IMPLEMENTING ISO 9001:2015 USING INTEGRATED MANAGEMENT SYSTEMS (IMS) AND ENTERPRISE WIDE QUALITY SOFTWARE

Chad Kymal

June 4th, 2015 Webinar Presented by Omnex

This webinar contains content from the book "Implementing Integrated Management Systems – QMS, EMS and OHSMS Including Aerospace, Automotive and Food Safety Management Systems" written by Chad Kymal, Gregory Gruska and R. Dan Reid.

OMNEX

DRIVING WORLDWIDE BUSINESS EXCELLENCE

Omnex Introduction

- International consulting, training and software development organization founded in 1985.
- Specialties:
  - Integrated management system solutions.
  - Elevating the performance of client organizations.
  - Consulting and training services in:
    - Quality Management Systems, e.g. ISO 9001, ISO/TS 16949, AS9100, QOS
    - Environmental Management Systems, e.g. ISO 14001
    - Health and Safety Management Systems, e.g. OHSAS 18001
- Leader in Lean, Six Sigma and other breakthrough systems and performance enhancement.
  - Provider of Lean Six Sigma services to Automotive Industry via AIAG alliance.

About Omnex

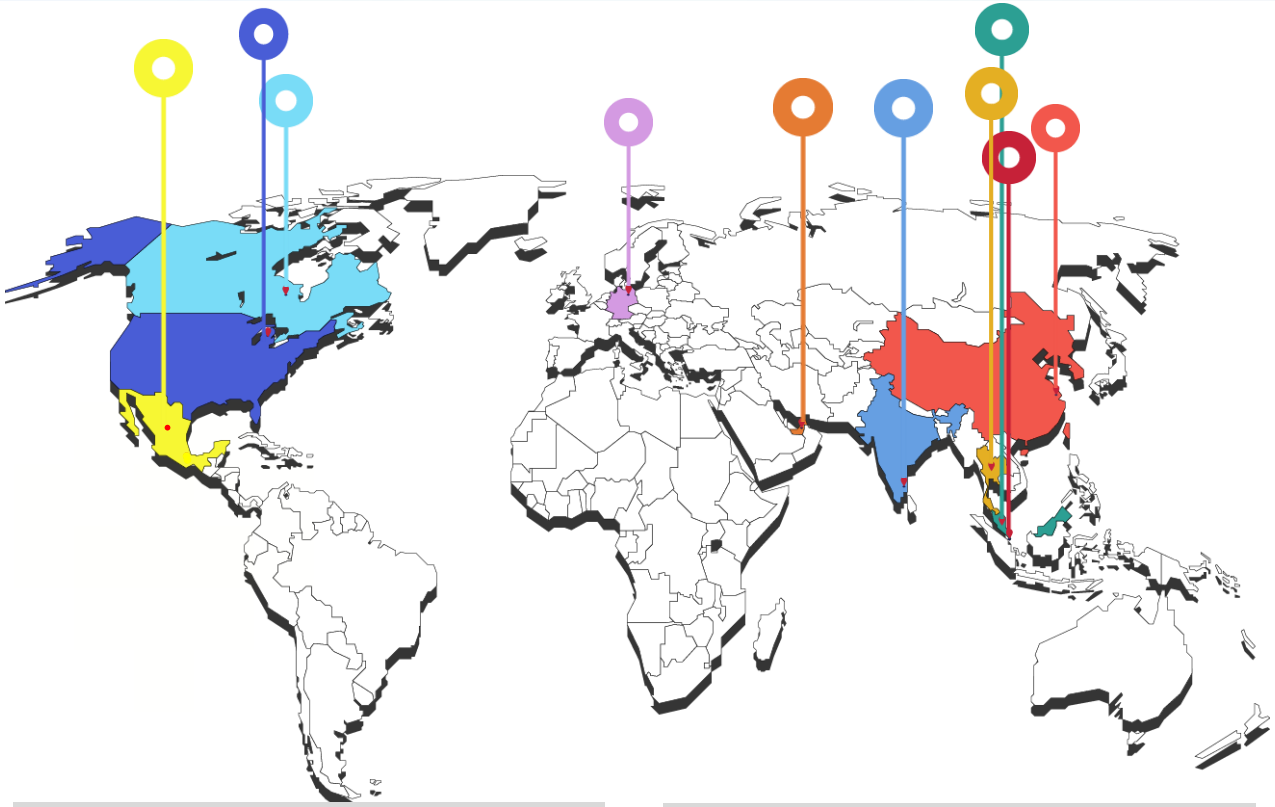
- Headquartered in Ann Arbor, Michigan with offices in major global markets.
- In 1995-97 provided global roll out supplier training and development for Ford Motor Company.
- Trained more than 100,000 individuals in over 30 countries.
- Workforce of over 400 professionals, speaking over a dozen languages.
- Former Delegation Leader of the International Automotive Task Force (IATF) responsible for ISO/TS16949.
- Served on committees that wrote QOS, ISO 9001:2000, QS-9000 and it's Semiconductor Supplement, ISO IWA 1 (ISO 9000 for healthcare).
- Member of AIAG manual writing committees for FMEA, SPC, MSA, Sub-tier Supplier Development, Error Proofing, and Effective Problem Solving (EPS).

Omnex Worldwide Offices

Omnex is headquartered and operates from the United States through offices in Michigan.

The company maintains international operations in many countries to provide comprehensive services to clients throughout Western Europe, Latin America and the Pacific Rim.

www.omnex.com
info@omnex.com



- **Omnex Global Head Quarters** (Michigan, USA)
  West Coast Operations (San Jose, CA)
- **Asia Pacific HQ** (Chennai, Pune, Delhi, Bangalore)
- **China** (Shanghai, Guangzhou, Wuhan, Chengdu)
- **Canada** (Mississauga)
- **Europe** (Berlin, Germany)
- **Middle East** (Dubai, Saudi Arabia, Bahrain)
- **Thailand** (Bangkok)
- **Mexico** (Guadalajara)
- **Singapore**
- **Malaysia** (Kuala Lumpur)

Who in the world is OMNEX?

Our global clients will tell you. We've implemented management systems for many of the world's top companies.

- Bell Helicopter
- Bosch
- BYD
- Chrysler
- Ford
- Fujitsu
- General Motors
- Henkel
- Magna
- Mazda
- Micron
- Nestlé
- Nvidia
- Pratt & Whitney
- Siemens
- Sony
- Suzalon
- Suzuki
- Texas Instruments
- Toyota
- TRW

ISO 9001 & ISO/TS 16949 : AS9100 : ISO 26262 : ISO 14001 : OHSAS 18001
ISO 50001 : FSSC 22000 : ISO 13485 : APQP : Risk Management : Lean Enterprise

OMNEX

Chad Kymal

- Chad Kymal is the CTO and founder of Omnex Inc., an international consulting and training organization headquartered in the United States. After graduating from the General Motors Institute, Chad spent a number of years working at General Motors and KPMG before founding Omnex Inc. in 1986. Over the course of Chad's successful career, he has served on the Malcolm Baldrige Board of Examiners and has received numerous quality achievement awards, including the Quality Professional of the Year award by the American Society for Quality (ASQ) Automotive Division in 2005. In addition to his bachelor's degree from GMI, Chad holds both a master's degree in industrial and operations engineering from the University of Michigan and an MBA from the University of Michigan.
- Chad both developed and teaches auditor training for ISO 9001, ISO 14001, and OHSAS 18001 / ISO 45001, as well as an Integrated Management Systems Lead Auditor training course where all three standards are combined in a single audit. Chad is the founder of AQSR, a global registrar that routinely provided integrated audits in QMS, EMS, and OHSMS.
- Chad is the author of five books and more than 100 papers including several on integrated management systems.

Webinar Agenda

- Key Changes in ISO 9001:2015
- Drivers of Integrated Management Systems
- Using Software for Integrated Management Systems
- Conclusion
- Questions and Answers?

KEY CHANGES IN ISO 9001:2015

Key Changes in ISO 9001

- **High Level Structure or HLS (Annex SL)**
- **Context, Interested Party Expectations, and Setting Objectives**
- **Risk-based Thinking**

} Focus of this Webinar

Other changes include:

- 4.3 Scope – removal of exclusions
- 5.1 Leadership and its Commitment – tying together quality policy and objectives with strategic direction and context of organization
- 6.1 Actions to Address Risks and Opportunities – running change and addition of risks in multiple locations
- 6.3 Planning of Changes and 8.5.6 Control of Changes
- 7.1.6 Organizational Knowledge
- 7.5 Documented Information
- 8.1 Operational Control – no statistical
- 8.3 Design and Development of Products and Services – removal of sub clauses Design Verification and Design Validation
- Removal of Preventive Action

And other changes….

OMNEX

Emergence of a High Level Structure

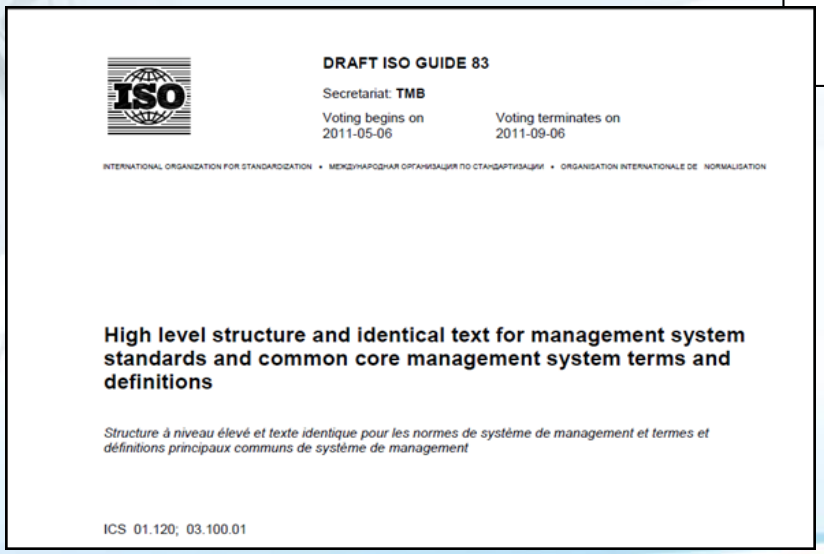
- ISO has long had high interest in developing an integrated management system standard.

De-proliferation mandate

ISO

ISO'S FURTHER INVOLVEMENT IN MANAGEMENT SYSTEM STANDARDS - A STRATEGY FOR THE FUTURE

Report of the ISO TMB Ad Hoc Group on Management Systems Standards
10 February, 2006



ISO

DRAFT ISO GUIDE 83

Secretariat: TMB

Voting begins on 2011-05-06 | Voting terminates on 2011-09-06

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

High level structure and identical text for management system standards and common core management system terms and definitions

Structure à niveau élevé et texte identique pour les normes de système de management et termes et définitions principaux communs de système de management

