis of data and information.
- **Mutually beneficial supplier relationships** - An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

These eight quality management principles form the basis for the quality management system standards within the ISO 9000 family.

Are these principles relevant for all parts of the organization?

Solutions?

ISO 9004 *Managing for the sustained success of an organization*
– *A quality management approach*

- Based on 8 principles
- Efficient use of resources
- Decision making based on factual evidence, and
- Focus on customer satisfaction and needs and expectations of other relevant interested parties
- Clause 4.4 Interested Parties, needs and expectations
Are individuals and other entities that add value to the organization, or are otherwise interested in, or affected by, the activities of the organization. Meeting the needs and expectations of interested parties contributes to the achievement of sustained success by the organization.

ISO 9004 attempts to take a broader approach to quality management





Thanks for Participating!

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References

- ISO 9000-2005, *Quality management systems – Fundamentals and vocabulary*
- ISO 9001-2008, *Quality management systems – Requirements*
- ISO 9004-2009, *Managing for the sustained success of an organization – A quality management approach*