

Executive Overview

Transitioning to ISO 9001:2015 Quality Management System

Biafore Associates Inc.

Overview Objectives

The overview objectives are as follows:

- General QMS / ISO 9001:2015 Useful Terms
- General: Why a need for Quality Management System?
- ISO Supporting Standards
- Process Approach – QMS Systems Map
- Plan-Do-Check (Study)-Act
- Seven Quality Management Principles
- Management System Standards (MSS) / High Level Structure (HLS) / Annex SL
- Risk Management
- ISO 9001:2008 to ISO9001:2015 Transition Review
- Understanding the Organization and it's Context
- Understanding the Needs & Expectations of Interested Parties
- Risk Management
- Transition to the new Standard

ISO 9001:2015 Management System Useful Terms

- Stakeholder
- Context of the Organization
- Interested Party
- Risk
- Risk Management
- Top Management
- Policy
- Objective
- Documented Information
- Process
- Performance
- Outsource (verb)
- Monitoring

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ISO Portfolio of Standards

- ISO Portfolio of Standards (ISO 9000, ISO 9004, ISO 9001)
 - ISO 9001:
 - The “Requirements” Standard
 - This is the standard an organization is 3rd party registered to
 - ISO 9004:
 - The “Best Practice Standard”
 - Supports ISO 9001 Requirements standard
 - Provides guidance for organizations that choose to progress beyond the requirements of the ISO 9001 Standard
 - ISO 9000:
 - Fundamentals and Vocabulary
 - Supports ISO 9001 Requirements standard
 - Provides an essential background for the proper understanding and implementation of the International Standard

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ISO Support Standards

- ISO Support Standards (ISO 19011 and ISO 31000, ISO 10000 Series)
 - ISO 19011:
 - The “Auditing” Standard
 - Supports ISO 9001 Requirements standard
 - Provides guidance and best practices on internal and external audits of Management Systems
 - ISO 31000:
 - The “Risk Management” Standard
 - Supports ISO 9001 Requirements standard
 - Provides guidance for organizations related to Risk Management methods including: identification, analysis, evaluation and mitigation
 - ISO 10000 series of Standards are Referenced for additional support in the implementation of ISO 9001
 - ISO 10001/2/3/5/6/7/8/12/13/14/15/17/18/19
 - See **ISO 9001:2015** for descriptions of each standard.

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Why a need for Quality Management System?

- A robust quality management system can help an organization
 - Prevent identified risks from occurring
 - improve its overall performance
- The requirements of the International Standard are
 - generic but the ways in which they are applied can differ from one organization to another.
 - are complementary to requirements for products and services
- The intent of the ISO 9001 is not to:
 - imply the need for uniformity in the structure of different quality management systems,
 - Define uniformity of documentation to align to the clause structure of the International Standard,
 - impose specific terminology to be used within the organization.