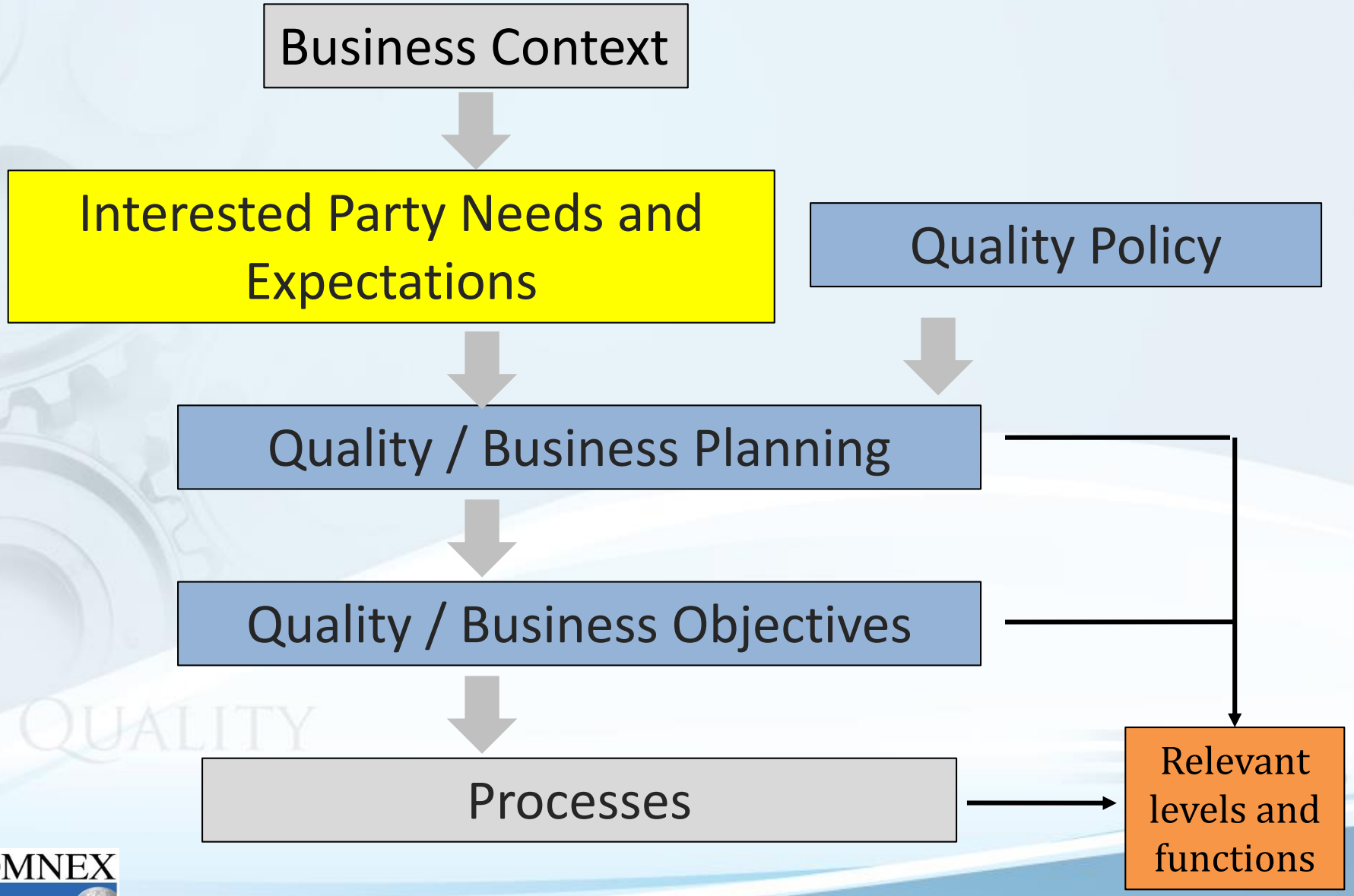
ICS 01.120; 03.100.01

Annex SL is the latest effort

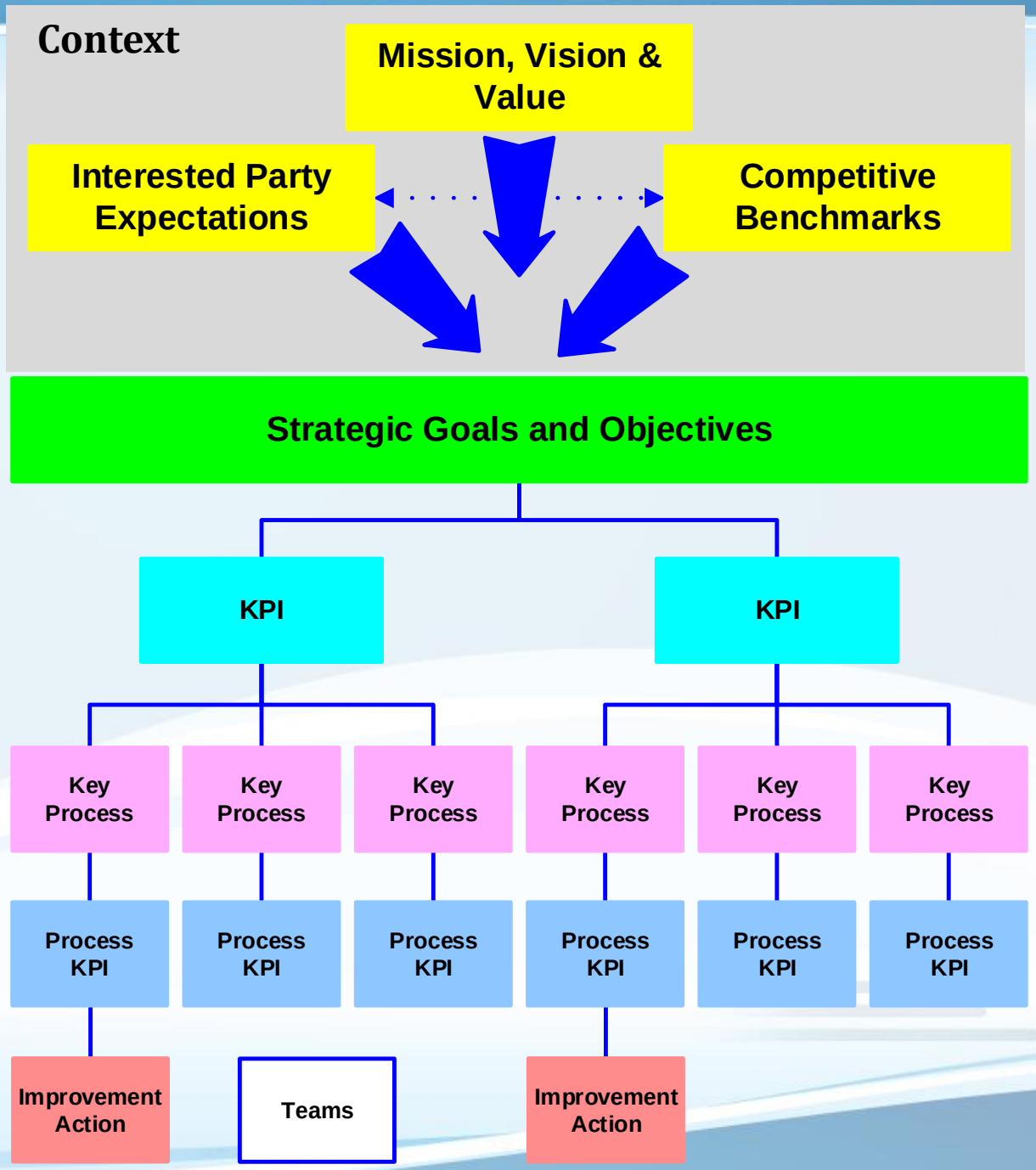
High Level Structure (HLS) is Changing New Clause Numbers

1. Scope
2. Normative References
3. Terms and Definitions
4. Context of the Organization
   - Understanding the Organization and its Context
   - Needs and Expectations
   - Scope
   - Management System
5. Leadership
   - Management Commitment
   - Policy
   - Roles, Responsibility and Authority
6. Planning
   - Actions to Address Risks and Opportunities
   - Objectives and Plans to Achieve Them
7. Support
   - Resources
   - Competence
   - Awareness
   - Communication
   - Documented Information
8. Operation
   - Operational Planning and Control
9. Performance Evaluation
   - Monitoring, Measurement, Analysis and Evaluation
   - Internal Audit
   - Management Review
10. Improvement
    - Nonconformity and Corrective Action
    - Continual Improvement

Align Expectations, Objectives and Processes



Business Operating System Alignment

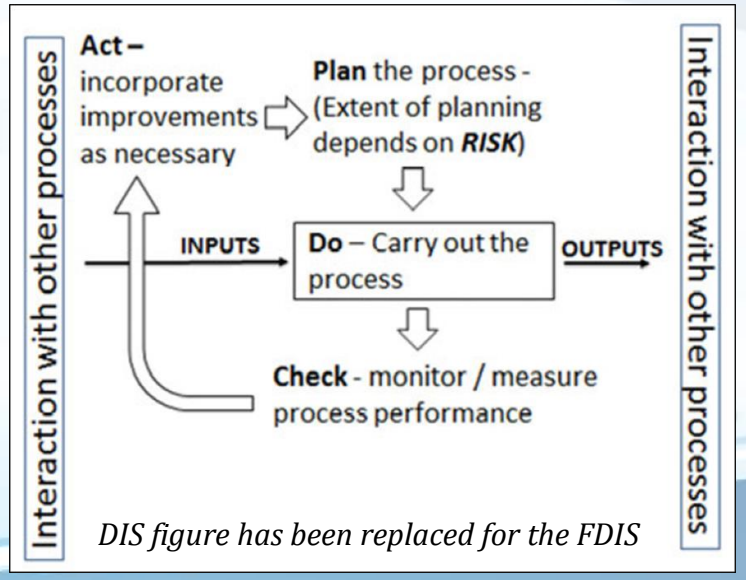


The Process Approach

- Applies systematic definition, management of processes and their interactions to achieve the intended results aligned with the Quality Policy and strategic direction of the organization.

- Management of the processes and the system as a whole can be achieved using a **Plan-Do-Check-Act** (PDCA) methodology with an overall focus on **Risk-based thinking** aimed at preventing undesirable outcomes.

- In this standard, *risk* is the effect of uncertainty on an expected result.



DIS figure has been replaced for the FDIS

Management System and Risk

- The goal of a management system is achieve conformity and customer satisfaction
- ISO 9001:2015 uses risk-based thinking to achieve this:
  - Clause 4 (**Context**): the organization is required to determine the risks
    - ***4.4 The risks and opportunities in accordance with the requirements in 6.1, and plan and implement the appropriate actions to address them***
  - Clause 5 (**Leadership**): top management are required to commit to ensuring Clause 4 is followed
    - ***5.1.2 The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed***

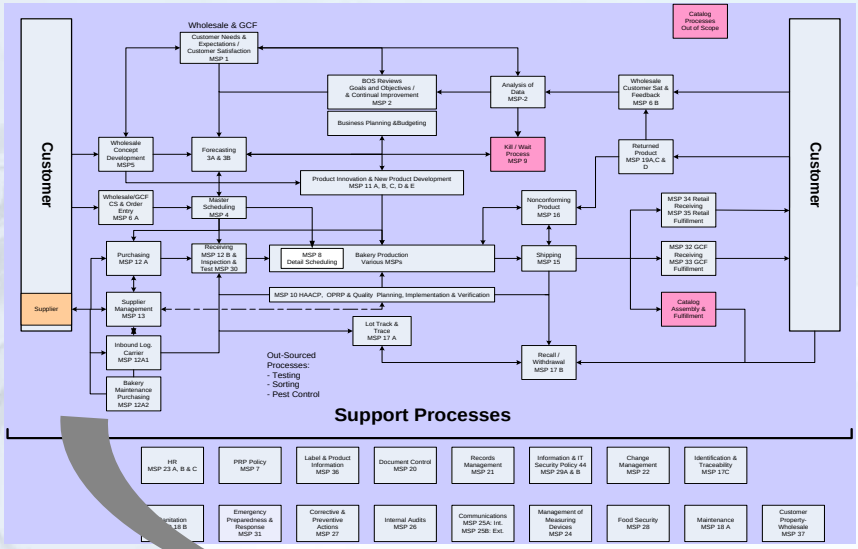
Risk and ISO 9001:2015

4.4 Process Approach

(risk and opportunities in accordance with the requirements of 6.1)

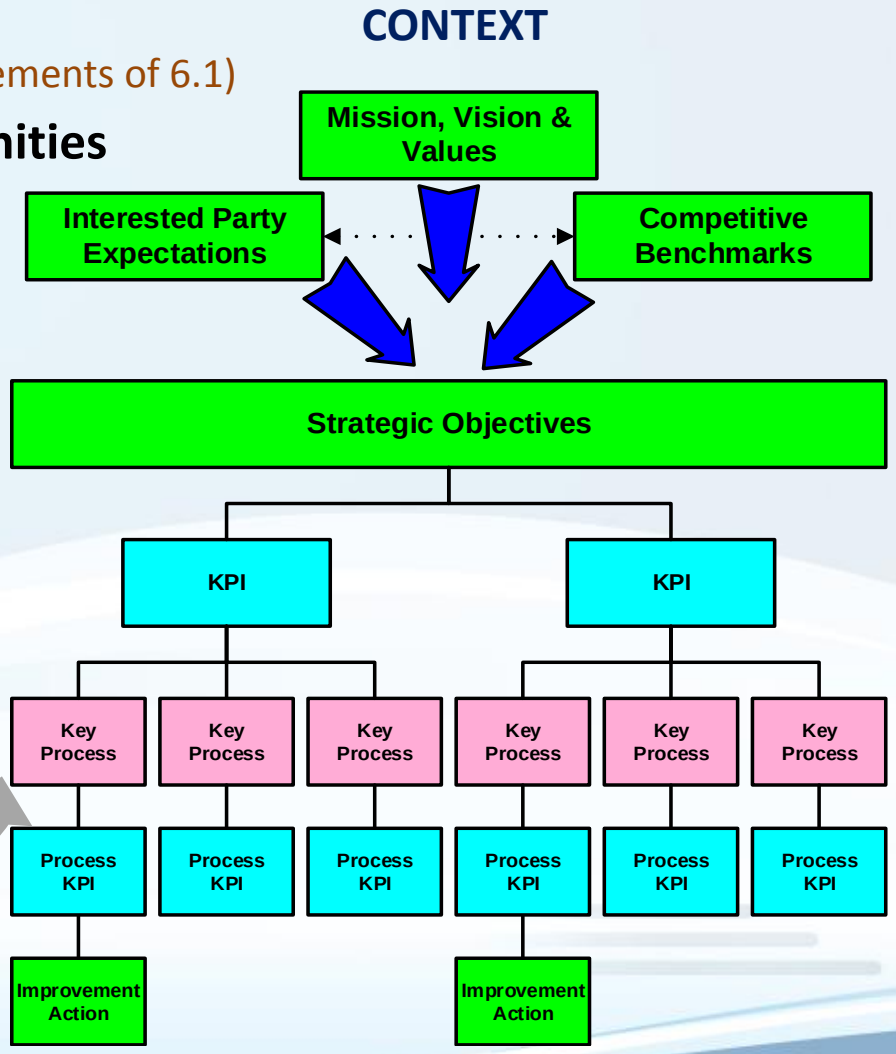
6.1 Actions to Address Risks and Opportunities