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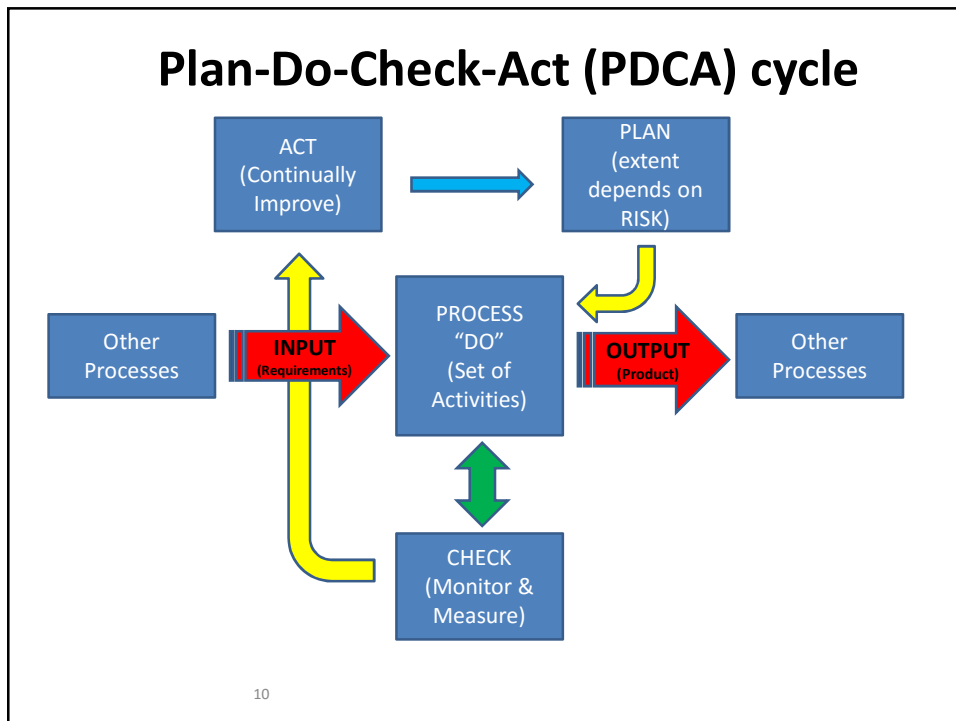
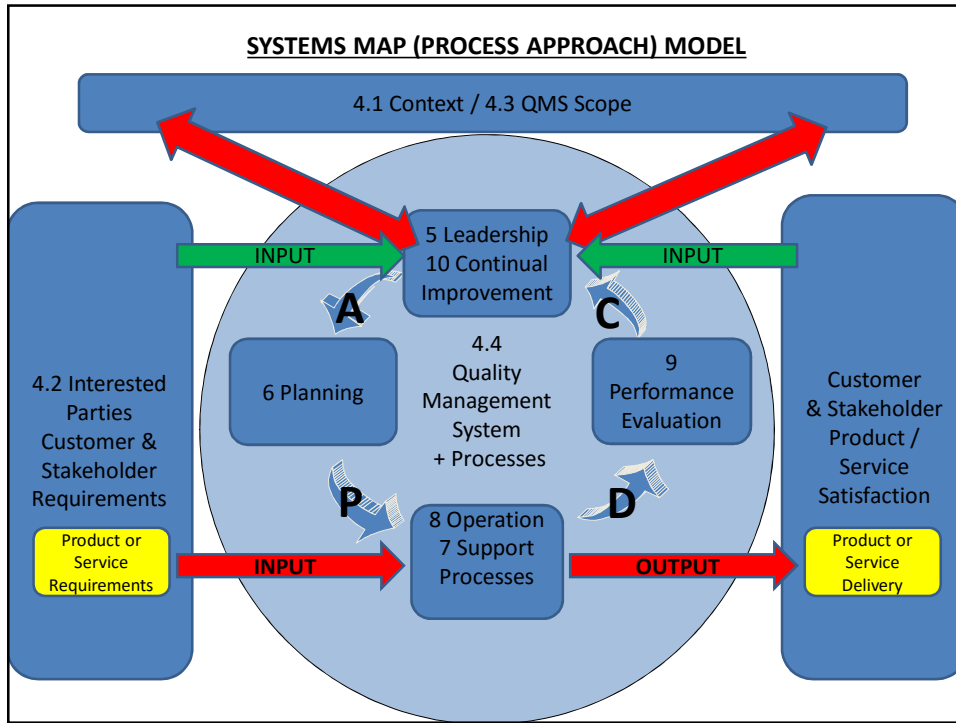
Why a need for Quality Management System?

- Along with the Organization’s context the QMS design will be influenced with respect to:
 - a) its specific objectives;
 - b) the risks associated with its context and objectives;
 - c) the needs and expectations of its customers and other relevant interested parties;
 - d) the products and services it provides;
 - e) the complexity of processes it employs and their interactions;
 - f) the competence of persons within or working on behalf of the organization;
 - g) its size and organizational structure.

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Major changes in Terminology

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Exclusions	Not used (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)
Management representative	Not used (Similar responsibilities and authorities are assigned but no requirement for a single management representative)
Documentation, quality manual, documented procedures, records	Documented information
Work environment	Environment for the operation of processes
Monitoring and measuring equipment	Monitoring and measuring resources
Purchased product	Externally provided products and services
Supplier	External provider



Quality Management Principles

Current (2008) ISO 9K QMPs	New 2015 ISO9K QMPs
1. Customer Focused	1. Customer Focused
2. Leadership	2. Leadership
3. Involvement of People	3. Engagement and Competence of People
4. Process Approach	4. Process Approach (Managing Processes as a System is Implied)
5. Systems Approach	5. Improvement
6. Continual Improvement	6. Informed Decision Making
7. Fact Based Decision Making	7. Relationship Management (as defined in Context of Organization)
8. Mutually Beneficial Supplier Relationships	*Changes in Red

2015 ISO 9001 Standard Transition

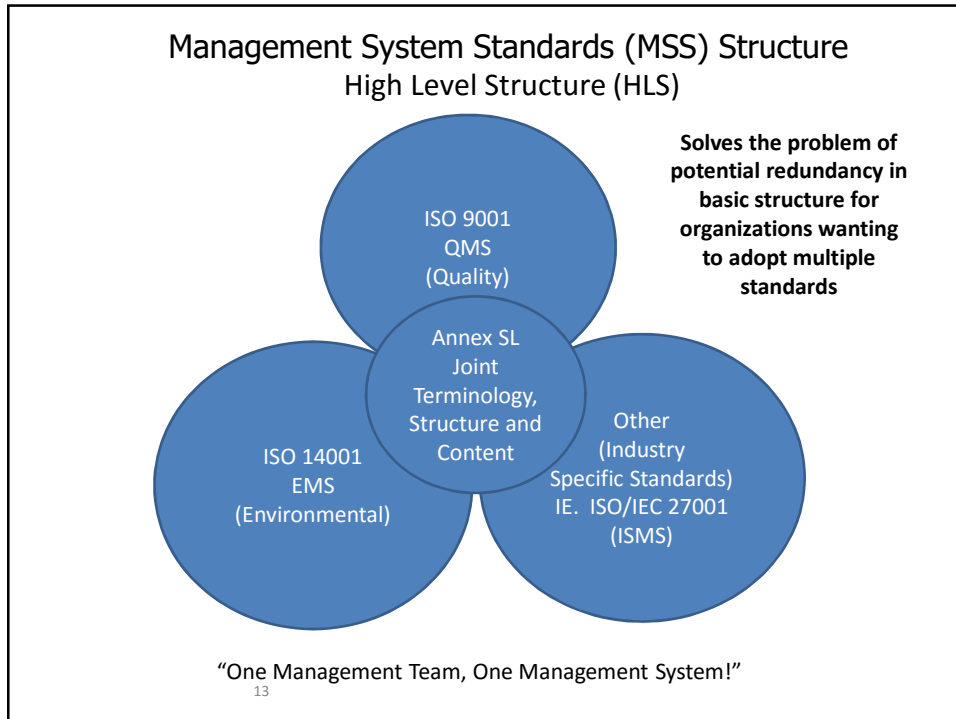
9001:2008 - 5 ISO Clauses

- 1.0 Scope**
- 2.0 Normative Reference**
- 3.0 Terms and Definitions**
- 4.0 Quality Management System**
- 5.0 Management Responsibility**
- 6.0 Resource Management**
- 7.0 Product Realization**
- 8.0 Measurement, Analysis and Improvement**