(related to planning/meeting quality objectives)



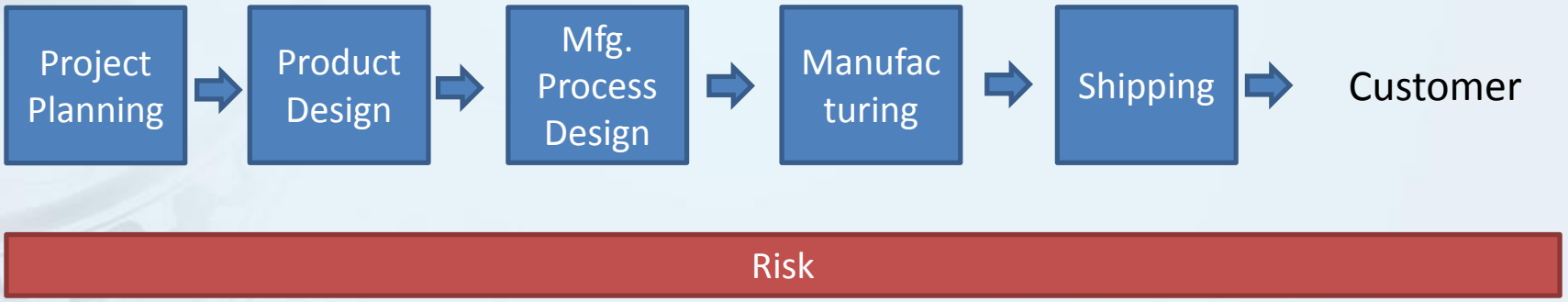
Process Map

"address risks and opportunities of selected processes"



OMNEX

5.1.2 Risks and Opportunities .. Products and Services



Project Risk + Product Design Risk+ Process Design Risk + Manufacturing Risk + Logistics Risk

See Webinar on Risk at the Omnex website – can we add link to webinar

Key Changes to ISO 9001:2015

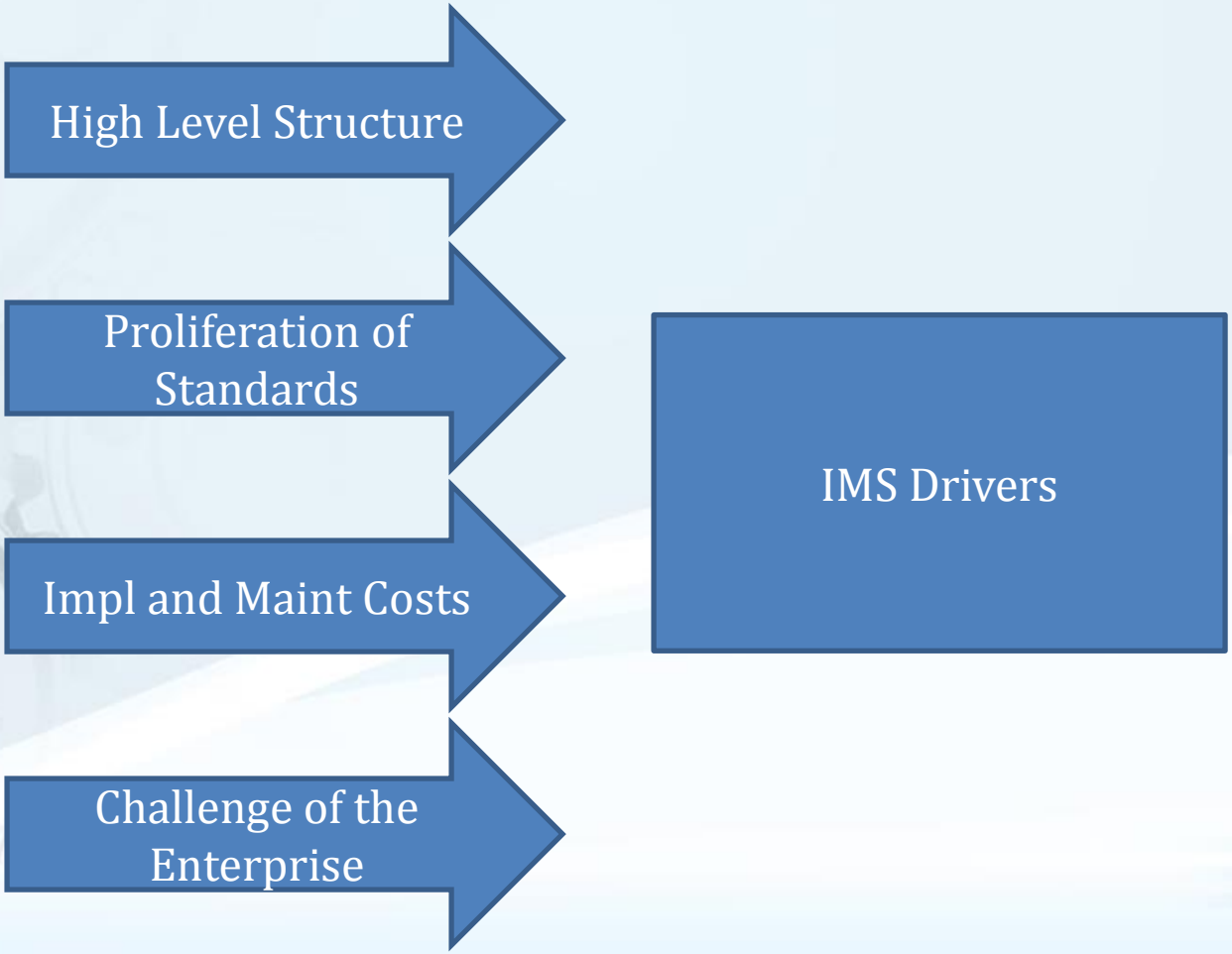
- High Level Structure Change – why is this important?
- Context, Interested Party Expectations, and Setting Objectives
- Risk-based Thinking

Common processes will not only satisfy QMS, but also EMS, and or OHSMS

DRIVERS OF INTEGRATED MANAGEMENT SYSTEMS

What is an IMS and What are its Benefits?

IMS Drivers



The Challenge: Growing Expectations

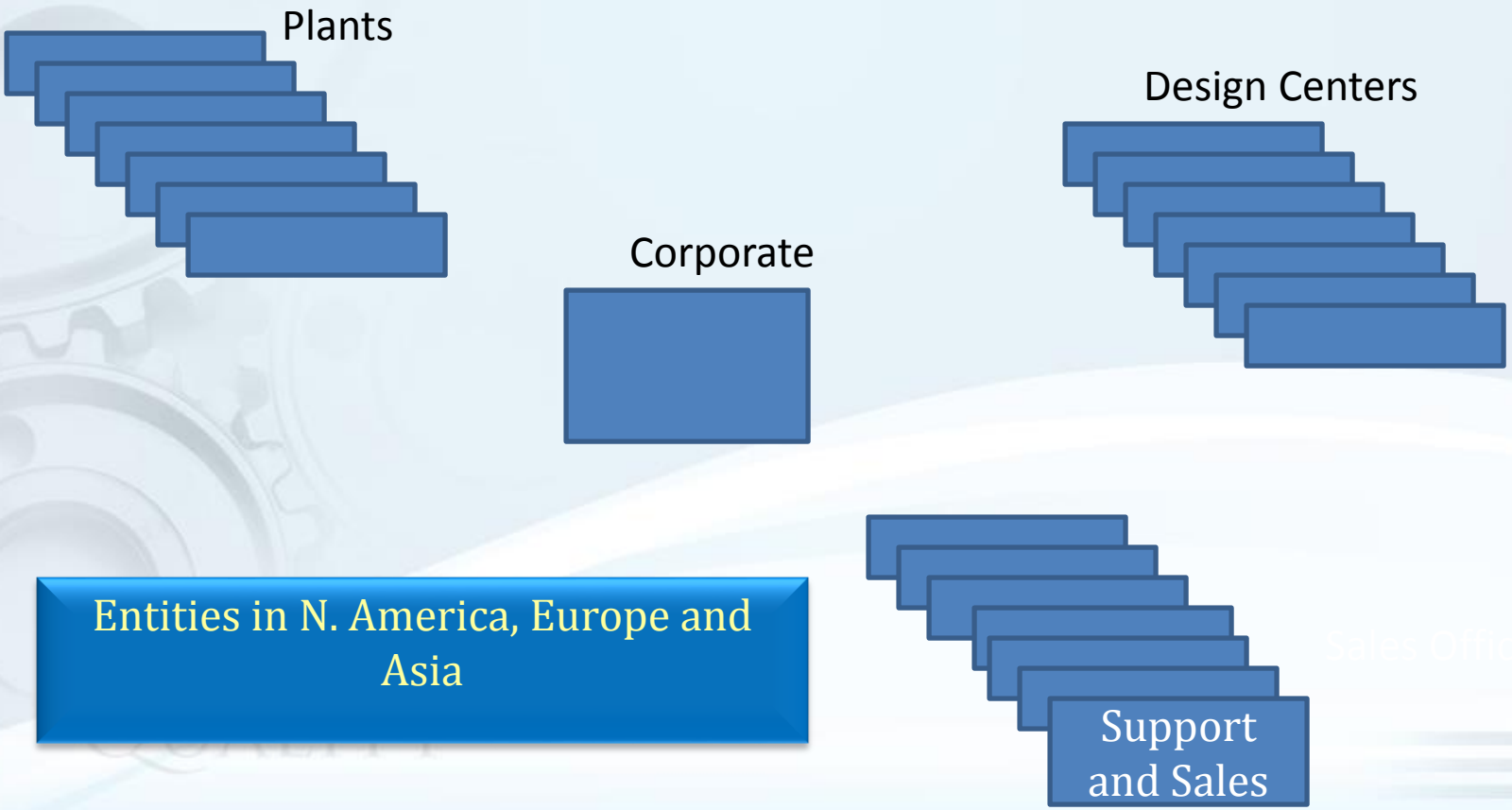
Source: W. Visser

Proliferation of Standards

Increasing Costs for Maintaining Standards

- As standards, customer specific requirements, and regulations grow the need for standards and staff grows
- Standards are expensive to implement and maintain
  - Cost of implementation – $50,000 to $70,000/standard
  - Cost to maintain – $30,000 - $35,000/standard

The Challenge of the Enterprise – Multi-Site, Multi-Language, and Multi-Cultural with Multiple Standards, Audits and Risk Management