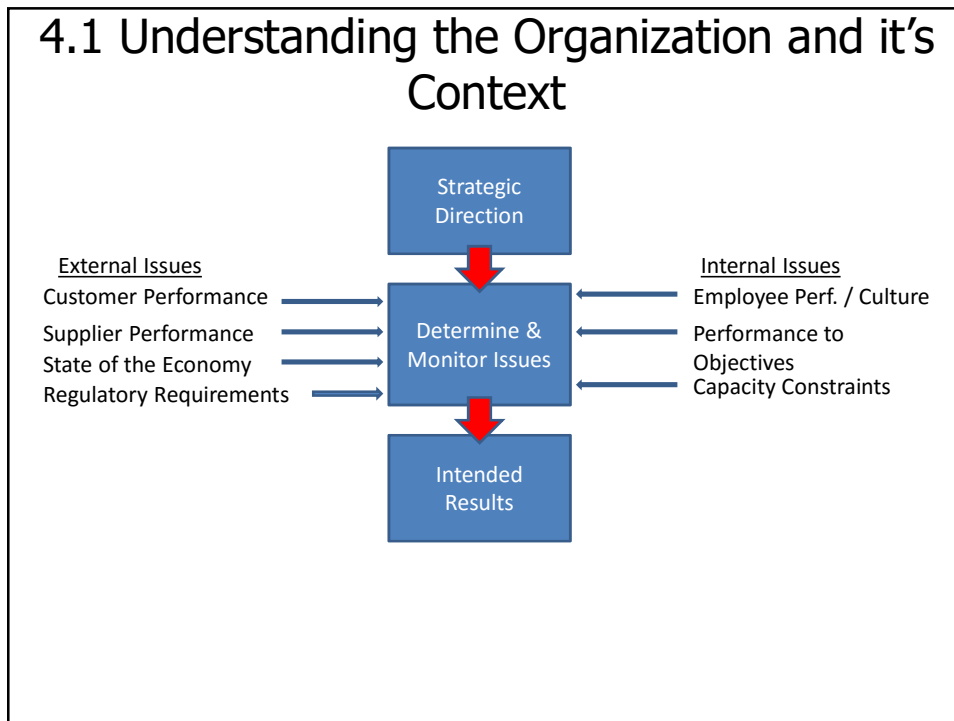
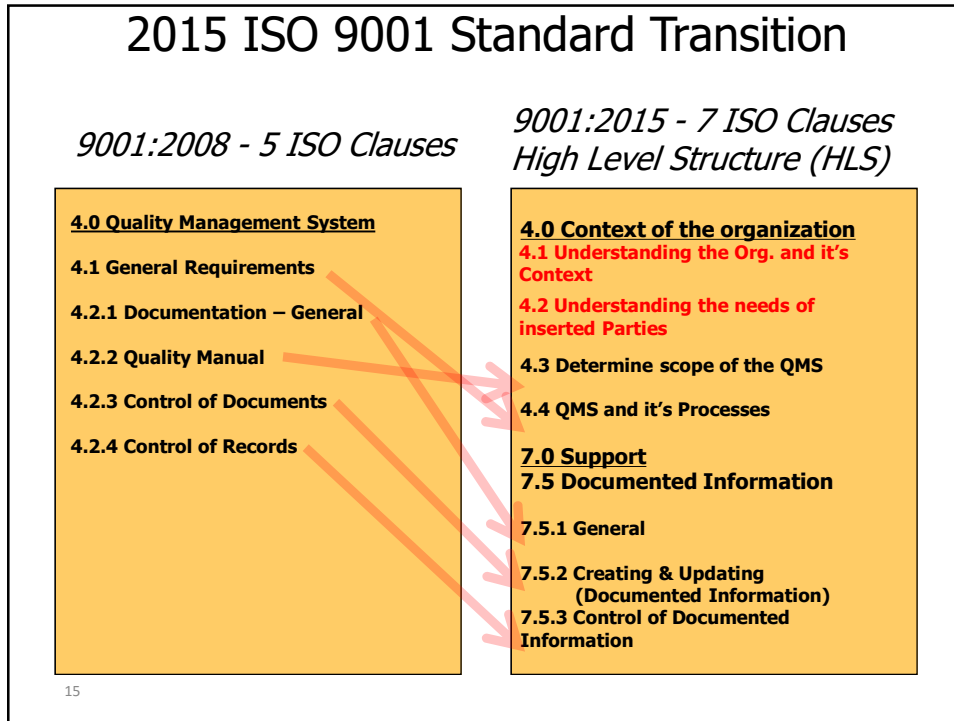
9001:2015 - 7 ISO Clauses High Level Structure (HLS)

- 1.0 Scope**
- 2.0 Normative Reference**
- 3.0 Terms and Definitions**
- 4.0 Context of the organization**
- 5.0 Leadership**
- 6.0 Planning**
- 7.0 Support**
- 8.0 Operation**
- 9.0 Performance evaluation**
- 10.0 Improvement**

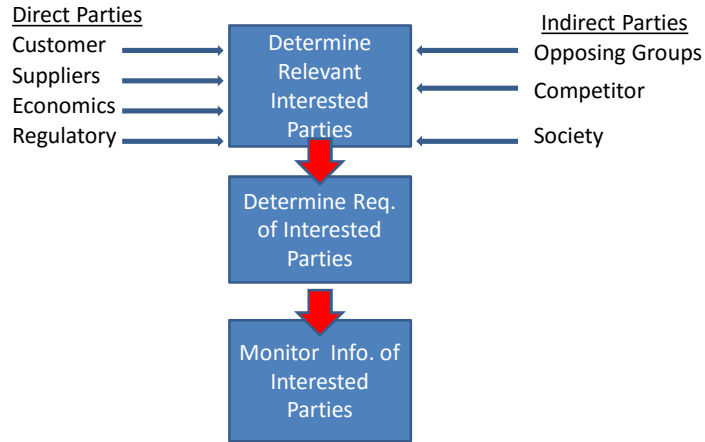
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- Management System Standards (MSS) Structure
High Level Structure (HLS)**
- **MSS’s adopting Annex SL (as of 2015):**
 - ISO/IEC 27001 Info. Security Man. Systems
 - ISO 22301 Business Continuity
 - ISO 30301 Info. & Documentation
 - ISO 20121: Event Sustainability
 - ISO 39001 Road Traffic Safety / ISO 55001 Asset Management
 - **Next In-line (as of 3rd QTR 2015):**
 - ISO 9001 Quality Management
 - ISO 14001 Environmental Management
 - ISO 13485 Medical Device
 - **Under Review (expected in 2016):**
 - ISO/TS 16949 Automotive
 - AS 9100/10/20 Aerospace
 - OHSAS 18001 Safety (or new ISO 45001)
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4.2 Understanding the Needs & Expectations of Interested Parties