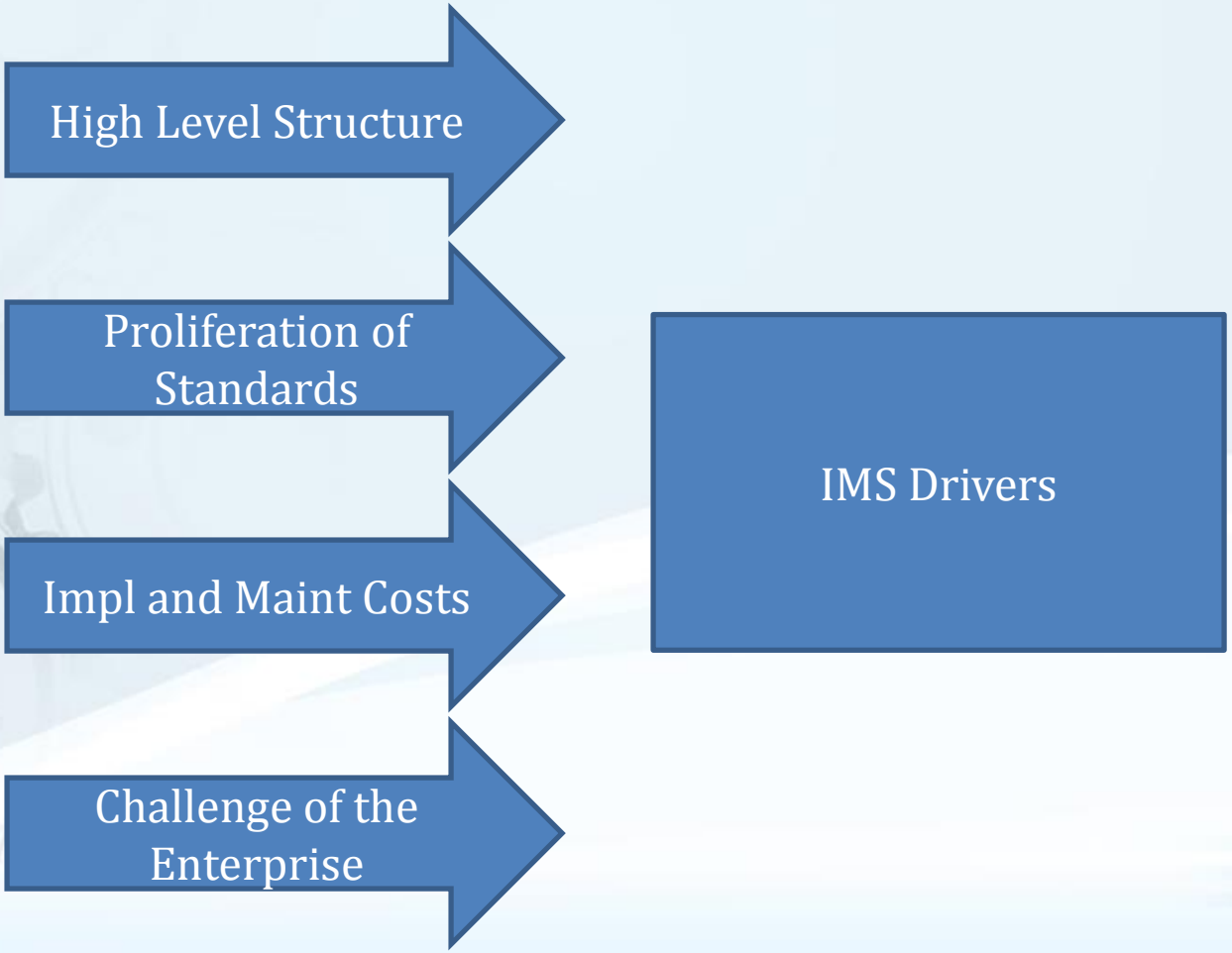


Enterprise Problem Statement

- Lack of consistency (of standards, processes, audits, risk management, problem solving) across the Enterprise
- No central access for quality data
  - Outdated systems, non-complaint software
  - Systems Incompatibility – Integration needs
- Process Inefficiencies
  - Little or no knowledge transfer or best practices between facilities.
  - No common nomenclature for quality metrics (including audit nonconformities).
  - No integration in quality and business planning efforts (audit practices).
- Lack of flexibility and functionality in current practices

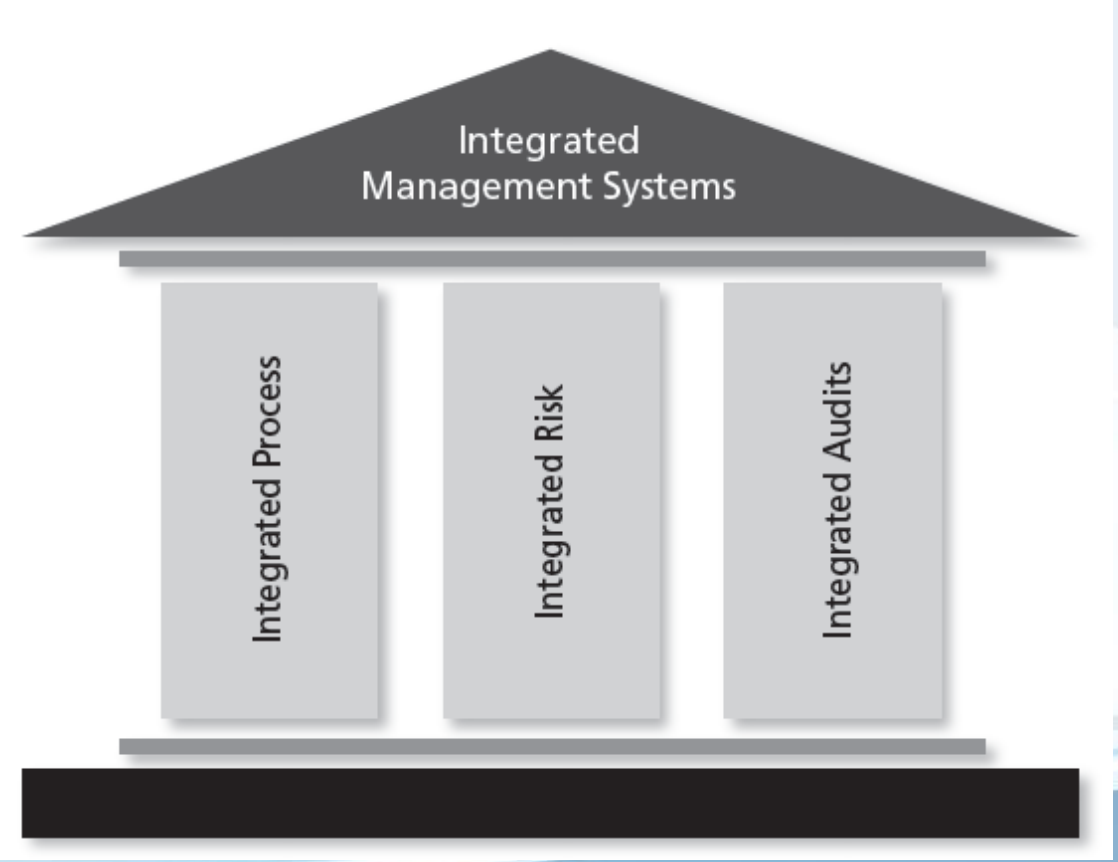
This leads to financial loss due to nonconforming product and non-value added activities

IMS Drivers



What is an Integrated Management System?

- An Integrated Management System includes integrated processes, integrated risk, and integrated audits.



Integrated Processes

- Management systems are considered integrated with 70% to 95% integration for the procedures and at least 30% for work instructions.
- For a process or work instruction to be fully integrated, it should be managed by one process owner.
- All processes do not have to be integrated.
  - Organizations need to determine what they want to integrate.

Single Site Process Integration Matrix

QMS			EMS				OHSMS			
Process Name	Procedure Number	Process Owner	Process Name	Procedure Number	Process Owner	INT	Process Name	Procedure Number	Process Owner	INT
Document Control	SOP-12	John Black	Same		Meg Ryan	Y	Document Control	OH-22	Kevin Rogers	Y
Records Control	SOP-14	Jim Johnson	Same		Jim Johnson	Y	Records Control	OH-15	Kevin Rogers	N
Policy, Objectives, and Business Planning	SOP-22	Kathy Down	Policy, EMS Planning	EMS-5		N	Policy and OH Planning	OH-17	Kevin Rogers	N
Integration			66% (2/3)		33% (1/3)	66% (2/3)	0%		0	33%

Integrated Risk

- Integrated management systems have integrated risks (common risk methodology) between quality, environmental, health and safety, and food safety (Q, E, HS, and or FS) and have comparable severity (Sev.) and occurrence (Occ.) risk ratings between the categories.
- Optimally, one team conducts the risk analysis for the three different categories.

Integrated Audits

- The use of one common audit process and audit program for Q, E, HS, or FSMS management systems in one site.
- The audit process uses an integrated audit checklist and an audit team capable of auditing the integrated system.

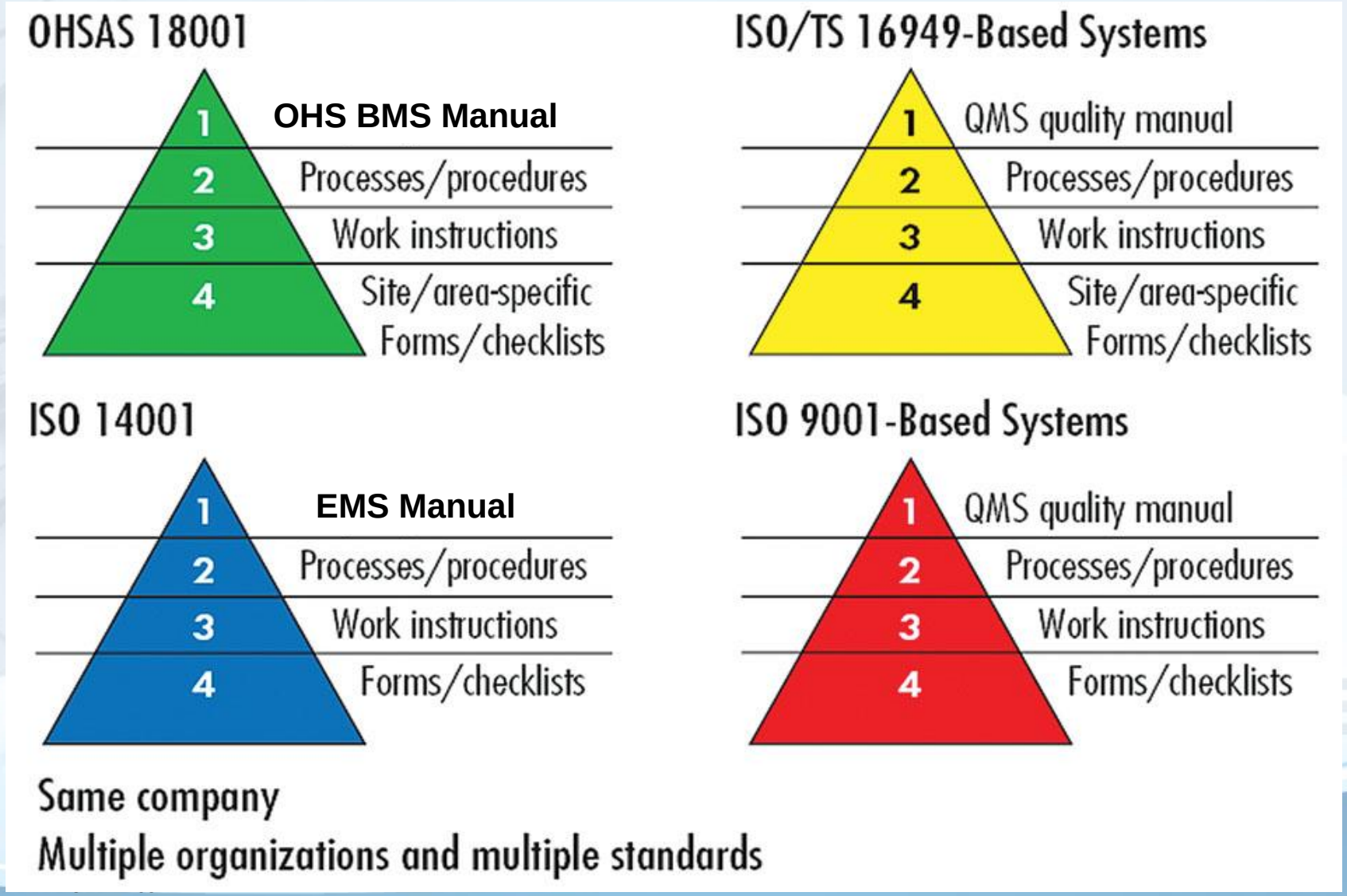
Rationale for Integration

- The object of each standard is reduction and control of variation *in processes* resulting in:
  - Product nonconformity and waste
  - Injuries, illness and deaths
  - Environmental impact and/or contamination
- System approaches to management, improvement and control are the same.

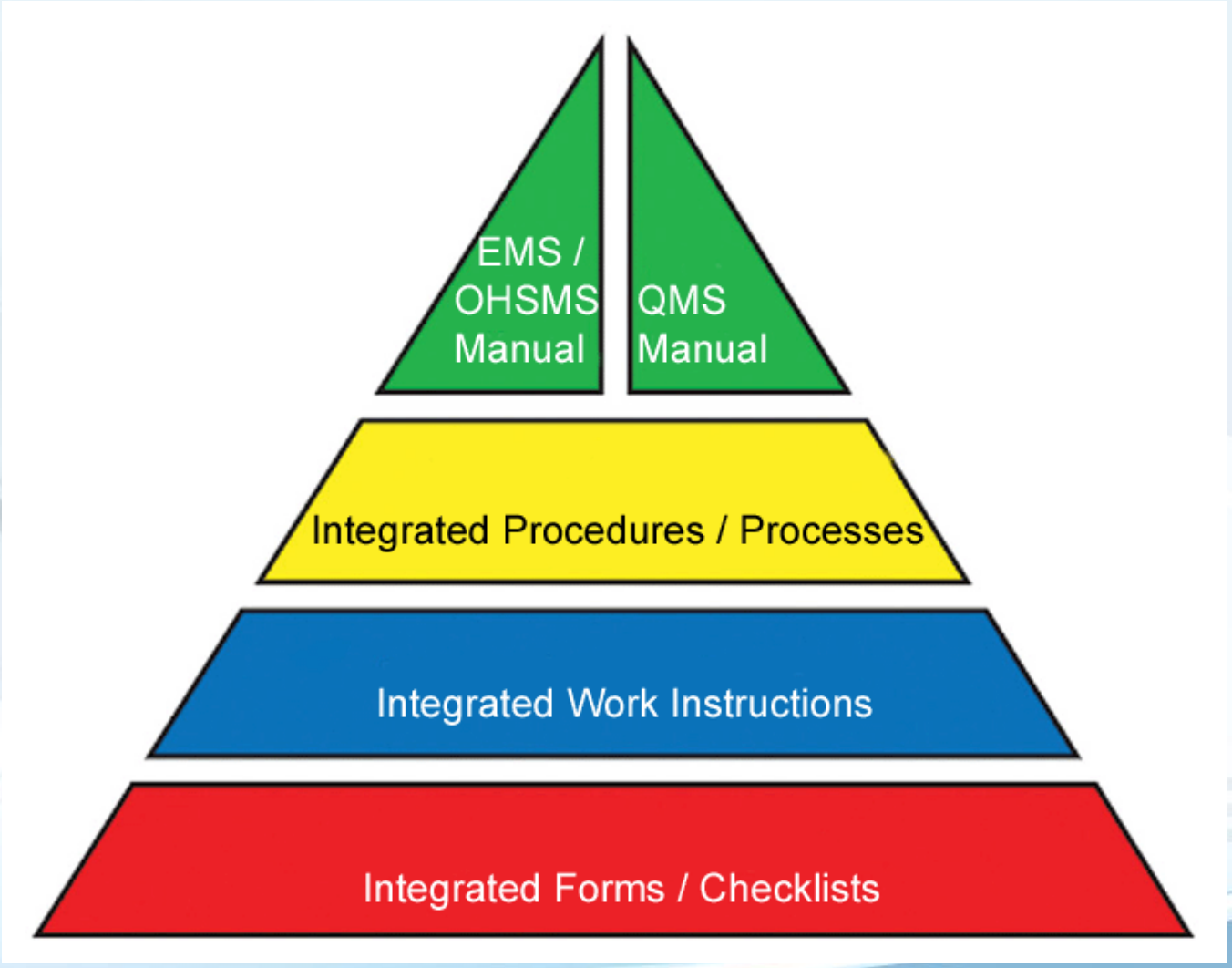
Benefits of Integration

- Focus
  - Integration of organization's overall goals and objectives.
- Efficiency
  - Reducing the number of processes and process owners.
  - Integration of management planning, realization and control processes.
- Effectiveness
  - Application of proven process and risk tool throughout the organization.

Single Entity – Stand-Alone Implementations Mean More Work

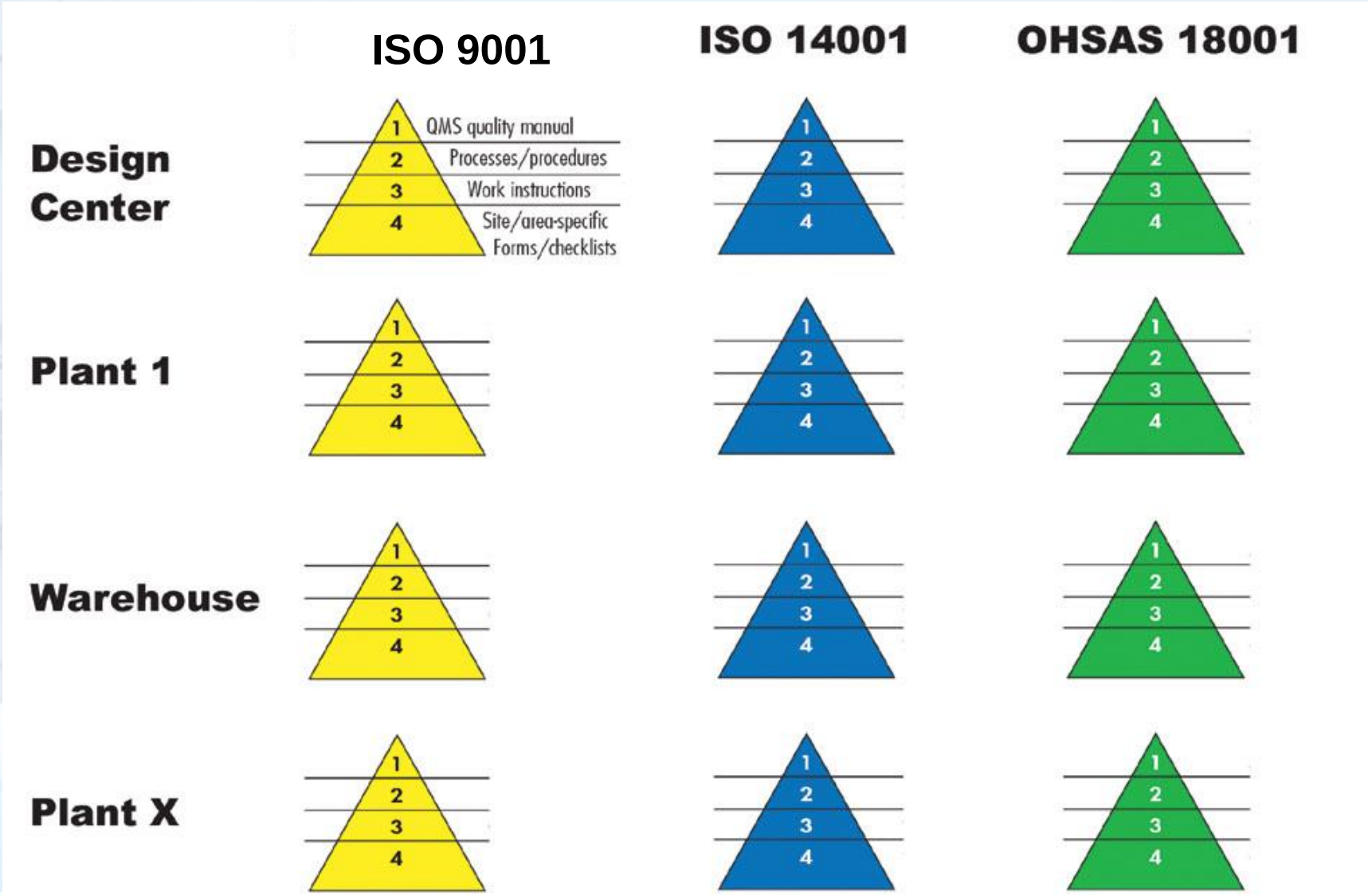


Integration in One Site



INTEGRATION VS STANDARDIZATION

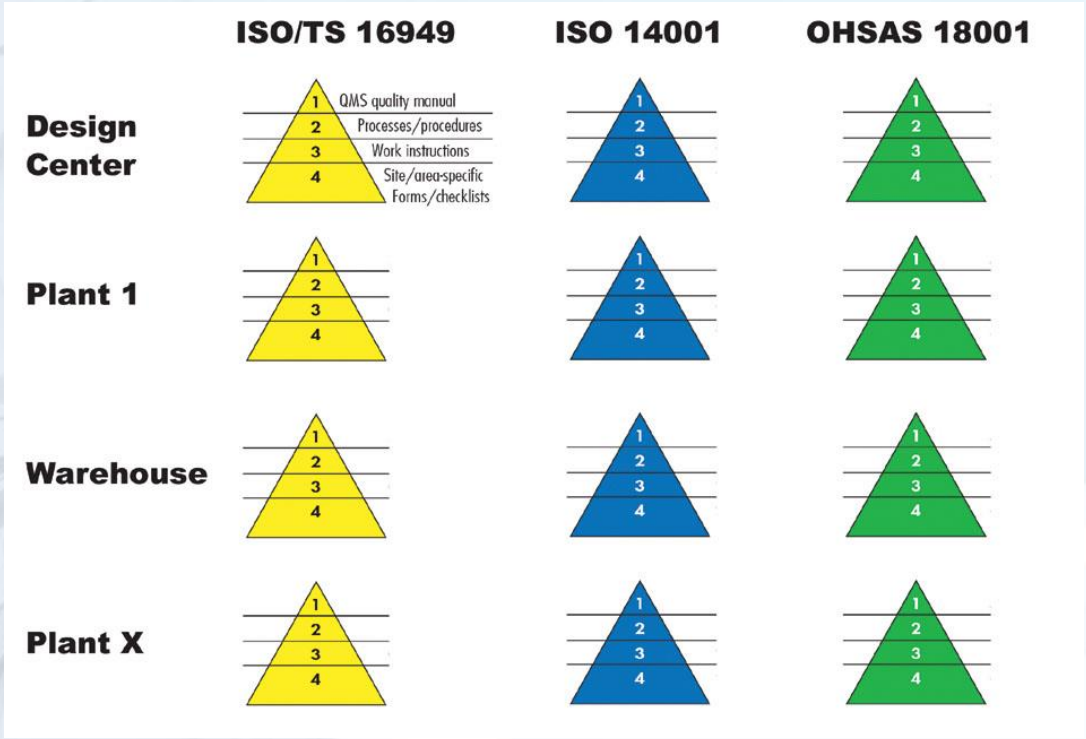
Lack of Integration and Standardization in Processes

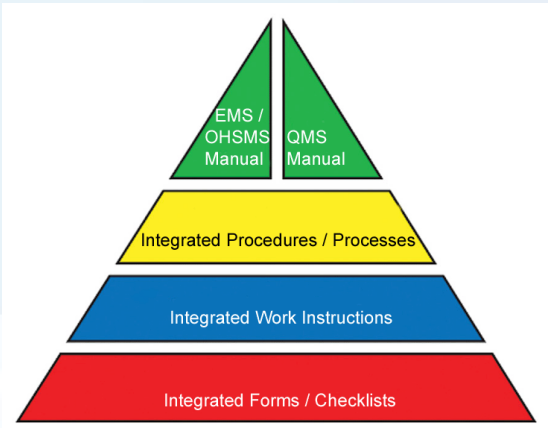


Integration vs Standardization

- Integration refers to stand-alone systems that duplicate training processes, document control, and internal audit processes for each standard within the company. There is a tremendous loss of value associated with stand-alone management systems within an organization as discussed above.
- Worse yet, many organizations continue this duplication of effort among their different sites—including plants, design centers, and sales offices. If there is a lack of efficiency and confusion caused by the duplication in one site, one can imagine the magnification of these same problems when duplication is repeated multiple times in a large organization.

Standardization





Lack of Integration and Standardization – Results

- Duplication of processes, audits and risk assessment
- Increased cost to implement and maintain management systems, audits, and the risk analysis
- Increased cost to maintain system, conduct audits or risk management systems

Rationale for Integration and Standardization

- In an enterprise of four sites with three management systems – twelve individual management systems vs. one integrated management system shows that
  - if there are five hundred documents on average in each of the systems, then there are six thousand documents in **twelve management systems vs. five hundred in one management system**.
- If there are one hundred process owners in one system it equates to twelve hundred process owners in the twelve sites each carrying out specific tasks assigned to them vs. one hundred process owners carrying out globally assigned processes.

Just the magnitude of extra work of twelve hundred processes vs. one hundred global processes should explain the efficacy of Integration and Standardization.