2015 ISO 9001 Standard Transition

9001:2008 - 5 ISO Clauses

*9001:2015 - 7 ISO Clauses
High Level Structure (HLS)*



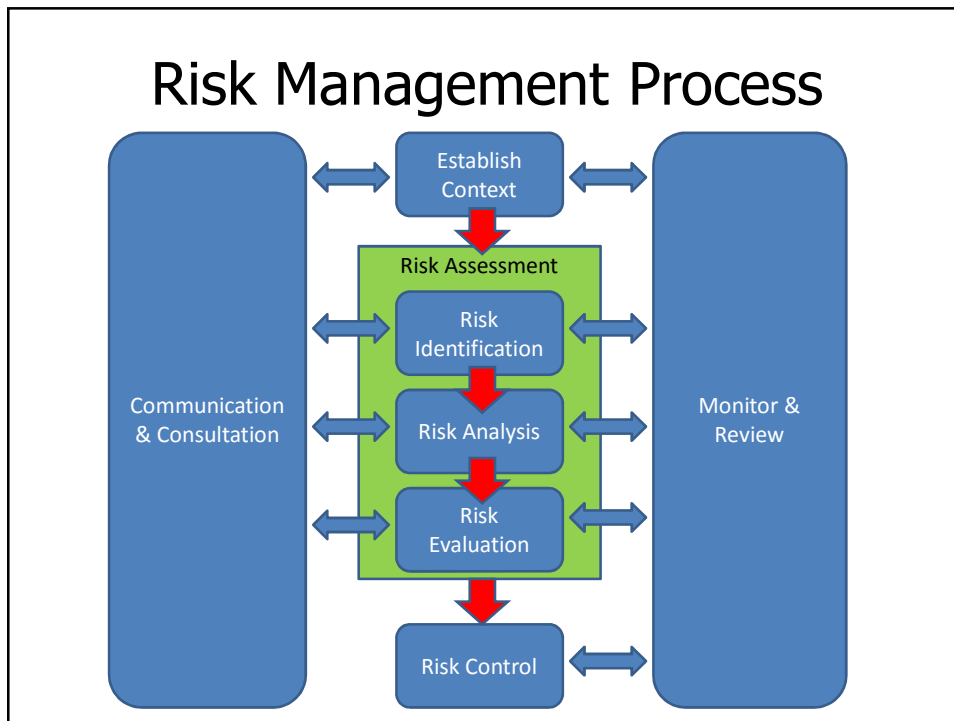
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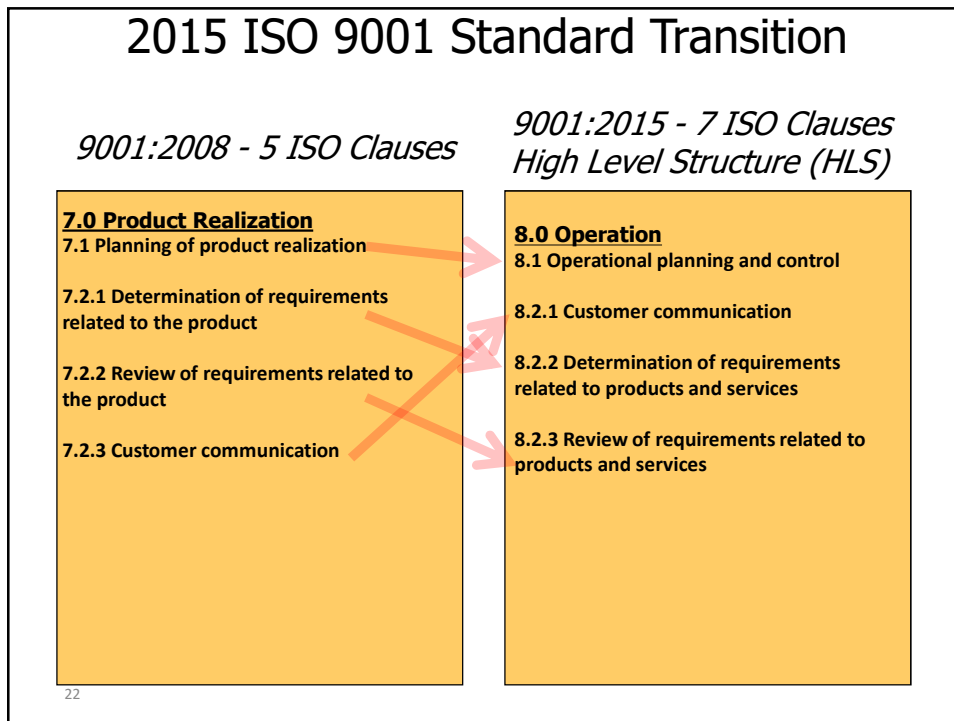
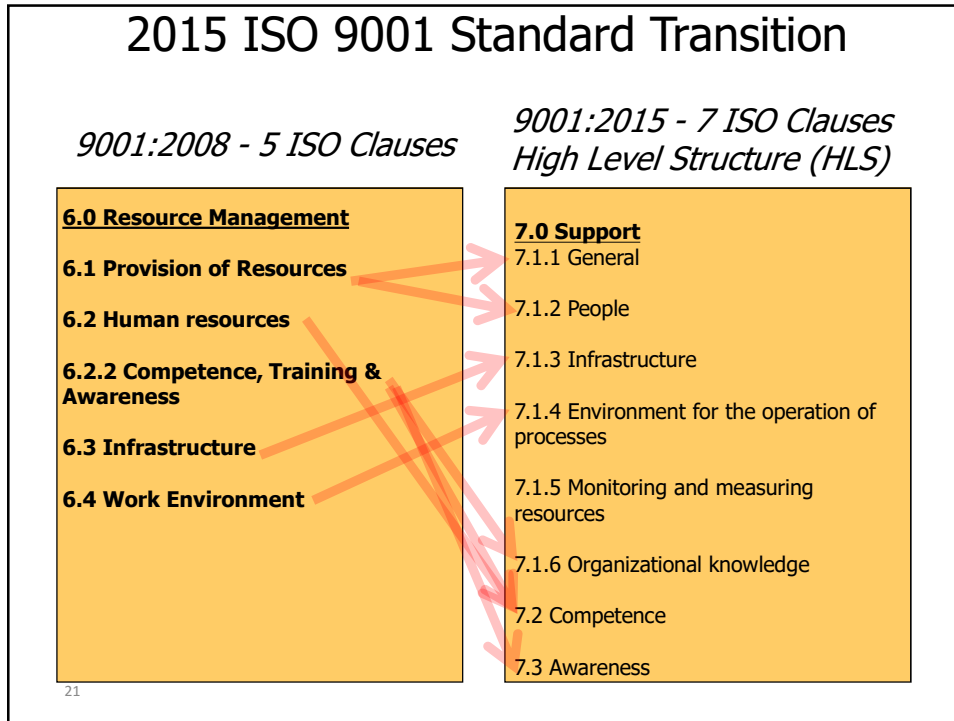
Risk Management

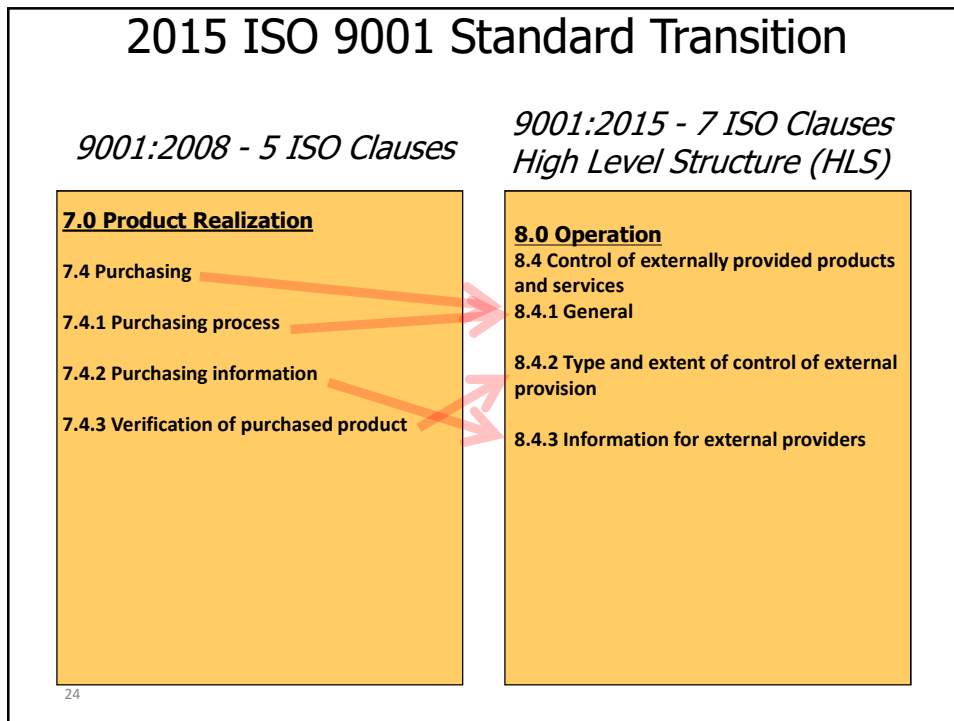
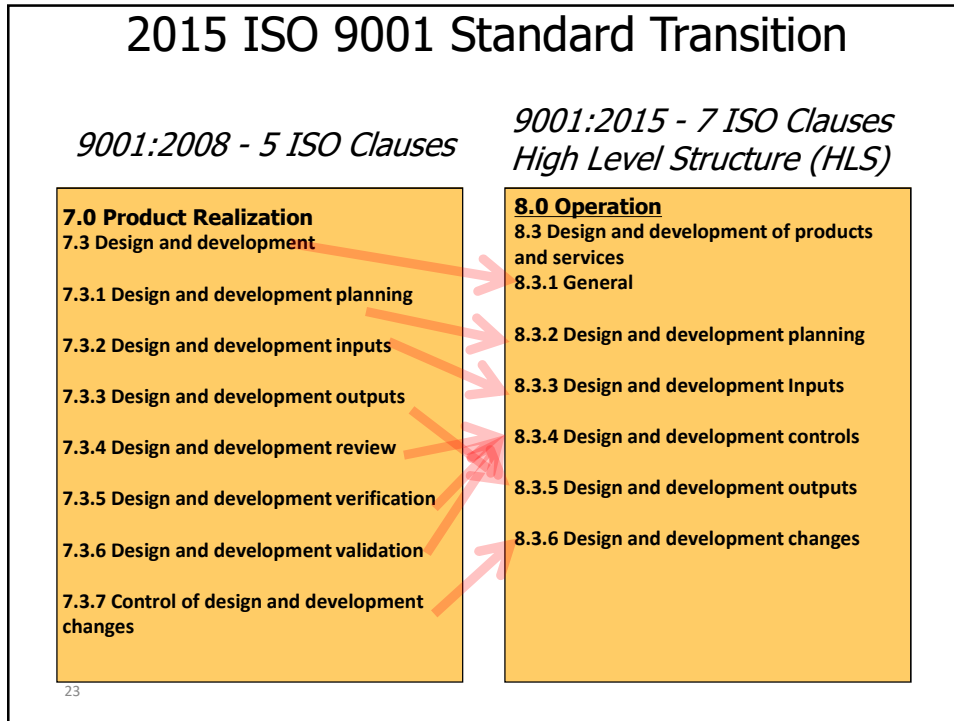
Useful Terms – (ref. ISO 31000)