Additional Efficiency

- Additional Efficiencies are gained by:
  - Integrated and Standardized Risk in the Enterprise
  - Integrated Audits

We will discuss this in greater detail in subsequent webinars

USING SOFTWARE FOR ENTERPRISE QUALITY AND INTEGRATED MANAGEMENT SYSTEMS

Enterprise Quality Management Systems

- Enterprise Quality Management Systems software was initially announced in 2002 in articles and presentations with ASQ and Quality Digest. At that time, we defined it as – EQMS satisfies all the requirements of ISO 9001:2000 and optimally including APQP, FMEA, and PPAP (risk-based defect prevention tool used in many sectors)
- Today, the definition of the EQMS software has to include the requirements of ISO 9001:2015 and including Risk-based Thinking. The software needs to include functionality to support the requirements of APQP, FMEA and PPAP.

Enterprise Quality Management System Software will help provide standardization and commonization of QMS processes.
They will not however, leverage the market need for Integration.

Enterprise Integrated Management Systems

Enterprise Integrated Management Systems Software is defined as:

- Satisfying the requirements of ISO 9001:2015, ISO 14001:2015, and ISO 45001:2016. In fact, EIMS software needs to satisfy and conform to the High Level Structure of ISO that satisfies the core requirements of all ISO standards.
- Satisfying Risk-based thinking requirements and also interested party expectations, business context, and setting objectives.
- By definition, EIMS Software is also EQMS software. In fact, EIMS software needs to satisfy the HLS of the management system standards and be able to have flexible processes to satisfy QMS, EMS, OHSMS, Information Security, or other MSS standards.

EQMS Solution

- Minimum ISO 9001:2015 Functionality including:
  - Context, Interested Party Expectations, and Objectives (related to QMS)
  - Risk-based thinking
    - QMS Process Risk
    - Product Realization Risk
    - Logistics Risk
  - APQP, FMEA, and PPAP (risk-based prevention tool that can support product realization risks)

EIMS Solutions

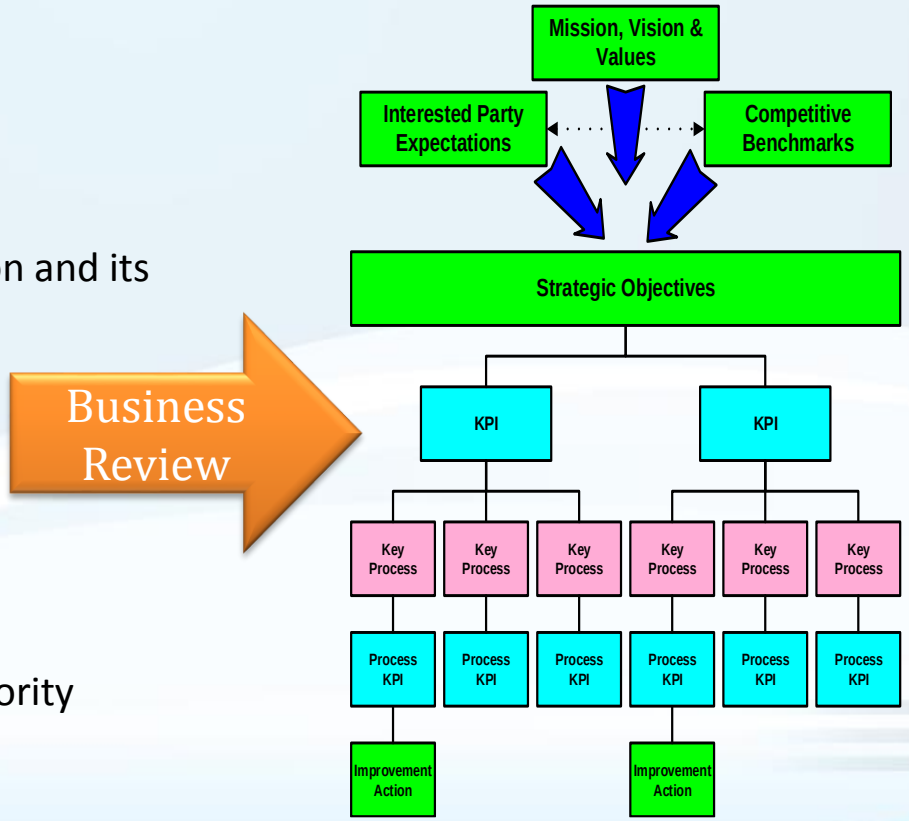
- Minimum High Level Structure Functionality including:
  - Context, Interested Party Expectations, and Objectives (related to QMS, EMS, OHSMS and other MSS)
  - Risk-based thinking
    - For QMS, EMS, OHSMS and other MSS
  - APQP, FMEA, and PPAP (risk-based prevention tool that can support product realization risks)

High Level Structure (HLS) is Changing New Clause Numbers

High level Structure

1. Scope
2. Normative References
3. Terms and Definitions
4. Context of the Organization
   - Understanding the Organization and its Context
   - Needs and Expectations
   - Scope
   - Management System
5. Leadership
   - Management Commitment
   - Policy
   - Roles, Responsibility and Authority
6. Planning
   - Actions to Address Risks and Opportunities
   - Objectives and Plans to Achieve Them

Functionality



High Level Structure (HLS) is Changing New Clause Numbers

High Level Structure

7. Support
   - Resources
   - Competence
   - Awareness
   - Communication
   - Documented Information
8. Operation
   - Operational Planning and Control
9. Performance Evaluation
   - Monitoring, Measurement, Analysis and Evaluation
   - Internal Audit
   - Management Review
10. Improvement
   - Nonconformity and Corrective Action
   - Continual Improvement

Software Functionality

MSA and Calibration Software

High Level Structure (HLS) is Changing New Clause Numbers

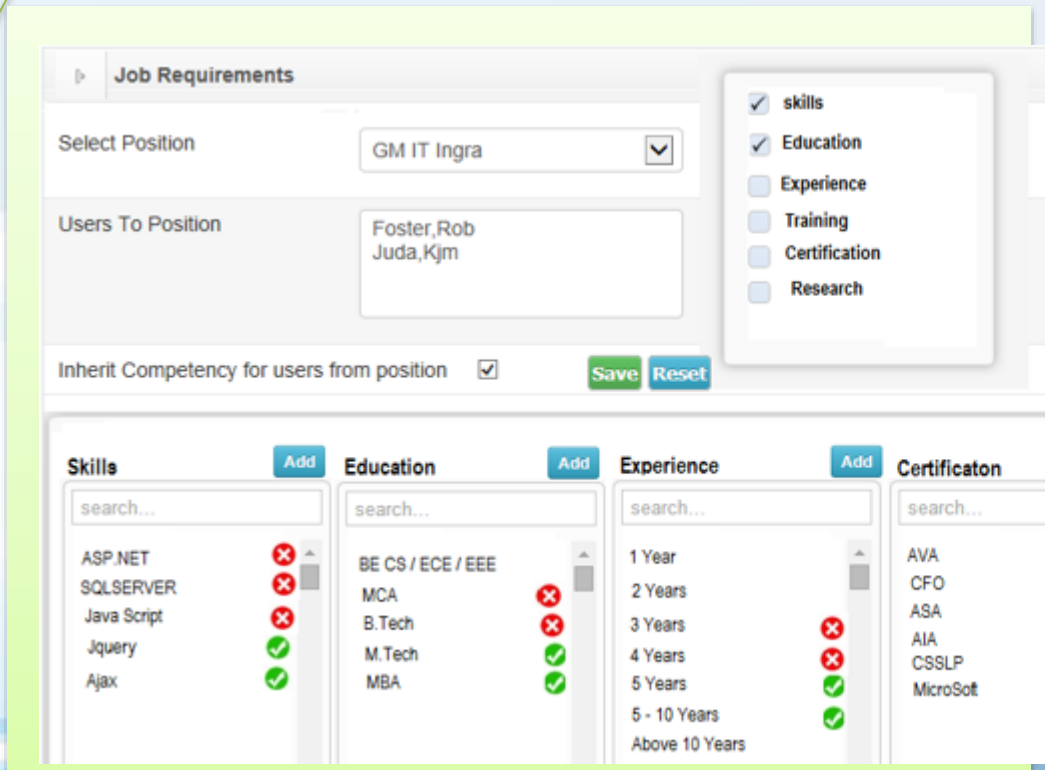
High Level Structure

7. Support
   - Resources
   - Competence
   - Awareness
   - Communication
   - Documented Information
8. Operation
   - Operational Planning and Control
9. Performance Evaluation
   - Monitoring, Measurement, Analysis and Evaluation
   - Internal Audit
   - Management Review
10. Improvement
   - Nonconformity and Corrective Action
   - Continual Improvement

Software Functionality

MSA and Calibration Software

Training and Competency Management



High Level Structure (HLS) is Changing New Clause Numbers

High Level Structure

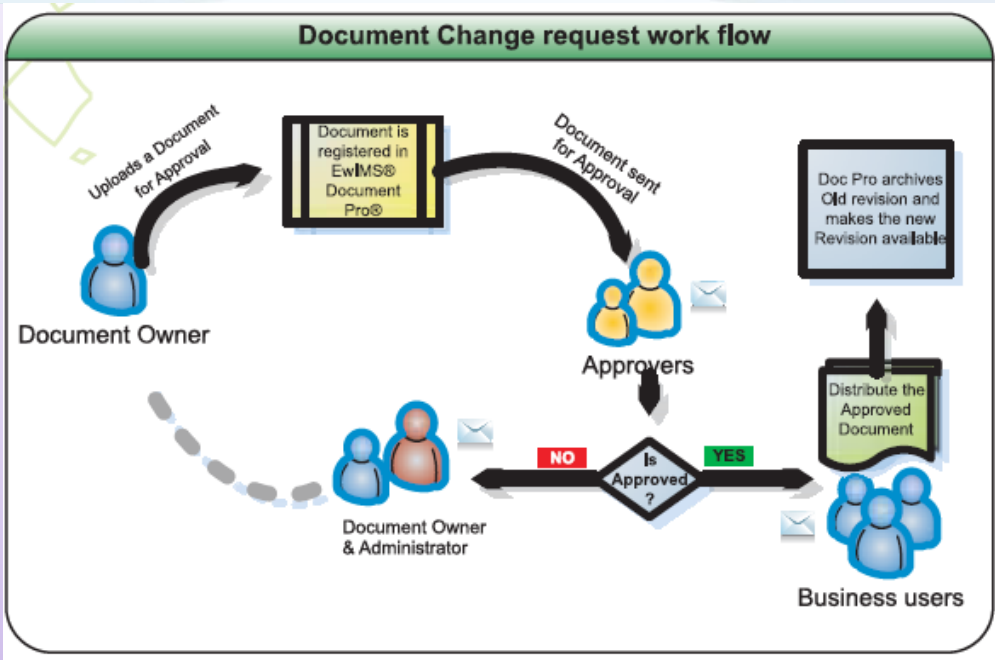
7. Support
   - Resources
   - Competence
   - Awareness
   - Communication
   - Documented Information
8. Operation
   - Operational Planning and Control
9. Performance Evaluation
   - Monitoring, Measurement, Analysis and Evaluation
   - Internal Audit
   - Management Review
10. Improvement
    - Nonconformity and Corrective Action
    - Continual Improvement

Software Functionality

MSA and Calibration Software

Training and Competency Management

Document and Record Management



High Level Structure (HLS) is Changing New Clause Numbers

High Level Structure

7. Support
   - Resources
   - Competence
   - Awareness
   - Communication
   - Documented Information
8. Operation
   - Operational Planning and Control
9. Performance Evaluation
   - Monitoring, Measurement, Analysis and Evaluation
   - Internal Audit
   - Management Review
10. Improvement
    - Nonconformity and Corrective Action
    - Continual Improvement