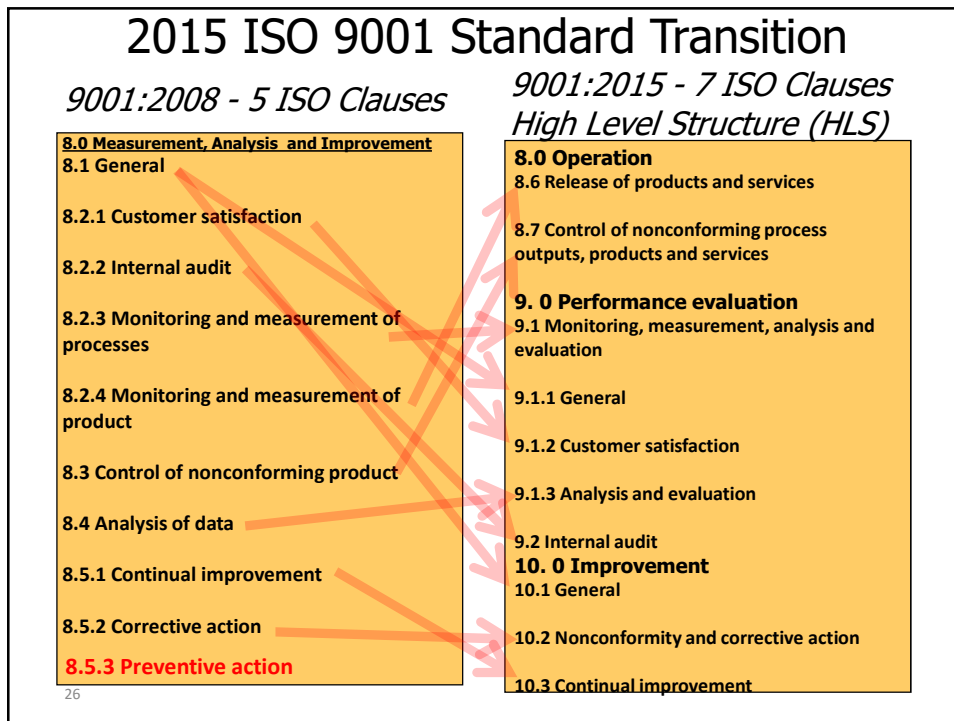
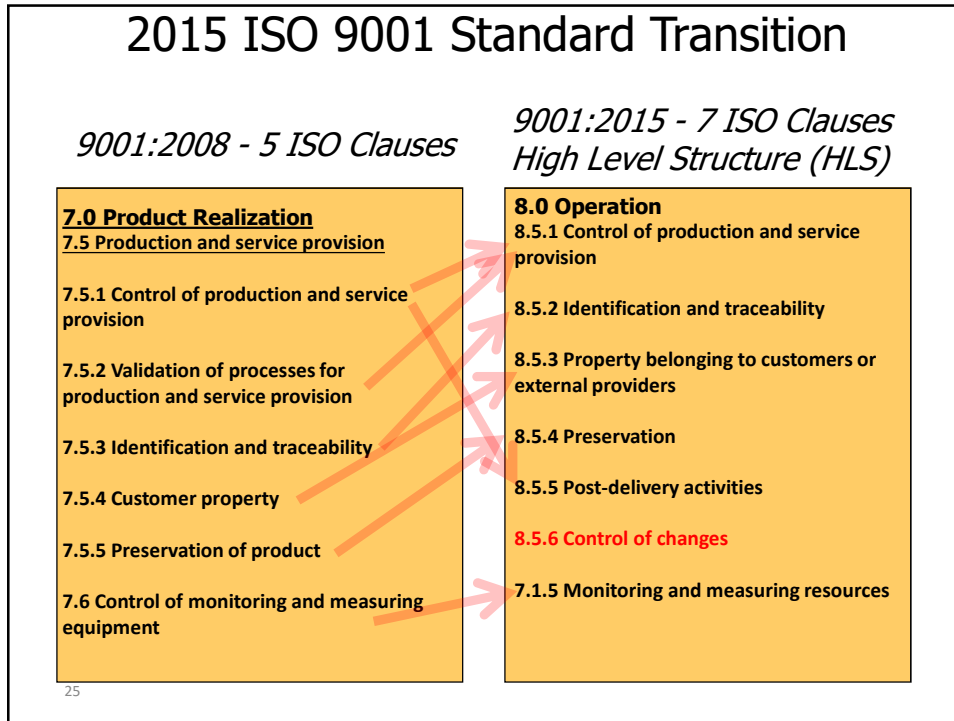
- Risk
- Risk Management
- Risk Management Framework
- Risk Management Process
- Risk Assessment
- Risk Analysis (*Quantitative / Qualitative*)
- Risk Evaluation
- Risk Criteria
- Likelihood
- Level of Risk
- Risk Control

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Transitioning to ISO 9001:2015

- Clients currently registered to ISO 9001:2015 will have a 3 year migration to the 2015 version from the date of the release of the new standard.
- **3rd Party Registrar's may have specific** policies on transitioning or new registrations to the new standard. They range as follows:
 - As soon as possible (adding .5 days for transition)
 - Next Re-registration audit (adding .5 days for transition)
 - new ISO 9001: 2008 certificates issued from now on must have an expiration date of **September 23, 2018**
 - new ISO 14001: 2004 certificates issued from now on must have an expiration date of **September 15, 2018**
 - last date we will be allowed to issue a **NEW** certificate for both ISO 9001: 2008 and ISO 14001: 2004, will be **September 15, 2017**
 - continue to allow clients to **RE-CERTIFY** to the older versions until **December 31, 2017**
 - Upgrades for ISO 9001: 2015 and ISO 14001: 2015 performed at **surveillance** will require a certification decision to be performed, but the new certificate will contain the **current expiration date of the current cycle**.
 - Upgrades for ISO 9001: 2015 and ISO 14001: 2015 performed at **re-certification** will require a certification decision to be performed, and they will begin a new 3-year certification cycle.
 - New Clients shall be registered to ISO 9001:2015
 - Refer to Registrar specific policies for direction.

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Session Overview

Review of learning objectives of the overview:

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Contact and Follow-up

Daniel Biafore
Biafore Associates Inc.
dbiafore@cogeco.ca
1-313-410-5938

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