Software Functionality

MSA and Calibration Software

Training and Competency Management

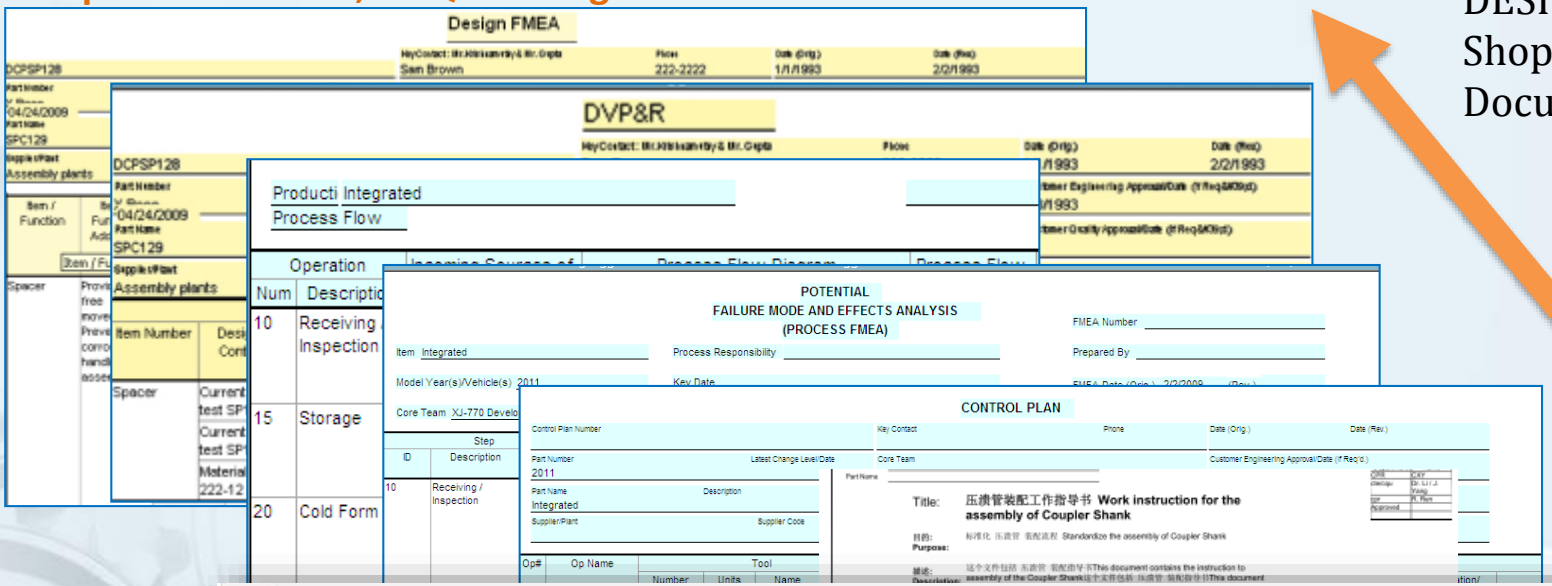
Document and Record Management

Inspection Control, APQP Management and PPAP

High Level Structure (HLS) is Changing New Clause Numbers

Inspection Control, APQP Management and PPAP

Connects DESIGN to Shop floor Documents



Inprocess Inspection Worksheet

Part Number:	24124/7	**Operation Number:**	40	**Shift:**	Default Shift	**W.O No:**	WO201407005
Part Name:	m560P LW - Report Test	**Operation Name:**	Grinding	**Preapred By:**	Jim Johnson	**Approved By:** Kim Pearlman	**Batch No:** BO2014070013
Date:	7/24/2014	**Department:**	Shaft Floor	**Acceptance Criteria:**	Zero Defects		**Lot No:** 1000891

Characteristics No	Characteristic Description	Characteristics Class	Tolerance/ Specification	Low Value	High Value	Gage	Evaluation Technique	Sample Frequency	10:00:00 AM	12:00:00 PM	2:00:00 PM	4:00:00 PM
8	Finished surface		40	3	3	P-001	Profilometer	Every 2 hours	46	43	42	
10	Finished diameter		0.4875	0.002	0.002	23-453BV	Electric Column	Every 2 hours	0.4877	0.4875	0.4875	
C002	Machine speeds and feeds		1760	100	100	G027	Visual/ Automated on Asm Fixture Proximity Sensor	Every 2 hours	1760	1770	1775	
11	Correct resin loaded	V	ETS RHD Panel Lower Assist is3114m16, Glove Box Inner is ETS-3115m72 and Glove Box Outer is ETS-3116m77 Motan Procedures			G038	Visual - Insert Present and properly inserted	Every 2 hours	ok	not ok	ok	
10	Resin Color	®	Per Excel Data Notes Color			JOF Checksheet	Job Order Form	Every 2 hours	not ok	not ok	not ok	

High Level Structure (HLS) is Changing New Clause Numbers

High Level Structure

7. Support
   - Resources
   - Competence
   - Awareness
   - Communication
   - Documented Information
8. Operation
   - Operational Planning and Control
9. Performance Evaluation
   - Monitoring, Measurement, Analysis and Evaluation
   - Internal Audit
   - Management Review
10. Improvement
    - Nonconformity and Corrective Action
    - Continual Improvement

Software Functionality

MSA and Calibration Software

Training and Competency Management

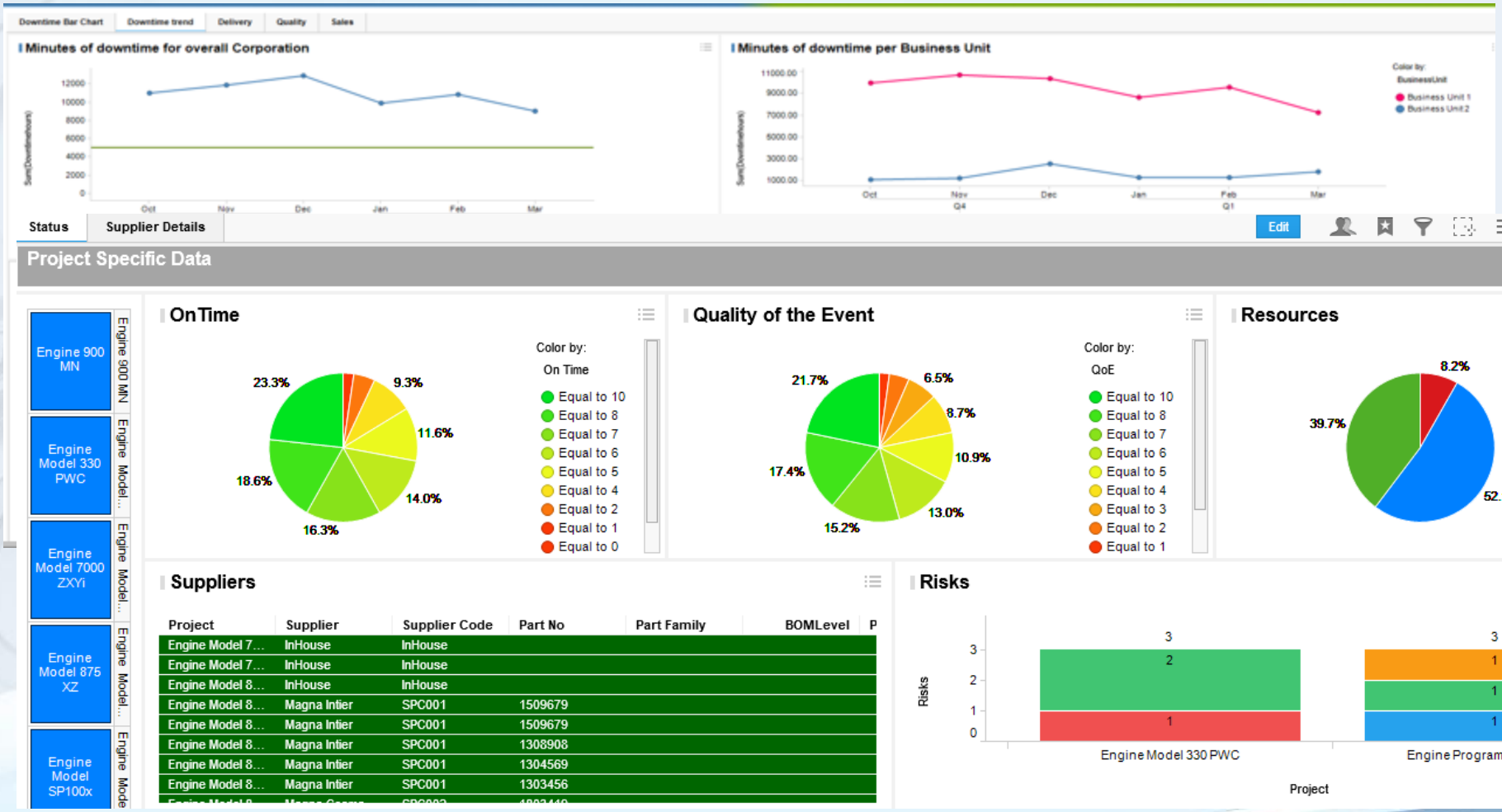
Document and Record Management

Inspection Control, APQP Management and PPAP

Dashboard, KPIs and Business Review (BOS)

High Level Structure (HLS) is Changing New Clause Numbers

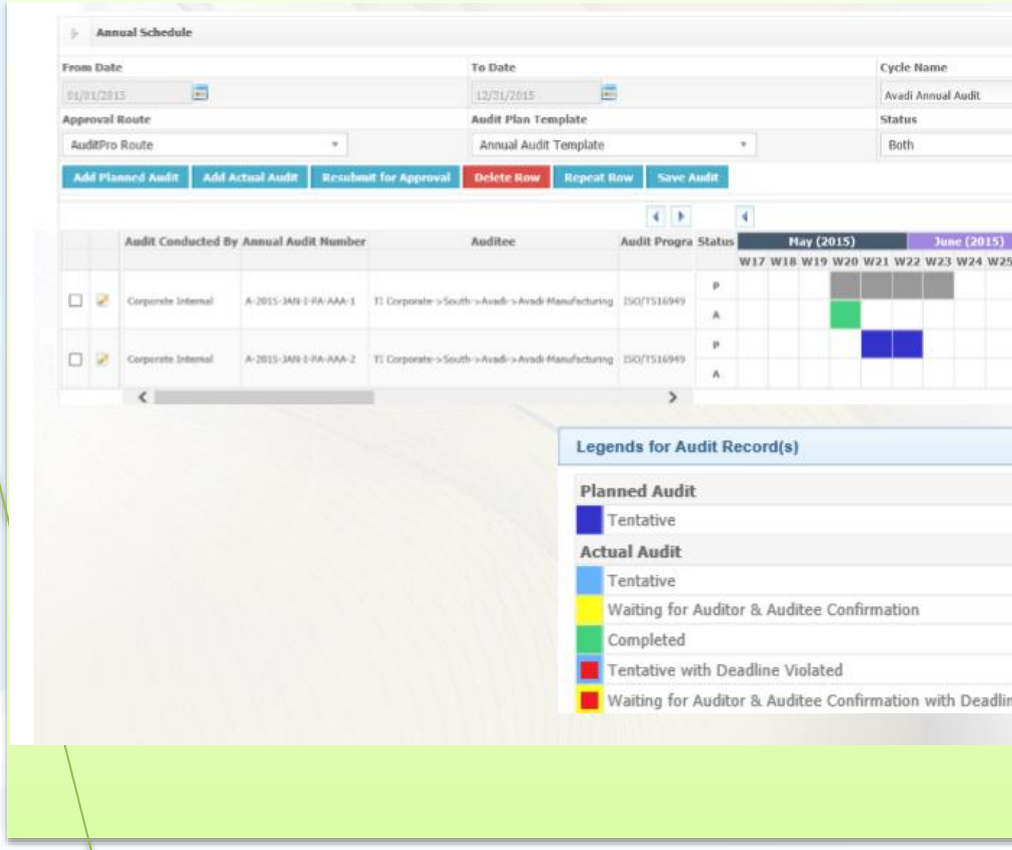
Dashboard, KPIs and Business Review (BOS)



High Level Structure (HLS) is Changing New Clause Numbers

High Level Structure

7. Support
   - Resources
   - Competence
   - Awareness
   - Communication
   - Documented Information
8. Operation
   - Operational Planning and Control
9. Performance Evaluation
   - Monitoring, Measurement, Analysis and Evaluation
   - Internal Audit
   - Management Review
10. Improvement
    - Nonconformity and Corrective Action
    - Continual Improvement



Auditing

High Level Structure (HLS) is Changing New Clause Numbers

High Level Structure

7. Support
   - Resources
   - Competence
   - Awareness
   - Communication
   - Documented Information
8. Operation
   - Operational Planning and Control
9. Performance Evaluation
   - Monitoring, Measurement, Analysis and Evaluation
   - Internal Audit
   - Management Review
10. Improvement
    - Nonconformity and Corrective Action
    - Continual Improvement

Software Functionality

MSA and Calibration Software

Training and Competency Management

Document and Record Management

Inspection Control, APQP Management and PPAP

Dashboard, KPIs and Business Review (BOS)

Auditing

Business Operating System (BOS)

Corrective Action and Continual Improvement

IS - IS Not Analysis Form

Concern Details

Site	Corporate	Entity	Corporate
Product/Service	XJ-770	Customer Name	Bell Helicopter

Possible Cause Analysis Form

Concern Details

Site	Corporate	Entity	Corporate
Product/Service	XJ-770	Customer Name	Bell Helicopter

Root Cause Analysis using 5 Whys

Concern Details

Site

Form Team
- Team Details

Describe the Problem
- 5W2H
- Is-Is Not
- 5Whys

Implement and Verify Interim Action

Find and Verify Root Cause
- 5W2H
- Is-Is Not
- 5Whys
- PossibleCause (Fish Bone)

Select Permanent Corrective Actions

Implement Permanent Corrective Actions
- PossibleCause (Fish Bone)

Prevent System Problems
- PossibleCause (Fish Bone)

Congratulate the Team

8D Form

Concern Details			
Site	Corporate	Entity	Corporate
Product/Service	XJ-870	Customer Name	UTC Aerospace
Concern Number	SQ19	Concern Title	Part supplied of XJ 870 Supplied by Magna interiors
Team Leader	UTC,MFP 1	Opened	5/26/2015

Form Team	
Team Name	Supplier 1 Problem Solving Team
Team Member	
John,Antony	
Barber,Kim	

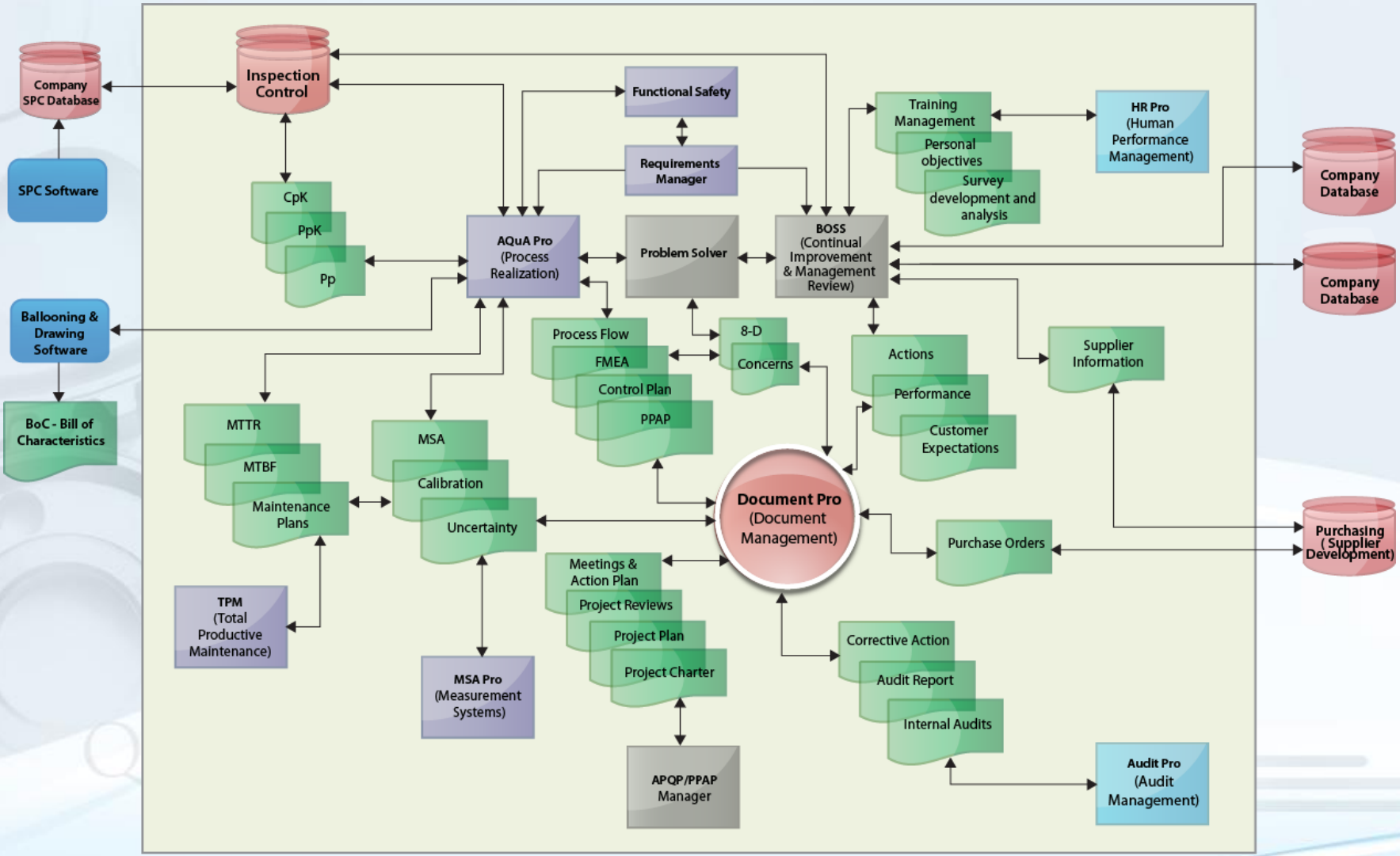
Describe the Problem	
Problem Description	Damage on Part of XJ 870

Implement and Verify Interim Actions					
Date Effective					
Action Description	Responsibility	Due Date	Actual Date	Status	Attachment
		6/5/2015		Active	
Comments					

Find and Verify Root Cause				
Verification Date				
Root Cause Description	%Contribution	Verification Date	Root Cause Category	Attachment
This is the first why	0			
Comments				

Select Permanent Corrective Actions

EwIMS Architecture



Business Systems | Product Realization | Information | Management

CONCLUSION

Conclusions – Why?

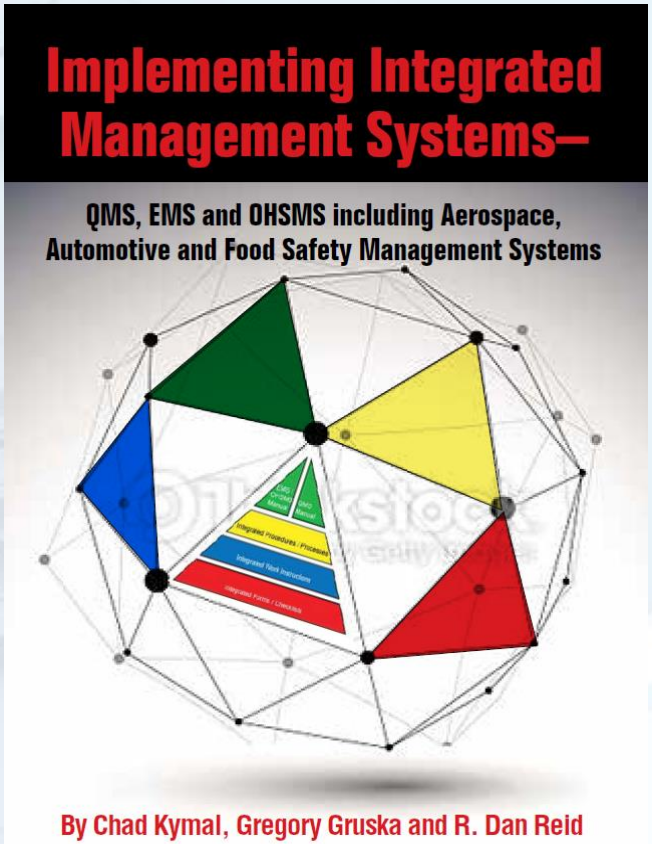
- Integrated Management Systems with Integrated Processes, Integrated Audits, and Risk Analysis are inevitable
- Integrated Management Systems, Integrated Audits and Risk Analysis save money
  - Reduces confusion and duplication of efforts
  - Reduces implementation costs by 50%, reduces maintenance costs by 60%
  - Reduces internal and external auditing costs by 25% **
  - Reduces Risk Analysis for QMS, EMS, and OHSMS by over 50%
- Using Enterprise Software Integrated Management Systems and Risk Analysis is made easy

** Note, some third party schemes do not allow a reduction in Third party auditing days for QMS

Omnex Risk Analysis Training for ISO 9001:2015

- Risk Analysis for QMS Processes for ISO 9001:2015
- BOS – Linking Interested Party Expectations to Objectives to Key Processes (including Planning and Risk)
- Project Risk and APQP
- System and Design FMEA
- Process FMEA and Control Plan
- Logistics FMEA

Implementing Integrated Management Systems



Much of the information from this webinar can be found in greater detail in the book "Implementing Integrated Management Systems – QMS, EMS and OHSMS Including Aerospace, Automotive and Food Safety Management Systems" written by Chad Kymal, Gregory Gruska and R. Dan Reid. NOW AVAILABLE through ASQ Press!

Other Books Available by Chad Kymal:

- AS9101D Auditing for Process Performance: Combining Conformance and Effectiveness to Meet Customer Satisfaction
- The ISO/TS 16949:2002 Auditor Handbook
- The ISO/TS 16949:2002 Implementation Guide: Gaining Value From Your ISO/TS 16949 Implementation
- How to Audit ISO 9001:2008 — A Handbook for Auditors

EwQIMS

APQP/PPAP MANAGER	Risk Management, Program Management, APQP/PPAP Internal use, PPAP management Suppliers, Change Management
AQuA pro product realization software	Linked DFMEA, Test Plans, Process Flow, PFMEA, Control Plans and Work Instructions by Product and Process Families
Document pro document management software	Managing Quality, environmental and HS management system (documentation management)
Audit pro audit management software	Integrated Audit Management
MSA pro measurement system analysis	Manage your gages and performs all MSA Studies - Bias, Calibration, GR&R, and Stability Studies for Variable and Attribute gages.
Inspection Control quality control inspection	Manage your In-Process, Incoming & Outgoing inspections
Problem solver manage your problems and incidents	Conducting integrated problem solving for internal quality, external quality, suppliers etc.
TPM pro equipment maintenance	Manages Total Productivity Maintenance of your plant(s). Addresses all TPM requirements
HR pro performance objectives	Training management and objectives deployment from Corporate to employees
BOSS continual improvement	Top management in implementing customer-focused continual improvement and tracking performance
Requirements Flowdown requirement flowdown	Flow customer requirements from contract and VOC to the System, Sub System, and Components. Link to DFMEA, PFMEA, Characterstics, Testing, to PPAP.

OMNEX

WWW.OMNEX.COM

Upcoming Webinars

- **QOS – Linking Goals and Quality Objectives –** TBD
- **CIV – Protecting the Environment and Context (ISO 14001)** – TBD
- **Understanding the Context of Business** – TBD
- **ISO 17025 Revision Update** – TBD
- **Enterprise Quality Management Systems (EQMS)** – TBD
- **Linkages of APQP Tools** – TBD

Contact us for information on how to register for these webinars or to view recorded versions

Upcoming Training – ISO 9001:2015 Transition Training

With the release of ISO 9001:2015 this fall, now is the time to prepare. Omnex is offering a one day transition training course that will highlight the intent and content of the key changes and features group breakout exercises on the new requirements.

- **June 16, 2015 — San Jose, CA**
- **June 22, 2015 — Ann Arbor, MI**
- **June 26, 2015 – Nashville, TN**
- **June 26, 2015 – Mississauga, ON**
- **July 9, 2015 – Ann Arbor, MI**
- **July 27, 2015 – Seattle, WA**

This transition training can also be delivered at your site.

Consulting and Implementation Assistance is also available.

Upcoming Training – ISO 14001:2015 Transition Training

With the release of ISO 14001:2015 this fall, now is the time to prepare. Omnex is offering a one day transition training course that will highlight the intent and content of the key changes and features group breakout exercises on the new requirements.

- **June 15, 2015 — San Jose, CA**
- **June 23, 2015 — Ann Arbor, MI**
- **June 26, 2015 – Mississauga, ON**
- **July 10, 2015 – Ann Arbor, MI**
- **July 28, 2015 – Seattle, WA**

This transition training can also be delivered at your site.

Consulting and Implementation Assistance is also available.

Upcoming Training – ISO 9001:2008

Understanding and Documenting: 2 days
Internal Auditor Training: 4 days
Lead Auditor Training: 5 days

- **June 8-12, 2015 — Boston, MA and Minneapolis, MN**
- **June 22-26, 2015 — Chicago, IL**
- **July 13-17, 2015 — Ann Arbor, MI**
- **July 13-17, 2015 — Mississauga, ON**
- **August 3-7, 2015 — Boston , MA**
- **August 10-14, 2015 — San Jose, CA**
- **August 17-21, 2015 — Irvine, CA**
- **September 21-25, 2015 — Chicago, IL and Orlando, FL**
- **September 28-October 2 — Ann Arbor, MI**
- **September 28-October 2 — Mississauga, ON**

These classes can also be delivered at your site.
Consulting and Implementation Assistance is also available.

Exemplar Global
Certified Training Provider

Note: These courses will be updated to ISO 9001:2015 once the FDIS is released and updated competency requirements are received from Exemplar Global.

Questions?

Thank You!

Chad Kymal
ckymal@omnex.com
734.761.4940